ンジャーとを有する注射器から成り、前記注射器は、前記血液貯蔵チャンバーを前記第２の開口部へ密封して連結する手段をさらに有している請求項(21)に記載の血液採取装置。

(23)前記流れ制御手段が、微孔質疎水性プラグから成る請求項(20)に記載の血液採取装置。

(24)血液サンプルを貯蔵する血液貯蔵手段をさらに有しており、前記血液貯蔵手段は、前記第１の開口部に密封して取り付け自在であって、前記プラグを通して挿入し、それによって、前記シャフトから前記血液貯蔵手段へ血液を導くようになっている針を有している請求項(23)に記載の血液採取装置。

(25)前記プラグを通して前記血液貯蔵手段の前記針を案内し、前記針を前記シャフトと同軸にする、前記プラグと前記第１の開口部との間の前記シャフト内に位置している案内手段をさらに備えている請求項(24)に記載の血液採取装置。

(26)前記流れ制御手段を通して前記血液貯蔵手段に結合している針を案内し、前記針を前記シャフトと同軸にする、前記流れ制御手段と前記第１の開口部との間の前記シャフト内に位置している案内手段をさらに備えている請求項(20)に記載の血液採取装置。

(27)前記シャフトと前記第２の開口部との間を選択的に連通できるように、バルブ手段をさらに備える請求項(20)に記載の血液採取装置。

(28)前記針手段が、血液サンプルを抜き取るために患者に挿入する針と、患者から抜き取られた血液を前記カップリング手段へ導く細長いチューブとを有し、前記チューブは可撓性を有し、かつ、前記チューブによって導かれている血液が医療作業員に見えるように概ね透明である請求項(20)に記載の血液採取装置。

(29)血液貯蔵チャンバーと該血液貯蔵チャンバー内に位置しているプランジャーとを有する注射器をさらに備え、前記注射器は、前記血液貯蔵チャンバーを前記第２の開口部へ密封して連結する手段をさらに備えている請求項(28)に記載の血液採取装置。

(30)前記第２の開口部を密封するキャップ手段をさらに備える請求項(11)に記載の血液採取装置。

(31)患者から血液サンプルを抜き取って集める際に医療作業員が使用する血液採取装置において、

挿入端部と取り付け端部を有する第１の細長い針部材を備え、前記挿入端部が患者に挿入するようになっており、前記第１の針部材が患者から抜き取られた血液を前記挿入端部から前記取付端部へ運ぶ同軸通路を有しており、

針受け入れ端部と、嵌合端部と、前記針受け入れ端部から前記嵌合端部へ延びる同軸通路と、を有する第１の雌コネクターと、

患者から抜き取られた血液が前記第１の針部材によって前記第１の雌コネクターに運ばれるように、前記第１の針部材の前記取り付け端部を前記第１の雌コネクターの受け入れ端部に固定してかつ密封自在に連結する手段と、

嵌合端部と、取り付け端部と、前記嵌合端部から前記取り付け端部へ延びる同軸通路を有する第１の雄コネクターをさらに備え、前記第１の雄コネクターの前記嵌合端部は、前記第１の雌コネクターへ運ばれた血液が前記第１の雄コネクターによって受け入れられるように、前記第１の雄コネクターの前記嵌合端部に密封自在に嵌合されており、

第１及び第２の端部と、前記第１の端部から前記第２の端部へ延びている通路とを有する細長いチューブをさらに備え、前記チューブの前記第１の端部は、前記第１の雄コネクターによって受け入れられた血液が前記チューブによって送られるように、前記第１の雄コネクターの前記取り付け端部に密封自在に取り付けられており、前記チューブは、可撓性を有し、かつ、前記チューブによって受け入れられた血液が医療作業員に見えるように概ね透明であり、

細長い中空のシャフトと、前記シャフトの第１の端部に取り付けられている接続部材とを有するカップリングをさらに備え、前記カップリングは、前記チューブの第２の端部を前記カップリングに固定して密封自在に連結し、それによって、前記チューブによって受け入れられた

血液を前記カップリングに送り、前記カップリングは、前記シャフトを血液貯蔵手段に接続する、前記シャフトの第２の端部に取り付けられたアダプタースリーブをさらに有し、前記カップリングは、前記アダプタースリーブと前記接続部材との間の前記シャフトに固定して取り付けられて、前記カップリングによって受け入れられた血液が前記第２の雌コネクターと連通するように、前記接続部材と連通している第２の雌コネクターをさらに有し、

前記第２の雌コネクターと前記アダプタースリーブとの間の前記カップリングの前記シャフト内に位置しているプラグをさらに備え、前記プラグは、気体を前記シャフトから逃がして前記シャフトから前記アダプタースリーブへ血液流れを有効に遮断するようになっている血液採取装置。

(32)挿入端部と、連結端部と、前記挿入端部から前記連結端部へ延びる同軸通路とを有する第２の針部材と、

患者から抜き取られた血液を貯蔵するバキュティナー手段とをさらに備え、前記バキュティナー手段は、前記第２の針部材に固定して取り付けられ、前記アダプタースリーブは、前記バキュティナー手段が前記アダプタースリーブの中へ圧入されるように、かつ、前記第２の針部材が前記プラグを通して挿入され、それによって前記カップリングの前記シャフトによって受け入れられた血液を前記バキュティナー手段へ運ぶように、形成されている請求項(31)に記載の血液採取装置。

(33)前記第２の針部材を案内して前記第２の針部材を前記カップリングと同軸の前記プラグへ挿入する、前記プラグと前記アダプタースリーブとの間の前記カップリング内に位置している針案内手段をさらに備えている請求項(32)に記載の血液採取装置。

(34)血液貯蔵手段に結合している針を案内して前記針を前記カップリングへ同軸に挿入する、前記プラグと前記アダプタースリーブとの間の前記カップリング内に位置している針案内手段をさらに備えている請求項(31)に記載の血液採取装置。

(35)前記第２の雌コネクターに係合しそれによって前記第２の雌コネクターから血液が流出するのを防止すべく前記第２の雌コネクターを密封するようになっているキャップ手段をさらに備える請求項(31)に記載の血液採取装置。

(36)一時的に血液を貯蔵する注射器をさらに備え、前記注射器は、血液貯蔵チャンバーと該血液貯蔵チャンバー内に位置するプランジャーとを有し、前記注射器は、前記血液貯蔵手段と連通していて、前記カップリングによって受け入れられた血液が前記注射器内に貯蔵されるように、前記第２の雌コネクターと嵌合するようになっている請求項(31)に記載の血液採取装置。

(37)前記第２の針部材を案内して前記第２の針部材を前記カップリングと同軸の前記プラグへ挿入する、前記プラグと前記アダプタースリーブとの間の前記カップリング内に位置している針案内手段をさらに備えている請求項(36)に記載の血液採取装置。

(38)挿入端部と、連結端部と、前記挿入端部から前記連結端部へ延びる同軸通路とを有する第２の針部材と、

患者から抜き取られた血液を貯蔵するバキュティナー手段とをさらに備え、前記バキュティナー手段は、前記第２の針部材に固定して取り付けられ、前記アダプタースリーブは、前記バキュティナー手段が前記アダプタースリーブの中へ圧入されるように、かつ、前記第２の針部材が前記プラグを通して挿入され、それによって前記カップリングの前記シャフトによって受け入れられた血液を前記バキュティナー手段へ運ぶように、形成されている請求項(37)に記載の血液採取装置。

(39)前記第１の針手段、前記第２の雌コネクター、及び前記アダプタースリーブを各々密封する、第１、第２及び第３のキャップ手段をさらに備える請求項(37)に記載の血液採取装置。

(40)前記第２の雌コネクターと前記シャフトとの間を選択的に連通する、前記第２の雌コネクターに連結されたバルブ手段をさらに備える請求項(31)に記載の血液採取装置。

(41)患者から血液サンプルを抜き取って貯蔵するために、医療作業員が使用する血液採取装置において、

患者から血液を抜き取る針手段と、

患者から抜き取った第1の血液部分を一時的に貯蔵する注射器手段と、

前記針手段を前記注射器手段へ密封自在に連結するカップリング手段とを備え、前記カップリング手段は、前記針手段と前記カップリング手段内にたまった空気を排気する流れ制御手段を有しており、前記カップリング手段は、血液貯蔵手段を受け入れて前記カップリング手段へ貯蔵のために血液を導くようになっているアダプター手段をさらに有しており、前記注射器手段と前記カップリング手段は、前記第1の血液部分を患者に戻すようにさらになっている血液採取装置。

(42)前記カップリング手段が、細長い中空シャフトを有するカップリングを備え、前記カップリング手段が、前記カップリングへ前記針手段を固定して連結する、前記シャフトの第1の端部に取り付けた接続部材をさらに有し、前記アダプター手段は、前記シャフトの第2の端部に取り付けられており、前記カップリングは、前記注射器手段を受け入れる、前記アダプター手段と前記接続部材との間の前記シャフトに固定して取り付けた接続部材をさらに有している請求項(41)に記載の血液採取装置。

(43)前記流れ制御手段が、前記接続部材と前記アダプター手段との間の前記カップリングの前記シャフト内に位置しているプラグから成る請求項(42)に記載の血液採取装置。

(44)前記プラグが微孔質疎水性プラグから成る請求項(43)に記載の血液採取装置。

(45)前記針手段が、血液サンプルを抜き取るために患者に挿入する針と、患者から抜き取られた血液を前記カップリングへ導く、細長いチューブとを有し、前記チューブは可撓性を有し、かつ、前記チューブによって導かれている血液が医療作業員に見えるように概ね透明である請求項(43)に記載の血液採取装置。

(46)前記血液採取装置にたまった空気を排気しながら患者から第1の血液部分を抜き取って前記血液採取装置を満たし、嫌気性サンプルが前記血液採取手段にたまった空気に汚染されないように、前記血液採取装置にたまった空気を概ね排気した後、患者から嫌気性サンプルを抜き取る、

ステップから成る患者から嫌気性血液サンプルを抜き取る方法。

(47)前記第1の血液部分を抜き取った後に、前記第1の血液部分を一時的に貯蔵し、

前記嫌気性血液サンプルを抜き取った後に、前記第1の血液部分を患者に戻す、

ステップをさらに含む請求項(46)に記載の方法。

(48)前記第1の血液部分を抜き取るステップが、

注射器にカップリングを連結するステップをさらに含み、前記カップリングは針組立体に密封自在に連結されており、

さらに、前記第1の血液部分を抜き取るステップが、

血液が前記針組立体を介して前記注射器を取り付けたカップリングの中に導かれるように、患者に前記針組立体を挿入し、

前記挿入された針組立体とカップリング内にたまった空気を排気し、

バキュティナーのバキュティナー針を前記通気されたカップリングに接続して、前記バキュティナー針を前記挿入された針組立体と連通させ、

前記バキュティナーを取り付けたカップリングから前記第1の血液部分を前記注射器の中に抜き取る、

ステップを含んでいる請求項(47)に記載の方法。

(49)前記嫌気性血液サンプルを抜き取るステップが、前記第1の血液部分が抜き取られた後で前記針組立体と前記バキュティナーとの間に血液の流れをつくるステップから成る請求項(48)に記載の方法。

(50)前記第1の血液部分を前記注射器へ抜き取るステップが、患者の心臓の圧力下で自由に血液

を流すステップから成る請求項(48)に記載の方法。

3.発明の詳細な説明

(産業上の利用分野)

本発明は、患者から血液サンプルを採取する装置に向けられたものであり、特に、サンプル内の気体分圧が、患者の生体内における血液内の気体分圧とほぼ等しくなるように、血液サンプルを受け取ることができる、改良された血液採取装置に向けられたものである。

(従来技術)

医療分野では、患者の血液内の、生体内における気体の平衡状態を決定することが必要である。医療作業員は、代表的には、酸素と二酸化炭素の分圧を気にかけるであろう。彼らは、また、例えば水素イオンやカルシウムイオンのような、活性が血液中の気体平衡に関連してくるイオンの種を気にかけるであろう。

血液サンプルを血液中の気体分析のために有効なものにするには、サンプルは、嫌気条件で、すなわち、検査すべき気体の分圧に変動が生ずるのを防止すべく血液が患者の体外の気体にさらされないように、採取されなければならない。現在市販されて利用できる主要な血液採取装置は、嫌気血液採取の完全性を保証しているという点では、概ね妥当であるとはいえない。従来装置の例としては、注射器及びベント式プランジャーが使用されており、バレル内の空隙がない状態からベント式プランジャーを引っ張ることによって、患者から正確な血液体積が得られるまで、患者から注射器のバレルの中に血液をゆっくりと抜き取る。しかしながら、これらの装置は、血液サンプルが外気にさらされるのをある程度許している。プランジャーが移動する前に、ある程度の外気量はバレル内に含有されるであろう。従って、血液の最初の部分はこれらの気体にさらされ、それによって、この最初のサンプルに含有している気体の分圧が変化する。抜き取られた血液のうち最初の部分を捨てる手段は提供されておらず、そのため、全サンプルが汚染されるであろう。

さらに、前述した装置を用いる際に、装置の医療作業員を、作業の途中で汚染された血液の偶発的な破裂や暴露に対して保護する手段も提供されていない。

ベクトンディケンソン(Becton and Dickenson)のバキュテイナー(Vacutainer)及びバキュテイナー付属装置のような他の装置は、抜き取られた血液に対する暴露から医療作業員を保護する、改良された特性を示している。しかしながら、これらの装置もまた、外気に対する血液サンプルの最初の部分の暴露を、ある程度許容してしまう。

前述した従来技術の欠点に加えて、嫌気性血液サンプルの採取を可能にしつつ、流し込み、すなわち血液の流れの中へ、例えば栄養剤や薬等を注入する手段を備える血液採取装置は、現在のところ知られていない。

従って、患者から嫌気性血液サンプルを抜き取る装置を提供することが望ましい。さらに、液体を患者の血液の流れに注入することもできる、血液サンプルを抜き取る装置を提供することがさらに望ましい。穿刺、すなわち針の配置を追加して行う必要のない、繰り返して血液を採取できる、前記装置を提供することがさらに望ましい。また、予定された区間の採取、すなわち他の引き続いて行なわれる血液の採取の間、患者に残してお

くことができる、血液サンプルを抜き取る装置を提供することが望ましい。

(発明の目的)

それゆえ、本発明の目的は、患者から嫌気性血液サンプルを抜き取る血液採取装置を提供することである。

また、本発明の目的は、最初の汚染された血液のサンプル部分を抜き取って、残りのサンプルにおける完全な嫌気性を維持できる、血液採取装置を提供することである。

さらに、本発明の目的は、外部の液体を患者の血液の流れの中に注入できる血液採取装置を提供することである。

さらに、本発明の目的は、穿刺、すなわち針の配置を追加して行なう必要のない、繰り返して血液を採取できる血液採取装置を提供することである。

さらに、本発明の別の目的は、予定された区間の採取、すなわち他の引き続いて行なわれる血液採取の間、患者に残しておくことができる血液採取装置を提供することである。

本発明の、これら及び他の目的は、患者から血液を抜き取ってこれを貯蔵するときに、医療作業員が使用するカップリングを提供することによって、かなえられる。このカップリングは、血液サンプルを引き出すべく、患者に針を注入する針組立体とともに使用するために、特に利用される。カップリングは、細長い中空シャフトと、針組立体を該シャフトに固定的に連結し、針によって引き出された血液をシャフトに送る、シャフトの第1の端部に取り付けられる接続部材と、から成る。カップリングは、シャフトを様々な血液貯蔵手段に接続する、シャフトの第2の端部に取りつけられたアダプタースリーブをさらに備えている。開口部が、アダプタースリーブと接続部材との中間のシャフトに連結されており、シャフトに受け入れられた血液がその開口部と連通するように、その開口部は、接続部材と連通している。

本発明の別の実施例では、血液の流れを遮断してシャフトにたまった空気を通気する装置が提提される。特に、流れ制御手段、例えば、微孔質の疎水性プラグが、シャフトからアダプタースリーブへの空気の流れを可能にしつつ、シャフトからアダプタースリーブへの血液の流れを制限するため、開口部とアダプタースリーブとの中間のシャフト内に位置している。本発明の他の実施例では、シャフトと開口部との選択的な連通を可能にするバルブが、シャフトと開口部との中間に設けられる。

本発明の他の実施例は、特許請求の範囲で特に示され、明瞭に請求される。しかしながら、本発明は、実施の構成や方法に関する限り、添付図面を参照して次の詳細な説明を読むことから最も良く理解できるであろう。

(実施例)

本発明の改良された血液採取装置を示す断面図が第1図に提供されている。血液採取装置は、患者の血液流れ(動脈あるいは静脈)内に挿入するようになった挿入端部102を有する細長い針100を備えている。針100は、さらに、円筒シール108を介して第1の接続部材106に取り付けられている取り付け端部104を有している。当業界で周知のように、針100は、患者から引き出された血液を第1の接続部材106へ導く、挿入端部102から取り付け端部104へ延びる同軸通路を有している。

円筒シール108は、内部に針100の取り付け端部104が固定して取り付けられている中央開口部110を有している。さらに、円筒シール108は、第1の接続部材106の針受け入れ端部112へ固定して取り付けられている。第2の接続部材114は、第1の接続部材106の嵌合端部118と嵌合するようになった嵌合端部116を有しており、その結果、第1の接続部材によって受け入れられた、針100からの血液は、嵌合接合116、118を介して第2の接続部材114に導かれる。

チューブ122の第1の端部120が、第2の接続部材114の取り付け端部124に密封して取り付けられている。チューブ122は、患者から引き出された血液を針100を介してカップリング126へ運ぶために設けられている。チューブ122は、針を患者の血液流れに容易に挿入可能であり、さらに、挿入後、針100に無用な動

きを与えて患者に不快感を生ぜしめることなく、医療作業員がカップリング１２６を操作可能となるように、可撓性であるのが好ましい。さらに、チューブ１２２は、医療作業員が患者から引き出された血液を視覚で観察できるように、透明であるのが好ましい。

針１００と、第１の接続部材１０６と、第２の接続部材１１４と、チューブ１２２との組合わせは、針組立体を構成し、当業界で周知の針、接続部材、及びチューブから容易に組立て可能である。一例として、第１及び第２の接続部材１０６及び１１４は、当業界で周知のように、雄及び雌のルエル(Luer)コネクターから成る。

カップリング１２６は、チューブの第２の端部１２８を、第１及び第２の血液貯蔵手段１３０及び１３２の各々と接続するために設けられている。この目的のために、カップリング１２６は、チューブ１２２の第２の端部１２８を受け入れる中央開口部を有する接続部材１３４を有している。接続部材１３４は、チューブ１２２によってカップリング１２６に送られる血液がシャフト１３６の内部に受け入れられるように、細長い中空シャフト１３６に一体に接続される。アダプタースリーブ１３８は、接続部材１３４が接続されている端部と反対側の端部でシャフト１３６に一体に接続されている。アダプタースリーブ１３８は、シャフト１３６と連通しており、後で完全に説明するように、第２の血液貯蔵手段１３２を受け入れるために設けられる。

カップリング１２６は、さらに、アダプタースリーブ１３８と接続部材１３４との中間のシャフト１３６に一体に接続されている開口部１４０を、さらに有している。開口部１４０は、第１の血液貯蔵手段１３０をカップリング１２６のシャフト１３６へ接続するために設けられる。通路１６２は、開口部１４０が接続部材１３４と連通するように、開口部１４０に近接してシャフト１３６に設けられている。従って、チューブ１２２によってカップリング１２６に送られてきた血液は、貯蔵のため、アダプタースリーブ１３８及び開口部１４０を経由して第１及び第２の血液貯蔵手段１３０及び１３２へ運ばれる。

カップリング１２６は、また、アダプタースリーブ１３８と開口部１４０との間のシャフト内に配置されたプラグ１４２を有している。プラグ１４２は、血液採取作業の初期の段階の間に、接続部材１０６、１１４、チューブ１２２、シャフト１３６、及び開口部１４０内にたまった空気を排気する、例えば、多孔質プラグのような液体流れ制御手段から成る。従って、プラグ１４２は、シャフト１３６からアダプタースリーブ１３８への血液の流れを制限して、シャフトからアダプタースリーブへの空気の流れを可能にするようになっている。本発明の好ましい実施例では、プラグ１４２は、当業界で周知の、微孔質の疎水性プラグから成る。しかしながら、他の液体流れ制御手段が、好ましい微孔質疎水性プラグ１４２の代わりに、用いることができることは、当業者には明らかであろう。

前述したように、開口部１４０は、第１の血液貯蔵手段１３０を受け入れるようになっている。キャップ１４４は、第１の血液貯蔵手段１３０がカップリング１２６に接続されていないときに、しばしばおこる不注意な血液損失から開口部を密封するため、開口部１４０と係合可能である。しかしながら、通常作業では、キャップ１４４は、開口部１４０から取り除かれ、そこに第１の血液貯蔵手段１３０を接続している。

本発明の好ましい実施例では、第１の血液貯蔵手段１３０は、血液貯蔵チャンバー１４６と、その血液貯蔵チャンバー１４６内に配置されたプランジャー１４８を有する形式の注射器から成る。周知のように、操作の際には、プランジャー１４８は、血液がチャンバー内に入るように、血液貯蔵チャンバー１４６からゆっくりと引き出される。血液貯蔵手段１３０は、さらに、血液貯蔵手段１３０を開口部１４０に接続するため、接続手段１５０を備えている。本発明の好ましい実施例では、開口部１４０と接続部材１５０は、各々、雄雌のルエルコネクターから成る。しかしながら、他のコネクター部材が第１の血液貯蔵手段１３０をカップリング１２６に密封して接続するために提供されることは、当業者には明らかであろう。

操作の際は、キャップ１４４は、開口部１４０から取り除かれて、そこに血液貯蔵手段１３０が接続される。次いで、血液が引き出され、あるいは好ましくは患者の心臓の圧力下で自由に流れることができるように、かつ、接続部材１０６、１１４及びチューブ１２２を介して、シャフト１３６に送られるように、患者の血液流れの中に針１００が挿入される。接続部材１０６、１１４、チューブ１２２、シャフト１３６及び開口部１４０内にたまった空気は、前述したように、流れ通路に入った患者の血液によって、置換され、多孔質プラグ１４２を介して通気される。引き出され、あるいは患者からの心臓の圧力下で流れる血液の第１の部分は、通気される前に、たまった空気にさらされるので、概ね汚染されており、それゆえ、嫌気性血液採取に適していない。従って、この第１の血液の部分は、一時的に貯蔵するために、血液貯蔵手段１３０の中へカップリング１２６から引き出され、一方、嫌気性血液サンプルは、第２の血液貯蔵手段１３２を介して受取られる。嫌気性血液サンプルが受取られた後、血液貯蔵手段１３０内に一時的に貯蔵された血液は、捨てられ、あるいは、チューブ１２２及び針１００を介して患者に戻される。

嫌気性血液サンプルを引き出すため、第２の血液貯蔵手段１３２がアダプタースリーブ１３８を介してカップリング１２６に接続されている。第２の血液貯蔵手段１３２は、当業界で周知のベクトン・ディケンソン・バキュティナーから成っていてもよい。血液貯蔵手段１３２は、患者から抜き取られた嫌気性血液サンプルを受け入れる血液貯蔵チャンバー１５２を有している。針１５４は、針ハブ１５６に密封して接続されており、それらの組立体は、適合性を有するカップリング１５８（普通は、バキュテイナーアダプターとして言及されている）を介して血液貯蔵チャンバー１５２に密封して接続されている。当業界で周知のように、針１５４は、血液貯蔵チャンバー１５２と連通することを防止するため、シールを有している。さらに、当業界で周知のように、血液貯蔵チャンバー１５２は、患者から抜き取られた血液を汚染する空気を含まないようにするため、排気されている。適合性を有するカップリング１５８は、針１５４を血液貯蔵チャンバー１５２と連通させて配置するため、針１５４からシールを取り除く手段を備えている。

アダプタースリーブ１３８は、針ハブ１５６をきちんと受け入れるような径でできた内部アダプターチャンバー１６０を有している。アダプタースリーブ１３８の長さとシャフト１３６内のプラグ１４２の位置は、血液貯蔵手段１３２がアダプタースリーブ１３８に完全に挿入され、針１５４がプラグ１４２を通って通路１６２とチューブ１２２の第２の端部１２８との間に位置するように、選択される。針がシャフト１３６と同軸になるようにカップリング１２６内に挿入されることを可能とするため、針ガイド１６４がアダプタースリーブ１３８とプラグ１４２との間のカップリング１２６内に配置されている。針ガイド１６４は、カップリング１２６内への血液貯蔵手段１３２の挿入の間、針１５４を受け入れて、かつ、針がシャフト１３６と同軸となるように、プラグ１４２への針の挿入前に針を位置決めするために、設けられている。

操作の際は、嫌気性血液サンプルを集めるために、血液貯蔵手段１３０が、前述した開口部１４０を介してカップリング１２６に連結される。針１００が患者の血液流れの中に挿入され、針１００、コネクター１０６、１１４、チューブ１２２及びカップリング１２６の内部にたまった空気が前述したようにプラグ１４２を介して排気される。次いで、血液貯蔵手段１３２の針１５４が、チューブ１２２の近傍の通路１６２を越えて位置するように、プラグ１４２を通してカップリング１２６内に挿入される。針１５４内にたまった汚染空気のどんなにわずかの部分でもプラグ１４２を介して排気されるように、すなわち、嫌気性血液サンプルを受け入れる前にカップリング１２６から取り除かれるように、血液サンプルの汚染された部分を貯蔵手段１３０内に貯蔵する前に、針１５４をカップリング１２６へ挿入することが望ましい。

針１５４がカップリング１２６内に適当に挿入された後、汚染された血液の第１の部分はカップ

リング１２６から一時貯蔵のため血液貯蔵手段１３０へ引き出される。このとき、針１５４のシールは、嫌気性血液サンプルが血液貯蔵１５２へ導かれるように、当業界で周知のように、適合性カップリング１５８によって除去される。血液貯蔵チャンバー１５２へ導かれた血液のほぼ全部がチューブ１２２から受け取った血液であって、血液貯蔵手段１３０の血液貯蔵チャンバー１４６から受け取った血液ではないようにするために、針１５４は、通路１６２とチューブ１２２との中間でかつ、チューブ１２２の第２の端部１２８の近傍の、シャフト１３６内のカップリング１２６内に位置していることが好ましい。

本発明の代わりの実施例では、嫌気性血液サンプルを受け取っているとき、血液貯蔵手段１３０内に貯蔵された汚染された血液サンプルを、操作中に、シャフト１３６からほぼ隔離することができるバルブ、あるいは他の選択性カップリング手段を備えることが望ましい。

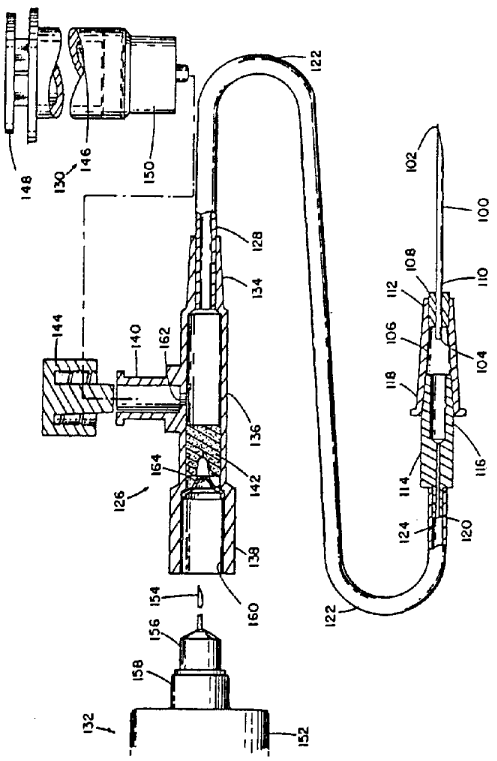
医療業界では普通となっているように、キャップ１４４に加えて、複数のキャップあるいは他のシール手段が、針１００に配置してアダプタースリーブ１３８のチャンバー１６０を密封するために設けられてもよい。

新規な血液採取装置の好ましい実施例のいくつかのみをここで詳細に説明したが、当業者には、多くの改良や変更が容易に明らかとなるであろう。本発明の真の範囲及び精神に入るこのようなすべての改良や変更を包含することが、特許請求の範囲の趣旨である。

4.図面の簡単な説明

第１図は、本発明の改良された血液採取装置の断面図を示す。

１００・・・・・針
１０６・・・・・第１の接続部材
１１４・・・・・第２の接続部材
１２２・・・・・チューブ
１２６・・・・・カップリング
１３０、１３２・血液貯蔵手段
１３４・・・・・接続部材
１３６・・・・・シャフト
１３８・・・・・アダプタースリーブ
１４０・・・・・開口部
１４２・・・・・プラグ
１４４・・・・・キャップ
１４６、１５２・血液貯蔵チャンバー
１４８・・・・・プランジャー
１５４・・・・・針



Espacenet

Bibliographic data: DE10243129 (A1) — 2004-04-01

Multiple compartment blood collecting device for collecting blood from small animals such as dogs and cats comprises a cannula, blood receiving vessels and tubes connected to the rear end of the cannula

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- **cooperative:** A61B5/15003 (EP); A61B5/150351 (EP); A61B5/150389 (EP); A61B5/150503 (EP); A61B5/15074 (EP); A61B5/154 (EP); A61D1/00 (EP)

Application number: DE20021043129 20020918

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Abstract of DE10243129 (A1)

Multiple compartment blood collecting device comprises a cannula (1), blood receiving vessels (7, 8, 9), and tubes (2, 3, 4, 5, 6) connected to the rear end of the cannula with their branches connected to the blood receiving vessels. Preferred Features: Each blood receiving vessel is closed by a semi-permeable stopper (10) through which air can pass and the blood collected can not. The stopper are made from an air-permeable stopper body and a semi-permeable membrane formed on its inner side. Each branch of the tube has a hollow needle penetrating the stopper.

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DESCRIPTION DE10243129A1

[0001]

13 The invention relates to a multiple blood collection device for use in smaller animals such as cats, dogs and the like, or for similar applications where only limited amounts of blood are available, for example in small children.

[0002]

19 Multiple blood sampling, i.e. filling several tubes with blood, is required for various examination methods. For example, one tube of untreated blood is required for standard analyses. For blood count and cell tests as well as for HbA1 you need a collection tube coated with EDTA, for coagulation tests you need a tube that has been mixed with citrate, etc.

[0003]

26 Known multiple blood collection systems are designed for adult humans.

27 They consist of a cannula that is inserted into the vein once and then several blood collection tubes can be coupled to the cannula in order to be filled. In the case of animals, a simple cannula, open at the back, is usually used, to which the blood collection tubes, which are also open and to be filled, are simply held out until they are sufficiently filled.

[0004]

34 These known systems are not very suitable for smaller animals such as cats, for example, where only a limited amount of blood is available.

36 If the front leg of the cat is tied off to take blood, the blood accumulates and shoots out violently when a cannula is inserted due to the pressure that has built up. When using an open system,

blood is often splattered, which is then lost and can also occur when the tubes are changed blood are lost. In addition, the first tube fills up very quickly and possibly overflows, and there is then no longer enough blood for a second and possibly a third tube.

[0005]

44 The object of the invention is to create a multiple blood sampling device that is particularly suitable for applications where only a limited amount of blood is available.

[0006]

49 According to the invention, this object is achieved by the multiple blood sampling device specified in claim 1 .

51 Advantageous configurations of the invention are the subject matter of the dependent claims.

[0007]

55 The multiple blood collection device according to the invention embodies a closed or quasi-closed system which avoids the above-mentioned problems of the conventional systems which are unsuitable for the purposes under discussion here.

58 In the blood collection device according to the invention, a cannula is connected via a branching hose to a plurality of blood collection tubes, which are filled at the same time.

60 Even if there is a strong flow of blood at the beginning, this is then distributed evenly over the connected tubes, so that the required number of sufficiently filled tubes are available without loss of blood drawn.

[0008]

66 The device according to the invention can be realized in several versions, for example with two tubes or with three tubes, in order to take account of the cases in which only two tubes of blood or in which three tubes of blood are required.

69 It is also possible, for example with a device comprising three tubes, to take blood from only two tubes by pinching off the hose branch to the third tube.

[0009]

74 Further details and advantageous refinements of the invention are described in more detail below using an exemplary embodiment with reference to the attached drawing.

[0010]

79 The drawing shows a schematic representation of a multiple blood sampling device according to

the invention.

[0011]

84 The multiple blood sampling device according to the invention shown in the drawing has a cannula 1, which is shown only schematically.

86 Its rear end is connected to three blood collection vessels 7 , 8 , 9 via a hose 2 which branches at a junction 3 into three branch hoses 4 , 5 , 6 in the exemplary embodiment.

[0012]

91 The blood collection vessels 7 , 8 , 9 can each be closed by a semi-permeable stopper 10 .

92 Such plugs are known per se.

93 They are permeable to air, so if blood enters the tube, air can escape through the stopper, but they seal up on contact with liquid so that blood cannot escape.

95 Such plugs can also consist of an air-permeable plug body and a semi-permeable membrane formed on the inside thereof.

97 The ends of the branch hoses can be connected to hollow needles that are inserted into the respective stopper 10 .

99 Since such stoppers are also self-sealing, each blood withdrawal vessel can be removed from the hollow needle after it has been filled, with the stopper closing itself automatically.

[0013]

104 As an alternative to this, each blood collection vessel can also be provided with a cap which has an air outlet opening.

106 This can be closed, for example with a cap, or it can be designed as a small piece of tubing that can be closed with a clamp.

[0014]

111 During use, the three blood collection vessels fill evenly after the cannula has been inserted into the vein.

113 If, in individual cases, only two of the three blood collection vessels are to be filled, the branch hose of the third vessel can be pinched off with a clamp, or where caps with a closable ventilation opening are used for the blood collection vessels, the ventilation opening can be closed, with the result that vessel also no blood enters.

117 By closing the ventilation opening, the further inflow of blood can also be terminated when the desired filling quantity is reached in one vessel, while other vessels continue to be filled.

[0015]

122 It is also possible to design the branch in such a way that access to a blood collection vessel that is not required can be blocked there.

[0016]

127 For frequently occurring applications, for example for filling two vessels or for filling three vessels, versions of the device with branching of the tube 2 into only two vessels or, as in the exemplary embodiment, into three vessels can preferably be kept ready.

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CLAIMS DE10243129A1

1.

13 Multiple blood collection device, consisting of a cannula (1), at least two blood collection vessels (7 , 8 , 9), and a hose connection (2 , 3 , 4 , 5 , 6), the branches of which are each connected to one of the blood collection vessels (7 , 8 , 9).

16 Blood collection apparatus according to claim 1, wherein each blood collection vessel (7, 8, 9) is closed with a semi-permeable plug (10) which allows air to escape but blocks the escape of liquid and through which the respective branch of the tubing connection passes.

19 A blood collection device according to claim 2, wherein said semi-permeable plug consists of an air-permeable plug body and a semi-permeable membrane formed on the inside thereof

21 Blood collection device according to claim 2 or 3, wherein each branch of the hose connection has a hollow needle penetrating the stopper (10), and wherein the stopper is self-closing after the hollow needle has been withdrawn.

24 Blood collection device according to one of claims 1 to 4, wherein the hose connection has a branch piece (3) which is connected via a hose (2) to the cannula (1) and connected to three branch hoses (4, 5, 6) connected to the blood collection vessels .

27 A blood collection device according to claim 5, wherein the branch piece (3) has a mechanism for selectively shutting off one of the branch tubes.

2.

32 A sheet of drawings follows

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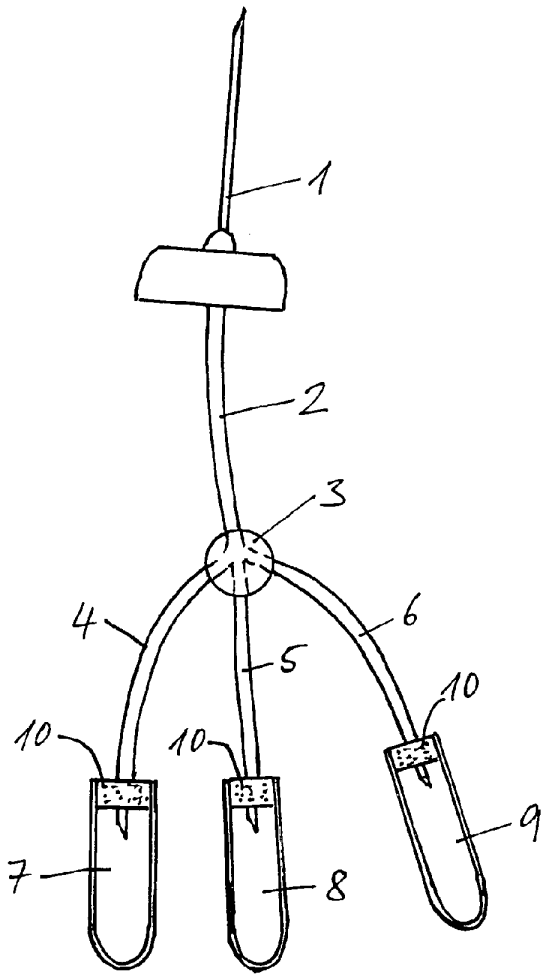
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Die folgenden Angaben sind den vom Anmelder eingereichten Unterlagen entnommen

Rechercheantrag gemäß § 43 Abs. 1 Satz 1 PatG ist gestellt.

(54) Bezeichnung: **Mehrfachblutentnahmegerät für Kleintiere und ähnliche Anwendungen**

(57) Zusammenfassung: Mehrfachblutentnahmegerät mit einer Kanüle, die über eine sich verzweigende Schlauchverbindung (2, 3, 4, 5, 69 mit einer Mehrzahl von Blutentnahmegefäßen (7, 8, 9) verbunden ist.



Beschreibung

[0001] Die Erfindung betrifft ein Mehrfachblutentnahmegerät zur Verwendung bei kleineren Tieren wie Katzen, Hunden und dergleichen, oder auch für ähnliche Anwendungen, wo nur begrenzte Blutmengen zur Verfügung stehen, also zum Beispiel bei Kleinkindern.

Stand der Technik

[0002] Eine Mehrfachblutentnahme, das heißt das Füllen mehrerer Röhrchen mit Blut, ist bei verschiedenen Untersuchungsmethoden erforderlich. So benötigt man ein Röhrchen unbehandeltes Blut für Standardanalysen. Für Blutbild- und Zelluntersuchungen sowie für HbA1 benötigt man ein mit EDTA beschichtetes Entnahmeröhrchen, für Gerinnungsuntersuchungen benötigt man ein Röhrchen, das mit Zitrat versetzt ist, usw.

[0003] Bekannte Mehrfachblutentnahmesysteme sind für erwachsene Menschen ausgelegt. Sie bestehen aus einer Kanüle, die einmal in die Vene eingestochen wird, und dann können mehrere Blutentnahmeröhrchen nacheinander zum Füllen mit der Kanüle gekuppelt werden. Bei Tieren wird meist eine einfache, hinten offene Kanüle verwendet, an die einfach die ebenfalls offenen, zu füllenden Blutentnahmeröhrchen hingehalten werden, bis sie genügend gefüllt sind.

[0004] Bei kleineren Tieren wie beispielsweise Katzen, wo nur eine begrenzte Blutmenge zur Verfügung steht, sind diese bekannten Systeme wenig geeignet. Wird der Katze zur Blutentnahme der Vorderlauf abgebunden staut sich das Blut und schießt beim Einstechen einer Kanüle aufgrund des aufgebauten Drucks erst einmal heftig heraus, wobei bei Verwenden eines offenen Systems oftmals Blut verspritzt wird, das dann verloren ist, und auch beim Wechseln der Röhrchen kann Blut verloren gehen. Außerdem läuft dadurch das erste Röhrchen sehr schnell voll und womöglich über, und für ein zweites und eventuell ein drittes Röhrchen ist dann nicht mehr genügend Blut vorhanden.

Aufgabenstellung

[0005] Aufgabe der Erfindung ist es, ein Mehrfachblutentnahmegerät zu schaffen, das sich besonders bei Anwendungsfällen eignet, wo nur eine begrenzte Blutmenge zur Verfügung steht.

[0006] Diese Aufgabe wird gemäß der Erfindung durch das im Anspruch 1 angegebene Mehrfachblutentnahmegerät gelöst. Vorteilhafte Ausgestaltungen der Erfindung sind Gegenstand der Unteransprüche.

[0007] Das erfindungsgemäße Mehrfachblutentnahmegerät verkörpert ein geschlossenes oder quasi-geschlossenes System, das die oben erwähnten Probleme der herkömmlichen, für die hier in Rede stehenden Anwendungszwecke ungeeigneten Systeme vermeidet. Bei dem erfindungsgemäßen Blutentnahmegerät ist eine Kanüle über einen sich verzweigenden Schlauch mit einer Mehrzahl von Blutentnahmeröhrchen verbunden, die gleichzeitig befillt werden. Auch bei anfänglich stark hereinschießendem Blut verteilt sich dieses dann gleichmäßig auf die angeschlossenen Röhrchen, so daß ohne Verlust von entnommenem Blut ausreichend befiillte Röhrchen in der erforderlichen Anzahl zur Verfügung stehen.

[0008] Das erfindungsgemäße Gerät kann in mehreren Versionen, beispielsweise mit zwei Röhrchen oder mit drei Röhrchen realisiert werden, um den Fällen Rechnung zu tragen, in denen nur zwei Röhrchen Blut oder in denen drei Röhrchen Blut benötigt werden. Es ist auch möglich, beispielsweise mit einem drei Röhrchen umfassenden Gerät nur zwei Röhrchen Blut zu entnehmen, indem der Schlauchzweig zum dritten Röhrchen abgeklemmt wird.

[0009] Weitere Einzelheiten und vorteilhafte Ausgestaltungen der Erfindung werden nachstehend anhand eines Ausführungsbeispiels unter Bezugnahme auf die anliegende Zeichnung mehr im einzelnen beschrieben.

Ausführungsbeispiel

[0010] Die Zeichnung zeigt in schematischer Darstellung ein Mehrfachblutentnahmegerät nach der Erfindung.

[0011] Das in der Zeichnung dargestellte erfindungsgemäße Mehrfachblutentnahmegerät weist eine Kanüle **1** auf, die nur schematisch dargestellt ist. Ihr rückwärtiges Ende ist über einen Schlauch **2** der sich an einer Verzweigung **3** in beim Ausführungsbeispiel drei Zweigschläuche **4**, **5**, **6** verzweigt, mit drei Blutentnahmegefäßen **7**, **8**, **9** verbunden.

[0012] Die Blutentnahmegefäße **7**, **8**, **9** können jeweils durch einen halbdurchlässigen Stopfen **10** verschlossen sein. Solche Stopfen sind an sich bekannt. Sie sind luftdurchlässig, so daß beim Eintritt von Blut in das Röhrchen Luft durch den Stopfen entweichen kann, aber sie verschließen sich bei Kontakt mit Flüssigkeit, so daß kein Blut austreten kann. Solche Stopfen können auch aus einem luftdurchlässigen Stopfenkörper und einer an dessen Innenseite gebildeten halbdurchlässigen Membran bestehen. Die Enden der Zweigschläuche können dabei mit Hohlnadeln verbunden sein, die in den jeweiligen Stopfen **10** eingestochen sind. Da solche Stopfen auch selbstverschließend sind, kann jedes Blutentnahmegefäß nach dem Füllen von der Hohlnadel abgezogen werden, wobei der Stopfen sich selbsttätig verschließt.

[0013] Alternativ dazu kann jedes Blutentnahmegefäß auch mit einer Kappe versehen sein, die eine Luftaustrittsöffnung hat. Diese kann verschließbar sein, beispielsweise mit einem Hütchen, oder sie kann als kleines Schlauchstück ausgebildet sein, das mit einer Klemme verschließbar ist.

[0014] Im Gebrauch füllen sich die drei Blutentnahmegefäße nach dem Einstechen der Kanüle in die Vene gleichmäßig. Sollen im Einzelfall nur zwei von den drei Blutentnahmegefäßen befüllt werden, kann der Zweigschlauch des dritten Gefäßes mit einer Klemme abgequetscht werden, oder wo bei den Blutentnahmegefäßen Kappen mit verschließbarer Entlüfteöffnung verwendet werden, kann die Entlüfteöffnung geschlossen werden, mit der Folge, daß dann in dieses Gefäß ebenfalls kein Blut eintritt. Durch verschließen der Entlüfteöffnung kann auch bei Erreichen der gewünschten Füllmenge in einem Gefäß der weitere Blutzutritt beendet werden, während andere Gefäße noch weiter befüllt werden.

[0015] Es ist auch möglich, die Verzweigung so auszubilden, daß dort wahlweise der Zutritt zu einem nicht benötigten Blutentnahmegefäß gesperrt werden kann.

[0016] Für häufig auftretende Anwendungsfälle, beispielsweise zum Befüllen von zwei Gefäßen oder zum Befüllen von drei Gefäßen, können vorzugsweise Versionen des Geräts mit Verzweigung des Schlauchs **2** auf nur zwei Gefäße oder, wie beim Ausführungsbeispiel, auf drei Gefäße bereitgehalten werden.

Patentansprüche

1. Mehrfachblutentnahmegerät, bestehend aus einer Kanüle (**1**), mindestens zwei Blutentnahmegefäßen (**7**, **8**, **9**), und einer mit dem rückwärtigen Ende der Kanüle verbundenen und sich in eine der Anzahl der Blutentnahmegefäße entsprechenden Anzahl von Zweigen verzweigenden Schlauchverbindung (**2**, **3**, **4**, **5**, **6**), deren Zweige mit jeweils einem der Blutentnahmegefäße (**7**, **8**, **9**) verbunden sind.

2. Blutentnahmegerät nach Anspruch 1, wobei jedes Blutentnahmegefäß (**7**, **8**, **9**) mit einem halbdurchlässigen Stopfen (**10**) verschlossen ist, der Luft austreten läßt, aber den Austritt von Flüssigkeit sperrt und durch welchen der jeweilige Zweig der Schlauchverbindung hindurchverläuft.

3. Blutentnahmegerät nach Anspruch 2, wobei der halbdurchlässige Stopfen aus einem luftdurchlässigen Stopfenkörper und einer an dessen Innenseite gebildeten halbdurchlässigen Membran besteht

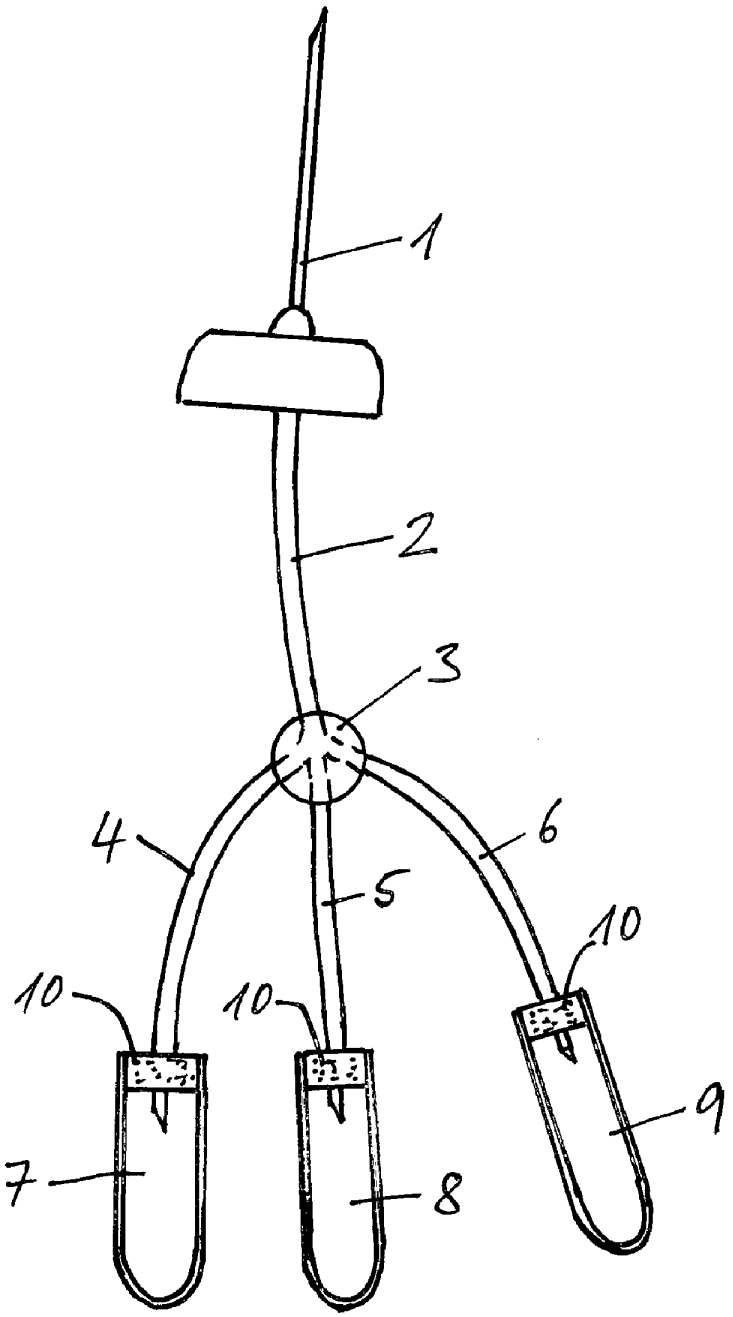
4. Blutentnahmegerät nach Anspruch 2 oder 3, wobei jeder Zweig der Schlauchverbindung eine den Stopfen (**10**) durchdringende Hohlnadel aufweist, und wobei der Stopfen nach Herausziehen der Hohlnadel selbstschließend ist.

5. Blutentnahmegerät nach einem der Ansprüche 1 bis 4, wobei die Schlauchverbindung ein Verzweigungsstück (**3**) aufweist, das über einen Schlauch (**2**) mit der Kanüle (**1**) verbunden und mit drei mit den Blutentnahmegefäßen verbundenen Zweigschläuchen (**4**, **5**, **6**) verbunden ist.

6. Blutentnahmegerät nach Anspruch 5, wobei das Verzweigungsstück (**3**) einen Mechanismus zum wahlweisen Absperren eines der Zweigschläuche aufweist.

Es folgt ein Blatt Zeichnungen

Anhängende Zeichnungen



Espacenet

Bibliographic data: DE10134913 (A1) — 2003-02-20

DEVICE AND METHOD FOR PREPARING BLOOD

Inventor(s): ECK MICHAEL [DE] ± (ECK, MICHAEL)

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Abstract not available for DE10134913 (A1)
Abstract of corresponding document: WO03008012 (A2)

The invention relates to a preparation device (100) for treating suspension samples, especially for preparing blood cryobanks. Said device comprises an arrangement of at least two containers for receiving suspension samples, sample parts and/or additives. Said containers are formed as chambers (13 to 15, 90) having fixed walls and are arranged in a fixed manner in relation to each other. A transfer device comprising at least one connecting line (22) is provided, by which means the chambers (13 to 15) can be interconnected.

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DESCRIPTION DE10134913A1

[0001]

13 The invention relates to a device for sample preparation, in particular a device for handling and treating blood samples, such as. B. for separating blood samples by centrifugation and for modifying blood samples by additives in preparation for cryopreservation of the blood samples, and methods for blood preparation, in particular for preparing blood samples for cryopreservation.

[0002]

21 It is known, for the cryopreservation of blood samples, to first prepare a blood unit from a blood donation for the state ready for freezing.

23 The preparation comprises in particular firstly a separation of the blood donation into an erythrocyte suspension which is to be cryopreserved and residual components and secondly the addition of a cryoadditive to the erythrocyte suspension. In conventional methods, blood samples are handled using flexible blood bags, as illustrated schematically in FIG. A blood donation is provided in a first blood bag 1' and centrifuged. After centrifugation, the blood donation is separated into the sediment and the supernatant (plasma). If necessary, the supernatant is drawn off into a waste container 4'. The erythrocyte suspension is transferred into another blood bag 2', to which a cryo-additive is added to provide the preserved product ready for freezing. The illustrated use of blood bags, described for example in DE 298 05 538 and WO 00/38762, has the following disadvantages.

[0003]

36 A major problem relates to the handling of the blood bags.

37 Since the blood bags do not have a fixed shape, careful handling of the blood bags must be

provided, in particular to preserve the phase boundary after centrifugation. In the conventional systems mentioned, devices for holding and transporting the blood bags are provided. However, these devices can only be automated to a very limited extent. The devices must be loaded manually and the operation must be continuously monitored. Furthermore, in the conventional devices, the blood bags are connected to one another via flexible hoses. To separate the erythrocyte suspension and the supernatant, the phase boundary on the blood bag or tube must be detected. Due to the flexibility of the respective containers, there is a risk of incorrect detection and thus a malfunction during preparation.

[0004]

49 Further disadvantages result from sterility problems when handling the blood bags.

50 The hose connections must be connected to the blood bags in a sterile manner and separated and sealed after the respective process step. In each step of the preparation, complex precautions must be taken to maintain the sterility and freedom from pyrogens of the blood samples. The conventional blood bag preparation is also problematic because of the risk of mix-ups. If a blood bag is mixed up during preparation or cross-contamination occurs between blood bags, the consequences for the recipient of the blood donation can be devastating. Extensive safety measures have to be implemented in conventional systems to rule out the risk of confusion.

[0005]

61 Another disadvantage of the technique described in WO 00/38762 is its specific tailoring to stem cell preparation.

63 When separating stem cells from biological fluid samples, only a very small amount of stem cells has to be separated from the samples. This allows for the use of special centrifugation techniques and less sensitivity to the use of blood bags.

[0006]

69 In modern medicine and in civil protection there is an interest in enlarged blood banks with a wide range of different blood types.

71 Automating the preparation of the canned goods is necessary for the production of modern blood banks. Because of the need for automation, the applicability of conventional preparation devices is limited.

[0007]

77 The problems illustrated in handling blood samples are not unique to the preparation of preserves for cryopreservation.

79 There is also a corresponding need for sterile, automated and safe sample handling when

processing biological cell suspensions for therapeutic purposes.

[0008]

84 The object of the invention is to provide an improved device for the preparation of suspended biological samples, with which the disadvantages of conventional systems are overcome and which is particularly suitable for automated and safe handling of a large number of samples.

87 The object of the invention is in particular to provide an improved system for the preparation of cryopreserves such. B. Blood cryopreserves. The object of the invention is also to specify a novel method for handling biologically suspended samples which can be automated and carried out safely.

[0009]

94 These objects are achieved with a preparation device, a preparation station and a method having the features according to patent claims 1, 9 and 12.

96 Advantageous embodiments and applications of the invention result from the dependent claims.

[0010]

100 The basic idea of the invention is to provide a preparation device that has at least two containers for receiving the suspension samples to be treated, the containers, in contrast to conventional systems, being formed by chambers with fixed walls that are positioned stationary relative to one another.

104 The chambers are connected to one another via line connections that can be actuated individually or are equipped with connecting pieces for the optional formation of line connections between the chambers. According to a first embodiment, the preparation device according to the invention is formed by an integral structure in which the chambers are formed in a chamber body, at one end of which the line connections can be attached or adjusted. According to a second embodiment, the preparation device comprises a framework into which the chambers can be inserted individually. The connection pieces of the individual chambers are all on one (e.g. B. lower) side of the rack arranged. Depending on requirements, the connecting pieces, which are initially sealed with a septum, are opened and connected in pairs via line connections. According to a third embodiment, the design with individual chambers is such that the framework is equipped with a valve plate with line connections via which the individual chambers can be connected in pairs.

116 The design of the preparation device as an integral structure or as a frame structure with at least two chambers has the advantages that the preparation device represents an object that can be safely gripped and manipulated within the scope of an automated process sequence and that the sample handling, in particular the independent pre-filling of the chambers, the treatment of samples in the chambers and the transfer of the samples between the chambers, is simplified. When using the preparation device according to the invention for the production

of blood samples for cryopreservation, at least three chambers are preferably provided.

[0011]

126 According to said first embodiment of the invention, the chambers are preferably formed in the form of right circular cylinders in a plastic body, at one end of which is attached a valve plate which contains at least one line connection for coupling two chambers each.

129 The construction with an integral plastic body has the advantage that the preparation device can be manufactured as a disposable product, so that problems with sterility and mix-ups can be ruled out. A further advantage is the high stability of the preparation device, particularly during centrifugation processes.

[0012]

136 The second and third embodiments of the invention mentioned each represent a modular structure.

138 The chambers can be used as disposable products. An additional advantage is the relatively low weight of the frame construction.

[0013]

143 The transfer of samples between the chambers is preferably effected by hydrostatic pressure applied as gas pressure or preferably with plungers located in each chamber.

145 Alternatively, it is possible to transfer the pressure with a mechanically actuated piston (e.g. B. with a connecting rod rod). In this configuration, the chambers of the preparation device according to the invention form piston pressure generators, which are set up both to receive the respective samples and to transfer the samples to adjacent chambers.

[0014]

152 According to a further preferred embodiment, the preparation device, in particular the chambers as the main components, consists at least partially of a transparent plastic material.

154 If non-transparent material is used, the chambers preferably have at least one transparent window for optical detection. A reliable and reproducible optical detection of sample properties, in particular the position of the phase boundary after centrifugation, is made possible.

[0015]

160 The invention also relates to a preparation station that is equipped with the preparation device according to the invention and also has a pressure device for transferring samples between the chambers, a detector device for measuring sample properties in the chambers and an actuating device for selectively coupling chambers.

[0016]

167 The invention also relates to a method for the preparation of suspensions containing biologically relevant components, such as e.g.

169 B. cells, cell components or macromolecules, using the preparation device according to the invention.

171 The method is characterized in particular by the fact that all preparation steps are carried out with the entire preparation device, which contains different chambers for receiving samples at different stages of preparation.

[0017]

177 The invention has the following advantages for sample preparation, particularly for the manufacture of cryopreserved blood.

179 The preparation process is designed to increase productivity in canning, i. H. to achieve the highest possible canning throughput, can be automated, while at the same time increasing the production quality and maintaining it independently of the manual skills of an operator. A blood unit produced according to the invention already experiences an increase in quality through the use of the preparation device, without the preparation becoming significantly more expensive.

[0018]

188 The preparation device according to the invention is completely closed off from the outside during the preparation procedure.

190 It only comes into contact with the environment once during filling and emptying. For example, the pre-treatment of a preserve is absolutely sterile until it is ready for freezing. Advantageously, the opening, connecting and closing of bags and connecting tubes according to the conventional systems is avoided. The suspension sample does not leave the preparation device during the preparation steps. A mix-up e.g. B. blood from different donors or contamination by foreign blood or microorganisms are excluded. The identity of the donor blood is guaranteed. The preparation process is greatly accelerated, since work steps that may be necessary several times in conventional systems can be completely eliminated according to the invention. Partial or complete sample loss or contamination of the working environment, including the laboratory staff, through leaking tube connections are ruled out with the preparation device according to the invention.

[0019]

204 The preparation device according to the invention forms a solid container which, in comparison with conventionally used blood bags, enables the device and the valves and/or nozzles

attached to it to be gripped and manipulated in a defined and reproducible manner.

207 There is no need to grip or position and clamp connecting hoses if the at least one connecting line is integrated into the preparation device and thus enables the individual chambers to be connected repeatedly and reproducibly over the shortest possible route. The short distances and the choice of a suitable cross-section for the respective connecting line allow the transfer time for transferring samples between the chambers to be optimized. The construction of the device enables a defined positioning of the at least one connecting line. Accidental connection of currently non-cooperating chambers is excluded. Deformation or squeezing of the chambers is avoided according to the invention. a z. B. set by centrifugation phase separation of sample components can not be blurred by a gripping process.

[0020]

219 The fixed and preferably symmetrical arrangement of the chambers in a preparation device according to the invention enables rapid and defined positioning of the chamber of interest in a preparation system, independently of the process step.

222 All sensors and actuators are automatically positioned correctly. Increased, error-free throughput is achieved. For example, with a preparation device according to the invention, around three times as many cryopreserves can be prepared per unit of time. The preparation device allows a free choice of material and dimensioning of the outer shape of the chamber arrangement. Advantageously, the device can be readily used with conventional centrifuge equipment.

[0021]

231 By manufacturing the preparation device from inexpensive plastic materials, large numbers of the device can be manufactured using injection molding or extrusion techniques.

233 This is advantageous for the use according to the invention of the solidly walled chambers as disposable products.

[0022]

238 The following additional advantages result in particular in the preparation of blood samples.

239 When using the preparation device according to the invention, there is no significant additional effort for blood donation services. No multiple bag systems are required. The preparation device can be coupled directly to a simple donation bag (single blood bag). The supernatant (plasma and buffy coat) which in conventional methods ends up in the waste or can only be obtained with great effort is available according to the invention as an additional end product if required. The preparation device also provides advantages when filling freezing bags after preparation. When docked to the preparation device, a filled freezing bag can be vented in a simple and sterile manner with this device by subjecting the respective chamber to negative pressure.

[0023]

251 Further advantages and details of the invention result from the following description of the accompanying drawings.

253 Show it:

[0024]

257 1 shows a schematic phantom view of an embodiment of a preparation device according to the invention in a partially expanded state,

[0025]

262 FIG. 2 shows an illustration of the integration of the preparation device according to FIG. 1 into a device for the production of blood reserves,

[0026]

267 3 shows an enlarged partial view of a chamber end of the preparation device according to FIG. 1,

[0027]

272 4 illustration of a modified embodiment of a preparation device according to the invention,

[0028]

276 5 shows a schematic sectional view of a single chamber used according to the invention, and

[0029]

280 6 shows an illustration of a conventional preparation technique (prior art).

[0030]

284 1 shows an embodiment of a preparation device 100 according to the invention in a schematic phantom view.

286 The preparation device 100 comprises a chamber body 10, in which three chambers are formed for receiving suspension samples, a transfer device 20, consisting of a valve plate 21 and at least one connecting line 22, a stamp device 30 with several pressure stamps 31 to 33 and a cover plate 40, which upper end of the chamber body 10 forms.

290 The chamber body 10 is integrally formed of a transparent plastic material (e.g.
291 B. PMMA, cycloolefin copolymers, polyamide, polycarbonate, PCHP, polyester or polysulfone).
292 It has the external shape of a right circular cylinder with a flat upper side 11 and a flat lower side 12.
294 In the interior of the chamber body 10, the three cylindrical chambers 13, 14 and 15 for receiving samples are formed.
296 At the upper end of the chamber body 10, the chambers open out freely into the top 11.
297 At the lower end, each chamber has a taper 16 with a connecting piece 17, as illustrated in FIG. 3 on an enlarged scale. The connecting piece 17 opens into the underside 12 of the chamber body 10.

[0031]

303 For use in the preparation of blood samples, the preparation device 100 has, for example, a diameter of approximately 18 to 20 cm, the height of the chamber body 10 being approximately 10 to 12 cm and the chambers 13 to 15 each having an internal diameter of approximately 6 to own 8 cm.
307 A chamber preferably has a volume in the range 400 ml to 600 ml. The chambers 13 to 15 are preferably distributed symmetrically relative to the axis of the chamber body 10 .

[0032]

312 The transfer device 20 is set up to transfer samples between the chambers 13 to 15 .
313 The valve plate 21 is rotatably attached to the bottom 12 of the chamber body 10 . The connecting line 22, which forms an overflow channel, is integrated into the valve plate 21, which is also made of plastic material. Sealing rings made of an elastic material (e.g. B. PTFE) attached. In addition to the sealing function, the sealing rings (not shown) can also serve as latching devices. Upon rotation of the connecting plate 21, the sealing rings snap into place at the desired positions of the connecting pieces or the mouth of the connecting pipe 22 when these are straightly aligned with one another.

[0033]

323 The valve plate 21 has a valve function since liquid is generally only ever pumped in one direction from one chamber to the adjacent chamber.
325 To rule out incorrect operation, a device for forced specification of a specific direction of rotation and/or a repeat lock can be provided on the valve plate 21 or on the chamber body 10 . This device includes, for example, teeth that prevent reverse rotation and/or an additional locking aid.

[0034]

332 The structure of the valve plate 21 can be modified depending on the application (see FIG. 4).
333 Several connecting lines can be provided. The at least one connecting line can be equipped with a blocking or valve device. Additional through-openings for charging the chambers can preferably be provided in the valve plate. However, loading can also take place from the top.

[0035]

339 Pressure is applied to the samples to transport the samples between the chambers.
340 The sample is transferred via the overflow channel in the valve plate 21 under the effect of an overpressure in the chamber from which the transfer originates. The transfer pressure is applied with a pressure device which is part of the preparation station (see FIG. 2) in which the preparation device according to the invention is preferably used. According to an advantageous embodiment of the invention, the pressure is transmitted using a stamp device 30 which has a pressure stamp 31 to 33 in each of the chambers 13 to 15 . The plunger 31 to 33 consist of plastic bodies z. B. in the form of a cylinder, which are fitted in a form-fitting manner into the respective chamber. Each plunger has at least one circumferential sealing lip, which seals any gaps that may occur between the plungers and the inner walls of the chamber. The sealing lips prevent the piston from passing through the liquid samples when pressure is applied. The pistons with the sealing lips are made of a plastic material (e.g.
351 e.g. PTFE). The use of the plungers 31 to 33 in the chambers has the advantage that when the preparation device 100 moves, a sample movement in the chambers is prevented when the plungers are respectively placed on the liquids. After a centrifugation, the phase boundary between the fractions is advantageously avoided.

[0036]

358 According to a preferred embodiment, the plungers 31 to 33 can each have a central bore (shown in dashed lines) with a closure (e.g.
360 B. a septum). This allows access to the samples or supplemental liquids in the chambers from the top of the device 100.

[0037]

365 According to a modified embodiment of the invention, the use of the plunger can also be dispensed with.
367 In this case, the transfer pressure is applied directly to the liquid surface in the respective chamber. In this design, the upper ends of the chambers are preferably equipped with a sterile filter insert at the top, which is only suitable for the sterile pressure medium used (e.g. B. air, inert gas) is permeable. The structure without a plunger has the advantages of an increased internal volume and a simplified structure of the chambers and thus cost savings.

[0038]

375 The upper cover plate 40 serves to close off the preparation device 100.

376 It is fixedly mounted on the chamber body 10 and has through openings or ports 41 aligned with the upper ends of the chambers 13-15, respectively. The connecting pieces 41 serve to connect individual chambers or all chambers at the same time to the pressure device and/or charging devices.

[0039]

383 The process sequence for producing a blood cryopreservation using a preparation device according to the invention is explained below with reference to FIG.

385 FIG. 2 shows the preparation device 100 analogous to the representation according to FIG. 1 in combination with parts of the preparation station.

[0040]

390 The components of the preparation device 100 are provided with the same reference symbols as in FIG. 1 .

[0041]

395 The preparation station includes, in particular, the printing device 50, a detector device 60, an actuating device 70 and a control device 80.

397 The pressure device 50 preferably comprises a pressure generator 51 with a motor 52 and a pump part 53.

399 Alternatively, the pressure device 50 comprises a lever device with a connecting rod. The mechanical power transmission has the advantage that the positioning of the plunger can be done with increased precision. According to alternative embodiments of the invention, the pressure generator can also be supplied by a pressure source (e.g. B. compressed gas cylinder) are formed with a control valve.

[0042]

407 The detector device 60 comprises, in particular, at least one light-sensitive element 61 for detecting the phase boundary.

409 Depending on the application, the light-sensitive element 61 can be equipped with filter devices (not shown). A plurality of light-sensitive elements can also be arranged corresponding to the positions of the chambers. Depending on the application, other detectors for detecting sample properties can also be provided, as are known from analytics (e.g. B. spectrophotometer, resistivity meter for density determination). The chambers can also each have a scale extending over their length for optical control of the filling level, the position of the plunger or the position of the phase boundary. The detectors can also be attached to other components

of the preparation device, e.g. B. be provided on a connecting line in the valve plate.

[0043]

420 To adjust the valve plate 21 explained above, the adjusting device 70 comprises an actuating element 71 and a servomotor 72.

422 The actuating element 71 has the form of a plate with at least one projection 73 which cooperates with at least one corresponding recess (not shown) on the underside of the valve plate 21. The projection 73 engages in the recess and rotates the valve plate 21 into the desired position when the servomotor 72 is actuated, so that one chamber can be opened or emptied, two chambers are connected via the connecting line 22 or all three chambers are closed.

[0044]

431 The control device 80 is connected to the components 50, 60 and 70 of the preparation system.

432 Depending on the operating state and the detector signal supplied by the detector device 60, the pressure generator 50 and the actuating device 70 are actuated in the following manner. In the case of semi-automatic or manual operation, the corresponding steps are at least partially carried out by an operator.

[0045]

439 In a starting state, the chambers of the preparation device 100 according to the invention are loaded as follows.

441 In the first chamber 13 there is a blood donation. The blood donation is poured into the first chamber 13 from a donor bag, which may be carried out with the application of a supporting negative pressure. The second chamber 14 is filled with a wash solution. A cryoadditive is located in the third chamber 15 . In the starting state, the first chamber 13 is completely filled, while the remaining chambers 14, 15 are only partially filled. There is as much free volume in these chambers as is required to take over the erythrocyte suspension after centrifugation (see below). After the starting state (all closed), the valve plate 21 is set in such a way that, for example, the first and second chambers 13, 14 are connected. Advantageously, there is essentially no liquid exchange via the connecting line despite the connection in the pressure-free state.

[0046]

454 In a first preparation step, the chamber body with the filled chambers is centrifuged using a centrifugation device.

456 The centrifugation device (not shown) has the design of a large centrifuge known per se with individual centrifuge buckets in which a large number of preparation devices can be

centrifuged at the same time. During centrifugation, the blood donation is only separated into fractions. The plungers 31 to 33 are not shifted. The chambers are sealed during centrifugation.

[0047]

464 The state of the preparation device after centrifugation is shown in FIG.

465 In the first chamber 13, the formed fractions of the blood donation with the erythrocyte sediment 1 of the so-called "Buffy Coat" layer 2 and the plasma supernatant 3 illustrated. Depending on the operation, the erythrocyte sediment 1 comprises a volume proportion of approx. 45% of the chamber 13. The volume fraction depends in particular on the centrifugation speed. A higher speed results in a higher packing density of the erythrocytes and thus a lower volume fraction. The “buffy coat” layer 2 is a greyish-colored coating containing thrombocytes and leukocytes, which forms between the deep red erythrocyte sediment 1 and the bright red plasma supernatant 3 after centrifugation.

[0048]

476 After the centrifugation, the preparation device 100 is inserted into the preparation station.

477 The valve plate 21 is rotated between the first and second chambers 13, 14 in the passage direction. This is done manually, e.g. B. with a knob wrench or with the adjusting device 70 (see above). The first chamber 13 is pressurized. Under the action of hydrostatic or mechanical pressure, the plunger 31 moves downwards and the plunger 32 moves upwards. The separated blood donation is transferred to the second chamber 14 . This preparation step is terminated as soon as the detector device 60 arranged at the lower end of the first chamber 13 detects the "buffy coat" layer 2 . In this state it is ensured that only erythrocyte sediment is still present in the narrowed area 16 (see FIG. 3) and the connecting line. When the buffy coat layer 2 has been detected, the print transfer is stopped. Then the valve plate is brought into the closed position. This occurs either immediately upon detection of the layer 2 or with a time delay, so that concentrate residues from the narrowed area 16 can still get into the connecting line.

[0049]

492 The erythrocytes transferred to the second chamber 14 mix with the washing solution.

493 The washing solution includes, for example, physiological saline. Another centrifugation follows, as a result of which the treated erythrocytes again collect as a concentrate in the lower part of the second chamber 14, while the remaining washing solution forms the supernatant.

[0050]

499 In a further preparation step, the washed erythrocyte sediment is transferred to the third

chamber 15 analogously to the manner described.

501 For this purpose, the valve plate 21 is rotated in such a way that the connecting line 22 is arranged between the second and third chambers 14 , 15 . In addition, the pressure distributor 56 is adjusted accordingly. The pressure transmission is in turn controlled as a function of the detector signal from the detector device 60 . A further sensor (not shown) can be provided on the second chamber 14 . Alternatively, it is possible to rotate the preparation device 100 towards the sensor 61 so that the phase boundary in the second chamber 14 can be detected.

[0051]

510 After the washed erythrocyte sediment has been transferred to the third chamber 15, it is mixed with the cryoadditive there.

512 The additives known per se are used as cryoadditive. For example, the cryoadditive comprises a solution of water-soluble starch derivative.

[0052]

517 After the washed erythrocytes have been transferred to the third chamber 15 and mixed with the cryoadditive, the cryopreserve is ready to be frozen.

519 This is followed by the transfer to the container selected depending on the application, e.g. B. a cryobag in which the freezing process takes place. After completion of the preparation, the plasma supernatant is advantageously present in the first chamber 13 as a donor-specific residual product. Depending on the application, the plasma can be used for other purposes.

[0053]

526 Details of a design of the preparation device according to the invention that is modified compared to FIG. 1 are shown in FIG.

528 The differences relate to the design of the valve plate 21. The lower side 12 of the chamber body 10 with the chambers 13 to 15 is illustrated in the top partial image of FIG. Each chamber has an inlet and outlet opening in the form of a connecting piece 17 (see FIG. 3). An O-ring seal 18 is provided on each connecting piece 17 . In the middle of the chamber body 10, corresponding to the cylinder axis, there is a threaded hole 19 for fastening the valve plate 21.

[0054]

536 In the middle part of Fig. 4, the valve plate 21 is shown individually.

537 In this design, two connecting lines (or overflow channels) 22, 23 are provided, which are arranged such that two chambers can be connected to one of the connecting lines 22 or 23, while the other connecting line 22 or 23 is closed. The use of two connecting lines has the advantage of shorter adjustment paths when setting the chamber connections in the individual preparation steps. Three inlet and outlet bores 24 are provided in the valve plate, which are

arranged in such a way that when one of the inlet and outlet bores 24 is aligned with one of the connecting pieces 17, the other connecting pieces remain closed.

[0055]

547 The valve plate 21 has a circumferential O-ring 25 which provides an additional seal against the underside 12 of the chamber body 10.

549 The reference number 26 refers to the axis of rotation and the bearing of the valve plate 21.

[0056]

553 In the lower partial image of FIG. 4, the valve plate 21 and the underside 12 of the chamber body 10 are shown in the assembled state.

555 If the valve plate 21 is turned to the left from the state shown, the chambers 13 and 14 are first connected to the connecting line 22 and the chambers 14 and 15 are connected via the connecting line 23 as the adjustment continues. The two preparation steps explained above can thus be carried out with a short travel distance.

[0057]

562 The embodiment of the invention illustrated in FIGS. 1 to 4 can be modified in many ways depending on the task at hand.

564 For example, further chambers for accommodating further additives can be provided in the chamber body in order to carry out further preparation steps. Instead of the 120° arrangement, the chambers can also be arranged differently in the chamber body or a frame (see below). Depending on the application, the chambers can be loaded from the top or bottom. This is preferably done using tubing or pipetting systems. According to a preferred embodiment of the invention, the inlet openings of the chambers are adapted to the outer diameter of standardized liquid pipettes or tube adapters, so that they can be easily attached and operated for loading. Depending on the application, the size of the preparation device can be scaled as desired. The transmission device with the valve plate can be replaced by a fixed arrangement of several connecting lines with valves that can be actuated.

[0058]

577 Additional gripping or fastening devices for handling the chamber body and/or for use in a centrifuge can be provided on the outside of the chamber body.

[0059]

582 According to the invention, the chamber body with the integrated chambers can be replaced by an arrangement of individual chambers in a frame.

584 This configuration has advantages with regard to separate filling of the individual chambers before composition for the preparation device and disposal of the chambers after use.

586 Any suitable structure can be used as the framework, into which the chambers can be inserted in a fixed manner in accordance with the desired arrangement and which has sufficient stability during centrifugation. Depending on the design of the chambers, the structure of the frame is adjusted.

[0060]

593 If ready-made plunger syringes with suitable plunger diameters are used as chambers, then the frame has recesses to accommodate the syringe plunger.

595 If the individual chambers are formed by straight tubular bodies, the recesses in the framework are adjusted accordingly. If necessary, conically preformed chamber floors are provided on the floor of the framework, as illustrated in FIG.

[0061]

601 5 shows a single chamber in a schematic sectional view.

602 Two or more such individual chambers (e.g. B. according to the above design three individual chambers) are provided on a frame (not shown). The single chamber 90 comprises a chamber wall 91 in the shape of a right circular cylinder and a tapered portion 92 which rests in a correspondingly shaped support base 93 which is part of the framework. Inside the single chamber 90 is the plunger (see above). In this configuration, the pressure ram is not cylindrical, but is designed as a ram plate 94 with a sealing ring 97 running around it on the outside. The stamp plate 94 consists of PMMA, for example. The sealing ring 97 is a z. B. made of PTFE molded part that is pulled positively over the outer edge of the stamp plate 94. The cross section of the sealing ring 97 has a U-shape, the open ends of which form two sealing lips. This shape ensures that the sealing lips lie tightly against the chamber wall. The upper side of the individual chamber 90 is closed with a cover plate 95, which has a passage opening 96 for the passage of the pressure medium.

[0062]

617 The individual chamber 90 has, for example, a volume of 470 ml with a diameter of approx. 80 mm, a length of the chamber wall 91 of approx. 110 mm and a height of the support base 93 of approx. 30 mm.

620 The partial area 92 delimits a partial volume of approximately 30 ml.

[0063]

624 In a method according to the invention for blood preparation, the following single-chamber centrifugation can be provided in deviation from the centrifugation of the entire preparation

device explained above.

627 The individual chamber of interest (e.g. B. according to FIG. 5) removed from the frame and centrifuged separately. Before or after centrifugation, the individual chamber is arranged in the frame for carrying out the remaining steps of sample preparation. This method is particularly advantageous if no suitable centrifuge is available for centrifugation.

[0064]

634 The features of the invention disclosed in the above description, the claims and the drawings can be important both individually and in any combination for the implementation of the invention in its various configurations.

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CLAIMS DE10134913A1

1.

13 Preparation device (100) for treating suspension samples, in particular for preparing cryopreserved blood, with an arrangement of at least two containers for holding suspension samples, sample parts and/or additives, characterized in that the containers are designed as chambers (13 to 15, 90) are formed with solid walls and are arranged in a fixed position relative to one another, a transmission device (20) having at least one connecting line (22) being provided, via which the chambers (13 to 15) can be connected to one another.

2.

22 Preparation device according to claim 1, wherein the chambers (13 to 15) are formed in a one-piece chamber body (10).

3.

27 Preparation device according to Claim 1, in which the chambers (90) are detachably fastened as individual chambers in a framework.

4.

32 Preparation device according to one of the preceding claims, in which the walls of the chambers or the chamber body (10) consist of a transparent material.

5.

37 Preparation device according to one of the preceding claims 1 or 2, in which the chambers (13

to 15) have the shape of straight hollow cylinders which run from an upper side (11) to an underside (12) of the chamber body (10), the underside (12) each chamber (13 to 15) has a connecting piece (17) to which one end of the at least one connecting line (22) can be connected.

6.

45 Preparation device according to one of the preceding claims, in which a pressure plunger (31 to 33) is provided in each chamber.

7.

50 Preparation device according to Claim 6, in which each pressure plunger (31 to 33) has a circumferential sealing lip.

8.

55 Preparation device according to one of the preceding claims, in which the transmission device (20) is formed by a valve plate (21) in which at least one connecting line (22) is integrated, the valve plate (21) being arranged rotatably.

9.

61 Preparation station for preparing suspension samples, comprising: at least one preparation device (100) according to one of the preceding claims, a printing device (50), a detector device (60), an actuating device (70), and a control device (80).

10.

67 Preparation station according to Claim 9, in which the pressure device (50) comprises a pneumatic pressure generator or a mechanical pressure generator with connecting rods.

11.

72 Preparation station according to Claim 9 or 10, in which the adjusting device (70) has an actuating element (71) with which the transmission device (20) can be adjusted in such a way that two chambers are connected via the at least one connecting line (22).

12.

78 A method for preparing suspension samples using a preparation device (100) according to any one of claims 1 to 8, in which treatment of a sample in at least one of the chambers (13 to 15,

90) and transfer of at least part of the sample between two chambers are alternated he follows.

13.

84 Method according to Claim 12, in which the sample treatment comprises centrifugation of the sample and/or treatment of the sample with additives.

14.

89 Method according to claim 13, in which the entire preparation device (100) or an individual chamber (90) is centrifuged during the centrifugation of the sample.

15.

94 A method according to any one of claims 12 to 14, in which a cryopreserved blood is prepared.

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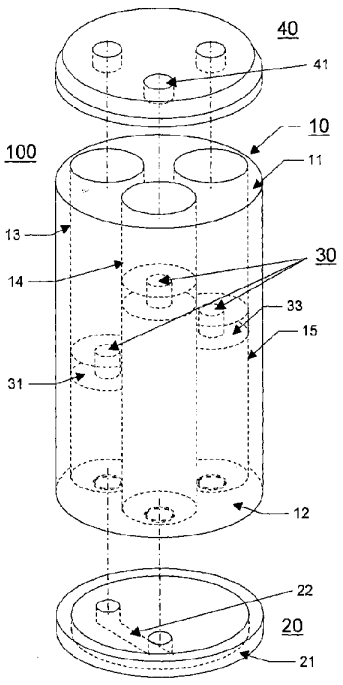
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Die folgenden Angaben sind den vom Anmelder eingereichten Unterlagen entnommen

Prüfungsantrag gem. § 44 PatG ist gestellt

(54) Vorrichtung und Verfahren zur Blutpräparation

(57) Es wird eine Präparationsvorrichtung (100) zur Behandlung von Suspensionsproben, insbesondere zur Präparation von Blut-Kryokonserven, mit einer Anordnung von mindestens zwei Behältnissen zur Aufnahme von Suspensionsproben, Probenteilen und/oder Zusatzstoffen beschrieben, wobei die Behältnisse als Kammern (13 bis 15, 90) mit festen Wänden gebildet und relativ zueinander ortsfest angeordnet sind, wobei eine Übertragungseinrichtung (20) mit mindestens einer Verbindungsleitung (22) vorgesehen ist, über die die Kammern (13 bis 15) miteinander verbunden werden können.



DE 101 34 913 A 1

Beschreibung

[0001] Die Erfindung betrifft eine Vorrichtung zur Probenpräparation, insbesondere eine Vorrichtung zur Handhabung und Behandlung von Blutproben, wie z. B. zum Trennen von Blutproben durch Zentrifugation und zur Modifizierung von Blutproben durch Zusatzstoffe zur Vorbereitung einer Kryokonservierung der Blutproben, und Verfahren zur Blutpräparation, insbesondere zur Vorbereitung von Blutproben für die Kryokonservierung.

[0002] Es ist bekannt, zur Kryokonservierung von Blutproben zunächst aus einer Blutspende eine Blutkonserve für den einfrierfertigen Zustand zu präparieren. Die Präparation umfasst insbesondere erstens eine Auftrennung der Blutspende in eine Erythrozytensuspension, die kryokonserviert werden soll, und Restbestandteile und zweitens den Zusatz eines Kryoadditives zur Erythrozytensuspension. Bei herkömmlichen Verfahren erfolgt die Handhabung der Blutproben unter Verwendung von flexiblen Blutbeuteln, wie es schematisch in **Fig.** 6 illustriert ist. Eine Blutspende wird in einem ersten Blutbeutel **1'** bereitgestellt und zentrifugiert. Nach dem Zentrifugieren ist die Blutspende in das Sediment und den Überstand (Plasma) getrennt. Der Überstand wird ggf. in einen Abfallbehälter **4'** abgezogen. Die Erythrozytensuspension wird in einen weiteren Blutbeutel **2'** umgefüllt, dem zur Bereitstellung der einfrierfertigen Konserve ein Kryoadditiv zugesetzt wird. Die illustrierte Verwendung von Blutbeuteln, die bspw. in DE 298 05 538 und WO 00/38762 beschrieben wird, besitzt die folgenden Nachteile.

[0003] Ein Hauptproblem betrifft die Handhabung der Blutbeutel. Da die Blutbeutel keine feste Form besitzen, muss insbesondere zur Erhaltung der Phasengrenze nach der Zentrifugation ein schonender Umgang mit den Blutbeuteln vorgesehen sein. Bei den genannten herkömmlichen Systemen sind zwar Vorrichtungen zur Halterung und zum Transport der Blutbeutel vorgesehen. Diese Vorrichtungen sind jedoch nur sehr eingeschränkt automatisierbar. Es müssen eine manuelle Beschickung der Vorrichtungen und eine laufende Überwachung des Betriebes erfolgen. Des Weiteren sind die Blutbeutel bei den herkömmlichen Vorrichtungen über flexible Schläuche miteinander verbunden. Zur Trennung von Erythrozytensuspension und Überstand muss die Phasengrenze am Blutbeutel oder am Schlauch detektiert werden. Wegen der Flexibilität der jeweiligen Behältnisse besteht das Risiko einer Fehldetektion und damit einer Fehlfunktion bei der Präparation.

[0004] Weitere Nachteile ergeben sich aus Sterilitätsproblemen beim Umgang mit den Blutbeuteln. Die Schlauchverbindungen müssen steril an die Blutbeutel angeschlossen und nach dem jeweiligen Verfahrensschritt abgetrennt und verschweißt werden. Bei jedem Präparationsschritt müssen aufwendige Vorkehrungen zur Erhaltung der Sterilität und Pyrogenfreiheit der Blutproben getroffen werden. Die herkömmliche Blutbeutelpräparation ist auch wegen der Verwechslungsgefahr problematisch. Wenn während der Präparation ein Blutbeutel verwechselt wird oder eine Kreuzkontamination zwischen Blutbeuteln auftritt, so kann dies verheerende Folgen für den Empfänger der Blutspende haben. Zum Ausschluss der Verwechslungsgefahr müssen bei herkömmlichen Systemen aufwendige Sicherheitsmaßnahmen realisiert werden.

[0005] Ein weiterer Nachteil der in WO 00/38762 beschriebenen Technik besteht in deren spezifischen Zuschnitt auf die Stammzellenpräparation. Bei der Trennung von Stammzellen aus biologischen Flüssigkeitsproben ist lediglich ein sehr geringer Stammzellengehalt aus den Proben abzutrennen. Dies ermöglicht den Einsatz spezieller Zentrifugationstechniken und eine geringere Empfindlichkeit in Bezug auf die Verwendung von Blutbeuteln.

[0006] In der modernen Medizin und im Katastrophenschutz besteht ein Interesse an vergrößerten Blutbanken mit einem breiten Spektrum verschiedenster Bluttypen. Zur Herstellung moderner Blutbanken ist eine Automatisierung der Konservenpräparation erforderlich. Wegen des Automatisierungsbedarfes ist die Anwendbarkeit herkömmlicher Präparationsvorrichtungen eingeschränkt.

[0007] Die illustrierten Probleme bei der Handhabung von Blutproben bestehen nicht nur bei der Vorbereitung von Konserven für die Kryokonservierung. Ein entsprechender Bedarf nach steriler, automatisierter und sicherer Probenhandhabung besteht auch bei der Bearbeitung von biologischen Zeilsuspensionen für therapeutische Zwecke.

[0008] Die Aufgabe der Erfindung ist es, eine verbesserte Vorrichtung zur Präparation suspendierter biologischer Proben bereitzustellen, mit der die Nachteile herkömmlichen Systeme überwunden werden und die insbesondere für eine automatisierbare und sichere Handhabung einer Vielzahl von Proben geeignet ist. Die Aufgabe der Erfindung besteht insbesondere in der Schaffung eines verbesserten Systems zur Präparation von Kryokonserven, wie z. B. Blut-Kryokonserven. Die Aufgabe der Erfindung ist es auch, ein neuartiges Verfahren zur Handhabung biologischer suspendierter Proben anzugeben, das insbesondere automatisierbar und sicher durchführbar ist.

[0009] Diese Aufgaben werden mit einer Präparationsvorrichtung, einer Präparationsstation und einem Verfahren mit den Merkmalen gemäß den Patentansprüchen 1, 9 und 12 gelöst. Vorteilhafte Ausführungsformen und Anwendungen der Erfindung ergeben sich aus den abhängigen Ansprüchen.

[0010] Die Grundidee der Erfindung ist es, eine Präparationsvorrichtung bereitzustellen, die mindestens zwei Behältnisse zur Aufnahme der zu behandelnden Suspensionsproben aufweist, wobei die Behältnisse im Unterschied zu herkömmlichen Systemen durch relativ zueinander ortsfest positionierte Kammern mit festen Wänden gebildet werden. Die Kammern sind über einzeln betätigbare Leitungsverbindungen miteinander verbunden oder mit Anschlussstücken zur optionalen Ausbildung von Leitungsverbindungen zwischen den Kammern ausgestattet. Die erfindungsgemäße Präparationsvorrichtung ist gemäß einer ersten Ausführungsform durch einen integralen Aufbau gebildet, bei dem die Kammern in einem Kammerkörper geformt sind, an dessen einem Ende die Leitungsverbindungen ansetzbar oder einstellbar sind. Gemäß einer zweiten Ausführungsform umfasst die Präparationsvorrichtung ein Rahmengestell, in das die Kammern einzeln einsetzbar sind. Die Anschlussstücke der einzelnen Kammern sind sämtlich auf einer (z. B. unteren) Seite des Rahmengestells angeordnet. Je nach Bedarf werden die zunächst mit einem Septum verschlossenen Anschlussstücke geöffnet und über Leitungsverbindungen paarweise in Verbindung gebracht. Die Gestaltung mit einzelnen Kammern ist gemäß einer dritten Ausführungsform derart ausgebildet, dass das Rahmengestell mit einer Ventilplatte mit Leitungsverbindungen ausgestattet ist, über die die einzelnen Kammern paarweise verbunden werden können. Die Ausbildung der Präparationsvorrichtung als integraler Aufbau oder als Gestellaufbau mit mindestens zwei Kammern besitzt die Vorteile, dass die Präparationsvorrichtung im Rahmen eines automatisierten Verfahrensablaufes einen sicher greif- und manipulierbaren Gegenstand darstellt und dass die Probenhandhabung, insbesondere die unabhängige Vorbefüllung der Kammern, die Behandlung von Proben in den Kammern und die Überführung der Proben zwischen den Kammern, vereinfacht wird. Bei Anwendung der erfindungsgemäßen Präparationsvorrichtung zur Her-

stellung von Blutproben für die Kryokonservierung sind vorzugsweise mindestens drei Kammern vorgesehen.

[0011] Gemäß der genannten ersten Ausführungsform der Erfindung sind die Kammern vorzugsweise in Form von geraden Kreiszylindern in einem Kunststoffkörper gebildet, an dessen einem Ende eine Ventilplatte angebracht ist, die mindestens eine Leitungsverbindung zur Kopplung von jeweils zwei Kammern enthält. Der Aufbau mit einem integralen Kunststoffkörper besitzt den Vorteil, dass die Präparationsvorrichtung als Einwegprodukt herstellbar ist, so dass Sterilitäts- und Verwechslungsprobleme ausgeschlossen werden können. Als weiterer Vorteil ergibt sich eine hohe Stabilität der Präparationsvorrichtung insbesondere bei Zentrifugationsvorgängen.

[0012] Die genannten zweiten und dritten Ausführungsformen der Erfindung stellen jeweils einen modularen Aufbau dar. Die Kammern können als Einwegprodukte verwendet werden. Als zusätzlicher Vorteil ergibt sich beim Rahmenaufbau ein relativ geringes Gewicht.

[0013] Die Übertragung von Proben zwischen den Kammern erfolgt vorzugsweise durch einen hydrostatischen Druck, der als Gasdruck oder vorzugsweise mit Druckstempeln ausgeübt wird, die jeweils in den Kammern angeordnet sind. Alternativ ist es möglich, den Druck mit einem mechanisch betätigbaren Kolben zu übertragen (z. B. mit einem Pleuelgestänge). Die Kammern der erfindungsgemäßen Präparationsvorrichtung bilden bei dieser Gestaltung Kolben-Druckerzeuger, die sowohl zur Aufnahme der jeweiligen Proben als auch zur Übertragung der Proben in benachbarte Kammern eingerichtet sind.

[0014] Gemäß einer weiteren bevorzugten Gestaltung besteht die Präparationsvorrichtung, insbesondere die Kammern als Hauptkomponenten, zumindest teilweise aus einem transparenten Kunststoffmaterial. Bei Verwendung von nicht-transparentem Material besitzen die Kammern vorzugsweise mindestens ein transparentes Fenster zur optischen Detektion. Es wird eine zuverlässige und reproduzierbare optische Detektion von Probeneigenschaften, insbesondere der Lage der Phasengrenze nach einer Zentrifugation, ermöglicht.

[0015] Gegenstand der Erfindung ist auch eine Präparationsstation, die mit der erfindungsgemäßen Präparationsvorrichtung ausgestattet ist und des Weiteren eine Druckeinrichtung zur Probenübertragung zwischen den Kammern, eine Detektoreinrichtung zur Messung von Probeneigenschaften in den Kammern und eine Stelleinrichtung zur selektiven Kopplung von Kammern aufweist.

[0016] Gegenstand der Erfindung ist auch ein Verfahren zur Präparation von Suspensionen, die biologisch relevante Komponenten, wie z. B. Zellen, Zellbestandteile oder Makromoleküle, enthalten, unter Verwendung der erfindungsgemäßen Präparationsvorrichtung. Das Verfahren zeichnet sich insbesondere dadurch aus, dass alle Präparationsschritte mit der gesamten Präparationsvorrichtung durchgeführt werden, die verschiedene Kammern zur Aufnahme von Proben in verschiedenen Präparationsstadien enthält.

[0017] Die Erfindung besitzt die folgenden Vorteile für die Probenpräparation, insbesondere für die Herstellung von Blut-Kryokonserven. Der Präparationsprozess ist zur Erhöhung der Produktivität bei der Konservenherstellung, d. h. zur Erzielung eines möglichst hohen Konservendurchsatzes, automatisierbar, wobei gleichzeitig die Herstellungsqualität gesteigert und unabhängig von der Handfertigkeit eines Bedieners aufrechterhalten wird. Eine erfindungsgemäß hergestellte Blutkonserve erfährt bereits durch die Verwendung der Präparationsvorrichtung eine Qualitätssteigerung, ohne dass die Präparation wesentlich verteuert wird.

[0018] Die erfindungsgemäße Präparationsvorrichtung ist während der Präparationsprozedur nach außen hin absolut abgeschlossen. Sie tritt lediglich einmalig jeweils beim Befüllen und beim Entleeren in Kontakt mit der Umgebung. Beispielsweise erfolgt die Vorbehandlung einer Konserve bis zum Erlangen des einfrierfertigen Zustandes absolut steril. Vorteilhafterweise wird das Öffnen, Verbinden und Verschließen von Beuteln und Verbindungsschläuchen entsprechend den herkömmlichen Systemen vermieden. Die Suspensionsprobe verlässt während der Präparationsschritte nicht die Präparationsvorrichtung. Eine Verwechslung z. B. von Blut verschiedener Spender oder eine Kontamination durch Fremdblut oder Mikroorganismen sind ausgeschlossen. Die Identität des Spenderblutes ist garantiert. Der Präparationsvorgang wird stark beschleunigt, da Arbeitsschritte, die bei herkömmlichen Systemen ggf. mehrfach notwendig sind, erfindungsgemäß vollständig entfallen können. Ein teilweiser oder vollständiger Probenverlust oder eine Kontamination der Arbeitsumgebung einschließlich des Laborpersonals durch undichte Schlauchverbindungen werden bei der erfindungsgemäßen Präparationsvorrichtung ausgeschlossen.

[0019] Die erfindungsgemäße Präparationsvorrichtung bildet ein festes Behältnis, das im Vergleich mit herkömmlich verwendeten Blutbeuteln ein definiertes und reproduzierbares Greifen und Handhaben der Vorrichtung und der an dieser angebrachten Ventile und/oder Stutzen ermöglicht. Das Greifen oder Positionieren und Klemmen von Verbindungsschläuchen entfällt, wenn die mindestens eine Verbindungsleitung in die Präparationsvorrichtung integriert ist und somit ein reproduzierbares und mehrfaches Verbinden der einzelnen Kammern auf kürzestem Weg ermöglicht. Durch die kurzen Wege und die Wahl eines geeigneten Querschnittes der jeweiligen Verbindungsleitung lässt sich die Transferzeit zur Übertragung von Proben zwischen den Kammern optimieren. Der Aufbau der Vorrichtung ermöglicht ein definiertes Positionieren der mindestens einen Verbindungsleitung. Ein versehentliches Verbinden von aktuell nicht kooperierenden Kammern wird ausgeschlossen. Ein Deformieren oder Quetschen der Kammern wird erfindungsgemäß vermieden. Eine z. B. durch Zentrifugation eingestellte Phasentrennung von Probenbestandteilen kann durch einen Greifvorgang nicht verwischt werden.

[0020] Die feste und vorzugsweise symmetrische Anordnung der Kammern in einer erfindungsgemäßen Präparationsvorrichtung ermöglicht ein schnelles und definiertes Positionieren der jeweils interessierenden Kammer in einem Präparationssystem unabhängig vom Verfahrensschritt. Alle Sensoren und Aktoren sind automatisch korrekt positioniert. Es wird ein erhöhter, fehlerfreier Durchsatz erzielt. Beispielsweise lassen sich mit einer erfindungsgemäß Präparationsvorrichtung rund dreifach mehr Kryokonserven pro Zeiteinheit präparieren. Die Präparationsvorrichtung ermöglicht eine freie Materialwahl und Dimensionierung der Außenform der Kammeranordnung. Vorteilhafterweise kann die Vorrichtung ohne Weiteres mit herkömmlichen Zentrifugiereinrichtungen verwendet werden.

[0021] Durch die Herstellung der Präparationsvorrichtung aus kostengünstigen Kunststoffmaterialien können große Stückzahlen der Vorrichtung in Spritzgieß- oder Extrusionstechniken hergestellt werden. Dies ist für die erfindungsgemäße Verwendung der fest bewandeten Kammern als Einwegprodukte von Vorteil.

[0022] Insbesondere bei der Präparation von Blutproben ergeben sich zusätzlich die folgenden Vorteile. Für Blutspendedienste entsteht bei Einsatz der erfindungsgemäßen Präparationsvorrichtung kein wesentlicher Zusatzaufwand. Es werden keine Mehrfachbeutelsysteme erforderlich. Die Präparationsvorrichtung kann direkt mit einem einfachen

Spendebeutel (Einfachblutbeutel) gekoppelt werden. Der bei herkömmlichen Verfahren ggf. in den Abfall gelangende oder nur mit großem Aufwand gewinnbare Überstand (Plasma und "Buffy Coat") steht erfindungsgemäß bei Bedarf als zusätzliches Endprodukt zur Verfügung. Die Präparationsvorrichtung liefert auch Vorteile bei der nach der Präparation vorgesehenen Befüllung von Einfrierbeuteln. Ein befüllter Einfrierbeutel kann im angedockten Zustand an der Präparationsvorrichtung mit dieser einfach und steril entlüftet werden, in dem die jeweilige Kammer mit einem Unterdruck beaufschlagt wird.

[0023] Weitere Vorteile und Einzelheiten der Erfindung ergeben sich aus der folgenden Beschreibung der beigefügten Zeichnungen. Es zeigen:

[0024] **Fig.** 1 eine schematische Phantomansicht einer Ausführungsform einer erfindungsgemäßen Präparationsvorrichtung in teilweise auseinander gezogenem Zustand,

[0025] **Fig.** 2 eine Illustration der Einbindung der Präparationsvorrichtung gemäß **Fig.** 1 in eine Vorrichtung zur Herstellung von Blutkonserven,

[0026] **Fig.** 3 eine vergrößerte Teilansicht eines Kammerendes der Präparationsvorrichtung gemäß **Fig.** 1,

[0027] **Fig.** 4 Illustration einer abgewandelten Ausführungsform einer erfindungsgemäßen Präparationsvorrichtung,

[0028] **Fig.** 5 eine schematische Schnittansicht einer erfindungsgemäß verwendeten Einzelkammer, und

[0029] **Fig.** 6 eine Illustration einer herkömmlichen Präparationstechnik (Stand der Technik).

[0030] In **Fig.** 1 ist eine Ausführungsform einer erfindungsgemäßen Präparationsvorrichtung **100** in schematischer Phantomansicht dargestellt. Die Präparationsvorrichtung **100** umfasst einen Kammerkörper **10**, in dem drei Kammern zur Aufnahme von Suspensionsproben gebildet sind, eine Übertragungseinrichtung **20**, bestehend aus einer Ventilplatte **21** und mindestens einer Verbindungsleitung **22**, einer Stempeleinrichtung **30** mit mehreren Druckstempeln **31** bis **33** und eine Deckplatte **40**, die den oberen Abschluss des Kammerkörpers **10** bildet. Der Kammerkörper **10** ist einstückig aus einem transparenten Kunststoffmaterial (z. B. PMMA, Cycloolefin-Copolymere, Polyamid, Polycarbonat, PCHP, Polyester oder Polysulfone) geformt. Er besitzt die äußere Form eines geraden Kreiszylinders mit einer ebenen Oberseite **11** und einer ebenen Unterseite **12**. Im Inneren des Kammerkörpers **10** sind die drei zylinderförmigen Kammern **13**, **14** und **15** zur Probenaufnahme gebildet. Am oberen Ende des Kammerkörpers **10** münden die Kammern frei in die Oberseite **11**. Am unteren Ende besitzt jede Kammer eine Verjüngung **16** mit einem Anschlussstutzen **17**, wie es vergrößert in **Fig.** 3 illustriert ist. Der Anschlussstutzen **17** mündet jeweils in die Unterseite **12** des Kammerköpers **10**.

[0031] Zur Anwendung bei der Präparation von Blutproben besitzt die Präparationsvorrichtung **100** bspw. einen Durchmesser von ca. 18 bis 20 cm, wobei die Höhe des Kammerkörpers **10** ca. 10 bis 12 cm beträgt und die Kammern **13** bis **15** jeweils einen Innendurchmesser von ca. 6 bis 8 cm besitzen. Eine Kammer besitzt vorzugsweise ein Volumen im Bereich von 400 ml bis 600 ml. Die Kammern **13** bis **15** sind vorzugsweise relativ zur Achse des Kammerkörpers **10** symmetrisch verteilt angeordnet.

[0032] Die Übertragungseinrichtung **20** ist zur Übertragung von Proben zwischen den Kammern **13** bis **15** eingerichtet. Die Ventilplatte **21** ist drehbar an der Unterseite **12** des Kammerkörpers **10** befestigt. In die ebenfalls aus Kunststoffmaterial hergestellte Ventilplatte **21** ist die Verbindungsleitung **22** integriert, die einen Überströmkanal bildet. An den Mündungen der Verbindungsleitungen **22** auf der inneren Seite der Verbindungsplatte **21**, die an die Unterseite **12** des Kammerkörpers **10** angrenzt, oder an den Anschlussstutzen **17** der einzelnen Kammern (siehe **Fig.** 3) sind Dichtungsringe aus einem elastischen Material (z. B. PTFE) angebracht. Neben der Dichtfunktion können die Dichtungsringe (nicht dargestellt) auch als Rasteinrichtungen dienen. Bei Drehung der Verbindungsplatte **21** rasten die Dichtungsringe an den gewünschten Positionen der Anschlussstutzen oder der Mündung der Verbindungsleitung **22** ein, wenn diese gerade zueinander ausgerichtet sind.

[0033] Die Ventilplatte **21** besitzt eine Ventilfunktion, da in der Regel Flüssigkeit immer nur in einer Richtung von einer Kammer zur benachbarten Kammer gepumpt wird. Zum Ausschluss einer Fehlbedienung kann an der Ventilplatte **21** oder am Kammerkörper **10** eine Vorrichtung zur erzwungenen Vorgabe einer bestimmten Drehrichtung und/oder eine Wiederholsperre vorgesehen sein. Diese Vorrichtung umfasst bspw. eine Verzahnung, die eine Rückwärtsdrehung ausschließt, und/oder eine zusätzliche Arretierhilfe.

[0034] Der Aufbau der Ventilplatte **21** kann anwendungsabhängig abgewandelt werden (siehe **Fig.** 4). Es können mehrere Verbindungsleitungen vorgesehen sein. Die mindestens eine Verbindungsleitung kann mit einer Sperr- oder Ventileinrichtung ausgestattet sein. In der Ventilplatte können vorzugsweise zusätzliche Durchgangsöffnungen zur Beschickung der Kammern vorgesehen sein. Die Beschikkung kann aber auch von der oberen Seite her erfolgen.

[0035] Zum Probentransport zwischen den Kammern werden die Proben mit einem Druck beaufschlagt. Unter der Wirkung eines Überdruckes in der Kammer, von der die Übertragung ausgeht, wird die Probe über den Überströmkanal in der Ventilplatte **21** übertragen. Der Übertragungsdruck wird mit einer Druckeinrichtung aufgebracht, die Teil der Präparationsstation (siehe **Fig.** 2) ist, in der die erfindungsgemäße Präparationsvorrichtung vorzugsweise verwendet wird. Gemäß einer vorteilhaften Ausführungsform der Erfindung wird der Druck mit einer Stempeleinrichtung **30** übertragen, die in den Kammern **13** bis **15** jeweils einen Druckstempel **31** bis **33** aufweist. Die Druckstempel **31** bis **33** bestehen aus Kunststoffkörpern z. B. in Zylinderform, die formschlüssig in die jeweilige Kammer eingepasst sind. Jeder Druckstempel weist mindestens eine umlaufende Dichtlippe auf, die ggf. auftretende Spalte zwischen den Druckstempeln und den Kammerinnenwänden abdichtet. Die Dichtlippen verhindern ein Durchlauf des Kolbens durch die flüssigen Proben bei Druckbeaufschlagung. Die Kolben mit den Dichtlippen bestehen aus einem Kunststoffmaterial (z. B. PTFE). Der Einsatz der Druckstempel **31** bis **33** in den Kammern besitzt den Vorteil, dass bei einer Bewegung der Präparationsvorrichtung **100** eine Probenbewegung in den Kammern verhindert wird, wenn die Druckstempel jeweils auf den Flüssigkeiten aufgesetzt sind. Nach einer Zentrifugation wird vorteilhafterweise eine Aufhebung der Phasengrenze zwischen den Fraktionen vermieden.

[0036] Die Druckstempel **31** bis **33** können gemäß einer bevorzugten Ausführungsform jeweils eine zentralen Bohrung (gestrichelt eingezeichnet) mit einem Verschluss (z. B. einem Septum) aufweisen. Dies ermöglicht einen Zugriff zu den Proben oder Zusatzflüssigkeiten in den Kammern von der Oberseite der Vorrichtung **100** her.

[0037] Gemäß einer abgewandelten Ausführungsform der Erfindung kann auf die Verwendung der Druckstempel auch verzichtet werden. In diesem Fall wird der Übertragungsdruck direkt auf die Flüssigkeitsoberfläche in der jeweiligen Kammer gegeben. Bei dieser Gestaltung sind die oberen Enden der Kammern an der Oberseite vorzugsweise mit einem Sterilfiltereinsatz ausgestattet, der nur für das jeweilig verwendete sterile Druckmedium (z. B. Luft, inertes Gas)

durchlässig ist. Der Aufbau ohne Druckstempel besitzt die Vorteile eines vergrößerten Innenvolumens und vereinfachten Aufbaus der Kammern und damit einer Kostenersparnis.

[0038] Die obere Deckplatte **40** dient dem Abschluss der Präparationsvorrichtung **100**. Sie ist fest auf dem Kammerkörper **10** angebracht und besitzt Durchtrittöffnungen oder Anschlussstutzen **41**, die jeweils mit den oberen Enden der Kammern **13** bis **15** ausgerichtet sind. Die Anschlussstutzen **41** dienen der Verbindung von einzelnen oder gleichzeitig allen Kammern mit der Druckeinrichtung und/oder Beschickungseinrichtungen.

[0039] Der Verfahrensablauf zur Herstellung einer Blut-Kryokonserve unter Verwendung einer erfindungsgemäßen Präparationsvorrichtung wird im Folgenden unter Bezug auf **Fig.** 2 erläutert. **Fig.** 2 zeigt die Präparationsvorrichtung **100** analog zur Darstellung gemäß **Fig.** 1 in Kombination mit Teilen der Präparationsstation.

[0040] Die Komponenten der Präparationsvorrichtung **100** sind mit den gleichen Bezugszeichen wie in **Fig.** 1 versehen.

[0041] Zur Präparationsstation gehören insbesondere die Druckeinrichtung **50**, eine Detektoreinrichtung **60**, eine Stelleinrichtung **70** und eine Steuereinrichtung **80**. Die Druckeinrichtung **50** umfasst vorzugsweise einen Druckerzeuger **51** mit einem Motor **52** und einem Pumpenteil **53**. Alternativ umfasst die Druckeinrichtung **50** eine Hebeleinrichtung mit einer Pleuelstange. Die mechanische Kraftübertragung besitzt den Vorteil, dass die Positionierung der Druckstempel mit einer erhöhten Präzision erfolgen kann. Gemäß alternativen Ausführungsformen der Erfindung kann der Druckerzeuger auch durch eine Druckquelle (z. B. Druckgasflasche) mit einem Regelventil gebildet werden.

[0042] Die Detektoreinrichtung **60** umfasst insbesondere mindestens ein lichtempfindliches Element **61** zur Erkennung der Phasengrenze. Das lichtempfindliche Element **61** kann anwendungsabhängig mit (nicht dargestellten) Filtereinrichtungen ausgestattet sein. Es können auch mehrere lichtempfindliche Elemente entsprechend den Positionen der Kammern angeordnet sein. Anwendungsabhängig können auch andere Detektoren zur Erfassung von Probeneigenschaften vorgesehen sein, wie sie an sich aus der Analytik bekannt sind (z. B. Spektralphotometer, Widerstandsmesser zur Dichtebestimmung). Die Kammern können auch eine sich jeweils über ihre Länge erstreckende Skalierung zur optischen Kontrolle des Füllstandes, der Position der Druckstempel oder der Position der Phasengrenze aufweisen. Die Detektoren können ferner an anderen Komponenten der Präparationsvorrichtung, z. B. an einer Verbindungsleitung in der Ventilplatte, vorgesehen sein.

[0043] Zur Verstellung der oben erläuterten Ventilplatte **21** umfasst die Stelleinrichtung **70** ein Betätigungselement **71** und einen Stellmotor **72**. Das Betätigungselement **71** besitzt die Form einer Platte mit mindestens einem Vorsprung **73**, der mit mindestens einer entsprechenden Ausnehmung (nicht dargestellt) auf der Unterseite der Ventilplatte **21** zusammenwirkt. Der Vorsprung **73** greift in die Ausnehmung ein und verdreht die Ventilplatte **21** bei Betätigung des Stellmotors **72** in die gewünschte Position, so dass jeweils eine Kammer geöffnet oder geleert werden kann, jeweils zwei Kammern über die Verbindungsleitung **22** verbunden sind oder alle drei Kammern verschlossen sind.

[0044] Die Steuereinrichtung **80** ist mit den Komponenten **50**, **60** und **70** des Präparationssystems verbunden. Je nach Betriebszustand und dem von der Detektoreinrichtung **60** gelieferten Detektorsignal werden in der folgenden Weise der Druckerzeuger **50** und die Stelleinrichtung **70** betätigt. Bei halbautomatischem oder manuellem Betrieb werden die entsprechenden Schritte zumindest teilweise durch einen Bediener durchgeführt.

[0045] In einem Startzustand sind die Kammern der erfindungsgemäßen Präparationsvorrichtung **100** wie folgt beschickt. In der ersten Kammer **13** befindet sich eine Blutspende. Die Blutspende wird aus einem Spenderbeutel in die erste Kammer **13** gefüllt, was ggf. unter Ausübung eines unterstützenden Unterdruckes erfolgt. Die zweite Kammer **14** ist mit einer Waschlösung gefüllt. In der dritten Kammer **15** befindet sich ein Kryoadditiv. Im Startzustand ist die erste Kammer **13** vollständig gefüllt, während die übrigen Kammern **14**, **15** lediglich teilweise befüllt sind. In diesen Kammern ist so viel Volumen frei, wie es zur Übernahme der Erythrozytensuspension nach der Zentrifugation (siehe unten) erforderlich ist. Die Ventilplatte **21** wird nach dem Startzustand (alle verschlossen) so eingestellt, dass bspw. die erste und zweite Kammer **13**, **14** verbunden sind. Vorteilhafterweise ist trotz der Verbindung im druckfreien Zustand über die Verbindungsleitung im Wesentlichen kein Flüssigkeitsaustausch gegeben.

[0046] In einem ersten Präparationsschritt wird der Kammerkörper mit den befüllten Kammern mit einer Zentrifugationseinrichtung zentrifugiert. Die (nicht dargestellte) Zentrifugationseinrichtung besitzt die Bauform einer an sich bekannten Großzentrifuge mit einzelnen Zentrifugenbechern, in denen eine Vielzahl von Präparationsvorrichtungen gleichzeitig zentrifugiert werden können. Während der Zentrifugation erfolgt lediglich die Auftrennung der Blutspende in die Fraktionen. Eine Verschiebung der Druckstempel **31** bis **33** erfolgt nicht. Während der Zentrifugation sind die Kammern verschlossen.

[0047] Der Zustand der Präparationsvorrichtung nach der Zentrifugation ist in **Fig.** 2 dargestellt. In der ersten Kammer **13** sind die gebildeten Fraktionen der Blutspende mit dem Erythrozytensediment **1** der sog. "Buffy Coat"-Schicht **2** und dem Plasmaüberstand **3** illustriert. Das Erythrozytensediment **1** umfasst betriebsabhängig einen Volumenanteil von ca. 45% der Kammer **13**. Der Volumenanteil hängt insbesondere von der Zentrifugationsgeschwindigkeit ab. Bei einer höheren Geschwindigkeit ergibt sich eine höhere Packungsdichte der Erythrozyten und damit ein geringerer Volumenanteil. Die "Buffy-Coat"-Schicht **2** ist ein thrombozyten- und leukozytenhaltiger Belag mit einer gräulichen Färbung, der sich nach der Zentrifugation zwischen den tiefroten Erythrozytensediment **1** und dem hellroten Plasmaüberstand **3** ausbildet.

[0048] Nach der Zentrifugation wird die Präparationsvorrichtung **100** in die Präparationsstation eingesetzt. Die Ventilplatte **21** wird in Durchlassrichtung zwischen die erste und zweite Kammer **13**, **14** gedreht. Dies erfolgt manuell, z. B. mit einem Noppenschlüssel oder mit der Stelleinrichtung **70** (siehe oben). Die erste Kammer **13** wird mit einem Überdruck beaufschlagt. Unter der hydrostatischen oder mechanischen Druckeinwirkung bewegen sich der Druckstempel **31** nach unten und der Druckstempel **32** nach oben. Die aufgetrennte Blutspende wird in die zweite Kammer **14** übertragen. Dieser Präparationsschritt wird beendet, sobald die am unteren Ende der ersten Kammer **13** angeordnete Detektoreinrichtung **60** die "Buffy Coat"-Schicht **2** erfasst. In diesem Zustand ist sichergestellt, dass in dem verjüngtem Bereich **16** (siehe **Fig.** 3) und der Verbindungsleitung noch ausschließlich Erythrozytensediment vorhanden ist. Wenn die "Buffy Coat"-Schicht **2** erfasst worden ist, wird die Druckübertragung gestoppt. Danach wird die Ventilplatte in Verschlussstellung gebracht. Dies erfolgt entweder unmittelbar bei Detektion der Schicht **2** oder zeitlich verzögert, so dass Konzentratreste aus dem verjüngten Bereich **16** noch in die Verbindungsleitung gelangen können.

[0049] Die in die zweite Kammer **14** übertragenen Ery-

throzyten vermengen sich mit der Waschlösung. Die Waschlösung umfasst bspw. physiologische Kochsalzlösung. Es folgt eine weitere Zentrifugation, in deren Ergebnis sich die behandelten Erythrozyten als Konzentrat wiederum im unteren Teil der zweiten Kammer **14** sammeln, während die übrige Waschlösung den Überstand bildet.

[0050] In einem weiteren Präparationsschritt wird analog zu der beschriebenen Weise das gewaschene Erythrozytensediment in die dritte Kammer **15** übertragen. Hierzu wird die Ventilplatte **21** so verdreht, dass die Verbindungsleitung **22** zwischen der zweiten und dritten Kammer **14**, **15** angeordnet ist. Außerdem wird der Druckverteiler **56** entsprechend verstellt. Die Druckübertragung wird wiederum in Abhängigkeit vom Detektorsignal der Detektoreinrichtung **60** gesteuert. Es kann an der zweiten Kammer **14** ein weiterer Sensor (nicht dargestellt) vorgesehen sein. Alternativ ist es möglich, die Präparationsvorrichtung **100** zu dem Sensor **61** hin zu verdrehen, so dass die Phasengrenze in der zweiten Kammer **14** erfasst werden kann.

[0051] Nach Übertragung des gewaschenen Erythrozytensedimentes in die dritte Kammer **15** erfolgt dort die Vermengung mit dem Kryoadditiv. Als Kryoadditiv werden die an sich bekannten Zusatzstoffe verwendet. Das Kryoadditiv umfasst bspw. eine Lösung aus wasserlöslichem Stärkederivat.

[0052] Nach Übertragung der gewaschenen Erythrozyten in die dritte Kammer **15** und Vermengung mit dem Kryoadditiv ist die Kryokonserve einfrierfertig. Es folgt die Übertragung in den anwendungsabhängig gewählten Behälter, z. B. einen Kryobeutel, in dem der Einfriervorgang erfolgt. Vorteilhafterweise ist nach Abschluss der Präparation in der ersten Kammer **13** der Plasmaüberstand als spenderspezifisches Restprodukt vorhanden. Anwendungsabhängig kann das Plasma einer weiteren Verwendung zugeführt werden.

[0053] Einzelheiten einer gegenüber **Fig.** 1 abgewandelten Gestaltung der erfindungsgemäßen Präparationsvorrichtung sind in **Fig.** 4 dargestellt. Die Unterschiede beziehen sich auf die Ausbildung der Ventilplatte **21**. Im obersten Teilbild von **Fig.** 4 ist die Unterseite **12** des Kammerkörpers **10** mit den Kammern **13** bis **15** illustriert. Jede Kammer besitzt eine Ein- und Auslassöffnung in Form eines Anschlussstutzens **17** (siehe **Fig.** 3). An jedem Anschlussstutzen **17** ist ein O-Dichtring **18** vorgesehen. In der Mitte des Kammerkörpers **10** befindet sich entsprechend der Zylinderachse eine Gewindebohrung **19** zur Befestigung der Ventilplatte **21**.

[0054] Im mittleren Teilbild von **Fig.** 4 ist die Ventilplatte **21** einzeln dargestellt. Bei dieser Gestaltung sind zwei Verbindungsleitungen (oder Überströmkanäle) **22**, **23** vorgesehen, die so angeordnet sind, dass mit einer der Verbindungsleitungen **22** oder **23** jeweils zwei Kammern verbunden werden können, während die jeweils andere Verbindungsleitung **22** oder **23** verschlossen ist. Die Verwendung von zwei Verbindungsleitungen besitzt den Vorteil geringerer Verstellwege bei der Einstellung der Kammerverbindungen bei den einzelnen Präparationsschritten. In der Ventilplatte sind drei Ein- und Auslassbohrungen **24** vorgesehen, die so angeordnet sind, dass wenn eine der Ein- und Auslassbohrungen **24** mit einem der Anschlussstutzen **17** ausgerichtet ist, die anderen Anschlussstutzen jeweils verschlossen bleiben.

[0055] Die Ventilplatte **21** besitzt einen umlaufenden O-Dichtring **25**, der eine zusätzliche Dichtung gegenüber der Unterseite **12** des Kammerkörpers **10** bereitstellt. Das Bezugszeichen **26** bezieht sich auf die Drehachse und das Lager der Ventilplatte **21**.

[0056] Im unteren Teilbild von **Fig.** 4 ist die Ventilplatte **21** und die Unterseite **12** des Kammerkörpers **10** im zusammenmontierten Zustand dargestellt. Wird die Ventilplatte **21** vom dargestellten Zustand nach links gedreht, so werden zunächst mit der Verbindungsleitung **22** die Kammern **13** und **14** verbunden und bei der weiteren Verstellung werden die Kammern **14** und **15** über die Verbindungsleitung **23** verbunden. Damit können mit einem kurzen Stellweg die beiden oben erläuterten Präparationsschritte ausgeführt werden.

[0057] Die in den **Fig.** 1 bis 4 illustrierte Ausführungsform der Erfindung kann je nach Aufgabenstellung vielfältig modifiziert werden. So können bspw. zur Durchführung weiterer Präparationsschritte im Kammerkörper weitere Kammern zur Aufnahme weiterer Zusatzstoffe vorgesehen sein. Anstelle der 120°-Anordnung können die Kammern auch anderweitig im Kammerkörper oder einem Rahmengestell (siehe unten) angeordnet werden. Die Beschickung der Kammern kann anwendungsabhängig von der Ober- oder Unterseite her erfolgen. Dies erfolgt vorzugsweise unter Verwendung von Schlauch- oder Pipettiersystemen. Gemäß einer bevorzugten Gestaltung der Erfindung sind die Einlassöffnungen der Kammern gerade an die Außendurchmesser von standardisierten Flüssigkeitspipetten oder Schlauchadapter angepasst, so dass diese zur Beschickung einfach angesetzt und betätigt werden können. Die Präparationsvorrichtung kann anwendungsabhängig in ihrer Größe beliebig skaliert werden. Die Übertragungseinrichtung mit der Ventilplatte kann durch eine fest eingestellte Anordnung mehrerer Verbindungsleitungen mit betätigbaren Ventilen ersetzt werden.

[0058] An der Außenseite des Kammerkörpers können zusätzliche Greif- oder Befestigungseinrichtungen zur Handhabung des Kammerkörpers und/oder zum Einsatz in eine Zentrifuge vorgesehen sein.

[0059] Der Kammerkörper mit den integrierten Kammern kann erfindungsgemäß durch eine Anordnung einzelner Kammern in einem Rahmengestell ersetzt werden. Diese Gestaltung besitzt Vorteile in Bezug auf eine separate Befüllung der einzelnen Kammern vor der Zusammensetzung zur Präparationsvorrichtung und die Entsorgung der Kammern nach Verwendung. Als Rahmengestell kann jede geeignete Struktur verwendet werden, in die die Kammern entsprechend der gewünschten Anordnung fixiert einsetzbar sind und die eine genügende Stabilität bei der Zentrifugation besitzt. Je nach der Gestaltung der Kammern ist die Struktur des Rahmengestells angepasst.

[0060] Werden als Kammern fertige Kolbenspritzen mit geeigneten Kolbendurchmessern verwendet, so besitzt das Rahmengestell Ausnehmungen zur Aufnahme der Spritzenkolben. Wenn die Einzelkammern durch gerade Rohrkörper gebildet sind, werden die Ausnehmungen des Rahmengestells entsprechend angepasst. Am Boden des Rahmengestells sind ggf. konisch vorgeformte Kammerböden vorgesehen, wie dies in **Fig.** 5 illustriert ist.

[0061] **Fig.** 5 zeigt eine Einzelkammer in schematischer Schnittansicht. Zwei oder mehr derartige Einzelkammern (z. B. entsprechend der obigen Gestaltung drei Einzelkammern) sind an einem Rahmengestell (nicht dargestellt) vorgesehen. Die Einzelkammer **90** umfasst eine Kammerwand **91** in Form eines geraden Kreiszylinders und einen sich verjüngenden Teilbereich **92**, der in einem entsprechend geformten Stützsockel **93** ruht, der Teil des Rahmengestells ist. Im Inneren der Einzelkammer **90** befindet sich der Druckstempel (siehe oben). Der Druckstempel ist bei dieser Gestaltung nicht zylinderförmig, sondern als Stempelplatte **94** mit einem außen umlaufenden Dichtring **97** ausgebildet. Die Stempelplatte **94** besteht beispielsweise aus PMMA. Der Dichtring **97** ist ein z. B. aus PTFE bestehendes Formteil, das formschlüssig über den äußeren Rand der Stempelplatte **94** gezogen ist. Der Querschnitt des Dichtringes **97** besitzt

eine U-Form, deren offenen Enden zwei Dichtlippen bilden. Durch diese Formgebung wird ein dichtendes Anlegen der Dichtlippen an die Kammerwand sicherstellt. Die Oberseite der Einzelkammer **90** ist mit einer Deckplatte **95** verschlossen, die eine Durchtrittsöffnung **96** zum Durchlass des Druckmediums aufweist.

[0062] Die Einzelkammer **90** besitzt bspw. ein Volumen von 470 ml bei einem Durchmesser von ca. 80 mm, einer Länge der Kammerwand **91** von ca. 110 mm und einer Höhe des Stützsockels **93** von ca. 30 mm. Der Teilbereich **92** grenzt ein Teilvolumen von ca. 30 ml ab.

[0063] Bei einem erfindungsgemäßen Verfahren zur Blutpräparation kann abweichend von der oben erläuterten Zentrifugation der gesamten Präparationsvorrichtung die folgende Einzelkammerzentrifugation vorgesehen sein. Dabei wird die jeweils interessierende Einzelkammer (z. B. gemäß **Fig.** 5) aus dem Rahmengestell entnommen und separat zentrifugiert. Vor oder nach der Zentrifugation ist die Einzelkammer im Rahmengestell zur Durchführung der übrigen Schritte der Probenpräparation angeordnet. Dieses Verfahren ist besonders vorteilhaft, falls zur Zentrifugation keine passende Zentrifuge zur Verfügung steht.

[0064] Die in der vorstehenden Beschreibung, den Ansprüchen und den Zeichnungen offenbarten Merkmale der Erfindung können sowohl einzeln als auch in beliebiger Kombination für die Verwirklichung der Erfindung in ihren verschiedenen Ausgestaltungen von Bedeutung sein.

Patentansprüche

1. Präparationsvorrichtung (**100**) zur Behandlung von Suspensionsproben, insbesondere zur Präparation von Blut-Kryokonserven, mit einer Anordnung von mindestens zwei Behältnissen zur Aufnahme von Suspensionsproben, Probenteilen und/oder Zusatzstoffen, **dadurch gekennzeichnet**, dass die Behältnisse als Kammern (**13** bis **15**, **90**) mit festen Wänden gebildet und relativ zueinander ortsfest angeordnet sind, wobei eine Übertragungseinrichtung (**20**) mit mindestens einer Verbindungsleitung (**22**) vorgesehen ist, über die die Kammern (**13** bis **15**) miteinander verbunden werden können.

2. Präparationsvorrichtung gemäß Anspruch 1, bei der die Kammern (**13** bis **15**) in einem einstückigen Kammerkörper (**10**) gebildet sind.

3. Präparationsvorrichtung gemäß Anspruch 1, bei dem die Kammern (**90**) als Einzelkammern lösbar in einem Rahmengestell befestigt sind.

4. Präparationsvorrichtung gemäß einem der vorhergehenden Ansprüche, bei der die Wände der Kammern oder der Kammerkörper (**10**) aus einem transparenten Material bestehen.

5. Präparationsvorrichtung gemäß einem der vorhergehenden Ansprüche 1 oder 2, bei der die Kammern (**13** bis **15**) die Gestalt gerader Hohlzylinder besitzen, die von einer Oberseite (**11**) bis zu einer Unterseite (**12**) des Kammerkörpers (**10**) verlaufen, wobei an der Unterseite (**12**) jede Kammer (**13** bis **15**) einen Anschlussstutzen (**17**) aufweist, mit dem jeweils ein Ende der mindestens einen Verbindungsleitung (**22**) verbunden werden kann.

6. Präparationsvorrichtung gemäß einem der vorhergehenden Ansprüche, bei der in jeder Kammer ein Druckstempel (**31** bis **33**) vorgesehen ist.

7. Präparationsvorrichtung gemäß Anspruch 6, bei der jeder Druckstempel (**31** bis **33**) eine umlaufende Dichtlippe aufweist.

8. Präparationsvorrichtung gemäß einem der vorhergehenden Ansprüche, bei der die Übertragungseinrichtung (**20**) durch eine Ventilplatte (**21**) gebildet wird, in der mindestens eine Verbindungsleitung (**22**) integriert ist, wobei die Ventilplatte (**21**) verdrehbar angeordnet ist.

9. Präparationsstation zur Präparation von Suspensionsproben, die umfasst:
mindestens eine Präparationsvorrichtung (**100**) gemäß einem der vorhergehenden Ansprüche,
eine Druckeinrichtung (**50**),
eine Detektoreinrichtung (**60**),
eine Stelleinrichtung (**70**), und
eine Steuereinrichtung (**80**).

10. Präparationsstation gemäß Anspruch 9, bei der die Druckeinrichtung (**50**) einen pneumatischen Druckerzeuger oder einen mechanischen Druckerzeuger mit Pleuelstangen umfasst.

11. Präparationsstation gemäß Anspruch 9 oder 10, bei der die Stelleinrichtung (**70**) ein Betätigungselement (**71**) aufweist, mit dem die Übertragungseinrichtung (**20**) derart einstellbar ist, dass jeweils zwei Kammern über die mindestens eine Verbindungsleitung (**22**) verbunden sind.

12. Verfahren zur Präparation von Suspensionsproben unter Verwendung einer Präparationsvorrichtung (**100**) gemäß einem der Ansprüche 1 bis 8, bei dem abwechselnd eine Behandlung einer Probe in mindestens einer der Kammern (**13** bis **15**, **90**) und eine Übertragung mindestens eines Teils der Probe zwischen zwei Kammern erfolgt.

13. Verfahren gemäß Anspruch 12, bei dem die Probenbehandlung eine Zentrifugation der Probe und/oder eine Behandlung der Probe mit Zusatzstoffen umfasst.

14. Verfahren gemäß Anspruch 13, bei dem bei der Zentifugation der Probe die gesamte Präparationsvorrichtung (**100**) oder eine Einzelkammer (**90**) zentrifugiert wird.

15. Verfahren gemäß einem der Ansprüche 12 bis 14, bei dem eine Blut-Kryokonserve herstellt wird.

Hierzu 5 Seite(n) Zeichnungen

Nummer: **DE 101 34 913 A1**
Int. Cl.[7]: **A 61 M 1/00**
Offenlegungstag: 20. Februar 2003

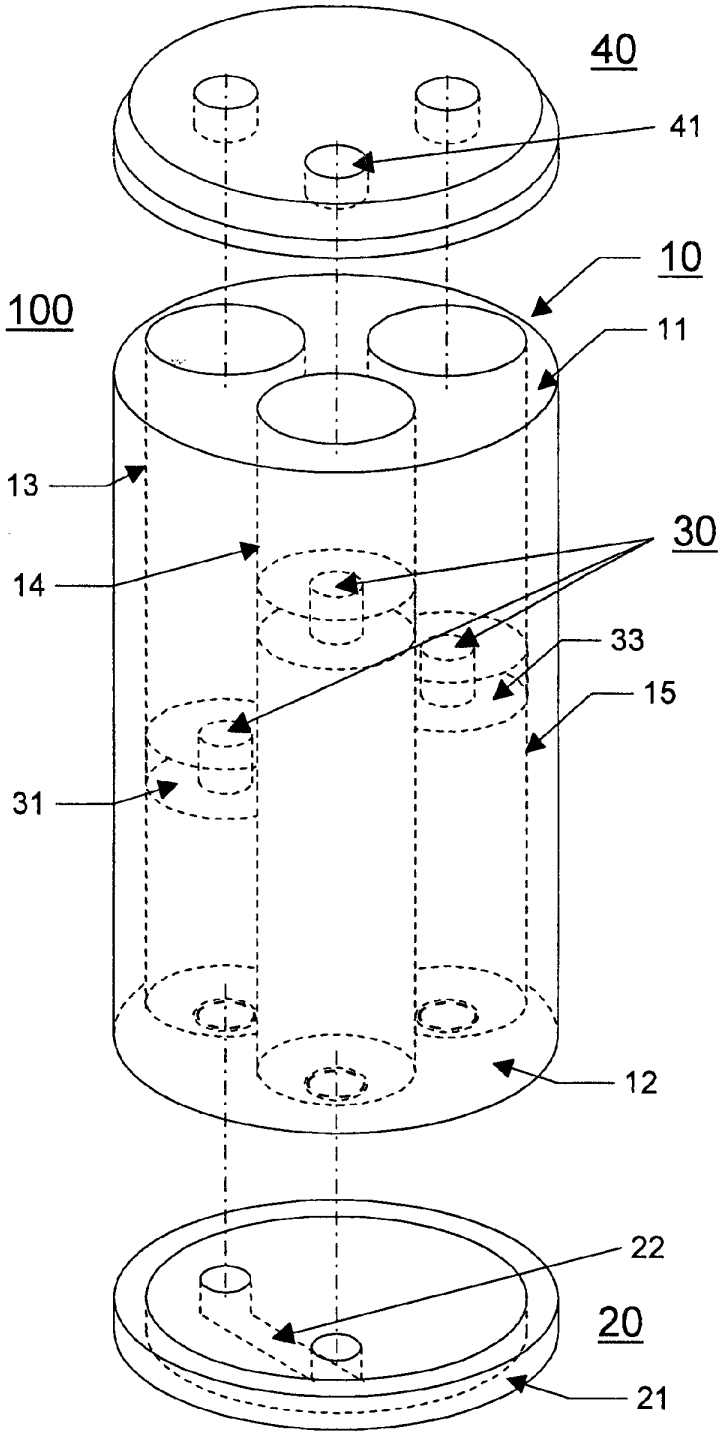


Fig. 1

Nummer: DE 101 34 913 A1
Int. Cl.[7]: A 61 M 1/00
Offenlegungstag: 20. Februar 2003

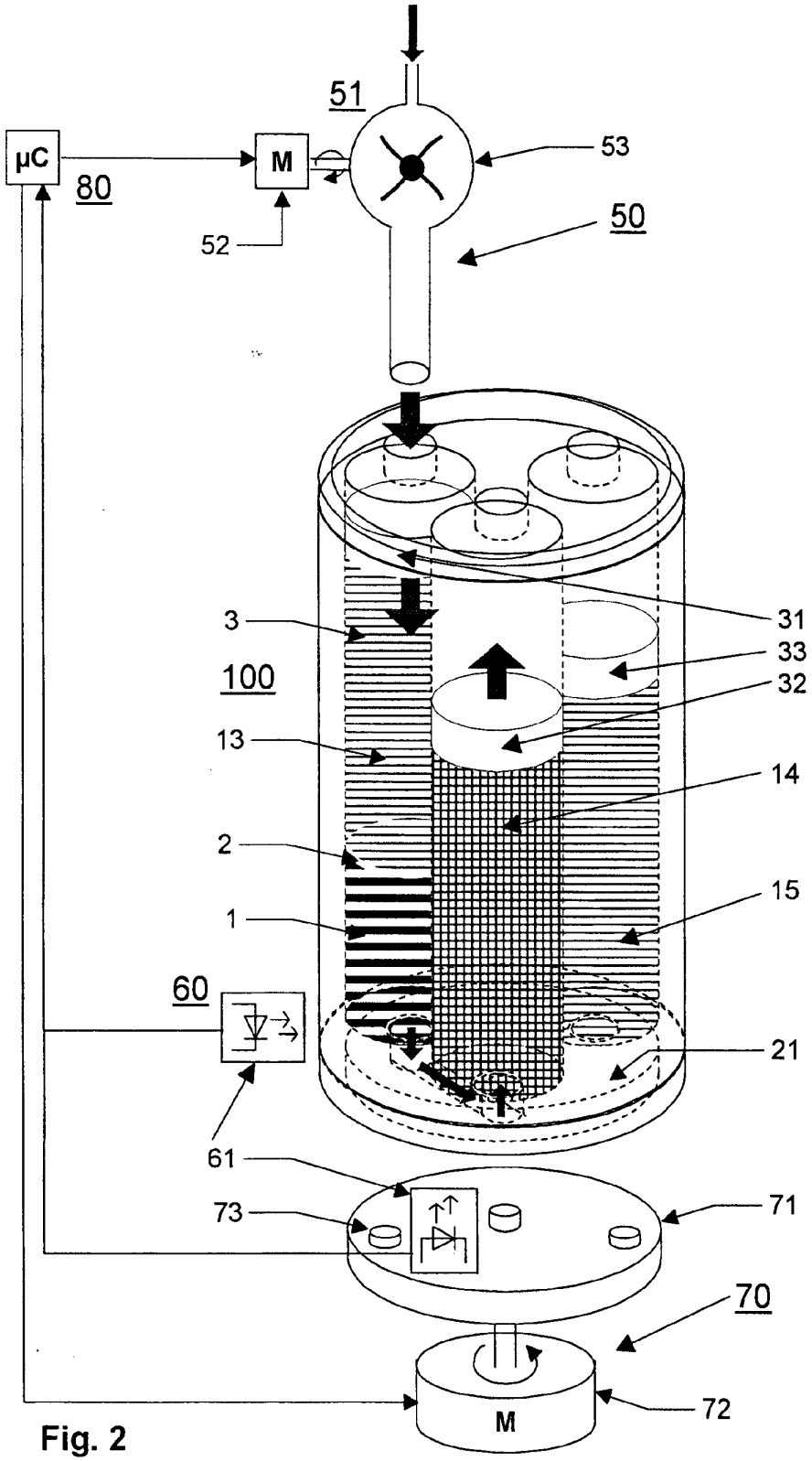


Fig. 2

102 680/59

Nummer: DE 101 34 913 A1
Int. Cl.[7]: A 61 M 1/00
Offenlegungstag: 20. Februar 2003

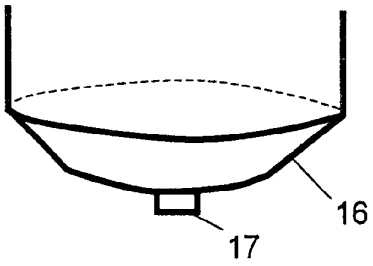


Fig. 3

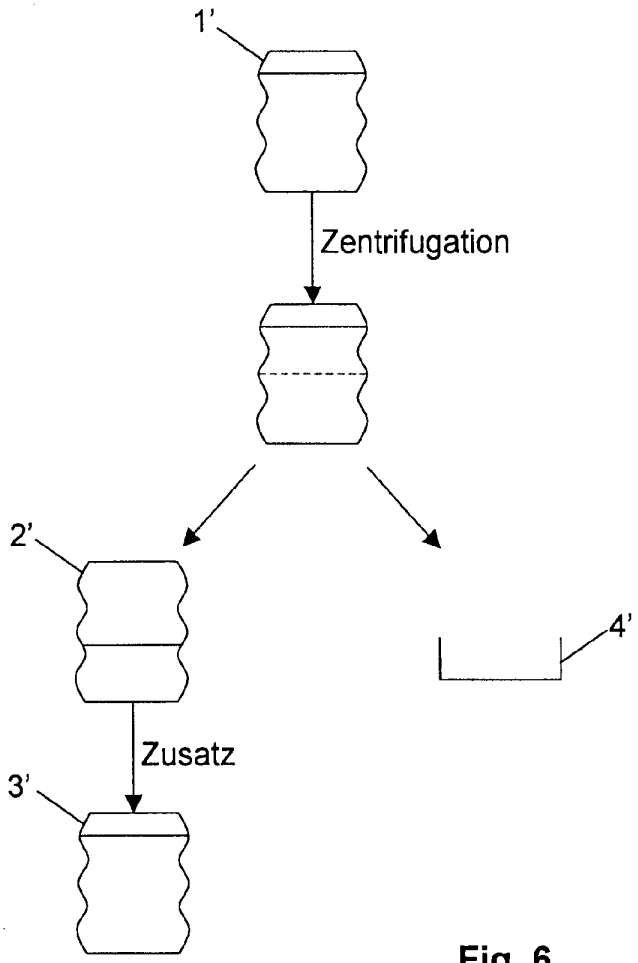
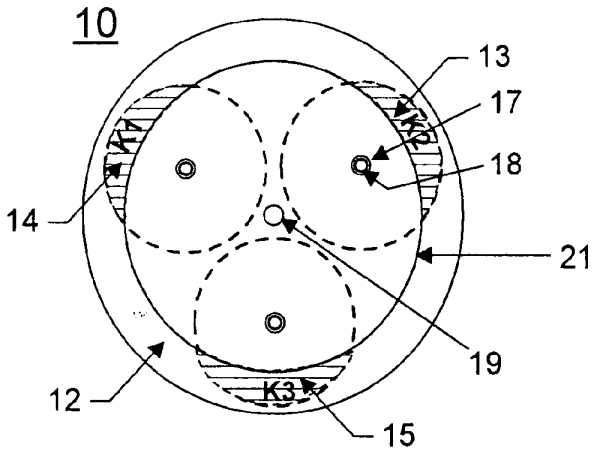
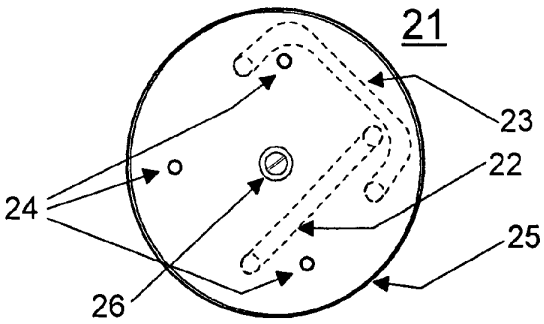


Fig. 6
(Stand der Technik)

Nummer: DE 101 34 913 A1
Int. Cl.[7]: A 61 M 1/00
Offenlegungstag: 20. Februar 2003





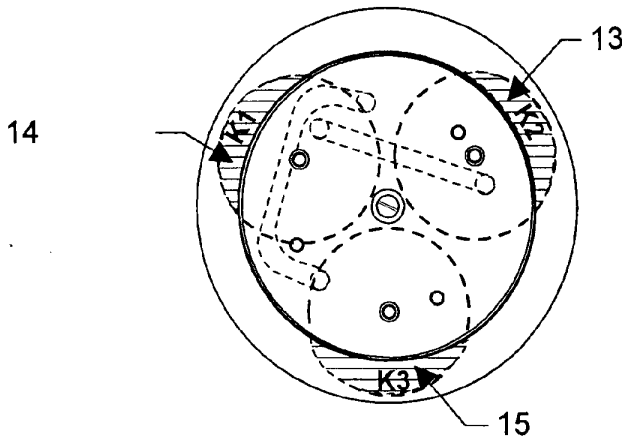


Fig. 4

102 680/59

Nummer: DE 101 34 913 A1
Int. Cl.[7]: A 61 M 1/00
Offenlegungstag: 20. Februar 2003

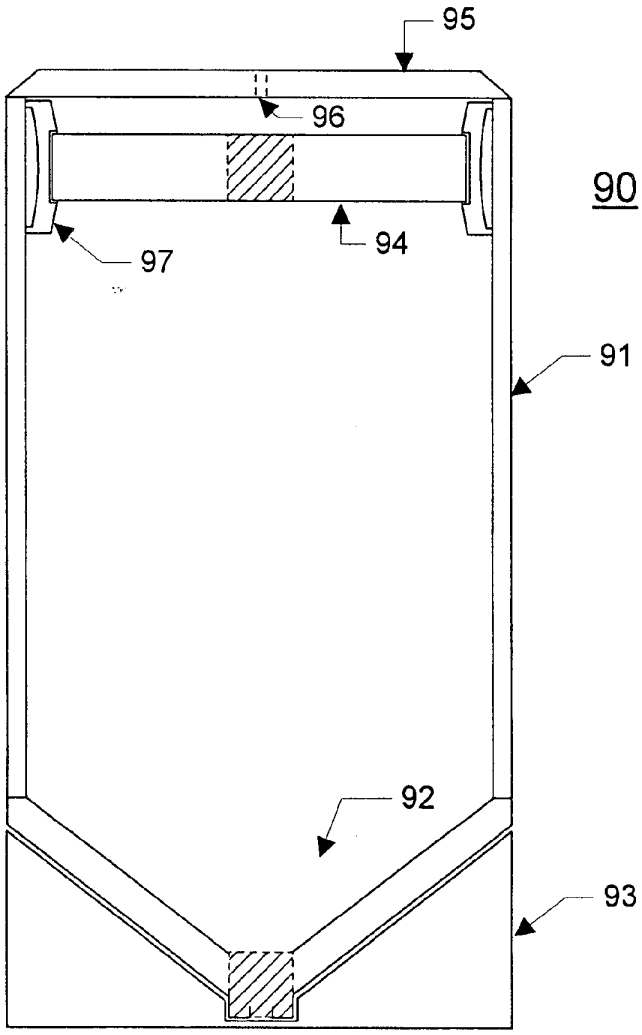


Fig. 5

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 5736-PCT	**FOR FURTHER ACTION**	see Form PCT/ISA/220 as well as, where applicable, item 5 below.
International application No. PCT/US 2015/035870	International filing date *(day/month/year)* 15 June 2015 (15.06.2015)	(Earliest) Priority Date *(day/month/year)* 13 June 2014 (13.06.2014)
Applicant GARRET, Chad et al.		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 2 sheets.

☐ It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**

a. With regard to the **language**, the international search was carried out on the basis of:

☒ the international application in the language in which it was filed.

☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

b. ☐ This international search report has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43.6*bis*(a)).

c. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2. ☐ **Certain claims were found unsearchable** (see Box No. II).

3. ☐ **Unity of invention is lacking** (see Box No. III).

4. With regard to the **title,**

☒ the text is approved as submitted by the applicant.

☐ the text has been established by this Authority to read as follows:

5. With regard to the **abstract,**

☒ the text is approved as submitted by the applicant.

☐ the text has been established, according to Rule 38.2, by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. With regard to the **drawings,**

a. the figure of the drawings to be published with the abstract is Figure No. 1

☒ as suggested by the applicant.

☐ as selected by this Authority, because the applicant failed to suggest a figure.

☐ as selected by this Authority, because this figure better characterizes the invention.

b. ☐ none of the figures is to be published with the abstract.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 2015/035870

A. CLASSIFICATION OF SUBJECT MATTER

A61B 5/15 *(2006.01)*
A61M 25/01 *(2006.01)*
G01N 33/48 *(2006.01)*

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61B 5/15, A61M 5/19, 25/01 G01N 33/48

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

PatSearch, Espacenet, USPTO, Google

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	WO 2013/082301 A1 (TELEFLEX MEDICAL, INC.) 06.06.2013 claims, [0006]-[0008], [0037], [0041], [0044]-[0054], fig. 1-5	1-9 10-13, 15-16, 18-19
Y	JP 2009131273 A (CSL BEHRING GMBH) 18.06.2009 abstract	10-13
X Y	EP 2593169 A1 (BECTON DICKINSON CO) 22.05.2013 abstract, [0006]-[0013]	14, 17 15-16, 18-19

☐ Further documents are listed in the continuation of Box C.

☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
19 October 2015 (19.10.2015)	05 November 2015 (05.11.2015)
Name and mailing address of the ISA/RU: Federal Institute of Industrial Property, Berezhkovskaya nab., 30-1, Moscow, G-59, GSP-3, Russia, 125993 Facsimile No: (8-495) 531-63-18, (8-499) 243-33-37	Authorized officer E. Kazak Telephone No. 8 (495) 531 64 81

Form PCT/ISA/210 (second sheet) (January 2015)

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

To:
HARMS, Donn K.
12702 Via Cortina, Suite 100
Del Mar, CA 92014
United States of America

Date of mailing *(day/month/year)* 05 November 2015 (05.11.2015)	
Applicant's or agent's file reference 5736-PCT	**FOR FURTHER ACTION** See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US 2015/035870	15 June 2015 (15.06.2015)	13 June 2014 (13.06.2014)

International Patent Classification (IPC) or both national classification and IPC
A61B 5/15 *(2006.01)*
A61M 25/01 *(2006.01)*
G01N 33/48 *(2006.01)*

Applicant
GARRET, Chad et al.

1. This opinion contains indications relating to the following items:

- [X] Box No. I Basis of the opinion
- [ ] Box No. II Priority
- [ ] Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- [ ] Box No. IV Lack of unity of invention
- [X] Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement
- [ ] Box No. VI Certain documents cited
- [ ] Box No. VII Certain defects in the international application
- [ ] Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

Name and mailing address of the ISA/RU:	Date of completion of this opinion	Authorized officer
Federal Institute of Industrial Property, Berezhkovskaya nab., 30-1, Moscow, G-59, GSP-3, Russia, 125993 Facsimile No: (8-495) 531-63-18, (8-499) 243-33-37	19 October 2015 (19.10.2015)	E. Kazak Telephone No. 8 (495) 531 64 81

Form PCT/ISA/237 (cover sheet) (January 2015)

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 2015/035870

Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of:

   [X] the international application in the language in which it was filed.

   [ ] a translation of the international application into _____ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

2. [ ] This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43*bis*.1(a))

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established on the basis of a sequence listing filed or furnished:

   a. [ ] forming part of the international application as filed:

      [ ] in the form of an Annex C/ST.25 text file.

      [ ] on paper or in the form of an image file.

   b. [ ] furnished together with the international application under PCT Rule 13*ter*.1(a) for the purposes of international search only in the form of an Annex C/ST.25 text file.

   c. [ ] furnished subsequent to the international filing date for the purposes of international search only:

      [ ] in the form of an Annex C/ST.25 text file (Rule 13*ter*.1(a)).

      [ ] on paper or in the form of an image file (Rule 13*ter*.1(b) and Administrative Instructions, Section 713).

4. [ ] In addition, in the case that more than one version or copy of a sequence listing has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

5. Additional comments:

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 2015/035870

Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	10-13, 15-16, 18-19	YES
	Claims	1-9, 14, 17	NO
Inventive step (IS)	Claims		YES
	Claims	10-13, 15-16, 18-19	NO
Industrial applicability (IA)	Claims	1-19	YES
	Claims		NO

2. Citations and explanations:

D1 - WO 2013/082301 A1
D2 - JP 2009131273 A
D3 - EP 2593169 A1

D1 can be regarded as the closest prior art of test component for blood according to claim 1.

D1 (claims, [0006] - [0008]) discloses a substrate configured to generate a visually discernable reaction to the presence or a threshold level of a substance in said blood; said substrate adapted for positioning in a fluid communication pathway carrying blood from a flash chamber defined by a surrounding sidewall of a housing of an introducer; and said substrate generating said visually discernable reaction viewable by a user of said introducer, subsequent to a fluid communication of said blood from said flash chamber to said substrate.

Thus, the invention according to claim 1 does not meet the criterion of novelty.

D3 can be regarded as the closest prior art of the inventions according to independent claims 14, 17.

D3 (abstract, [0006] - [0013]) discloses an introducer for the introduction of a catheter into the vein or artery of a patient: said introducer having a needle in axial communication between a distal end and a flash chamber with a housing of said introducer; a testing substrate within a substrate housing, said substrate housing in a fluid communication with said flash chamber through a passage in a sidewall of said flash chamber; said testing substrate configured to generate a visually discernable result, to a substance contained within blood communicated through said needle to said flash chamber; and said testing substrate viewable through a cover of said substrate housing, whereby said user can concurrently introduce a catheter to a patient and view test results for the presence of said substance with said blood from said patient communicated to said flash chamber.

D3 (abstract, [0006] - [0013]) discloses a method of testing a patient's blood for a substance comprising the steps of: placing a substrate having a visually discernable reaction area thereon to a said substance, in a fluid communication with a flash chamber of an introducer employed for the insertion of a catheter into the vein or artery of a patient; puncturing the vein or artery of said patient with a needle engaged to said introducer; allowing blood from said vein or artery to communicate axially through said needle to a flash chamber in said introducer; allowing a portion of said blood to fluidly communicate with said substrate; and viewing said substrate to ascertain said visually discernable reaction.

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.
Continuation of V:

Thus, the inventions according to independent claims 14, 17 do not meet the criterion of novelty.

The features of dependent claims 2-4, describing the fluid communication being through the microporous membrane disposed within the flash chamber, are disclosed in D1 ([0037], [0041], [0044], [0054]).

The features of dependent claims 5-6, indicating that positioned within a chamber of a substrate housing, said housing being engageable with an exterior of said sidewall of said substrate housing; and said fluid communication to said substrate communicating through an aperture in said sidewall , are disclosed in D1 ([0054]).

The features of dependent claims 7-9, indicating that substrate housing having a transparent cover in an engagement with a base having a passage aligned with said aperture in said sidewall; and providing for visually discernable reaction are disclosed in D1 ([0054], fig.1-5).

Thus, the invention according to dependent claims 2-9 does not meet the criterion of novelty.

The features of dependent claims 10-13, indicating that a clotting factor on or adjacent to said separation membrane generating a cessation of said fluid communication through said separation membrane subsequent to a duration of time sufficient to clot said blood at said separation membrane are disclosed in D2 (abstract).

The features of dependent claim 15 indicating that a separation membrane interposed between said flash chamber and said substrate: and said separation membrane allowing only blood plasma from said portion of blood therethrough to a said fluid communication with said substrate are disclosed in D1 ([0044], [0054]).

The features of dependent claim 16, indicating a plurality of said testing substrates, each located within separate said substrate housing, each said substrate housing in a fluid communication with said flash chamber through a passage in a sidewall of said flash chamber are also disclosed inD1 ([0044], [0054]).

The features of dependent claims 18, 19, indicating a visually discernable reaction area of substrate positioned in substrate housing are disclosed in D1 ([0044]).

Thus, the invention according to dependent claims 10-13, 15, 16, 18, 19 does not meet the criterion of inventive step.

The inventions according to claims 1-19 meet the criterion of industrial applicability.

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MINIREVIEW

Blood Culture Contamination: Persisting Problems and Partial Progress

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Although it has been widely appreciated for many years among physicians and microbiologists that blood cultures are among the most important laboratory tests performed in the diagnosis of serious infections (35), it has become equally apparent in more recent years that contaminated blood cultures are common (25, 42), enormously costly (3, 29), and frequently confusing for clinicians (1, 12, 14, 26). Clinical studies of bloodstream infections over 3 decades have provided guidelines for differentiating true pathogens from contaminants or organisms of unknown significance (14, 18, 41, 42); however, a true "gold standard" for differentiating pathogens from contaminants does not exist (4, 25). Moreover, the most common blood culture contaminants, coagulase-negative staphylococci (CoNS), which were almost always such several decades ago (18, 41), now are pathogens more frequently (19, 25, 26, 42), and judging the clinical significance of this group of microorganisms in blood has proven to be especially problematic (1, 11, 22, 24, 26, 42; S. J. Peacock, I. C. Bowler, and D. W. Crook., Letter, Lancet **346:**191-192, 1995). This review focuses on how pathogen-contaminant decisions are made, the phenomenon of increasing contamination of blood cultures, potential methods for addressing high contamination rates, and practical laboratory approaches to the workup of likely contaminants.

TOOLS FOR INTERPRETING THE CLINICAL SIGNIFICANCE OF POSITIVE BLOOD CULTURES

A number of clinical and laboratory tools have been proposed to aid microbiologists and physicians in deciding whether a blood isolate is a pathogen or a contaminant. These include the identity of the microorganism itself; clinical features such as fever, leukocytosis, and results of imaging studies (available to the clinician but usually not to the microbiologist); the proportion of blood culture sets positive as a function of the number of sets obtained; the time it takes for growth to be detected once a blood culture is received in the laboratory; and the number of culture vials within a culture set that show growth. Some of these tools have proven to be quite useful, whereas others have not.

The identity of the microorganism that grows from a positive blood culture provides important interpretative information. MacGregor and Beaty (18) documented this observation in the early 1970s, and studies by my colleagues and I confirmed and updated the earlier findings (41, 42). A predictive model that assessed multiple variables also documented microorganism identity as an independent predictor (4). Microorganisms that always or nearly always (>90%) represent true bacteremia or fungemia include *Staphylococcus aureus*, *Streptococcus pneumoniae*, *Escherichia coli* and other members of the *Enterobacteriaceae*, *Pseudomonas aeruginosa*, and *Candida albicans* (42). Although published data from large studies with multiple isolates of the following organisms are lacking, it is my observation that *Streptococcus pyogenes*, *Streptococcus agalactiae*, *Listeria monocytogenes*, *Neisseria meningitidis*, *Neisseria gonorrhoeae*, *Haemophilus influenzae*, members of the *Bacteroides fragilis* group, *Candida* species other than *C. albicans*, and *Cryptococcus neoformans* always or virtually always represent true infection. In contrast, microorganisms such as *Corynebacterium* species, *Bacillus* species other than *B. anthracis*, and *Propionibacterium acnes* represent true bacteremia only rarely (42). Detection of CoNS, the most frequent of all blood culture isolates, can be especially vexing. These bacteria are most often contaminants, but they have taken on increased clinical importance as the etiologic agents of catheter-associated bacteremia and bacteremia in patients with vascular and other prostheses (19, 26, 42). Accordingly, one can no longer judge the clinical significance of a CoNS isolate solely on the basis of its identity. Similarly, the clinical significance of other microorganisms also cannot be judged based only their identity. For example, in a recent study, enterococci and viridans group streptococci were pathogens 78 and 38% of the time, respectively, and *Clostridium perfringens* most often (77%) was a contaminant, whereas other *Clostridium* species most often (80%) were pathogens (42).

The number of blood culture sets that grow microorganisms, especially when measured as a function of the total number obtained, has proved to be a useful aid in interpreting the clinical significance of positive blood cultures (18, 41, 42). In contrast to patients with endocarditis or other bloodstream infections, in whom all blood cultures or the majority thereof are positive, patients whose blood cultures grow contaminants usually have only a single blood culture (when two or more are obtained) that is positive (42). Although obvious, it bears emphasis that if only a single blood culture is obtained, the value

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of this tool ceases to exist; and this is but one reason (another being increased blood volume) that at least two blood culture specimens are recommended as standard practice (2, 23, 37). The value of obtaining more than a single blood culture is that it also assists in interpreting the clinical significance of positive results by virtue of the following calculation. If an institution has a baseline blood culture contamination rate of 3%, the probability of recovering the same organism in two culture sets from a patient, and of that organism being a contaminant, is less than 1 in 1,000 ($0.03 \times 0.03 = 0.0009$)!

A laboratory tool that has been used as an aid to differentiating clinically significant isolates from contaminants is assessment of the time necessary for microbial growth to occur (4). The underlying premise is that growth of pathogens, which are likely to be present in larger inocula, will be detected earlier than that of contaminants, which are likely to be present in much smaller quantities (18). Whereas this concept likely has validity, the degree of overlap in the detection times of true pathogens versus contaminants is such that this variable cannot be relied upon as a predictor of a true-positive culture (8). Moreover, with the wide use of continuously monitoring blood culture systems and the concomitant decrease in the time to detection of growth, the time difference between the detection of true pathogens and contaminants has been narrowed even further.

Some microbiologists and clinicians have used the number of culture bottles positive within a blood culture set as a guide to determine whether isolates represent true pathogens or contaminants. However, there now are published data, at least for CoNS, that show that this technique is not clinically useful (22; Peacock et al., letter). Although clinically significant CoNS may grow more often in multiple bottles within a set as opposed to a single bottle, and contaminants may more often grow in only one bottle of a set, the degree of overlap is such that for a given culture this information cannot predict clinical significance reliably (22; Peacock et al., letter). Accordingly, this criterion should not be used.

THE PARADOX OF INCREASING NUMBERS OF CONTAMINANTS

Despite numerous advances in blood culture methodology and systems in recent decades, some hospitals and laboratories have noted that an increasing proportion of blood culture isolates represent contamination compared with those in years past (42). There are several possible explanations for this unexpected observation. The newer continuously monitoring blood culture systems have improved algorithms for detecting microbial growth and may be detecting microorganisms present in low numbers that previously were missed. Moreover, several broth medium formulations such as the BACTEC Plus Resin media (Becton Dickinson, Sparks, Md.) and BacT/ALERT FN media (bioMerieux, Durham, N.C.) have been shown to have improved detection of staphylococci, including CoNS which most often are contaminants (10, 20, 28, 38, 40, 43, 45). Thus, the ability of new systems and media to detect these organisms, even when present in small numbers, may be responsible in part for the observed increase in the proportion of blood cultures with contaminants.

The increased use of central venous access catheters and utilization of these devices for the purpose of obtaining blood specimens for culture may also be contributing to the increased numbers of contaminated blood cultures. Several studies have documented increased contamination when blood cultures are obtained in this fashion (5, 6, 7; R. B. Sivadas, B. Vazirani, S. Mirrett, and M. P. Weinstein, Abstr. 101st Gen. Meet. Am. Soc. Microbiol., abstr. C10, 2001), perhaps because it is more difficult to sterilize these devices than it is the skin before blood is obtained. Although physicians and nurses may believe they are saving patients the pain of an extra needle stick when blood cultures are obtained from catheters rather than by venipuncture, they may actually be doing their patients and the health care system a disservice if contaminants are grown from the culture resulting in the need for even more cultures, other diagnostic studies, unnecessary antibiotic therapy, and the associated incremental costs of care.

Prior to the human immunodeficiency virus (HIV) era, blood cultures traditionally were obtained by a two-needle technique, using a sterile needle and syringe to perform the venipuncture, then changing to a second sterile needle before inoculating the blood culture vial. The purpose of the two-needle technique was to reduce the chance that skin microorganisms that might be present on the needle used for the venipuncture would be inoculated into the blood culture vial, thereby resulting in a contaminated blood culture. As the knowledge of HIV as a bloodborne pathogen and the risks of needle stick transmission of HIV became evident, several studies were undertaken to determine whether contamination rates would be affected if only one needle was used for both venipuncture and inoculation of blood culture vials (9, 15, 16). The results of each of these studies showed no significant increase in contamination rates when the single-needle technique was used. Subsequently, however, a meta-analysis suggested that single-needle blood cultures were associated with contamination rates of 3.7% compared with 2.0% when a two-needle technique was used (30). Since the current standard of care continues to be the single-needle technique in order to reduce the risk of occupational needle stick injuries, slightly higher contamination rates may have to be tolerated.

REDUCING THE NUMBER OF CONTAMINATED BLOOD CULTURES

Although it is not possible to achieve contamination rates of zero or even close to zero (31), there are potential means by which contamination can be reduced. These include the use of collection methods that increase the chances for sterility, for example, obtaining blood via venipuncture rather than from an intravascular catheter or using a two-needle rather than a single-needle technique, as has already been mentioned. For the reasons already stated, the two-needle method is unlikely to return to widespread use; however, laboratories and institutions can and should actively promote blood cultures obtained from venipuncture rather than intravascular devices as a means of practicing evidence-based medicine.

There is also evidence that some antiseptic preparations may be more efficacious than others in reducing contamination rates. Povidone iodine preparations require 1.5 to 2 min of contact time to produce their maximum antiseptic effect, whereas iodine tincture requires approximately 30 s (13). Health care

workers who obtain blood cultures are often in a hurry, do not understand the importance of antiseptic preparation contact time, and are less likely to wait 1.5 to 2 min as opposed to half a minute before obtaining blood. At least two studies have documented a significantly lower contamination rate using iodine tincture compared with an iodophor (17, 31). Another report compared the use of 0.2% chlorine peroxide and 10% povidone iodine and demonstrated lower contamination rates when chlorine peroxide was used (29). Lastly, an alcoholic solution of 0.5% chlorhexidine gluconate used as an antiseptic prior to blood culture was associated with significantly lower contamination rates compared with a standard povidone-iodine preparation (21).

Several published studies have shown that trained phlebotomists or blood culture teams can reduce contamination rates in individual institutions (27, 32, 36), and this has been confirmed in my own institution (Sivadas et al., 101st Gen. Meet. Am. Soc. Microbiol.). At a New York City, N.Y., community teaching hospital, the contamination rate for blood cultures drawn by a blood culture team using a commercially available blood culture prep kit was approximately 1% compared with rates of 4.8% for blood cultures drawn by resident physicians using the same method (36). The contamination rate when residents did not use the commercial prep kit was even higher (8.4%) (36). In a large survey of over 600 hospitals sponsored by the College of American Pathologists, median contamination rates for institutions in which more than half of all blood cultures were collected by resident physicians was 3.9%, compared with 2.2% in the remaining institutions (27). In a pilot study at my institution, contamination of blood cultures obtained by phlebotomists trained and monitored monthly by microbiology laboratory staff was 3%, compared with nearly 11% for blood cultures obtained by resident physicians, nondegree nursing assistants, and nurses (M. P. Weinstein, unpublished observation). Subsequently, my colleagues and I assessed contamination in a larger study and again found that samples collected by phlebotomists had lower contamination rates than those collected by nondegree nursing assistants, nurses, and resident physicians (the last of whose samples had the highest contamination rates) (Sivadas et al., 101st Gen. Meet. Am. Soc. Microbiol.).

Whether or not commercially marketed blood culture prep kits are associated with reduced blood culture contamination rates remains controversial. Some studies have shown reduced contamination (27, 36) with commercial prep kits, whereas others have shown no difference (44). The manufacturer of at least one commercial prep kit has offered ongoing in-service education for personnel obtaining blood cultures (M. P. Weinstein, personal observation), which itself may be associated with reduced contamination rates.

LABORATORY WORKUP OF LIKELY BLOOD CULTURE CONTAMINANTS

In the real world of clinical microbiology laboratories, nearly half of all positive blood cultures represent contamination (42). Complete laboratory workup of contaminant isolates is associated with increased technologist workload and institutional cost. Therefore, some laboratories have developed algorithms for dealing with this problem based, at least in part, on many of the studies reviewed in this article.

At the University of Iowa, for example, Richter et al. (25) tested, validated, and implemented an algorithm to minimize the workup of blood culture contaminants. CoNS, aerobic and anaerobic diphtheroids, *Micrococcus* spp., *Bacillus* spp., and viridans group streptococci are considered contaminants if certain criteria are met. If two or more blood cultures are obtained and only one is positive, the isolate is reported as a probable contaminant and susceptibility testing is not done unless the physician calls the laboratory. If only a single blood culture is obtained and grows one of the likely contaminants, a pathology resident reviews the patient's chart and judges the clinical significance of the isolate based on published data (42). Susceptibility testing is not done if the isolate is judged to be a contaminant. If two or more blood cultures are obtained and two cultures are positive within a 48-h period, one of two actions is taken. If the isolates are viridans group streptococci, they are presumed to be clinically significant and a full workup is done. If one of the other likely contaminants is present, the pathology resident reviews the patient's chart, and the laboratory workup proceeds according to the resident's judgment regarding clinical significance.

In my laboratory, a similar protocol is followed, but it is modified somewhat based on the fact that pathology residents are not always assigned to microbiology. The same microorganisms are considered likely contaminants. If two or more blood cultures are submitted and only one is positive, neither species identification nor susceptibility testing is done; the isolate is reported as a probable contaminant. If only one blood culture is submitted and it grows a likely contaminant, the workup is the same; the isolate is reported to be of indeterminate significance and the physician is advised to call the laboratory director if additional workup is needed. If two or more blood cultures grow a likely contaminant other than CoNS (see below) within a 48-h period, a full workup is done. If the isolates are the same, the identification and susceptibility results are reported. If the isolates are different, they are reported as probable contaminants without susceptibility results.

When two or more blood cultures grow CoNS, my laboratory undertakes species identification and reports susceptibility results. I find that the additional information assists in determining whether the isolates are clinically significant (12, 39). If the strains isolated have the same biochemical profile and antibiogram, it is probable that they are identical (although only molecular typing provides proof). This information increases the likelihood that the isolates represent clinically significant bacteremia, and identification and susceptibility results are reported to the clinician. However, if the biochemical profiles and antibiograms are not the same (i.e., two or more differences in biochemical results and susceptibilities [susceptible versus resistant]), the isolates are much more likely to represent contamination. In this instance, the laboratory reports that two different CoNS strains were identified, and susceptibility results are not provided. Although this technique has proven clinically useful in most circumstances, the algorithm is not foolproof. Two studies from the same center in Belgium have described polyclonal CoNS bacteremia (33, 34). Thus, in patients who have multiple positive blood cultures growing CoNS that appear to be different strains, the labora-

tory may need to perform additional testing if clinicians believe clinically significant infection is present.

As is apparent from the foregoing discussion, the current state of the art remains suboptimal. Although progress has been made, the interpretation of the clinical significance of microorganisms that are common blood culture contaminants and the technical effort and institutional costs associated with working up probable contaminants remain problematic. Gold standards for solving these problems still are elusive.

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BLOOD SAMPLE OPTIMIZATION SYSTEM AND BLOOD CONTAMINANT SEQUESTRATION DEVICE AND METHOD

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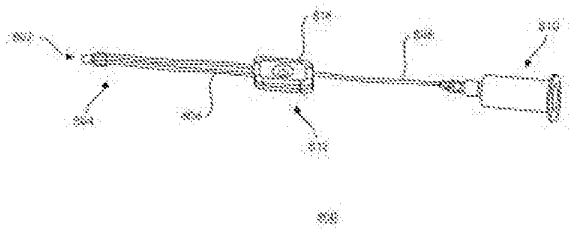
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Blood sample optimization systems and methods are described that reduce or eliminate contaminates in collected blood samples, which in turn reduces or eliminates false positive readings in blood cultures or other testing of collected blood samples. A blood sample optimization system can include a blood sequestration device located between a patient needle and a sample needle. The blood sequestration device can include a sequestration chamber for sequestering an initial, potentially contaminated aliquot of blood, and may further include a sampling channel that bypasses the sequestration chamber to convey likely uncontaminated blood between the patient needle and the sample needle after the initial aliquot of blood is sequestered in the sequestration chamber.

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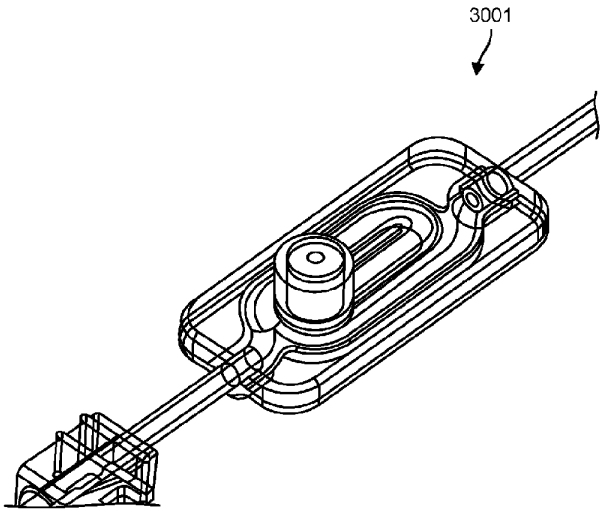


FIG. 30B

(57) Abstract: Blood sample optimization systems and methods are described that reduce or eliminate contaminates in collected blood samples, which in turn reduces or eliminates false positive readings in blood cultures or other testing of collected blood samples. A blood sample optimization system can include a blood sequestration device located between a patient needle and a sample needle. The blood sequestration device can include a sequestration chamber for sequestering an initial, potentially contaminated aliquot of blood, and may further include a sampling channel that bypasses the sequestration chamber to convey likely uncontaminated blood between the patient needle and the sample needle after the initial aliquot of blood is sequestered in the sequestration chamber.

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BLOOD SAMPLE OPTIMIZATION SYSTEM AND BLOOD CONTAMINANT SEQUESTRATION DEVICE AND METHOD

BACKGROUND

[0001] Bacteraemia is the presence of microorganisms in the blood. Sepsis, on the other hand, is bacteraemia in the presence of clinical symptoms and signs such as fever, tachycardia, tachypnea and hypotension. Bacteraemia and sepsis are associated with a high mortality and an increased incidence and duration of hospital stay and associated costs. Many bacteraemias, sepsis, fungaemias and other pathogens actually occur within a hospital or other healthcare settings with catheters and venipunctures being a source of contamination as potential carriers of these pathogens.

[0002] Blood cultures are the standard test used to detect microbial pathogens related to bacteraemia and sepsis in a patient's blood. The term blood culture refers to a single venipuncture, either from a peripheral site or central or arterial line, with the blood inoculated into one or more blood culture bottles or containers. One bottle is considered a blood culture where two or more are considered a set. Multiple sets may be obtained from multiple venipunctures and are associated with different sites on the patient.

[0003] These methods allow for microbial identification and susceptibility testing to be performed, which is a critical component to managing sepsis, however the lack of rapid results and decreased sensitivity for fastidious pathogens has led to the development of improved systems and adjunctive molecular or proteomic testing.

[0004] Collection of blood samples for conducting blood cultures is a critical component of modern patient care and can either positively affect the patient outcome by providing an accurate diagnosis, or can adversely affect the outcome by prolonging unnecessary antimicrobial therapy, the length of hospital stays, and increasing costs.

[0005] One outcome of collection of blood cultures is contamination. Blood culture contamination can lead to a false positive culture result and/or significant increase in healthcare related costs. Sources of blood culture contamination include improper skin antisepsis, improper collection tube disinfection, and contamination of the initial blood draw which may then skew results.

[0006] Blood culture collection kits generally consist of a "butterfly" set, infusion set, or other type of venipuncture device as offered by companies like BD, Smiths, B. Braun and others, and aerobic and anaerobic blood culture bottles. Various different bottles are also available depending on the test requirements. These bottles are specifically designed to optimize recovery of both aerobic and anaerobic organisms. In conventional kits, a bottle used is known generally as a "Vacutainer," which is a blood collection tube formed of a sterile glass or plastic tube with a closure that is evacuated to create a vacuum inside the tube to facilitate the draw of a predetermined volume of liquid such as blood.

[0007] False positive blood cultures are typically a result of poor sampling techniques. They cause the use of antibiotics when not needed, increasing hospital costs and patient anxiety. Blood cultures are drawn from a needlestick into the skin, and then a Vacutainer is attached to capture a sample of blood. Contamination may occur from improper or incomplete disinfection of the skin area in and around the puncture site. It may also occur from the coring of the skin by the needle during insertion, with the cored skin cells and any associated contamination being pulled into the sample.

[0008] Blood flow through a hypodermic needle is laminar, and as such, a velocity gradient can be developed over the flow tube as a pressure drop is applied to the hypodermic needle. Either forceful aspiration of blood, or using a very small hypodermic needle, can cause lysis and a release of potassium from the red blood cells, thereby rendering the blood samples abnormal.

[0009] In other instances, some patients have delicate veins that can collapse under a pressure drop or vacuum, particularly as applied by a syringe's plunger that is drawn too quickly for the patient's condition. Since such condition is impossible to know beforehand, such vein collapses are a risk and very difficult to control.

[0010] Various strategies have been implemented to decrease blood culture contamination rates, e.g. training staff with regard to aseptic collection technique, feedback with regard to contamination rates and implementation of blood culture collection kits. Although skin antisepsis can reduce the burden of contamination, 20% or more of skin organisms are located deep within the dermis and are unaffected by

antisepsis. Changing needles before bottle inoculation is not advisable as it increases the risk to acquire needle stick injuries without decreasing contamination rates.

[0011] Some conventional systems and techniques for reducing blood culture contamination include discarding the initial aliquot of blood taken from central venous catheters, venipunctures, and other vascular access systems. However, these systems require the user to mechanically manipulate an intravascular device, or require a complex series of steps that are difficult to ensure being followed.

SUMMARY

[0012] This document presents systems and methods for reducing blood culture contamination, lysing of cells, and vein collapse. In some implementations, a system and method can eliminate user variability in disinfection, and also eliminate the risk of skin cells getting into the blood culture sample. The systems and methods disclosed herein do not require a change in existing clinical processes, other than to potentially indicate when a vacutainer or other blood collection device (i.e., syringe) should be attached for drawing contaminant-free blood samples.

[0013] In some implementations of the systems and methods disclosed herein the withdrawal of blood is accomplished passively by use of the patient's own blood pressure, thereby reducing the risk of vein collapse and eliminating any additional user steps over current practice. The systems and methods can be applied to accommodate short-path direct stick or butterfly venipuncture systems. They can also be used with samples drawn through a catheter.

[0014] In one aspect, a blood sequestration device is presented. The blood sequestration device includes an inlet port and an outlet port. The blood sequestration device further includes a sequestration chamber connected with the inlet port, the sequestration chamber having a vent comprising an air permeable blood barrier. The blood sequestration device further includes a sampling channel having a proximal end connected with the inlet port and a distal end connected with the outlet port.

[0015] In another aspect, a blood sequestration device connected with a blood sampling pathway is described. The blood sampling pathway has a patient needle and a sample collection device. The blood sequestration device includes an inlet port connected

with the patient needle, and a sequestration chamber connected with the inlet port, the sequestration chamber having a vent comprising an air permeable blood barrier. The blood sequestration device further includes a sampling channel having a proximal end connected with the inlet port, and an outlet port connected with a distal end of the sampling channel and with the sample collection device.

[0016] In yet another aspect, a blood sequestration device connected with a blood sampling system is described. The blood sampling system includes a patient needle for accessing a blood sample from a patient, and a sample needle that is sealed and adapted for receiving an evacuated blood collection tube. The blood sequestration device includes an inlet port connected with the patient needle to receive the blood sample from the patient. The blood sequestration device further includes a sequestration chamber connected with the inlet port and having a vent comprising an air permeable blood barrier, the sequestration chamber for receiving and sequestering a first portion of the blood sample prior to the sample needle being unsealed by the evacuated blood collection tube. The blood sequestration device further includes a sampling channel having a proximal end connected with the inlet port, the sampling channel for conveying a subsequent portion of the blood sample once the sample needle is unsealed by the evacuated blood collection tube. The blood sequestration device further includes an outlet port connected with a distal end of the sampling channel for conveying the subsequent portion of the blood sample to the sample needle.

[0017] In yet another aspect, a blood sample optimization system is disclosed and described. The blood sample optimization system includes a blood sampling system for accessing and acquiring one or more samples of a patient's blood, and a blood sequestration device for receiving and sequestering a first portion of the one or more samples of the patient's blood which might be contaminated by a venipuncture process and which could result in a false positive identification of a pathogen in the patient's blood.

[0018] The blood sampling system includes a patient needle configured for a venipuncture of a patient to access a sample of blood of a patient, a blood sampling pathway connected with the patient needle for conveying the sample of blood, and a sample needle configured for receiving an evacuated blood collection container to collect and contain a subsequent portion of the sample of blood.

[0019] In yet another aspect, a blood sequestration device is disclosed and described. In some implementations, the blood sequestration device can include an inlet port, an outlet port connected with the inlet port, and a sequestration chamber connected with the inlet port. The sequestration chamber can have a vent comprising an air permeable blood barrier.

[0020] The blood sequestration device, in one aspect can include an inlet port, an outlet port, a sequestration chamber connected with the inlet port via a junction, the sequestration chamber having a vent that includes an air permeable blood barrier, the vent being defined by an outer wall that at least partially circumscribes the air permeable blood barrier and includes one or more air vents, the vent further includes a cap that at least partially covers the wall and a one-way seal abutting the air permeable blood barrier that inhibits air from entering the sequestration chamber, and a sampling channel having a proximal end connected with the inlet port via the junction, and a distal end connected with the outlet port. In certain related aspects, the sequestration chamber, the sampling channel and the junction are sized and configured such that a first portion of blood flows into the sequestration chamber toward the air permeable blood barrier for sequestration therein, and a second portion of blood bypasses the sequestration chamber and the first portion of blood sequestered therein and is directed into the sampling channel toward the outlet port.

[0021] In another aspect, the sampling channel and the junction is sized and configured such that a first portion of blood flows into and fills the sequestration chamber to displace air therein through the vent, and such that a second portion of blood bypasses the sequestration chamber and the first portion of blood sequestered therein and is directed into the sampling channel toward the outlet port.

[0022] The blood sequestration and sampling system sequestration device, in certain aspects can include a blood sampling pathway having a patient needle on a proximal end and a sample collection device on a distal end; and a blood sequestration device attached on the blood sampling pathway between the proximal end and distal end of the blood sampling pathway. The blood sequestration device in one aspect can include an inlet port coupled with the blood sampling pathway toward the patient needle, an outlet port coupled with the blood sampling pathway toward the sample collection device, a sequestration chamber connected with the inlet port via a junction, which chamber has a

vent that includes an air permeable blood barrier, the vent being defined by an outer wall that at least partially circumscribes the air permeable blood barrier and includes one or more air vents, the vent further including a cap that at least partially covers the wall and a one-way seal abutting the air permeable blood barrier that inhibits air from entering the sequestration chamber; and a sampling channel having a proximal end connected with the inlet port via the junction, and a distal end connected with the outlet port. In a certain related aspect, the sequestration chamber, the sampling channel and the junction can be sized and configured such that a first portion of blood flows into the sequestration chamber toward the air permeable blood barrier for sequestration therein, and a second portion of blood bypasses the sequestration chamber and the first portion of blood sequestered therein and is directed into the sampling channel toward the outlet port.

[0023] The blood sequestration device is connected along the blood sampling pathway between the patient needle and the sample needle, and includes an inlet port for receiving the sample of blood. The blood sequestration device further includes a sequestration chamber connected with the inlet port for receiving a first amount of the sample of blood, the sequestration chamber having a vent comprising an air permeable blood barrier for sequestering at least a first portion of the first amount of the sample of blood. The blood sequestration device may further include a sampling channel having a proximal end connected with the inlet port, the sampling channel conveying a subsequent amount of the sample of blood to the evacuated blood collection container upon the sequestration chamber sequestering at least the first portion of the first amount of the sample of blood. The blood sequestration device further includes an outlet port connected with a distal end of the sampling channel, the outlet port for outputting the subsequent amount of the sample of blood.

[0024] The details of one or more embodiments are set forth in the accompanying drawings and the description below. Other features and advantages will be apparent from the description and drawings, and from the claims.

BRIEF DESCRIPTION OF THE DRAWINGS

[0025] These and other aspects will now be described in detail with reference to the following drawings.

[0026] FIG. 1 illustrates a blood sample optimization system.

[0027] FIG. 2 illustrates a blood sample optimization system in accordance with an alternative implementation.

[0028] FIG. 3 illustrates a blood sample optimization system in accordance with another alternative implementation.

[0029] FIG. 4 illustrates a blood sample optimization system in accordance with another alternative implementation.

[0030] FIG. 5 illustrates a blood sample optimization system in accordance with another alternative implementation.

[0031] FIG. 6 illustrates a blood sample optimization system in accordance with an alternative implementation.

[0032] FIG. 7 is a flowchart of a method for optimizing a quality of a blood culture.

[0033] FIGS. 8A – 8E illustrate a blood sequestration system for non-contaminated blood sampling, in accordance with some implementations.

[0034] FIG. 9 illustrates a pathway splitter for use in a blood sequestrations system.

[0035] FIGS. 10A – 10D illustrate a blood sequestration system for non-contaminated blood sampling, in accordance with alternative implementations.

[0036] FIGS. 11A – 11E illustrate a blood sequestration system for non-contaminated blood sampling, in accordance with other alternative implementations.

[0037] FIGS. 12A-12D illustrate a blood sample optimization system including a blood sequestration device in accordance with yet other alternative implementations.

[0038] FIGS. 13A-13D illustrate a blood sample optimization system 1300 in accordance with yet another alternative implementations.

[0039] FIGS. 14A-14E illustrate yet another implementation of a blood sampling system to sequester contaminates of an initial aliquot or sample to reduce false positives in blood cultures or tests performed on a patient's blood sample.

[0040] FIGS. 15A-15G illustrate a blood sequestration device and method of using the same, in accordance with yet another implementation.

[0041] FIGS. 16A-16D illustrate a blood sequestration device in accordance with yet another implementation.

[0042] FIGS. 17A – 17E illustrate a bottom member of a housing for a blood sequestration device.

[0043] FIGS. 18A – 18F illustrate a top member of a housing for a blood sequestration device.

[0044] FIGS. 19A and 19B illustrate a blood sequestration device having a top member mated with a bottom member.

[0045] FIG. 20 shows a blood sample optimization system including a blood sequestration device.

[0046] FIG. 21 illustrates a non-vented blood sequestration device using a wicking material chamber.

[0047] FIGS. 22A and 22B illustrate a material makeup of a filter for sequestering blood in a sequestration chamber of a blood sequestration device.

[0048] FIGS. 23A – 23E illustrate another implementation of a blood sequestration device that uses a vacuum force from a blood collection device.

[0049] FIGS. 24A – 24D illustrate another implementation of a blood optimization system and blood sequestration device.

[0050] FIGS. 25A – 25D illustrate another implementation of a blood optimization system and blood sequestration device.

[0051] FIGS. 26A – 26E illustrate another implementation of a blood optimization system and blood sequestration device.

[0052] FIGS. 27A – 27D illustrate another implementation of a blood optimization system and blood sequestration device.

[0053] FIGS. 28A – 28F illustrate another implementation of a blood optimization system and blood sequestration device.

[0054] FIGS. 29A – 29C illustrate another implementation of a blood optimization system and blood sequestration device.

[0055] FIGS. 30A – 30G illustrate another implementation of a blood optimization system and blood sequestration device.

[0056] Like reference symbols in the various drawings indicate like elements.

DETAILED DESCRIPTION

[0057] This document describes blood sample optimization systems and methods for reducing or eliminating contaminates in collected blood samples, which in turn reduces or eliminates false positive readings in blood cultures or other testing of collected blood samples. In some implementations, a blood sample optimization system includes a patient needle for vascular access to a patient's bloodstream, a sample needle for providing a blood sample to a blood collection container, such as an evacuated blood collection container or tube like a Vacutainer™ or the like, or other sampling device, and a blood sequestration device located between the patient needle and the sample needle. The blood sequestration device includes a sequestration chamber for sequestering an initial, potentially contaminated aliquot of blood, and may further include a sampling channel that bypasses the sequestration chamber to convey likely uncontaminated blood between the patient needle and the sample needle after the initial aliquot of blood is sequestered in the sequestration chamber.

[0058] FIG. 1 illustrates a blood sample optimization system in accordance with some implementations. The system includes a patient needle 1 to puncture the skin of a patient to access the patient's vein and blood therein. The system further includes a sample needle (i.e., a resealably closed needle for use with Vacutainers™ or the like) 5, which may be contained within and initially sealed by a resealable boot 10, a Luer activated valve, or another collection interface or device. The resealable boot 10 can be

pushed aside or around the sample needle 5 by application of a Vacutainer™ bottle (not shown) for drawing the patient's blood. The system can further include a low volume chamber 30 that leads to the sample needle 5, but also includes an orifice or one or more channels 45 that lead to a sequestration chamber 55 formed by a housing 50.

[0059] The sequestration chamber 55 is a chamber, channel, pathway, lock, or other structure for receiving and holding a first aliquot of the patient's blood, which may be in a predetermined or measured amount, depending on a volume of the sequestration chamber 55. The first draw of blood typically contains or is more susceptible to containing organisms that cause bacteraemia and sepsis or other pathogens than subsequent blood draws. The sequestration chamber 55 can be a vessel encased in a solid housing, formed in or defined by the housing itself, or can be implemented as tubing or a lumen. The sequestration chamber 55, regardless how formed and implemented, may have a predetermined volume. In some implementations, the predetermined volume may be based on a volume of the patient needle, i.e. ranging from less than the volume of the patient needle to any volume up to or greater than 20 times or more of the volume of the patient needle. The predetermined volume of the sequestration chamber 55 may also be established to economize or minimize an amount of blood to be sequestered and disposed of.

[0060] The sequestration chamber 55 can be formed, contained or housed in a chamber housing 50, and can be made of plastic, rubber, steel, aluminum or other suitable material. For example, the sequestration chamber 55 could be formed of flexible tubing or other elastomeric materials. The sequestration chamber 55 further includes an air permeable blood barrier 20 that allows air to exit the sequestration chamber 55. As used herein the term "air permeable blood barrier" means an air permeable but substantially blood impermeable substance, material, or structure. Examples may include hydrophobic membranes and coatings, a hydrophilic membrane or coating combined with a hydrophobic membrane or coating, mesh, a filter, a mechanical valve, antimicrobial material, or any other means of allowing air to be displaced from the sequestration chamber 55 as it is filled with blood. In various exemplary embodiments, an air permeable blood barrier may be formed by one or more materials that allow air to pass through until contacted by a liquid, such material then becomes completely or partially sealed to prevent or inhibit the passage of air and/or liquid. In other words, prior to contact with liquid, the material forms a barrier that is air permeable. After contact with a

liquid, the material substantially or completely prevents the further passage of air and/or liquid.

[0061] The orifice or channel 45 can be any desired length, cross-sectional shape or size, and/or can be formed to depart from the low volume chamber 30 at any desired angle or orientation. The orifice or channel 45 may also include a one-way flap or valve 60 that maintains an initial aliquot of blood sample within the sequestration chamber 55. In some specific implementations, the orifice or channel 45 can include a "duck bill" or flapper valve 60, or the like, for one-way flow of blood from low volume chamber 30 to the sequestration chamber 55. The air permeable blood barrier 20 can also be constructed of a material that allows air to exit but then seals upon contact with blood, thereby not allowing external air to enter sequestration chamber 55. This sealing would eliminate the need for a valve.

[0062] Valve 60 can be any type of valve or closing mechanism. Chamber 30 is designed to hold virtually no residual blood, and can be designed to be adapted to hold or allow pass-through of a particular volume or rate of blood into sequestration chamber 55. Likewise, sequestration chamber 55 may also include any type of coating, such as an anti-microbial coating, or a coating that aids identification and/or diagnosis of components of the first, sequestered blood draw.

[0063] Housing 50 and 40 can be formed of any suitable material, including plastic, such as acrylonitrile butadiene styrene (ABS) or other thermoplastic or polymeric material, rubber, steel, or aluminum. The air permeable blood barrier 20 can include a color-providing substance, or other signaling mechanism, that is activated upon contact with blood from the initial blood draw, or when air displacement is stopped, or any combination of events with blood in the sequestration chamber 55. The air permeable barrier may also include an outer layer such as a hydrophobic membrane or cover that inhibits or prevents the inadvertent or premature sealing of the filter by an external fluid source, splash etc. Sequestration chamber 55 can also be translucent or clear to enable a user to visually confirm the chamber is filled.

[0064] FIG. 2 illustrates a blood sample optimization system in accordance with some alternative implementations. In the implementation shown in FIG. 2, a sequestration chamber 55, or waste chamber, surrounds the patient needle 1, with an

open-ended cuff or housing connected with the waste chamber and encircling the sample needle housing base and housing. The patient needle 1 and sample needle 5 are connected together by a boot 56, which forms a continuous blood draw channel therethrough. The boot 56 includes a single orifice or channel leading from the blood draw channel into sequestration chamber 55. The device can include more than one single orifice or channel, in other implementations. Each orifice or channel can include a one-way valve, and can be sized and adapted for predetermined amount of blood flow.

[0065] The sequestration chamber 55 includes an air permeable blood barrier. The filter can further include a sensor or indicator to sense and/or indicate, respectively, when a predetermined volume of blood has been collected in the sequestration chamber 55. That indication will alert a user to attach an evacuated blood collection tube or bottle, such as a Vacutainer™ to the sample needle 5. The housing for the sequestration chamber 55 can be any size or shape, and can include any type of material to define an interior space or volume therein. The interior space is initially filled only with air, but can also be coated with an agent or substance, such as a decontaminate, solidifying agent, or the like. Once evacuated blood collection tube is attached to the sample needle 5, blood will flow automatically into the patient needle 1, through the blood draw channel and sample needle 5, and into the bottle. The sample needle 5 is covered by a resealable boot, coating or membrane that seals the sample needle when a blood collection bottle is not attached thereon or thereto.

[0066] FIG. 3 illustrates a blood sample optimization system in accordance with some alternative implementations. In the implementation shown, a sample needle 5 is surrounded by a resealable boot or membrane, and is further connected with a patient needle 1. A blood flow channel is formed through the sample needle and the patient needle. The connection between the sample needle and patient needle includes a "T" or "Y" connector 102, which includes a channel, port or aperture leading out from the main blood flow channel to a sequestration chamber 104.

[0067] The T or Y connector 102 may include a flap or one-way valve, and have an opening that is sized and adapted for a predetermined rate of flow of blood. The sequestration chamber 104 can be formed from tubing, or be formed by a solid housing, and is initially filled with air. The sequestration chamber 104 will receive blood that flows out of a patient automatically, i.e. under pressure from the patient's own blood

pressure. The sequestration chamber 104 includes an air permeable blood barrier 106, preferably at the distal end of tubing that forms the sequestration chamber 104, and which is connected at the proximal end to the T or Y connector 102. The T or Y connector 102 can branch off at any desired angle for most efficient blood flow, and can be formed so as to minimize an interface between the aperture and channel and the main blood flow channel, so as to minimize or eliminate mixing of the initial aliquot of blood with main blood draw samples.

[0068] In some alternative implementations, the sample needle may be affixed to a tubing of any length, as shown in FIG. 4, connecting at its opposite end to the T or Y connector 102. The sequestration chamber 104 can be any shape or volume so long as it will contain a predetermined amount of blood sample in the initial aliquot. The T or Y connector 102 may also include an opening or channel that is parallel to the main blood flow channel. The air permeable blood barrier may further include an indicator 107 or other mechanism to indicate when a predetermined amount of blood has been collected in the sequestration chamber, or when air being expelled reaches a certain threshold, i.e. to zero. The tubing can also include a clip 109 that can be used to pinch off and prevent fluid flow therethrough.

[0069] Once the air permeable blood barrier and primary chamber are sealed the initial aliquot of blood is trapped in the sequestration chamber 104, an evacuated blood collection tube, such as a Vacutainer™ bottle may be attached to the sample needle 5 to obtain the sample. The blood collection tube can be removed, and the sample needle 5 will be resealed. Any number of follow-on blood collection tubes can then be attached for further blood draws or samples. Upon completion of all blood draws, the system can be discarded, with the initial aliquot of blood remaining trapped in the sequestration chamber 104.

[0070] FIG. 5 illustrates a blood sample optimization system in accordance with some alternative implementations. In the implementation shown, a sample needle 5 is connected with a patient needle by tubing. A "T" or "Y" connector 120 is added along the tubing at any desired location, and includes an aperture, port or channel leading to a sequestration chamber 204, substantially as described above.

[0071] FIG. 6 illustrates a blood sample optimization system in accordance with some alternative implementations, in which a sequestration chamber 304, formed as a primary collection channel, receives an initial aliquot of blood, and is provided adjacent to the blood sampling channel. The sequestration chamber 304 can encircle the blood sampling channel, the patient needle 1, and/or the sample needle 5. The primary collection channel can include a T or Y connector 120, or other type of aperture or channel. The sequestration chamber 304 includes an air permeable blood barrier, which can also include an indicator of being contacted by a fluid such as blood, as described above.

[0072] In some implementations, either the patient needle 1 or the sample needle 5, or both, can be replaced by a Luer lock male or female connector. However, in various implementations, the connector at a sample needle end of the blood sample optimization system is initially sealed to permit the diversion of the initial aliquot of blood to the sequestration chamber, which is pressured at ambient air pressure and includes the air outlet of the air permeable blood barrier. In this way, the system passively and automatically uses a patient's own blood pressure to overcome the ambient air pressure of the sequestration chamber to push out air through the air permeable blood barrier and displace air in the sequestration chamber with blood.

[0073] FIG. 7 is a flowchart of an exemplary method for optimizing the quality of a blood culture. At 702, a clinician places a needle into a patient's vein. At 704, blood then flows into a sequestration chamber, pushing the air in the sequestration chamber out of the sequestration chamber through an air permeable blood barrier. In some implementations, the volume of the sequestration chamber is less than 0.1 to more than 5 cubic centimeters (cc's), or more. The sequestration chamber is sized and adapted to collect a first portion of a blood sample, which is more prone to contamination than secondary and other subsequent portion of the blood sample or subsequent draws. Since the sequestration chamber has an air-permeable blood barrier through which air can be displaced by blood pushed from the patient's vein, such blood will naturally and automatically flow into the sequestration chamber before it is drawn into or otherwise enters into a Vacutainer or other bottle for receiving and storing a blood sample.

[0074] When the sequestration chamber fills, the blood will gather at or otherwise make contact with the air permeable blood barrier, which will inhibit or prevent blood

from passing therethrough. At 706, when the blood comes into contact with the entire internal surface area of the air permeable blood barrier, the air permeable blood barrier is then closed and air no longer flows out or in. At 708, the clinician may be provided an indictor or can see the full chamber, to indicate the evacuated blood collection tube, such as a Vacutainer™ can be attached. The indicator can include visibility into the primary chamber to see whether it is full, the blood barrier changing color, for example, or other indicator. The fill time of the sequestration chamber may be substantially instantaneous, so such indicator, if present, may be only that the sequestration chamber is filled.

[0075] Prior to an evacuated blood collection tube being attached, communication between the needle, sampling channel, and the sequestration chamber is restricted by the sealing of the sequestration chamber blood barrier thereby not permitting air to reenter the system through the sequestration. Sealing the communication path could also be accomplished with a mechanical twist or other movement, a small orifice or tortuous pathway, eliminating the need for a separate valve or mechanical movement or operation by the clinician. At 710, once the evacuated blood collection tube is removed, the self-sealing membrane closes the sample needle, and at 712, additional subsequent evacuated blood collection tubes may be attached. Once samples have been taken, at 714 the device is removed from the patient and discarded.

[0076] FIGS. 8A – 8E illustrate an exemplary blood sample optimization system 800 for non-contaminated blood sampling, in accordance with some implementations. The blood sample optimization system 800 includes an inlet port 802 that can be connected to tubing, a patient needle (or both), or other vascular or venous access device, and a pathway splitter 804 having a first outlet to a sequestration chamber tubing 806 and a second outlet to sample collection tubing 808. One or both of the sequestration chamber tubing 806 and the sample collection tubing 808 can be formed of tubing. In some implementations, the sequestration chamber tubing 806 is sized so as to contain a particular volume of initial blood sample. The sample collection tubing 808 will receive a blood sample once the sequestration chamber tubing 806 is filled. The sample collection tubing 808 can be connected to a Vacutainer™ base or housing 810, or other blood sample collection device.

[0077] The blood sequestration system 800 further includes a blood sequestration device 812 which, as shown in more detail in FIGS. 8B – 8D, includes a housing 818 that

includes a sampling channel 820 defining a pathway for the non-contaminated sample collection tubing 808 or connected at either end to the non-contaminated sample collection tubing 808. The sampling channel 820 can be curved through the housing 818 so as to better affix and stabilize the housing 818 at a location along the non-contaminated sample collection tubing 808.

[0078] The blood sequestration device 812 further includes a sequestration chamber 822 connected with the sequestration chamber tubing 806 or other chamber. The sequestration chamber 822 terminates at an air permeable blood barrier 824. The air permeable blood barrier 824 can also include a coloring agent that turns a different color upon full contact with blood, as an indicator that the regular collection of blood samples (i.e. the non-contaminated blood samples) can be initiated. Other indicators may be used, such as a small light, a sound generation mechanism, or the like. In some implementations, the air permeable blood barrier is positioned at a right angle from the direction of sequestration chamber 822, but can be positioned at any distance or orientation in order to conserve space and materials used for the housing 818. The housing 818 and its contents can be formed of any rigid or semi-rigid material or set of materials.

[0079] FIG. 9 illustrates a pathway splitter 900 for use in a blood sequestrations system, such as those shown in FIGS. 8A – 8E, for example. The pathway splitter 900 includes an inlet port 902, a main line outlet port 904, and a sequestration channel outlet port 906. The inlet port 902 can be connected to main tubing that is in turn connected to a patient needle system, or directly to a patient needle. The main line outlet port 904 can be connected to main line tubing to a blood sampling system, such as a vacutainer base or housing, or directly to such blood sampling system. The sequestration channel outlet port 906 can be connected to sequestration tubing for receiving and sequestering a first sample of blood, up to a measured amount or predetermined threshold. Alternatively, the sequestration channel outlet port 906 can be connected to a sequestration chamber. The sequestration channel outlet port 906 is preferably 20-70 degrees angled from the main line outlet port 904, which in turn is preferably in-line with the inlet port 902. Once the predetermined amount of initial blood sample is sequestered in the sequestration tubing or chamber, in accordance with mechanisms and techniques described herein, follow-on blood samples will flow into the inlet port 902 and directly out the main line outlet port 904, without impedance.

[0080] FIGS. 10A – 10D illustrate a blood sequestration device 1000 in accordance with alternative implementations. The blood sequestration device 1000 includes an inlet port 1002, a main outlet port 1004, and a sequestration channel port 1006. The inlet port 1002 can be connected to a patient needle or related tubing. The main outlet port 1004 can be connected to a blood sample collection device such as a Vacutainer, associated tubing, or a Luer activated valve, or the like. The sequestration channel port 1006 splits off from the main outlet port 1004 to a sequestration chamber 1008. In some implementations, the sequestration chamber 1008 is formed as a helical channel within a housing or other container 1001.

[0081] The sequestration chamber 1008 is connected at the distal end to an air permeable blood barrier 1010, substantially as described above. Air in the sequestration chamber 1008 is displaced through the air permeable blood barrier 1010 by an initial aliquot of blood that is guided into the sequestration channel port 1006. Once the sequestration chamber 1008 is filled, further blood draws through the main outlet port 1004 can be accomplished, where these samples will be non-contaminated.

[0082] FIGS. 11A – 11E illustrate a blood sequestration device 1100 in accordance with other alternative implementations. The blood sequestration device 1100 includes an inlet port 1102, similar to the inlet ports described above, a main outlet port 1104, and a sequestration channel port 1106 that splits off from the main outlet port 1104 and inlet port 1102. The sequestration channel port is connected to a sequestration chamber 1108. In the implementation shown in FIGS. 11A – 11E, the blood sequestration device includes a base member 1101 having a channel therein, which functions as the sequestration chamber 1108. The channel can be formed as a tortuous path through the base member 1101, which is in turn shaped and formed to rest on a limb of a patient.

[0083] A portion of the sequestration chamber 1108 can protrude from the base member or near a top surface of the base member, just before exiting to an air permeable blood barrier 1110, to serve as a blood sequestration indicator 1109. The indicator 1109 can be formed of a clear material, or a material that changes color when in contact with blood.

[0084] In some implementations, the blood sequestration device 1100 can include a blood sampling device 1120 such as a normally closed needle, Vacutainer™ shield or other collection device. The blood sampling device 1120 can be manufactured and sold with the blood sequestration device 1100 for efficiency and convenience, so that a first aliquot of blood that may be contaminated by a patient needle insertion process can be sequestered. Thereafter, the blood sampling device 1120 can draw non-contaminated blood samples to reduce the risk of false positive testing and ensure a non-contaminated sample.

[0085] FIGS. 12A-12D illustrate a blood sample optimization system 1200 in accordance with yet other alternative implementations. The system 1200 includes a blood sequestration device 1202 for attaching to a blood sampling device 1204, such as a Vacutainer™ or other collection and sampling device. The blood sequestration device 1202 is configured and arranged to receive, prior to a Vacutainer™ container or vial being attached to a collection needle of the blood sampling device 1204, a first aliquot or amount of blood, and sequester that first aliquot or amount in a sequestration channel of the blood sequestration device 1202.

[0086] In some implementations, the blood sequestration device 1202 can include an inlet port 1212, a main outlet port, and a sequestration channel port. The inlet port 1212 can be connected to a patient needle or related tubing. The main outlet port 1214 can be connected to a normally closed needle or device to enable connection with an evacuated blood collection container or other collection device such as a Vacutainer™, associated tubing, luer connectors, syringe, a Luer activated valve, or the like. The sequestration channel port splits off from the main outlet port to a sequestration chamber 1218.

[0087] In some implementations, the sequestration chamber 1218 is formed as a channel within the body of a sequestration device 1202. The sequestration chamber 1218 can be a winding channel, such as a U-shaped channel, an S-shaped channel, a helical channel, or any other winding channel. The sequestration device 1202 can include a housing or other containing body, and one or more channels formed therein. As shown in FIGS. 12A and 12B, the sequestration device 1202 includes a main body 1206 and a cap 1208. The main body 1206 is formed with one or more cavities or channels, which are further formed with one or more arms 1210 that extend from the cap 1208, and which

abut the cavities or channels in the main body 1206 to form the primary collection port and main outlet port.

[0088] FIGS. 13A-13D illustrate a blood sample optimization system 1300 in accordance with yet other alternative implementations. The system 1300 includes a blood sequestration device 1302 for attaching to a blood sampling device 1304, such as a Vacutainer or other bodily fluid collection and sampling device. The blood sequestration device 1302 is configured and arranged to receive, prior to a Vacutainer container or vial being attached to a collection needle of the blood sampling device 1304, a first aliquot or amount of blood, and to sequester that first aliquot or amount of blood or other bodily fluid in a sequestration channel of the blood sequestration device 1302.

[0089] The blood sequestration device 1302 includes a housing 1301 having an inlet port 1314, a main outlet port 1312, and a sequestration channel port 1316. The inlet port 1314 can be connected to a patient needle or associated tubing. The main outlet port 1312 can be connected to a normally closed needle or device to enable connection with an evacuated blood collection container or other collection device such as a Vacutainer™, associated tubing, luer connectors, syringe, a Luer activated valve, or the like. The sequestration channel port 1316 splits off from the main inlet port 1314 to a sequestration chamber 1318.

[0090] In the implementation shown in FIGS. 13A-D, the sequestration chamber 1318 is formed as a cavity or chamber within housing 1301 or formed by walls that define housing 1301. The sequestration chamber 1318 can be a winding channel, such as a U-shaped channel, an S-shaped channel, a helical channel, or any other winding channel, that is defined by the cooperation and connection of housing 1301 with cap 1307 which cap 1307 can include a protrusion 1305 that provides one or more walls or directors for the winding channel in the sequestration chamber 1318. The protrusion 1305 from the cap 1307 can be straight or curved, and may have various channels, apertures or grooves embedded therein, and can extend from the cap 1307 any angle or orientation. When the cap 1307 is connected with the housing 1301 to complete the formation of the sequestration chamber 1318, the protrusion 1305 forms at least part of the winding channel to sequester a first aliquot or amount of blood or other bodily fluid in a sequestration channel formed in the sequestration chamber 1318 and by the winding channel.

[0091] The sequestration chamber 1318 includes an air permeable blood barrier 1310, substantially as described above. Air in the sequestration chamber 1318 is displaced through the air permeable blood barrier 1310 by an initial aliquot of blood that is provided into the sequestration chamber 1318 by the blood pressure of the patient. Once the sequestration chamber 1318 is filled and the air in the sequestration chamber 1318 displaced, the blood pressure of the patient will be insufficient to drive or provide further blood into the blood sequestration device 1302, and in particular the outlet port 1312, until a force such as a vacuum or other pressure, such as provided by the blood sample collection device like Vacutainer is provided to draw out a next aliquot or amount of blood or bodily fluid. Further blood draws through the main outlet port 1312 can be accomplished, where these samples will be non-contaminated since any contaminants would be sequestered in the sequestration chamber 1318 with the first aliquot of blood.

[0092] FIGS. 14A-14E illustrate yet another implementation of a blood sampling system 1400 to sequester contaminates of an initial aliquot or sample to reduce false positives in blood cultures or tests performed on a patient's blood sample. The blood sampling system 1400 includes a blood sequestration device 1401 that can be connected between a blood sample collection device 1403 and a patient needle (not shown). The blood sample collection device 1403 can be a Vacutainer or the like. The blood sequestration device 1401 includes an inlet port 1402 that can be connected with a patient needle that is inserted into a patient's vascular system for access to and withdrawing of a blood sample. The inlet port 1402 may also be connected with tubing or other conduit that is in turn connected with the patient needle.

[0093] The inlet port 1402 defines an opening into the blood sequestration device 1401, which opening can be the same cross sectional dimensions as tubing or other conduit connected with the patient needle or the patient needle itself. For instance, the opening can be circular with a diameter of approximately 0.045 inches, but can have a diameter of between 0.01 inches or less to 0.2 inches or more. The blood sequestration device 1401 further includes an outlet port 1404, which defines an opening out of the blood sequestration device 1401 and to the blood sample collection device 1403. The outlet port 1404 may also be connected with tubing or other conduit that is in turn connected with the blood sequestration device 1403. The outlet port 1404 can further include a connector device such as a threaded cap, a Luer connector (male or female), a

non threaded interference or glue joint fitting for attachment of various devices including but not limited to tubing, or the like.

[0094] The blood sequestration device 1401 further includes a sampling channel 1406 between the inlet port 1402 and the outlet port 1404, and which functions as a blood sample pathway once a first aliquot of blood has been sequestered. The sampling channel 1406 can be any sized, shaped or configured channel, or conduit. In some implementations, the sampling channel 1406 has a substantially similar cross sectional area as the opening of the inlet port 1402. In other implementations, the sampling channel 1406 can gradually widen from the inlet port 1402 to the outlet port 1404.

[0095] The blood sequestration device 1401 further includes a sequestration chamber 1408 that is connected to and split off or diverted from the sampling channel 1406 at any point between the inlet port 1402 and the outlet port 1404, but preferably from a proximal end of the sampling channel 1406 near the inlet port 1402. The sequestration chamber 1408 is at first maintained at atmospheric pressure, and includes an air outlet 1412 at or near a distal end of the sequestration chamber 1408 opposite the diversion point from the sampling channel 1406. The air outlet 1412 includes an air permeable blood barrier 1412. As shown in FIG. 14B, the air permeable blood barrier 1412 can be overlaid with a protective cover 1416. The protective cover 1416 can be sized and configured to inhibit a user from touching the air permeable blood barrier 1412 with their finger or other external implement, while still allowing air to exit the air permeable blood barrier 1412 as the air is displaced from the sequestration chamber 1408 by blood being forced into the sequestration chamber 1408 by a patient's own blood pressure. In addition the protective cover 1416 can be constructed to inhibit or prevent accidental exposure of the air permeable blood barrier to environmental fluids or splashes. This can be accomplished in a variety of mechanical ways including but not limited to the addition of a hydrophobic membrane to the protective cover.

[0096] As shown in FIGS. 14C and 14D, the sampling channel 1406 can be cylindrical or frusto-conical in shape, going from a smaller diameter to a larger diameter, to minimize a potential to lyse red blood cells. Likewise, the sampling channel 1406 is formed with a minimal amount of or no sharp turns or edges, which can also lyse red blood cells. The sampling channel 1406 splits off to the sequestration chamber 1408 near the inlet port 1402 via a diversion pathway 1409. The diversion pathway 1409 can have

any cross-sectional shape or size, but is preferably similar to the cross-sectional shape of at least part of the inlet port 1402.

[0097] In some implementations, the sampling channel 1406 and the sequestration chamber 1408 are formed by grooves, channels, locks or other pathways formed in housing 1414. The housing 1414 can be made of plastic, metal or other rigid or semi-rigid material. The housing 1414 can have a bottom member that sealably mates with a top member. One or both of the bottom member and the top member can include the sampling channel 1406 and the sequestration chamber 1408, as well as the diversion pathway 1409, the inlet port 1402, and the outlet port 1404. In some other implementations, one or more of the diversion pathway 1409, the inlet port 1402, and/or the outlet port 1404 can be at least partially formed by a cap member that is connected to either end of the housing 1414. In some implementations, the top member and the bottom member, as well as the cap member(s), can be coupled together by laser welding, heat sealing, gluing, snapping, screwing, bolting, or the like. In other implementations, some or all of the interior surface of the diversion pathway 1409 and/or sequestration chamber 1408 can be coated or loaded with an agent or substance, such as a decontaminate, solidifying agent, or the like. For instance, a solidifying agent can be provided at the diversion pathway 1409 such that when the sequestration chamber 1408 is filled and the initial aliquot of blood backs up to the diversion pathway 1409, that last amount of sequestered blood could solidify, creating a barrier between the sequestration chamber 1408 and the sampling channel 1406.

[0098] FIGS. 15A-15G illustrate a blood sequestration device 1500. The blood sequestration device 1500 can be connected to a normally closed needle or device to enable connection with an evacuated blood collection container or other collection device such as a Vacutainer™, associated tubing, luer connectors, syringe, a Luer activated valve, or the like.

[0099] The blood sequestration device 1500 includes an inlet port 1502 that can be connected with a patient needle that is inserted into a patient's vascular system for access to and withdrawing of a blood sample. The inlet port 1502 may also be connected with tubing or other conduit that is in turn connected with the patient needle. The inlet port 1502 defines an opening into the blood sequestration device 1500, which opening may be the same cross sectional dimensions as tubing or other conduit connected with the

patient needle or the patient needle itself. For instance, the opening can be circular with a diameter of approximately 0.045 inches, but can have a diameter of between 0.01 inches or less to 0.2 inches or more.

[00100] The inlet port 1502 can also include a sealing or fluid-tight connector or connection, such as threading or Luer fitting, or the like. In some implementations, tubing or other conduit associated with the patient needle can be integral with the inlet port 1502, such as by co-molding, gluing, laser weld, or thermally bonding the parts together. In this manner, the blood sequestration device 1500 can be fabricated and sold with the patient needle as a single unit, eliminating the need for connecting the patient needle to the blood sequestration device 1500 at the time of blood draw or sampling.

[00101] The blood sequestration device 1500 further includes an outlet port 1504, which defines an opening out of the blood sequestration device 1500 and to the blood sample collection device. The outlet port 1504 may also be connected with tubing or other conduit that is in turn connected with the blood sequestration device, and may also include a sealing or fluid-tight connector or connection, such as threading or Luer fitting, or the like. Accordingly, as discussed above, the blood sequestration device 1500 can be fabricated and sold with the patient needle and/or tubing and the blood sample collection device as a single unit, eliminating the need for connecting the patient needle and the blood sample collection device to the blood sequestration device 1500 at the time of blood draw or sampling.

[00102] The blood sequestration device 1500 further includes a sampling channel 1506 between the inlet port 1502 and the outlet port 1504, and which functions as a blood sample pathway once a first aliquot of blood has been sequestered. The sampling channel 1506 can be any sized, shaped or configured channel or conduit. In some implementations, the sampling channel 1506 has a substantially similar cross sectional area as the opening of the inlet port 1502. In other implementations, the sampling channel 1506 can gradually widen from the inlet port 1502 to the outlet port 1504.

[00103] The blood sequestration device 1500 further includes a sequestration chamber 1508 that is connected to and split off or diverted from the sampling channel 1506 at any point between the inlet port 1502 and the outlet port 1504, but preferably from a proximal end of the sampling channel 1506 near the inlet port 1502. In some

implementations, the diversion includes a Y-shaped junction. The sequestration chamber 1508 is preferably maintained at atmospheric pressure, and includes a vent 1510 at or near a distal end of the sequestration chamber 1508. The vent 1510 includes an air permeable blood barrier 1512. FIG. 15C illustrates the blood sequestration device 1500 with the sequestration chamber 1508 filled with a first aliquot or sample of blood from the patient.

[00104] The air permeable blood barrier 1512 can be covered with a protective cover 1516. The protective cover 1516 can be sized and configured to inhibit a user from touching the air permeable blood barrier 1512 with their finger or other external implement, while still allowing air to exit the air permeable blood barrier 1512 as the air is displaced from the sequestration chamber 1508 by blood being forced into the sequestration chamber 1508 by a patient's own blood pressure. The protective cover 1516 can be constructed to inhibit or prevent accidental exposure of the filter to environmental fluids or splashes. This can be accomplished in a variety of mechanical ways including but not limited to the addition of a hydrophobic membrane to the protective cover.

[00105] FIG. 15B is a perspective view of the blood sequestration device 1500 from the outlet port 1504 and top side of a housing 1501 of the blood sequestration device 1500 that includes the vent 1510, and illustrating an initial aliquot of blood filling sequestration chamber 1508 while the sampling channel 1506 is empty, before a sample collection device is activated. FIG. 15G is a perspective view of the blood sequestration device 1500 from the outlet port 1504 and bottom side of the housing 1501 of the blood sequestration device 1500, and illustrating the initial aliquot of blood filling sequestration chamber 1508 while the sampling channel 1506 is empty, before the sample collection device is activated. FIG. 15C is another perspective view of the blood sequestration device 1500 from the inlet port 1502 and top side of a housing 1501 of the blood sequestration device 1500 that includes the vent 1510, and illustrating blood now being drawn through sampling channel 1506 while the sequestered blood remains substantially in the sequestration chamber 1508.

[00106] FIG. 15D is a cross section of the blood sequestration device 1500 in accordance with some implementations, showing the housing 1501 that defines the sampling channel 1506 and the sequestration chamber 1508. FIGS. 15E and 15F

illustrate various form factors of a housing for a blood sequestration device, in accordance with one or more implementations described herein.

[00107] The sequestration chamber 1508 can have a larger cross-sectional area than the sampling channel 1506, and the cross-sectional area and length can be configured for a predetermined or specific volume of blood to be sequestered or locked. The sampling channel 1506 can be sized to be compatible with tubing for either or both of the patient needle tubing or the blood collection device tubing.

[00108] The housing 1501 can be formed of multiple parts or a single, unitary part. In some implementations, and as illustrated in FIG. 15D, the housing 1501 includes a top member 1520 and a bottom member 1522 that are mated together, one or both of which having grooves, channels, locks, conduits or other pathways pre-formed therein, such as by an injection molding process or by etching, cutting, drilling, etc. The top member 1520 can be connected with the bottom member 1522 by any mating or connection mechanism, such as by laser welding, thermal bonding, ultrasonic welding, gluing, using screws, rivets, bolts, or the like, or by other mating mechanisms such as latches, grooves, tongues, pins, flanges, or the like.

[00109] In some implementations, such as shown in FIG. 15D, the top member 1520 can include the grooves, channels, locks, conduits or other pathways, while the bottom member 1522 can include a protrusion 1524 that is sized and adapted to fit into at least one of the grooves, channels, locks or other pathways of the top member 1520. The protrusion 1524 can provide a surface feature, such as a partial groove or channel, for instance, to complete the formation of either the sampling channel 1506 and/or the sequestration chamber 1508. In some implementations, the protrusion 1524 can be formed with one or more angled sides or surfaces for a tighter fit within the corresponding groove, channel, lock or other pathway. In yet other implementations, both the top member 1520 and the bottom member can include grooves, channels, locks or other pathways, as well as one or more protrusions 1524.

[00110] In some implementations, the sampling channel 1506 and the sequestration chamber 1508 are formed by grooves, channels, locks or other pathways formed in housing 1501. The housing 1501 can be made of any suitable material, including rubber, plastic, metal or other material. The housing 1501 can be formed of a clear or translucent

material, or of an opaque or non-translucent material. In other implementations, the housing 1501 can be mostly opaque or non-translucent, while the housing surface directly adjacent to the sampling channel 1506 and/or the sequestration chamber 1508 is clear or translucent, giving a practitioner a visual cue or sign that the sequestration chamber 1508 is first filled to the extent necessary or desired, and/or then a visual cue or sign that the sequestered blood remains sequestered while a clean sample of blood is drawn through the sampling channel 1506. Other visual cues or signs of the sequestration can include, without limitation: the air permeable blood barrier 1512 turning a different color upon contact, saturation, or partial saturation with blood; a color-coded tab or indicator at any point along or adjacent to the sequestration chamber; an audible signal; a vibratory signal; or other signal.

[00111] After a venipuncture by a patient needle of a patient (not shown), which could gather a number of pathogens from the patient's skin, a first amount of the patient's blood with those pathogens will make its way into the inlet port 1502 blood sequestration device 1500 and flow into the sequestration chamber 1508 by following the path of least resistance, as the patient's own blood pressure overcomes the atmospheric pressure in the sequestration chamber 1508 to displace air therein through the air permeable blood barrier 1512. The patient's blood pressure will not be sufficient to overcome the air pressure that builds up in the sealed sampling channel 1506. Eventually, the sequestration chamber 1508, which has a predetermined volume, is filled with blood that displaces air through the air permeable blood barrier 1512. Once the blood hits the air permeable blood barrier, the blood interacts with the air permeable blood barrier 1512 material to completely or partially seal the vent 1510. A signal or indication may be provided that the practitioner can now utilize the Vacutainer capsule or other blood sample collection device to acquire a next amount of the patient's blood for sampling. The blood in the sequestration chamber 1508 is now effectively sequestered in the sequestration chamber.

[00112] Upon filling the blood sequestration pathway 1508 but prior to use of the Vacutainer or other blood sample collection device, the patient's blood pressure may drive compression of the air in the sampling channel 1506, possibly resulting in a small amount of blood moving past the diversion point to the sequestration chamber 1508 and into the sampling channel 1506, queuing up the uncontaminated blood to be drawn through the sampling channel 1506.

[00113] In some instances, as shown in FIG. 15H, an inlet port 1532 can include a male luer connector for connecting to a removable patient needle, and an outlet port 11534 can include a female luer connector for connecting with a syringe. This implementation of the inlet port and outlet port can be used with any device described herein, for avoiding a propensity of a Vacutainer-type device collapsing a patient's vein. In this implementation, a clinician can use the syringe in a modulated fashion to obtain a blood sample. In operation, the syringe is attached to the outlet port 1004, and the needle is attached to the inlet port 1002. A venipuncture is performed with the needle, and without the clinician pulling on the syringe. An initial aliquot of blood fills a sequestration chamber, and then the syringe can be used to draw a sample of blood through the collection channel, bypassing the sequestered blood in the sequestration chamber.

[00114] FIGS. 16-19 illustrate yet another implementation of a blood sequestration device. FIGS. 16A-16D illustrate a blood sequestration device 1600 that can be connected between a blood sample collection device, such as an evacuated blood collection container like a Vacutainer™ (not shown), and a patient needle (not shown) and/or associated tubing. FIG. 17 illustrates a bottom member of the blood sequestration device, and FIG. 18 illustrates a top member of the blood sequestration device, which top member and bottom member can be mated together to form an inlet port, and outlet port, a sequestration chamber and a sampling channel, as explained more fully below. FIGS. 19A and B show the top member and bottom member mated together. It should be understood that FIGS. 16-19 illustrate one exemplary manner of constructing a blood sequestration device as described herein, and other forms of construction are possible.

[00115] Referring to FIGS. 16A – D, the blood sequestration device 1600 includes an inlet port 1602 that can be connected with a patient needle that is inserted into a patient's vascular system for access to and withdrawing of a blood sample. The inlet port 1602 may also be connected with tubing or other conduit that is in turn connected with the patient needle. The inlet port 1602 defines an opening into the blood sequestration device 1600, which opening can be the same cross sectional dimensions as tubing or other conduit connected with the patient needle or the patient needle itself. For instance, the opening can be circular with a diameter of approximately 0.045 inches, but can have a diameter of between 0.01 inches or less to 0.2 inches or more.

[00116] The inlet port 1602 can also include a sealing or fluid-tight connector or connection, such as threading or Luer fitting, or the like. In some implementations, tubing or other conduit associated with the patient needle can be integral with the inlet port 1602, such as by co-molding, gluing, laser weld, or thermally bonding the parts together. In this manner, the blood sequestration device 1600 can be fabricated and sold with the patient needle and/or tubing as a single unit, eliminating the need for connecting the patient needle to the blood sequestration device 1600 at the time of blood draw or sampling.

[00117] The blood sequestration device 1600 further includes an outlet port 1604, which defines an opening out of the blood sequestration device 1600 and to the blood sample collection device. The outlet port 1604 may also be connected with tubing or other conduit that is in turn connected with the blood sequestration device, and may also include a sealing or fluid-tight connector or connection, such as threading or Luer fitting, or the like. Accordingly, as discussed above, the blood sequestration device 1600 can be fabricated and sold with the patient needle and/or tubing and the blood sample collection device as a single unit, eliminating the need for connecting the patient needle and the blood sample collection device to the blood sequestration device 1600 at the time of blood draw or sampling.

[00118] The blood sequestration device 1600 further includes a sampling channel 1606 between the inlet port 1602 and the outlet port 1604, and a sequestration chamber 1608 that is connected to and split off or diverted from the sampling channel 1606 at any point between the inlet port 1602 and the outlet port 1604. The sampling channel 1606 functions as a blood sampling pathway once a first aliquot of blood has been sequestered in the sequestration chamber 1608. The sampling channel 1606 can be any sized, shaped or configured channel, or conduit. In some implementations, the sampling channel 1606 has a substantially similar cross sectional area as the opening of the inlet port 1602. In other implementations, the sampling channel 1606 can gradually widen from the inlet port 1602 to the outlet port 1604. The sequestration chamber 1608 may have a larger cross section to form a big reservoir toward the sequestration channel path so that the blood will want to enter the reservoir first versus entering a smaller diameter on the sampling channel 1606, as is shown more fully in FIGS. 17 and 19.

[00119] In some exemplary implementations, the diversion between the sampling channel 1606 and the sequestration chamber 1608 is by diverter junction 1607. Diverter junction 1607 may be a substantially Y-shaped, T-shaped, or U-shaped. In some preferred exemplary implementations, and as shown in FIG. 17A – 17B, the diverter junction 1607 is configured such that the flow out of the inlet port 1602 is preferentially directed toward the sequestration chamber 1608. The sequestration chamber 1608 may also include or form a curve or ramp to direct the initial blood flow toward and into the sequestration chamber 1608.

[00120] The sequestration chamber 1608 is preferably maintained at atmospheric pressure, and includes a vent 1610 at or near a distal end of the sequestration chamber 1608. The vent 1610 may include an air permeable blood barrier 1612 as described above.

[00121] The blood sequestration device 1600 can include a housing 1601 that can be formed of multiple parts or a single, unitary part. In some implementations, and as illustrated in FIGS. 17A – 17E and FIGS. 18A – 18F, the housing 1601 includes a top member 1620 and a bottom member 1622 that are mated together. The blood sequestration device 1600 can also include a gasket or other sealing member (not shown) so that when the top member 1620 is mechanically attached with the bottom member 1622, the interface between the two is sealed by the gasket or sealing member. The FIGS. 17A – 17E illustrate a bottom member 1622 of a housing for a blood sequestration device 1600. The bottom member 1622 can include grooves, channels, locks, conduits or other pathways pre-formed therein, such as by an injection molding process or by etching, cutting, drilling, etc., to form the sampling channel 1606, the sequestration chamber 1608, and diverter junction 1607.

[00122] The sequestration chamber 1608 may have a larger cross section than the sampling channel 1606 so that the blood will preferentially move into the sequestration chamber first versus entering a smaller diameter on the sampling channel 1606.

[00123] FIGS. 18A – 18F illustrate the top member 1620, which can be connected with the bottom member 1622 by any mating or connection mechanism, such as by laser welding, thermal bonding, gluing, using screws, rivets, bolts, or the like, or by other mating mechanisms such as latches, grooves, tongues, pins, flanges, or the like. The top

member 1620 can include some or all of the grooves, channels, locks, conduits or other pathways to form the sampling channel 1606, the sequestration chamber 1608, and the diverter junction 1607. In yet other implementations, both the top member 1620 and the bottom member 1622 can include the grooves, channels, locks or other pathways.

[00124] In some implementations, the sampling channel 1606 and the sequestration chamber 1608 are formed by grooves, channels, locks or other pathways formed in housing 1601. The housing 1601 can be made of rubber, plastic, metal or any other suitable material. The housing 1601 can be formed of a clear or translucent material, or of an opaque or non-translucent material. In other implementations, the housing 1601 can be mostly opaque or non-translucent, while the housing surface directly adjacent to the sampling channel 1606 and/or the sequestration chamber 1608 may be clear or translucent, giving a practitioner a visual cue or sign that the sequestration chamber 1608 is first filled to the extent necessary or desired, and/or then a visual cue or sign that the sequestered blood remains sequestered while a clean sample of blood is drawn through the sampling channel 1606. Other visual cues or signs of the sequestration can include, without limitation: the air permeable blood barrier 1612 turning a different color upon contact, saturation, or partial saturation with blood; a color-coded tab or indicator at any point along or adjacent to the sequestration chamber; an audible signal; a vibratory signal; or other signal.

[00125] As shown in FIGS. 18A – 18F, the air permeable blood barrier 1612 can be covered with, or surrounded by, a protective member 1616. The protective member 1616 can be sized and configured to inhibit a user from touching the air permeable blood barrier 1612 with their finger or other external implement, while still allowing air to exit the air permeable blood barrier 1612 as the air is displaced from the sequestration chamber 1608. In some implementations, the protective member 1616 includes a protrusion that extends up from a top surface of the top member 1620 and around the air permeable blood barrier 1612. The protective member 1616 can be constructed to inhibit or prevent accidental exposure of the filter to environmental fluids or splashes. This can be accomplished in a variety of mechanical ways including but not limited to the addition of a hydrophobic membrane to the protective cover.

[00126] In use, the blood sequestration device 1600 includes a sampling channel 1606 and a sequestration chamber 1608. Both pathways are initially air-filled at

atmospheric pressure, but the sampling channel 1606 is directed to an outlet port 1604 that will be initially sealed by a Vacutainer or other such sealed blood sampling device, and the sequestration chamber 1608 terminates at a vent 1610 to atmosphere that includes an air permeable blood barrier 1612.

[00127] After a venipuncture by a patient needle of a patient (not shown), which could gather a number of pathogens from the patient's skin, a first amount of the patient's blood with those pathogens will pass through inlet port 1602 of blood sequestration device 1600. This initial volume of potentially contaminated blood will preferentially flow into the sequestration chamber 1608 by finding the path of least resistance. The patient's own blood pressure overcomes the atmospheric pressure in the vented sequestration chamber 1608 to displace air therein through the air permeable blood barrier 1612, but is not sufficient to overcome the air pressure that builds up in the sealed sampling channel 1606. In various exemplary embodiments, the sequestration chamber 1608 and sampling channel 1606 can be configured such that the force generated by the patient's blood pressure is sufficient to overcome any effect of gravity, regardless of the blood sequestration device's orientation.

[00128] Eventually, the sequestration chamber 1608 fills with blood that displaces air through the air permeable blood barrier 1612. Once the blood contacts the air permeable blood barrier, the blood interacts with the air permeable blood barrier 1612 material to completely or partially seal the vent 1610. A signal or indication may be provided that the practitioner can now utilize the Vacutainer or other blood sampling device.

[00129] Upon filling the blood sequestration pathway 1608 but prior to use of the Vacutainer or other blood sample collection device, the patient's blood pressure may drive compression of the air in the sampling channel 1606, possibly resulting in a small amount of blood moving past the diversion point into the sampling channel 1606, queuing up the uncontaminated blood to be drawn through the sampling channel 1606.

[00130] FIG. 19A is a side view, and FIG. 19B is a cross-sectional view, of the blood sequestration device 1600, illustrating the top member 1620 mated with the bottom member 1622.

[00131] FIG. 20 shows a blood sample optimization system 2000 that includes a patient needle 2002 for vascular access to a patient's bloodstream, a blood sample collection device 2004 to facilitate the collecting of one or more blood samples, and a conduit 2006 providing a fluid connection between the patient needle 2002 and the blood sample collection device 2004. In some implementations, the blood sample collection device 2004 includes a protective shield that includes a sealed collection needle on which a sealed vacuum-loaded container is placed, which, once pierced by the collection needle, draws in a blood sample under vacuum pressure or force through the conduit 2006 from the patient needle 2002.

[00132] The blood sample optimization system 2000 further includes a blood sequestration device 2008, located at any point on the conduit 2006 between the patient needle 2002 and the blood sample collection device 2004 as described herein.

[00133] FIG. 21 illustrates a non-vented blood sequestration device 2100 using a wicking material chamber. The blood sequestration device 2100 includes a housing 2101 that has a sampling channel 2104 that is at least partially surrounded or abutted by a sequestration chamber 2102 that is filled with a wicking material. An initial aliquot of blood is drawn in from the patient needle into the sampling channel 2104 where it is immediately wicked into the wicking material of the sequestration chamber 2102. The wicking material and/or sequestration chamber 2102 is sized and adapted to receive and hold a predetermined amount of blood, such that follow-on or later blood draws pass by the wicking material and flow straight through the sampling channel 2104 to a sampling device such as a Vacutainer. The wicking material can include a substance such as a solidifier, a decontaminate, or other additive.

[00134] As described herein, an air permeable blood barrier may be created using a wide variety of different structures and materials. As shown in FIGS. 22A and B, an air permeable blood barrier 2202 of a blood sequestration device 2200 can include a polymer bead matrix 2204, in which at least some beads are treated to make them hydrophilic. The air permeable blood barrier 2202 further includes a self-sealing material 2206, such as carboxymethyl cellulose (CMC) or cellulose gum, or other sealing material. The air permeable blood barrier 2202 can further include voids 2208 that permit air flow before contact or during partial contact with a fluid such as blood. As shown in FIG. 22B,

contact with a fluid causes the self-sealing material 2206 to swell and close off the voids 2208, occluding air flow through the voids 2208 and creating a complete or partial seal.

[00135] FIGS. 23A and B illustrate yet another implementation of a blood sequestration device 2300, having an inlet port 2302 to connect with a patient needle, an outlet port 2304 to connect with a blood sample collection device, a sequestration chamber 2306, and a sampling channel 2308 that bypasses the sequestration chamber 2306 once the sequestration chamber is filled to an initial aliquot of potentially contaminated blood to be sequestered. The sequestration chamber 2306 includes a hydrophobic plug 2312 at a distal end of the sequestration chamber 2306 that is farthest from the inlet port 2302. A vacuum or other drawing force applied from the outlet port 2304, such as from a Vacutainer or the like, draws in blood into the inlet port 2302 and directly into the sequestration chamber 2306, where the initial aliquot of blood will contact the hydrophobic plug 2312 and cause the initial aliquot of blood to back up into the sequestration chamber 2306 and be sequestered there. A small amount of blood may make its way into the sampling channel 2308, which is initially closed off by valve 2308. Upon release of the valve 2308, and under further force of the vacuum or other force, follow-on amounts of blood will flow into inlet port 2302, bypass the sequestration chamber 2306, and flow into and through sampling channel 2308 toward the outlet port 2304 and to the collection device.

[00136] The sampling channel 2308 can have any suitable geometry and can be formed of plastic tubing or any other suitable material. Valve 2308 can be a clip or other enclosing device to pinch, shunt, bend or otherwise close off the sampling channel 2308 before the initial aliquot of blood is sequestered in the sequestration chamber 2306. For instance, valve 2308 can also be formed as a flap, door or closable window or barrier within the sampling channel 2308.

[00137] FIGS. 23C – 23E illustrate an alternative implementation of the blood sequestration device 2300', in which a sequestration chamber 2320 branches off from a main collection channel 2322 between an inlet port 2316 to connect with a patient needle and an outlet port 2318 to connect with a blood sample collection device, such as a Vacutainer, a syringe, or the like. The sequestration chamber 2320 includes an air-permeable, blood impermeable blood barrier 2324, such as a hydrophobic plug of material, or a filter formed of one or more layers, for example. A valve 2324 closes off

and opens the collection channel 2322, and the device 2300' can be used similarly as described above.

[00138] FIG. 24A – 24D illustrate a blood sample optimization system 2400 that includes a patient needle 2402 for vascular access to a patient's bloodstream, a blood sample collection device 2404 to facilitate the collecting of one or more blood samples for blood testing or blood cultures, and a conduit 2406 providing a fluid connection between the patient needle 2402 and the blood sample collection device 2404. In some implementations, the blood sample collection device 2404 includes a protective shield that includes a sealed collection needle on which a sealed vacuum-loaded container is placed, which, once pierced by the collection needle, draws in a blood sample under vacuum pressure or force through the conduit 2006 from the patient needle 2402.

[00139] The blood sample optimization system 2400 further includes a blood sequestration device 2408, located at any point on the conduit 2406 between the patient needle 2402 and the blood sample collection device 2404. The location of the blood sequestration device 2408 can be based on a length of the conduit between the blood sequestration device 2408 and the patient needle 2402, and the associated volume that length provides.

[00140] The blood sequestration device 2408 includes an inlet port 2412 for being connected to the conduit 2406 toward the patient needle 2402, and an outlet port 2414 for being connected to the conduit 2406 toward the blood sample collection device 2404, and a housing 2416. The housing 2416 can be any shape, although it is shown in FIGS. 24A – D as being substantially cylindrical, and includes the inlet port 2412 and outlet port 2414, which can be located anywhere on the housing although shown as being located on opposite ends of the housing 2416.

[00141] The blood sequestration device 2408 further includes a blood sequestration chamber 2418 connected with the inlet port 2412. The blood sequestration chamber 2418 is defined by an inner chamber housing 2419 that is movable from a first position to receive and sequester a first aliquot of blood, to a second position to expose one or more apertures 2424 at a proximal end of the inner chamber housing 2419 to allow blood to bypass and/or flow around the inner chamber housing 2419 and through a blood sample channel 2422 defined by the outer surface of the inner chamber housing 2419 and the

inner surface of the housing 2416. The blood sequestration chamber 2418 includes an air permeable blood barrier 2420 at a distal end of the blood sequestration chamber 2418.

[00142] In operation, the inner chamber housing 2419 is in the first position toward the inlet port 2412, such that the one or more apertures 2424 are closed, and the blood sequestration chamber 2418 is in a direct path from the patient needle. Upon venipuncture of a patient, and drawing of blood by way of a syringe or Vacutainer, or other blood collection device 2404, the initial aliquot of blood flows into the blood sequestration chamber 2418. As the initial aliquot of blood flows into the blood sequestration chamber, it displaces air therein and eventually the blood contacts the blood barrier 2420, forcing the inner chamber housing to the second position. The inner chamber housing 2419 and/or housing 2416 can include a locking mechanism of one or more small tabs, grooves, detents, bumps, ridges, or the like, to maintain the inner chamber housing 2419 in the first position until the blood sequestration chamber 2418 is filled, providing force to overcome the locking mechanism to enable movement of the inner chamber housing 2419 to the second position. Once in the second position, the initial aliquot of blood is sequestered in the blood sequestration chamber 2418 and the one or more apertures 2424 are opened to create a pathway from the inlet port 2412 to the blood sampling channel 2422, bypassing and/or flowing around the blood sequestration chamber 2418.

[00143] As described above, the housing 2416 and/or inner chamber housing 2419 can be formed as cylindrical and concentric, but can be any shape, such as squared, rectangular, elliptical, oval, or other cross-sectional shape. The outer surface of the distal end of the inner chamber housing 2419 can have one or more outwardly projecting tangs 2421with gaps therebetween. The tangs 2421 contact the inner surface of the housing 2416 to help define the blood sampling channel 2422 therebetween, and to help stop the inner chamber housing 2419 in the second position. The gaps between the tangs 2421 enable blood to flow through the blood sampling channel 2422 and to the outlet port 2414. When the inner chamber housing 2419 is in the second position and the blood sequestration chamber 2418 is filled with the first aliquot of blood, further blood samples will automatically flow through the inlet port 2412, through the one or more apertures 2424, through the blood sampling channel 2422, through the gaps between the tangs 2421, and ultimately through the outlet port 2414 to be collected by a blood sampling device 2404.

[00144] FIGS. 25A – D show a blood optimization system 2500 and blood sequestration device 2502, formed substantially as described in FIGS. 15, 16, 17, 18 and 19, but being formed to inhibit a user or other object from touching or blocking an air venting mechanism from a blood sequestration chamber 2520. Air initially in the blood sequestration chamber 2520 is displaced by an initial aliquot of blood upon venipuncture, where a patient's blood pressure overcomes the ambient air pressure in the blood sequestration chamber 2520. The air venting mechanism includes an air permeable blood barrier 2506, such as a porous material or set of materials that allows air to escape but blocks blood from leaving the blood sequestration chamber 2520.

[00145] The air venting mechanism includes an inner wall 2516 that at least partially circumscribes or surrounds the air permeable blood barrier 2506, and an outer wall 2504 spaced apart from the inner wall 2516. The outer wall 2504 can have one or more air vents 2514 formed therein. The outer wall 2504 extends higher upward than the inner wall 2516, such that a lid 2510, such as a cap, plug, cover, etc., can be attached to the outer wall 2504 and be displaced by a small distance from the top of the inner wall 2516. A seal 2508 in the form of a silicone wafer, or other elastomeric material, fits within the outer wall 2504 to cover the air permeable blood barrier 2506 and abut the top of the inner wall 2516. The seal 2508 covers and seals the air permeable blood barrier 2506 and inhibits air from entering the blood sequestration chamber 2520 through the air permeable blood barrier 2506. A fulcrum 2512 on an underside of the lid 2510 allows the seal 2508 to flexibly disconnect from the top of the inner wall 2516 when pushed by air displaced from the blood sequestration chamber 2520, to allow air to vent from the air permeable blood barrier 2506 and through the one or more air vents 2514 in the outer wall 2504.

[00146] FIG. 26A – E illustrate a blood sample optimization system 2600 that includes a patient needle 2602 for vascular access to a patient's bloodstream, a blood sample collection device 2604 to facilitate the collecting of one or more blood samples for blood testing or blood cultures, and a conduit 2606 providing a fluid connection between the patient needle 2602 and the blood sample collection device 2604. The conduit 2606 can include flexible tubing. In preferred implementations, the blood sample collection device 2604 includes a protective shield 2605 that includes a sealed collection needle on which a sealed vacuum-loaded container is placed, which, once pierced by the

collection needle, draws in a blood sample under vacuum pressure or force through the conduit 2006 from the patient needle 2602.

[00147] The blood sample optimization system 2600 further includes a blood sequestration device 2608, located at any point on the conduit 2606 between the patient needle 2602 and the blood sample collection device 2604. The location of the blood sequestration device 2608 can be based on a length of the conduit between the blood sequestration device 2608 and the patient needle 2602, and the associated volume that length provides.

[00148] The blood sequestration device 2608 includes an inlet port 2612 for being connected to the conduit 2606 toward the patient needle 2602, and an outlet port 2614 for being connected to the conduit 2606 toward the blood sample collection device 2604. The blood sequestration device 2608 includes an outer housing 2616 and an inner housing 2617, both having a cylindrical form, and being connected concentrically. The outer housing 2616 includes an outer wall 2618 and an inner conduit 2620 that defines a blood sampling channel 2622 to convey blood through the conduit 2606 to the blood sampling device 2604. The inner housing 2617 fits snugly between the inner conduit 2620 and the outer wall 2618 of the outer housing, and is rotatable in relation to the outer housing 2616. The fit between the outer housing 2616 and the inner housing 2617 can be a friction fit that maintains the housings in a particular position. The inner housing 2617 defines a blood sequestration chamber 2624, preferably a helical or corkscrew channel around the outer surface of inner conduit 2620 of the outer housing 2616, and which terminates at an air vent 2628 having an air permeable blood barrier, as shown in FIG. 26E.

[00149] The blood sequestration chamber 2624 is connected with the blood sampling channel 2622 via diversion junction 2624 formed in the inner conduit 2620, when the blood sequestration device in a first state, illustrated in FIG. 26C. The protective shield 2606 on the collection needle 2604 provides a block for air or blood, enabling a diversion of an initial aliquot of blood into the blood sequestration chamber 2624 as the patient's blood pressure overcomes the ambient air pressure in the blood sequestration channel 2624 to displace air therefrom through air vent 2628.

[00150] When the inner housing 2617 is rotated relative to the outer housing 2616, or vice versa, to a second state, as illustrated in FIG. 26D, the blood sequestration chamber 2624 is shut off from diversion junction 2624, enabling a direct path from the patient needle through the conduit 2606 to the collection needle 2604, via blood sampling channel 2622. The outer housing 2616 and/or inner housing 2617 can include ridges or grooves formed within a portion of their surfaces, to facilitate relative rotation from the first state to the second state.

[00151] FIGS. 27A – D illustrate a blood optimization system 2700 and blood sequestration device 2702, formed substantially as described with reference to at least FIGS. 15, 16, 17, 18, 19, and 25, but being formed to inhibit a user or other object from touching or blocking an air venting mechanism from a blood sequestration chamber 2720. Air initially in the blood sequestration chamber 2720 is displaced by an initial aliquot of blood upon venipuncture, where a patient's blood pressure overcomes the ambient air pressure in the blood sequestration chamber 2720. The air venting mechanism includes an air permeable blood barrier 2706, such as a porous material or set of materials that allows air to escape but blocks blood from leaving the blood sequestration chamber 2720.

[00152] The air venting mechanism includes an inner wall 2716 that at least partially circumscribes or surrounds the air permeable blood barrier 2706, and an outer wall 2704 spaced apart from the inner wall 2716. A cap 2722 is positioned on the air venting mechanism, preferably by having a lower cap wall 2728 that fits between the inner wall 2716 and the outer wall 2704 of the air venting mechanism, and frictionally abutting either the the inner wall 2716 or the outer wall 2704 or both. The cap 2722 further includes one or more vent holes 2724 or slits, apertures, openings, or the like, which extend through an upper surface of the cap 2722 around a downwardly extending plug 2726. The plug 2726 is sized and adapted to fit snugly within the space defined by inner wall 2716.

[00153] In a first position, as illustrated in FIG. 27C, the cap 2722 is extended from the air venting mechanism to allow air from the blood sequestration chamber 2720 to exit through the air permeable blood barrier 2706 and through the one or more vent holes 2724. Once the air from the blood sequestration chamber 2720 has been displaced, i.e., when the blood sequestration chamber 2720 is filled with the first aliquot of potentially tainted blood from the patient, then the cap 2722 can be pushed down on the air venting

mechanism in a second position as shown in FIG. 27D, so that the plug 2726 fits within the inner wall 2716 over the air permeable blood barrier 2706 to seal the air venting mechanism. In either the first position or the second position, the cap 2722 protects the air permeable blood barrier 2706 from outside air or from being touched by a user.

[00154] FIGS. 28A – F illustrate a blood optimization system 2800 and blood sequestration device 2802, formed substantially as described with reference to at least FIGS. 15, 16, 17, 18, 19, 25 and 26, but utilizing a multi-layered filter, and in some implementations, a filter with trapped reactive material, for an air permeable blood barrier. As shown in FIGS. 28C and D, an air permeable blood barrier 2803 includes a first layer 2804 of an air permeable but blood impermeable material, and a second layer 2806 that includes a reactive material, such as a hydrophobic material, for repelling blood while still allowing air to pass through both layers. As shown in FIGS. 28E and F, the air permeable blood barrier 2803 can include any number of layers, such as a third layer 2808 formed of the same air permeable but blood impermeable material as first layer 2804, while a second layer 2806 includes trapped or embedded blood reactive material.

[00155] FIGS. 29A – C illustrate a blood optimization system 2900 and blood sequestration device 2902, formed substantially as described with reference to at least FIGS. 15, 16, 17, 18, 19, 25 and 26, but in which a blood sequestration chamber 2904 is at least partially filled with a blood-absorptive material 2906. The blood-absorptive material 2906 can act as a wicking material to further draw in blood to be sequestered upon venipuncture of the patient, and prior to use of a blood drawing device such as a Vacutainer™ or a syringe, or the like.

[00156] FIGS. 30A – G illustrate a blood optimization system 3000 and blood sequestration device 3002, formed substantially as described with reference to at least FIGS. 15, 16, 17, 18, 19, 25 and 26. The blood sequestration device 3000 includes an inlet port 3002 that can be connected with a patient needle that is inserted into a patient's vascular system for access to and withdrawing of a blood sample. The inlet port 3002 may also be connected with tubing or other conduit that is in turn connected with the patient needle. The inlet port 3002 defines an opening into the blood sequestration device 3000, which opening can be the same cross sectional dimensions as tubing or other conduit connected with the patient needle or the patient needle itself. For instance, the

opening can be circular with a diameter of approximately 0.045 inches, but can have a diameter of between 0.01 inches or less to 0.2 inches or more.

[00157] The inlet port 3002 can also include a sealing or fluid-tight connector or connection, such as threading or Luer fitting, or the like. In some implementations, tubing or other conduit associated with the patient needle can be integral with the inlet port 3002, such as by co-molding, gluing, laser weld, or thermally bonding the parts together. In this manner, the blood sequestration device 3000 can be fabricated and sold with the patient needle and/or tubing as a single unit, eliminating the need for connecting the patient needle to the blood sequestration device 3000 at the time of blood draw or sampling.

[00158] The blood sequestration device 3000 further includes an outlet port 3004, which defines an opening out of the blood sequestration device 3000 and to the blood sample collection device. The outlet port 3004 may also be connected with tubing or other conduit that is in turn connected with the blood sequestration device, and may also include a sealing or fluid-tight connector or connection, such as threading or Luer fitting, or the like. Accordingly, as discussed above, the blood sequestration device 3000 can be fabricated and sold with the patient needle and/or tubing and the blood sample collection device as a single unit, eliminating the need for connecting the patient needle and the blood sample collection device to the blood sequestration device 3000 at the time of blood draw or sampling.

[00159] The blood sequestration device 3000 further includes a sampling channel 3006 between the inlet port 3002 and the outlet port 3004, and a sequestration chamber 3008 that is connected to and split off or diverted from the sampling channel 3006 at any point between the inlet port 3002 and the outlet port 3004. The sampling channel 3006 functions as a blood sampling pathway once a first aliquot of blood has been sequestered in the sequestration chamber 3008. The sampling channel 3006 can be any sized, shaped or configured channel, or conduit. In some implementations, the sampling channel 3006 has a substantially similar cross sectional area as the opening of the inlet port 3002. In other implementations, the sampling channel 3006 can gradually widen from the inlet port 3002 to the outlet port 3004. The sequestration chamber 3008 may have a larger cross section to form a big reservoir toward the sequestration channel path so that the

blood will want to enter the reservoir first versus entering a smaller diameter on the sampling channel 3006.

[00160] In some exemplary implementations, the diversion between the sampling channel 3006 and the sequestration chamber 3008 is by diverter junction 3007. Diverter junction 3007 may be a substantially Y-shaped, T-shaped, or U-shaped. In some preferred exemplary implementations, and as shown in FIG. 17A – 17B, the diverter junction 3007 is configured such that the flow out of the inlet port 3002 is preferentially directed toward the sequestration chamber 3008. The sequestration chamber 3008 may also include or form a curve or ramp to direct the initial blood flow toward and into the sequestration chamber 3008.

[00161] The sequestration chamber 3008 is preferably maintained at atmospheric pressure, and includes a vent 3010 at or near a distal end of the sequestration chamber 3008. The vent 3010 may include an air permeable blood barrier 3012 as described above.

[00162] The blood sequestration device 3000 can include a housing 3001 that can be formed of multiple parts or a single, unitary part. In some implementations, and as illustrated FIG. 30F, the housing 3001 includes a top member 3020 and a bottom member 3022 that are mated together. The blood sequestration device 3000 can also include a gasket or other sealing member (not shown) so that when the top member 3020 is mechanically attached with the bottom member 3022, the interface between the two is sealed by the gasket or sealing member. The bottom member 3022 can include grooves, channels, locks, conduits or other pathways pre-formed therein, such as by an injection molding process or by etching, cutting, drilling, etc., to form the sampling channel 3006, the sequestration chamber 3008, and diverter junction 3007.

[00163] The sequestration chamber 3008 may have a larger cross section than the sampling channel 3006 so that the blood will preferentially move into the sequestration chamber first versus entering a smaller diameter on the sampling channel 3006.

[00164] In some implementations, the sampling channel 3006 and the sequestration chamber 3008 are formed by grooves, channels, locks or other pathways formed in housing 3001. The housing 3001 can be made of rubber, plastic, metal or any other suitable material. The housing 3001 can be formed of a clear or translucent material, or

of an opaque or non-translucent material. In other implementations, the housing 3001 can be mostly opaque or non-translucent, while the housing surface directly adjacent to the sampling channel 3006 and/or the sequestration chamber 3008 may be clear or translucent, giving a practitioner a visual cue or sign that the sequestration chamber 3008 is first filled to the extent necessary or desired, and/or then a visual cue or sign that the sequestered blood remains sequestered while a clean sample of blood is drawn through the sampling channel 3006. Other visual cues or signs of the sequestration can include, without limitation: the air permeable blood barrier 3012 turning a different color upon contact, saturation, or partial saturation with blood; a color-coded tab or indicator at any point along or adjacent to the sequestration chamber; an audible signal; a vibratory signal; or other signal.

[00165] The air permeable blood barrier 3012 can be covered with, or surrounded by, a cap 3032. The cap 3032 can be sized and configured to inhibit a user from touching the air permeable blood barrier 3012 with their finger or other external implement, while still allowing air to exit the air permeable blood barrier 3012 as the air is displaced from the sequestration chamber 3008. The cap 3032 can be constructed to inhibit or prevent accidental exposure of the filter to environmental fluids or splashes. This can be accomplished in a variety of mechanical ways including but not limited to the addition of a hydrophobic membrane to the protective cover.

[00166] The air venting mechanism includes a wall 3030 that at least partially circumscribes or surrounds the air permeable blood barrier 3012. The wall 3030 can have one or more air vents formed therein. The cap 3032 covers wall 3030 and can be snapped, glued, or otherwise attached in place. A seal 3017 in the form of a silicone wafer, or other elastomeric material, fits within the wall 3030 to cover the air permeable blood barrier 3012 and abut the top of the wall 3030. The seal 3017 covers and seals the air permeable blood barrier 3012 and inhibits air from entering the blood sequestration chamber 3008 through the air permeable blood barrier 3012. A fulcrum 3012 on an underside of the cap 3032 allows the seal 3008 to flexibly disconnect from the top of the inner wall 3016 when pushed by air displaced from the blood sequestration chamber 3008, to allow air to vent from the air permeable blood barrier 3012 and through the one or more air vents in the wall 3030 and/or cap 3032.

[00167] In use, the blood sequestration device 3000 includes a sampling channel 3006 and a sequestration chamber 3008. Both pathways are initially air-filled at atmospheric pressure, but the sampling channel 3006 is directed to an outlet port 3004 that will be initially sealed by a Vacutainer or other such sealed blood sampling device, and the sequestration chamber 3008 terminates at a vent 3010 to atmosphere that includes an air permeable blood barrier 3012.

[00168] After a venipuncture by a patient needle of a patient (not shown), which could gather a number of pathogens from the patient's skin, a first amount of the patient's blood with those pathogens will pass through inlet port 3002 of blood sequestration device 3000. This initial volume of potentially contaminated blood will preferentially flow into the sequestration chamber 3008 by finding the path of least resistance. The patient's own blood pressure overcomes the atmospheric pressure in the vented sequestration chamber 3008 to displace air therein through the air permeable blood barrier 3012, but is not sufficient to overcome the air pressure that builds up in the sealed sampling channel 3006. In various exemplary embodiments, the sequestration chamber 3008 and sampling channel 3006 can be configured such that the force generated by the patient's blood pressure is sufficient to overcome any effect of gravity, regardless of the blood sequestration device's orientation.

[00169] Eventually, the sequestration chamber 3008 fills with blood that displaces air through the air permeable blood barrier 3012. Once the blood contacts the air permeable blood barrier, the blood interacts with the air permeable blood barrier 3012 material to completely or partially seal the vent 3010. A signal or indication may be provided that the practitioner can now utilize the Vacutainer or other blood sampling device.

[00170] Upon filling the blood sequestration pathway 3008 but prior to use of the Vacutainer or other blood sample collection device, the patient's blood pressure may drive compression of the air in the sampling channel 3006, possibly resulting in a small amount of blood moving past the diversion point into the sampling channel 3006, queuing up the uncontaminated blood to be drawn through the sampling channel 3006.

[00171] In yet another aspect, the blood sequestration chamber and/or blood sampling channel, or other component, of any of the implementations described herein,

can provide a visually discernable warning or result in a component adapted for operative fluid communication with the flash chamber of an introducer for an intravenous catheter into a blood vessel of a patient. The device and method provides a visually discernable alert when blood from the patient communicates with a test component reactive to communicated blood plasma, to visually change. The reaction with the blood or the plasma occurs depending on one or a plurality of reagents positioned therein configured to test for blood contents, substances or threshold high or low levels thereof, to visually change in appearance upon a result.

[00172] In yet other aspects, the blood sequestration chamber and/or blood sampling channel can be sized and adapted to provide a particular volumetric flow of blood, either during the sequestration process and/or the sampling process.

[00173] Although a variety of embodiments have been described in detail above, other modifications are possible. Other embodiments may be within the scope of the following claims.

CLAIMS

1. A blood sequestration device comprising;

an inlet port;

an outlet port;

a sequestration chamber connected with the inlet port via a junction, the sequestration chamber having a vent that includes an air permeable blood barrier, the vent being defined by an outer wall that at least partially circumscribes the air permeable blood barrier and includes one or more air vents, the vent further including a cap that at least partially covers the wall and a one-way seal abutting the air permeable blood barrier that inhibits air from entering the sequestration chamber; and

a sampling channel having a proximal end connected with the inlet port via the junction, and a distal end connected with the outlet port;

the sequestration chamber, the sampling channel and the junction being sized and configured such that a first portion of blood flows into the sequestration chamber toward the air permeable blood barrier for sequestration therein, and a second portion of blood bypasses the sequestration chamber and the first portion of blood sequestered therein and is directed into the sampling channel toward the outlet port.

2. The blood sequestration device in accordance with claim 1, further comprising a housing that houses and defines the inlet port, the outlet port, the sequestration chamber, and the sampling channel.

3. The blood sequestration device in accordance with claim 1, wherein the vent further includes an inner wall within the outer wall and that contains the air permeable blood barrier.

4. The blood sequestration device in accordance with claim 1, wherein the one-way seal is positioned over the inner wall and within the outer wall of the vent.

5. The blood sequestration device in accordance with claim 4, wherein the cap includes an inner surface that faces the air permeable blood barrier, the

inner surface of the cap including a fulcrum against which the seal can flexibly unseal from the air permeable blood barrier to allow air to escape the sequestration chamber.

6. The blood sequestration device in accordance with claim 1, wherein the air permeable blood barrier includes a sealing material that seals the vent upon contact with blood.

7. The blood sequestration device in accordance with claim 1, wherein the air permeable blood barrier includes a filter having a first layer and a second layer, the second layer of the filter having a hydrophobic material to repel blood.

8. A blood sequestration and sampling system comprising;

a blood sampling pathway having a patient needle on a proximal end and a sample collection device on a distal end; and

a blood sequestration device attached on the blood sampling pathway between the proximal end and distal end of the blood sampling pathway, the blood sequestration device comprising:

an inlet port coupled with the blood sampling pathway toward the patient needle;

an outlet port coupled with the blood sampling pathway toward the sample collection device;

a sequestration chamber connected with the inlet port via a junction, the sequestration chamber having a vent that includes an air permeable blood barrier, the vent being defined by an outer wall that at least partially circumscribes the air permeable blood barrier and includes one or more air vents, the vent further including a cap that at least partially covers the wall and a one-way seal abutting the air permeable blood barrier that inhibits air from entering the sequestration chamber; and

a sampling channel having a proximal end connected with the inlet port via the junction, and a distal end connected with the outlet port;

the sequestration chamber, the sampling channel and the junction being sized and configured such that a first portion of blood flows into the sequestration chamber toward the air permeable blood barrier for sequestration therein, and a second portion of blood bypasses the sequestration chamber and the

first portion of blood sequestered therein and is directed into the sampling channel toward the outlet port.

9. The blood sequestration system in accordance with claim 8, wherein the blood sequestration device further comprises a housing that houses and defines the inlet port, the outlet port, the sequestration chamber, and the sampling channel.

10. The blood sequestration system in accordance with claim 8, wherein the vent of the blood sequestration device further includes an inner wall within the outer wall and that contains the air permeable blood barrier.

11. The blood sequestration system in accordance with claim 8, wherein the one-way seal of the vent is positioned over the inner wall and within the outer wall of the vent.

12. The blood sequestration system in accordance with claim 11, wherein the cap includes an inner surface that faces the air permeable blood barrier, the inner surface of the cap including a fulcrum against which the seal can flexibly unseal from the air permeable blood barrier to allow air to escape the sequestration chamber.

13. The blood sequestration system in accordance with claim 8, wherein the air permeable blood barrier of the blood sequestration device includes a sealing material that seals the vent upon contact with blood.

14. The blood sequestration system in accordance with claim 8, wherein the air permeable blood barrier of the blood sequestration device includes a filter having a first layer and a second layer, the second layer of the filter having a hydrophobic material to repel blood.

15. A blood sequestration device comprising;

an inlet port;

an outlet port;

a sequestration chamber connected with the inlet port via a junction, the sequestration chamber having a vent that includes an air permeable blood barrier, the vent being defined by an outer wall that at least partially circumscribes the air permeable blood barrier and includes one or more air vents, the vent further including a cap that at least partially covers the wall and a one-way seal abutting the air permeable blood barrier that inhibits air from entering the sequestration chamber; and

a sampling channel having a proximal end connected with the inlet port via the junction, and a distal end connected with the outlet port;

the sequestration chamber, the sampling channel and the junction being sized and configured such that a first portion of blood flows into and fills the sequestration chamber to displace air therein through the vent, and such that a second portion of blood bypasses the sequestration chamber and the first portion of blood sequestered therein and is directed into the sampling channel toward the outlet port.

16. The blood sequestration device in accordance with claim 15, further comprising a housing that houses and defines the inlet port, the outlet port, the sequestration chamber, and the sampling channel.

17. The blood sequestration device in accordance with claim 15, wherein the vent further includes an inner wall within the outer wall and that contains the air permeable blood barrier.

18. The blood sequestration device in accordance with claim 15, wherein the one-way seal is positioned over the inner wall and within the outer wall of the vent.

19. The blood sequestration device in accordance with claim 18, wherein the cap includes an inner surface that faces the air permeable blood barrier, the inner surface of the cap including a fulcrum against which the seal can flexibly unseal from the air permeable blood barrier to allow air to escape the sequestration chamber.

20. The blood sequestration device in accordance with claim 15, wherein the air permeable blood barrier includes a sealing material that seals the vent upon contact with blood.

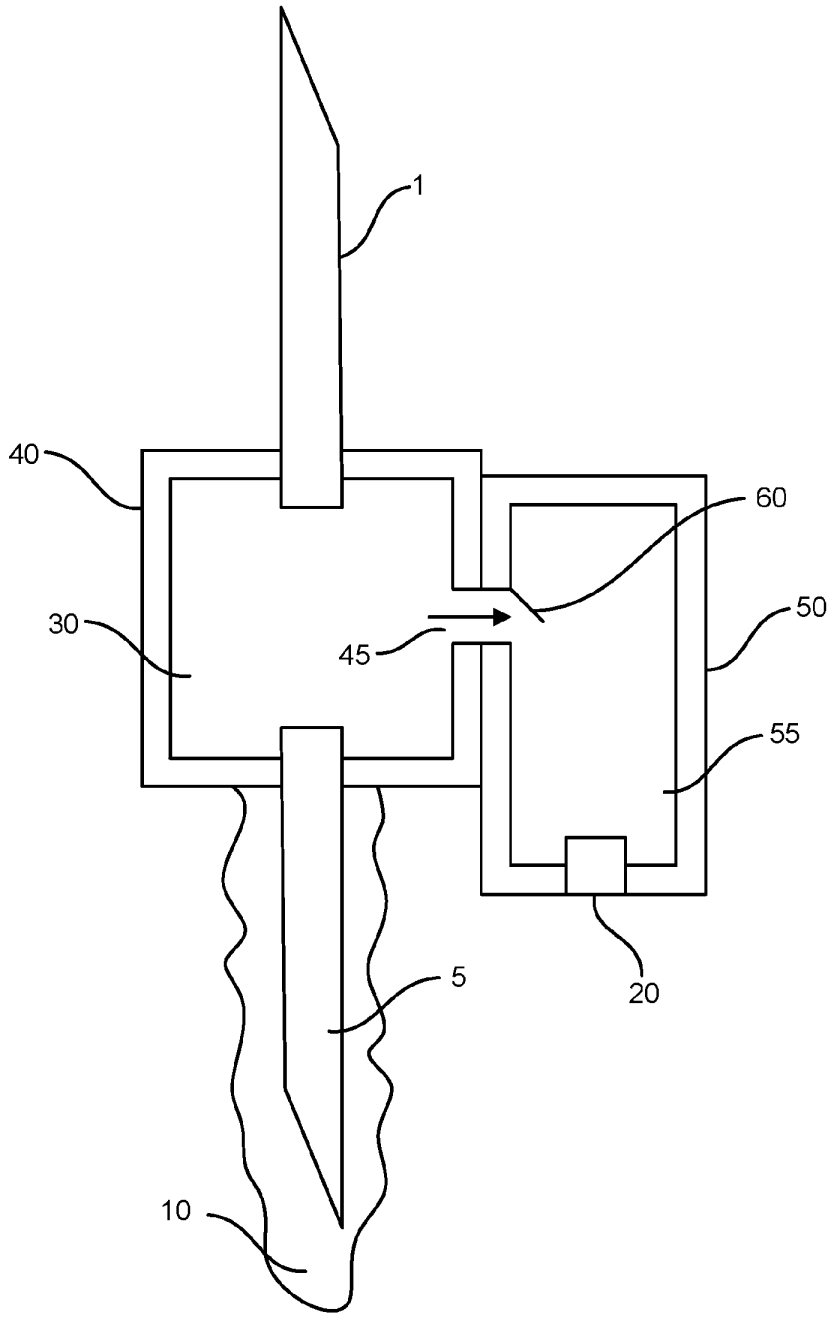


FIG. 1

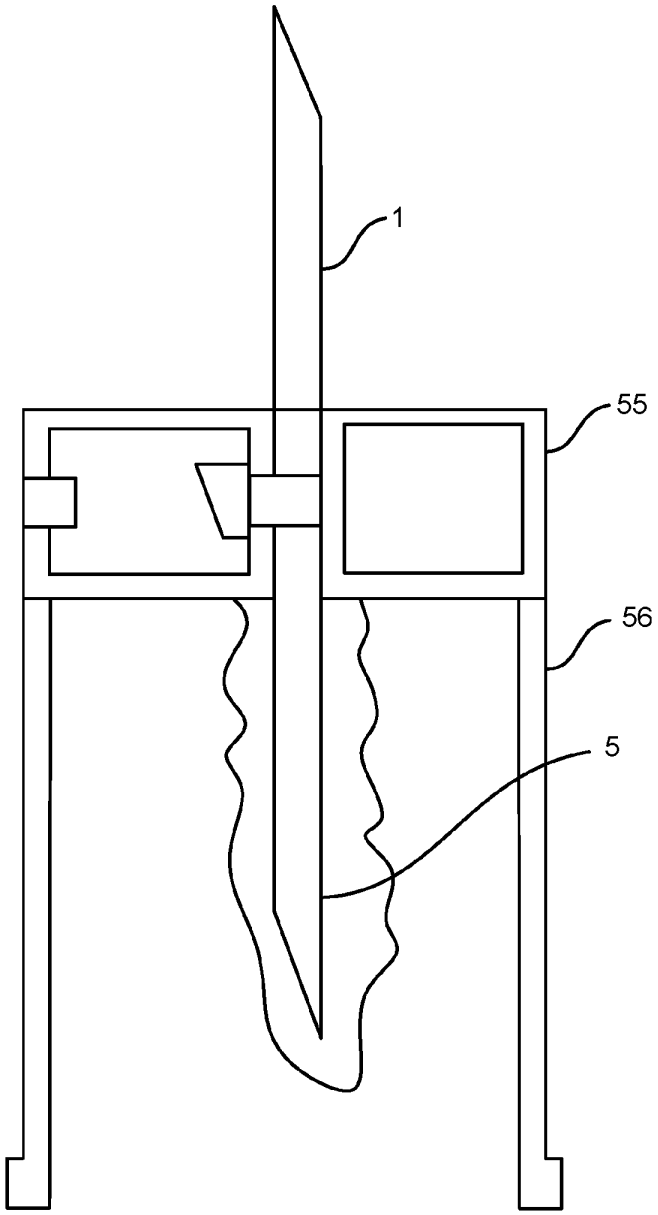


FIG. 2

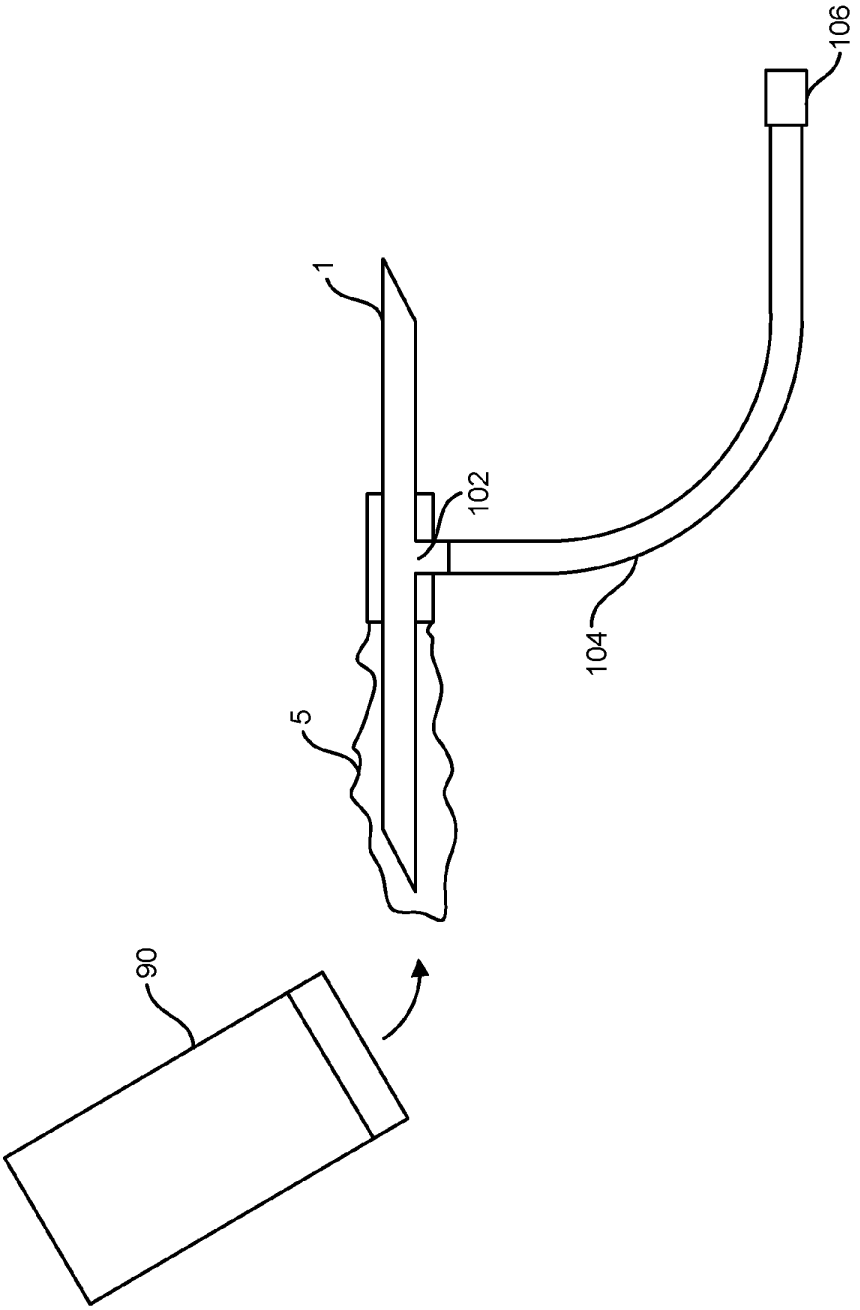


FIG. 3

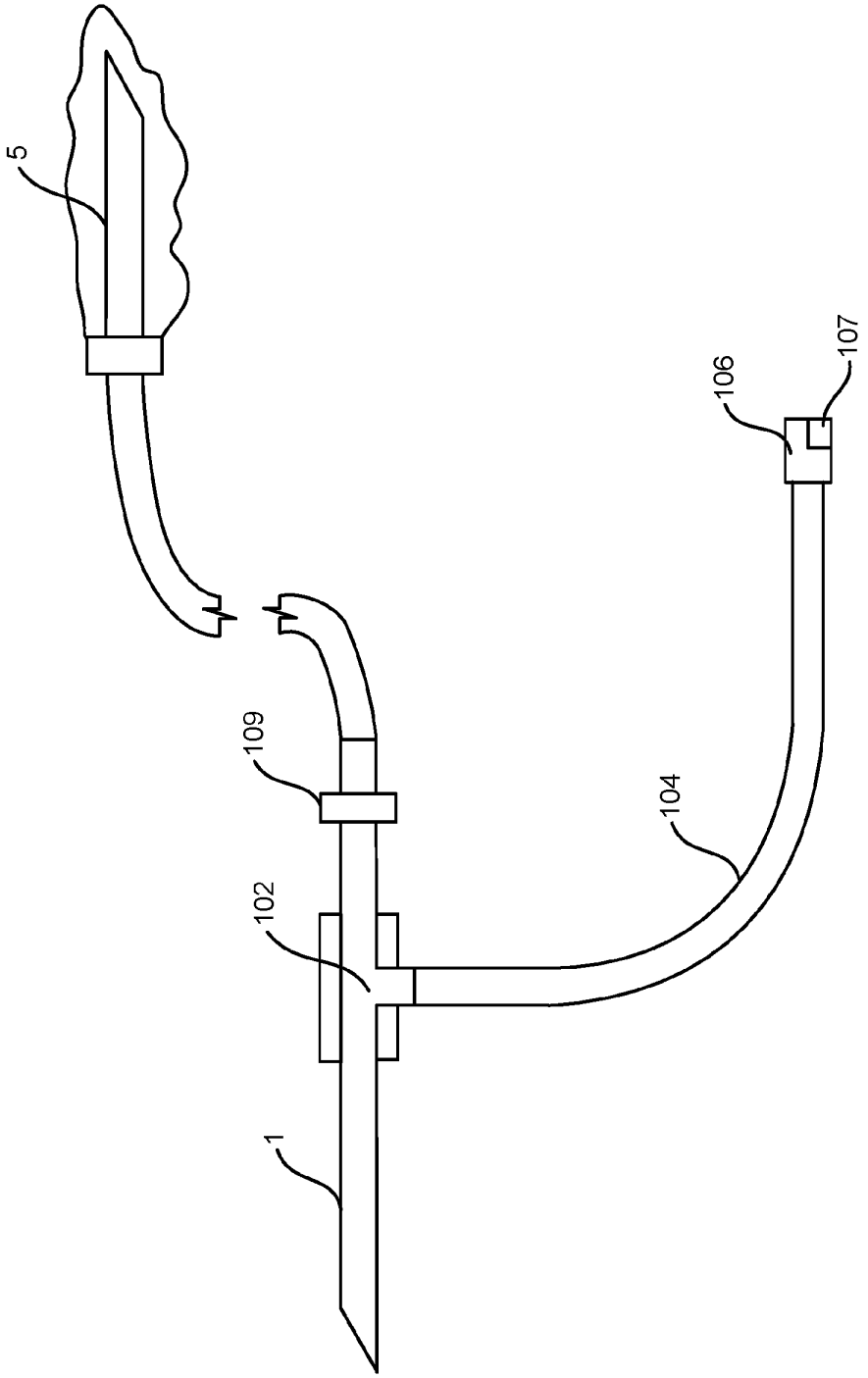


FIG. 4

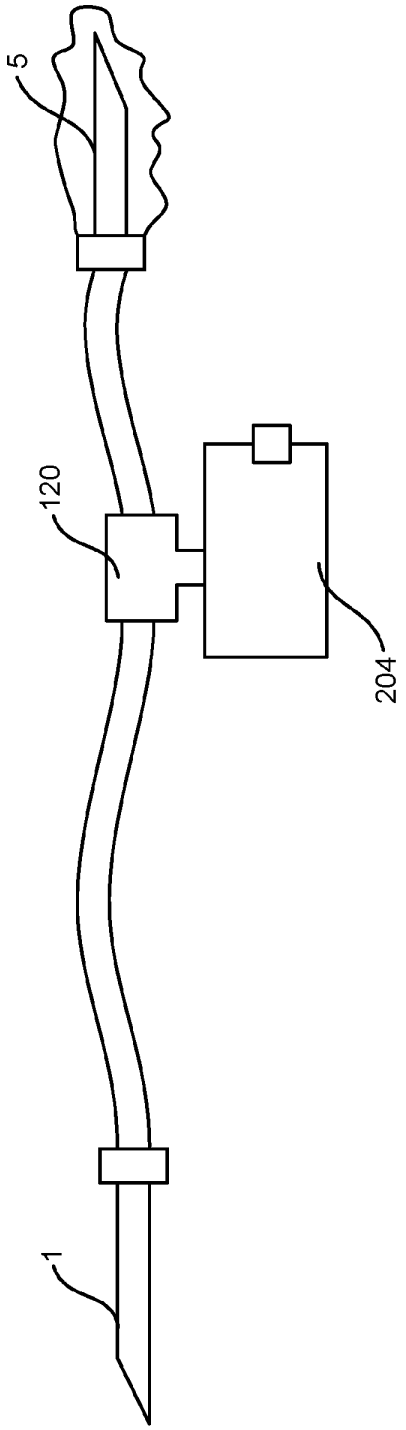


FIG. 5

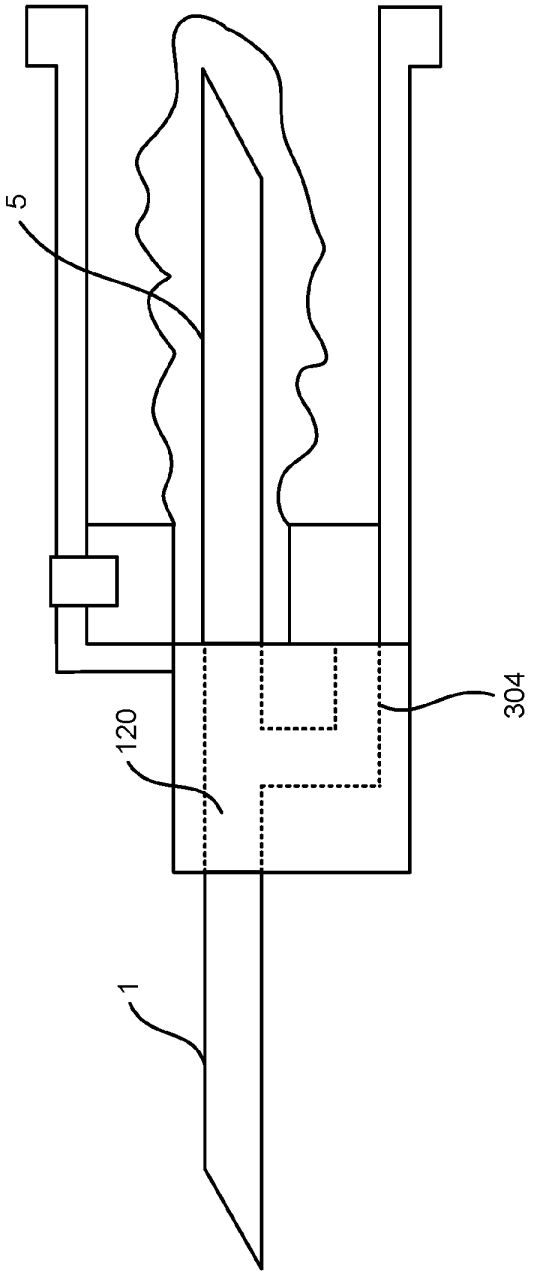


FIG. 6

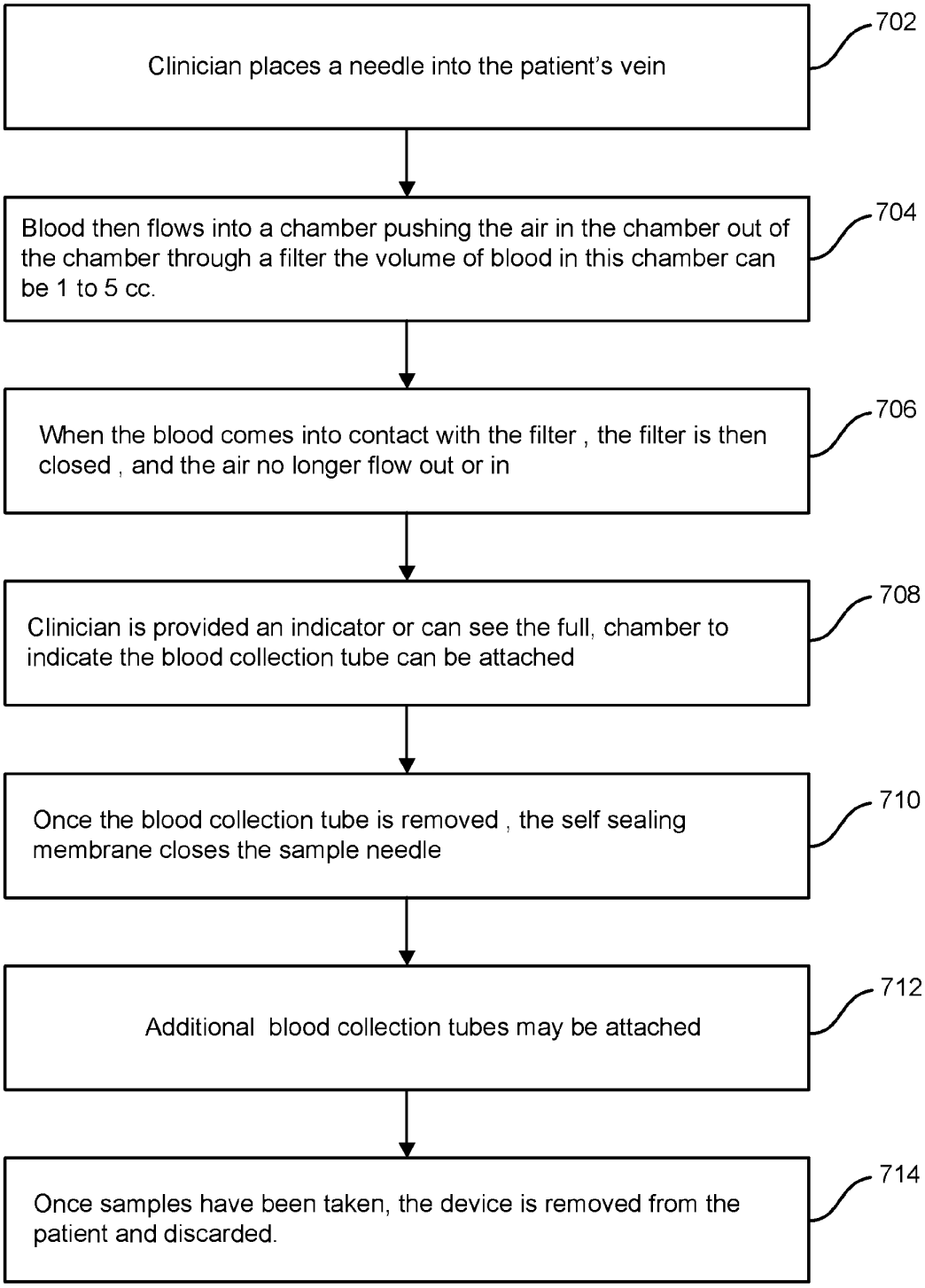

Clinician places a needle into the patient's vein
702
Blood then flows into a chamber pushing the air in the chamber out of the chamber through a filter the volume of blood in this chamber can be 1 to 5 cc.
704
When the blood comes into contact with the filter , the filter is then closed , and the air no longer flow out or in
706
Clinician is provided an indicator or can see the full, chamber to indicate the blood collection tube can be attached
708
Once the blood collection tube is removed , the self sealing membrane closes the sample needle
710
Additional blood collection tubes may be attached
712
Once samples have been taken, the device is removed from the patient and discarded.
714

FIG. 7

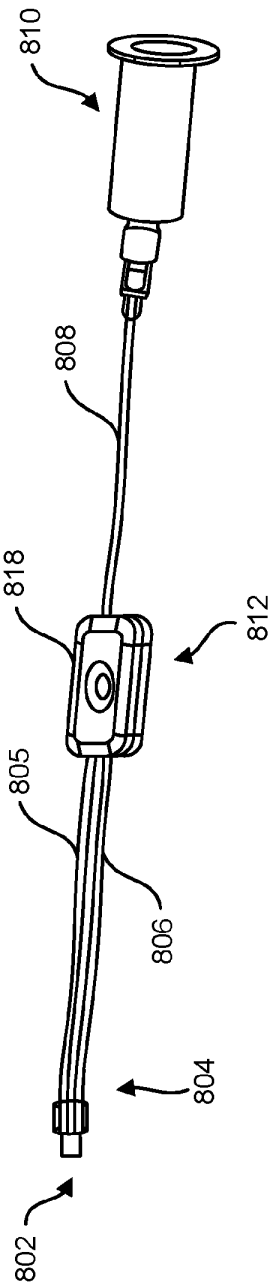


FIG. 8A

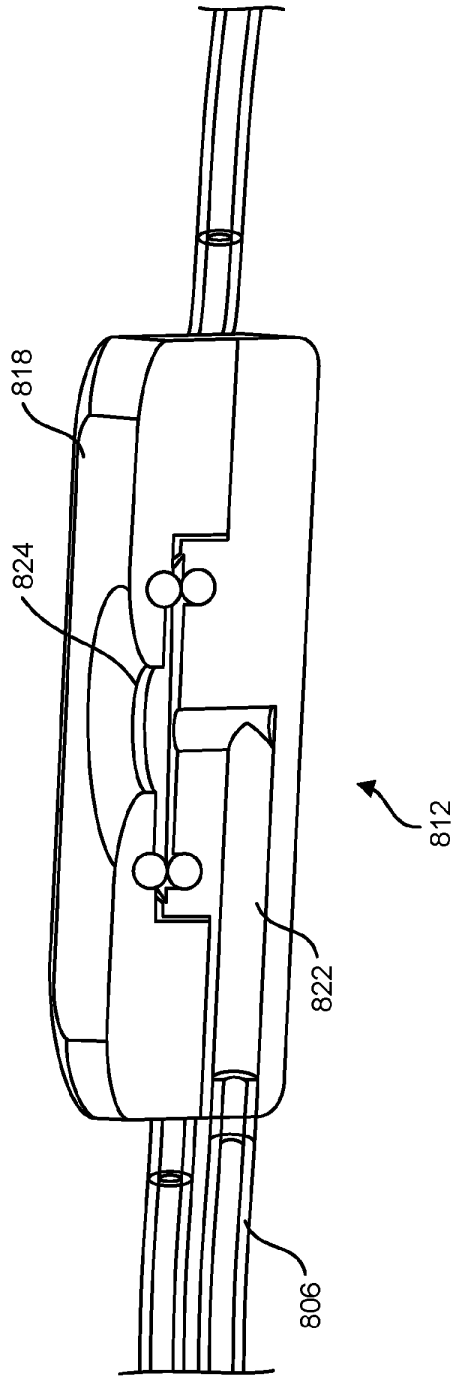


FIG. 8B

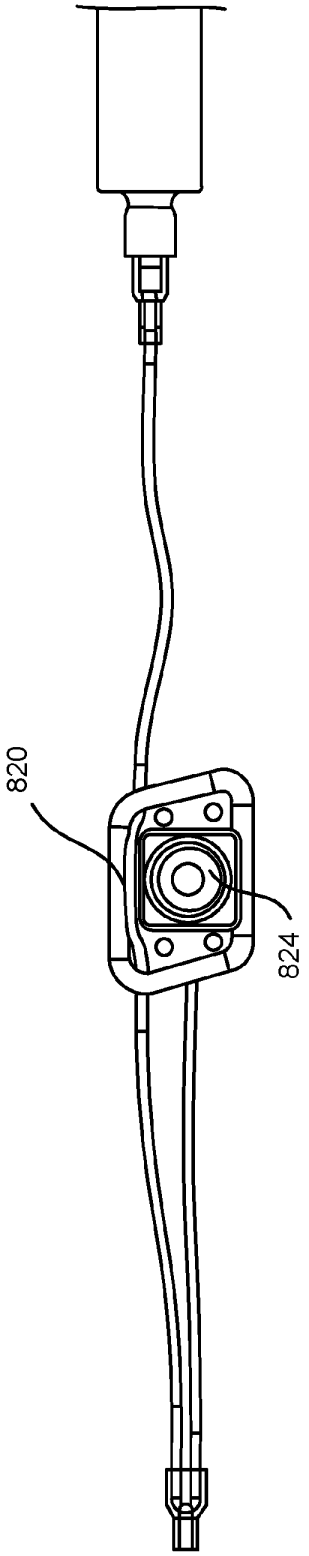


FIG. 8C

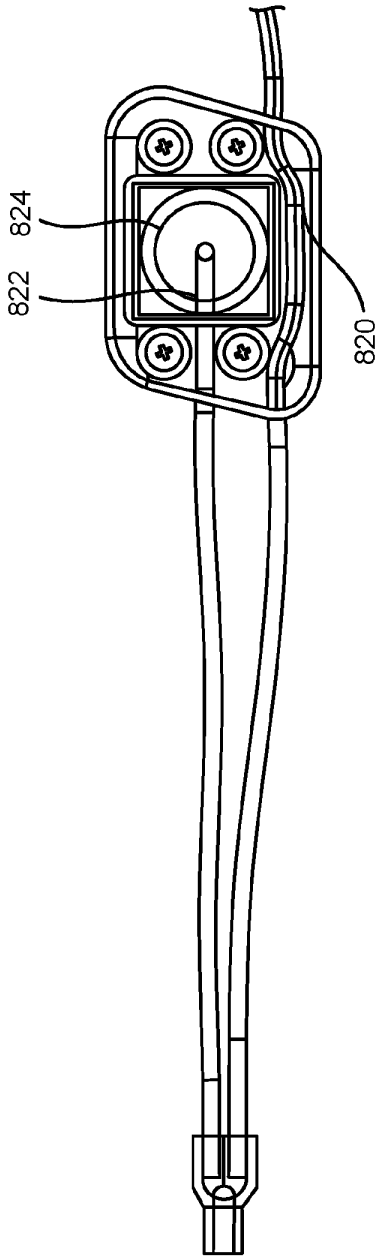


FIG. 8D

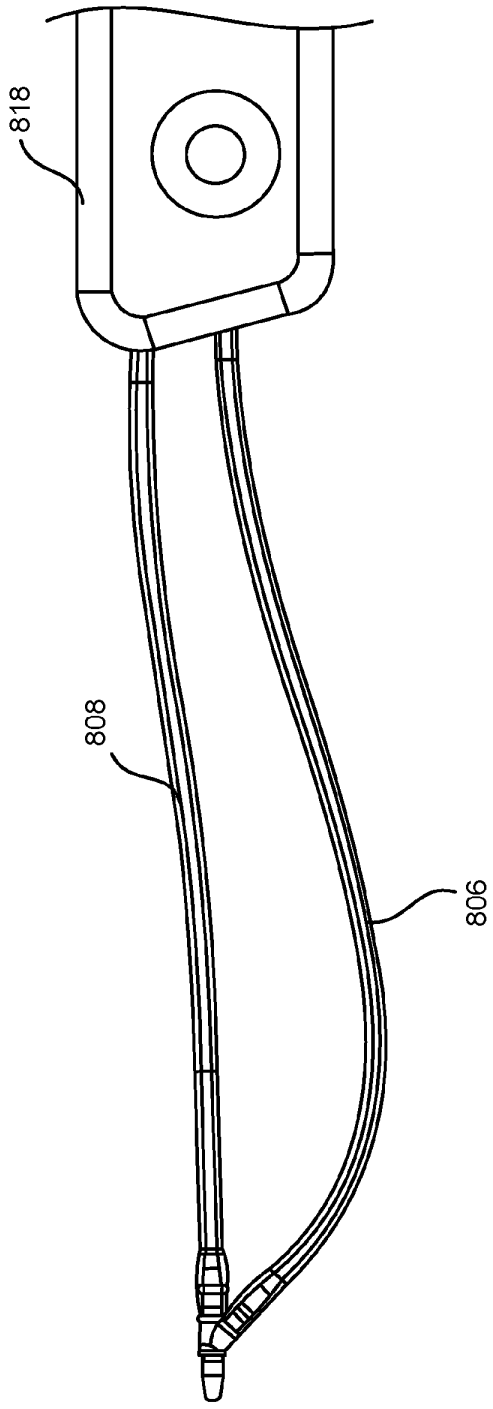


FIG. 8E

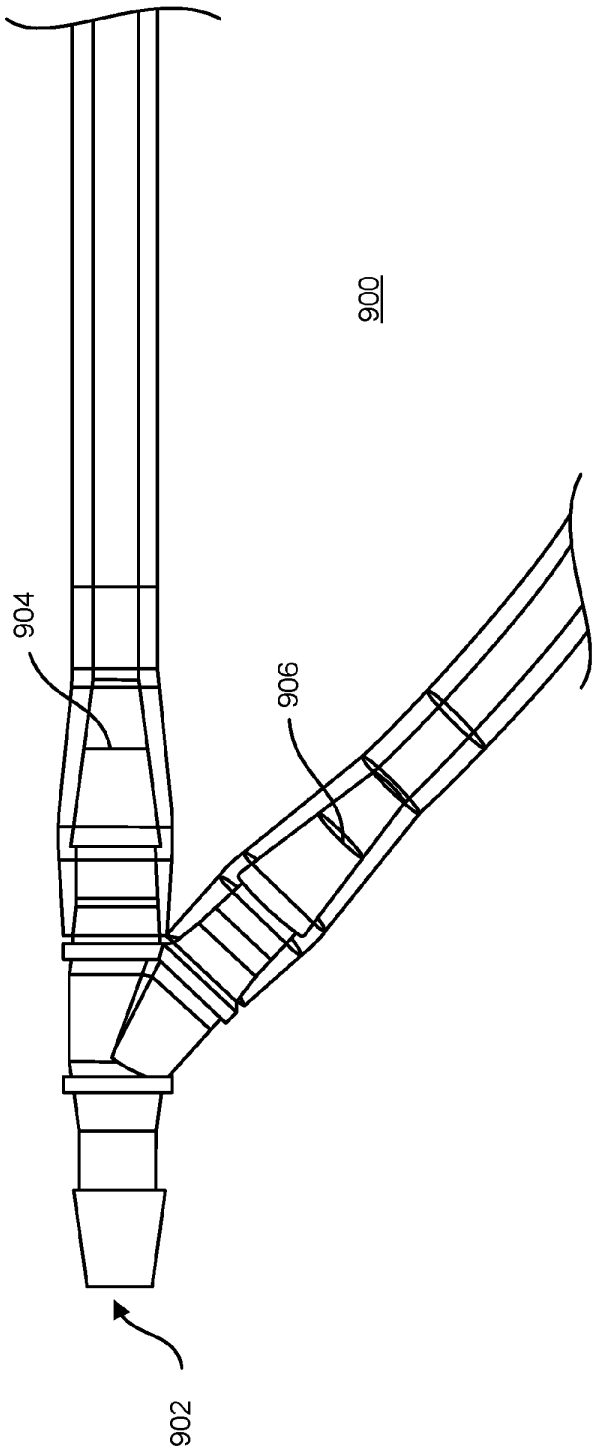


FIG. 9

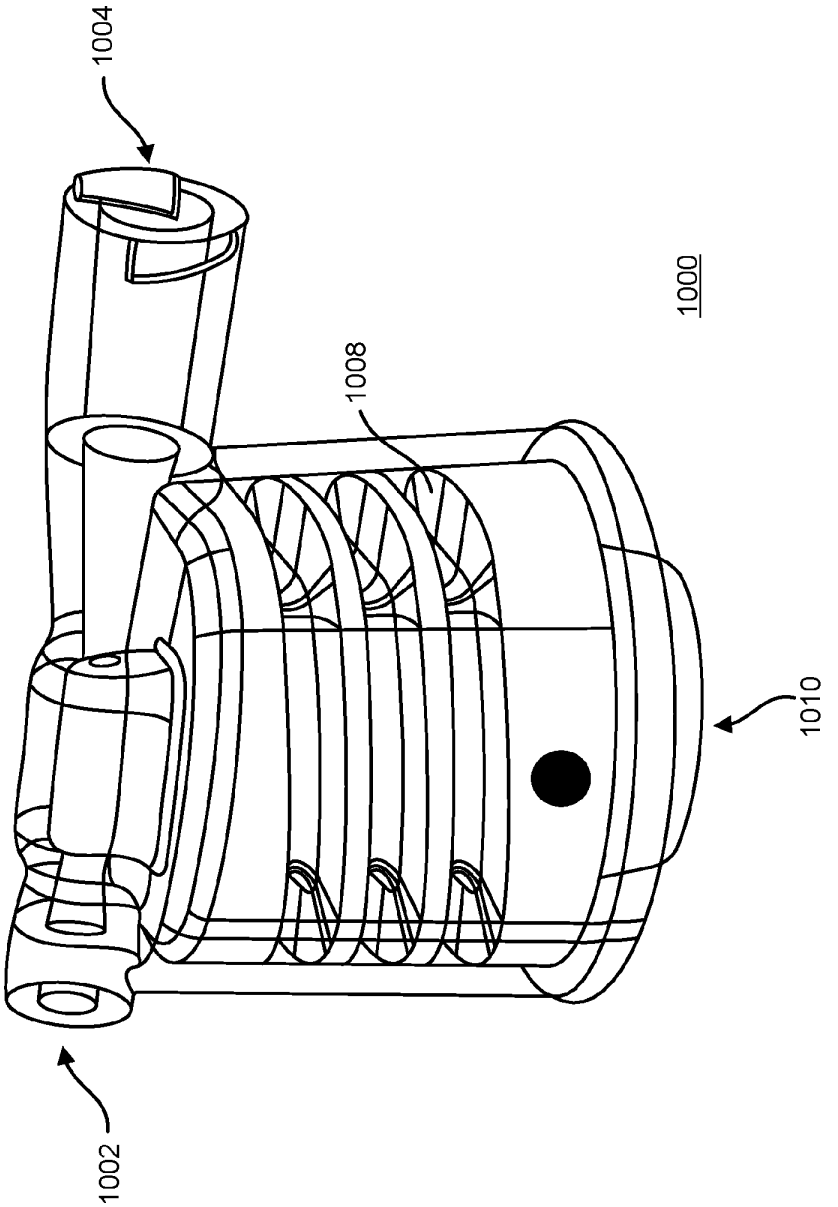


FIG. 10A

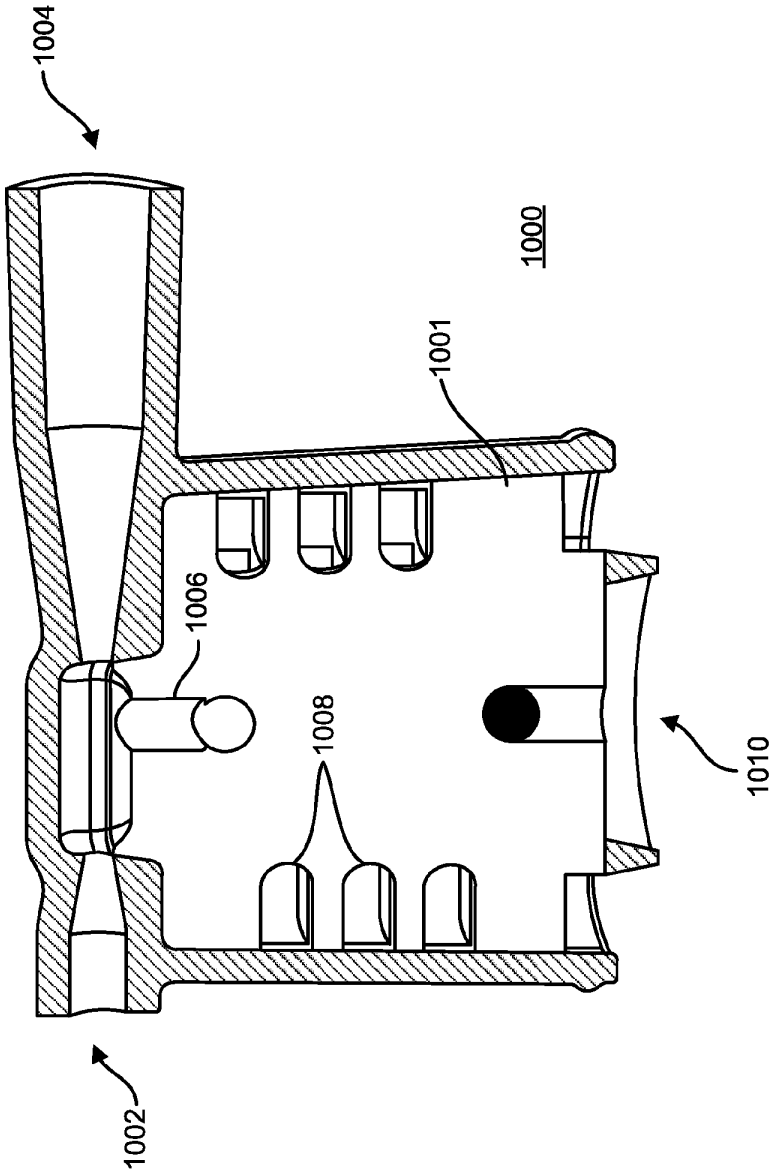


FIG. 10B

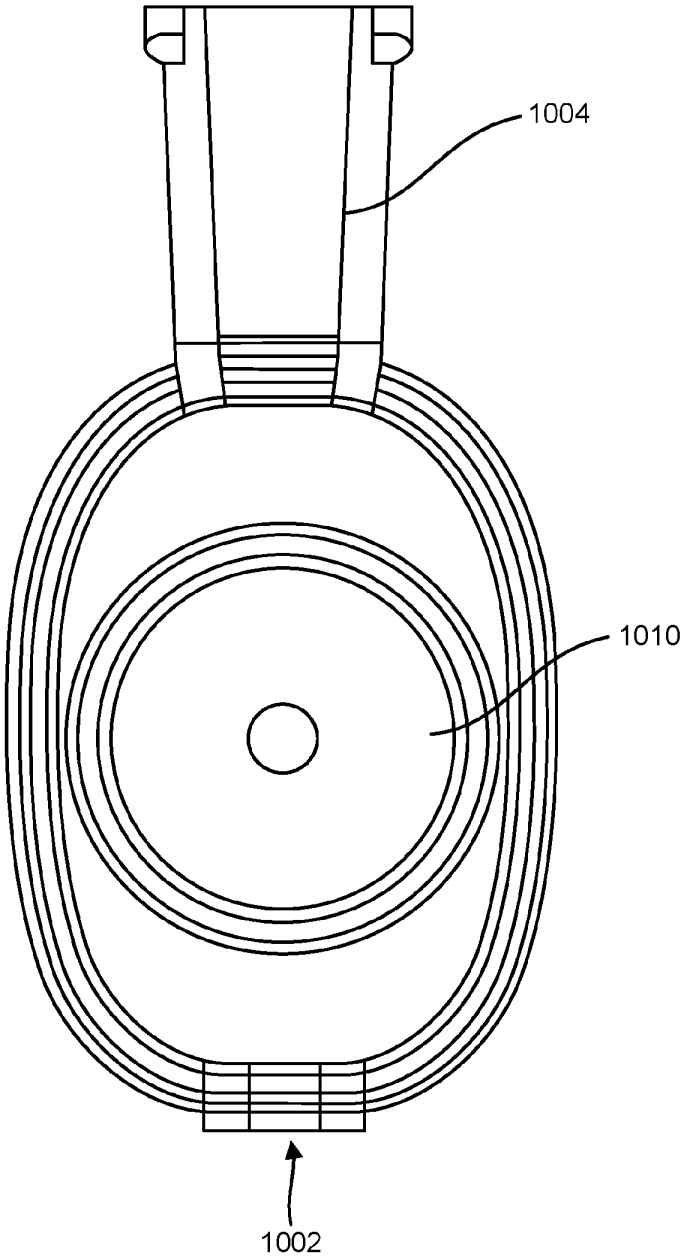


FIG. 10C

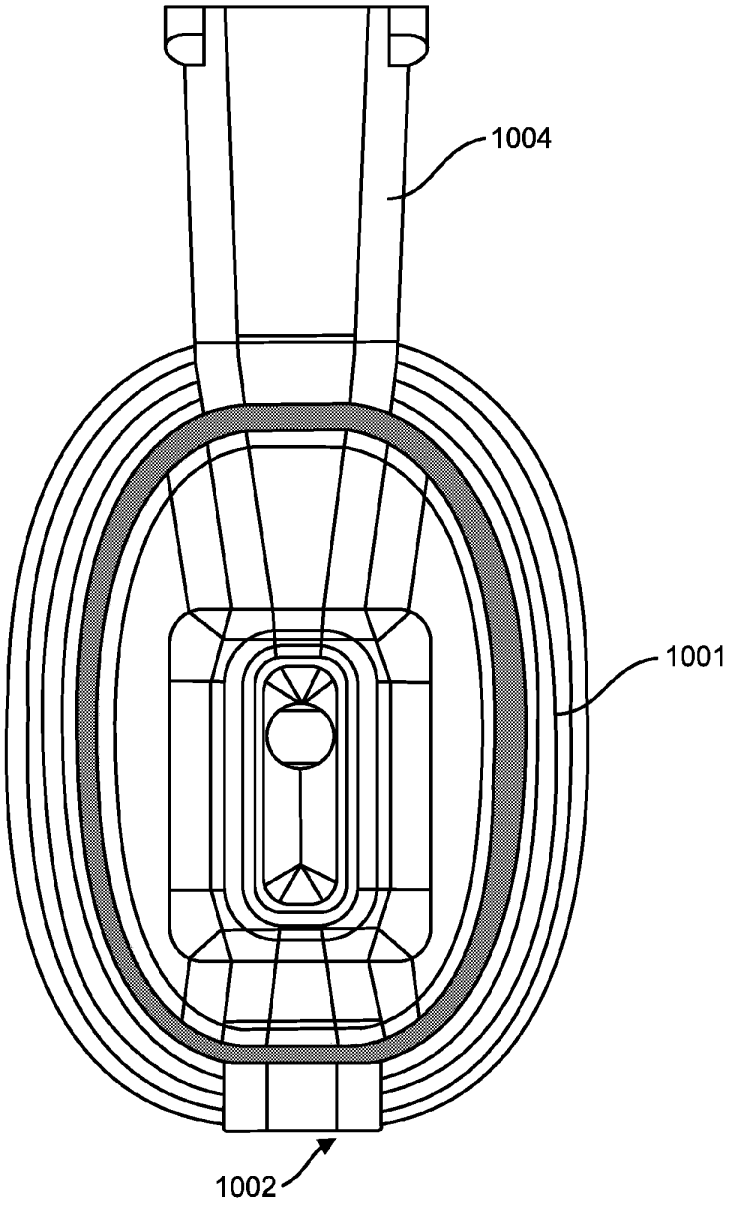


FIG. 10D

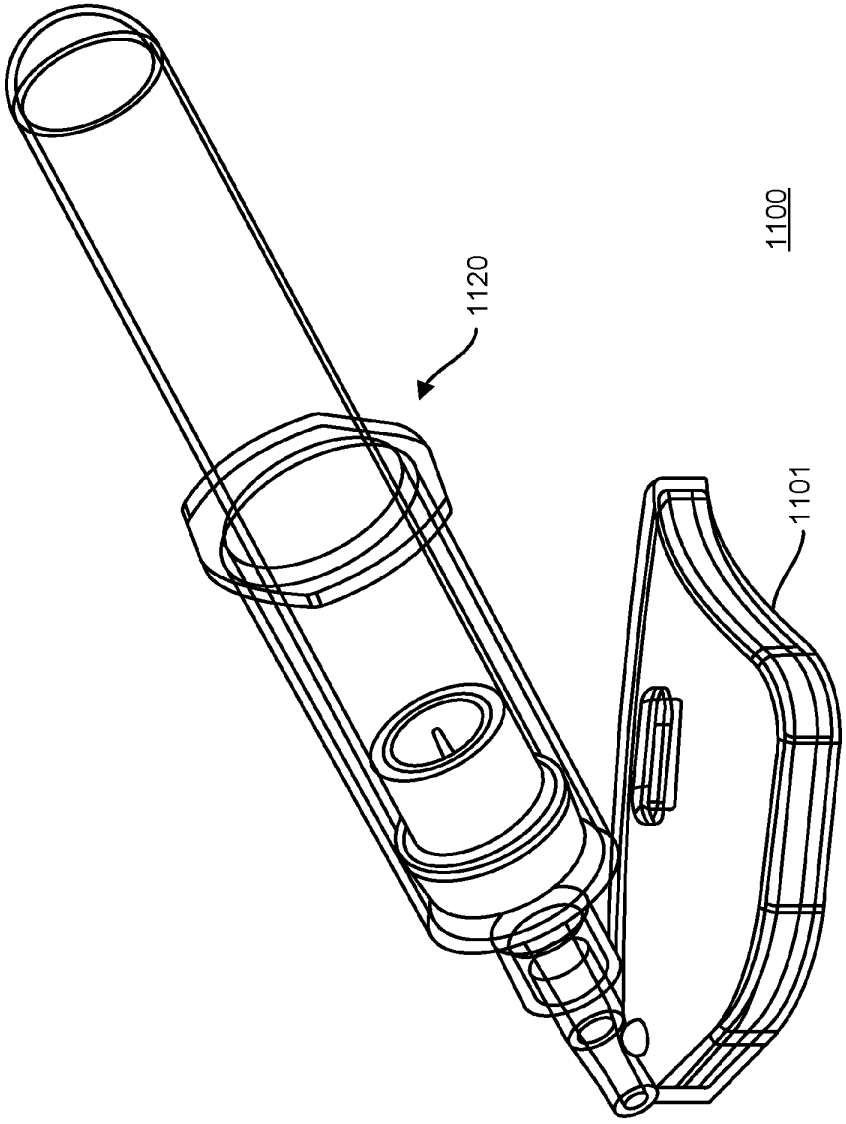


FIG. 11A

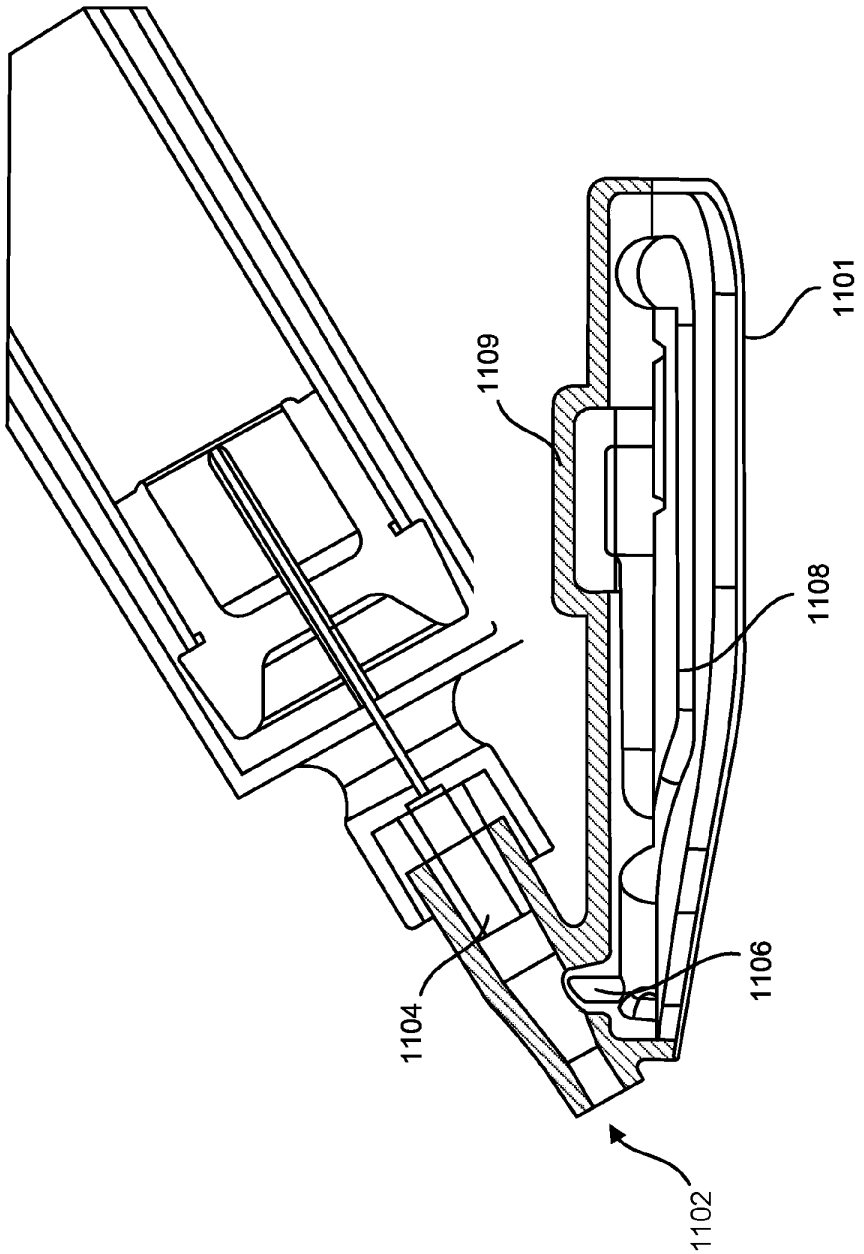


FIG. 11B

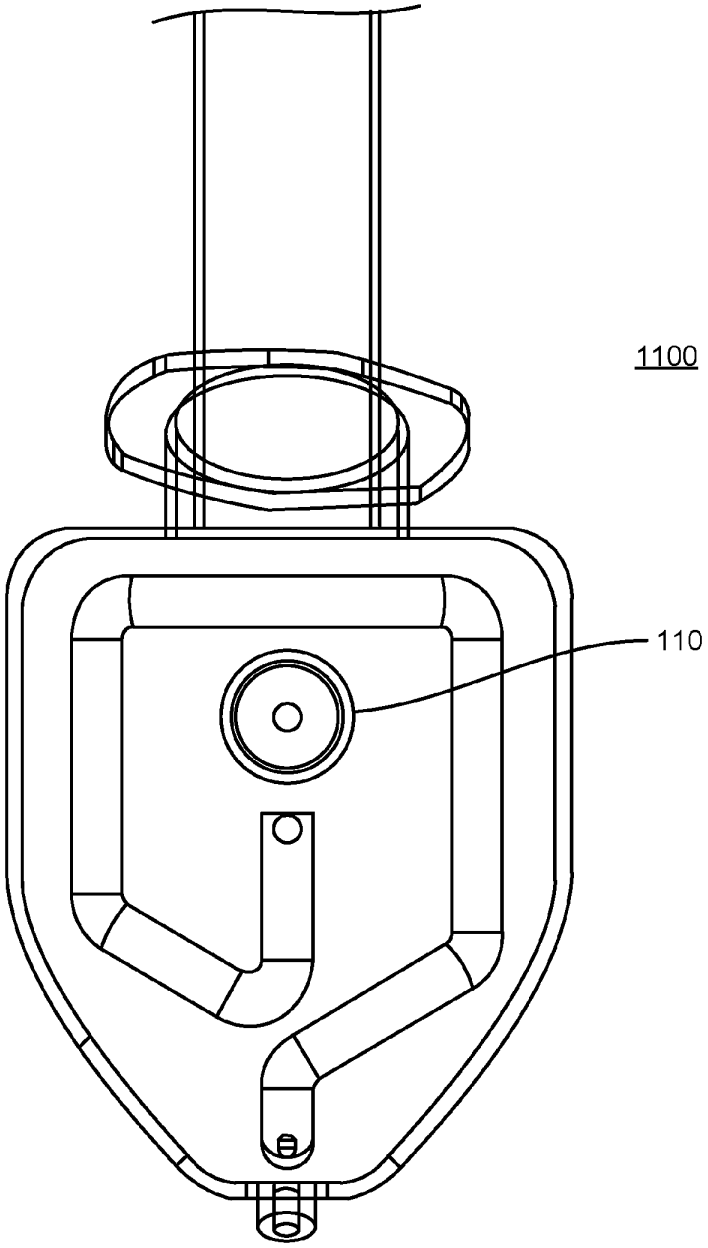


FIG. 11C

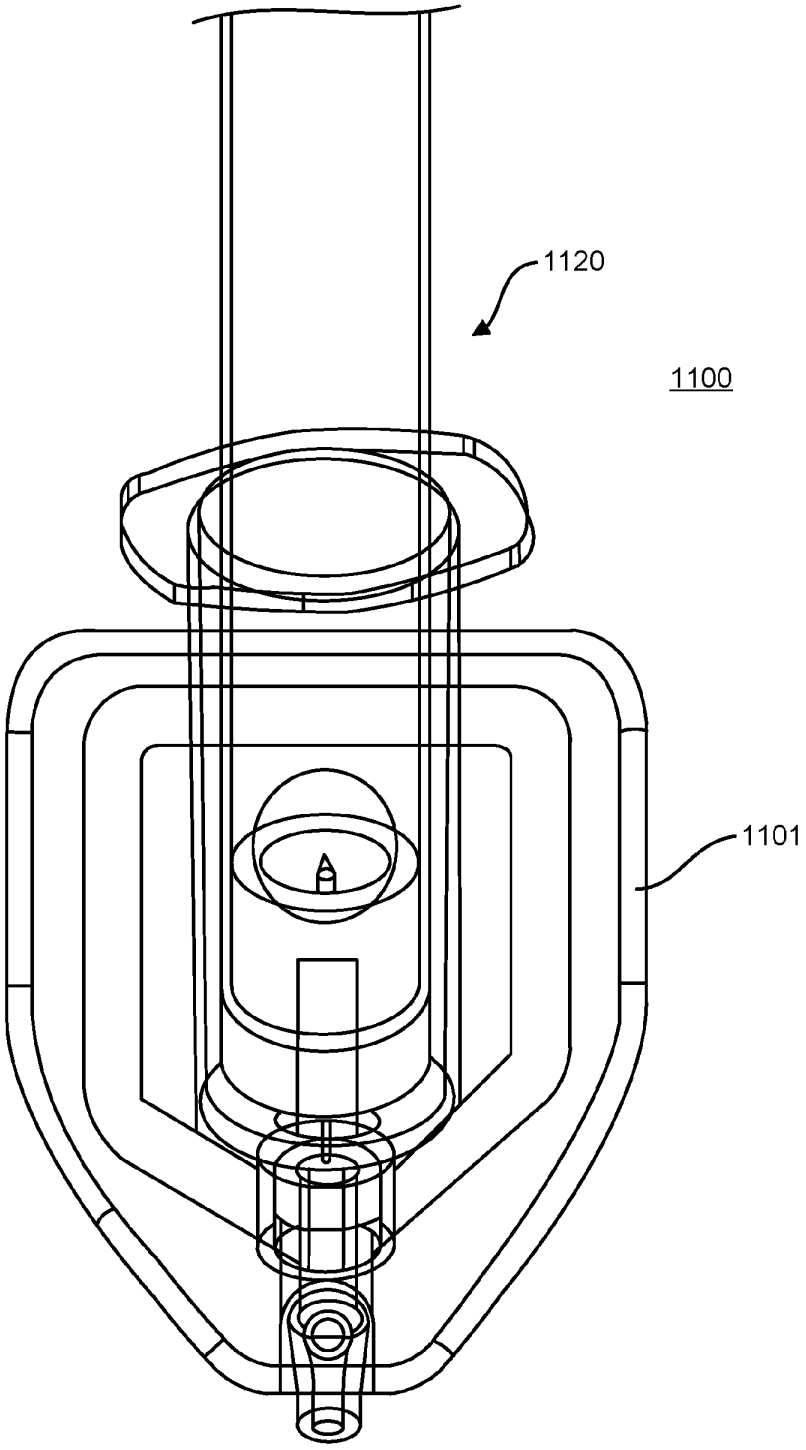


FIG. 11D

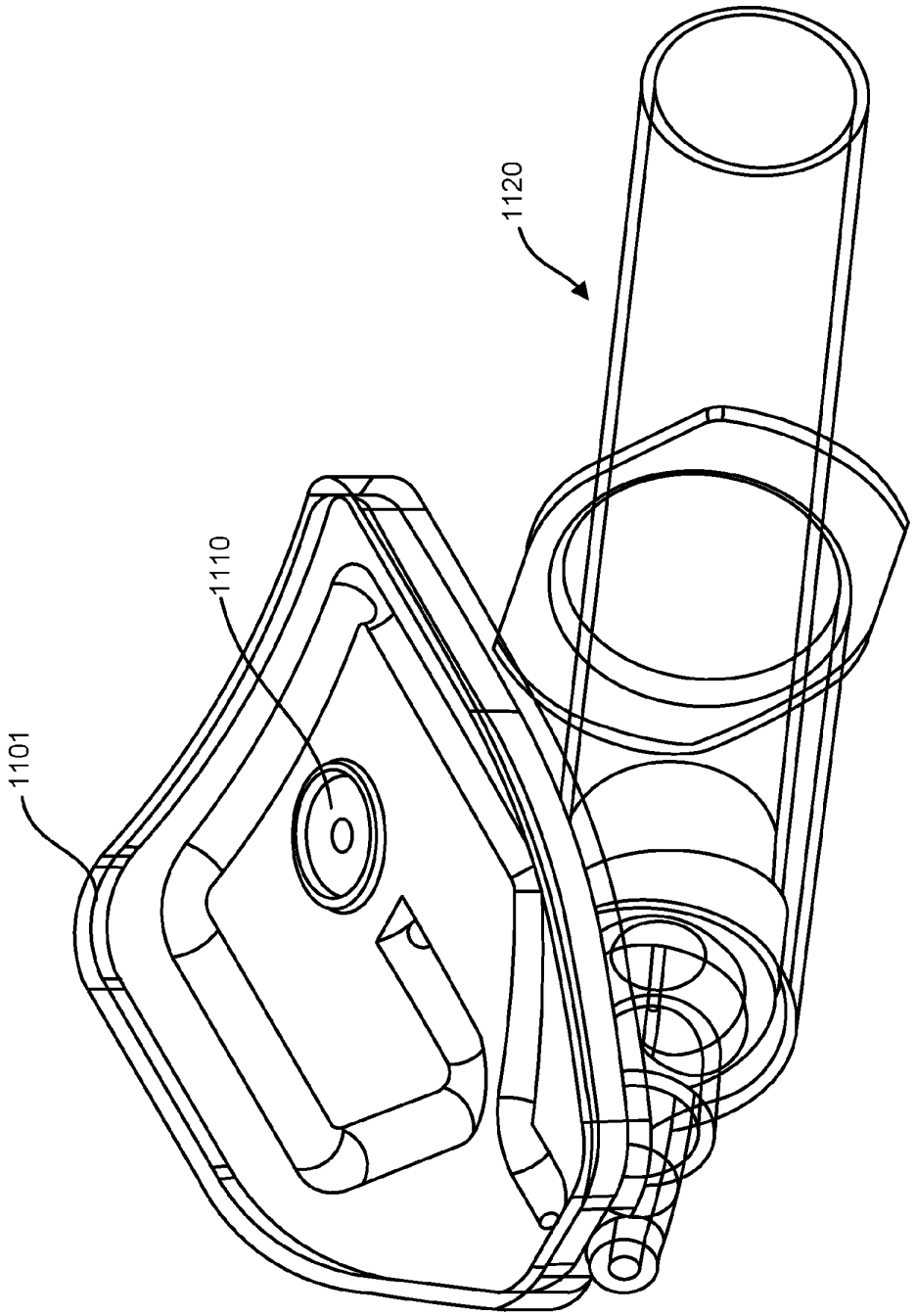


FIG. 11E

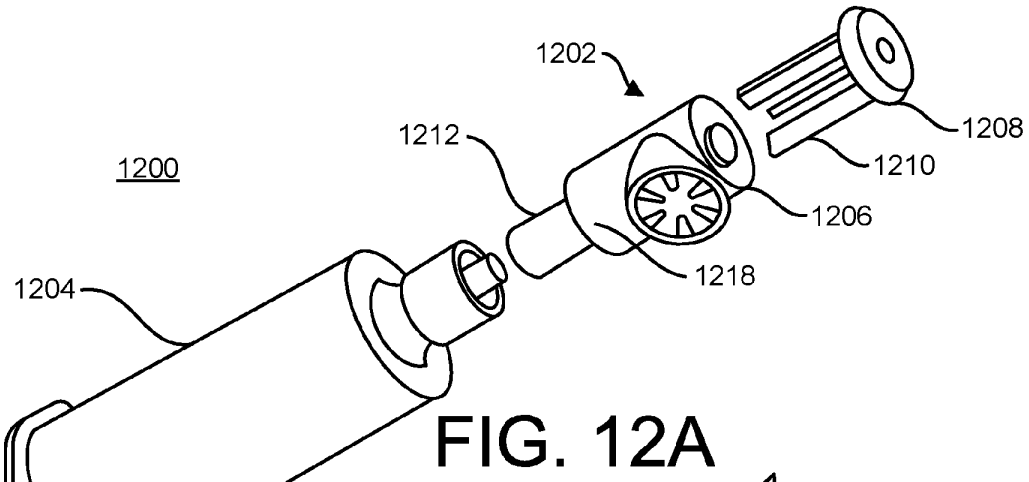


FIG. 12A

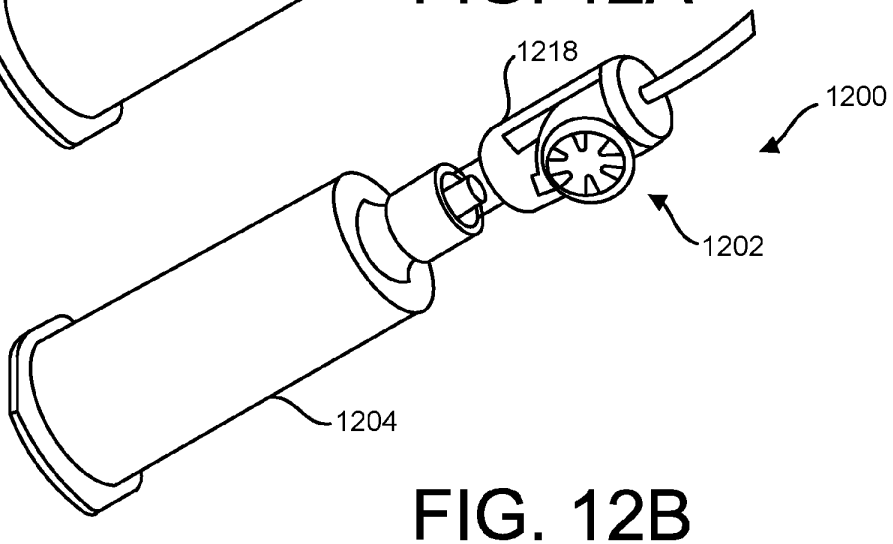


FIG. 12B

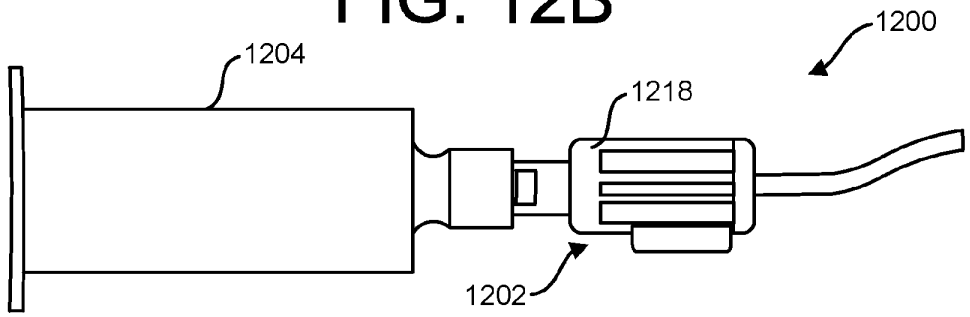


FIG. 12C

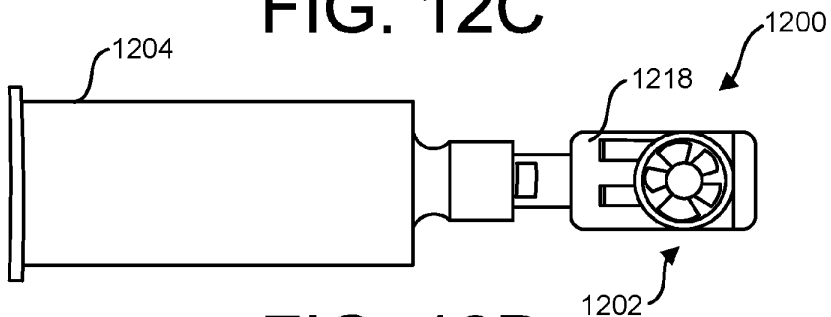


FIG. 12D

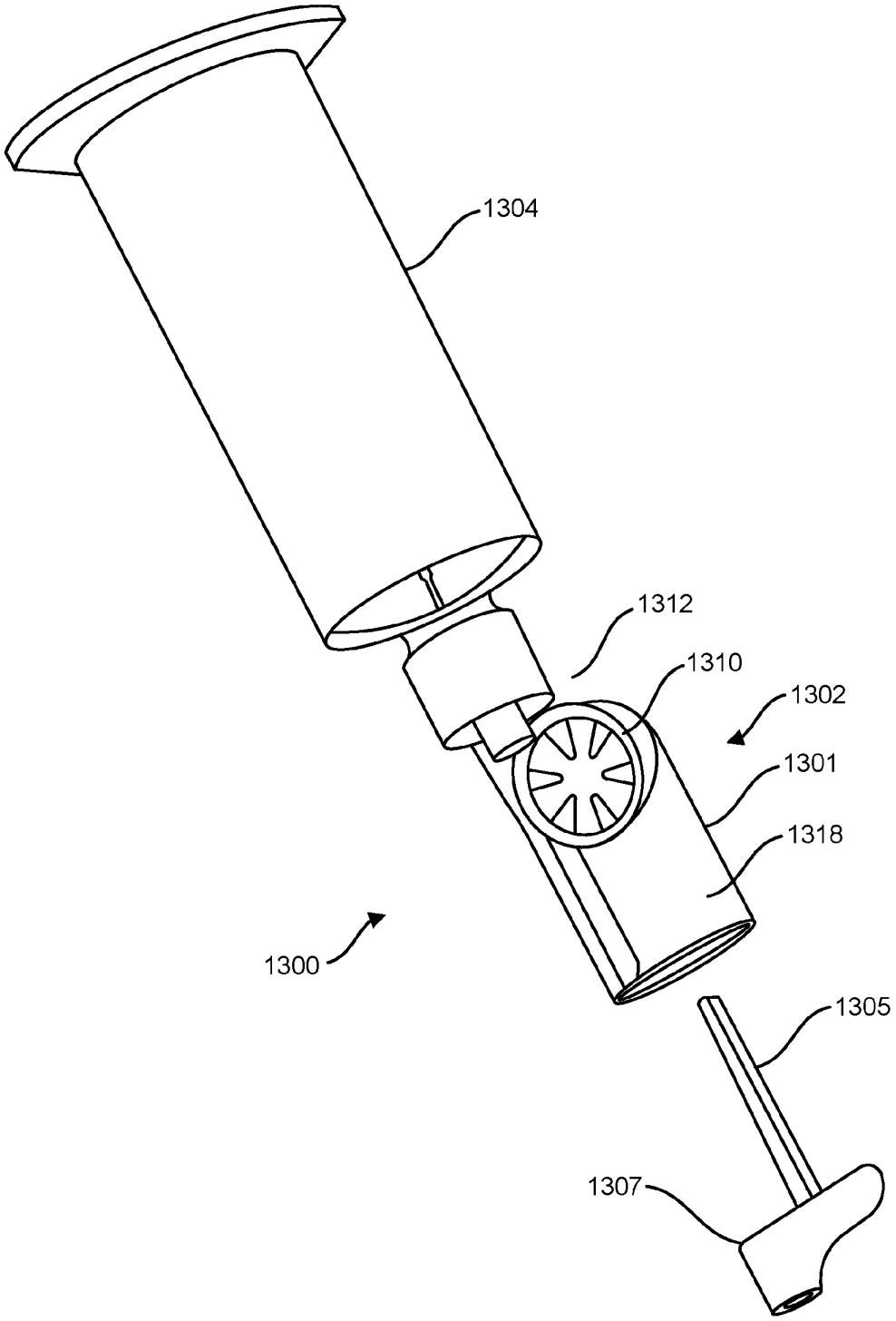


FIG. 13A

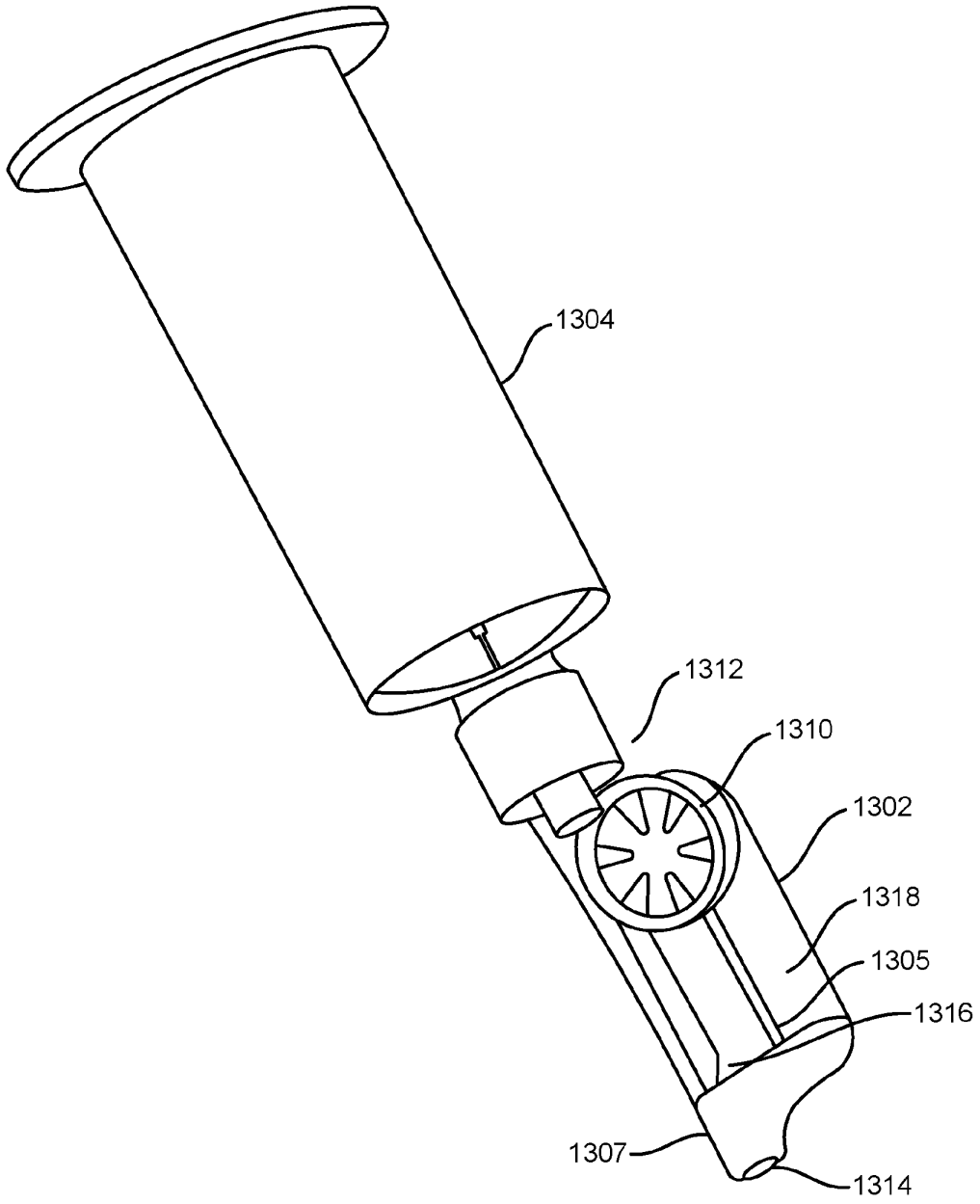


FIG. 13B

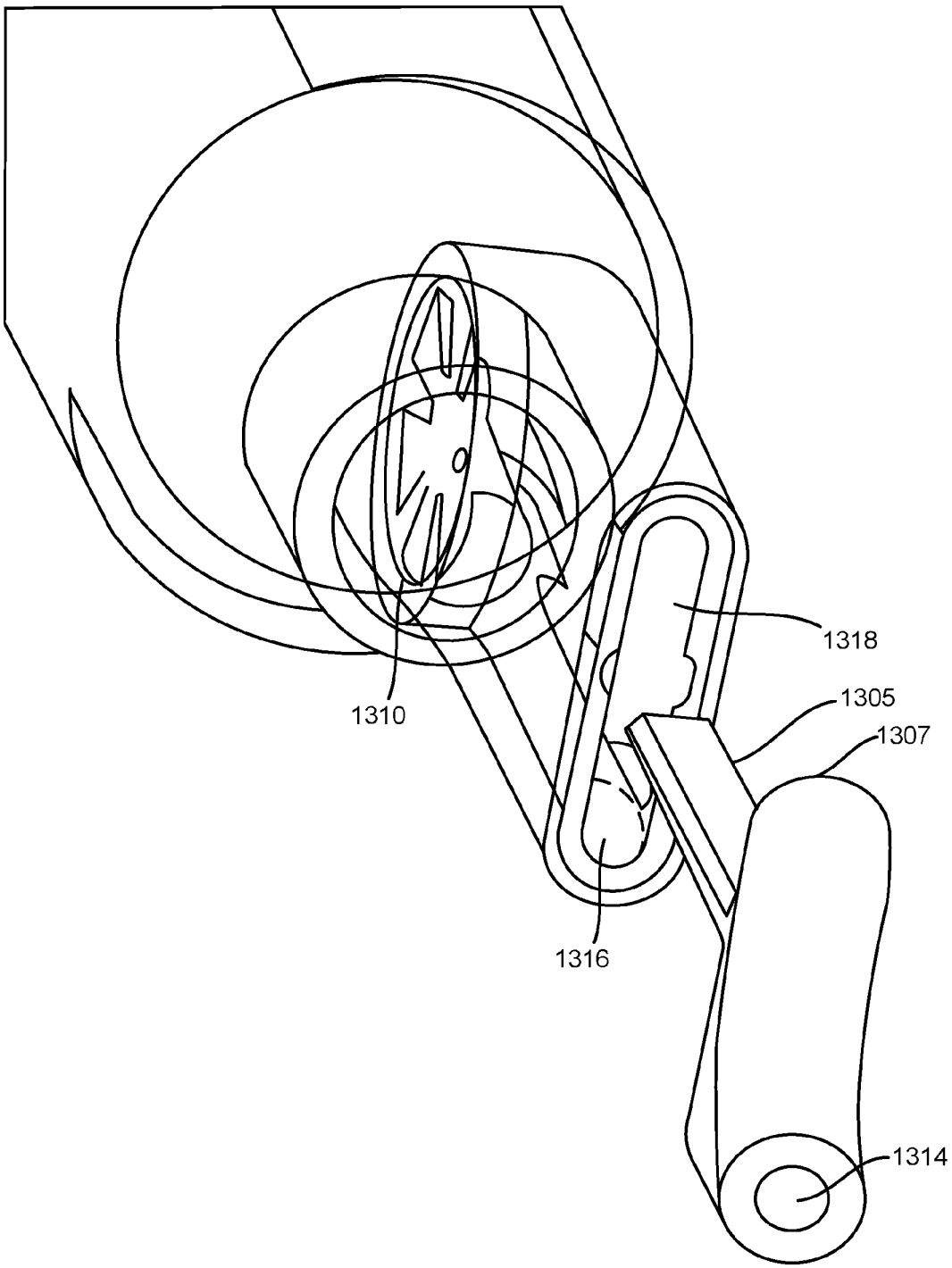


FIG. 13C

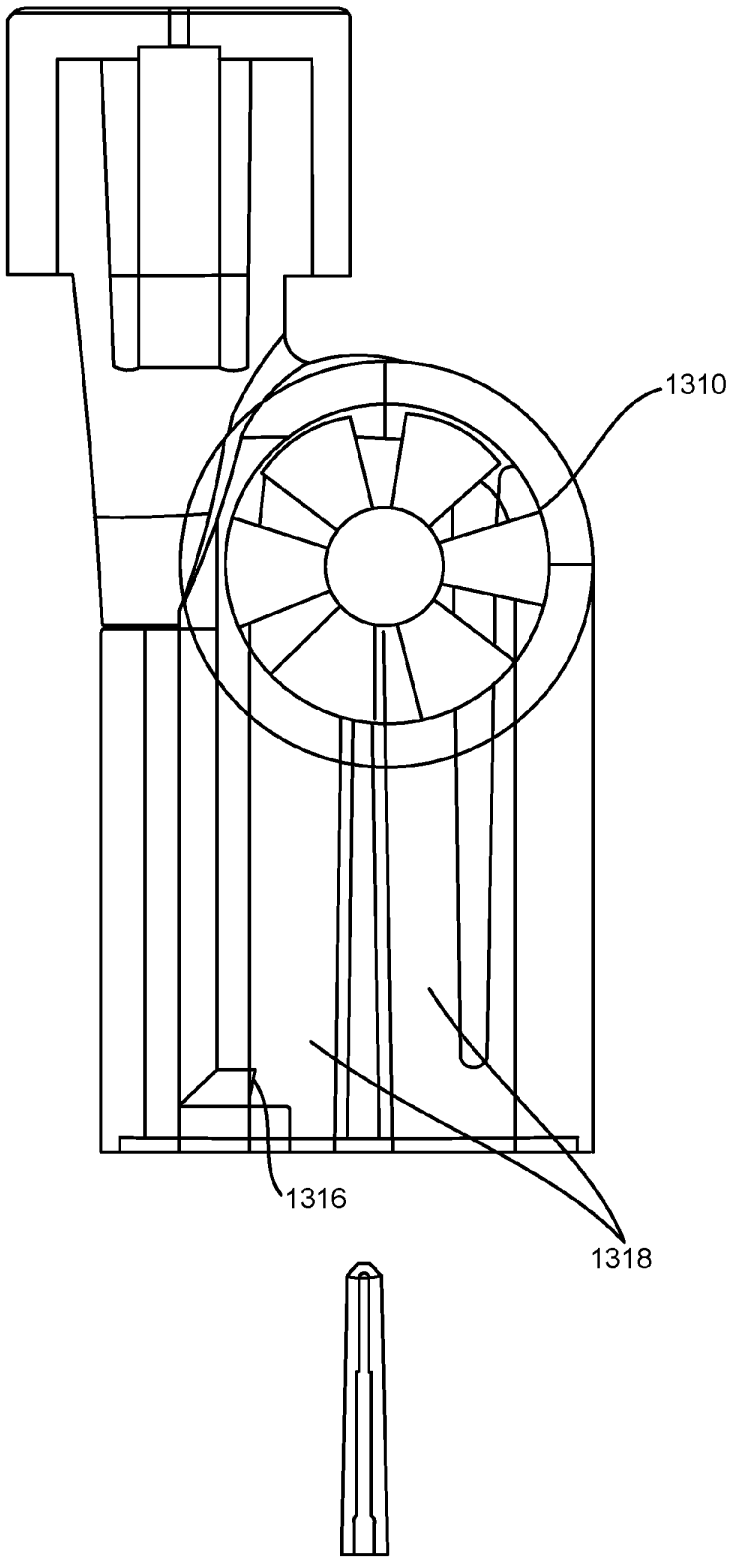


FIG. 13D

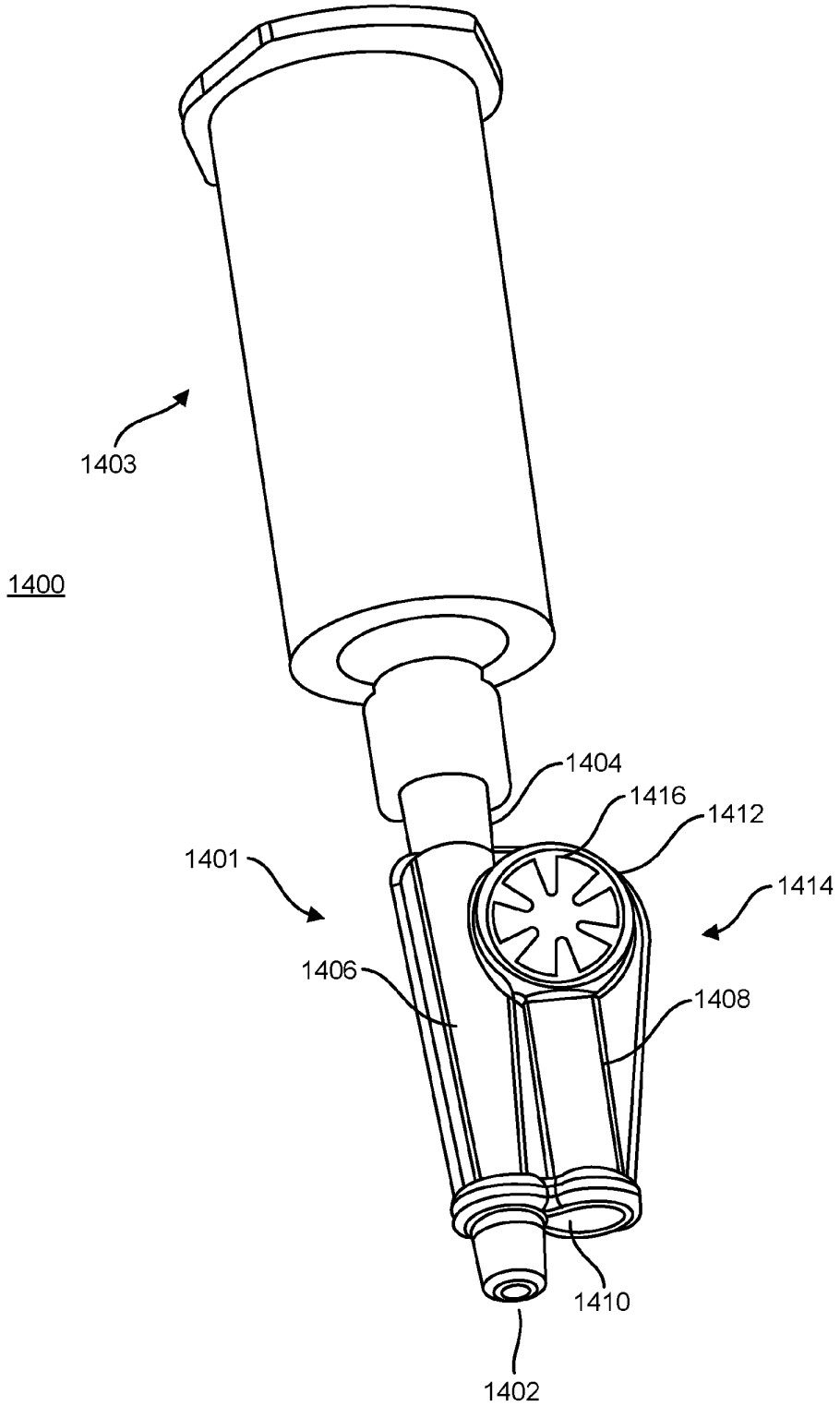


FIG. 14A

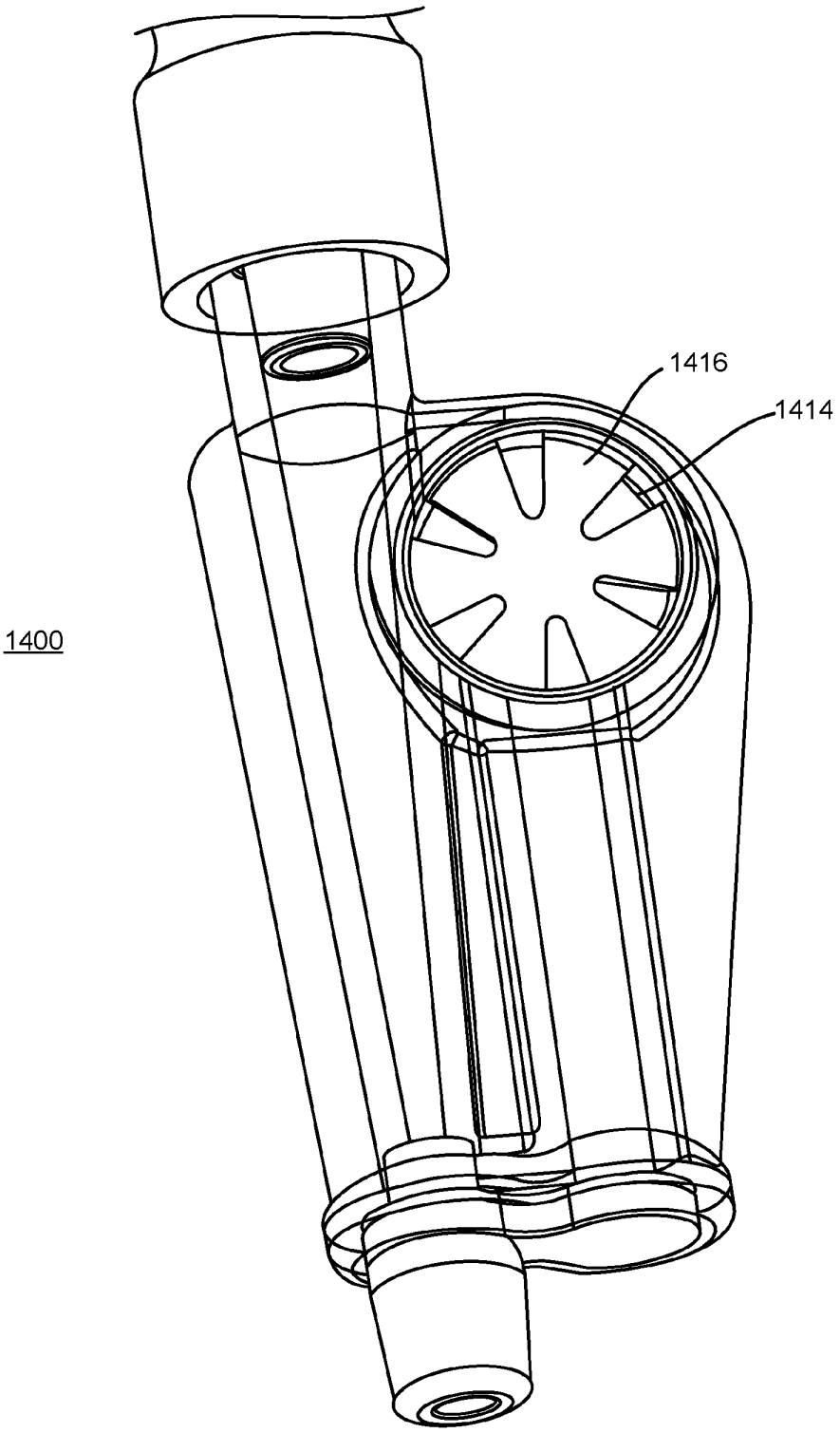


FIG. 14B

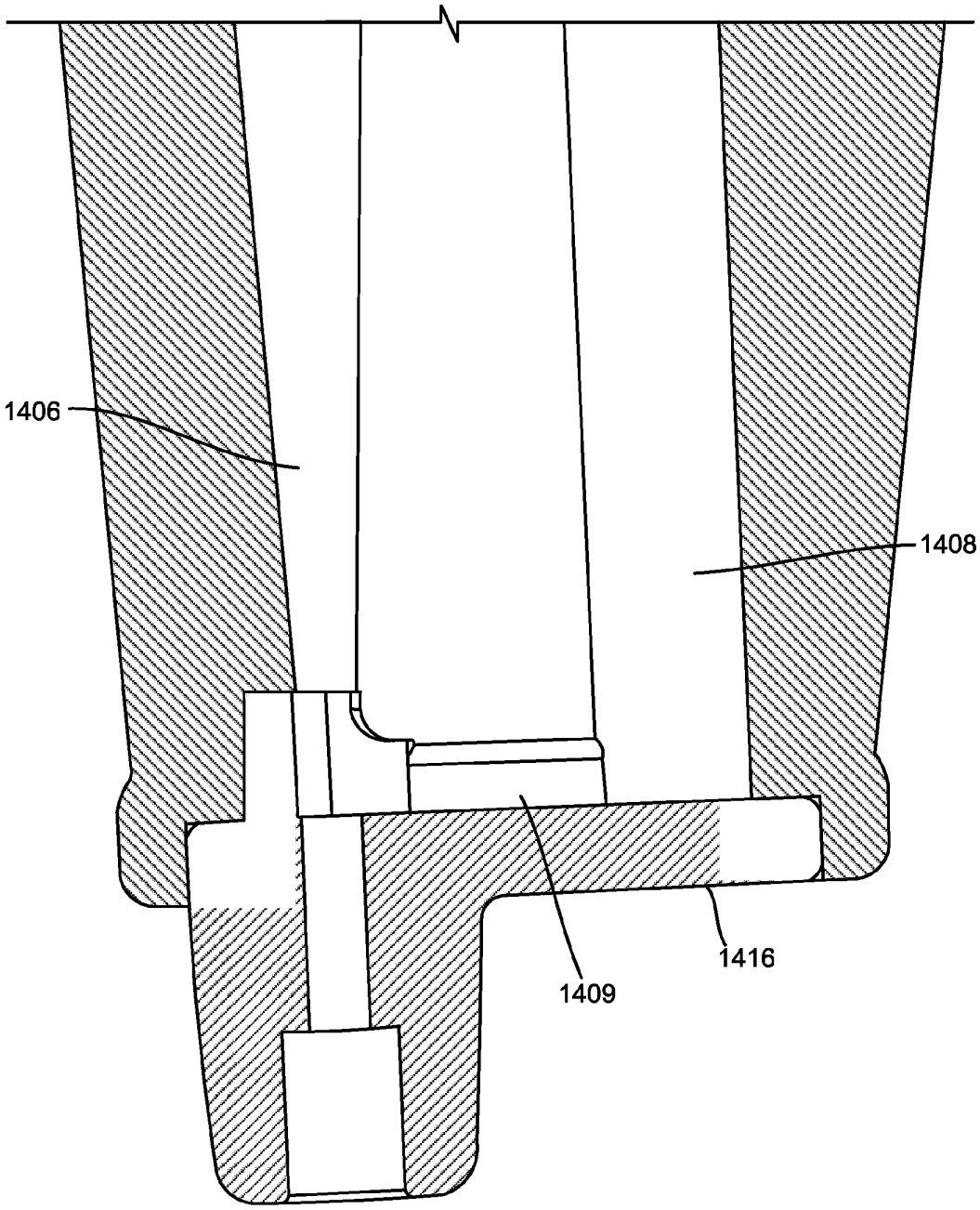


FIG. 14C

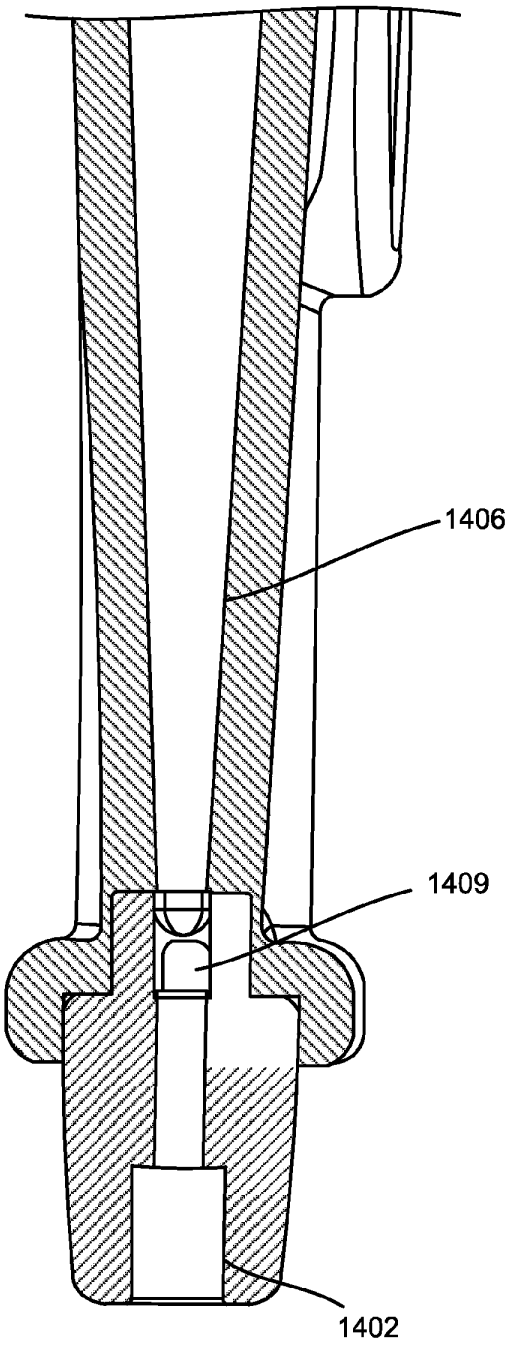


FIG. 14D

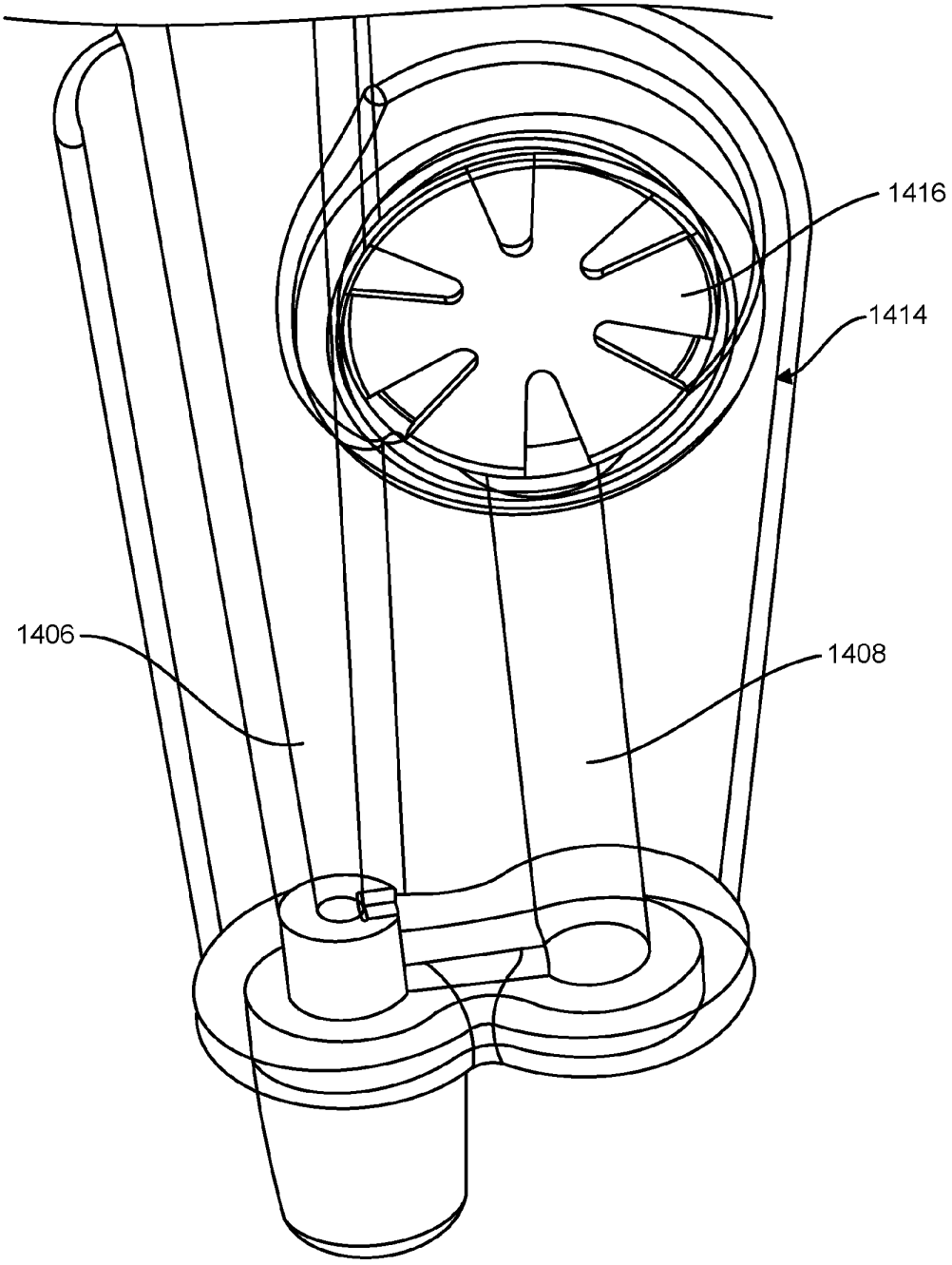


FIG. 14E

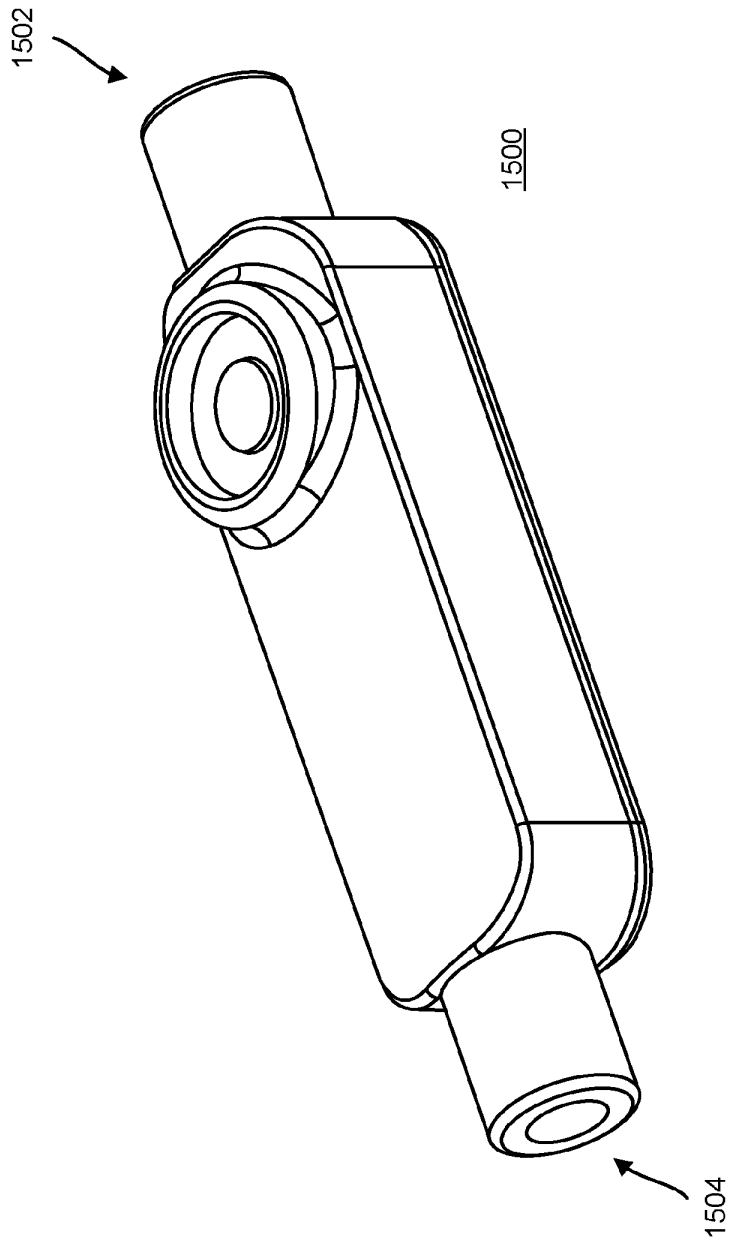


FIG. 15A

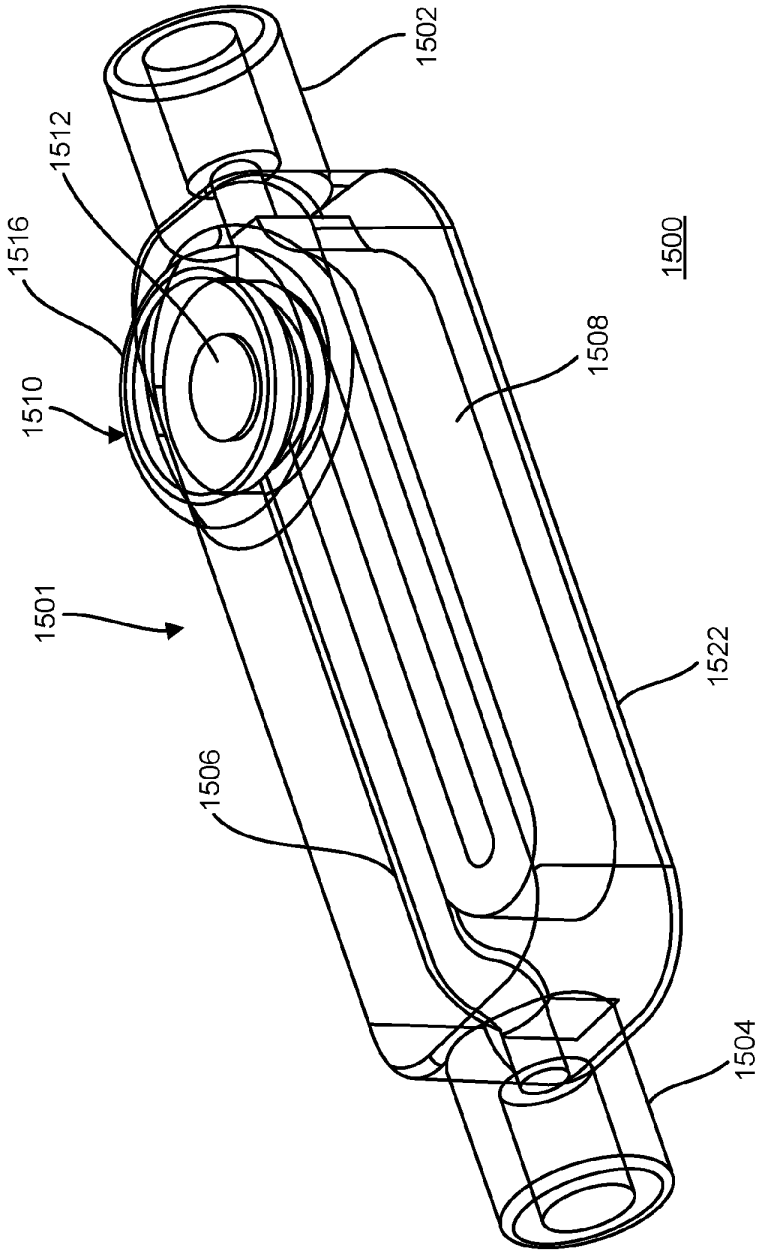


FIG. 15B

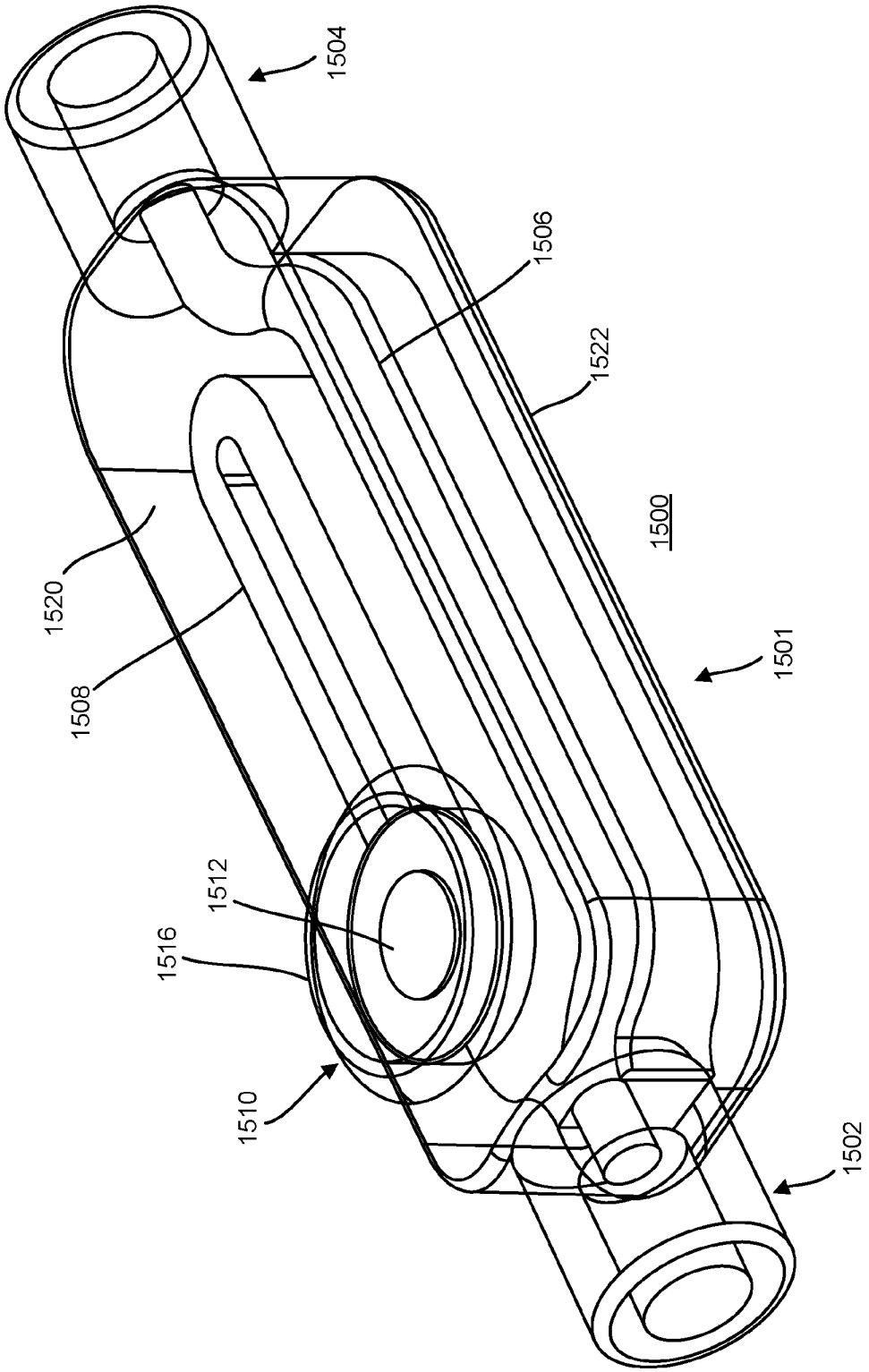


FIG. 15C

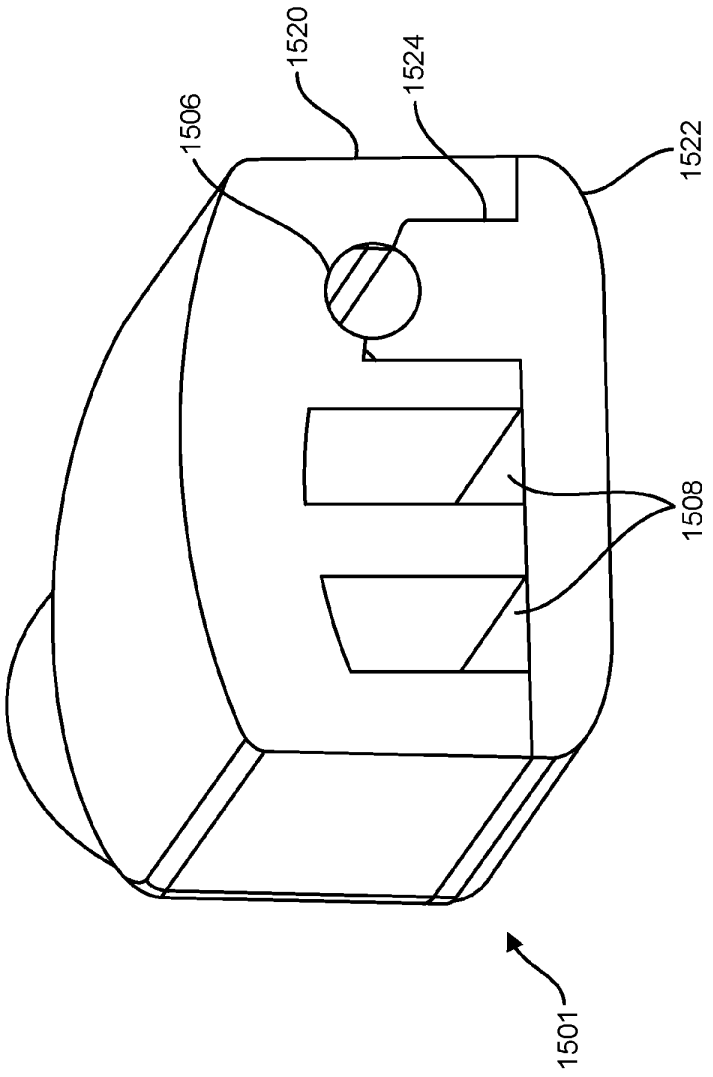


FIG. 15D

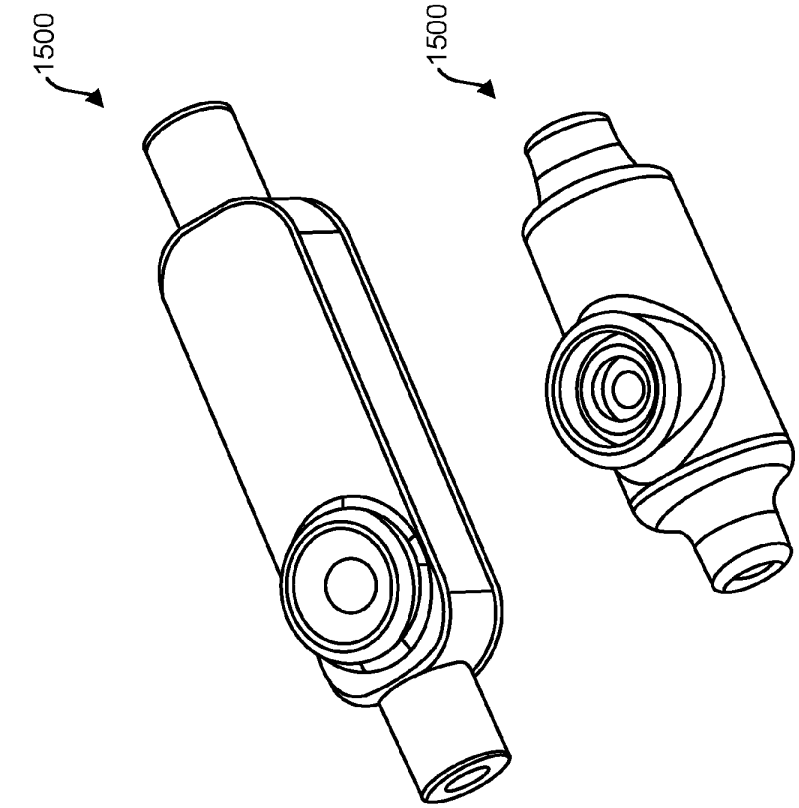


FIG. 15F

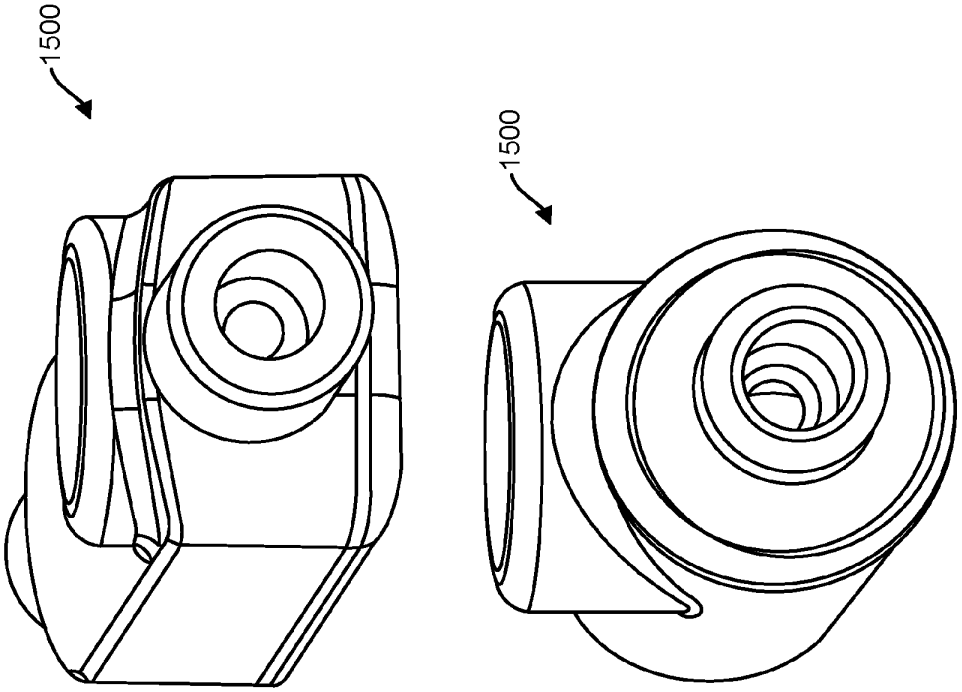


FIG. 15E

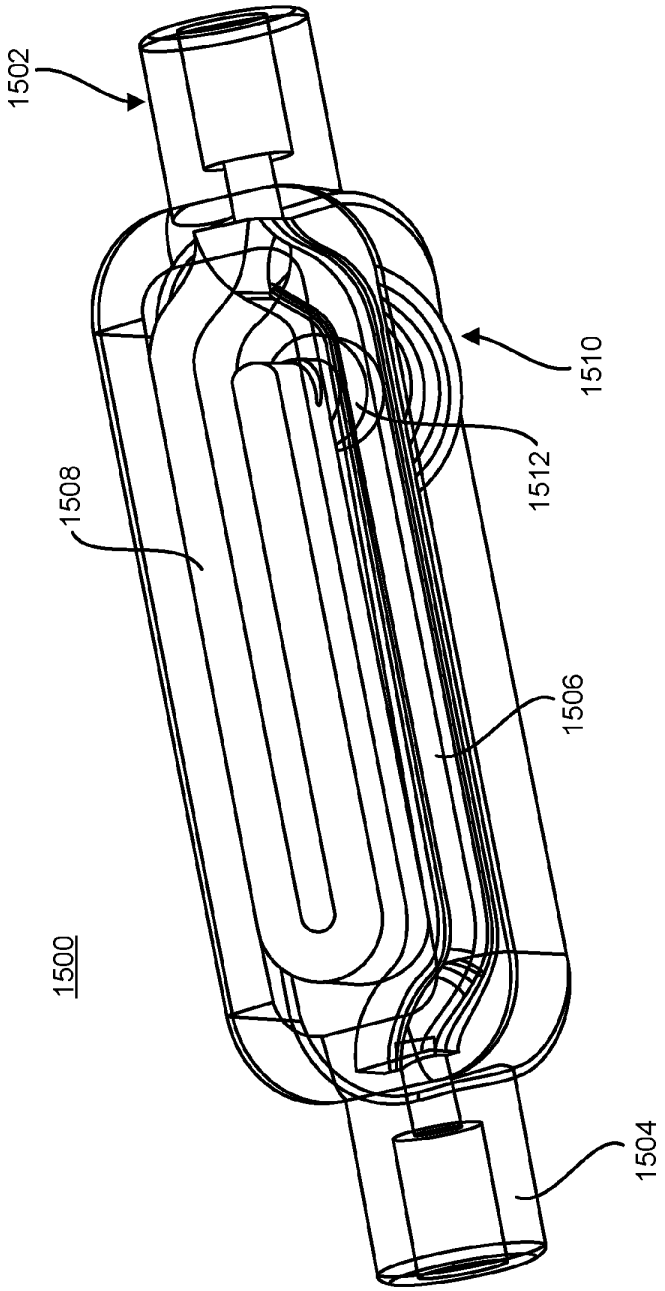


FIG. 15G

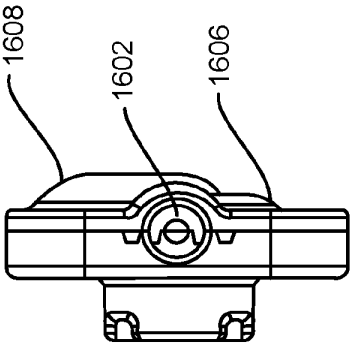


FIG. 16C

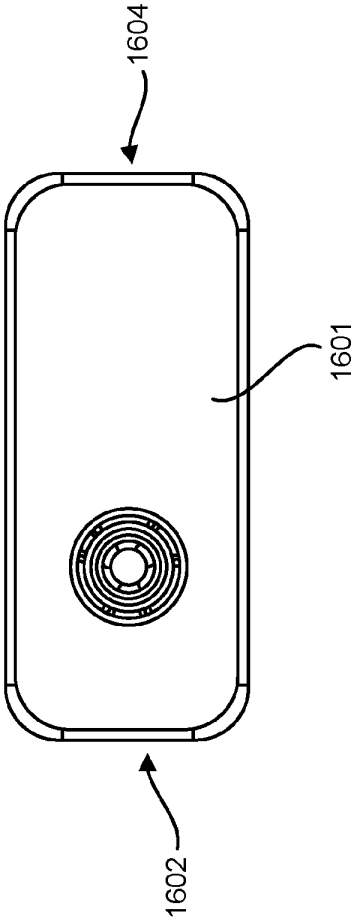


FIG. 16A

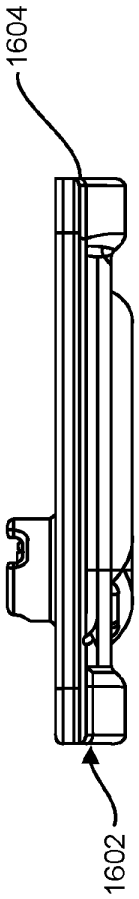


FIG. 16B

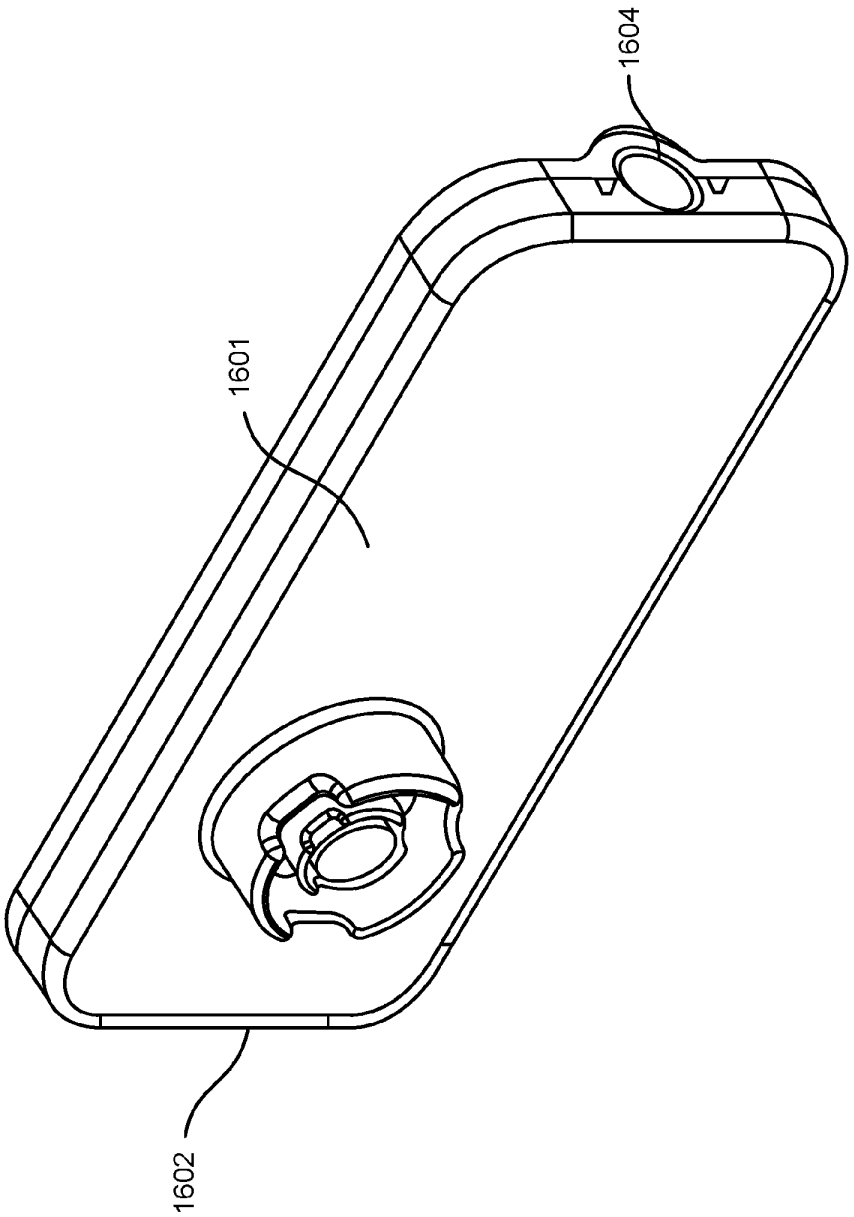


FIG. 16D

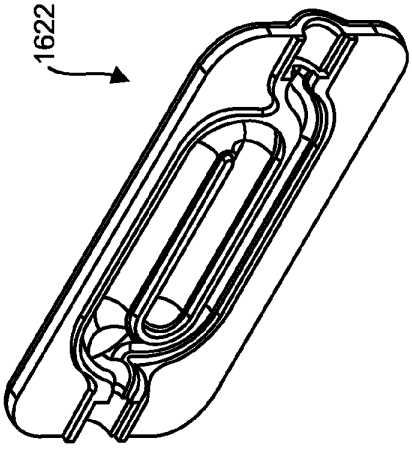


FIG. 17B



FIG. 17E

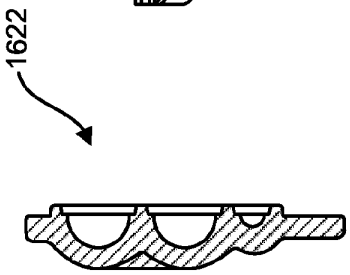


FIG. 17D

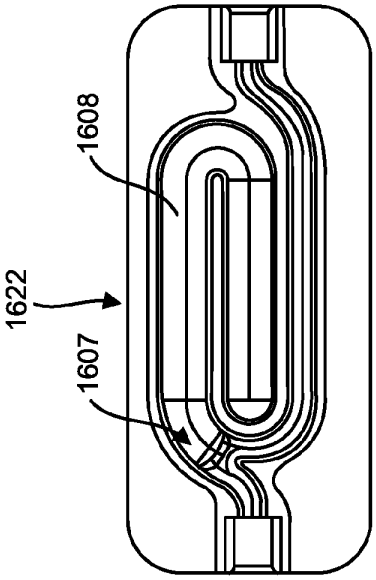


FIG. 17A

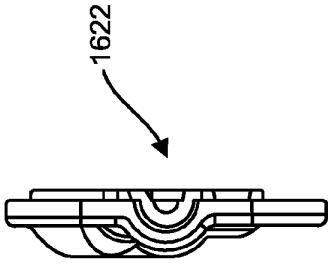


FIG. 17C

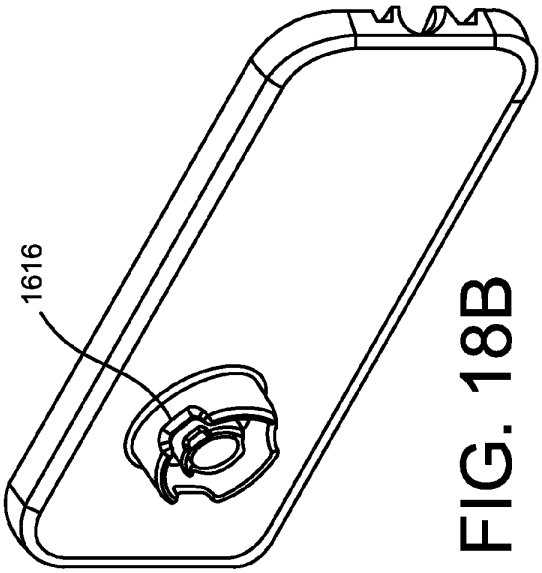


FIG. 18B

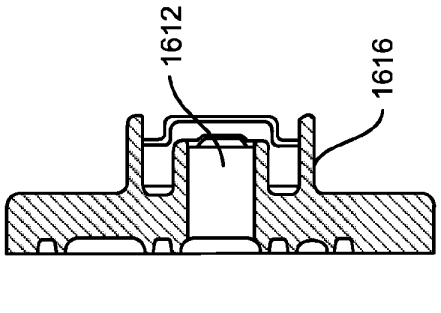


FIG. 18F

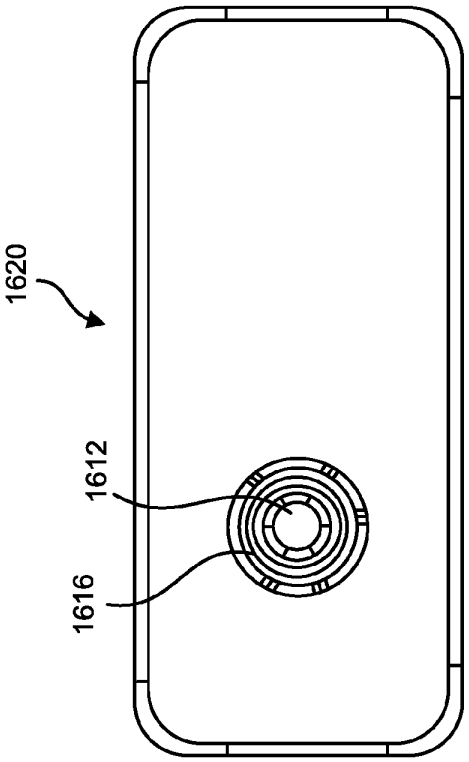


FIG. 18A

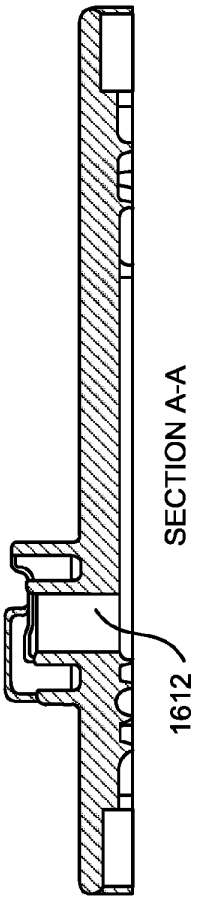


FIG. 18D

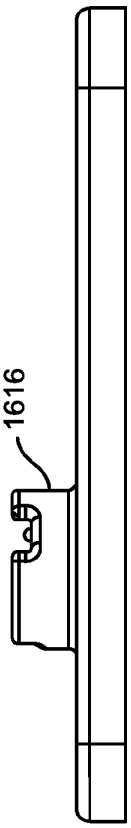


FIG. 18E

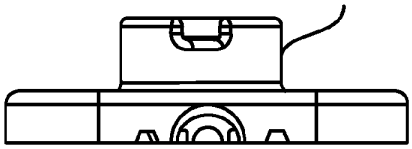


FIG. 18C

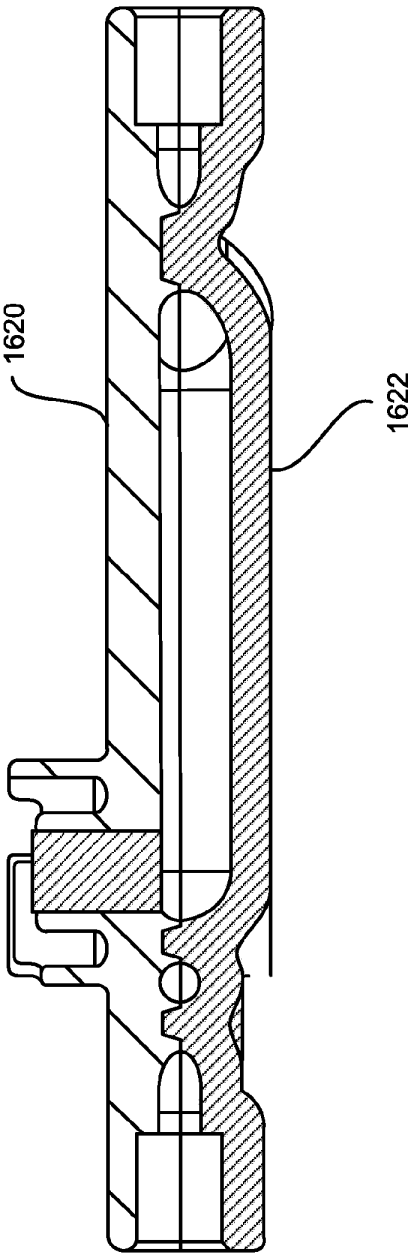


FIG. 19A

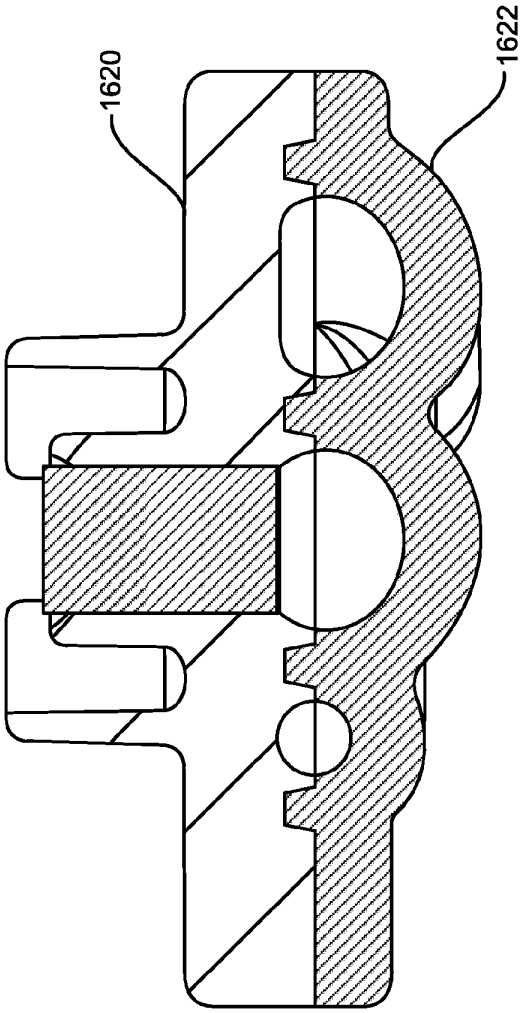


FIG. 19B

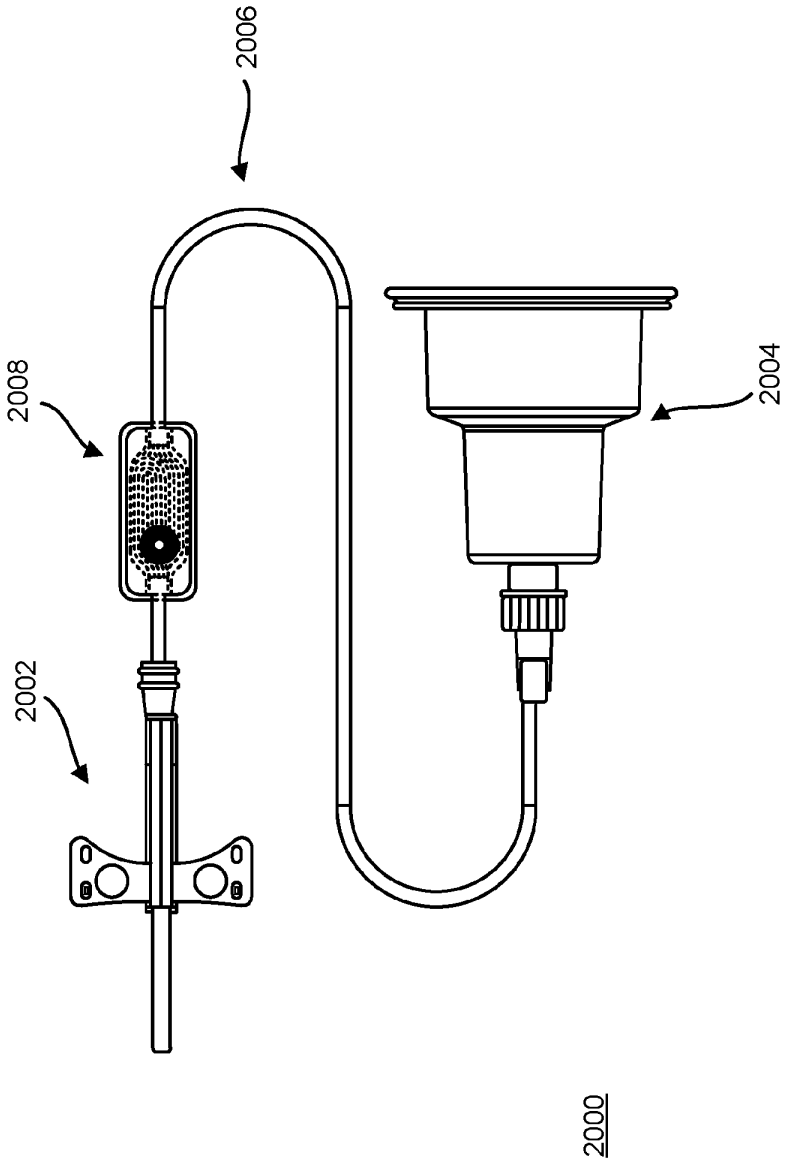


FIG. 20

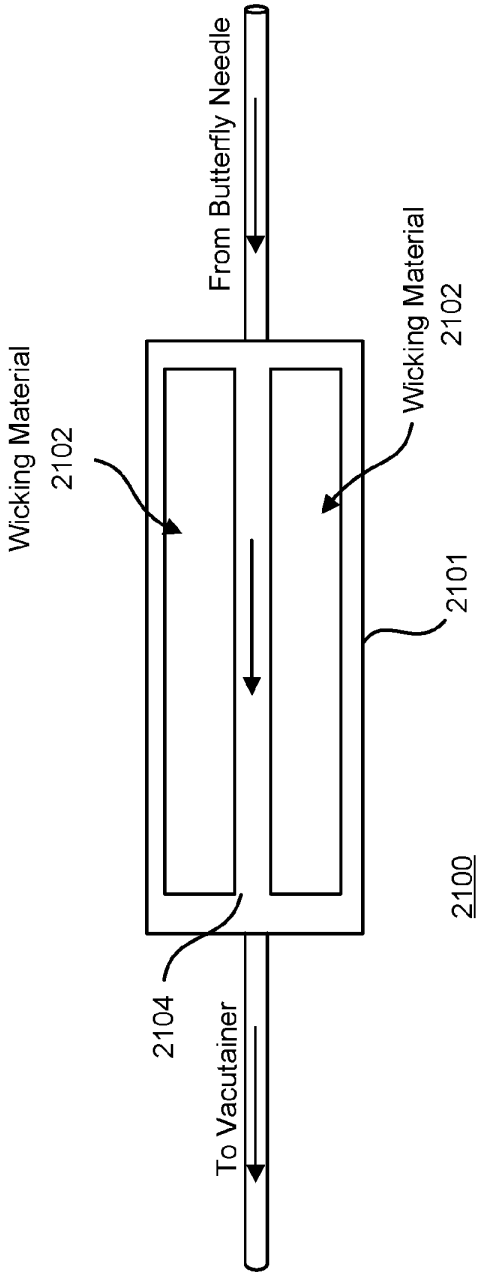

From Butterfly Needle
Wicking Material
2102
Wicking Material
2102
2101
2100
2104
To Vacutainer

FIG. 21

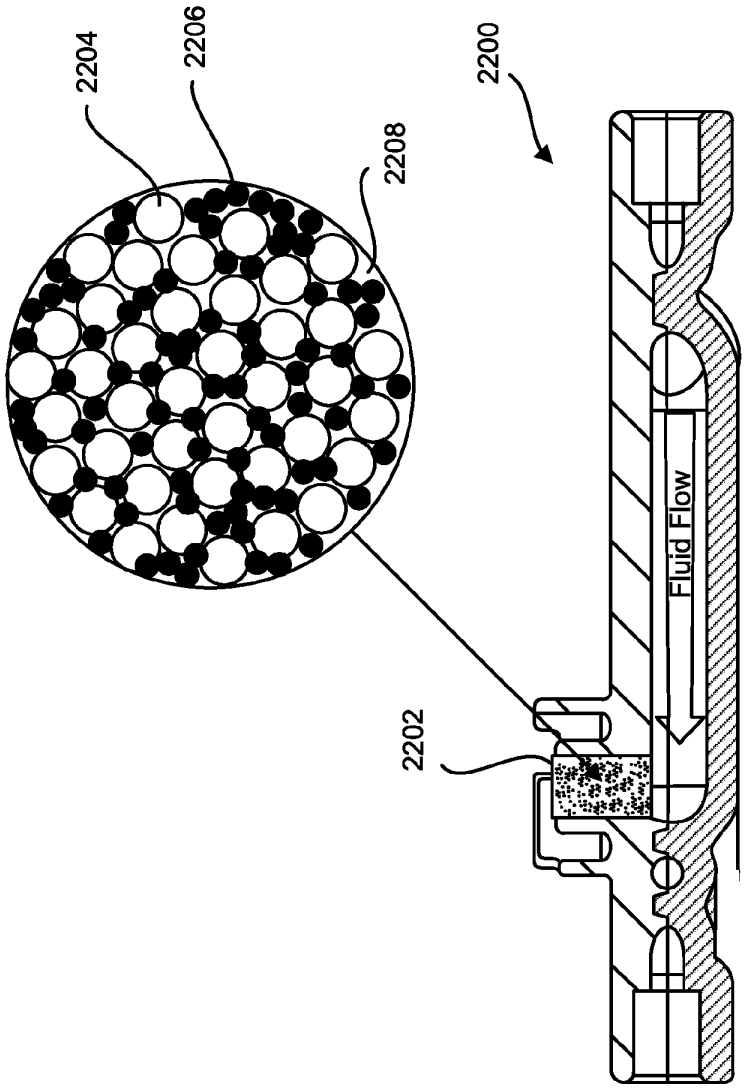


FIG. 22A

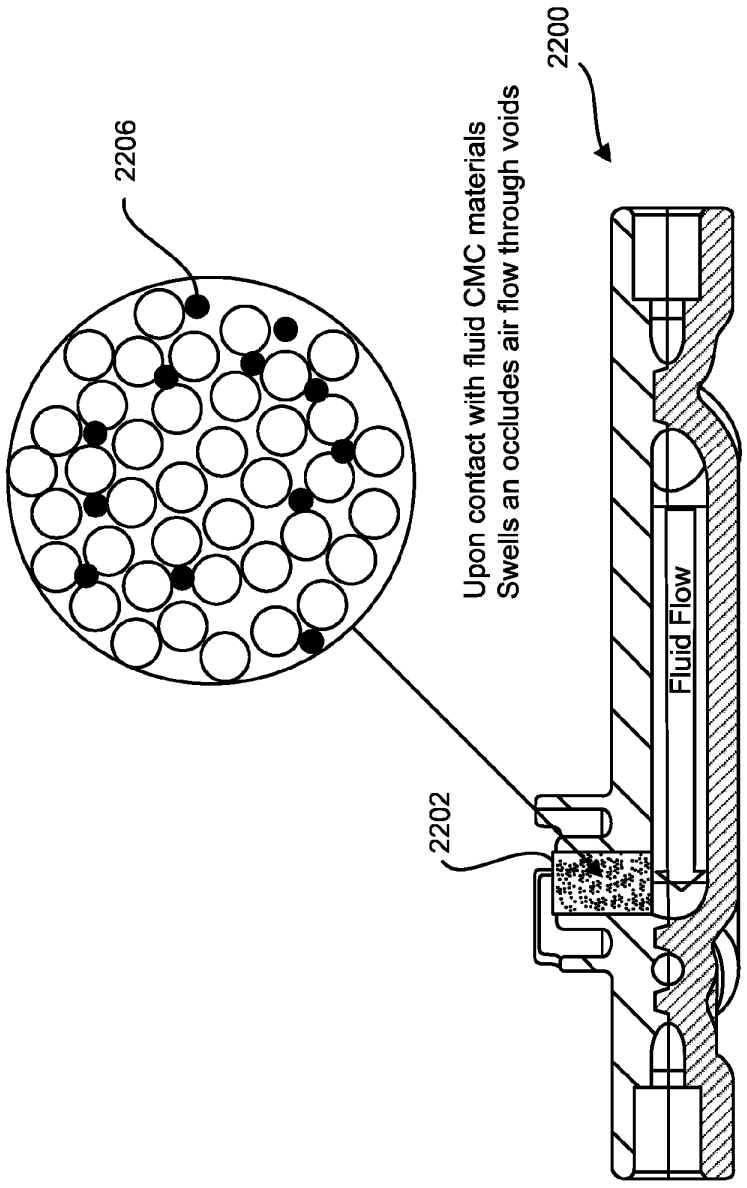

2200
2206
Upon contact with fluid CMC materials
Swells an occludes air flow through voids
Fluid Flow
2202

FIG. 22B

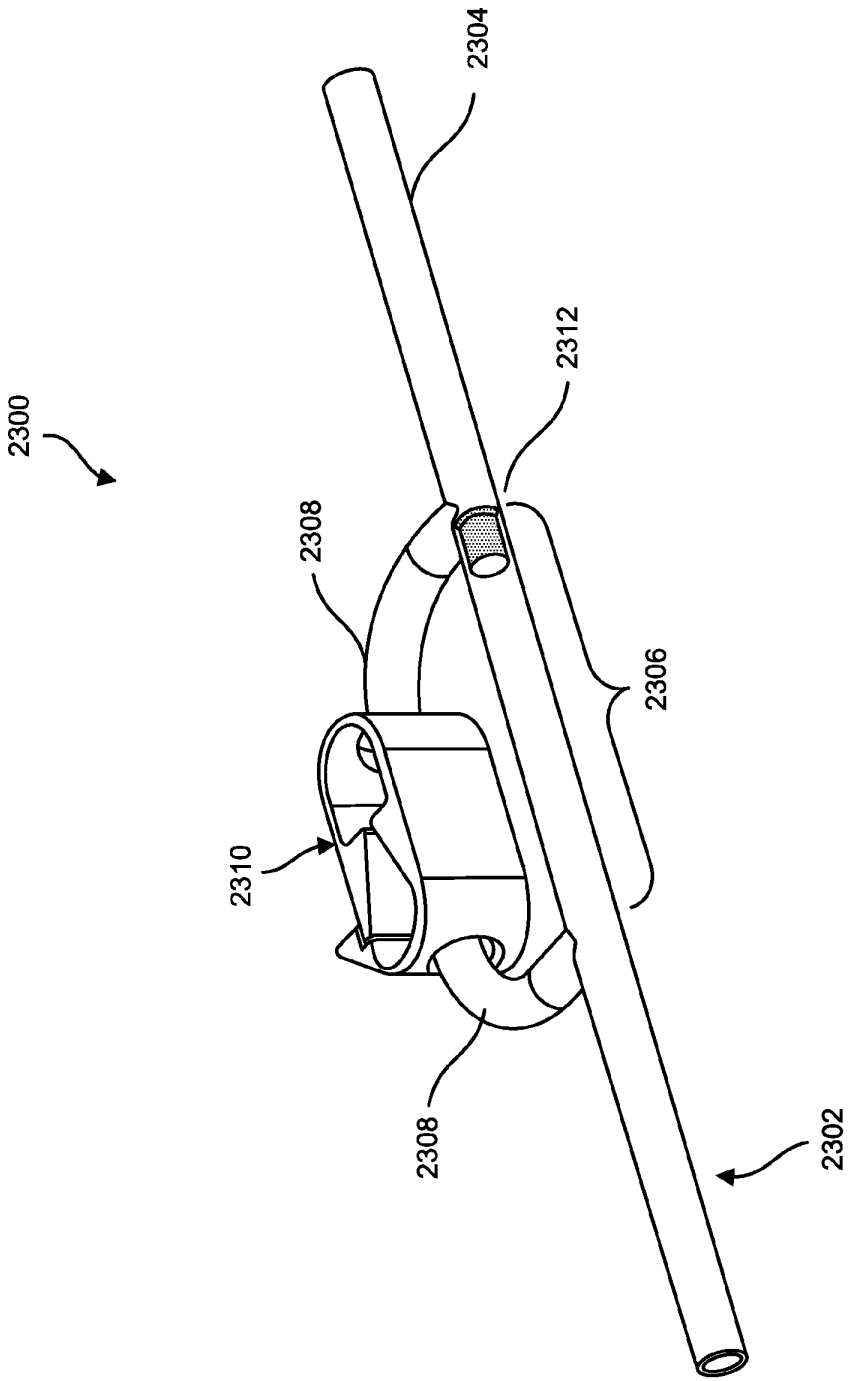


FIG. 23A

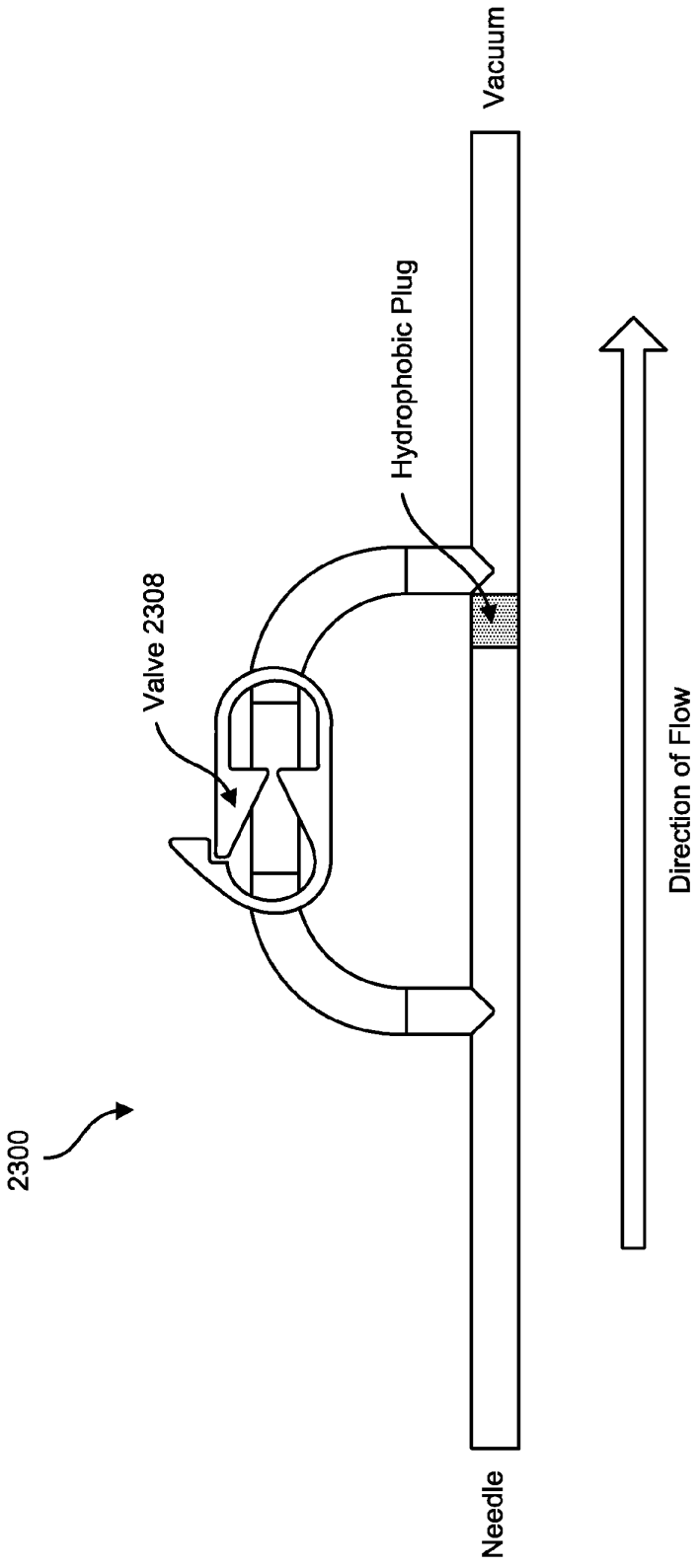

Vacuum
Hydrophobic Plug
Valve 2308
Direction of Flow
2300
Needle

FIG. 23B

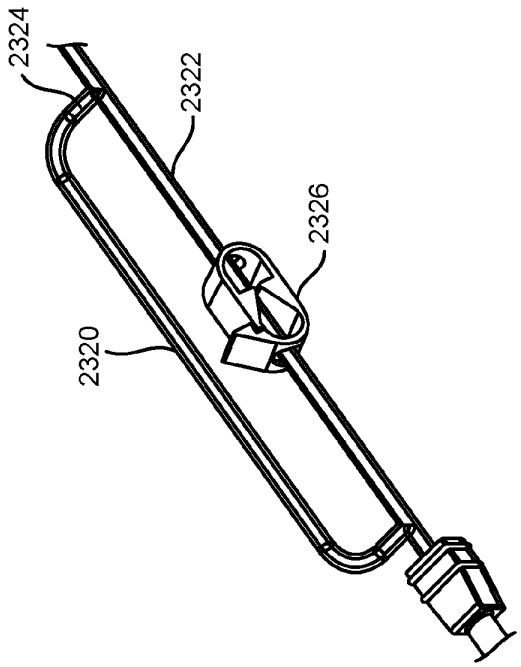


FIG. 23D

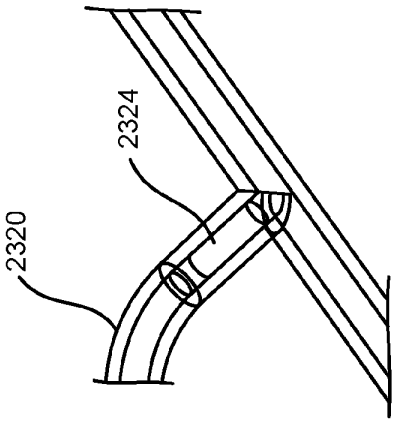


FIG. 23E

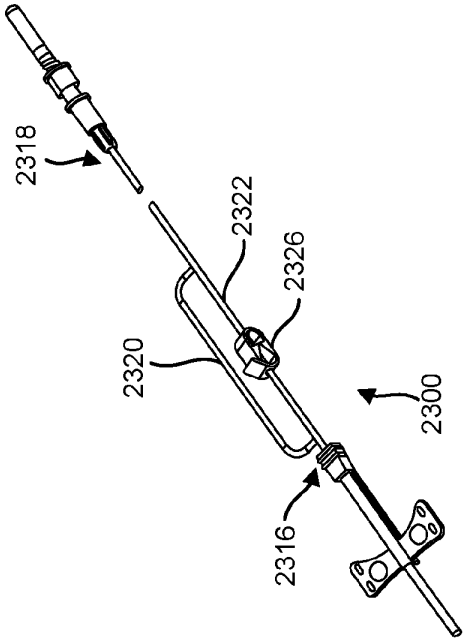


FIG. 23C

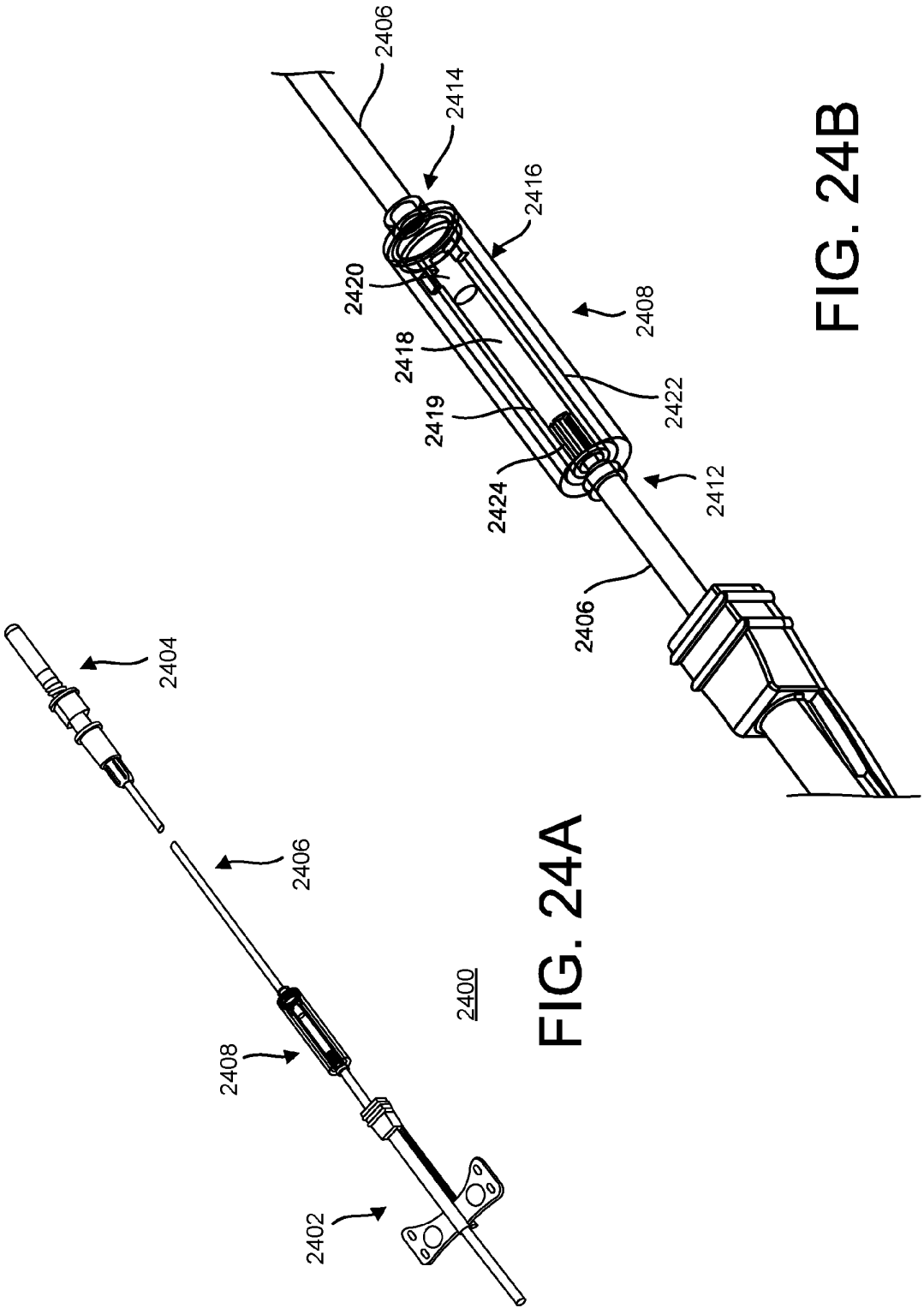


FIG. 24B

FIG. 24A

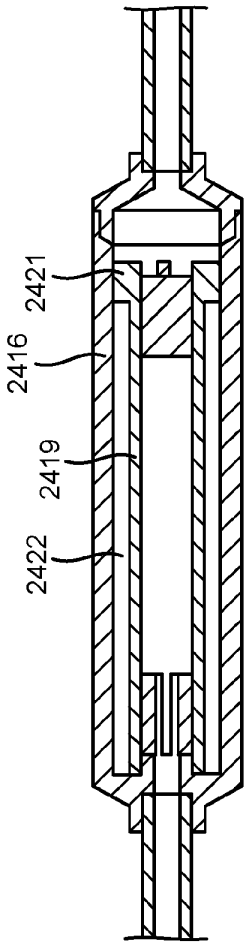


FIG. 24C

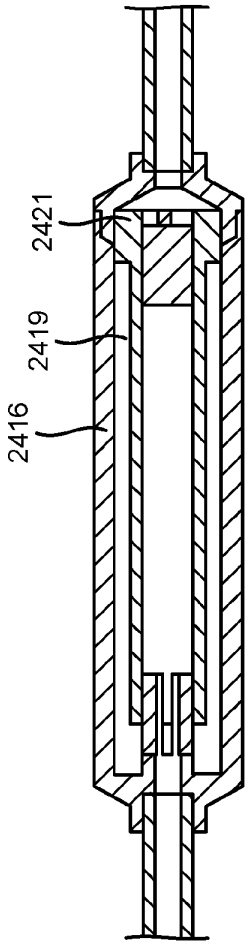


FIG. 24D

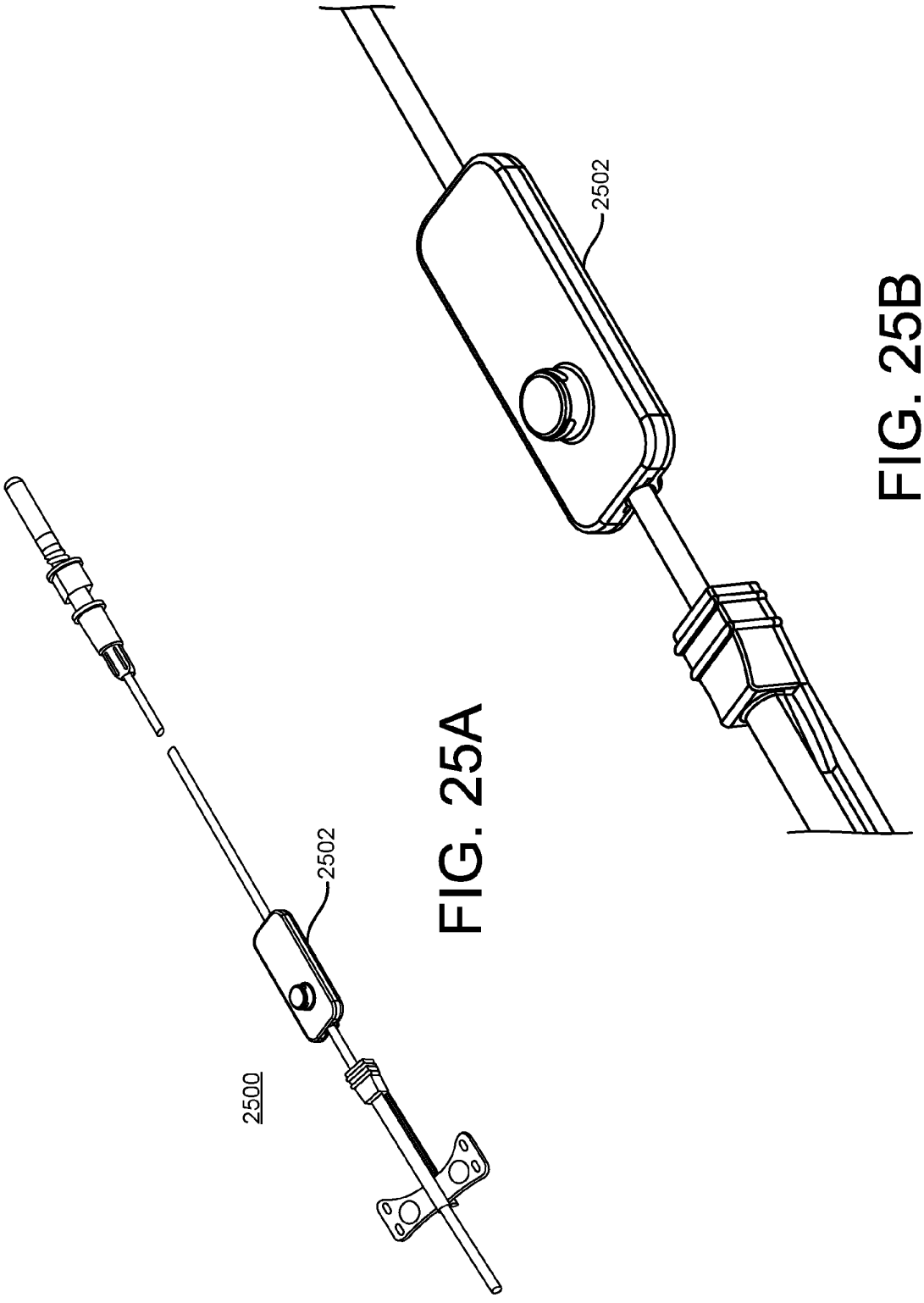


FIG. 25A

FIG. 25B

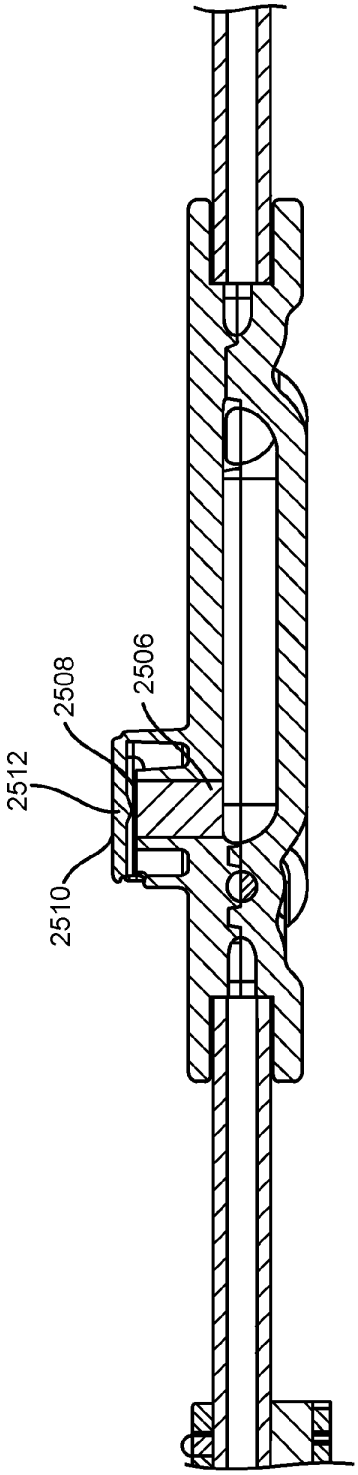


FIG. 25C

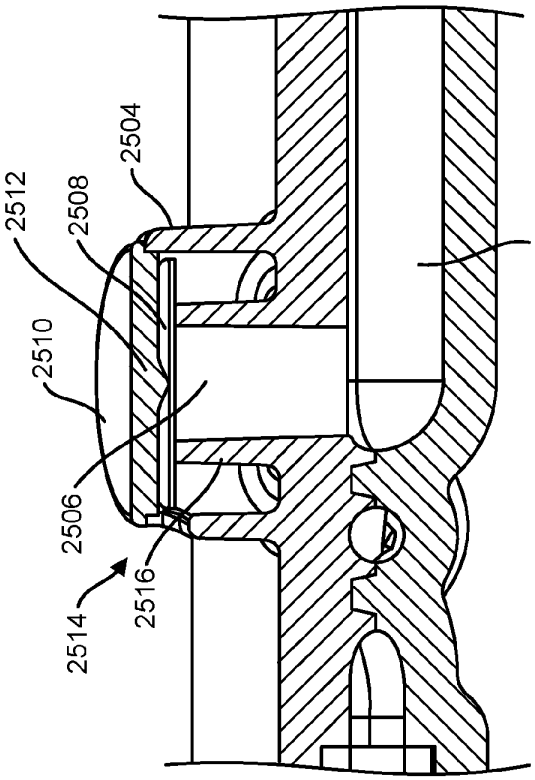


FIG. 25D

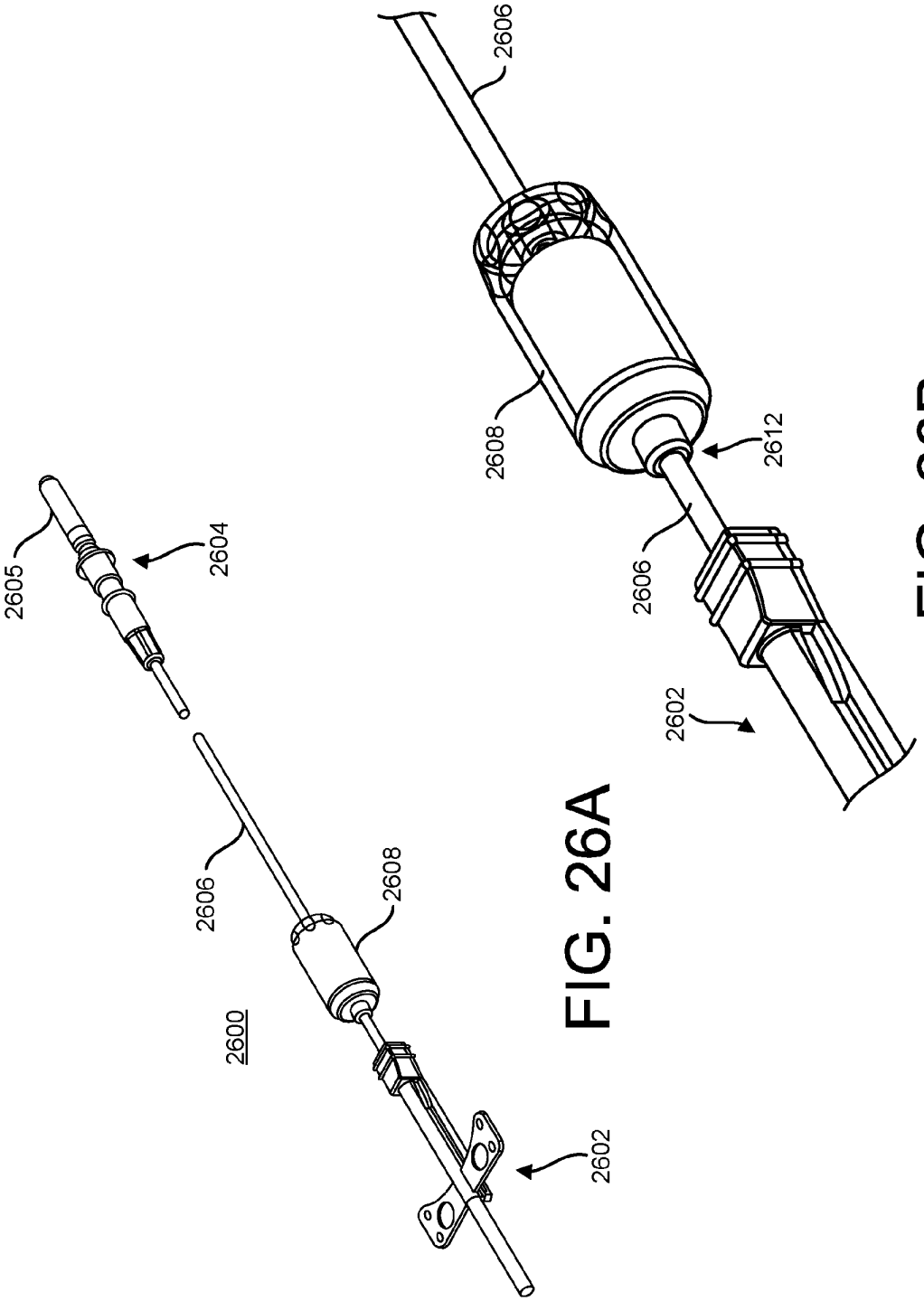


FIG. 26A

FIG. 26B

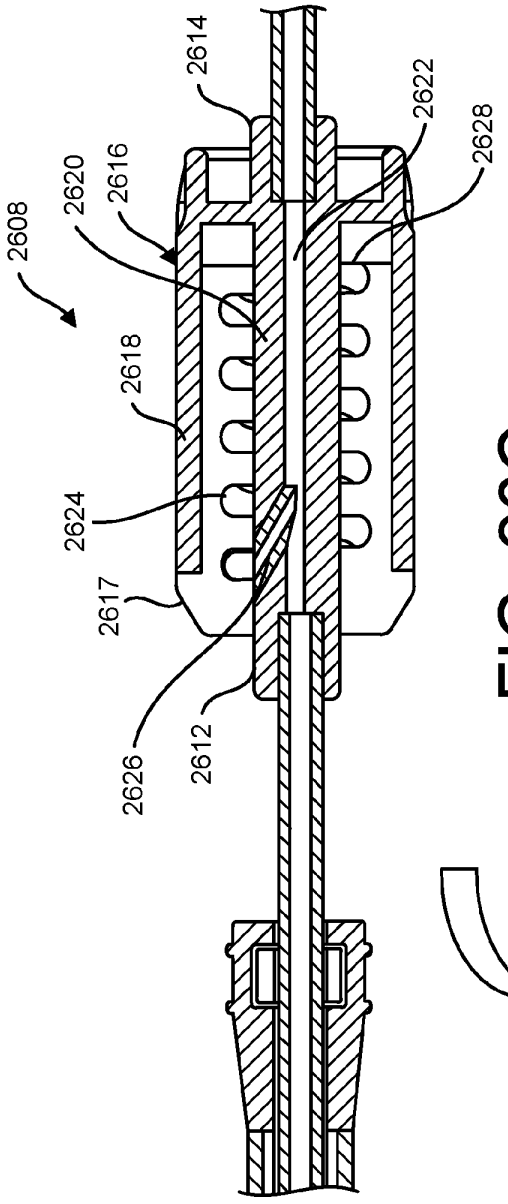


FIG. 26C

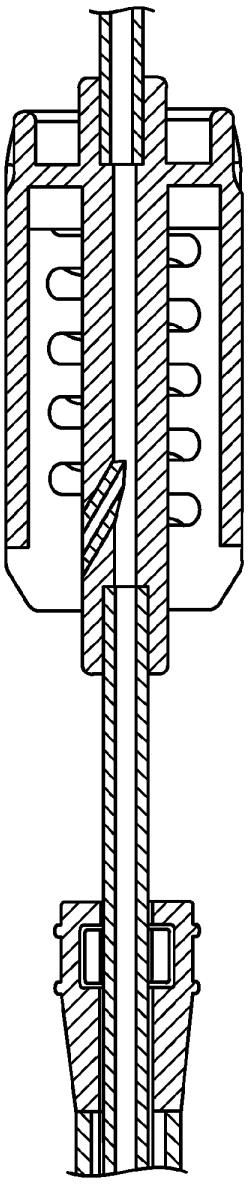


FIG. 26D

Replacement Sheet
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PCT/US2017/068569

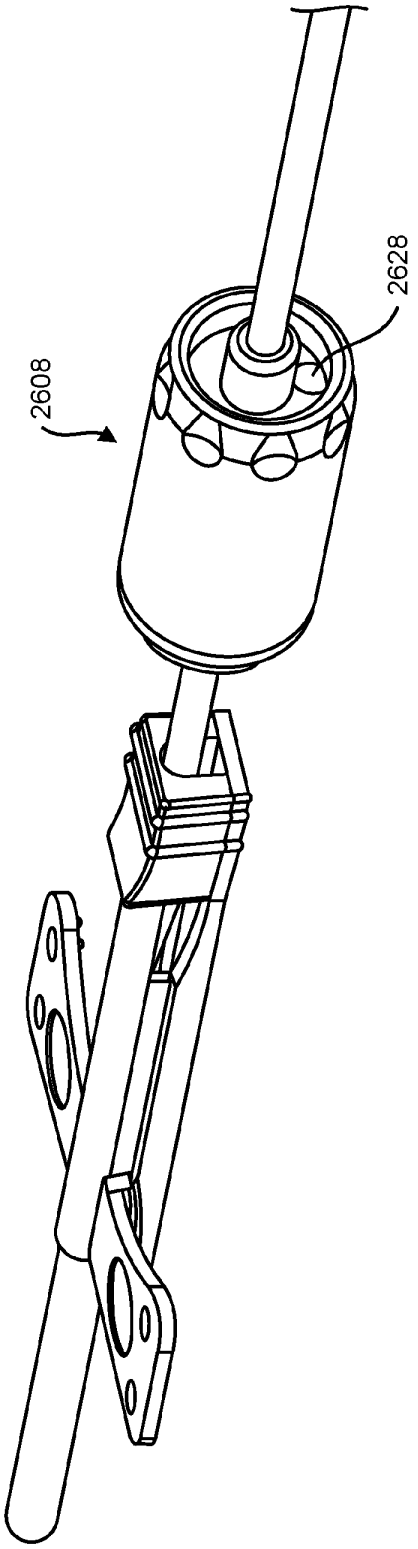


FIG. 26E

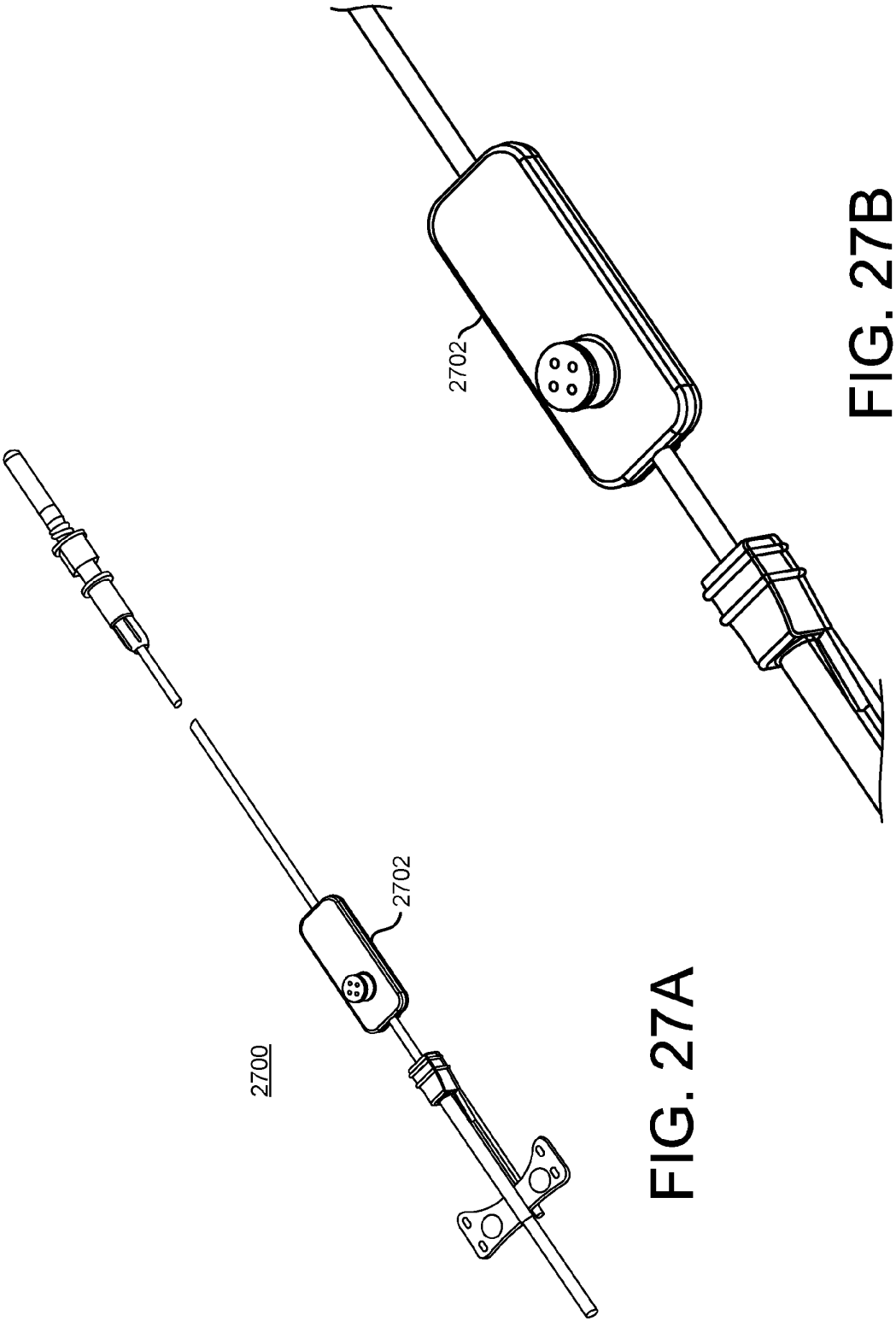


FIG. 27A

FIG. 27B

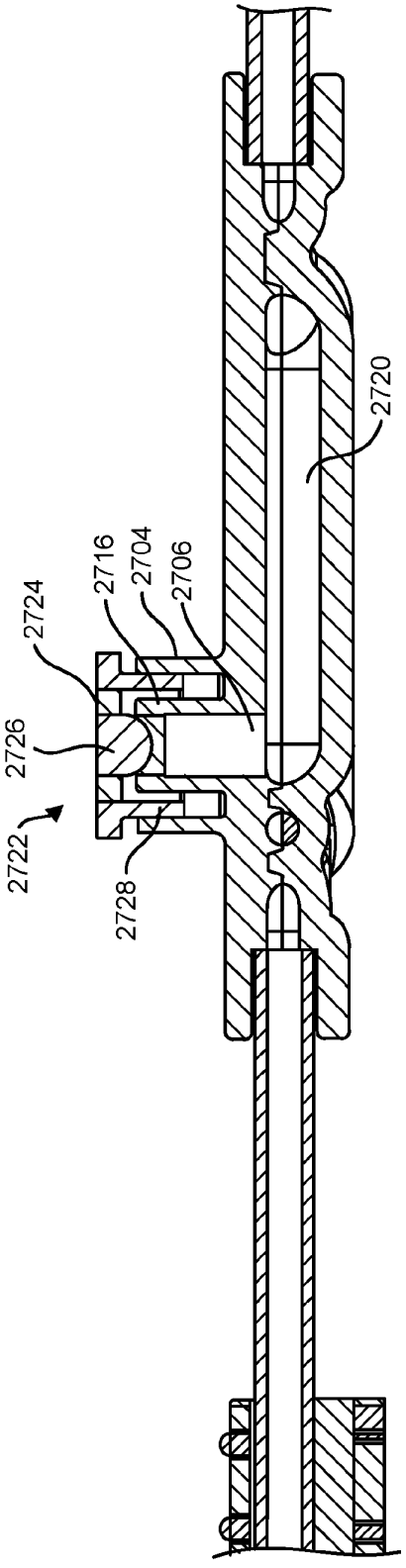


FIG. 27C

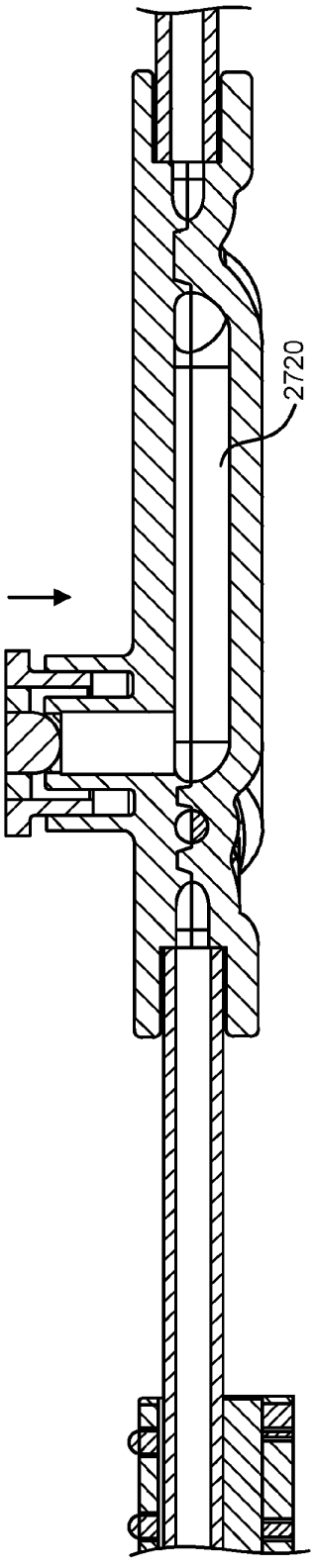


FIG. 27D

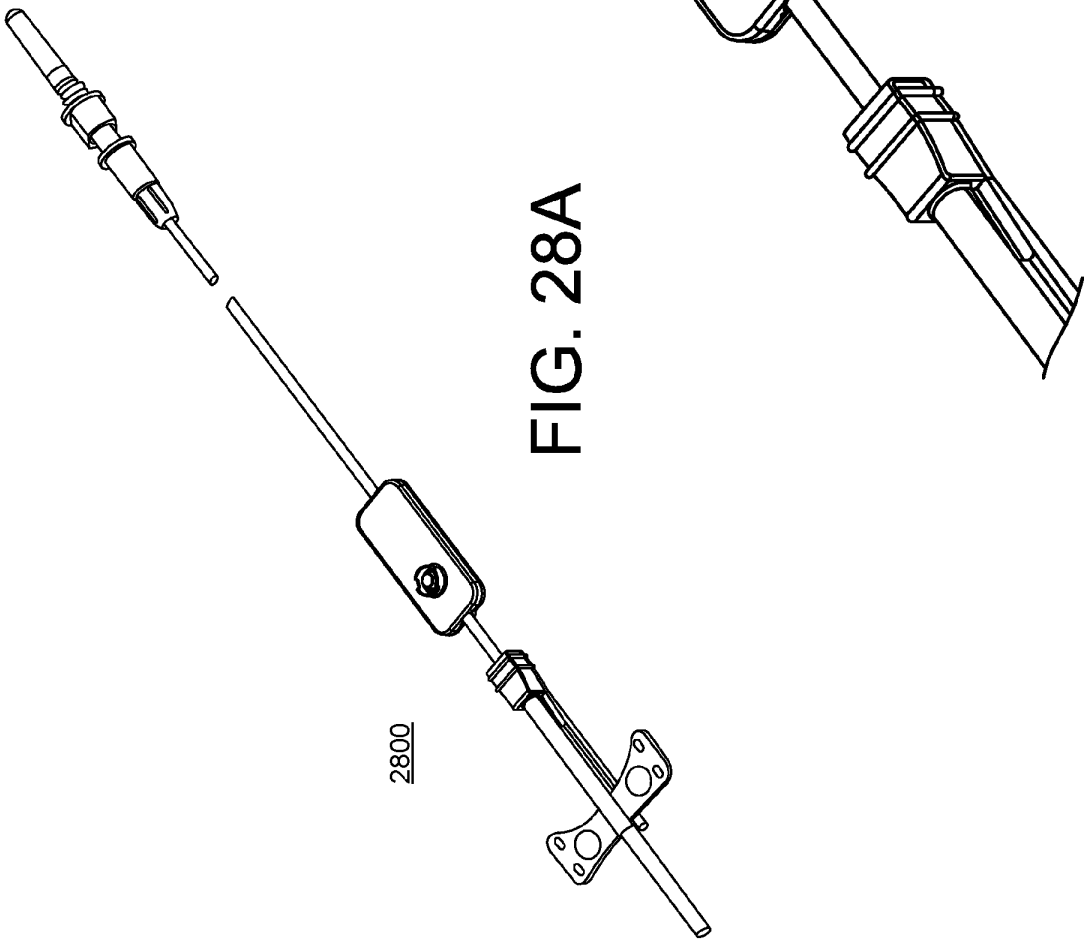


FIG. 28B

FIG. 28A

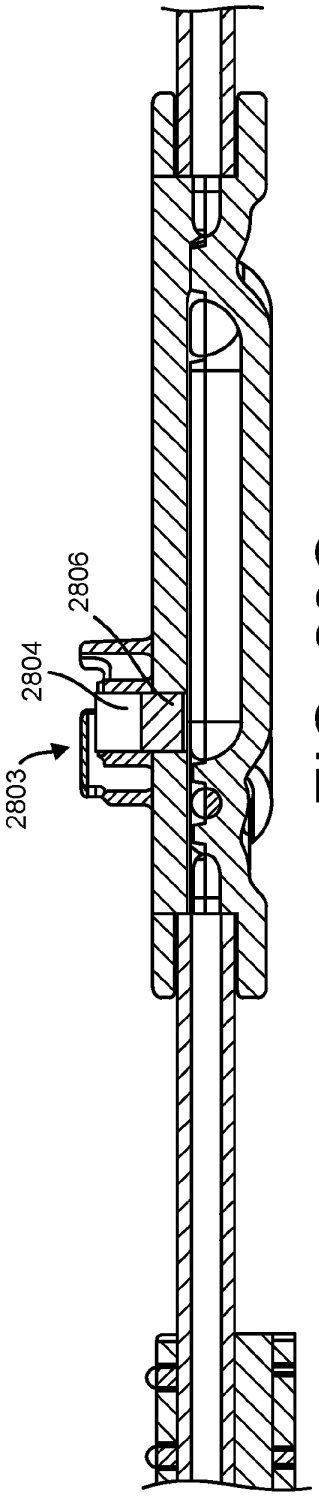


FIG. 28C

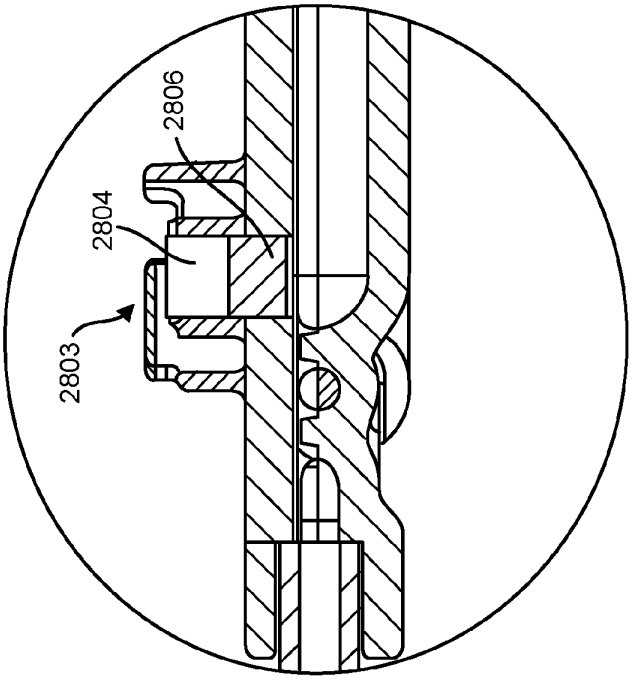


FIG. 28D

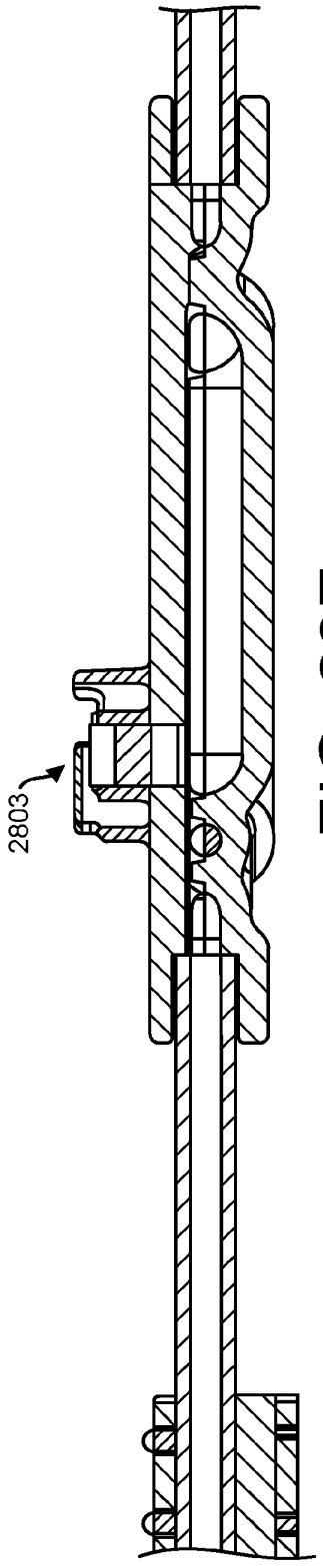


FIG. 28E

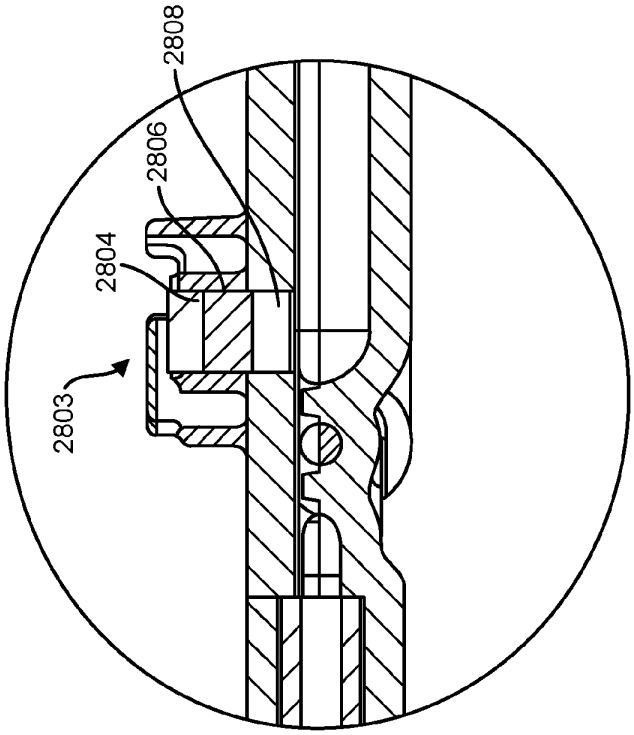


FIG. 28F

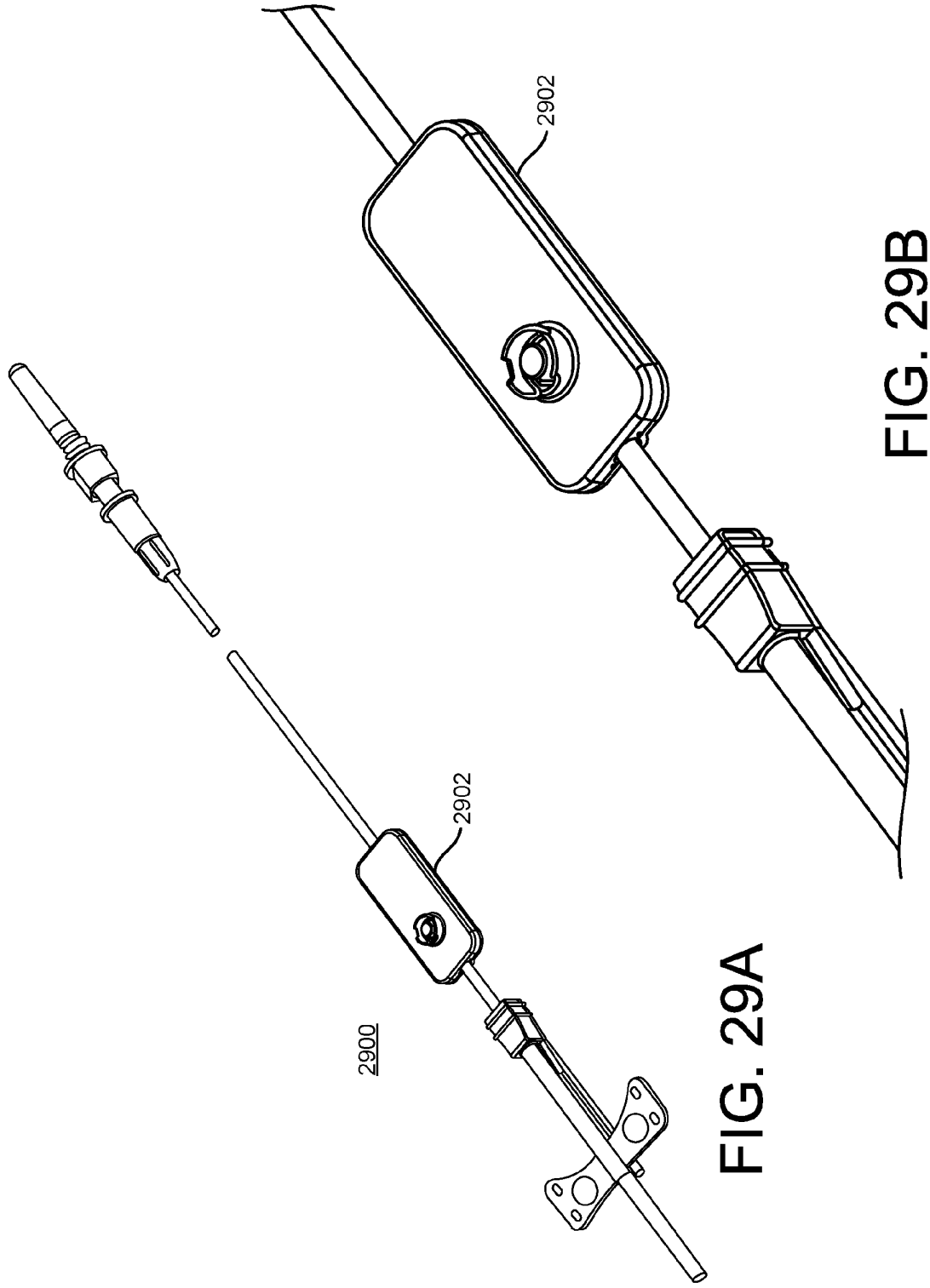


FIG. 29B

FIG. 29A

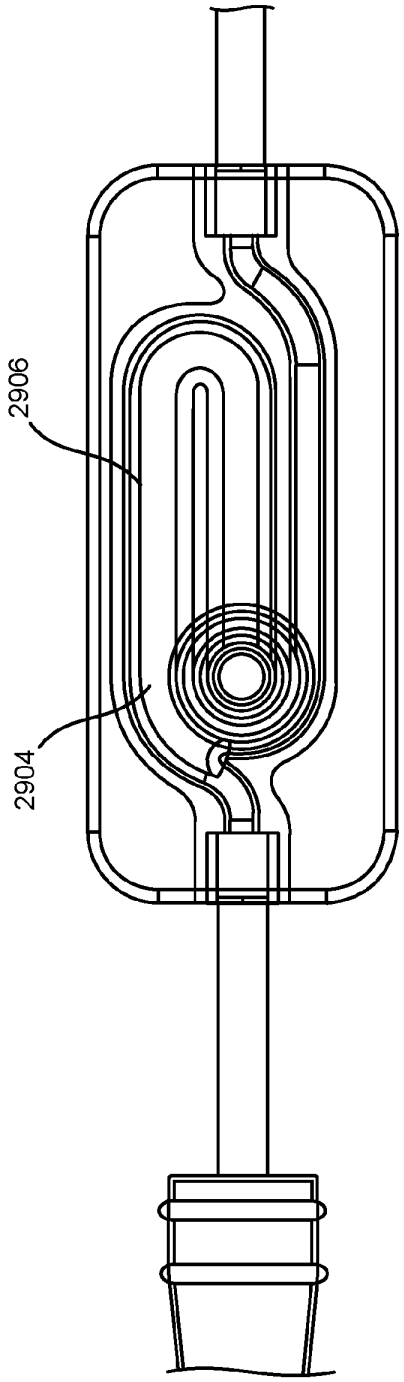


FIG. 29C

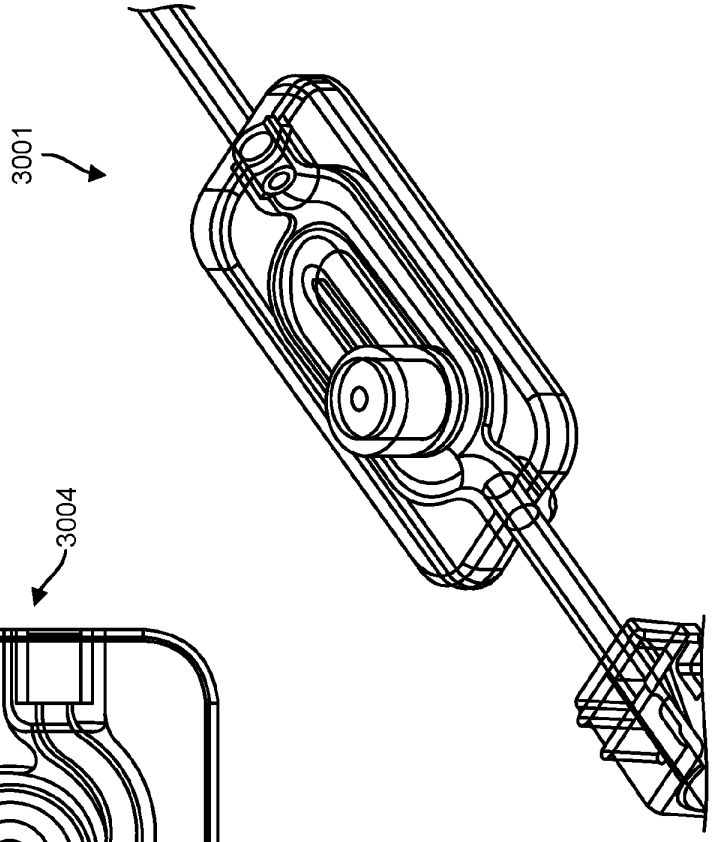


FIG. 30B

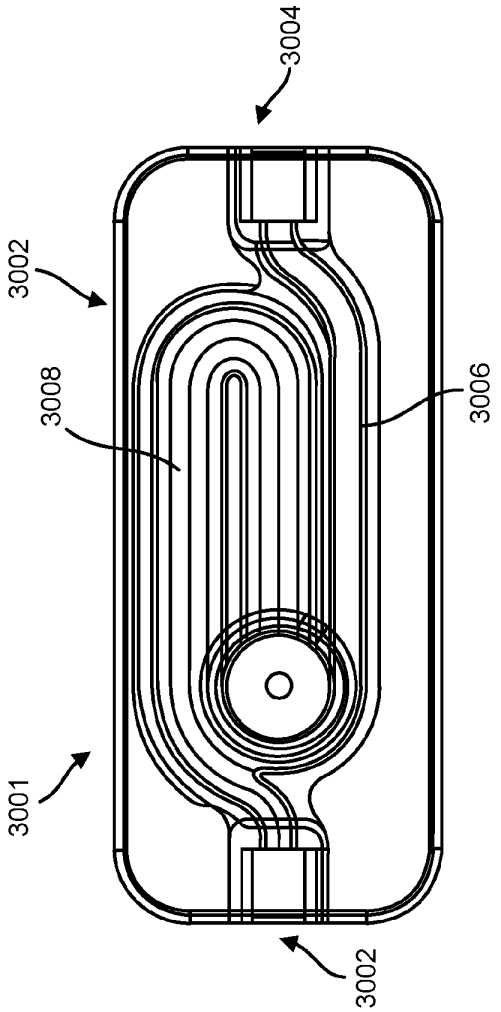


FIG. 30A

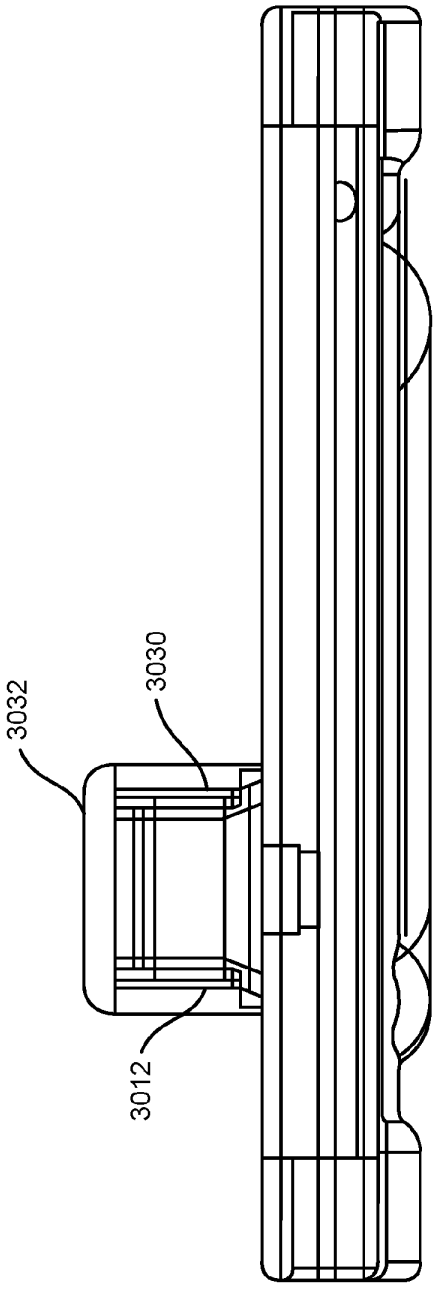


FIG. 30C

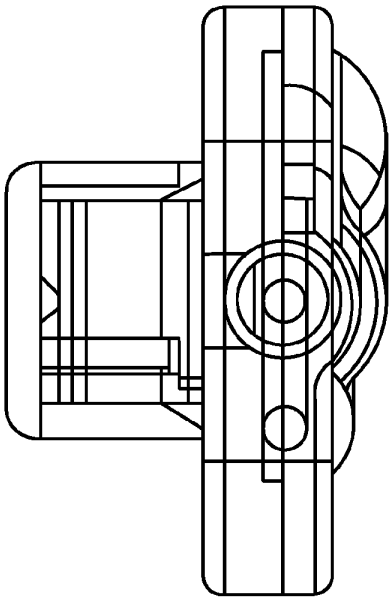


FIG. 30D

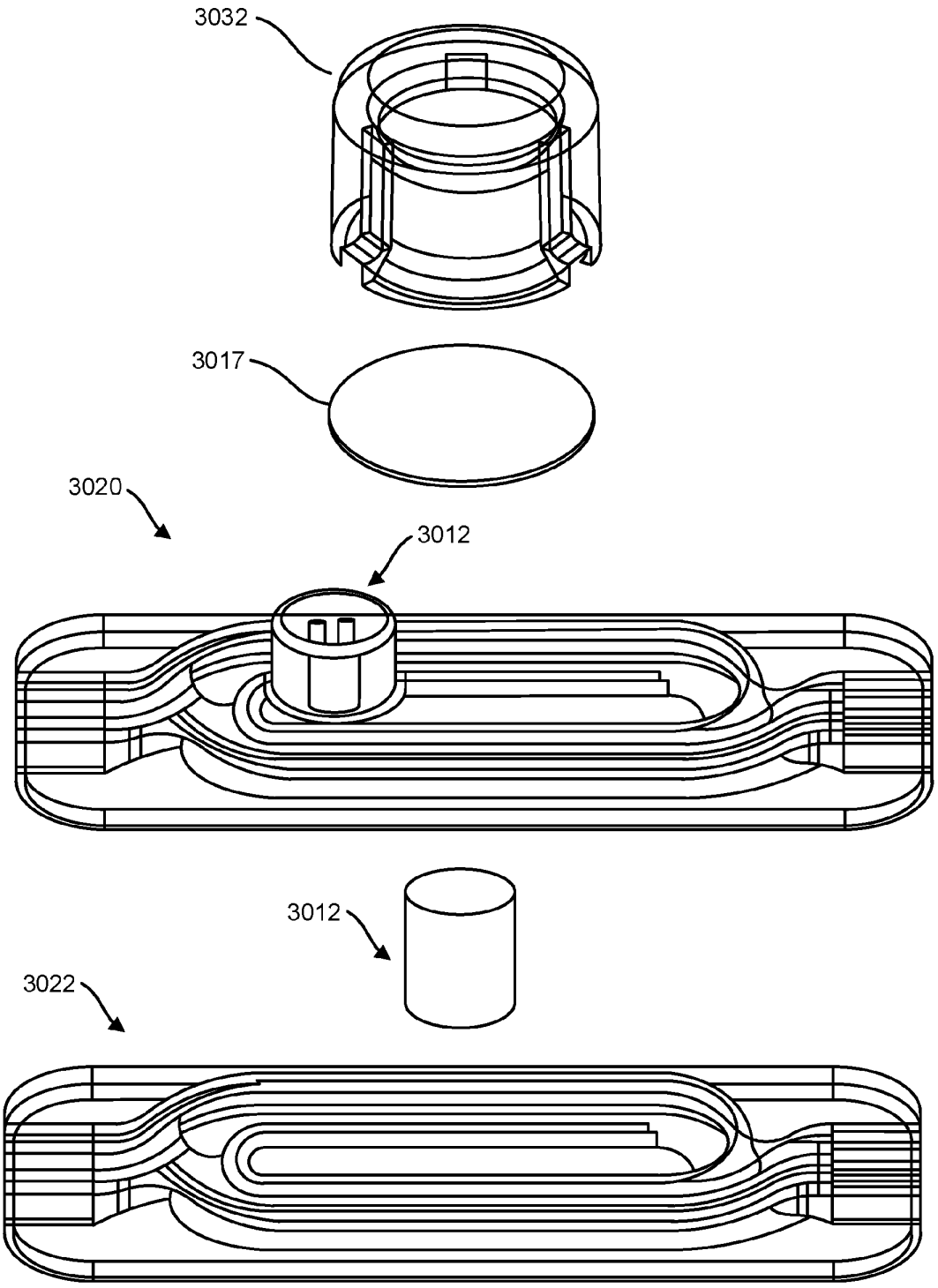


FIG. 30E

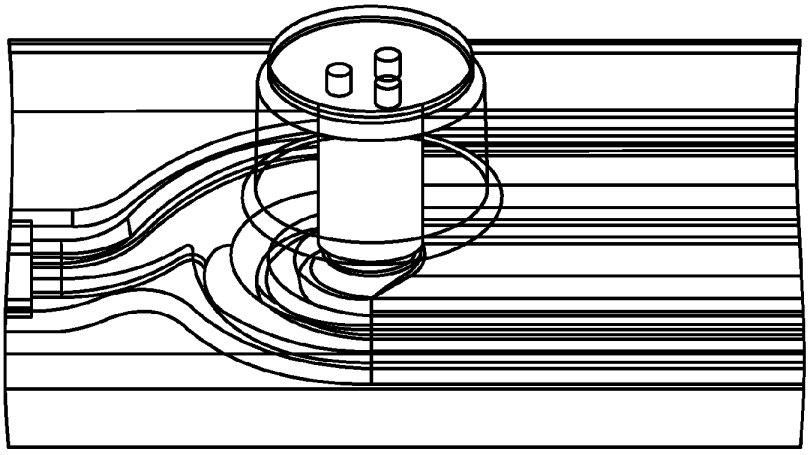


FIG. 30F

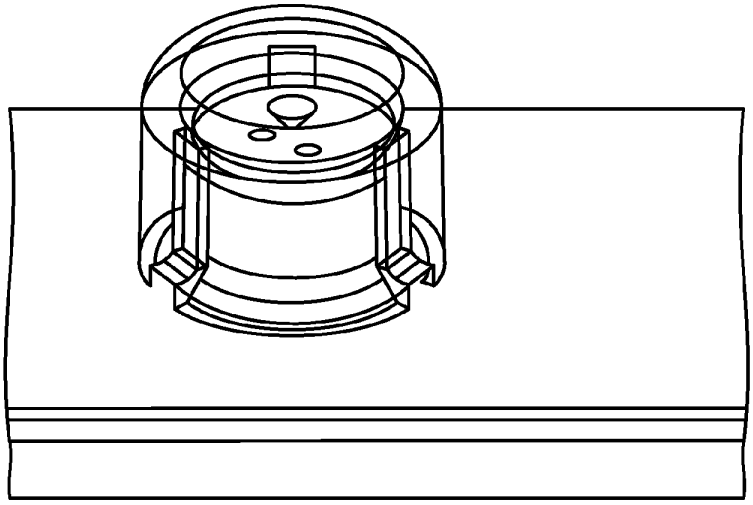


FIG. 30G

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2017/068569

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B5/15 A61B5/153 A61B5/154 A61B5/157
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2014/039348 A1 (BULLINGTON GREGORY J [US] ET AL) 6 February 2014 (2014-02-06) the whole document	1-20
A	US 2014/107564 A1 (BULLINGTON GREGORY J [US] ET AL) 17 April 2014 (2014-04-17) the whole document	1-20
A	US 4 813 433 A (DOWNEY JOHN M [US]) 21 March 1989 (1989-03-21) the whole document	1-20
A	US 2013/317391 A1 (BULLINGTON GREGORY J [US] ET AL) 28 November 2013 (2013-11-28) abstract paragraph [0048] - paragraph [0075]; figures 2-12	1-20

-/--

[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
29 March 2018	25/04/2018

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Nielsen, Michael

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INTERNATIONAL SEARCH REPORT

International application No
PCT/US2017/068569

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 2013/181352 A1 (MAGNOLIA MEDICAL TECHNOLOGIES INC [US]; BULLINGTON GREGORY J [US]; PAT) 5 December 2013 (2013-12-05) abstract paragraph [1090]; figures 11,12 -----	1-20

1

Form PCT/ISA/210 (continuation of second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2017/068569

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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		US 2016113560 A1	28-04-2016
		WO 2014022275 A1	06-02-2014
US 2014107564 A1	17-04-2014	EP 2906269 A1	19-08-2015
		US 2014107564 A1	17-04-2014
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		US 2015351679 A1	10-12-2015
		WO 2013181352 A1	05-12-2013

Bibliographic data: EP3562397 (A1) — 2019-11-06

BLOOD SAMPLE OPTIMIZATION SYSTEM AND BLOOD CONTAMINANT SEQUESTRATION DEVICE AND METHOD

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Applicant(s): KURIN INC [US] ± (Kurin, Inc)

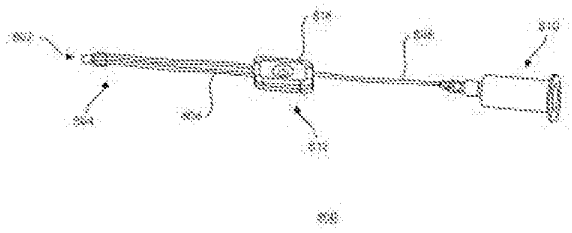
Classification: **- international:** ***A61B5/15; A61B5/153; A61B5/154; A61B5/157***
- cooperative: **A61B5/15003 (EP, US); A61B5/150213 (EP, US); A61B5/150221 (US); A61B5/150251 (EP, US); A61B5/150274 (EP, US); A61B5/150351 (US); A61B5/150755 (US); A61B5/150786 (US); A61B5/150946 (US); A61B5/150992 (EP, US); A61B5/1535 (EP, US); A61B5/1545 (EP, US);** A61B5/150389 (EP, US); A61B5/150488 (EP, US); A61B5/157 (EP, US)

Application number: EP20170840467 20171227 Global Dossier

Priority number(s): US201662439426P 20161227 ; WO2017US68569 20171227

Also published as: EP3562397 (B1) EP3777684 (A1) EP3777684 (B1) EP4091544 (A1) IL267684 (A) more

Abstract not available for EP3562397 (A1)
Abstract of corresponding document: US2018177445 (A1)



Blood sample optimization systems and methods are described that reduce or eliminate contaminates in collected blood samples, which in turn reduces or eliminates false positive readings in blood cultures or other testing of collected blood samples. A blood sample optimization system can include a blood sequestration device located between a patient needle and a sample needle. The blood sequestration device can include a sequestration chamber for sequestering an initial, potentially contaminated aliquot of blood, and may further include a sampling channel that bypasses the sequestration chamber to convey likely uncontaminated blood between the patient needle and the sample needle after the initial aliquot of blood is sequestered in the sequestration chamber.

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Demande internationale publiée par l'Organisation Mondiale de la Propriété Intellectuelle sous le numéro:

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(11) EP 3 622 890 A1

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04.04.2016 US 201662318194 P
27.04.2016 US 201615140448
27.04.2016 US 201615140443

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81541 München (DE)

Remarks:
This application was filed on 01-10-2019 as a divisional application to the application mentioned under INID code 62.

(54) BLOOD SAMPLE OPTIMIZATION SYSTEM AND BLOOD CONTAMINANT SEQUESTRATION DEVICE

(57) Blood sample optimization systems and methods are described that reduce or eliminate contaminates in collected blood samples, which in turn reduces or eliminates false positive readings in blood cultures or other testing of collected blood samples. A blood sample optimization system can include a blood sequestration device (1500) located between a patient needle and a sample needle. The blood sequestration device can include a sequestration chamber (1508) for sequestering an initial, potentially contaminated aliquot of blood, and may further include a sampling channel (1506) that bypasses the sequestration chamber to convey likely uncontaminated blood between the patient needle and the sample needle after the initial aliquot of blood is sequestered in the sequestration chamber.

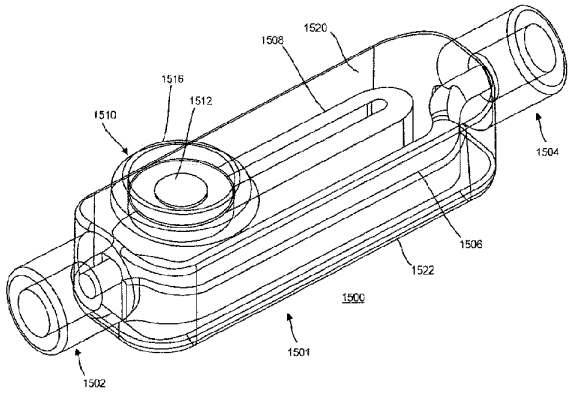


FIG. 15C

EP 3 622 890 A1

Printed by Jouve, 75001 PARIS (FR)

Description

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit of priority of U.S. Non-Provisional Application Serial No. 15/140,443, filed on April 27, 2016 and titled "BLOOD SAMPLE OPTIMIZATION SYSTEM AND BLOOD CONTAMINANT SEQUESTRATION DEVICE AND METHOD" and U.S. Non-Provisional Application Serial No. 15/140,448, filed on April 27, 2016 and titled "BLOOD SAMPLE OPTIMIZATION SYSTEM AND BLOOD CONTAMINANT SEQUESTRATION DEVICE AND METHOD", both of which claim priority to U.S. Provisional Application Serial No. 62/196,797, filed on July 24, 2015 and titled "BLOOD CULTURE IMPROVEMENT SYSTEM AND METHOD"; U.S. Provisional Application Serial No. 62/238,636, filed on October 7, 2015 and titled "BLOOD SEQUESTRATION SYSTEM FOR NON-CONTAMINATED BLOOD SAMPLING"; and U.S. Provisional Application Serial No. 62/318,194, filed on April 4, 2016 and titled "BLOOD SAMPLE OPTIMIZATION SYSTEM AND BLOOD CONTAMINANT SEQUESTRATION DEVICE AND METHOD," the disclosures of which are incorporated by reference in their entirety.

BACKGROUND

[0002] Bacteraemia is the presence of microorganisms in the blood. Sepsis, on the other hand, is bacteraemia in the presence of clinical symptoms and signs such as fever, tachycardia, tachypnea and hypotension. Bacteraemia and sepsis are associated with a high mortality and an increased incidence and duration of hospital stay and associated costs. Many bacteraemias, sepsis, fungaemias and other pathogens actually occur within a hospital or other healthcare settings with catheters and venipunctures being a source of contamination as potential carriers of these pathogens.

[0003] Blood cultures are the standard test used to detect microbial pathogens related to bacteraemia and sepsis in a patient's blood. The term blood culture refers to a single venipuncture, either from a peripheral site or central or arterial line, with the blood inoculated into one or more blood culture bottles or containers. One bottle is considered a blood culture where two or more are considered a set. Multiple sets may be obtained from multiple venipunctures and are associated with different sites on the patient.

[0004] These methods allow for microbial identification and susceptibility testing to be performed, which is a critical component to managing sepsis, however the lack of rapid results and decreased sensitivity for fastidious pathogens has led to the development of improved systems and adjunctive molecular or proteomic testing.

[0005] Collection of blood samples for conducting blood cultures is a critical component of modern patient care and can either positively affect the patient outcome by providing an accurate diagnosis, or can adversely affect the outcome by prolonging unnecessary antimicrobial therapy, the length of hospital stays, and increasing costs.

[0006] One outcome of collection of blood cultures is contamination. Blood culture contamination can lead to a false positive culture result and/or significant increase in healthcare related costs. Sources of blood culture contamination include improper skin antisepsis, improper collection tube disinfection, and contamination of the initial blood draw which may then skew results.

[0007] Blood culture collection kits generally consist of a "butterfly" set, infusion set, or other type of venipuncture device as offered by companies like BD, Smiths, B. Braun and others, and aerobic and anaerobic blood culture bottles. Various different bottles are also available depending on the test requirements. These bottles are specifically designed to optimize recovery of both aerobic and anaerobic organisms. In conventional kits, a bottle used is known generally as a "Vacutainer," which is a blood collection tube formed of a sterile glass or plastic tube with a closure that is evacuated to create a vacuum inside the tube to facilitate the draw of a predetermined volume of liquid such as blood.

[0008] False positive blood cultures are typically a result of poor sampling techniques. They cause the use of antibiotics when not needed, increasing hospital costs and patient anxiety. Blood cultures are drawn from a needlestick into the skin, and then a Vacutainer is attached to capture a sample of blood. Contamination may occur from improper or incomplete disinfection of the skin area in and around the puncture site. It may also occur from the coring of the skin by the needle during insertion, with the cored skin cells and any associated contamination being pulled into the sample.

[0009] Blood flow through a hypodermic needle is laminar, and as such, a velocity gradient can be developed over the flow tube as a pressure drop is applied to the hypodermic needle. Either forceful aspiration of blood, or using a very small hypodermic needle, can cause lysis and a release of potassium from the red blood cells, thereby rendering the blood samples abnormal.

[0010] In other instances, some patients have delicate veins that can collapse under a pressure drop or vacuum, particularly as applied by a syringe's plunger that is drawn too quickly for the patient's condition. Since such condition is impossible to know beforehand, such vein collapses are a risk and very difficult to control.

[0011] Various strategies have been implemented to decrease blood culture contamination rates, e.g. training staff with regard to aseptic collection technique, feedback with regard to contamination rates and implementation of blood culture collection kits. Although skin antisepsis can reduce the burden of contamination, 20% or more of skin organisms are located deep within the dermis and are unaffected by antisepsis. Changing needles before bottle inoculation is not advisable as it increases the risk to acquire needle stick injuries without decreasing con-

tamination rates.

[0012] Some conventional systems and techniques for reducing blood culture contamination include discarding the initial aliquot of blood taken from central venous catheters, venipunctures, and other vascular access systems. However, these systems require the user to mechanically manipulate an intravascular device, or require a complex series of steps that are difficult to ensure being followed.

SUMMARY

[0013] This document presents systems and methods for reducing blood culture contamination, lysing of cells, and vein collapse. In some implementations, a system and method can eliminate user variability in disinfection, and also eliminate the risk of skin cells getting into the blood culture sample. The systems and methods disclosed herein do not require a change in existing clinical processes, other than to potentially indicate when a vacutainer or other blood collection device (i.e., syringe) should be attached for drawing contaminant-free blood samples.

[0014] In some implementations of the systems and methods disclosed herein the withdrawal of blood is accomplished passively by use of the patient's own blood pressure, thereby reducing the risk of vein collapse and eliminating any additional user steps over current practice. The systems and methods can be applied to accommodate short-path direct stick or butterfly venipuncture systems. They can also be used with samples drawn through a catheter.

[0015] In one aspect, a blood sequestration device is presented. The blood sequestration device includes an inlet port and an outlet port. The blood sequestration device further includes a sequestration chamber connected with the inlet port, the sequestration chamber having a vent comprising an air permeable blood barrier. The blood sequestration device further includes a sampling channel having a proximal end connected with the inlet port and a distal end connected with the outlet port.

[0016] In another aspect, a blood sequestration device connected with a blood sampling pathway is described. The blood sampling pathway has a patient needle and a sample collection device. The blood sequestration device includes an inlet port connected with the patient needle, and a sequestration chamber connected with the inlet port, the sequestration chamber having a vent comprising an air permeable blood barrier. The blood sequestration device further includes a sampling channel having a proximal end connected with the inlet port, and an outlet port connected with a distal end of the sampling channel and with the sample collection device.

[0017] In yet another aspect, a blood sequestration device connected with a blood sampling system is described. The blood sampling system includes a patient needle for accessing a blood sample from a patient, and a sample needle that is sealed and adapted for receiving an evacuated blood collection tube. The blood sequestration device includes an inlet port connected with the patient needle to receive the blood sample from the patient. The blood sequestration device further includes a sequestration chamber connected with the inlet port and having a vent comprising an air permeable blood barrier, the sequestration chamber for receiving and sequestering a first portion of the blood sample prior to the sample needle being unsealed by the evacuated blood collection tube. The blood sequestration device further includes a sampling channel having a proximal end connected with the inlet port, the sampling channel for conveying a subsequent portion of the blood sample once the sample needle is unsealed by the evacuated blood collection tube. The blood sequestration device further includes an outlet port connected with a distal end of the sampling channel for conveying the subsequent portion of the blood sample to the sample needle.

[0018] In yet another aspect, a blood sample optimization system is disclosed and described. The blood sample optimization system includes a blood sampling system for accessing and acquiring one or more samples of a patient's blood, and a blood sequestration device for receiving and sequestering a first portion of the one or more samples of the patient's blood which might be contaminated by a venipuncture process and which could result in a false positive identification of a pathogen in the patient's blood.

[0019] The blood sampling system includes a patient needle configured for a venipuncture of a patient to access a sample of blood of a patient, a blood sampling pathway connected with the patient needle for conveying the sample of blood, and a sample needle configured for receiving an evacuated blood collection container to collect and contain a subsequent portion of the sample of blood.

[0020] In yet another aspect, a blood sequestration device is disclosed and described. In some implementations, the blood sequestration device can include an inlet port, an outlet port connected with the inlet port, and a sequestration chamber connected with the inlet port. The sequestration chamber can have a vent comprising an air permeable blood barrier.

[0021] The blood sequestration device is connected along the blood sampling pathway between the patient needle and the sample needle, and includes an inlet port for receiving the sample of blood. The blood sequestration device further includes a sequestration chamber connected with the inlet port for receiving a first amount of the sample of blood, the sequestration chamber having a vent comprising an air permeable blood barrier for sequestering at least a first portion of the first amount of the sample of blood. The blood sequestration device may further include a sampling channel having a proximal end connected with the inlet port, the sampling channel conveying a subsequent amount of the sample of blood to the evacuated blood collection container upon the sequestration chamber sequestering at least the first por-

tion of the first amount of the sample of blood. The blood sequestration device further includes an outlet port connected with a distal end of the sampling channel, the outlet port for outputting the subsequent amount of the sample of blood.

[0022] The details of one or more embodiments are set forth in the accompanying drawings and the description below. Other features and advantages will be apparent from the description and drawings, and from the claims.

BRIEF DESCRIPTION OF THE DRAWINGS

[0023] These and other aspects will now be described in detail with reference to the following drawings.

FIG. 1 illustrates a blood sample optimization system.

FIG. 2 illustrates a blood sample optimization system in accordance with an alternative implementation.

FIG. 3 illustrates a blood sample optimization system in accordance with another alternative implementation.

FIG. 4 illustrates a blood sample optimization system in accordance with another alternative implementation.

FIG. 5 illustrates a blood sample optimization system in accordance with another alternative implementation.

FIG. 6 illustrates a blood sample optimization system in accordance with an alternative implementation.

FIG. 7 is a flowchart of a method for optimizing a quality of a blood culture.

FIGS. 8A - 8E illustrate a blood sequestration system for non-contaminated blood sampling, in accordance with some implementations.

FIG. 9 illustrates a pathway splitter for use in a blood sequestrations system.

FIGS. 10A - 10D illustrate a blood sequestration system for non-contaminated blood sampling, in accordance with alternative implementations.

FIGS. 11A - 11E illustrate a blood sequestration system for non-contaminated blood sampling, in accordance with other alternative implementations.

FIGS. 12A-12D illustrate a blood sample optimization system including a blood sequestration device in accordance with yet other alternative implementations.

FIGS. 13A-13D illustrate a blood sample optimization system 1300 in accordance with yet another alternative implementations.

FIGS. 14A-14E illustrate yet another implementation of a blood sampling system to sequester contaminates of an initial aliquot or sample to reduce false positives in blood cultures or tests performed on a patient's blood sample.

FIGS. 15A-15G illustrate a blood sequestration device and method of using the same, in accordance with yet another implementation.

FIGS. 16A-16D illustrate a blood sequestration device in accordance with yet another implementation.

FIGS. 17A - 17E illustrate a bottom member of a housing for a blood sequestration device.

FIGS. 18A - 18F illustrate a top member of a housing for a blood sequestration device.

FIGS. 19A and 19B illustrate a blood sequestration device having a top member mated with a bottom member.

FIG. 20 shows a blood sample optimization system including a blood sequestration device.

FIG. 21 illustrates a non-vented blood sequestration device using a wicking material chamber.

FIGS. 22A and 22B illustrate a material makeup of a filter for sequestering blood in a sequestration chamber of a blood sequestration device.

FIGS. 23A and 23B illustrate another implementation of a blood sequestration device that uses a vacuum force from a blood collection device.

[0024] Like reference symbols in the various drawings indicate like elements.

DETAILED DESCRIPTION

[0025] This document describes blood sample optimization systems and methods for reducing or eliminating contaminates in collected blood samples, which in turn reduces or eliminates false positive readings in blood cultures or other testing of collected blood samples. In some implementations, a blood sample optimization system includes a patient needle for vascular access to a patient's bloodstream, a sample needle for providing a blood sample to a blood collection container, such as an evacuated blood collection container or tube like a Vacutainer™ or

the like, or other sampling device, and a blood sequestration device located between the patient needle and the sample needle. The blood sequestration device includes a sequestration chamber for sequestering an initial, potentially contaminated aliquot of blood, and may further include a sampling channel that bypasses the sequestration chamber to convey likely uncontaminated blood between the patient needle and the sample needle after the initial aliquot of blood is sequestered in the sequestration chamber.

[0026] FIG. 1 illustrates a blood sample optimization system in accordance with some implementations. The system includes a patient needle 1 to puncture the skin of a patient to access the patient's vein and blood therein. The system further includes a sample needle (i.e., a resealably closed needle for use with Vacutainers™ or the like) 5, which may be contained within and initially sealed by a resealable boot 10, a Luer activated valve, or another collection interface or device. The resealable boot 10 can be pushed aside or around the sample needle 5 by application of a Vacutainer™ bottle (not shown) for drawing the patient's blood. The system can further include a low volume chamber 30 that leads to the sample needle 5, but also includes an orifice or one or more channels 45 that lead to a sequestration chamber 55 formed by a housing 50.

[0027] The sequestration chamber 55 is a chamber, channel, pathway, lock, or other structure for receiving and holding a first aliquot of the patient's blood, which may be in a predetermined or measured amount, depending on a volume of the sequestration chamber 55. The first draw of blood typically contains or is more susceptible to containing organisms that cause bacteraemia and sepsis or other pathogens than subsequent blood draws. The sequestration chamber 55 can be a vessel encased in a solid housing, formed in or defined by the housing itself, or can be implemented as tubing or a lumen. The sequestration chamber 55, regardless how formed and implemented, may have a predetermined volume. In some implementations, the predetermined volume may be based on a volume of the patient needle, i.e. ranging from less than the volume of the patient needle to any volume up to or greater than 20 times or more of the volume of the patient needle. The predetermined volume of the sequestration chamber 55 may also be established to economize or minimize an amount of blood to be sequestered and disposed of.

[0028] The sequestration chamber 55 can be formed, contained or housed in a chamber housing 50, and can be made of plastic, rubber, steel, aluminum or other suitable material. For example, the sequestration chamber 55 could be formed of flexible tubing or other elastomeric materials. The sequestration chamber 55 further includes an air permeable blood barrier 20 that allows air to exit the sequestration chamber 55. As used herein the term "air permeable blood barrier" means an air permeable but substantially blood impermeable substance, material, or structure. Examples may include hydrophobic membranes and coatings, a hydrophilic membrane or coating combined with a hydrophobic membrane or coating, mesh, a filter, a mechanical valve, antimicrobial material, or any other means of allowing air to be displaced from the sequestration chamber 55 as it is filled with blood. In various exemplary embodiments, an air permeable blood barrier may be formed by one or more materials that allow air to pass through until contacted by a liquid, such material then becomes completely or partially sealed to prevent or inhibit the passage of air and/or liquid. In other words, prior to contact with liquid, the material forms a barrier that is air permeable. After contact with a liquid, the material substantially or completely prevents the further passage of air and/or liquid.

[0029] The orifice or channel 45 can be any desired length, cross-sectional shape or size, and/or can be formed to depart from the low volume chamber 30 at any desired angle or orientation. The orifice or channel 45 may also include a one-way flap or valve 60 that maintains an initial aliquot of blood sample within the sequestration chamber 55. In some specific implementations, the orifice or channel 45 can include a "duck bill" or flapper valve 60, or the like, for one-way flow of blood from low volume chamber 30 to the sequestration chamber 55. The air permeable blood barrier 20 can also be constructed of a material that allows air to exit but then seals upon contact with blood, thereby not allowing external air to enter sequestration chamber 55. This sealing would eliminate the need for a valve.

[0030] Valve 60 can be any type of valve or closing mechanism. Chamber 30 is designed to hold virtually no residual blood, and can be designed to be adapted to hold or allow pass-through of a particular volume or rate of blood into sequestration chamber 55. Likewise, sequestration chamber 55 may also include any type of coating, such as an anti-microbial coating, or a coating that aids identification and/or diagnosis of components of the first, sequestered blood draw.

[0031] Housing 50 and 40 can be formed of any suitable material, including plastic, such as acrylonitrile butadiene styrene (ABS) or other thermoplastic or polymeric material, rubber, steel, or aluminum. The air permeable blood barrier 20 can include a color-providing substance, or other signaling mechanism, that is activated upon contact with blood from the initial blood draw, or when air displacement is stopped, or any combination of events with blood in the sequestration chamber 55. The air permeable barrier may also include an outer layer such as a hydrophobic membrane or cover that inhibits or prevents the inadvertent or premature sealing of the filter by an external fluid source, splash etc. Sequestration chamber 55 can also be translucent or clear to enable a user to visually confirm the chamber is filled.

[0032] FIG. 2 illustrates a blood sample optimization system in accordance with some alternative implementations. In the implementation shown in FIG. 2, a sequestration chamber 55, or waste chamber, surrounds the patient needle 1, with an open-ended cuff or housing con-

nected with the waste chamber and encircling the sample needle housing base and housing. The patient needle 1 and sample needle 5 are connected together by a boot 56, which forms a continuous blood draw channel therethrough. The boot 56 includes a single orifice or channel leading from the blood draw channel into sequestration chamber 55. The device can include more than one single orifice or channel, in other implementations. Each orifice or channel can include a one-way valve, and can be sized and adapted for predetermined amount of blood flow.

[0033] The sequestration chamber 55 includes an air permeable blood barrier. The filter can further include a sensor or indicator to sense and/or indicate, respectively, when a predetermined volume of blood has been collected in the sequestration chamber 55. That indication will alert a user to attach an evacuated blood collection tube or bottle, such as a Vacutainer™ to the sample needle 5. The housing for the sequestration chamber 55 can be any size or shape, and can include any type of material to define an interior space or volume therein. The interior space is initially filled only with air, but can also be coated with an agent or substance, such as a decontaminate, solidifying agent, or the like. Once evacuated blood collection tube is attached to the sample needle 5, blood will flow automatically into the patient needle 1, through the blood draw channel and sample needle 5, and into the bottle. The sample needle 5 is covered by a resealable boot, coating or membrane that seals the sample needle when a blood collection bottle is not attached thereon or thereto.

[0034] FIG. 3 illustrates a blood sample optimization system in accordance with some alternative implementations. In the implementation shown, a sample needle 5 is surrounded by a resealable boot or membrane, and is further connected with a patient needle 1. A blood flow channel is formed through the sample needle and the patient needle. The connection between the sample needle and patient needle includes a "T" or "Y" connector 102, which includes a channel, port or aperture leading out from the main blood flow channel to a sequestration chamber 104.

[0035] The T or Y connector 102 may include a flap or one-way valve, and have an opening that is sized and adapted for a predetermined rate of flow of blood. The sequestration chamber 104 can be formed from tubing, or be formed by a solid housing, and is initially filled with air. The sequestration chamber 104 will receive blood that flows out of a patient automatically, i.e. under pressure from the patient's own blood pressure. The sequestration chamber 104 includes an air permeable blood barrier 106, preferably at the distal end of tubing that forms the sequestration chamber 104, and which is connected at the proximal end to the T or Y connector 102. The T or Y connector 102 can branch off at any desired angle for most efficient blood flow, and can be formed so as to minimize an interface between the aperture and channel and the main blood flow channel, so as to minimize or eliminate mixing of the initial aliquot of blood with main blood draw samples.

[0036] In some alternative implementations, the sample needle may be affixed to a tubing of any length, as shown in FIG. 4, connecting at its opposite end to the T or Y connector 102. The sequestration chamber 104 can be any shape or volume so long as it will contain a predetermined amount of blood sample in the initial aliquot. The T or Y connector 102 may also include an opening or channel that is parallel to the main blood flow channel. The air permeable blood barrier may further include an indicator 107 or other mechanism to indicate when a predetermined amount of blood has been collected in the sequestration chamber, or when air being expelled reaches a certain threshold, i.e. to zero. The tubing can also include a clip 109 that can be used to pinch off and prevent fluid flow therethrough.

[0037] Once the air permeable blood barrier and primary chamber are sealed the initial aliquot of blood is trapped in the sequestration chamber 104, an evacuated blood collection tube, such as a Vacutainer™ bottle may be attached to the sample needle 5 to obtain the sample. The blood collection tube can be removed, and the sample needle 5 will be resealed. Any number of follow-on blood collection tubes can then be attached for further blood draws or samples. Upon completion of all blood draws, the system can be discarded, with the initial aliquot of blood remaining trapped in the sequestration chamber 104.

[0038] FIG. 5 illustrates a blood sample optimization system in accordance with some alternative implementations. In the implementation shown, a sample needle 5 is connected with a patient needle by tubing. A "T" or "Y" connector 120 is added along the tubing at any desired location, and includes an aperture, port or channel leading to a sequestration chamber 204, substantially as described above.

[0039] FIG. 6 illustrates a blood sample optimization system in accordance with some alternative implementations, in which a sequestration chamber 304, formed as a primary collection channel, receives an initial aliquot of blood, and is provided adjacent to the blood sampling channel. The sequestration chamber 304 can encircle the blood sampling channel, the patient needle 1, and/or the sample needle 5. The primary collection channel can include a T or Y connector 120, or other type of aperture or channel. The sequestration chamber 304 includes an air permeable blood barrier, which can also include an indicator of being contacted by a fluid such as blood, as described above.

[0040] In some implementations, either the patient needle 1 or the sample needle 5, or both, can be replaced by a Luer lock male or female connector. However, in various implementations, the connector at a sample needle end of the blood sample optimization system is initially sealed to permit the diversion of the initial aliquot of blood to the sequestration chamber, which is pressured at ambient air pressure and includes the air outlet of the air permeable blood barrier. In this way, the system passive-

ly and automatically uses a patient's own blood pressure to overcome the ambient air pressure of the sequestration chamber to push out air through the air permeable blood barrier and displace air in the sequestration chamber with blood.

[0041] FIG. 7 is a flowchart of an exemplary method for optimizing the quality of a blood culture. At 702, a clinician places a needle into a patient's vein. At 704, blood then flows into a sequestration chamber, pushing the air in the sequestration chamber out of the sequestration chamber through an air permeable blood barrier. In some implementations, the volume of the sequestration chamber is less than 0.1 to more than 5 cubic centimeters (cc's), or more. The sequestration chamber is sized and adapted to collect a first portion of a blood sample, which is more prone to contamination than secondary and other subsequent portion of the blood sample or subsequent draws. Since the sequestration chamber has an air-permeable blood barrier through which air can be displaced by blood pushed from the patient's vein, such blood will naturally and automatically flow into the sequestration chamber before it is drawn into or otherwise enters into a Vacutainer or other bottle for receiving and storing a blood sample.

[0042] When the sequestration chamber fills, the blood will gather at or otherwise make contact with the air permeable blood barrier, which will inhibit or prevent blood from passing therethrough. At 706, when the blood comes into contact with the entire internal surface area of the air permeable blood barrier, the air permeable blood barrier is then closed and air no longer flows out or in. At 708, the clinician may be provided an indictor or can see the full chamber, to indicate the evacuated blood collection tube, such as a Vacutainer™ can be attached. The indicator can include visibility into the primary chamber to see whether it is full, the blood barrier changing color, for example, or other indicator. The fill time of the sequestration chamber may be substantially instantaneous, so such indicator, if present, may be only that the sequestration chamber is filled.

[0043] Prior to an evacuated blood collection tube being attached, communication between the needle, sampling channel, and the sequestration chamber is restricted by the sealing of the sequestration chamber blood barrier thereby not permitting air to reenter the system through the sequestration. Sealing the communication path could also be accomplished with a mechanical twist or other movement, a small orifice or tortuous pathway, eliminating the need for a separate valve or mechanical movement or operation by the clinician. At 710, once the evacuated blood collection tube is removed, the self-sealing membrane closes the sample needle, and at 712, additional subsequent evacuated blood collection tubes may be attached. Once samples have been taken, at 714 the device is removed from the patient and discarded.

[0044] FIGS. 8A - 8E illustrate an exemplary blood sample optimization system 800 for non-contaminated blood sampling, in accordance with some implementations. The blood sample optimization system 800 includes an inlet port 802 that can be connected to tubing, a patient needle (or both), or other vascular or venous access device, and a pathway splitter 804 having a first outlet to a sequestration chamber tubing 806 and a second outlet to sample collection tubing 808. One or both of the sequestration chamber tubing 806 and the sample collection tubing 808 can be formed of tubing. In some implementations, the sequestration chamber tubing 806 is sized so as to contain a particular volume of initial blood sample. The sample collection tubing 808 will receive a blood sample once the sequestration chamber tubing 806 is filled. The sample collection tubing 808 can be connected to a Vacutainer™ base or housing 810, or other blood sample collection device.

[0045] The blood sequestration system 800 further includes a blood sequestration device 812 which, as shown in more detail in FIGS. 8B - 8D, includes a housing 818 that includes a sampling channel 820 defining a pathway for the non-contaminated sample collection tubing 808 or connected at either end to the non-contaminated sample collection tubing 808. The sampling channel 820 can be curved through the housing 818 so as to better affix and stabilize the housing 818 at a location along the non-contaminated sample collection tubing 808.

[0046] The blood sequestration device 812 further includes a sequestration chamber 822 connected with the sequestration chamber tubing 806 or other chamber. The sequestration chamber 822 terminates at an air permeable blood barrier 824. The air permeable blood barrier 824 can also include a coloring agent that turns a different color upon full contact with blood, as an indicator that the regular collection of blood samples (i.e. the non-contaminated blood samples) can be initiated. Other indicators may be used, such as a small light, a sound generation mechanism, or the like. In some implementations, the air permeable blood barrier is positioned at a right angle from the direction of sequestration chamber 822, but can be positioned at any distance or orientation in order to conserve space and materials used for the housing 818. The housing 818 and its contents can be formed of any rigid or semi-rigid material or set of materials.

[0047] FIG. 9 illustrates a pathway splitter 900 for use in a blood sequestrations system, such as those shown in FIGS. 8A - 8E, for example. The pathway splitter 900 includes an inlet port 902, a main line outlet port 904, and a sequestration channel outlet port 906. The inlet port 902 can be connected to main tubing that is in turn connected to a patient needle system, or directly to a patient needle. The main line outlet port 904 can be connected to main line tubing to a blood sampling system, such as a vacutainer base or housing, or directly to such blood sampling system. The sequestration channel outlet port 906 can be connected to sequestration tubing for receiving and sequestering a first sample of blood, up to a measured amount or predetermined threshold. Alternatively, the sequestration channel outlet port 906 can be connected to a sequestration chamber. The sequestra-

tion channel outlet port 906 is preferably 20-70 degrees angled from the main line outlet port 904, which in turn is preferably in-line with the inlet port 902. Once the predetermined amount of initial blood sample is sequestered in the sequestration tubing or chamber, in accordance with mechanisms and techniques described herein, follow-on blood samples will flow into the inlet port 902 and directly out the main line outlet port 904, without impedance.

[0048] FIGS. 10A - 10D illustrate a blood sequestration device 1000 in accordance with alternative implementations. The blood sequestration device 1000 includes an inlet port 1002, a main outlet port 1004, and a sequestration channel port 1006. The inlet port 1002 can be connected to a patient needle or related tubing. The main outlet port 1004 can be connected to a blood sample collection device such as a Vacutainer, associated tubing, or a Luer activated valve, or the like. The sequestration channel port 1006 splits off from the main outlet port 1004 to a sequestration chamber 1008. In some implementations, the sequestration chamber 1008 is formed as a helical channel within a housing or other container 1001.

[0049] The sequestration chamber 1008 is connected at the distal end to an air permeable blood barrier 1010, substantially as described above. Air in the sequestration chamber 1008 is displaced through the air permeable blood barrier 1010 by an initial aliquot of blood that is guided into the sequestration channel port 1006. Once the sequestration chamber 1008 is filled, further blood draws through the main outlet port 1004 can be accomplished, where these samples will be non-contaminated.

[0050] FIGS. 11A - 11E illustrate a blood sequestration device 1100 in accordance with other alternative implementations. The blood sequestration device 1100 includes an inlet port 1102, similar to the inlet ports described above, a main outlet port 1104, and a sequestration channel port 1106 that splits off from the main outlet port 1104 and inlet port 1102. The sequestration channel port is connected to a sequestration chamber 1108. In the implementation shown in FIGS. 11A - 11E, the blood sequestration device includes a base member 1101 having a channel therein, which functions as the sequestration chamber 1108. The channel can be formed as a tortuous path through the base member 1101, which is in turn shaped and formed to rest on a limb of a patient.

[0051] A portion of the sequestration chamber 1108 can protrude from the base member or near a top surface of the base member, just before exiting to an air permeable blood barrier 1110, to serve as a blood sequestration indicator 1109. The indicator 1109 can be formed of a clear material, or a material that changes color when in contact with blood.

[0052] In some implementations, the blood sequestration device 1100 can include a blood sampling device 1120 such as a normally closed needle, Vacutainer™ shield or other collection device. The blood sampling device 1120 can be manufactured and sold with the blood sequestration device 1100 for efficiency and convenience, so that a first aliquot of blood that may be contaminated by a patient needle insertion process can be sequestered. Thereafter, the blood sampling device 1120 can draw non-contaminated blood samples to reduce the risk of false positive testing and ensure a non-contaminated sample.

[0053] FIGS. 12A-12D illustrate a blood sample optimization system 1200 in accordance with yet other alternative implementations. The system 1200 includes a blood sequestration device 1202 for attaching to a blood sampling device 1204, such as a Vacutainer™ or other collection and sampling device. The blood sequestration device 1202 is configured and arranged to receive, prior to a Vacutainer™ container or vial being attached to a collection needle of the blood sampling device 1204, a first aliquot or amount of blood, and sequester that first aliquot or amount in a sequestration channel of the blood sequestration device 1202.

[0054] In some implementations, the blood sequestration device 1202 can include an inlet port 1212, a main outlet port, and a sequestration channel port. The inlet port 1212 can be connected to a patient needle or related tubing. The main outlet port 1214 can be connected to a normally closed needle or device to enable connection with an evacuated blood collection container or other collection device such as a Vacutainer™, associated tubing, luer connectors, syringe, a Luer activated valve, or the like. The sequestration channel port splits off from the main outlet port to a sequestration chamber 1218.

[0055] In some implementations, the sequestration chamber 1218 is formed as a channel within the body of a sequestration device 1202. The sequestration chamber 1218 can be a winding channel, such as a U-shaped channel, an S-shaped channel, a helical channel, or any other winding channel. The sequestration device 1202 can include a housing or other containing body, and one or more channels formed therein. As shown in FIGS. 12A and 12B, the sequestration device 1202 includes a main body 1206 and a cap 1208. The main body 1206 is formed with one or more cavities or channels, which are further formed with one or more arms 1210 that extend from the cap 1208, and which abut the cavities or channels in the main body 1206 to form the primary collection port and main outlet port.

[0056] FIGS. 13A-13D illustrate a blood sample optimization system 1300 in accordance with yet other alternative implementations. The system 1300 includes a blood sequestration device 1302 for attaching to a blood sampling device 1304, such as a Vacutainer or other bodily fluid collection and sampling device. The blood sequestration device 1302 is configured and arranged to receive, prior to a Vacutainer container or vial being attached to a collection needle of the blood sampling device 1304, a first aliquot or amount of blood, and to sequester that first aliquot or amount of blood or other bodily fluid in a sequestration channel of the blood sequestration device 1302.

[0057] The blood sequestration device 1302 includes a housing 1301 having an inlet port 1314, a main outlet port 1312, and a sequestration channel port 1316. The inlet port 1314 can be connected to a patient needle or associated tubing. The main outlet port 1312 can be connected to a normally closed needle or device to enable connection with an evacuated blood collection container or other collection device such as a Vacutainer™, associated tubing, luer connectors, syringe, a Luer activated valve, or the like. The sequestration channel port 1316 splits off from the main inlet port 1314 to a sequestration chamber 1318.

[0058] In the implementation shown in FIGS. 13A-D, the sequestration chamber 1318 is formed as a cavity or chamber within housing 1301 or formed by walls that define housing 1301. The sequestration chamber 1318 can be a winding channel, such as a U-shaped channel, an S-shaped channel, a helical channel, or any other winding channel, that is defined by the cooperation and connection of housing 1301 with cap 1307 which cap 1307 can include a protrusion 1305 that provides one or more walls or directors for the winding channel in the sequestration chamber 1318. The protrusion 1305 from the cap 1307 can be straight or curved, and may have various channels, apertures or grooves embedded therein, and can extend from the cap 1307 any angle or orientation. When the cap 1307 is connected with the housing 1301 to complete the formation of the sequestration chamber 1318, the protrusion 1305 forms at least part of the winding channel to sequester a first aliquot or amount of blood or other bodily fluid in a sequestration channel formed in the sequestration chamber 1318 and by the winding channel.

[0059] The sequestration chamber 1318 includes an air permeable blood barrier 1310, substantially as described above. Air in the sequestration chamber 1318 is displaced through the air permeable blood barrier 1310 by an initial aliquot of blood that is provided into the sequestration chamber 1318 by the blood pressure of the patient. Once the sequestration chamber 1318 is filled and the air in the sequestration chamber 1318 displaced, the blood pressure of the patient will be insufficient to drive or provide further blood into the blood sequestration device 1302, and in particular the outlet port 1312, until a force such as a vacuum or other pressure, such as provided by the blood sample collection device like Vacutainer is provided to draw out a next aliquot or amount of blood or bodily fluid. Further blood draws through the main outlet port 1312 can be accomplished, where these samples will be non-contaminated since any contaminants would be sequestered in the sequestration chamber 1318 with the first aliquot of blood.

[0060] FIGS. 14A-14E illustrate yet another implementation of a blood sampling system 1400 to sequester contaminates of an initial aliquot or sample to reduce false positives in blood cultures or tests performed on a patient's blood sample. The blood sampling system 1400 includes a blood sequestration device 1401 that can be connected between a blood sample collection device 1403 and a patient needle (not shown). The blood sample collection device 1403 can be a Vacutainer or the like. The blood sequestration device 1401 includes an inlet port 1402 that can be connected with a patient needle that is inserted into a patient's vascular system for access to and withdrawing of a blood sample. The inlet port 1402 may also be connected with tubing or other conduit that is in turn connected with the patient needle.

[0061] The inlet port 1402 defines an opening into the blood sequestration device 1401, which opening can be the same cross sectional dimensions as tubing or other conduit connected with the patient needle or the patient needle itself. For instance, the opening can be circular with a diameter of approximately 0.045 inches, but can have a diameter of between 0.01 inches or less to 0.2 inches or more. The blood sequestration device 1401 further includes an outlet port 1404, which defines an opening out of the blood sequestration device 1401 and to the blood sample collection device 1403. The outlet port 1404 may also be connected with tubing or other conduit that is in turn connected with the blood sequestration device 1403. The outlet port 1404 can further include a connector device such as a threaded cap, a Luer connector (male or female), a non threaded interference or glue joint fitting for attachment of various devices including but not limited to tubing, or the like.

[0062] The blood sequestration device 1401 further includes a sampling channel 1406 between the inlet port 1402 and the outlet port 1404, and which functions as a blood sample pathway once a first aliquot of blood has been sequestered. The sampling channel 1406 can be any sized, shaped or configured channel, or conduit. In some implementations, the sampling channel 1406 has a substantially similar cross sectional area as the opening of the inlet port 1402. In other implementations, the sampling channel 1406 can gradually widen from the inlet port 1402 to the outlet port 1404.

[0063] The blood sequestration device 1401 further includes a sequestration chamber 1408 that is connected to and split off or diverted from the sampling channel 1406 at any point between the inlet port 1402 and the outlet port 1404, but preferably from a proximal end of the sampling channel 1406 near the inlet port 1402. The sequestration chamber 1408 is at first maintained at atmospheric pressure, and includes an air outlet 1412 at or near a distal end of the sequestration chamber 1408 opposite the diversion point from the sampling channel 1406. The air outlet 1412 includes an air permeable blood barrier 1412. As shown in FIG. 14B, the air permeable blood barrier 1412 can be overlaid with a protective cover 1416. The protective cover 1416 can be sized and configured to inhibit a user from touching the air permeable blood barrier 1412 with their finger or other external implement, while still allowing air to exit the air permeable blood barrier 1412 as the air is displaced from the sequestration chamber 1408 by blood being forced into the sequestration chamber 1408 by a patient's own blood

pressure. In addition the protective cover 1416 can be constructed to inhibit or prevent accidental exposure of the air permeable blood barrier to environmental fluids or splashes. This can be accomplished in a variety of mechanical ways including but not limited to the addition of a hydrophobic membrane to the protective cover.

[0064] As shown in FIGS. 14C and 14D, the sampling channel 1406 can be cylindrical or frusto-conical in shape, going from a smaller diameter to a larger diameter, to minimize a potential to lyse red blood cells. Likewise, the sampling channel 1406 is formed with a minimal amount of or no sharp turns or edges, which can also lyse red blood cells. The sampling channel 1406 splits off to the sequestration chamber 1408 near the inlet port 1402 via a diversion pathway 1409. The diversion pathway 1409 can have any cross-sectional shape or size, but is preferably similar to the cross-sectional shape of at least part of the inlet port 1402.

[0065] In some implementations, the sampling channel 1406 and the sequestration chamber 1408 are formed by grooves, channels, locks or other pathways formed in housing 1414. The housing 1414 can be made of plastic, metal or other rigid or semi-rigid material. The housing 1414 can have a bottom member that sealably mates with a top member. One or both of the bottom member and the top member can include the sampling channel 1406 and the sequestration chamber 1408, as well as the diversion pathway 1409, the inlet port 1402, and the outlet port 1404. In some other implementations, one or more of the diversion pathway 1409, the inlet port 1402, and/or the outlet port 1404 can be at least partially formed by a cap member that is connected to either end of the housing 1414. In some implementations, the top member and the bottom member, as well as the cap member(s), can be coupled together by laser welding, heat sealing, gluing, snapping, screwing, bolting, or the like. In other implementations, some or all of the interior surface of the diversion pathway 1409 and/or sequestration chamber 1408 can be coated or loaded with an agent or substance, such as a decontaminate, solidifying agent, or the like. For instance, a solidifying agent can be provided at the diversion pathway 1409 such that when the sequestration chamber 1408 is filled and the initial aliquot of blood backs up to the diversion pathway 1409, that last amount of sequestered blood could solidify, creating a barrier between the sequestration chamber 1408 and the sampling channel 1406.

[0066] FIGS. 15A-15G illustrate a blood sequestration device 1500. The blood sequestration device 1500 can be connected to a normally closed needle or device to enable connection with an evacuated blood collection container or other collection device such as a Vacutainer™, associated tubing, luer connectors, syringe, a Luer activated valve, or the like.

[0067] The blood sequestration device 1500 includes an inlet port 1502 that can be connected with a patient needle that is inserted into a patient's vascular system for access to and withdrawing of a blood sample. The inlet port 1502 may also be connected with tubing or other conduit that is in turn connected with the patient needle. The inlet port 1502 defines an opening into the blood sequestration device 1500, which opening may be the same cross sectional dimensions as tubing or other conduit connected with the patient needle or the patient needle itself. For instance, the opening can be circular with a diameter of approximately 0.045 inches, but can have a diameter of between 0.01 inches or less to 0.2 inches or more.

[0068] The inlet port 1502 can also include a sealing or fluid-tight connector or connection, such as threading or Luer fitting, or the like. In some implementations, tubing or other conduit associated with the patient needle can be integral with the inlet port 1502, such as by co-molding, gluing, laser weld, or thermally bonding the parts together. In this manner, the blood sequestration device 1500 can be fabricated and sold with the patient needle as a single unit, eliminating the need for connecting the patient needle to the blood sequestration device 1500 at the time of blood draw or sampling.

[0069] The blood sequestration device 1500 further includes an outlet port 1504, which defines an opening out of the blood sequestration device 1500 and to the blood sample collection device. The outlet port 1504 may also be connected with tubing or other conduit that is in turn connected with the blood sequestration device, and may also include a sealing or fluid-tight connector or connection, such as threading or Luer fitting, or the like. Accordingly, as discussed above, the blood sequestration device 1500 can be fabricated and sold with the patient needle and/or tubing and the blood sample collection device as a single unit, eliminating the need for connecting the patient needle and the blood sample collection device to the blood sequestration device 1500 at the time of blood draw or sampling.

[0070] The blood sequestration device 1500 further includes a sampling channel 1506 between the inlet port 1502 and the outlet port 1504, and which functions as a blood sample pathway once a first aliquot of blood has been sequestered. The sampling channel 1506 can be any sized, shaped or configured channel or conduit. In some implementations, the sampling channel 1506 has a substantially similar cross sectional area as the opening of the inlet port 1502. In other implementations, the sampling channel 1506 can gradually widen from the inlet port 1502 to the outlet port 1504.

[0071] The blood sequestration device 1500 further includes a sequestration chamber 1508 that is connected to and split off or diverted from the sampling channel 1506 at any point between the inlet port 1502 and the outlet port 1504, but preferably from a proximal end of the sampling channel 1506 near the inlet port 1502. In some implementations, the diversion includes a Y-shaped junction. The sequestration chamber 1508 is preferably maintained at atmospheric pressure, and includes a vent 1510 at or near a distal end of the sequestration chamber 1508. The vent 1510 includes an air per-

meable blood barrier 1512. FIG. 15C illustrates the blood sequestration device 1500 with the sequestration chamber 1508 filled with a first aliquot or sample of blood from the patient.

[0072] The air permeable blood barrier 1512 can be covered with a protective cover 1516. The protective cover 1516 can be sized and configured to inhibit a user from touching the air permeable blood barrier 1512 with their finger or other external implement, while still allowing air to exit the air permeable blood barrier 1512 as the air is displaced from the sequestration chamber 1508 by blood being forced into the sequestration chamber 1508 by a patient's own blood pressure. The protective cover 1516 can be constructed to inhibit or prevent accidental exposure of the filter to environmental fluids or splashes. This can be accomplished in a variety of mechanical ways including but not limited to the addition of a hydrophobic membrane to the protective cover.

[0073] FIG. 15B is a perspective view of the blood sequestration device 1500 from the outlet port 1504 and top side of a housing 1501 of the blood sequestration device 1500 that includes the vent 1510, and illustrating an initial aliquot of blood filling sequestration chamber 1508 while the sampling channel 1506 is empty, before a sample collection device is activated. FIG. 15G is a perspective view of the blood sequestration device 1500 from the outlet port 1504 and bottom side of the housing 1501 of the blood sequestration device 1500, and illustrating the initial aliquot of blood filling sequestration chamber 1508 while the sampling channel 1506 is empty, before the sample collection device is activated. FIG. 15C is another perspective view of the blood sequestration device 1500 from the inlet port 1502 and top side of a housing 1501 of the blood sequestration device 1500 that includes the vent 1510, and illustrating blood now being drawn through sampling channel 1506 while the sequestered blood remains substantially in the sequestration chamber 1508.

[0074] FIG. 15D is a cross section of the blood sequestration device 1500 in accordance with some implementations, showing the housing 1501 that defines the sampling channel 1506 and the sequestration chamber 1508. FIGS. 15E and 15F illustrate various form factors of a housing for a blood sequestration device, in accordance with one or more implementations described herein.

[0075] The sequestration chamber 1508 can have a larger cross-sectional area than the sampling channel 1506, and the cross-sectional area and length can be configured for a predetermined or specific volume of blood to be sequestered or locked. The sampling channel 1506 can be sized to be compatible with tubing for either or both of the patient needle tubing or the blood collection device tubing.

[0076] The housing 1501 can be formed of multiple parts or a single, unitary part. In some implementations, and as illustrated in FIG. 15D, the housing 1501 includes a top member 1520 and a bottom member 1522 that are mated together, one or both of which having grooves, channels, locks, conduits or other pathways pre-formed therein, such as by an injection molding process or by etching, cutting, drilling, etc. The top member 1520 can be connected with the bottom member 1522 by any mating or connection mechanism, such as by laser welding, thermal bonding, ultrasonic welding, gluing, using screws, rivets, bolts, or the like, or by other mating mechanisms such as latches, grooves, tongues, pins, flanges, or the like.

[0077] In some implementations, such as shown in FIG. 15D, the top member 1520 can include the grooves, channels, locks, conduits or other pathways, while the bottom member 1522 can include a protrusion 1524 that is sized and adapted to fit into at least one of the grooves, channels, locks or other pathways of the top member 1520. The protrusion 1524 can provide a surface feature, such as a partial groove or channel, for instance, to complete the formation of either the sampling channel 1506 and/or the sequestration chamber 1508. In some implementations, the protrusion 1524 can be formed with one or more angled sides or surfaces for a tighter fit within the corresponding groove, channel, lock or other pathway. In yet other implementations, both the top member 1520 and the bottom member can include grooves, channels, locks or other pathways, as well as one or more protrusions 1524.

[0078] In some implementations, the sampling channel 1506 and the sequestration chamber 1508 are formed by grooves, channels, locks or other pathways formed in housing 1501. The housing 1501 can be made of any suitable material, including rubber, plastic, metal or other material. The housing 1501 can be formed of a clear or translucent material, or of an opaque or non-translucent material. In other implementations, the housing 1501 can be mostly opaque or non-translucent, while the housing surface directly adjacent to the sampling channel 1506 and/or the sequestration chamber 1508 is clear or translucent, giving a practitioner a visual cue or sign that the sequestration chamber 1508 is first filled to the extent necessary or desired, and/or then a visual cue or sign that the sequestered blood remains sequestered while a clean sample of blood is drawn through the sampling channel 1506. Other visual cues or signs of the sequestration can include, without limitation: the air permeable blood barrier 1512 turning a different color upon contact, saturation, or partial saturation with blood; a color-coded tab or indicator at any point along or adjacent to the sequestration chamber; an audible signal; a vibratory signal; or other signal.

[0079] After a venipuncture by a patient needle of a patient (not shown), which could gather a number of pathogens from the patient's skin, a first amount of the patient's blood with those pathogens will make its way into the input port 1502 blood sequestration device 1500 and flow into the sequestration chamber 1508 by following the path of least resistance, as the patient's own blood pressure overcomes the atmospheric pressure in the sequestration chamber 1508 to displace air therein through

the air permeable blood barrier 1512. The patient's blood pressure will not be sufficient to overcome the air pressure that builds up in the sealed sampling channel 1506. Eventually, the sequestration chamber 1508, which has a predetermined volume, is filled with blood that displaces air through the air permeable blood barrier 1512. Once the blood hits the air permeable blood barrier, the blood interacts with the air permeable blood barrier 1512 material to completely or partially seal the vent 1510. A signal or indication may be provided that the practitioner can now utilize the Vacutainer capsule or other blood sample collection device to acquire a next amount of the patient's blood for sampling. The blood in the sequestration chamber 1508 is now effectively sequestered in the sequestration chamber.

[0080] Upon filling the blood sequestration pathway 1508 but prior to use of the Vacutainer or other blood sample collection device, the patient's blood pressure may drive compression of the air in the sampling channel 1506, possibly resulting in a small amount of blood moving past the diversion point to the sequestration chamber 1508 and into the sampling channel 1506, queuing up the uncontaminated blood to be drawn through the sampling channel 1506.

[0081] FIGS. 16-19 illustrate yet another implementation of a blood sequestration device. FIGS. 16A-16D illustrate a blood sequestration device 1600 that can be connected between a blood sample collection device, such as an evacuated blood collection container like a Vacutainer™ (not shown), and a patient needle (not shown) and/or associated tubing. FIG. 17 illustrates a bottom member of the blood sequestration device, and FIG. 18 illustrates a top member of the blood sequestration device, which top member and bottom member can be mated together to form an input port, and output port, a sequestration chamber and a sampling channel, as explained more fully below. FIGS. 19A and B show the top member and bottom member mated together. It should be understood that FIGS. 16-19 illustrate one exemplary manner of constructing a blood sequestration device as described herein, and other forms of construction are possible.

[0082] Referring to FIGS. 16A - D, the blood sequestration device 1600 includes an inlet port 1602 that can be connected with a patient needle that is inserted into a patient's vascular system for access to and withdrawing of a blood sample. The inlet port 1602 may also be connected with tubing or other conduit that is in turn connected with the patient needle. The inlet port 1602 defines an opening into the blood sequestration device 1600, which opening can be the same cross sectional dimensions as tubing or other conduit connected with the patient needle or the patient needle itself. For instance, the opening can be circular with a diameter of approximately 0.045 inches, but can have a diameter of between 0.01 inches or less to 0.2 inches or more.

[0083] The inlet port 1602 can also include a sealing or fluid-tight connector or connection, such as threading or Luer fitting, or the like. In some implementations, tubing or other conduit associated with the patient needle can be integral with the inlet port 1602, such as by co-molding, gluing, laser weld, or thermally bonding the parts together. In this manner, the blood sequestration device 1600 can be fabricated and sold with the patient needle and/or tubing as a single unit, eliminating the need for connecting the patient needle to the blood sequestration device 1600 at the time of blood draw or sampling.

[0084] The blood sequestration device 1600 further includes an outlet port 1604, which defines an opening out of the blood sequestration device 1600 and to the blood sample collection device. The outlet port 1604 may also be connected with tubing or other conduit that is in turn connected with the blood sequestration device, and may also include a sealing or fluid-tight connector or connection, such as threading or Luer fitting, or the like. Accordingly, as discussed above, the blood sequestration device 1600 can be fabricated and sold with the patient needle and/or tubing and the blood sample collection device as a single unit, eliminating the need for connecting the patient needle and the blood sample collection device to the blood sequestration device 1600 at the time of blood draw or sampling.

[0085] The blood sequestration device 1600 further includes a sampling channel 1606 between the inlet port 1602 and the outlet port 1604, and a sequestration chamber 1608 that is connected to and split off or diverted from the sampling channel 1606 at any point between the inlet port 1602 and the outlet port 1604. The sampling channel 1606 functions as a blood sampling pathway once a first aliquot of blood has been sequestered in the sequestration chamber 1608. The sampling channel 1606 can be any sized, shaped or configured channel, or conduit. In some implementations, the sampling channel 1606 has a substantially similar cross sectional area as the opening of the inlet port 1602. In other implementations, the sampling channel 1606 can gradually widen from the inlet port 1602 to the outlet port 1604. The sequestration chamber 1608 may have a larger cross section to form a big reservoir toward the sequestration channel path so that the blood will want to enter the reservoir first versus entering a smaller diameter on the sampling channel 1606, as is shown more fully in FIGS. 17 and 19.

[0086] In some exemplary implementations, the diversion between the sampling channel 1606 and the sequestration chamber 1608 is by diverter junction 1607. Diverter junction 1607 may be a substantially Y-shaped, T-shaped, or U-shaped. In some preferred exemplary implementations, and as shown in FIG. 17A -17B, the diverter junction 1607 is configured such that the flow out of the inlet port 1602 is preferentially directed toward the sequestration chamber 1608. The sequestration chamber 1608 may also include or form a curve or ramp to direct the initial blood flow toward and into the sequestration chamber 1608.

[0087] The sequestration chamber 1608 is preferably maintained at atmospheric pressure, and includes a vent

1610 at or near a distal end of the sequestration chamber 1608. The vent 1610 may include an air permeable blood barrier 1612 as described above.

[0088] The blood sequestration device 1600 can include a housing 1601 that can be formed of multiple parts or a single, unitary part. In some implementations, and as illustrated in FIGS. 17A - 17D and FIGS. 18A - 18F, the housing 1601 includes a top member 1620 and a bottom member 1622 that are mated together. The blood sequestration device 1600 can also include a gasket or other sealing member (not shown) so that when the top member 1620 is mechanically attached with the bottom member 1622, the interface between the two is sealed by the gasket or sealing member. The FIGS. 17A - 17D illustrate a bottom member 1622 of a housing for a blood sequestration device 1600. The bottom member 1622 can include grooves, channels, locks, conduits or other pathways pre-formed therein, such as by an injection molding process or by etching, cutting, drilling, etc., to form the sampling channel 1606, the sequestration chamber 1608, and diverter junction 1607.

[0089] The sequestration chamber 1608 may have a larger cross section than the sampling channel 1606 so that the blood will preferentially move into the sequestration chamber first versus entering a smaller diameter on the sampling channel 1606.

[0090] FIGS. 18A - 18F illustrate the top member 1620, which can be connected with the bottom member 1622 by any mating or connection mechanism, such as by laser welding, thermal bonding, gluing, using screws, rivets, bolts, or the like, or by other mating mechanisms such as latches, grooves, tongues, pins, flanges, or the like. The top member 1620 can include some or all of the grooves, channels, locks, conduits or other pathways to form the sampling channel 1606, the sequestration chamber 1608, and the diverter junction 1607. In yet other implementations, both the top member 1620 and the bottom member 1622 can include the grooves, channels, locks or other pathways.

[0091] In some implementations, the sampling channel 1606 and the sequestration chamber 1608 are formed by grooves, channels, locks or other pathways formed in housing 1601. The housing 1601 can be made of rubber, plastic, metal or any other suitable material. The housing 1601 can be formed of a clear or translucent material, or of an opaque or non-translucent material. In other implementations, the housing 1601 can be mostly opaque or non-translucent, while the housing surface directly adjacent to the sampling channel 1606 and/or the sequestration chamber 1608 may be clear or translucent, giving a practitioner a visual cue or sign that the sequestration chamber 1608 is first filled to the extent necessary or desired, and/or then a visual cue or sign that the sequestered blood remains sequestered while a clean sample of blood is drawn through the sampling channel 1606. Other visual cues or signs of the sequestration can include, without limitation: the air permeable blood barrier 1612 turning a different color upon contact, saturation, or partial saturation with blood; a color-coded tab or indicator at any point along or adjacent to the sequestration chamber; an audible signal; a vibratory signal; or other signal.

[0092] As shown in FIGS. 18A - 18F, the air permeable blood barrier 1612 can be covered with, or surrounded by, a protective member 1616. The protective member 1616 can be sized and configured to inhibit a user from touching the air permeable blood barrier 1612 with their finger or other external implement, while still allowing air to exit the air permeable blood barrier 1612 as the air is displaced from the sequestration chamber 1608. In some implementations, the protective member 1616 includes a protrusion that extends up from a top surface of the top member 1620 and around the air permeable blood barrier 1612. The protective cover 1616 can be constructed to inhibit or prevent accidental exposure of the filter to environmental fluids or splashes. This can be accomplished in a variety of mechanical ways including but not limited to the addition of a hydrophobic membrane to the protective cover.

[0093] In use, the blood sequestration device 1600 includes a sampling channel 1606 and a sequestration chamber 1608. Both pathways are initially air-filled at atmospheric pressure, but the sampling channel 1606 is directed to an output port 1604 that will be initially sealed by a Vacutainer or other such sealed blood sampling device, and the sequestration chamber 1608 terminates at a vent 1610 to atmosphere that includes an air permeable blood barrier 1612.

[0094] After a venipuncture by a patient needle of a patient (not shown), which could gather a number of pathogens from the patient's skin, a first amount of the patient's blood with those pathogens will pass through input port 1602 of blood sequestration device 1600. This initial volume of potentially contaminated blood will preferentially flow into the sequestration chamber 1608 by finding the path of least resistance. The patient's own blood pressure overcomes the atmospheric pressure in the vented sequestration chamber 1608 to displace air therein through the air permeable blood barrier 1612, but is not sufficient to overcome the air pressure that builds up in the sealed sampling channel 1606. In various exemplary embodiments, the sequestration chamber 1608 and sampling channel 1606 can be configured such that the force generated by the patient's blood pressure is sufficient to overcome any effect of gravity, regardless of the blood sequestration device's orientation.

[0095] Eventually, the sequestration chamber 1608 fills with blood that displaces air through the air permeable blood barrier 1612. Once the blood contacts the air permeable blood barrier, the blood interacts with the air permeable blood barrier 1612 material to completely or partially seal the vent 1610. A signal or indication may be provided that the practitioner can now utilize the Vacutainer or other blood sampling device.

[0096] Upon filling the blood sequestration pathway 1608 but prior to use of the Vacutainer or other blood

sample collection device, the patient's blood pressure may drive compression of the air in the sampling channel 1606, possibly resulting in a small amount of blood moving past the diversion point into the sampling channel 1606, queuing up the uncontaminated blood to be drawn through the sampling channel 1606.

[0097] FIG. 19A is a side view, and FIG. 19B is a cross-sectional view, of the blood sequestration device 1600, illustrating the top member 1620 mated with the bottom member 1622.

[0098] FIG. 20 shows a blood sample optimization system 2000 that includes a patient needle 2002 for vascular access to a patient's bloodstream, a blood sample collection device 2004 to facilitate the collecting of one or more blood samples, and a conduit 2006 providing a fluid connection between the patient needle 2002 and the blood sample collection device 2004. In some implementations, the blood sample collection device 2004 includes a protective shield that includes a sealed collection needle on which a sealed vacuum-loaded container is placed, which, once pierced by the collection needle, draws in a blood sample under vacuum pressure or force through the conduit 2006 from the patient needle 2002.

[0099] The blood sample optimization system 2000 further includes a blood sequestration device 2008, located at any point on the conduit 2006 between the patient needle 2002 and the blood sample collection device 2004 as described herein.

[0100] FIG. 21 illustrates a non-vented blood sequestration device 2100 using a wicking material chamber. The blood sequestration device 2100 includes a housing 2101 that has a sampling channel 2104 that is at least partially surrounded or abutted by a sequestration chamber 2102 that is filled with a wicking material. An initial aliquot of blood is drawn in from the patient needle into the sampling channel 2104 where it is immediately wicked into the wicking material of the sequestration chamber 2102. The wicking material and/or sequestration chamber 2102 is sized and adapted to receive and hold a predetermined amount of blood, such that follow-on or later blood draws pass by the wicking material and flow straight through the sampling channel 2104 to a sampling device such as a Vacutainer. The wicking material can include a substance such as a solidifier, a decontaminate, or other additive.

[0101] As described herein, an air permeable blood barrier may be created using a wide variety of different structures and materials. As shown in FIGS. 22A and B, an air permeable blood barrier 2202 of a blood sequestration device 2200 can include a polymer bead matrix 2204, in which at least some beads are treated to make them hydrophilic. The air permeable blood barrier 2202 further includes a self-sealing material 2206, such as carboxymethyl cellulose (CMC) or cellulose gum, or other sealing material. The air permeable blood barrier 2202 can further include voids 2208 that permit air flow before contact or during partial contact with a fluid such as blood. As shown in FIG. 22B, contact with a fluid causes the self-sealing material 2206 to swell and close off the voids 2208, occluding air flow through the voids 2208 and creating a complete or partial seal.

[0102] FIGS. 23A and B illustrate yet another implementation of a blood sequestration device 2300, having an inlet port 2302 to connect with a patient needle, an outlet port 2304 to connect with a blood sample collection device, a sequestration chamber 2306, and a sampling channel 2308 that bypasses the sequestration chamber 2306 once the sequestration chamber is filled to an initial aliquot of potentially contaminated blood to be sequestered. The sequestration chamber 2306 includes a hydrophobic plug 2312 at a distal end of the sequestration chamber 2306 that is farthest from the inlet port 2302. A vacuum or other drawing force applied from the outlet port 2304, such as from a Vacutainer or the like, draws in blood into the inlet port 2302 and directly into the sequestration chamber 2306, where the initial aliquot of blood will contact the hydrophobic plug 2312 and cause the initial aliquot of blood to back up into the sequestration chamber 2306 and be sequestered there. A small amount of blood may make its way into the sampling channel 2308, which is initially closed off by valve 2308. Upon release of the valve 2308, and under further force of the vacuum or other force, follow-on amounts of blood will flow into inlet port 2302, bypass the sequestration chamber 2306, and flow into and through sampling channel 2308 toward the outlet port 2304 and to the collection device.

[0103] The sampling channel 2308 can have any suitable geometry and can be formed of plastic tubing or any other suitable material. Valve 2308 can be a clip or other enclosing device to pinch, shunt, bend or otherwise close off the sampling channel before the initial aliquot of blood is sequestered in the sequestration chamber 2306.

[0104] Although a variety of embodiments have been described in detail above, other modifications are possible. Other embodiments may be within the scope of the following claims.

Aspects useful for understanding the invention:

[0105]

1. A blood sequestration device comprising;
an inlet port;
an outlet port;
a sequestration chamber connected with the inlet port, the sequestration chamber having a vent comprising an air permeable blood barrier;
a sampling channel having a proximal end connected with the inlet port and a distal end connected with the outlet port; and
a housing that houses and defines the inlet port, the outlet port, the sequestration chamber, and the sampling channel.

2. The blood sequestration device in accordance

with aspect 1, wherein the air permeable blood barrier includes an air permeable material that seals at least partially upon contact with blood.

3. The blood sequestration device in accordance with aspect 1 or 2, wherein the sequestration chamber includes a sequestration channel defined in the housing.

4. The blood sequestration device in accordance with aspect 3, further comprising a blood sampling pathway connected with the inlet port, and wherein the inlet port defined by the housing has a cross-sectional geometry consistent with the blood sampling pathway.

5. The blood sequestration device in accordance with aspect 3 or 4, wherein the sampling channel defined by the housing has a cross-sectional geometry consistent with the inlet port.

6. The blood sequestration device in accordance with one of the previous aspects, wherein the sequestration chamber and the sampling channel are connected with the inlet port by a junction that is configured to direct a first portion of blood to the sequestration chamber.

7. The blood sequestration device in accordance with one of the previous aspects, wherein the housing comprises a bottom member mated with a top member, each of the bottom member and the top member defining a part of each of the inlet port, the outlet port, the sequestration chamber, and the sampling channel.

8. A blood sequestration device connected with a blood sampling pathway having a patient needle and a sample collection device, the blood sequestration device comprising;
an inlet port connected with the patient needle;
a sequestration chamber connected with the inlet port, the sequestration chamber having a vent comprising an air permeable blood barrier;
a sampling channel having a proximal end connected with the inlet port; and
an outlet port connected with a distal end of the sampling channel and with the sample collection device; and
a housing that houses and defines the inlet port, the outlet port, the sequestration chamber, and the sampling channel.

9. The blood sequestration device in accordance with aspect 8, wherein the inlet port is connected with the patient needle via a first portion of the blood sampling pathway.

10. The blood sequestration device in accordance with aspect 8 or 9, wherein the outlet port is connected with the sample collection device via a second portion of the blood sampling pathway.

11. The blood sequestration device in accordance with one of aspects 8 to 10, wherein the air permeable blood barrier includes an air permeable material that seals at least partially upon contact with blood.

12. The blood sequestration device in accordance with one of aspects 8 to 11, wherein the sequestration chamber includes a sequestration channel defined in the housing.

13. The blood sequestration device in accordance with aspect 12, wherein the sequestration channel has a proximal end connected with the inlet port, and a distal end having the vent comprising an air permeable blood barrier.

14. The blood sequestration device in accordance with one of aspects 8 to 13, wherein the sequestration chamber and the sampling channel are connected with the inlet port by a junction that is configured to direct a first portion of blood to the sequestration chamber.

15. The blood sequestration device in accordance with one of aspects 8 to 14, wherein the sampling channel has a substantially uniform cross-sectional geometry that is consistent with the blood sampling pathway.

16. The blood sequestration device in accordance with aspect 15, wherein the sequestration chamber includes a sequestration chamber that has a cross-sectional area that is larger than the cross-sectional geometry of the sampling channel.

17. A blood sequestration device connected with a blood sampling system comprising a patient needle for accessing a blood sample from a patient, and a sample needle that is sealed, the blood sequestration device comprising;
an inlet port connected with the patient needle to receive the blood sample from the patient;
a sequestration chamber connected with the inlet port and having a vent comprising an air permeable blood barrier, the sequestration chamber for receiving and sequestering a first portion of the blood sample prior to the sample needle being unsealed; and
a sampling channel having a proximal end connected with the inlet port, the sampling channel for conveying a second portion of the blood sample once the sample needle is unsealed;
an outlet port connected with a distal end of the sampling channel for conveying the second portion of

the blood sample to the sample needle; and
a housing that houses and defines the inlet port, the outlet port, the sequestration chamber, and the sampling channel.

18. The blood sequestration device in accordance with aspect 17, wherein the sequestration chamber is at ambient air pressure, and wherein the sequestration chamber receives the first portion of the blood sample by blood pressure of the patient overcoming the ambient air pressure in the sequestration chamber.

19. The blood sequestration device in accordance with aspect 17 or 18, wherein the sampling channel causes the second portion of the blood sample to bypass the sequestered first portion of blood, and exit the outlet port for conveyance to a blood collection device.

20. The blood sequestration device in accordance with aspect 17, 18 or 19, wherein the air permeable blood barrier includes an air permeable material that seals upon contact with blood.

Claims

1. A blood sequestration device (1500) comprising;

   an inlet port (1502);
   a junction (1607) connected with the inlet port (1502);
   a sequestration chamber (1508) having a vent (1510) comprising an air permeable blood barrier (1512);
   a sampling channel (1506) having a proximal end connected with the inlet port (1502) via the junction (1607), and a distal end connected with an outlet port (1504); and
   a housing (1501) that houses and defines the inlet port (1502), the junction (1607), the sequestration chamber (1508), the sampling channel (1506), and the outlet port (1504),
   characterized in that the sequestration chamber (1508) is connected with the
   inlet port (1502) via the junction (1607) which is configured to direct a first portion of blood to the sequestration chamber (1508), and the air permeable blood barrier (1512) includes an air permeable material that seals at least partially upon contact with a portion of the first portion of blood.

2. The blood sequestration device (1500) in accordance with claim 1,
   wherein the sequestration chamber (1508) includes a sequestration channel defined in the housing (1501).

3. The blood sequestration device (1500) in accordance with claim 1 or 2, further comprising a blood sampling pathway connected with the inlet port (1502) opposite the junction (1607), and
   wherein the inlet port (1502) defined by the housing (1501) has a cross-sectional geometry consistent with the blood sampling pathway.

4. The blood sequestration device (1500) in accordance with one of the preceding claims, wherein
   the sampling channel (1506) defined by the housing (1501) has a cross-sectional geometry consistent with the inlet port (1502).

5. The blood sequestration device (1500) in accordance with one of claims 2 to 4, wherein the housing (1501) comprises a bottom member (1522) mated with a top member (1520), each of the bottom member (1522) and the top member (1520) defining a part of each of the inlet port (1502), the outlet port (1504), the sequestration chamber (1508), and the sampling channel (1506).

6. A system of a blood sequestration device (1500), a blood sampling pathway having a patient needle, and a sample collection device, the blood sequestration device (1500) comprising;
   an inlet port (1502) connected with the patient needle;
   a junction (1607) connected with the inlet port (1502) opposite the blood sampling pathway;
   a sequestration chamber (1508) having a vent (1510) comprising an air permeable blood barrier (1512);
   a sampling channel (1506) having a proximal end connected with the inlet port (1502); and
   an outlet port (1504) connected with a distal end of the sampling channel (1506) and with the sample collection device; and
   a housing (1501) that houses and defines the inlet port (1502), the outlet port (1504), the sequestration chamber (1508), and the sampling channel (1506), **characterized in that** the sequestration chamber (1508) is connected with the inlet port (1502) and the air permeable blood barrier (1512) includes an air permeable material that seals at least partially upon contact with blood.

7. The system in accordance with claim 6, wherein the inlet port (1502) is connected with the patient needle via a first portion of the blood sampling pathway.

8. The system in accordance with claim 6 or 7, wherein the outlet port (1504) is connected with the sample collection device via a second portion of the blood sampling pathway.

9. The system in accordance with one of claims 6 to 8,

wherein the sequestration chamber (1508) includes a sequestration channel defined in the housing (1501).

10. The system in accordance with claim 9, wherein the sequestration channel has a proximal end connected with the inlet port (1502), and a distal end having the vent (1510) comprising an air permeable blood barrier (1512).

11. The system in accordance with one of claims 6 to 10, wherein the sequestration chamber (1508) and the sampling channel (1506) are connected with the inlet port (1502) by
the junction (1607) that is configured to direct a first portion of blood to the sequestration chamber (1508).

12. The system in accordance with one of claims 6 to 11, wherein the sampling channel (1506) has a substantially uniform cross-sectional geometry that is consistent with the blood sampling pathway.

13. The system in accordance with claim 12, wherein the sequestration chamber (1506) includes a sequestration chamber that has a cross-sectional area that is larger than the cross-sectional geometry of the sampling channel (1506).

14. The system in accordance with claim 7, member (1520), wherein the housing (1501) comprises a bottom member (1522) mated with a top member (1520), each of the bottom member (1522) and the top member (1520) defining a part of each of the inlet port (1502), the outlet port (1504), the sequestration chamber (1508), and the sampling channel (1506).

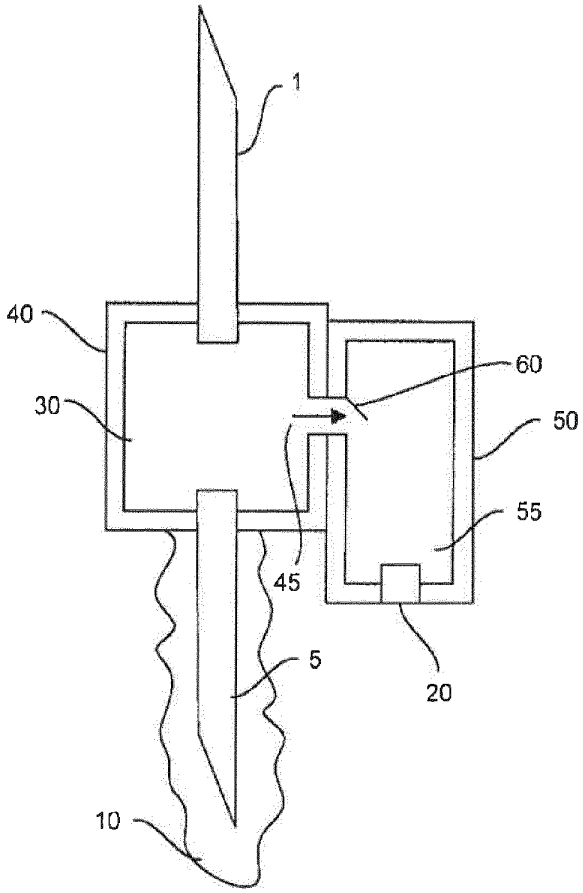


FIG. 1

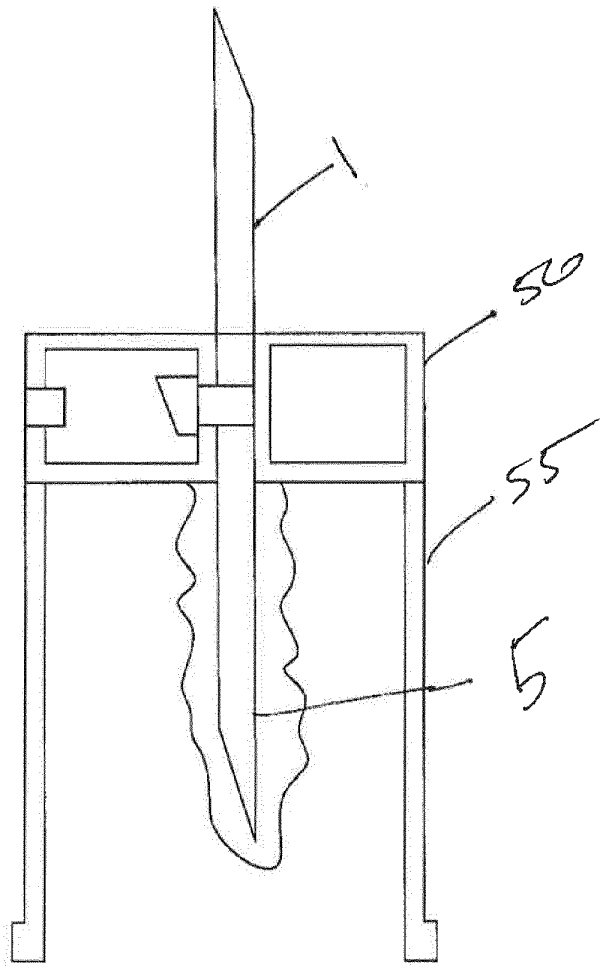


FIG. 2

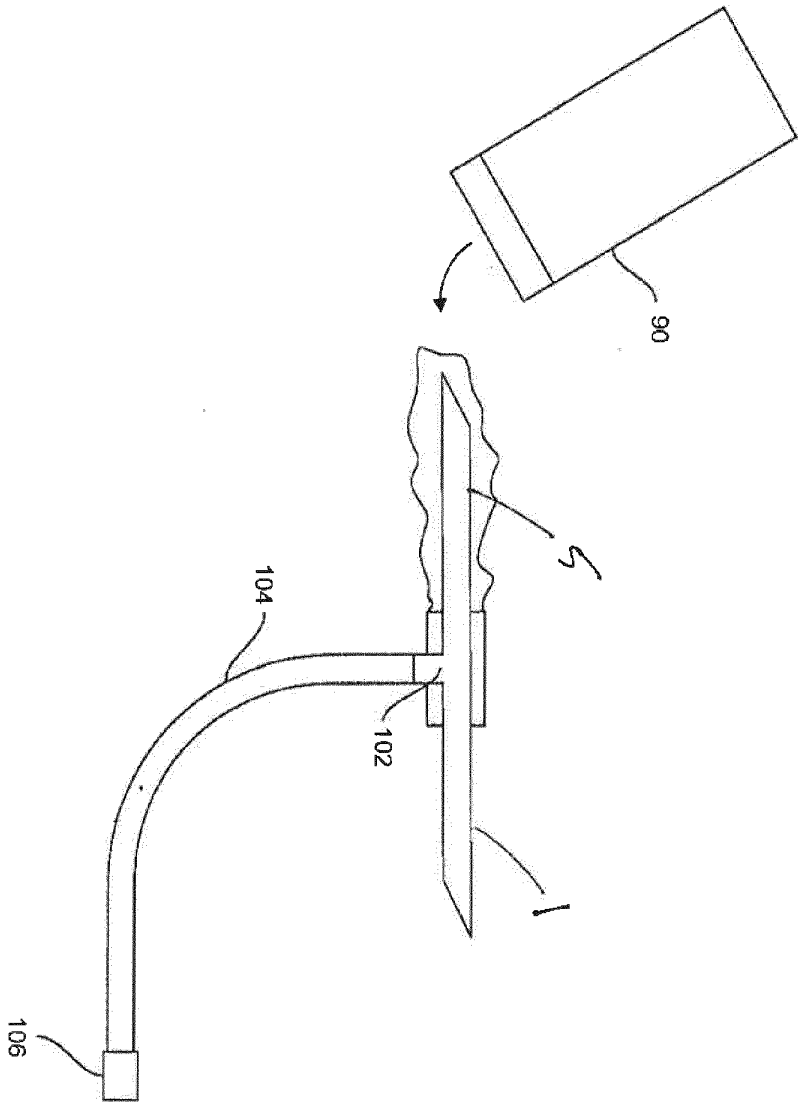


FIG. 3

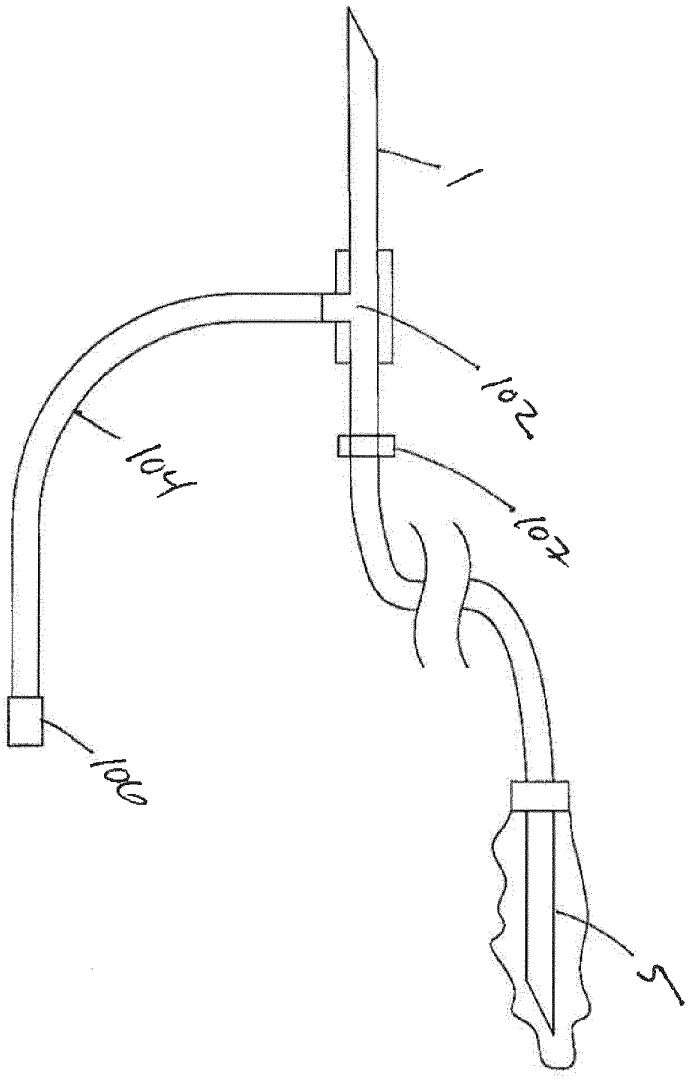


FIG. 4

FIG. 5

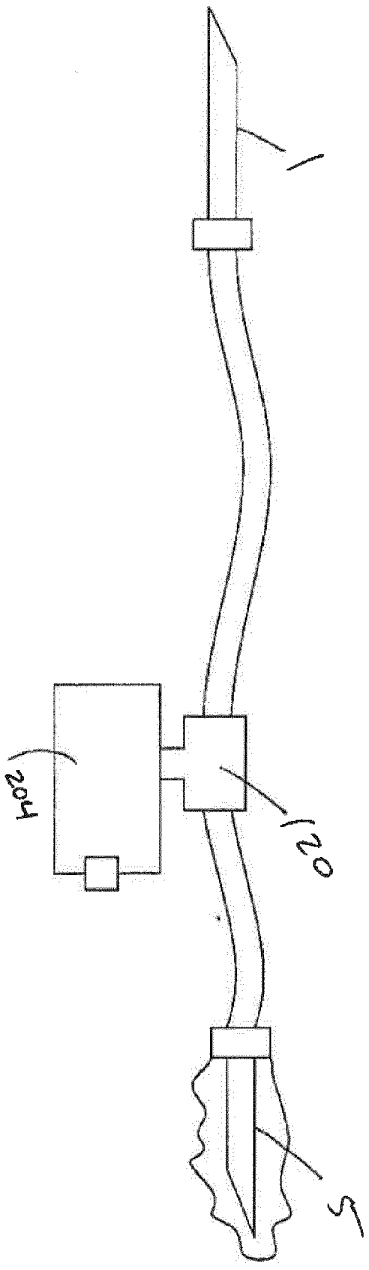
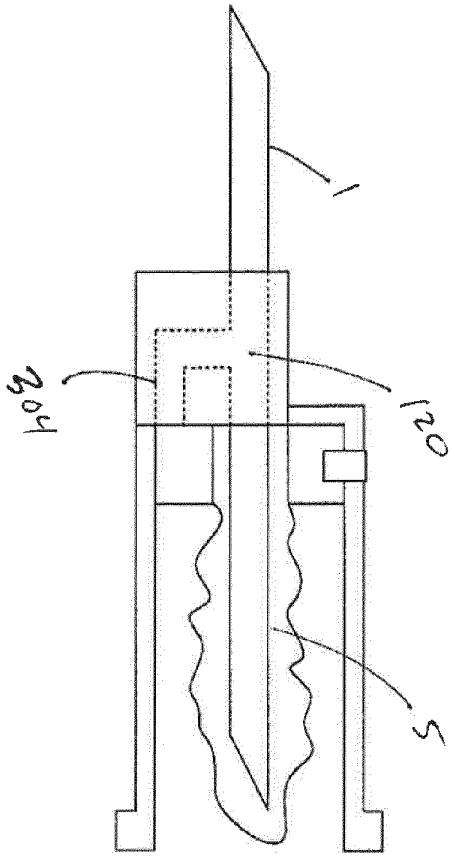


FIG. 6



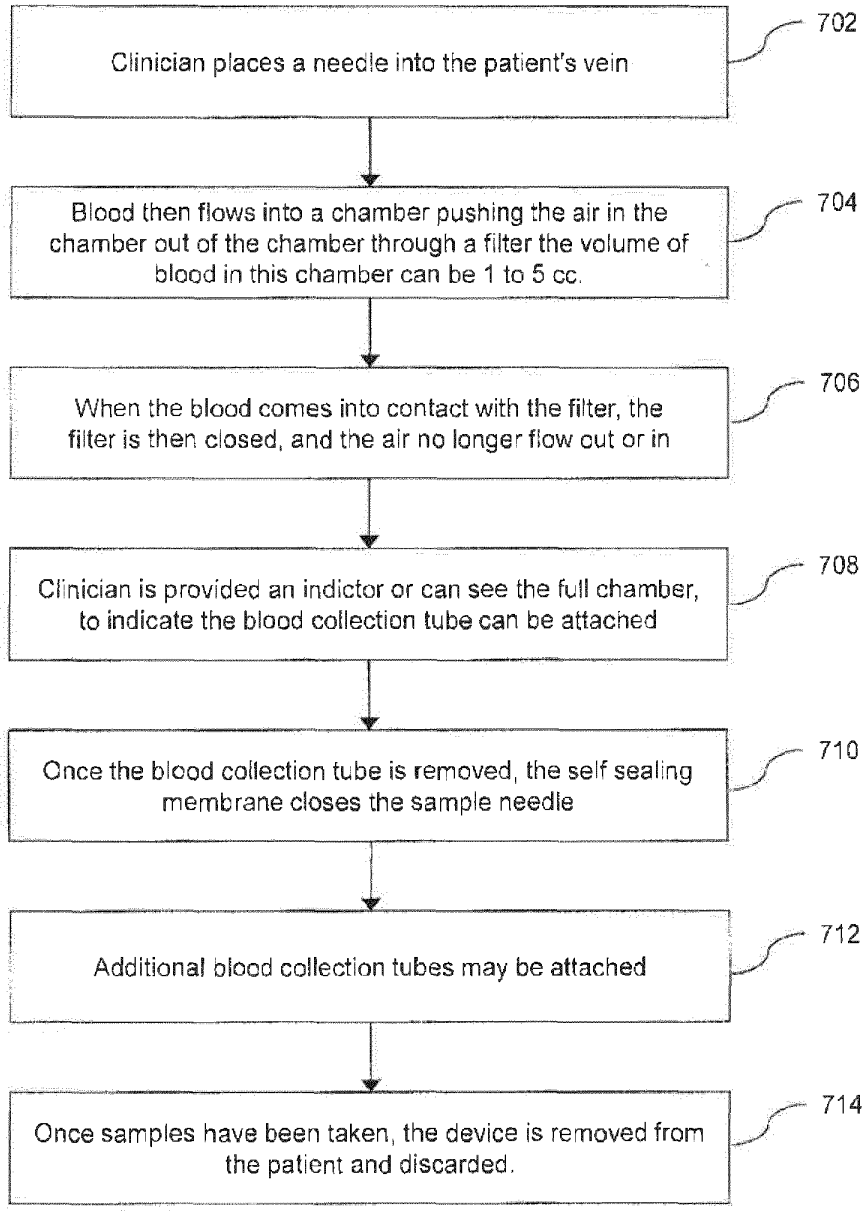

Clinician places a needle into the patient's vein
702
Blood then flows into a chamber pushing the air in the chamber out of the chamber through a filter the volume of blood in this chamber can be 1 to 5 cc.
704
When the blood comes into contact with the filter, the filter is then closed, and the air no longer flow out or in
706
Clinician is provided an indictor or can see the full chamber, to indicate the blood collection tube can be attached
708
Once the blood collection tube is removed, the self sealing membrane closes the sample needle
710
Additional blood collection tubes may be attached
712
Once samples have been taken, the device is removed from the patient and discarded.
714

FIG. 7

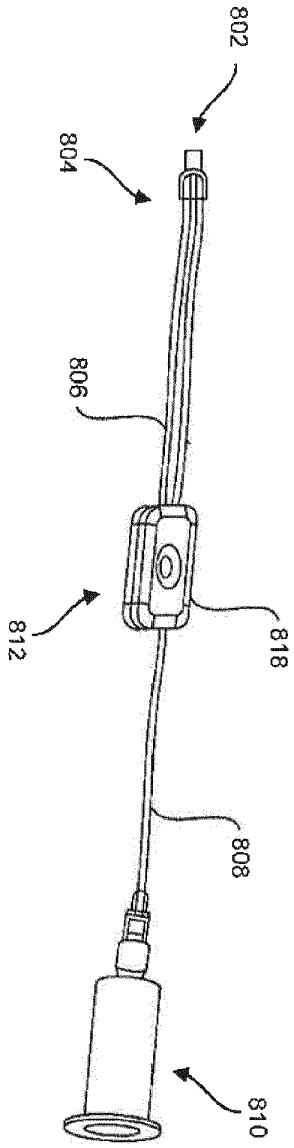


FIG. 8A

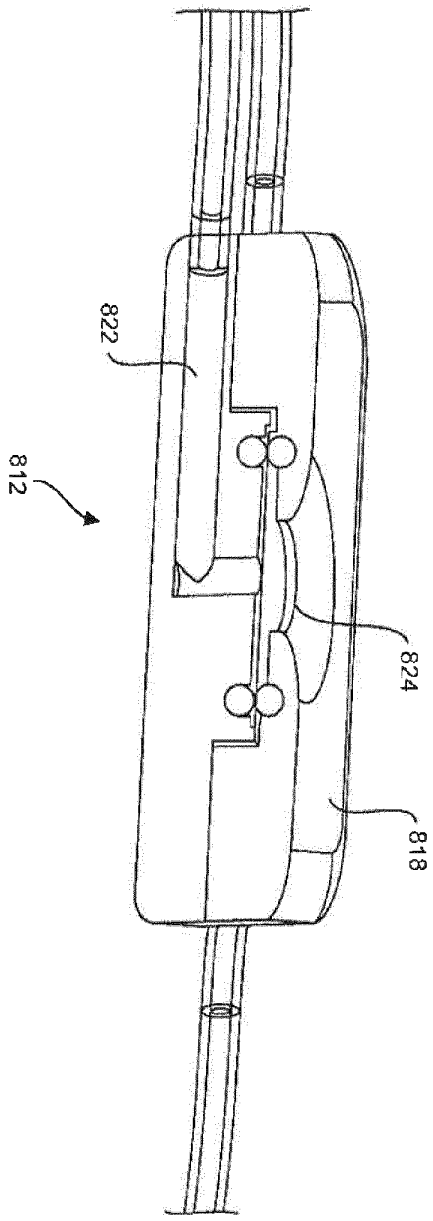


FIG. 8B

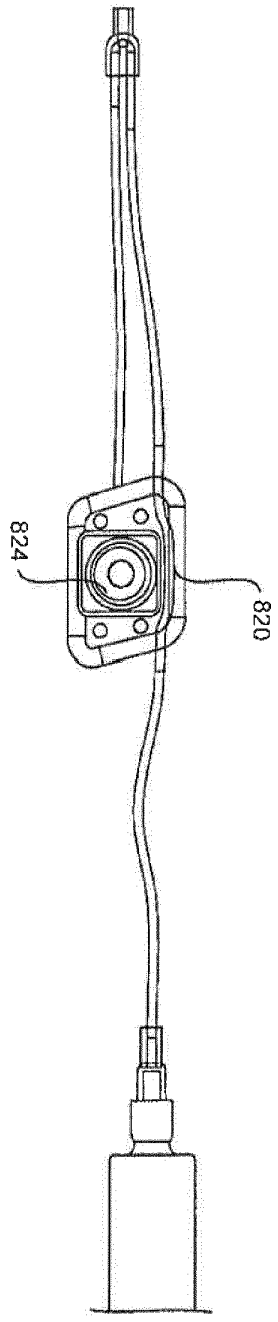


FIG. 8C

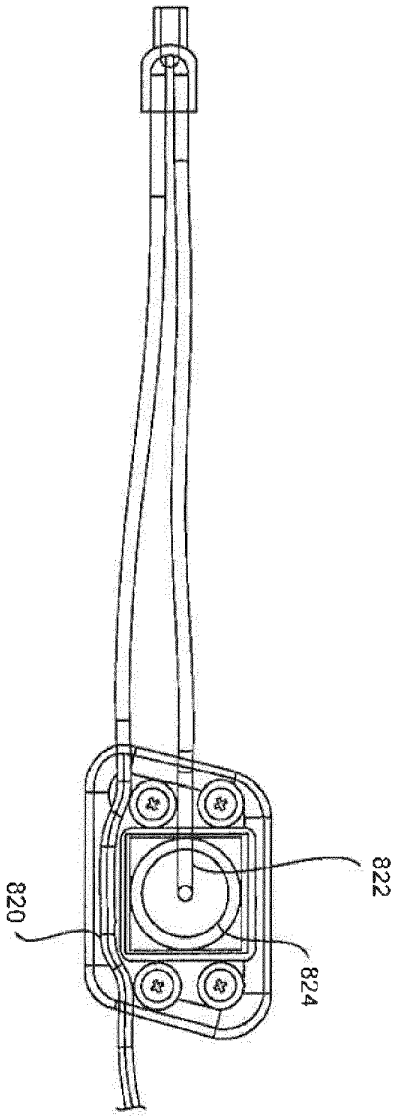


FIG. 8D

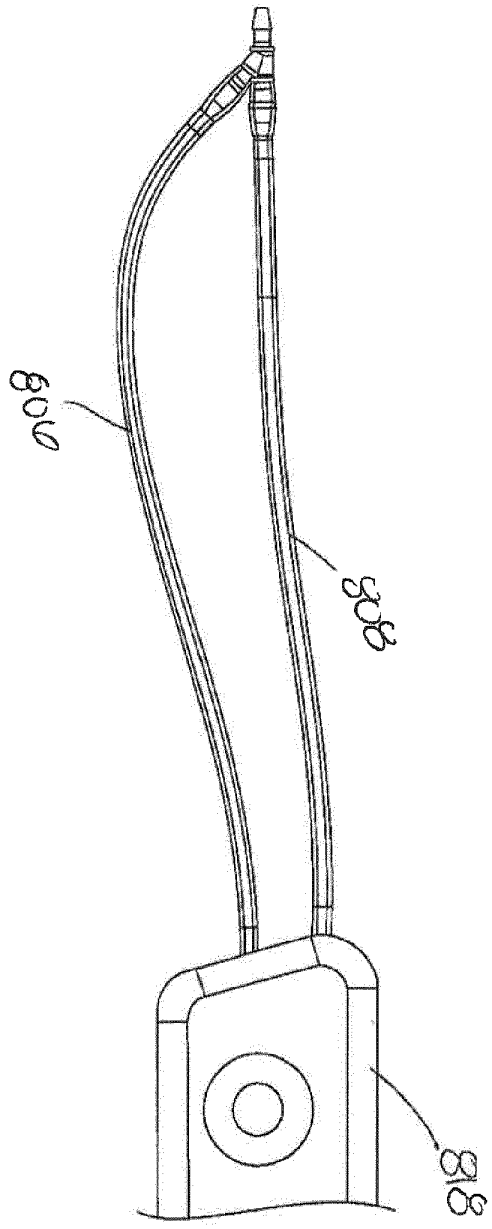


FIG. 8E

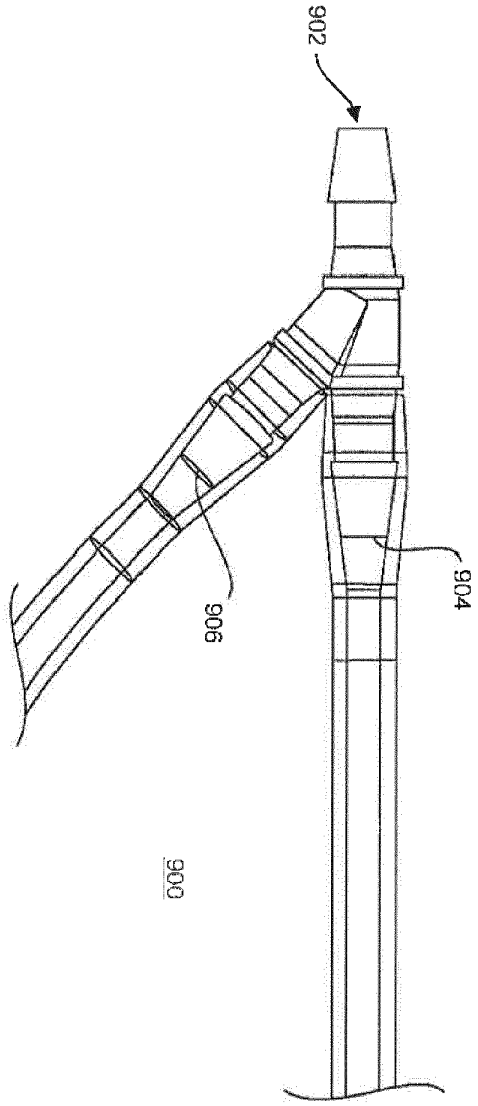


FIG. 9

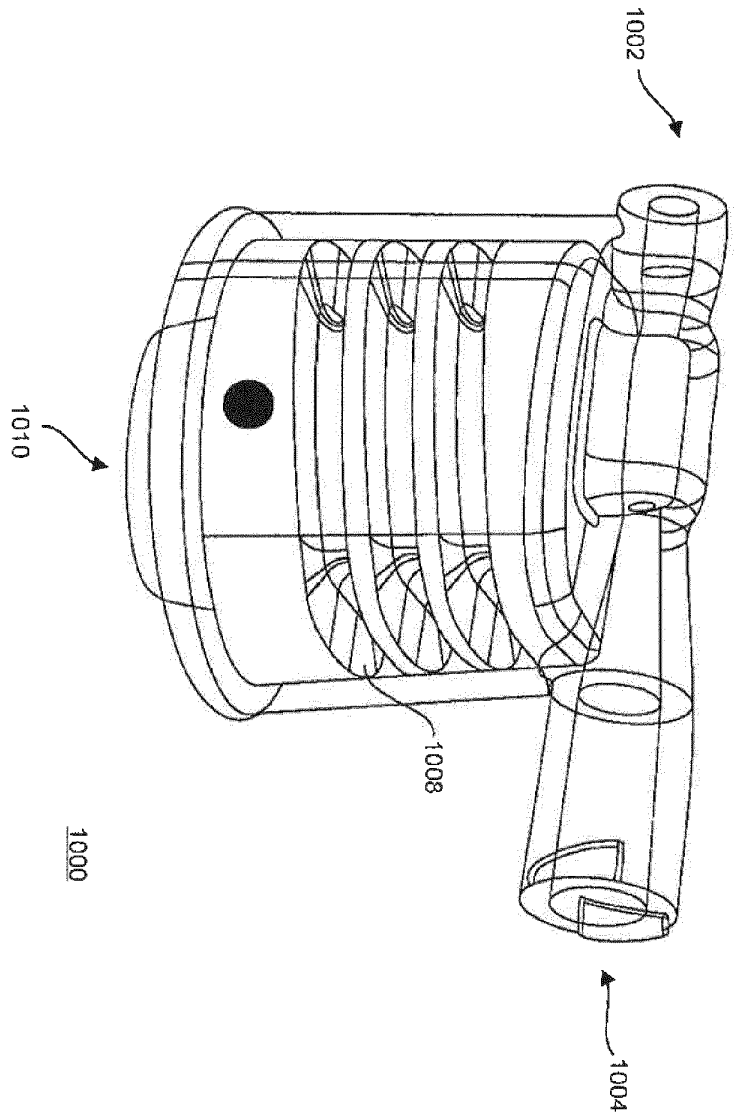


FIG. 10A

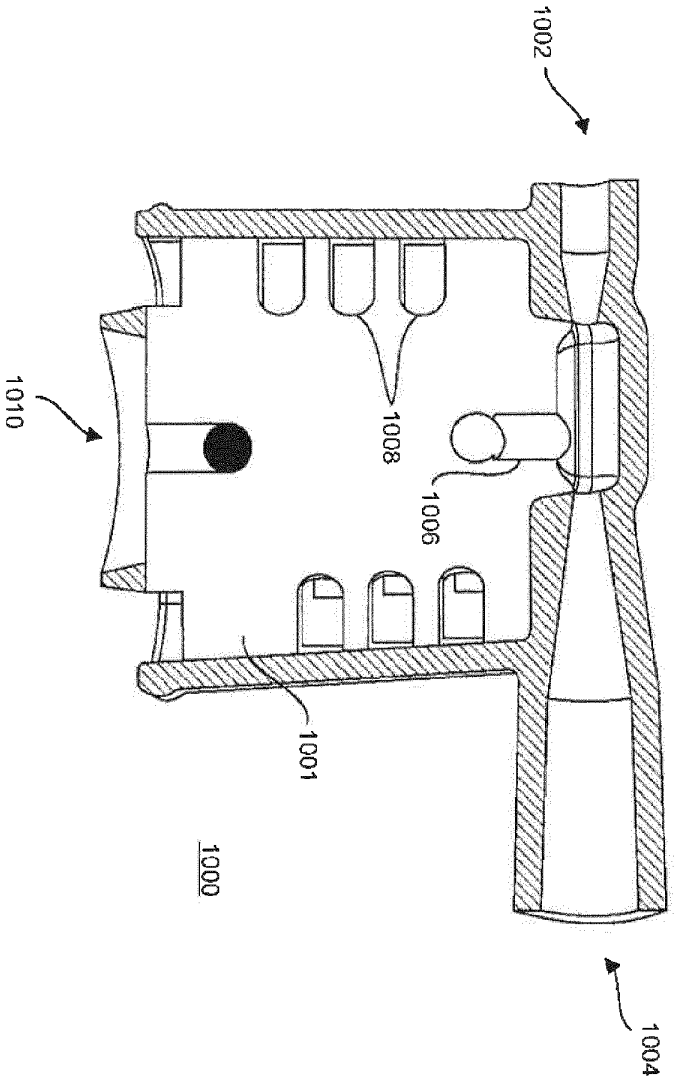


FIG. 10B

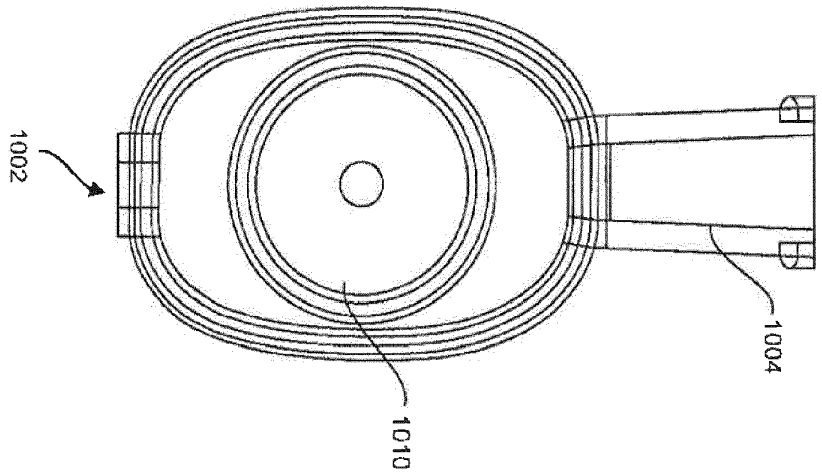


FIG. 10C

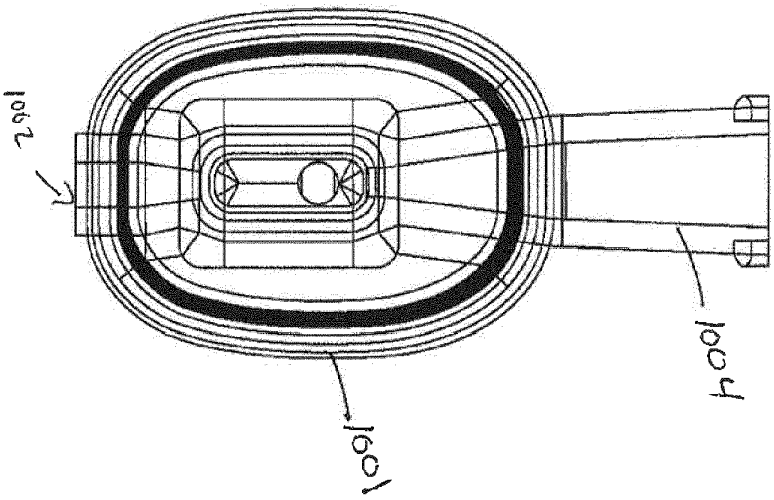
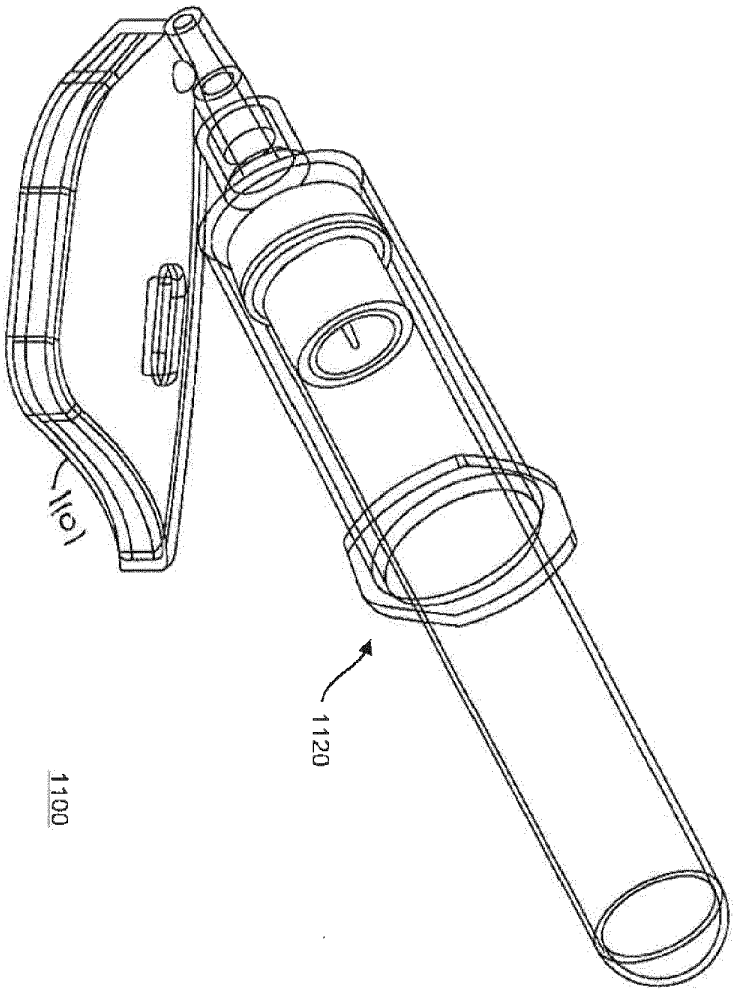


FIG. 10D

FIG. 11A



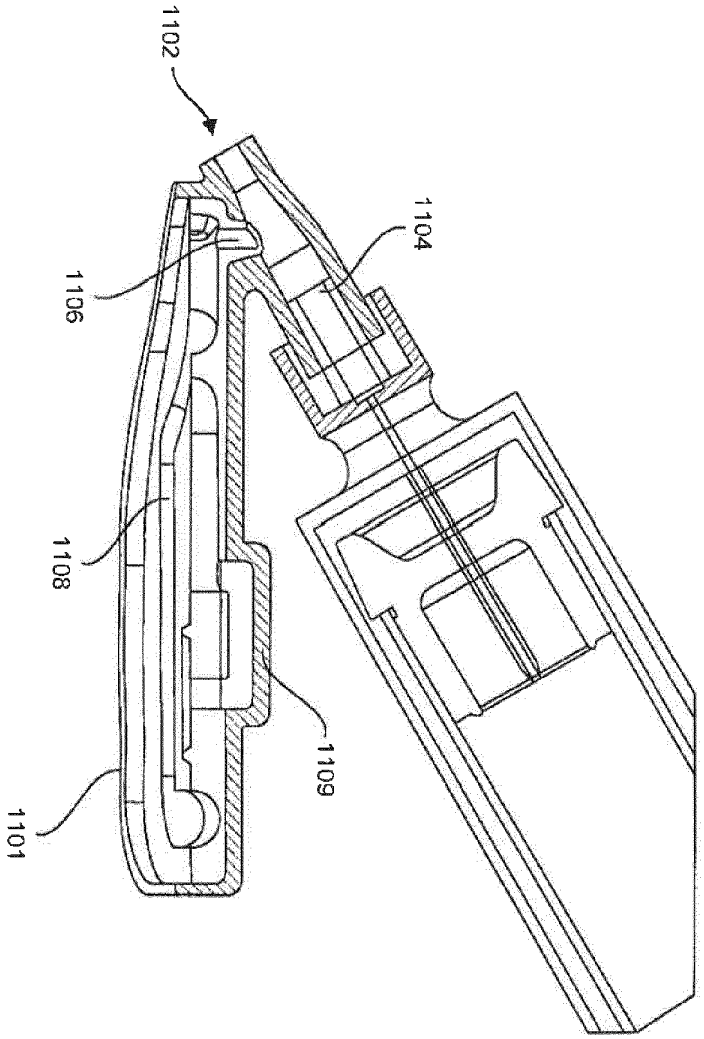


FIG. 11B

FIG. 11C

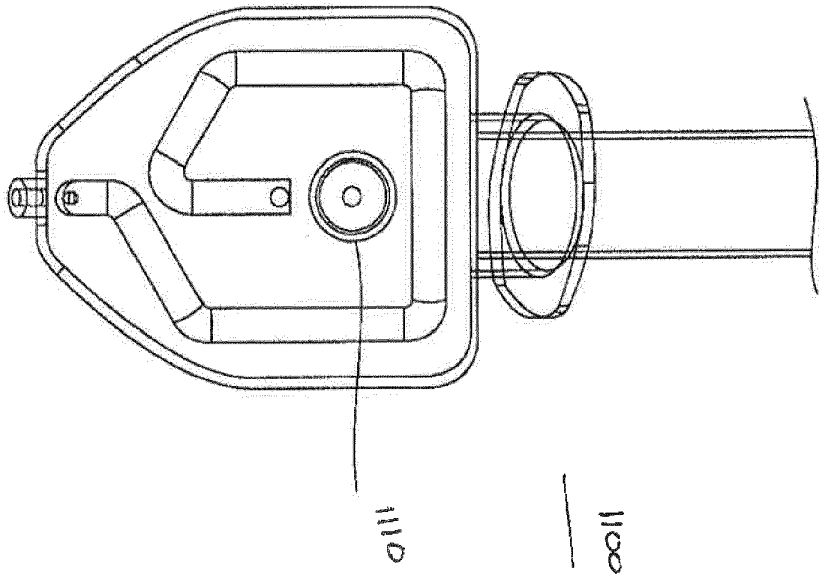
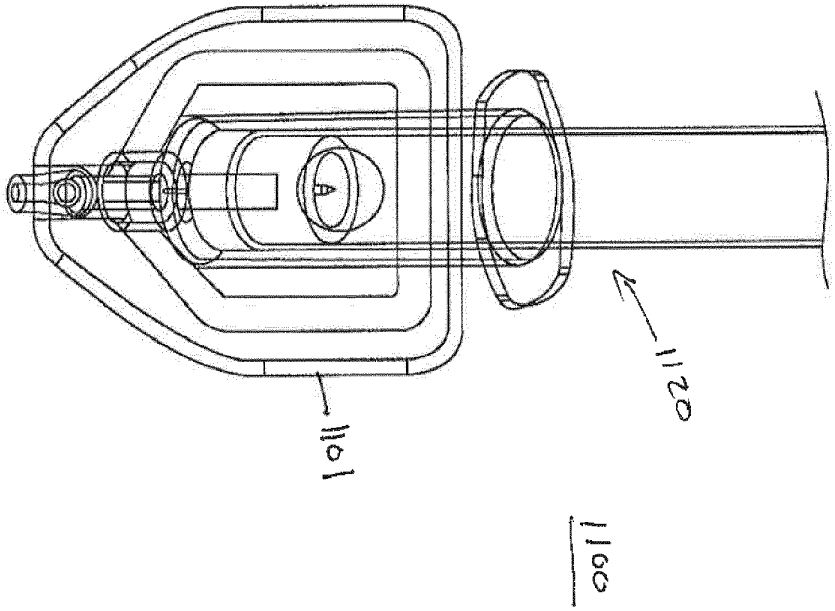


FIG. 11D



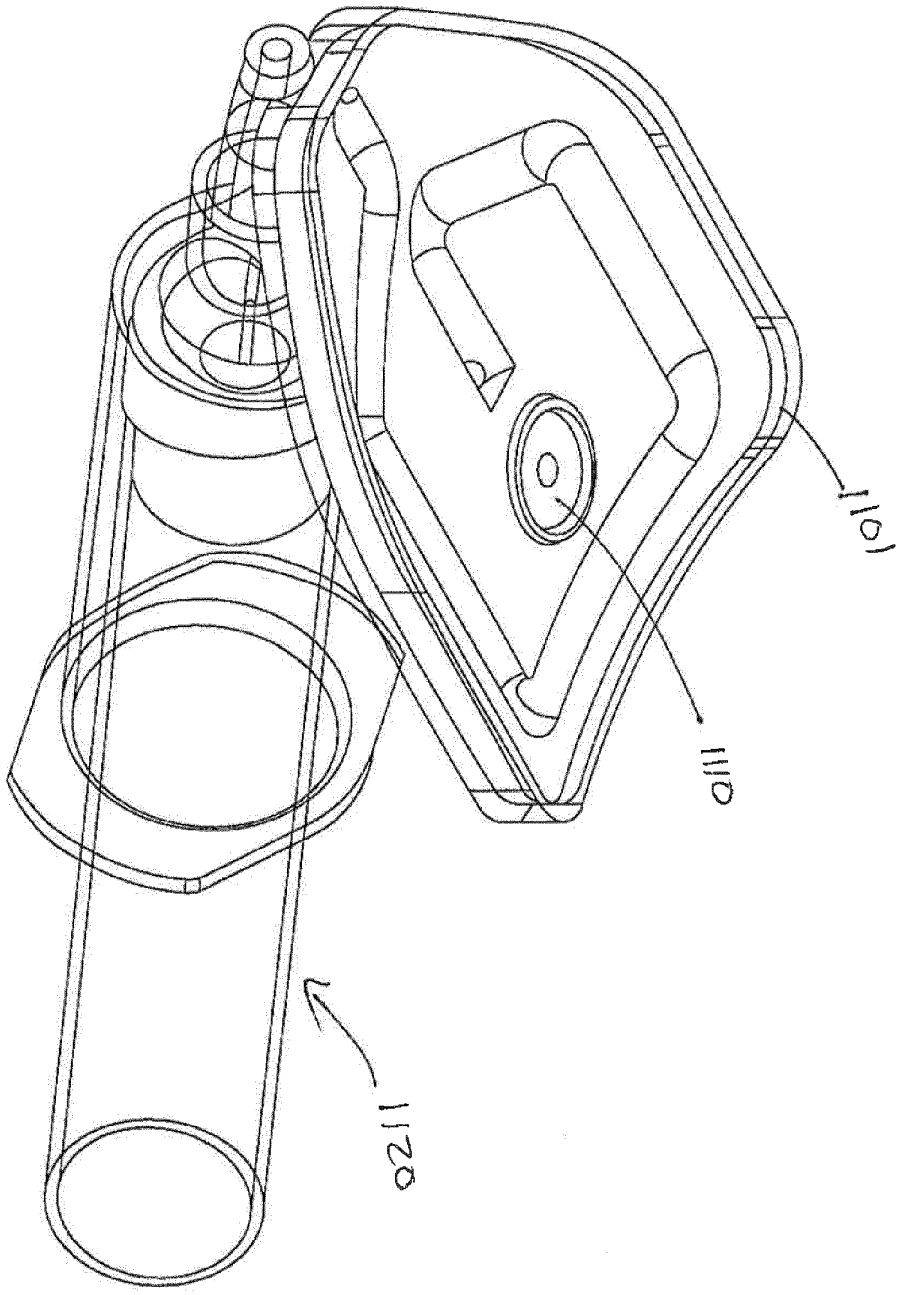


FIG. 11E

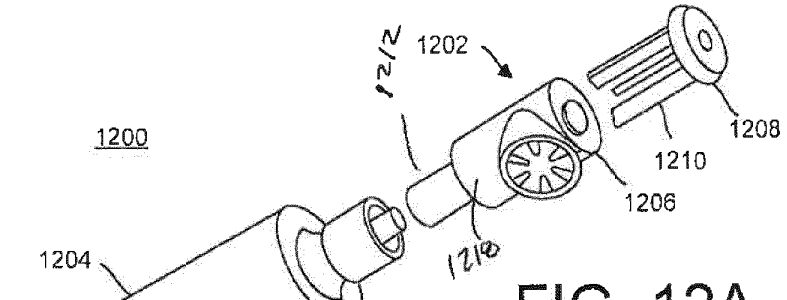


FIG. 12A

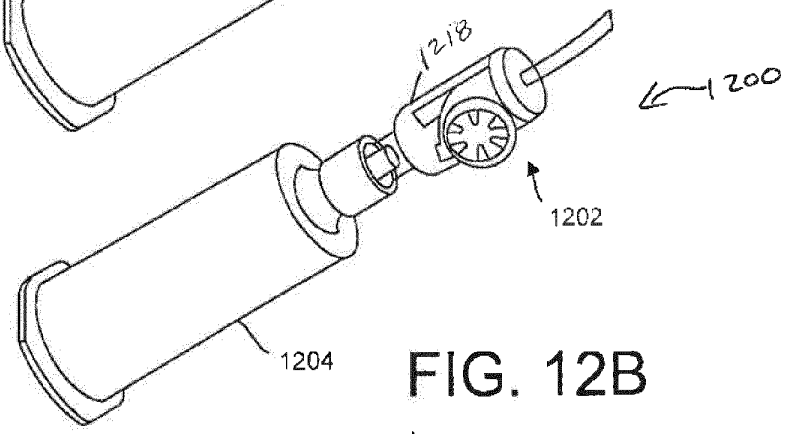


FIG. 12B

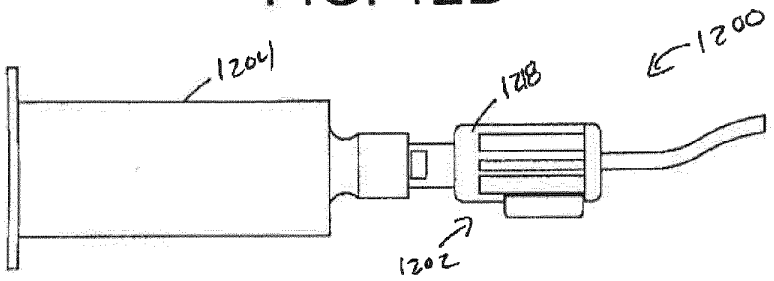


FIG. 12C

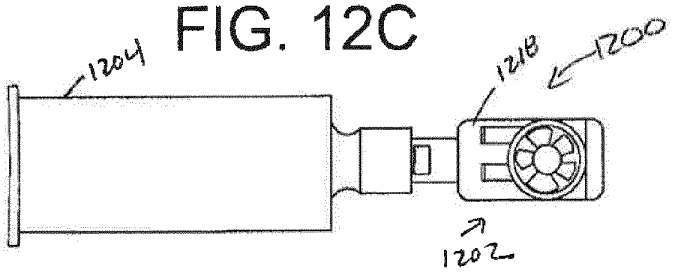


FIG. 12D

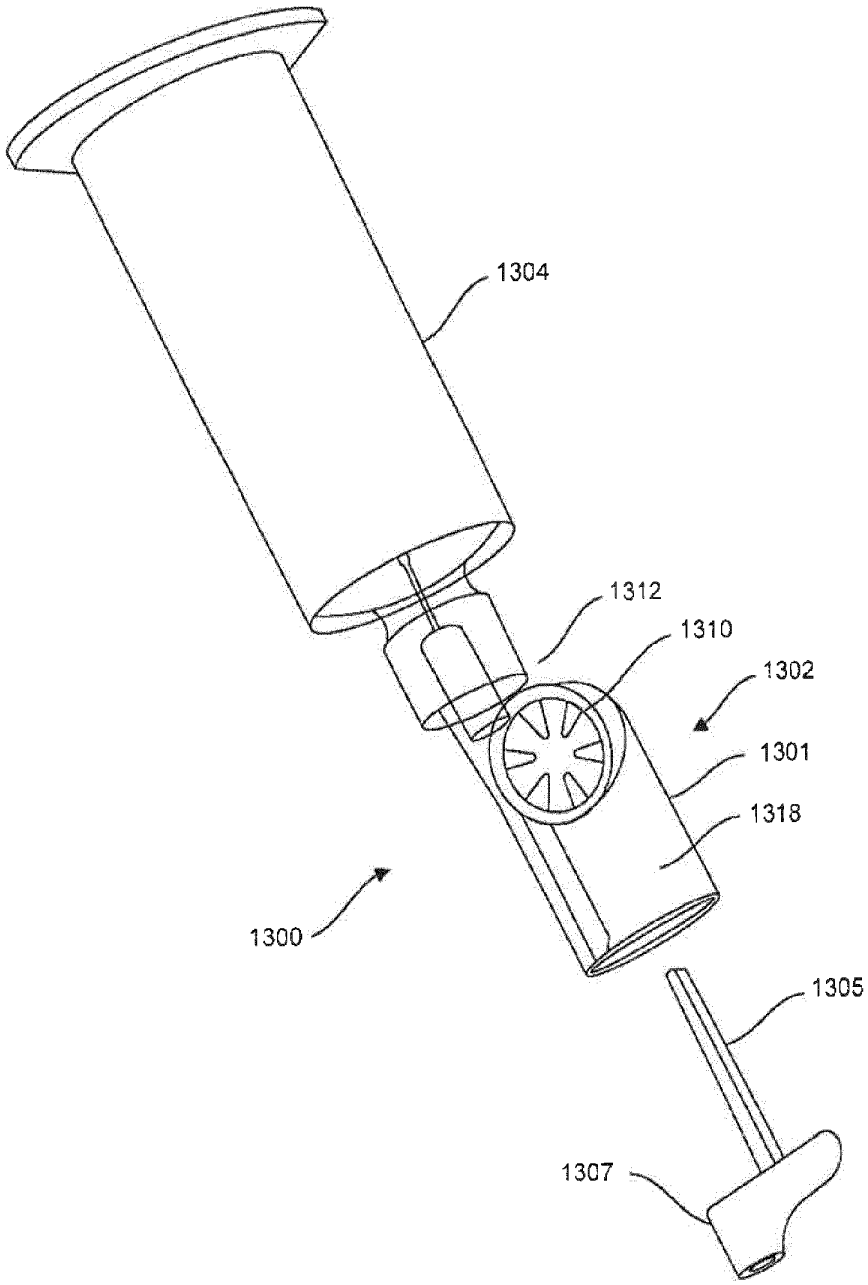


FIG. 13A

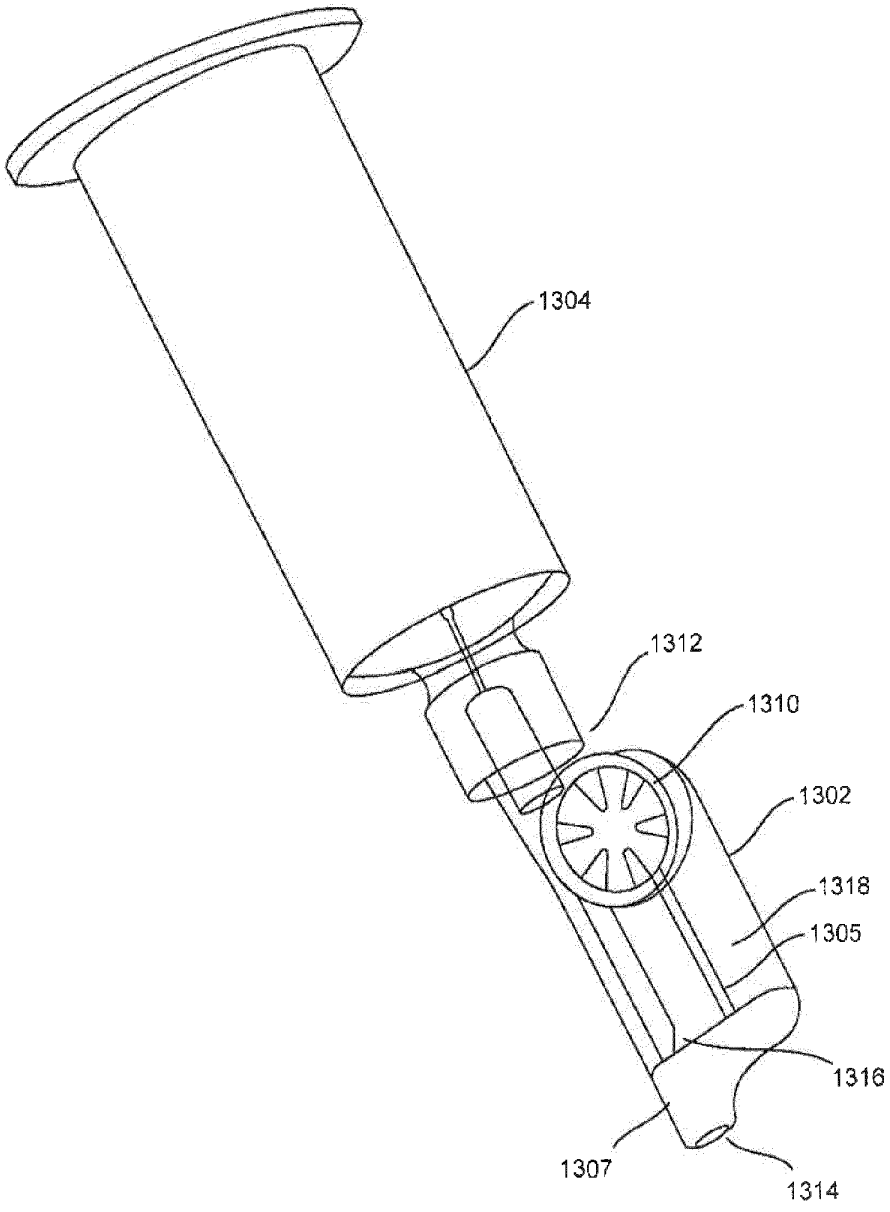


FIG. 13B

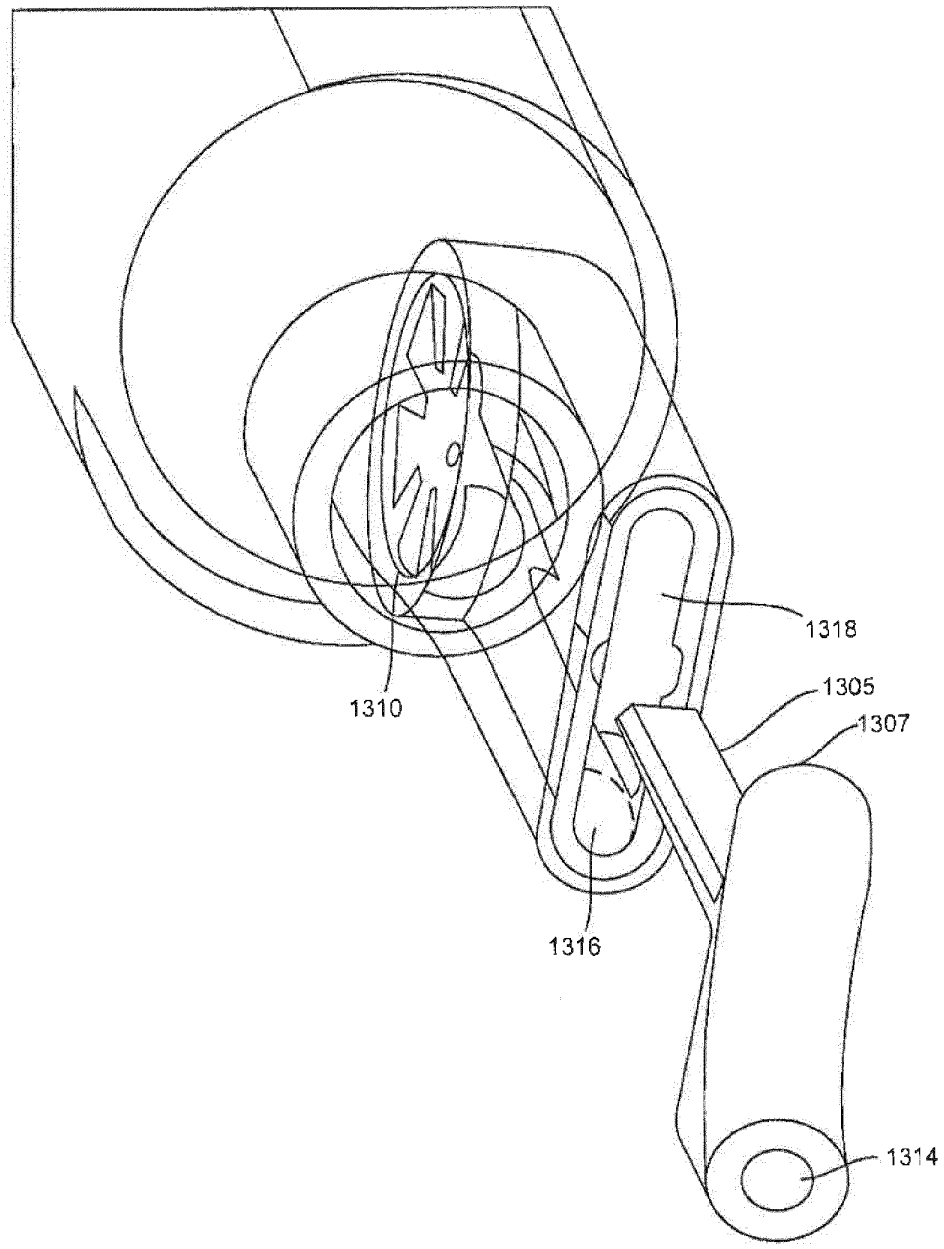


FIG. 13C

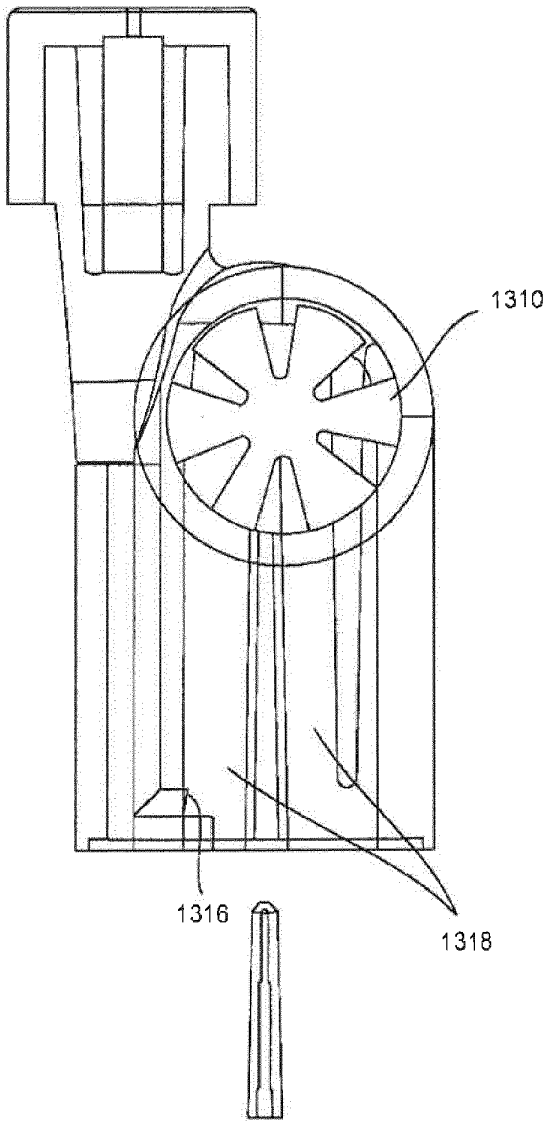


FIG. 13D

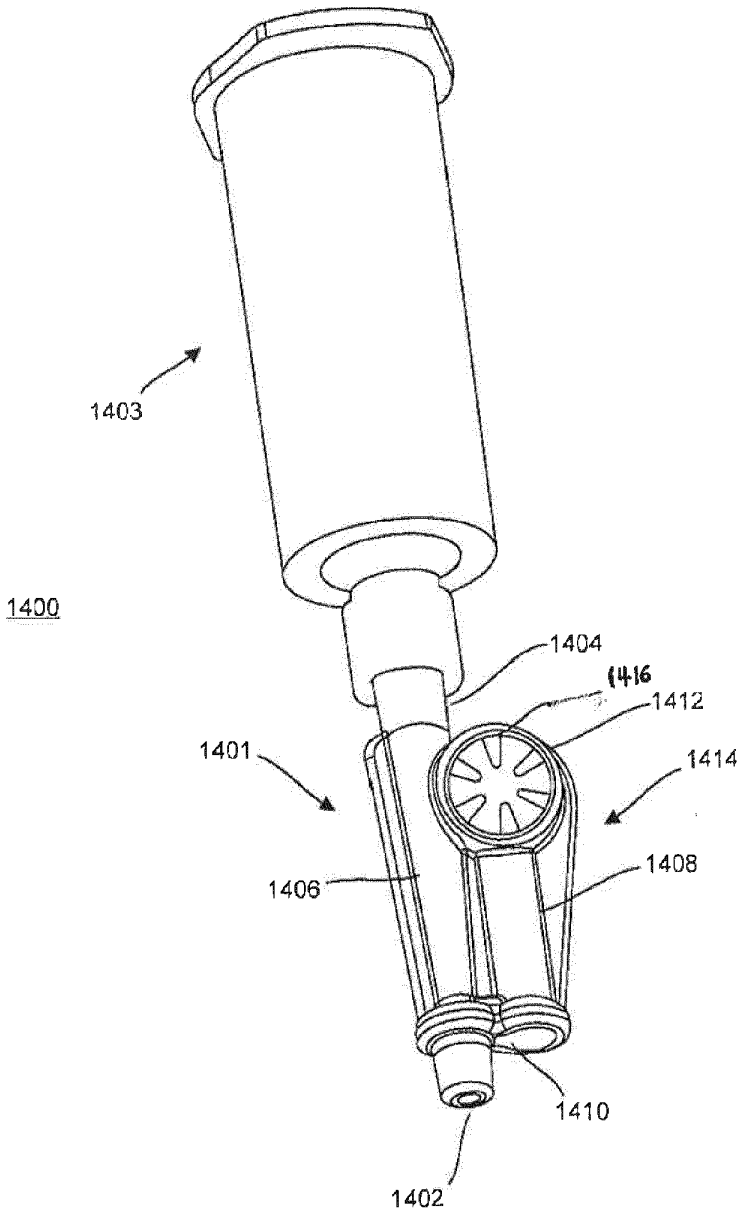


FIG. 14A

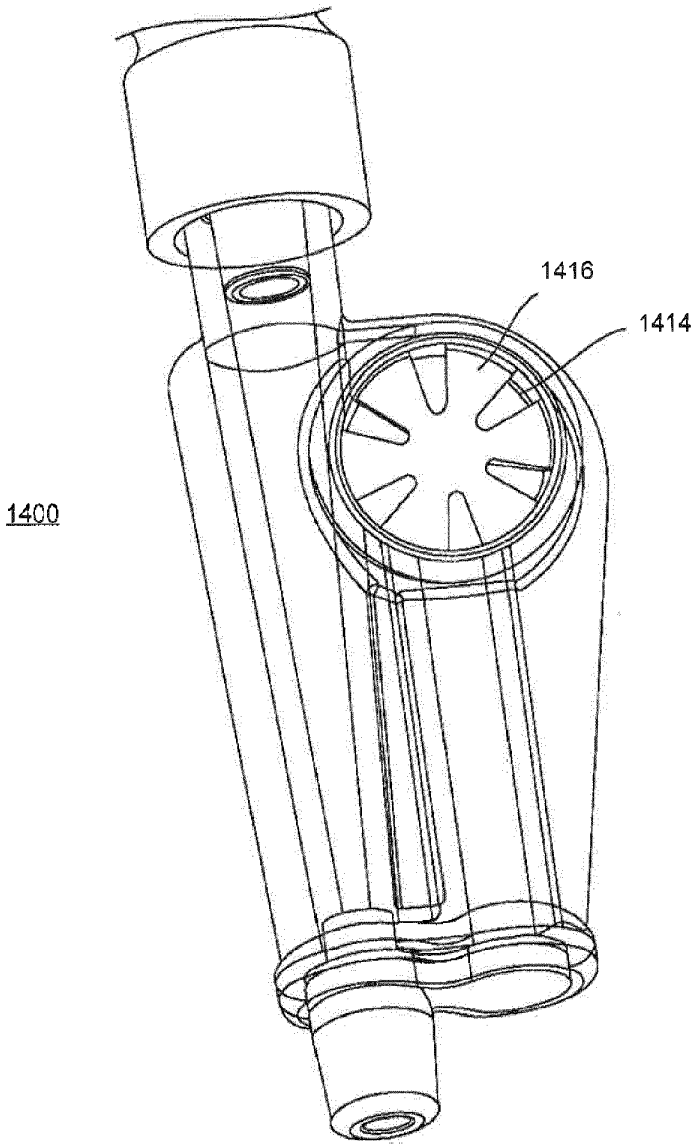


FIG. 14B

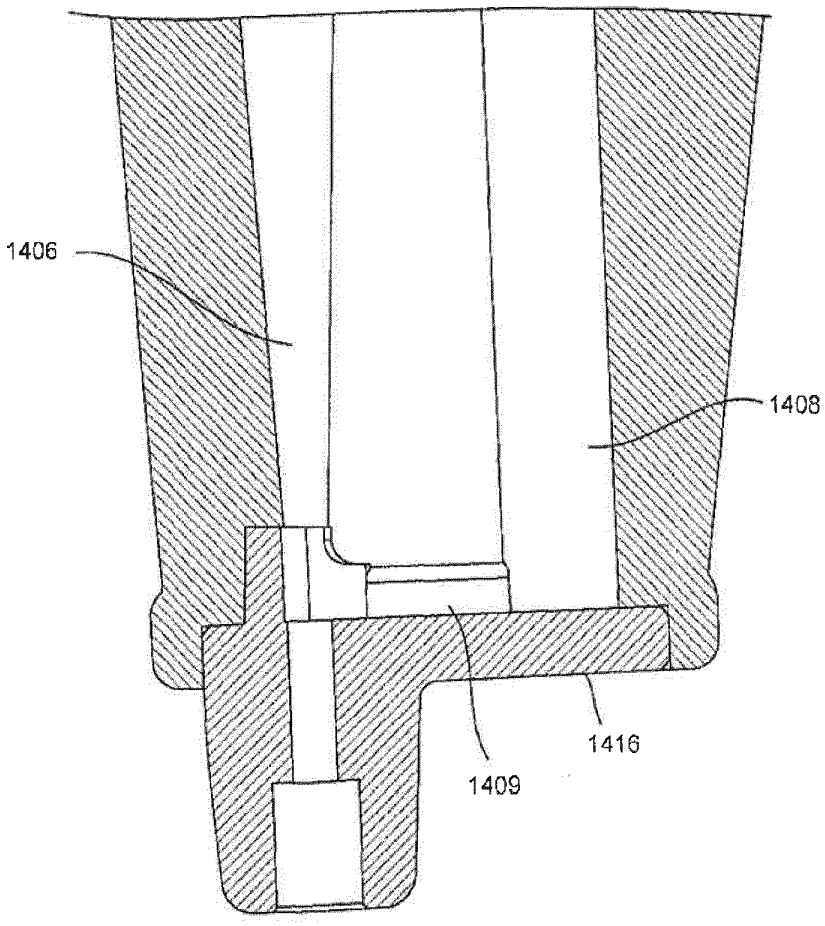


FIG. 14C

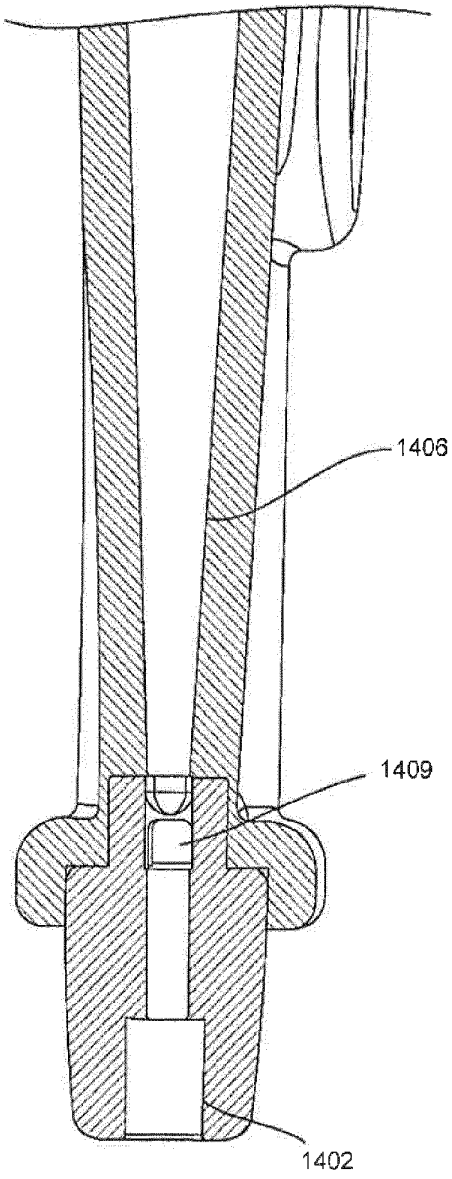


FIG. 14D

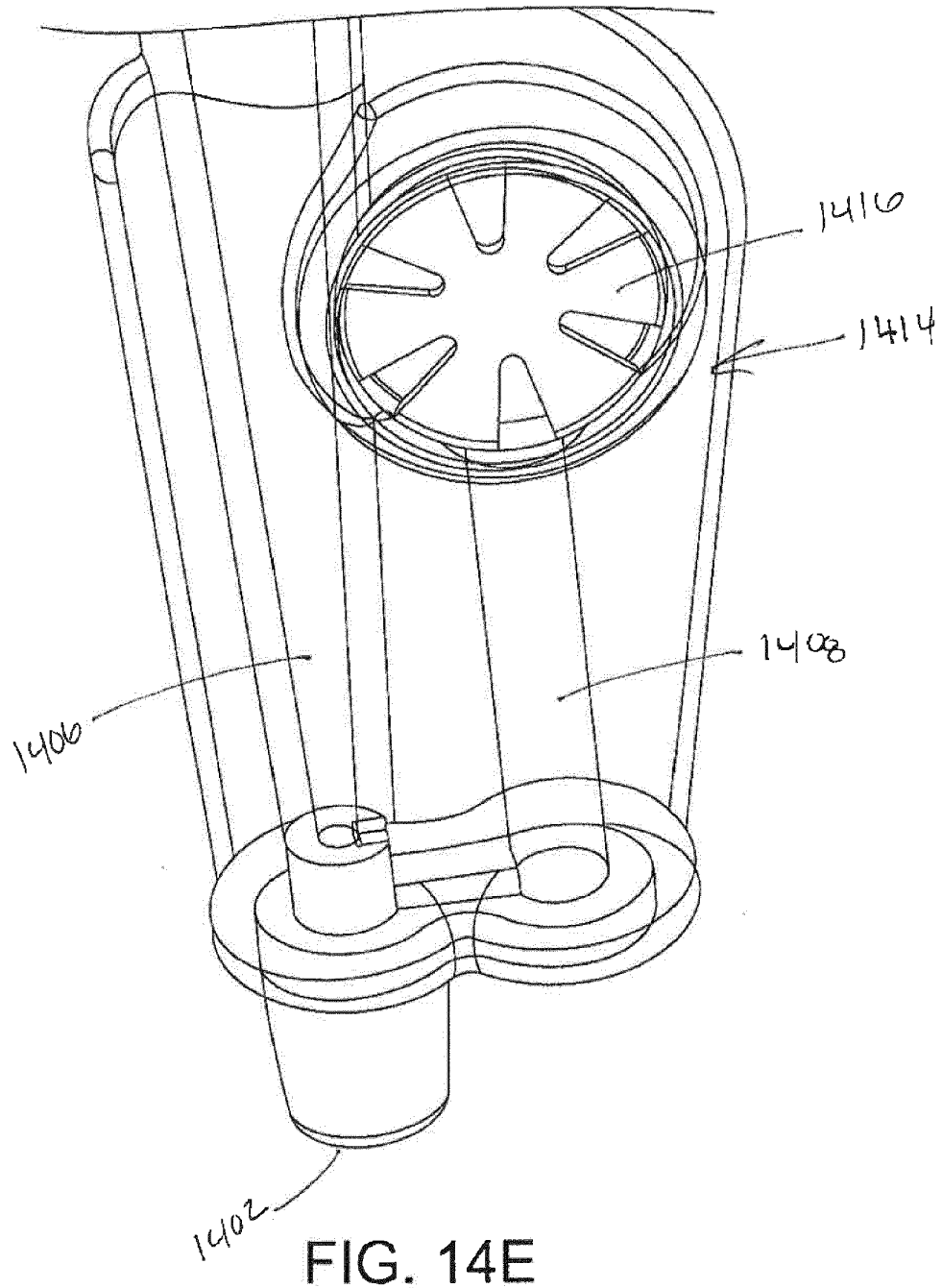


FIG. 14E

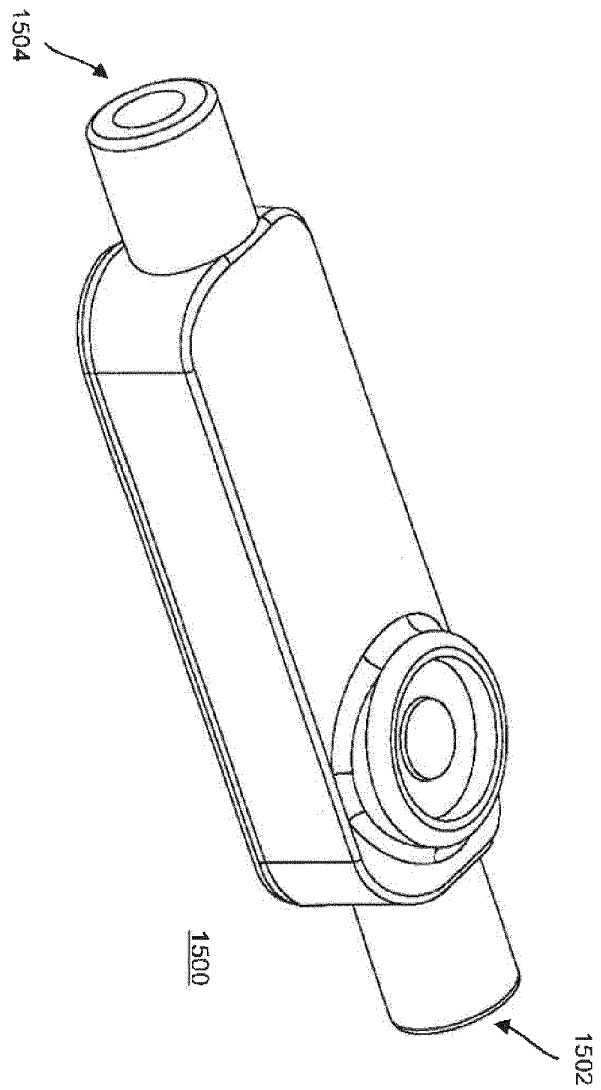


FIG. 15A

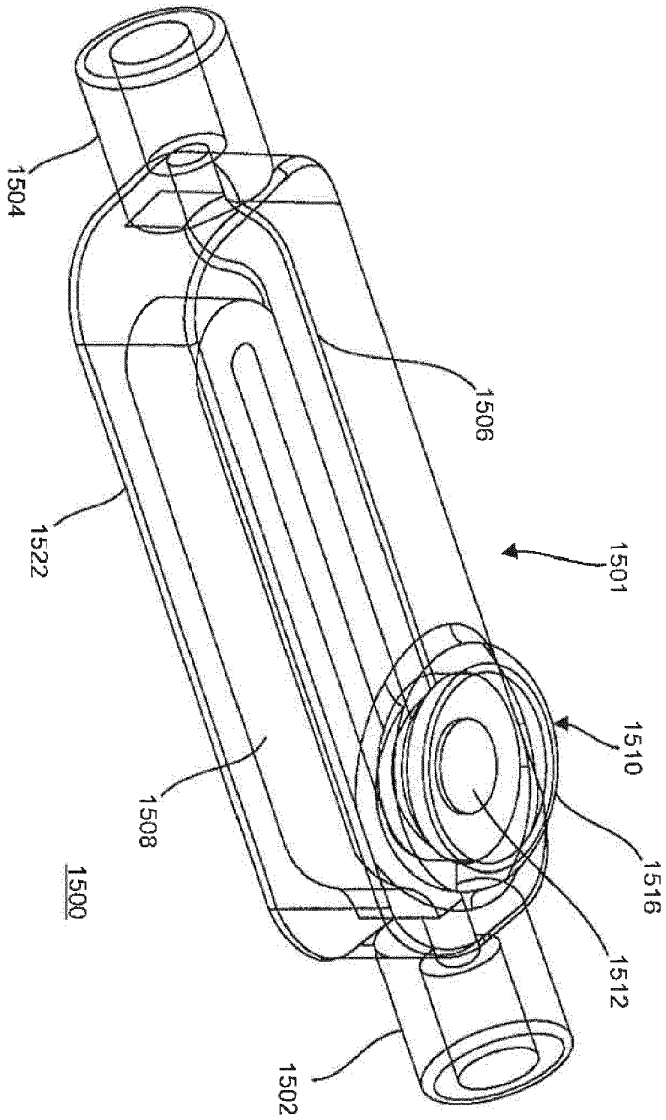


FIG. 15B

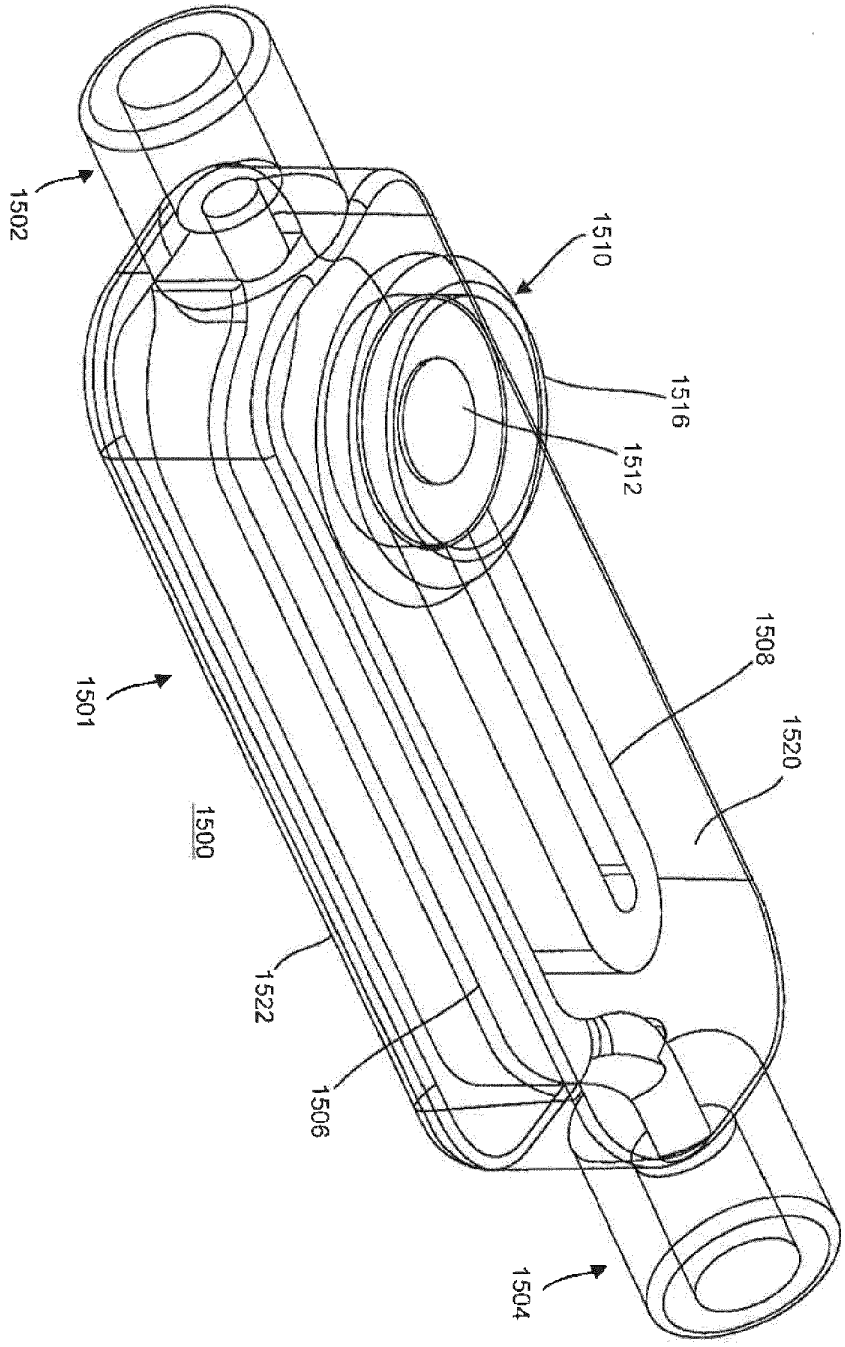


FIG. 15C

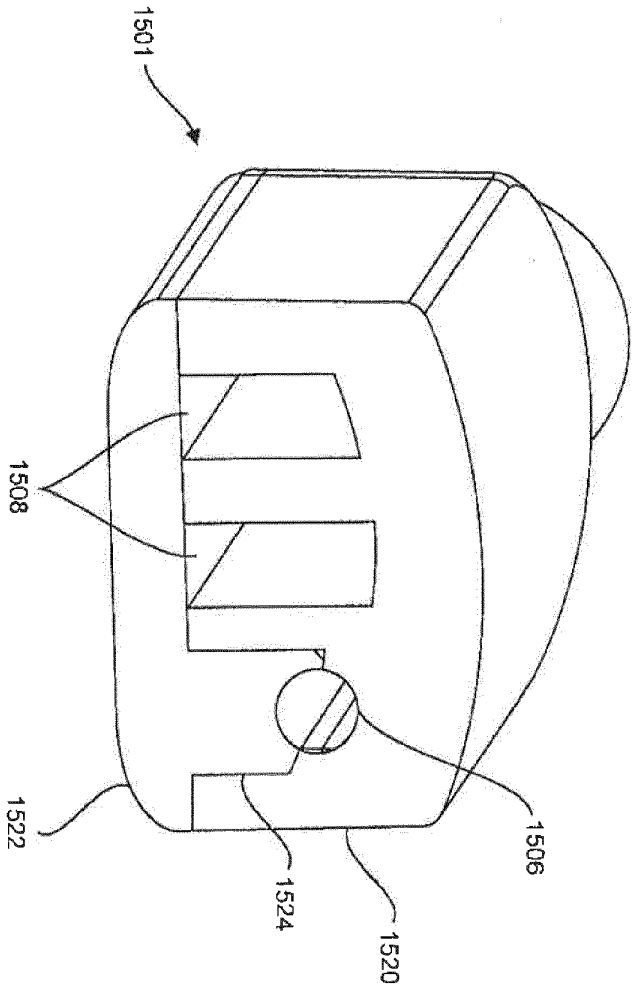


FIG. 15D

FIG. 15E

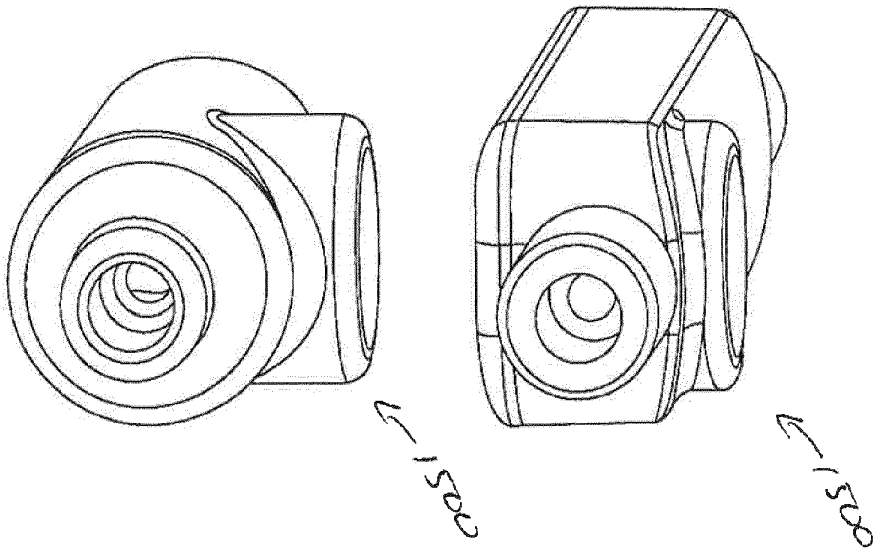
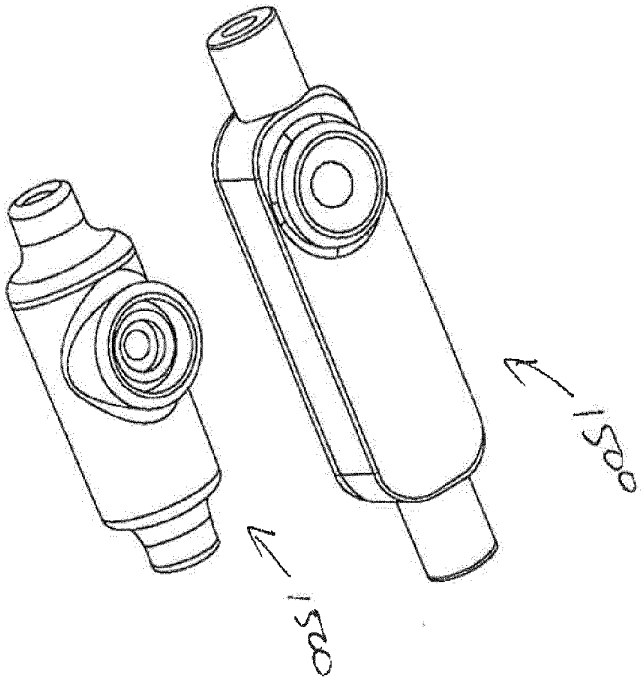


FIG. 15F



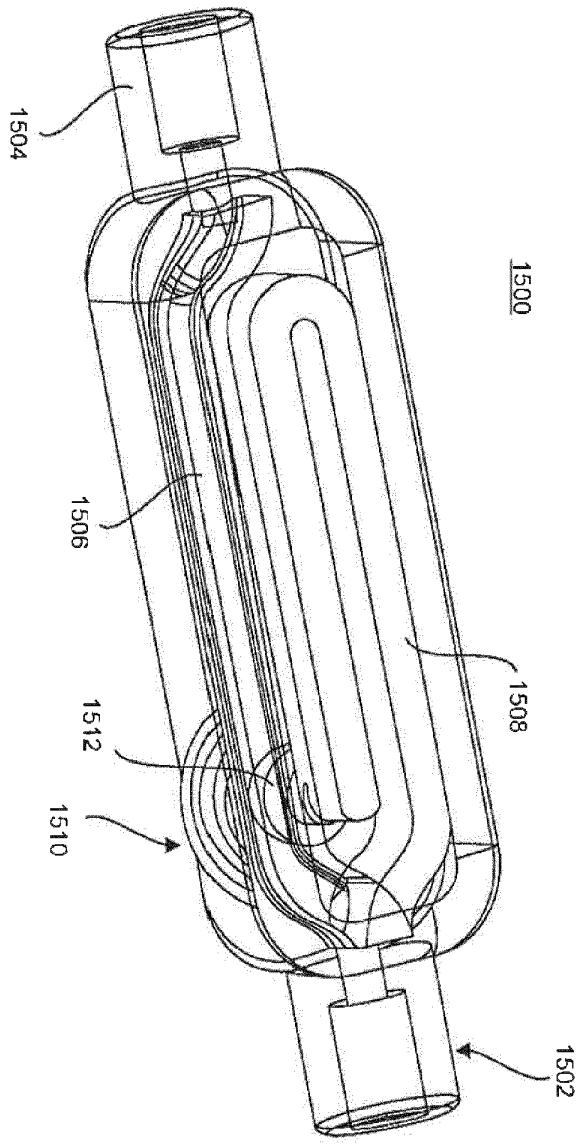


FIG. 15G

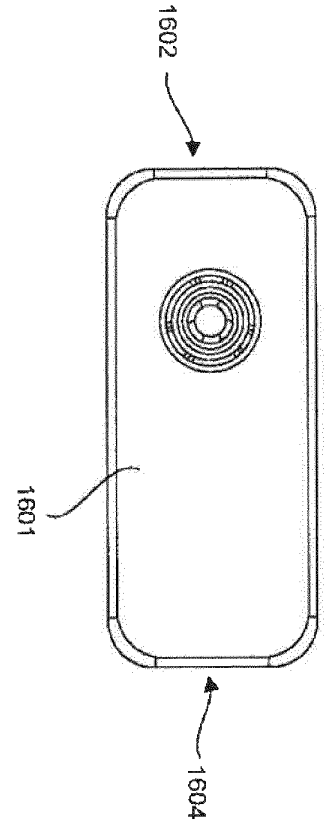


FIG. 16A

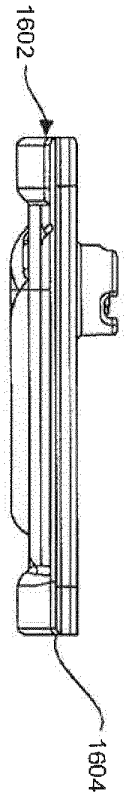


FIG. 16B

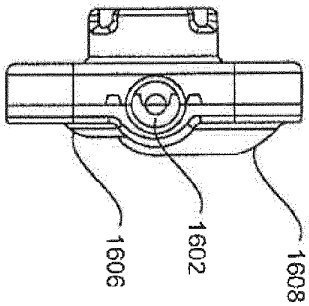


FIG. 16C

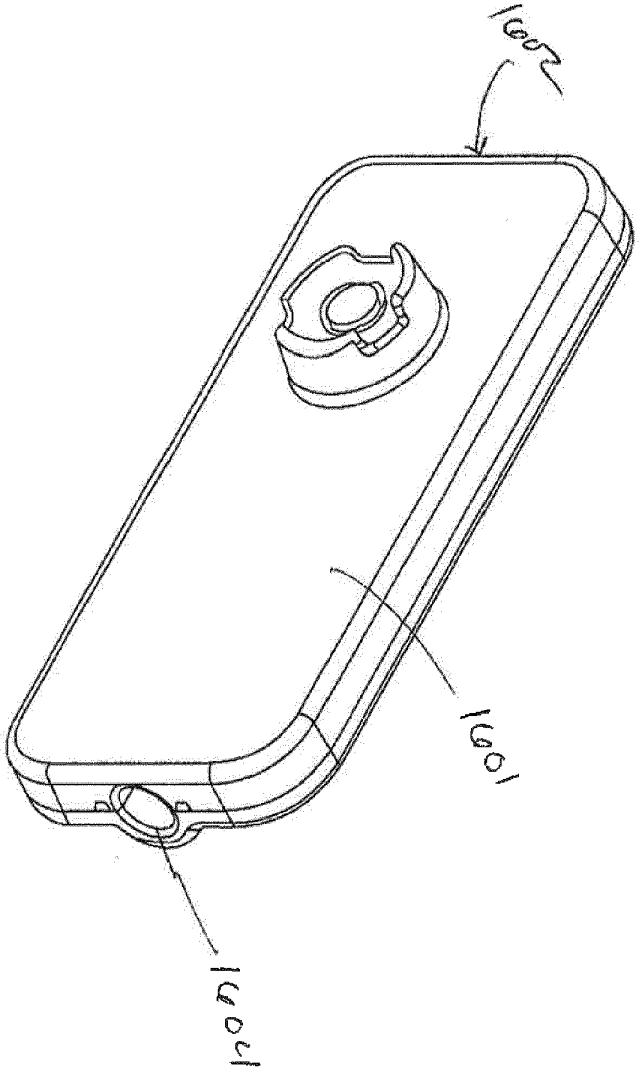


FIG. 16D

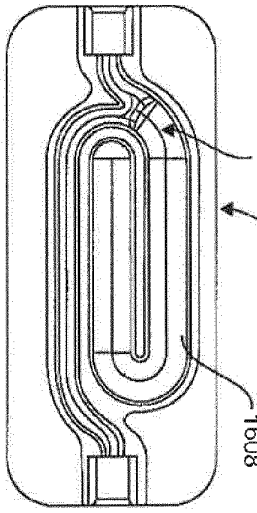


FIG. 17A

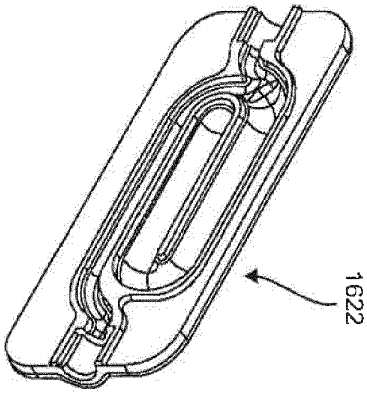


FIG. 17B

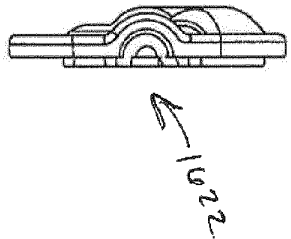


FIG. 17C

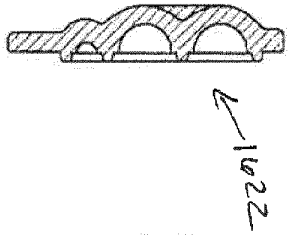


FIG. 17D

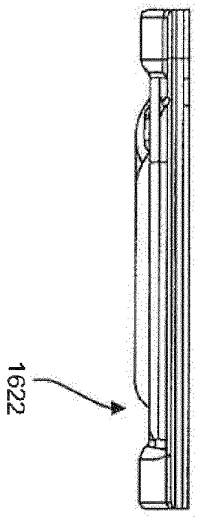


FIG. 17E

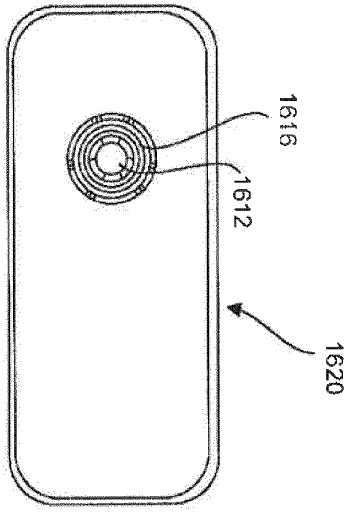


FIG. 18A

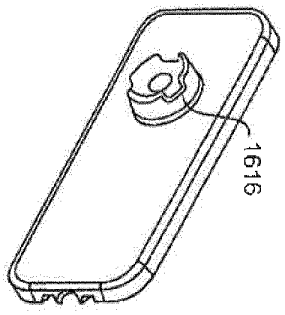


FIG. 18B

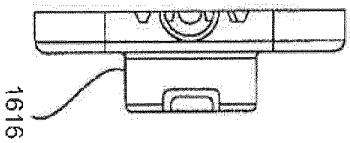


FIG. 18C

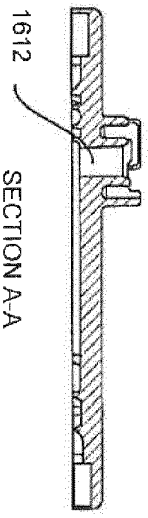


FIG. 18D

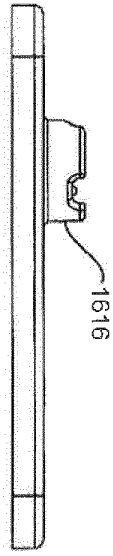


FIG. 18E

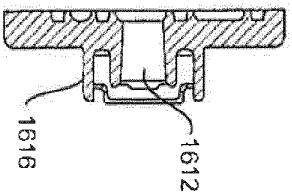


FIG. 18F

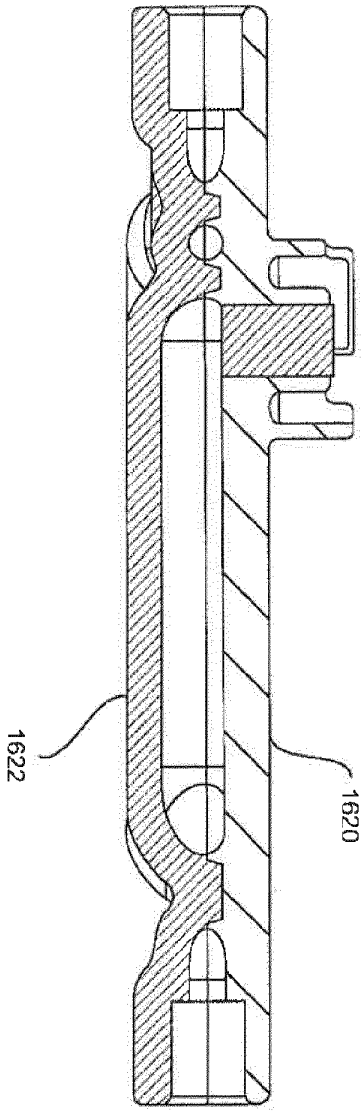


FIG. 19A

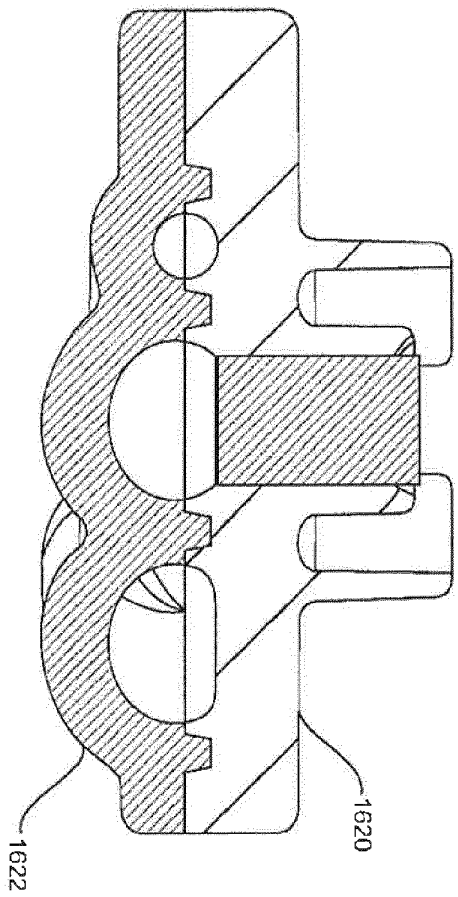


FIG. 19B

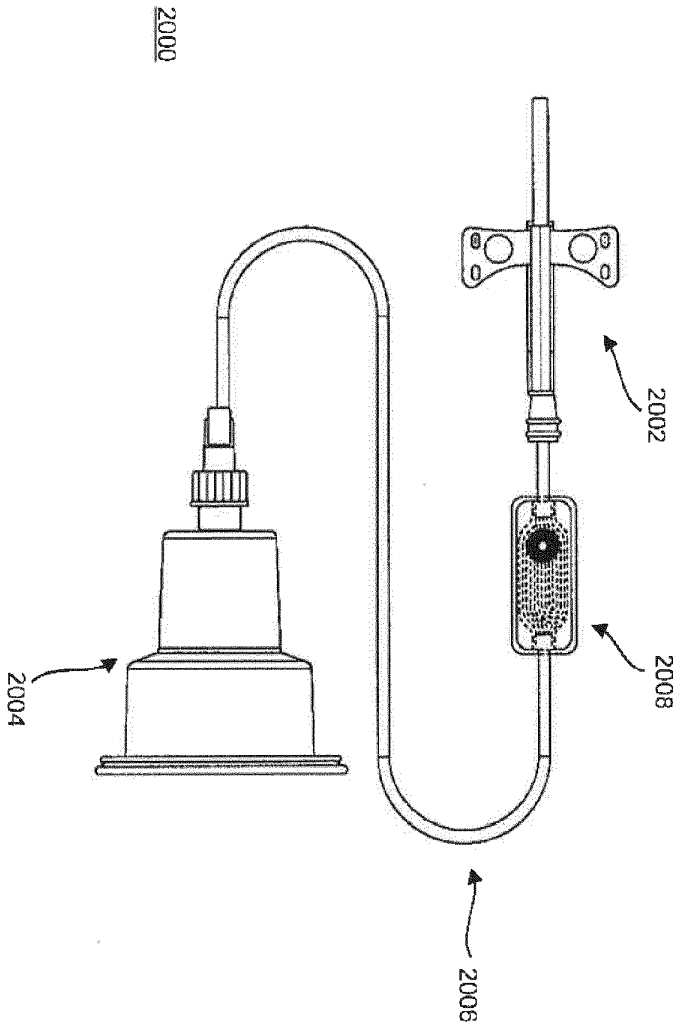


FIG. 20

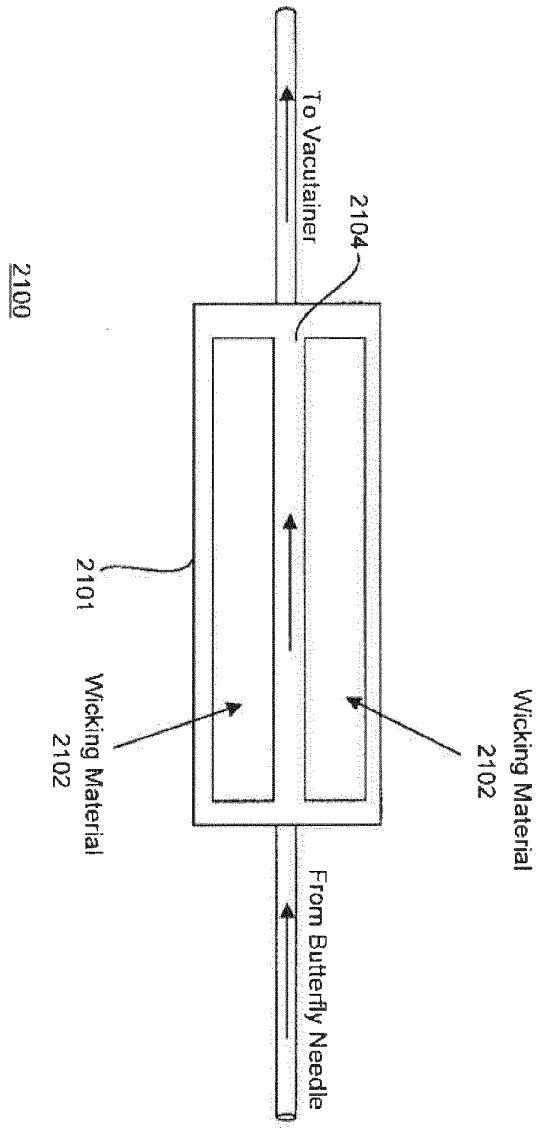

2100
To Vacutainer
2104
2101
Wicking Material
2102
Wicking Material
2102
From Butterfly Needle

FIG. 21

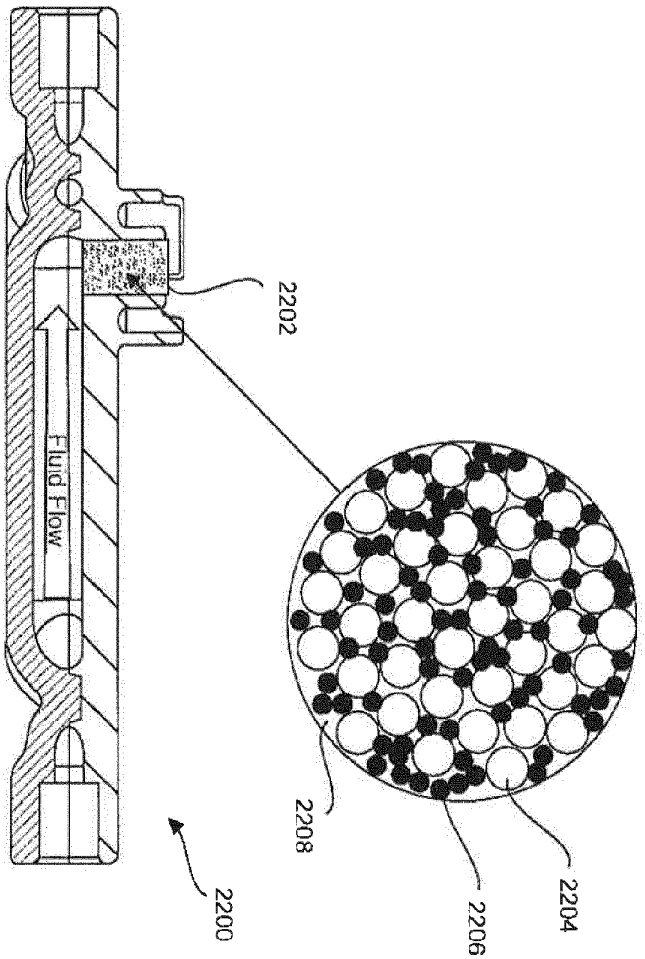


FIG. 22A

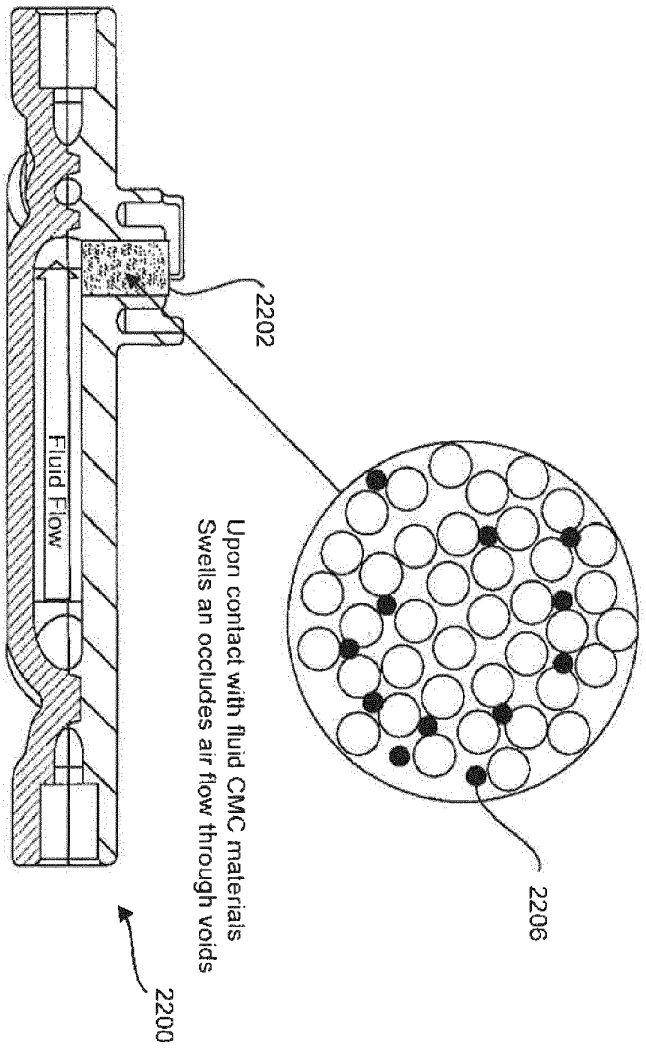

2202
Fluid Flow
Upon contact with fluid CMC materials
Swells an occludes air flow through voids
2206
2200

FIG. 22B

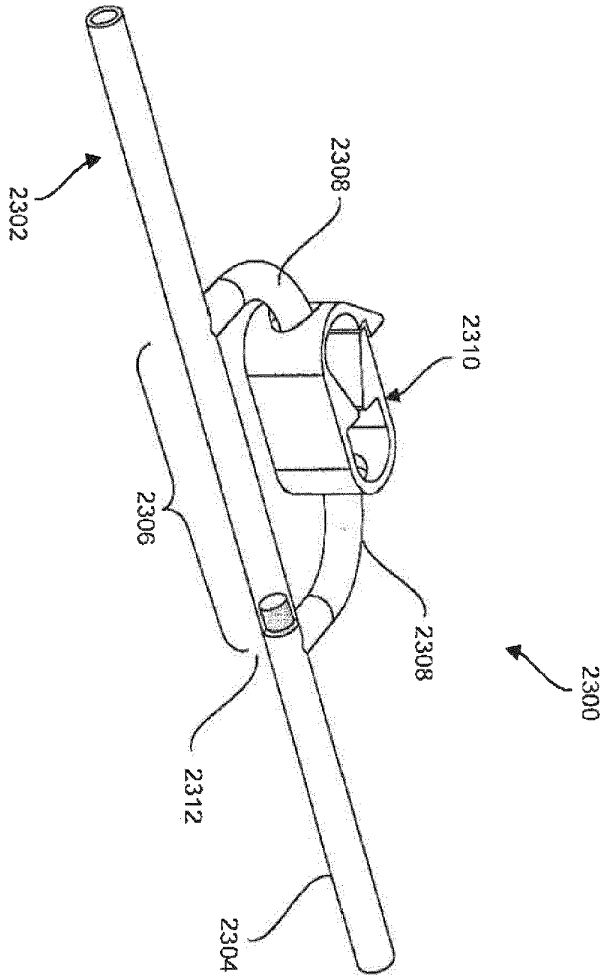


FIG. 23A

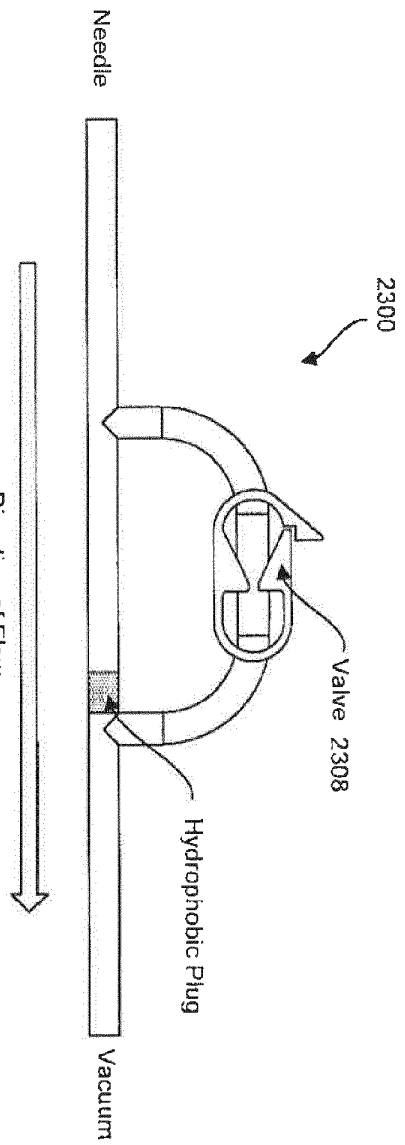

Needle
2300
Direction of Flow
Valve 2308
Hydrophobic Plug
Vacuum

FIG. 23B

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EUROPEAN SEARCH REPORT

Application Number
EP 19 20 0766

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (IPC)
X	WO 96/05875 A1 (BAXTER INT [US]) 29 February 1996 (1996-02-29) * the whole document *	1-14	INV. A61B5/15 A61B5/153 A61B5/154
A	WO 2011/162772 A1 (CLEARVIEW PATIENT SAFETY TECHNOLOGIES LLC [US]; FISCHEL LLOYD [US]; BR) 29 December 2011 (2011-12-29) * paragraph [0070] * * figure 15 * * abstract *	1-14	
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A	EP 1 665 986 A1 (BECTON DICKINSON CO [US]) 7 June 2006 (2006-06-07) * figures 13,14 *	1-14	
A	US 4 056 101 A (GEISSLER ULRICH C ET AL) 1 November 1977 (1977-11-01) * abstract; figures *	1-14	

-/--

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
Berlin	18 November 2019	Schultz, Ottmar

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
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D : document cited in the application
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& : member of the same patent family, corresponding document

EPO FORM 1503 03.82 (P04C01)

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EUROPEAN SEARCH REPORT

Application Number
EP 19 20 0766

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (IPC)
A	US 2013/317391 A1 (BULLINGTON GREGORY J [US] ET AL) 28 November 2013 (2013-11-28) * paragraphs [0084] - [0094] * * figures 16-18 * -----	1-14	

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The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
Berlin	18 November 2019	Schultz, Ottmar

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
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A : technological background
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T : theory or principle underlying the invention
E : earlier patent document, but published on, or after the filing date
D : document cited in the application
L : document cited for other reasons

& : member of the same patent family, corresponding document

EPO FORM 1503 03.82 (P04C01)

ANNEX TO THE EUROPEAN SEARCH REPORT ON EUROPEAN PATENT APPLICATION NO. EP 19 20 0766

This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report. The members are as contained in the European Patent Office EDP file on
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18-11-2019

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EPO FORM P0459

For more details about this annex : see Official Journal of the European Patent Office, No. 12/82

REFERENCES CITED IN THE DESCRIPTION

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- US 14044816 **[0001]**
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Literature display help

1 / 1 display

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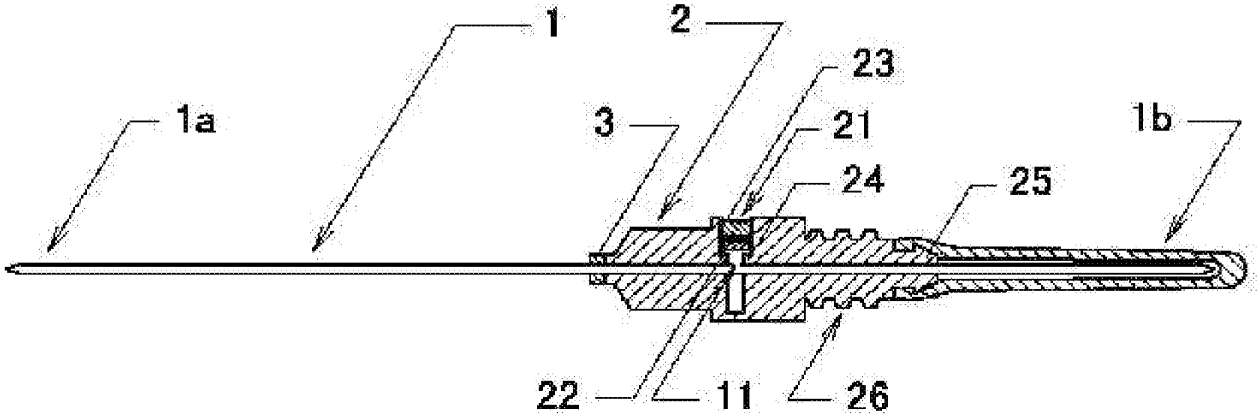
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(19) [Country of issue] Japan Patent Office (JP)
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(11) [Publication number] JP 2001-424 (P2001-424A)
(43) [Published date]] January 9, 2001 (2001.1.9)
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[FI]
A61B 5/14 300 H
[Request for examination: Unclaimed
[Number of claims] 4
[Application form] OL
[Total number of pages] 3
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(22) [Filing date] June 21, 1999 (1999.6.21)
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[Theme code (reference)]
4C038
[F term (reference)]
4C038 TA06 UJ02 UJ06

wrap up close —

(57) [Summary]
[Problem] To provide a blood collection needle that enables confirmation immediately after pu ncturing that the needle has definitely punctured a vein of a subject at the time of blood colle ction.
A needle tube (A) having a hole in at least a part of its side wall and having blade surfaces at both ends, and a passage provided so as to cover the hole and communicating between the o utside and the inside of the needle tube through the hole. an air-permeable, blood-impermea ble member (C) engaged with the open end of the passageway; and a needle tube support m ember (C) engaged with the needle tube support so as to seal one end of the needle tube. A b lood collection needle having a rubber-like cap (D) that is closed and a sealing member (E) th at is provided in the passage and can block the hole or the passage.



The scope of the claims open —

What is claimed is
: 1. A needle tube (A) having a hole in at least a part of its side wall and having blade surface

s at both ends; an air-permeable blood-impermeable member (C) secured to the open end of the passageway, and one end of the needle tube so as to seal , a rubber-like cap (D) engaged with the needle tube support, and a sealing member (E) provided in the passage and capable of closing the hole or the passage.

2. The blood collection needle according to claim 1, wherein the passageway has a protrusion for locking the sealing member.

3. The blood collection needle according to claim 1, wherein the air-permeable blood-impermeable member is a swelling material.

4. The blood collection needle according to claim 1, 2 or 3, wherein the needle tube support is transparent or translucent.

detailed description open —

Description: BACKGROUND OF THE INVENTION

1.

Field of the Invention The present invention relates to a blood-collecting needle, and more particularly, one end of which is pierced into a blood vessel of a subject and the other end of which is communicated with a vacuum blood-collecting tube. , relates to a blood collection needle capable of collecting an amount of blood corresponding to the negative pressure in a vacuum blood collection tube. According to the blood collection needle of the present invention, it can be confirmed that one end has been punctured into the subject's vein before connecting the other end to the vacuum blood collection tube.

2.

Description of the Related Art Conventionally, when collecting blood using a vacuum blood collection tube, there has been a blood collection needle that can confirm that the needle has definitely punctured the vein of a subject, that is, so-called flashback, before attaching the vacuum blood collection tube. is proposed. As such a conventional blood collection needle, for example, JP-A-61-64234 discloses a housing having a front end portion, a rear end portion, and a sample collection chamber provided with a passage for communicating with the outside air; A blood collection needle is disclosed having a cannula extending from the rear end and a tablet that expands upon contact with blood and blocks communication with the atmosphere. However, with this blood collection needle, when a vacuum blood collection tube is attached, negative pressure is applied to the tablet, and outside air may flow into the blood collection needle.

[0003] Further, Japanese Patent Application Laid-Open No. 4-132541 discloses an elastic tip having a ventilation hole for communication between the inner cavity and the outside atmosphere, and an air-permeable filter provided at the outer opening of the ventilation hole. Also disc

losed are blood collection needles with translucent hubs or elastic tips that allow flashback to be seen. However, since the elastic tip of this blood collection needle is housed inside the bloo d collection needle holder and held by hand from above, it is very difficult to confirm flashback with the elastic tip. In addition, when one end is punctured into a subject's vein, blood that en ters the inside of the needle tube due to venous pressure fills the lumen of the elastic tip and then enters the vent hole. check flashbackIt takes time to do so. SUMMARY OF THE INVENTIO N The present invention has been made in view of the above circumstances

.

To provide a blood-collecting needle which does not impinge on the body and allows immediat e confirmation of flashback after one end of the needle is punctured into a vein. Means for Sol ving the Problems As a result of extensive studies, the inventors of the present invention have found that a hole is provided in the side wall of the needle tube, a passage is provided throug h the hole to allow communication between the outside and the inside of the needle tube, and a vacuum is provided

.

The present inventors have found that a blood collection needle provided with a mechanism fo r blocking the inside of the needle tube from the outside when the blood collection tube is atta ched solves the above problems, and arrived at the present invention.

[0006] That is, the present invention provides a needle tube (A) having a hole in at least a pa rt of its side wall and blade surfaces at both ends, a needle tube (A) provided so as to cover t he hole, and communicating the outside and the inside of the needle tube through the hole. a n air-permeable blood-impermeable member (C) secured to the open end of the passageway; and one end of the needle tube is sealed so as to seal the needle tube. A blood collection nee dle having a rubber-like cap (D) engaged with a support and a sealing member (E) provided i n the passage and capable of closing the hole or the passage.

DETAILED

DESCRIPTION OF THE INVENTION The present invention will now be described in detail with r eference to the drawings. FIG. 1 is a sectional view showing one embodiment of the blood coll ection needle of the present invention. The needle tube 1 is preferably made of stainless stee l. One end 1a is a blade surface and is formed so as to pierce the blood vessel of the subject, and the other end 1b is also a blade surface and is formed so as to be inserted into a vacuum blood collection tube (not shown).

[0008] A hole 11 is provided in the side wall of the needle tube 1 . The hole 11 may be provid ed in any part of the needle tube 1 as long as it is inside the needle tube support 2 . The need le tube 1 is provided with a transparent or translucent needle tube support 2 so as to cover th e hole 11 . The needle tube support 2 is hermetically fixed to the needle tube 1 on the one en d 1a side of the needle tube 1, for example, with an adhesive 3. As shown in FIG.

[0009] A passage 21 is formed in the needle tube support 2 to communicate the outside and t he inside of the needle tube 1 through the hole 11 . As long as the passage 21 communicates

with the outside, the open end to the outside may be provided anywhere. When the blade surf ace of one end 1a of the needle tube 1 is punctured into a vein of a subject through the passa ge 21, the blood that has entered the inside of the needle tube 1 enters the passage 21 throu gh the hole 11, and the blood that has entered the needle tube is removed. Flashback can be confirmed by viewing from the side of the support 2 .

A sealing member 22 is provided in the passage 21 . As the sealing member 22, plastic materi als such as polypropylene, Teflon (registered trademark) and silicon rubber can be used.It ma y be metal or ceramic such as. Further, in the passage 21, there is a gap between the sealing member 22 and the needle tube support 2 through which air and blood can pass.

An air-permeable, blood-impermeable member 23 is hermetically engaged with the open end of the passageway 21 to the outside of the needle tube 1 . This member 23 keeps the passag e 21 air-permeable and prevents the blood that has flowed in during blood collection from lea king to the outside. As the air-permeable and blood-impermeable member 23, a layered filter made of a polymer sintered body such as polypropylene or polyethylene is usually preferably used. It may be a membrane filter.

As shown in FIG. 2, when one end 1a of the needle tube 1 is punctured into the subject, the b lood that has flowed from the inside of the needle tube 1 through the hole 11 into the passag e 21 flows through the sealing member 22 and the needle tube support. It passes through the gap with the body 2 and is blocked by the air permeable blood impermeable member 23 . Afte r that, when the vacuum blood collection tube is attached to the other end 1b of the needle tu be 1, the negative pressure of the vacuum blood collection tube pulls the sealing member 22 t oward the needle tube 1 and closes the passage 21, as shown in FIG. As a result, negative pr essure is not directly applied to the air-permeable blood-impermeable member 23, so that a p redetermined amount of blood can be collected. Further, considering the sealing performance i nside the needle tube 1, it is more preferable that the passage 21 is provided with a protrusio n 24 for locking the sealing member 22 therein. As for the shape of the projection 24, in addit ion to the L-shaped cross section shown in FIG. etc.

As the air-permeable and blood-impermeable member 23, swelling substances such as acrylic copolymers, starch and gelatin can be used alone or in combination with other compounds. W hen one end 1a of the needle tube 1 is punctured into the subject, the air-permeable blood-im permeable member 23 expanded by the blood that has flowed in causes the sealing member 22 to pass directly into the needle tube 1 or as shown in FIG. 21 to block the hole 11 or the p assage 21. As a result, immediately after confirming the flash bag, the inside of the needle tu be 1part is sealed. Further, when the vacuum blood collection tube is attached, the negative p ressure of the vacuum blood collection tube further brings the sealing member 22 into close c ontact with the needle tube 1 or the convex portion 24, so that the inside of the needle tube 1 is more tightly sealed.

On the other end 1b side of the needle tube support 2, a rubber-like cap 4 that seals the blad e surface of the needle tube 1 is locked by a flange 25. As shown in FIG. Synthetic isoprene r

ubber, silicon rubber, or the like is used as the material of the rubber-like cap 4 . A threaded portion 26 is formed in the needle tube support 2, and the blood collection needle and the holder can be integrated by being screwed into the opening (not shown) of the holder. INDUSTRIAL APPLICABILITY The blood collecting needle of the present invention has a hole in a part of the side wall, so that flashback can be confirmed immediately after one end of the blood collecting needle is punctured into a vein

.

In addition, since it has a sealing member, there is no possibility that negative pressure will be applied to the air-permeable blood-impermeable member when the vacuum blood collection tube is attached.

Brief description of the drawing open —

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a cross-sectional view showing a blood collection needle according to one embodiment of the present invention;

2 is an enlarged sectional view of a needle tube support portion of the blood collection needle of FIG. 1; FIG.

3 is an enlarged cross-sectional view of the needle tube support portion of the blood collection needle of FIG. 1 when the vacuum blood collection tube is attached; FIG.

FIG. 4 is an enlarged cross-sectional view of a needle tube support portion in another blood collection needle of the present invention;

[Description of Symbols]

1 Needle tube

11 Hole

2 Needle tube support

21 Passage

22 Sealing member

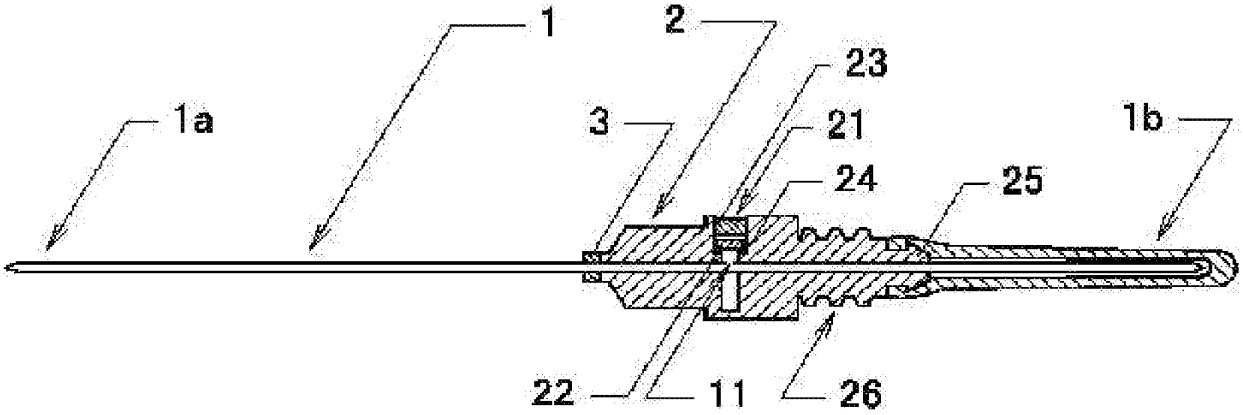
23 Air permeable blood impermeable member

24 Convex portion

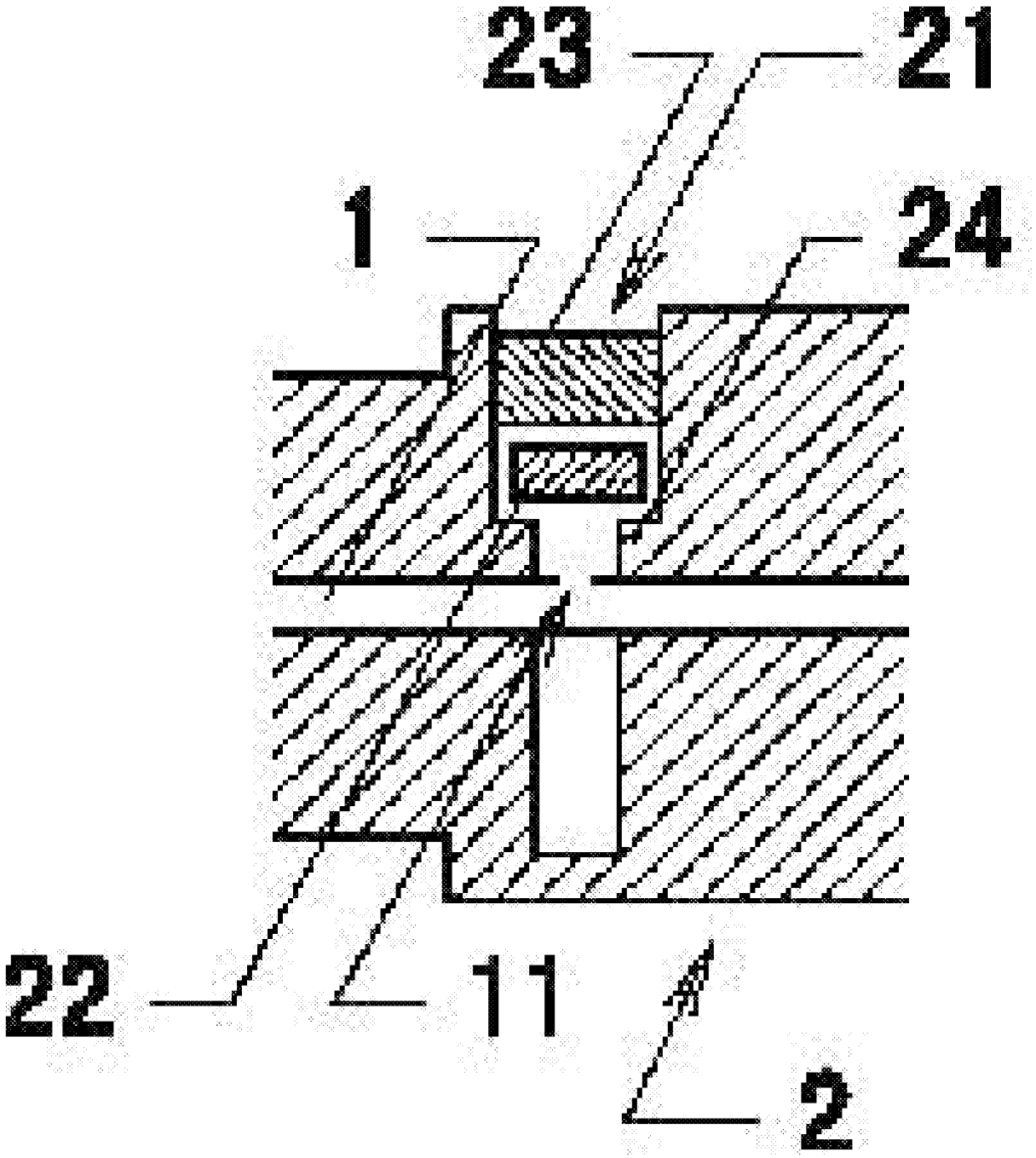
4 Rubber cap

drawing open —

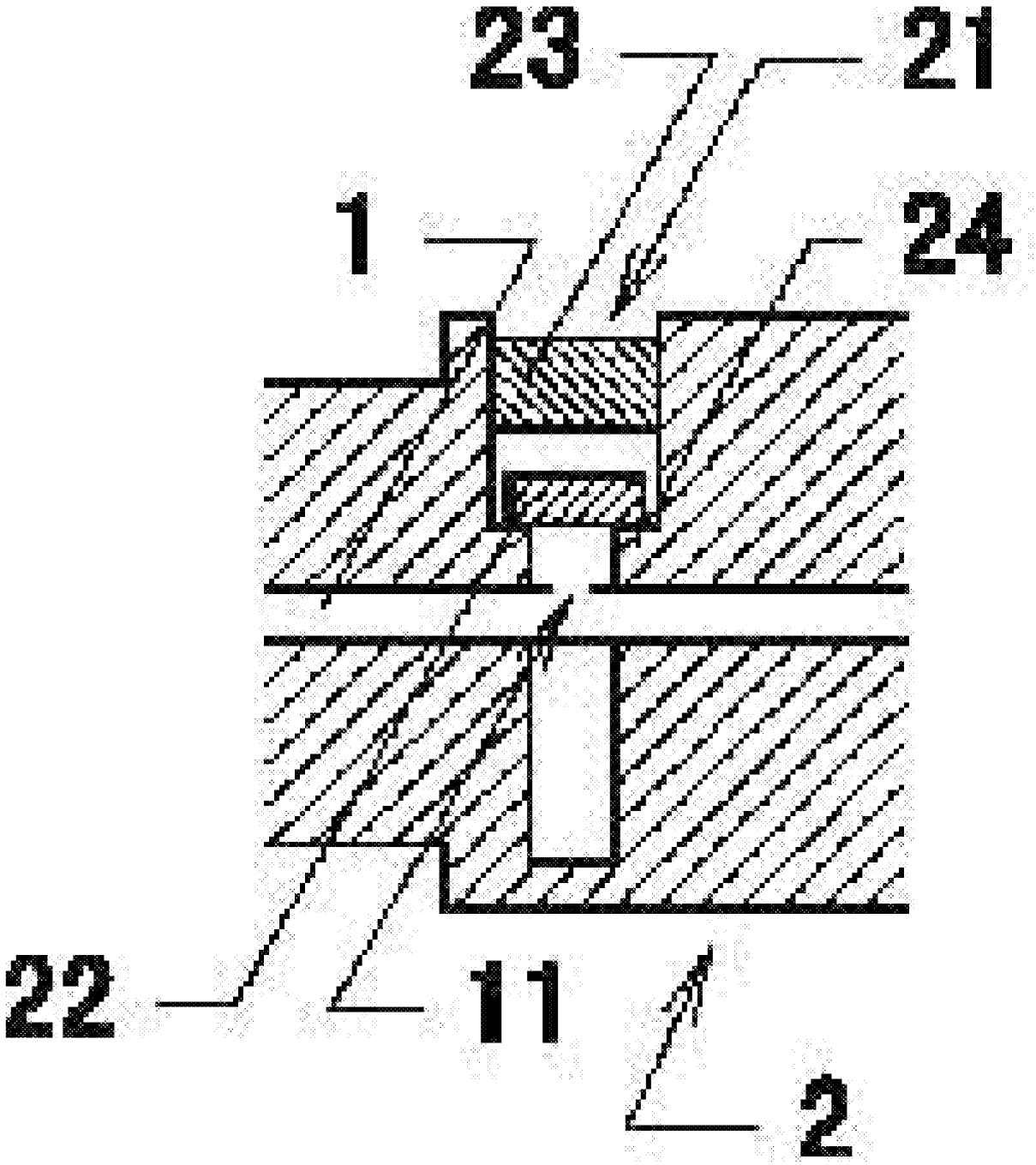
[Fig. 1]



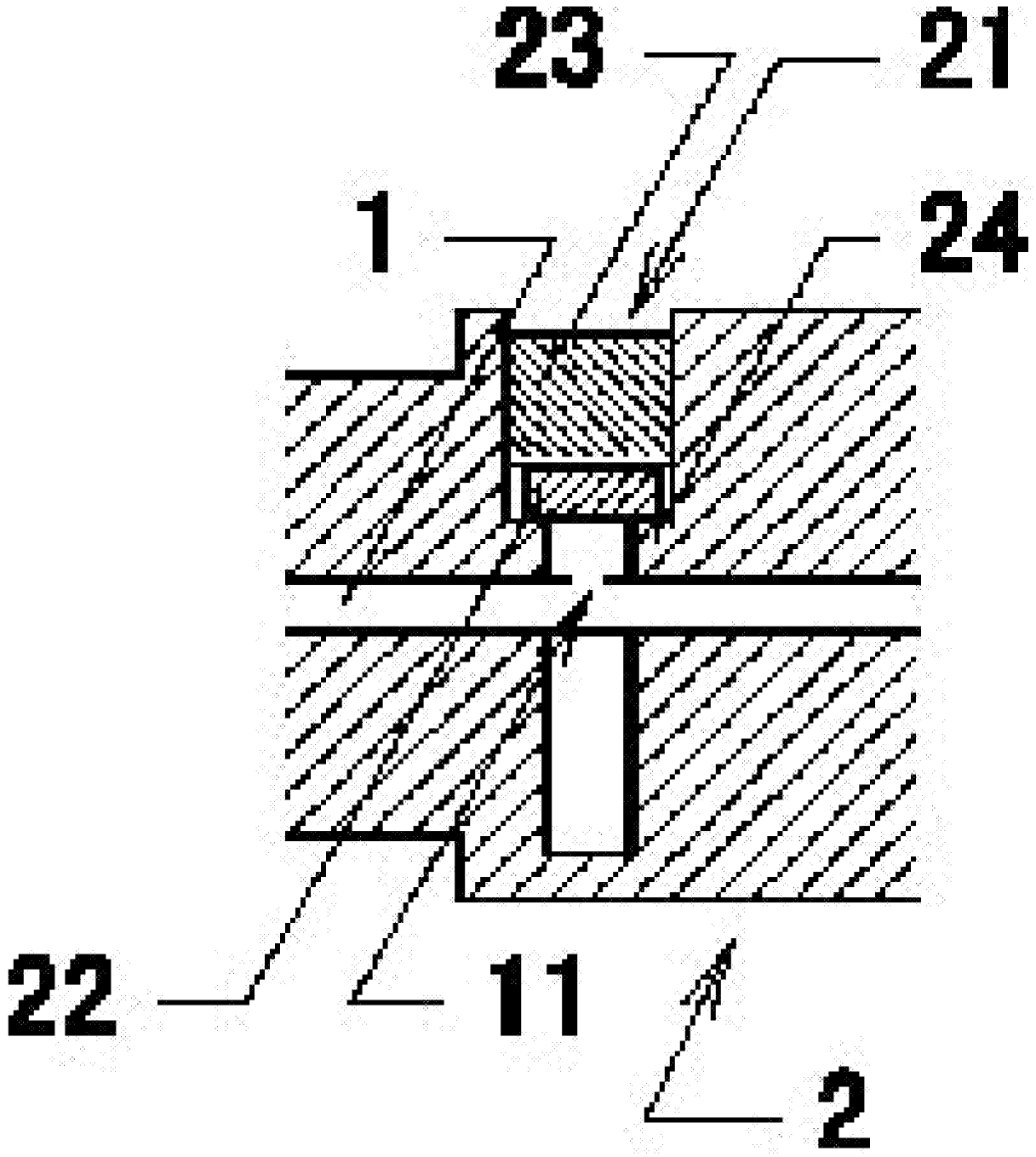
[Figure 2]



[Figure 3]



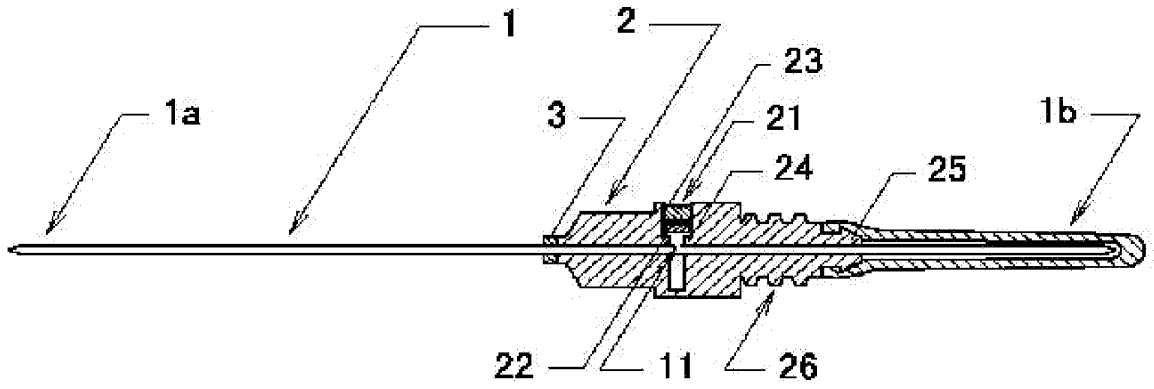
[Figure 4]



drawing open

Representative drawing | 1 | 2 | 3 | Four

Magnify and Rotate



Representative drawing

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(19)日本国特許庁（ＪＰ）　(12) **公開特許公報**（Ａ）　(11)特許出願公開番号
特開2001－424
（P2001－424A）
(43)公開日　平成13年１月９日(2001.1.9)

(51)Int.Cl.[7]	識別記号	ＦＩ	ﾃｰﾏｺｰﾄﾞ(参考)
Ａ６１Ｂ　5/15		Ａ６１Ｂ　5/14	３００Ｈ　４Ｃ０３８

審査請求　未請求　請求項の数４　ＯＬ　（全　３　頁）

(21)出願番号　特願平11－174400

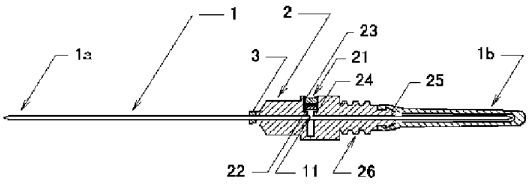
(22)出願日　平成11年６月21日(1999.6.21)

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Ｆターム(参考)　4C038 TA06 UJ02 UJ06

(54)【発明の名称】　採血針

(57)【要約】
【課題】採血時に針が確実に被検者の静脈に穿刺されたことを穿刺後、直ちに確認できる採血針を提供する。
【解決手段】側壁の少なくとも一部に孔を有し、両端が刃面である針管（Ａ）、該孔を覆うように設けられ、該孔を通じて外部と針管の内部とを連通した通路を備えた針管支持体（Ｂ）、該通路の外部への開放端に係止された空気透過性血液不透過性部材（Ｃ）、針管の一方の端を密封するように、前記針管支持体に係止されてなるゴム状キャップ（Ｄ）、および前記通路内に設けられ、前記孔あるいは通路を塞ぎ得る封止部材（Ｅ）とを有する採血針である。



【特許請求の範囲】
【請求項１】　側壁の少なくとも一部に孔を有し、両端が刃面である針管（Ａ）、該孔を覆うように設けられ、該孔を通じて外部と針管の内部とを連通した通路を備えた針管支持体（Ｂ）、該通路の外部への開放端に係止された空気透過性血液不透過性部材（Ｃ）、針管の一方の端を密封するように、前記針管支持体に係止されてなるゴム状キャップ（Ｄ）、および前記通路内に設けられ、前記孔あるいは通路を塞ぎ得る封止部材（Ｅ）とを有する採血針。
【請求項２】　通路が封止部材を係止する凸部を有する請求項１記載の採血針。
【請求項３】　空気透過性血液不透過性部材が膨潤物質である請求項１、または２記載の採血針。
【請求項４】　針管支持体が透明または半透明である請求項１、２、または３記載の採血針。
【発明の詳細な説明】
【０００１】
【発明の属する技術分野】本発明は採血針に関し、さらに詳細にはその一端を被検者の血管に穿刺し、他端を真空採血管内に連通させて、真空採血管内の負圧に応じた量の血液を採取できるようにした採血針に関する。本発明の採血針によれば、他端を真空採血管に連通させる前に一端が被検者の静脈に穿刺されたことを確認できる。
【０００２】
【従来の技術】従来から真空採血管による採血に際して、真空採血管を取り付ける前に、針が確実に被検者の静脈に穿刺されたこと、いわゆるフラッシュバックを確認できるような採血針が提案されている。このような従来の採血針としては、例えば、特開昭６１－６４２３４号公報には、前端部と後端部および外気と流通する通路を備えた試料収集室を有するハウジングと、その前端部および後端部から延設されたカニューレと、血液と接触して膨張し、外気との流通を遮断するタブレットを備えた採血針が開示されている。しかし、この採血針は、真空採血管を取り付けた時、タブレットに陰圧がかかるため、採血針内部に外気が流入するおそれがあり、既定の採血量が得られないことがある。
【０００３】また、特開平４－１３２５４１号公報には、弾性チップ内腔部と外部雰囲気とを連通させる通気孔を有し、該通気孔の外部口部に通気性フィルタを備えており、透明ないし半透明のハブまたは弾性チップによりフラッシュバックを確認できる採血針が開示されている。しかしながら、この採血針の弾性チップは、採血針ホルダー内部に収納され、しかも、その上から手で保持されるため、弾性チップによるフラッシュバックの確認は非常に困難である。また、一端を被検者の静脈に穿刺したときに静脈圧により針管内部に侵入した血液は、弾性チップ内腔部に充満したあと、通気孔に侵入する構造を有しているため、ハブによりフラッシュバックを確認するまでに時間を要する。
【０００４】
【発明が解決しようとする課題】本発明は上記事情に鑑みてなされたもので、真空採血管取り付け時、フィルタ部（以下、空気透過性血液不透過性部材と呼ぶ）に陰圧がかからず、採血針の一端が静脈に穿刺された後、直ちにフラッシュバックを確認できる採血針を提供することを目的とする。
【０００５】
【課題を解決するための手段】本発明者らは種々鋭意検討の結果、針管の側壁に孔を設け、その孔を通じて外部と針管内部とを連通させるような通路を設け、さらに真空採血管取り付け時に、針管内部を外部から遮断するような機構を設けた採血針が、上記課題を解決するものであることを見出し、本発明に到達した。
【０００６】すなわち本発明は、側壁の少なくとも一部に孔を有し、両端が刃面である針管（Ａ）、該孔を覆うように設けられ、該孔を通じて外部と針管の内部とを連通した通路を備えた針管支持体（Ｂ）、該通路の外部への開放端に係止された空気透過性血液不透過性部材（Ｃ）、針管の一方の端を密封するように、前記針管支持体に係止されてなるゴム状キャップ（Ｄ）、および前記通路内に設けられ、前記孔あるいは通路を塞ぎ得る封止部材（Ｅ）とを有する採血針である。
【０００７】
【発明の実施の形態】次に本発明を図面に基づいて詳細に説明する。図１は本発明の採血針の一実施例を示す断面図である。針管１はステンレス製であるのが好ましい。その一端１ａは刃面であり被検者の血管を刺すように形成されており、他端１ｂも刃面であり、真空採血管（図示せず）に差し込むように形成される。
【０００８】前記針管１の側壁には孔１１が設けられている。該孔１１は針管支持体２内であれば、針管１のどの部分に設けられていてもよい。該針管１には前記孔１１を覆うように、透明または半透明の針管支持体２が設けられる。該針管支持体２は針管１の一端１ａ側で、針管１と例えば接着剤３により密封的に固着されている。
【０００９】この針管支持体２内には、前記孔１１を通じて外部と針管１の内部とを連通した通路２１が形成されている。該通路２１は、外部と連通していれば、その外部への開放端はどこに設けられていてもよい。前記通路２１により、針管１の一端１ａの刃面を被検者の静脈に穿刺したとき、針管１内部に侵入した血液は、孔１１を通って前記通路２１に侵入し、侵入した血液を針管支持体２の側面から目視することで、フラッシュバックを確認することができる。
【００１０】前記通路２１内には、封止部材２２が設けられている。該封止部材２２としては、ポリプロピレン、テフロン（登録商標）およびシリコンゴムなどのプラスチック材料を使用することができるが、ステンレス

などの金属やセラミックであっても構わない。また通路２１内において、該封止部材２２と針管支持体２との間に空気及び血液が通過できる間隙を有している。

【００１１】前記通路２１の針管１外部への開放端には、空気透過性血液不透過性部材２３が密封的に係止されている。この部材２３により通路２１内の通気性を保ちながら、採血時に流入した血液は外部へ漏らすことがない。空気透過性血液不透過性部材２３としては、通常、ポリプロピレンやポリエチレンなどのポリマー焼結体からなる層状のフィルターが好適に使用されるが、ポリプロピレンやポリエチレンなどの疎水性樹脂からなる膜状のいわゆるメンブレンフィルターであってもよい。

【００１２】図２に示すように、針管１の一端１ａを被検者に穿刺したとき、針管１内部から孔１１を通って通路２１内に流入してきた血液は、封止部材２２と針管支持体２との間隙を通って、空気透過性血液不透過性部材２３で堰き止められる。その後、真空採血管を針管１の他端１ｂに取り付けると、図３に示すように、真空採血管の陰圧により封止部材２２が針管１に引き寄せられ、通路２１を塞ぐ。これにより、空気透過性血液不透過性部材２３に直接陰圧がかからないので、既定の採血量が得られる。また、前記通路２１は、内部に封止部材２２を係止する凸部２４を設けたものが、針管１内部の密封性を考慮するとより好ましい。凸部２４の形状としては、図１に示される断面がＬ字状であるものの他に、開放端に向かってテーパー状に広がるものや、通路２１の中間部で通路内方へ突出しているものなどが挙げられる。

【００１３】また、空気透過性血液不透過性部材２３としては、アクリル酸系共重合体、スターチおよびゼラチンなどの膨潤物質を、単独あるいは他の化合物と混合して使用することができる。針管１の一端１ａを被検者に穿刺したとき、流入してきた血液によって膨張した空気透過性血液不透過性部材２３は、封止部材２２を直接針管１に、あるいは図４に示すように通路２１内の凸部２４に押しつけ、孔１１または通路２１を塞ぐ。これにより、フラッシュバックを確認したあと、すぐに針管１内部が密封される。また、真空採血管取り付け時には、真空採血管の陰圧により、さらに封止部材２２は針管１、あるいは凸部２４に密着するので、針管１内部の密封性はより高くなる。

【００１４】針管支持体２の他端１ｂ側には、針管１の刃面を密閉的に覆うゴム状キャップ４がフランジ２５により係止されている。このゴム状キャップ４の材料としては、合成イソプレンゴムやシリコンゴムなどが採用される。また、この針管支持体２にはねじ部２６が形成されており、ホルダーの口部（図示せず）に螺合されることにより、採血針とホルダーを一体化させることができる。

【００１５】

【発明の効果】本発明の採血針は側壁の一部に孔を設けることにより、採血針の一端が静脈に穿刺された後、直ちにフラッシュバックを確認することができる。また、封止部材を有しているため、真空採血管取り付け時に、空気透過性血液不透過性部材に陰圧がかかるおそれがない。

【図面の簡単な説明】

【図１】本発明の一実施例の採血針を示す断面図である。

【図２】図１の採血針における針管支持体部分の拡大断面図である。

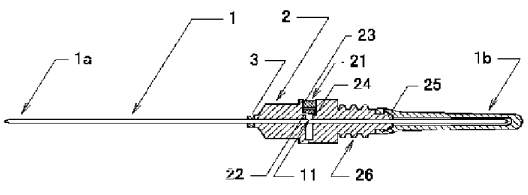
【図３】真空採血管取り付け時の、図１の採血針における、針管支持体部分の拡大断面図である。

【図４】本発明の他の採血針における、針管支持体部分の拡大断面図である。

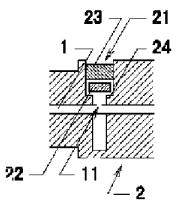
【符号の説明】

１　針管
１１　孔
２　針管支持体
２１　通路
２２　封止部材
２３　空気透過性血液不透過性部材
２４　凸部
４　ゴム状キャップ

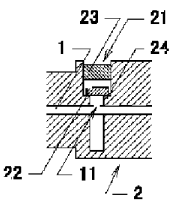
【図１】



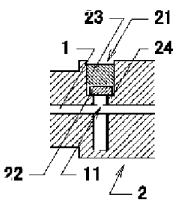
【図２】



【図３】



【図４】



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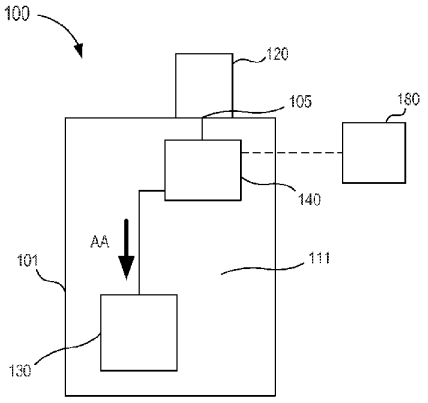


FIG. 1

(57) Abstract: An apparatus includes a cannula assembly, a housing, a fluid reservoir, a flow control mechanism, and an actuator. The housing includes an inlet port removably coupled to the cannula assembly and defines an inner volume. The fluid reservoir is fluidically coupled to the housing and configured to receive and isolate a volume of bodily fluid from a patient. The flow control mechanism is at least partially disposed in the inner volume. The actuator is operably coupled to the flow control mechanism and is configured to move the flow control mechanism between a first configuration, in which bodily fluid can flow, via a fluid flow path defined by the flow control mechanism, from the cannula assembly, through the inlet port and into the fluid reservoir, to a second configuration, in which the fluid reservoir is fluidically isolated from the cannula assembly.

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SYSTEMS AND METHODS FOR DELIVERING A FLUID TO A PATIENT WITH REDUCED CONTAMINATION

Cross-Reference to Related Applications

[1001] This application claims priority to and the benefit of U.S. Provisional Patent Application Serial No. 61/712,468, filed October 11, 2012, entitled, "Systems and Methods for Delivering a Fluid to a Patient with Reduced Contamination," the disclosure of which is incorporated herein by reference in its entirety.

Background

[1002] Embodiments described herein relate generally to delivering a fluid to a patient, and more particularly to devices and methods for delivering a parenteral fluid to a patient with reduced contamination from microbes or other contaminants exterior to the body and/or the fluid source, such as dermally residing microbes.

[1003] Human skin is normally habituated in variable small amounts by certain bacteria such as coagulase-negative Staphylococcus species, Proprionobacterium acnes, Micrococcus species, Streptococci Viridans group, Corynebacterium species, and Bacillus species. These bacteria for the most part live in a symbiotic relationship with human skin but in some circumstances can give rise to serious infections in the blood stream known as septicemia. Septicemia due to these skin residing organisms is most often associated with an internal nidus of bacterial growth at the site of injured tissue, for example a damaged, scarred heart valve, or a foreign body (often an artificial joint, vessel, or valve). Furthermore, there are predisposing factors to these infections such as malignancy, immunosuppression, diabetes mellitus, obesity, rheumatoid arthritis, psoriasis, and advanced age. In some instances, these infections can cause serious illness and/or death. Moreover, these infections can be very expensive and difficult to treat and often can be associated with medical related legal issues.

[1004] In general medical practice, blood is drawn from veins (phlebotomy) for two main purposes; (1) donor blood in volumes of approximately 500mL is obtained for the treatment of anemia, deficient blood clotting factors including platelets and other medical conditions; and (2) smaller volumes (e.g., from a few drops to 10mL or more) of blood are obtained for testing purposes. In each case, whether for donor or testing specimens, a fluid communicator (e.g., catheter, cannula, needle, etc.) is used to penetrate and enter a vein (known as venipuncture) enabling withdrawing of blood into a tube or vessel apparatus in the desired

amounts for handling, transport, storage and/or other purposes. The site of venipuncture, most commonly the antecubital fossa, is prepared by cleansing with antiseptics to prevent the growth of skin residing bacteria in blood withdrawn from the vein. It has been shown venipuncture needles dislodge fragments of skin including hair and sweat gland structures as well as subcutaneous fat and other adnexal structures not completely sterilized by skin surface antisepsis. These skin fragments can cause septicemia in recipients of donor blood products, false positive blood culture tests and other undesirable outcomes. Furthermore, methods, procedures and devices are in use, which divert the initial portion of venipuncture blood enabling exclusion of these skin fragments from the venipuncture specimen in order to prevent septicemia in recipients of donor blood products, false positive blood culture tests and other undesirable outcomes.

[1005] Venipuncture is also the most common method of accessing the blood stream of a patient to deliver parenteral fluids into the blood stream of patients needing this type of medical treatment. Fluids in containers are allowed to flow into the patient's blood stream through tubing connected to the venipuncture needle or through a catheter that is placed into a patient's vasculature (e.g. peripheral IV, central line, etc.). During this process, fragments of incompletely sterilized skin can be delivered into the blood stream with the flow of parenteral fluids and/or at the time of venipuncture for introduction and insertion of a peripheral catheter. These fragments are undesirable in the blood stream and their introduction into the blood stream of patients (whether due to dislodging of fragments by venipuncture needle when inserting a catheter or delivered through tubing attached to needle or catheter) is contrary to common practices of antisepsis. Further, these microbes can be associated with a well-known phenomenon of colonization by skin residing organisms of the tubing and tubing connectors utilized to deliver parenteral fluids. The colonization is not typically indicative of a true infection but can give rise to false positive blood culture tests, which may result in unnecessary antibiotic treatment, laboratory tests, and replacement of the tubing apparatus with attendant patient risks and expenses. Furthermore, the risk of clinically significant serious infection due to skin residing organisms is increased.

[1006] As such, a need exists for improved fluid transfer devices, catheter introduction techniques and devices, as well as methods for delivering a parenteral fluid to a patient that reduce microbial contamination and inadvertent injection of undesirable external microbes into a patient's blood stream.

Summary

[1007] Devices and methods for delivering a fluid to a patient and/or introducing a peripheral catheter with reduced contamination from dermally residing microbes or other contaminants exterior to the body and/or an external fluid source are described herein. In some embodiments, an apparatus includes a cannula assembly, a housing, a fluid reservoir, a flow control mechanism, and an actuator. The housing has a proximal end portion and a distal end portion and defines an inner volume therebetween. The housing includes an inlet port removably coupled to the cannula assembly. The fluid reservoir is fluidically coupled to the housing and configured to receive and isolate a first volume of bodily fluid withdrawn from a patient. The flow control mechanism is at least partially disposed in the inner volume and is configured to move relative to the housing between a first configuration and a second configuration. The flow control mechanism defines a fluid flow path between the cannula assembly and the fluid reservoir in the first configuration. The actuator is operably coupled to the flow control mechanism to move the flow control mechanism from the first configuration, in which the inlet port is placed in fluid communication the fluid reservoir such that bodily fluid can flow from the cannula assembly, through the inlet port via the fluid flow path and to the fluid reservoir, to the second configuration, in which the fluid reservoir is fluidically isolated from the cannula assembly.

Brief Description of the Drawings

[1008] FIGS. 1 and 2 are schematic illustrations of a fluid transfer device according to an embodiment.

[1009] FIG. 3 is a schematic illustration of a fluid transfer device according to an embodiment.

[1010] FIG. 4 is a perspective view of a fluid transfer device according to an embodiment.

[1011] FIG. 5 is an exploded view of the fluid transfer device of FIG. 4.

[1012] FIG. 6 is a cross-sectional view of the fluid transfer device taken along the line X_1-X_1 in FIG. 4, in a first configuration.

[1013] FIG. 7 is an enlarged view of a portion of the fluid transfer device labeled as region **A** in FIG. 6.

[1014] FIGS. 8 and 9 are cross-sectional views of the fluid transfer device taken along the line X_1-X_1 in FIG. 4, in a second and third configuration, respectively.

[1015] FIG. 10 is a side view of the fluid transfer device of FIG. 4 in a fourth configuration.

[1016] FIG. 11 is a perspective view of a fluid transfer device according to an embodiment.

[1017] FIG. 12 is an exploded view of the fluid transfer device of FIG. 11.

[1018] FIGS. 13 and 14 are cross-sectional views of the fluid transfer device taken along the line X_2-X_2 in FIG. 11, in a first and second configuration, respectively.

[1019] FIG. 15 is a side view of the fluid transfer device of FIG. 11 in a third configuration.

[1020] FIG. 16 is a perspective view of a fluid transfer device according to an embodiment.

[1021] FIG. 17 is an exploded view of the fluid transfer device of FIG. 16.

[1022] FIG. 18 is a cross-sectional perspective view of a housing included in the fluid transfer device taken along the line X_4-X_4 in FIG. 17.

[1023] FIG. 19 is a cross-sectional perspective view of a portion of a flow control mechanism included in the fluid transfer device taken along the line X_5-X_5 in FIG. 17.

[1024] FIG. 20 is a cross-sectional view of the fluid transfer device taken along the line X_3-X_3 in FIG. 16, in a first configuration.

[1025] FIG. 21 is a front view of the fluid transfer device of FIG. 16 in a second configuration.

[1026] FIG. 22 is a cross-sectional view of the fluid transfer device taken along the line X_3-X_3 in FIG. 16, in the second configuration.

[1027] FIG. 23 is a side view of the fluid transfer device of FIG. 16 in a third configuration.

[1028] FIG. 24 is a perspective view of a fluid transfer device according to an embodiment.

[1029] FIG. 25 is an exploded view of the fluid transfer device of FIG. 24.

[1030] FIG. 26 is a cross-sectional perspective view of a fluid reservoir included in the fluid transfer device taken along the line X_7-X_7 in FIG. 25.

[1031] FIG. 27 is a cross-sectional perspective view of a flow control mechanism included in the fluid transfer device taken along the line X_8-X_8 in FIG. 25.

[1032] FIGS. 28-30 are cross-sectional views of the fluid transfer device taken along the line X_6-X_6 in FIG. 24, in a first, second, and third configuration, respectively.

[1033] FIG. 31 is a perspective view of a fluid transfer device according to an embodiment.

[1034] FIG. 32 is an exploded view of the fluid transfer device of FIG. 31.

[1035] FIGS. 33 and 34 are cross-sectional views of the fluid transfer device taken along the line X_9-X_9 in FIG. 31, in a first configuration and a second configuration, respectively.

[1036] FIG. 35 is a perspective view of a fluid transfer device according to an embodiment.

[1037] FIG. 36 is an exploded view of the fluid transfer device of FIG. 35.

[1038] FIG. 37 is a cross-sectional view of the fluid transfer device taken along the line X_{10}-X_{10} in FIG. 35, in a first configuration.

[1039] FIG. 38 is a front view of the fluid transfer device of FIG. 35 in a second configuration.

[1040] FIG. 39 is a cross-sectional view of the fluid transfer device taken along the line X_{10}-X_{10} in FIG. 35, in the second configuration.

[1041] FIG. 40 is a flowchart illustrating a method of delivering a fluid to a patient using a fluid transfer device according to an embodiment.

Detailed Description

[1042] Devices and methods for delivering a fluid to a patient with reduced contamination from dermally residing microbes or other contaminants exterior to the body are described herein. In some embodiments, an apparatus includes a cannula assembly, a housing, a fluid reservoir, a flow control mechanism, and an actuator. The housing has a proximal end portion and a distal end portion and defines an inner volume therebetween. The housing includes an inlet port configured to be removably coupled to the cannula assembly. The fluid reservoir is fluidically coupled to the housing and configured to receive and isolate a first volume of bodily fluid withdrawn from a patient. The flow control mechanism is at least partially disposed in the inner volume and is configured to move relative to the housing between a first configuration and a second configuration. The flow control mechanism defines a fluid flow path between the cannula assembly and the fluid reservoir in the first configuration. The actuator is operably coupled to the flow control mechanism to move the flow control mechanism from the first configuration, in which the inlet port is placed in fluid communication the fluid reservoir such that bodily fluid can flow from the cannula assembly, through the inlet port via the fluid flow path and to the fluid reservoir, to the second configuration, in which the fluid reservoir is fluidically isolated from the cannula assembly.

[1043] In some embodiments, a device for delivering a fluid to a patient with reduced contamination includes a housing, a fluid reservoir, and a flow control mechanism. The housing has a proximal end portion and a distal end portion and defines an inner volume therebetween. The housing includes a first port configured to be removably coupled to a cannula assembly, and a second port configured to be fluidically coupled to a fluid source. The fluid reservoir is fluidically coupleable to the cannula assembly and configured to receive and isolate a predetermined volume of bodily fluid withdrawn from the patient. The flow control mechanism is at least partially disposed in the inner volume of the housing and is configured to move between a first configuration and a second configuration. When in the first configuration, the first port is placed in fluid communication with the fluid reservoir such that bodily fluid can flow from the cannula assembly, through the first port and to the fluid reservoir. When in the second configuration, the fluid reservoir is fluidically isolated

from the cannula assembly and fluid can flow from the fluid source, in the second port, through the flow control mechanism, out the first port and to the cannula assembly.

[1044] In some embodiments, a method of delivering a fluid to a patient using a fluid transfer device includes establishing fluid communication between the patient and the fluid transfer device. Once in fluid communication, a predetermined volume of a bodily fluid is withdrawn from the patient. The predetermined volume of bodily fluid is transferred to a fluid reservoir. The fluid transfer device is fluidically isolated from the fluid reservoir to sequester the predetermined volume of bodily fluid in the fluid reservoir. The method further includes establishing fluid communication between the patient and a fluid source with the fluid transfer device.

[1045] In some embodiments, an apparatus includes a housing, a cannula assembly, a flow control mechanism, and a fluid reservoir. The flow control mechanism is configured to move relative to the housing between a first configuration and a second configuration. The cannula assembly is coupled to the housing and fluidically coupled to the fluid reservoir when the flow control mechanism is in the first configuration. The fluid reservoir is fluidically isolated from the cannula assembly when the flow control mechanism is in a second configuration such that the cannula assembly can be fluidically coupled to an external fluid reservoir and/or an external fluid source.

[1046] As referred to herein, "bodily fluid" can include any fluid obtained from a body of a patient, including, but not limited to, blood, cerebrospinal fluid, urine, bile, lymph, saliva, synovial fluid, serous fluid, pleural fluid, amniotic fluid, and the like, or any combination thereof.

[1047] As used herein, the term "set" can refer to multiple features or a singular feature with multiple parts. For example, when referring to set of walls, the set of walls can be considered as one wall with distinct portions, or the set of walls can be considered as multiple walls. Similarly stated, a monolithically constructed item can include a set of walls. Such a set of walls can include, for example, multiple portions that are in discontinuous from each other. A set of walls can also be fabricated from multiple items that are produced separately and are later joined together (e.g., via a weld, an adhesive or any suitable method).

[1048] As used in this specification, the words "proximal" and "distal" refer to the direction closer to and away from, respectively, a user who would place the device into

contact with a patient. Thus, for example, the end of a device first touching the body of the patient would be the distal end, while the opposite end of the device (e.g., the end of the device being manipulated by the user) would be the proximal end of the device.

[1049] FIGS. 1 and 2 are schematic illustrations of a fluid transfer device 100 according to an embodiment, in a first and second configuration, respectively. Generally, the fluid transfer device 100 (also referred to herein as "transfer device") is configured to facilitate the insertion of a piercing member (e.g., a needle, a trocar, a cannula, or the like) into a patient to withdrawal and isolate a predetermined amount of bodily fluid from the patient containing, for example, dermally residing microbes. The fluid transfer device 100 is further configured to facilitate the delivery of parenteral fluid to the patient that does not substantially contain, for example, the dermally residing microbes. In other words, the transfer device 100 is configured to transfer and fluidically isolate the predetermined amount of bodily fluid, including dermally residing microbes dislodged from a venipuncture, within a collection reservoir and deliver parenteral fluids to the patient that are substantially free from the dislodged dermally residing microbes and/or other undesirable external contaminants.

[1050] The transfer device 100 includes a housing 101, a cannula assembly 120, a fluid reservoir 130, a flow control mechanism 140, and an actuator 180. The housing 101 can be any suitable shape, size, or configuration and is described in further detail herein with respect to specific embodiments. As shown in FIG. 1, the housing 101 defines an inner volume 111 that can movably receive and/or movably house at least a portion of the flow control mechanism 140, as described in further detail herein. A portion of the housing 101 can be, at least temporarily, physically and fluidically coupled to the cannula assembly 120. For example, in some embodiments, a distal end portion of the housing 101 can include an inlet port 105 or the like configured to physically and fluidically couple to a lock mechanism (not shown in FIGS. 1 and 2) included in the cannula assembly 120. In such embodiments, the lock mechanism can be, for example, a Luer-Lok® or the like that can engage the port. In some embodiments, the housing 101 can be monolithically formed with at least a portion of the cannula assembly 120. In other words, in some embodiments, the inlet port 105 can be monolithically formed with a portion of the cannula assembly 120 to define a fluid flow path between a portion of the housing 101 the cannula assembly 120. In this manner, a portion of the housing 101 can receive a bodily fluid from and/or deliver a parenteral fluid to a patient via a cannula included in the cannula assembly 120, as described in further detail herein.

[1051] The cannula assembly 120 can be any suitable configuration. For example, in some embodiments, the cannula assembly 120 includes an engagement portion and a cannula portion (not shown in FIGS. 1 and 2). In such embodiments, the engagement portion can physically and fluidically couple the cannula assembly 120 to the housing 101 (e.g., it can be the lock mechanism physically and fluidically coupled to the inlet port 105 as described above). The cannula portion can be configured to be inserted into a portion of a patient to deliver a fluid to or receive a fluid from the patient. For example, in some embodiments, the cannula portion can include a distal end with a sharp point configured to pierce a portion of the patient to dispose the cannula portion, at least in part, within a vein of the patient. In other embodiments, a piercing member (e.g., a lumen defining needle) can be movably disposed within the cannula assembly 120 to facilitate the insertion of the cannula portion 120 into the portion of the patient.

[1052] As shown in FIG. 1, the housing 101 can house and/or define the fluid reservoir 130. Similarly stated, in some embodiments, the fluid reservoir 130 can be disposed within and/or at least partially defined by the inner volume 111 of the housing 101. The fluid reservoir 130 can be configured to receive a predetermined amount of the bodily fluid and fluidically isolate the bodily fluid from a volume outside the fluid reservoir 130, as described in further detail herein. While shown in FIGS. 1 and 2 as being disposed within the inner volume 111 of the housing 101, in some embodiments, the fluid reservoir 130 can be disposed substantially outside the housing 101. In such embodiments, the fluid reservoir 130 can be physically and fluidically coupled to a portion of the housing 101. For example, in some embodiments, the fluid reservoir 130 can be coupled to an outlet port (not shown in FIGS. 1 and 2). In other embodiments, the fluid reservoir 130 can be operably coupled to the housing 101 via an intervening structure, such as, for example, a Luer-Lok® and/or flexible sterile tubing. In still other embodiments, the fluid reservoir 130 can be monolithically formed with at least a portion of the housing 101.

[1053] The flow control mechanism 140 included in the transfer device 100 is disposed, at least partially, within the inner volume 111 of the housing 101 and can be moved between a first configuration (FIG. 1) and a second configuration (FIG. 2). The flow control mechanism 140 can be any suitable mechanism configured to control or direct a flow of a fluid. For example, in some embodiments, the flow control mechanism 140 can include a valve (e.g., a check valve or the like) that allows a flow of a fluid in a single direction. In

other embodiments, a valve can selectively control a flow of a fluid in multiple directions. In still other embodiments, the flow control mechanism 140 can define one or more lumens configured to selectively receive a flow of a fluid. In such embodiments, the flow control mechanism 140 can be moved relative to the housing 101 to selectively place a lumen in fluid communication with a portion of the transfer device 100 (e.g., the housing 101, the cannula assembly 120, and/or the fluid reservoir 130). For example, in some embodiments, a portion of the flow control mechanism 140 can be movably disposed, at least temporarily, within the cannula assembly 120 to selectively place the fluid reservoir 130 in fluid communication with the cannula assembly 120. In some embodiments, the portion of the flow control mechanism 140 can include a piercing member such as, for example, a needle configured to extend beyond a distal end of the cannula assembly 120 (not shown in FIGS. 1 and 2) to pierce the skin of a patient and facilitate the insertion of the cannula assembly 120 into a vein of the patient.

[1054] In some embodiments, the transfer device 100 can include an actuator 180 operably coupled to the flow control mechanism 140 and configured to move the flow control mechanism 140 between the first and the second configuration. For example, in some embodiments, the actuator 180 can be a push button, a slider, a toggle, a pull-tab, a handle, a dial, a lever, an electronic switch, or any other suitable actuator. In this manner, the actuator 180 can be movable between a first position corresponding to the first configuration of the flow control mechanism 140, and a second position, different from the first position, corresponding to the second configuration of the flow control mechanism 140. In some embodiments, the actuator 180 can be configured for uni-directional movement. For example, the actuator 180 can be moved from its first position to its second position, but cannot be moved from its second position back to its first position. In this manner, the flow control mechanism 140 is prevented from being moved to its second configuration before its first configuration, as described in further detail herein.

[1055] In use, the flow control mechanism 140 can be in the first configuration to place the fluid reservoir 130 in fluid communication with the cannula assembly 120, as indicated by the arrow AA in FIG. 1. In this manner, the fluid reservoir 130 can receive a flow of bodily fluid that can include dermally residing microbes dislodged during a venipuncture event (e.g., when the cannula assembly 120 and/or the flow control mechanism 140 pierces the skin of the patient). In some embodiments, the fluid reservoir 130 can be configured to

receive a predetermined volume of the bodily fluid. With a desired amount of bodily fluid transferred to the fluid reservoir 130, a user (e.g., a doctor, physician, nurse, technician, phlebotomist, etc.) can manipulate the actuator 180 to move the flow control mechanism 140 from the first configuration to the second configuration. For example, the flow control mechanism 140 can be in the first configuration when the flow control mechanism 140 is in a distal position relative to the housing 101 (FIG. 1) and the actuator 180 can move the flow control mechanism 140 in a proximal direction relative to the housing 101 to place the flow control mechanism in the second configuration, as indicated by the arrow BB in FIG. 2. Moreover, when in the second configuration, the flow control mechanism 140 no longer facilitates the fluidic coupling of the fluid reservoir 130 to the cannula assembly 120. Thus, the fluid reservoir 130 is fluidically isolated from the cannula assembly 120.

[1056] While shown in FIGS. 1 and 2 as being moved in the proximal direction (e.g., in the direction of the arrow BB), in other embodiments, the actuator 180 can move the flow control mechanism 140 between the first configuration and the second configuration in any suitable manner or direction. For example, in some embodiments, the flow control mechanism 140 can be moved in a rotational motion between the first configuration and the second configuration. In other embodiments, the flow control mechanism 140 can be moved in a transverse motion (e.g., substantially perpendicular to the direction of the arrow BB). In such embodiments, the rotational or transverse motion can be such that the flow control mechanism 140 selectively defines one or more fluid flow paths configured to receive a fluid from a patient or to deliver a fluid to the patient, as described in further detail herein.

[1057] In some embodiments, the movement of the flow control mechanism 140 to the second configuration can substantially correspond to a physical and fluidic decoupling of at least a portion of the housing 101 from the cannula assembly 120 such that an external fluid reservoir 199 (e.g., also referred to herein as "fluid source") can be physically and fluidically coupled to the cannula assembly 120. For example, as shown in FIG. 2, in some embodiments, the housing 101 can be moved in the proximal direction (e.g., in the direction of the arrow BB) to be physically and fluidically decoupled from the cannula assembly 120. In some embodiments, the proximal movement of the flow control mechanism 140 urges the housing 101 to move in the proximal direction. In other embodiments, a user (e.g., a physician, phlebotomist, or nurse) can move the housing 101 in the proximal direction. In this manner, the external fluid reservoir 199 can be fluidically coupled to the cannula

assembly 120. Expanding further, with the predetermined amount of bodily fluid transferred to the fluid reservoir 130, the external fluid reservoir 199 can be fluidically coupled to the cannula assembly 120 to deliver a flow of a parenteral fluid that is substantially free from dermally residing microbes dislodged during the venipuncture event, as indicated by the arrow CC in FIG. 2. Similarly stated, the dermally residing microbes that are dislodged during the venipuncture event can be entrained in the flow of the bodily fluid delivered to the fluid reservoir 130. Thus, when the flow control mechanism 140 is moved to the second configuration and the fluid reservoir 130 is fluidically isolated from the cannula assembly 120, the external fluid reservoir 199 can deliver the flow of parenteral fluid substantially free from dermally residing microbes.

[1058] While the housing 101 is shown in FIG. 2 as being moved in the proximal direction such that the external fluid reservoir 199 can be physically and fluidically coupled to the cannula assembly 120, in other embodiments, a housing need not be decoupled from a cannula assembly. For example, FIG. 3 is a schematic illustration of a transfer device 200 according to an embodiment. The transfer device 200 includes a housing 201, a cannula assembly 220, a fluid reservoir 230, and a flow control mechanism 240.

[1059] As shown in FIG. 3, the housing 201 includes a proximal end portion 202 and a distal end portion 203 and defines an inner volume 211 therebetween. The distal end portion 203 can be physically and fluidically coupled to the cannula assembly 220, as described above in reference to FIG. 1. For example, in some embodiments, the distal end portion 203 can include an inlet port 205 (also referred to herein as "first port") or the like that can be physically and fluidically coupled to the cannula assembly 220. The proximal end portion 202 includes an outlet port 206 (also referred to herein as "second port") that can be physically and fluidically coupled to an external fluid reservoir 299. The external fluid reservoir 299 can be any suitable fluid reservoir and can be coupled to the second port 206 via an adhesive, a resistance fit, a mechanical fastener, any number of mating recesses, a threaded coupling, and/or any other suitable coupling or combination thereof. For example, in some embodiments, the external fluid reservoir 299 can be substantially similar to known fluid reservoirs configured to deliver a parenteral fluid (e.g., a fluid source). In some embodiments, the external fluid reservoir 299 is monolithically formed with the second port 206. In still other embodiments, the external fluid reservoir 299 can be operably coupled to the second port 206 via an intervening structure (not shown in FIG. 3), such as, for example,

a flexible sterile tubing. More particularly, the intervening structure can define a lumen configured to place the external fluid reservoir 299 in fluid communication with the second port 206.

[1060] The housing 201 can house or define at least a portion of the fluid reservoir 230. Similarly stated, the fluid reservoir 230 can be at least partially disposed within the inner volume 211 of the housing 201. The fluid reservoir 230 can receive and fluidically isolate a predetermined amount of the bodily fluid, as described above in reference to FIGS. 1 and 2. Similarly, the flow control mechanism 240 is at least partially disposed within the inner volume 211 of the housing 201 and can be moved between a first configuration and a second configuration. More specifically, the flow control mechanism 240 defines a first lumen 246 that fluidically couples the cannula assembly 220 to the fluid reservoir 230 when the flow control mechanism 240 is in the first configuration and a second lumen 247 that fluidically couples the cannula assembly 220 to the external fluid reservoir 299 when the flow control mechanism 240 is in the second configuration.

[1061] In use, the flow control mechanism 240 can be placed in the first configuration to fluidically couple the cannula assembly 220 to the fluid reservoir 230 via the first lumen 246. In this manner, a flow of a bodily fluid can be delivered to the fluid reservoir 230, as indicated by the arrow DD in FIG. 3. More specifically, the bodily fluid can flow from the cannula assembly 220, through the first port 205 (e.g., the inlet port) and into the fluid reservoir 230. As described above in the previous embodiment, the flow of the bodily fluid can contain dermally residing microbes dislodged by a venipuncture event (e.g., the insertion of a portion of the cannula assembly 220 into a vein of the patient).

[1062] With a predetermined amount of bodily fluid disposed within the fluid reservoir 230, the flow control mechanism 240 can be moved (e.g., by an actuator and/or manual intervention from the user) to the second configuration to fluidically isolate the fluid reservoir 230 from the cannula assembly 220. More specifically, the flow control mechanism 240 can be moved from the first configuration to fluidically isolate the first lumen 246 from the cannula assembly 220 and/or the fluid reservoir 230, thereby fluidically isolating the fluid reservoir 230 from the cannula assembly 220. In addition, the movement of the flow control mechanism 240 to the second configuration can place the second lumen 247 in fluid communication with the cannula assembly 220 and the outlet port 206 (e.g., the second port) disposed at the proximal end portion 202 of the housing 201. Thus, the external fluid

reservoir 299 can be fluidically coupled (as described above) to the second port 206 to deliver a flow of parenteral fluid to the patient via the second lumen 247 and the cannula assembly 220, as indicated by the arrow EE. For example, the flow of parenteral fluid can flow from the external fluid reservoir 299 (e.g., a fluid source), in the second port 206, through the second lumen 247 defined by the flow control mechanism 240, out the first port 205 and to the cannula assembly 220 to be delivered to the patient. Moreover, the flow of the parenteral fluid is substantially free from dermally residing microbes and/or other undesirable external contaminants.

[1063] In some embodiments, the transfer device 200 can be configured such that the first amount of bodily fluid needs to be conveyed to the fluid reservoir 230 before the transfer device 200 will permit the flow of the parenteral fluid to be conveyed through the transfer device 200 to the patient. In this manner, the transfer device 200 can be characterized as requiring compliance by a health care practitioner regarding the collection of the predetermined amount of bodily fluid prior to the delivery of the parenteral fluid. Similarly stated, the transfer device 200 can be configured to prevent a health care practitioner from delivering the parenteral fluid to the patient without first diverting or transferring the predetermined amount of bodily fluid to the fluid reservoir 230. In this manner, the health care practitioner is substantially prevented from introducing (whether intentionally or unintentionally) bodily surface microbes and/or other undesirable external contaminants into, for example, the flow of the parenteral fluid and/or the blood stream of the patient. In other embodiments, the fluid transfer device 200 need not include a forced-compliance feature or component.

[1064] FIGS. 4-10 illustrate a transfer device 300 according to an embodiment. The transfer device 300 includes a housing 301, a cannula assembly 320, a fluid reservoir 330, a flow control mechanism 340, and an actuator 380. The transfer device 300 can be any suitable shape, size, or configuration. For example, while shown in FIG. 4 as being substantially cylindrical, the transfer device 300 can be square, rectangular, polygonal, and/or any other non-cylindrical shape. Moreover, any portion of the transfer device 300 can include any feature or finish configured to enhance the ergonomics of the transfer device 300. For example, the housing 301 can include a portion configured to form a grip configured to be engaged by a user's hand.

[1065] The housing 301 includes a proximal end portion 302 and a distal end portion 303 and defines an inner volume 311 therebetween (see e.g., FIG. 6). As shown in FIG. 5, the proximal end portion 302 of the housing 301 includes a protrusion 304 that selectively engages a portion of the fluid reservoir 330, as described in further detail herein. The distal end portion 303 of the housing 301 is coupled to a port 305. More specifically, the port 305 can be coupled to the distal end portion 303 in any suitable manner such as, for example, via a friction fit, a threaded coupling, a mechanical fastener, an adhesive, any number of mating recesses, and/or any combination thereof. In other embodiments, the port 305 can be monolithically formed with the housing 301. Moreover, the port 305 can be coupled to the distal end portion 303 of the housing 301 such that a seal member 316 is disposed between the port 305 and a distal wall 308 of the housing 301. In this manner, when the port 305 is coupled to the housing 301, the seal member 316 can engage the distal wall 308 of the housing 301 and the port 305 to selectively form a substantially fluid tight seal, as described in further detail herein.

[1066] As shown in FIG. 6, the port 305 is removably coupled to a lock mechanism 321 of the cannula assembly 320. The lock mechanism 321 of the cannula assembly 320 can be, at least temporarily, coupled to the port 305 to selectively place the housing 301 in fluid communication with the cannula assembly 320. For example, in some embodiments, the lock mechanism 321 can be a Luer-Lok® that receives a portion of the port 305 to physically and fluidically couple the cannula assembly 320 to the housing 301. In other embodiments, the lock mechanism 321 and the port 305 can be removably coupled in any suitable manner.

[1067] As shown in FIGS. 5 and 6, the fluid reservoir 330 defines an inner volume 333 between a proximal end portion 331 and a distal end portion 332. More specifically, the inner volume 333 is closed at the proximal end portion 331 of the fluid reservoir 330 such that at the proximal end, the inner volume 333 is fluidically isolated from a volume outside the fluid reservoir 330. Conversely, the distal end portion 332 of the fluid reservoir 330 is open such that at the distal end, the inner volume 333 can be in fluid communication with a volume outside the fluid reservoir 330. The distal end portion 332 of the fluid reservoir 330 is movably disposed about the proximal end portion 302 of the housing 301, as shown in FIG. 6. Similarly stated, the proximal end portion 302 of the housing 301 is movably disposed within the inner volume 333 defined by the fluid reservoir 330 such that the inner volume 311 defined by the housing 301 is in fluid communication with the inner volume 333 of the fluid

reservoir 330. Moreover, the distal end portion 332 of the fluid reservoir 330 includes a protrusion 335 that can be placed in contact with the protrusion 304 disposed at the proximal end portion 302 of the housing 301 to substantially limit the movement of the fluid reservoir 330 relative to the housing 301, as described in further detail herein.

[1068] The flow control mechanism 340 included in the transfer device 300 is at least partially disposed within the inner volume 311 of the housing 301 and is configured to be moved between a first configuration and a second configuration. Expanding further, the flow control mechanism 340 is in the first configuration when disposed in a distal position relative to the housing 301 (see e.g., FIG. 6) and is in the second configuration when disposed in a proximal position relative to the housing 301 (see e.g., FIG. 9). As shown in FIGS. 6 and 7, the flow control mechanism 340 includes a first member 341 and a second member 360. The first member 341 includes a proximal end portion 342 and a distal end portion 343 and defines a lumen 346 therethrough. The first member 341 can be any suitable shape, size, or configuration. For example, as shown in FIG. 5, the first member 341 can be substantially cylindrical and can have a diameter substantially corresponding to the diameter of the inner volume 311 of the housing 301.

[1069] The second member 360 of the flow control mechanism 340 includes a proximal end portion 361 and a distal end portion 362 and defines a lumen 363 therethrough. As shown in FIG. 6, at least a portion of the second member 360 is movably disposed within the cannula assembly 320. More specifically, the second member 360 can be substantially cylindrical and can have a diameter substantially corresponding to the inner diameter of the cannula 324 included in the cannula assembly 320. As shown in the enlarged view of FIG. 7, the proximal end portion 361 of the second member 360 is configured to extend through the port 305 and the seal member 316 (described above), and through an opening 309 defined in the distal wall 308 to allow the second member 360 to be coupled to the first member 341. Expanding further, the proximal end portion 361 of the second member 360 is disposed within the lumen 346 defined by the first member 341. In some embodiments, the proximal end portion 361 of the second member 360 can form a friction fit with the walls of the first member 341 that define the lumen 346, thereby coupling the second member 360 to the first member 341. In other embodiments, the second member 360 can be coupled to the first member 341 via an adhesive or the like.

[1070] The distal end portion 362 of the second member 360 is configured to extend beyond a distal end of the cannula 324 included in the cannula assembly 320, when the flow control mechanism 340 is in the first configuration. Furthermore, the distal end portion 362 of the second member 360 can include a sharp point that can facilitate the insertion of the transfer device 300 (e.g., the flow control mechanism 340 and the cannula assembly 320) into a portion of a patient. For example, the distal end portion 362 of the second member 360 can be used to access a vein of the patient and facilitate the introduction of the cannula 324 into the vein. Moreover, with the cannula 324 and the distal end portion 362 of the second member 360 disposed within the vein of the patient the transfer device 300 can be configured to transfer a portion of a bodily fluid from the patient to the fluid reservoir 330 to prevent injection of dislodged dermally residing microbes that have been incompletely sterilized by surface antisepsis and/or other undesirable external contaminants.

[1071] As shown in FIG. 8, the transfer device 300 can be moved to a second configuration to begin a flow of bodily fluid (e.g., blood) from the patient to the transfer device 300. More specifically, the fluid reservoir 330 can be moved in the proximal direction relative to the housing 301 to place the transfer device 300 in the second configuration, as indicated by the arrow FF. The arrangement of the fluid reservoir 330 and the housing 301 is such that the proximal motion of the fluid reservoir 330, relative to the housing 301, increases the inner volume 333 defined by the fluid reservoir 330. Expanding further, the proximal end portion 302 of the housing 301 can be disposed within the inner volume 333 of the fluid reservoir 330 such that the protrusion 304 engages an inner surface of the fluid reservoir 330 to define a substantially fluid tight seal. In addition, the protrusion 335 of the fluid reservoir 330 can be placed in contact with the protrusion 304 of the housing 301 to limit the proximal motion of the fluid reservoir 330 relative to the housing 301. In this manner, the proximal motion of the fluid reservoir 330 relative to the housing 301 increases the collective volume of both the inner volume 311 defined by the housing 301 and the inner volume 333 of the fluid reservoir 330.

[1072] The increase of volume introduces a negative pressure within the inner volume 333 of the fluid reservoir 330 and within the inner volume 311 of the housing 301. Therefore, with the cannula 324 and the second member 360 of the flow control mechanism 340 disposed within the vein of the patient, the negative pressure urges a flow of bodily fluid (e.g., blood) through the lumen 363 and 346 defined by the second member 360 and first

member 341 of the flow control mechanism 340, respectively. As indicated by the arrow GG in FIG. 8, the bodily fluid can flow through the lumen 363 and 346 of the flow control mechanism 340 and enter the collective volume formed and/or defined by the inner volume 311 of the housing 301 and the inner volume 333 of the fluid reservoir 330.

[1073] As shown in FIG. 9, when a predetermined amount of bodily fluid is disposed within the fluid reservoir 330, the flow control mechanism 340 can be moved to its second configuration (e.g., the proximal position relative to the housing 301) to place the transfer device 300 a third configuration. More specifically, the flow control mechanism 340 includes a spring 349 that is in contact with the distal wall 308 of the housing 301 and the distal end portion 343 of the first member 341 included in the flow control mechanism 340. As shown in FIGS. 6-8, the spring 349 is maintained in a compressed configuration while the transfer device 300 is in the first and second configuration. As shown in FIG. 9, when the spring 349 is allowed to expand, the spring 349 exerts a force to move the flow control mechanism 340 in the proximal direction, as indicated by the arrow HH. In some embodiments, the expansion of the spring 349 can be in response to the actuator 380. The actuator 380 can be any suitable mechanism configured to selectively interact with the spring 349 such as, for example, a push button. In other embodiments, the actuator 380 can be a slider, a pull-tab, a lever, a toggle, an electronic switch, or the like.

[1074] The proximal motion of the flow control mechanism 340 can be such that both the first member 341 and the second member 360 of the flow control mechanism 340 are disposed within the collective volume defined by the fluid reservoir 330 and the housing 301. Similarly stated, the spring 349 moves the flow control mechanism 340 in the proximal direction a sufficient distance to move the distal end portion 362 of the second member 360 through the port 305, the seal member 316, and the distal wall 308 to be disposed within the housing 301. Furthermore, the seal member 316 can be configured such that as the distal end portion 362 passes beyond the distal wall 308 of the housing 301, the seal member 316 acts to seal the opening 309 through which the second member 360 was disposed. Thus, when the flow control mechanism 340 is completely disposed within the collective volume defined by the housing 301 and the fluid reservoir 330 (e.g., the combination of the inner volume 311 and the inner volume 333, respectively), the seal member 316 seals the distal end portion 303 of the housing 301 and the fluid reservoir 330 is substantially fluidically isolated from the cannula assembly 320.

[1075] With the fluid reservoir 330 fluidically isolated from the cannula assembly 320, the transfer device 300 can be placed in a fourth configuration, as shown in FIG. 10. More specifically, the housing 301 and the fluid reservoir 330 can be collectively moved in the proximal direction such that the port 305 is physically decoupled from the lock mechanism 321 of the cannula assembly 320, as indicated by the arrow II. In this manner, the fluid reservoir 330 can contain and fluidically isolate a portion of the bodily fluid (e.g., blood) that includes, for example, dermally residing microbes dislodged during the venipuncture event (e.g., the insertion of the distal end portion 362 of the second member 360 of the flow control mechanism 340). Furthermore, with the port 305 decoupled from the lock mechanism 321 of the cannula assembly 320, the cannula assembly 320 can be physically and fluidically coupled to an external fluid reservoir (not shown in FIG. 10) that can deliver a flow of a parenteral fluid that is substantially free from the dermally residing microbes.

[1076] While the fluid reservoir 330 is shown in FIGS. 4-10 as being disposed about a portion of the housing 301, in some embodiments, a transfer device can include a fluid reservoir the is substantially enclosed within a housing. For example, FIGS. 11-15 illustrate a transfer device 400 according to an embodiment. The transfer device 400 includes a housing 401, a cannula assembly 420, a fluid reservoir 430, a flow control mechanism 440, and an actuator 480. As shown in FIGS. 11 and 12, the overall size and shape of the transfer device 400 can be substantially similar to the overall size and shape of the transfer device 300 described above in reference to FIG. 4. In addition, the cannula assembly 420, the flow control mechanism 440, and the actuator 480 can be substantially similar in form and function to the cannula assembly 320, the flow control mechanism 340, and the actuator 380 included in the transfer device 300, described above in reference to FIGS. 4-10. Therefore, the cannula assembly 420, the flow control mechanism 440, and the actuator 480 are not described in further detail herein.

[1077] The housing 401 of the transfer device 400 includes a proximal end portion 402 and a distal end portion 403 and defines an inner volume 411 therebetween. More specifically, the housing 401 is substantially closed at the proximal end portion 402 such that at the proximal end, the inner volume 411 is fluidically isolated from a volume outside the housing 401. The distal end portion 403 of the housing 401 is coupled to a port 405. The port 405 is substantially similar to the port 305 described above, and can be coupled to the distal end portion 403 of the housing 401 such that a seal member 416 is disposed between

the port 405 and a distal wall 408 of the housing 401. In this manner, the seal member 416 can form a substantially fluid tight seal between the distal wall 408 and the port 405 (described in detail with reference the port 305 shown in FIGS. 6 and 7). Furthermore, the port 405 can be configured to removably couple the housing 401 to the cannula assembly 420. For example, the port 405 can be, at least temporarily, physically and fluidically coupled to a lock mechanism 421 included in the cannula assembly 420. In this manner, the housing 401 and the cannula assembly 420 can be selectively placed in fluid communication.

[1078] The fluid reservoir 430 included in the transfer device 400 is movably disposed within the inner volume 411 defined housing 401. More specifically, the fluid reservoir 430 is configured to move within the housing 401 between a first configuration (FIG. 13) and a second configuration (FIG. 14). The fluid reservoir 430 defines an inner volume 433 between a proximal end portion 431 and a distal end portion 432. The inner volume 433 is configured to selectively receive at least a portion of the flow control mechanism 440. Furthermore, the flow control mechanism 440 can moved between a first position and a second position to move the fluid reservoir 430 between the first configuration and the second configuration, as described in further detail herein.

[1079] As shown in FIG. 13, the flow control mechanism 440 is in the first position when disposed in a distal position relative to the housing 401. While in the first position, a first member 441 of the flow control mechanism 440 is completely contained within the inner volume 433 and a second member 460 is configured to extend from the first member 441 through the distal end portion 432 of the fluid reservoir 430. The second member 460 of the flow control mechanism 460 further extends through the housing 401 and the port 405 to be at least partially disposed within the cannula assembly 420 (as described above in detail with reference to the second member 360 shown in FIGS. 6 and 7). In this manner, a distal end portion 462 of the second member 460 can extend beyond a cannula 424 of the cannula assembly 420 to facilitate the insertion of the cannula 424 into a portion of a patient. Moreover, with the distal end portion 462 of the second member 460 disposed within the portion of the patient, a lumen 463 defined by the second member 460 and a lumen 446 defined by the first member 441 can place the fluid reservoir 430 in fluid communication with the portion of the patient.

[1080] In use, the transfer device 400 can be moved from the first configuration (FIG. 13) to the second configuration (FIG. 14) to facilitate the flow of a bodily fluid (e.g., blood) into

the fluid reservoir 430. More specifically, the flow control mechanism 440 includes a mechanical actuator 449 (e.g., a spring) that is in contact with the distal wall 408 of the housing 401 and the first member 441 of the flow control mechanism 440. As shown in FIG. 13, the mechanical actuator 449 is maintained in a compressed configuration while the transfer device 400 is in the first configuration. Similarly stated, the flow control mechanism 440 is in the first position relative to the housing 401 when the mechanical actuator 449 is in the compressed configuration. As shown in FIG. 14, when the mechanical actuator 449 is allowed to expand, the mechanical actuator 449 exerts a force to move the flow control mechanism 440 in the proximal direction, as indicated by the arrow JJ. In some embodiments, the expansion of the mechanical actuator 449 can be in response to an actuation of the actuator 480.

[1081] The proximal motion of the flow control mechanism 440 moves within the inner volume 433 to place the first member 441 in contact with the proximal end portion 441 of the fluid reservoir 430. In this manner, the flow control mechanism 440 urges the proximal end portion 431 of the fluid reservoir 430 to move in the direction of the arrow JJ (e.g., the proximal direction). Moreover, the distal end portion 432 of the fluid reservoir 430 can be coupled to the distal wall 408 of the housing 401 such that as the proximal end portion 431 moves in the proximal direction, the fluid reservoir 430 expands. Similarly stated, the fluid reservoir 430 can form a bellows in which the proximal motion of the flow control mechanism 440 moves the fluid reservoir 430 from a compressed configuration (e.g., the first configuration) to an expanded configuration (e.g., the second configuration).

[1082] The movement of the proximal end portion 431 relative to the distal end portion 432 increases the inner volume 433 defined by the fluid reservoir 430 and introduces a negative pressure within the inner volume 433. Moreover, with the lumen 446 of the first member 441 and the lumen 463 of the second member 460 in fluid communication with the fluid reservoir 430, at least a portion of the negative pressure is transferred through the flow control mechanism 440. Therefore, while the flow control mechanism 440 is being moved to the second position (FIG. 14), the negative pressure urges a flow of bodily fluid (e.g., blood) through the lumen 463 and 446 defined by the second member 460 and first member 441 of the flow control mechanism 440, respectively. Expanding further, as shown in FIG. 14, the proximal motion of the flow control mechanism 440 is such that the second member 460 is retracted to a proximal position relative to the distal wall 408 of the housing 401. Prior to

being disposed in the proximal position relative to the distal wall 408, however, the lumen 463 is maintained in fluid communication with the portion of the patient via the cannula 424. In this manner, the flow control mechanism 440 transfers the bodily fluid to the fluid reservoir 430 while being moved in the proximal direction and prior to being disposed in the second position. Thus, when the second member 460 is retracted to the proximal position relative to the distal wall 408, the flow control mechanism 440 has transferred a predetermined amount of bodily fluid to the fluid reservoir 430 and the seal member 416 can act to fluidically isolate the fluid reservoir 430. Similarly stated, the flow control mechanism 440 is configured to transfer the predetermined amount of bodily fluid to the fluid reservoir 430 concurrently with the proximal motion of both the flow control mechanism 440 and the fluid reservoir 430.

[1083] With the fluid reservoir 430 fluidically isolated from the cannula assembly 420, the transfer device 400 can be placed in a third configuration, as shown in FIG. 15. More specifically, the housing 401 and the fluid reservoir 430 can be collectively moved in the proximal direction to physically decouple the port 405 from the lock mechanism 421 of the cannula assembly 420, as indicated by the arrow KK. In some embodiments, the actuator 480 can facilitate the decoupling of the port 405 from the lock mechanism 421. In other embodiments, a second actuator (not shown) can be engaged to decouple the port 405 from the lock mechanism 421. In other embodiments, an actuator need not be engaged to decouple the port 405 from the lock mechanism 421.

[1084] With the port 405 decoupled from the lock mechanism 421, the fluid reservoir 430 can contain and fluidically isolate a portion of the bodily fluid (e.g., blood) that includes, for example, dermally residing microbes dislodged during the venipuncture event (e.g., the insertion of the distal end portion 462 of the second member 460 of the flow control mechanism 440). Furthermore, with the port 405 decoupled from the lock mechanism 421, the cannula assembly 420 can be physically and fluidically coupled to an external fluid reservoir (not shown in FIG. 15) that can deliver a flow of a parenteral fluid that is substantially free from the dermally residing microbes, as described above.

[1085] While the fluid reservoir 430 is shown in FIGS. 11-15 as being disposed within the inner volume 411 of the housing 401, in some embodiments, a fluid reservoir can be physically and fluidically coupled to a portion of the transfer device. For example, FIGS. 16-23 illustrate a transfer device 500 according to an embodiment. The transfer device 500

includes a housing 501, a cannula assembly 520, a flow control mechanism 540, and an actuator mechanism 580. As shown in FIGS. 16 and 17, the overall size and shape of the transfer device 500 can be substantially similar to the overall size and shape of the transfer device 300 described above in reference to FIG. 4. In other embodiments, the overall size and shape of the transfer device 500 can be square, rectangular, polygonal, and/or any other non-cylindrical shape. In addition, the cannula assembly 520 can be substantially similar in form and function to the cannula assembly 320 included in the transfer device 300, described above in reference to FIGS. 4-10. Therefore, the cannula assembly 520 is not described in further detail herein.

[1086] As shown in FIG. 18, the housing 501 of the transfer device 500 includes a proximal end portion 502 and a distal end portion 503 and defines an inner volume 511 therebetween. The housing 501 is substantially closed at the proximal end portion 502 such that at the proximal end, the inner volume 511 is fluidically isolated from a volume outside the housing 501. The distal end portion 503 of the housing 501 includes a distal wall 508 that defines an opening 509 configured to receive, at least temporarily, a portion of the flow control mechanism 540, as described in further detail herein. The housing 501 further defines an actuator chamber 510 configured to receive at least a portion of the actuator mechanism 580. As shown in FIG. 18, the walls of the housing 501 can be arranged such that the actuator chamber 510 is a bore with a centerline that is substantially perpendicular to a centerline defined by the inner volume 511.

[1087] Referring back to FIG. 17, the actuator mechanism 580 includes a first actuator member 581 and a second actuator member 585. As described in further detail herein, the actuator mechanism 580 can be moved between a first configuration (see e.g., FIG. 16) and a second configuration (see e.g., FIG. 21). The first actuator member 581 can be rotatably coupled to the walls of the housing 501 defining the actuator chamber 510. Similarly stated, the first actuator member 581 is configured to be disposed substantially outside the housing 501 and can be rotatably coupled to the walls of the housing 501 that define the actuator chamber 510. The first actuator member 581 includes an engagement portion 582 and a port 583 configured to be physically and fluidically coupled to a fluid reservoir, as described in further detail herein.

[1088] As shown in FIG. 19, the second actuator member 585 can be substantially cylindrical and is configured to be disposed within the actuator chamber 510 defined by the

housing 501. The second actuator member 585 defines a lumen 587 and a flow control channel 588. The lumen 587 is configured to be in fluid communication with the port 583 of the first actuator member 581. In this manner, the lumen 587 and the port 583 can receive a flow of a bodily fluid when the actuator mechanism 580 is in the first configuration, as described in further detail herein. The flow control channel 588 is configured to receive at least a portion of the flow control mechanism 540 when the actuator mechanism 580 is placed in the second configuration, as described in further detail herein.

[1089] The flow control mechanism 540 included in the transfer device 500 is at least partially disposed within the inner volume 511 of the housing 501 and is configured to be moved between a first position and a second position. Expanding further, the flow control mechanism 540 is in the first position when disposed in a distal position relative to the housing 501 (see e.g., FIG. 20) and is in the second position when disposed in a proximal position relative to the housing 501 (see e.g., FIG. 22). As shown in FIGS. 17 and 20, the flow control mechanism 540 includes a first member 541 and a second member 560. The first member 541 includes a proximal end portion 542 and a distal end portion 543 and defines a lumen 546 therethrough. The first member 541 can be any suitable shape, size, or configuration. For example, as shown in FIG. 17, the first member 541 can be substantially cylindrical with the proximal end portion 542 having a first diameter that substantially corresponds to the diameter of the flow control channel 588 defined by the second actuator member 585. As shown in FIG. 20, the first member 541 can be configured such that when the flow control mechanism 540 is in the first position, the lumen 546 defined by the first member 541 is in fluid communication with the lumen 587 defined by the second actuator member 585, as described in further detail herein.

[1090] The distal end portion 543 of the first member 541 can have a second diameter, smaller than the first diameter, substantially corresponding to an inner diameter of a lock mechanism 521 included in the cannula assembly 520. For example, in some embodiments, the distal end portion 543 can extend through the opening 509 defined by the distal wall 508 of the housing 501 to be disposed within the lock mechanism 521. In some embodiments, the distal end portion 543 can form a friction fit with an inner surface of the lock mechanism 521 to removably couple the flow control mechanism 540 to the cannula assembly 520. Furthermore, with the proximal end portion 542 of the first member 541 disposed in a proximal position relative to the distal wall 508 and with the diameter of the proximal end

portion 542 substantially larger than the diameter of the opening 509, the flow control mechanism 540 operatively couples the housing 501 to the cannula assembly 520.

[1091] The second member 560 of the flow control mechanism 540 includes a proximal end portion 561 and a distal end portion 562 and defines a lumen 563 therethrough. As shown in FIG. 20, at least a portion of the second member 560 is movably disposed within a cannula 524 of the cannula assembly 520. As described above with respect to the flow control mechanism 340, the proximal end portion 561 of the second member 560 is configured to extend through the lock mechanism 521 to be coupled to the first member 541. Expanding further, the proximal end portion 561 of the second member 560 is disposed within the lumen 546 defined by the first member 541. The distal end portion 562 of the second member 560 is configured to extend beyond a distal end of the cannula 524 included in the cannula assembly 520, when the flow control mechanism 540 is in the first configuration. In this manner, the second member 560 can facilitate the insertion of the transfer device 500 into a portion of a patient (e.g., the distal end can include a sharp point) and can further facilitate a transfer of a bodily fluid from the patient to a fluid reservoir (e.g., via the lumen 563).

[1092] For example, as shown in FIG. 20, the transfer device 500 can be in a first configuration when the flow control mechanism 540 is in the first position and the actuator mechanism 580 is in its first configuration. In this manner, the second member 560 of the flow control mechanism 540 and the cannula 524 of the cannula assembly 520 can be inserted into a portion of the patient, such as a vein, to place the transfer device 500 in fluid communication with the portion of the patient. Furthermore, a fluid reservoir (not shown in FIGS. 16-23) can be physically and fluidically coupled to the port 583 of the second actuator member 581. The arrangement of the flow control mechanism 540 and the actuator mechanism 580 is such that when the fluid reservoir is physically and fluidically coupled to the port 583, the fluid reservoir is in fluid communication with the lumen 587 defined by the second actuator member 585 and the two lumen 546 and 563 defined by the first member 541 and the second member 560 of the flow control mechanism 540, respectively. In some embodiments, the fluid reservoir can be, for example, a Vacutainer®. In such embodiments, the fluid reservoir can define a negative pressure such that when fluidically coupled to the port 583, the fluid reservoir introduces a suction force within the portion of the patient (e.g., via the lumen 587, 546, and 563). In this manner, a portion of the suction force can urge a

flow of bodily fluid through the lumen 563, 546, and 587 and into the fluid reservoir, as indicated by the arrow LL in FIG. 20. Moreover, the flow of bodily fluid can be such that dermally residing microbes dislodged during a venipuncture event (e.g., the insertion of the flow control mechanism 540 and the cannula 524) become entrained therein and are transferred to the fluid reservoir.

[1093] With a predetermined amount of bodily fluid transferred to the fluid reservoir, the fluid reservoir can be decoupled from the port 583 (e.g., physically and fluidically or only fluidically). In this manner, a user can engage the first actuator member 581 to move the actuator mechanism 580 to its second configuration and thereby place the transfer device in a second configuration. For example, as indicated by the arrow MM in FIG. 21, the user (e.g., a physician, a nurse, a phlebotomist, etc.) can rotate the first actuator member 581 in a clockwise direction relative to the housing 501.

[1094] The actuator mechanism 580 is such that the rotation of the first actuator member 581 urges the second actuator member 585 to also rotate relative to the housing 501. In this manner, a centerline defined by the flow control channel 587 is rotated from a first configuration in which the centerline is substantially perpendicular to the centerline defined by the inner volume 511 to a second configuration in which the centerline is substantially parallel to the centerline of the inner volume 511. Similarly stated, the second actuator member 585 is rotated such that the centerline defined by the flow control channel 587 is aligned with the centerline defined by the inner volume 511.

[1095] As shown in FIG. 22, the rotation of the actuator mechanism 580 toward the second configuration can facilitate the movement of the flow control mechanism 540 from the first position toward the second position. More specifically, the flow control mechanism 540 includes a spring 549 that is disposed about the distal end portion 543 of the first member 541 and is in contact with the distal wall 508 of the housing 501 and a surface of the first member 541. The spring 549 is maintained in a compressed configuration while the transfer device 500 is in the first configuration. For example, as shown in FIG. 20, a proximal surface of the first member 541 of the flow control mechanism 540 can be in contact with a surface of the second actuator mechanism 585 such that the second actuator mechanism 585 prevents proximal movement of the flow control mechanism 540. When the actuator mechanism 580 is moved to the second configuration and the flow control channel 587 is aligned with the inner volume 511 (as described above), however, the proximal surface of the first member

541 is no longer in contact with the surface of the second actuator member 585 and the spring 549 is allowed to expand.

[1096] The expansion of the spring 549 exerts a force on the first member 541 of the flow control mechanism 540 to move the flow control mechanism 540 in the proximal direction, as indicated by the arrow NN in FIG. 22. In this manner, the flow control mechanism 540 can pass through the flow control channel 587 defined by the second actuator member 585 to be disposed in the second position (e.g., the distal position). The proximal motion of the flow control mechanism 540 is such that both the first member 541 and the second member 560 of the flow control mechanism 540 are disposed within the inner volume 511 defined by the housing 501. Similarly stated, the spring 549 moves the flow control mechanism 540 in the proximal direction a sufficient distance to move the distal end portion 562 of the second member 560 through the opening 509 defined by the distal wall 508 to be disposed within the housing 501.

[1097] As shown in FIG. 23, with the flow control mechanism 540 disposed within the housing 501, the distal end portion 543 of the first member 541 is no longer disposed within the lock mechanism 521 of the cannula assembly 520. In this manner, the housing 501 is physically and fluidically decoupled from the cannula assembly 520 and can be moved away from the cannula assembly 520, as indicated by the arrow OO in FIG. 23. Furthermore, with the housing 501 decoupled from the lock mechanism 521, the cannula assembly 520 can be physically and fluidically coupled to an external fluid reservoir (not shown in FIG. 23) that can deliver a flow of a parenteral fluid to the portion of the patient that is substantially free from the dermally residing microbes.

[1098] While the transfer devices described above are configured to include a cannula assembly that is physically and fluidically decoupled from a portion of the transfer device to receive a parenteral fluid, in some embodiments, a transfer device can include a cannula assembly configured to remain physically coupled to a portion of the transfer device. For example, FIGS. 24-30 illustrate a transfer device 600 according to an embodiment. The transfer device 600 includes a housing 601, a cannula assembly 620, a fluid reservoir 630, and a flow control mechanism 640. In use, the transfer device 600 can be moved between a first, a second, and a third configuration to receive a predetermined amount of a bodily fluid from a patient and to deliver a flow of a parenteral fluid to the patient that is substantially free from, for example, dermally residing microbes.

[1099] As shown in FIGS. 24 and 25, the housing 601 includes a proximal end portion 602 and a distal end portion 603 and defines an inner volume 611 therebetween. The proximal end portion 602 is substantially open such that the inner volume 611 can selectively receive the fluid reservoir 630 and at least a portion of the flow control mechanism 640. In addition, the proximal end portion 602 includes a protrusion 604 configured to engage a portion of the flow control mechanism 640, as described in further detail herein.

[1100] The distal end portion 603 of the housing 601 includes a distal port 605 and a reservoir seat 618. The reservoir seat 618 is configured to engage, at least temporarily, a portion of the fluid reservoir 630, as described in further detail herein. The distal port 605 is configured to be physically and fluidically coupled to a lock mechanism 621 included in the cannula assembly 620. For example, in some embodiments, the lock mechanism 621 can be a Luer-Lok® configured to receive the port 605. In other embodiments, the port 605 and the lock mechanism 621 can be coupled in any suitable manner such as, for example, a threaded coupling, a friction fit, or the like. In still other embodiments, the port 605 and the lock mechanism 621 can be coupled via an adhesive or the like to fixedly couple the cannula assembly 620 to the housing 601. With the lock mechanism 621 coupled to the port 605, the inner volume 611 of the housing 601 is in fluid communication with a cannula 624 included in the cannula assembly 620, as further described herein.

[1101] As described above, the fluid reservoir 630 is disposed within the inner volume 611 of the housing 601. More particularly, the fluid reservoir 630 is movably disposed within the inner volume 611 between a first position in which the fluid reservoir 630 is in a distal position relative to the housing 601 (see e.g., FIG. 28) and a second position in which the fluid reservoir 630 is in a proximal position relative to the housing 601 (see e.g., FIG. 30). As shown in FIG. 26, the fluid reservoir 630 includes a proximal end portion 631 and a distal end portion 632 and defines an inner volume 633 therebetween. The proximal end portion 631 includes a flange 634 and a protrusion 635 and defines a set of openings 636. Furthermore, the proximal end portion 631 of the fluid reservoir 630 is substantially open to receive a portion of the flow control mechanism 640. In this manner, the proximal end portion 631 is configured to engage, interact, or otherwise correspond with a portion of the flow control mechanism 640, as further described herein.

[1102] The distal end portion 632 of the fluid reservoir 630 includes a valve seat 637. The valve seat 637 includes a port 638 and receives a valve 639 (see e.g., FIG. 28-30). The

valve seat 637 is selectively disposed about the reservoir seat 618 of the housing 601, as described in further detail herein. The valve 639 can be any suitable valve such as, for example, a check valve or the like. In this manner, the distal end portion 632 can be selectively placed in fluid communication with the inner volume 611 when the fluid reservoir 630 is disposed within the housing 601, as described in further detail herein.

[1103] As described above, the flow control mechanism 640 can be at least partially disposed within the housing 601. More particularly and as shown in FIG. 27, the flow control mechanism 640 includes an engagement portion 645 configured to be disposed outside the housing 601 and a plunger portion 650 configured to be at least partially disposed within the inner volume 611 defined by the housing 601. As described in further detail herein, the engagement portion 645 can be engaged by a user to move the flow control mechanism 640 between a first configuration and a second configuration.

[1104] The plunger portion 650 of the flow control mechanism 640 is configured to extend in a distal direction from a surface of the engagement portion 645. The plunger 650 includes a first surface 652, a second surface 655, a protrusion 653, a first seal member 658, and a second seal member 659. As shown in FIG. 27, the plunger portion 650 is substantially cylindrical and defines a channel 651 that receives, for example, a cannula 664 that defines a lumen 646. More particularly, the cannula 664 is configured to be disposed within an opening 654 defined by the first surface 652 to place the lumen 646 in fluid communication with an inner volume 656 defined between the first surface 652 and the second surface 655. The plunger 650 is further configured to define a set of openings 657 that can selectively place the inner volume 656 in fluid communication with a portion of the housing 601, as described in further detail herein.

[1105] In use, the transfer device 600 can be moved between a first configuration (FIG. 28), a second configuration (FIG. 29), and a third configuration (FIG. 30). Referring to FIG. 28, while in the first configuration, the cannula 624 of the cannula assembly 620 can be inserted into a portion of a patient to place the cannula 624 in fluid communication with, for example, a vein. In some embodiments, the cannula 624 can include a sharp point at a distal end such that the cannula 624 can pierce the portion of the patient. In other embodiments, the cannula assembly 620 can include a trocar (not shown) to facilitate the insertion of the cannula 624. As described above, the cannula assembly 620 is physically and fluidically coupled to the port 605 of the housing 601 such that when the cannula 624 is placed in fluid

communication with the vein of the patient, the port 605 is concurrently placed in fluid communication with the vein. With the port 605 in fluid communication with the portion of the patient (e.g., the vein), a user (e.g., a physician, nurse, technician, or the like) can engage the engagement portion 645 of the flow control mechanism 640 to place the transfer device 600 in the second configuration.

[1106] As shown in FIG. 29, the transfer device 600 is placed in the second configuration when the plunger portion 650 of the flow control mechanism 640 is moved within the fluid reservoir 630 from a first position (e.g., a distal position) to a proximal position (e.g., a proximal position), as indicated by the arrow PP. More specifically, the transfer device 600 includes a spring 649 configured to engage the protrusion 604 of the housing 601 and the flange 634 of the fluid reservoir 630 to maintain the fluid reservoir 630 in the first position while the flow control mechanism 640 is moved to its second position. Similarly, stated the flow control mechanism 640 is moved in a proximal direction relative to the fluid reservoir 630.

[1107] In addition, the first seal member 658 can engage an inner surface of the fluid reservoir 630 such that the proximal movement of the flow control mechanism 640 produces a negative pressure within a portion of the inner volume 633 of the fluid reservoir 630 (e.g., the portion of the inner volume 633 that is disposed distally relative to the first seal member 658). In this manner, the negative pressure introduces a suction force that can be operable placing the valve 639 in an open configuration. Thus, with the cannula 624 and the port 605 in fluid communication with the portion of the patient (e.g., the vein), a flow of bodily fluid (e.g., blood) can pass through the valve 639 and enter the inner volume 633 of the fluid reservoir 630, as indicated by the arrow QQ.

[1108] As shown in FIG. 29, the proximal movement of the flow control mechanism 640 relative to the fluid reservoir 630 is configured to stop when the flow control mechanism 640 is in the second position (e.g., the proximal position). More specifically, the protrusion 635 of the fluid reservoir 630 can engage the protrusion 653 of the plunger portion 650 to limit the proximal movement of the flow control mechanism 640 relative to the fluid reservoir 630. Furthermore, when the flow control mechanism 640 is in the second position relative to the fluid reservoir 630, the openings 657 of the plunger portion 650 are in fluid communication with the openings 636 defined by the fluid reservoir 630. Thus, the inner volume 656 defined by the plunger portion 650 of the flow control mechanism 640 is placed in fluid

communication with the inner volume 611 of the housing 601, as described in further detail herein.

[1109] With the transfer device 600 in the second configuration, a flow of a predetermined amount of bodily fluid can be transferred to the inner volume 633 of the fluid reservoir 630 that can include, for example, dermally residing microbes dislodged during a venipuncture event (e.g., the insertion of the cannula 624 into the vein and/or otherwise accessing the vasculature of the patient). In addition, when the predetermined amount of bodily fluid is transferred to the inner volume 633 of the fluid reservoir 630, the valve 639 can be placed in a closed configuration. For example, in some embodiments, the transfer of the predetermined amount of bodily fluid can be such that the negative pressure within the inner volume 633 is brought into equilibrium with the pressure of the vein, thus allowing the valve 639 to move to the closed configuration. In other embodiments, the valve 639 can be manually actuated by user interference (e.g., engagement of an actuator, a switch, a button, a toggle, or the like). In this manner, the bodily fluid disposed in the inner volume 633 between the first seal member 658 and the distal end portion 632 of the fluid reservoir 630 can be fluidically isolated from a volume outside the inner volume 633. Expanding further, the first seal member 658 prevents a flow of the bodily fluid in the proximal direction and the valve 639, being in the closed configuration, prevents a flow of the bodily fluid in the distal direction. Thus, the predetermined amount of bodily fluid is fluidically isolated from a volume outside the inner volume 633 of the fluid reservoir 630 defined between the first seal member 658 and the distal end portion 632.

[1110] As indicated by the arrow RR in FIG. 30, the user can continue to move the flow control mechanism 640 in the proximal direction to place the transfer device 600 in the third configuration. More specifically, with the protrusion 653 of the flow control mechanism 640 in contact with the protrusion 635 of the fluid reservoir 630, the proximal movement of the flow control mechanism 640 is such that the flow control mechanism 640 and the fluid reservoir 630 move, concurrently, in the proximal direction relative to the housing 601. Furthermore, the proximal movement is such that the valve seat 637 is moved in the proximal direction relative to the reservoir seat 618. Similarly stated, the proximal movement of the fluid reservoir 630 is such that the valve seat 637 is no longer disposed about the reservoir seat 618 of the housing 601. In this manner, the port 605 is placed in fluid communication with the inner volume 611 of the housing 601.

[1111] With the transfer device 600 in the third configuration, an external fluid source (not shown in FIG. 30) can be placed in fluid communication with a portion of the transfer device 600 to transfer a flow of parenteral fluid to the portion of the patient. For example, in some embodiments, the transfer device 600 can include a proximal lock mechanism 613 that can physically and fluidically couple the transfer device 600 to the external fluid source. The proximal lock mechanism 613 can be any of those described herein. In this manner, the external fluid source can deliver a flow of parenteral fluid to the lumen 646, as indicated by the arrow SS. Moreover, with the lumen 646 in fluid communication with the inner volume 656 defined between the first surface 652 and the second surface 655, the flow of the parenteral fluid can pass through the openings 657 defined by the plunger portion 650 of the flow control mechanism 640. In addition, the first seal member 658 and the second seal member 659 can act to define a fluid flow path that directs the flow of the parenteral fluid to the openings 636 defined by the fluid reservoir 630. In this manner, the flow of parenteral fluid can pass through the openings 636 of the fluid reservoir 630 to enter the inner volume 611 defined by the housing 601. Similarly stated, upon exiting the openings 636, the parenteral fluid can flow within the inner volume 611 defined by the housing 601 and outside of the fluid reservoir 630, as indicated by the arrows SS. Expanding further, the parenteral fluid can flow within the housing 601 in the distal direction and enter the port 605 to transfer the flow parenteral fluid to the cannula assembly 620. Therefore, the external fluid source can deliver a flow of parenteral fluid to the patient that is fluidically isolated from the predetermined amount of bodily fluid disposed in the fluid reservoir 630 and is thus, substantially free from dermally residing microbes and/or other undesirable external contaminants.

[1112] In some embodiments, user intervention maintains the transfer device 600 in the third configuration. Expanding further and as described above, the proximal movement of the fluid reservoir 630 is such that a portion of the force applied by the user (e.g., the physician, nurse, technician, or the like) to move the flow control mechanism 640 and fluid reservoir 630 is used to move the spring 649 to a compressed configuration. In such embodiments, the removal of the portion of the force would allow the spring 649 to expand and thereby move the fluid reservoir 630 in the distal direction. In other embodiments, a transfer device can include a catch, protrusion, latch or the like configured to maintain the spring in the compressed configuration.

[1113] While the transfer device 600 is shown in FIGS. 24-30 as including a fluid reservoir 630, in other embodiments, a transfer device can include a flow control mechanism with an integrated fluid reservoir. For example, FIGS. 31-34 illustrate a transfer device 700 according to an embodiment. The transfer device 700 includes a housing 701, a cannula assembly 720, and a flow control mechanism 740. In use, the transfer device 700 can be moved between a first configuration and a second configuration to receive a predetermined amount of a bodily fluid from a patient and to deliver a flow of a parenteral fluid to the patient that is substantially free from, for example, dermally residing microbes and/or other undesirable external contaminants.

[1114] As shown in FIGS. 31 and 32, the housing 701 includes a proximal end portion 702 having a proximal port 706 and a distal end portion 703 having a distal port 705. The proximal port 706 is configured to be physically and fluidically coupled to an external fluid source, as described in further detail herein. The distal port 705 is configured to be physically and fluidically coupled to a lock mechanism 721 included in the cannula assembly 720. For example, in some embodiments, the lock mechanism 721 can be a Luer-Lok® configured to receive the distal port 705. In other embodiments, the distal port 705 and the lock mechanism 721 can be coupled in any suitable manner such as, for example, a threaded coupling, a friction fit, or the like. In still other embodiments, the distal port 705 and the lock mechanism 721 can be coupled via an adhesive or the like to fixedly couple the cannula assembly 720 to the housing 701. With the lock mechanism 721 coupled to the distal port 705, the distal port 705 is placed in fluid communication with a cannula 724 included in the cannula assembly 720, as further described herein.

[1115] The housing 701 defines an inner volume 711 and a set of recess 710. The inner volume 711 is configured to receive at least a portion of the flow control mechanism 740. As shown in FIG. 31, the set of recesses 710 are defined by the housing 701 in a perpendicular orientation relative to the proximal port 706 and distal port 705. Similarly stated, the recesses 710 are perpendicular to a centerline defined by the proximal port 706 and the distal port 705. In this manner, a portion of the flow control mechanism 740 can extend through the recesses 710 when the flow control mechanism 740 is disposed within the inner volume 711 of the housing 701, as described in further detail herein.

[1116] The flow control mechanism 740 defines a first lumen 746, a second lumen 747, and a fluid reservoir 730. The first lumen 746 extends though a portion of the flow control

mechanism 740 and is in fluid communication with the fluid reservoir 730. Similarly stated, the first lumen 746 extends through a portion of the flow control mechanism 740 to selectively place the fluid reservoir 730 in fluid communication with a volume substantially outside of the flow control mechanism 740, as described in further detail herein. As shown in FIG. 33, the second lumen 747 extends through the flow control mechanism 740 and is fluidically isolated from the fluid reservoir 730. In this manner, the second lumen 747 can be selectively placed in fluid communication with the proximal port 706 and the distal port 705 of the housing 701 to deliver a flow of parenteral fluid, as described in further detail herein.

[1117] The flow control mechanism 740 has a circular cross-sectional shape such that when the flow control mechanism 740 is disposed within the inner volume 711, a portion of the flow control mechanism 740 forms a friction fit with the walls of the housing 701 defining the inner volume 711. For example, in some embodiments, the flow control mechanism 740 is formed from silicone and has a diameter larger than the diameter of the inner volume 711. In this manner, the diameter of the flow control mechanism 740 is reduced when the flow control mechanism 740 is disposed within the inner volume 711. Thus, the outer surface of the flow control mechanism 740 forms a friction fit with the inner surface of the walls defining the inner volume 711. In other embodiments, the flow control mechanism 740 can be any suitable elastomer configured to deform when disposed within the inner volume 711 of the housing 701.

[1118] In use, while in the first configuration, the cannula 724 of the cannula assembly 720 can be inserted into a portion of a patient to place the cannula 724 in fluid communication with, for example, a vein. In some embodiments, the cannula 724 can include a sharp point at a distal end such that the cannula 724 can pierce the portion of the patient. In other embodiments, the cannula assembly 720 can include a trocar (not shown) to facilitate the insertion of the cannula 724. As described above, the cannula assembly 720 is physically and fluidically coupled to the distal port 705 of the housing 701 such that when the cannula 724 is placed in fluid communication with the vein of the patient, the distal port 705 is placed in fluid communication with the vein.

[1119] As shown in FIG. 33, when the transfer device 700 is in the first configuration, the first lumen 746 of the flow control mechanism 740 is in fluid communication with the distal port 705 of the housing 701. In this manner, the fluid reservoir 730 defined by the flow control mechanism 740 is placed in fluid communication with the vein of the patient and can

rcccivc a flow of a bodily fluid (c.g., blood). Morcovcr, with thc flow control mcchanism 740 forming a friction fit with the inner surface of the housing 701 (as described above), the flow control mechanism 740 and the housing 701 can form a substantially fluid tight seal about an inlet of the first lumen 746. In this manner, the cannula assembly 720, the distal port 705, and the first lumen 746 collectively define a flow path configured to deliver a flow of bodily fluid from the portion of the patient to the fluid reservoir 730, as indicated by the arrow TT. In addition, the flow of bodily fluid can be such that dermally residing microbes dislodged during a venipuncture event (e.g., the insertion of the cannula 724) are entrained in the flow of bodily fluid and are transferred to the fluid reservoir 740.

[1120] With a desired amount of bodily fluid transferred to the fluid reservoir 730, a user can engage the transfer device 700 to move the transfer device 700 from the first configuration to the second configuration. In some embodiments, the desired amount of bodily fluid transferred to the fluid reservoir 730 is a predetermined amount of fluid. For example, in some embodiments, the transfer device 700 can be configured to transfer bodily fluid until the pressure within the fluid reservoir 730 is equilibrium with the pressure of the portion of the body in which the cannula 724 is disposed (e.g., the vein). In some cmbodimcnts, at lcast a portion of thc flow control mcchanism 740 can bc transparcnt to allow visualization of the bodily fluid flowing into the fluid reservoir 730. The flow control mechanism 740 can include indicators (e.g., 0.1 mL, 0.5 mL, 1 mL, 1.5 mL, 2 mL, 3 mL, 4 mL, 5 mL, etc. graduation marks) to the user can visualize the volume of bodily fluid that has been received in the fluid reservoir 730.

[1121] As shown in FIG. 34, the transfer device 700 can be moved from the first configuration to the second configuration by moving the flow control mechanism 740 in the direction of the arrow UU. In this manner, the first lumen 746 is fluidically isolated from the distal port 705. While not shown in FIGS. 31-34, the first lumen 746 can include a valve or seal configured to fluidically isolate the bodily fluid disposed within the fluid reservoir 730 from a volume outside the flow control mechanism 740. In some embodiments, the valve can be, for example, a one-way check valve. Thus, the fluid reservoir 730 can receive the flow of fluid from a volume outside the fluid reservoir 730 but prevent a flow of fluid from the fluid reservoir 730.

[1122] When moved to the second configuration, the second lumen 747 defined by the flow control mechanism 740 is placed in fluid communication with the distal port 705 and the

proximal port 706 of the housing 701. As described above, the proximal port 706 can be physically and fluidically coupled to an external fluid source (not shown in FIGS. 31-34) such that when the transfer device 700 is in the second configuration, the proximal port 706, the second lumen 747, the distal port 705, and the cannula assembly 720 collectively define a fluid flow path. In this manner, the transfer device 700 can facilitate the delivery of a flow of parenteral fluid from the external fluid source to the portion of the patient (e.g., the vein), as indicated by the arrow VV in FIG. 34. Expanding further, with the predetermined amount of bodily fluid fluidically isolated within the fluid reservoir 730, the transfer device 700 can facilitate the delivery of the flow of parenteral fluid to the patient that is substantially free from, for example, the dermally residing microbes dislodged during the venipuncture event.

[1123] While the flow control mechanism 740 is shown in FIGS. 31-34 as including the integrated fluid reservoir 730, in other embodiments, a transfer device can be configured to be physically and fluidically coupled to an external fluid reservoir. For example, FIGS. 35-39 illustrate a transfer device 800 according to an embodiment. As shown in FIGS. 35 and 36, the transfer device 800 includes a housing 801, a cannula assembly 820, and a flow control mechanism 880. In use, the transfer device 800 can be moved between a first configuration and a second configuration to receive a predetermined amount of a bodily fluid from a patient and to deliver a flow of a parenteral fluid to the patient that is substantially free from, for example, dermally residing microbes.

[1124] The housing 801 includes a proximal end portion 802, a distal end portion 803, and defines an inner volume 811. The inner volume 811 can receive at least a portion of the flow control mechanism 880 and the actuator 880, as further described herein. As shown in FIG. 37, the distal end portion 803 of the housing 801 defines a distal port 805 and the proximal end portion 802 of the housing 801 defines a first proximal port 806, and a second proximal port 807. The distal port 805, the first proximal port 806, and the second proximal port 807 are configured to be in fluid communication with the inner volume 811 defined by the housing 801.

[1125] The distal port 805 is configured to receive a distal cannula 817. The distal cannula 817 (e.g., a lumen defining cannula) is configured to be physically and fluidically coupled to a port 822 included in the cannula assembly 820. The port 822 can be any suitable port. For example, in some embodiments, the distal cannula 817 and the port 822 can be coupled via an adhesive or the like to fixedly couple the cannula assembly 820 to the housing

801. With the port 822 of the cannula assembly 820 coupled to the distal cannula 817 and with the distal cannula 817 coupled to the distal port 805, the distal port 805 is in fluid communication with a cannula 824 included in the cannula assembly 820, as further described herein.

[1126] The first proximal port 806 and the second proximal port 807 are configured to receive a first proximal cannula 812 and a second proximal cannula 814, respectively (e.g., lumen defining cannulas). Furthermore, the first proximal cannula 812 is physically and fluidically coupled to a first lock mechanism 813 that can further be physically and fluidically coupled to an external fluid reservoir (not shown in FIGS. 35-39). Similarly, the second proximal cannula 814 is physically and fluidically coupled to a second lock mechanism 815 that can further be physically and fluidically coupled to an external fluid source (not shown in FIGS. 35-39). In this manner, the cannula assembly 820, the external fluid reservoir (not shown), and the external fluid source (not shown) can be selectively placed in fluid communication with the inner volume 811 defined by the housing 801, as described in further detail herein.

[1127] Referring back to FIG. 36, the actuator mechanism 880 includes an engagement portion 882 and an activation surface 884. The activation surface 844 is configured to contact, mate, or otherwise engage the flow control mechanism 840. The engagement portion 882 can be engaged by a user to rotate the actuator mechanism 880 relative to the housing 801 to move the transfer device 800 between a first configuration and a second configuration, as described in further detail herein.

[1128] The flow control mechanism 840 defines a first lumen 846 and a second lumen 847 and is disposed within the inner volume 821 defined by the housing 801. The flow control mechanism 840 defines a circular cross-sectional shape such that when the flow control mechanism 840 is disposed within the inner volume 821, a portion of the flow control mechanism 840 forms a friction fit with the walls of the housing 801 defining the inner volume 821, as described in detail above. The flow control mechanism 840 is operably coupled to and/or otherwise engages the actuator 880. For example, in some embodiments, the actuator mechanism 880 can be coupled to the flow control mechanism 840 via a mechanical fastener and/or adhesive. In other embodiments, the actuator mechanism 880 and the flow control mechanism 840 can be coupled in any suitable manner. Therefore, the flow control mechanism 840 is configured to move concurrently with the actuator mechanism 880

when the actuator mechanism 880 is rotated relative to the housing 801. In this manner, the flow control mechanism 840 can be moved to place the first lumen 846 or the second lumen 847 in fluid communication with the distal port 805, the first proximal port 806, and/or the second proximal port 807, as described in further detail herein.

[1129] In use, while in the first configuration, the cannula 824 of the cannula assembly 820 can be inserted into a portion of a patient to place the cannula 824 in fluid communication with, for example, a vein. In some embodiments, the cannula 824 can include a sharp point at a distal end such that the cannula 824 can pierce the portion of the patient. In other embodiments, the cannula assembly 820 can include a trocar (not shown) to facilitate the insertion of the cannula 824. As described above, the cannula assembly 820 is physically and fluidically coupled to the distal port 805 of the housing 801 such that when the cannula 824 is placed in fluid communication with the vein of the patient, the distal port 805 is placed in fluid communication with the vein.

[1130] Furthermore, a user (e.g., a physician, a nurse, a technician, or the like) can engage the transfer device 800 to physically and fluidically couple the first lock mechanism 813 to an external fluid reservoir (not shown). The external fluid reservoir can be any suitable reservoir. For example, in some embodiments, the external fluid reservoir can be a BacT/ALERT® SN or a BacT/ALERT® FA, manufactured by BIOMERIEUX, INC. In this manner, the external fluid reservoir can define a negative pressure within an inner volume of the reservoir. Therefore, when the flow control mechanism 840 is in the first configuration, a negative pressure differential introduces a suction force within the first proximal cannula 812, the first lumen 846 defined by the flow control mechanism 840, the distal cannula 817, and the cannula assembly 820. In this manner, the first proximal cannula 812, the first lumen 846 defined by the flow control mechanism 840, the distal cannula 817, and the cannula assembly 820 collectively define a fluid flow path configured to transfer a flow of a bodily fluid to the external fluid reservoir, as indicated by the arrow WW in FIG. 37. In addition, the flow of bodily fluid can be such that dermally residing microbes dislodged during a venipuncture event (e.g., the insertion of the cannula 824) are entrained in the flow of bodily fluid and are transferred to the external fluid reservoir.

[1131] As shown in FIG. 38, in some embodiments, the magnitude of the suction force can be modulated by moving the actuator mechanism 880 in the direction of the arrow XX. For example, in some instances, it can be desirable to limit the amount of suction force

introduced to a vein. In such instances, the user can move the actuator mechanism 880 and the flow control mechanism 840 to reduce the size of the fluid pathway (e.g., an inner diameter) between the distal port 805 of the housing 801 and the first lumen 846 of the flow control mechanism 840, thereby reducing the suction force introduced into the vein of the patient.

[1132] With the desired amount of bodily fluid transferred to the external fluid reservoir, a user can engage the actuator mechanism 880 to move the transfer device 800 from the first configuration to the second configuration. In some embodiments, the desired amount of bodily fluid transferred to the external fluid reservoir is a predetermined amount of fluid. For example, in some embodiments, the transfer device 800 can be configured to transfer bodily fluid until the pressure within the external fluid reservoir is equilibrium with the pressure of the portion of the body in which the lumen-defining device is disposed (e.g., the vein), as described above. In some embodiments, at least a portion of the external fluid reservoir can be transparent to allow visualization of the bodily fluid flowing into the fluid reservoir. The external fluid reservoir can include indicators (e.g., 0.1 mL, 0.5 mL, 1 mL, 1.5 mL, 2 mL, 3 mL, 4 mL, 5mL, etc. graduation marks to accommodate identification of diversion volumes ranging from just a few drops or centiliters of blood to a larger volumes) so the user can visualize the volume of bodily fluid that has been received in the external fluid reservoir.

[1133] The transfer device 800 can be moved from the first configuration to the second configuration by further moving the actuator mechanism 880 in the direction of the arrow XX in FIG. 38. As the actuator mechanism 880 is moved from the first configuration toward the second configuration, the actuator mechanism 880 rotates the flow control mechanism 840 toward its second configuration. In this manner, the first lumen 846 is fluidically isolated from the distal port 805 and the first proximal port 806 and the external fluid reservoir can be physically and fluidically decoupled from the transfer device 800. In addition, the second lumen 847 defined by the flow control mechanism 840 is placed in fluid communication with the distal port 805 and the second proximal port 807, as shown in FIG. 39.

[1134] With the transfer device in the second configuration, the second proximal lock mechanism 815 can be physically and fluidically coupled to the external fluid source (not shown in FIGS. 35-39). In this manner, the second proximal cannula 814, the second lumen 847 of the flow control mechanism 840, the distal cannula 817, and the cannula assembly 820 collectively define a fluid flow path. Thus, the transfer device 800 can facilitate the delivery

of a flow of parenteral fluid from the external fluid source to the portion of the patient (e.g., the vein), as indicated by the arrow YY in FIG. 39. Expanding further, with the predetermined amount of bodily fluid transfer to the external fluid reservoir and with the external fluid reservoir decoupled from the transfer device 800, the transfer device 800 can facilitate the delivery of the flow of parenteral fluid to the patient that is substantially free from, for example, the dermally residing microbes dislodged during the venipuncture event or otherwise introduced to the fluid flow path to the patient.

[1135] FIG. 40 is a flowchart illustrating a method 990 of delivering a fluid to a patient using a fluid transfer device, according to an embodiment. The method 990 includes establishing fluid communication between the patient and the fluid transfer device, at 991. The fluid transfer device can be any of those described herein. As such, the fluid transfer device can include a cannula assembly or the like that can be inserted percutaneously to place the fluid transfer device in fluid communication with the patient (e.g., inserted into a vein of the patient). More specifically, in some embodiments, the cannula assembly of the fluid transfer device can include a sharpened distal end configured to pierce the skin of the patient. In other embodiments, the transfer device can include a flow control mechanism that can include a sharpened distal end portion that is configured to extend beyond a distal end portion of the cannula assembly to pierce the skin of the patient. For example, in some embodiments, the fluid transfer device can include a flow control mechanism that is substantially similar to the flow control mechanism 340 of the transfer device 300 described above with reference to FIGS. 4-10.

[1136] With the cannula assembly in fluid communication with the patient, a predetermined volume of a bodily fluid is withdrawn from the patient, at 991. For example, in some embodiments, the fluid transfer device can include a flow control mechanism, such as those described above, that can be moved between a first configuration and a second configuration. In some embodiments, flow control mechanism can be configured to define a fluid flow path between, for example, the cannula assembly and a fluid reservoir included in and/or fluidically coupled to the fluid transfer device. In other embodiments, any portion of fluid transfer device can define at least a portion of the fluid flow path. For example, the fluid transfer device can include a housing or the like that can define at least a portion of the fluid flow path. Thus, the predetermined volume of the bodily fluid is transferred to the fluid reservoir, at 993. In some embodiments, the predetermined volume of the bodily fluid can

include, for example, dermally residing microbes that were dislodged during, for example, the venipuncture event (e.g., inserting the cannula assembly into the patient).

[1137] Once the predetermined volume of bodily fluid is disposed in the fluid reservoir, the fluid transfer device is fluidically isolated from the fluid reservoir to sequester the predetermined volume of bodily fluid in the fluid reservoir, at 994. For example, in some embodiments, once the predetermined volume of bodily fluid is disposed in the fluid reservoir, the fluid transfer device can be physically and/or fluidically decoupled from the fluid reservoir. In other embodiments, the flow control mechanism (as described above) can be moved from the first configuration to the second configuration to fluidically isolate the fluid reservoir from a volume outside of the fluid reservoir. For example, in some embodiments, the flow control mechanism can define a lumen or the like that can define a fluid flow path between the cannula assembly and the fluid reservoir when in the first configuration. In such embodiments, the flow control mechanism can be transitioned (e.g., moved, rotated, and/or otherwise reconfigured) from the first configuration to the second configuration in which the lumen is removed from fluid communication with the cannula assembly and/or the fluid reservoir, thereby fluidically isolating the fluid reservoir from the cannula assembly. In some embodiments, the flow control mechanism can be configured to transition from the first configuration to the second configuration automatically once the predetermined volume of bodily fluid is disposed in the fluid reservoir.

[1138] With the fluid reservoir fluidically isolated from at least a portion of the fluid transfer device, fluid communication is established between the patient and a fluid source via the fluid transfer device, at 995. For example, in some embodiments, the fluid source can be operably coupled to the fluid transfer device to place the fluid source in fluid communication with at least a portion of the fluid transfer device. In some embodiments, the flow control mechanism (described above) can define a second lumen that can place the fluid source in fluid communication with the cannula assembly when in the second configuration. In other embodiments, with the fluid reservoir decoupled from the fluid transfer device that fluid source can be placed in fluid communication with the cannula assembly via any other portion of the fluid transfer device (e.g., a portion of a housing and/or the like). In this manner, a fluid can flow from the fluid source, through the fluid transfer device and into the patient. Moreover, by fluidically isolating the predetermined volume of bodily fluid the flow of fluid

from the fluid source can be substantially free of contaminants such as, for example, the dermally residing microbes, as described above.

[1139] While various embodiments have been described above, it should be understood that they have been presented by way of example only, and not limitation. Where methods and steps described above indicate certain events occurring in certain order, those of ordinary skill in the art having the benefit of this disclosure would recognize that the ordering of certain steps may be modified and that such modifications are in accordance with the variations of the invention. Additionally, certain of the steps may be performed concurrently in a parallel process when possible, as well as performed sequentially as described above. Additionally, certain steps may be partially completed before proceeding to subsequent steps.

[1140] While various embodiments have been particularly shown and described, various changes in form and details may be made. For example, while the actuator 580 is shown and described with respect to FIG. 21 as being rotated in a single direction, in other embodiments, an actuator can be rotated in a first direction (e.g., in the direction of the arrow MM in FIG. 21) and a second direction, opposite the first. In such embodiments, the rotation in the second direction can be configured to move a transfer device through any number of configurations. In other embodiments, the rotation of the actuator in the second direction can be limited.

[1141] Although various embodiments have been described as having particular features and/or combinations of components, other embodiments are possible having any combination or sub-combination of any features and/or components from any of the embodiments described herein.

[1142] The specific configurations of the various components can also be varied. For example, the size and specific shape of the various components can be different from the embodiments shown, while still providing the functions as described herein. More specifically, the size and shape of the various components can be specifically selected for a desired rate of bodily fluid flow into a fluid reservoir or for a desired rate of parenteral fluid flow into the patient.

Claims

1. An apparatus, comprising:

a cannula assembly;

a housing including a proximal end portion and a distal end portion and defining an inner volume therebetween, the housing having an inlet port configured to be removably coupled to the cannula assembly;

a fluid reservoir fluidically coupled to the housing and configured to receive and isolate a first volume of bodily fluid withdrawn from the patient;

a flow control mechanism at least partially disposed in the inner volume of the housing and configured to move relative to the housing between a first configuration and a second configuration, the flow control mechanism defining a fluid flow path between the cannula assembly and the fluid reservoir in the first configuration; and

an actuator operably coupled to the flow control mechanism and configured to move the flow control mechanism from the first configuration in which the inlet port is placed in fluid communication with the fluid reservoir such that bodily fluid can flow from the cannula assembly, through inlet port via the fluid flow path and to the fluid reservoir, to the second configuration, in which the fluid reservoir is fluidically isolated from the cannula assembly.

2. The apparatus of claim 1, wherein the flow control mechanism includes a fluid communicator configured to be moved from a first position to a second position to place the flow control mechanism in the second configuration.

3. The apparatus of claim 2, wherein the fluid communicator is configured to extend through the inlet port and beyond the distal end portion of the housing in the first position.

4. The apparatus of claim 2, wherein the fluid communicator is retracted into the inner volume of the housing in the second position.

5. The apparatus of claim 1, wherein the flow control mechanism includes a first member movably disposed in the inner volume of the housing, and a second member coupled to the first member and configured to extend through the inlet port and beyond the distal end portion of the housing in the first configuration.

6. The apparatus of claim 5, wherein the first member includes a proximal end portion and a distal end portion, and defines a lumen therethrough.

7. The apparatus of claim 6, wherein the second member includes a proximal end portion and a distal end portion, and defines a lumen therethrough.

8. The apparatus of claim 7, wherein the proximal end portion of the second member is configured to be disposed in the lumen defined by the first member.

9. The apparatus of claim 7, wherein the distal end portion of the second member is configured to extend beyond a distal end of the cannula assembly when the flow control mechanism is in the first configuration.

10. The apparatus of claim 9, wherein the second member is a needle configured to be inserted into the patient

11. The apparatus of claim 1, wherein the cannula assembly is removably coupled to the housing.

12. The apparatus of claim 1, wherein the flow control mechanism includes a spring configured to expand and move the flow control mechanism from the first configuration to the second configuration.

13. The apparatus of claim 12, wherein the actuator is configured to release the spring from a compressed state when actuated by a user.

14. The apparatus of claim 1, wherein the fluid reservoir is movably coupled to the housing and configured to be moved from a first position to a second position, the movement from the first position to the second position configured to create a negative pressure in the fluid reservoir.

15. The apparatus of claim 1, wherein the fluid reservoir is movably disposed within the inner volume of the housing, the fluid reservoir including a proximal end portion and a

distal end portion and defining an inner volume therebetween, the inner volume configured to selectively receive at least a portion of the flow control mechanism.

16. The apparatus of claim 15, wherein the proximal end portion of the fluid reservoir is configured to move relative to the distal end portion of the fluid reservoir to increase the inner volume defined by the fluid reservoir and create a negative pressure within the inner volume.

17. The apparatus of claim 1, wherein the fluid reservoir is movably disposed within the inner volume of the housing and configured to move from a first configuration to a second configuration to create a negative pressure in the fluid reservoir.

18. The apparatus of claim 17, wherein the actuator is configured to move the fluid reservoir from the first configuration to the second configuration when actuated by a user.

19. The apparatus of claim 1, wherein the actuator includes an outlet port configured to be fluidically coupled to the fluid reservoir.

20. The apparatus of claim 19, wherein the actuator defines a lumen configured to allow fluid communication between the fluid flow path and the outlet port when the flow control mechanism is in the first configuration.

21. The apparatus of claim 20, wherein the actuator is configured to rotate from a first position in which bodily fluid can flow from the flow control mechanism, through the outlet port and to the fluid reservoir, to a second position, in which the flow control mechanism is placed in the second configuration and the fluid reservoir is fluidically isolated from the cannula assembly.

22. A device for delivering a fluid to a patient with reduced contamination, the device comprising:

a housing including a proximal end portion and a distal end portion and defining an inner volume therebetween, the housing having a first port configured to be removably coupled to a cannula assembly, and a second port configured to be fluidically coupled to a fluid source;

a fluid reservoir fluidically couplcablc to a cannula assembly and configured to receive and isolate a predetermined volume of bodily fluid withdrawn from the patient; and

a flow control mechanism at least partially disposed in the inner volume of the housing and configured to move relative to the housing between a first configuration in which the first port is placed in fluid communication with the fluid reservoir such that bodily fluid can flow from the cannula assembly, through first port and to the fluid reservoir, and a second configuration in which (a) the fluid reservoir is fluidically isolated from the cannula assembly, and (b) fluid can flow from the fluid source, in the second port, through the flow control mechanism, out the first port and to the cannula assembly.

23. The device of claim 22, wherein the fluid reservoir is disposed in the inner volume of the housing and is at least partially defined by the flow control mechanism.

24. The device of claim 23, wherein the fluid reservoir includes an inlet port configured to be fluidically coupled to the first port of the housing.

25. The device of claim 24, further comprising a valve disposed in the inlet port of the fluid reservoir.

26. The device of claim 25, wherein the valve is a check valve.

27. The device of claim 24, wherein the fluid reservoir is configured to move relative to the housing from a first position in which the inlet port is fluidically coupled to the first port of the housing, to a second position in which the inlet port is fluidically isolated from the first port of the housing.

28. The device of claim 22, wherein the flow control mechanism includes a first sealing member and a second sealing member spaced apart from the first sealing member, the first sealing member at least partially defining the fluid reservoir.

29. The device of claim 28, wherein the flow control mechanism is configured to move the first sealing member and the second sealing member from a first position to a second position to place the flow control mechanism in the second configuration.

30. The device of claim 29, wherein the movement of the first sealing member from the first position to the second position is configured to create a negative pressure in the fluid reservoir.

31. The device of claim 22, wherein the fluid reservoir is defined by the flow control mechanism.

32. The device of claim 31, wherein the fluid reservoir includes an inlet port configured to be fluidically coupled to the first port of the housing in the first configuration, and fluidically isolated from the first port of the housing in the second configuration.

33. The device of claim 22, wherein the flow control mechanism defines a lumen, the lumen configured to be fluidically isolated from the first port and the second port of the housing in the first configuration, and in fluid communication with the first port and the second port of the housing in the second configuration such that fluid can flow from the fluid source, in the second port of the housing, through the lumen of the flow control mechanism, and out the first port of the housing.

34. The device of claim 22, wherein the flow control mechanism is configured to rotate from a first position in which the flow control mechanism is in the first configuration, to a second position in which the flow control mechanism is placed in the second configuration.

35. A method of delivering a fluid to a patient using a fluid transfer device, the method comprising:

establishing fluid communication between the patient and the fluid transfer device;

withdrawing a predetermined volume of a bodily fluid from the patient;

transferring the predetermined volume of the bodily fluid to a fluid reservoir;

fluidically isolating the fluid transfer device from the fluid reservoir to sequester the predetermined volume of bodily fluid in the fluid reservoir; and

establishing fluid communication between the patient and a fluid source with the fluid transfer device.

36. The method of claim 35, whereby sequestering the predetermined volume of the bodily fluid in the fluid reservoir establishes a sterile fluid flow path between the fluid source and the patient.

37. The method of claim 35, wherein the fluid transfer device includes a flow control mechanism, the method further comprising:

disposing the flow control mechanism in a first configuration prior to withdrawing the predetermined volume of bodily fluid from the patient, the first configuration establishing fluid communication between the patient and the fluid reservoir.

38. The method of clam 37, further comprising:

after the predetermined volume of bodily fluid has been transferred the fluid reservoir, moving the flow control mechanism to a second configuration, the second configuration establishing fluid communication between the fluid source and the patient.

39. The method of claim 38, wherein the flow control mechanism is automatically moved from the first configuration to the second configuration after the predetermined volume of bodily fluid has been transferred to the fluid reservoir.

40. The method of claim 35, further comprising:

delivering fluid from the fluid source to the patient.

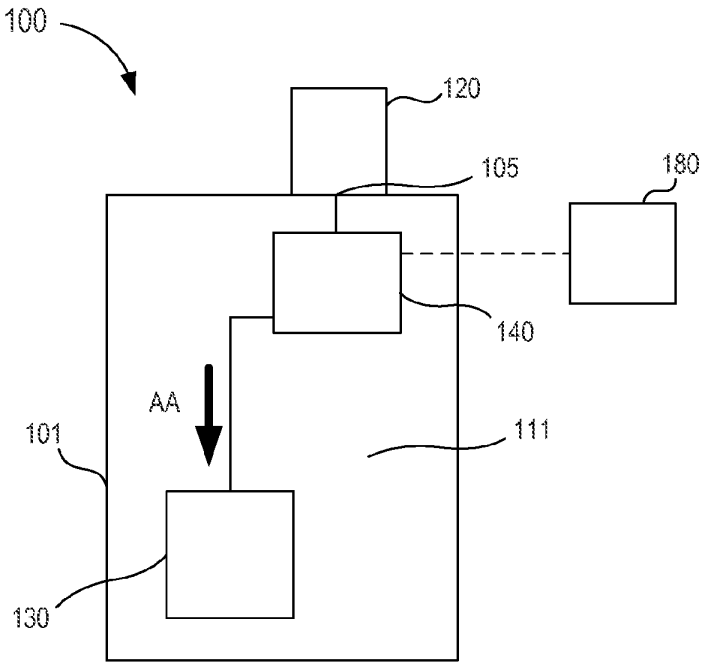

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FIG. 1

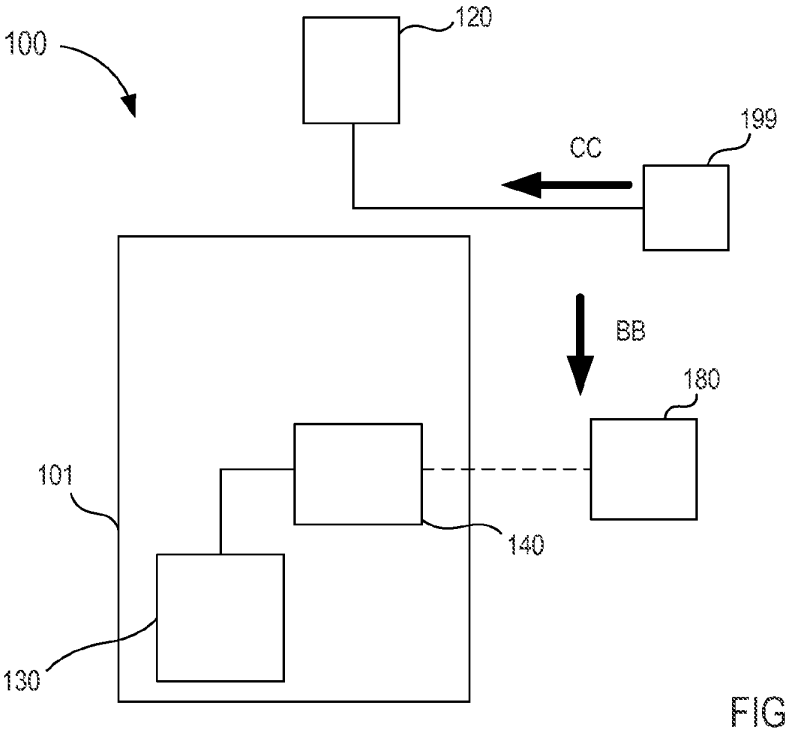

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FIG. 2

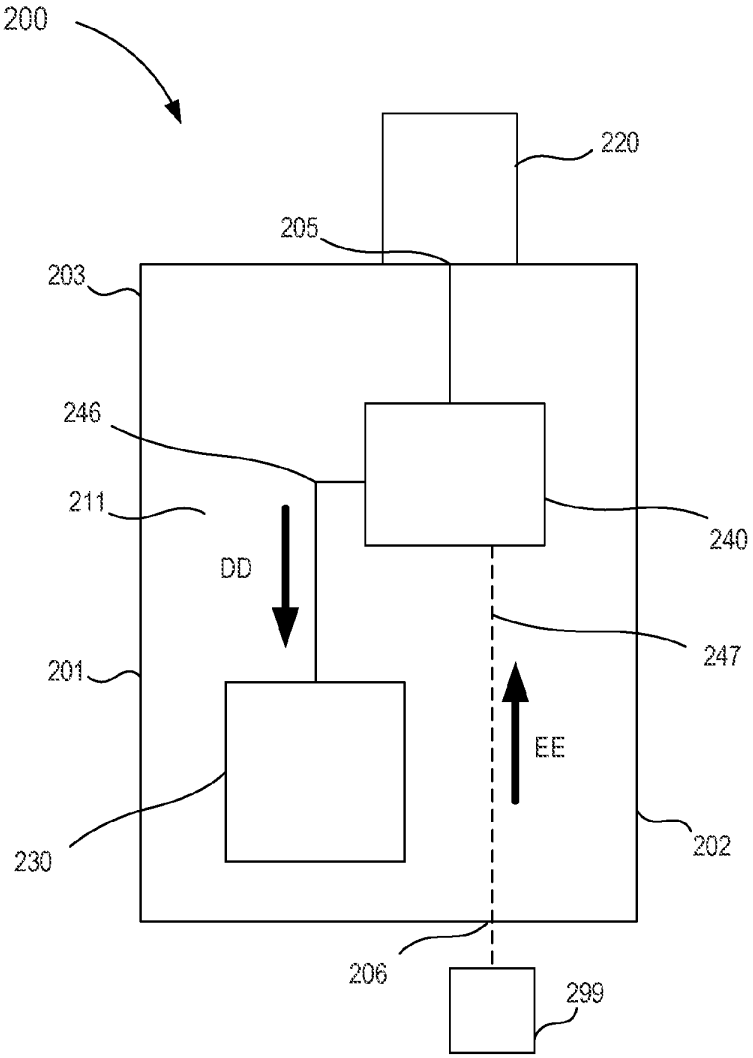


FIG. 3

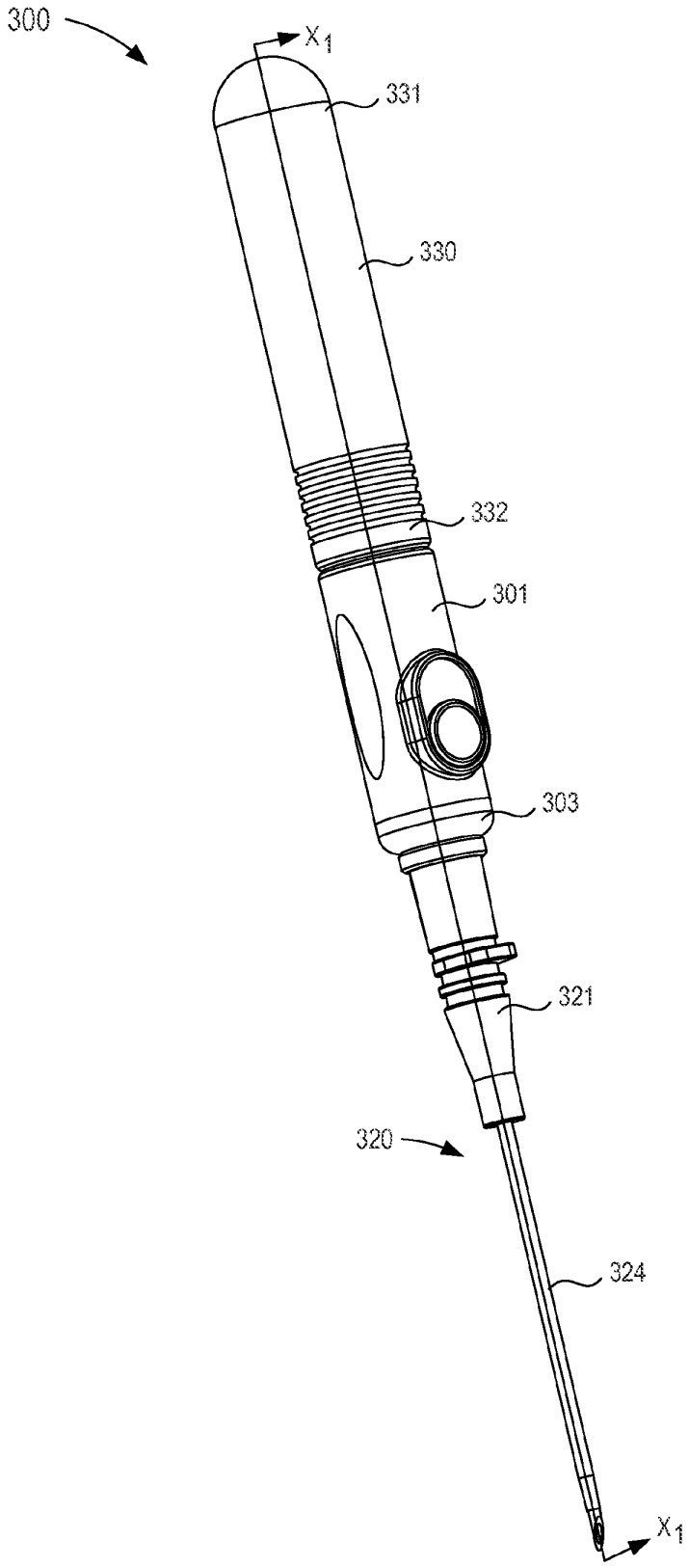


FIG. 4

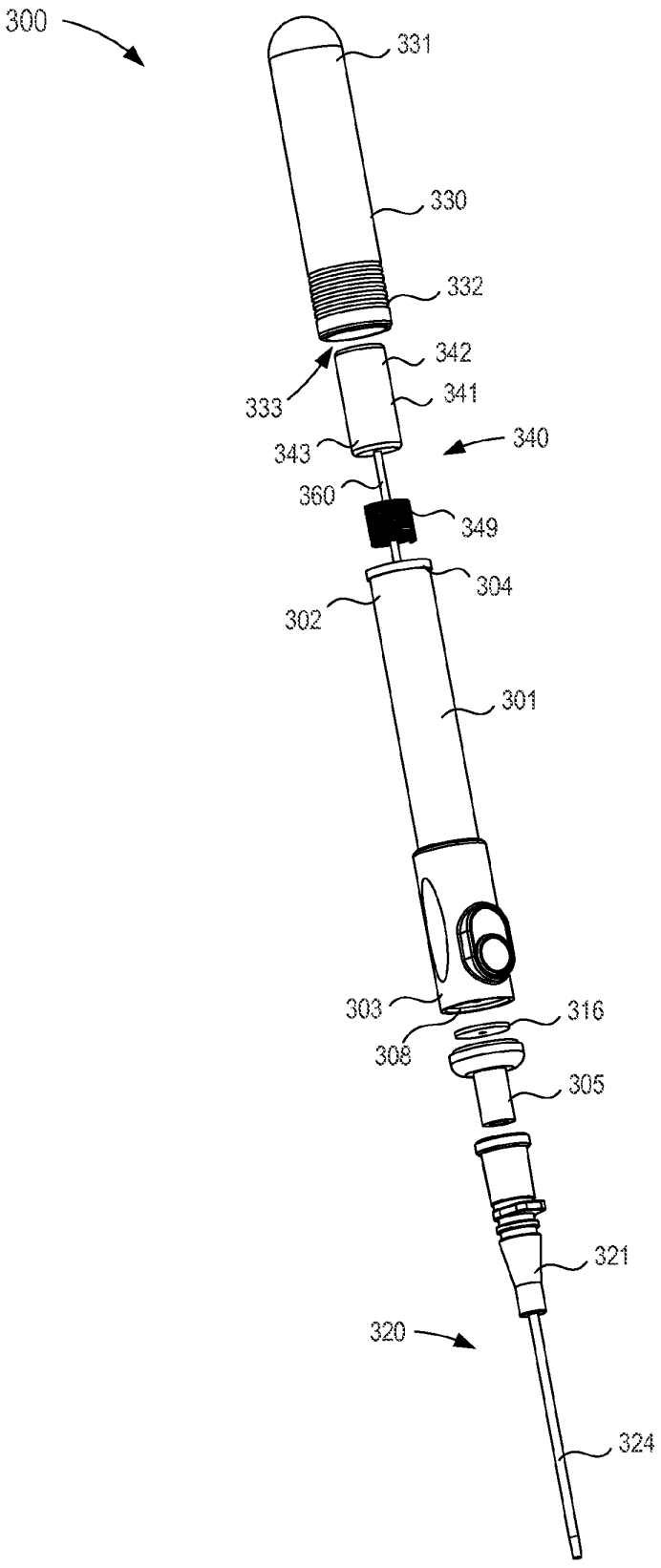

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FIG. 5

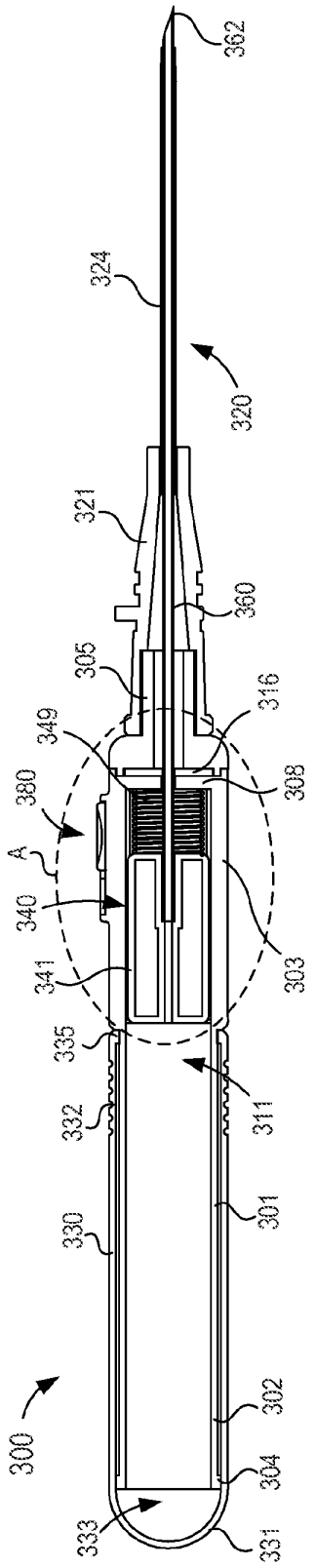

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FIG. 6

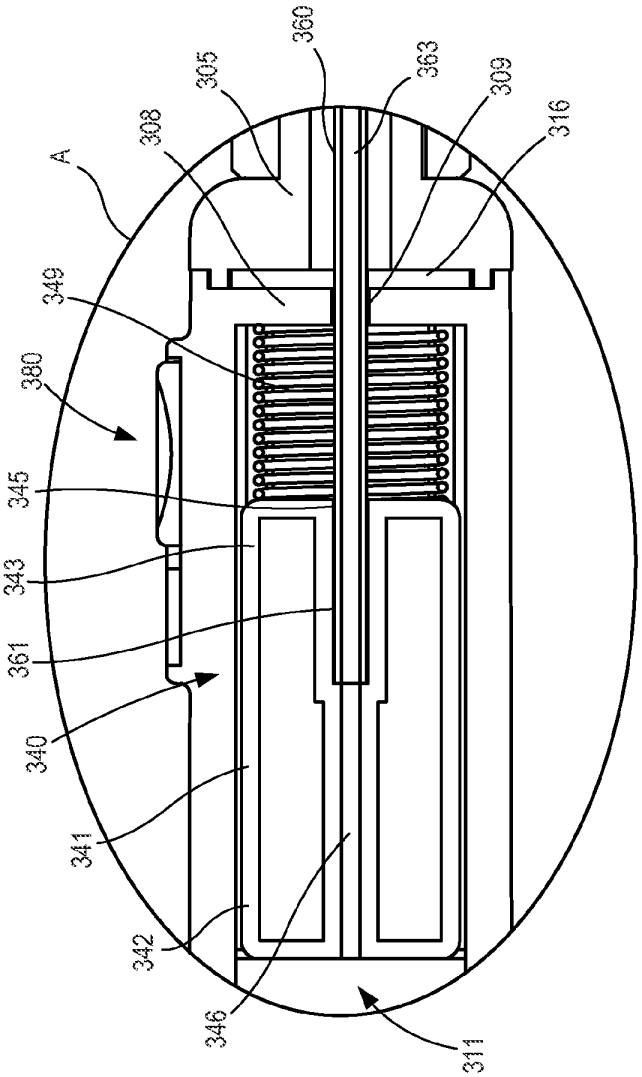

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FIG. 7

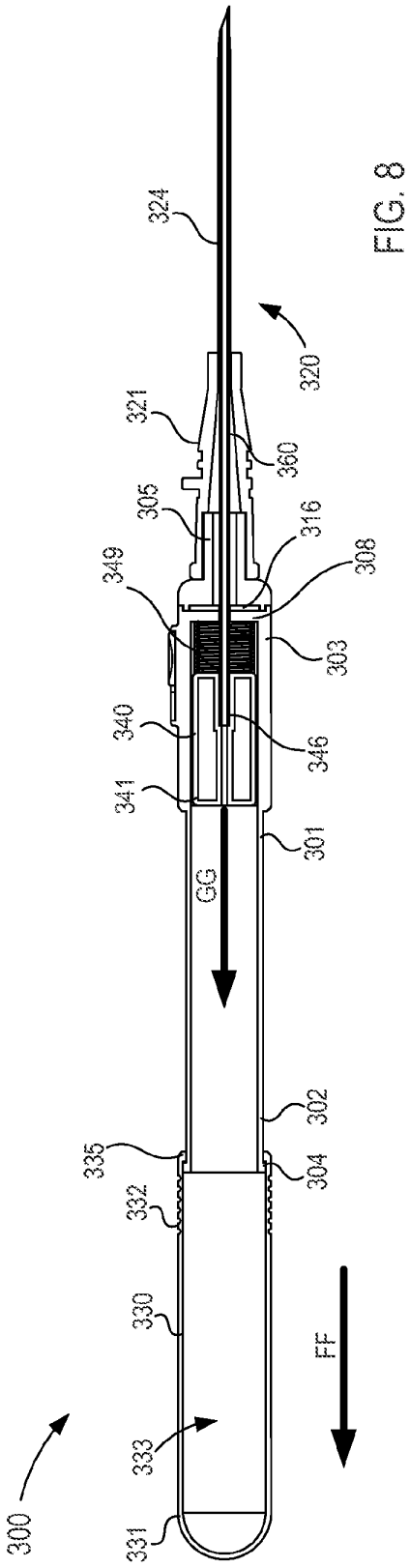

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FIG. 8

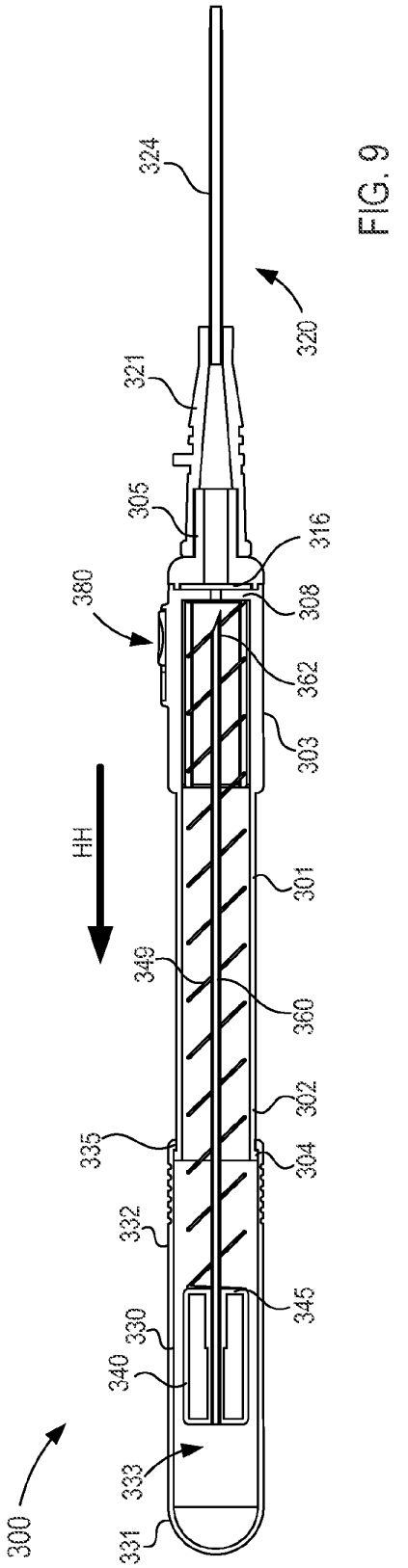

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FIG. 9

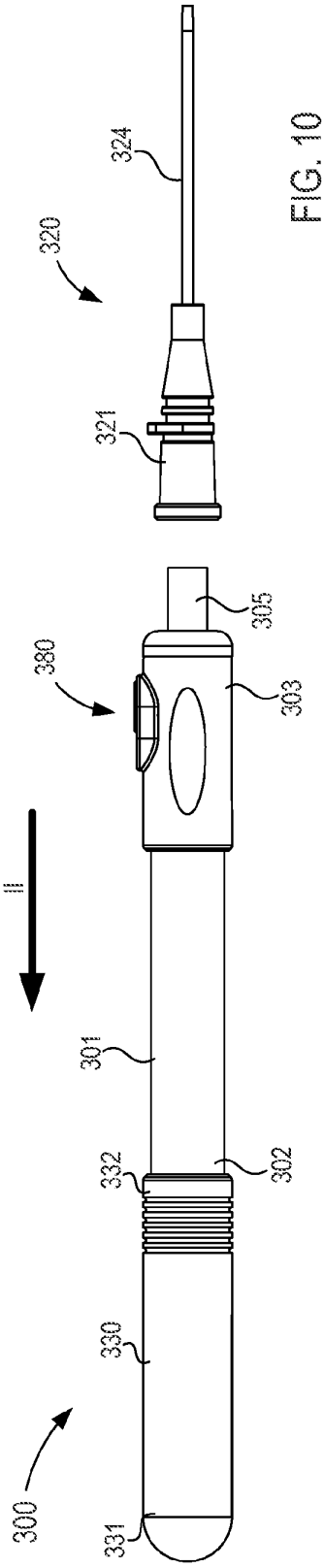


FIG. 10

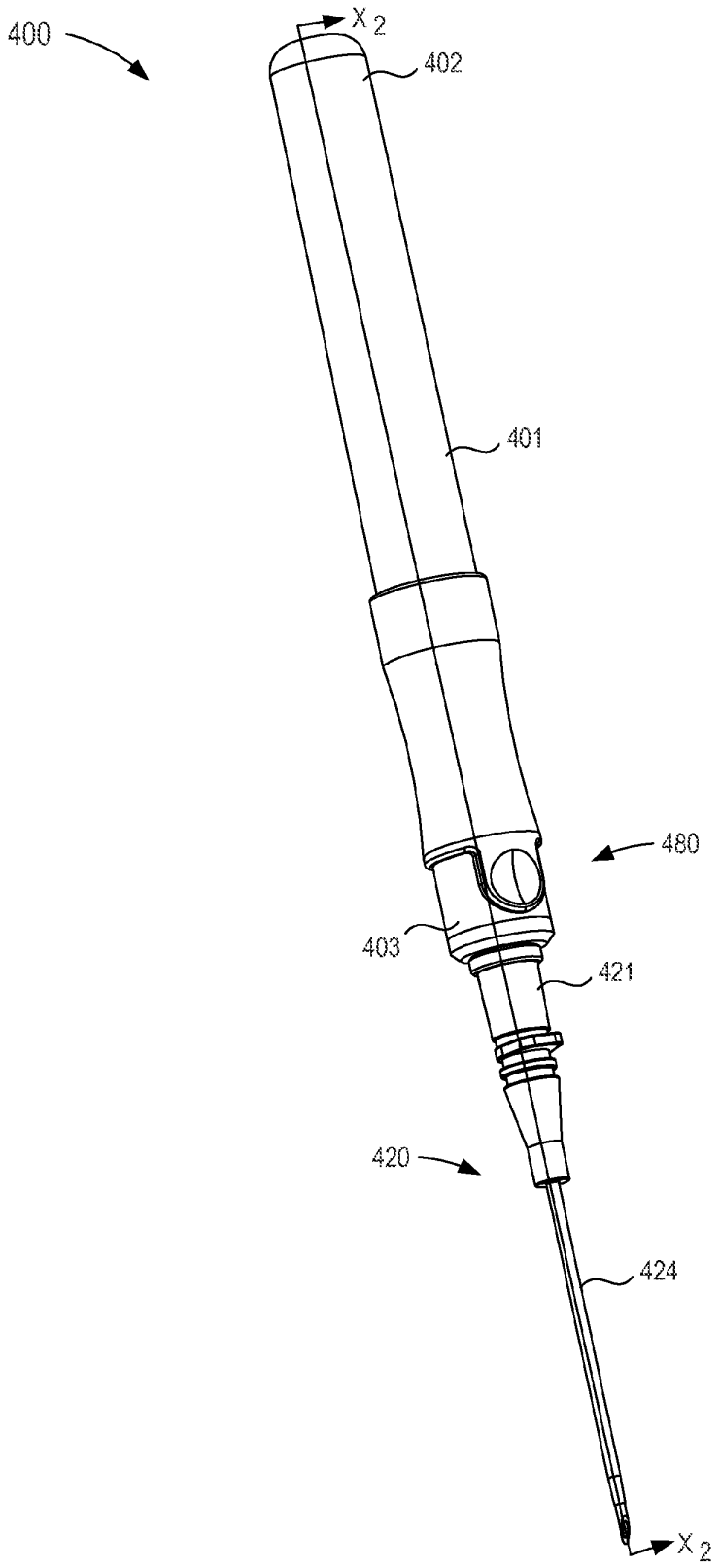


FIG. 11

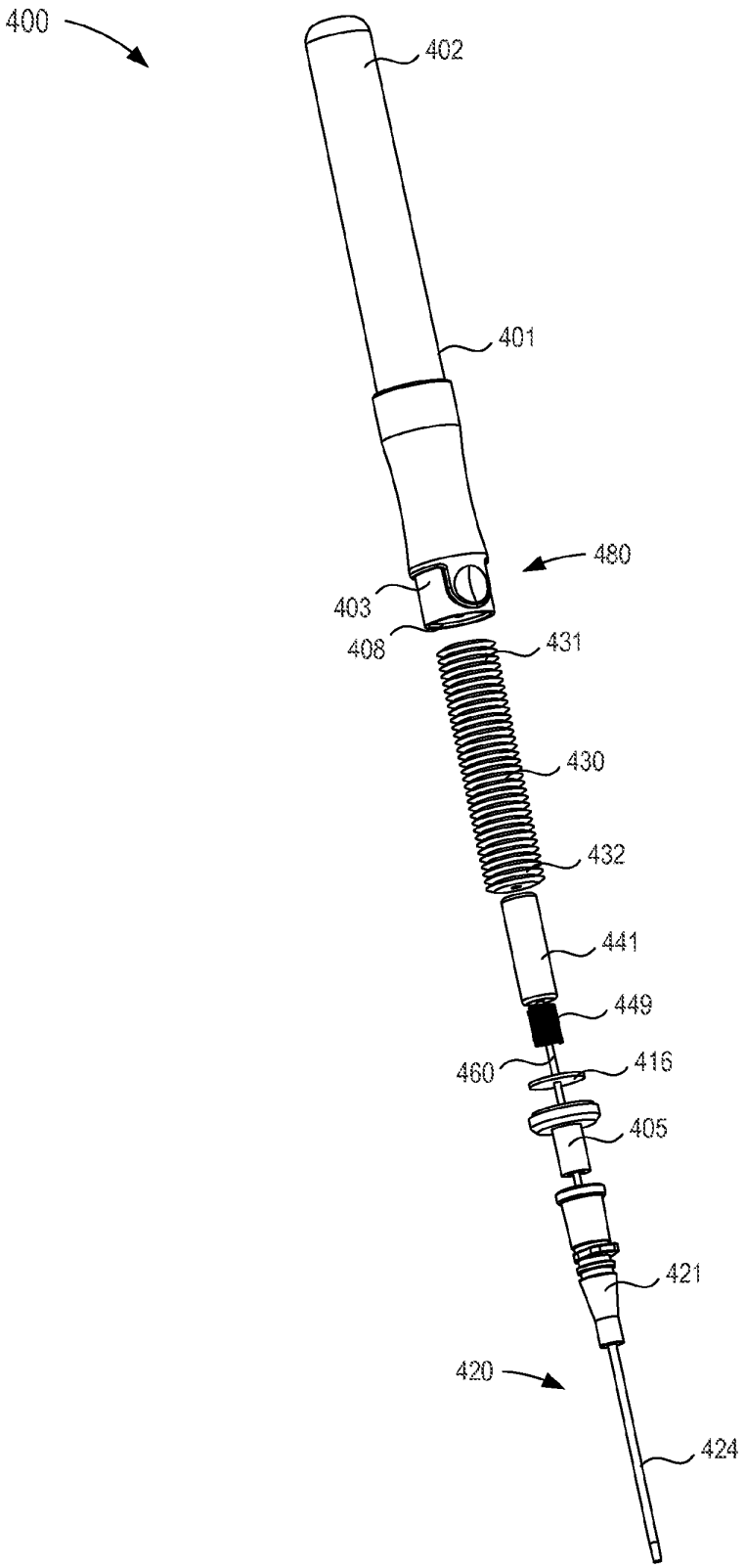

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FIG. 12

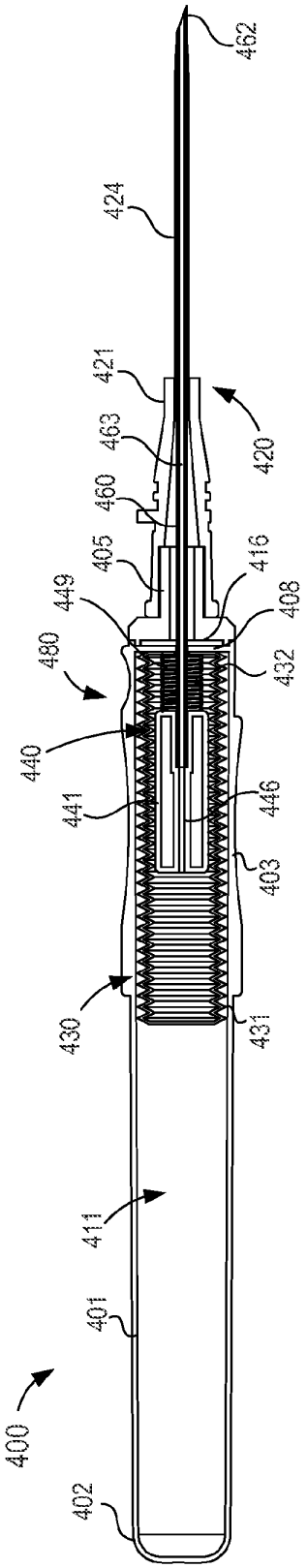

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FIG. 13

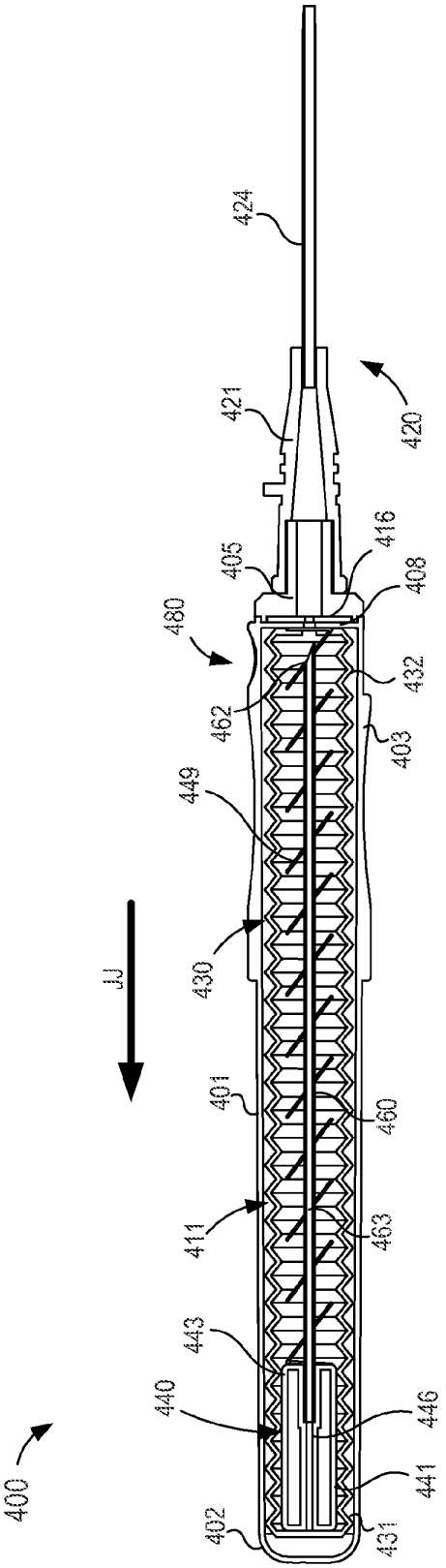

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FIG. 14

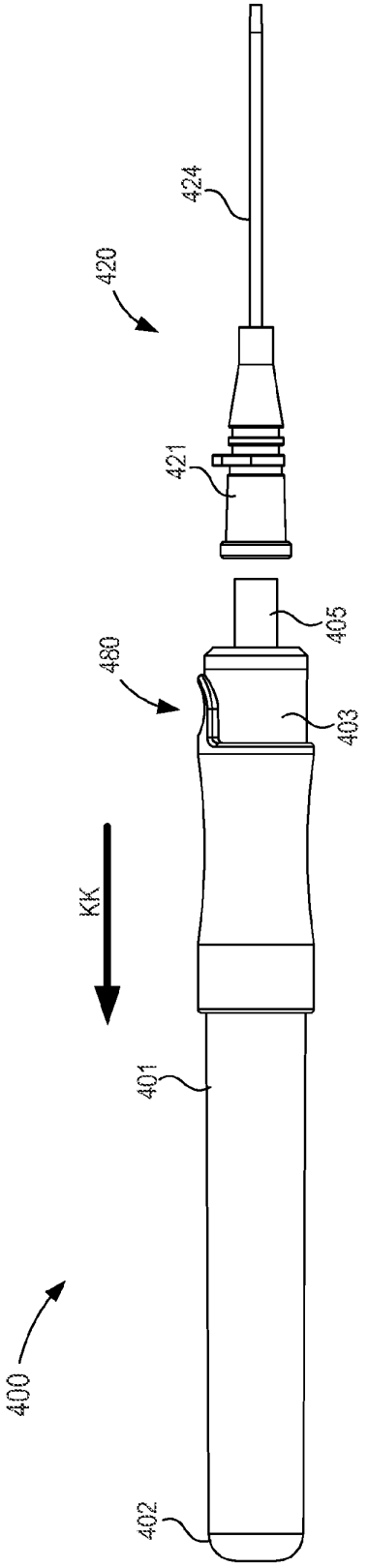


FIG. 15

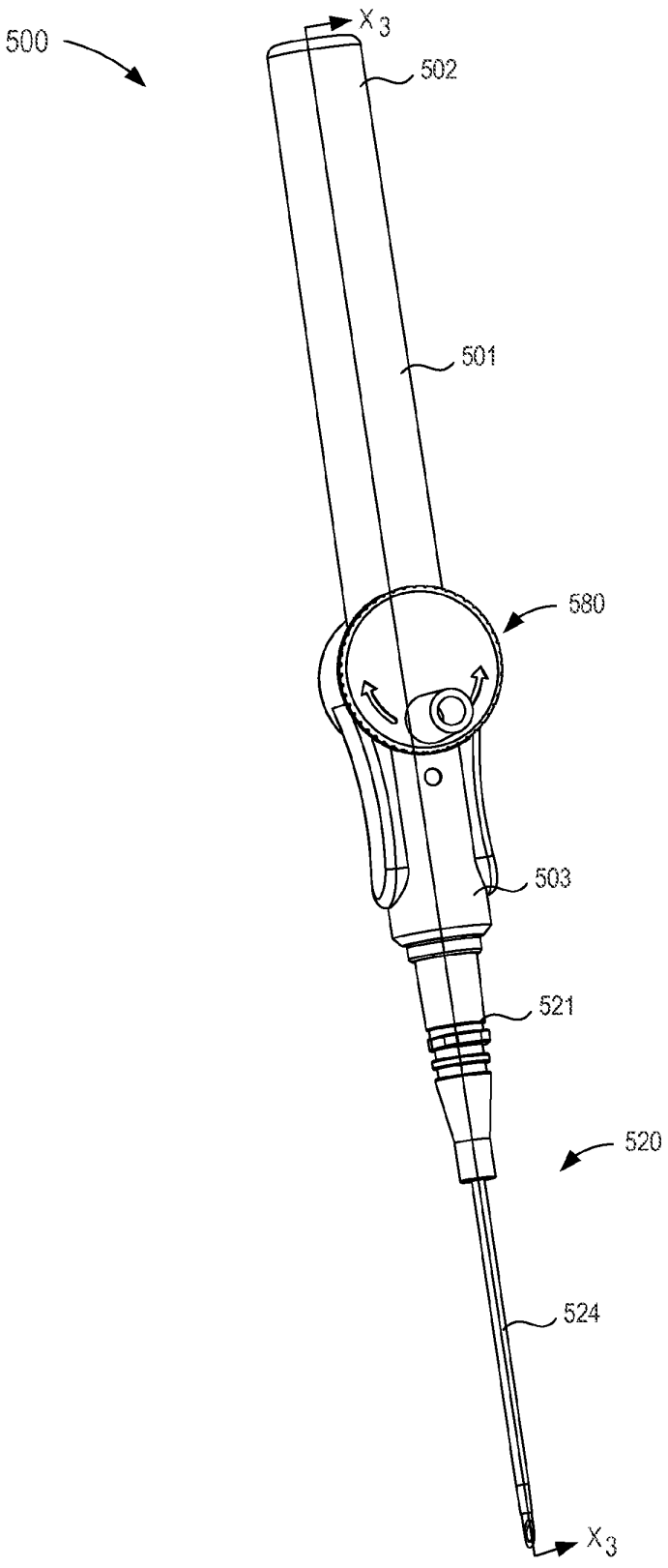


FIG. 16

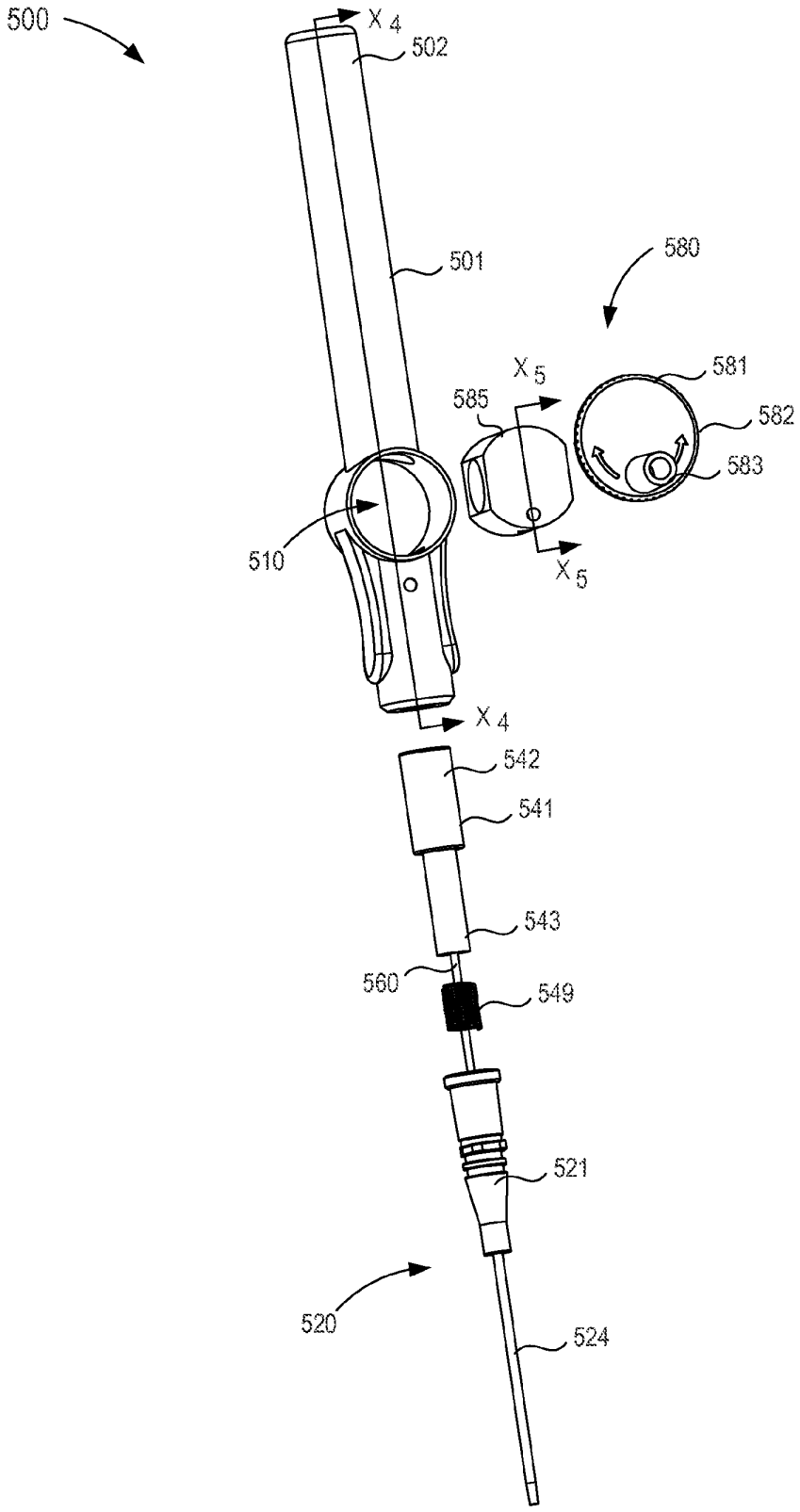

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X 5
X 4
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FIG. 17

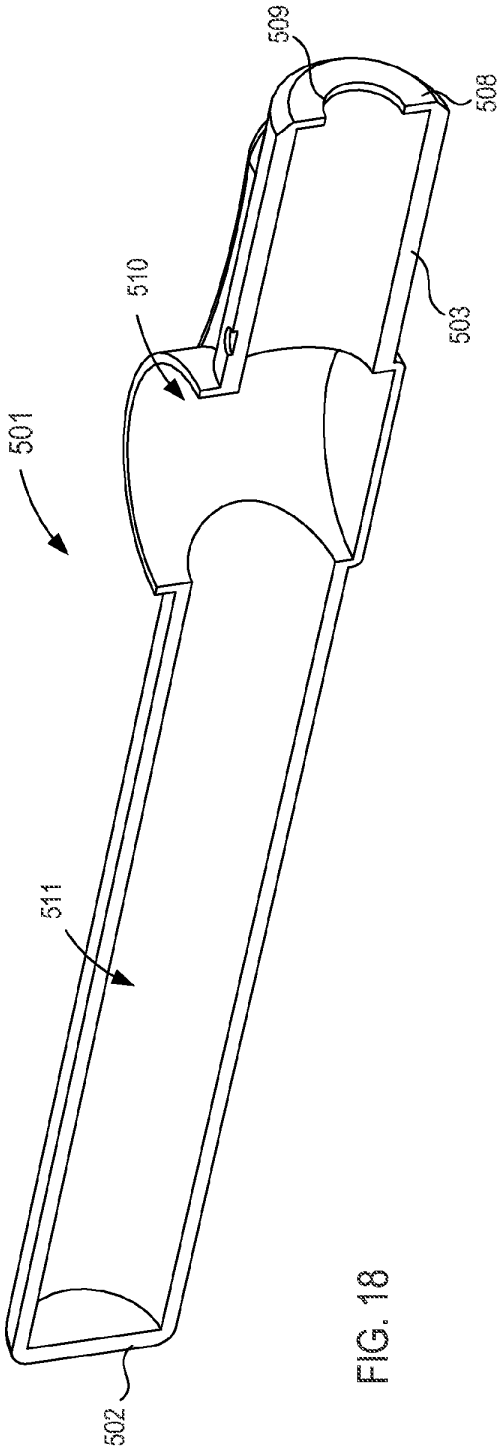


FIG. 18

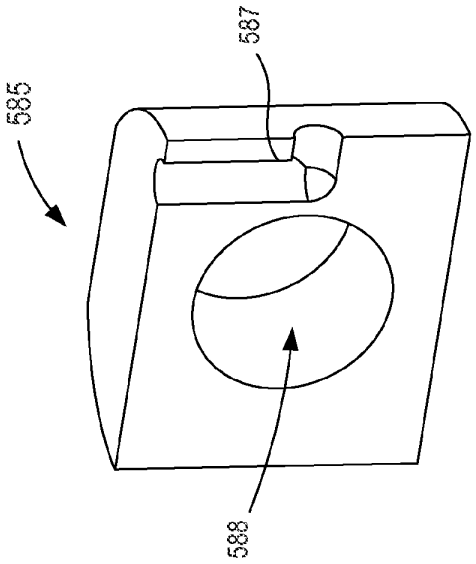


FIG. 19

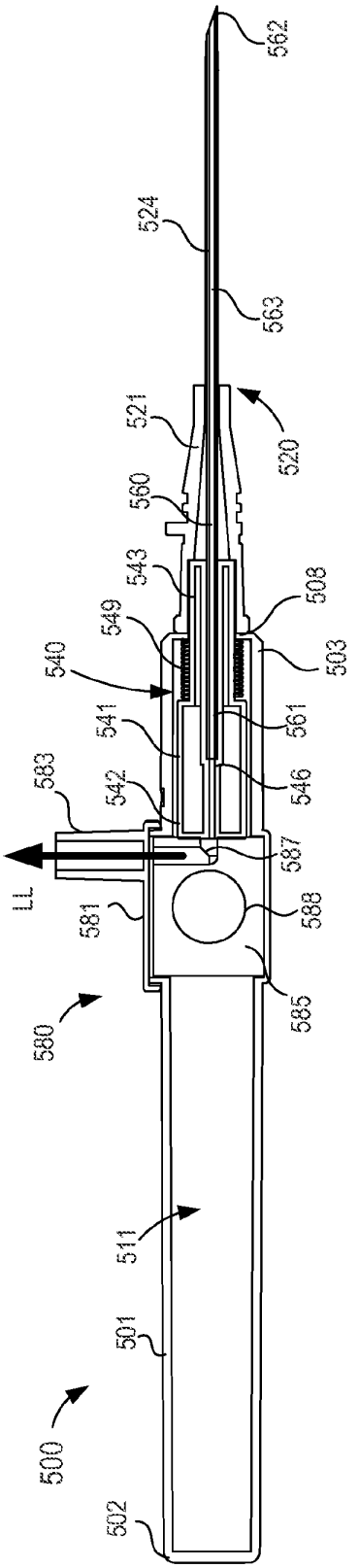

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FIG. 20

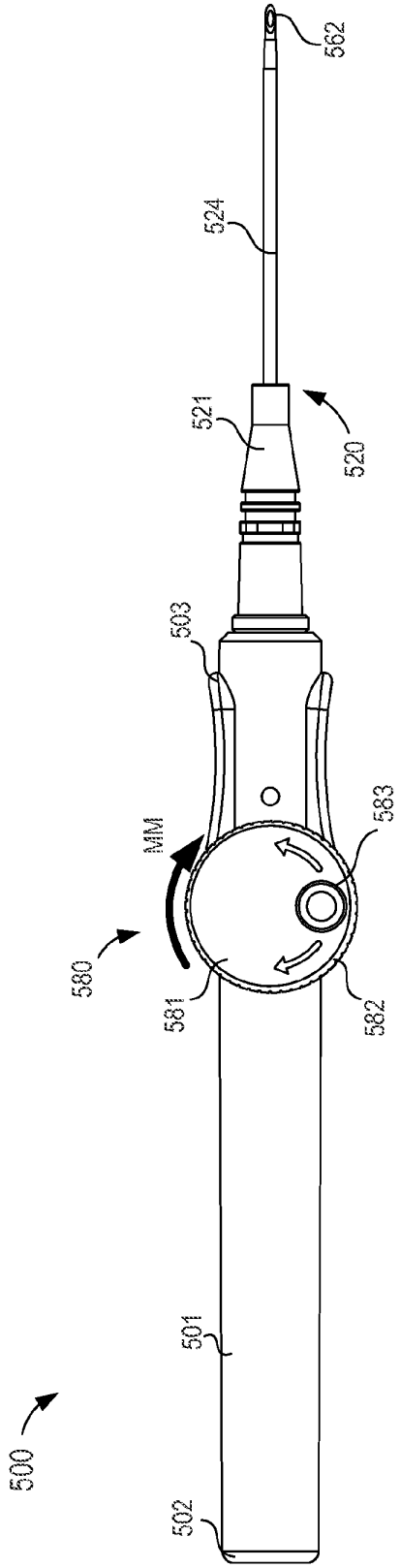

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FIG. 21

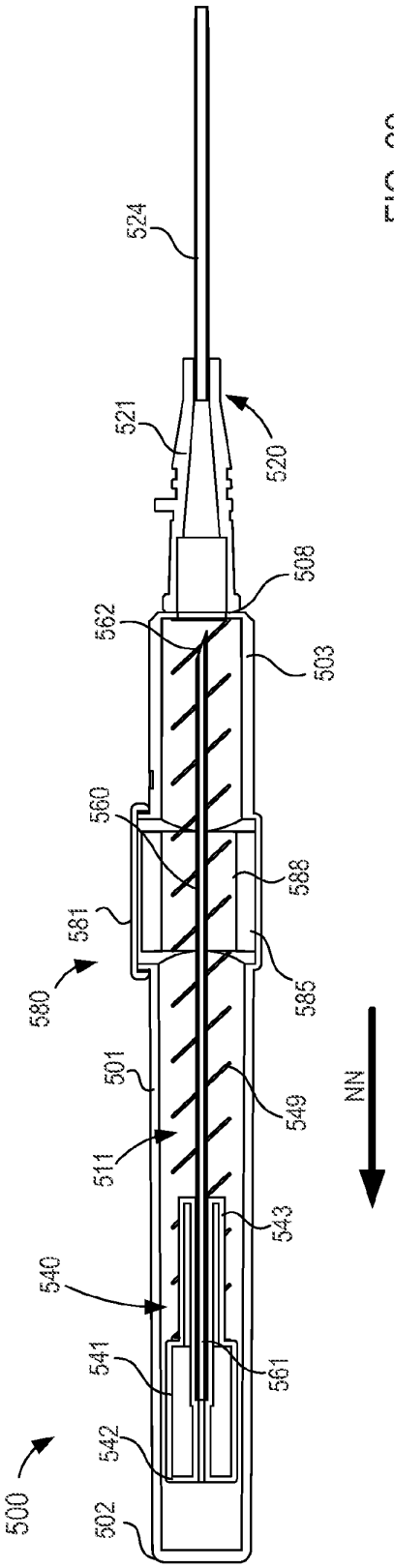

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FIG. 22

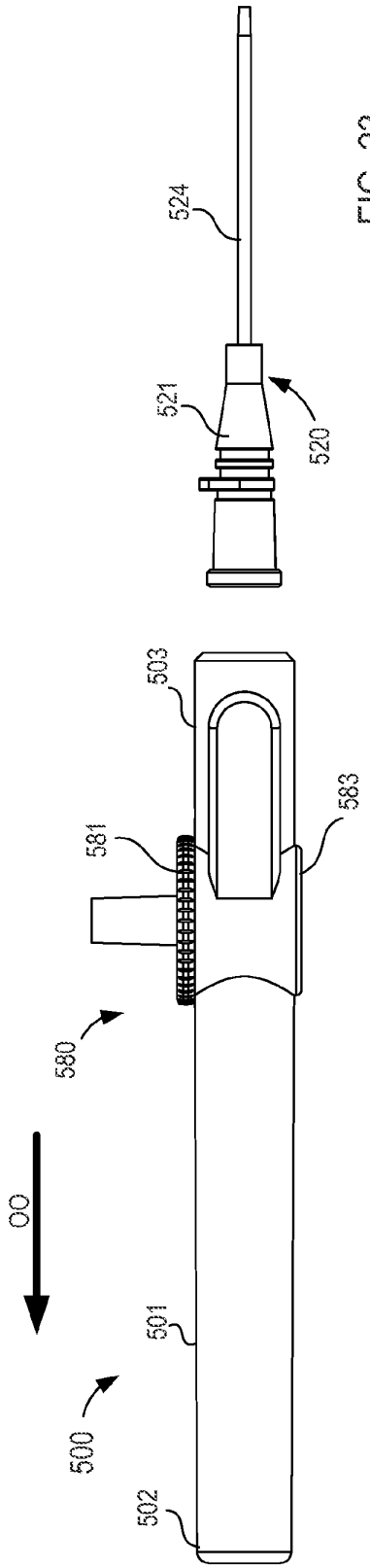

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FIG. 23

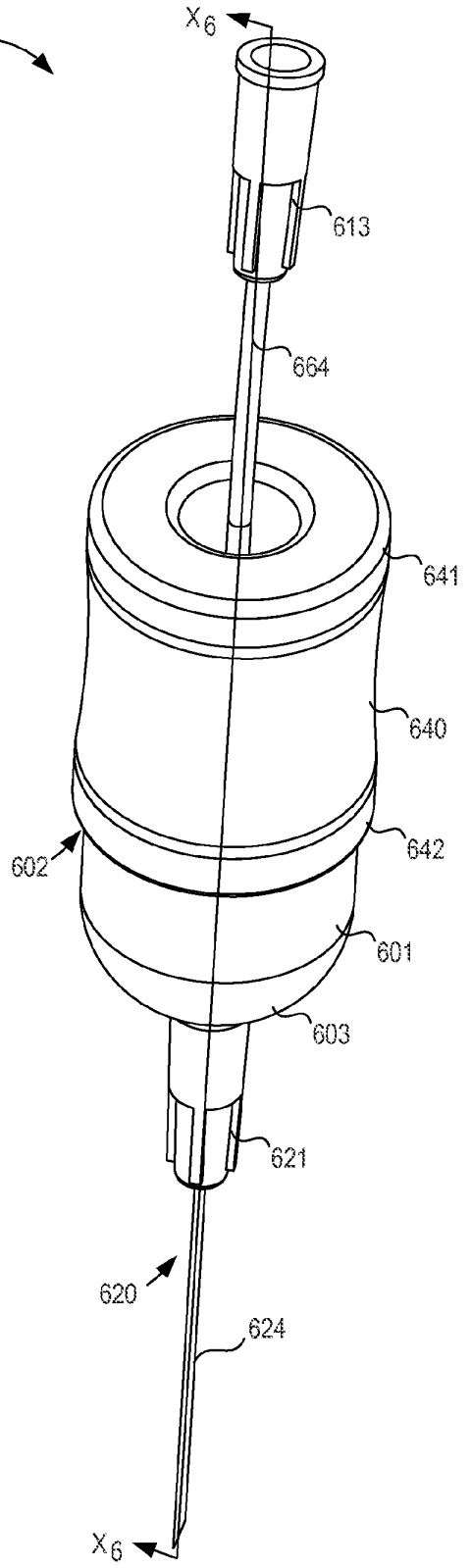


FIG. 24

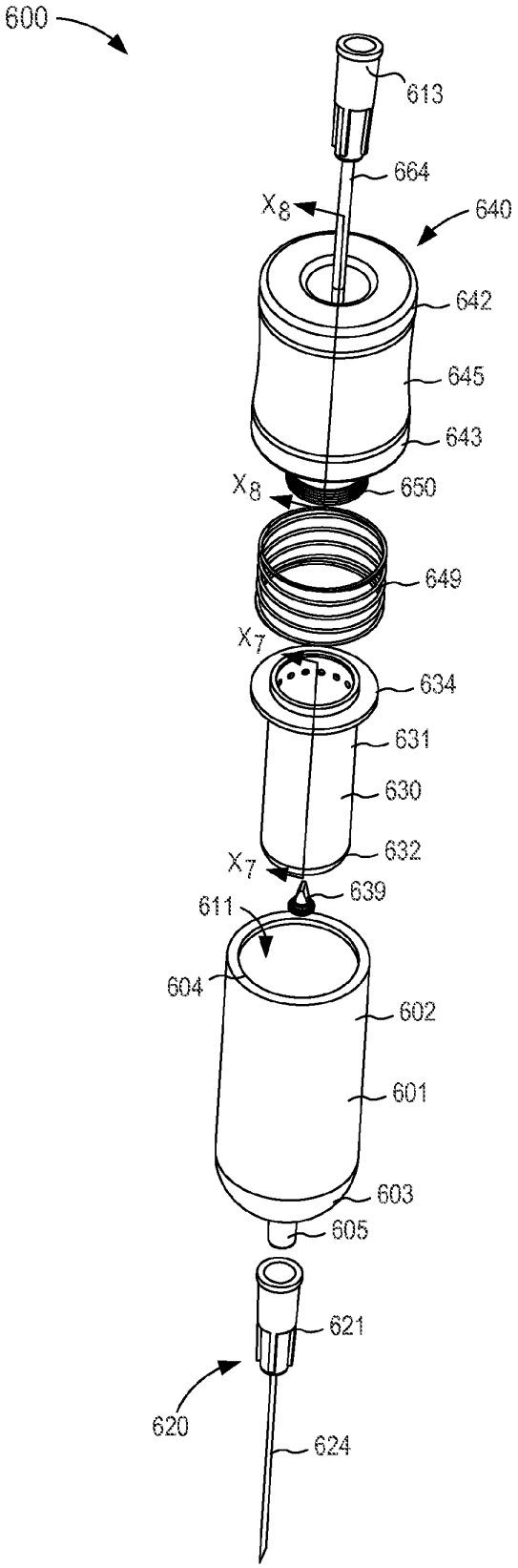

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FIG. 25

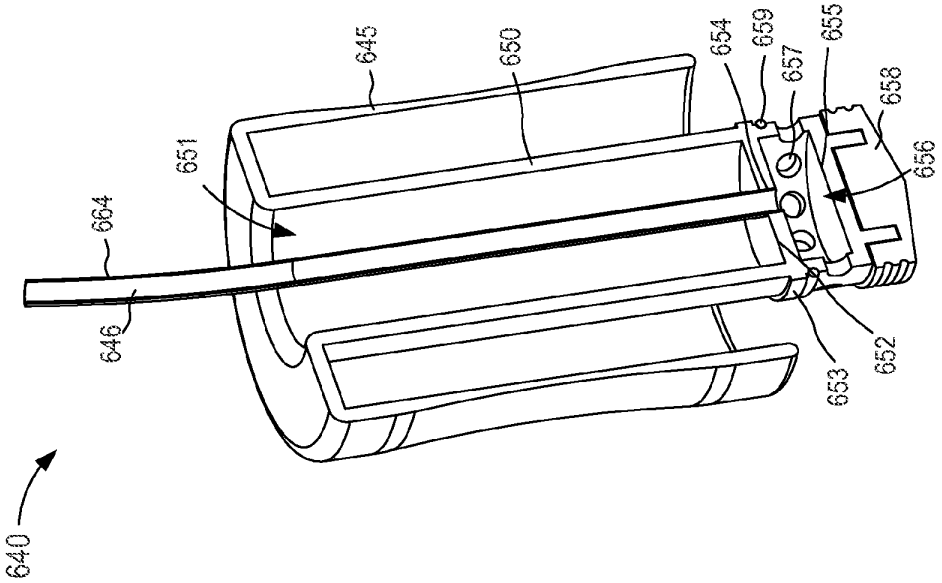

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FIG. 27

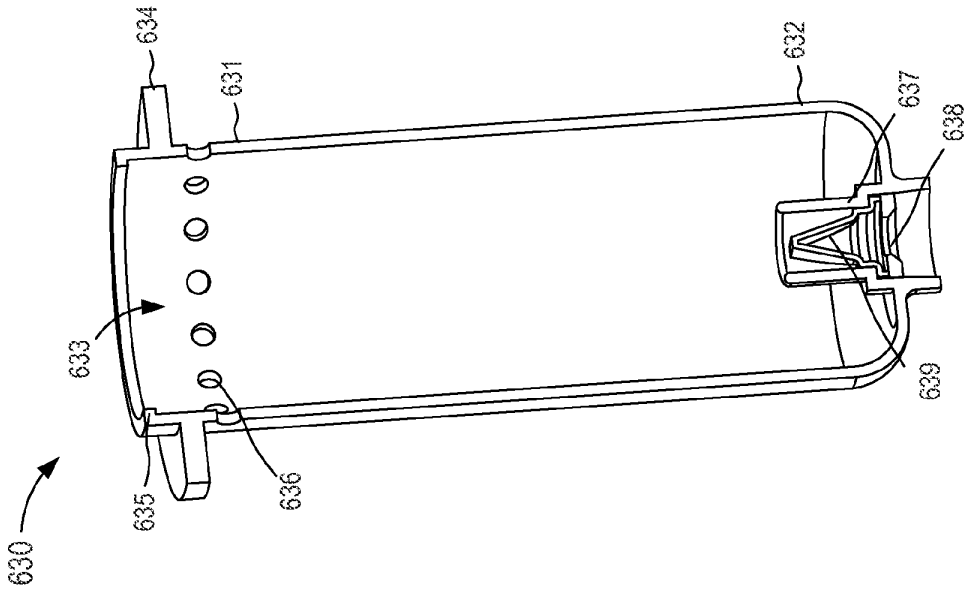

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FIG. 26

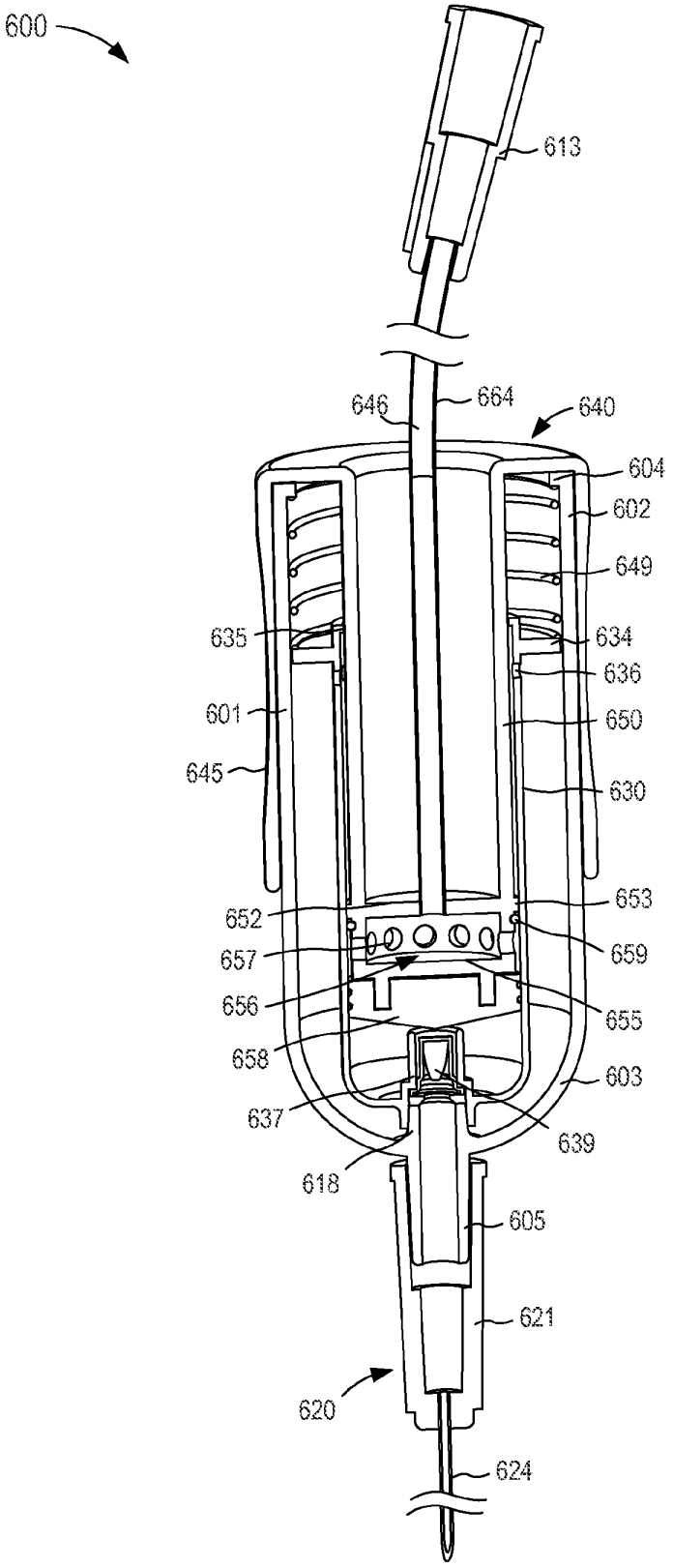

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FIG. 28

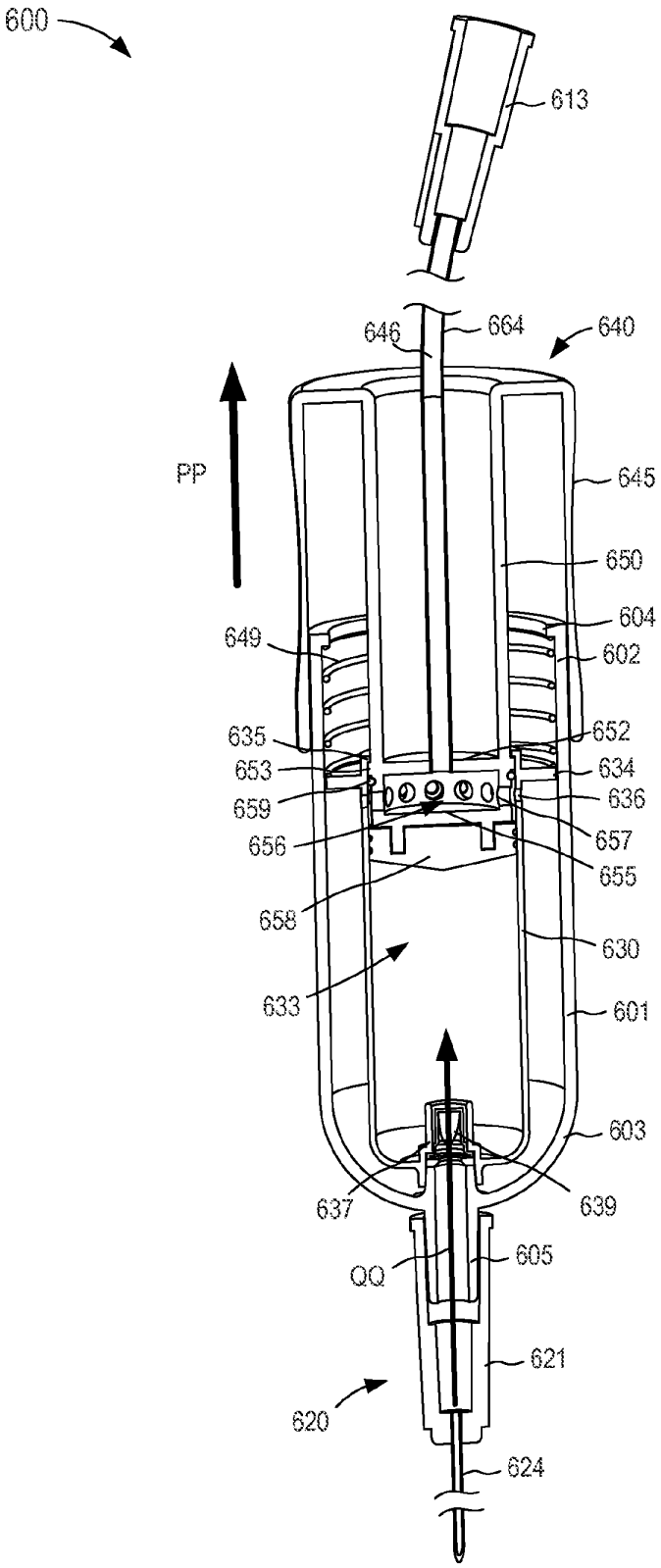

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FIG. 29

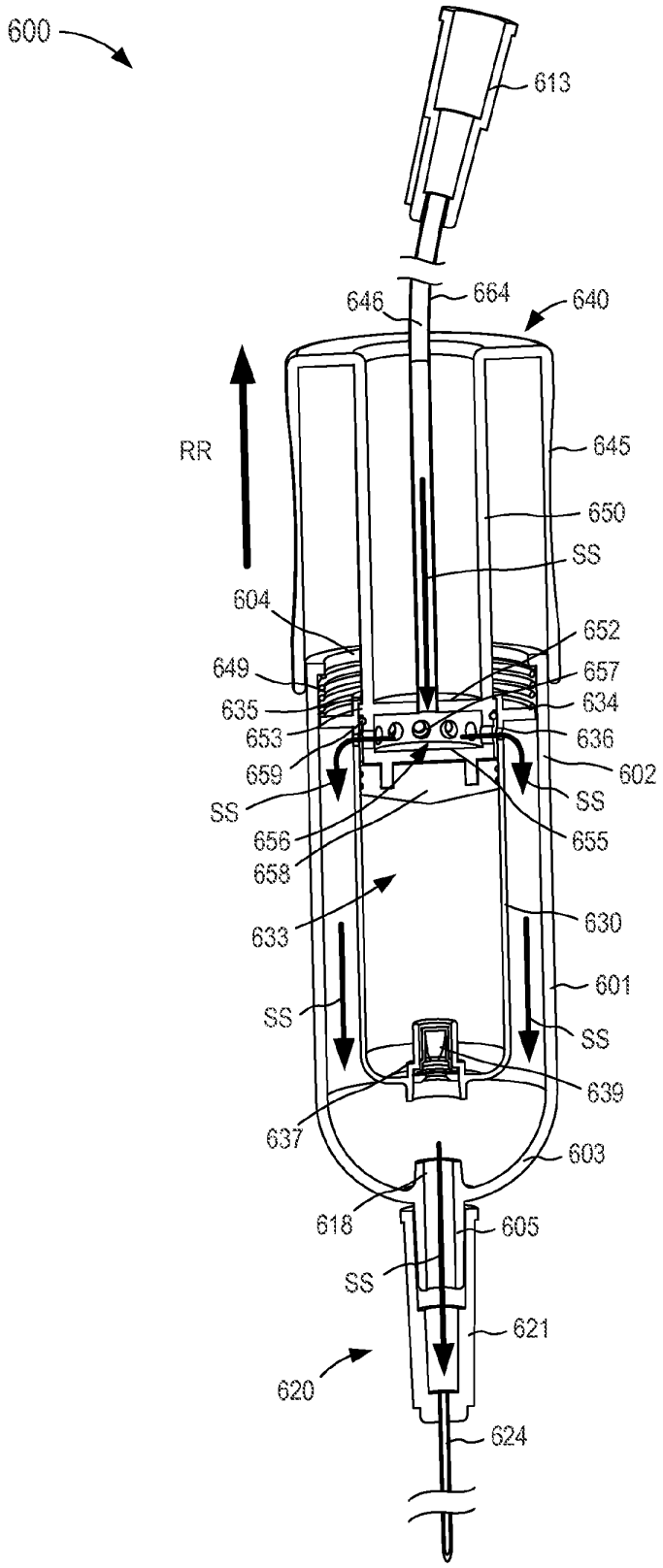

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FIG. 30

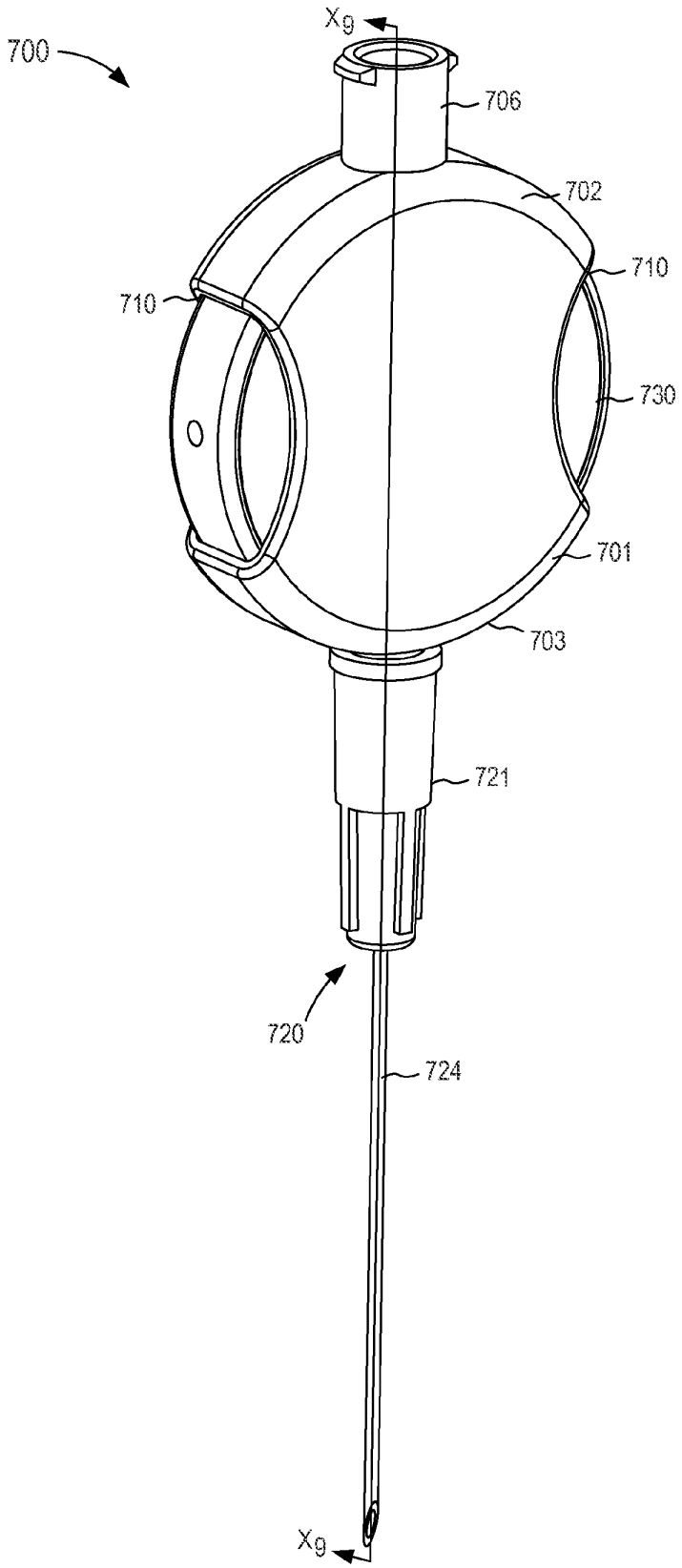


FIG. 31

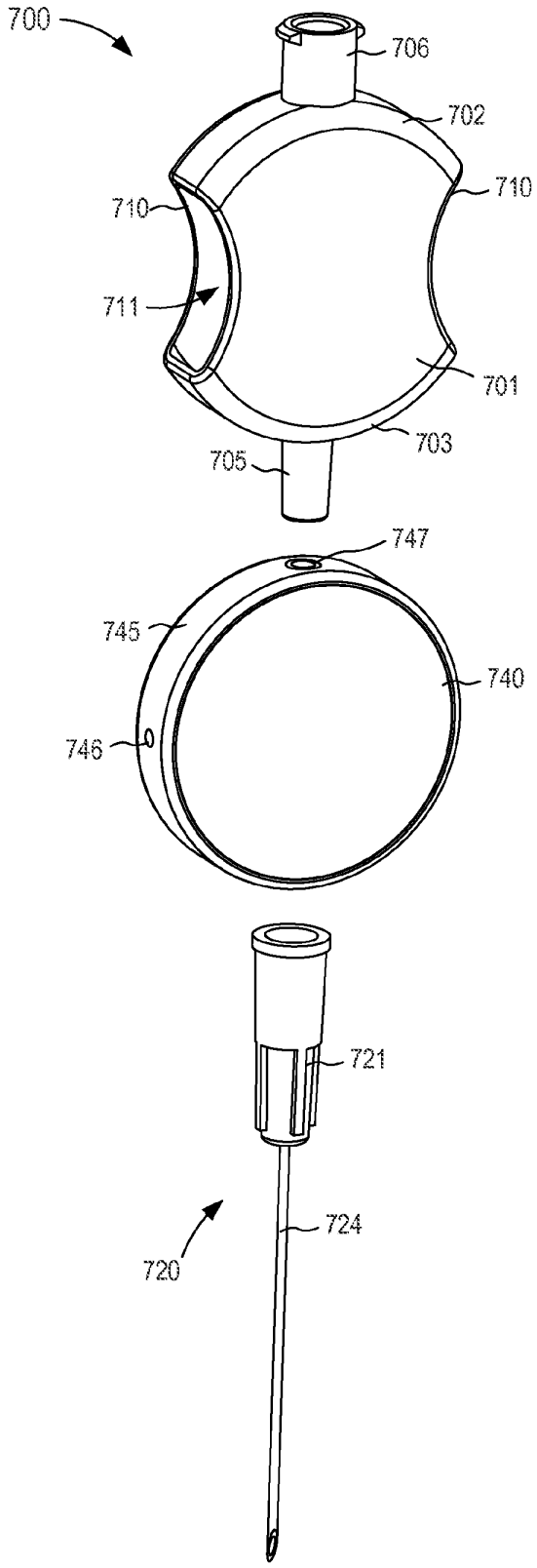


FIG. 32

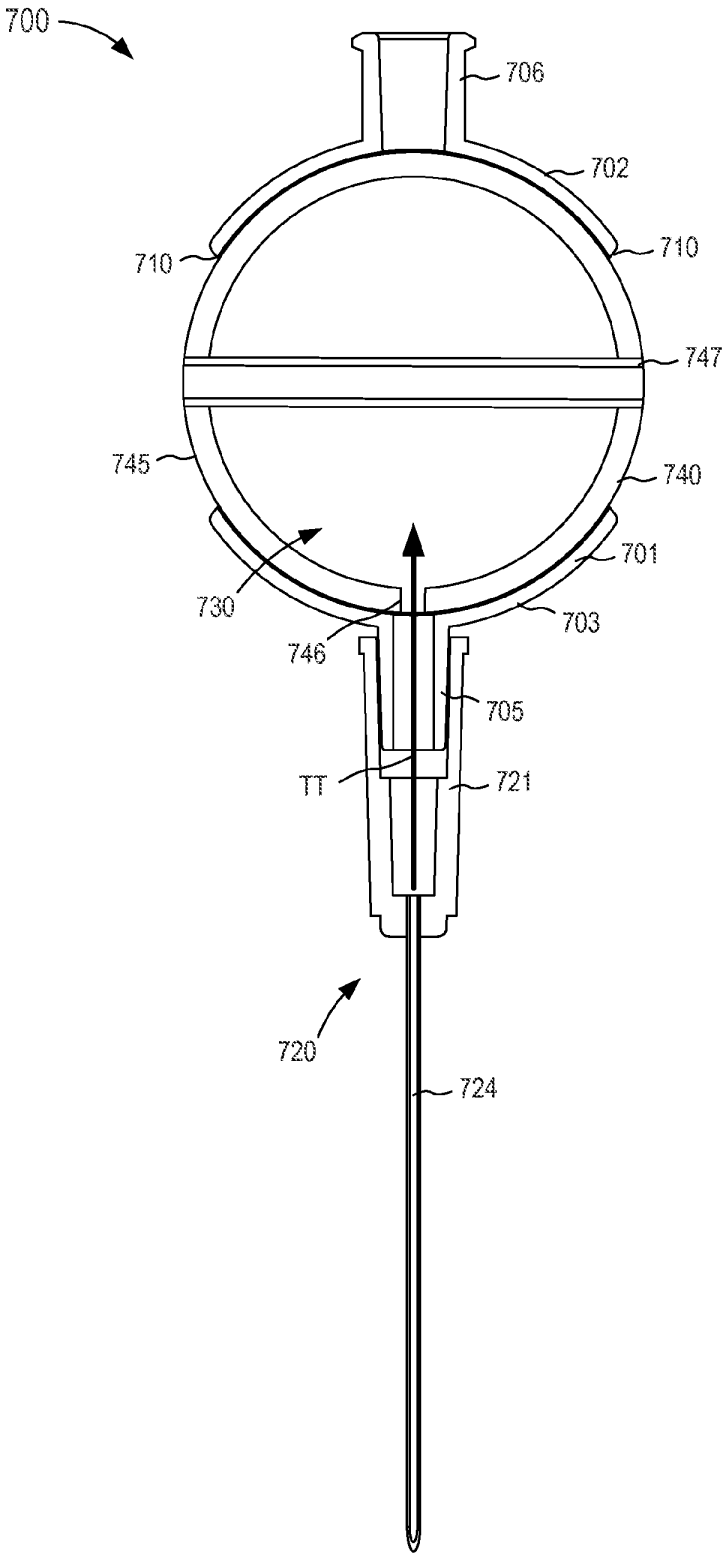

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FIG. 33

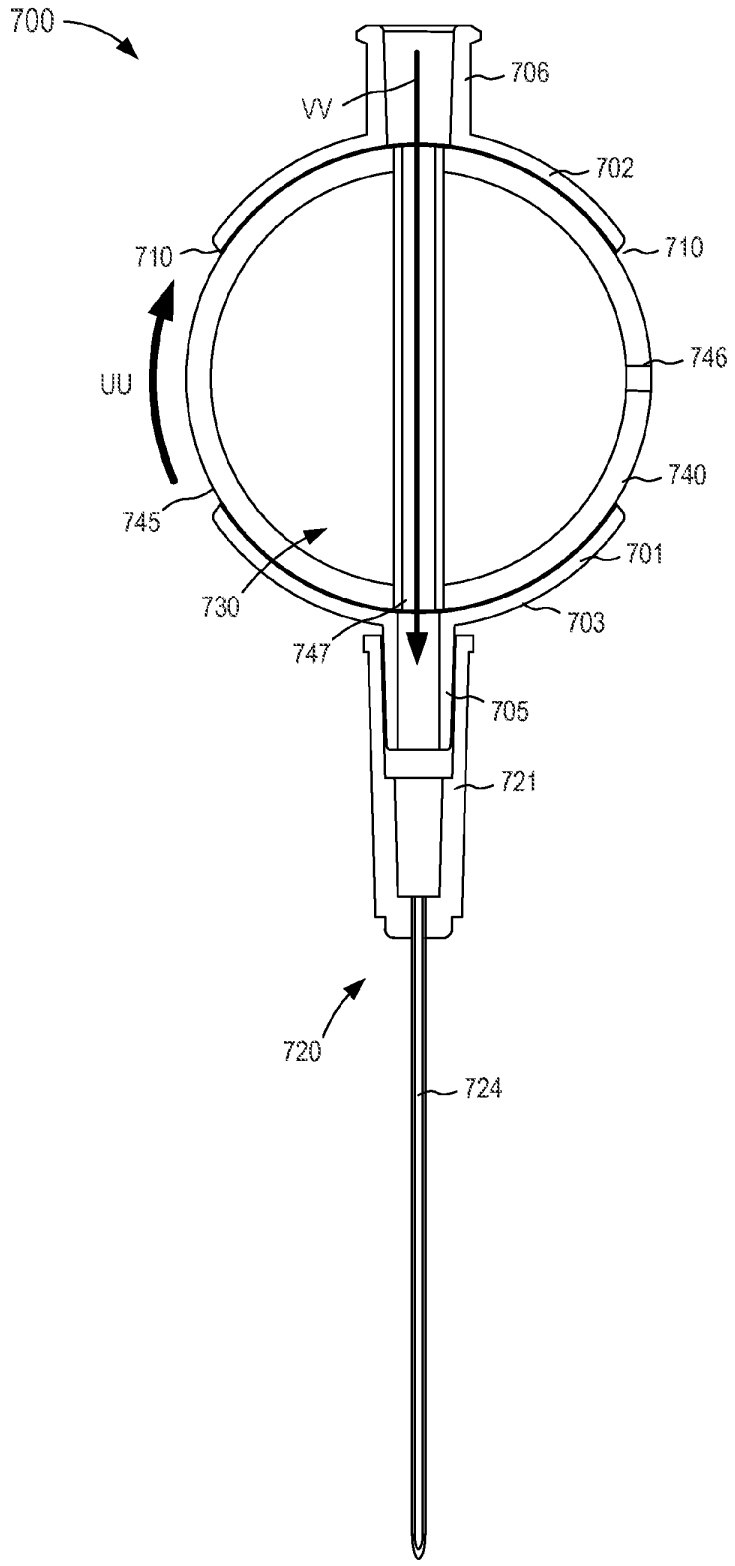

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FIG. 34

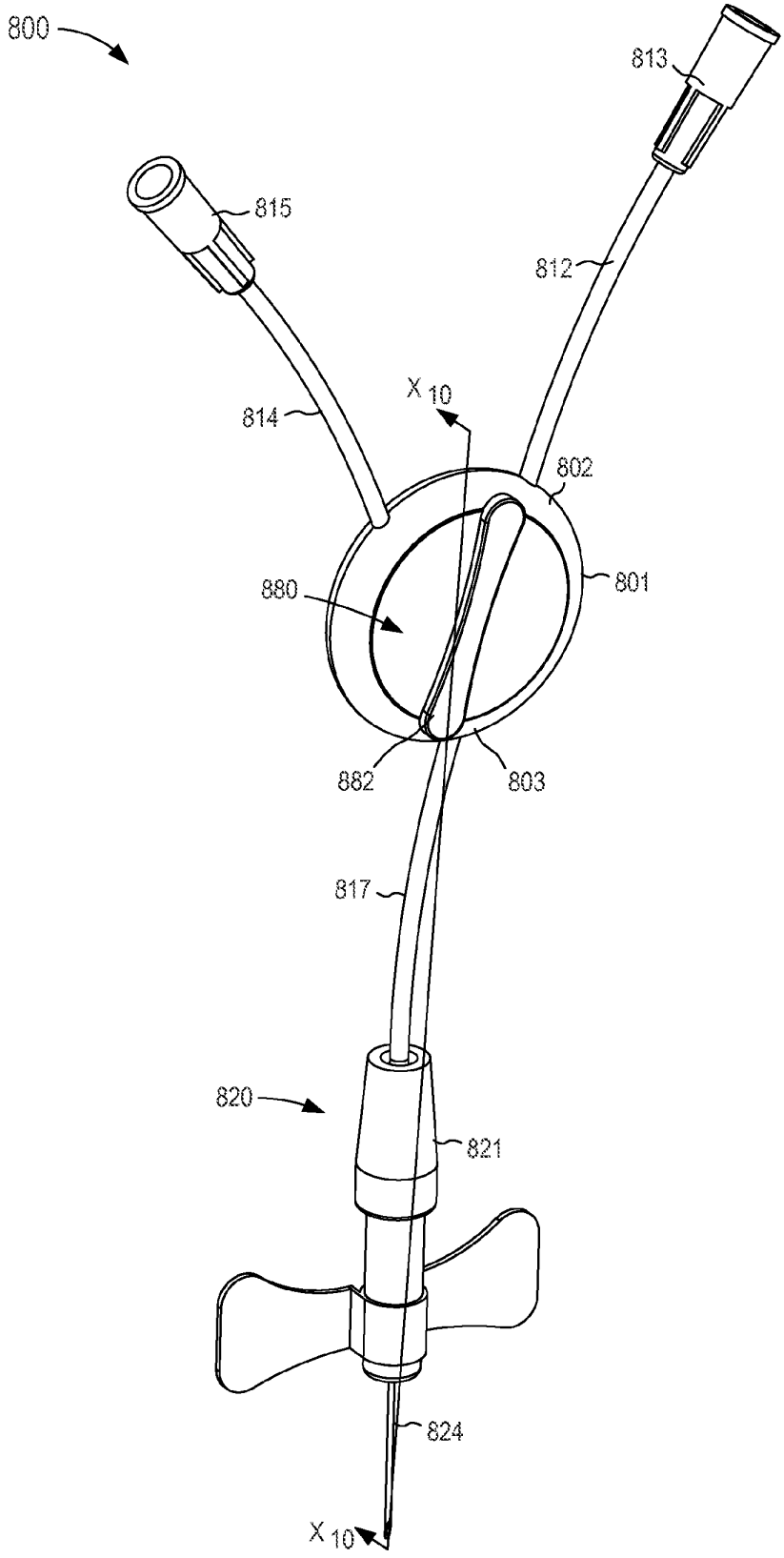


FIG. 35

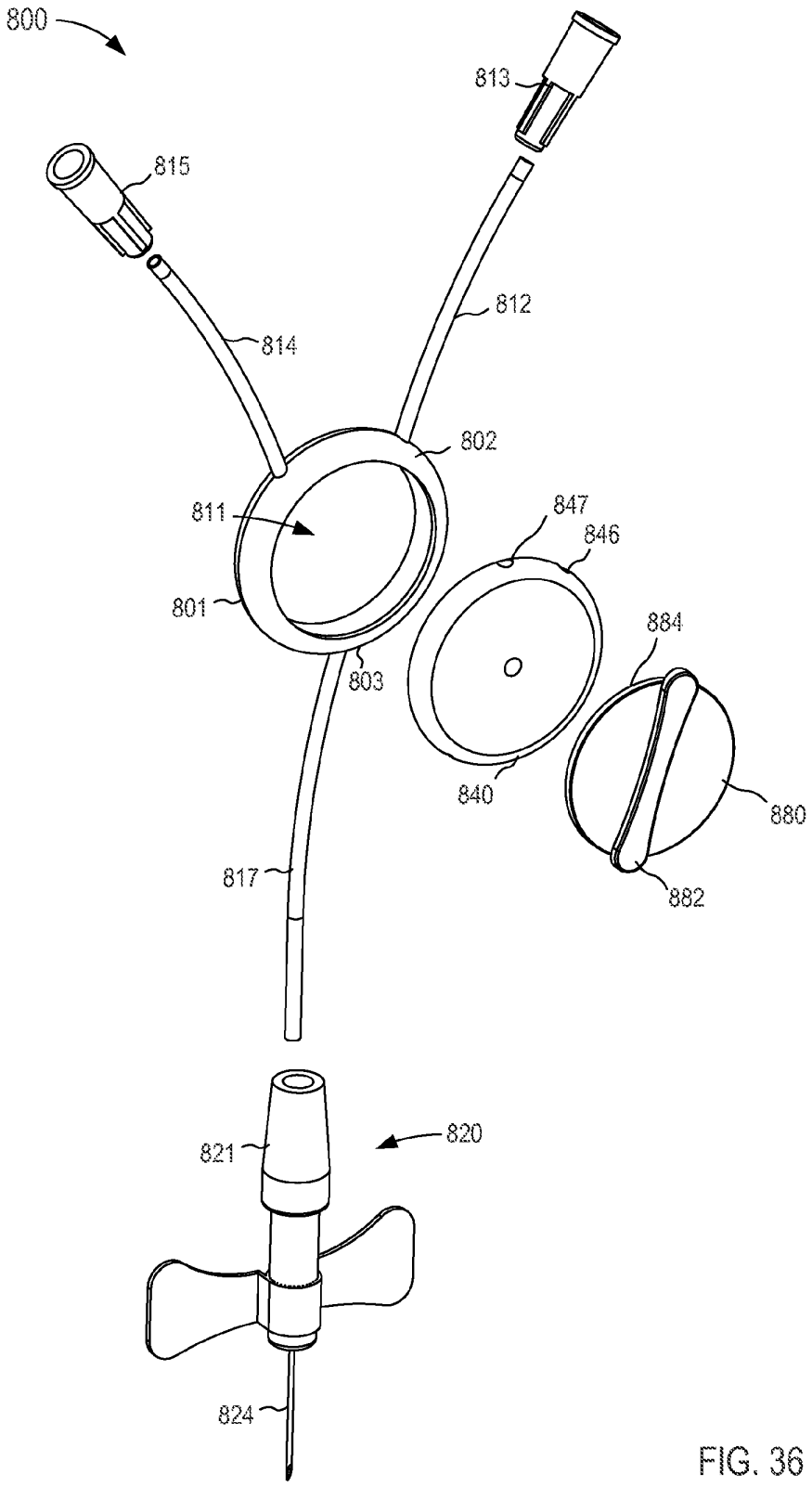

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FIG. 36

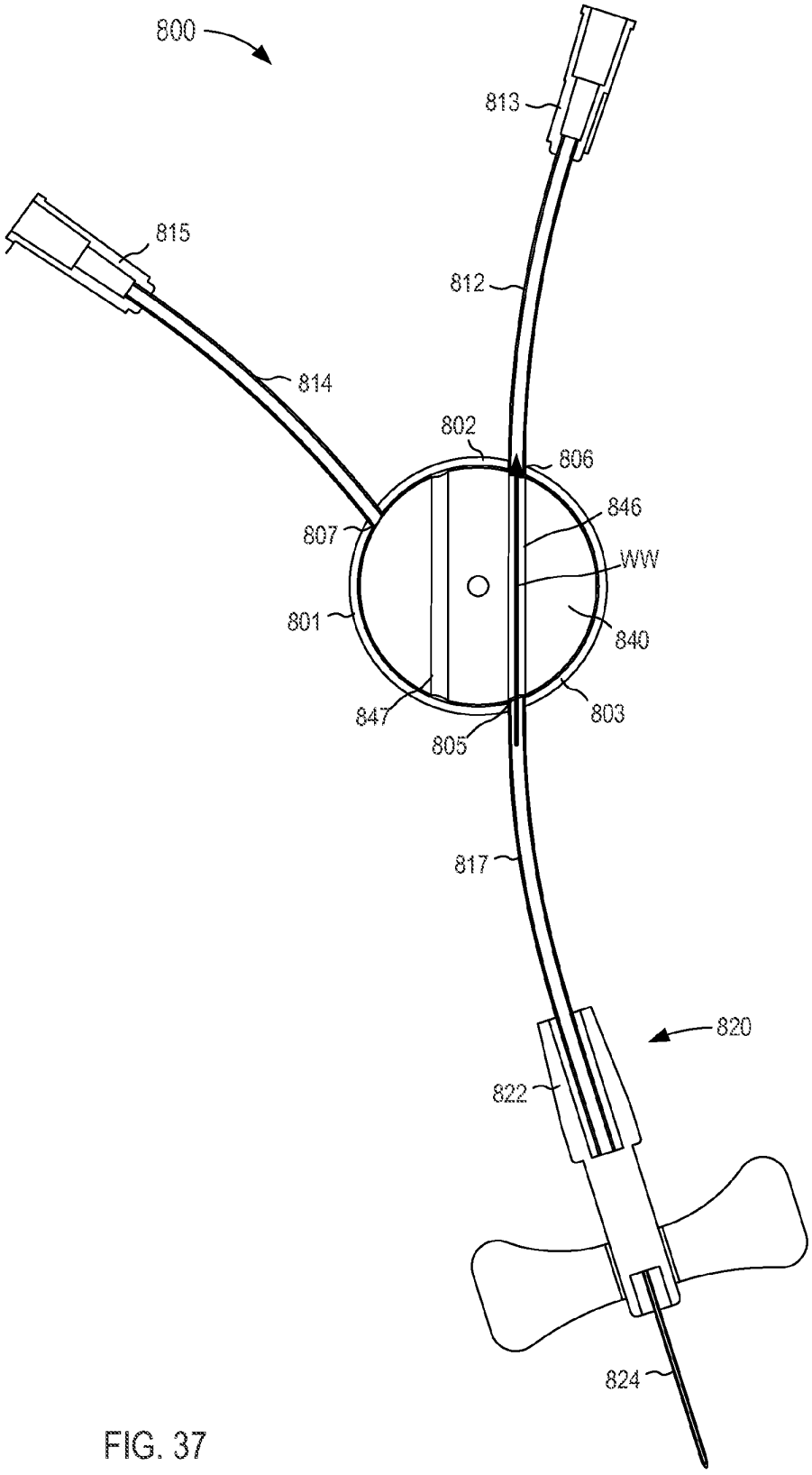

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FIG. 37

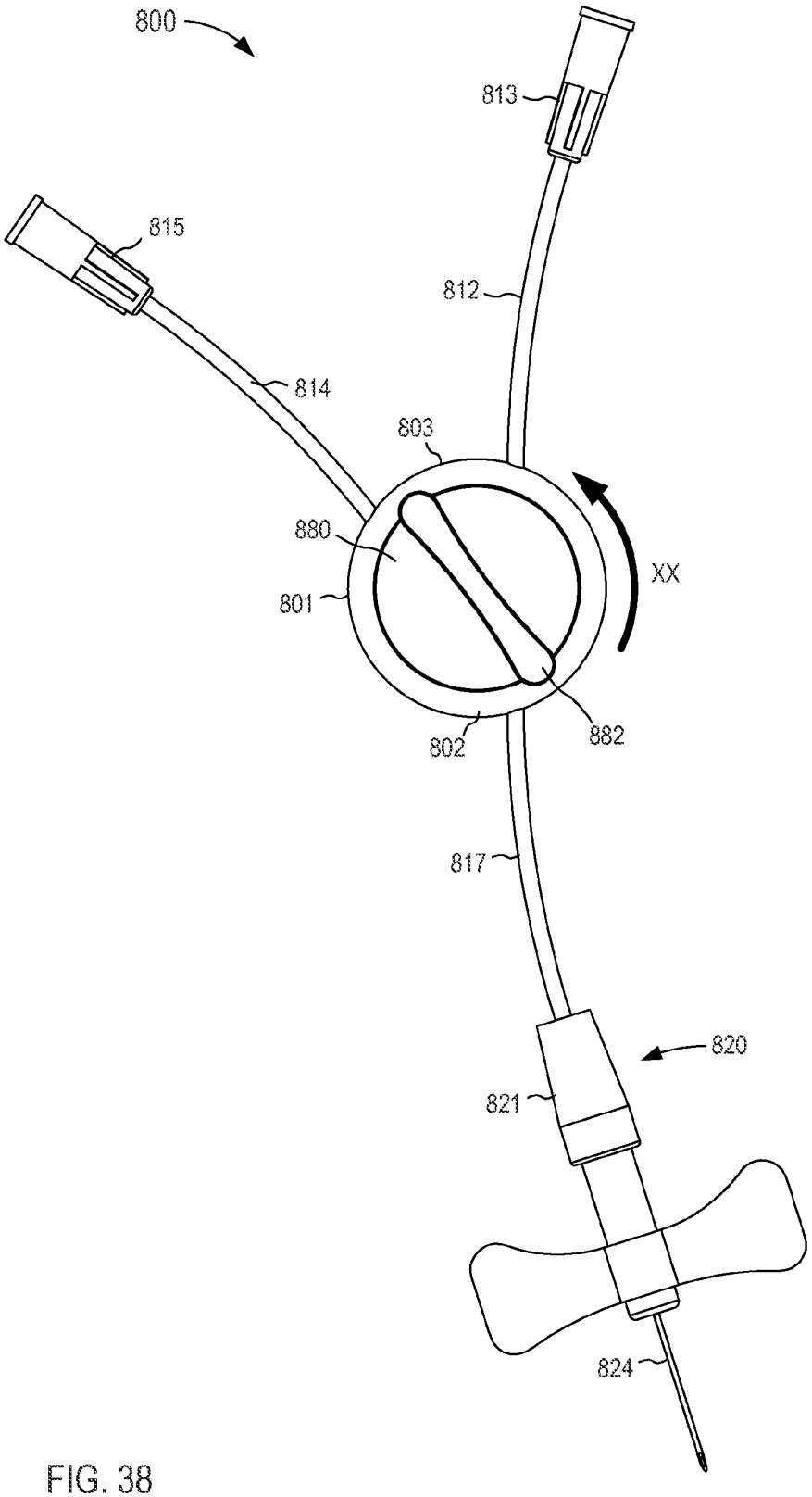


FIG. 38

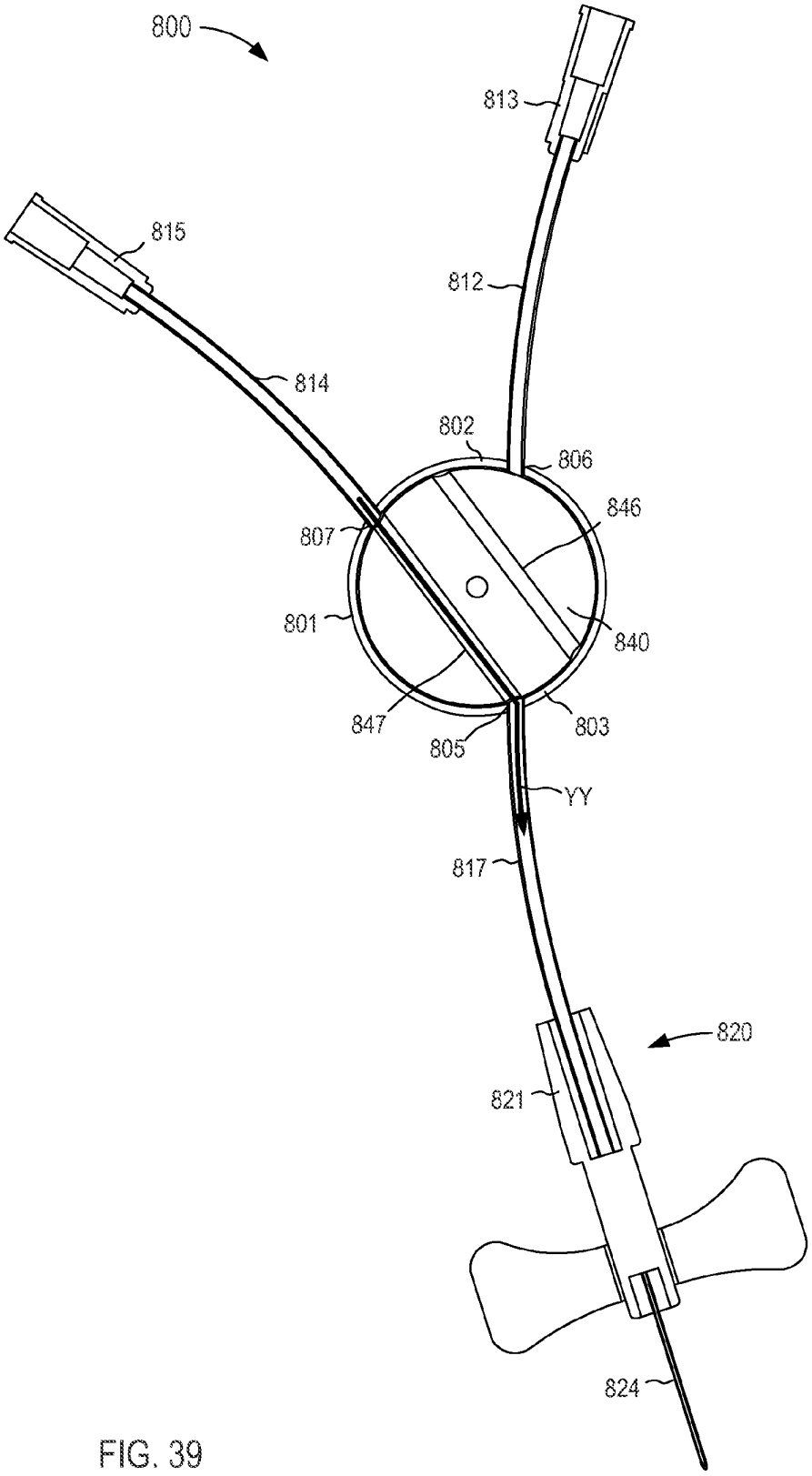

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FIG. 39

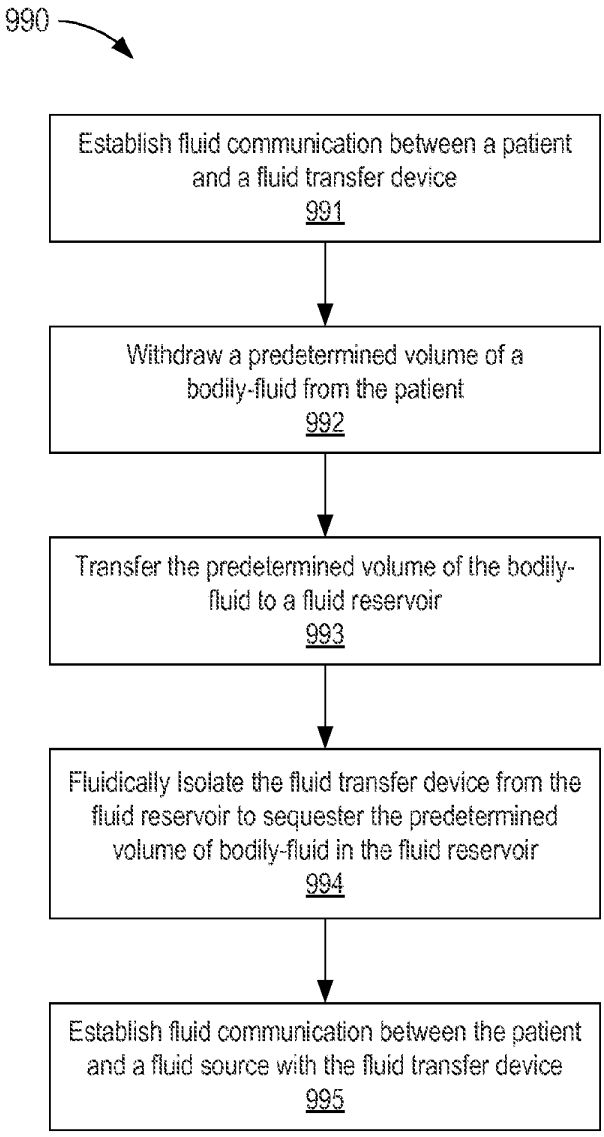

990
Establish fluid communication between a patient and a fluid transfer device
991
Withdraw a predetermined volume of a bodily-fluid from the patient
992
Transfer the predetermined volume of the bodily-fluid to a fluid reservoir
993
Fluidically isolate the fluid transfer device from the fluid reservoir to sequester the predetermined volume of bodily-fluid in the fluid reservoir
994
Establish fluid communication between the patient and a fluid source with the fluid transfer device
995

FIG. 40

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2013/063975

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61B 5/155 (2014.01)
USPC - 600/575
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC(8) - A61B 5/15, 5/155; A61M 1/00, 5/00, 5/31, 5/32, 5/178, 5/315, 25/06; B01L 3/14 (2014.01)
USPC - 600/573, 575, 576, 577, 578, 579; 604/110, 164.01, 164.08, 191, 228, 246, 403, 411

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
CPC - A61B 5/1405, 5/1427, 5/1428 (2013.01)

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
PatBase, Google Patents, Google

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2009/0306601 A1 (SHAW et al) 10 December 2009 (10.12.2009) entire document	1-30, 33, 34
Y	US 2012/0215131 A1 (PATTON) 23 August 2012 (23.08.2012) entire document	1-30, 33, 34
Y	US 5,573,510 A (ISAACSON) 12 November 1996 (12.11.1996) entire document	14-18, 23-27
Y	US 4,988,339 A (VADHER) 29 January 1991 (29.01.1991) entire document	14-17, 28-30
Y	US 2002/0193751 A1 (THEEUWES et al) 19 December 2002 (19.12.2002) entire document	22-30, 33, 34
Y	US 6,016,712 A (WARDEN et al) 25 January 2000 (25.01.2000) entire document	26
Y	US 2003/0208151 A1 (KRAUSE et al) 06 November 2003 (06.11.2003) entire document	33

☐ Further documents are listed in the continuation of Box C. ☐

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
06 March 2014	20 MAR 2014
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer: Blaine R. Copenheaver PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

Form PCT/ISA/210 (second sheet) (July 2009)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2013/063975

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

SEE CONTINUATION SHEET ATTACHED

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
1-34

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.

Form PCT/ISA/210 (continuation of first sheet (2)) (July 2009)

INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.
PCT/US2013/063975

CONTINUATION OF BOX III

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I, claims 1-34 are drawn to an apparatus.

Group II, claims 35-40 are drawn to a method of delivering a fluid to a patient using a fluid transfer device.

The inventions listed as Groups I - II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the special technical features of Group I, housing including a proximal end portion and a distal end portion; a fluid reservoir fluidically coupled to the housing; and a flow control mechanism, are not present in Group II; and the special technical features of Group II, establishing fluid communication between the patient and the fluid transfer device; fluidically isolating the fluid transfer device from the fluid reservoir to sequester the predetermined volume of bodily fluid in the fluid reservoir, are not present in Group I.

Further, Groups I and II share the technical features of a fluid reservoir fluidically coupled and configured to receive and isolate a first volume of bodily fluid withdrawn from a patient.
However, these technical features do not represent a contribution over the prior art. Specifically, US 2011/0306853 A1 to Black et al teaches a body fluid sampling system (10; Abstract; Fig. 2A) comprising a fluid reservoir (18) fluidically coupled to an array of microchannels (16; para. [00060]) and configured to receive and isolate a first volume of bodily fluid withdrawn from a patient (paras. [0061] and [0062]).

Since none of the special technical features of the Groups I - II inventions is found in more than one of the inventions, unity is lacking.

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[Continued on next page]

(54) Title: FLUID DIVERSION MECHANISM FOR BODILY-FLUID SAMPLING

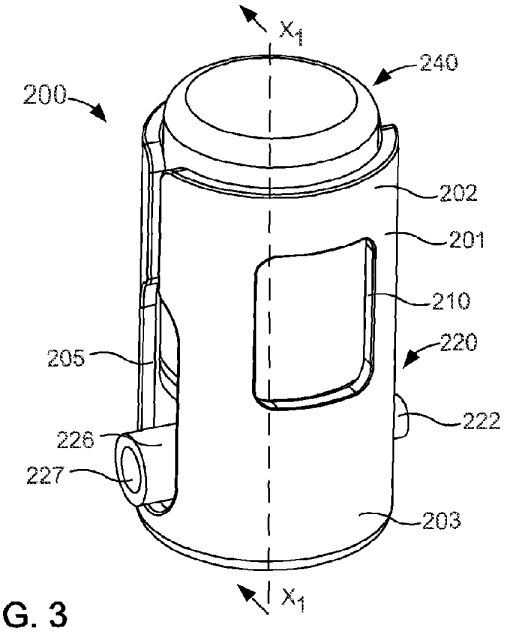


FIG. 3

(57) Abstract: An apparatus includes a housing, a fluid reservoir, a flow control mechanism, and an actuator. The housing defines an inner volume and has an inlet port that can be fluidically coupled to a patient and an outlet port. The fluid reservoir is disposed in the inner volume to receive and isolate a first volume of a bodily-fluid. The flow control mechanism is rotatable in the housing from a first configuration, in which a first lumen places the inlet port is in fluid communication with the fluid reservoir, and a second configuration, in which a second lumen places the inlet port in fluid communication with the outlet port. The actuator is configured to create a negative pressure in the fluid reservoir and is configured to rotate the flow control mechanism from the first configuration to the second configuration after the first volume of bodily-fluid is received in the fluid reservoir.

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FLUID DIVERSION MECHANISM FOR BODILY-FLUID SAMPLING

Cross-Reference to Related Applications

[1001] This application is a continuation-in-part of and claims priority to U.S. Patent Application No. 13/904,691, filed May 29, 2013, entitled "Fluid Diversion Mechanism For Bodily-Fluid Sampling," which claims priority to and the benefit of U.S. Provisional Application No. 61/652,887, filed May 30, 2012, entitled "Fluid Diversion Mechanism for Bodily-Fluid Sampling," both of which are hereby incorporated by reference in their entirety.

[1002] This application also claims priority to and the benefit of U.S. Provisional Application Serial No. 61/652,887, filed May 30, 2012, entitled, "Fluid Diversion Mechanism for Bodily-Fluid Sampling," the disclosure of which is hereby incorporated by reference in its entirety.

Background

[1003] The invention relates generally to the parenteral procurement of bodily-fluid samples, and more particularly to devices and methods for parenterally-procuring bodily-fluid samples with reduced contamination from microbes or other contaminants exterior to the bodily-fluid source, such as dermally-residing microbes.

[1004] Health care practitioners routinely perform various types of microbial tests on patients using parenterally-obtained bodily-fluids. Patient samples (e.g., bodily-fluids) are sometimes tested for the presence of one or more potentially undesirable microbes, such as bacteria, fungi, or yeast (e.g., Candida). Microbial testing may include incubating patient samples in one or more sterile vessels containing culture media that is conducive to microbial growth. Generally, when microbes tested for are present in the patient sample, the microbes flourish over time in the culture medium. After a pre-determined amount of time (e.g., a few hours to several days), the culture medium can be tested for the presence of the microbes. The presence of microbes in the culture medium suggests the presence of the same microbes in the patient sample which, in turn, suggests the presence of the same microbes in the bodily-fluid of the patient from which the sample was obtained. Accordingly, when microbes are determined to be present in the culture medium, the patient may be prescribed one or

more antibiotics or other treatments specifically designed to treat or otherwise remove the undesired microbes from the patient.

[1005] Patient samples, however, can sometimes become contaminated during procurement. One way in which contamination of a patient sample may occur is by the transfer of microbes from a bodily surface (e.g., dermally-residing microbes) dislodged during needle insertion into a patient and subsequently transferred to a culture medium with the patient sample. The bodily surface microbes may be dislodged either directly or via dislodged tissue fragments, hair follicles, sweat glands and other adnexal structures. The transferred microbes may thrive in the culture medium and eventually yield a positive microbial test result, thereby falsely indicating the presence of such microbes in vivo. Such inaccurate results are a concern when attempting to diagnose or treat a suspected illness or condition. For example, false positive results from microbial tests may result in the patient being unnecessarily subjected to one or more anti-microbial therapies, which may cause serious side effects to the patient including, for example, death, as well as produce an unnecessary burden and expense to the health care system.

[1006] As such, a need exists for improved bodily-fluid transfer devices and methods that reduce microbial contamination in bodily-fluid test samples.

Summary

[1007] Devices for parenterally-procuring bodily-fluid samples with reduced contamination from microbes exterior to the bodily-fluid source, such as dermally-residing microbes, are described herein. In some embodiments, a device for procuring bodily-fluid samples from a patient includes a housing, a fluid reservoir, a flow control mechanism, and an actuator. The housing includes a proximal end portion and a distal end portion and defines an inner volume therebetween. The housing has an inlet port that is configured to be fluidically coupled to a patient and an outlet port that is configured to be fluidically coupled to a sample reservoir. The fluid reservoir is disposed within the inner volume of the housing and is configured to receive and isolate a first volume of a bodily-fluid withdrawn from the patient. The flow control mechanism defines a first lumen and a second lumen and is disposed in the housing for rotational movement from a first configuration, in which the inlet port is placed in fluid communication with the fluid reservoir such that the bodily-fluid can

flow from the inlet port, through the first lumen, and to the fluid reservoir, to a second configuration, in which the inlet port is placed in fluid communication with the outlet port such that the bodily-fluid can flow from the inlet, through the second lumen and to the outlet port. The actuator is configured to create a negative pressure in the fluid reservoir when actuated by a user. The actuator is operably coupled to the flow control mechanism and is configured to rotate the flow control mechanism from the first configuration to the second configuration after the first volume of bodily-fluid is received in the fluid reservoir from the patient.

Brief Description of the Drawings

[1008] FIG. 1 is a schematic illustration of a bodily-fluid transfer device according to an embodiment.

[1009] FIG. 2 is a front view of a bodily-fluid transfer device according to an embodiment.

[1010] FIG. 3 is a perspective view of the bodily-fluid transfer device of FIG. 2.

[1011] FIG. 4 is an exploded view of the bodily-fluid transfer device of FIG. 2.

[1012] FIG. 5 is a perspective view of a housing included in the bodily-fluid transfer device illustrated in FIG. 2.

[1013] FIG. 6 is a cross-sectional view of the housing illustrated in FIG. 5 taken along the line X_2-X_2.

[1014] FIG. 7 is a perspective view of a diverter included in the bodily-fluid transfer device of FIG. 2.

[1015] FIG. 8 is a cross-sectional view of the diverter illustrated in FIG. 8 taken along the line X_3-X_3.

[1016] FIG. 9 is a perspective view of a flow control mechanism included in the bodily-fluid transfer device of FIG. 2.

[1017] FIG. 10 is an exploded view of an actuator mechanism included in the bodily-fluid transfer device of FIG. 2.

[1018] FIG. 11 is a cross-sectional view of the bodily-fluid transfer device of FIG. 2 taken along the line X_1-X_1, in a first configuration.

[1019] FIG. 12 is a cross-sectional view of the bodily-fluid transfer device of FIG. 2 taken along the line X_1-X_1, in a second configuration.

[1020] FIG. 13 is a front view of a bodily-fluid transfer device according to an embodiment.

[1021] FIG. 14 is a perspective view of the bodily-fluid transfer device of FIG. 13.

[1022] FIG. 15 is an exploded view of the bodily-fluid transfer device of FIG. 13.

[1023] FIG. 16 is a cross-sectional view of a housing included in the bodily-fluid transfer device of FIG. 13 taken along the line X_5-X_5 in FIG. 14.

[1024] FIG. 17 is a cross-sectional view of the bodily-fluid transfer device taken along the line X_4-X_4 in FIG. 14, in a first configuration.

[1025] FIG. 18 is a perspective view of the bodily-fluid transfer device of FIG. 13, in a second configuration.

[1026] FIG. 19 is a cross-sectional view of the bodily-fluid transfer device of FIG. 18 taken along the line X_6-X_6.

[1027] FIG. 20 is a front view of a bodily-fluid transfer device according to an embodiment.

[1028] FIG. 21 is a perspective view of the bodily-fluid transfer device of FIG. 20.

[1029] FIG. 22 is an exploded view of the bodily-fluid transfer device of FIG. 20.

[1030] FIG. 23 is a cross-sectional view of a housing included in the bodily-fluid transfer device of FIG. 20 taken along the line X_8-X_8 in FIG. 21.

[1031] FIG. 24 is a perspective view of a first control member and a second control member included in a flow control mechanism of the bodily-fluid transfer device of FIG. 20.

[1032] FIG. 25 is a cross-sectional view of the bodily-fluid transfer device of FIG. 20 taken along the line X_7-X_7 in FIG. 21, in a first configuration.

[1033] FIG. 26 is a perspective view of the bodily-fluid transfer device of FIG. 20, in a second configuration.

[1034] FIG. 27 is a cross-sectional view of the bodily-fluid transfer device of FIG. 25 taken along the line X_9-X_9.

[1035] FIGS. 28 and 29 schematic illustrations of a bodily-fluid transfer device according to an embodiment, in a first and second configuration, respectively.

[1036] FIG. 30 is a perspective view of a bodily-fluid transfer device according to an embodiment.

[1037] FIG. 31 is an exploded perspective view of the bodily-fluid transfer device of FIG. 30.

[1038] FIG. 32 is a perspective view of a housing included in the bodily-fluid transfer device of FIG. 30.

[1039] FIG. 33 is a cross-sectional view of the housing illustrated in FIG. 32 taken along the line X_{11}-X_{11}.

[1040] FIG. 34 is a perspective view of a diverter included in the bodily-fluid transfer device of FIG. 30.

[1041] FIG. 35 is a cross-sectional view of the diverter illustrated in FIG. 34 taken along the line X_{12}-X_{12}.

[1042] FIG. 36 is a perspective view of a portion of a flow control mechanism included in the bodily-fluid transfer device of FIG. 30.

[1043] FIG. 37 is a cross-sectional view of the portion of the flow control mechanism illustrated in FIG. 36 taken along the line X_{13}-X_{13}.

[1044] FIGS. 38-41 are cross-sectional views of the bodily-fluid transfer device of FIG. 32 taken along the line X_{10}-X_{10}, in a first, second, third, and fourth configuration, respectively.

[1045] FIG. 42 is a perspective view of a bodily-fluid transfer device according to an embodiment.

[1046] FIG. 43 is an exploded perspective view of the bodily-fluid transfer device of FIG. 42.

[1047] FIG. 44 is a perspective exploded view of a flow control mechanism included in the bodily-fluid transfer device of FIG. 42.

[1048] FIGS. 45 and 46 are cross-sectional views of the bodily-fluid transfer device of FIG. 42 taken along the line X_{14}-X_{14}, in a first configuration and a second configuration, respectively.

[1049] FIG. 47 is a flowchart illustrating a method for parenterally procuring a bodily-fluid sample that is substantially free from microbes.

Detailed Description

[1050] Devices for parenterally procuring bodily-fluid samples with reduced contamination from microbes exterior to the bodily-fluid source, such as dermally-residing microbes, are described herein. In some embodiments, a device for procuring bodily-fluid samples from a patient includes a housing, a fluid reservoir, a flow control mechanism, and an actuator. The housing includes a proximal end portion and a distal end portion and defines an inner volume therebetween. The housing has an inlet port that is configured to be fluidically coupled to a patient and an outlet port that is configured to be fluidically coupled to a sample reservoir. The fluid reservoir is disposed within the inner volume of the housing and is configured to receive and isolate a first volume of a bodily-fluid withdrawn from the patient. The flow control mechanism defines a first lumen and a second lumen and is disposed in the housing for rotational movement from a first configuration, in which the inlet port is placed in fluid communication with the fluid reservoir such that the bodily-fluid can flow from the inlet port, through the first lumen, and to the fluid reservoir, to a second configuration, in which the inlet port is placed in fluid communication with the outlet port

such that the bodily-fluid can flow from the inlet, through the second lumen and to the outlet port. The actuator is configured to create a negative pressure in the fluid reservoir when actuated by a user. The actuator is operably coupled to the flow control mechanism and is configured to rotate the flow control mechanism from the first configuration to the second configuration after the first volume of bodily-fluid is received in the fluid reservoir from the patient.

[1051] In some embodiments, a device for procuring bodily-fluid samples from a patient includes a housing, an actuator, a diverter, and a flow control mechanism. The housing has a proximal end portion and a distal end portion and defines an inner volume therebetween. The actuator is movably disposed in the housing. The actuator includes a sealing member and a fluid reservoir defined, at least in part, by the sealing member. The actuator is configured to create a negative pressure in the fluid reservoir when actuated by a user. The diverter is disposed in the housing and has an inlet port that is configured to be fluidically coupled to the patient, a first outlet port that is configured to be fluidically coupled to the fluid reservoir, and a second outlet port that is configured to be fluidically coupled to a sample reservoir. The flow control mechanism defines a first lumen and a second lumen. The flow control mechanism is disposed in the diverter and is rotatable from a first configuration, in which the inlet port is placed in fluid communication with the first outlet port such that bodily-fluid can flow from the inlet port, through the first lumen and to the first outlet port, to a second configuration, in which the inlet port is placed in fluid communication with the second outlet port such that the bodily-fluid can flow from the inlet, through the second lumen and to the second outlet port.

[1052] In some embodiments, a device for procuring bodily-fluid samples from a patient includes a housing, a flow control mechanism, and an actuator. The housing has a proximal end portion and a distal end portion and defines an inner volume therebetween. The housing has an inlet port configured to be fluidically coupled to the patient and an outlet port configured to be fluidically coupled to a sample reservoir. The flow control mechanism defines a first lumen and a second lumen. The flow control mechanism is disposed in the housing and is rotatable between a first configuration, in which the inlet port is placed in fluid communication with a fluid reservoir defined, at least in part, by the housing such that bodily-fluid can flow from the inlet port, through the first lumen and to the fluid reservoir, to a second configuration, in which the inlet port is placed in fluid communication with the

outlet port such that the bodily-fluid can flow from the inlet, through the second lumen and to the outlet port. The actuator is movably disposed in the housing and is operably coupled to the flow control mechanism. The actuator is configured to create a negative pressure in the fluid reservoir when actuated by the user. The actuator is further configured to rotate the flow control mechanism from the first configuration to the second configuration after a first volume of bodily-fluid is received in the fluid reservoir from the patient.

[1053] In some embodiments, a device for procuring bodily-fluid samples from a patient includes a housing, a seal member, a fluid reservoir, a flow control mechanism, and an actuator. The housing has a proximal end portion and a distal end portion and defines an inner volume therebetween. The housing has an inlet port configured to be fluidically coupled to the patient. The seal member is movably disposed in the inner volume and is configured to define, at least partially, the fluid reservoir disposed in the inner volume. The fluid reservoir is configured to receive and isolate a first volume of bodily-fluid withdrawn from the patient. The flow control mechanism is movably disposed in the housing and is configured to move between a first configuration, in which the bodily-fluid can flow from the inlet port, through the flow control mechanism and to the fluid reservoir, to a second configuration, in which the fluid reservoir is fluidically isolated from the inlet port. The actuator is operably coupled to the seal member and the flow control mechanism. The actuator includes a spring configured to move the seal member from a first position to a second position to create a negative pressure in the fluid reservoir. The actuator is configured to move the flow control mechanism from the first configuration to the second configuration after a first volume of bodily-fluid is received in the fluid reservoir from the patient.

[1054] In some embodiments, a device for procuring bodily-fluid samples from a patient includes a housing, a flow control mechanism, and an actuator. The housing has a proximal end portion and a distal end portion and defines an inner volume therebetween. The housing has an inlet port configured to be fluidically coupled to the patient and an outlet port configured to be fluidically coupled to a sample reservoir. The flow control mechanism is disposed in the housing and includes a first control member and a second control member. The second control member defines a first lumen and a second lumen and is rotatably movable between a first configuration, in which the inlet port is placed in fluid communication with a fluid reservoir defined, at least in part, by the housing such that bodily-fluid can flow from the inlet port, through the first lumen and to the fluid reservoir, to

a second configuration, in which the inlet port is placed in fluid communication with the outlet port such that the bodily-fluid can flow from the inlet, through the second lumen and to the outlet port. The actuator is movably disposed in the housing and is operably coupled to the flow control mechanism. The actuator is configured to create a negative pressure in the fluid reservoir when actuated by the user. The actuator is further configured to rotate the second control member from the first configuration to the second configuration after a first volume of bodily-fluid is received in the fluid reservoir from the patient.

[1055] In some embodiments, a device for procuring bodily-fluid samples from a patient includes a diverter, a flow control mechanism, and an actuator mechanism. The diverter defines an inlet port, a first outlet port, and a second outlet port. The first outlet port is fluidically coupled to a first fluid reservoir and the second outlet port is fluidically coupled to a second reservoir, fluidically isolated from the first fluid reservoir. The flow control mechanism is configured to be disposed, at least partially within the diverter. The actuator mechanism is configured to engage the flow control mechanism to move the flow control mechanism between a first configuration, in which a flow of bodily-fluid can enter the first fluid reservoir, and a second configuration, in which a flow of bodily-fluid can enter the second fluid reservoir.

[1056] In some embodiments, a bodily-fluid transfer device can be configured to selectively divert a first, predetermined amount of a flow of a bodily-fluid to a first reservoir before permitting the flow of a second amount of the bodily-fluid into a second reservoir. In this manner, the second amount of bodily-fluid can be used for diagnostic or other testing, while the first amount of bodily-fluid, which may contain microbes from a bodily surface, is isolated from the bodily-fluid to be tested. The first amount of bodily-fluid can be subsequently used for different types of testing (e.g., CBC, other blood chemistry tests) or can be simply sequestered.

[1057] In some embodiments, a bodily-fluid transfer device is configured to automatically move from a first configuration to a second configuration, for example, without requiring an input or other action by a health care practitioner. In some embodiments, the bodily-fluid transfer device prevents bodily-fluid from flowing or otherwise being introduced into a second reservoir before at least a first amount of bodily-fluid (e.g., a predetermined amount) is first introduced into a first reservoir.

[1058] In some embodiments, a method for procuring a bodily-fluid sample using a parenteral sampling device that has a needle with a lumen and a fluid reservoir fluidically coupled to the needle includes inserting the needle of the device into a patient. The method includes establishing fluid communication between the needle and the fluid reservoir. An actuator is moved a first distance to create a negative pressure in the fluid reservoir to withdraw a predetermined volume of the bodily-fluid. The actuator is moved a second distance to engage a flow control mechanism and rotate the flow control mechanism from a first configuration to a second configuration. The first configuration is operable in allowing bodily-fluid to flow through a first flow path from the needle to the fluid reservoir and the second configuration is operable in allowing bodily-fluid to flow through a second flow path from the needle to a sample reservoir.

[1059] As used in this specification, "bodily-fluid" can include any fluid obtained from a body of a patient, including, but not limited to, blood, cerebrospinal fluid, urine, bile, lymph, saliva, synovial fluid, serous fluid, pleural fluid, amniotic fluid, and the like, or any combination thereof.

[1060] As used herein, the term "set" can refer to multiple features or a singular feature with multiple parts. For example, when referring to set of walls, the set of walls can be considered as one wall with distinct portions, or the set of walls can be considered as multiple walls. Similarly stated, a monolithically constructed item can include a set of walls. Such a set of walls can include, for example, multiple portions that are in discontinuous from each other. A set of walls can also be fabricated from multiple items that are produced separately and are later joined together (e.g., via a weld, an adhesive or any suitable method).

[1061] As used herein, the words "proximal" and "distal" refer to the direction closer to and away from, respectively, a user who would place the device into contact with a patient. Thus, for example, the end of a device first touching the body of the patient would be the distal end, while the opposite end of the device (e.g., the end of the device being manipulated by the user) would be the proximal end of the device.

[1062] As used herein, the singular forms "a," "an" and "the" include plural referents unless the context clearly dictates otherwise. Thus, for example, the term "an engagement surface" is intended to mean a single surface or multiple surfaces unless explicitly expressed otherwise.

[1063] FIG. 1 is a schematic illustration of a portion of a bodily-fluid transfer device 100, according to an embodiment. Generally, the bodily-fluid transfer device 100 (also referred to herein as "fluid transfer device" or "transfer device") is configured to permit the withdrawal of bodily-fluid from a patient such that a first portion or amount of the withdrawn fluid is diverted away from a second portion or amount of the withdrawn fluid that is to be used as a biological sample, such as for testing for the purpose of medical diagnosis and/or treatment. In other words, the transfer device 100 is configured to transfer a first, predetermined amount of a bodily-fluid to a first collection reservoir and a second amount of bodily-fluid to one or more bodily-fluid collection reservoirs fluidically isolated from the first collection reservoir, as described in more detail herein.

[1064] The transfer device 100 includes a diverter 120, a first reservoir 170, and a second reservoir 180, different from the first reservoir 170. The diverter 120 includes an inlet port 122 and two or more outlet ports, such as a first outlet port 124 and a second outlet port 126 shown in FIG. 1. The inlet port 122 is configured to be fluidically coupled to a medical device defining a pathway **P** for withdrawing and/or conveying the bodily-fluid from the patient to the transfer device 100. For example, the inlet port 122 can be fluidically coupled to a needle or other lumen-containing device (e.g., flexible sterile tubing). In this manner, the diverter 120 can receive the bodily-fluid from the patient via the needle or other lumen-containing device.

[1065] The first outlet port 124 of the diverter 120 is configured to be fluidically coupled to the first reservoir 170. In some embodiments, the first reservoir 170 is monolithically formed with the first outlet port 124 and/or a portion of the diverter 120. In other embodiments, the first reservoir 170 can be mechanically and fluidically coupled to the diverter 120 via an adhesive, a resistance fit, a mechanical fastener, any number of mating recesses, a threaded coupling, and/or any other suitable coupling or combination thereof. Similarly stated, the first reservoir 170 can be physically (e.g., mechanically) coupled to the diverter 120 such that an interior volume defined by the first reservoir 170 is in fluid communication with the first outlet port 120 of the diverter 120. In still other embodiments, the first reservoir 170 can be operably coupled to the first outlet port 124 of the diverter 120 via an intervening structure (not shown in FIG. 1), such as a flexible sterile tubing. More particularly, the intervening structure can define a lumen configured to place the first reservoir 170 in fluid communication with the first outlet port 124.

[1066] The first reservoir 170 is configured to receive and contain the first, predetermined amount of the bodily-fluid. In some embodiments, the first reservoir 170 is configured to contain the first amount of the bodily-fluid such that the first amount is fluidically isolated from a second amount of the bodily-fluid (different from the first amount of bodily-fluid) that is subsequently withdrawn from the patient. The first reservoir 170 can be any suitable reservoir for containing a bodily-fluid, such as a pre-sample reservoir described in detail in U.S. Patent No. 8,197,420 ("the '420 Patent"), the disclosure of which is incorporated herein by reference in its entirety. As used in this specification, the terms "first, predetermined amount" and "first amount" describe an amount of bodily-fluid configured to be received or contained by the first reservoir 170. Furthermore, while the term "first amount" does not explicitly describe a predetermined amount, it should be understood that the first amount is the first, predetermined amount unless explicitly described differently.

[1067] The second outlet port 126 of the diverter 120 is configured to be fluidically coupled to the second reservoir 180. In some embodiments, the second reservoir 180 is monolithically formed with the second outlet port 126 and/or a portion of the diverter 120. In other embodiments, the second reservoir 180 can be mechanically coupled to the second outlet port 126 of the diverter 120 or operably coupled to the second outlet port 126 via an intervening structure (not shown in FIG. 1), such as described above with reference to the first reservoir 170. The second reservoir 180 is configured to receive and contain the second amount of the bodily-fluid. For example, the second amount of bodily-fluid can be an amount withdrawn from the patient subsequent to withdrawal of the first amount. In some embodiments, the second reservoir 180 is configured to contain the second amount of the bodily-fluid such that the second amount is fluidically isolated from the first amount of the bodily-fluid.

[1068] The second reservoir 170 can be any suitable reservoir for containing a bodily-fluid, including, for example, a sample reservoir as described in the '420 Patent incorporated by reference above. As used in this specification, the term "second amount" describes an amount of bodily-fluid configured to be received or contained by the second reservoir 180. In some embodiments, the second amount can be any suitable amount of bodily-fluid and need not be predetermined. In other embodiments, the second amount received and contained by the second reservoir 180 is a second predetermined amount.

[1069] In some embodiments, the first reservoir 170 and the second reservoir 180 can be coupled to (or formed with) the diverter 120 in a similar manner. In other embodiments, the first reservoir 170 and the second reservoir need not be similarly coupled to the diverter 120. For example, in some embodiments, the first reservoir 170 can be monolithically formed with the diverter 120 (e.g., the first outlet port 124) and the second reservoir 180 can be operably coupled to the diverter 120 (e.g., the second outlet port 126) via an intervening structure, such as a flexible sterile tubing.

[1070] As shown in FIG. 1, the transfer device 100 further includes an actuator 140 and a flow control mechanism 130 defining a first channel 138 and a second channel 139. In some embodiments, the actuator 140 can be included in or otherwise operably coupled to the diverter 120. In this manner, the actuator 140 can be configured to control a movement of the flow control mechanism 130 (e.g., between a first configuration and a second configuration). For example, the actuator 140 can be movable between a first position corresponding to the first configuration of the flow control mechanism 130, and a second position, different from the first position, corresponding to the second configuration of the flow control mechanism 130. In some embodiments, the actuator 140 is configured for uni-directional movement. For example, the actuator 140 can be moved from its first position to its second position, but cannot be moved from its second position to its first position. In this manner, the flow control mechanism 130 is prevented from being moved to its second configuration before its first configuration, thus requiring that the first amount of the bodily-fluid be directed to the first reservoir 170 and not the second reservoir 180.

[1071] The flow control mechanism 130 is configured such that when in the first configuration, the first channel 138 fluidically couples the inlet port 122 to the first outlet port 124 and when in the second configuration, the second channel 139 fluidically couples the inlet portion 122 to the second outlet port 126. In some embodiments, the actuator 140 is coupled to the flow control mechanism 130 and is configured to move the flow control mechanism 130 in a translational motion between the first configuration and the second configuration. For example, in some embodiments, the flow control mechanism 130 can be in the first configuration when the flow control mechanism 130 is in a distal position relative to the transfer device 100. In such embodiments, the actuator 140 can be actuated to move the flow control device 130 in the proximal direction to a proximal position relative to the transfer device 100, thereby placing the flow control mechanism 130 in the second

configuration. In other embodiments, the actuator 140 can be actuated to move the flow control mechanism 130 in a rotational motion between the first configuration and the second configuration.

[1072] Accordingly, when the flow control mechanism 130 is in the first configuration, the second outlet port 126 is fluidically isolated from the inlet port 122. Similarly, when the flow control mechanism 130 is in the second configuration, the first outlet port 124 is fluidically isolated from the inlet port 122. In this manner, the flow control mechanism 130 can direct, or divert the first amount of the bodily-fluid to the first reservoir 170 via the first outlet port 124 when the flow control mechanism 130 is in the first configuration and can direct, or divert the second amount of the bodily-fluid to the second reservoir 180 via the second outlet port 126 when the flow control mechanism 130 is in the second configuration.

[1073] In some embodiments, at least a portion of the actuator 140 can be operably coupled to the first reservoir 170. In this manner, the actuator 140 (or at least the portion of the actuator 140) can be configured to cause a vacuum within the first reservoir 170, thereby initiating flow of the bodily-fluid through the transfer device 100 and into the first reservoir 170 when the diverter 120 is in its first configuration. The actuator 140 can include any suitable mechanism for actuating the transfer device 100 (e.g., at least the flow control mechanism 130), such as, for example, a rotating disc, a plunger, a slide, a dial, a button, and/or any other suitable mechanism or combination thereof. Examples of suitable actuators are described in more detail herein with reference to specific embodiments.

[1074] In some embodiments, the diverter 120 is configured such that the first amount of bodily-fluid need be conveyed to the first reservoir 170 before the diverter 120 will permit the flow of the second amount of bodily-fluid to be conveyed through the diverter 120 to the second reservoir 180. In this manner, the diverter 120 can be characterized as requiring compliance by a health care practitioner regarding the collection of the first, predetermined amount (e.g., a pre-sample) prior to a collection of the second amount (e.g., a sample) of bodily-fluid. Similarly stated, the diverter 120 can be configured to prevent a health care practitioner from collecting the second amount, or the sample, of bodily-fluid into the second reservoir 180 without first diverting the first amount, or pre-sample, of bodily-fluid to the first reservoir 170. In this manner, the health care practitioner is prevented from including (whether intentionally or unintentionally) the first amount of bodily-fluid, which is more likely to contain bodily surface microbes and/or other undesirable external contaminants that

are not representative of the in vivo conditions of a patient's bodily-fluid system, in the bodily-fluid sample to be used for analysis. The forced-compliance aspect of the diverter 120 is described in more detail herein with reference to specific embodiments.

[1075] In some embodiments, the diverter 120 is configured to automatically (i.e., without requiring an input or other action by a health care practitioner or other operator of the transfer device 100) fluidically isolate the inlet port 122 from the first outlet port 124. For example, the diverter 120 can be configured such that the flow control mechanism 130 will automatically fluidically isolate the first outlet port 124 from the inlet port 122 when the first reservoir 170 has received the first, predetermined amount of bodily-fluid. As such, additional flow of bodily-fluid in excess of the first amount into the first reservoir 170 is prevented. In some embodiments, the diverter 120 is configured such that the flow control mechanism 130 automatically moves from its first configuration to its second configuration after the first amount of bodily-fluid is conveyed to the first reservoir 170.

[1076] In some embodiments, the actuator 140 can have a third position, different from the first and second positions, which corresponds to a third configuration of the flow control mechanism 130. When in the third configuration, the flow control mechanism 130 can fluidically isolate the inlet port 122 from both the first outlet port 124 and the second outlet port 126 simultaneously. Therefore, when the flow control mechanism 130 is in its third configuration, flow of bodily-fluid from the inlet port 122 to either the first reservoir 170 or the second reservoir 180 is prevented. In use, for example, the actuator 140 can be actuated to place the flow control mechanism 130 in the first configuration such that a bodily-fluid can flow from the inlet port 122 to the first reservoir 170, then moved to the second configuration such that the bodily-fluid can flow from the inlet port 122 to the second reservoir 180, then moved to the third configuration to stop the flow of bodily-fluid into and/or through the diverter 120. In some embodiments, the flow control mechanism 130 can be moved to the third configuration between the first configuration and the second configuration. In some embodiments, the flow control mechanism 130 can be in the third configuration before being moved to either of the first configuration or the second configuration.

[1077] In some embodiments, one or more portions of the transfer device 100 are disposed within a housing (not shown in FIG. 1). For example, in some embodiments, at least a portion of one or more of the diverter 120, the first reservoir 170, and the actuator 140 can be disposed within the housing. In such an embodiment, at least a portion of the actuator

140 is accessible through the housing. Examples of suitable housings are described in more detail herein with reference to specific embodiments.

[1078] Referring now to FIGS. 2-12, a transfer device 200 includes a housing 201, a diverter 220, a flow control mechanism 230, and an actuator 240. The transfer device 200 can be any suitable shape, size, or configuration. For example, while shown in FIGS. 2 and 3 as being substantially cylindrical, the transfer device 200 can be square, rectangular, polygonal, and/or any other non-cylindrical shape.

[1079] The housing 201 includes a proximal end portion 202 and a distal end portion 203. The distal end portion 203 includes a base 206 from which a set of walls 204 extend. More specifically, the walls 204 of the housing 201 define a substantially annular shape and define an inner volume 211 therebetween. The proximal end portion 202 of the housing 201 is configured to be open such that the inner volume 211 can receive at least a portion of the diverter 220, a portion of the flow control mechanism 230, and a portion of the actuator 240 (FIG. 4). Similarly stated, the housing 201 is configured to house at least the portion of the diverter 220, the portion of the flow control mechanism 230, and the portion of the actuator 240

[1080] The walls 204 of the housing 201 define a set of status windows 210 and a set of channels 205. The status windows 210 can be any suitable shape or size and are configured to allow a user to visually inspect at least a portion of the transfer device 200. While shown in FIG. 5 as including two status windows 210, in other embodiments, the housing 201 can define any number of status windows 210, such as, for example, one, three, four, or more. The channels 205 defined by the housing 201 are configured to extend from the distal end portion 203 and through the proximal end portion 202. Similarly stated, the channels 205 extend through a proximal surface of the housing 201. Said yet another way, the channels 205 are open ended at the proximal end portion 202 of the housing 201.

[1081] The housing 201 further includes a set of guide posts 207 and a set of flow control protrusions 208. While shown in FIGS. 5 and 6 as cylindrical protrusions, the guide posts 207 can be any suitable shape or size and are configured to extend from the base 206 in the proximal direction. In this manner, the guide posts 207 are configured to engage a portion of the diverter 220 and a portion of the actuator 240, as further described herein. The flow control protrusions 208 extend from the base 206 in the proximal direction and define notches

209. In this manner, the flow control protrusions 208 are configured to selectively engage the flow control mechanism 230 to move the flow control mechanism 230 between a first configuration and a second configuration, as described in further detail herein. While only one flow control protrusion 208 is shown in FIGS. 5 and 6, the housing 201 is configured to include two flow control protrusions 208. In other embodiments, the housing 201 can include any number flow control protrusions 208 such as for example, one, three, four, or more.

[1082] As shown in FIGS. 7 and 8, the diverter 220 includes a proximal end portion 228 and a distal end portion 229 and defines an inner volume 221. The inner volume 221 is configured to receive at least a portion of the flow control mechanism 230, as further described herein. The proximal end portion 228 of the diverter 220 includes a first outlet port 224 and can engage a portion of the actuator 240. The distal end portion 229 includes an inlet port 222 and a second outlet port 226. As shown in FIGS. 1 and 2, the diverter 220 is disposed within the inner volume 211 of the housing 201 such that a portion of the inlet port 222 extends through a first channel 205 defined by the walls 204 of the housing 201 and a portion of the second outlet port 226 extends through a second channel 205 opposite the first channel. While not explicitly shown in FIGS. 2-12, the distal end portion 229 of the diverter 220 is configured to engage the guide posts 207 such that lateral movement of the diverter 220 is limited. Similarly stated, the distal end portion 229 of the diverter 220 can engage the guide posts 207 of the housing 201 such that the diverter 220 is substantially limited to movement in the proximal or distal direction, relative to the housing 201, as further described herein.

[1083] The inlet port 222 included in the distal end portion 229 of the diverter 220 defines an inlet lumen 223. As shown in FIG. 8, the inlet lumen 223 is configured to be in fluid communication with the inner volume 221. Similarly stated, the inlet lumen 223 of the inlet port 222 extends through a wall defining the inner volume 221 of the diverter 220. The inlet port 222 is further configured to be fluidically coupled to a medical device (not shown) defining a fluid flow pathway for withdrawing and/or conveying the bodily-fluid from a patient to the transfer device 200. For example, the inlet port 222 can be fluidically coupled to a needle or other lumen-containing device (e.g., flexible sterile tubing). Similarly stated, the inlet lumen 223 defined by the inlet port 222 is placed in fluid communication with a lumen defined by a lumen-containing device, when the lumen-containing device is coupled to the inlet port 222. Expanding further, when the lumen-containing device is disposed within a

portion of a body of the patient (e.g., within a vein of the patient), the inner volume 221 of the diverter 220 is placed in fluid communication with the portion of the body of the patient.

[1084] The first outlet port 224 included in the proximal end portion 228 of the diverter 220 defines a first outlet lumen 225. As shown in FIG. 8, the first outlet lumen 225 is configured to be in fluid communication with the inner volume 221 of the diverter 220 (e.g., the first outlet lumen 225 extends through the wall defining the inner volume 221). Similarly, the second outlet port 226 included in the distal end portion 229 of the diverter 220 defines a second outlet lumen 227 in fluid communication with the inner volume 221.

[1085] As shown in FIG. 9, the flow control mechanism 230 includes a first control member 231 and a second control member 235. At least a portion of the flow control mechanism 230 is configured to be disposed within the inner volume 221 defined by the diverter 220. In this manner, the flow control mechanism 230 defines a circular cross-sectional shape such that when the flow control mechanism 230 is disposed within the inner volume 221, a portion of the flow control mechanism 230 forms a friction fit with the walls of the diverter 220 defining the inner volume 221, as described in further detail herein.

[1086] The first control member 231 includes a set of activation protrusions 232 and a set of cross members 234 (only one of each is shown in FIG. 9). The activation protrusions 232 are configured to engage the flow control protrusion 208 of the housing 201. More specifically, the activation protrusions 232 can be disposed within the notch 209 defined by the flow control protrusion 208. Therefore, in use, the flow control protrusions 208 can engage the activation protrusions 232 to move the flow control mechanism 230 between a first configuration and a second configuration.

[1087] The second control member 235 defines a first lumen 238, a second lumen 239, and a set of channels 237 and is configured to be disposed, at least partially, within the first control member 231. More particularly, the first control member 231 has a first diameter D_1 and the second control member 235 has a second diameter D_2 larger than the first diameter D_1. Therefore, when the second control member 235 is disposed within the first control member 231 a portion of the second control member 235 extends beyond a surface of the first control member 231 that defines the first diameter D_1.

[1088] The channels 237 defined by the second control member 235 receive the cross members 234 of the first control member 231. The arrangement of the cross members 234

disposed within the channels 237 is such that the second control member 235 is maintained in a desired position relative to the first control member 231. In this manner, the second control member 235 is configured to move concurrently with the first control member 231 when the flow control protrusions 208 engage the activation protrusions 232 of the first control member 231. Similarly stated, the flow control mechanism 230 is moved between the first configuration and the second configuration when the first control member 231 and the second control member 235 are moved between the first configuration and the second configuration, respectively. Furthermore, when the flow control mechanism 230 is in the first configuration, the first lumen 238 is placed in fluid communication with the inlet lumen 223 defined by the inlet port 222 and the first outlet lumen 225 defined by the first outlet port 224. When the flow control mechanism 230 is in the second configuration, the second lumen 239 is placed in fluid communication with the inlet lumen 223 defined by the inlet port 222 and the second outlet lumen 227 defined by the second outlet port 226, as described in further detail herein.

[1089] As shown in FIG. 10, the actuator mechanism 240 includes an actuator housing 262, a plunger 248, a cap 255, and a spring 261. The actuator mechanism 240 is configured to move between a first configuration and a second configuration, thereby moving the transfer device 200 between a first configuration and a second configuration, as described in further detail herein. The actuator housing 262 includes a proximal end portion 263 and a distal end portion 264 and defines an inner volume 265. The actuator housing 262 can be any suitable shape, size or configuration. For example, the actuator housing 262 can be substantially cylindrical and be configured to be disposed, at least partially, within the housing 201. The inner volume 265 is configured to receive the plunger 248, the spring 261, and at least a portion of the cap 255. The plunger 248 includes a proximal end portion 249 and a distal end portion 249 and a side wall 251. The distal end portion 250 is configured to receive the guide posts 207 of the housing 201, as described in further detail herein. The proximal end portion 249 includes a set of retention tabs 253 and can receive a portion of the spring 261. More particularly, the retention tabs 253 included in the proximal end portion 249 of the plunger 248 are configured to engage the spring 261 to removably couple the spring 261 to the plunger 248.

[1090] The side wall 251 of the plunger 248 define a set of notches 252 configured to receive a set of seal members 254. The seal members 254 can be any suitable seal members 254 such as for example, o-rings formed from any suitable elastomeric material. In this

manner, the plunger 248 is disposed within the inner volume 265 of the actuator housing 262 such that the seal members 254 define a friction fit with the inner walls (not shown in FIG. 10) that define the inner volume 265 of the actuator housing 262. Similarly stated, the seal members 254 define a fluidic seal with the inner walls of the actuator housing 262. Furthermore, the plunger 248 is disposed within the inner volume 265 such that the plunger 248 divides the inner volume 265 into a first portion 267 that is fluidically isolated from a second portion 270 (see e.g., FIGS. 11 and 12). The first portion 267 of the inner volume 265 is defined between a surface of the proximal end portion 263 of the actuator housing 262 and the proximal end portion 249 of the plunger 248. As such, the first portion 267 of the inner volume 265 is configured contain the spring 261 such that the spring 261 is in contact with the surface of the proximal end portion 263 of the actuator housing 262 and the proximal end portion 249 of the plunger 248.

[1091] The cap 255 can be any suitable shape or size and is configured to be disposed, at least partially, within the inner volume 265 of the actuator housing 262. Furthermore, the cap 255 can be formed from any suitable material. For example, in some embodiments, the cap 255 is formed from an elastomeric material such as silicone. In other embodiments, the cap 255 can be formed from any polymeric material such as, for example, rubber, vinyl, neoprene, or the like.

[1092] The cap 255 includes a proximal end portion 256 and a distal end portion 257. The proximal end portion 256 is disposed within the inner volume 265 of the actuator housing 262 such that the distal end portion 250 of the plunger 248 and the proximal end portion 256 of the cap defines the second portion 270 of the inner volume (referred to henceforth as "first reservoir") of the inner volume 265. Expanding further, the proximal end portion 256 of the cap 255 is configured to define a friction fit with the inner walls (not shown in FIG. 10) that define the inner volume 265. Similarly stated, the proximal end portion 254 defines a fluidic seal with the inner walls of the actuator housing 262. Therefore, the fluidic seal defined by the actuator housing 262 and the plunger 248 and the fluidic seal defined by the actuator housing 262 and the proximal end portion 256 of the cap 255 fluidically isolate the fluid reservoir 270 from a portion outside of the fluid reservoir 270 (i.e., the second portion of the inner volume 265).

[1093] The distal end portion 257 of the cap 255 includes a set of notches 260 configured to receive a set of protrusions 266 of the actuator housing 262 when the proximal end portion

256 is disposed within the inner volume 265. The arrangement of the notches 260 defined by the cap 255 and the protrusions 266 of the actuator housing 262 is such that the protrusions 266 form a friction fit with the walls defining the notches 260. In this manner, the protrusions 266 engage the walls defining the notches 260 to maintain the cap 255 in a desired position relative to the actuator housing 262 when the proximal end portion 256 is disposed within the inner volume 265. Moreover, the actuator mechanism 240 and the diverter 220 are disposed within the housing 201 such that the distal end portion 257 of the cap 255 is in contact with the proximal end portion 228 of the diverter 220, as described in further detail herein.

[1094] The cap 255 further defines an inlet port 258 and a set of guide post ports 259. The inlet port 258 is configured to receive a portion of the first outlet port 224 included in the diverter 220. More specifically, the inlet port 258 receives the first outlet port 224 such that the inlet port 258 form a fluidic seal with an outer surface of the first outlet port 224. Similarly, the guide post ports 259 receive a portion of the guide posts 207 of the housing 201 such that the guide post ports 259 form a fluidic seal with an outer surface of the guide posts 207. In this manner, a portion of the guide posts 207 and a portion of the first outlet port 224 are disposed within the fluid reservoir 270 defined by the actuator housing 262. Furthermore, with the portion of the first outlet port 224 disposed within the fluid reservoir 270, the fluid reservoir 270 (i.e., the second portion of the inner volume 265) is in fluid communication with the first outlet lumen 225, as described in further detail herein.

[1095] In some embodiments, the transfer device 200 can be stored in a storage configuration in which the second control member 235 of the flow control mechanism 230 fluidically isolates the inlet port 222, the first outlet port 224, and the second outlet port 226 from the inner volume 221 defined by the diverter 220. In such embodiments, first lumen 238 and the second lumen 239 are fluidically isolated from the inlet lumen 223, the first outlet lumen 225, and the second outlet lumen 227. Furthermore, the friction fit defined by the second control member 235 and the walls of the diverter 220 defining the inner volume 221 maintain the flow control mechanism 230 in the storage configuration until the flow control mechanism 230 is moved from the storage configuration.

[1096] In use, a user can engage the transfer device 200 to couple the inlet port 222 to a proximal end portion of a lumen-defining device (not shown) such as, for example, a butterfly needle or, as an additional example, surgical tubing coupleable with a Luer-Lok-

type connection that allows for mating to an indwelling catheter or hub or other general vascular access device(s)/product(s). With the inlet port 222 coupled to the lumen-defining device the inlet lumen 223 is placed in fluid communication with the lumen defined by the lumen-defining device. Furthermore, the distal end portion of the lumen-defining device can be disposed within a portion of the body of a patient (e.g., a vein), thus, the inlet lumen 223 is in fluid communication with the portion of the body of the patient. In a similar manner, the second outlet port 226 can be coupled to an external fluid reservoir (not shown). The external fluid reservoir can be any suitable reservoir. For example, in some embodiments, the external fluid reservoir can be a BacT/ALERT® SN or a BacT/ALERT® FA, manufactured by BIOMERIEUX, INC.

[1097] With the inlet port 222 coupled to the lumen-defining device and the second outlet port 226 coupled to the external fluid reservoir, a user can place the transfer device 200 in the first configuration by applying an activation force to the actuator mechanism 240, thereby moving at least a portion of the actuator mechanism 240, the diverter 220, and the flow control mechanism 230 in the distal direction towards the first configuration, as shown by the arrow **AA** in FIG. 11. More specifically and as described above, the distal end portion 250 of the plunger 248 engages the guide posts 207 of the housing 201. The arrangement of the plunger 248 and the guide posts 207 is such that as the user applies the activation force to the actuator mechanism 240, the position of the plunger 248, relative to the housing 201, is maintained. Therefore, the activation force applied by the user moves the actuator housing 262, the cap 255, the diverter 220, and the flow control mechanism 230 in the direction of the arrow **AA**, but not the plunger 248. Thus, the distal movement of the actuator housing 262 is such that a portion of the activation force is configured to compress the spring 261, and as such, the height of the second portion 267 of the inner volume is reduced. The compression of the spring 261 is such that the spring 261 exerts a reaction force (e.g., a force of expansion) in response to the portion of the activation force compressing the spring 261. Similarly stated, the spring 261 is configured return to an expanded configuration when the activation force is removed.

[1098] The distal movement of the actuator housing 262 relative to the plunger 248 is such that the height of the fluid reservoir 270 is increased. With the fluid reservoir 270 being fluidically isolated (as described above) the increase in the height (i.e., the increase in volume) produces a negative pressure within the fluid reservoir 270. Furthermore, as the

actuator mechanism 240 is moved from the storage configuration toward the first configuration, the flow control protrusions 208 engage the activation protrusions 232 (not shown in FIG. 11) included in the first control member 231 to move the flow control mechanism 230 toward the first configuration, as indicated by the arrow **BB**. Thus, when the flow control mechanism 230 is moved to the first configuration, the first lumen 238 defined by the second control member 235 is placed in fluid communication with the inlet lumen 223 defined by the inlet port 222 and the first outlet lumen 225 defined by the first outlet port 224.

[1099] As shown by the arrow **CC**, the inlet lumen 223 of the inlet port 222, the first lumen 238 of the second control member 235, and the first outlet lumen 225 of the first outlet port 224 define a fluid flow path such that the fluid reservoir 270 defined by the actuator housing 262 is in fluid communication with the inlet port 222. Furthermore, with the inlet port 222 coupled to the lumen-defining device the fluid reservoir 270 of the actuator housing 262 is placed in fluid communication with the portion of the patient (e.g., the vein). The negative pressure within the fluid reservoir 270 is such that the negative pressure differential introduces a suction force within the portion of the patient. In this manner, a bodily-fluid is drawn into the fluid reservoir 270 of the actuator housing 262. In some embodiments, the bodily-fluid can contain undesirable microbes such as, for example, dermally-residing microbes.

[1100] In some embodiments, the magnitude of the suction force can be modulated by increasing or decreasing the amount of activation force applied to the actuator mechanism 240. Excess suction force can, in some cases, collapse a patient's vein thereby cutting off sample flow. Once a vein is collapsed, one or more additional venipunctures may be required to access a non-collapsed vein. Excess suction force may also cause hemolysis at the needle tip within the vein due to excessive negative pressure. Thus, in some embodiments, it can be desirable to limit the amount of suction force (i.e., modulate the negative pressure during a blood draw) introduced to a vein to reduce, minimize, or even eliminate vein collapse and/or one potential source of hemolysis. In such embodiments, the user can reduce the amount of force applied to the actuator mechanism 240. In this manner, the reaction force exerted by the expansion of the spring 261 (e.g., as described above) is sufficient to overcome a portion of the activation force applied by the user. Thus, the spring 261 can expand to move the plunger 248 and the housing 201 in the distal direction, relative to the actuator housing 262,

the cap 255, the diverter 220, and the flow control mechanism 230. The distal movement of the plunger 248 and housing 201 is such that the flow control protrusions 208 engage the activation protrusions 232 of the flow control mechanism 230 to move the flow control mechanism 230 towards the storage configuration. The rotation of the flow control mechanism 230 (e.g., in a direction opposite the arrow **BB**) reduces the size of the fluid pathway (e.g., an inner diameter) between the inlet lumen 223 and the first lumen 238 and the first outlet port 225 and the first lumen 238, thereby reducing the suction force introduced into the vein of the patient.

[1101] With the desired amount of bodily-fluid transferred to the fluid reservoir 270 defined by the actuator housing 262, a user can engage the transfer device 200 to move the transfer device 200 from the first configuration to the second configuration, wherein a flow of bodily-fluid is transferred to the external reservoir (e.g., such as those described above). In some embodiments, the desired amount of bodily-fluid transferred to the actuator housing 262 is a predetermined amount of fluid. For example, in some embodiments, the transfer device 200 can be configured to transfer bodily-fluid until the pressure within the fluid reservoir 270 defined by the actuator housing 262 is in equilibrium with the pressure of the portion of the body in which the lumen-defining device is disposed (e.g., the vein). In such embodiments, the equalizing of the pressure between the second portion 176 of the inner volume 265 and the portion of the body stops the flow of the bodily-fluid into the actuator housing 262. In some embodiments, the predetermined amount of bodily-fluid (e.g., volume) is at least equal to the combined volume of the inlet lumen 223, the first lumen 238, the first outlet lumen 225, and the lumen-defining device.

[1102] As shown in FIG. 12, the transfer device 200 can be moved from the first configuration to the second configuration by further moving the actuator mechanism 240 in the distal direction, as indicated by the arrow **DD**. Expanding further, the user can apply an activation force to the actuator mechanism 240 such that the actuator housing 262, the cap 255, the diverter 220, and the flow control mechanism 230 move in the distal direction. With the desired amount of the bodily-fluid disposed within the fluid reservoir 270 the volume of the fluid reservoir 270 is configured to remain constant as the actuator housing 262 and the cap 255 move relative to the plunger 248. Similarly stated, the pressure of the fluid reservoir 270 is configured to remain substantially unchanged as the transfer device 200 is moved from the first configuration to the second configuration.

[1103] As the actuator mechanism 240 is moved from the first configuration toward the second configuration, the flow control protrusions 208 engage the activation protrusions 232 (not shown in FIG. 12) included in the first control member 231 to move the flow control mechanism 230 toward the second configuration, as indicated by the arrow **EE**. Thus, when the flow control mechanism 230 is moved to the second configuration, the second lumen 239 defined by the second control member 235 is placed in fluid communication with the inlet lumen 223 defined by the inlet port 222 and the second outlet lumen 227 defined by the second outlet port 226.

[1104] As shown by the arrow **FF**, the inlet lumen 223 of the inlet port 222, the second lumen 239 of the second control member 235, and the second outlet lumen 227 of the second outlet port 226 define a fluid flow path such that the external reservoir (not shown in FIG. 12) is in fluid communication with the inlet port 222 and, therefore, the portion of the patient (e.g., the vein). Furthermore, the external reservoir is configured to define a negative pressure (e.g., the known external reservoirs referred to herein are vessels defining a negative pressure). The negative pressure within the external reservoir is such that the negative pressure differential between the external reservoir and the portion of the body of the patient introduces a suction force within the portion of the patient. Therefore, a desired amount of bodily-fluid is drawn into the external reservoir and is fluidically isolated from the first, predetermined amount of bodily-fluid contained within the fluid reservoir 270 defined by the actuator housing 262. In this manner, the bodily-fluid contained in the external reservoir is substantially free from microbes generally found outside of the portion of the patient (e.g., dermally residing microbes, microbes within a lumen defined by the transfer device 200, microbes within the lumen defined by the lumen defining device, and/or any other undesirable microbe(s)). With the desired amount of bodily-fluid contained in the external fluid reservoir, the user can remove the activation force from the actuator mechanism 240 (e.g., remove the portion of the hand engaging the actuator mechanism 240). With the removal of the activation force, the spring 261 exerts the force of expansion (described above) to move the transfer device 200 from the second configuration to the storage configuration. With the transfer device 200 in the storage configuration, the first outlet port 224 is fluidically isolated from the first lumen 238 and/or the second lumen 239 of the flow control mechanism 230. Thus, the bodily-fluid contained within the actuator housing 262 is fluidically isolated from a volume outside the actuator housing 262 and the external reservoir can be decoupled from the transfer device 200. In addition, the bodily-fluid contained within

the actuator housing 262 is isolated from the patient and the healthcare worker, and can be safely disposed of (e.g., in a biohazard materials container) in a "closed" device.

[1105] While the transfer device 200 is shown and described in FIGS. 2-12 as disposing the diverter 220 within the housing 201, in some embodiments, a transfer device can include a diverter and housing that are monolithically formed. For example, FIGS. 13-19 illustrate a transfer device 300 according to an embodiment. FIGS. 13 and 14 illustrate the transfer device 300 in a first configuration. The transfer device 300 includes a housing 301, having a diverter 320 and defining a fluid reservoir 370, a flow control mechanism 330, and an actuator 340.

[1106] The housing 301 includes a proximal end portion 302 and a distal end portion 303. The distal end portion 303 of the housing 301 includes a set of walls 304 that define a channel 305 configured to receive a distal portion 342 of the actuator 340. The walls 304 can be configured to define the channel 305 with any suitable shape, size, or configuration. For example as shown in FIG. 16, the walls 304 can be configured to further define a slot 319 in the channel 305 configured to receive an activation extension 346 included in the actuator 340 (FIG. 15). Similarly stated, the slot 319 can be configured to receive the activation extension 346 included in the distal portion 342 of the actuator 340, disposed within the channel 305, such that the activation extension 346 can pass through the walls 304 and be disposed substantially outside the channel 305, as described in further detail herein.

[1107] The walls 304 of the distal end portion 303 of the housing 301 also include a recessed surface 315 and a stop 313 (FIGS. 15 and 16). The stop 313 defines a proximal boundary of the channel 305 that can limit the movement of the actuator 340 within the channel 305. Furthermore, the stop 313 defines a passageway 314 configured to receive a portion of the actuator 340 such that the portion of the actuator 340 can extend in the proximal direction beyond the stop 313, as further described herein. The recessed surface 315 is configured to be a flat surface from which the diverter 320 can extend. Similarly stated, the diverter 320 is a set of walls configured to extend perpendicularly from the recessed surface 315. In this manner, the diverter 320 receives at least a portion of the flow control mechanism 340, as described in further detail herein. While shown and described as extending perpendicularly from the recessed surface 315, in other embodiments, the diverter 320 can extend from the recessed surface 315 at any suitable angular orientation.

[1108] As shown in FIG. 15, the proximal end portion 302 of the housing 301 includes a set of walls 318 that extend from the stop 313 in the proximal direction. In this manner, the walls 318 define a tubular shape substantially enclosed at the distal end by the stop 313 and open at the proximal end. The walls 318 define a slot 312 and an inner volume 311 configured to receive a proximal end portion 341 of the actuator 340. As further described herein, the proximal end portion 302 of the housing 301, the stop 313, and the proximal end portion 341 of the actuator 340 define a fluid reservoir 370 configured to receive and/or contain a bodily fluid.

[1109] As shown in FIG. 16, the diverter 320 includes an inlet port 322, a first outlet port 324, and a second outlet port 326, and defines an inner volume 321. The inner volume 321 is configured to receive at least a portion of the flow control mechanism 330, as further described herein. The inlet port 322 of the diverter 320 defines an inlet lumen 323. The inlet lumen 323 is configured to be in fluid communication with the inner volume 321. Similarly stated, the inlet lumen 323 of the inlet port 322 extends through a wall defining the inner volume 321 of the diverter 320.

[1110] The inlet port 322 is further configured to be fluidically coupled to a medical device (not shown) defining a fluid flow pathway for withdrawing and/or conveying the bodily-fluid from a patient to the transfer device 300. For example, the inlet port 322 can be fluidically coupled to a needle or other lumen-containing device (e.g., flexible sterile tubing). Similarly stated, the inlet lumen 323 defined by the inlet port 322 is placed in fluid communication with a lumen defined by a lumen-containing device, when the lumen-containing device is coupled to the inlet port 322. Expanding further, when the lumen-containing device is disposed within a portion of a body of the patient (e.g., within a vein of the patient), the inner volume 321 of the diverter 320 is placed in fluid communication with the portion of the body of the patient.

[1111] The first outlet port 324 of the diverter 320 defines a first outlet lumen 325. The first outlet lumen 325 is configured to be in fluid communication with the inner volume 321 of the diverter 320 and the fluid reservoir 370 (described above). Similarly stated, the first outlet lumen 325 is configured to extend through the wall defining the inner volume 321 and through a portion of the stop 313 defining the fluid reservoir 370, thereby placing the fluid reservoir 370 in fluid communication with the inner volume 321. The second outlet port 326 of the diverter 320 defines a second outlet lumen 327 and can be coupled to an external fluid

reservoir. In this manner, the second outlet lumen 327 can extend through the wall defining the inner volume 321 to be in fluid communication with the inner volume 321 and can be fluidically coupled to the external reservoir to place the external fluid reservoir in fluid communication with the inner volume 321.

[1112] As shown in FIG. 15, the flow control mechanism 330 includes a first control member 331 and a second control member 335. At least a portion of the flow control mechanism 330 is configured to be disposed within the inner volume 321 defined by the diverter 320. In this manner, the flow control mechanism 330 defines a circular cross-sectional shape such that when the flow control mechanism 330 is disposed within the inner volume 321, a portion of the flow control mechanism 330 forms a friction fit with the walls of the diverter 320 defining the inner volume 321, as described in further detail herein.

[1113] The first control member 331 includes a set of activation protrusions 332 configured to engage a set of protrusion 347 included in the activation extension 346 of the actuator 340. Therefore, in use, the actuator 340 can engage the activation protrusions 332 to move the flow control mechanism 330 between a first configuration and a second configuration. The second control member 335 defines a first lumen 338 and a second lumen 339 and can be formed from any suitable material. For example, in some embodiments, the second control member 335 is formed from silicone. In other embodiments, the second control member 335 can be any suitable elastomer configured to deform when disposed within the inner volume 321 of the diverter. Expanding further, the second control member 335 has a diameter larger than the diameter of the inner volume 321. In the manner, the diameter of the second control member 335 is reduced when the second control member 335 is disposed within the inner volume 321. Thus, the outer surface of the second control member 335 forms a friction fit with the inner surface of the walls defining the inner volume 321.

[1114] The second control member 335 is configured to be coupled to the first control member 331. For example, in some embodiments, the first control member 331 can be coupled to the second control member 335 via a mechanical fastener and/or adhesive. In other embodiments, the first control member 331 and the second control member 335 can be coupled in any suitable manner. In this manner, the second control member 335 is configured to move concurrently with the first control member 331 when the activation extension 347 of the actuator 340 engages the activation protrusions 332 of the first control

member 331. Similarly stated, the flow control mechanism 330 is moved between the first configuration and the second configuration when the first control member 331 and the second control member 335 are moved between the first configuration and the second configuration, respectively. Furthermore, when the flow control mechanism 330 is in the first configuration, the first lumen 338 is placed in fluid communication with the inlet lumen 323 defined by the inlet port 322 and the first outlet lumen 325 defined by the first outlet port 324. When the flow control mechanism 330 is in the second configuration, the second lumen 339 is placed in fluid communication with the inlet lumen 323 defined by the inlet port 322 and the second outlet lumen 327 defined by the second outlet port 326, as described in further detail herein.

[1115] As described above, the actuator mechanism 340 includes the proximal end portion 341, the distal end portion 342, and an actuator arm 343 therebetween. The actuator mechanism 340 is configured to move between a first configuration and a second configuration, thereby moving the transfer device 300 between a first configuration and a second configuration, as described in further detail herein. The proximal end portion 341 includes a plunger 348 configured to be disposed within the inner volume 311 of the housing 301. More particularly, the plunger 348 includes a seal member 354 configured to define a friction fit with the inner surface of the walls 318 defining the inner volume 311. Similarly stated, the seal member 354 defines a fluidic seal with the inner surface of the walls 318 defining the inner volume 311 such that a portion of the inner volume 311 proximal of the seal member 354 is fluidically isolated from a portion of the inner volume 311 distal of the seal member 354.

[1116] The actuator arm 343 is configured to extend from the proximal end portion 341 of the actuator 340 through the passageway 314 defined by the stop 313. Therefore, as described above, the distal end portion 342 of the actuator 340 is disposed on a distal side of the stop 313. More specifically, the distal end portion 342 includes an engagement portion 344 and the activation portion 346. The engagement portion 344 and at least a portion (e.g., a distal portion) of the actuator arm 343 are configured to be disposed within the channel 305 such that the activation portion 346 can extend through the slot 319, as described above. In this manner, a user can engage the engagement portion 344 to move the actuator 340 in a distal direction between a first configuration and a second configuration, as further described herein.

[1117] In some embodiments, the transfer device 300 can be stored in the first configuration in which the first lumen 338 of the second control member 335 is in fluid communication with the inlet port 322 and the first outlet port 324. In such embodiments, the friction fit defined by the second control member 335 and the walls of the diverter 320 defining the inner volume 321 maintain the flow control mechanism 330 in the first configuration until the actuator 340 moves the flow control mechanism 330 to the second configuration.

[1118] In use, a user can engage the transfer device 300 to couple the inlet port 322 to a proximal end portion of a lumen-defining device (not shown) such as, for example, a butterfly needle. With the inlet port 322 coupled to the lumen-defining device the inlet lumen 323 is placed in fluid communication with the lumen defined by the lumen-defining device. Furthermore, the distal end portion of the lumen-defining device can be disposed within a portion of the body of a patient (e.g., a vein), thus, the inlet lumen 323 is in fluid communication with the portion of the body of the patient. In a similar manner, the second outlet port 326 can be coupled to an external fluid reservoir (not shown). The external fluid reservoir can be any suitable reservoir. For example, in some embodiments, the external fluid reservoir can be a BacT/ALERT® SN or a BacT/ALERT® FA blood culture collection bottle with media specifically designed to facilitate the growth of certain types of microbes (e.g., aerobic media/broth and/or aerobic media/broth), manufactured by BIOMERIEUX, INC.

[1119] With the inlet port 322 coupled to the lumen-defining device and the second outlet port 326 coupled to the external fluid reservoir, a user can begin the transfer of a bodily-fluid by applying an activation force to the engagement portion 344 of the actuator 340, thereby moving the actuator 340 the distal direction, as shown by the arrow **GG** in FIG. 17. More specifically and as described above, the plunger 348 engages the inner surface of the walls 318 defining the inner volume 311 such that the volume of the fluid reservoir 370 is increased (e.g., as defined by the plunger 348, the walls 318 of the housing 301 and the stop 313). With the fluid reservoir 370 being fluidically isolated (as described above) from a volume on the proximal side of the seal member 354, the increase in the volume of the fluid reservoir 370 produces a negative pressure within the fluid reservoir 370. Moreover, with the flow control mechanism 330 in the first configuration, negative pressure differential introduces a suction force within the first lumen 338, the inlet lumen 323, and the first outlet lumen 325.

[1120] As shown by the arrow **HH**, the inlet lumen 323 of the inlet port 322, the first lumen 338 of the second control member 335, and the first outlet lumen 325 of the first outlet port 324 define a fluid flow path such that the second portion 376 of the inner volume 373 defined by the fluid reservoir 370 is in fluid communication with the inlet port 322. Furthermore, with the inlet port 322 coupled to the lumen-defining device the fluid reservoir 370 is in fluid communication with the portion of the patient (e.g., the vein) and at least a portion of the suction force is introduced to the portion of the patient. In this manner, a bodily-fluid is drawn into the fluid reservoir 370. In some embodiments, the bodily-fluid can contain undesirable microbes such as, for example, dermally-residing microbes dislodged during the insertion of the lumen-defining device.

[1121] In some embodiments, the magnitude of the suction force can be modulated by moving the actuator 340 in the proximal or distal direction. For example, in some embodiments, it can be desirable to limit the amount of suction force introduced to a vein. In such embodiments, the user can move the actuator 340 in the proximal direction (e.g., the direction of the arrow **II** in FIG. 18) such the activation extension 346 can engage the protrusions 332 of the first control member 331. In this manner, the protrusions 347 included in the activation extension 346 can mesh with the protrusions 332 of the first control member 331 to rotate the first control member 331 in the direction of the arrow **JJ**. The rotation of the flow control mechanism 330 (e.g., in a direction opposite the arrow **JJ**) reduces the size of the fluid pathway (e.g., an inner diameter) between the inlet lumen 323 and the first lumen 338 and the first outlet port 325 and the first lumen 338, thereby reducing the suction force introduced into the vein of the patient.

[1122] With the desired amount of bodily-fluid transferred to the fluid reservoir 370, a user can engage the transfer device 300 to move the transfer device 300 from the first configuration to the second configuration, wherein a flow of bodily-fluid is transferred to the external reservoir (e.g., such as those described above). In some embodiments, the desired amount of bodily-fluid transferred to the fluid reservoir 370 is a predetermined amount of fluid. For example, in some embodiments, the transfer device 300 can be configured to transfer bodily-fluid until the pressure within the fluid reservoir 370 is equilibrium with the pressure of the portion of the body in which the lumen-defining device is disposed (e.g., the vein). In such embodiments, the equalizing of the pressure between the fluid reservoir 370 and the portion of the body stops the flow of the bodily-fluid into the fluid reservoir 370. In

some embodiments, the predetermined amount of bodily-fluid (e.g., volume) is at least equal to the combined volume of the inlet lumen 323, the first lumen 338, the first outlet lumen 325, and the lumen-defining device.

[1123] As shown in FIG. 18, the transfer device 300 can be moved from the first configuration to the second configuration by further moving the actuator mechanism 340 in the distal direction, as indicated by the arrow **II**. As the actuator mechanism 340 is moved from the first configuration toward the second configuration, the protrusions 347 of the activation extension 346 further engage the activation protrusions 332 included in the first control member 331 to move the flow control mechanism 330 to the second configuration, as indicated by the arrow **KK** in FIG. 19. In this manner, the flow control mechanism 330 is moved to the second configuration, and the first lumen 238 is fluidically isolated from the inlet lumen 223 and the first outlet lumen 225. In addition, the second lumen 339 defined by the second control member 335 is placed in fluid communication with the inlet lumen 323 defined by the inlet port 322 and the second outlet lumen 327 defined by the second outlet port 326.

[1124] As shown by the arrow **LL**, the inlet lumen 323 of the inlet port 322, the second lumen 339 of the second control member 335, and the second outlet lumen 327 of the second outlet port 326 define a fluid flow path such that the external reservoir (not shown in FIG. 19) is in fluid communication with the inlet port 322 and, therefore, the portion of the patient (e.g., the vein). Furthermore, the external reservoir is configured to define a negative pressure (e.g., the known external reservoirs referred to herein are vessels defining a negative pressure). The negative pressure within the external reservoir is such that the negative pressure differential between the external reservoir and the portion of the body of the patient introduces a suction force within the portion of the patient. Therefore, a desired amount of bodily-fluid is drawn into the external reservoir and is fluidically isolated from the first, predetermined amount of bodily-fluid contained within the fluid reservoir 370.

[1125] The bodily-fluid contained in the external reservoir is substantially free from microbes generally found outside of the portion of the patient (e.g., dermally residing microbes, microbes within a lumen defined by the transfer device 300, microbes within the lumen defined by the lumen defining device, and/or any other undesirable microbe). In some embodiments, with the desired amount of bodily-fluid contained in the external fluid reservoir, the user can further move the actuator 340 in the proximal direction to place the

transfer device 300 in a third configuration. In such embodiments, the actuator 340 can be moved in the proximal direction such that the engagement portion 344 and/or the activation extension 346 contact the stop 313, thereby limiting further proximal movement of the actuator 340. In this configuration, the actuator 340 can place the flow control mechanism 330 in a third configuration configured to fluidically isolate the first lumen 338 and the second lumen 339 from the inlet lumen 323, the first outlet lumen 325, and the second outlet lumen 327. Thus, the bodily-fluid contained within the fluid reservoir 370 is fluidically isolated from a volume outside the fluid reservoir 370 and the external reservoir can be decoupled from the transfer device 300.

[1126] While the transfer device 300 is shown and described in FIGS. 13-19 as being configured to actuated by continual user influence (e.g., the user manually moves the actuator 340 in the proximal direction), in some embodiments, a transfer device need not require continual user influence. For example, FIGS. 20-26 illustrate a transfer device 400 according to an embodiment. FIGS. 20 and 21 illustrate the transfer device 400 in a first configuration. The transfer device 400 includes a housing 401, having a diverter 420 and defining a fluid reservoir 470, a flow control mechanism 430, and an actuator mechanism 440.

[1127] The housing 401 includes a proximal end portion 402 and a distal end portion 403. The distal end portion 403 of the housing 401 includes a set of walls 404 having a recessed portion 415 and a stop 413 (FIGS. 22 and 23). The stop 413 defines a distal boundary of the recessed portion 415 and defines a passageway 414. The passageway 414 is configured to receive an activation extension 346 included in the actuator mechanism 440 such that the activation extension 346 extends through the stop 413, as further described herein. The recessed portion 415 includes a substantially flat surface from which the diverter 420 can extend (FIG. 22). Similarly stated, the diverter 420 is a set of walls configured to extend perpendicularly from the surface of the recessed portion 415. In this manner, the diverter 420 receives at least a portion of the flow control mechanism 430, as described in further detail herein. While shown and described as extending perpendicularly from the surface of the recessed portion 415, in other embodiments, the diverter 420 can extend from the surface at any suitable angular orientation.

[1128] The proximal end portion 402 of the housing 401 includes a set of walls 418 that extend from the stop 413 in the proximal direction. In this manner, the walls 418 define a tubular shape substantially enclosed at the distal end by the stop 413 and open at the proximal

end. The proximal end portion 402 of the housing 401 can be formed from any suitable material. For example, in some embodiments, the proximal end portion 402 can be formed from a relatively flexible material. In such embodiments, the proximal end portion 402 can be configured to deform (e.g., bend, compress, or otherwise reconfigure) under a given force, as described in further detail herein. As shown in FIG. 23, the walls 418 include shoulder 416 and retention tabs 417 and define an inner volume 411 configured to receive a portion of the actuator mechanism 440. As further described herein, the proximal end portion 402 of the housing 401, the stop 413, and a portion of the actuator mechanism 440 define a fluid reservoir 470 configured to receive and/or contain a bodily fluid.

[1129] As shown in FIG. 23, the diverter 420 includes an inlet port 422, a first outlet port 424, and a second outlet port 426, and defines an inner volume 421. The inner volume 421 is configured to receive at least a portion of the flow control mechanism 430, as further described herein. The inlet port 422 of the diverter 420 defines an inlet lumen 423. The inlet lumen 423 is configured to be in fluid communication with the inner volume 421. Similarly stated, the inlet lumen 423 of the inlet port 422 extends through a wall defining the inner volume 421 of the diverter 420.

[1130] The inlet port 422 is further configured to be fluidically coupled to a medical device (not shown) defining a fluid flow pathway for withdrawing and/or conveying the bodily-fluid from a patient to the transfer device 400. For example, the inlet port 422 can be fluidically coupled to a needle or other lumen-containing device (e.g., flexible sterile tubing). Similarly stated, the inlet lumen 423 defined by the inlet port 422 is placed in fluid communication with a lumen defined by a lumen-containing device, when the lumen-containing device is coupled to the inlet port 422. Expanding further, when the lumen-containing device is disposed within a portion of a body of the patient (e.g., within a vein of the patient), the inner volume 421 of the diverter 420 is placed in fluid communication with the portion of the body of the patient.

[1131] The first outlet port 424 of the diverter 420 defines a first outlet lumen 425. The first outlet lumen 425 is configured to be in fluid communication with the inner volume 421 of the diverter 420 and the fluid reservoir 470 (described above). Similarly stated, the first outlet lumen 425 is configured to extend through the wall defining the inner volume 421 and through a portion of the stop 413 defining the fluid reservoir 470, thereby placing the fluid reservoir 470 in fluid communication with the inner volume 421. The second outlet port 426

of the diverter 420 defines a second outlet lumen 427 and is configured to be coupled to an external fluid reservoir. In this manner, the second outlet lumen 427 can extend through the wall defining the inner volume 421 to be in fluid communication with the inner volume 421 and can be fluidically coupled to the external reservoir to place the external fluid reservoir in fluid communication with the inner volume 421.

[1132] As shown in FIG. 24, the flow control mechanism 430 includes a first control member 431 and a second control member 435. At least a portion of the flow control mechanism 430 is configured to be disposed within the inner volume 421 defined by the diverter 420. In this manner, the flow control mechanism 430 defines a circular cross-sectional shape such that when the flow control mechanism 430 is disposed within the inner volume 421, a portion of the flow control mechanism 430 forms a friction fit with the walls of the diverter 420 defining the inner volume 421, as described in further detail herein.

[1133] The first control member 431 includes an activation protrusion 432 and engagement protrusions 433. The activation protrusion 432 is configured to engage a protrusion 447 included in the activation extension 446 of the actuator mechanism 440. Therefore, in use, the actuator mechanism 440 can engage the activation protrusion 432 to move the flow control mechanism 430 between a first configuration and a second configuration. The second control member 435 defines a first lumen 438, a second lumen 439, and a set of grooves 437. The second control member 435 can be formed from any suitable material such as, for example, silicone. In other embodiments, the second control member 435 can be any suitable elastomer configured to deform when disposed within the inner volume 421 of the diverter. Expanding further, the second control member 435 has a diameter larger than the diameter of the inner volume 421. In the manner, the diameter of the second control member 435 is reduced when the second control member 435 is disposed within the inner volume 421. Thus, the outer surface of the second control member 435 forms a friction fit with the inner surface of the walls defining the inner volume 421.

[1134] The grooves 437 defined by the second control member 435 are configured to receive the engagement protrusions 433. In this manner, the first control member 431 can selectively engage the second control member 435 such that the second control member 435 is moved concurrently with the first control member 431 when the activation extension 447 of the actuator mechanism 440 engages the activation protrusion 432 of the first control member 431. Similarly stated, the flow control mechanism 430 is moved between the first

configuration and the second configuration when the first control member 431 and the second control member 435 are moved between the first configuration and the second configuration, respectively. Furthermore, when the flow control mechanism 430 is in the first configuration, the first lumen 438 is placed in fluid communication with the inlet lumen 423 defined by the inlet port 422 and the first outlet lumen 425 defined by the first outlet port 424. When the flow control mechanism 430 is in the second configuration, the second lumen 439 is placed in fluid communication with the inlet lumen 423 defined by the inlet port 422 and the second outlet lumen 427 defined by the second outlet port 426, as described in further detail herein.

[1135] As shown in FIGS. 22 and 25, the actuator mechanism 440 includes an engagement member 444, the activation extension 446, a plunger 448, and a spring 461. The engagement member 444 is configured to be coupled to the distal end portion 403 of the housing 401. In this manner, the housing 401 and the engagement member 444 house the flow control mechanism 430 and at least a portion of the diverter 420. The engagement member 444 includes a throttling button 445. The throttling button 445 is configured such that when engaged by a user, the throttling button 445 interacts with the flow control mechanism 430 to modulate the movement of the flow control mechanism 440, as described in further detail herein.

[1136] The plunger 448 includes a proximal end portion 449 and a distal end portion 450 and is configured to be disposed within the inner volume 411 defined by the housing 401. The proximal end portion 449 of the plunger 448 is configured to selectively engage the retention protrusions 417 included in the housing 401. The plunger 448 further includes a sealing member 454 disposed at the distal end portion 450. The seal member 454 is configured to define a friction fit with the inner surface of the walls 418 defining the inner volume 411. Similarly stated, the seal member 454 defines a fluidic seal with the inner surface of the walls 418 defining the inner volume 411 such that a portion of the inner volume 411 proximal of the seal member 454 is fluidically isolated from a portion of the inner volume 411 distal of the seal member 454.

[1137] The spring 461 includes a proximal end portion 462 and a distal end portion 463 and is configured to circumscribe the plunger 448. Similarly stated, the plunger 448 is disposed within the spring 461 when the spring 461 and the plunger 448 are disposed within the housing 401. Furthermore, when disposed within the inner volume 411, the distal end portion 463 of the spring 461 is configured to engage the shoulder 416 of the housing 401

and the proximal end portion 462 is configured to engage the proximal end portion 449 of the plunger 448. In this manner, the spring 461, when urged to move from a first (compressed) configuration to a second (expanded) configuration, is configured to move the plunger 448 in the proximal direction, as described in further detail herein.

[1138] The activation extension 446 can be any suitable size, shape, or configuration. For example, as shown in FIG. 22, the activation extension 446 can be a flexible tether formed from, for example, nylon. In this manner, the activation extension 446 can be substantially flexible in a lateral direction and substantially rigid in an axial direction. Similarly stated, in some embodiments, the activation extension 446 is configured to bend, twist, conform, and/or otherwise reconfigure without stretching. Said yet another way, the length of the activation extension 446 is configured to remain substantially unchanged as the activation extension 446 is bent or otherwise reconfigured.

[1139] The activation extension 446 is configured to be coupled to the distal end portion 450 of the plunger 448. More specifically, a proximal end portion of the activation extension 446 is disposed within the inner volume 411 of the housing 401 and is coupled to the plunger 448 and a distal end portion of the activation extension 446 passes through the stop 413 and is disposed within the recessed portion 415 of the housing 401. In this manner, the activation extension 446 is configured engage the activation protrusion 432 of the first control member 431 to move the flow control mechanism 430 between the first configuration and the second configuration, as described in further detail herein.

[1140] In some embodiments, the transfer device 400 can be stored in a storage configuration in which the second control member 435 of the flow control mechanism 430 fluidically isolates the inlet port 422, the first outlet port 424, and the second outlet port 426 from the inner volume 421 defined by the diverter 420. In such embodiments, first lumen 438 and the second lumen 439 are fluidically isolated from the inlet lumen 423, the first outlet lumen 425, and the second outlet lumen 427. Furthermore, the friction fit defined by the second control member 435 and the walls of the diverter 420 defining the inner volume 421 maintain the flow control mechanism 430 in the storage configuration until the flow control mechanism 430 is moved from the storage configuration.

[1141] In use, a user can engage the transfer device 400 to couple the inlet port 422 to a proximal end portion of a lumen-defining device (not shown) such as, for example, a

butterfly needle. With the inlet port 422 coupled to the lumen-defining device the inlet lumen 423 is placed in fluid communication with the lumen defined by the lumen-defining device. Furthermore, the distal end portion of the lumen-defining device can be disposed within a portion of the body of a patient (e.g., a vein), thus, the inlet lumen 423 is in fluid communication with the portion of the body of the patient. In a similar manner, the second outlet port 426 can be coupled to an external fluid reservoir (not shown). The external fluid reservoir can be any suitable reservoir. For example, in some embodiments, the external fluid reservoir can be a BacT/ALERT® SN or a BacT/ALERT® FA, manufactured by BIOMERIEUX, INC.

[1142] With the inlet port 422 coupled to the lumen-defining device and the second outlet port 426 coupled to the external fluid reservoir, a user can begin a transfer of a bodily-fluid by applying an activation force to the transfer device 400. More specifically, the user can introduce an activation force to the proximal end portion 402 of the housing 401 by squeezing, for example, the sides of the proximal end portion 402 such that the proximal end portion 402 deforms in response to the activation force, as described above. Thus, the proximal end portion 402 is urged (in response to the activation force) to reconfigure such that the retention tabs 417 are removed from contact with the proximal end portion 449 of the plunger 448. Expanding further, the retention tabs 417 are configured to apply a reaction force to the proximal end portion 449 of the plunger 448 in response to an expansion force exerted by the spring 461, thereby maintaining the spring 461 in the compressed configuration. With the retention tabs 417 removed from contact with the plunger 448 and with the distal end portion 463 of the spring 461 in contact with the shoulder 416 of the housing 401, the proximal end portion 462 of the spring 462 expands to move the plunger 448 in the direction of the arrow **MM** in FIG. 25.

[1143] As described above, the plunger 448 engages the inner surface of the walls 418 defining the inner volume 411 such that the volume of the fluid reservoir 470 is increased (e.g., as defined by the plunger 448, the walls 418 of the housing 401 and the stop 413). With the fluid reservoir 470 being fluidically isolated (as described above) from a volume on the proximal side of the seal member 454, the increase in the volume of the fluid reservoir 470 produces a negative pressure within the fluid reservoir 470. Moreover, movement of the plunger 448 in the proximal direction is such that the activation extension 446 is moved in the proximal direction. In this manner, the protrusion 447 of the activation extension 446

engages the protrusion 432 of the first control member 431 to move the flow control mechanism 430 from the storage configuration to the first configuration, as indicated by the arrow **NN**. With the flow control mechanism 430 in the first configuration, the negative pressure of the fluid reservoir 470 introduces a suction force within the first lumen 438, the inlet lumen 423, and the first outlet lumen 425.

[1144] As shown by the arrow **OO**, the inlet lumen 423 of the inlet port 422, the first lumen 438 of the second control member 435, and the first outlet lumen 425 of the first outlet port 424 define a fluid flow path such that the second portion 476 of the inner volume 473 defined by the fluid reservoir 470 is in fluid communication with the inlet port 422. Furthermore, with the inlet port 422 coupled to the lumen-defining device the fluid reservoir 470 is in fluid communication with the portion of the patient (e.g., the vein) and at least a portion of the suction force is introduced to the portion of the patient. In this manner, a bodily-fluid is drawn into the fluid reservoir 470. In some embodiments, the bodily-fluid can contain undesirable microbes such as, for example, dermally-residing microbes dislodged during the insertion of the lumen-defining device.

[1145] In some embodiments, the rate of expansion of the spring 461 can be modulated by engaging the throttling button 445 included in the engagement portion 444 of the actuator mechanism 440. For example, in some embodiments, it can be desirable to limit the amount of suction force introduced to a vein. In such embodiments, the user can exert a force on the throttling button 445 such that the throttling button 445 is moved to engage the flow control mechanism 430. In this manner, the throttling button 445 can increase the friction between, for example, the second control member 435 and the walls defining the inner volume 421 of the diverter. Thus, the increase in friction between the second control member 435 and the walls defining the inner volume 411 resist the force exerted by the activation extension 446, thereby slowing the rate of expansion of the spring. In this manner, the reduction of pressure (e.g., the increase in negative pressure) of the fluid reservoir 470 can be controlled to maintain a desired pressure differential between the vein and the fluid reservoir 470 and limit the suction force introduced to the vein.

[1146] In some embodiments, the user can depress the throttling button 445 to maintain the transfer device 400 in the first configuration. With the desired amount of bodily-fluid transferred to the fluid reservoir 470, a user can disengage the throttling button 445 to disengage the throttling button 445 from the flow control mechanism 430. In this manner,

the friction between the second control member 435 and the walls defining the inner volume 411 is reduced and the force of expansion exerted by the spring is sufficient to again overcome the friction between the second control member 435 and the walls defining the inner volume 411. Therefore, the transfer device 400 is moved 400 from the first configuration to the second configuration, wherein a flow of bodily-fluid is transferred to the external reservoir (e.g., such as those described above).

[1147] In some embodiments, the desired amount of bodily-fluid transferred to the fluid reservoir 470 is a predetermined amount of fluid. For example, in some embodiments, the transfer device 400 can be configured to transfer bodily-fluid until the pressure within the fluid reservoir 470 is equilibrium with the pressure of the portion of the body in which the lumen-defining device is disposed (e.g., the vein). In such embodiments, the equalizing of the pressure between the fluid reservoir 470 and the portion of the body stops the flow of the bodily-fluid into the fluid reservoir 470. In some embodiments, the predetermined amount of bodily-fluid (e.g., volume) is at least equal to the combined volume of the inlet lumen 423, the first lumen 438, the first outlet lumen 425, and the lumen-defining device.

[1148] As described above, the transfer device 400 is moved from the first configuration to the second configuration by further moving the plunger 448 in the distal direction. As the plunger 448 is moved from the first configuration toward the second configuration, the protrusions 447 of the activation extension 446 further engage the activation protrusions 432 included in the first control member 431 to move the flow control mechanism 430 to the second configuration, as indicated by the arrow **PP** in FIG. 26. In this manner, the flow control mechanism 430 is moved to the second configuration, and the first lumen 438 is fluidically isolated from the inlet lumen 423 and the first outlet lumen 425. In addition, the second lumen 439 defined by the second control member 435 is placed in fluid communication with the inlet lumen 423 defined by the inlet port 422 and the second outlet lumen 427 defined by the second outlet port 426.

[1149] As shown by the arrow **QQ** in FIG. 27, the inlet lumen 423 of the inlet port 422, the second lumen 439 of the second control member 435, and the second outlet lumen 427 of the second outlet port 426 define a fluid flow path such that the external reservoir (not shown in FIG. 19) is in fluid communication with the inlet port 422 and, therefore, the portion of the patient (e.g., the vein). Furthermore, the external reservoir is configured to define a negative pressure (e.g., the known external reservoirs referred to herein are vessels defining a negative

pressure). The negative pressure within the external reservoir is such that the negative pressure differential between the external reservoir and the portion of the body of the patient introduces a suction force within the portion of the patient. In some embodiments, the user can engage throttling button 445 to again increase the friction between the second control member 435 and the walls defining the inner volume 411. In this manner, further expansion of the spring 461 is limited and a desired amount of bodily-fluid can be drawn into the external reservoir such that the desired amount of bodily fluid is fluidically isolated from the first, predetermined amount of bodily-fluid contained within the fluid reservoir 470.

[1150] The bodily-fluid contained in the external reservoir is substantially free from microbes generally found outside of the portion of the patient (e.g., dermally-residing microbes, microbes within a lumen defined by the transfer device 400, microbes within the lumen defined by the lumen defining device, and/or any other undesirable microbe). In some embodiments, with the desired amount of bodily-fluid contained in the external fluid reservoir, the user can disengage the throttling button 445 such that the transfer device returns to the storage configuration. As described above, in this configuration the actuator mechanism 440 can place the flow control mechanism 430 in a third configuration configured to fluidically isolate the first lumen 438 and the second lumen 439 from the inlet lumen 423, the first outlet lumen 425, and the second outlet lumen 427. Thus, the bodily-fluid contained within the fluid reservoir 470 is fluidically isolated from a volume outside the fluid reservoir 470 and the external reservoir can be decoupled from the transfer device 400.

[1151] While the transfer device 400 is described above with reference to FIGS. 20-27 as being stored in a storage configuration, in some embodiments, a transfer device can be stored in a first configuration (e.g., defining a flow path between an inlet port and a fluid reservoir). For example, FIGS. 28 and 29 illustrate a transfer device 500 according to an embodiment. In some embodiments, aspects of the transfer device 500 can be substantially similar to corresponding aspects of the transfer device 200. In this manner, details of certain aspects are not described in further detail herein and it should be understood that such aspects are substantially similar in form or function to the corresponding aspects.

[1152] The transfer device 500 includes a housing 501, a diverter 520, a flow control mechanism 530, and an actuator 540. The housing 501 includes a proximal end portion 502 and a distal end portion 503. The proximal end portion 502 defines an inner volume configured to receive at least a portion of the actuator mechanism 540, as described in further

detail herein. The distal end portion 503 of the housing 501 includes the diverter 520. Similarly stated, the diverter 520 is monolithically formed with the distal end portion 503 of the housing 501. The diverter 520 receives at least a portion of the flow control mechanism 530, as described in further detail herein.

[1153] As shown in FIG. 28, the diverter 520 includes an inlet port 522, a first outlet port 524, and a second outlet port 526, and defines an inner volume 521. The inner volume 521 is configured to receive at least a portion of the flow control mechanism 530, as further described herein. The inlet port 522 of the diverter 520 defines an inlet lumen 523. The inlet lumen 523 is configured to be in fluid communication with the inner volume 521. Similarly stated, the inlet lumen 523 of the inlet port 522 extends through a wall defining the inner volume 521 of the diverter 520.

[1154] The flow control mechanism 530 includes a first control member 531 and a second control member 535. At least a portion of the flow control mechanism 530 is configured to be disposed within the inner volume 521 defined by the diverter 520. In this manner, the flow control mechanism 530 defines a circular cross-sectional shape such that when the flow control mechanism 530 is disposed within the inner volume 521, a portion of the flow control mechanism 530 forms a friction fit with the walls of the diverter 520 defining the inner volume 521, as described further detail herein.

[1155] The first control member 53 is configured to engage an activation extension 546 of the actuator mechanism 540 and move between a first configuration and a second configuration. The second control member 535 defines a first lumen 538 and a second lumen 539and is configured to be coupled to the first control member 531. Therefore, the second control member 535 is configured to move concurrently with the first control member 531 when the activation extension 546 engages the first control member 531. Similarly stated, the flow control mechanism 530 is moved between the first configuration and the second configuration when the first control member 531 and the second control member 535 are moved between the first configuration and the second configuration, respectively. Furthermore, when the flow control mechanism 530 is in the first configuration, the first lumen 538 is placed in fluid communication with the inlet lumen 523 defined by the inlet port 522 and the first outlet lumen 525 defined by the first outlet port 524. When the flow control mechanism 530 is in the second configuration, the second lumen 539 is placed in fluid

communication with the inlet lumen 523 defined by the inlet port 522 and the second outlet lumen 527 defined by the second outlet port 526, as described in further detail herein.

[1156] The actuator mechanism 540 is configured to move between a first configuration and a second configuration, thereby moving the transfer device 500 between a first configuration and a second configuration, as described in further detail herein. The actuator mechanism 540 includes a plunger 548 and the activation extension 546. The plunger 548 includes a proximal end portion 549, a distal end portion 550, and an engagement portion 544 and is configured to be disposed, at least partially within the inner volume 511 of the housing 501. The engagement portion 544 is configured to extend in the distal direction from the proximal end portion 549 of the plunger 548. In this manner, the engagement portion 544 can be engaged by a user to move the actuator mechanism 540 between the first configuration and the second configuration, as described in further detail herein.

[1157] The distal end portion 550 of the plunger 548 includes a seal member 554 configured to define a friction fit with the inner surface of the walls defining the inner volume 511. Similarly stated, the seal member 554 defines a fluidic seal with the inner surface of the walls defining the inner volume 511 such that a portion of the inner volume 511 proximal of the seal member 554 is fluidically isolated from a portion of the inner volume 511 distal of the seal member 554. Furthermore, the portion of the inner volume 511 distal of the seal member 554 defines a fluid reservoir 570. Similarly stated, the fluid reservoir 570 defined by the walls defining the inner volume 511 and the seal member 554 of the plunger 548.

[1158] The activation extension 546 includes a protrusion 547 configured to selectively engage the proximal end portion 549 of the plunger 548. In this manner, the proximal end portion 549 of the plunger 548 can move the activation extension 546 when the plunger 548 moves from a first configuration to a second configuration, as further described herein.

[1159] As described above, the transfer device 500 is stored in the first configuration in which the first lumen 538 of the second control member 535 is in fluid communication with the inlet port 522 and the first outlet port 524. In such embodiments, the friction fit defined by the second control member 535 and the walls of the diverter 520 defining the inner volume 521 maintain the flow control mechanism 530 in the first configuration until the actuator 540 moves the flow control mechanism 530 to the second configuration.

[1160] In use, a user can engage the transfer device 500 to couple the inlet port 522 to a proximal end portion of a lumen-defining device (not shown) such as, for example, a butterfly needle. With the inlet port 522 coupled to the lumen-defining device the inlet lumen 523 is placed in fluid communication with the lumen defined by the lumen-defining device. Furthermore, the distal end portion of the lumen-defining device can be disposed within a portion of the body of a patient (e.g., a vein), thus, the inlet lumen 523 is in fluid communication with the portion of the body of the patient. In a similar manner, the second outlet port 526 can be coupled to an external fluid reservoir (not shown).

[1161] With the inlet port 522 coupled to the lumen-defining device and the second outlet port 526 coupled to the external fluid reservoir, a user can begin the transfer of a bodily-fluid by applying an activation force to the engagement portion 544 of the actuator 540, thereby moving the plunger 548 in the distal direction, as shown by the arrow **RR** in FIG. 28. More specifically and as described above, the plunger 548 engages the inner surface of the walls defining the inner volume 511 such that the volume of the fluid reservoir 570 is increased (e.g., as defined by the plunger 548 and the housing 501). With the fluid reservoir 570 being fluidically isolated (as described above) from a volume on the proximal side of the seal member 554, the increase in the volume of the fluid reservoir 570 produces a negative pressure within the fluid reservoir 570. Moreover, with the flow control mechanism 530 in the first configuration, negative pressure differential introduces a suction force within the first lumen 538, the inlet lumen 523, and the first outlet lumen 525.

[1162] As shown by the arrow **SS**, the inlet lumen 523 of the inlet port 522, the first lumen 538 of the second control member 535, and the first outlet lumen 525 of the first outlet port 524 define a fluid flow path such that the second portion 576 of the inner volume 573 defined by the fluid reservoir 570 is in fluid communication with the inlet port 522. Furthermore, with the inlet port 522 coupled to the lumen-defining device the fluid reservoir 570 is in fluid communication with the portion of the patient (e.g., the vein) and at least a portion of the suction force is introduced to the portion of the patient. In this manner, a bodily-fluid is drawn into the fluid reservoir 570. In some embodiments, the bodily-fluid can contain undesirable microbes such as, for example, dermally-residing microbes dislodged during the insertion of the lumen-defining device.

[1163] As shown in FIG. 28, the actuator mechanism 540 is configured such that the proximal end portion 549 of the plunger 548 is spaced apart from the protrusion 547 of the

activation extension 546. In this manner, the plunger 548 can move in the proximal direction without engaging the protrusion 547 of the activation extension 546. Thus, the plunger 548 can move to introduce the change of the volume in the fluid reservoir 570 without the activation extension 546 moving the first control member 531 from the first configuration toward the second configuration. Therefore, the transfer device 500 can be stored in the first configuration, as described above.

[1164] With a desired amount of bodily-fluid transferred to the fluid reservoir 570, a user can move the transfer device 500 from the first configuration to the second configuration, wherein a flow of bodily-fluid is transferred to the external reservoir (e.g., such as those described above). In some embodiments, the desired amount of bodily-fluid transferred to the fluid reservoir 570 is a predetermined amount of fluid. For example, in some embodiments, the transfer device 500 can be configured to transfer bodily-fluid until the pressure within the fluid reservoir 570 is equilibrium with the pressure of the portion of the body in which the lumen-defining device is disposed (e.g., the vein). In such embodiments, the equalizing of the pressure between the fluid reservoir 570 and the portion of the body stops the flow of the bodily-fluid into the fluid reservoir 570. In some embodiments, the predetermined amount of bodily-fluid (e.g., volume) is at least equal to the combined volume of the inlet lumen 523, the first lumen 538, the first outlet lumen 525, and the lumen-defining device.

[1165] As shown in FIG. 29, the transfer device 500 can be moved from the first configuration to the second configuration by further moving the actuator mechanism 540 in the distal direction, as indicated by the arrow **TT**. As the actuator mechanism 540 is moved from the first configuration toward the second configuration, the protrusions 547 of the activation extension 546 is engaged by the proximal end portion 549 of the plunger 548 such that the activation extension 546 is moved in the direction **TT**. Furthermore, the proximal motion of the activation extension 546 moves the first control member 331 and places the flow control mechanism 530 in the second configuration, as indicated by the arrow **UU**. In this manner, the first lumen 538 is fluidically isolated from the inlet lumen 523 and the first outlet lumen 525. In addition, the second lumen 539 defined by the second control member 535 is placed in fluid communication with the inlet lumen 523 defined by the inlet port 522 and the second outlet lumen 527 defined by the second outlet port 526.

[1166] As shown by the arrow **VV**, the inlet lumen 523 of the inlet port 522, the second lumen 539 of the second control member 535, and the second outlet lumen 527 of the second

outlet port 526 define a fluid flow path such that the external reservoir (not shown in FIGS. 28 and 29) is in fluid communication with the inlet port 522 and, therefore, the portion of the patient (e.g., the vein). Furthermore, the external reservoir is configured to define a negative pressure (e.g., the known external reservoirs referred to herein are vessels defining a negative pressure). The negative pressure within the external reservoir is such that the negative pressure differential between the external reservoir and the portion of the body of the patient introduces a suction force within the portion of the patient. Therefore, a desired amount of bodily-fluid is drawn into the external reservoir and is fluidically isolated from the first, predetermined amount of bodily-fluid contained within the fluid reservoir 570.

[1167] The bodily-fluid contained in the external reservoir is substantially free from microbes generally found outside of the portion of the patient (e.g., dermally residing microbes, microbes within a lumen defined by the transfer device 500, microbes within the lumen defined by the lumen defining device, and/or any other undesirable microbe). As described above, the bodily-fluid contained within the fluid reservoir 570 is fluidically isolated from a volume outside the fluid reservoir 570 and the external reservoir can be decoupled from the transfer device 500.

[1168] While some embodiments described above include a flow control mechanism that can be rotated to control the flow of a bodily-fluid (e.g., the flow rate) and/or to control the amount of negative pressure within a fluid reservoir, in other embodiments, bodily-fluid transfer device can include any suitable device, mechanism, and/or assembly that can control, at least partially, a flow of bodily-fluid (e.g., the flow rate of the bodily-fluid). For example, FIGS. 30-41 illustrate a transfer device 600 according to an embodiment. The transfer device 600 includes a housing 601, a diverter 620, a flow control mechanism 630, and adjustment mechanism 685, and an actuator 640. The transfer device 600 can be any suitable shape, size, or configuration. For example, the transfer device 600 can have a shape and size that is substantially similar to the transfer device 200 described above with reference to FIGS. 2-12. As such, portions of the transfer device 600 can be substantially similar in form and/or function to corresponding portions of the transfer device 200 of FIGS. 2-12. Thus, aspects of the transfer device 600 are not described in further detail herein.

[1169] The housing 601 of the transfer device 600 includes a proximal end portion 602 and a distal end portion 603. The distal end portion 603 includes a base 606 from which a set of walls 604 extend. The walls 604 of the housing 601 define a substantially annular shape

and define an inner volume 611 between the proximal end portion 602 and the distal end portion 603. The proximal end portion 602 of the housing 601 is open to receive at least a portion of the diverter 620, a portion of the flow control mechanism 630, and a portion of the actuator 640 within the inner volume 611 (see e.g., FIG. 31). The walls 604 of the housing 601 define a set of status windows 610 and a set of channels 605. The status windows 610 and the channels 605 can be any suitable shape or size. For example, the status windows 610 and the channels 605 can be substantially similar in form and function to the status windows 210 and the channels 205 of the transfer device 200.

[1170] As shown in FIGS. 32 and 33, the housing 601 includes a set of guide posts 607 and a set of flow control protrusions 608 and defines a passageway 614. The guide posts 607 engage a portion of the diverter 620 and a portion of the actuator 640, as further described herein. The flow control protrusions 608 extend from the base 606 in the proximal direction and can be arranged to selectively engage a portion of the flow control mechanism 630 to move the flow control mechanism 630 between a first configuration and a second configuration, as described in further detail herein. While only one flow control protrusion 608 is shown in FIGS. 32 and 33, the housing 601 can include, for example, two flow control protrusions 608 that are disposed adjacent to a guide post 607. As shown in FIG. 33, the passageway 614 extends through the base 606 and can be arranged to receive a portion of the flow control mechanism 630, as described in further detail herein.

[1171] As shown in FIG. 31, the actuator mechanism 640 includes the actuator housing 662, a plunger 648, and a cap 655. The actuator mechanism 640 is configured to move between a first configuration and a second configuration, thereby moving the transfer device 600 between a first configuration and a second configuration, as described in further detail herein. The actuator housing 662 includes a proximal end portion 663 and a distal end portion 664 and defines an inner volume 665. The inner volume 665 of the actuator housing 662 receives the plunger 648 and at least a portion of the cap 655. The plunger 648 includes a set of seal member 654 that can form a friction fit with an inner surface (not shown in FIG. 31) of the actuator housing 662 that defines the inner volume 665 of the actuator housing 662. Thus, the plunger 648 can be configured to divide the inner volume 665 into a first portion 667 that is fluidically isolated from a second portion 670 (also referred to herein as "fluid reservoir"). The cap 655 defines an inlet port 658 and a set of guide post ports 659. The inlet port 658 receives a portion of a first outlet port 624 of the diverter 620. The guide

post ports 659 movably receive the guide posts 607 of the housing 601 to allow the guide posts 607 to be in contact with the plunger 648. In this manner, the actuator housing 662, the plunger 648, and the cap 655 of the actuator mechanism 640 can be substantially similar to or the same as the actuator housing 262, the plunger 248, and the cap 255, respectively, of the actuator mechanism 640 included in the transfer device 200 described above with reference to FIGS. 2-12. Thus, aspects of the actuator housing 662, the plunger 648, and the cap 655 are not described in further detail herein. As shown in FIG. 31, the actuator mechanism 640 can differ from the actuator mechanism 240 in that the actuator mechanism 640 does not include a spring such as the spring 261 of the actuator mechanism 240. In other embodiments, however, the actuator mechanism 640 can include a spring that is substantially similar to the spring 261.

[1172] As shown in FIGS. 34 and 35, the diverter 620 of the transfer device 600 includes a proximal end portion 628 and a distal end portion 629 and defines an inner volume 621. The inner volume 621 can receive at least a portion of the flow control mechanism 630, as described above with reference to the transfer device 200. The proximal end portion 628 of the diverter 620 includes a first outlet port 624. The distal end portion 629 includes an inlet port 622 and a second outlet port 626. The diverter 620 is movably disposed within the inner volume 611 of the housing 601 such that a portion of the inlet port 622 extends through a first channel 605 defined by the walls 604 of the housing 601 and a portion of the second outlet port 626 extends through a second channel 605 opposite the first channel (see e.g., FIG. 30). While not explicitly shown in FIGS. 30-41, the distal end portion 629 of the diverter 620 can engage the guide posts 607 to limit, for example, lateral movement of the diverter 620 as the diverter 620 is moved in the inner volume 611. Similarly stated, the guide posts 607 of the housing 601 can engage the diverter 620 to substantially limit its movement to a proximal direction or distal direction relative to the housing 601, as further described herein.

[1173] As shown in FIG. 35, the inlet port 622, the first outlet port 624, and the second outlet port 626 define an inlet lumen 623, a first outlet lumen 625, and a second outlet lumen 627, respectively, that are each in fluid communication with the inner volume 621. The inlet port 622 can be fluidically coupled to a needle or other lumen-containing device (not shown in FIGS. 30-41) that can be disposed within a portion of a body of the patient (e.g., within a vein of the patient), the first outlet port 624 can be fluidically coupled to a portion of the actuator 640, and the second outlet port 626 can be fluidically coupled to an external

reservoir (e.g., a sample reservoir not shown in FIGS. 30-41). In this manner, the diverter 620 can be arranged to selectively place the portion of the actuator 640 or the external reservoir in fluid communication with the portion of the body via the inlet port 622 and the first outlet port 624 or via the inlet port 622 and the second outlet port 626, respectively. As shown in FIG. 35, the diverter 620 also defines an opening 689 that can receive a portion of the flow control mechanism 630, as described in further detail herein.

[1174] As shown in FIGS. 36 and 37, the flow control mechanism 630 includes a first activation mechanism 631A, a second activation mechanism 631B, a control member 635, and an adjustment mechanism 685. At least a portion of the flow control mechanism 630 is configured to be disposed within the inner volume 621 defined by the diverter 620. More specifically, the flow control mechanism 630 has a circular cross-sectional shape such that when the flow control mechanism 630 is disposed in the inner volume 621, a portion of the control member 635 forms a friction fit with the walls of the diverter 620 defining the inner volume 621, as described in further detail herein. Although not shown in FIGS. 30-41, the flow control mechanism 630 can be arranged within the inner volume 611 of the housing 601 and the inner volume 621 of the diverter 620 such that the first activation mechanism 631A and the second activation mechanism 631B are disposed adjacent to and in contact with the control member 635. More specifically, the first activation mechanism 631A and the second activation mechanism 631B can be in frictional contact with the control mechanism 635. In other embodiments, the first activation mechanism 631A and the second activation mechanism 631B can be coupled to the control member 635 via a mechanical fastener and/or an adhesive. In this manner, the first activation mechanism 631A and the second activation mechanism 631B can be moved concurrently to move the control member 635, as described in further detail herein.

[1175] The first activation mechanism 631A and the second activation mechanism 631B include a set of engagement members 634A and 634B, respectively (although only one engagement member 634B is shown in FIG. 36, the second activation mechanism 631B is arranged in similar manner as the first activation mechanism 631A). The engagement members 634A and 634B are configured to engage the flow control protrusion 608 of the housing 601. For example, the diverter 620 and the flow control mechanism 630 can be moved within the inner volume 611 of the housing 601 to place the engagement members 634A and 634B in contact with the flow control protrusions 608. Moreover, once the

engagement members 634A and 634B are placed in contact with the flow control protrusions 608, further movement of the diverter 620 and the flow control mechanism 630 can rotate the flow control mechanism 630 relative to the diverter 620 between a first configuration and a second configuration, as described in further detail herein.

[1176] As shown in FIG. 37, the control member 635 defines a first lumen 638, a second lumen 639, and a set of channels 637. The channels 637 can be configured to receive a portion of the adjustment mechanism 685, as described in further detail herein. The flow control mechanism 630 can be arranged such that when in its first configuration, the first lumen 638 is placed in fluid communication with the inlet lumen 623 defined by the inlet port 622 and the first outlet lumen 625 defined by the first outlet port 624. Similarly, when the flow control mechanism 630 is in the second configuration, the second lumen 639 is placed in fluid communication with the inlet lumen 623 defined by the inlet port 622 and the second outlet lumen 627 defined by the second outlet port 626. Therefore, the flow control mechanism 630 can be rotated relative to the diverter 620 to selectively place the first outlet port 624 or the second outlet port 626 in fluid communication with the inlet port 622.

[1177] The adjustment mechanism 685 includes a dial 686 and an adjustment member 688 (see e.g., FIG. 31). In some embodiments, the adjustment member 688 can be, for example, a screw or the like. As shown in FIG. 30, the adjustment mechanism 685 can be disposed adjacent to the base 606 of the housing 601. More specifically, the dial 686 includes a receiving portion 686A that can be inserted into the passageway 614 defined by the base 606. In this manner, a coupler 687 (e.g., a retaining ring or the like) can be positioned about the receiving portion 686 to limit movement of the dial 686 relative to the base 606. For example, the coupler 687 can be configured to limit translational movement of the dial 686 relative to the base 606 while allowing rotational movement of the dial 686 relative to the base 606. The adjustment mechanism 685 can be arranged such that at least a portion of the adjustment member 688 is movably disposed in the opening 689 defined by the diverter 620. For example, the adjustment member 688 and a set of walls defining the opening 689 of the diverter 620 can define a threaded coupling. Thus, the adjustment member 688 can be rotated relative to the diverter 620 and, as such, the adjustment member 688 can be moved in a translation motion (e.g., proximal or distal direction) relative to the diverter 620. For example, a portion of the adjustment member 688 (e.g., a head of a bolt or screw) can be disposed within the receiving portion 686A of the dial 686 such that as the dial

686 is rotated relative to the housing 601, the adjustment member 688 is rotated relative to the diverter 620. Moreover, a portion of the adjustment member 688 can be disposed within one of the channels 637 of the control member 635. As such, the adjustment mechanism 685 can be manipulated to advance the adjustment member 688 relative to the diverter 620 to place the adjustment member 688 in contact with an engagement surface 636 of the control member 635 (see e.g., FIG. 37). In this manner, the movement of the adjustment member 688 can exert a force on the engagement surface 636 that can be sufficient to deform, bend, or otherwise reconfigure a wall of the control member 635 defining either the first lumen 638 or the second lumen 639, as described in further detail herein.

[1178] In some embodiments, the transfer device 600 can be stored in a storage configuration (e.g., a first configuration) in which the control member 635 of the flow control mechanism 630 fluidically isolates the inlet port 622, the first outlet port 624, and the second outlet port 626 from the inner volume 621 defined by the diverter 620. In such embodiments, first lumen 638 and the second lumen 639 are fluidically isolated from the inlet lumen 623, the first outlet lumen 625, and the second outlet lumen 627, as shown in FIG. 38. Furthermore, the friction fit defined by the control member 635 and the walls of the diverter 620 defining the inner volume 621 maintain the flow control mechanism 630 in the storage configuration until the flow control mechanism 630 is moved from the storage configuration.

[1179] In use, a user can manipulate the transfer device 600 to couple the inlet port 622 to a proximal end portion of a lumen-defining device (not shown) such as, for example, a butterfly needle. The distal end portion of the lumen-defining device can be disposed within a portion of the body of a patient (e.g., a vein), thereby placing the inlet lumen 623 in fluid communication with the portion of the body of the patient. In a similar manner, the second outlet port 626 can be coupled to an external fluid reservoir (not shown). The external fluid reservoir can be any suitable reservoir. For example, in some embodiments, the external fluid reservoir can be a BacT/ALERT® SN or a BacT/ALERT® FA, manufactured by BIOMERIEUX, INC.

[1180] With the inlet port 622 coupled to the lumen-defining device and the second outlet port 626 coupled to the external fluid reservoir, a user can move the transfer device 600 from the first configuration to a second configuration by applying an activation force to the actuator mechanism 640. In this manner, at least a portion of the actuator mechanism 640, the diverter 620, and the flow control mechanism 630 are moved in the distal direction

toward the second configuration, as indicated by the arrow **WW** in FIG. 39. More specifically and as described above, the arrangement of the plunger 648 and the guide posts 607 is such that as the user applies the activation force to the actuator mechanism 640, the position of the plunger 648, relative to the housing 601, is maintained. Therefore, the activation force applied by the user moves the actuator housing 662, the cap 655, the diverter 620, and the flow control mechanism 630 in the direction of the arrow **WW**, but not the plunger 648. The distal movement of the actuator housing 662 is such that the height of the first portion 667 of the inner volume 665 is reduced and the height of the fluid reservoir 670 is increased. With the fluid reservoir 670 being fluidically isolated (as described above) the increase in the height (i.e., the increase in volume) produces a negative pressure within the fluid reservoir 670. Said another way, the movement of the plunger 648 increases the volume of the fluid reservoir 670, which, in turn, produces a negative pressure therein.

[1181] As the actuator mechanism 640 is moved from the storage configuration toward the first configuration, the flow control protrusions 608 engage the engagement members 634A and 634B of the first activation mechanism 631A and the second activation member 631B, respectively, (not shown in FIG. 39) to move the flow control mechanism 630 toward the first configuration, as indicated by the arrow **XX** in FIG. 39. Thus, when the flow control mechanism 630 is moved to its first configuration, the first lumen 638 defined by the control member 635 is placed in fluid communication with the inlet lumen 623 defined by the inlet port 622 and the first outlet lumen 625 defined by the first outlet port 624. As indicated by the arrow **YY** in FIG. 39, the inlet lumen 623 of the inlet port 622, the first lumen 638 of the control member 635, and the first outlet lumen 625 of the first outlet port 624 define a fluid flow path such that the fluid reservoir 670 defined by the actuator housing 662 is placed in fluid communication with the inlet port 622. Thus, the negative pressure within the fluid reservoir 670 is such that the negative pressure differential introduces a suction force within the portion of the patient. In this manner, a bodily-fluid is drawn into the fluid reservoir 670 of the actuator housing 662, as indicated by the arrow **YY**. In some embodiments, the bodily-fluid can contain undesirable microbes such as, for example, dermally-residing microbes. In some instances, the magnitude of the suction force can be modulated by increasing or decreasing the amount of activation force applied to the actuator mechanism 640. In this manner, the change in the volume of the fluid reservoir 670 can be modulated such that a desired amount of a suction force is exerted within the vein of the patient.

[1182] With the desired amount of bodily-fluid transferred to the fluid reservoir 670 defined by the actuator housing 662, a user can manipulate the transfer device 600 to move the transfer device 600 from the second configuration to the third configuration, wherein a flow of bodily-fluid is transferred to the external reservoir (e.g., such as those described above). In some embodiments, the desired amount of bodily-fluid transferred to the actuator housing 662 is a predetermined amount of fluid, as described in detail above.

[1183] The transfer device 600 can be moved from the second configuration to the third configuration by further moving the actuator mechanism 640 in the distal direction, as indicated by the arrow **ZZ** in FIG. 40. Expanding further, the user can apply an activation force to the actuator mechanism 640 such that the actuator housing 662, the cap 655, the diverter 620, and the flow control mechanism 630 move in the distal direction. With the desired amount of the bodily-fluid disposed within the fluid reservoir 670 the volume of the fluid reservoir 670 is configured to remain constant as the actuator housing 662 and the cap 655 move relative to the plunger 648. Similarly stated, the pressure of the fluid reservoir 670 is configured to remain substantially unchanged as the transfer device 600 is moved from the first configuration to the second configuration. As the actuator mechanism 640 is moved from its first configuration toward its second configuration, the flow control protrusions 608 engage the engagement members 634A and 634B to rotate the flow control mechanism 630 toward the second configuration, as indicated by the arrow **AAA**. Thus, when the flow control mechanism 630 is moved to its second configuration, the second lumen 639 defined by the control member 635 is placed in fluid communication with the inlet lumen 623 defined by the inlet port 622 and the second outlet lumen 627 defined by the second outlet port 626.

[1184] As shown by the arrow **BBB**, the inlet lumen 623 of the inlet port 622, the second lumen 639 of the control member 635, and the second outlet lumen 627 of the second outlet port 626 define a fluid flow path such that the external reservoir (not shown in FIG. 40) is in fluid communication with the inlet port 622 and, therefore, the portion of the patient (e.g., the vein). Furthermore, the external reservoir is configured to define a negative pressure (e.g., the known external reservoirs referred to herein are vessels defining a negative pressure). The negative pressure within the external reservoir is such that the negative pressure differential between the external reservoir and the portion of the body of the patient introduces a suction force within the portion of the patient. Therefore, a desired amount of bodily-fluid can be drawn into the external reservoir that is fluidically isolated from the first,

predetermined amount of bodily-fluid contained within the fluid reservoir 670 defined by the actuator housing 662. In this manner, the bodily-fluid contained in the external reservoir is substantially free from microbes generally found outside of the portion of the patient (e.g., dermally residing microbes, microbes within a lumen defined by the transfer device 600, microbes within the lumen defined by the lumen defining device, and/or any other undesirable microbe).

[1185] In some instances, it may be desirable to limit and/or modulate the amount of a suction force exerted on the vein of the patient and/or a flow rate of the bodily-fluid. In such instances, the user can manipulate the adjustment mechanism 685 to move the adjustment member 688 relative to the control member 635. For example, the distal movement of the diverter 620 relative to the housing 601 is such that a portion of the adjustment member 688 is disposed in the receiving portion 686A of the dial 686. In this manner, the dial 686 can be rotated to advance the adjustment member 688 relative to the control member 635, as indicated by the arrow **CCC** in FIG. 41. Thus, the adjustment member 688 can be moved into contact with the engagement surface 636 to deform a portion of the control member 635 defining the second lumen 639. As such, the wall of the control member 635 constricts the second lumen 639 (e.g., reduces a diameter of at least a portion of the second lumen 639), thereby reducing the suction force exerted within the vein and/or slowing the rate at which the bodily-fluid flows within the second lumen 639. In some embodiments, the dial 686 can be rotated in alternating directions to alternately move the adjustment member 688 in the proximal direction and the distal direction. In this manner, the flow of the bodily-fluid can be, for example, pulsed or the like. In this manner, bodily-fluid that is substantially free from microbes (e.g., dermally residing microbes or the like) can flow with a desired set of characteristics into the external reservoir.

[1186] While the transfer device 200 is described above with reference to FIGS. 2-12 as including a linear spring 261 (e.g., a compression spring), in other embodiments, a transfer device can include any suitable spring that can be configured to modulate, change, and/or control a negative pressure within a fluid reservoir and/or a flow rate of a bodily-fluid. For example, FIGS. 42-47 illustrate a transfer device 700 according to another embodiment. The transfer device 700 includes a housing 701, a diverter 720, a flow control mechanism 730, and adjustment mechanism 785, and an actuator 740. The transfer device 700 can be any suitable shape, size, or configuration. For example, portions of the transfer device 700 can be

substantially similar to or the same as corresponding portions of the transfer device 200 (described above with reference to FIGS. 2-12) and/or the transfer device 600 (described above with reference to FIGS. 30-41). As such, aspects of the transfer device 700 of the transfer device 700 are not described in further detail herein.

[1187] The housing 701 of the transfer device 700 includes a proximal end portion 702 and a distal end portion 703. The distal end portion 703 includes a base 706 from which a set of walls 704 extend. The walls 704 of the housing 701 define a substantially annular shape and define an inner volume 711 between the proximal end portion 702 and the distal end portion 703. The proximal end portion 702 of the housing 701 is open to receive at least a portion of the diverter 720, a portion of the flow control mechanism 730, and a portion of the actuator 740 within the inner volume 711 (see e.g., FIG. 31). The walls 704 of the housing 701 define a set of status windows 710 and a set of channels 705. The status windows 710 and the channels 705 can be any suitable shape or size. For example, the status windows 710 and the channels 705 can be substantially similar in form and function to the status windows 210 and the channels 205 of the transfer device 200. The housing 701 includes a set of guide posts 707 and a set of flow control protrusions (not shown in FIGS. 43-46). In this manner, the housing 701 can function similarly to the housing 601 included in the transfer device 600 described above.

[1188] As shown in FIG. 31, the actuator mechanism 740 includes the actuator housing 762, a plunger 748, and a cap 755. The actuator mechanism 740 is configured to move between a first configuration and a second configuration, thereby moving the transfer device 700 between a first configuration and a second configuration, as described in further detail herein. The actuator housing 762 includes a proximal end portion 763 and a distal end portion 764 and defines an inner volume 765. The inner volume 765 of the actuator housing 762 receives the plunger 748 and at least a portion of the cap 755. As such, the actuator mechanism 740 can be substantially similar in form and function as the actuator mechanism 640 included in the transfer device 600 described above with reference to FIGS. 30-41. Thus, the plunger 748 can be disposed in the actuator housing 762 to divide the inner volume 765 into a first portion 767 and a second portion 770 (also referred to herein as "fluid reservoir").

[1189] As shown in FIGS. 43, the diverter 720 of the transfer device 700 includes an inlet port 722, a first outlet port 724, and a second outlet port 726 and defines an inner volume 721. The inner volume 721 can receive at least a portion of the flow control mechanism 730,

as described above with reference to the transfer device 200. The diverter 720 is movably disposed within the inner volume 711 of the housing 701 such that a portion of the inlet port 722 extends through a first channel 705 defined by the walls 704 of the housing 701 and a portion of the second outlet port 726 extends through a second channel 705 opposite the first channel (see e.g., FIG. 42). While not explicitly shown in FIGS. 42-46, the distal end portion 729 of the diverter 720 can engage the guide posts 707 to limit, for example, lateral movement of the diverter 720 as the diverter 720 is moved in the inner volume 711. Similarly stated, the guide posts 707 of the housing 701 can engage the diverter 720 to substantially limit its movement to a proximal direction or distal direction relative to the housing 701, as further described herein.

[1190] The inlet port 722, the first outlet port 724, and the second outlet port 726 define an inlet lumen 723, a first outlet lumen 725, and a second outlet lumen 727, respectively, that are each in fluid communication with the inner volume 721 (see e.g., FIGS. 45 and 46). The inlet port 722 can be fluidically coupled to a needle or other lumen-containing device (not shown in FIGS. 30-41) that can be disposed within a portion of a body of the patient (e.g., within a vein of the patient), the first outlet port 724 can be fluidically coupled to a portion of the actuator 740, and the second outlet port 726 can be fluidically coupled to an external reservoir (e.g., a sample reservoir not shown in FIGS. 30-41). In this manner, the diverter 720 can be arranged to selectively place the portion of the actuator 740 or the external reservoir in fluid communication with the portion of the body via the inlet port 722 and the first outlet port 724 or via the inlet port 722 and the second outlet port 726, respectively.

[1191] As shown in FIG. 44, the flow control mechanism 730 includes a first activation mechanism 731A, a second activation mechanism 731B, a control member 735, a first torsion spring 761A, and a second torsion spring 761B. At least a portion of the flow control mechanism 730 is configured to be disposed within the inner volume 721 defined by the diverter 720, as described above. Although not shown in FIGS. 42-46, the flow control mechanism 730 can be arranged within the inner volume 711 of the housing 701 and the inner volume 721 of the diverter 720 such that the first activation mechanism 731A and the second activation mechanism 731B are disposed adjacent to and in contact with the control member 735. More specifically, the first activation mechanism 731A and the second activation mechanism 731B can be in frictional contact with the control mechanism 735. In other embodiments, the first activation mechanism 731A and the second activation

mechanism 731B can be coupled to the control member 735 via a mechanical fastener and/or an adhesive. In this manner, the first activation mechanism 731A and the second activation mechanism 731B can be moved concurrently to move the control member 735, as described in further detail herein.

[1192] The first activation mechanism 731A and the second activation mechanism 731B include a set of engagement members 734A and 734B, respectively (although only one engagement member 734B is shown in FIG. 36, the second activation mechanism 731B is arranged in similar manner as the first activation mechanism 731A). The engagement members 734A and 734B are configured to engage the flow control protrusion 708 of the housing 701, as described with reference to the transfer device 600 of FIGS. 30-41. In use, once the engagement members 734A and 734B are placed in contact with the flow control protrusions 708, further movement of the diverter 720 and the flow control mechanism 730 can rotate the flow control mechanism 730 relative to the diverter 720 between a first configuration and a second configuration. As such, the torsion springs 761A and 761B can be moved from a first configuration having a substantially smaller potential energy to a second configuration having a substantially larger potential energy. In other words, the rotational movement of the flow control mechanism 730 relative to the diverter 720 can transfer the torsion springs 761A and 761B to a configuration having a larger potential energy than the potential energy prior to the rotation of the flow control mechanism 730 relative to the diverter 720, as described in further detail herein.

[1193] As shown in FIG. 44, the control member 735 defines a first lumen 738, a second lumen 739. The flow control mechanism 730 can be arranged such that when in its first configuration, the first lumen 738 is placed in fluid communication with the inlet lumen 723 defined by the inlet port 722 and the first outlet lumen 725 defined by the first outlet port 724. Similarly, when the flow control mechanism 730 is in the second configuration, the second lumen 739 is placed in fluid communication with the inlet lumen 723 defined by the inlet port 722 and the second outlet lumen 727 defined by the second outlet port 726. Therefore, the flow control mechanism 730 can be rotated relative to the diverter 720 to selectively place the first outlet port 724 or the second outlet port 726 in fluid communication with the inlet port 722.

[1194] In some embodiments, the transfer device 700 can be stored in a storage configuration in which the control member 735 of the flow control mechanism 730 fluidically

isolates the inlet port 722, the first outlet port 724, and the second outlet port 726 from the inner volume 721 defined by the diverter 720. In such embodiments, first lumen 738 and the second lumen 739 are fluidically isolated from the inlet lumen 723, the first outlet lumen 725, and the second outlet lumen 727. Furthermore, the friction fit defined by the control member 735 and the walls of the diverter 720 defining the inner volume 721 maintain the flow control mechanism 730 in the storage configuration until the flow control mechanism 730 is moved from the storage configuration.

[1195] In use, a user can manipulate the transfer device 700 to couple the inlet port 722 to a proximal end portion of a lumen-defining device (not shown) such as, for example, a butterfly needle. The distal end portion of the lumen-defining device can be disposed within a portion of the body of a patient (e.g., a vein), thereby placing the inlet lumen 723 in fluid communication with the portion of the body of the patient. In a similar manner, the second outlet port 726 can be coupled to an external fluid reservoir (not shown). The external fluid reservoir can be any suitable reservoir. For example, in some embodiments, the external fluid reservoir can be a BacT/ALERT® SN or a BacT/ALERT® FA, manufactured by BIOMERIEUX, INC.

[1196] With the inlet port 722 coupled to the lumen-defining device and the second outlet port 726 coupled to the external fluid reservoir, a user can move the transfer device 700 from the first configuration to a second configuration by applying an activation force to the actuator mechanism 740. In this manner, at least a portion of the actuator mechanism 740, the diverter 720, and the flow control mechanism 730 are moved in the distal direction toward the second configuration, as indicated by the arrow **DDD** in FIG. 45. More specifically and as described above, the distal movement of the actuator housing 762 is such that a height of the first portion 767 of the inner volume 765 is reduced and a height of the fluid reservoir 770 is increased. With the fluid reservoir 770 being fluidically isolated (as described above) the increase in the height (i.e., the increase in volume) produces a negative pressure within the fluid reservoir 770. Said another way, the movement of the plunger 748 increases the volume of the fluid reservoir 770, which, in turn, produces a negative pressure therein.

[1197] As shown in FIG. 45, when the flow control mechanism 730 is moved to its first configuration (e.g., from a storage configuration), the first lumen 738 defined by the control member 735 is placed in fluid communication with the inlet lumen 723 defined by the inlet

port 722 and the first outlet lumen 725 defined by the first outlet port 724. As indicated by the arrow **EEE** in FIG. 45, the inlet lumen 723 of the inlet port 722, the first lumen 738 of the control member 735, and the first outlet lumen 725 of the first outlet port 724 define a fluid flow path such that the fluid reservoir 770 defined by the actuator housing 762 is placed in fluid communication with the inlet port 722. Thus, the negative pressure within the fluid reservoir 770 is such that the negative pressure differential introduces a suction force within the portion of the patient. In this manner, a bodily-fluid is drawn into the fluid reservoir 770 of the actuator housing 762, as indicated by the arrow **EEE**. In some embodiments, the bodily-fluid can contain undesirable microbes such as, for example, dermally-residing microbes.

[1198] In some instances, the magnitude of the suction force can be modulated by increasing or decreasing the amount of activation force applied to the actuator mechanism 740. More specifically and as described above, the rotational movement of the flow control mechanism 730 can increase the potential energy of the torsion springs 761A and 761B (not shown in FIG. 45). For example, in some embodiments, an end portion of the torsion springs 761A and 761B can be placed in contact with the flow control protrusions 708 to substantially limit the movement of the end portion of the torsion springs 761A and 761B. Thus, the rotational movement of the first activation mechanism 731A and the second activation mechanism 731B rotates a second end portion of the torsion springs 761A and 761B, respectively, relative to the end portion in contact with the flow control protrusions 708, thereby changing the potential energy of the torsion springs 761A and 761B. In this manner, the torsion springs 761A and 761B can exert a reaction force that can resist the activation force applied to the user on the actuator mechanism 740. Therefore, by reducing the activation force, the flow control mechanism 730 can rotate relative to the diverter 720 to change the alignment of the first lumen 738 of the control member 735 relative to the inlet lumen 723 and the first outlet lumen 725 of the diverter 720. As such, the negative pressure within the fluid reservoir 770 can be reduced and/or otherwise changed.

[1199] With the desired amount of bodily-fluid transferred to the fluid reservoir 770 defined by the actuator housing 762, a user can manipulate the transfer device 700 to move the transfer device 700 from the second configuration to the third configuration, wherein a flow of bodily-fluid is transferred to the external reservoir (e.g., such as those described above). In some embodiments, the desired amount of bodily-fluid transferred to the actuator

housing 762 is a predetermined amount of fluid, as described in detail above. The transfer device 700 can be moved from the first configuration to the second configuration by further moving the actuator mechanism 740 in the distal direction, as indicated by the arrow **FFF** in FIG. 46. Expanding further, the user can apply an activation force to the actuator mechanism 740 such that the actuator housing 762, the cap 755, the diverter 720, and the flow control mechanism 730 move in the distal direction. As the actuator mechanism 740 is moved from its first configuration toward its second configuration, the flow control protrusions 708 engage the engagement members 734A and 734B to rotate the flow control mechanism 730 toward the second configuration, as indicated by the arrow **GGG**. Thus, when the flow control mechanism 730 is moved to its second configuration, the second lumen 739 defined by the control member 735 is placed in fluid communication with the inlet lumen 723 defined by the inlet port 722 and the second outlet lumen 727 defined by the second outlet port 726.

[1200] As shown by the arrow **HHH** in FIG. 46, the inlet lumen 723 of the inlet port 722, the second lumen 739 of the control member 735, and the second outlet lumen 727 of the second outlet port 726 define a fluid flow path such that the external reservoir (not shown in FIG. 46) is in fluid communication with the inlet port 722 and, therefore, the portion of the patient (e.g., the vein). Furthermore, the external reservoir is configured to define a negative pressure (e.g., the known external reservoirs referred to herein are vessels defining a negative pressure). The negative pressure within the external reservoir is such that the negative pressure differential between the external reservoir and the portion of the body of the patient introduces a suction force within the portion of the patient. Therefore, a desired amount of bodily-fluid can be drawn into the external reservoir that is fluidically isolated from the first, predetermined amount of bodily-fluid contained within the fluid reservoir 770 defined by the actuator housing 762. In this manner, the bodily-fluid contained in the external reservoir is substantially free from microbes generally found outside of the portion of the patient (e.g., dermally residing microbes, microbes within a lumen defined by the transfer device 700, microbes within the lumen defined by the lumen defining device, and/or any other undesirable microbe).

[1201] In some instances, it may be desirable to limit and/or modulate the amount of a suction force exerted on the vein of the patient and/or a flow rate of the bodily-fluid. In such instances, the user can decrease the activation force applied to the actuator mechanism 740. In this manner, the torsion springs 761A and 761B can exert a force that is operable in

rotating the control member 735 relative to the diverter 720. Thus, the flow control mechanism 730 can rotate relative to the diverter 720 to change the alignment of the first lumen 738 of the control member 735 relative to the inlet lumen 723 and the first outlet lumen 725 of the diverter 720. As such, the negative pressure within the fluid reservoir 770 can be reduced, modulated, pulsed and/or otherwise changed.

[1202] Referring now to FIG. 47, a flowchart illustrates a method 1000 for parenterally procuring a bodily-fluid sample that is substantially free from microbes. In some embodiments, the method 1000 includes inserting a needle of a parenteral sampling device into a patient, at 1001. In some embodiments, the parenteral sampling device can be, for example, a fluid transfer device such as those described herein. As such, the parenteral sampling device (also referred to herein as "device") can include at least the needle, an actuator, a flow control mechanism, and a fluid reservoir. As described above with reference to the transfer devices 100, 200, 300, 400, 500, 600, and/or 700, the device can be configured to selectively place the needle in fluid communication with the fluid reservoir.

[1203] The method 1000 includes establishing fluid communication between the needle and the fluid reservoir, at 1002. For example, in some embodiments, the device can be in a storage configuration prior to use in which the needle is fluidically isolated from the fluid reservoir. Therefore, in use, the device can be manipulated to define a fluid flow path between the needle and the fluid reservoir. In some embodiments, for example, the device can be manipulated to arrange the flow control mechanism included in the device in a first configuration such that the flow control mechanism defines at least a portion of the fluid flow path. For example, the flow control mechanism can be substantially similar to the flow control mechanism 230 included in the transfer device 200 described above with reference to FIGS. 2-12.

[1204] With the flow path defined between the needle and the fluid reservoir, an actuator is moved a first distance to create a negative pressure in the fluid reservoir and to withdraw a predetermined volume of bodily-fluid, at 1003. For example, in some embodiments, a user can exert an activation force on the actuator to move the actuator relative to a portion of the device. In such embodiments, the actuator can include a plunger or the like that can be disposed within a portion of the actuator and arranged such that the plunger defines, at least partially, the fluid reservoir. Thus, when the activation force is applied to the actuator, the actuator can move relative to the plunger such that a negative pressure is produced within the

fluid reservoir. In this manner, a bodily-fluid can flow through a first flow path from the needle to the fluid reservoir (e.g., via a lumen defined by the flow control mechanism). In some instances, the negative pressure in the fluid reservoir can be reduced, for example, by reducing the activation force applied to the actuator and/or releasing the actuator, at 1004. For example, in some embodiments, the actuator can include a spring and/or any other suitable device, mechanism, or member that can be operable in constricting at least a portion of the fluid flow path. The negative pressure in a subsequent sample reservoir can also be reduced, for example, by apply an activation force to the actuator, at 1004, as described herein.

[1205] The method 1000 includes moving the actuator a second distance to engage the flow control mechanism to move the flow control mechanism between the first configuration and a second configuration that is operable in allowing bodily-fluid to flow through a second flow path from the needle to a sample reservoir, at 1005. For example, in some embodiments, by moving the actuator the second distance, the flow control mechanism is rotated such that a lumen defined therein defines at least a portion of the second fluid flow path. In this manner, bodily-fluid can flow through the second flow path to be disposed within the sample reservoir. In some embodiments, the collection and/or the isolation of a first volume of the bodily-fluid can reduce and/or eliminate, for example, an amount of microbes (e.g., dermally-residing microbes, other undesirable external contaminants, or the like) in the sample volume.

[1206] While various embodiments have been described above, it should be understood that they have been presented by way of example only, and not limitation. Where methods and steps described above indicate certain events occurring in certain order, those of ordinary skill in the art having the benefit of this disclosure would recognize that the ordering of certain steps may be modified and that such modifications are in accordance with the variations of the invention. Additionally, certain of the steps may be performed concurrently in a parallel process when possible, as well as performed sequentially as described above. Additionally, certain steps may be partially completed and/or omitted before proceeding to subsequent steps.

[1207] While various embodiments have been particularly shown and described, various changes in form and details may be made. Although various embodiments have been described as having particular features and/or combinations of components, other

embodiments are possible having any combination or sub-combination of any features and/or components from any of the embodiments described herein. For example, while the not shown in FIGS. 28 and 29, in some embodiments, the transfer device 500 can include a throttling button, similar in form and function to the throttling button 445 included in the transfer device 400. By way of another example, although not shown in FIGS. 30-41, in some embodiments, the transfer device 600 can include one or more springs such as, for example, the spring 261 of the transfer device and/or the torsion springs 761A and 761B of the transfer device 700.

[1208] The specific configurations of the various components can also be varied. For example, the size and specific shape of the various components can be different than the embodiments shown, while still providing the functions as described herein. More specifically, the size and shape of the various components can be specifically selected for a desired rate of bodily-fluid flow into a fluid reservoir.

Claims

1. A device for procuring bodily-fluid samples from a patient, the device comprising:

a housing including a proximal end portion and a distal end portion and defining an inner volume therebetween, the housing having an inlet port configured to be fluidically coupled to the patient, and an outlet port configured to be fluidically coupled to a sample reservoir;

a fluid reservoir disposed in the inner volume and configured to receive and isolate a first volume of bodily-fluid withdrawn from the patient;

a flow control mechanism disposed in the housing and defining a first lumen and a second lumen, the flow control mechanism configured for rotational movement from a first configuration, in which the inlet port is placed in fluid communication with the fluid reservoir such that bodily-fluid can flow from the inlet port, through the first lumen and to the fluid reservoir, to a second configuration, in which the inlet port is placed in fluid communication with the outlet port such that the bodily-fluid can flow from the inlet, through the second lumen and to the outlet port; and

an actuator operably coupled to the flow control mechanism and configured to create a negative pressure in the fluid reservoir when actuated by a user, the actuator further configured to rotate the flow control mechanism from the first configuration to the second configuration after the first volume of bodily-fluid is received in the fluid reservoir from the patient.

2. The device of claim 1, wherein the actuator is further configured to move a first distance to create the negative pressure in the fluid reservoir when actuated by a user.

3. The device of claim 2, wherein the actuator is further configured to move a second distance to rotate the flow control mechanism from the first configuration to the second configuration.

4. The device of claim 1, wherein the actuator is configured to move in a first direction to create the negative pressure in the fluid reservoir, and to move in a second direction to reduce the negative pressure created in the fluid reservoir from movement in the first direction.

5. The device of claim 1, wherein the actuator is configured to allow the user to modulate the negative pressure created in the fluid reservoir.

6. A device for procuring bodily-fluid samples from a patient, the device comprising:

a housing including a proximal end portion and a distal end portion and defining an inner volume therebetween;

an actuator movably disposed in the housing, the actuator including a sealing member and a fluid reservoir defined at least in part by the sealing member, the actuator configured to create a negative pressure in the fluid reservoir when actuated by a user;

a diverter disposed in the housing, the diverter having an inlet port configured to be fluidically coupled to the patient, a first outlet port configured to be fluidically coupleable to the fluid reservoir, and a second outlet port configured to be fluidically coupled to a sample reservoir; and

a flow control mechanism disposed in the diverter and defining a first lumen and a second lumen, the flow control mechanism configured for rotational movement between a first configuration, in which the inlet port is placed in fluid communication with the first outlet port such that bodily-fluid can flow from the inlet port, through the first lumen and to the first outlet port, to a second configuration, in which the inlet port is placed in fluid communication with the second outlet port such that the bodily-fluid can flow from the inlet, through the second lumen and to the second outlet port.

7. The device of claim 6, wherein the actuator is further configured to rotate the flow control mechanism from the first configuration to the second configuration after a first volume of bodily-fluid is received in the fluid reservoir from the patient.

8. The device of claim 7, wherein the actuator is configured to move a first distance to create the negative pressure in the fluid reservoir, and to move a second distance to rotate the flow control mechanism from the first configuration to the second configuration, when actuated by a user.

9. The device of claim 6, wherein the actuator is configured to move in a first direction to create the negative pressure in the fluid reservoir, and to move in a second direction to

reduce the negative pressure created in the fluid reservoir from movement in the first direction.

10. The device of claim 6, wherein the actuator further includes a plunger operably coupled to the sealing member.

11. The device of claim 10, wherein the actuator further includes a spring operably coupled to the plunger, the spring configured to compress in response to an activation force when the actuator is actuated by a user.

12. The device of claim 11, wherein the spring is configured to expand and exert a reaction force when the activation force is removed.

13. The device of claim 12, wherein the spring is configured to allow the user to modulate the negative pressure created in the fluid reservoir.

14. A device for procuring bodily-fluid samples from a patient, the device comprising:

a housing including a proximal end portion and a distal end portion and defining an inner volume therebetween, the housing having an inlet port configured to be fluidically coupled to the patient, and an outlet port configured to be fluidically coupled to a sample reservoir;

a flow control mechanism disposed in the housing and defining a first lumen and a second lumen, the flow control mechanism configured for rotational movement between a first configuration, in which the inlet port is placed in fluid communication with a fluid reservoir defined at least in part by the housing such that bodily-fluid can flow from the inlet port, through the first lumen and to the fluid reservoir, to a second configuration, in which the inlet port is placed in fluid communication with the outlet port such that the bodily-fluid can flow from the inlet, through the second lumen and to the outlet port; and

an actuator movably disposed in the housing and operably coupled to the flow control mechanism, the actuator configured to create a negative pressure in the fluid reservoir when actuated by a user, the actuator further configured to rotate the flow control mechanism from the first configuration to the second configuration after a first volume of bodily-fluid is received in the fluid reservoir from the patient.

15. The device of claim 14, wherein the actuator includes an activation mechanism configured to rotate the flow control mechanism from the first configuration to the second configuration.

16. The device of claim 15, wherein the activation mechanism includes a first set of protrusions and the flow control mechanism includes a second set of protrusions, the first set of protrusions configured to operably engage the second set of protrusions to rotate the flow control mechanism from the first configuration to the second configuration.

17. The device of claim 14, wherein the actuator is further configured to create the negative pressure in the fluid reservoir when the actuator is moved from a first position to a second position by the user.

18. The device of claims 17, wherein the actuator is further configured to rotate the flow control mechanism from the first configuration to the second configuration when the actuator is moved from the second position to a third position by the user.

19. The device of claim 18, wherein the actuator includes an activation mechanism and the flow control mechanism includes a set of protrusions, the activation mechanism configured to operably engage the set of protrusions to rotate the flow control mechanism from the first configuration to the second configuration when the actuator is moved from the second position to a third position by the user.

20. A device for procuring bodily-fluid samples from a patient, the device comprising:

a housing including a proximal end portion and a distal end portion and defining an inner volume therebetween, the housing having an inlet port configured to be fluidically coupled to the patient;

a seal member movably disposed in the inner volume;

a fluid reservoir disposed in the inner volume and at least partially defined by the seal member, the fluid reservoir configured to receive and isolate a first volume of bodily-fluid withdrawn from the patient;

a flow control mechanism movably disposed in the housing, the flow control mechanism configured to move between a first configuration, in which the bodily-fluid can flow from the inlet port, through the flow control mechanism and to the fluid reservoir, and a

second configuration, in which the fluid reservoir is fluidically isolated from the inlet port; and

an actuator operably coupled to the seal member and to the flow control mechanism, the actuator including a spring configured to move the seal member from a first position to a second position to create a negative pressure in the fluid reservoir, the actuator further configured to move the flow control mechanism from the first configuration to the second configuration after a first volume of bodily-fluid is received in the fluid reservoir from the patient.

21. The device of claim 20, further comprising:

a throttling button operably coupled to the actuator and configured to modulate the rate at which the spring moves the seal member from the first position to the second position based on user manipulation of the throttling button.

22. The device of claim 20, wherein the flow control mechanism includes a first control member and a second control member, the second control member defining a first lumen and a second lumen, the flow control mechanism configured for rotational movement between the first configuration in which the inlet port is placed in fluid communication with the fluid reservoir such that bodily-fluid can flow from the inlet port, through the first lumen and to the fluid reservoir, to a second configuration, in which the inlet port is placed in fluid communication with a sample reservoir such that the bodily-fluid can flow from the inlet, through the second lumen and to the sample reservoir.

23. The device of claim 22, wherein the first control member includes a protrusion movably disposed in a grove defined by the second control member, the protrusion configured to move in the grove as the spring moves the seal member from the first position to the second position.

24. The device of claim 23, wherein the protrusion is configured to rotate the second control member when the spring moves the seal member from the second position to a third position.

25. A device for procuring bodily-fluid samples from a patient, the device comprising:

a housing including a proximal end portion and a distal end portion and defining an inner volume therebetween, the housing having an inlet port configured to be fluidically coupled to the patient, and an outlet port configured to be fluidically coupled to a sample reservoir;

a flow control mechanism disposed in the housing, the flow control mechanism including a first control member and a second control member, the second control member defining a first lumen and a second lumen and configured for rotational movement between a first configuration in which the inlet port is placed in fluid communication with a fluid reservoir defined at least in part by the housing such that bodily-fluid can flow from the inlet port, through the first lumen and to the fluid reservoir, to a second configuration, in which the inlet port is placed in fluid communication with the outlet port such that the bodily-fluid can flow from the inlet, through the second lumen and to the outlet port; and

an actuator movably disposed in the housing and operably coupled to the first control member, the actuator configured to create a negative pressure in the fluid reservoir when actuated by a user, the actuator further configured to rotate the second control member from the first configuration to the second configuration after a first volume of bodily-fluid is received in the fluid reservoir from the patient.

26. The device of claim 25, wherein the actuator includes an activation mechanism operably coupled to the first control member and configured to rotate the second control member from the first configuration to the second configuration.

27. The device of claim 25, wherein the actuator is further configured to create the negative pressure in the fluid reservoir when the actuator is moved from a first position to a second position by the user.

28. The device of claims 27, wherein the actuator is further configured to rotate the second control member from the first configuration to the second configuration when the actuator is moved from the second position to a third position by the user.

29. The device of claim 28, further comprising:

an activation mechanism coupled to the first control member, the activation mechanism including a protrusion configured to operably engage the actuator when the actuator is moved from the second position to a third position by the user.

30. A method for procuring bodily-fluid samples using a parenteral sampling device, the device including a needle having a lumen configured for insertion into the patient, and a fluid reservoir fluidically coupleable to the needle, the method comprising:

inserting the needle of the device into the patient;

establishing fluid communication between the needle and the fluid reservoir;

moving an actuator a first distance to create a negative pressure in the fluid reservoir and to withdraw a predetermined volume of bodily-fluid;

moving the actuator a second distance to engage a flow control mechanism and rotate the flow control mechanism from a first configuration to a second configuration, the first configuration operable to allow bodily-fluid to flow through a first flow path from the needle to the fluid reservoir, the second configuration operable to allow bodily-fluid to flow through a second flow path from the needle to a sample reservoir.

31. The method of claim 30, wherein moving the actuator the first distance includes applying an activation force to the actuator in a first direction.

32. The method of claim 31, wherein releasing the activation force allows the actuator to move in a second direction opposite the first direction, to reduce the negative pressure created in the fluid reservoir.

33. The method of claim 30, further comprising:

moving the actuator a third distance to reduce the flow rate of bodily-fluid through the second flow path to the sample reservoir in the second configuration.

34. The method of claim 33, further comprising:

moving the actuator a third distance to engage a control member and deform the second flow path reduce the flow rate of bodily-fluid through the
second flow path to the sample reservoir in the second configuration.

35. A method for procuring bodily-fluid samples using a parenteral sampling device, the device including a needle having a lumen configured for insertion into the patient, and a fluid reservoir fluidically coupleable to the needle, the method comprising:

inserting the needle of the device into the patient;

establishing fluid communication between the needle and the fluid reservoir;

applying a first activation force to an actuator to create a negative pressure in the fluid reservoir and to withdraw a predetermined volume of bodily-fluid;

reducing the first activation force applied to the actuator to reduce the negative pressure created in the fluid reservoir; and

applying a second activation force to the actuator to engage a flow control mechanism and move the flow control mechanism from a first configuration to a second configuration, the first configuration operable to allow bodily-fluid to flow through a first flow path from the needle to the fluid reservoir, the second configuration operable to allow bodily-fluid to flow through a second flow path from the needle to a sample reservoir.

36. The method of claim 35, wherein the first activation force moves the actuator a first distance in a first direction to create the negative pressure in the fluid reservoir.

37. The method of claim 36, wherein reducing the first activation force allows the actuator to move in a second direction opposite the first direction, to reduce the negative pressure created in the fluid reservoir.

38. The method of claim 35, wherein the second activation force moves the actuator a second distance in the first direction to move the flow control mechanism from the first configuration to the second configuration.

39. The method of claim 35, further comprising:

applying a third activation force to reduce the flow rate of bodily-fluid through the second flow path to the sample reservoir in the second configuration.

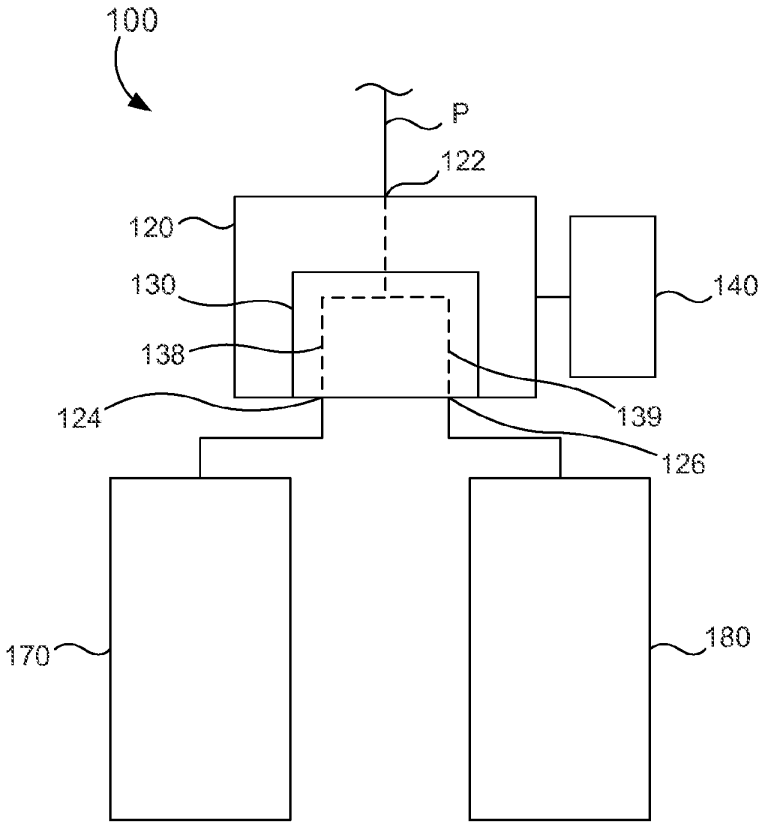


FIG. 1

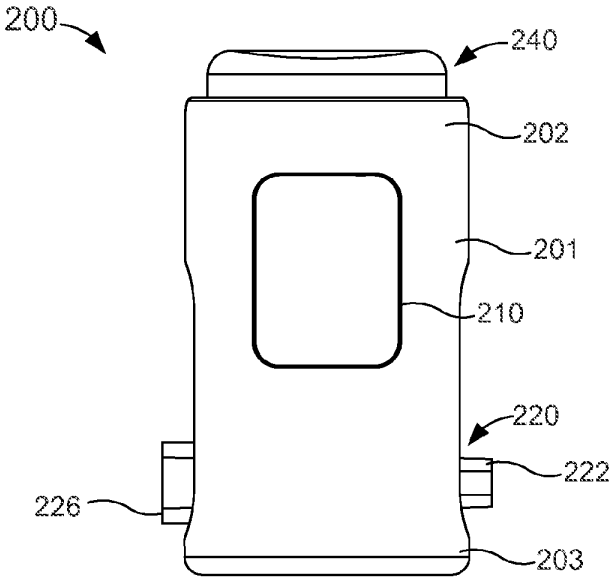

200
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FIG. 2

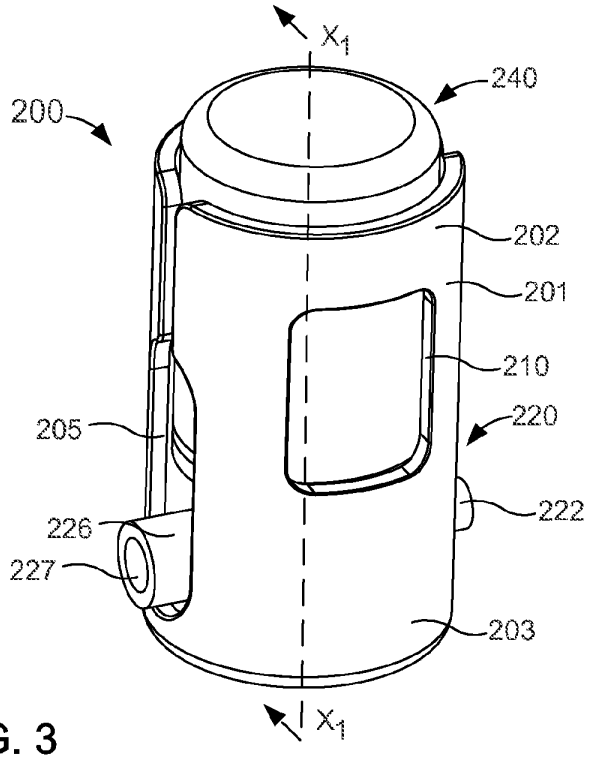

X1
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227
203
X1

FIG. 3

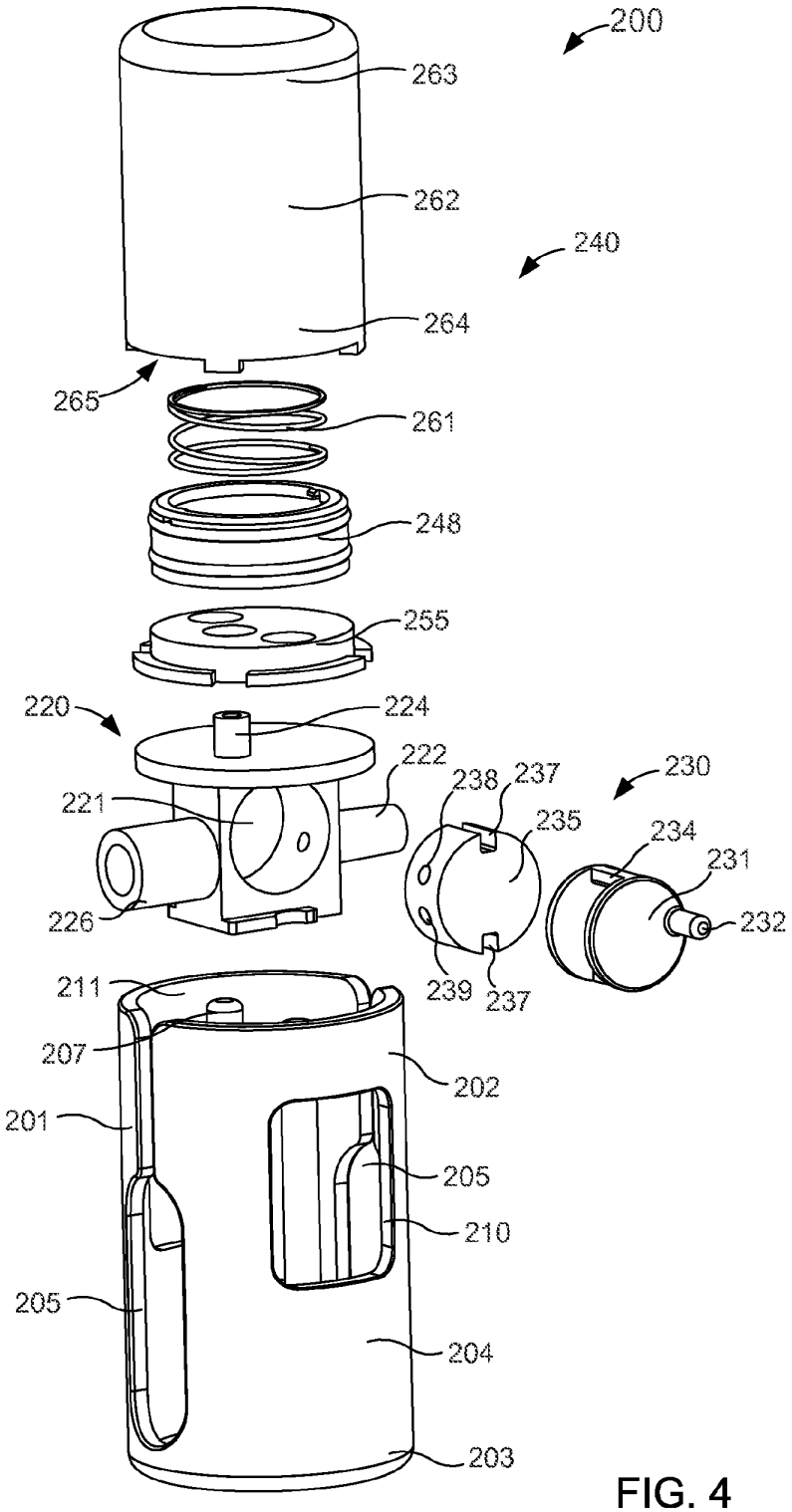

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FIG. 4

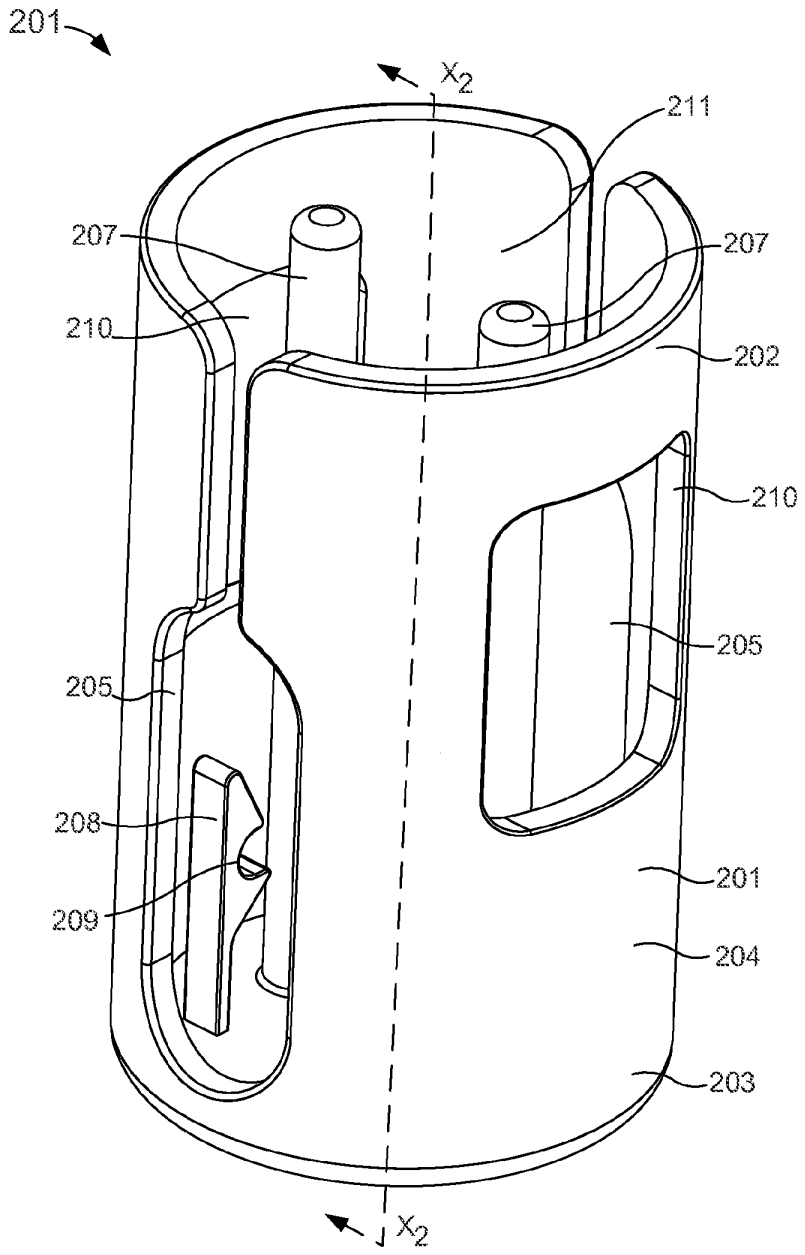


FIG. 5

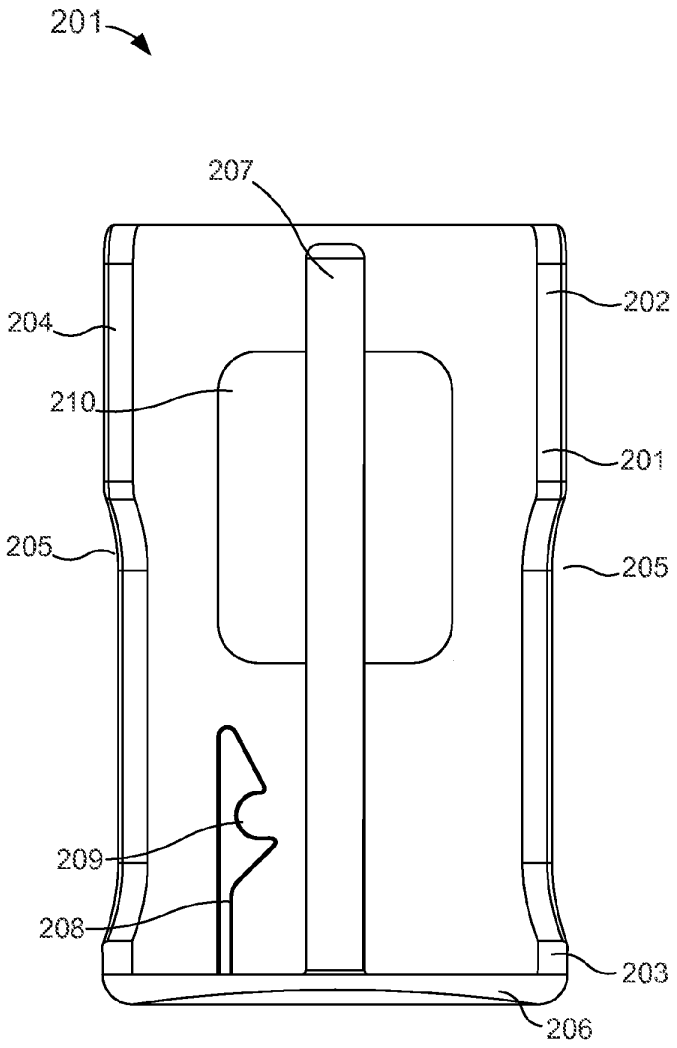


FIG. 6

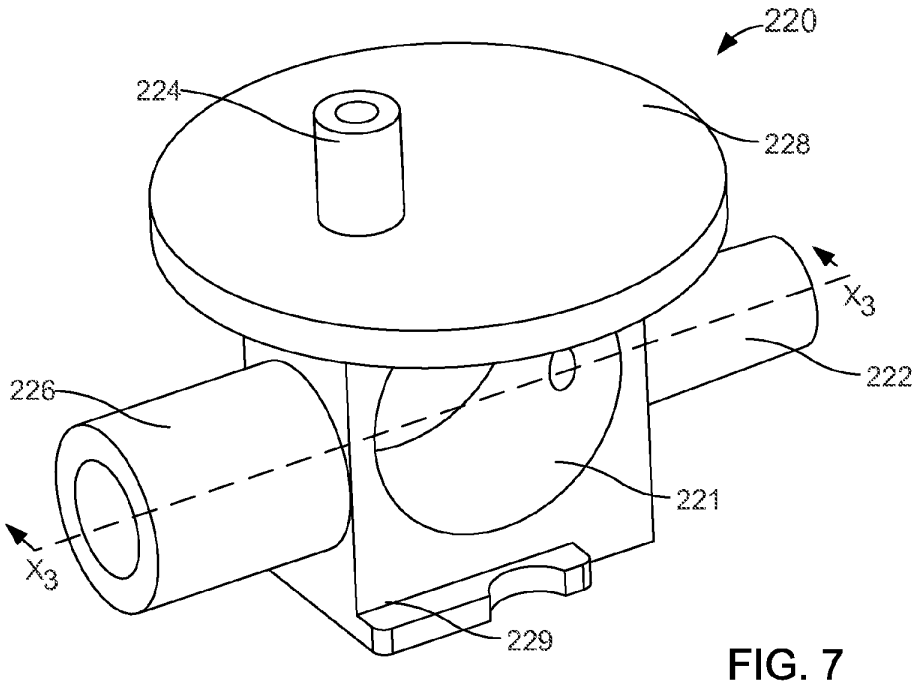

220
224
228
X_3
222
226
221
X_3
229

FIG. 7

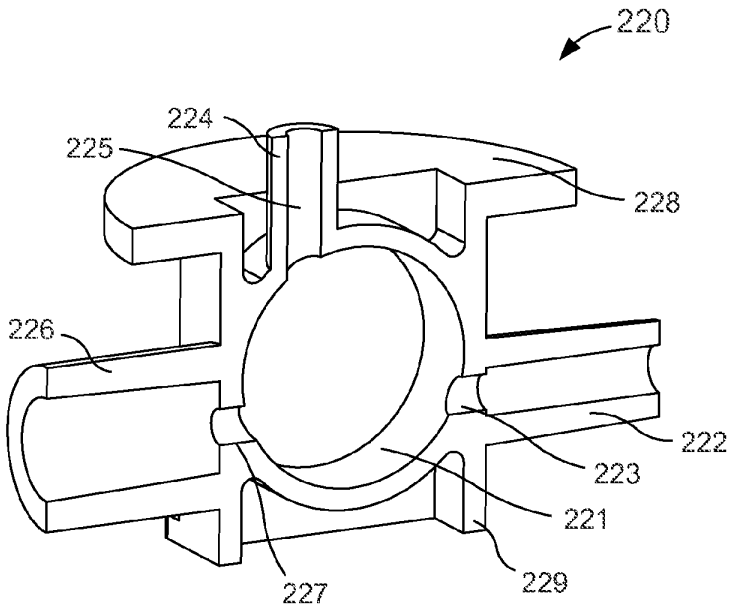

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FIG. 8

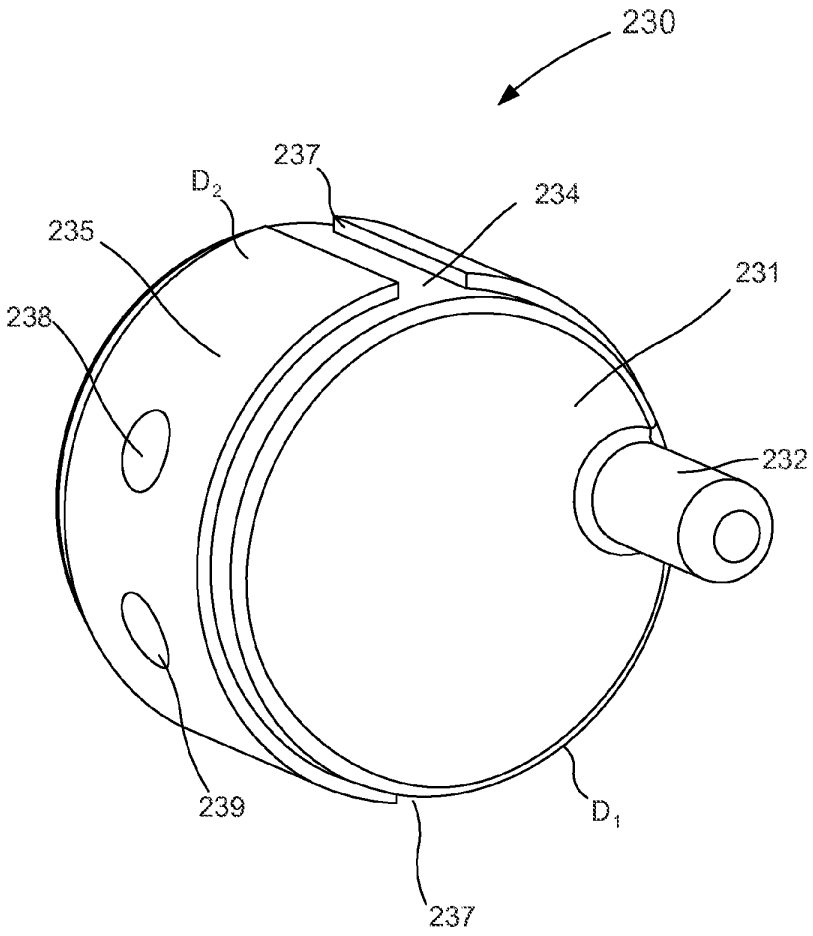


FIG. 9

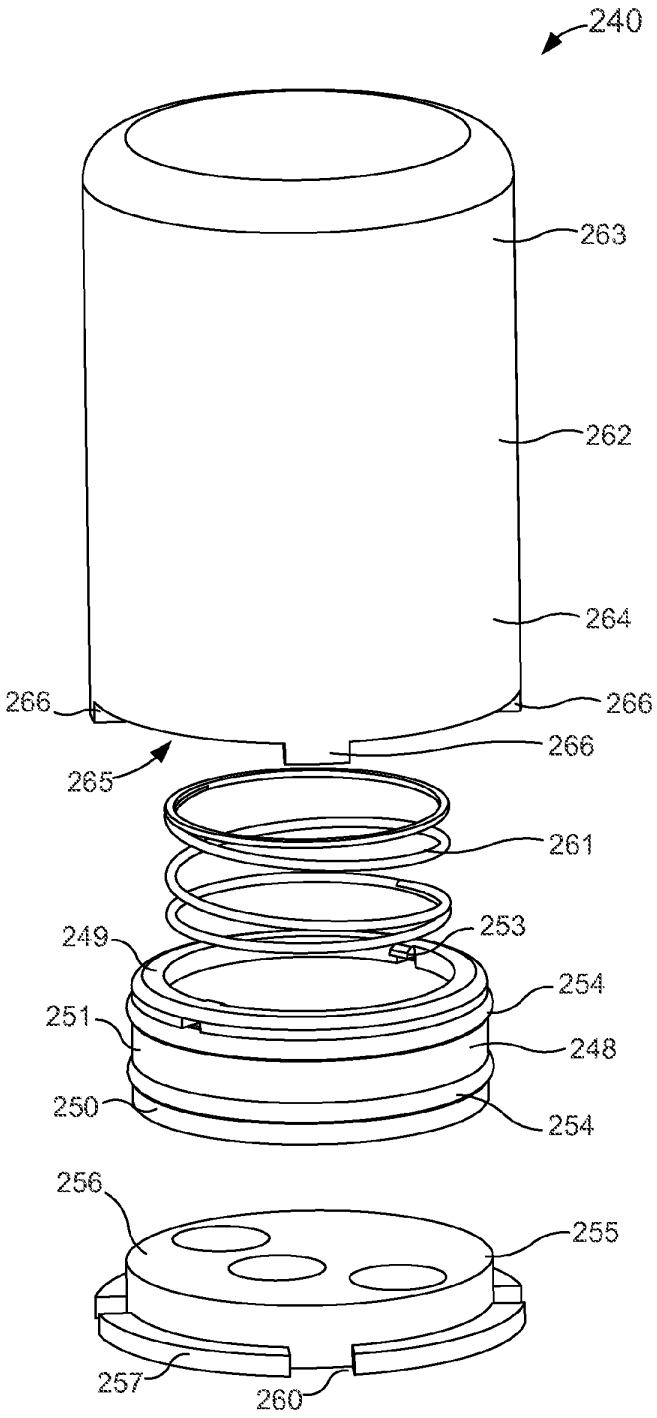

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FIG. 10

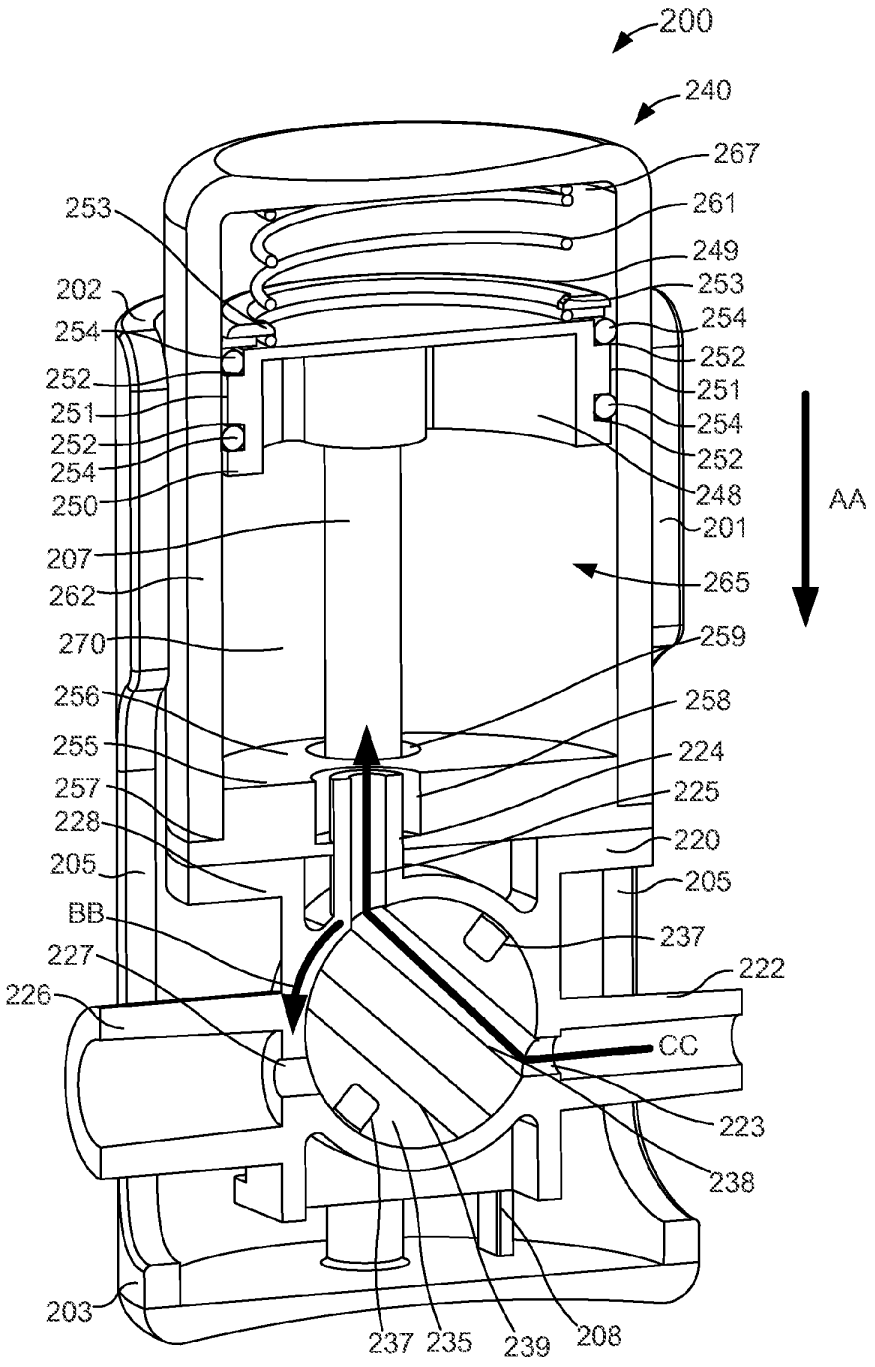

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AA
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265
262
259
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224
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FIG. 11

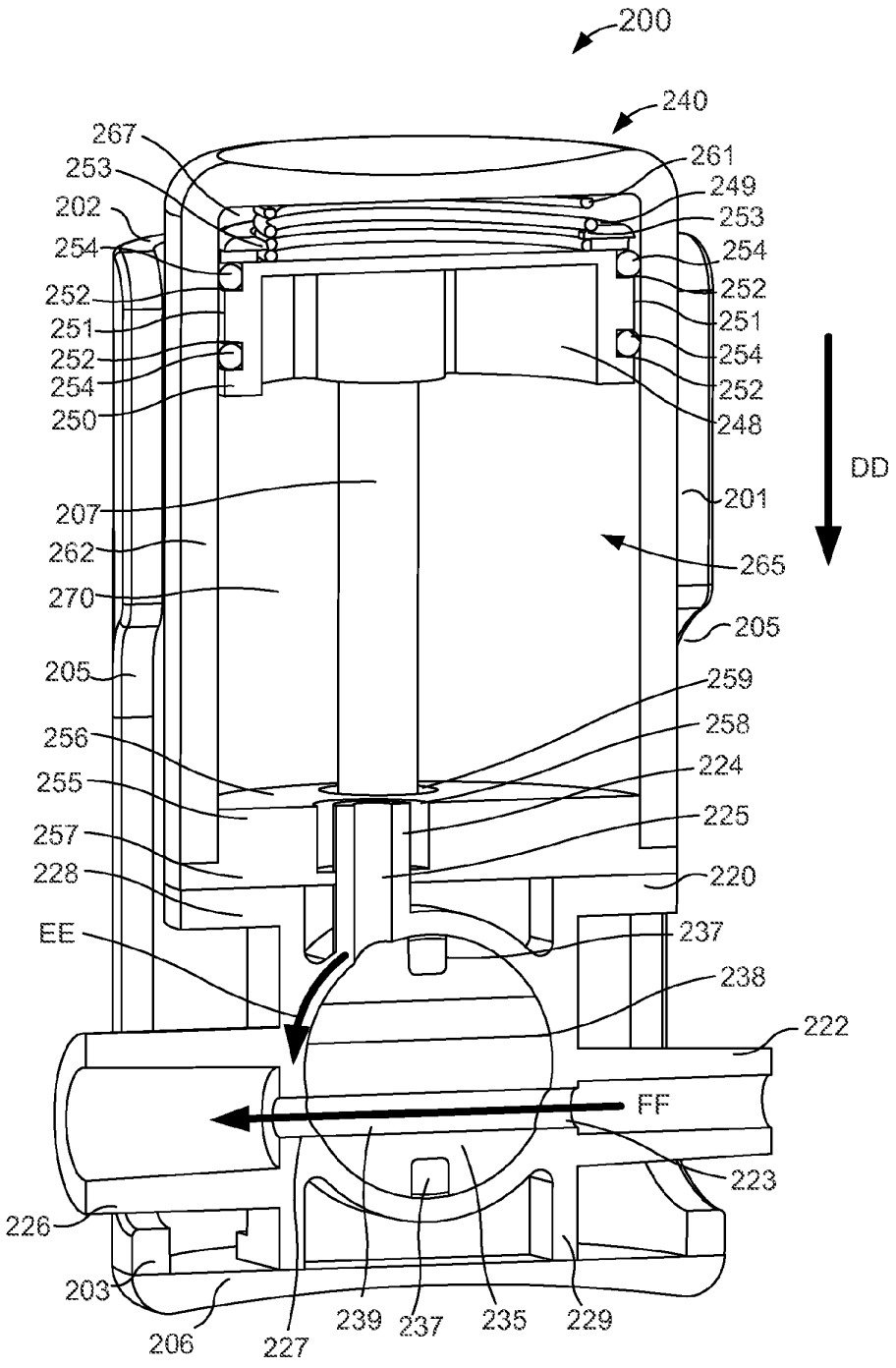

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DD
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FIG. 12

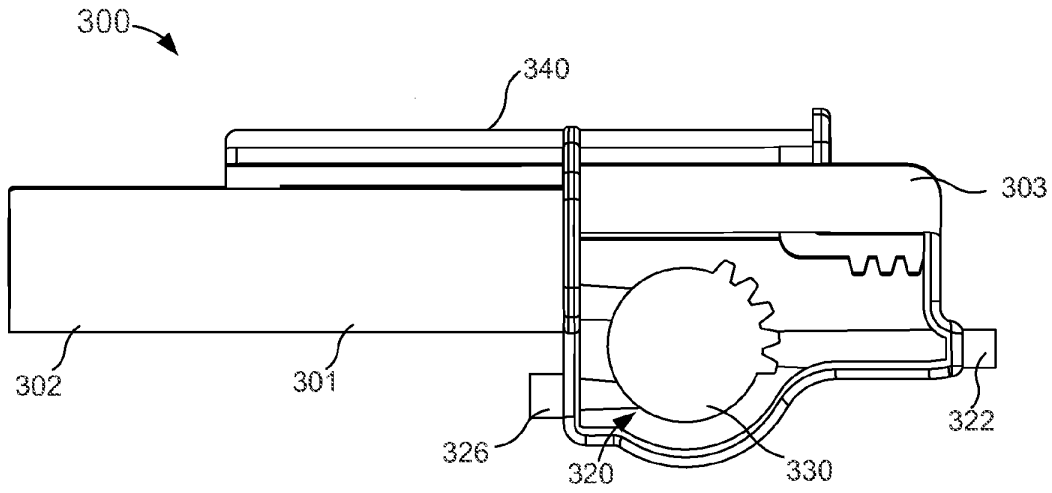

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FIG. 13

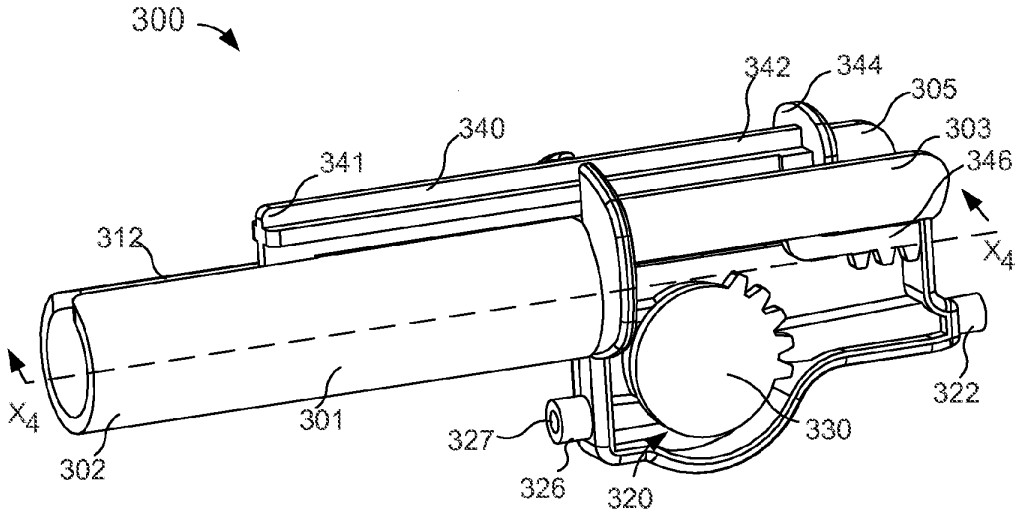

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341
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X4
X4
301
322
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330
302
326
320

FIG. 14

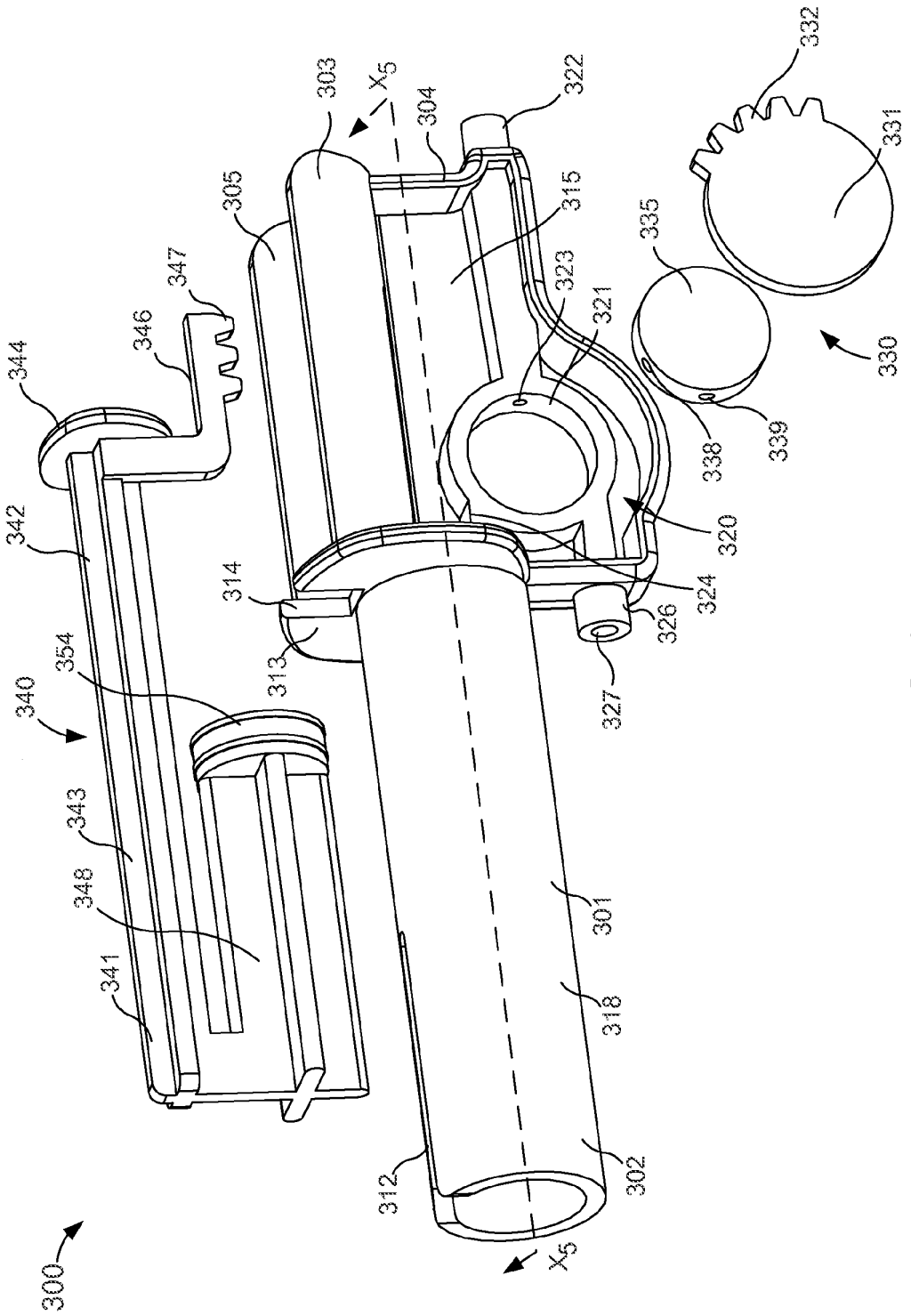

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X_5
X_5

FIG. 15

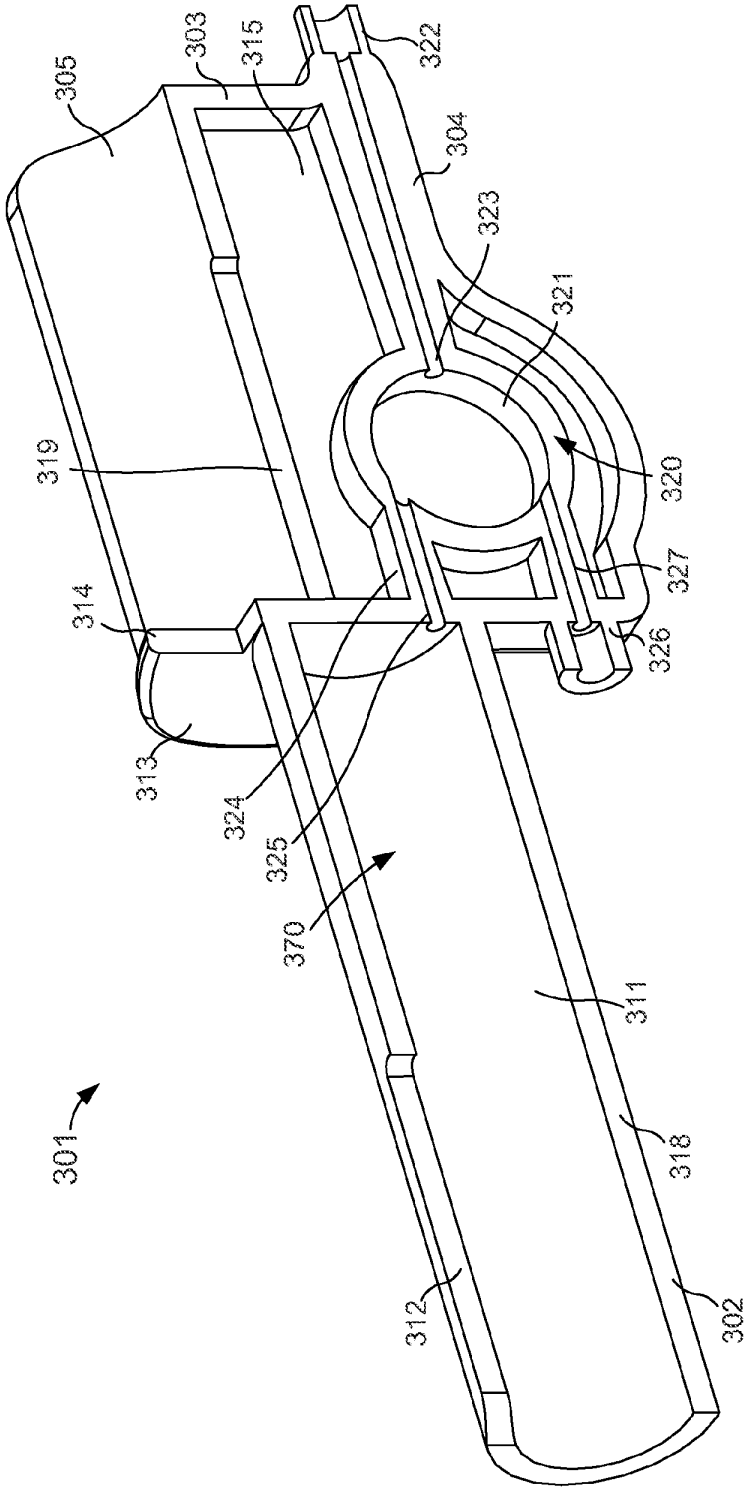

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FIG. 16

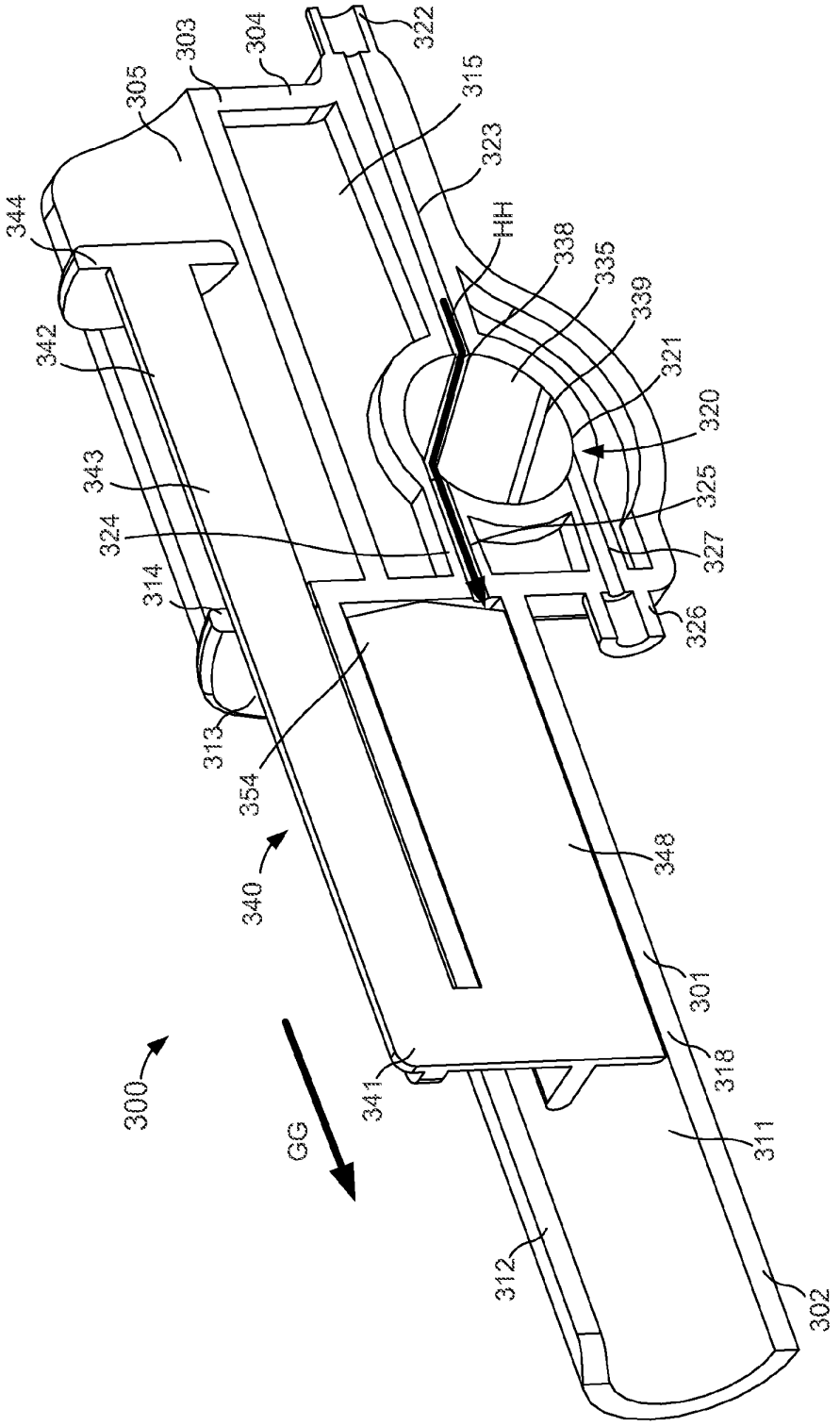

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HH
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FIG. 17

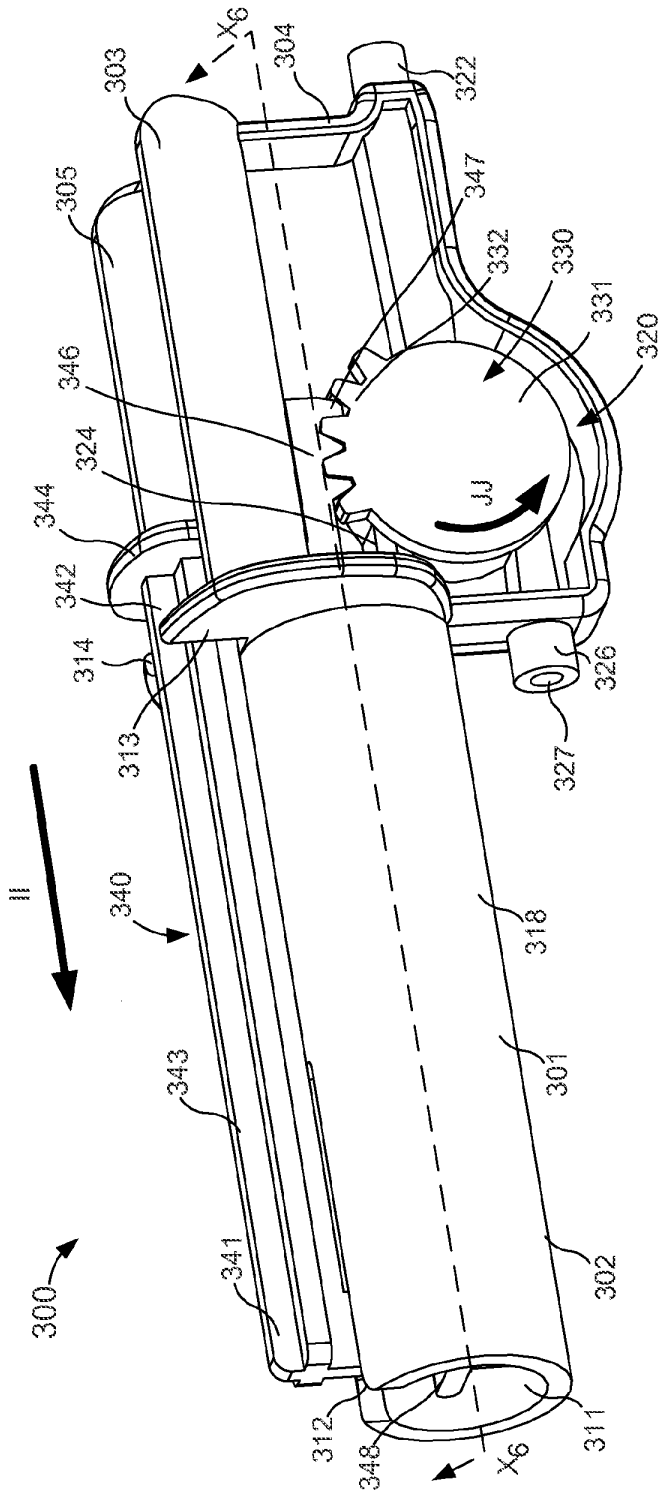

X6
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332
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331
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JJ
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II
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343
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341
302
300
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348
311
X6

FIG. 18

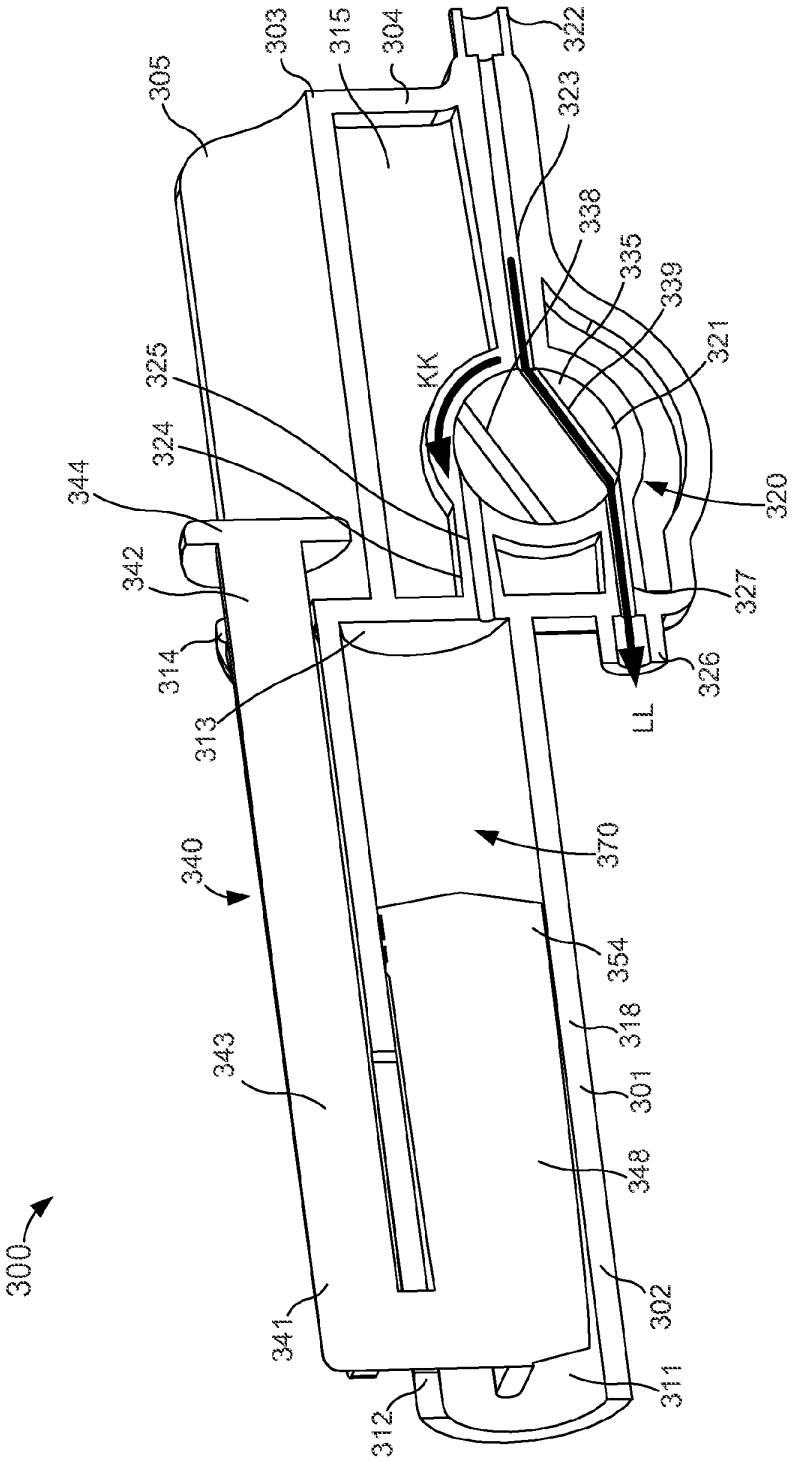

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FIG. 19

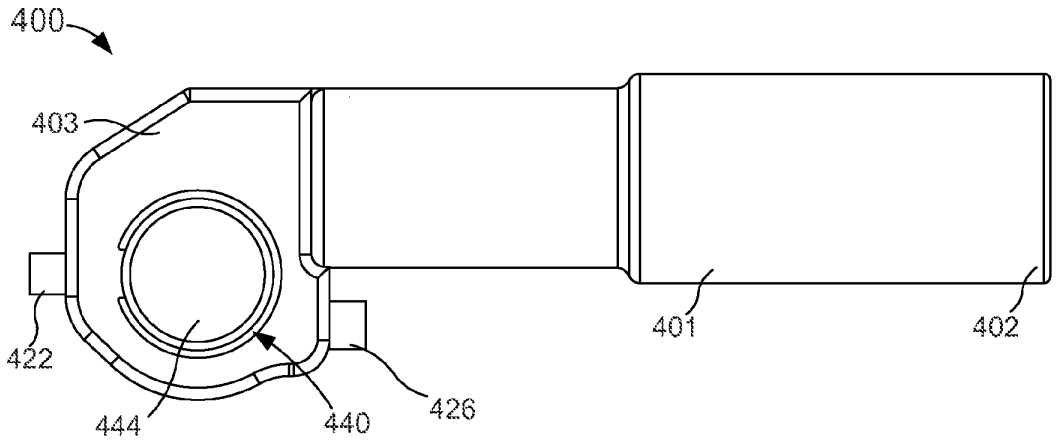

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401
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FIG. 20

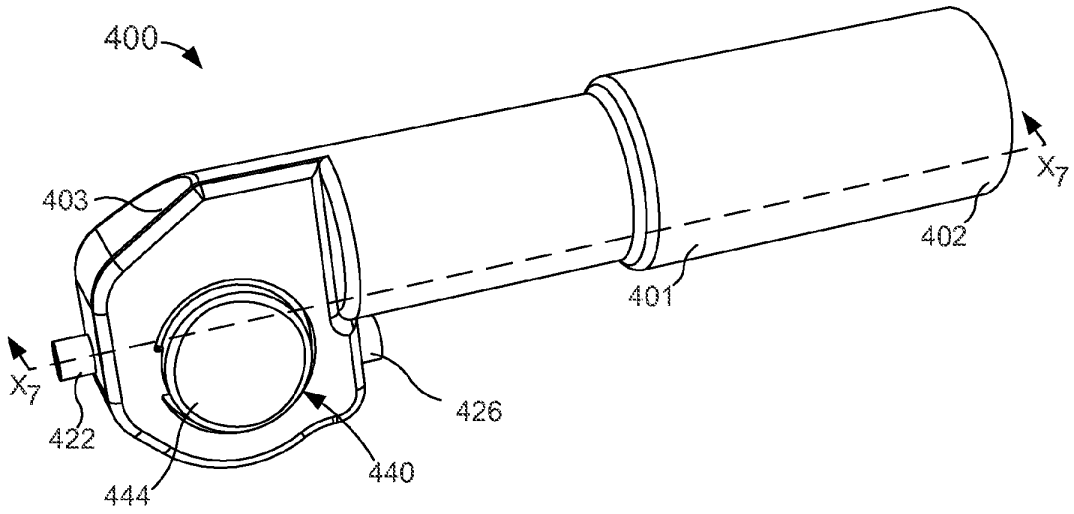

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X7
X7

FIG. 21

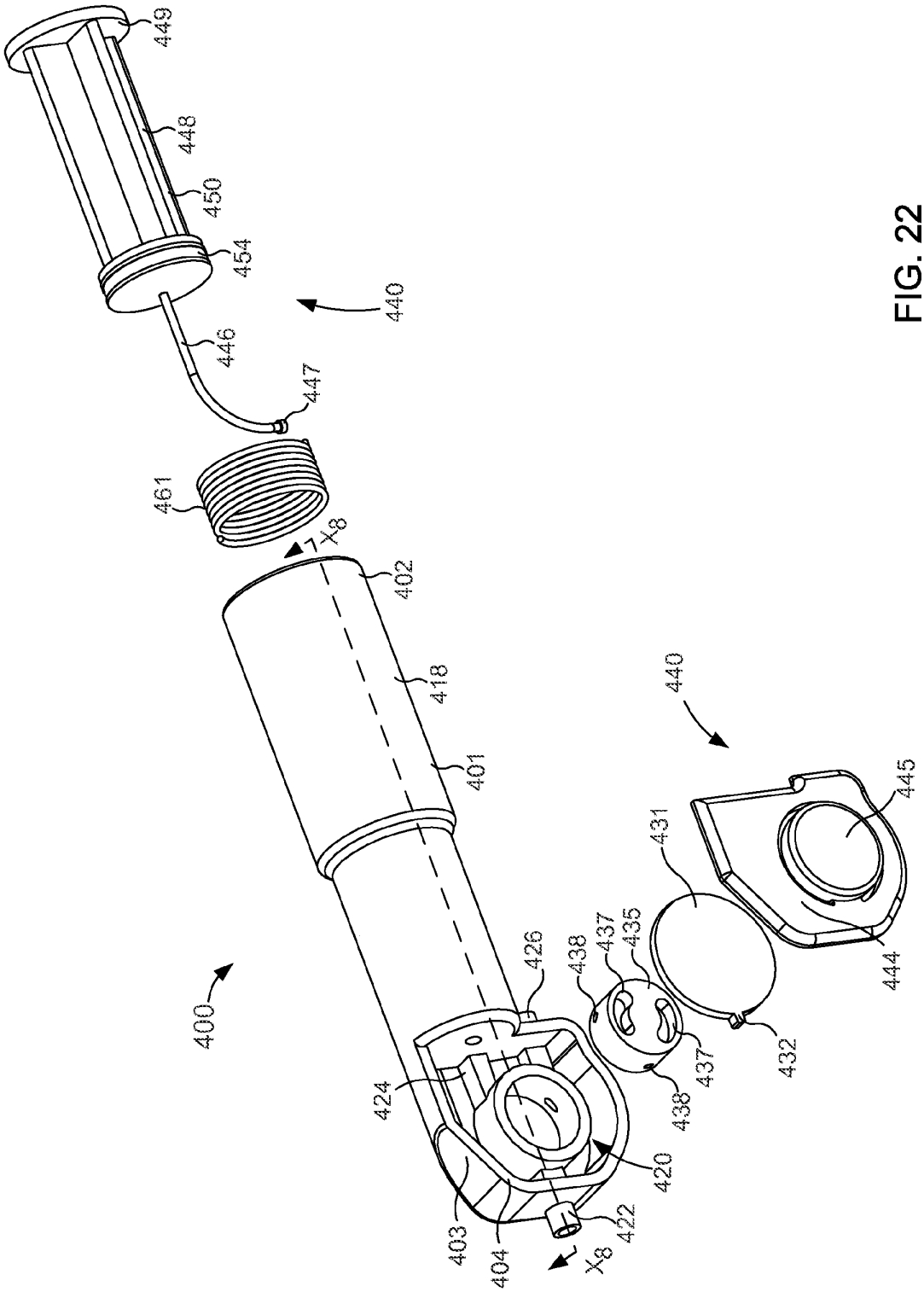

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X8
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422
403
404
X8

FIG. 22

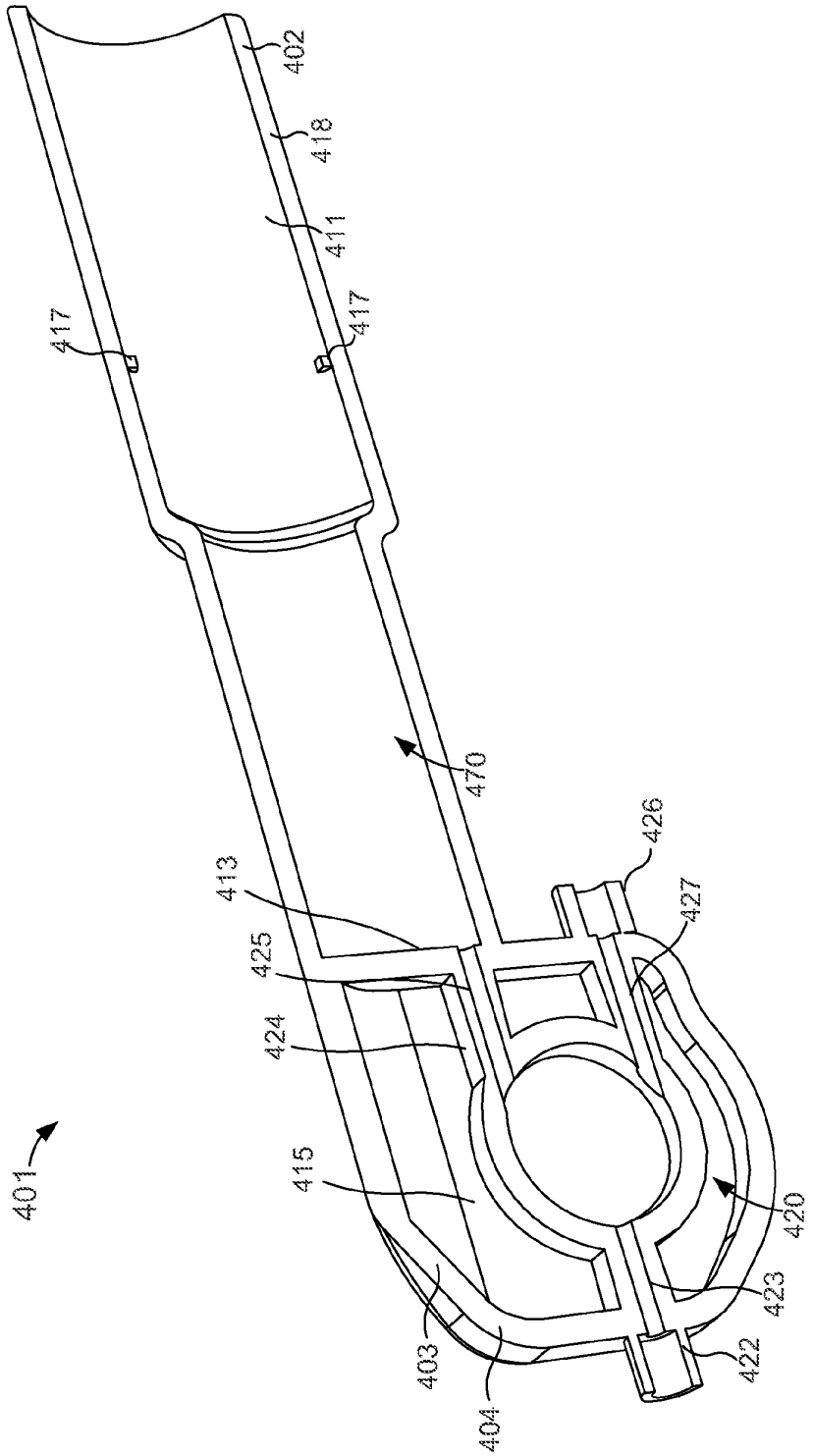

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FIG. 23

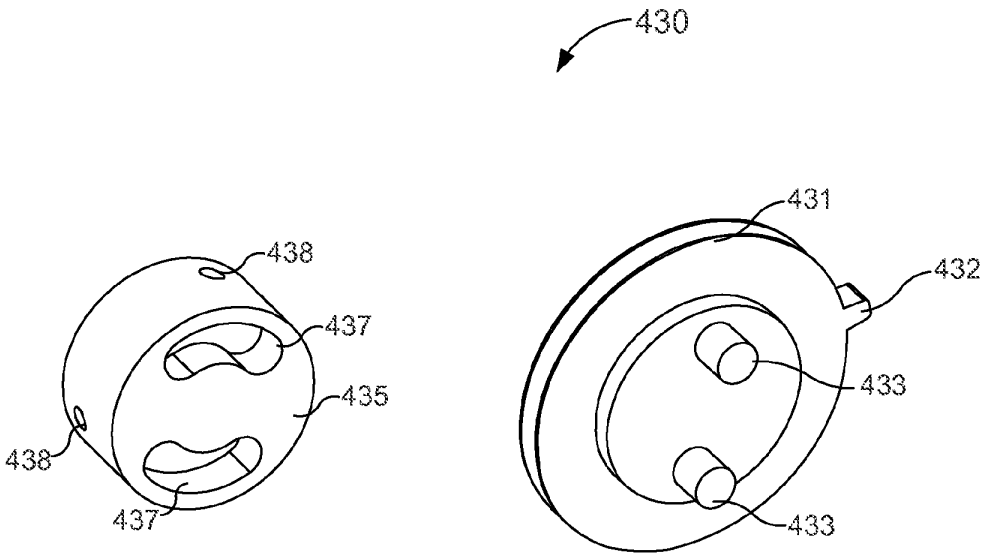


FIG. 24

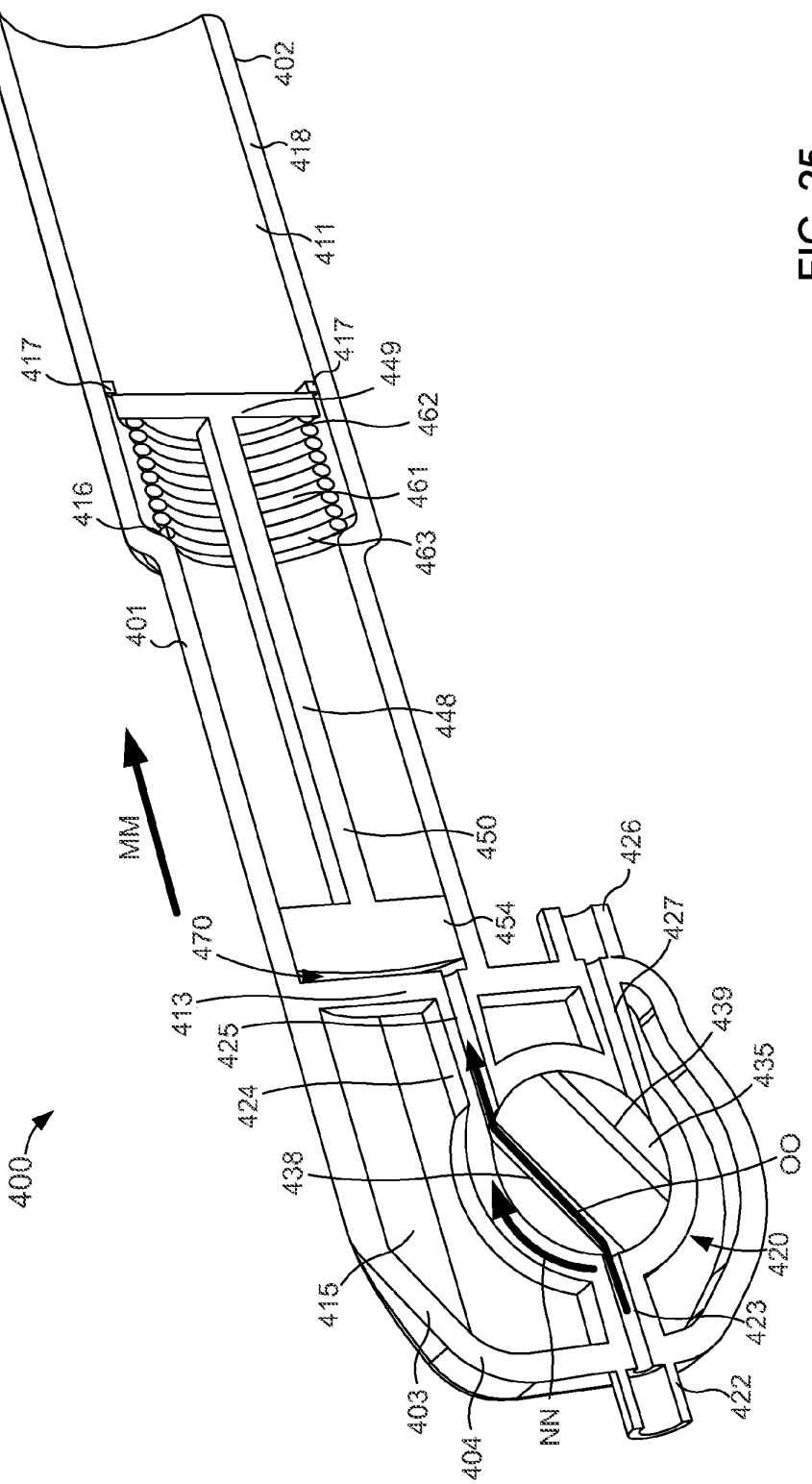

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NN
MM

FIG. 25

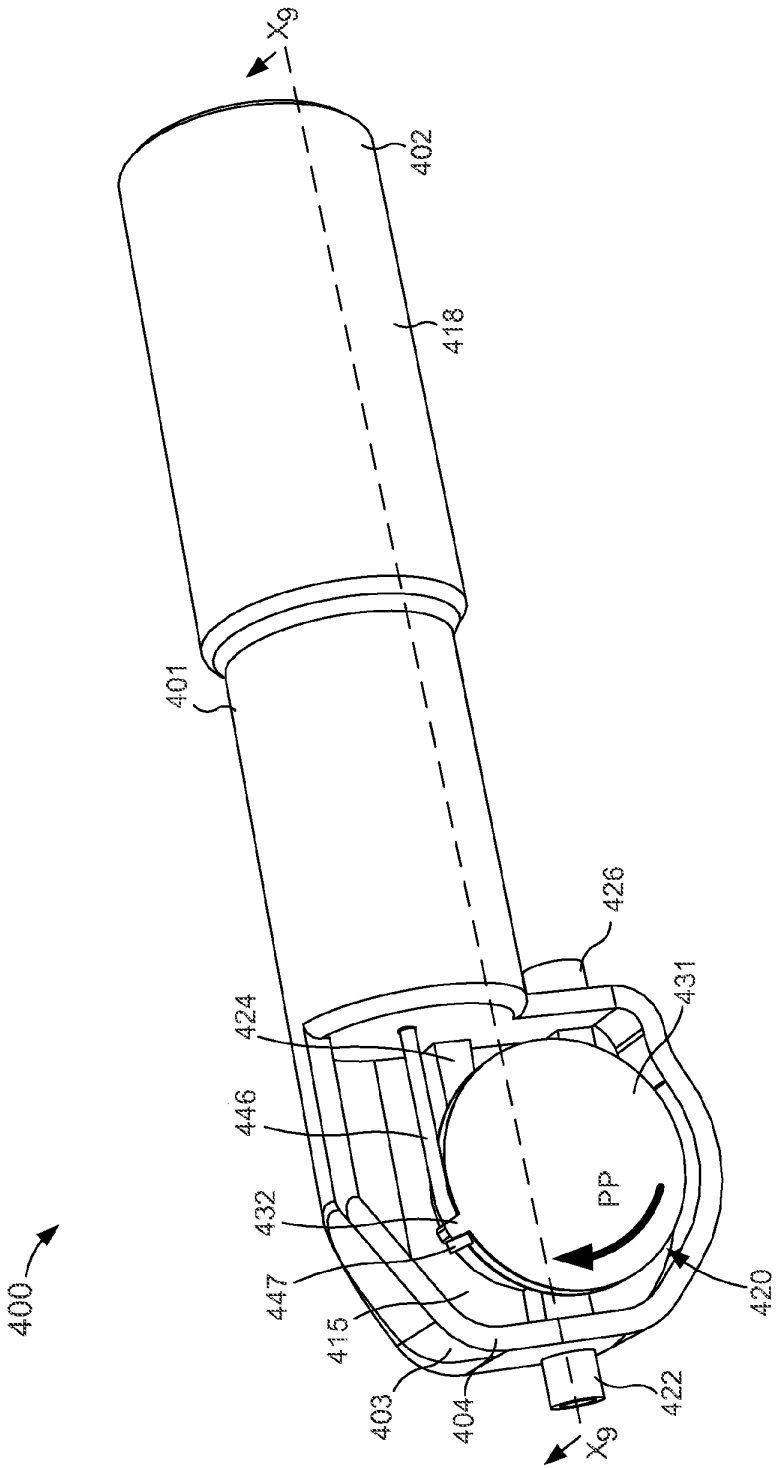

X9
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426
431
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PP
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X9

FIG. 26

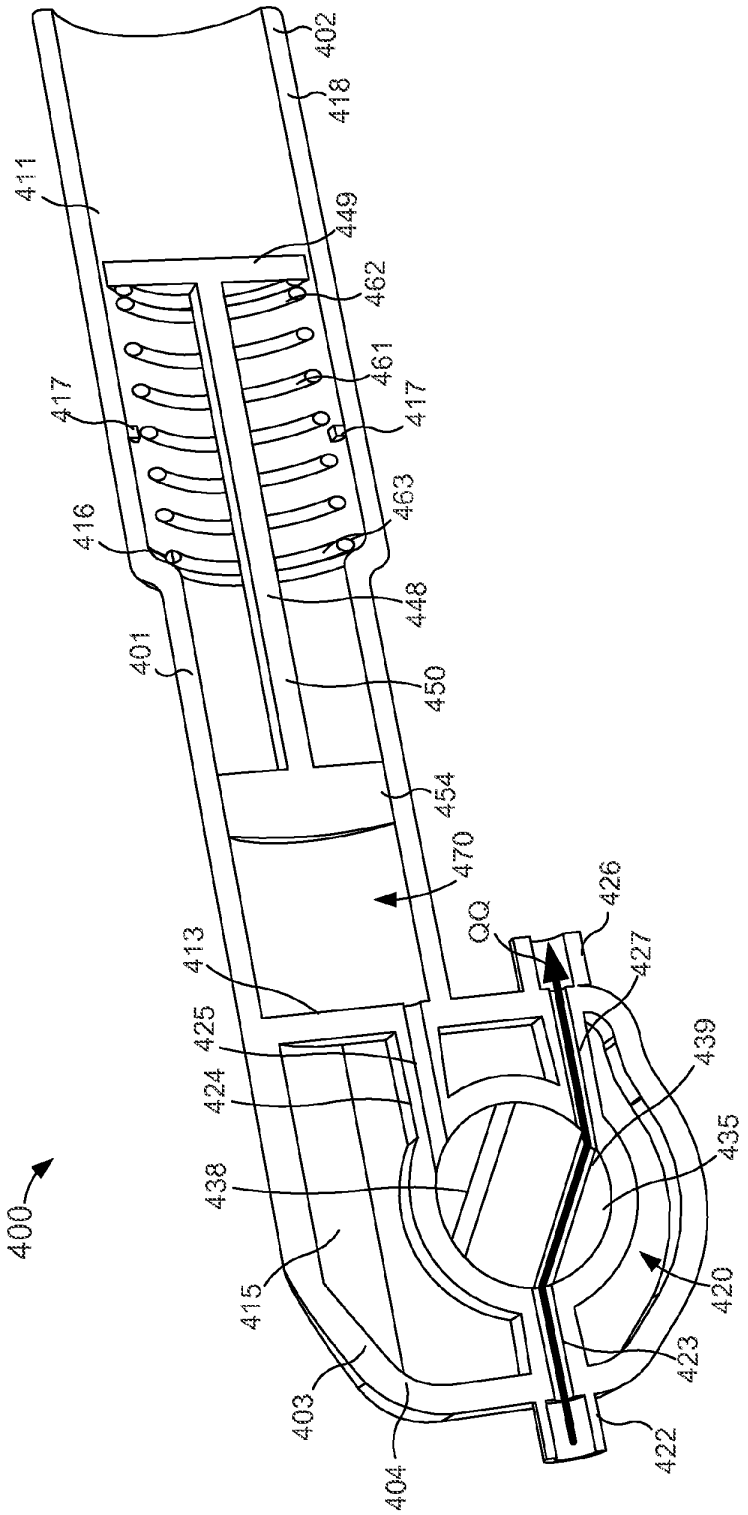

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FIG. 27

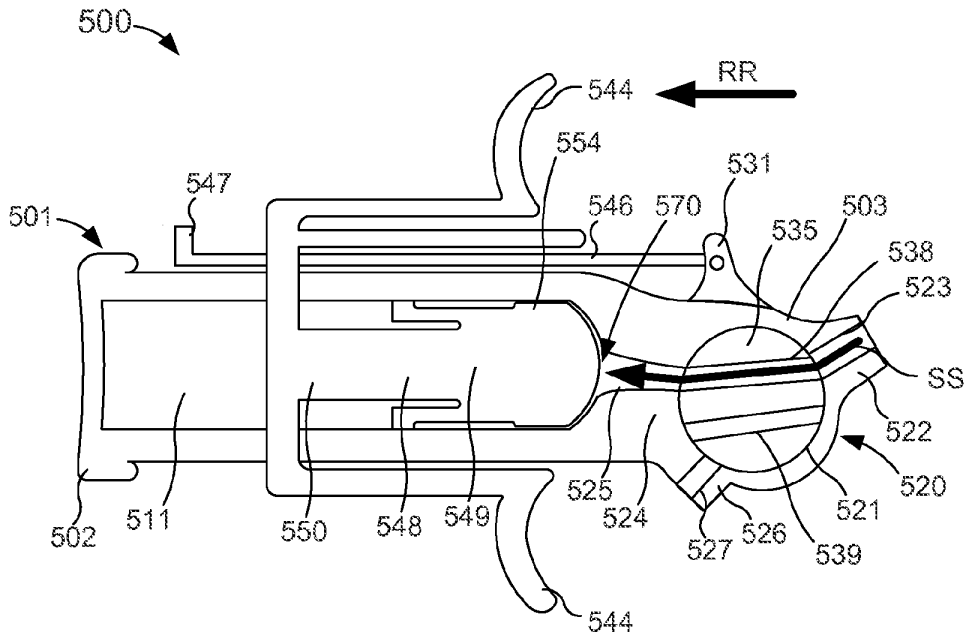

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RR
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FIG. 28

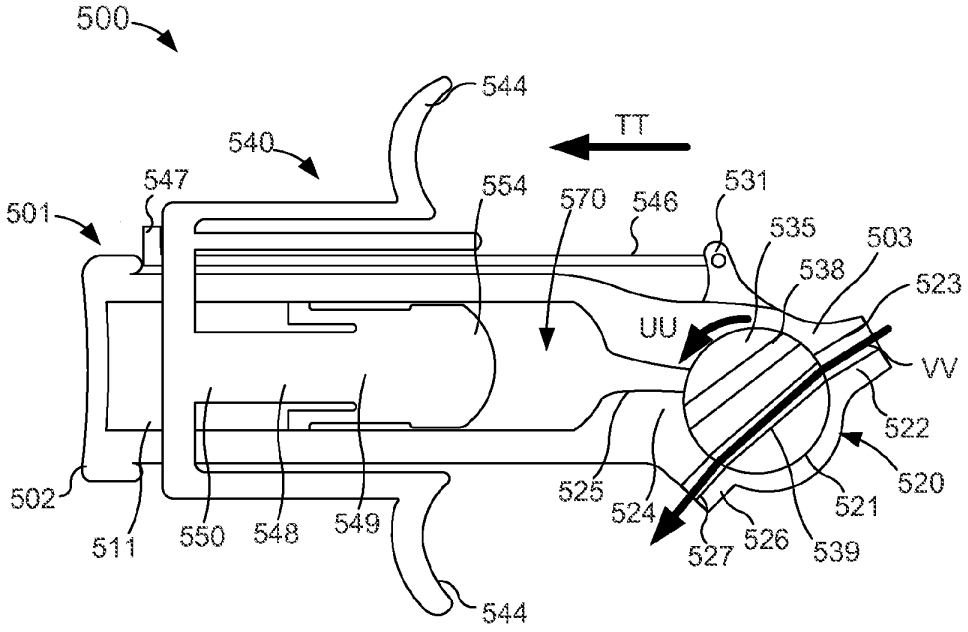

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TT
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544

FIG. 29

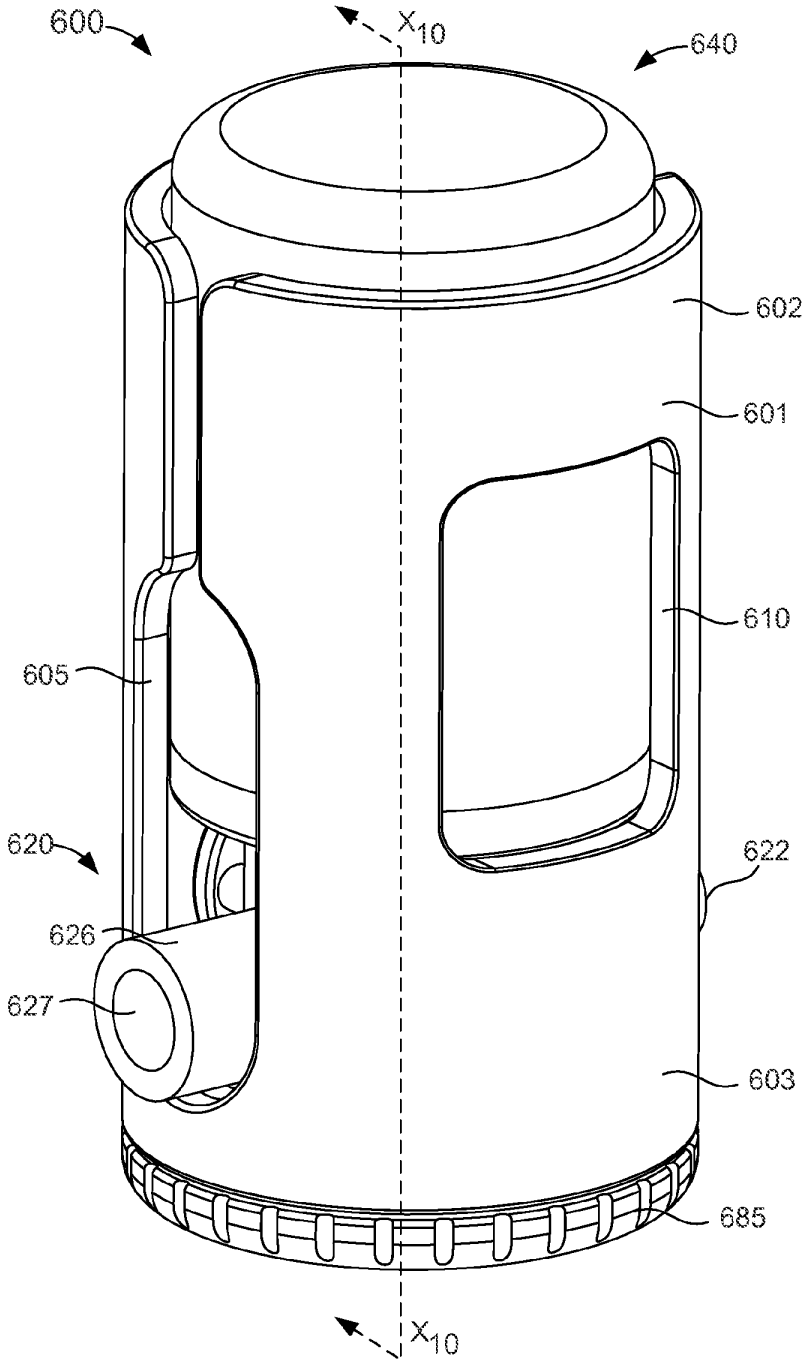


FIG. 30

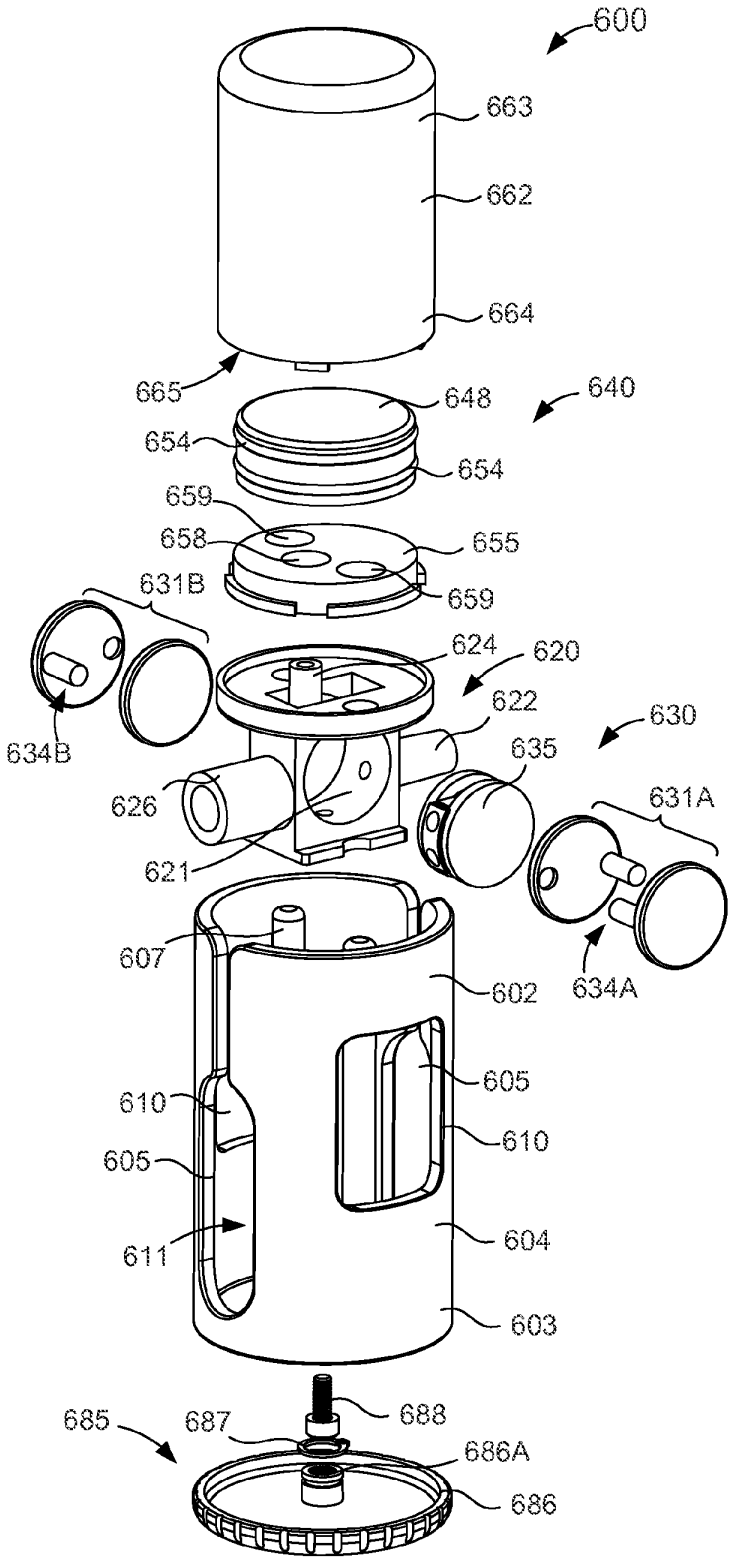

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659
631B
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634B
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626
631A
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634A
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686A
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FIG. 31

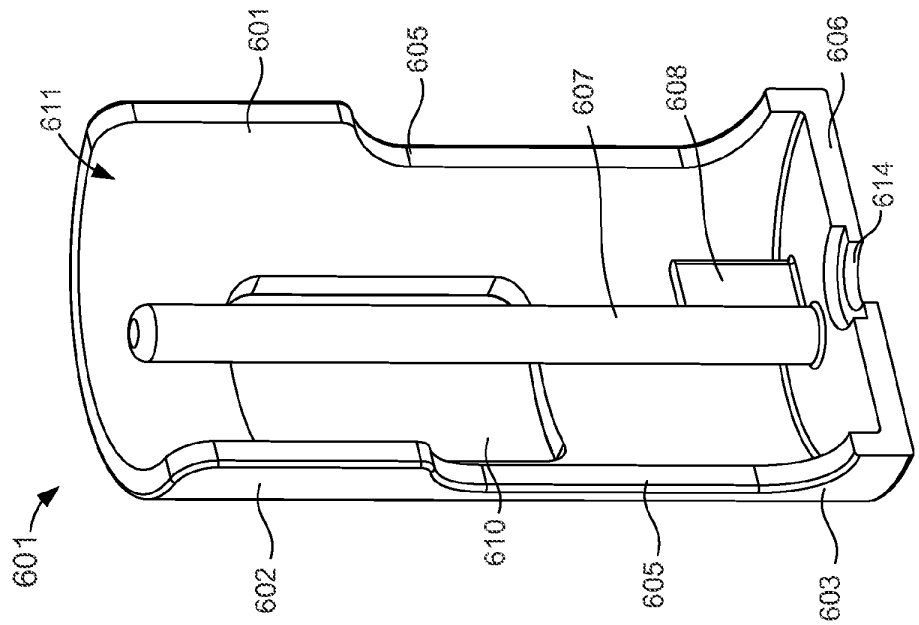

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FIG. 33

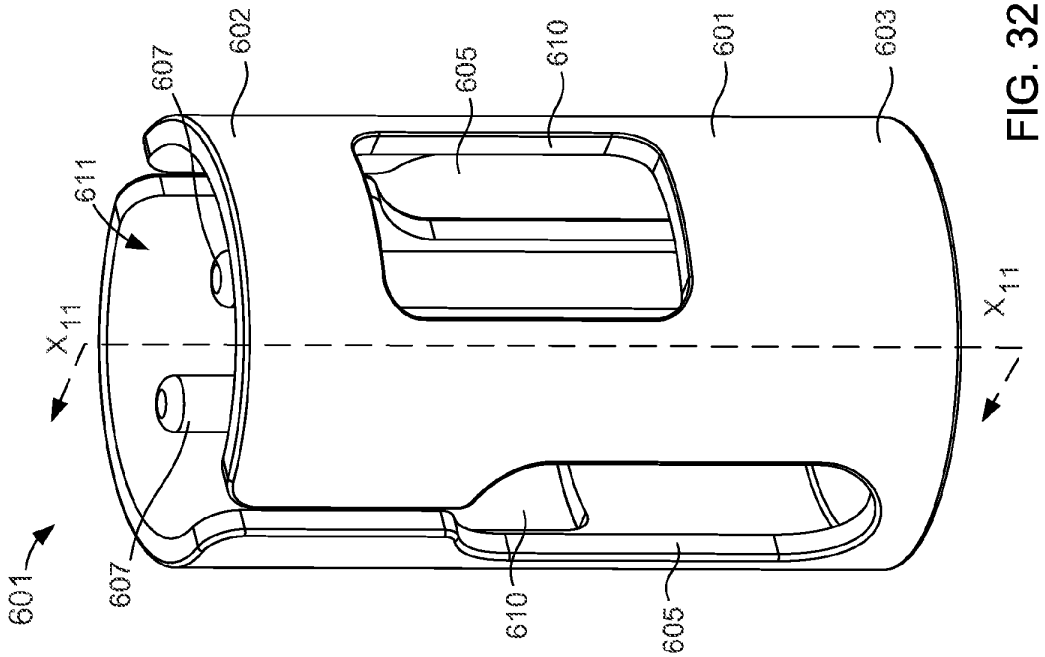

607
602
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603
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X11
X11
601
607
610
605

FIG. 32

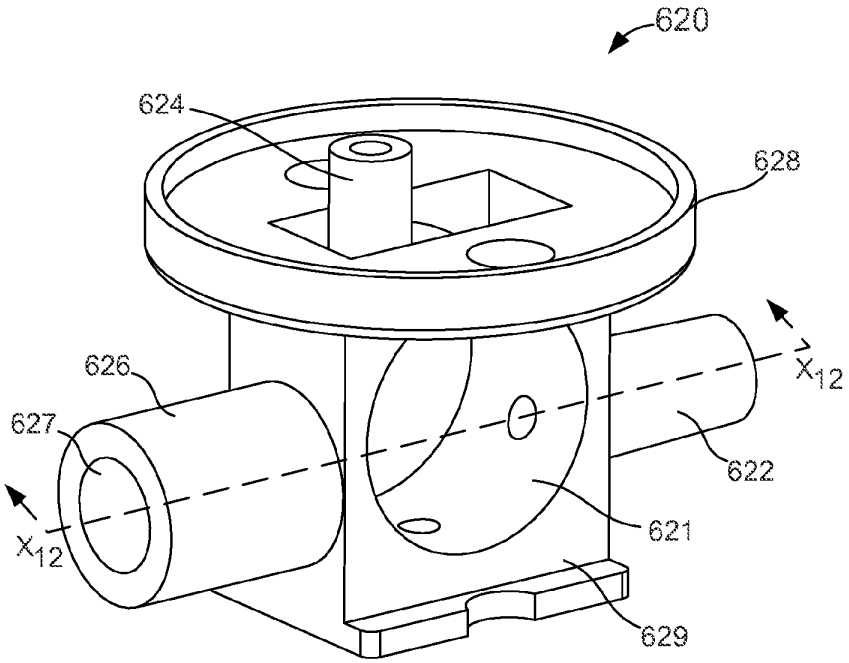

620
624
628
626
627
X_{12}
622
621
X_{12}
629

FIG. 34

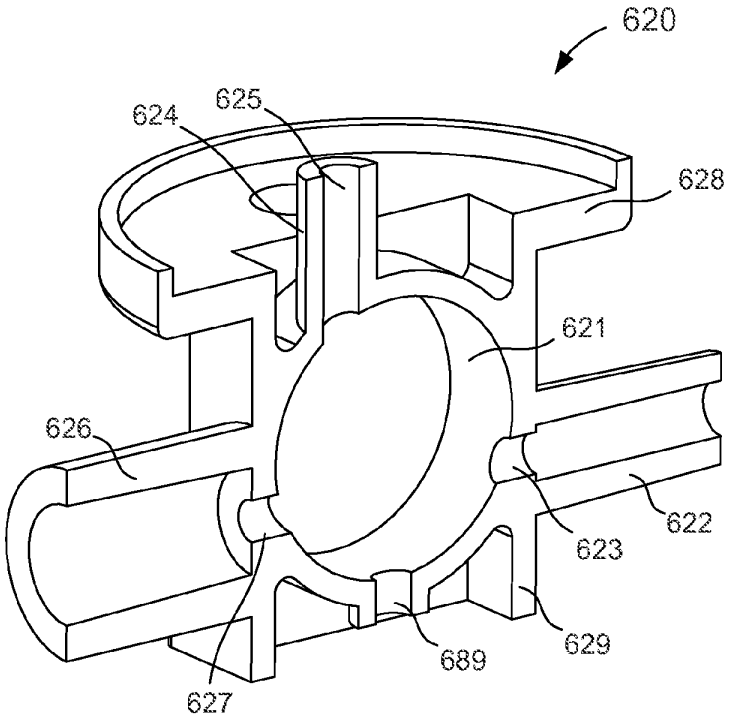

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689
627

FIG. 35

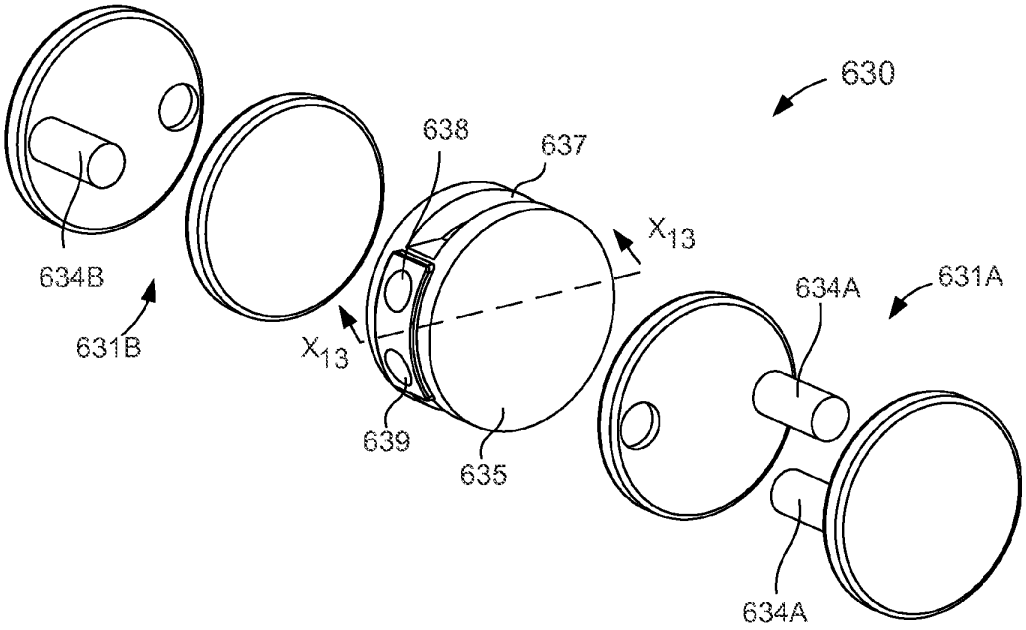

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X_{13}
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X_{13}
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FIG. 36

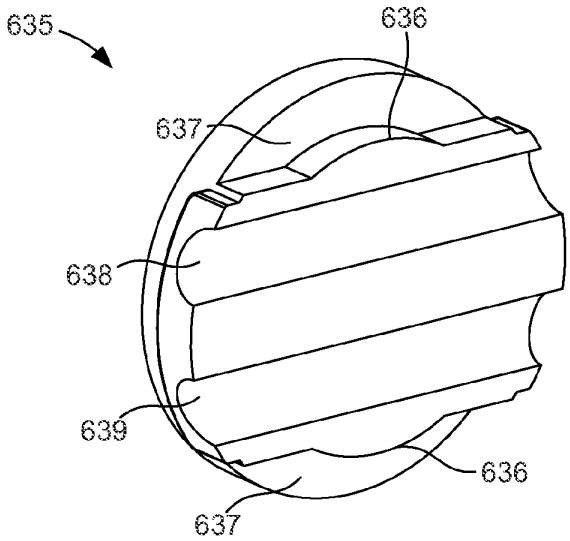

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FIG. 37

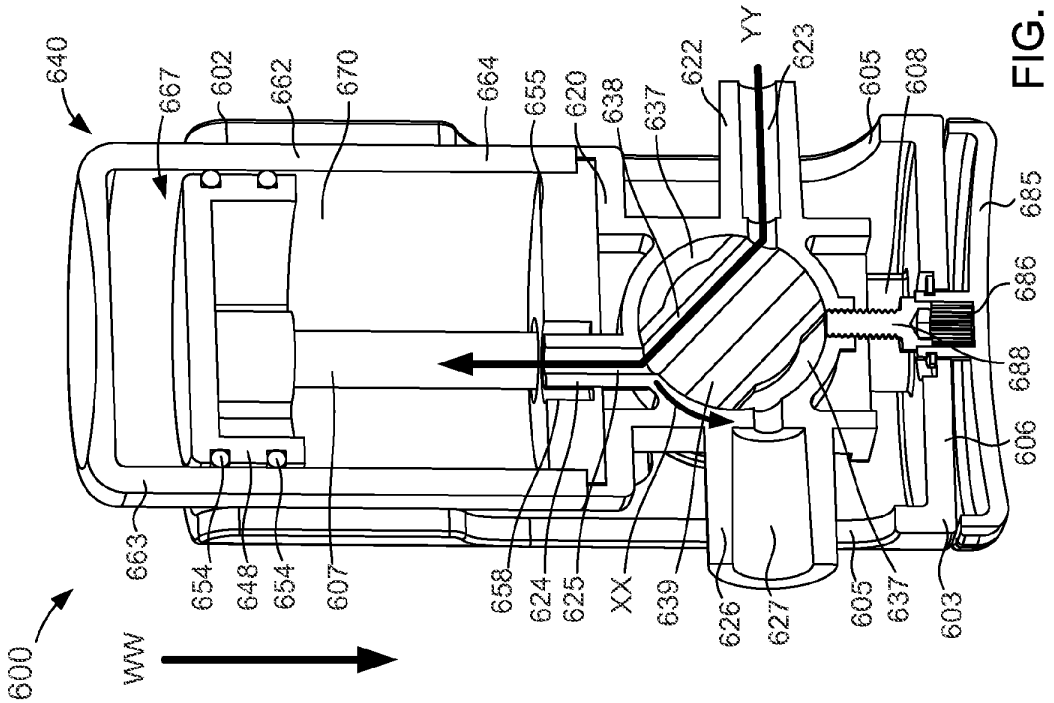

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FIG. 39

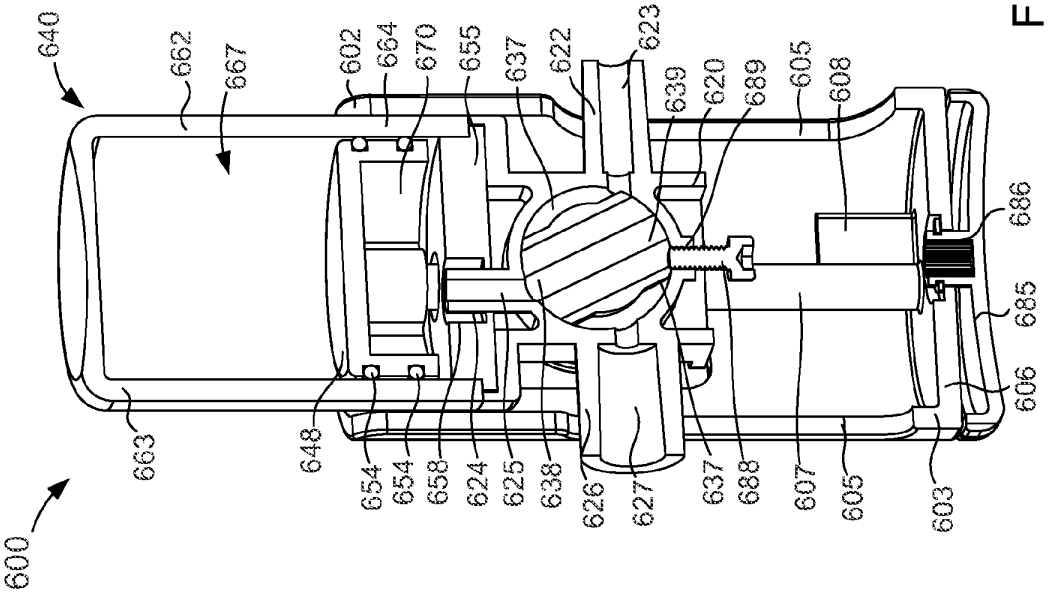

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FIG. 38

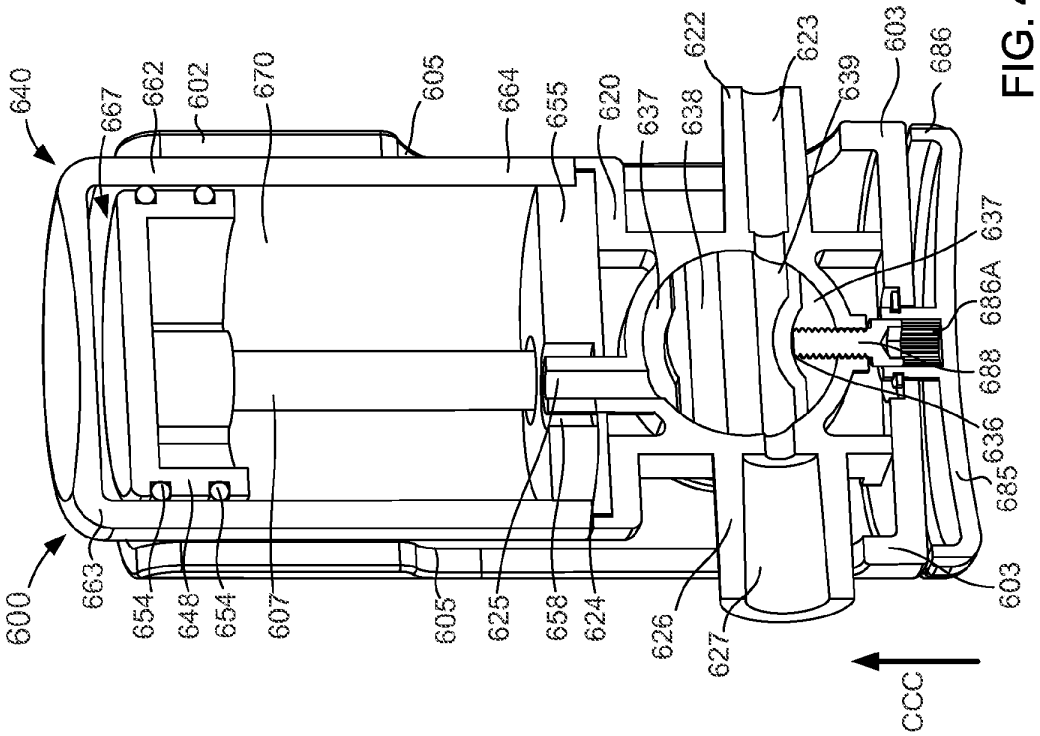

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FIG. 41

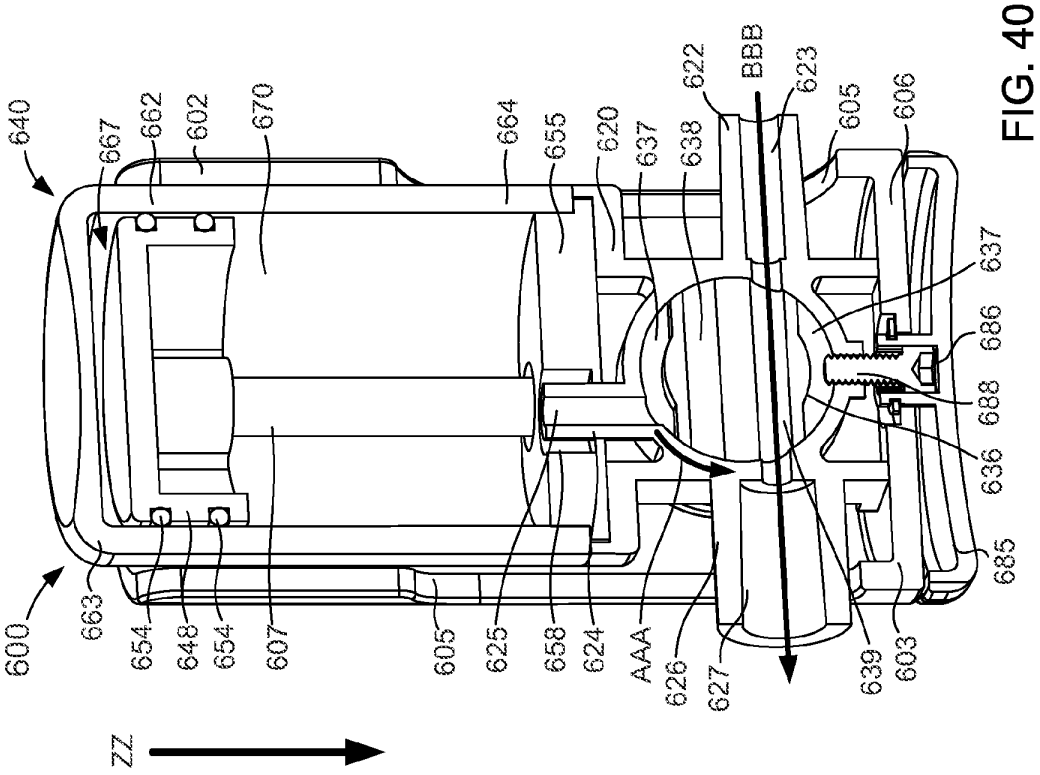

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FIG. 40

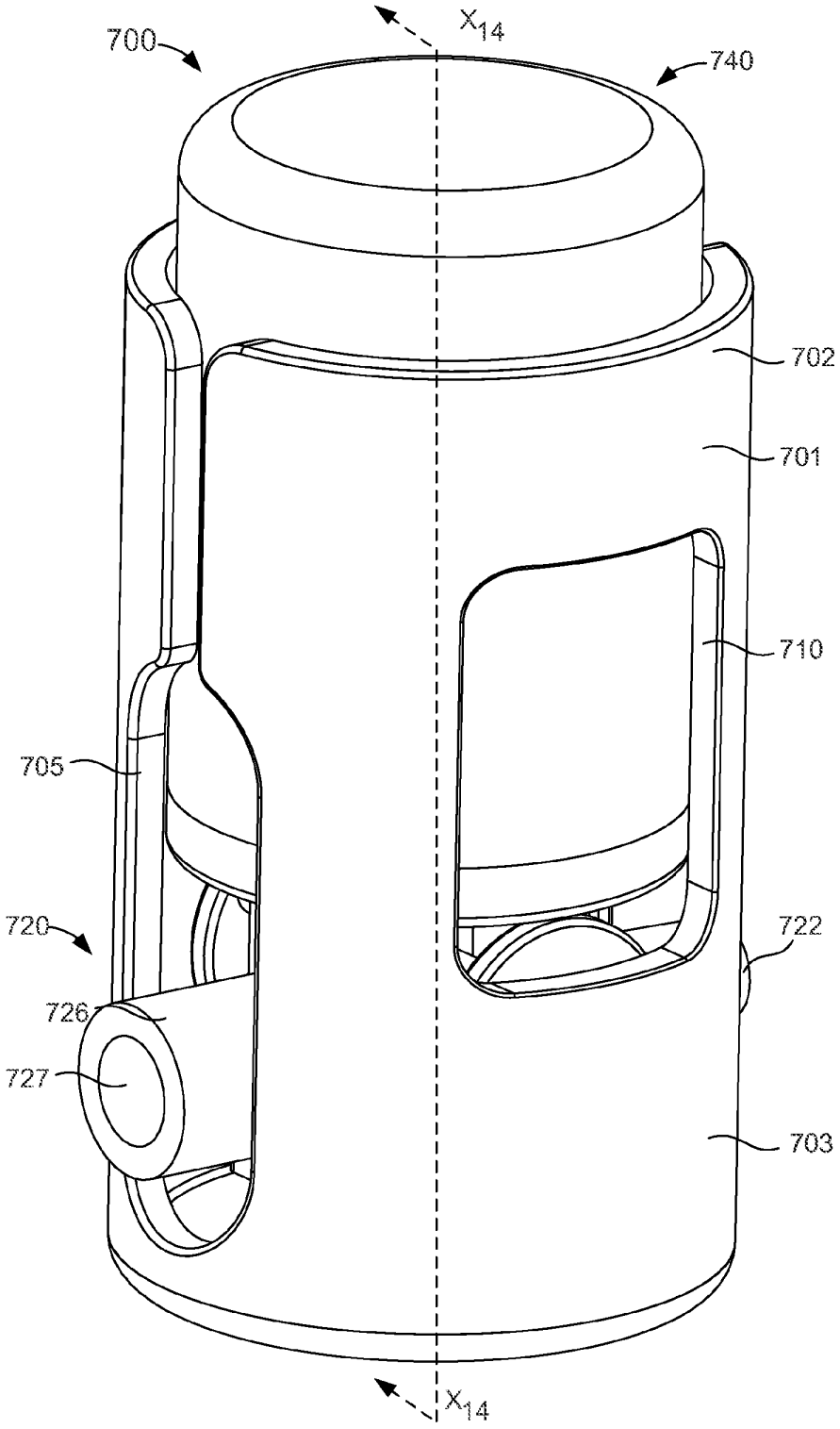


FIG. 42

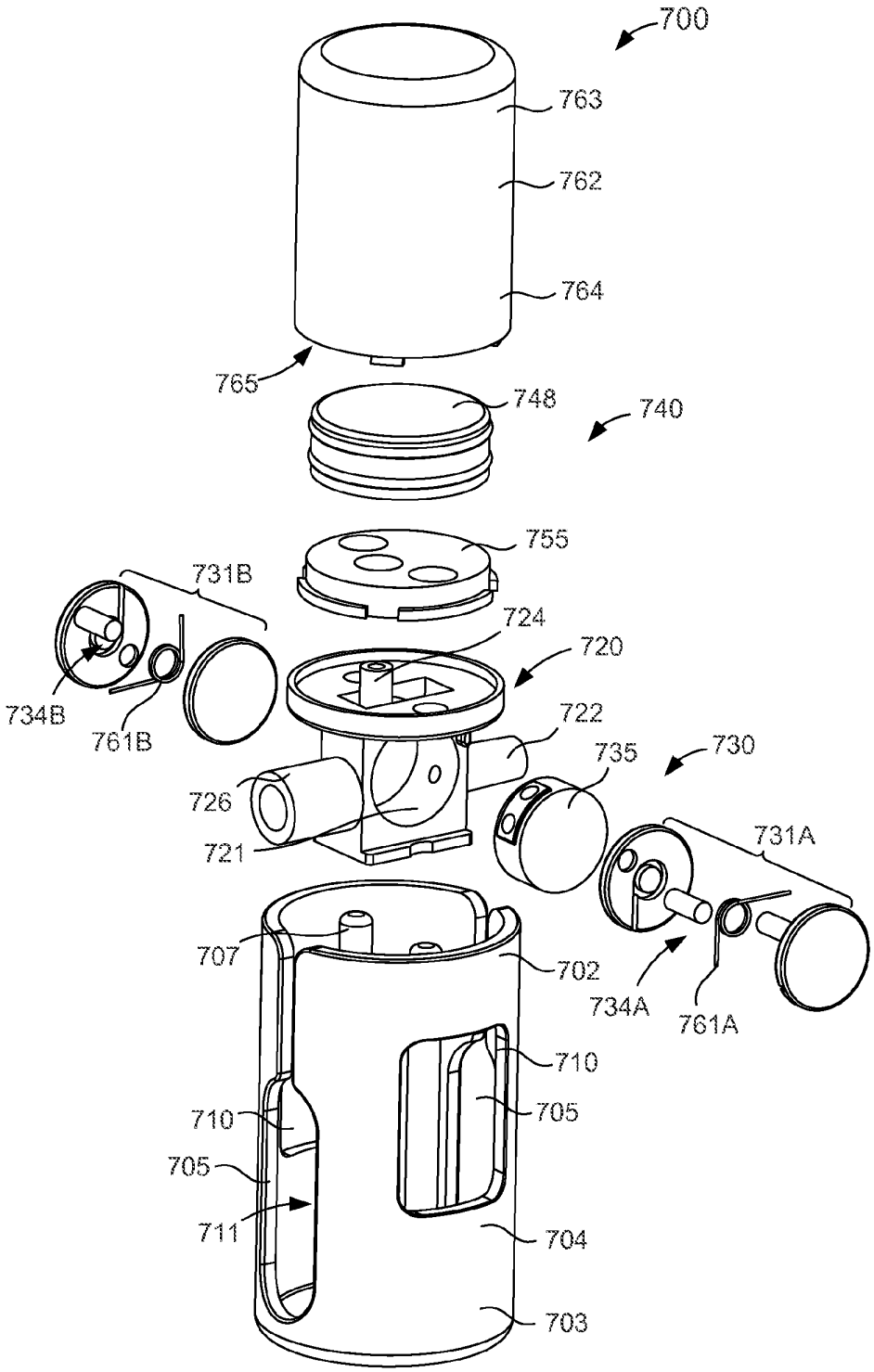

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FIG. 43

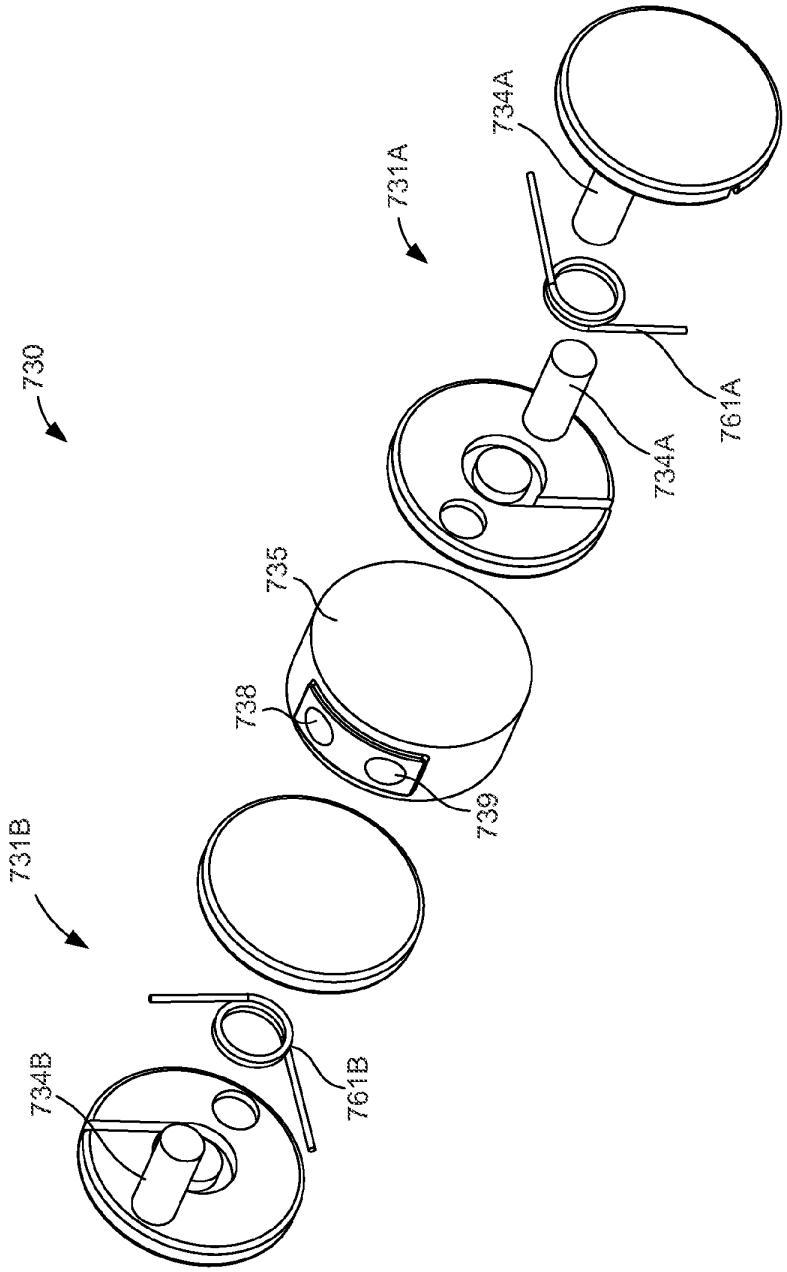


FIG. 44

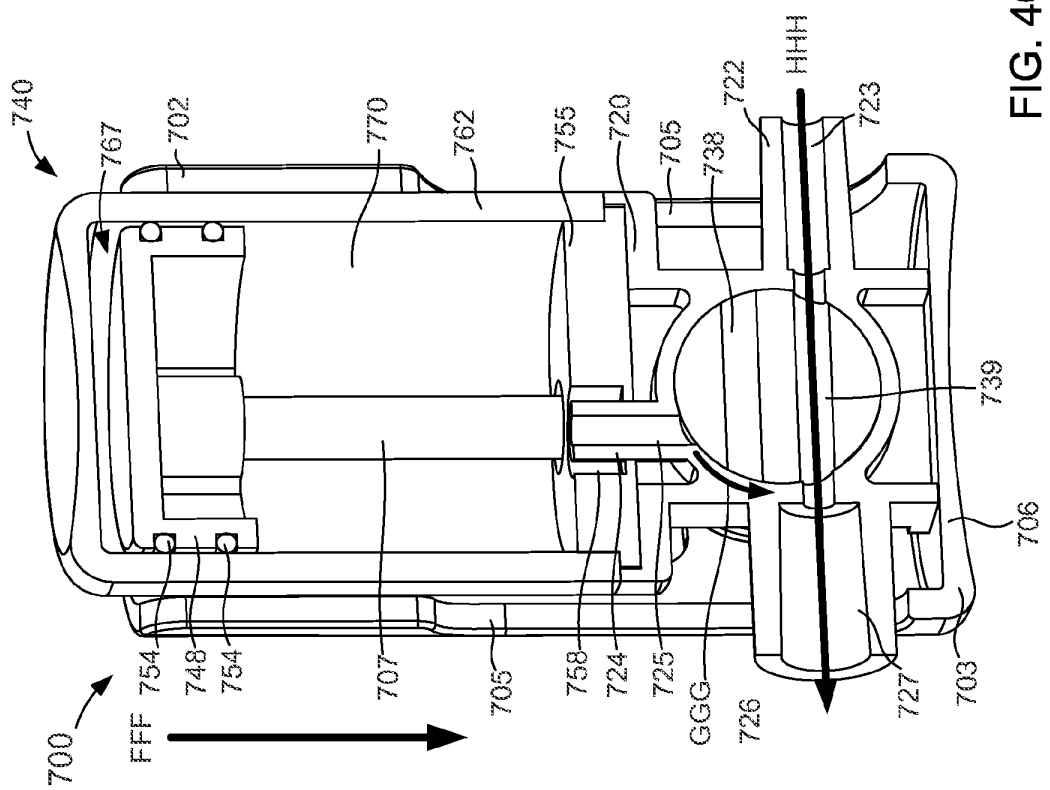

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FIG. 46

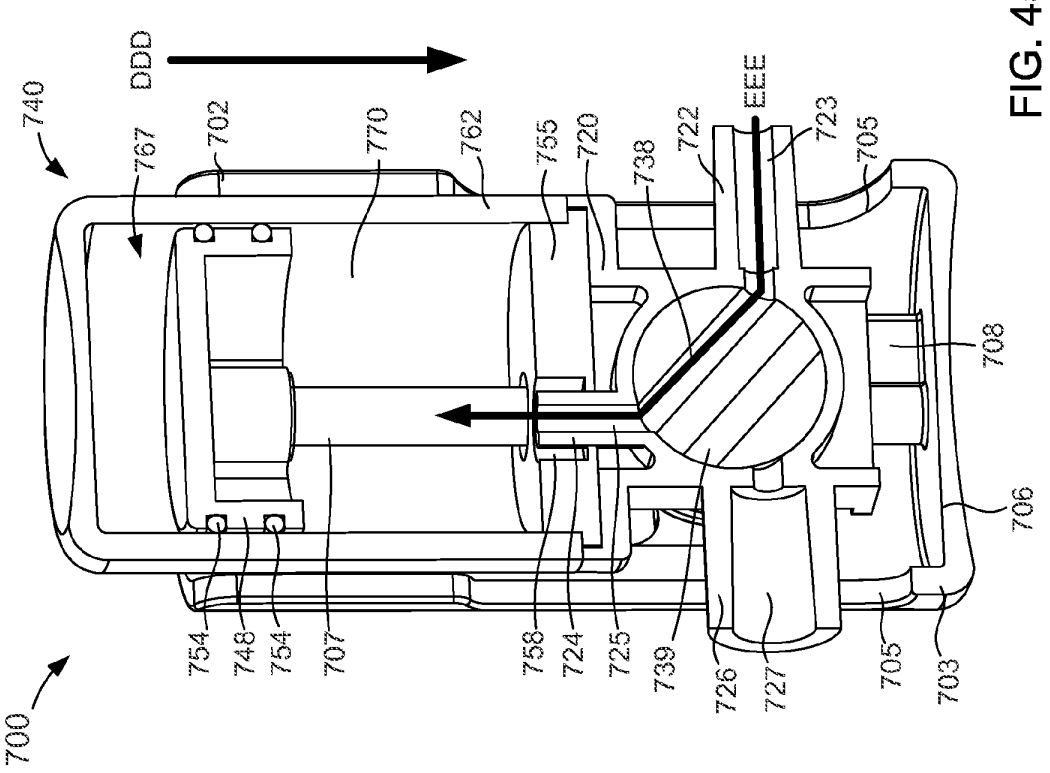

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FIG. 45

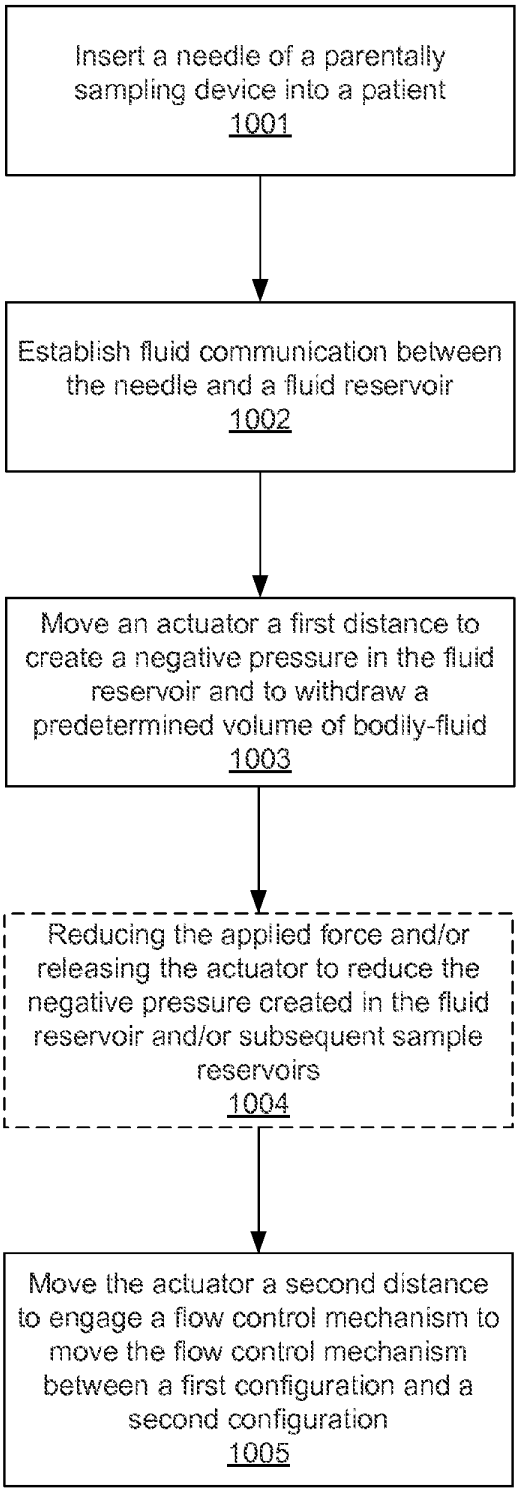

Insert a needle of a parentally sampling device into a patient
1001
Establish fluid communication between the needle and a fluid reservoir
1002
Move an actuator a first distance to create a negative pressure in the fluid reservoir and to withdraw a predetermined volume of bodily-fluid
1003
Reducing the applied force and/or releasing the actuator to reduce the negative pressure created in the fluid reservoir and/or subsequent sample reservoirs
1004
Move the actuator a second distance to engage a flow control mechanism to move the flow control mechanism between a first configuration and a second configuration
1005

FIG. 47

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US13/43289

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61B5/15; B01D43/00; B01L3/14; C12M1/00; C12N5/02; G01N33/49 (2013.01)
USPC - 210/516, 789; 422/918, 533; 600/573, 576, 579; 604/30, 33, 248
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC(8): A61B5/15; B01D43/00; B01L3/14; C12M1/00; C12N5/02; G01N33/49 (2013.01)
USPC: 210/516, 789; 422/918, 533; 600/573, 576, 579; 604/30, 33, 248

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
MicroPatent (US-G, US-A, EP-A, EP-B, WO, JP-bib, DE-C,B, DE-A, DE-T, DE-U, GB-A, FR-A); Public Patent Application Information Retrieval (PAIR); Google/Google Scholar; DialogPro; Pubmed/Medline: negative pressure, vacuum, contamination, sterile, low valve, rotating, actuator, inlet, outlet, reservoir, housing, body fluid, blood, semen, urine, sample, collection, specimen, assay, medical, diversion

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 4425235 A (CORNELL, WD et al.) January 10, 1984; figures 1-4; column 2, lines 56-67; column 3, lines 1-11, 18-36; column 4, lines 26-67; column 5, lines 1-13, 25-57	1-5, 14-19, 25-34
Y	US 2012/0095367 A1 (PATTON, RG) April 19, 2012; paragraphs [0041]-[0044]; claims 33, 38-41	1-5, 14-19, 25-34
Y	US 2008/0108954 A1 (MATHIAS, JM et al.) May 8, 2008; figures 6a-b; paragraph [0064]	16, 19, 29
E, X	US 2013/0116599 A1 (BULLINGTON, GJ et al.) May 9, 2013; figures 2-3; paragraphs [0037], [0068]-[0069]	1, 14, 25, 30

☐ Further documents are listed in the continuation of Box C. ☐

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
16 October 2013 (16.10.2013)	24 OCT 2013
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer: Shane Thomas PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

Form PCT/ISA/210 (second sheet) (July 2009)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US13/43289

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I: Claims 1-5, 14-19 and 25-34 are directed toward a device and method for procuring bodily-fluid samples from a patient comprising an outlet port configured to be fluidically coupled to a sample reservoir; the fluid reservoir disposed in the inner volume and configured to receive and isolate a first volume of bodily-fluid withdrawn from the patient.

Group II: Claims 6-13 are directed toward a device for procuring bodily-fluid samples from a patient, the device comprising: a diverter.

Group III: Claims 20-24 are directed toward device for procuring bodily-fluid samples from a patient, the device comprising: a seal member.

-***-Continued Within the Next Supplemental Box-***-

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
1-5, 14-19 and 25-34

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US13/43289

-***-Continued from Box No. III: Observations where unity of invention is lacking-***-

Group IV: Claims 35-39 are directed toward a method for procuring bodily-fluid samples using a parenteral sampling device, the device including a needle having a lumen configured for insertion into the patient, and a fluid reservoir fluidically coupleable to the needle, the method comprising: a first and second activation force.

The inventions listed as Groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the special technical features of Group I include an outlet port configured to be fluidically coupled to a sample reservoir; a fluid reservoir disposed in the inner volume and configured to receive and isolate a first volume of bodily-fluid withdrawn from the patient; moving an actuator a first distance to create a negative pressure in the fluid reservoir and to withdraw a predetermined volume of bodily-fluid; moving the actuator a second distance to engage a flow control mechanism and rotate the flow control mechanism from a first configuration to a second configuration, the first configuration operable to allow bodily-fluid to flow through a first flow path from the needle to the fluid reservoir, the second configuration operable to allow bodily-fluid to flow through a second flow path from the needle to a sample reservoir, which are not present in Groups II-IV; the special technical features of Group II include a diverter disposed in the housing, the diverter having an inlet port configured to be fluidically coupled to the patient, a first outlet port configured to be fluidically coupleable to the fluid reservoir, and a second outlet port configured to be fluidically coupled to a sample reservoir, which are not present in Groups I and III-IV; the special technical features of Group III include a seal member movably disposed in the inner volume; a fluid reservoir disposed in the inner volume and at least partially defined by the seal member, the fluid reservoir configured to receive and isolate a first volume of bodily-fluid withdrawn from the patient, which are not present in Groups I-II and IV; the special technical features of Group IV include applying a first activation force to an actuator; reducing the first activation force applied to the actuator to reduce the negative pressure created in the fluid reservoir; and applying a second activation force to the actuator, which are not present in Groups I-III.

The common technical features of Groups I-III are a housing including a proximal end portion and a distal end portion and defining an inner volume therebetween, the housing having an inlet port configured to be fluidically coupled to the patient; the actuator configured to create a negative pressure in the fluid reservoir when actuated by a user; a flow control mechanism movably disposed in the housing, the flow control mechanism configured to move between a first configuration, in which the bodily-fluid can flow from the inlet port, through the flow control mechanism and to the fluid reservoir, and a second configuration, in which the fluid reservoir is fluidically isolated from the inlet port; create a negative pressure in the fluid reservoir, the actuator further configured to move the flow control mechanism from the first configuration to the second configuration after a first volume of bodily-fluid is received in the fluid reservoir from the patient.

The common technical features of Groups I and II further include an actuator movably disposed in the housing.

These common technical features are disclosed by the Cornell reference. Cornell discloses an actuator movably disposed in the housing (chamber 14 is a fluid reservoir configured to receive whole blood; figures 1-4; column 4, lines 26-37).

Since the common technical features are previously disclosed by the Cornell reference, the common features are not special and so Groups I and II lack unity.

The common technical features of Groups I and III further include an actuator operably coupled to the flow control mechanism.

These common technical features are disclosed by the Cornell reference. Cornell discloses an actuator operably coupled to the flow control mechanism (chamber 14 is a fluid reservoir configured to receive whole blood; figures 1-4; column 4, lines 26-37).

Since the common technical features are previously disclosed by the Cornell reference, the common features are not special and so Groups I and III lack unity.

The common technical features of Groups I and IV further include inserting the needle of the device into the patient; establishing fluid communication between the needle and the fluid reservoir.

These common technical features are disclosed by the Cornell reference. Cornell discloses inserting the needle of the device into the patient (distal end of cannula is inserted into vein of patient; column 4, lines 26-37); establishing fluid communication between the needle and the fluid reservoir (whole blood flows into container; column 4, lines 26-37).

Since the common technical features are previously disclosed by the Cornell reference, the common features are not special and so Groups I and IV lack unity.

The common technical features of Groups II and III further include a sealing member and a fluid reservoir defined at least in part by the sealing member.

These common technical features are disclosed by the Cornell reference. Cornell discloses a sealing member and a fluid reservoir defined at least in part by the sealing member (stopper 20 serves as a seal and is pierceable by a cannula which can be coupled to a patient; column 3, lines 1-11),

Since the common technical features are previously disclosed by the Cornell reference, the common features are not special and so Groups II and III lack unity.

J-PlatPat 特許情報プラットフォーム

English close

Literature display help

1 / 1 display

JP 2020-000340

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bibliography close

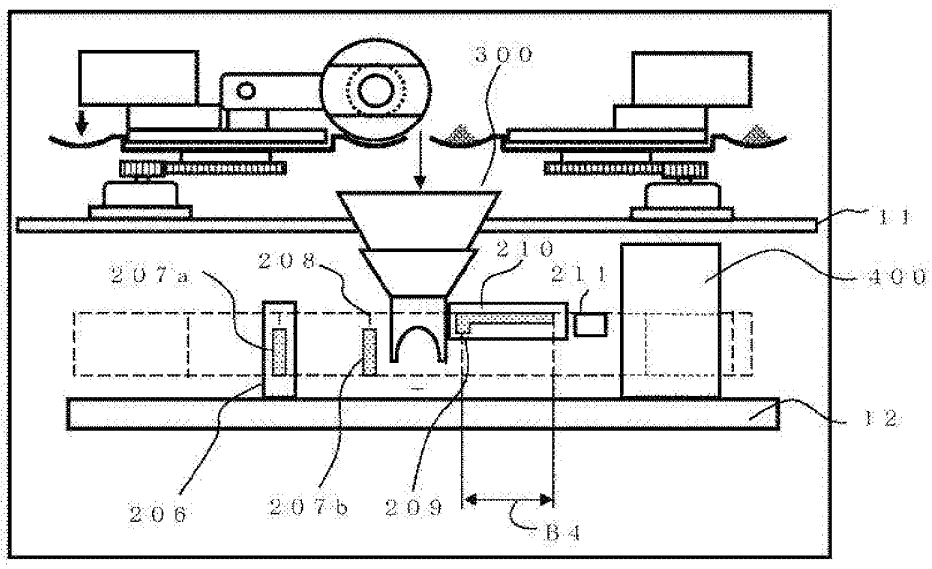
(19) [Country of issue] Japan Patent Office (JP)
(12) [Type of publication] Published patent publication (A)
(11) [Publication number] JP 2020-340 (P2020-340A)
(43) [Published date] January 9, 2020 (2020.1.9)
(54) [Title of the invention] Drug packaging device and method for manufacturing a packaged drug
(51) [International patent classification]
A61J 3/00 (2006.01)
B65B 61 /00 (2006.01)
B26F 1/18 (2006.01)
[FI]
A61J 3/00 310E
B65B 61/00
B26F 1/18
[Request for examination] Unclaimed
[Number of claims] 7
[Application form] OL
[Total number of pages]] 15

(21) [Application number] Patent application 2018-120789 (P2018-120789)
(22) [Application date] June 26, 2018 (2018.6.26)
(71) [Applicant]
[Identification number] 000151472
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[Identification number] 100107928
[Patent attorney]
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[Name] Shiro Omura
(72) [Inventor]
[Name] Shigeyuki Yamamoto
(72) [Inventor]
[Name] Taku Yamamoto
(72) [Inventor]
[Name] Kunio Fukatsu
[Theme code (reference)]
3C060
3E056
4C047
[F term (参考）】
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3C060BD01
3C060BE08
3C060BF01
3C060BG08
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4C047JJ13
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wrap up close

(57) [Summary]
[Problem] To provide a drug packaging device and a method for manufacturing a packaged dr ug that does not break at the perforated portion of the packaging paper during transportation. A packaging paper storage unit in which V-shaped packaging paper is wound, a transport path for pulling out and transporting the packaging paper from the packaging paper storage unit, a nd a transport path provided in the middle of the transportation path. a heat sealing unit that forms a heat seal for dividing the packaging paper into individual packages; and a drive roller for sandwiching and driving the packaging paper containing the medicine supplied by the med icine supply unit, and a driving roller provided downstream in the transportation direction of t he packaging paper from the driving roller, and the heat seal a perforation forming part for for ming perforations in the portion heat-sealed by the part.
[Selection drawing] Fig. 4



The scope of the claims open —

Claims:

1.

A packaging paper storage unit around which V-shaped packaging paper is wound, a transport path for pulling out and transporting the packaging paper from the packaging paper storage unit,

A heat seal portion provided in the middle of the transport path for forming a heat seal for dividing the packaging paper into individual packages

; A drug supply unit that supplies each package,

a drive roller that sandwiches and drives the packaging paper containing the drug supplied by the drug supply unit, and a downstream downstream of the drive roller in the transportation direction of the packaging paper

. and a perforation forming section provided in the heat-sealing section for forming perforations in the portion heat-sealed by the heat-sealing section

.

2.

The perforation forming section is

provided on one side of the transportation path for the packaging paper, and includes a blade storage section in which a perforation blade is retractably stored, and the transportation path for the packaging paper

. a blade receiving portion provided opposite to the blade housing portion on the other side of the blade housing portion and forming perforations in the packaging paper between the perf

orating blade protruding from the blade housing portion

; a first drive unit for moving the unit and the blade receiving portion toward the packing pa per to sandwich the packing paper

; and a second driving section for forming perforations in the packaging paper by driving the perforating blade of the blade accommodating section so as to protrude toward the blade rece iving section while holding

the A drug packaging device as described.

[Claim 3]

The perforating blade includes

a base portion and a

cutting edge portion including a plurality of blade pieces protruding from the base portion an d having a chevron-shaped cutting edge formed at the tip thereof, with a predetermined inter val between adjacent blade pieces. and

the second drive unit

forms perforations in the packaging paper by projecting partway of the blade piece of the pe rforation blade toward the blade receiving portion, and the base portion

of the perforation blade.

3. The medicine packaging device according to claim 2 , wherein the packaging paper is cut by protruding up to the blade receiving portion side .

4.

The perforating blade

is formed such that the width of the blades at both ends in the direction perpendicular to the conveying direction of the packing paper is larger than the width of the blades of the inner bla des,

4. The drug packaging device according to claim 3 , wherein the cutting start portions are fo rmed at both ends of the packaging paper in a direction orthogonal to the conveying direction of the packaging paper .

5.

The perforating blade

is formed so that each of the blade pieces has the longest length from the base of the centra l blade piece, and the length gradually decreases toward the end.

5. The medicine packaging device according to claim 3 or 4, characterized in that:

6.

The perforating blade has a horizontal blade having

a blade width larger than the thickness of said blade and inserted between said plurality of b lades.

By forming a plurality of cross-shaped blades, the cross-shaped blades form a perforation for med in the packaging paper to form a cutting start portion when separated along the perforati on

. The drug packaging device according to any one of claims 3 to 5.

7. A

pre-stored V-folded packaging sheet is pulled out to a conveying path, a

heat-sealed portion is formed on the pulled-out packaging sheet for dividing into individual p ackages, and the

heat-sealed portion is formed. The medicine is supplied and stored one by one between the packaging papers on which is formed, and the

packaging paper containing the medicine is nipped by the driving roller and driven to convey one by one, and the driving

roller

A method for manufacturing a packaged medicine , comprising: forming perforations in the heat-sealed portion of the packaging paper downstream of the packaging paper in the conveyi ng direction of the packaging paper.

detailed description open —

Description: BACKGROUND OF THE INVENTION 1.

Field of the Invention The present invention relates to a medicine packaging device for suppl ying and packaging medicines one by one and to a method for manufacturing divided medicin es. 2. Description of the Related Art A drug packaging device has been developed and put int o practical use for automating drug dispensing work. As an example of such a medicine packa ging device, there is one described in Patent Document 1. [0003] That is, the ends of the pa ckaging paper are pulled out from a roll around which the V-folded packaging paper is wound, and the end portion of the packaging paper is pulled through a plurality of support shafts onto a conveying path inclined downward in the conveying direction. and fed to a funnel-shaped dr ug hopper. A thermal pressure contact portion is provided downstream of the drug hopper, an d the thermal pressure contact portion is provided with a heat seal and a perforation forming portion. Then, a T-shaped heat seal for separating the individual packages is formed by heat s ealing, and perforations for separating the individual packages are formed. After heat-sealing, one packet of medicine is supplied from the medicine hopper to the space between the packa ging papers. [0004] When the drug is supplied, the packaging paper is nipped by driving roll ers provided downstream of the thermal pressure contact portion and pulled out by the length of one package to prepare for the next individual package. Heat sealing and perforation are p erformed. By repeating such an individual packaging operation, a single prescription of a pack aged drug is created. [Prior Art Document] [Patent Document] [Patent Document 1] Japanese Unexamined Patent Application Publication No. 2012-131551 [Summary of the Invention] [Pro

blems to be Solved by the Invention]

[0006]

In the apparatus disclosed in Patent Document 1, the driving rollers for conveying the packaging paper are provided downstream of the perforation forming section. Therefore, when the packaging paper is pulled out by the drive roller, if an excessive load is applied to the packaging paper, there is a risk that the packaging paper will be torn at the perforations. In addition, since the drug is enclosed in the lower portion between the packaging papers, the driving rollers must inevitably hold the upper side of the packaging papers to convey them. In order to prevent the packing paper from tearing during transportation, the upper edge of the packing paper cannot be perforated (cut). As a result, there is also the problem that it is difficult for an elderly person or a person with weakened muscles to cut along the perforations from the upper end side.

[0007]

Therefore, in some conventional packing machines, perforations (cuts) are made at the lower end of the paper so that the paper is cut from the lower side. then
In addition, the printing direction is reversed and the visibility is poor, and after cutting it off, it is necessary to turn it upside down again and cut it horizontally by hand to open it, which is inconvenient.

[0008]

An object of the present invention is to provide a drug packaging device and a method for manufacturing a packaged drug, in which paper for packaging is not cut at perforations (cuts) during transportation. aim. The second problem is that perforations (cuts) can be made on the upper end side of the packaging paper so that the patient can easily cut the single package along the perforations. An object of the present invention is to provide a highly convenient drug

packaging device and a method for manufacturing a packaged drug.

[0009]

Furthermore, as a secondary effect, by providing perforations (cuts) at the upper and lower ends of the packaging paper in this way, long packaging paper can be packed three times a d ay (morning, noon, evening), for example. I would also like to raise the point that the appear ance is neat when everything is folded because it is easy to make the creases firmly when fold ing it for storage.

Means for Solving the Problems

[0010]

A medicine packaging device of the present invention comprises a packaging paper storing s ection in which a V-folded packaging paper is wound, and a packaging paper from the packagi ng paper storing section. a transport path for pulling out and transporting paper, a heat seal p ortion provided in the middle of the transport path for forming a heat seal that separates the packaging paper into individual packages, and a heat seal portion provided in the middle of th e transport path. , a medicine supply unit for supplying the medicine one package at a time b etween the packaging papers; a driving roller for pinching and driving the packaging paper co ntaining the medicine supplied by the medicine supply unit; and the driving roller. a perforatio n creating section provided downstream in the conveying direction of the packaging paper and forming perforations in the portion heat-sealed by the heat-sealing section.

[0011]

Further, in the method for manufacturing a packaged medicine of the present invention, a pr e-stored V-folded packaging sheet is pulled out to a conveying path, and the pulled-out packa ging sheet is divided into individual packages by a heat-sealing section. is formed, and the me dicine is supplied and stored one by one between the packaging papers on which the heat-sea led portion is formed, and the packaging paper containing the medicine is sandwiched by the driving rollers to make one package. The perforations are formed in the heat-sealed portion of the packaging paper downstream of the drive roller in the transportation direction of the pack aging paper.

BRIEF DESCRIPTION OF THE DRAWINGS

[0012]

FIG. 1 is a plane cross-sectional view of a disc distribution unit of an automatic powder medici ne packaging machine according to an embodiment;

FIG. 2 is a front cross-sectional view showing the raised position of the drop hopper of the aut omatic powder medicine packaging machine of the embodiment;

FIG. 3 is a diagram showing the structure and operation outline of a drop hopper;

FIG. 4 is a front cross-sectional view showing the lowered position of the drop hopper of the a utomatic powder medicine packaging machine of the embodiment;

FIG. 5 is a cross-sectional plan view of the printing and packaging machine section of the auto matic powder medicine packaging machine of the embodiment;

FIG. 6 is a perspective view of the perforation forming device of the embodiment, showing a s tate in which the blade storage section and the blade receiving section are opened;
FIG. 7 is a perspective view of the perforation forming device of the embodiment, showing a s tate in which the packaging paper is being conveyed between the blade storage section and th e blade receiving section;
FIG. 8 is a perspective view of the perforation forming device of the embodiment, with the bla de housing portion and the blade receiving portion opened and the cover of the blade housing portion removed;
FIG. 9 is a perspective view of the perforation forming device of the embodiment, showing a s tate in which perforations are being formed with the blade storage section and the blade recei ving section closed;
FIG. 10 is a perspective view of the perforation forming device of the embodiment, with the c over of the blade housing section removed in a state where the blade housing section and the blade receiving section are closed to form perforations;
FIG. 11 is a perspective view of the perforation forming device of the embodiment, showing a state in which the blade storage section and the blade receiving section are closed to cut the packaging paper;
FIG. 12 is a perspective view of the perforation creating device of the embodiment, in which t he blade housing portion and the blade receiving portion are closed and the packaging is perf ormed;
FIG. 10 is a view of the blade storage section with the cover removed, in a state where the pa per is being cut;
13A and 13B are diagrams for explaining the shape and movement distance of the perforation blade of the perforation creating device according to the embodiment; FIG.
14A and 14B are diagrams for explaining the shape of a perforation blade of the perforation cr eating device according to the embodiment; FIG.
FIG. 15 is a diagram for explaining the relationship between the shape of the perforation blad e of the perforation creating device of the embodiment and the packaging paper;
FIG. 16 is a diagram showing an example of a packaged medicine manufactured by the autom atic powder medicine packaging machine of the embodiment;
17 is a plan view for explaining a printing packaging machine according to a second embodim ent; FIG.
FIG. 18 is a front view for explaining a printing packaging machine according to a second emb odiment; FIG.
BEST MODE FOR CARRYING OUT THE INVENTION
[0013]
An automatic powder medicine packaging machine according to an embodiment will be descr ibed below with reference to the drawings.
In the following description, an automatic powder medicine packing machine will be taken as

an example, but the present invention is not limited to the automatic powder medicine packin g machine, and can also be applied to an automatic tablet packing machine. Further, it is need less to say that the present invention can also be applied to a medicine packaging device for p ackaging a plurality of medicines into one individual package as described in Japanese Patent No. 6255528 and Japanese Patent Application Laid-Open No. 2000-24087.

FIG .

1 is a plan view of an automatic powder medicine packing machine of this embodiment, and FIG. 2 is a front view of the automatic powder medicine packing machine. Above the intermed iate table 11 of the housing 10 is arranged a disk distribution section 100 as a drug supply sec tion, and below the intermediate table 11 is arranged a printing packaging machine 200 as a drug packaging section. A drop hopper 300 serves to introduce the powdered medicine discha rged from the disc distribution unit 100 through the inner surface of the drop hopper 300 into the printing packaging machine 200 side.

[0015]

The disc distributor 100 is provided with two sets of distributors. In the disc distribution unit 100, 101 is a detachable powdered medicine cassette, which is loaded with powdered medicin e in the amount necessary for the prescription at another place in advance, and manually ope rated by a staff member or by an automatic device such as a robot arm (not shown). It is plac ed on the vibration table 102 from another shelf. The vibration table 102 generates vibration by an electromagnet (not shown) or the like, and by transmitting the vibration force to the po wdered medicine cassette 101, the powdered medicine in the powdered medicine cassette 10 1 is transported by vibration, and the powdered medicine is dropped little by little in the direct ion of the arrow 103. It is.

Reference

numeral 104 denotes a horizontally arranged distribution disk, a large wheel of which is rotat ed by a stepping motor 105 via a gear 106 in the direction of an arrow 104a. Further, an arc-s haped concave surface 107 is formed on the upper surface of the distribution disk 104 in the outer peripheral direction. Here, when the vibrating table 102 is driven while the stepping mot or 105 is continuously rotated, the powdered medicine falls little by little onto the arcuate con cave surface 107 of the distribution disc 104 to form a doughnut-shaped powdered medicine mountain P1. can be done. This operation is called a "circumferential scattering operation".

Reference numeral

108 denotes a scraping disk portion, and a lever 108a can rotate up and down around a shaf t 109. As shown in FIG. A disc 110 whose circumference is made of silicone rubber is attached to the tip of the lever 108a, and can be rotated in the direction of an arrow 110a by a motor 1 11. As shown in FIG. This disc 110 has a waterwheel-like shape in which blades are provided between two discs. It should be noted that the disk diameter of the disk 110 is the same as th e diameter of the concave surface of the arcuate concave surface 107 .

[0018]

In the case of the above-mentioned "circumferential scattering operation", the disk 110 is ro tated upward and retracted, and does not interfere with the formation of the donut-shaped po wdered drug pile P1. Next, during the "one-pack distribution operation", the disk 110 of the sc raping disk portion 108 rotates downward, and the disk 110 comes into close contact with the arc-shaped concave surface 107 without any gap. In this state, when the motor 111 is driven, the blades provided on the disk of the disk 110 scrape the powdered medicine on the arcuate concave surface 107 onto the drop hopper 300 . Then, when the stepping motor 105 is rotate d by a predetermined angle R, the amount of powdered medicine corresponding to that angle is dispensed to the drop hopper 300 side. Here, the predetermined angle R is not specified se parately.

This is the angle for the dose to be packaged in one package specified by the label. For exa mple, in the case of making a prescription for 36 packets of a powdered medicine of 1g per pa cket, 36g of powdered medicine is loaded in the powdered medicine cassette 101 in advance, and this is referred to as a "circumferential spreading operation"

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", spread the entire amount evenly in a donut shape. Next, in the "single package distribution operation", when the stepping motor 105 is rotated by 10 degrees while the disc 110 is being rotated, one package of 1 g of powdered medicine can be correctly dispensed to the drop hop per 300. be. The disc distribution unit 100 and the drop hopper 300 constitute a medicine sup ply unit.

Two pairs of discs 112a and

112b are arranged in the disc distribution unit 100 in a symmetrical manner. is for enabling t he other disk portion 112b to perform a "single package dispensing operation" so that a plural ity of consecutive prescriptions can be continuously packaged without wasting time.

[0021]

FIG. 3 outlines the shape and operation of the drop hopper 300 . The drop hopper 300 has a double structure of an upper hopper 301 and a lower hopper 302, and a lower opening 303 of the upper hopper 301 is closed by a shutter 304 that can be opened and closed. The upper en d of the upper hopper 301 is formed with an upper opening 300a for receiving the powdered medicine from the disc distribution unit 100 . The lower end of the lower hopper 302 is forme d in a wedge shape as shown in FIGS.) 305c are formed. The drop hopper 300 can move up and down as a whole. Then, at the timing of dispensing the powdered medicine from the disc distribution unit 100 in the "one packet dispensing operation", it is positioned at the upper pos ition in FIGS. 3(a) and 3(b). At this time, the shutter 304 is closed as shown in the side view of FIG. At this time, the left and right claws 305a and 305b at the lower end of the drop hop per 300 are inserted into the open end B1 of the packaging paper B folded in two to be conve yed

. When the powdered medicine is discharged, as shown in FIG . 3(c), the entire drop hopper 300 moves downward. It acts as a guide when entering the When the shutter is opened as sh

own in 304a in this state, the powdered medicine is stored inside the packaging paper B. FIG. After that, the drop hopper 300 rises to the position shown in FIG. 3(b). [0024]

Next, the configuration and operation of the printing packaging machine 200 will be describe d with reference to FIGS. 4 and 5. FIG. FIG. 4 is a cross-sectional view of the front of the pow der medicine packaging machine, showing a state in which the drop hopper 300 positioned ab ove in FIG. 2 has moved downward. FIG. 5 is a top cross-sectional view of the printing and pa ckaging machine 200. As shown in FIG. Reference numeral 201 denotes a packing paper roll a s a packing paper storage unit, which is formed by winding a double-folded paper having ther mal adhesiveness on a reel with the valley-fold side facing downward, and is placed on the lo wer stage 12. It is The packaging paper pulled out from the leading end of the paper on the o uter peripheral side of the reel is conveyed along the conveying path along a route such as th e one-dotted chain line B2 to B3. A printing unit 202 is composed of an ink ribbon 203, a ther mal printing head 204, a platen roller 205, etc., and prints prescription information on the surf ace of the packaging paper B for each package.

Reference numeral

206 denotes a vertical sealing mechanism, which is a heat sealing portion provided on the lo wer table 12. By pressing the packing paper B from the front and back (top and bottom in FI G. 5) with a hot plate, the vertical sealing mechanism 207a is classified into individual packag es by performing the sealing. 207b shows vertical sealing at a position moved by one packag e, but the upper open end 208 of the packaging paper B is not sealed. This is so that the pack ing sheets B can be transported in a state in which the claw portions 305a and 305b of the dr op hopper 300 are inserted between the packing sheets B as shown in FIG. 3(a). The drop ho ok to be placed next

A drop hopper cleaning device 310 is attached to the back side of the hopper 300 . Since the drop hopper cleaning device 310 is not directly related to the present invention, detailed descr iption thereof will be omitted.

Next , reference

numeral 209 denotes a horizontal sealing mechanism, which presses the packing paper B fro m the front and back with a hot plate to seal the unsealed portions in the horizontal direction and the vertical direction, as indicated by 210 . With the vertical seal 207 and the horizontal s eal 210, the packaging paper B is sealed as a single package. Although not shown in the draw ing, the vertical seal 7 does not seal the perforated portion but seals both sides of the perfora ted portion, which will be described in detail later.

A driving roller 211

is driven synchronously with the platen roller 205 of the printing unit 202, and rotates while

nipping the upper end portion of the packaging paper B from both sides to cover the distance of the one-packing pitch B4. , is driven as one step. Reference numeral 400 denotes a perfora tion forming device, which forms vertical perforations in the non-sealed portion provided in th e middle of the vertically sealed portion, thereby facilitating the separation of individual packe ts by the patient. 2 and 4 do not indicate perforations, but indicate boundaries between single packages. Also, in FIGS. 2 and 4, the description of the vertical seal downstream of the drop h opper 300 is omitted for the sake of clarity of explanation. As auxiliary equipment for the dr op hopper cleaning device 310, a dust collection blower 320 and a compressed air generating compressor 330 are arranged at the rear of the housing and used as air sources for the drop hopper cleaning device 310

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[0029]

The configuration and operation of the perforation forming apparatus 400 will be described b elow with reference to FIGS. 6 to 15. FIG. FIG. 6 is a perspective view of the perforation formi ng device, showing a standby state in which the blade housing portion 402 and the blade rece iving portion 404 are open, and FIG. 4 is a diagram showing a state in which packing paper B is inserted. FIG. For the packaging paper B, the blade housing portion 402 and the blade recei ving portion 404 are arranged so as to be positioned between the blade housing portion 402 a nd the blade receiving portion 404 . FIG. 8 is a diagram showing a state in which the cover of the blade housing portion 402 is removed. A motor base 406 is fixed to the lower stage 12 s hown in FIGS. 4 and 5, and a stepping motor 408 is fixed to the motor base 406. As shown in FIG

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A base 410 of a perforating blade unit 401 is fixed to the lower table 12 .

The base 410 of the perforating blade unit 401 is slidably provided with a supporting portion 4 28 to

which the blade housing portion 402 is fixed. A support portion 424 to which the blade recei ving portion 404 is fixed is slidably provided on the base 410, and slides integrally with a slide shaft 422 fixed to the support portion 424. As shown in FIG. The support portion 424 and the support portion 428 are slidable in the directions of contacting and separating from each othe r. A spring 426 is provided between the supporting portion 424 and the supporting portion 42 8 to bias them away from each other.

A shaft 434 is slidably provided inside the support portion 428 of the blade housing portion 40 2 , and

a sewing machine blade 432 is fixed to the left end of the shaft 434 . The perforating blade 4 32 is slidably provided between the two covers of the blade housing portion 402 in a direction in which the perforating blade 432 protrudes from the blade housing portion 402 .

[0033]

A timing belt is stretched between a shaft (not shown) of the stepping motor 408 and a pulle y 414 fixed to the camshaft 412, so that the camshaft 412 is rotated by the rotation of the ste pping motor 408. .

Three cam plates 416 ,

418 and 420 are fixed to the camshaft 412 . The lowermost first cam plate 416 drives the bl ade receiving portion 404, and the first cam plate 416

By rotating , the slide shaft 422 is pulled rightward in the figure by a cam follower (not show n). Since the supporting portion 424 to which the blade receiving portion 404 is fixed is conne cted to the slide shaft 422, the blade receiving portion 404 is also drawn rightward in the figur e. A second cam plate 418 on the second stage from the bottom drives the blade housing po rtion 402. By rotating the cam plate 418, a cam follower attached to a support portion 428 to which the blade housing portion 402 is fixed is driven

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430 is driven leftward in the figure. Therefore, by rotating the stepping motor 408, the blade accommodating portion 402 and the blade receiving portion 404 are moved in the direction of coming into contact with each other, and the packing paper B is sandwiched. The shape of the cam plates 416 and 418 keeps the packaging paper B sandwiched between the blade accomm odating portion 402 and the blade receiving portion 404 even if the cam plates 416 and 418 r otate further. Thus, the drive mechanism for the blade receiving portion 404 by the cam plate 416 and the drive mechanism for the blade housing portion 402 by the cam plate 418 constitu te a first drive portion. Further, the third cam plate 420 on the uppermost stage is for driving a perforating blade 432, and a cam follower 436 fixed to a shaft 434 is in contact with the thir d cam plate 420. As shown in FIG

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As the stepping motor 408 rotates, the third cam plate 420 rotates and pushes the cam follow er 436 to drive the shaft 434 to the left in the figure. As a result, the perforating blade 432 fix ed to the shaft 434 protrudes from the blade accommodating portion 402 toward the blade re ceiving portion 404 to form perforations in the packing paper B. As shown in FIG. A mechanis m for driving the perforating blade by the cam plate 420 constitutes a second driving section.

[0037]

FIG. 8 shows the standby state of the perforating blade unit 401 . As shown in FIG. 8A, whe n the perforating blade unit 401 is in the standby state, the perforating blade 432 is sunk insi de the cover of the blade housing portion 402 . The state of cam plate 420 and cam follower 4 36 at this time is shown in FIG.

Next, FIGS

. 9 and 10 show a state in which the stepping motor 408 rotates to form perforations on the packaging paper B. FIG. As shown in FIGS. 9 and 10, by rotating the first cam plate 416 and t he second cam plate 418, the blade housing portion 402 and the blade receiving portion 404 c ome into contact with each other to sandwich the packing paper B. becomes. 9 and 10, illustr

ation of the packaging paper B is omitted. When perforations are formed on the packaging pa per B, the cam plate 420 pushes the cam follower 436 as shown in FIG. It will be in a protrud ed state. After the perforations are formed on the packaging paper B, the stepping motor 40 8 rotates in reverse, so that the cam plate 420 reverses from the state shown in FIG. 9(b) to t he standby position shown in FIG. 8(b)

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back to After the perforations are formed in the packaging paper B by such an operation, the packaging paper B is conveyed by the drive roller 211 to form the next individual package. Fo rmation of vertical seals, supply of medicine, and formation of horizontal seals are performed i n synchronism with the formation of perforations. When the perforations are formed, the pack aging paper B is stopped, and the vertical seal formation, drug supply, and horizontal seal for mation are performed while the packaging paper B is stopped. be. The above operation compl etes the cycle for one package.

[0040]

Here, the medicine is prescribed to the person taking the medicine, for example, 42 doses fo r two weeks in the morning, afternoon and evening. Perforations are made between 42 individ ual packages for one drug taker, and when individual packages for one drug taker are complet ed, the prescription drug is released by cutting the packaging paper B instead of the perforati ons. There is a need to. Therefore, in this embodiment, the perforation forming device 400 a lso cuts the packaging paper B. As shown in FIG

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As shown in FIGS. 11 and 12, the cam plate 420 is shown in FIG. 9(b).

After the formation of the stitches, the stepping motor 408 is further rotated to rotate the ca m plate 420 to the position shown in FIG. 11(b). Cam follower 436 is then pushed to the farth est position from camshaft 412 . As a result, the perforating blade 432 further protrudes into t he blade receiving portion 404 to the base of the perforating blade 432 . As a result, the pack aging paper B is cut by the perforating blade 432 . When cutting the packaging paper B, the r otation of the camshaft 412 need only be rotated once without returning. Next, FIG. 13 sho ws the shape and amount of movement of the perforating blade 432. As shown in FIG . The perforating blade 432 is composed of a fixed portion 432a to the shaft 434, a blad e base portion 432b, and a cutting edge portion 432c protruding from the blade base portion 432b. A plurality of blades 432d each having a chevron-shaped blade edge formed at the tip o f the blade edge portion 432c are formed at predetermined intervals between adjacent blades 432d. Between the blades 432d and 432d, there are three horizontal blades having a blade wi dth wider than the thickness t of the blade edge, but they are omitted in FIGS. ing. As for the length to the tip of each blade 432d, the blade at the center is the longest, and the length gra dually decreases toward the ends. The angle θ between the straight line L1 connecting the tip s of the blades 432d and the straight line L2 parallel to the tips of the bases is set to about 4 degrees. As a result, when perforations are formed on the packaging paper B, the cutting port

ion gradually shifts from the central blade 432d to the end blade 432d, so that the driving force required to move the perforating blade 432 is small. done. [0043]

In addition, the lengthwise ends of the perforating blade 432, that is, the blade widths of the blade pieces 432e, 432e at the ends in the direction orthogonal to the transport direction of the packaging paper B are formed larger than the blade width of the inner blade piece 432d. It is 13(b), the width of the packaging paper B is configured so that the ends of the packaging paper B are located at the positions of the edge pieces 432e, 432e of the perforating blade 432. It is Therefore, even if the transportation position of the packaging paper B is shifted, a cutting start portion (cut) can be reliably formed at the end of the packaging paper B when the patient cuts off the individual package, and the patient can easily separate. You can separate the package.

FIG.

13(b) shows the projection distance of the perforation blade 432 when the perforation is formed by the perforation blade 432 and the packing paper B is cut. When forming perforations, the perforation blade 432 protrudes from the blade receiving portion 404 to the position M, which is the intermediate portion of the blade tip portion 432c of the perforation blade 432. As shown in FIG. When cutting the packaging paper B, the perforating blade 432 protrudes from the blade receiving portion 404 to the position C of the base portion 432b of the blade beyond the position of the blade tip portion 432c. With this configuration, the formation of perforations between individual packages of the packaging paper B and the cutting of the packaging paper B between one prescription can be achieved by changing the protruding amount of the perforation blade 432. It is. Next, a cross-cut blade by inserting a horizontal blade piece between the blade pieces 432d of the perforating blade 432 will be described with reference to FIGS. 14 and 15. FIG

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14(a) is a perspective view, (b) is a left side view, (c) is a front view, and (d) is a top view. [0046]

That is, three horizontal blades are provided between the fifth and sixth blades, between the eighth and ninth blades, and between the eleventh and twelfth blades from the top in FIG. 432g is inserted. The horizontal blade 432g has a blade width larger than the thickness t of the blade 432d, and is press-fitted between the blades 432d. The base 432b of the blade 432 is press-fitted and held. By using the perforation blade 432 configured in this manner, perforations are formed, and a cutting start portion (cut) is formed when opening each individual package when the packaging paper B is separated into individual packages. It is something to do. The insertion position and the number of horizontal blades 432g are not limited to the above examples, and they can be inserted at any position between blades 432d

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Especially when the amount of powdered medicine stored in each individual packet is small, it is better to open it at the cross-cut position at the bottom of each individual packet to reduce the amount of leftovers.

Therefore, the insertion position and the number of sheets can be selected in consideration of this.

FIG .

15(a) illustrates the relationship between the perforating blade 432 and the packaging pape r. As shown in FIG. 15(a), the sealed portion (shaded portion) of the packing paper is formed by the vertical sealing mechanism 206 leaving a perforated portion (non-sealed portion) of, fo r example, 4 mm. It is formed in the sealing portion. Assuming that the width of the packagin g paper B, that is, the width in the direction perpendicular to the transport direction is, for exa mple, 70 mm, the length of the perforating blade 432 is set to 75 mm, which is larger than th e width of the packaging paper B. As a result, the ends of the packing paper B can be oppose d to the edge pieces 432e of the perforating blades 432, and as a result, the cutting start port ions (cuts) B1 are formed at both ends of the packing paper B. can be done. Further, as sho wn in FIG. 15(b), by setting the width of the horizontal blade to about 4 mm, which is larger t han the thickness t of the perforating blade 432 (=1 mm), the width of the unsealed portion o f the packing paper B is reduced

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A cross cut portion B2 can be formed over 4 mm, which serves as a cutting start portion when opening the individual package. Therefore, it is possible to provide a packaged drug that can be easily opened by a patient/user.

FIG .

16 shows an example of a cross-sectional view of a manufactured packaged medicine, showi ng an example in which three cross-cut portions are formed at intervals of 9 mm from a positi on 20 mm from the upper end, for example. In the first embodiment, the packing paper B is conveyed in the horizontal direction, and along the conveying direction, the vertical sealing po rtion 206, the drop hopper 300 serving as the medicine supply portion, the horizontal sealing portion 209, and the conveying rollers

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211 and the perforation creating unit 400 are arranged, but if the packaging paper B is config ured to be conveyed along the conveying path inclined downward in the conveying direction, t he vertical seal portion is located downstream of the medicine supply unit. It is also possible t o provide

Next ,

a printing packaging machine 500 of a second embodiment will be described with reference t o FIGS. 17 and 18. FIG. 17 is a plan view, and FIG. 18 is a front view of the same. The base p late 515 is provided with a packaging paper storage unit 533 in which the V-folded packaging

paper B is wound into a roll. , is conveyed upward via a plurality of support rolls 534 and 535, the conveying direction is changed by the twist roller 531, and conveyed to a conveying path i nclined downward by 45 degrees along the conveying direction. On the upper surface of the base plate 515, a conveying base 516 for the packaging paper B having an inclination of 45 d egrees with respect to the horizontal plane is provided

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The sheet B is transported along the transport path. A drop hopper 518 having a lower exit en tered from the upper opening side of the valley-folded packaging paper B is provided substant ially vertically in the center of this transport path, and a drug supply hopper 519 is provided a bove it. The lower part of the medicine supply hopper 519 is open, and the shutter mechanis m 520 that blocks this opening temporarily holds the medicine to be put in one sachet, and op ens the medicine like 520a by an actuator (not shown), thereby lowering the medicine. Via th e drop hopper 518, the drug is dropped into the inner space of the folded packaging paper B a nd supplied.

[0054]

This space is blocked on the left and right by a paper holding plate 521 arranged on the upp er left upstream side of the transport and an inverted L-shaped heat seal portion 522 arrange d on the downstream lower right side. The paper pressing plate 521 is opened and closed by a rotating actuator 523, and is controlled to open when the packing paper B is being conveyed and to close when it is stopped. The heat seal portion 522 has a surface heating element 524 held by a carriage 525a. The carriage 525a is pivotally supported by a guide rod 526 and confi gured to be movable forward and backward by a feed screw 528 directly connected to a motor 527 . When the carriage 525a advances, the upper end of the packaging paper B is pressed a gainst the receiving plate 525b, and the packaging paper B is sealed by heating.

[0055]

With the packaging paper B stationary, the carriage 525a is advanced for a predetermined ti me, and the shutter mechanism 520 is opened as indicated by 520a at the timing when the p aper pressing plate 521 is closed. to fall. Next, when the packaging paper B is conveyed by a predetermined distance P and the carriage 525a is moved forward again, the portion containin g the medicine that has just dropped is sealed all at once. By repeating this operation, the pac kaging paper B is continuously sealed. At this time, if the types and amounts of the medicines to be put in sequentially are controlled according to the prescription and the dosing order, for example, two weeks' worth of medicine can be taken. , One dose is divided into each package and completed. The pair of rubber rollers 529 is means for pinching and conveying the packin g paper B, and by installing them at a plurality of locations on the continuous packing paper B, the paper can be conveyed without slack. The drive roller pair 529 is controlled by a pulse motor 530 to stop the conveyance of a predetermined distance. A perforation forming device 540 similar to the perforation forming device 400 described as the first embodiment is provide d downstream of the driving roller 529 on the downstream side

. [0057] In the operation of creating a medicine package, the transported packaging paper B is longitudinally sealed by the heat seal portion 522 to separate one package. At this time, the previous individual package is laterally sealed at the same time. Next, one package of medicin e is supplied between the packaging sheets B from the medicine supply 519 via the drop hopp er 518 . The packaging paper B to which the medicine is supplied is conveyed by the drive roll er 529 by the length of one package. [0058]

Next, the second medicine is supplied between the packaging papers B, and the packaging p apers B are further conveyed by the driving roller 529 . At this stage, the first vertical seal por tion comes to the perforation forming device 540, so the perforation forming device 540 forms a perforation in the central portion of the vertical seal portion. After this operation is repeated to complete one prescription of packaged medicine, the perforated line forming device 540 cut s the vertically sealed portion to manufacture the packaged medicine.
[0059]
Thus, the position of the heat seal portion is not limited to the upstream side of the drug sup ply section, but may be the downstream side of the drug supply section. While several embo diments and variations of the invention have been described, these embodiments and variatio ns are provided by way of example and are not intended to limit the scope of the invention
.
These novel embodiments and modifications can be implemented in various other forms, and various omissions, replacements, and modifications can be made without departing from the s cope of the invention. These embodiments and modifications thereof are included in the scope and gist of the invention, and are included in the scope of the invention described in the claim s and equivalents thereof.
[Description of Reference Numerals]
100
... Disk distribution section (medicine supply section)
200... Printing and packaging machine
201... Packaging paper roll (packaging paper storage section)
206... Vertical sealing mechanism
209 ... Horizontal sealing mechanism
211 ... Driving roller
300 ... Dropping hopper (medicine supply section)
400 ... Perforation creating device
402 ... Blade storage section
404... Blade receiving portions

416, 418... Cam plate

420... Cam plate

432 Perforating blade

432b Perforating blade base

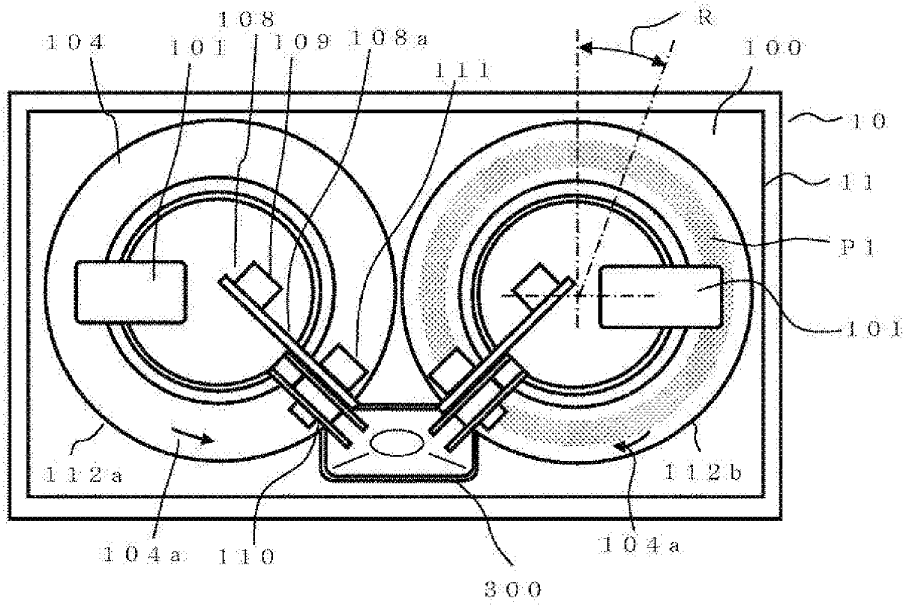
432c Perforating blade tip

B Packaging paper

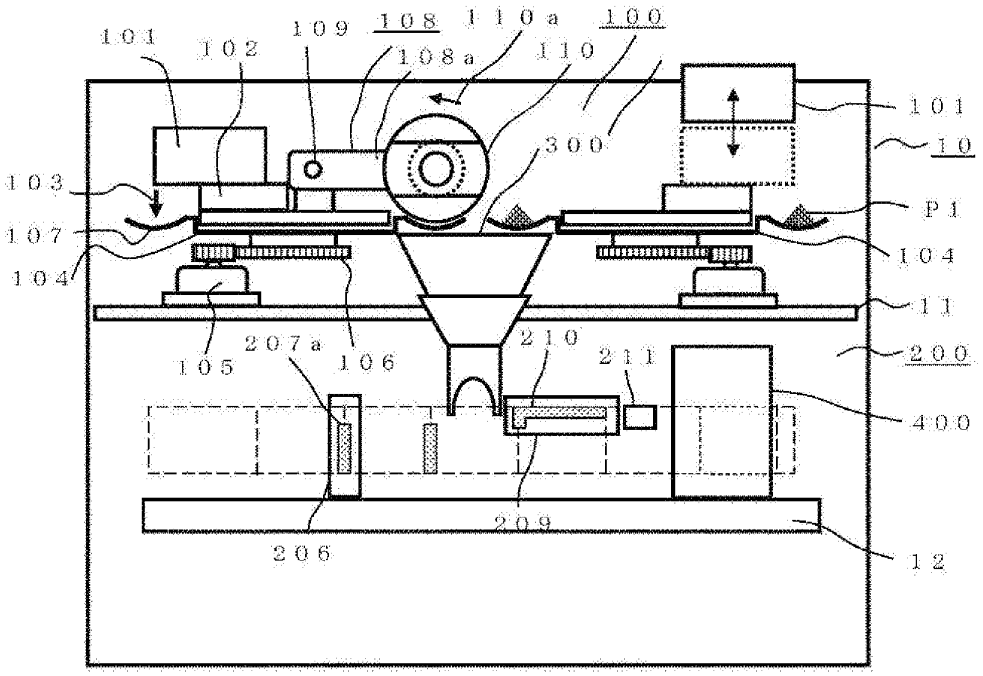
B2, B3 Conveyance path (conveyance path)

drawing open —

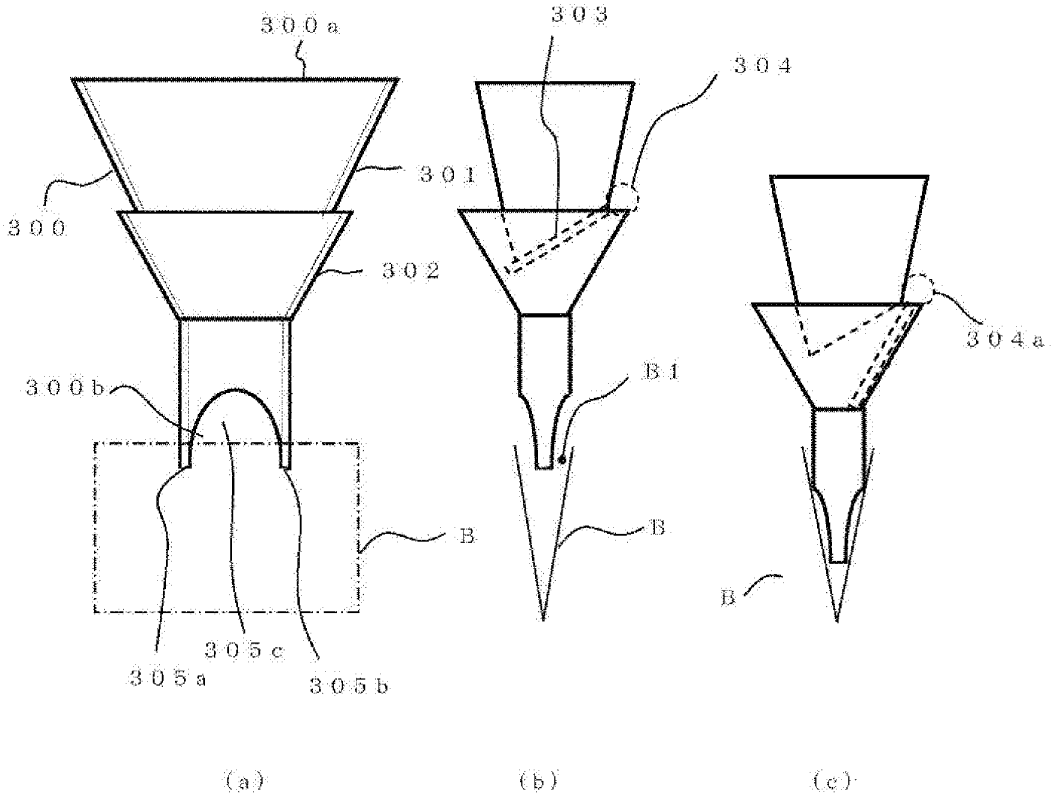
[Fig. 1]



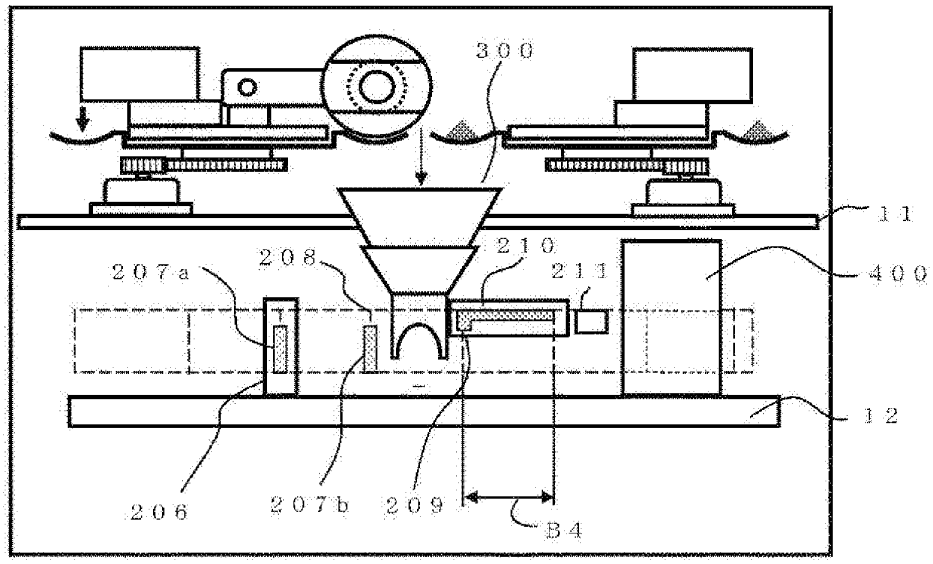
[Figure 2]



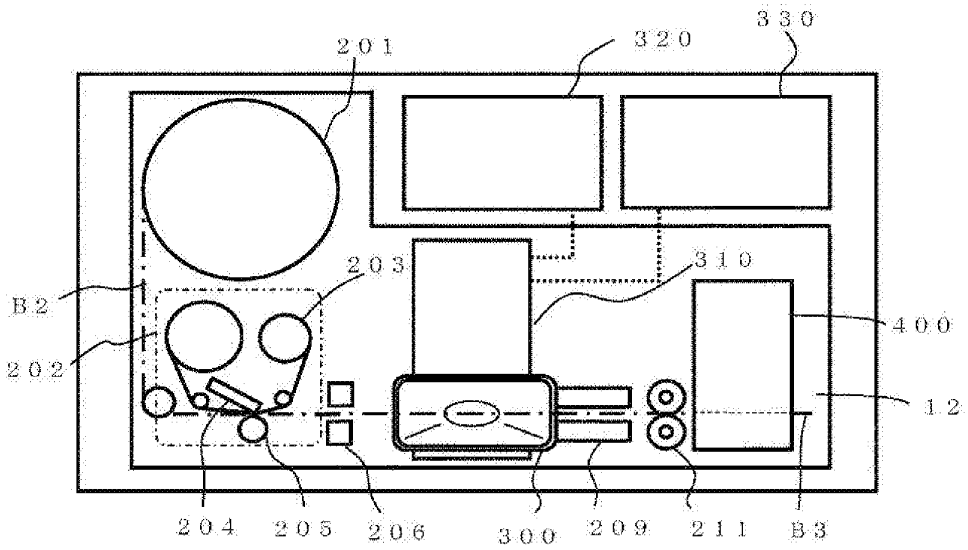
[Figure 3]



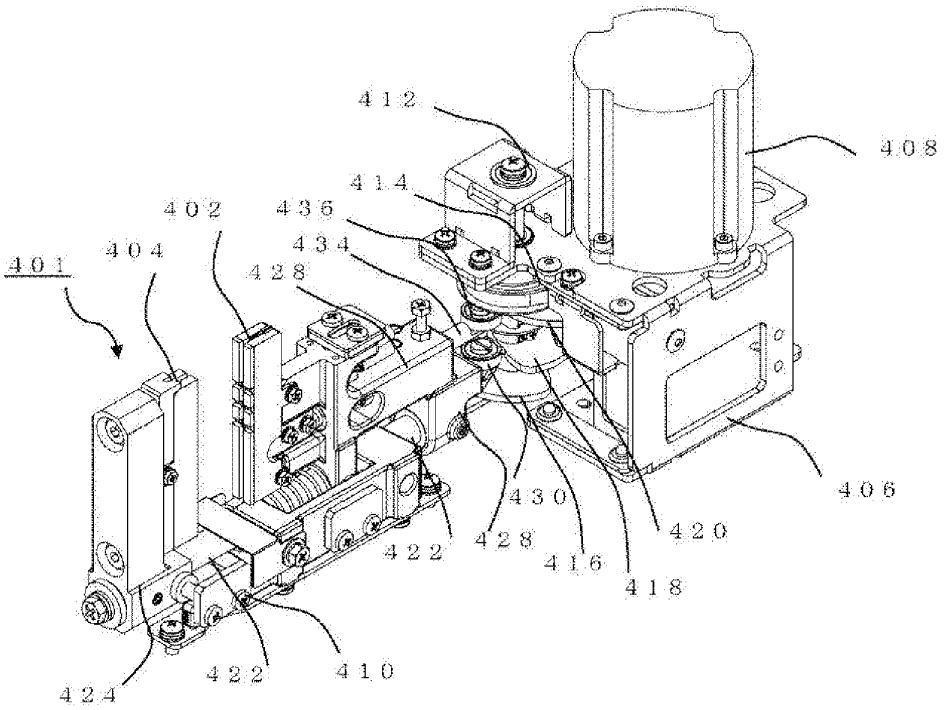
[Figure 4]



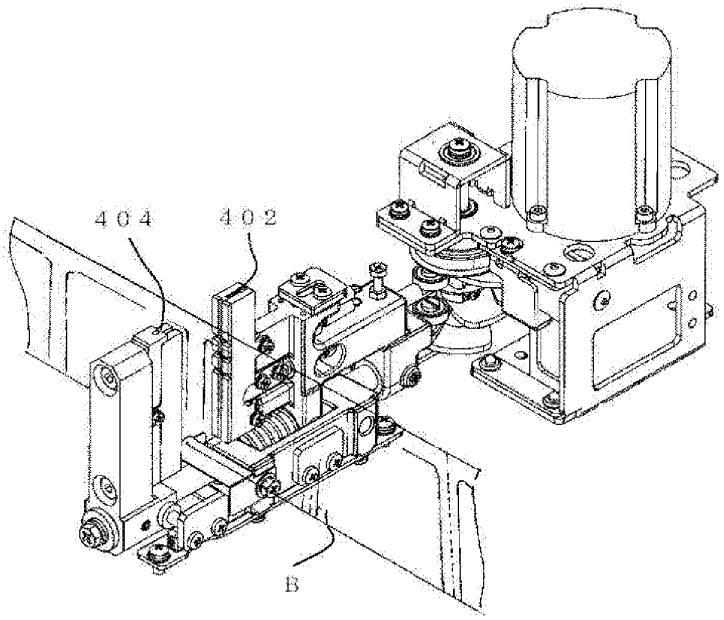
[Figure 5]



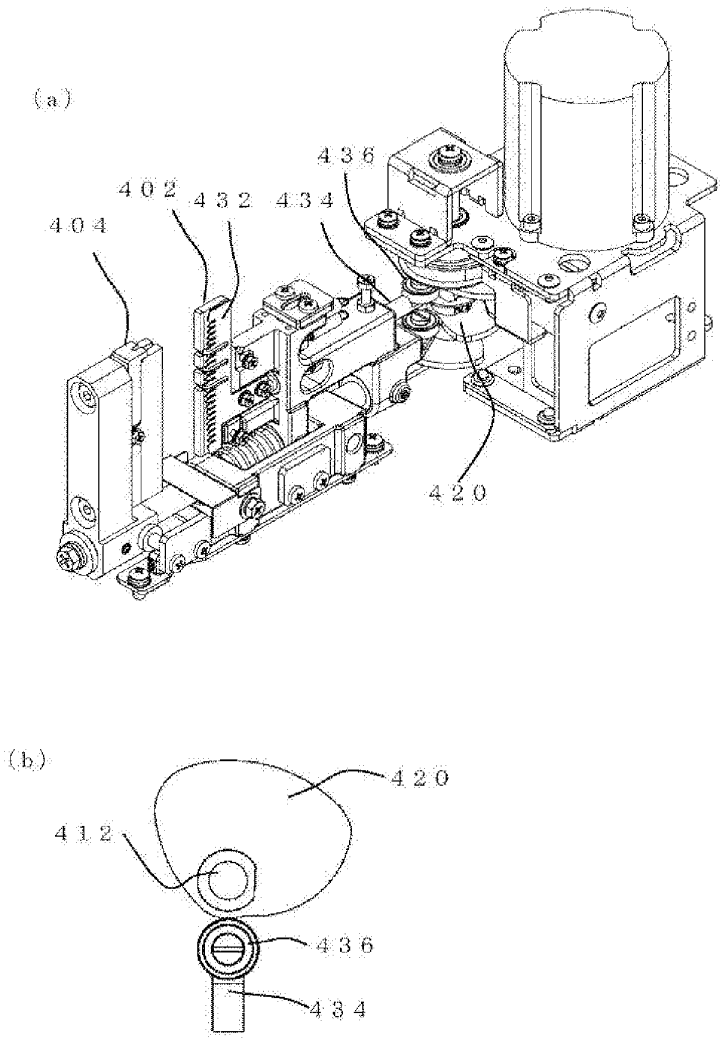
[Fig. 6]


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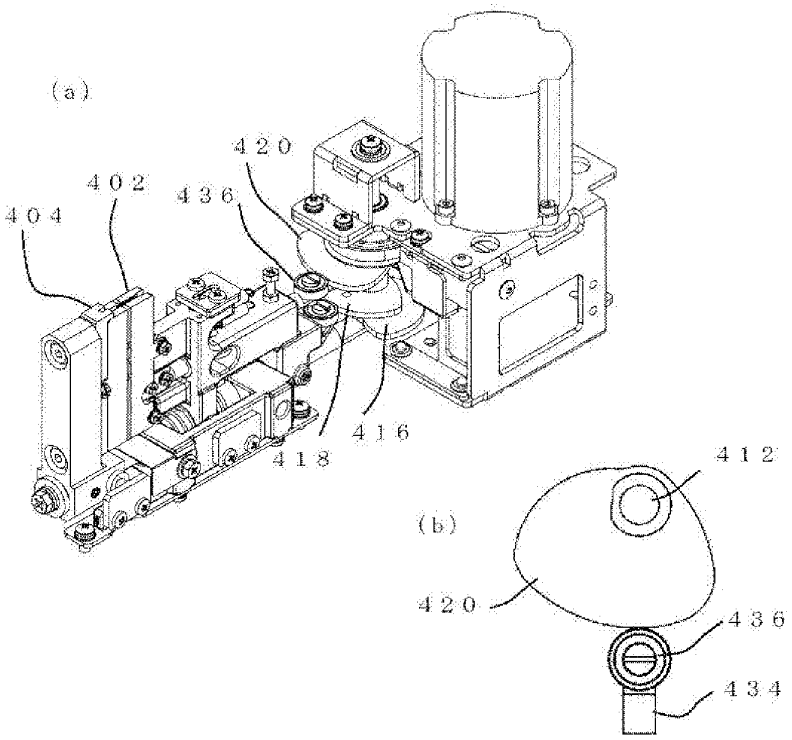
[Fig. 7]


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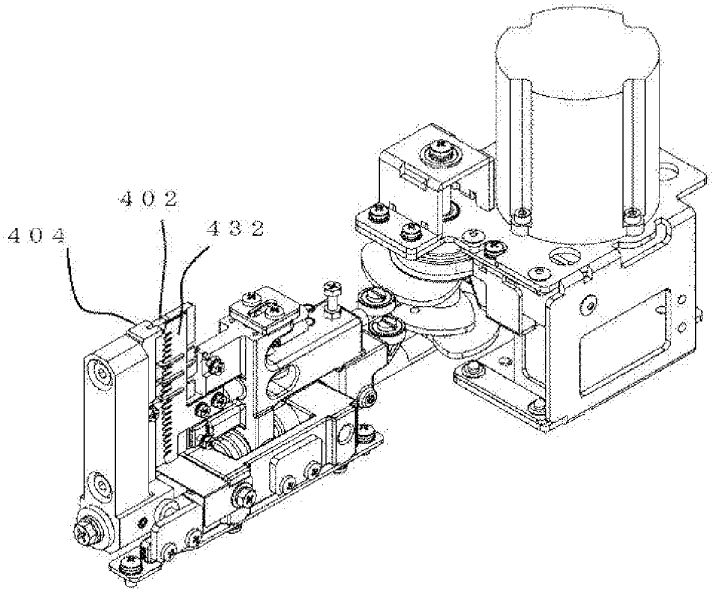
[Fig. 8]



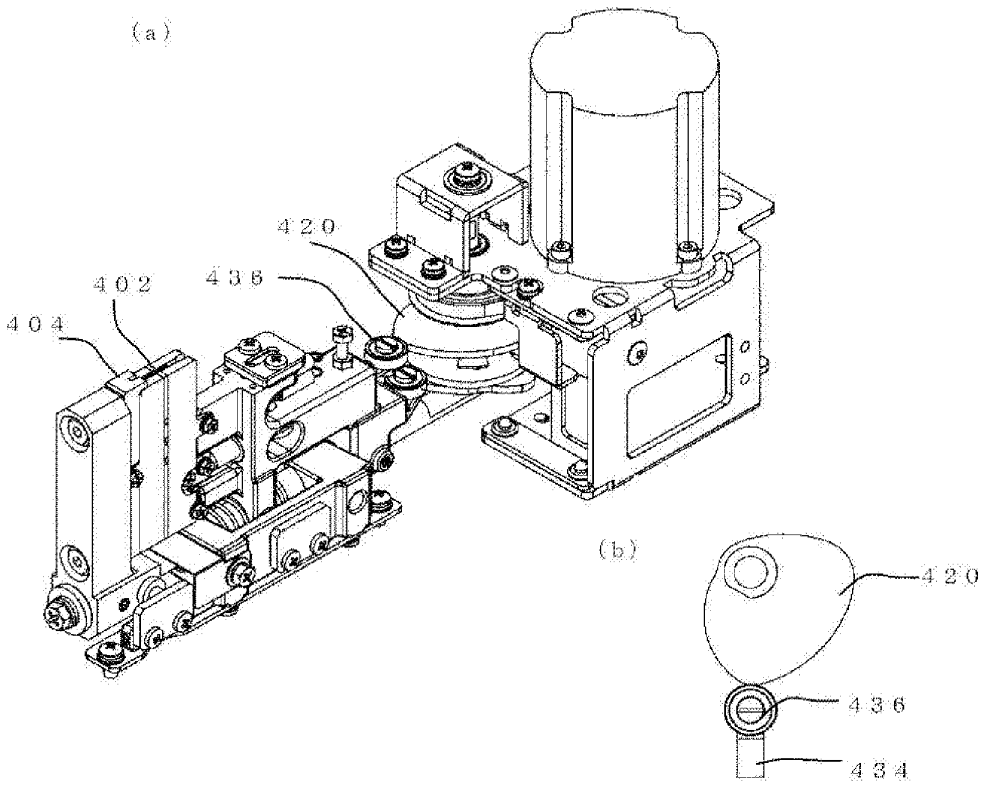
[Fig. 9]



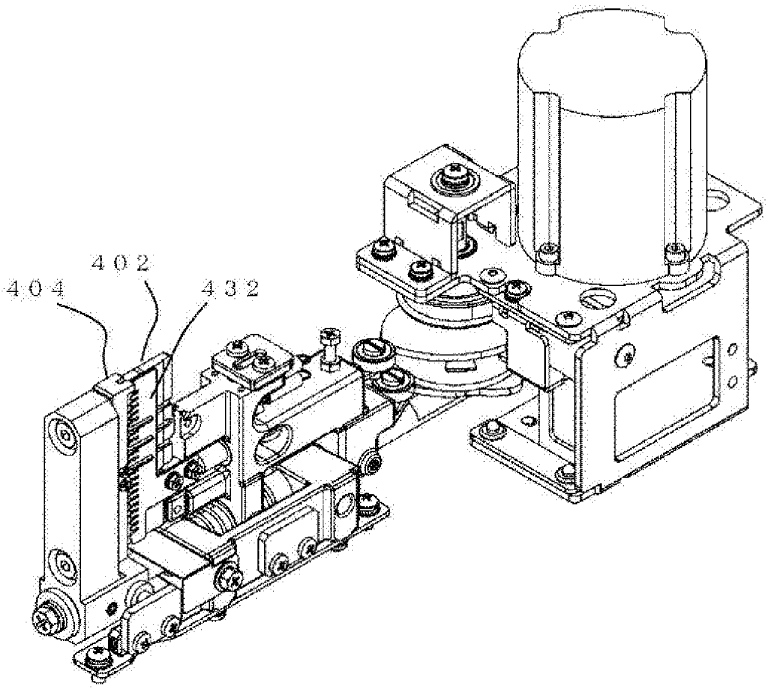
[Fig. 10]



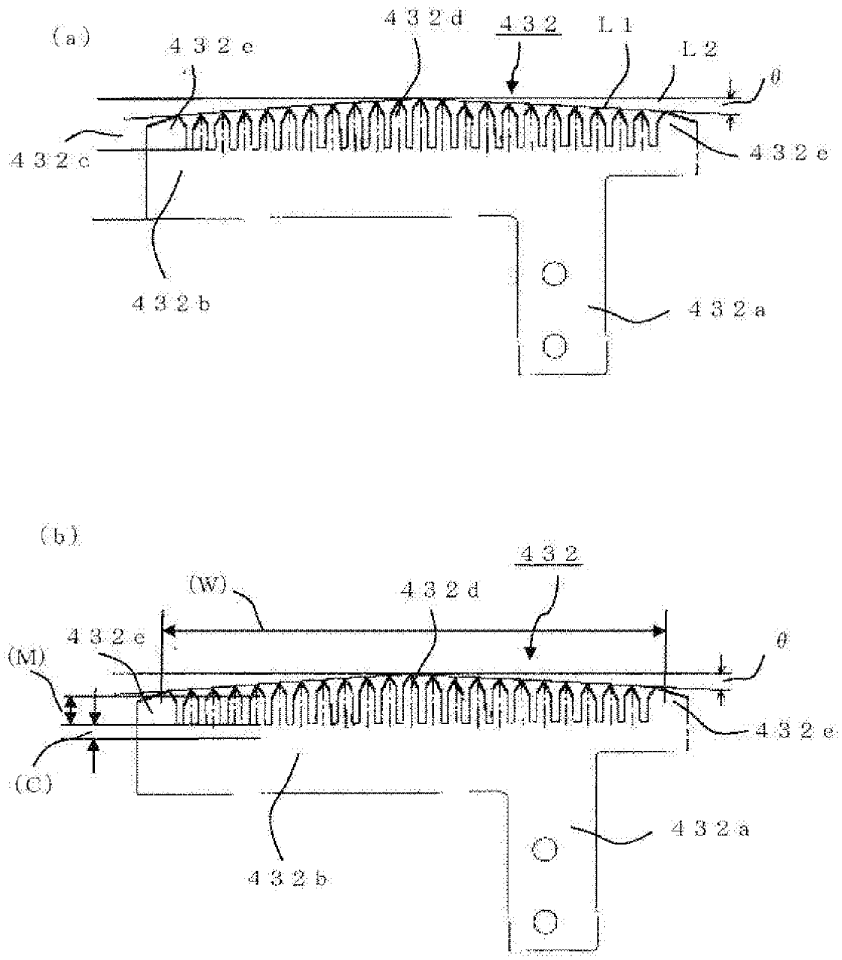
[Fig. 11]



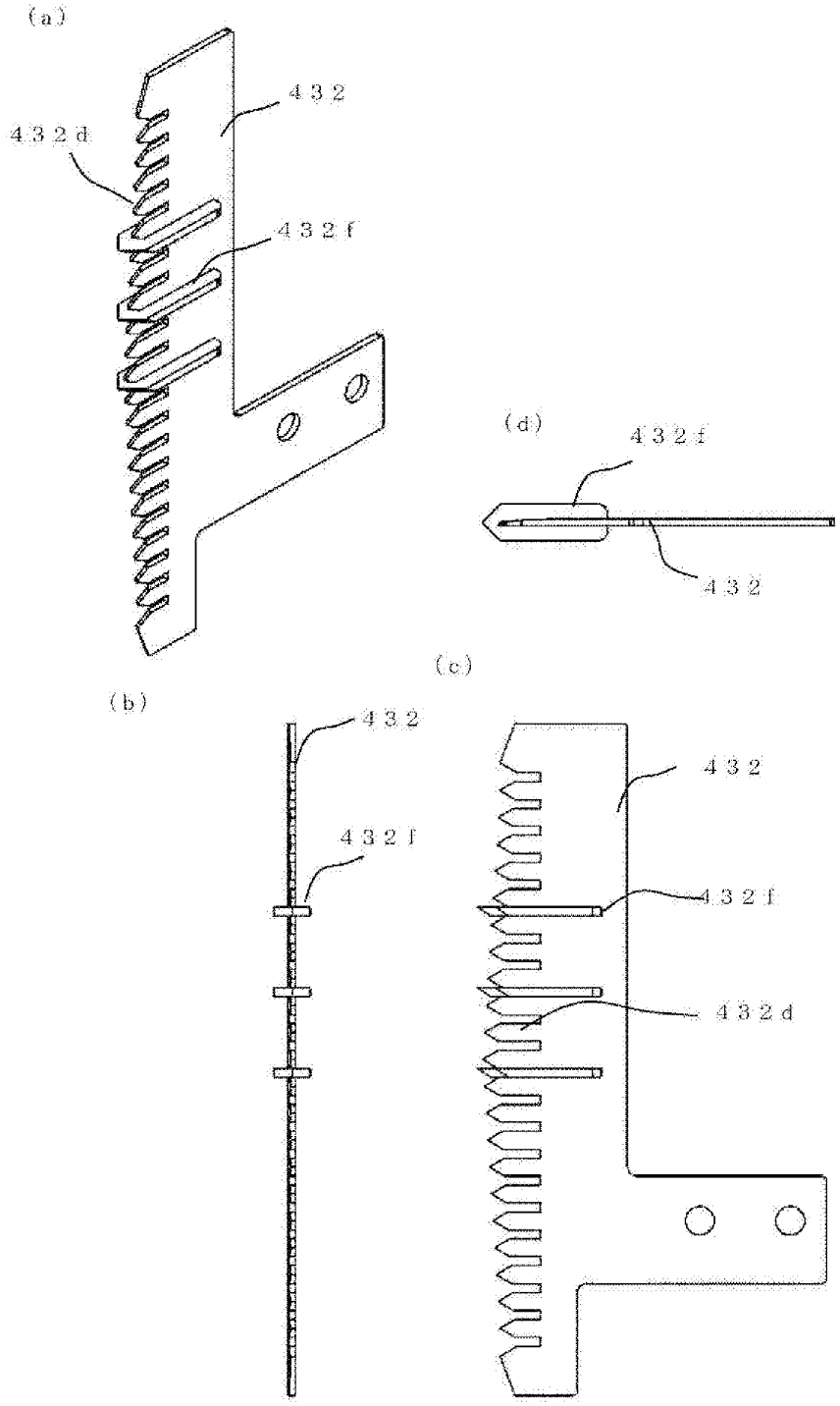
[Fig. 12]



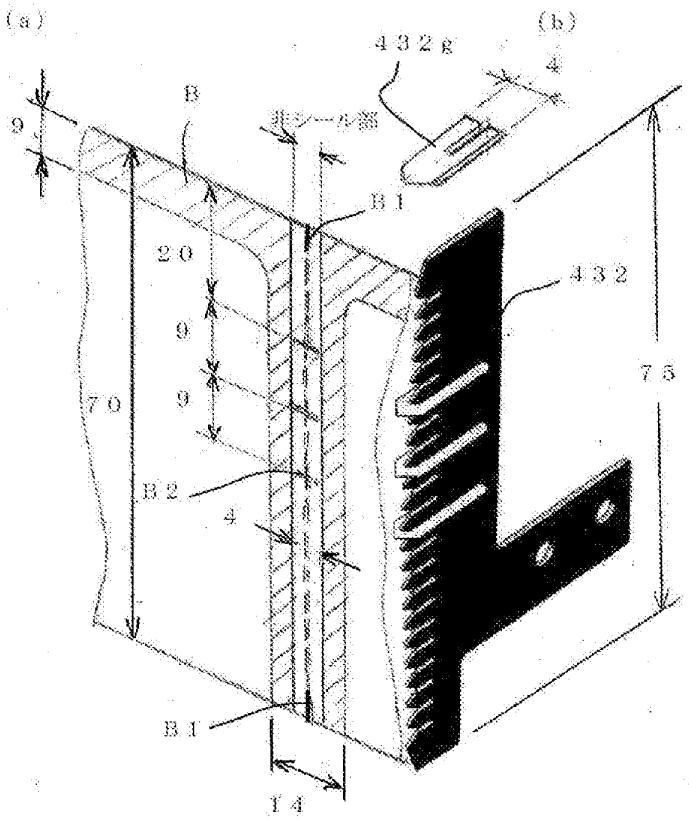
[Fig. 13]


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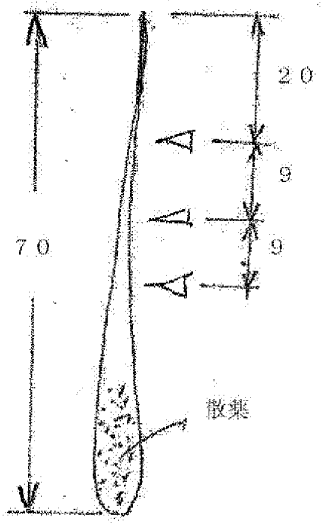
[Fig. 14]



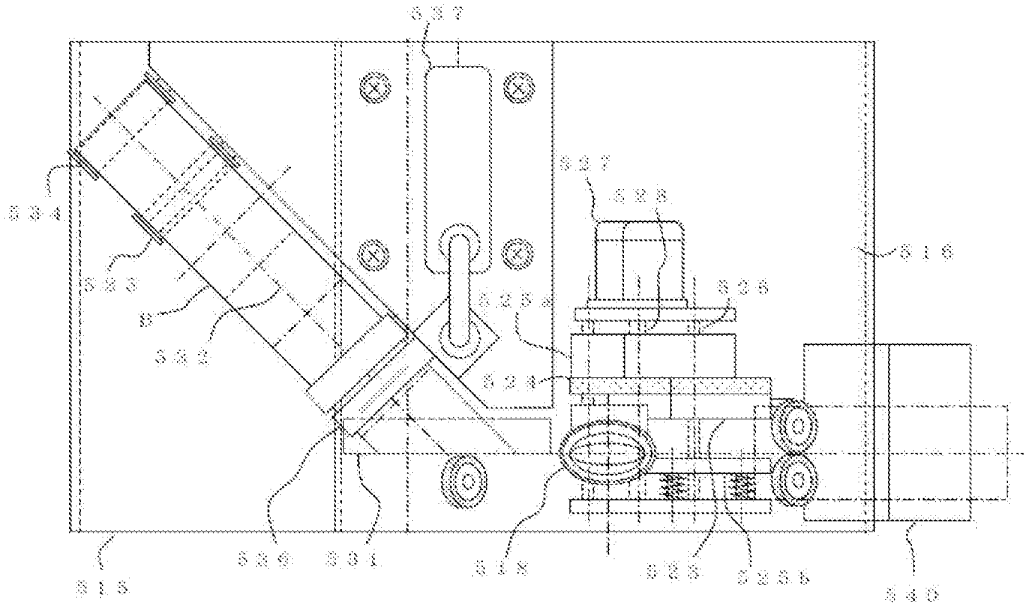
[Fig. 15]



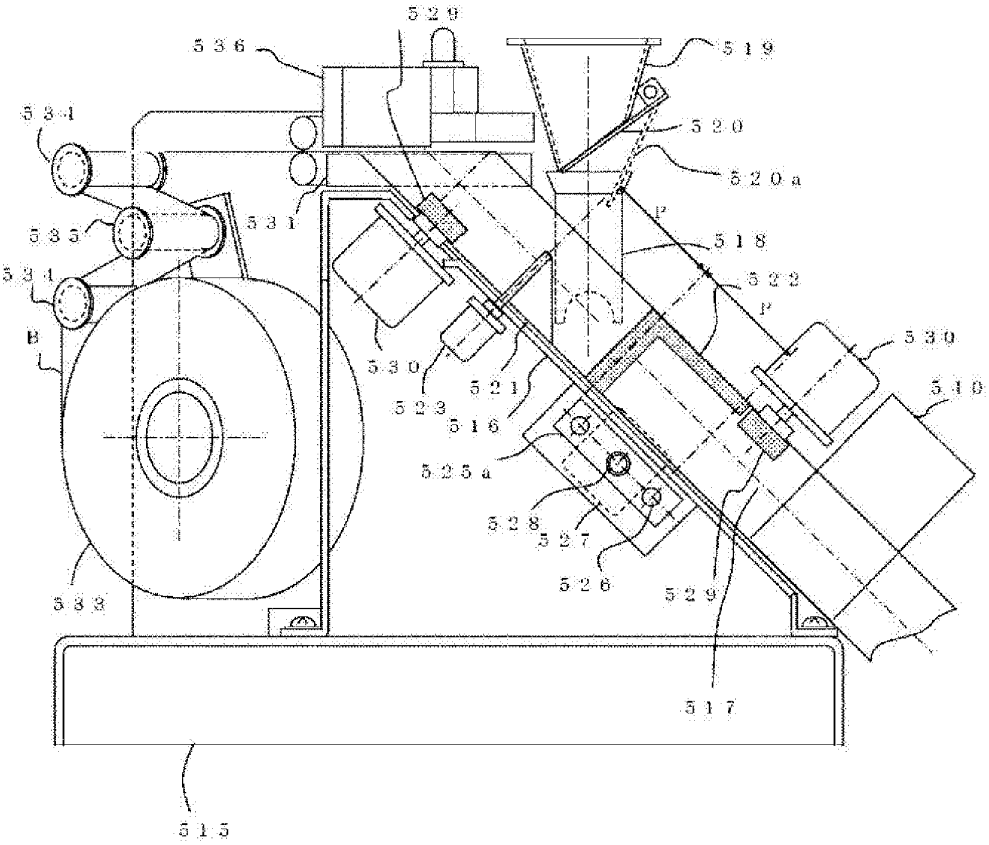
[Fig. 16]



[Fig. 17]

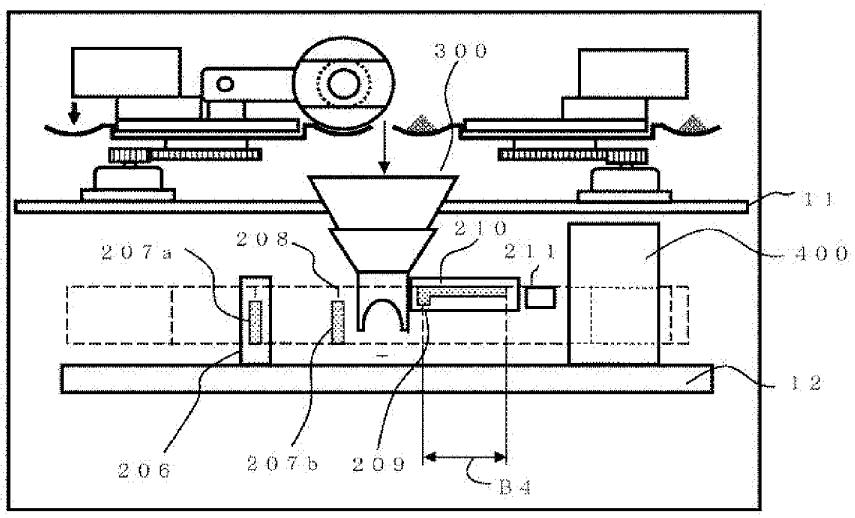


[Fig. 18]



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Representative drawing

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Bibliographic data: JP2020000340 (A) — 2020-01-09

MEDICINE DISPENSING/PACKAGING DEVICE AND PRODUCTION METHOD OF DISPENSING/PACKAGING MEDICINE

Inventor(s): OMURA SHIRO; YAMAMOTO SHIGEYUKI; YAMAMOTO TAKU; FUKATSU KUNIO ± (大村 司郎, ; 山本 繁幸, ; 山本 拓, ; 深津 邦夫)

Applicant(s): TOSHO INC ± (株式会社トーショー)

Classification: **- international:** ***A61J3/00; B65B61/00***
- cooperative:

Application number: JP20180120789 20180626 Global Dossier

Priority number(s): JP20180120789 20180626

Abstract of JP2020000340 (A)

To provide a medicine dispensing/packaging device that is never cut in a perforation portion of the dispensing/packaging paper during conveyance, and provide a production method of the dispensing/packaging medicine.SOLUTION: A medicine dispensing/packaging device has: a dispensing/packaging paper storage part where the V-folded dispensing/packaging paper is wound; a conveyance path for drawing the dispensing/packaging paper out of the dispensing/packaging paper storage part, and conveying it; a heat seal part provided in the middle of the conveyance path, and forming a heat seal to divide a dispensing/packaging paper into one package at a time; a medicine supplying part provided in the middle of the conveyance path, and supplying medicine by one package at a time between the dispensing/packaging papers; a drive roller for holding the dispensing/packaging paper where the medicine supplied by the medicine supplying part is stored, and performing conveyance drive; and a perforation making part provided at a conveyance direction down-stream of the dispensing/packaging paper from the drive roller, and forming the perforation in a portion heat-sealed by the heat seal part.SELECTED DRAWING: Figure 4

(19)日本国特許庁(JP)　(12)公開特許公報(A)　(11)特許出願公開番号
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(P2020-340A)
(43)公開日　令和2年1月9日(2020.1.9)

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B26F 1/18	(2006.01)	B26F	1/18		4C047

審査請求 未請求　請求項の数 7　OL　（全 15 頁）

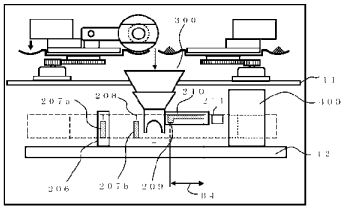
(21)出願番号　特願2018-120789 (P2018-120789)
(22)出願日　平成30年6月26日 (2018.6.26)

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最終頁に続く

(54)【発明の名称】薬剤分包装置及び分包薬剤の製造方法

【要約】
【課題】搬送中に分包用紙のミシン目部分で切れることの無い薬剤分包装置及び分包薬剤の製造方法を提供する。
【解決手段】Ｖ字折りされた分包用紙が巻回された分包用紙収納部と、前記分包用紙収納部から分包用紙を引出して搬送する搬送路と、前記搬送路の途中に設けられ、前記分包用紙を１個包分ずつに区分するヒートシールを形成するヒートシール部と、前記搬送路の途中に設けられ、前記分包用紙間に薬剤を１包分ずつ供給する薬剤供給部と、前記薬剤供給部によって供給された薬剤が収納された分包用紙を挟持して搬送駆動する駆動ローラと、前記駆動ローラよりも前記分包用紙の搬送方向下流に設けられ、前記ヒートシール部によってヒートシールされた部分にミシン目を形成するミシン目作成部と、を有する。
【選択図】図４



【特許請求の範囲】
【請求項１】
Ｖ字折りされた分包用紙が巻回された分包用紙収納部と、
前記分包用紙収納部から分包用紙を引出して搬送する搬送路と、
前記搬送路の途中に設けられ、前記分包用紙を１個包分ずつに区分するヒートシールを形成するヒートシール部と、
前記搬送路の途中に設けられ、前記分包用紙間に薬剤を１包分ずつ供給する薬剤供給部と、
前記薬剤供給部によって供給された薬剤が収納された分包用紙を挟持して搬送駆動する駆動ローラと、
前記駆動ローラよりも前記分包用紙の搬送方向下流に設けられ、前記ヒートシール部によってヒートシールされた部分にミシン目を形成するミシン目作成部と、
を有する薬剤分包装置。
【請求項２】
前記ミシン目作成部は、
前記分包用紙の搬送路の一方の面側に設けられ、ミシン刃が突没自在に収納された刃収納部と、
前記分包用紙の搬送路の他方の面側に、前記刃収納部と対向して設けられ、前記刃収納部から突出した前記ミシン刃との間で前記分包用紙にミシン目を形成する刃受け部と、
前記刃収納部と前記刃受け部とをそれぞれ前記分包用紙側に移動させて分包用紙を挟持するように駆動する第１の駆動部と、
前記刃収納部と前記刃受け部とによって前記分包用紙を挟持した状態で、前記刃収納部のミシン刃を前記刃受け部側に突出するように駆動することにより前記分包用紙にミシン目を形成する第２の駆動部と、
を有する請求項１記載の薬剤分包装置。
【請求項３】
前記ミシン刃は、
基部と、
前記基部から突出して設けられ、先端に山形の刃先が形成された複数の刃片が、隣接する刃片との間に所定の間隔を設けて形成された刃先部と、を有し、
前記第２の駆動部は、
前記ミシン刃の刃片の途中まで前記刃受け部側に突出させることにより、前記分包用紙にミシン目を形成し、
前記ミシン刃の基部まで前記刃受け部側に突出させることにより、前記分包用紙を切断する、
ことを特徴とする請求項２記載の薬剤分包装置。
【請求項４】
前記ミシン刃は、
前記分包用紙の搬送方向と直交する方向の両端部の刃片の刃の幅が内側の刃片の刃の幅よりも大きく形成され、これら両端部の刃片により分包用紙の搬送方向と直交する方向の両端部に切断開始部を形成する、
ことを特徴とする請求項３記載の薬剤分包装置。
【請求項５】
前記ミシン刃は、
前記それぞれの刃片が、中央部の刃片の基部からの長さが最も長く、端部に行くにつれて長さが徐々に短くなるように形成された、
ことを特徴とする請求項３又は請求項４記載の薬剤分包装置。
【請求項６】
前記ミシン刃は、
前記複数の刃片と刃片との間に、前記刃片の厚さよりも刃幅の広い横刃片を挿入するこ

とにより、十字状の刃を複数形成し、この十字状の刃により分包用紙に形成されるミシン目に、ミシン目に沿って分離されたときの切断開始部を形成する、
ことを特徴とする請求項３乃至請求項５のいずれか１項記載の薬剤分包装置。
【請求項７】
予め収納されたＶ字折りされた分包用紙を搬送路に引出し、
前記引出された分包用紙に１個包分ずつに区分するヒートシール部を形成し、
前記ヒートシール部が形成された分包用紙間に薬剤を１個包分ずつ供給して収納し、
前記薬剤が収納された分包用紙を駆動ローラにより挟持して１個包分ずつ搬送駆動し、
前記駆動ローラよりも前記分包用紙の搬送方向の下流側で、前記分包用紙のヒートシールされた部分にミシン目を形成する、
分包薬剤の製造方法。
【発明の詳細な説明】
【技術分野】
【０００１】
本発明は、薬剤を１個包分ずつ供給して分包する薬剤分包装置及び分包薬剤の製造方法に関する。
【背景技術】
【０００２】
薬剤調剤業務の自動化のために薬剤分包装置が開発され実用に供している。このような薬剤分包装置の例として特許文献１記載のものがある。
【０００３】
すなわち、Ｖ字折りされた分包用紙が巻回されたロールから、分包用紙の端部が引出され、複数の支持軸を介して搬送方向に向かって下方に傾斜した搬送路に沿って搬送され、漏斗状の薬剤ホッパ部に供給される。薬剤ホッパよりも下流側には、熱圧接部が設けられており、この熱圧接部にはヒートシール及びミシン目形成部が設けられている。そして、ヒートシールによって１個包を分離するＴ字形状のヒートシールが成されるとともに、各個包に分離するためのミシン目が形成される。ヒートシールが成された後に１個包分の薬剤が薬剤ホッパから分包用紙間に供給される。
【０００４】
薬剤が供給されると、熱圧接部よりも下流側に設けられた駆動ローラによって分包用紙が挟持されて１個包分の長さだけ引き出されて、次の個包のためのヒートシールとミシン目の作成が行われる。このような個包化動作を繰返すことによって１処方分の分包薬剤が作成される。
【先行技術文献】
【特許文献】
【０００５】
【特許文献１】特開２０１２－１３１５５１号公報
【発明の概要】
【発明が解決しようとする課題】
【０００６】
特許文献１記載の装置では、分包用紙を搬送する駆動ローラがミシン目作成部よりも下流側に設けられている。このため、駆動ローラによって分包用紙を引出した際に、分包用紙に過大な負荷が掛かるとミシン目部分で分包用紙が切れてしまうという虞があった。また、分包用紙間の下部には薬剤が封入されているので駆動ローラは必然的に分包用紙の上方を挟持して搬送する必要がある。搬送中に分包用紙が切れないようにするためには、分包用紙の上端にはミシン目（カット）を入れることができない。その結果、老人や筋力の衰えた人は上端側からミシン目に沿って切り取ることが困難であるという問題もあった。
【０００７】
そこで従来の分包機では、用紙の下端にミシン目（カット）を入れて、下側から切り取るようにする場合もあったが、これでは都度分包用紙を逆さにする必要があり、そのとき

に印字の向きが逆になって視認性が悪く、さらに切り取った後、もう一度逆さに元の状態にして、手で横方向に切って開封する必要があり、その不便さが指摘されていた。
【０００８】
本発明が解決しようとする課題は、搬送中に分包用紙のミシン目（カット）部分で切れることの無いようにした薬剤分包装置及び分包薬剤の製造方法を提供することを目的とする。また、第２の課題は、服用者が１個包をミシン目に沿って切断するのが容易なように分包用紙の上端部側にミシン目（カット）が入れられることのできる服用者にとって利便性の高い薬剤分包装置及び分包薬剤の製造方法を提供することを目的とする。
【０００９】
さらに、副次的な効果としては、このように分包用紙の上下端にミシン目（カット）を設けることで、長い分包用紙を例えば１日３包（朝・昼・晩）ごとに折りたたんで保管するような場合に、その折り目がしっかり付けやすいので、全て折りたたんだときの外観がきちんとしているという点も上げておきたい。
【課題を解決するための手段】
【００１０】
本発明の薬剤分包装置は、Ｖ字折りされた分包用紙が巻回された分包用紙収納部と、前記分包用紙収納部から分包用紙を引出して搬送する搬送路と、前記搬送路の途中に設けられ、前記分包用紙を１個包分ずつに区分するヒートシールを形成するヒートシール部と、前記搬送路の途中に設けられ、前記分包用紙間に薬剤を１包分ずつ供給する薬剤供給部と、前記薬剤供給部によって供給された薬剤が収納された分包用紙を挟持して搬送駆動する駆動ローラと、前記駆動ローラよりも前記分包用紙の搬送方向下流に設けられ、前記ヒートシール部によってヒートシールされた部分にミシン目を形成するミシン目作成部と、を有する。
【００１１】
また、本発明の分包薬剤の製造方法は、予め収納されたＶ字折りされた分包用紙を搬送路に引出し、前記引出された分包用紙に１個包分ずつに区分するヒートシール部を形成し、前記ヒートシール部が形成された分包用紙間に薬剤を１個包分ずつ供給して収納し、前記薬剤が収納された分包用紙を駆動ローラにより挟持して１個包分ずつ搬送駆動し、前記駆動ローラよりも前記分包用紙の搬送方向の下流側で、前記分包用紙のヒートシールされた部分にミシン目を形成する。
【図面の簡単な説明】
【００１２】
【図１】実施形態の散薬自動分包機の円盤配分部の平面の断面図。
【図２】実施形態の散薬自動分包機の落下ホッパの上昇位置を示す正面の断面図。
【図３】落下ホッパの構造と動作概要を示す図。
【図４】実施形態の散薬自動分包機の落下ホッパの下降位置を示す正面の断面図。
【図５】実施形態の散薬自動分包機の印刷包装機部の平面の断面図。
【図６】実施形態のミシン目作成装置の斜視図で、刃収納部と刃受け部とが開いた状態を示す図。
【図７】実施形態のミシン目作成装置の斜視図で、刃収納部と刃受け部との間に分包用紙が搬送されている状態を示す図。
【図８】実施形態のミシン目作成装置の斜視図で、刃収納部と刃受け部とが開いた状態で刃収納部のカバーを外した図。
【図９】実施形態のミシン目作成装置の斜視図で、刃収納部と刃受け部とが閉じてミシン目を作成している状態を示す図。
【図１０】実施形態のミシン目作成装置の斜視図で、刃収納部と刃受け部とが閉じてミシン目を作成している状態の刃収納部のカバーを外した図。
【図１１】実施形態のミシン目作成装置の斜視図で、刃収納部と刃受け部とが閉じて分包用紙を切断している状態を示す図。
【図１２】実施形態のミシン目作成装置の斜視図で、刃収納部と刃受け部とが閉じて分包

用紙を切断している状態の刃収納部のカバーを外した図。
【図１３】実施形態のミシン目作成装置のミシン刃の形状と移動距離を説明するための図。
【図１４】実施形態のミシン目作成装置のミシン刃の形状を説明するための図。
【図１５】実施形態のミシン目作成装置のミシン刃の形状と分包用紙との関係を説明するための図。
【図１６】実施形態の散薬自動分包機で製造された分包薬剤の例を示す図。
【図１７】第２の実施形態の印刷包装機を説明するための平面図。
【図１８】第２の実施形態の印刷包装機を説明するための正面図。
【発明を実施するための形態】
【００１３】
以下、実施形態に係る散薬自動分包機を、図面を用いて説明する。
以下の説明では散薬自動分包機を例にとって説明するが、本発明は散薬自動分包機に限定されるものではなく、錠剤自動分包機にも適用可能である。また、特許第６２５５５２８号公報や特開２０００－２４０８７号公報に記載されたような複数の薬剤を１つの個包に分包する薬剤分包装置にも適用可能なことは勿論である。
【００１４】
図１は本実施形態の散薬自動分包機の平面図、図２は散薬自動分包機の正面図である。筐体１０の中間台１１の上部には薬剤供給部である円盤配分部１００、中間台１１の下部には、薬剤包装部である印刷包装機２００が配置されている。また３００は落下ホッパであって、円盤配分部１００から放出される散薬をこの落下ホッパ３００の内面側を通して、印刷包装機２００側に導入する働きをなすものである。
【００１５】
円盤配分部１００には２組の配分部が設けられている。円盤配分部１００において、１０１は着脱自在な散薬カセットで、事前に別の場所で、当該処方に必要な分量の散薬が装填され、係員の手動操作か、図示しないロボットアーム等の自動装置によって、別の棚から振動台１０２に載置される。振動台１０２は、図示しない電磁石などによって振動を発生させ、この振動力を散薬カセット１０１に伝達させることで、散薬カセット１０１内の散薬を振動輸送し、矢印１０３の方向に散薬を少量ずつ落下させるものである。
【００１６】
１０４は水平に配置された配分円盤で、大きな円輪がステッピング・モータ１０５によって、歯車１０６を介して矢印１０４ａ方向に回転させられるようになっている。さらに配分円盤１０４の外周方向の上面には円弧状凹面１０７を形成していている。ここで、ステッピング・モータ１０５を連続的に回転しながら、振動台１０２を駆動すると、散薬が配分円盤１０４の円弧状凹面１０７に少量ずつ落下して、ドーナツ状の散薬の山Ｐ１を形成することができる。この動作を「円周撒き動作」と呼ぶこととする。
【００１７】
また、１０８は掻き出しディスク部で、レバー１０８ａが軸１０９を中心にして上下に回動できる。このレバー１０８ａの先端には、その円周外周がシリコンゴム製のディスク１１０が取り付けられ、モータ１１１で矢印１１０ａ方向に回転可能である。このディスク１１０は２枚の円板の間に羽根が設けられた水車状の形状である。なお、このディスク１１０の円板の直径は、円弧状凹面１０７の凹面の直径と同一である。
【００１８】
先の「円周撒き動作」の場合は、このディスク１１０は上方に回動して待避していて、ドーナツ状の散薬の山Ｐ１の形成を妨げない。次に「１包分配分動作」時は、掻き出しディスク部１０８のディスク１１０が下方に回動して、ディスク１１０が、円弧状凹面１０７に隙間なく密着する。この状態で、モータ１１１を駆動するとディスク１１０の円板に設けられた羽根によって円弧状凹面１０７の上の散薬が落下ホッパ３００に掻き落とされる。そして、ステッピング・モータ１０５を所定角度Ｒだけ回転させると、その角度分の散薬の量が、落下ホッパ３００側に払出される。ここで、先の所定角度Ｒとは、別に処方

箋から指定される１個包に包装すべき用量分の角度である。
【００１９】
例えば、処方箋で、ある散薬を１個包あたり１ｇで３６個包作成する場合にあっては、事前に散薬カセット１０１に３６ｇの散薬を装填しておき、これを「円周撒き動作」で、全量をドーナツ状に均一に撒く。次に「１包分配分動作」で、ディスク１１０を回転させながら、ステッピング・モータ１０５を１０度回転させると、正しく１個包分の１ｇの散薬が落下ホッパ３００に払出させることができるものである。このような円盤配分部１００と落下ホッパ３００で薬剤供給部を構成する。
【００２０】
円盤配分部１００には、左右に対称形に、２組の円盤部１１２ａと１１２ｂが配置しているが、これは、一方の円盤部１１２ａで「円周撒き動作」しているときは、他方の円盤部１１２ｂが「１包分配分動作」を出来るようにして、複数の連続する処方において無駄時間がなく、連続的に分包できるようにするためのものである。
【００２１】
図３は落下ホッパ３００の形状と動作の概要を示すものである。落下ホッパ３００は上ホッパ３０１と下ホッパ３０２の二重構造となっており、上ホッパ３０１の下開放部３０３を開閉自在なシャッタ３０４で閉鎖している。上ホッパ３０１の上端は、円盤配分部１００からの散薬を受け入れる上開口部３００ａが形成されている。下ホッパ３０２の下端部は図３（ａ）（ｂ）に示すように楔状に形成され、両端に突部である爪部３０５ａ、３０５ｂが形成され、その間に散薬を払出す刃部（下開口部）３０５ｃが形成されている。この落下ホッパ３００は全体として上下移動できるようになっている。そして、「１包分配分動作」で、円盤配分部１００から散薬を払出すタイミングでは、図３（ａ）（ｂ）の上位置に位置する。この時、シャッタ３０４は図３（ｂ）の側面図に示すように閉鎖しているので、落下した散薬は一旦このシャッタ３０４上に保持される。
【００２２】
このとき落下ホッパ３００の下端の左右の爪部３０５ａと３０５ｂは、搬送される谷折り状に二つ折された分包用紙Ｂの開放端Ｂ１にその先端を入れ込んでいる。
【００２３】
散薬の放出時は図３（ｃ）のように、落下ホッパ３００全体を下方に移動するが、左右の爪部３０５ａ、３０５ｂｃ楔状の形状が、落下ホッパ３００が分包用紙Ｂ間に進入するときのガイドの働きをしている。この状態でシャッタを３０４ａのように開くと、散薬は分包用紙Ｂの内部に収納されるものである。その後、落下ホッパ３００は図３（ｂ）の位置まで上昇する。
【００２４】
次に、図４と図５を用いて印刷包装機２００の構成と動作を説明する。図４は散薬分包機の正面の断面図であって、区２で上方に位置していた落下ホッパ３００は、下方に移動した状態を示している。図５は印刷包装機２００の上面の断面図である。２０１は分包用紙収納部としての分包用紙ロールであって、熱接着性を持つ二つ折りした用紙が谷折側を下にして、リールに巻き上げたものであり、下段台１２の上に設置されている。リールの外周側の用紙先端から引き出された分包用紙は、一点鎖線Ｂ２からＢ３のような経路で搬送路を搬送されるようになっている。２０２は印刷部で、インクリボン２０３、感熱印刷ヘッド２０４、プラテンローラ２０５等によって構成され、分包用紙Ｂの表面に、１包分ずつの処方情報を印字するものである。
【００２５】
２０６は下段台１２上に設けられたヒートシール部である縦シール機構で、分包用紙Ｂを前後（図５では上下）から熱板によって圧接することで、２０７ａのように縦方向のシールが行われることで１個包分ずつに区分する。１包分移動した位置での縦シールを２０７ｂに示すが、分包用紙Ｂの上開放端２０８はシールしないようになっている。これは、図３（ａ）のように、落下ホッパ３００の爪部３０５ａ、３０５ｂが、分包用紙Ｂ間に挿入した状態で、分包用紙Ｂを搬送できるようにするためである。次に配置される落下ホッ

パ３００の奥側には落下ホッパ洗浄装置３１０が取り付けられている。この落下ホッパ洗浄装置３１０については、本発明と直接関係しないので詳細な説明は省略する。

【００２６】

次の２０９は横シール機構で、分包用紙Ｂを前後から熱板によって圧接することで、２１０のように横方向と縦方向の未シール部分とのシールが行われる。先の縦シール２０７と横シール２１０とによって、分包用紙Ｂは１個包としてシールされるものである。なお、図では省略しているが、縦シール７はミシン目が形成される部分をシールせずに、ミシン目形成部を挟んだ両側をシールするようになっており、詳細は後述する。

【００２７】

２１１は駆動ローラであって、印刷部２０２のプラテンローラ２０５と同期駆動され、分包用紙Ｂの上端部分を両面から挟持して回転することにより、１個包分ピッチＢ４の距離を、１工程として駆動される。４００はミシン目作成装置で、縦シールされた部分の中間に設けられた非シール部に、縦方向のミシン目を形成することにより、服薬者が１個包ずつに分離しやすくなっている。なお、図２及び図４に示す縦方向の破線はミシン目ではなく、１個包の境目を示したものである。また、図２及び図４においては、説明を判りやすくするために落下ホッパ３００より下流側の縦シールの記載は省略している。

【００２８】

なお、落下ホッパ洗浄装置３１０の補機として、集塵ブロア３２０と、圧縮空気発生コンプレッサ３３０が、筐体後方に配置されて、それぞれ、落下ホッパ洗浄装置３１０の空気源として利用される。

【００２９】

以下、図６～図１５を用いてミシン目作成装置４００の構成と動作について説明する。図６はミシン目作成装置の斜視図であり、刃収納部４０２と刃受け部４０４とが開いている待機状態を示す図で、図７は刃収納部４０２と刃受け部４０４との間に分包用紙Ｂを挿入した状態を示す図である。分包用紙Ｂは刃収納部４０２と刃受け部４０４との中間に位置するように刃収納部４０２と刃受け部４０４とが配置されている。図８は刃収納部４０２のカバーを外した状態を示す図である。

【００３０】

図４及び図５に記載された下段台１２にはモータ用ベース４０６が固定され、このモータ用ベース４０６にはステッピング・モータ４０８が固定されている。また、下段台１２にはミシン刃ユニット４０１のベース４１０が固定されている。

【００３１】

ミシン刃ユニット４０１のベース４１０には刃収納部４０２が固定された支持部４２８が摺動自在に設けられている。また、ベース４１０には刃受け部４０４が固定された支持部４２４が摺動自在に設けられ、支持部４２４に固定されたスライド軸４２２と一体になって摺動するものである。そして、支持部４２４と支持部４２８とは互いに接離する方向に摺動自在である。これら支持部４２４と支持部４２８との間にはスプリング４２６が設けられ、互いに離間する方向に付勢されている。

【００３２】

刃収納部４０２の支持部４２８の内部にはシャフト４３４がスライド自在に設けられ、このシャフト４３４の左端にはミシン刃４３２が固定されている。そして、ミシン刃４３２は刃収納部４０２の２枚のカバーの間に、ミシン刃４３２が刃収納部４０２から突没する方向にスライド自在に設けられている。

【００３３】

ステッピング・モータ４０８の図示しない軸とカムシャフト４１２に固定されたプーリ４１４との間にはタイミングベルトが掛け渡され、ステッピング・モータ４０８が回転することによりカムシャフト４１２が回転するようになっている。

【００３４】

また、カムシャフト４１２には３つのカム板４１６，４１８，４２０が固定されている。最下段の第１のカム板４１６は刃受け部４０４を駆動するもので、第１のカム板４１６

を回転することで図示しないカムフォロワによってスライド軸４２２を図中右方向に引き寄せる。スライド軸４２２には刃受け部４０４が固定された支持部４２４が接続されているので、刃受け部４０４も図中右方向に引き寄せられる。

【００３５】

下から２段目の第２のカム板４１８は刃収納部４０２を駆動するもので、カム板４１８を回転することにより刃収納部４０２が固定された支持部４２８に取付けられたカムフォロワ４３０を図中、左方向に駆動するものである。したがって、ステッピング・モータ４０８を回転することによって刃収納部４０２と刃受け部４０４とが互いに接触する方向に移動して分包用紙Ｂを挟持する。カム板４１６と４１８の形状はそれ以上回転しても刃収納部４０２と刃受け部４０４とは分包用紙Ｂを挟持したままである。このようにカム板４１６による刃受け部４０４の駆動機構、及びカム板４１８による刃収納部４０２の駆動機構で第１の駆動部を構成している。

【００３６】

さらに最上段の第３のカム板４２０はミシン刃４３２駆動用のもので、シャフト４３４に固定されたカムフォロワ４３６が第３のカム板４２０に接触している。そして、ステッピング・モータ４０８が回転することによって第３のカム板４２０が回転し、カムフォロワ４３６を押すことによりシャフト４３４を図中左側に駆動する。その結果、シャフト４３４に固定されたミシン刃４３２が刃収納部４０２から刃受け部４０４側に突出して、分包用紙Ｂにミシン目を形成するものである。カム板４２０によるミシン刃の駆動機構が第２の駆動部を構成する。

【００３７】

ミシン刃ユニット４０１の待機状態を図８に示す。図８（ａ）に示すようにミシン刃ユニット４０１の待機状態ではミシン刃４３２は刃収納部４０２のカバー内に没した状態である。このときのカム板４２０とカムフォロワ４３６の状態を図８（ｂ）に示すが、カムフォロワ４３６がカムシャフト４１２に最も近い位置にある。

【００３８】

次に、ステッピング・モータ４０８が回転して分包用紙Ｂにミシン目を形成している状態を図９及び図１０に示す。図９及び図１０に示すように第１のカム板４１６及び第２のカム板４１８が回転することにより、刃収納部４０２と刃受け部４０４とは接触して分包用紙Ｂを挟持した状態となる。なお、図９及び図１０では分包用紙Ｂの記載は省略している。分包用紙Ｂにミシン目を形成する状態ではカム板４２０は図９（ｂ）に示すようにカムノォロワ４３６を押し込んでおり、図１０に示すようにミシン刃４３２の先端が刃受け部４０４内に突出した状態となる。

【００３９】

分包用紙Ｂにミシン目を形成した後は、ステッピング・モータ４０８が逆転することにより、カム板４２０が図９（ｂ）の状態から逆転して図８（ｂ）に示す待機位置に戻る。このような動作によって分包用紙Ｂにミシン目を形成すると、次の個包を形成するために駆動ローラ２１１によって分包用紙Ｂの搬送が行われる。なお、ミシン目の形成と同期して縦シールの形成、薬剤の供給、横シールの形成が行われる。これは、ミシン目の形成時には分包用紙Ｂが停止した状態にあり、分包用紙Ｂの停止した状態での作業である縦シールの形成、薬剤の供給、横シールの形成が行われるものである。以上の動作で１個包分のサイクルが終了する。

【００４０】

ここで、薬剤の処方は服薬者に対して、例えば朝昼晩で２週間分４２回分を処方する。１人の服薬者に対する４２回分の個包の間はミシン目を入れ、１人の服薬者に対する個包が完了した段階ではミシン目ではなく、分包用紙Ｂを切断することにより処方薬を放出する必要がある。

【００４１】

このため、本実施の形態では、ミシン目作成装置４００によって分包用紙Ｂの切断も行うようになっている。図１１及び図１２に示すように、カム板４２０が図９（ｂ）のミシ

ン目を形成する状態を越えて、ステッピング・モータ４０８をさらに回転させ、カム板４２０を図１１（ｂ）に示す位置まで回転させる。すると、カムフォロワ４３６はカムシャフト４１２から最も離れた位置まで押される。これによりミシン刃４３２がさらに突出してミシン刃４３２の基部まで刃受け部４０４内に突出する。これにより、分包用紙Ｂはミシン刃４３２により切断されることになる。なお、分包用紙Ｂの切断時はカムシャフト４１２の回転を戻すことなく、１回転させるのみでよい。

【００４２】

次に、ミシン刃４３２の形状と移動量とを図１３に示す。

ミシン刃４３２はシャフト４３４への固定部４３２ａ、刃の基部４３２ｂ、及び刃の基部４３２ｂから突出して設けられた刃先部４３２ｃとからなる。刃先部４３２ｃの先端に山形の刃先が形成された複数の刃片４３２ｄが、隣接する刃片４３２ｄとの間に所定の間隔を設けて形成されている。刃片４３２ｄと刃片４３２ｄとの間には３箇所に、刃先部の厚さｔよりも刃幅の広い横刃片が設けられているが、図１３（ａ）、（ｂ）では省略している。そして各刃片４３２ｄの先端までの長さは中央部の刃片が最も長く、端部に行くにつれて徐々に長さが短くなっている。各刃片４３２ｄの先端を結ぶ直線Ｌ１と基部の先端に平行な直線Ｌ２とのなす角度θは約４度の角度が設けられている。これにより、分包用紙Ｂにミシン目を形成する際は、カット部が中央の刃片４３２ｄから徐々に端部の刃片４３２ｄへと移るので、ミシン刃４３２の移動に要する駆動力も小さいもので済む。

【００４３】

また、ミシン刃４３２の長さ方向の端部、すなわち分包用紙Ｂの搬送方向に直交する方向の端部の刃片４３２ｅ、４３２ｅの刃幅は内側の刃片４３２ｄの刃幅よりも大きく形成されている。そして分包用紙Ｂの幅は図１３（ｂ）に記号Ｗと記載したように、分包用紙Ｂの端部が、ミシン刃４３２の端部の刃片４３２ｅ、４３２ｅの位置になるように構成されている。従って、分包用紙Ｂの搬送位置がずれても、分包用紙Ｂの端部に、服薬者が個包を切り離すときの切断開始部（カット）を確実に形成でき、服薬者が容易に分包を切り離すことができる。

【００４４】

図１３（ｂ）にミシン刃４３２によるミシン目形成と分包用紙Ｂの切断のときのミシン刃４３２の突出距離を示す。ミシン目形成時にはミシン刃４３２の刃先部４３２ｃの中間部であるＭの位置まで刃受け部４０４にミシン刃４３２が突出する。また、分包用紙Ｂの切断時は刃先部４３２ｃの位置を越えた刃の基部４３２ｂの位置Ｃまで刃受け部４０４にミシン刃４３２が突出する。このように構成することによって分包用紙Ｂの個包間へのミシン目の形成と、１処方間の分包用紙Ｂの切断とがミシン刃４３２の突出量を変えることによって達成することができるものである。

【００４５】

次に、ミシン刃４３２の刃片４３２ｄ間に横刃片を挿入することによる、十字カット刃について図１４及び図１５を参照して説明する。図１４（ａ）は斜視図、（ｂ）は左側面図、（ｃ）は正面図、（ｄ）は上面図をそれぞれ示している。

【００４６】

すなわち、ミシン刃４３２の、図１４で上から５枚目と６枚目の間、８枚目と９枚目の間、及び１１枚目と１２枚目の間の３箇所には、横刃４３２ｇが挿入されている。この横刃片４３２ｇは刃片４３２ｄの厚さｔよりも刃の幅が広く形成されており、各刃片４３２ｄの間に圧入されるとともに、横刃４３２ｆの基部側に設けられた溝部にミシン刃４３２の基部４３２ｂが圧入されることにより保持されている。このように構成されたミシン刃４３２とすることにより、ミシン目が形成されるとともに、分包用紙Ｂが各個包に分離されたときに各個包を開封するときの切断開始部（カット）を形成するものである。

【００４７】

横刃４３２ｇの挿入位置と枚数は上述の例に限定されるものではなく、刃片４３２ｄの間であればどの位置にも挿入できるものである。特に各個包に収納される散薬の量が少ないときは、各個方の下のほうの十字カット位置で開封したほうが飲み残しの量が少なくな

るので、それを考慮して挿入する位置、枚数を選択することができる。
【００４８】
図１５（ａ）にミシン刃４３２と分包用紙との関係を例示する。図１５（ａ）に示すように、分包用紙のシール部（斜線部）は、縦シール機構２０６によって、ミシン目形成部（非シール部）を例えば４ｍｍ残して形成され、ミシン目はこの非シール部に形成される。そして、例えば、分包用紙Ｂの幅、すなわち、搬送方向と直交する方向の幅が例えば７０ｍｍであると仮定すると、ミシン刃４３２の長さを分包用紙Ｂの幅よりも大きい７５ｍｍとする。これにより、分包用紙Ｂの端部はミシン刃４３２の端部の刃片４３２ｅに対向するようにでき、その結果、分包用紙Ｂの両端部に切断開始部（カット）Ｂ１を形成することができる。
【００４９】
また、図１５（ｂ）に示すように、横刃の刃幅をミシン刃４３２の厚さｔ＝１ｍｍよりも大きい４ｍｍ程度とすることにより、分包用紙Ｂの非シール部の幅４ｍｍに亘って十字カット部Ｂ２を形成することができ、個包の開封のときの切断開始部となる。よって、患者・利用者による開封が容易な分包薬剤を提供できるものである。
【００５０】
なお、図１６は製造された分包薬剤の断面図の例を示すもので、例えば、上端から２０ｍｍの位置から、９ｍｍ間隔で３個の十字カット部形成した例を示している。
【００５１】
なお、第１の実施形態では、分包用紙Ｂを水平方向に搬送し、搬送方向に沿って、縦シール部２０６、薬剤供給部である落下ホッパ３００、横シール部２０９、搬送ローラ２１１及びミシン目作成部４００を配置したが、分包用紙Ｂを搬送方向に向かって下方に傾斜した搬送路に沿って搬送するように構成すれば、縦シール部は薬剤供給部の下流側に設けることも可能である。
【００５２】
次に図１７及び図１８を用いて第２の実施形態の印刷包装機５００について説明する。図１７は平面図、図１８は、同じく正面図である。ベース板５１５にはＶ字折りされた分包用紙Ｂをロール状に巻回した分包用紙収納部５３３が設けられ、この分包用紙収納部５３３から１端を引出された分包用紙Ｂは、複数の支持ロール５３４，５３５を介して上方へ搬送され、ひねりローラ５３１によって搬送方向が変換され、搬送方向に沿って下方に４５度傾斜した搬送経路に搬送される。
【００５３】
ベース板５１５の上面には水平面に対して４５度の傾きを有する分包用紙Ｂの搬送ベース５１６が設けられ、この４５度平面に平行な中心線５１７に沿って立位の分包用紙Ｂの搬送経路にそって搬送される。この搬送経路の中央部には谷折りした分包用紙Ｂの上部開口側から下出口を侵入させた落下ホッパ５１８がほぼ垂直に設けられ、さらにその上部に薬剤供給ホッパ５１９が設けられる。薬剤供給ホッパ５１９の下部は開口していて、この開口を遮るシャッタ機構５２０は、一つの分包に入れるべき薬剤を一旦保持し、図示しないアクチュエータによって５２０ａのように開放することで、薬剤を下の落下ホッパ５１８を介して、谷折りした分包用紙Ｂの内部空間に薬剤を落下させて供給する。
【００５４】
この空間は左上の搬送上流に配置された紙押さえ板５２１と、下流側右下に配置された逆Ｌ字型ヒートシール部５２２によって左右を遮られている。紙押さえ板５２１は回動アクチュエータ５２３によって開閉動作し、分包用紙Ｂが搬送されているときは開き、停止している時は閉じるように制御される。ヒートシール部５２２は、面発熱体５２４をキャリッジ５２５ａに保持されている。キャリッジ５２５ａはガイドロッド５２６に軸支され、モータ５２７に直結された送りネジ５２８によって前進後退可能なごとくに構成される。キャリッジ５２５ａが前進すると、分包用紙Ｂの上端横方向と縦方向とが、受け板５２５ｂに圧接され、加熱によって、分包用紙Ｂはシールされるように構成される。
【００５５】

分包用紙Ｂが静止した状態で、キャリッジ５２５ａを所定時間前進させた状態で、かつ紙押さえ板５２１を閉じたタイミングで、シャッタ機構５２０を５２０ａのように開くと、薬剤が分包用紙Ｂ内に落下する。次に分包用紙Ｂを所定間隔Ｐ搬送して、再度キャリッジ５２５ａを前進させると、先ほど落下した薬剤の収納部分が一括してシールされる。この動作を繰り返すことで、分包用紙Ｂが連続的にシールされるが、この時、順次投入する薬剤の種類と量を処方箋に従って、服用順序に従って制御すれば、例えば２週間分の服用薬剤が、一回の服用分は一包毎に分割されて完成する。なお、ゴムローラ対５２９は分包用紙Ｂを挟持して搬送する手段であり、連続する分包用紙Ｂの複数箇所に設置することによって、用紙をたるみなく搬送できるようになっている。駆動ローラ対５２９はパルスモータ５３０によって、所定距離の搬送停止制御ができるようになっている。

【００５６】

下流側の駆動ローラ５２９の下流には第１の実施形態として説明したミシン目作成装置４００と同様のミシン目作成装置５４０が設けられている。

【００５７】

薬剤の分包を作成する動作は、搬送される分包用紙Ｂをヒートシール部５２２によって１包分を区分する縦シールを行う。なお、このとき前の個包に対して横シールも同時に成される。次に薬剤供給５１９から落下ホッパ５１８を介して１包分の薬剤を分包用紙Ｂ間に供給する。薬剤が供給された分包用紙Ｂは駆動ローラ５２９によって１個包分の長さ分搬送される。

【００５８】

次に２包目の薬剤が分包用紙Ｂ間に供給されて、さらに駆動ローラ５２９によって分包用紙Ｂが搬送される。この段階で最初の縦シール部がミシン目作成装置５４０の部分に来るので、ミシン目作成装置５４０によって縦シール部の中央部にミシン目が形成される。以下、この動作を繰返して１処方分の分包薬剤が完成したら、ミシン目作成装置５４０によって縦シール部をミシン目作成装置５４０によって切断することにより分包薬剤を製造するものである。

【００５９】

このように、ヒートシール部の位置は薬剤供給部の上流に限定されず、薬剤供給部の下流側であっても良いものである。

【００６０】

本発明のいくつかの実施形態、変形例を説明したが、これらの実施形態、変形例は、例として提示したものであり、発明の範囲を限定することは意図していない。これら新規な実施形態、変形例は、その他の様々な形態で実施されることが可能であり、発明の要旨を逸脱しない範囲で、種々の省略、置き換え、変更を行うことができる。これら実施形態やその変形は、発明の範囲や要旨に含まれるとともに、特許請求の範囲に記載された発明とその均等の範囲に含まれる。

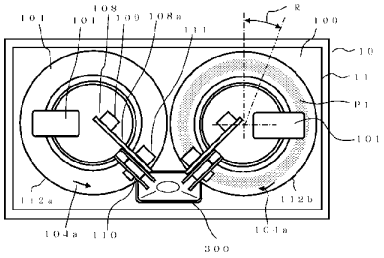
【符号の説明】

【００６１】

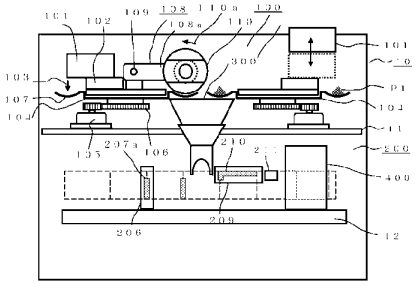
１００・・・円盤配分部（薬剤供給部）
２００・・・印刷包装機
２０１・・・分包用紙ロール（分包用紙収納部）
２０６・・・縦シール機構
２０９・・・横シール機構
２１１・・・駆動ローラ
３００・・・落下ホッパ（薬剤供給部）
４００・・・ミシン目作成装置
４０２・・・刃収納部
４０４・・・刃受け部
４１６，４１８・・・カム板
４２０・・・カム板

４３２・・・ミシン刃
４３２ｂ・・・ミシン刃の基部
４３２ｃ・・・ミシン刃の刃先
Ｂ・・・分包用紙
Ｂ２，Ｂ３・・・搬送経路（搬送路）

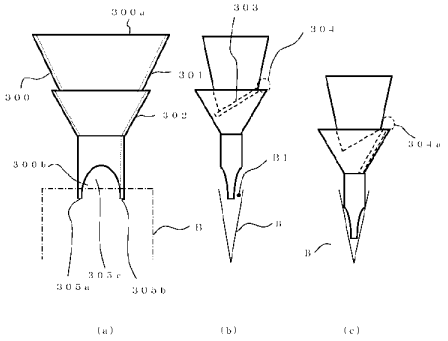
【図１】



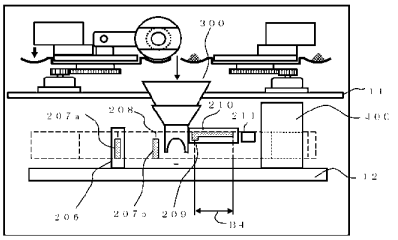
【図２】



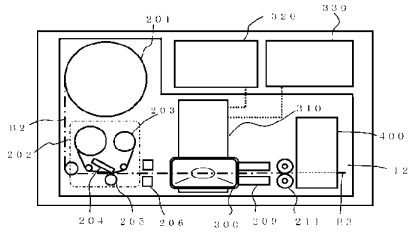
【図３】



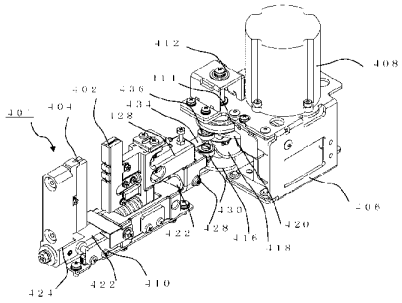
【図４】



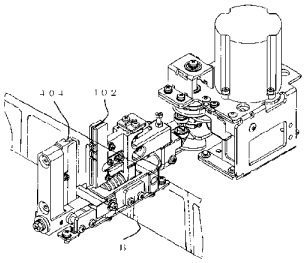
【図５】



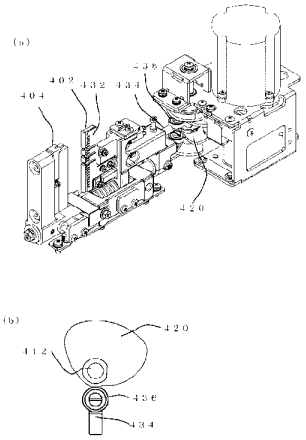
【図６】



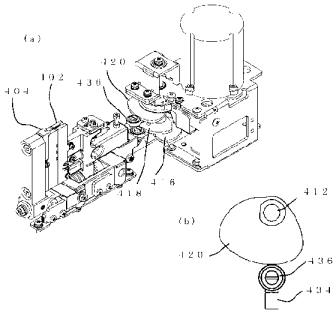
【図７】



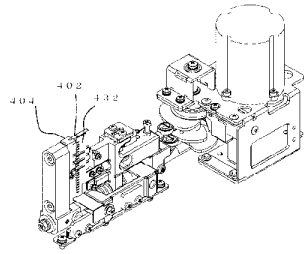
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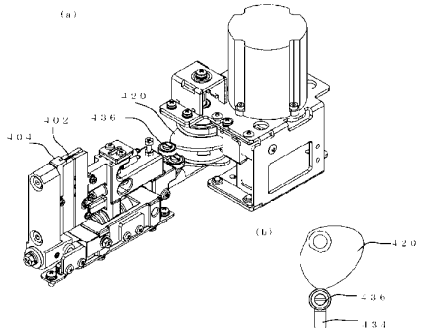
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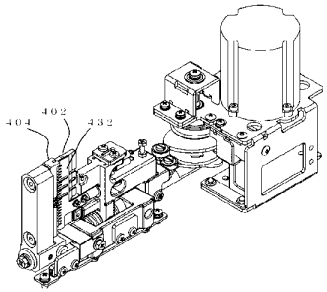
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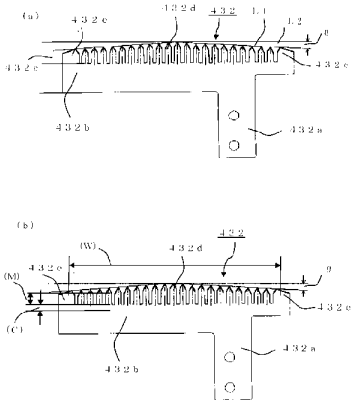
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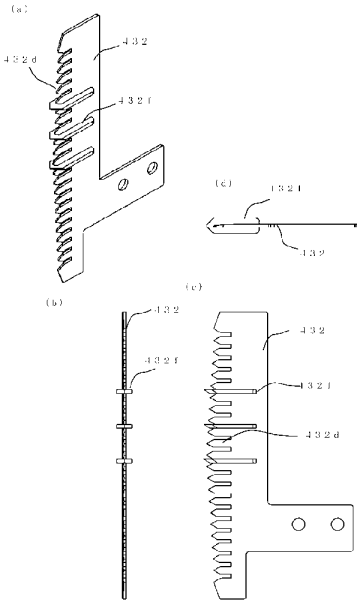
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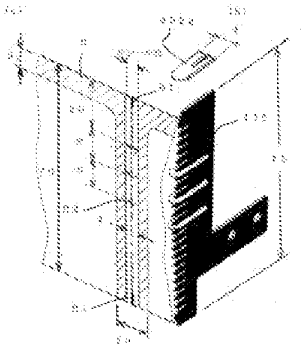
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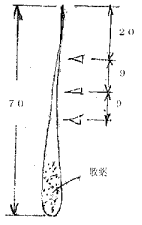
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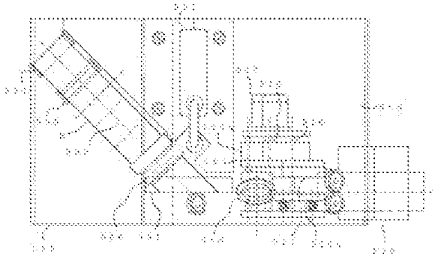
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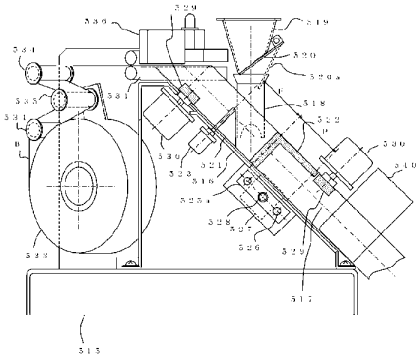
【図１６】



【図１７】



【図１８】



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Fibronectin (cold insoluble globulin) in the neonate

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FIBRONECTIN (referred to in older literature as cold insoluble globulin), a ubiquitous glycoprotein, participates in cellular, vascular, and plasma coagulant functions.[1] Acting as a nonspecific opsonin, plasma fibronectin potentiates reticuloendothelial clearance of intravascular debris to protect against organ dysfunction secondary to microvascular occlusion and altered vascular permeability.[1] Found on cell surfaces, fibronectin is important in wound healing and embryogenesis.[2] Fibronectin is a substrate for thrombin, plasmin, and activated fibrin–stabilizing factor (factor XIII), and can be lysed by granulocyte and other proteases.[3]

Fibronectin has potentially important roles in hemostasis and control of infection in the neonate. Decreased plasma values of fibronectin, measured by Laurell immunoelectrophoresis, have been reported in apparently healthy full-term infants.[4] We present the fibronectin values measured by immunoelectrophoresis in reference full-term and preterm infants and in neonates with sepsis of early onset.

MATERIALS AND METHODS

For adult reference values, blood samples were collected from healthy laboratory personnel who were not receiving any medication (including birth control pills or aspirin), had no chronic or recent acute illness, and had not exercised vigorously just prior to blood sampling.

Cord blood samples were collected from 18 healthy full-term infants (gestational age mean 40 weeks, range 37 to 41 weeks) and 15 healthy preterm infants (gestational age mean 35 weeks, range 32 to 36 weeks). Infants met the following criteria: (1) definite maternal dates that agreed within two weeks with the Dubowitz score; (2) Apgar scores at 1 minute of ≥ 7 and at 5 minutes of ≥ 8 in preterm infants (32 to 36 weeks gestational age), and Apgar scores of ≥ 8 at 1 minute and ≥ 9 at 5 minutes in full-term infants; (3) appropriate weight for gestational age; (4) no hypoxia, acidosis, hypotension, or hypothermia by gestational and postnatal age-appropriate definitions; (5) healthy during the first 48 hours of life; (6) inborn; (7) no family history of bleeding disorders; (8) the mothers had not received medications during pregnancy except vitamins, iron, inhibitors of uterine activity, steroids for maturation of fetal lung, and local, general, or epidural anesthesia; (9) the mothers had uncomplicated pregnancies; (10) the mothers of full-term infants delivered by cesarian section did not have labor.

Other preterm infants studied (gestational age mean 35 weeks) did not fit the above criteria because of intrauterine growth retardation (seven infants) or diabetic mothers (two infants). These infants had otherwise uncomplicated, uneventful perinatal courses. The eight ill neonates studied (mean gestational age 33 weeks) had birth asphyxia or hypotension.

Because adults with sepsis have decreased plasma values for fibronectin,[5] we studied infants with early-onset sepsis. In all infants blood cultures were positive for either β-hemolytic streptococcus (two infants) or *Listeria monocytogenes* (four infants) (mean gestational age 37 weeks, range 30 to 40 weeks).

This study was approved by the Hospital and University Ethical Review Committees. Informed parental consent was obtained prior to collection of blood specimens.

All blood samples tested were collected by the two-syringe technique, in which the first 0.5 ml blood drawn

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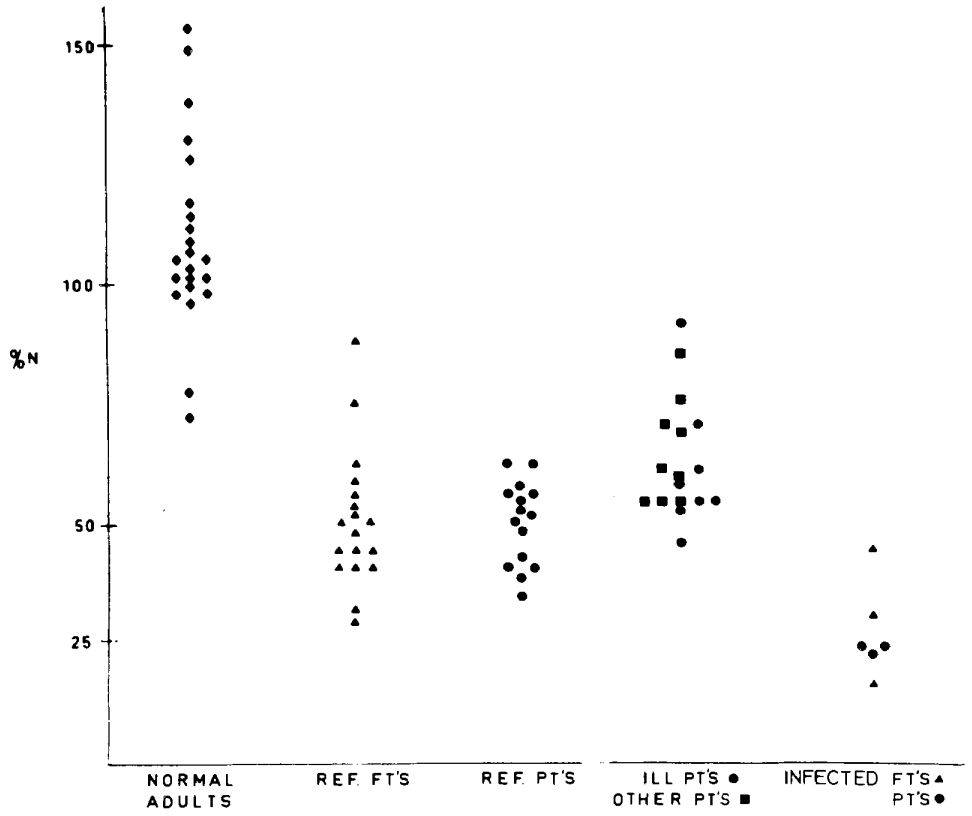


Figure. Fibronectin values in adults, in infected infants, and in healthy infants. *FT*, Full-term; *PT*, preterm.

into a dry syringe was discarded or used for other tests (to prevent contamination of the test sample by tissue thromboplastin). The test sample was then drawn into a syringe containing the anticoagulant to give a ratio of 1 volume anticoagulant to 9 volumes blood. To rule out in vitro artifact from platelet release or thrombin or protease action, the anticoagulant used was buffered citrate (anticoagulant A) or buffered citrate with inhibitors (anticoagulant B). Inhibitors added to the buffered citrate were: theophylline, an inhibitor of platelet release reaction, 1.8 mg/ml (Sigma Chemical, St. Louis); hirudin, an inhibitor of thrombin, 2 antithrombin units/ml (Sigma); and aprotinin, an inhibitor of plasmin and protease, 100 Kunitz IU/ml (Boehringer-Mannheim, Canada).

Cord blood samples were drawn from the umbilical vein of double-clamped cords obtained before placental separation. Samples were collected randomly, first into anticoagulant A or B. Immediately after collection, plasma was separated by refrigerated centrifugation at 5000 *g* for 20 minutes, respun to remove all platelets, and kept frozen at −80°C until assayed. Pooled plasma from normal adults (obtained from George King Ltd., Kansas) was used as control plasma. Our samples were collected by venipuncture, but conceivably samples could be obtained by heelstick using anticoagulated Miale pipettes.

Fibronectin was measured by Laurell immunoelectrophoresis.[5] Plasma samples were diluted with barbital-EDTA buffer (0.03 M barbiturate, 1.0 gm sodium ethylenediaminetetraacetate, 0.1 gm sodium azide in 1000 ml distilled water). The same buffer was used to make 1% agarose (Seakem Marine Colloids, Lockland, Me.). Rabbit antiserum to human fibronectin (lot 153955) was obtained from Cappell Laboratories (Cochranville, Pa.). Glass slides (7.5 cm × 5 cm) were prepared with 4 ml agarose per slide (antiserum concentration approximately 1.675%). Eleven holes (2 mm diameter) were punched per slide. Three lambda samples were applied to each well. The standard curve was made with 100%, 50%, and 25% normal pooled plasma. A normal control plasma was run in duplicate at 50% on each slide. The chamber buffer was a 0.75 M barbital (pH 8.6, 2.07 gm diethylbarbituric acid, 13.14 gm sodium barbitone, 1.0 gm EDTA, 0.1 gm sodium azide in 1000 ml distilled water). Slides were electrophoresed at 15 mamp (constant current) for two hours.

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Normally, slides were washed for 24 hours in 0.5 M sodium chloride and subsequently rinsed in tap water. However, slides can be washed and stained immediately. Interassay coefficient of variation was ±8%.

The paired and unpaired t tests were used for statistical analysis.

RESULTS

Plasma values for fibronectin in 18 reference full-term infants were decreased, compared with values in 22 reference adults (Figure). Measurements of plasma fibronectin in 15 reference preterm infants 32 to 36 weeks gestational age were not statistically different from those in 18 reference full-term infants. Cord blood fibronectin concentrations from nine other preterm infants were not different from values found in the 15 reference preterm infants. The eight ill neonates had cord plasma fibronectin measurements comparable to those of the reference preterm infants. In contrast, six infants, at the time of diagnosis of early-onset sepsis, had decreased plasma values of fibronectin when compared with healthy neonates.

There was no statistical difference by paired t test in plasma fibronectin measurements in paired samples randomly collected first into buffered citrate (anticoagulant A) or into buffered citrate plus inhibitors (anticoagulant B) (53 ± 2% versus 55 ± 2%, mean ± SD).

DISCUSSION

Several thorough reviews have been published recently stressing potential physiologic roles for fibronectin.[1, 2, 7, 8]

Our results confirm the previously reported decreased plasma fibronectin values measured by immunoelectrophoresis in plasma of cord blood from 22 healthy neonates (adult 101 ± 27%, neonates 39 ± 6%).[4] Fibronectin measurements by immunoelectrophoresis were decreased in plasma obtained from cord blood samples of newborn infants when compared with measurements of plasma fibronectin in normal adults; values for normal full-term and healthy preterm infants were not statistically different. Three healthy, extremely premature infants (gestational age 29 weeks) had cord plasma fibronectin values of 27%, 35%, and 45%, respectively (D. Barnard, unpublished data). Because samples collected randomly first into buffered citrate or buffered citrate plus additional inhibitors were not statistically different, the decreased plasma fibronectin measurements in neonates are not related to in vitro proteolysis.

The six full-term and preterm neonates with early-onset sepsis (mean age 14 hours, range 4 to 20 hours at testing) had depressed fibronectin concentrations in plasma from venous blood collected into anticoagulant B. The two infants who died had the lowest plasma fibronectin values measured. Decreased survival[9] has been reported in adults with sepsis and persistently low plasma fibronectin values. In an uncontrolled study, adult patients with sepsis and pulmonary dysfunction (ventilation-perfusion imbalance and presumed increase of lung water) improved after infusion of cryoprecipitate containing approximately 1 gm fibronectin.[10] Decreased levels of fibronectin in neonates may increase their susceptibility to and morbidity from septicemia.

Intrauterine growth retardation, maternal diabetes, and birth asphyxia or hypotension apparently do not affect plasma cord values of fibronectin.

Low plasma fibronectin measurements in adults with trauma, disseminated intravascular coagulation, or sepsis are thought to result from utilization of fibronectin in reticuloendothelial system clearance function, consumption by incorporation into intravascular thrombin, proteolytic destruction by granulocyte or tissue protease, binding to areas of tissue damage or denatured collagen, or decreased synthesis.[1] The cause of the decreased plasma values of fibronectin in neonates is speculative.

We acknowledge the excellent cooperation of the nurses and physicians of the Grace Maternity Hospital in obtaining cord blood specimens, and Drs. R. A. Bortolussi, A. Allen, D. Stinson, and E. Rees for blood specimens from septic infants.

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Page 1 of 1	**Matter Number**	0581370_KUR2C07US

GENERAL

Pursuant to 37 C.F.R. 1.97 and 1.98 and to the duty of disclosure set forth in 37 C.F.R. 1.56, the Examiner in charge of the above-identified application is requested to consider and make of record the references listed herewith. A copy of each listed reference, other than U.S. patents/applications and references cited in a parent application, is enclosed.

Although the information submitted herewith may be "material" to the Examiner's consideration of the subject application, this submission is not intended to constitute an admission that such information is "prior art" as to the claimed invention, nor is it intended to constitute an admission that such information is "analogous prior art".

In accordance with 37 C.F.R. 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made.

TIMING

In accordance with 37 CFR 1.97(b), this Information Disclosure Statement is being filed within three months of the filing of a national application other than a continued prosecution application under 37 CFR 1.53(d); within three months of the date of entry of the national stage as set forth in 37 CFR 1.491 in an international application; before the mailing of a first Office Action on the merits; or before the mailing of a first Office Action after the filing of a request for continued examination under 37 CFR 1.114.

CERTIFICATION STATEMENT

No certification statement is required. This Information Disclosure Statement is being filed in accordance with 37 CFR 1.97(b).

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Signature	/Benjamin F. Hudson/	**Date**	2024-09-27
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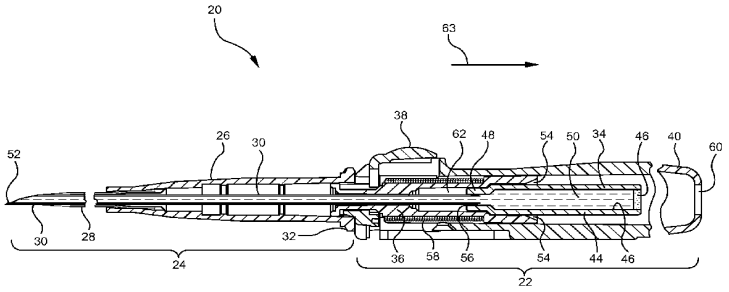
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(54) **Title**: A REMOVABLE FLASH CHAMBER

FIG. 2



(57) **Abstract**: A needle hub (36) and catheter assembly are (20) disclosed herein. The needle hub includes an introducer needle (30) having a lumen extending therethrough. A needle hub is coupled to a proximal end of the introducer needle. A flash chamber (34) is removably coupled to the needle hub or the introducer needle. An interior of the flash chamber is in fluid communication with the lumen of the introducer needle when the flash chamber is coupled to the needle hub or the introducer needle. As such, the flash chamber can collect a sample of blood that can be accessed when the flash chamber is removed. In some instances, the blood can also be dispensed from the flash chamber into a test strip (70) or other testing device.

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A REMOVABLE FLASH CHAMBER

BACKGROUND

[0001] The present disclosure relates to venting air and blood sampling with vascular access devices. Blood sampling is a common health care procedure involving the withdrawal of at least a drop of blood from a patient. Blood samples are commonly taken from hospitalized, homecare, and emergency room patients either by finger stick, heel stick, or venipuncture. Once collected, blood samples are analyzed via one or more blood test levels.

[0002] Blood tests determine the physiological and biochemical states of the patient, such as disease, mineral content, drug effectiveness, and organ function. Blood tests may be performed in a laboratory, a distance away from the location of the patient, or performed at the point of care, near the location of the patient. One example of point of care blood testing is the routine testing of a patient's blood glucose levels. This involves the extraction of blood via a finger stick and the mechanical collection of blood into a diagnostic cartridge. Thereafter the diagnostic cartridge analyzes the blood sample and provides the clinician a reading of the patient's blood glucose level. Other devices are available which analyze blood gas electrolyte levels, lithium levels, ionized calcium levels. Furthermore, some point-of-care devices identify markers for acute coronary syndrome (ACS) and deep vein thrombosis/pulmonary embolism (DVT/PE).

[0003] Blood testing is frequently necessary prior to surgery or other medical procedures. For example, there are indications that diabetes contributes to an increase risk of Surgical Site Infection (SSI). Accordingly some guidelines suggest that diabetes is one characteristic that may influence the development of SSI. As such, preoperative blood glucose control is deemed a possible SSI risk reduction measure. Testing of creatine-based estimated glomerular filtration rate (GFR) can also be useful prior to some medical procedures. In February 2002, The National Kidney Foundation published that GFR is the best overall indicator of kidney function. The demonstration of normal kidney function may be important prior to a patient obtaining a contrast enhanced CT scan, which can have significant impact on the kidneys. Despite these needs, blood diagnosis is typically done at remote labs, which do not produce immediate results.

[0004] Furthermore, despite the rapid advancement in point of care testing and diagnostics, blood sampling techniques have remained relatively unchanged. Blood samples are frequently drawn using hypodermic needles or vacuum tubes coupled to a proximal end

of a needle or a catheter assembly. In some instances, clinicians collect blood from a catheter assembly using a needle and syringe that is inserted into the catheter to withdraw blood from a patient through the inserted catheter. These procedures utilize needles and vacuum tubes as intermediate devices from which the collected blood sample is typically withdrawn prior to testing. These processes are thus device intensive, utilizing multiple devices in the process of obtaining, preparing, and testing blood samples. Furthermore, each device required adds time and cost to the testing process. Accordingly, there is a need for more efficient blood sampling and testing devices and methods.

SUMMARY

[0005] The present invention has been developed in response to problems and needs in the art that have not yet been fully resolved by currently available blood sampling devices and methods. Thus, these devices and methods are developed to efficiently collect a blood sample from a flash chamber that is removably coupled to the proximal end of an introducer needle. Since blood is already collected in this chamber, the use of this blood can avoid the need for a separate blood sampling procedures and devices, which can decrease the cost and time of blood diagnosis. Once removed, blood can be dispensed from the flash chamber into a point-of-care diagnostic device, for prompt test results, which can enable time-sensitive health information, such as the risk of diabetes or impaired kidney function to be more quickly and easily acquired. Furthermore, the flash chamber can be sized to accommodate the desired blood sample. As such, the flash chamber can be enlarged, which increases the flashback visualization period.

[0006] In one aspect of the invention, a needle hub comprises: an introducer needle having a lumen extending therethrough; a needle hub coupled to a proximal end of the introducer needle; and a flash chamber removably coupled to the needle hub, an interior of the flash chamber being in fluid communication with the lumen of the introducer needle when the flash chamber is coupled to the needle hub.

[0007] Implementation may include one or more of the following features. A portion of the flash chamber can be compressible. The flash chamber can comprise: a chamber body defining an internal cavity; and an air permeable membrane coupled to the chamber body and in fluid communication with the internal cavity. The internal cavity of the chamber body of the flash chamber can have in an internal volume between about 0.1 mL to about 10 mL. The flash chamber can be press fit into the needle hub or introducer needle. The flash chamber can be screwed onto the needle hub. The flash chamber can be selectively coupled to the needle hub or the introducer needle via a keyed connection. The flash chamber can be

selectively coupled to the needle hub or the introducer needle via a breakable connection. The flash chamber can be a breakable ampoule.

[0008] In another aspect of the invention, a catheter assembly comprises: an introducer needle having a lumen extending therethrough; a needle hub coupled to a proximal end of the introducer needle; a flash chamber selectively coupled to the needle hub or the introducer needle, an interior of the flash chamber being in fluid communication with the lumen of the introducer needle when the flash chamber is coupled to the needle hub, the flash chamber having an air permeable membrane and a distal connector portion; the chamber body defining an internal cavity, the chamber body having at least a compressible portion that decreases the internal volume of the internal cavity when compressed; the air permeable membrane coupled to the chamber body and in fluid communication with the internal cavity; and the distal connector portion of the chamber body for selectively coupling to the needle hub.

[0009] Implementation may include one or more of the following features. At least a portion of the flash chamber can be compressible. The flash chamber can have an internal volume between about 0.1 mL to about 10 mL. The flash chamber can be press fit into the needle hub or introducer needle. The flash chamber can be screwed onto the needle hub. The flash chamber can be selectively coupled to the needle hub or the introducer needle via a breakable connection, the breakable connection including at least one scored line and a stress riser. The flash chamber is a breakable ampoule.

[0010] In another aspect of the invention, a method for providing a removable flash chamber of a catheter assembly, the method comprising: providing a catheter assembly having a needle hub, the needle hub having an introducer needle coupled thereto; providing an introducer needle coupled to the needle hub, the introducer needle having a lumen extending therethrough; and providing a flash chamber removably coupled to the needle hub, an interior of the flash chamber being in fluid communication with the lumen of the introducer needle when the flash chamber is coupled to the needle hub.

[0011] Implementation may include one or more of the following features. The method may further comprise providing at least a single compressible portion of the flash chamber for selectively ejecting blood within the flash chamber from therefrom. The method may further comprise providing an inner cavity within a body of the flash chamber having an internal volume about 0.1 mL to 10 mL. The flash chamber can have a distal connector portion, the distal connector portion having at least one of a press fit connector, screw threads, a keyed connection, and a breakable connection.

[0012] These and other features and advantages of the present invention may be incorporated into certain embodiments of the invention and will become more fully apparent from the following description and appended claims, or may be learned by the practice of the invention as set forth hereinafter. The present invention does not require that all the advantageous features and all the advantages described herein be incorporated into every embodiment of the invention.

BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWINGS

[0013] In order that the manner in which the above-recited and other features and advantages of the invention are obtained will be readily understood, a more particular description of the invention briefly described above will be rendered by reference to specific embodiments thereof which are illustrated in the appended drawings. These drawings depict only typical embodiments of the invention and are not therefore to be considered to limit the scope of the invention.

[0014] Figure 1 illustrates a perspective view of a catheter assembly with a removable flash chamber, according to some embodiments.

[0015] Figure 2 illustrates a cross-section view of a catheter assembly of Figure 1 taken along line 2-2, according to some embodiments.

[0016] Figure 3 illustrates a cross-section view of a catheter assembly with a removable flash chamber after the introducer needle has been withdrawn from the catheter, according to some embodiments.

[0017] Figure 4 illustrates a perspective view of a catheter assembly with a removable flash chamber that has been removed therefrom, according to some embodiments.

[0018] Figure 5 illustrates a perspective view of a removable flash chamber dispensing a sample of blood on a blood test strip, according to some embodiments.

[0019] Figure 6 illustrates a cross-section view of a proximal portion of a catheter assembly with a removable flash chamber, according to some embodiments.

[0020] Figure 7 illustrates a cross-section view of a proximal portion of another catheter assembly with a removable flash chamber, according to some embodiments.

[0021] Figure 8 illustrates a perspective view of a keyed connection between a flash chamber and a needle hub or safety barrel, according to some embodiments.

[0022] Figure 9 illustrates a cross-section view of a removable flash chamber, according to some embodiments.

DETAILED DESCRIPTION OF THE INVENTION

[0023] Embodiments of the present invention can be understood by reference to the drawings, wherein like reference numbers indicate identical or functionally similar elements. It will be readily understood that the components of the present invention, as generally described and illustrated in the figures herein, could be arranged and designed in a wide variety of different configurations. Thus, the following more detailed description, as represented in the figures, is not intended to limit the scope of the invention as claimed, but is merely representative of presently preferred embodiments of the invention.

[0024] Reference will now be made to Figure 1, which illustrates a catheter assembly 20 that can be used to access the vascular system of a patient, such as the BD Insyte (TM) Autoguard (TM) from Beckton, Dickinson and Company, Inc. (as shown), the BD Protect IV (TM) also from Beckton, Dickinson and Company, Inc., and the Medikit Z5 from Medikit Company Inc. The catheter assembly 20 can include various other configurations. The catheter assembly 20 generally includes a catheter adapter 24 and a needle assembly 22. The catheter adapter 24 is inserted into a patient to establish fluid communication with the patient's vasculature, and may be used to infuse fluids therethrough. The needle assembly 22 includes an introducer needle 30 that is used to assist the catheter assembly 24 to be accurately placed into the vasculature of the patient. After the catheter assembly 24 is properly placed, the needle assembly 22 is removed and uncoupled from the catheter assembly 24.

[0025] The needle assembly 22 includes a generally rigid introducer needle 30 that provides structural support to the flexible or semi-flexible catheter 28 of the catheter assembly 24. In a pre-use position, the introducer needle 30 is inserted through the catheter 28, as shown. During infusion or other such procedures the introducer needle 30 and catheter 28 are inserted through the skin of a patient and advanced into the vasculature of a patient. Once the catheter 28 is properly placed, the introducer needle 30 is removed from the catheter 28.

[0026] As shown in Figure 1, the catheter adapter 24 includes a catheter hub 26 that is coupled to a catheter 28 that extends distally from the distal end of the catheter hub 26. The catheter hub 26 includes an inner lumen that extends therethrough and provides fluid communication to an inner lumen of the catheter 28. In some configurations, the catheter hub 26 also includes a proximal connector 32, such as a threaded luer connector, that can connect to a needle assembly 22 or other vascular access device.

[0027] The needle assembly 22 includes an introducer needle 30 that extends through the catheter assembly 20 in a pre-insertion state. The introducer needle 30 is coupled to a needle hub 36 at its proximal end. In some embodiments, as shown, the needle hub 36 is disposed within a safety barrel 40 that shields the introducer needle 30 after it is withdrawn from the patient and out of the catheter adapter 24. In the illustrated embodiment, the introducer needle 30 is withdrawn, via a spring force, from the catheter adapter 24 when a user presses a button 38 of the needle assembly 22. The button 38 releases a fastener that holds the introducer needle 30 in place, permitting it to be withdrawn proximally through the catheter 28 and catheter hub 26 into the safety barrel 40.

[0028] With continued reference to Figure 1, in some embodiments, a flash chamber (also known as "flashback chamber") 34 is coupled to the needle hub 36 or directly to the proximal end of the introducer needle 30. The flash chamber 34 can receive blood therein from the introducer needle 30. In some configurations, the flash chamber 34 is transparent or semi-transparent such that a user can view blood flowing into the flash chamber 34 from the introducer needle 30.

[0029] In some catheter placement procedures, flashback occurs when blood from within the vasculature of a patient enters into the catheter 28 and/or introducer needle 30 of the catheter assembly 20. In some instances, the catheter 28 is transparent or semi-transparent such that the clinician can recognize blood flowing through the catheter 28 after the introducer needle 30 has entered the patient's vascular. To provide an extended flashback period that may enable a clinician to verify that the catheter 28 has entered and remains properly placed. In some embodiments, the catheter hub 26 and/or the needle assembly 22 can include a flash chamber 34. A flash chamber 34 of the needle assembly 22 can be in fluid communication with the introducer needle 30 so that blood flowing through the introducer needle 30 enters into the flash chamber 34. The size of the flash chamber 34 can be varied so that the length of time required to fill the chamber provides the clinician adequate time to properly position the catheter 28. As mentioned, once the catheter 28 is properly placed, the introducer needle 30 can be withdrawn from the catheter 28.

[0030] After the needle assembly 22 is uncoupled from the catheter adapter 24, the sample of blood within the flash chamber 34 can be use for diagnosis. In some embodiments, the flash chamber 34 can be selectively uncoupled from the needle assembly 22 so that the blood therein can be accessed and tested. Thus, in some embodiments, there is a means for extracting the blood from the flash chamber 34. This means can include compressing at least a portion of the flash chamber 34 to dispense blood therefrom. This means can also include

breaking the flash chamber 34, sucking or wicking blood from the flash chamber 34, or otherwise removing the blood therefrom.

[0031] In some embodiments, the flash chamber 34 extends through a proximal opening 60 in the safety barrel 40 after the needle is withdrawn from the catheter adapter 24. Thus, the flash chamber 34 can be larger, with an increased internal volume, than it could be without a proximal opening 60. In some configurations, the flash chamber 34 has in an internal volume between about 0.1 mL to 10 mL. In other configurations, the flash chamber 34 has in an internal volume between about 0.5 mL to 7 mL. In other configurations, the flash chamber 34 has in an internal volume between about 1 mL to 3 mL. In other configurations, the flash chamber 34 has in an internal volume greater or less than the listed volumes. The larger internal volume of the flash chamber 34 can provide longer flashback indication periods. As such, a clinician can have more time to place and ensure proper placement of the catheter 28.

[0032] Reference will now be made to Figure 2, which depicts a cross section of the catheter assembly 20 of Figure 1 taken along line 2-2. This figure depicts at least some of the inner components of the catheter adapter 24 and needle assembly 22. For simplicity, the catheter hub 26 is depicted as having few features or components therein. However, it will be understood that the catheter hub 26 can include various known components and features, such as a valve, blood control valve, inner ridges, or other known elements.

[0033] As shown in Figure 2, in some embodiments, the needle assembly 22 includes a needle hub 36 coupled to an introducer needle 30, a spring 58, and a removable flash chamber 34. These components can be at least partially disposed within a safety barrel 40 that prevents blood and needle exposure after the introducer needle 30 is drawn into the safety barrel 40. A cross section of the button 38 and its related components shows how the button 38, when depressed, disengages the needle hub 36, which is then moved proximally 62 under the force of the spring 58. The spring 58 is positioned between the safety barrel 40 and the needle hub 36, so that when the button 38 is depressed it releases its mechanical energy, uncompresses, and forces the needle hub 36 proximally 62. In some instances, the spring 58 is a compression spring that stored energy when compressed. In some configurations, the flash chamber 34 is disposed on the proximal end of the needle hub 36, and the flash chamber 34 extends at least partially out of a proximal opening 60 in the safety barrel 40 as it moves to the proximal end of the safety barrel 40. The tip of the introducer needle 30 can be drawn into the safety barrel 40 as the needle hub 36 is forced proximally 63. This movement draws the introducer needle 30 and its tip into a shielded position, within the covering and the

containment of the safety barrel 40, which can serve as a shield between the introducer needle 30 and the clinician to prevent needle stick injuries and blood contamination.

[0034] In some instances, in the shielded position as shown in Figure 3, the introducer needle 30 is safely contained within the safety barrel 40 while the flash chamber 34 extends at least partly out of a proximal opening 60 of the safety barrel 40. In some embodiments, the proximal opening 60 is shaped and sized to conform quite closely to the outer geometry of the flash chamber 34 so as to minimize any spacing therebetween that might otherwise provide room for blood flow of blood within the safety barrel 40. In the shielded position, a proximal portion of the flash chamber 34 can be accessed by a clinician and selectively uncoupled from the needle hub 36. Depending on the type of coupling between the flash chamber 34 and the needle hub 36 or introducer needle 30, the clinician will pull and/or twist, or otherwise manipulate the flash chamber 34 to uncouple it from the needle hub 36. In some configurations, the flash chamber 34 is directly coupled to the needle hub 36 and the introducer needle 30, as shown in Figure 2. In some configurations, the flash chamber 34 is indirectly coupled to the needle hub 36 and directly coupled to the introducer needle 30, which is directly coupled to the needle hub 36. In other configurations, the flash chamber 34 is indirectly coupled to the needle 30 and directly coupled to the needle hub 36, which is directly coupled to the introducer needle 30, as shown in Figure 6.

[0035] Referring again to Figure 2, in some embodiments, the flash chamber 34 is removably or selectively coupled to the needle hub 36. This removable coupling can have various configurations, such as a press-fit coupling, a threaded screw-on coupling, a keyed connection, a breakable connection, and other various types of removable couplings. As shown, the flash chamber 34 is press fit within an inner bore 62 of the needle hub 36. Also shown, the introducer needle 30 is press fit within the flash chamber 34. In some embodiments, only one of these press-fit couplings is used, rather than both. In a press-fit coupling, the inner geometry of the inner bore 62 approximates and may be approximately equal to or slightly smaller than the outer geometry of the chamber body 44 of the flash chamber 34. Additionally or alternatively, the inner surface of the inner bore 62 can include one or more inward protrusions 54 that press against the outer surface of the chamber body 44 to provide pressure between these components. In other embodiments, the outer surface of the chamber body of the flash chamber 34 includes one or more outward protrusions that press against the inner surface of the inner bore 62 to provide pressure between these components.

[0036] In some embodiments, flash chamber 34 includes a distal connector portion 48 of the chamber body 44 for selectively coupling to the needle hub 36. As shown in Figure 2, this distal connector portion 48 includes the distal portion of the chamber body 44, which has an outer geometry that is press fit into the needle hub 36 and over the proximal end of the introducer needle 30. In other embodiments, the distal connector portion 48 includes a threaded member used to screw the flash chamber 34 into the needle hub 36. In some embodiments, the distal connector portion 48 includes a keyed connection that mates with a keyed portion of the needle hub 36, as shown in Figure 8. In some embodiments, the distal connector portion 48 includes a breakable connection having, for example, a scored line and/or a stress riser.

[0037] In some embodiments, the flash chamber 34 includes a membrane 46 that is air permeable, through which air from within the introducer needle 30 passes. In some embodiments, the membrane 46 is hydrophobic so that it does not permit blood to pass through it. In such embodiments, blood 50 entering the introducer needle 30 forces air out the membrane 46 as it enters the introducer needle 30 and fills the introducer needle 30 and the flash chamber 34 to the membrane 46. At this point, blood 50 ceases to flow into the introducer needle 30.

[0038] In some embodiments, the membrane 46 is both air permeable and hydrophobic, to permit air, but not blood 50 to pass therethrough. In other embodiments, the membrane 46 is hydrophilic. The membrane 46 can include various materials and components that provide these properties. For example, in some embodiments, the membrane 46 includes glass, polyethylene terephthalate (PET), a microfiber material, and/or other synthetic material made of high-density polyethylene fibers, such as TYVEK® material from DuPont. Other such materials and components can also be used as a layer of the membrane 46 or as the entire membrane 46 to enable the membrane 46 to be hydrophobic, hydrophilic, and/or air permeable, according to some configurations.

[0039] In some embodiments, the flash chamber 34 is configured to retain blood 50 as it is withdrawn from the needle hub 36 to prevent blood spills and blood contamination. Thus, in some configurations, a distal opening 56 of the flash chamber 34 is shaped and sized to retain blood 50. Blood retention within the internal cavity 66 is governed, at least in part, by the inner perimeter of the distal opening 56, the surface tension of blood 50, and the force on the blood 50 to flow out of the distal opening 56. Accordingly, the inner perimeter of the distal opening 56 can be designed so that blood 50 is retained within the internal cavity 66 when the

force of the blood 50 to flow out of the distal opening 56 is within a certain range, but permit at least some blood to flow out when the pressure on the blood 50 exceeds this range.

[0040] For example, in some embodiments, when the distal opening 56 is circular, an inner perimeter of less than or equal to approximately 2.0 mm, and a diameter of less than or equal to approximately 0.6 mm, permits the retention of blood 50 within the internal cavity 66 against approximately the force of gravity. When the force on the blood 50 is greater than the force of gravity some blood 50 can flow out of the distal opening 56. Similarly, a circular distal opening 56 with a diameter of about 0.3 mm may retain blood 50 therein against forces stronger than gravity, such as bumping, jarring, and movement of the filled flash chamber 34. When the distal opening 56 has a very small inner perimeter, the force required to expel blood 50 will be very large.

[0041] In some embodiments, the distal opening 56 has a inner perimeter greater than or equal to about 0.3 mm, which when the distal opening 56 is a circular opening, corresponds to a diameter of about 0.1 mm. Thus, in some configurations, the distal opening 56 has an inner perimeter between about 0.3 mm to about 2.0 mm. In some configurations, the distal opening 56 is approximately circular and has a diameter between about 0.1 mm to about 0.6 mm. In other embodiments, the distal lumen opening 58 is non-circular.

[0042] Reference will now be made to Figure 3, which depicts the needle assembly 22 in the shielded position, with the spring 58 released to a decompressed state, which has forced the needle hub 36 to the proximal end of the safety barrel 40 and the flash chamber 34 at least partially out of the proximal opening 60 of the safety barrel 40. The internal cavity 66 of the flash chamber 34 is filled at least partially with blood 50. In this shielded position, the proximal portion of the chamber body 44 can be gripped and selectively decoupled from the needle hub 36. In this manner, the blood 50 sample within the flash chamber 34 can be used for diagnosis.

[0043] As shown in Figure 4, flash chamber 34 is decoupled from the needle assembly 22. This flash chamber 34 can now be used as a storage vial of blood 50 as it is transported to a testing facility. Additionally, the blood 50 sample within the flash chamber 34 can be immediately used for point-of-care blood diagnostic testing.

[0044] Reference will now be made to Figure 5, which depicts the flash chamber 34 dispensing blood 50 onto a blood test strip 70. The test strip 70 can be used to test for glucose, creatine, cystatin C test, or other such test at the point of care, the location of the patient. Such diagnosis can provide rapid diagnostic results at the point of care, without the need to withdraw a blood 50 sample via a syringe, vacuum tube, or other traditional device.

In some instances, the blood 50 can be dispensed into a diagnostic test device that performs diagnostic testing on the blood. In other instances, the blood 50 can be dispensed from the flash chamber 34 into a sterile vial or tube, such as a in-vitro test tube that is taken to a medical laboratory for testing.

[0045] The chamber body 44 of the flash chamber 34 can have various embodiments that can facilitate the dispensing blood 50 from the flash chamber 34. In some embodiments, at least a portion of the chamber body 44 is compressible to at least a small degree. When compressed, such as in an inward direction 72, the internal volume of the internal cavity 66 of the flash chamber 34 decreases, increasing the internal pressure of the internal cavity 66, and dispensing a sample of blood 50 from the distal opening 56. In some embodiments, the flash chamber 34 is rigid or semi-rigid. In some embodiments, only a portion of the flash chamber 34 is compressible. The compressible portion can be located and designed so that it does not compress during normal removal of the flash chamber 34 from the needle hub 36. In other embodiments, the chamber body 44 of the flash chamber 34 is a breakable ampoule, which when broken, dispenses blood 50 therefrom. In some embodiments, the distal opening 56 of the flash chamber 34 is shaped and sized so that a clinician can wick blood 50 therefrom using a test strip 70 or other device.

[0046] Reference will now be made to Figure 6, which depicts another embodiment of a connection between the needle hub 36 and the flash chamber 34. As shown, in some embodiments, the needle hub 36 includes a valve 80 that can prevent blood 50 from spilling out of the proximal opening 60 of the inner bore 62 of the needle hub 36 when the flash chamber 34 is removed therefrom. In some configurations, the valve 80 is flexible and selectively opens upon insertion of the flash chamber 34 therein. In some embodiments, the valve 80 is made of an elastomeric material, such as silicon rubber or the like. The valve 80 can selectively close and seal when the flash chamber 34 is removed therefrom. The valve 80 can provide a fluid tight connection between the flash chamber 34 and the valve 80 when the flash chamber 34 is inserted therein. As shown, in some embodiments, the flash chamber 34 can coupled directly into the valve 80 with a press fit connection. As further shown, in some embodiments, the flash chamber 34 is not coupled to, nor does it contact, the introducer needle 30.

[0047] As shown, in some embodiments, the valve 80 includes a connection portion 90 that is coupled to the inner surface of the needle hub 36 and a barrier portion 82. The barrier portion 82 spans a cross section of inner bore 62 to seal the inner bore 62 upon removal of the flash chamber 34. The barrier portion 82 can include a hole or slit that selectively open and

closes. The slit can be a straight slit, a Y-shaped slit, or a cross-shaped slit. The barrier portion 82 can also include an inward facing duckbill shape that at least partially can prevent the slit from opening in response to proximally oriented internal pressure on the valve 80. The valve 80 can retain the flash chamber 34 within the needle hub 36 until a threshold force is applied proximally 63 on the flash chamber. In some embodiments, the flash chamber 34 is retained in the needle hub 36 with a breakable connection 92, which breaks when a threshold force is applied proximally 63 on the flash chamber 34. The breakable connection 92 can be made of a breakable material. The breakable connection 92 can also have a scored line 94 and/or a stress riser that facilitates breaking at that point.

[0048] Referring still to Figure 6, in some embodiments, the needle hub 36 includes a latch member 86 that extends distally from the needle hub 36. The latch member 86 permits the needle hub 36 to be is drawn proximally 62 and distally within the safety barrel 40 until the latch member 86 is drawn proximally passed an inward ridge 84. The inward ridge 84 can have a steep proximal face 92 that restricts the latch member's 86 distal movement. As such, the latch member 86 and the inward ridge 84 can prevent the needle hub 34 from advancing the introducer needle 30 out the safety barrel 40. The shape and configuration of the latch member 86 and the inward ridge can be adjusted, anticipated, and/or changed. Furthermore, other such means for limiting the needle hub's 36 distal movement can be incorporated into the needle assembly 22.

[0049] Figure 9 depicts another embodiment of a flash chamber 34 that can be used with the valve 80 and needle hub 36 of Figure 6. This flash chamber 34 includes a distal connector portion 48 that includes a narrow nose extension 130. The narrow nose extension 130 can pierce through the valve 80 and allows for effective resealing of the valve 80 after the removal of the flash chamber 34.

[0050] Reference will now be made to Figure 7, which depicts yet another embodiment of a connection between the needle hub 36 and the flash chamber 34. As shown, flash chamber 34 is removably coupled to the needle hub 36. The distal connector portion 48 of the flash chamber 34 includes an annular flange 102 that extends outwardly from the flash chamber 34. This distal connector portion 48 is positioned within proximal portion of the inner bore 62 of the needle hub 36. A valve 80 is located within this proximal portion of the inner bore 62. The valve 80 includes an inner cavity 108 that receives the distal connector portion 48 therein. The annular flange 102 of the distal connector portion 48 is interlocked within an inner groove 100 of the valve 80. The valve 80 is disposed within a distal region 110 of the inner cavity 108. The valve 80 and/or the flash chamber 34 can longitudinally within this

distal region 110. This distal region is terminated at its distal end with an inward flange 104 of the needle hub 36. This inward flange 104 prevents the annular flange 102 of the flash chamber 34 from being withdrawn from the needle hub 36 until a threshold force is applied to the flash chamber 34. When a threshold force pulls the flash chamber 34, the proximal movement of the annular flange 102 forces the valve 80 and the inward flange 104 to flex outwardly into the space 106 between the needle hub 36 and the safety barrel 40. The characteristics, shapes, dimensions, and properties of the needle hub 36 and the valve 80 can be designed to require a certain threshold force that will allow a user to easily remove the flash chamber 34, while preventing the flash chamber 34 from falling out when it is slightly jarred, bumped, or touched.

[0051] In other embodiments, the flash chamber 34 is screwed onto the needle hub 36. As shown, the annular flange 102 can be angled to form one or more male threaded connectors and the inner groove 100 of the valve 80 and/or the inward flange 104 of the needle hub 36 can form a female threaded connector. Thus configured, the flash chamber 34 can be screwed into the needle hub 36. To remove the flash chamber 34 it can be unscrewed from the needle hub 36.

[0052] As shown in Figure 8, in some embodiments, the flash chamber 34 is connected to the needle hub 36 via a keyed connection. The distal connector portion 48 can include a one or more keyed connector components 120 that mates with keyed connector components 122 in the proximal opening 60 of the safety barrel 40 and/or the needle hub 36. For example, in some instances, the keyed distal connector portion 48 is inserted into the keyed safety barrel 40 and/or the needle hub 36 in a distal direction 124. When fully inserted, the flash chamber 34 can be rotated, for example in a clockwise direction 126, to lock it in place. To remove the flash chamber 34, the clinician rotates the flash chamber 34 in a counter-clockwise direction and withdraws the flash chamber 34 in the proximal direction 63. In addition to the connections between the flash chamber 34 and the needle hub 36 described herein, other such connecting means for connecting the flash chamber 34 to the needle hub 36 can be incorporated into the catheter assembly 20.

[0053] From the foregoing, it will be seen that the present devices and methods efficiently collect a blood sample from a flash chamber that is removably coupled to the proximal end of an introducer needle. Since blood is already collected in this chamber, the use of this blood can avoid the need for a separate blood sampling procedure. Once removed, blood can be dispensed from the flash chamber into a point-of care diagnostic device, for rapid, prompt test results, which can enable time-sensitive health information, such as the risk of diabetes or

impaired kidney function to be more quickly and easily acquired. Furthermore, the flash chamber can be sized for accommodate the needed blood sample. As such, the flash chamber can be enlarged, which increases the flashback visualization period.

[0054] The present invention may be embodied in other specific forms without departing from its structures, methods, or other essential characteristics as broadly described herein and claimed hereinafter. The described embodiments are to be considered in all respects only as illustrative, and not restrictive. The scope of the invention is, therefore, indicated by the appended claims, rather than by the foregoing description. All changes that come within the meaning and range of equivalency of the claims are to be embraced within their scope.

CLAIMS

1. A needle hub comprising:

an introducer needle having a lumen extending therethrough;

a needle hub coupled to a proximal end of the introducer needle; and

a flash chamber removably coupled to the needle hub, an interior of the flash chamber being in fluid communication with the lumen of the introducer needle when the flash chamber is coupled to the needle hub.

2. The catheter assembly of claim 1, wherein at least a portion of the flash chamber is compressible.

3. The catheter assembly of claim 1, wherein the flash chamber comprises:

a chamber body defining an internal cavity; and

an air permeable membrane coupled to the chamber body and in fluid communication with the internal cavity.

4. The catheter assembly of claim 3, wherein the internal cavity of the chamber body of the flash chamber has in an internal volume between about 0.1 mL to about 10 mL.

5. The catheter assembly of claim 1, wherein the flash chamber is press fit into the needle hub or introducer needle.

6. The catheter assembly of claim 1, wherein the flash chamber is screwed onto the needle hub.

7. The catheter assembly of claim 1, wherein the flash chamber is selectively coupled to the needle hub or the introducer needle via a keyed connection.

8. The catheter assembly of claim 1, wherein the flash chamber is selectively coupled to the needle hub or the introducer needle via a breakable connection.

9. The catheter assembly of claim 1, wherein the flash chamber is a breakable ampoule.

10. A catheter assembly comprising:

an introducer needle having a lumen extending therethrough;

a needle hub coupled to a proximal end of the introducer needle;

a flash chamber selectively coupled to the needle hub or the introducer needle, an interior of the flash chamber being in fluid communication with the lumen of the introducer needle when the flash chamber is coupled to the needle hub, the flash chamber having an air permeable membrane and a distal connector portion;

the chamber body defining an internal cavity, the chamber body having at least a compressible portion that decreases the internal volume of the internal cavity when compressed;

the air permeable membrane coupled to the chamber body and in fluid communication with the internal cavity; and

the distal connector portion of the chamber body for selectively coupling to the needle hub.

11. The catheter assembly of claim 10, wherein at least a portion of the flash chamber is compressible.

12. The catheter assembly of claim 10, wherein the flash chamber has in an internal volume between about 0.1 mL to 10 mL.

13. The catheter assembly of claim 10, wherein the flash chamber is press fit into the needle hub or introducer needle.

14. The catheter assembly of claim 10, wherein the flash chamber is screwed onto the needle hub.

15. The catheter assembly of claim 10, wherein the flash chamber is selectively coupled to the needle hub or the introducer needle via a breakable connection, the breakable connection including at least one scored line and a stress riser.

16. The catheter assembly of claim 10, wherein the flash chamber is a breakable ampoule.

17. A method for providing a removable flash chamber of a catheter assembly, the method comprising:

providing a catheter assembly having a needle hub, the needle hub having an introducer needle coupled thereto;

providing an introducer needle coupled to the needle hub, the introducer needle having a lumen extending therethrough;

providing a flash chamber removably coupled to the needle hub, an interior of the flash chamber being in fluid communication with the lumen of the introducer needle when the flash chamber is coupled to the needle hub.

18. The method of claim 17, further comprising providing at least a single compressible portion of the flash chamber for selectively ejecting blood within the flash chamber from therefrom.

19. The method of claim 18, providing an inner cavity within a body of the flash chamber having an internal volume about 0.1 mL to 10 mL.

20. The method of claim 19, wherein the flash chamber has a distal connector portion, the distal connector portion having at least one of a press fit connector, screw threads, a keyed connection, and a breakable connection.

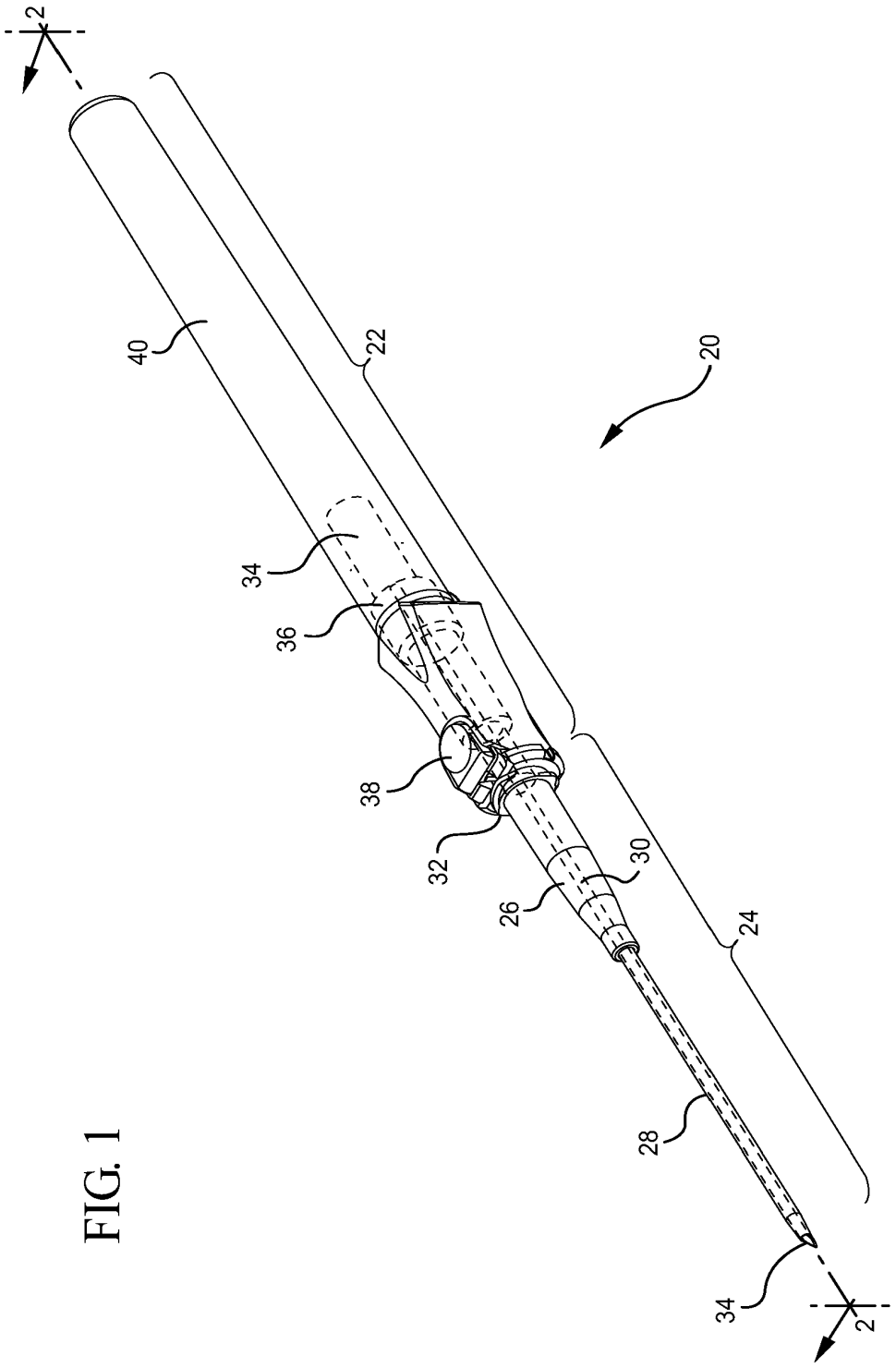


FIG. 1

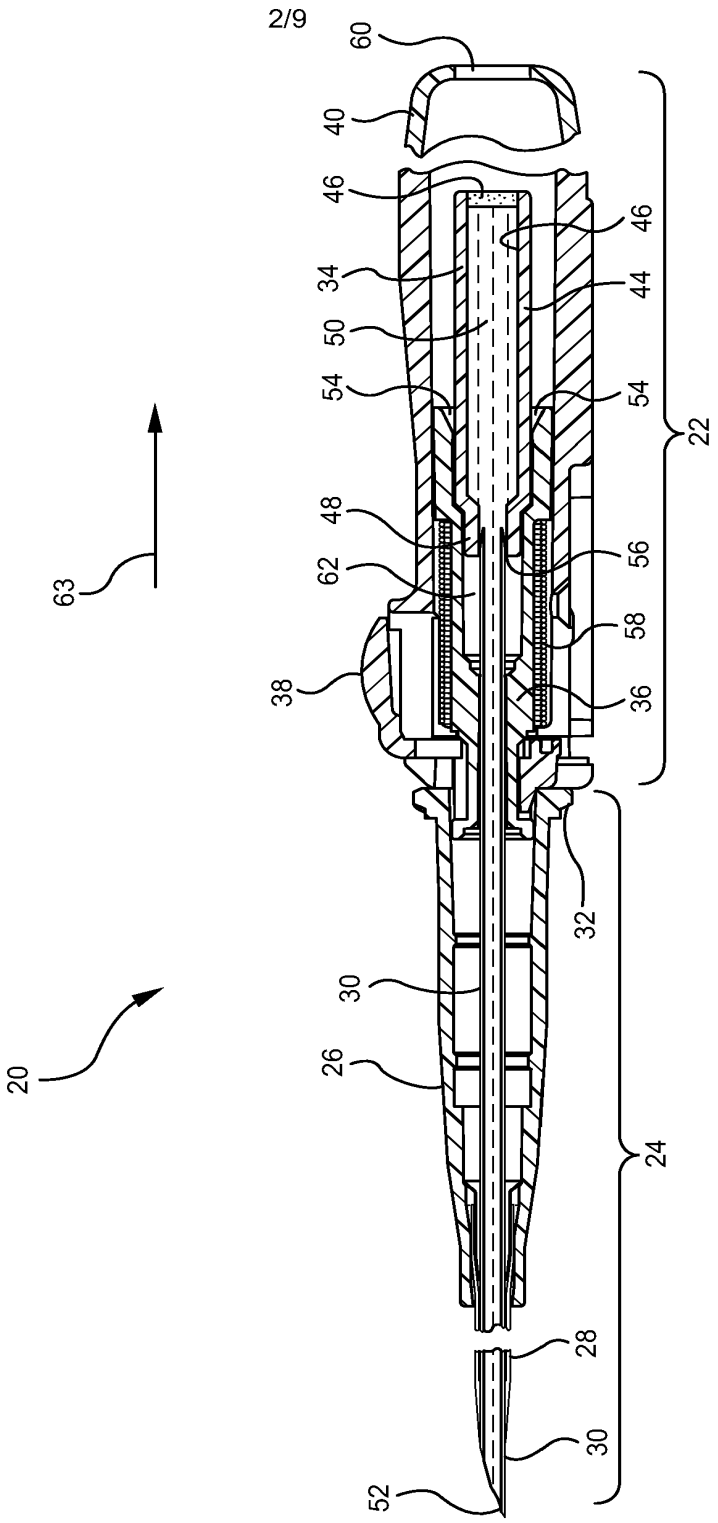

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FIG. 2

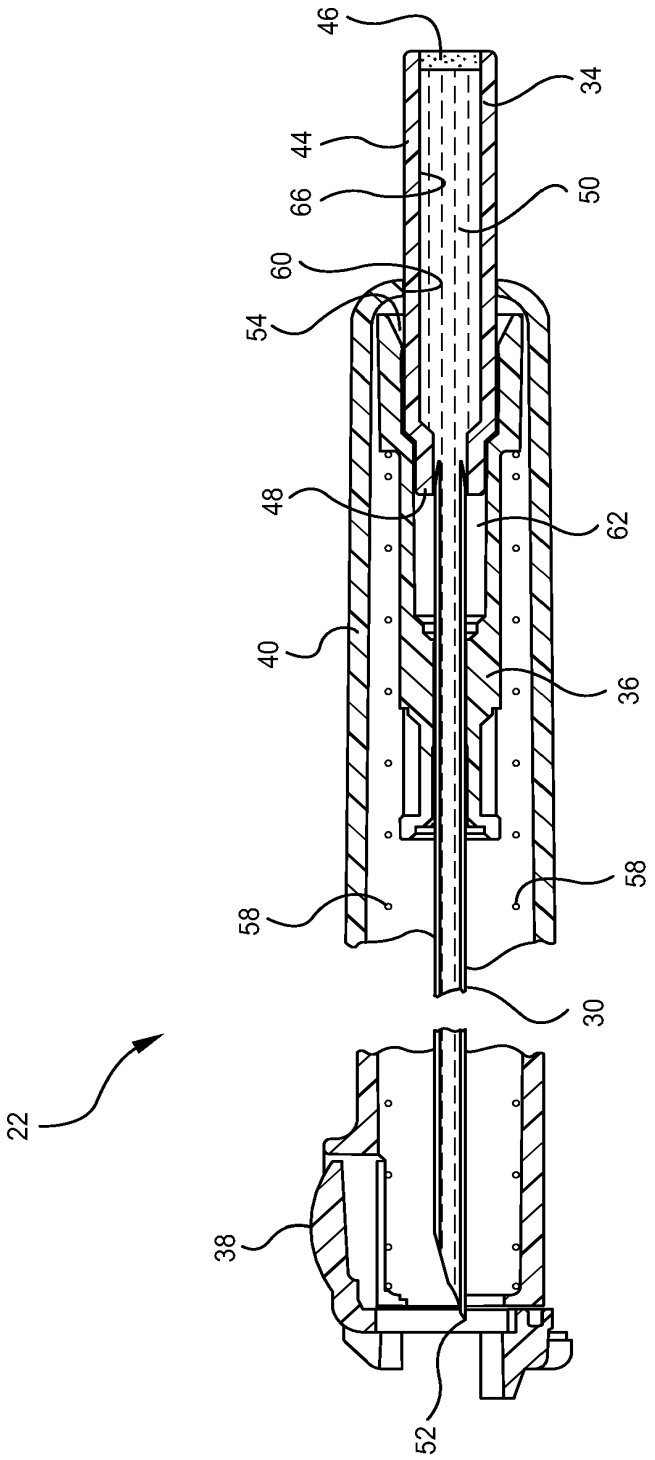


FIG. 3

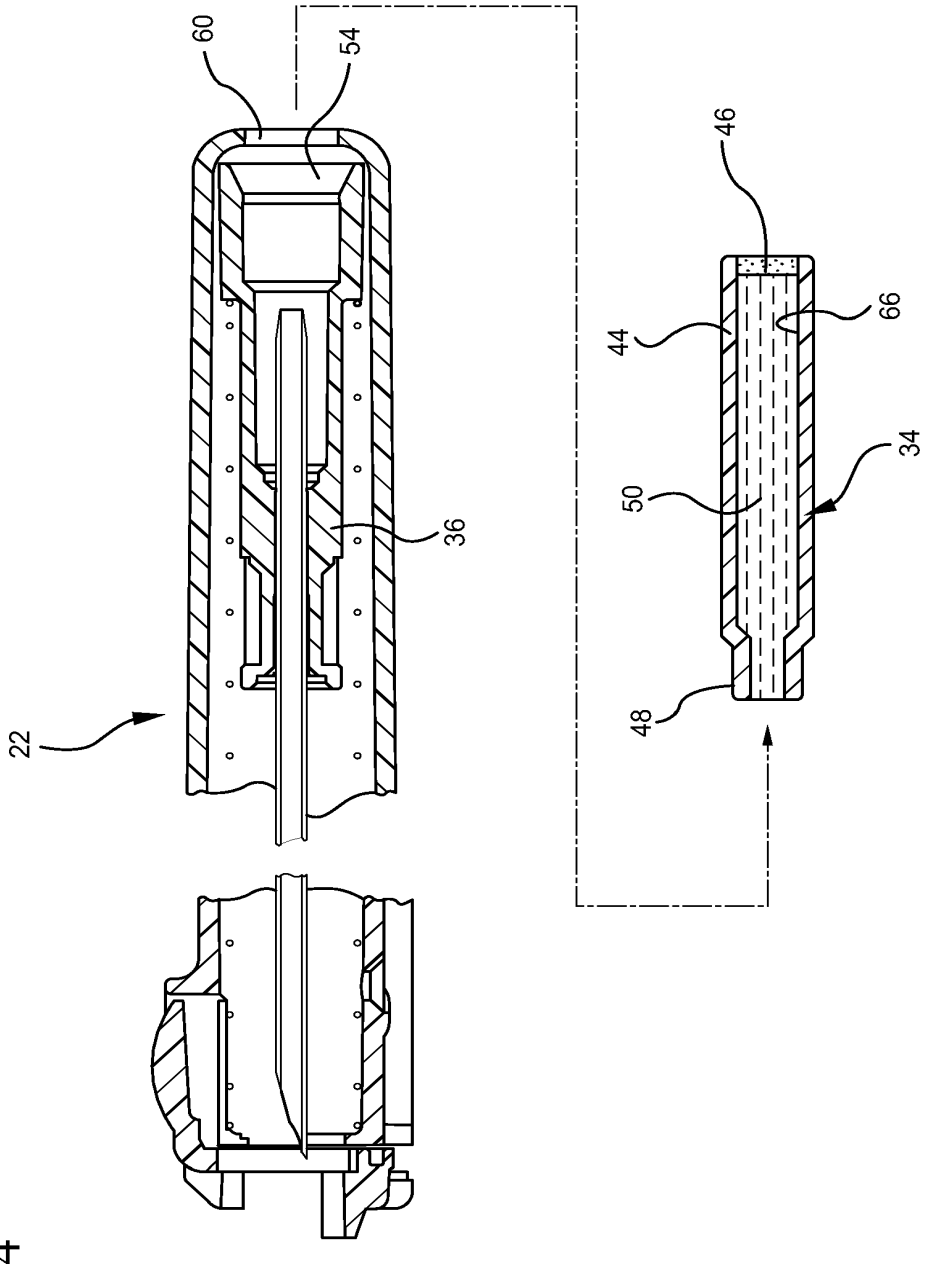


FIG. 4

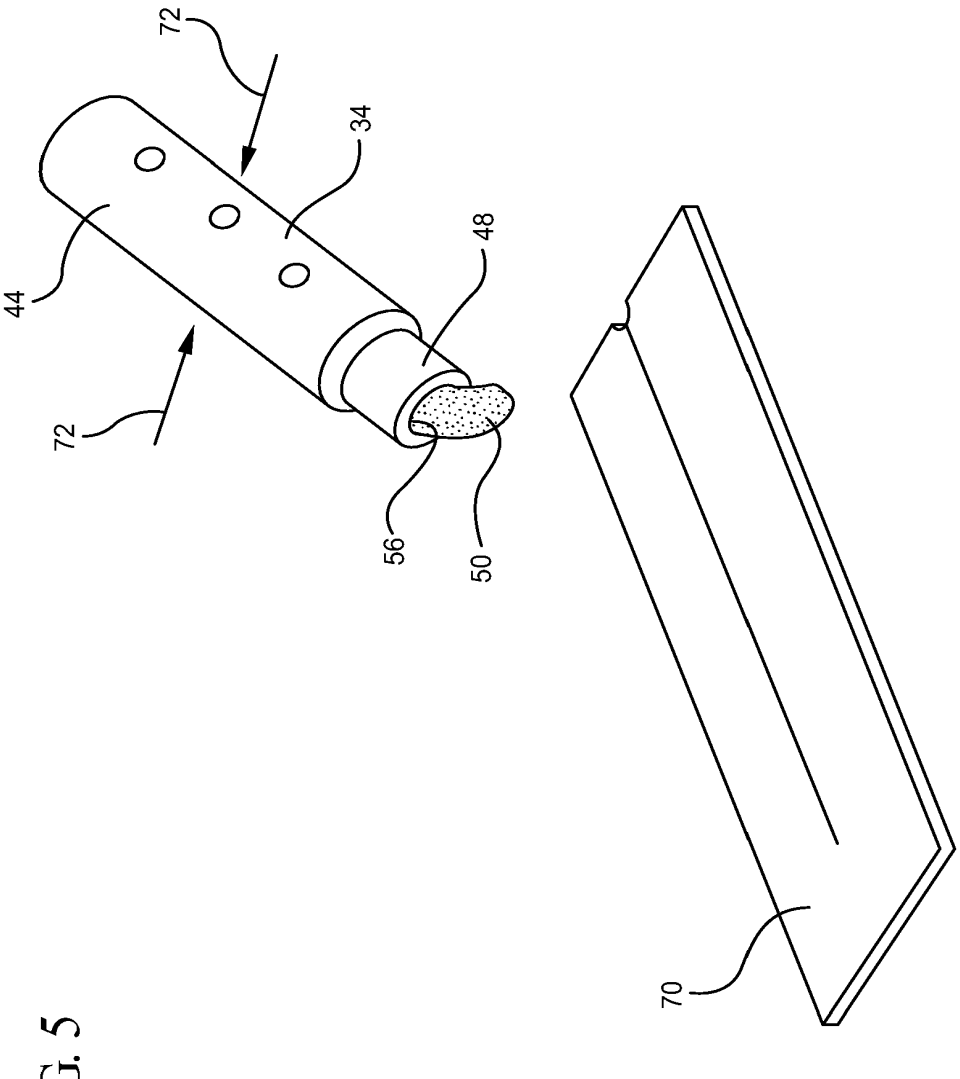


FIG. 5

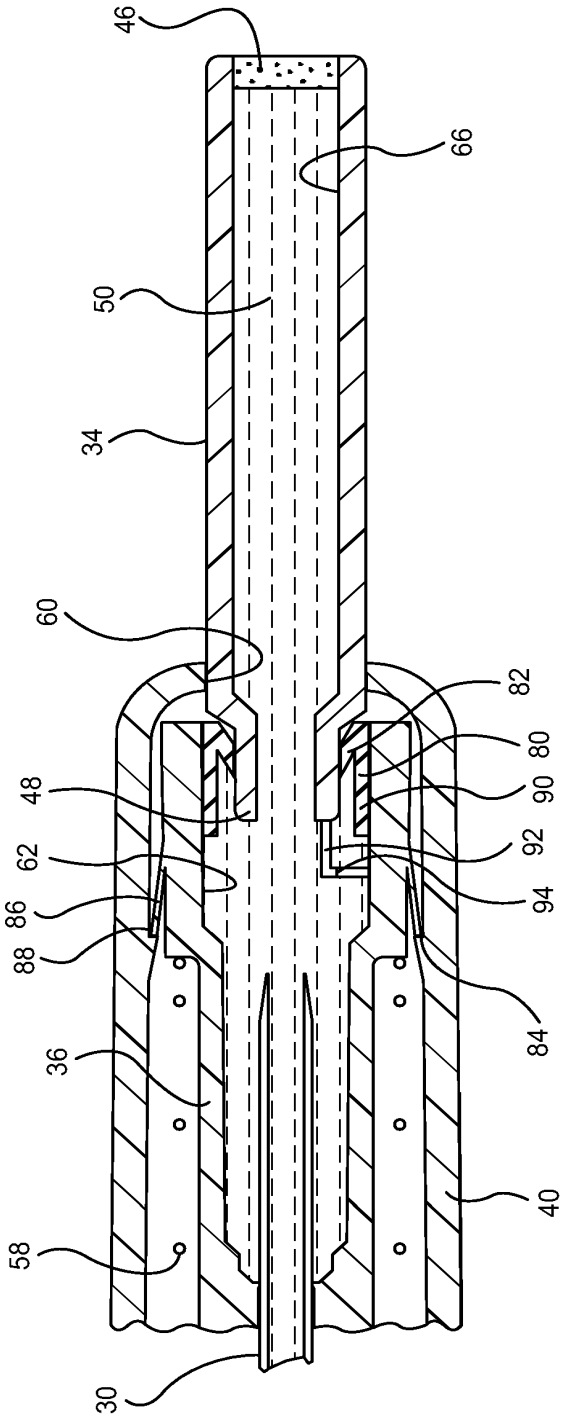


FIG. 6

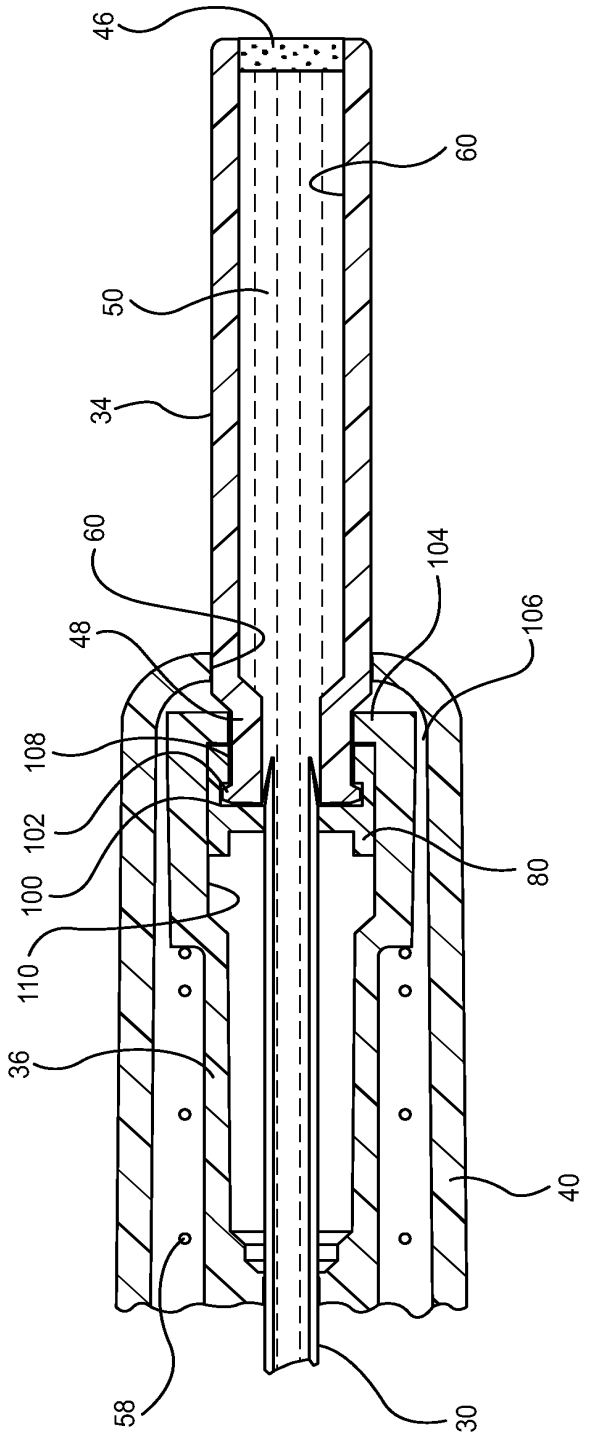


FIG. 7

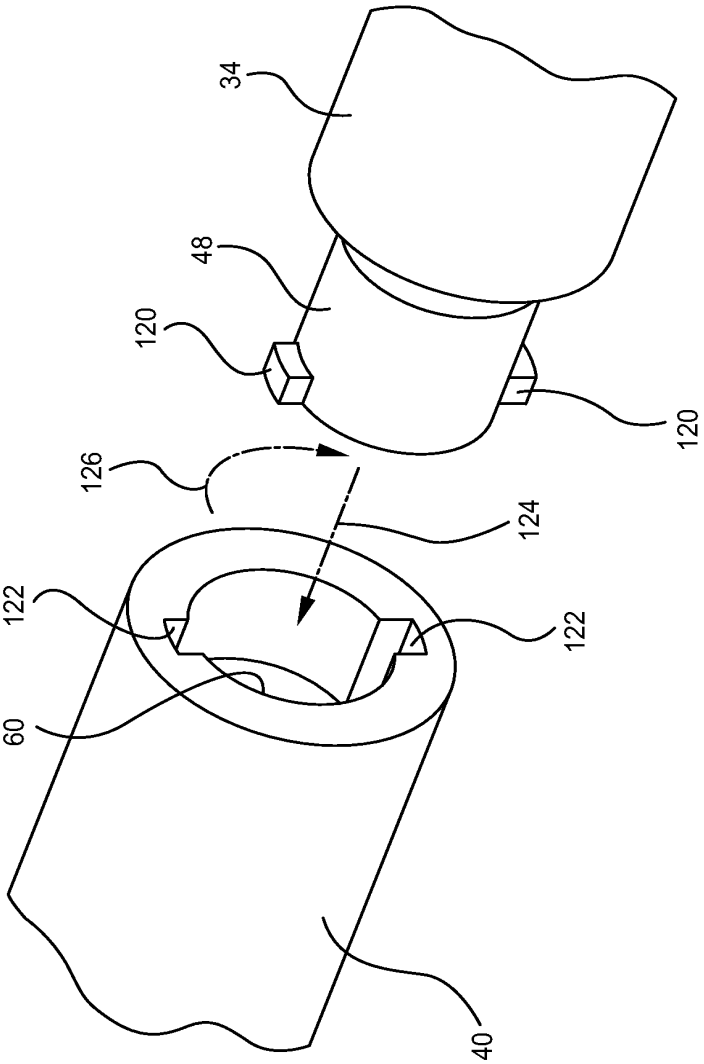


FIG. 8

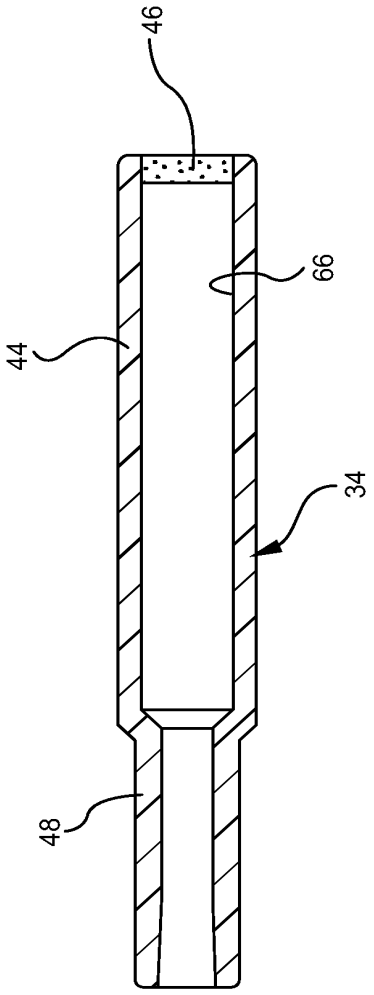


FIG. 9

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2011/043892

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M25/06 A61B5/153
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61M A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 1 884 257 A1 (SHUE MING-JENG [TW]; HUANG DEBORAH [TW]; SHUE PHILLIP [TW]) 6 February 2008 (2008-02-06)	1,2,4-9, 17-20
Y	figures 3, 4, 30-35, 41-46 paragraph [0019] paragraph [0039] - paragraph [0041]	3,10-16
X	WO 01/12254 A1 (BECTON DICKINSON CO [US]) 22 February 2001 (2001-02-22)	1,3-9,17
Y	figures 1-6	3,10-16
A	page 4, line 4 - line 7 page 4, line 10 - page 6, line 16 page 6, line 19 - line 29	2,18-20
A	EP 0 812 601 A2 (BECTON DICKINSON CO [US]) 17 December 1997 (1997-12-17) column 3, line 35 - column 5, line 55; figures 1-6	1-20

-/--

[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
24 August 2011	31/08/2011

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Przykutta, Andreas

Form PCT/ISA/210 (second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2011/043892

Box No. IV Text of the abstract (Continuation of item 5 of the first sheet)

A needle hub (36) and catheter assembly are (20) disclosed herein. The needle hub includes an introducer needle (30) having a lumen extending therethrough. A needle hub is coupled to a proximal end of the introducer needle. A flash chamber (34) is removably coupled to the needle hub or the introducer needle. An interior of the flash chamber is in fluid communication with the lumen of the introducer needle when the flash chamber is coupled to the needle hub or the introducer needle. As such, the flash chamber can collect a sample of blood that can be accessed when the flash chamber is removed. In some instances, the blood can also be dispensed from the flash chamber into a test strip (70) or other testing device.

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2011/043892

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2007/191777 A1 (KING ALAN D [US]) 16 August 2007 (2007-08-16) paragraph [0015] - paragraph [0026]; figures 1-5 -----	1-20

Form PCT/ISA/210 (continuation of second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2011/043892

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP 1884257 A1	06-02-2008	NONE	
WO 0112254 A1	22-02-2001	AU 6537300 A	13-03-2001
		US 6273874 B1	14-08-2001
EP 0812601 A2	17-12-1997	CA 2206215 A1	10-12-1997
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		ES 2327679 T3	02-11-2009
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		WO 2007094841 A1	23-08-2007

J-PlatPat 特許情報プラットフォーム English close

Literature display help

1 / 1 display

Japanese Patent Application Laid-Open No. 58-025146

Registration Gazette public notice Document unit PDF progress information OPD search key URLs

Display format of the document display screen:
text display PDF display
primary literature

bibliography close

(19) [Country of issue] Japan Patent Office (JP)
(12) [Type of publication] Unexamined patent publication (A)
(11) [Publication number] JP-A-58-25146
(43) [Published date] 1983 (1983) February 15
(54) [Title of Invention] Blood vessel puncture display type multi-sample needle assembly
(51) [International Patent Classification 5th edition]
A61B 5/14
[FI]
A61B 5/14
[Request for examination] Yes
[Total number of pages] 9
(21) [Application number] Japanese Patent Application Showa 57-126629
(22) [Filing date] July 20, 1982
(31) [Priority claim number] 284894
(32) [Priority date] July 20, 1981
(33) [Country claiming priority] United States of America (US)
(71) [Applicant]

[Identification number] 999999999
[Name] Becton, Ditzkinson & Company
(72)) [Inventor]
[Name] Josef Kaufmann
(74) [Agent]
[Name] Kyozo Yuasa

wrap up close

(57) [Abstract] Since this gazette is application data before electronic filing, abstract data is n ot recorded.

The scope of the claims open

[Claims]
1. A multi-sample needle assembly capable of recognizing a vascular puncture when collecting blood from a patient, the assembly having a front end, a rear end and an internal chamber, th e chamber being translucent surrounding at least the chamber for user perception. a first pun cture needle in fluid communication with the chamber and extending outwardly from the front end and insertable into the patient; and a first puncture needle in fluid communication with th e chamber and outwardly from the rear end. a second puncture needle extending outward an d penetrating into the vacuum container for blood sample collection; an air permeable blood i mpermeable porous plug positioned within the lumen of a second needle in the space between said transverse holes; and a second puncture. a resilient slidable valve mounted on the outsid e of the needle in a closed position covering at least one of said lateral holes to prevent blood from flowing out of said second puncture needle, said valve being slidable to an open position. means, in the open position, for allowing blood to flow out of a lateral hole near said chamber and return to the second needle through the other lateral hole, whereby blood is collected fro m the second needle; A sample needle assembly with a blood vessel puncture indicator, chara cterized by:
2. 3. The assembly of claim 1, wherein said valve is a sleeve in airtight slidable contact over t he second puncture needle.
3. 3. An assembly as claimed in claim 2, wherein said sleeve covers the lateral hole near said chamber in airtight contact under unforced conditions.
4. 3. The assembly according to claim 2, wherein said sleeve includes an inner diameter porti on that fits over the outer diameter of the second puncture needle and covers at least one of t

he lateral holes in airtight contact.

5. The means for permitting blood flow includes a cavity formed in the sleeve and having a di ameter greater than the fitting diameter, the length of the cavity extending inwardly toward th e trailing end of the sleeve. ToWhen slid, the lateral holes are covered so that blood flows fro m the lateral hole closer to the chamber, through the cavity, back through the other lateral hol e, bypassing the plug, and continuing through the second puncture needle. 5. An assembly as claimed in claim 4 for collecting blood.

6. 6. The assembly of claim 5, wherein the cavity-free portion of said sleeve is compressible a gainst said trailing end during inward sliding of the sleeve.

7. 7. The assembly of claim 6, wherein the compressible portion of the sleeve is a peripheral wall thinner than the portion of the sleeve containing the cavity.

8. 6. An assembly according to claim 2 or 5, wherein said sleeve is made of an elastomeric m aterial.

9. 2. The assembly according to claim 1, wherein said first and second puncture needles are c oupled within said chamber, and both puncture needles communicate with said chamber throu gh a common lateral hole.

10. 3. The assembly of claim 1, wherein said porous plug is made of sintered polyethylene.

11. 2. An assembly according to claim 1, including means for connecting a holder for a vacuu m vessel to said housing.

12. 12. An assembly according to claim 11, comprising a holder for a vacuum vessel connecte d to said housing.

13. A multi-sample needle assembly for collecting a fluid sample from a source, comprising a housing having a chamber therein and a first piercing needle in fluid communication with the chamber for insertion into the fluid source and fluid passing through the chamber. a second pu ncture needle that feeds a collection device through a piercing device; a device mounted withi n the lumen of the second piercing needle that permits gas and liquid to pass through the sec ond piercing needle; and a device for operatively collecting fluid from the second puncture ne edle by diverting the fluid away from the impermeable device.

14. The device for operatively collecting liquid has a lateral hole passing laterally between the second puncture needle liquid flow blocker and the chamber, and is attached to the second pu ncture needle and covers the lateral hole in the closed position. and a resiliently movable valv e that prevents fluid from flowing out of the second puncture needle, and when said valve is moved to an open position, said lateral hole is opened to allow fluid to flow out through said la teral hole. 14. The assembly of claim 13 collected.

15. 14. The assembly according to claim 13, wherein said first and second puncture needles a re integrally formed to form one puncture needle device, and a common lateral hole communi cating with said chamber is provided.

16. A multi-sample needle assembly capable of recognizing a vascular puncture when collectin g blood from a patient, the assembly having a front end, a rear end and an internal chamber

which is translucent to allow the assembly user to view the chamber. a housing; a first piercin g needle in fluid communication with the chamber and extending outwardly from the front end and insertable into a patient; a second puncture needle penetrating into the vacuum container for sample collection; an air permeable blood impermeable porous plug positioned within the l umen of the second puncture needle in the space between the transverse holes; and a sleeve made of elastic slidable elastomer that covers at least one of the lateral holes in air-tight cont act to prevent outflow of blood from the second puncture needle in the stationary mounting p osition, and the inner diameter of the sleeve is the same as that of the second puncture needl e. The airtight contact is caused as a fit on the outer diameter, the sleeve is provided with a c avity having an inner diameter larger than the fitting inner diameter, the cavity is long enough to cover both lateral holes, and the sleeve is directed toward the rear end. Sliding to the open position, the cavity covers both lateral holes, blood flows out from the lateral hole near the ch amber bypassing the plug, enters the cavity, returns through the other lateral hole, and passe s through the second puncture needle. Generating a continuous flow to allow collection, chara cterized in that the non-cavity portion of the sleeve is compressible towards the trailing end w hen the sleeve is slid during collection of blood from the second puncture needle. A multi-sam ple needle assembly with a vessel puncture indicator.

detailed description open —

DETAILED DESCRIPTION OF THE INVENTION

The present invention relates to a needle assembly for collecting fluids from a patient or the li ke, and more particularly to collecting multiple samples of blood from a patient in multiple eva cuated tubes to prevent blood leakage when changing tubes. More particularly, it relates to a needle assembly having a device for indicating that the needle assembly has entered a patien t's blood vessel.

It is now standard practice to collect multiple samples of fluid, such as blood, from a patient i n a single procedure. Once the needle is inserted into the patient's blood vessel, the evacuate d blood collection tube is then inserted into the holder. A holder is configured to connect to th e needle and accommodate the vacuum tube. The needle remains inserted in the patient's ves sel as each filled tube is removed from the holder. Various valves are currently in use to preve nt blood from flowing out of the holder during removal of a filled tube and insertion of the nex t evacuated tube for subsequent sample collection. An elastomeric sleeve surrounding the inn er needle is commonly used as this valve. Although the valve for this multi-sample needle ass embly has the required functionality, various ways to improve this device are being explored. Additionally, it would be desirable to provide a mechanism by which the user of the multi-sam

ple needle assembly can perceive when the intravenous needle has entered the patient's bloo d vessel. Blood flow within the collection device is often minimal due to difficulty in locating th e vessel or other reasons when collecting blood from the patient. In this case, it is most desira ble to be able to rapidly determine that an intravascular insertion is made and blood flows into the needle assembly. When this determination has been made and the endovascular puncture has been performed, an evacuated blood collection container is inserted into the collection de vice during a single collection procedure by well-known techniques for multiple sample collecti on.

A problem that arises during the vascular puncture process is air pockets. This is found in vari ous needle assemblies used for multi-sample blood collection. When a vascular puncture is pe rformed and a vacuum blood collection container has not yet been attached to the other end o f the needle device, pockets of air may prevent blood from flowing into the needle assembly. T hat is, the pocket remains within the needle assembly under steady atmospheric pressure. Th erefore, even if a vascular puncture is performed, venous pressure may not allow blood to flo w through the intravascular needle and into the collection device, and if a vacuum blood conta iner is attached, the vacuum force will be sufficient within the needle assembly. Acts as a forc e of attraction. As recognized by the inventors in US Pat. No. 4,207,870, this air block proble m prevents blood from flowing through the blood immersion needle to a point visible to the us er. The device of this patent combines a porous evacuation device with a bypass valve throug h which air within the needle assembly escapes during the initial stages of the blood collection procedure. This evacuation device prevents the outflow of blood.

Kaufman, U.S. patent application Ser. No. 160.781, entitled "Multi-Sample Needle With Vascul ar Puncture Indicator," filed Jun. 18, 1980, shows a different type of needle device wherein an air-permeable blood-impermeable porosity is present within the actuation valve. use the plug. U.S. Pat. No. 4,207,870 and the Kaufman invention are preferred as a combination one-way v alve and air exclusion device, but are subject to further improvement. The present invention i mproves upon this device so that air is evacuated from the needle assembly and blood can flo w directly into the needle assembly by evacuating the air.

A multi-sample needle assembly according to the present invention is useful for collecting liqui d samples from a liquid supply. The needle assembly has a housing with a chamber and a pun cture needle device in communication with the chamber. The piercing needle device includes a first piercing needle that inserts into a fluid supply and a second piercing needle that delivers f luid through a chamber to a collection device. A device is provided within the lumen of the sec ond puncture needle that allows gas and liquid to pass through the second puncture needle. A device is provided for shunting the liquid flow preventer to the needle assembly to operatively collect liquid from the second puncture needle.

In accordance with a preferred embodiment of the present invention, a housing is provided wi th a front end, a rear end and an interior chamber. The housing surrounds at least the chamb er and is translucent so that a user of the assembly can view the chamber. A first puncture ne

edle extends outwardly from the forward end for insertion into the patient. A second piercing needle extends outwardly from the rear end to be penetrable into an evacuated blood collectio n container for blood sample collection. Two lateral holes are formed in the lateral side of the outward extension of the second puncture needle, and the lateral holes communicate with the lumen of the second puncture needle. An air permeable liquid impermeable porous plug is ins erted into the space between the lateral holes of the lumen of the second puncture needle. A r esilient slidable valve is provided on the outer surface of the second puncture needle to cover one lateral hole in the stationary position of the closed position of the valve to prevent blood f rom flowing out of the second puncture needle. The valve is slidable to an open position, allow ing blood to flow out of a lateral port near the chamber and into a secondMeans are provided f or returning through the lateral hole and blood is collected from the second puncture needle. Structurally, the multi-sample needle assembly of the present invention is significantly differe nt from devices for the same purpose. In particular, the present invention mounts the anti-flo w device directly into the second puncture needle. One or more lateral holes are provided in t he second puncture needle to allow fluid such as blood to bypass the fluid impermeable plug. According to a preferred embodiment, a slidable sleeve valve is associated with the lateral por t to control liquid flow bypassing the liquid impermeable plug. Known devices place liquid-imp ermeable members in the chamber. There are no valves or liquid-impermeable plugs in the ch amber with the configuration of the present invention. Thus, the user can easily see blood ent ering the chamber during the vascular puncture procedure. By using a gas permeable plug me mber in the second puncture needle, air is evacuated from within the assembly as blood enter s the chamber, eliminating the problem of air blocking in the absence of a gas permeable me mber. Of particular advantage, during a multi-sample blood collection procedure, the present i nvention prevents blood leakage during blood collection container changes while the needle as sembly remains inserted into the patient. The present invention provides automatic blood flow control to prevent blood leakage from the chamber after the filled blood collection container is removed from the assembly.

Embodiments and drawings illustrating the invention will now be described. The following desc riptions of various embodiments are illustrative of the principles of the invention and are not i ntended to limit the invention.

FIG. 1 shows a multi-sample needle assembly 10 according to a preferred embodiment of the invention. The basic outer members of needle assembly 10 include a housing 12, a first punct ure needle 14 for insertion into the patient, a second puncture needle 15 at the opposite end of housing 12, and a second puncture needle. The needle punctures the vacuum vessel 16 to collect a blood sample. The housing 12 has a threaded portion 18 adjacent the second piercin g needle 15 to which internal threads 20 at the front end of the container holder 19 are threa ded to attach the holder 19 . The vacuum container 16 is slid into the holder 19 and the secon d puncture needle 15 penetrates the penetrable stopper 21 at the front end of the container 1 6 . Multi-sample blood collection device schemes of the type described above are well known.

2 and 4 show details of the needle assembly 10. FIG. The housing 12 has a front end 24 and a rear end 25, and in the preferred embodiment the ends are manufactured as separate piece s to facilitate replacement of parts and to allow for chambering within the housing. Front end 24 is preferably cylindrical with a large bore extending inwardly through a portion of the body. This hole becomes the chamber 28 in the housing 12 after assembly. A small hole 29 is forme d in the rear end and is sized to fit the puncture needle 14 . The puncture needle 14 is inserte d into the hole 29, the inner end slightly entering the chamber 28 and communicating with th e chamber. The tip of puncture needle 14 protrudes outward from end 25 . After positioning th e puncture needle, it can be secured by adhesive or the like.

The front end 24 of the housing is formed with a number of proximal ribs 31 to surround the o utwardly extending piercing needle. A needle shield, not shown, normally surrounds the outw ard extension of the puncture needle and likewise has internal ribs. Engagement ribs between the needle shield and the needle assembly facilitate the user's insertion and removal of the ne edle assembly into and out of the tube holder. A portion 34 of the front end surrounding the c hamber 18 is smooth and preferably translucent or transparent to allow the user to see inside the housing. In many cases the entire front end and preferably the rear end are also made of translucent or transparent material to facilitate manufacturing and minimize the variety of ma terials used. A translucent rigid synthetic resin is the most preferred material. There may also be various sealed windows, ports, etc. for the user to view into the room. Such a window or p ort is sealed to prevent leakage of blood entering chamber 28 when the needle enters the ves sel. An annular flange 35 is provided at the front end 24 to form a surface for joining the two parts of the housing during assembly. Both portions of the housing are secured using any desi red securing means, such as adhesive.

The rear end 25 is provided with a short projection 36 to give it a generally cylindrical shape. This projecting portion serves as a reinforcing portion for supporting the inner end of the seco nd puncture needle 15 in this embodiment. The end opposite the rear end is formed with exte rnal threads 18 as previously described to provide a connection to the tube holder. A bore 38 extends through the rear end of the housing. the hole is sized to receive the diameter of the s econd puncture needle 15, the inner end 39 of the second puncture needle projecting into the chamber 28;It is in fluid communication with chamber 28 when the front and rear ends are joi ned. The second puncture needle 15 is fixed in the hole 38 with an adhesive or the like. A larg e hole 40 extends a short dimension into rear end 25 and communicates with hole 38 . A slee ve valve 41 is slidable around the outward extension of the second puncture needle 15 . The s leeve valve 41 has a thick wall portion 42, a thin wall portion 42 and a flange 45 at the end of the thin wall portion. The sleeve valve is positioned so that the flange 45 and thin walled porti on slide into the bore 40 and the flange 45 contacts the inner wall of the rear end of the housi ng. Furthermore, a cavity portion 46 is provided in the thick wall portion 42 . The inner diame ter of the sleeve valve 41 is fitted to the outer diameter of the second puncture needle 15 exc ept for the cavity portion. The inner diameter of the cavity 46 is larger than the inner diamete

r of the sleeve and larger than the outer diameter of the puncture needle. Functional differenc es between the two inner diameters will be made clear in the instructions for use below.

As shown in FIG. 4, two holes 48 and 50 are provided in the side wall of the outward extensio n of the second puncture needle 15 . At steady state, the resilient sleeve valve 41 covers the holes 48,50. Both holes can be covered by the tight-fitting inner diameter of the sleeve, but it is preferred to cover only the hole 48 near the chamber in the housing. The sleeve valve 41 m akes an airtight contact over the bore 48 in the steady position. At the same time cavity 46 su rrounds hole 50 and the valve is not in hermetic contact with hole 50 .

A gas-permeable, liquid-impermeable porous member 52 is placed within the lumen 51 of the second puncture needle 15 . In a preferred embodiment, this member is an air permeable, blo od impermeable, porous plug. A plug 52 is placed in the space between holes 48,50. Blood pa ssing through the second puncture needle 15 is therefore blocked by the blood impermeable p roperties of the porous plug 52 and blood does not flow out of the tip of the second puncture needle. The air permeable properties of the porous plug 52 allow air within the chamber 28 an d within the second needle to flow freely and out the tip of the second needle.

An annular flange 54 is provided at the rear end of the housing to facilitate joining the rear an d front ends of the housing. To ensure the required fluid flow within the housing, an elastomer ic ring 55 is interposed between the flanges 35, 54 in the example shown. When assembling t he front and rear ends, the flanges 35, 54 are fixed by a required fixing means such as an ad hesive.

The sleeve valve 41 is compressible toward the rear end 25 when a thin walled portion 44 slid es the valve as described below. The thick walled portion of the sleeve valve 41 has a cavity 4 6 and is not axially compressed like the thin walled portion. Further, the cavity 46 is of a lengt h that communicates both bores 48, 50 together when the sleeve valve is slid inward toward t he rearward end. Various materials can be used to manufacture the sleeve valve, but elastom eric materials are preferred.

For the porous plug 52, a porous material, such as sintered polyethylene, having an average p ore size of about 10 microns.

Before explaining the operation of the present invention, another embodiment of the puncture needle is shown in FIG. In the illustrated example, the multiple sample needle assembly 60 ha s elements similar to those shown in FIG. 2, and has similar characteristics, so that similar ele ments are indicated by the same reference numerals with the suffix a. In the embodiment of FIG. 2, separate front and rear puncture needles are used, but in the example of FIG. 3, a sin gle puncture needle 61, preferably a single puncture needle 61, is passed through the housing 12a. First puncture needle portion 14a extends outwardly from front end 24a. The second pun cture needle portion 15a extends outward from the rear end portion 25a. A common fluid outl et hole 62 is formed in the central portion of the puncture needle 61 and communicates with t he chamber 28a. In the example of FIG. 3, blood flows through the lateral hole 62 and fills th e chamber 28a when the sleeve valve is closed. This provides a visual indication to the user th

at the vascular puncture has been successfully performed.

FIG. 5 shows the needle assembly 10 or 60 of the present invention connected to the multi-sa mple holder 19. FIG. A puncture needle 14 extending from a front end 24 is inserted into the patient P during a vessel puncture procedure. At this time the needle assembly is at steady re st and the sleeve valve is in fluid tight contact over the lateral bore 48 . At steady venous pres sure, blood from the patient is forced into the puncture needle 14 and into the chamber 28 th rough the front end 24 of the housing. Incoming blood expels air that was originally in chamb er 28 through porous plug 52 . Plug 52 is air permeable, blood impermeableis sex. Air exits th e open end of the second puncture needle. Blood flows through the first puncture needle 14 a nd fills the chamber 28 through the internal opening 30 shown in FIG. 2 or the transverse hol e 62 shown in FIG. At least front end 24 or a portion thereof, such as wall 34, is translucent s o that a user of the needle assembly can perceive if blood has entered chamber 28. FIG. If th e user sees blood in the chamber, it is an indication that a vascular puncture has been perfor med. Conversely, if the puncture needle 14 is inserted into the patient and no blood is visible within the chamber 28, this indicates an inadequate vessel puncture. This feature eliminates t he need for the user to attach the evacuated blood collection container to the second punctur e needle 15 in the holder 19 until viewing the vascular puncture indication. Since the blood im permeable plug 52 and the sleeve valve 41 prevent blood flow from the second needle, no blo od will flow from the second needle. When the user is satisfied with the vessel puncture, evac uated blood collection container 16 is slid into holder 19 and second puncture needle 15 penet rates penetrable stopper 21 . This combination is shown in FIG.

FIG. 6 shows the evacuated blood collection container 16 fully inserted into the holder 19, the second puncture needle 15 penetrating the penetrable stopper 21 and the tip entering the blo od collection container ready to supply blood. . A resilient sleeve valve 41 slides along the out er surface of the puncture needle and is compressed against the trailing end 25 when the pun cture needle 15 penetrates the penetrable stopper 21 . An enlarged view of the compressed sl eeve valve 41 is shown in FIG. As shown, the thin walled portion 44 is compressed in an accor dion fashion within the bore 40 and pressed against the rear end of the needle assembly. The thick wall portion 42 is not compressed or folded against it, but simply slides toward the rear end portion 25 . Due to the sliding of the thick wall portion 42, the cavity 46 is above both lat eral holes 48 and 50, and neither hole becomes a liquid impermeable block. As a result, the bl ood in the second puncture needle 15, which was blocked by the blood-impermeable plug 52, is supplied around this obstacle. That is, blood flows through lateral hole 48, cavity 46, and by passes plug 52, as shown in FIG. Blood flows continuously from the cavity through the lateral hole 50 and back into the lumen 51 of the second puncture needle. Blood that exits the open end of the second puncture needle is collected in a blood collection container.

Once blood fills the blood collection container, the filled container is removed from holder 19 w hile needle 14 remains punctured within the patient's blood vessel. Removal of the blood colle ction container simultaneously removes the compressive force against the slidable sleeve 41 a

nd the sleeve slides outward back to the position shown in FIG. This position is the valve close d position and prevents blood from flowing out of the second puncture needle 15 . This sleeve valve movement automatically prevents blood from flowing out of the second puncture needl e. In particular, no blood leakage occurs between exchanges of the evacuated blood collection container. Blood therefore flows from the patient's vessel into chamber 28, the next blood coll ection container is inserted into the holder, and the inward compression movement of the slid able valve is repeated as described above. Once the multi-sample blood collection is complet e, the puncture needle 14 is removed from the patient and the entire needle assembly discard ed.

Various modifications are possible for the present invention. The embodiment shown in Figure s 8 and 9 prevents blood from flowing out of the puncture needle during valve closure and allo ws air to pass through for evacuation purposes. In the embodiment of FIG. 8, the multiple sa mple needle assembly 70 is largely similar to the previous embodiment, except that the pierci ng needle 71 pierces the penetrable stopper 72 of the blood collection container and leaves on ly one side hole 74. prepare. The location of this lateral hole at the puncture needle 71 is signi ficantly away from the rear end 75 of the needle assembly and close to the open end 76 of th e puncture needle. A gas-permeable, liquid-impermeable, porous plug 78 is positioned within the lumen 79 between the transverse bore 74 and the open end 76 . Sleeve valve 80 is subst antially similar to sleeve valve 41 previously described, but is somewhat longer to contact cro ssbore 74 in a fluid impermeable manner. Further, sleeve valve 80 does not require the cavity noted for sleeve valve 41 described above. Furthermore, although the sleeve valve 80 is provi ded with the thick wall portion 81 and the thin wall portion 82 in the illustrated example, this i s a suitable example, and the thickness of the sleeve may be uniform throughout.

When the sleeve 80 is in the closed position of FIG. 8, air in the needle assembly flows throug h the air permeable plug 78 and blood does not pass through the plug. Furthermore, the sleev e 80 effectively closes the lateral hole 74 so that no blood escapes. FIG. 9 shows the compres sed position of sleeve valve 80 and is similar to FIG. Needle 71 penetratesA puncture is made in the possible stopper 72 and the lateral hole 74 is in the blood collection container. The sleev e valve 80 is slid and compressed toward the rear end 75 of the needle assembly. Since the la teral hole 74 is exposed, blood in the lumen 79 flows through the lateral hole 74 directly into t he blood collection container. As shown in FIG. 9, blood bypasses plug 78 and diverts to latera l hole 74 and does not flow out the open end of the puncture needle. Once the blood collectio n container is full, the container is removed from the holder and the sleeve valve 80 is slid ba ck to the position shown in FIG. This prevents blood from flowing out of the puncture needle b etween exchanges of the blood collection container.

As noted above, a multi-sample needle assembly according to the present invention controls t he flow of liquids, such as blood, therethrough. To prevent blood from leaking out of the asse mbly during exchange of blood collection containers between multiple sample collection proce sses. Additionally, the present invention provides a visual indication to the user so that they c

an immediately recognize when the vessel has been punctured for blood collection. The above characteristics contribute to the efficient use of the needle assembly for multiple sample collec tion.

Brief description of the drawing open —

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view of the multiple sample needle assembly, evacuated vessel holder and evacuated blood collection vessel of the present invention used to collect blood from a pat ient; FIG. FIG. 3 is an enlarged cross-sectional view of the multi-sample needle assembly take n along line 2-2, FIG. 3 is an enlarged cross-sectional view showing another embodiment of th e multi-sample needle assembly, and FIG. FIG. 5 is an enlarged cross-sectional view showing the valve portion in a normally closed position for blocking the blood flow of the patient; FIG. FIG. 7 is an enlarged cross-sectional view showing the valve in the open position and blood flo wing through the puncture needle; FIG. 8 is another embodiment of the present invention sho wn in FIG. 4 and FIG. 9 is a sectional view showing a similar valve closed position, and FIG. 9 is a sectional view showing the valve open position of the embodiment of FIG.

Reference Signs List 10 Multi-sample needle assembly

12 Housings

14, 15 Puncture needle

16 Vacuum blood collection container

19 Container holder 24

Front end

25 Rear end

28 Chamber

41 Sleeve valve

42 Thick wall portion

44 Thin Wall portion

46... Cavities

48, 50... Lateral hole

52... Porous plug

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⑤4血管穿刺表示器付き多サンプル針組立体

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明　細　書

1.〔発明の名称〕

血管穿刺表示器付き多サンプル針組立体

2.〔特許請求の範囲〕

1. 患者から血液を収集する時に血管穿刺を認識し得る多サンプル針組立体であつて、前端部と後端部と内部の室とを有し少なくとも室を囲んで半透明として使用者が室を認識し得るようにしたハウジングと、上記室に流体連通し上記前端部から外方に延長して患者内に挿入可能の第1の穿刺針と、上記室に流体連通して上記後端部から外方に延長し血液サンプル収集用の真空容器内に貫通させる第2の穿刺針と、第2の穿刺針の上記外方延長部の側部に形成し第2の穿刺針の内腔に連通させた2個の互に離間した横孔と、第2の穿刺針の内腔内に上記両横孔間のスペースの位置とした空気透過性血液不透過性の多孔性プラグと、第2の穿刺針の外側に取付け閉位置では上記両横孔の少なくとも一方を覆つて血液が第2の穿刺針から流出するのを防ぐ弾性の滑動可能の弁とを備え、上記弁は開位置に滑動可能とし、開位置では血液が上記室に近い横孔から流出して他方の横孔から第2の穿刺針に戻ることを可能にする手段を有し、これによつて血液が第2の穿刺針から収集されることを特徴とする血管穿刺表示器付きサンプル針組立体。

2. 前記弁は気密に滑動可能に第2の穿刺針上に接触するスリーブである特許請求の範囲第1項記載の組立体。

3. 前記スリーブは力を受けない条件で前記室に近い横孔を気密接触によつて覆う特許請求の範囲第2項記載の組立体。

4. 前記スリーブには第2の穿刺針の外径に嵌合して少なくとも一方の横孔を気密接触によつて覆う内径部分を含む特許請求の範囲第2項記載の組立体。

5. 前記血液流を可能にする手段には前記スリーブ内に形成して前記嵌合直径より大きな直径を有するキヤビテイーを含み、上記キヤビテイーの長さは前記スリーブが前記後端部に向けて内方に

滑動した時に前記両横孔を覆うようにし、これによつて血液は上記室に近い横孔から上記キャビティを経て他方の横孔から戻つて前記プラグをバイパスして第2の穿刺針を通る連続流と血液収集とを行なう特許請求の範囲第4項記載の組立体。

6. 前記スリーブのキャビティを含まない一部がスリーブの内方滑動間前記後端部に圧縮可能である特許請求の範囲第5項記載の組立体。

7. 前記スリーブの圧縮可能部分はスリーブのキャビティーを含む部分より薄い周壁である特許請求の範囲第6項記載の組立体。

8. 前記スリーブはエラストマー材料製である特許請求の範囲第2項又は第5項記載の組立体。

9. 前記第1，第2の穿刺針を前記室内で結合し、両穿刺針は上記室に共通横孔によつて連通する特許請求の範囲第1項記載の組立体。

10. 前記多孔性プラグは焼結ポリエチレン製である特許請求の範囲第1項記載の組立体。

11. 前記ハウジングには真空容器用のホルダーを連結する手段を含む特許請求の範囲第1項記載の組立体。

12. 前記ハウジングに連結する真空容器用のホルダを備える特許請求の範囲第11項記載の組立体。

13. 供給源から液サンプルを収集するための多サンプル針組立体であつて、内部に室を有するハウジングと、上記室に流体連通し液供給源内に挿入する第1の穿刺針と液を室を通つて収集装置に供給する第2の穿刺針とを含む穿刺針装置と、第2の穿刺針の内腔内に取付け第2の穿刺針から液を通さずガスを通す装置と、上記液流を通さない装置を離れて液を分流することによつて第2の穿刺針から液を作動的に収集する装置とを備えることを特徴とする多サンプル針組立体。

14. 前記液を作動的に収集する装置には前記第2の穿刺針の液流防止装置と室との間で側面を通す横孔と、第2の穿刺針に取付け閉位置では上記横孔を覆つて液が第2の穿刺針から流出するのを防ぐ弾性の可動の弁とを含み、上記弁が開位置に動いた時は上記横孔を開放して液が横孔を通つて流出して収集される特許請求の範囲第13項記載の組立体。

15. 前記第1，第2の穿刺針を一体形成して1本の穿刺針装置とし、上記室に連通した共通横孔を設ける特許請求の範囲第13項記載の組立体。

16. 患者から血液を収集する時に血管穿刺を認識し得る多サンプル針組立体であつて、前端部と後端部と内部の室とを有し組立体使用者が室を見得るようにした半透明ハウジングと、上記室に流体連通し上記前端部から外方に延長して患者内に挿入可能の第1の穿刺針と、上記室に流体連通して上記後端部から外方に延長し血液サンプル収集用の真空容器内に貫通させる第2の穿刺針と、第2の穿刺針の上記外方延長部の側部に形成し第2の穿刺針の内腔に連通させた2個の互に離間した横孔と、第2の穿刺針の内腔内に上記両横孔間のスペースの位置とした空気透過性血液不透過性の多孔性のプラグと、第2の穿刺針の外面に取付け定常位置では上記両横孔の少なくとも一方を気密接触で覆つて第2の穿刺針から血液の流出を防ぐ弾性滑動可能エラストマー製のスリーブとを備え、上記スリーブの内径を第2の穿刺針の外径に嵌合として上記気密の接触を生じさせ、上記スリーブに上記嵌合内径より大きな内径のキャビティを設け、上記キャビティは両横孔を覆い得る長さとし、上記スリーブは後端部に向けて開位置に滑動して上記キャビティーが両横孔を覆い血液は上記プラグをバイパスとして室に近い横孔から流出してキャビティーに入り他方の横孔を通つて戻り第2の穿刺針を通る連続流を生じて収集を可能にし、上記スリーブのキャビティーを含まない部分を第2の穿刺針からの血液収集間スリーブが滑動した時に後端部に向けて圧縮可能とすることを特徴とする血管穿刺表示器付き多サンプル針組立体。

3.〔発明の詳細な説明〕

本発明は患者等から液を収集する針組立体に関し、特に患者からの血液の複数のサンプルを複数の真空管内に収集し、管を交換する際に血液の漏洩がなく、針組立体が患者の血管内に入つたことを表示する装置を有する針組立体に関する。

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患者から液例えば血液の複数のサンプルを収集する場合に1回の手順で行なうことは現在では標準の手法である。針が患者の血管内に挿入されれば、次に真空血液収集管をホルダーに挿入する。ホルダーは針に接続し、真空管を収容する構成である。各充填した管をホルダーから取外す時に針は患者の血管内に挿入された状態を保つ。充填した管を取外し次のサンプル収集のための次の真空管を挿入する間にホルダーから血液が流出するのを防ぐ各種の弁が現用されている。内側針を囲むエラストマーのスリーブが通常はこの弁として使用される。この多サンプル針組立体用の弁は所要の機能を有するが、この装置の改良のための各種方途が探求されている。

更に、静脈内針が患者の血管に入つた時に多サンプル針組立体の使用者が認識し得る機構を設けることが望ましい。患者から血液を収集する時に血管の位置を探すことの困難又は他の理由によつて収集装置内の血流が最小であることが多い。この場合、血管内挿入が行なわれ、血液が針組立体内に流入することを急速に定め得ることが最も望ましい。この決定が行なわれ、血管内穿刺が行なわれた時に、真空血液収集容器を多サンプル収集の周知の技法によつて1回の収集手順間に収集装置内に挿入する。

血管穿刺過程間に生ずる問題として、空気のポケットがある。これは多サンプル血液収集に使用する各種針組立体に見られる。血管穿刺を行ない、針装置の他端に真空血液収集容器がまだ取付けてない時は、エアのポケットのため血液は針組立体内に流れないことがある。即ち、ポケットは定常大気圧下では針組立体内に残る。それ故、血管穿刺が行なわれていても、静脈圧では血液は血管内針を通つて収集装置内に流入しないことがあり、真空血液収容容器が取付けられれば真空力は針組立体内に十分な吸引力を作用する。米国特許第4.207.870号での発明者の認識では、このエアブロックの問題によつて、血液は使用者の見得る点まで血液内針を流れることを防止される。この特許の装置では多孔性排気装置をバイパス弁に組合せ、針組立体内のエアが血液収集手順の最初の段階で排気装置を通つて流出する。この排気装置は血液の流出を防ぐ。

1980年6月18日出願のカウフマンの米国特許願第160.781号、"血管穿刺表示器付き多サンプル針"には異なる型式の針装置を示し、作動弁内に空気透過血液不透過多孔性プラグを使用する。

米国特許第4.207.870号及びカウフマンの発明は一方弁と空気排除装置との組合せとして好適であるが更に改良の余地がある。本発明はこの装置を改良して空気を針組立体から排出し、血液はエアの排出によつて直に針組立体内に流入可能とするようにする。

本発明による多サンプル針組立体は液供給源から液サンプルを収集するために有効である。この針組立体には室を有するハウジングと、室に連通した穿刺針装置とを有する。この穿刺針装置には液供給源内に挿入する第1の穿刺針と、液を室を経て収集装置に供給する第2の穿刺針とを含む。第2の穿刺針の内腔内に、第2の穿刺針内を液を通さずガスを通す装置を設ける。針組立体に液流防止装置を分流して液を第2の穿刺針から作動的に収集する装置を設ける。

本発明の好適な実施例によつて、ハウジングに前端部と、後端部と、内部の室とを設ける。ハウジングは少なくとも室を囲んで半透明とし、組立体使用者が室を見得るようにする。第1の穿刺針は前端部から外方に延長して患者内に挿入可能とする。第2の穿刺針は後端部から外方に延長して血液サンプル収集用の真空血液収集容器に貫入可能とする。第2の穿刺針の外方延長部の側面に2個の互に離間した横孔を形成し、横孔は第2の穿刺針の内腔に連通させる。第2の穿刺針の内腔の両横孔間のスペースに空気透過性液不透過性の多孔性プラグを挿入する。第2の穿刺針の外面に弾性の滑動可能の弁を設け、弁の閉位置とした定常位置で一方の横孔を覆つて血液が第2の穿刺針から流出するのを防ぐ。この弁は開位置に滑動可能とし、血液が室に近い横孔から流出して第2の

横孔を通つて戻る手段を設け、血液が第２の穿刺針から収集される。

構造的に本発明の多サンプル針組立体は同じ目的の装置とは著しく異なる。特に本発明は液流防止装置を直接第２の穿刺針内に取付ける。第２の穿刺針に１個以上の横孔を設けて、血液等の液は液不透過性プラグをバイパスして流れる。好適な実施例によつて、滑動可能のスリーブ弁を横孔に組合せ、液不透過プラグをバイパスする液流を制御する。既知の装置では液不透過性部材を室内に置く。本発明の構成によつて室内には弁又は液不透過性プラグがない。このため、使用者は血管穿刺手順間に室に流入する血液を容易に見られる。第２の穿刺針内にガス透過性プラグ部材を使用することによつて、血液が室に流入する時に空気は組立体内から排出され、ガス透過性部材がない時のエアブロックの問題は生じない。特に有利な点は、多サンプル血液収集手順間、本発明は血液収集容器交換間に血液の漏洩を防ぎ、この間針組立体は患者に挿入された状態にある。本発明は自動血流制御を行ない、充填した血液収集容器を組立体から外した後に室からの血液漏洩を防ぐ。

本発明を例示とした実施例並びに図面について説明する。以下各種の実施例についての説明は本発明の原理についての例示であり、発明を限定するものではない。

第１図は本発明の好適な実施例による多サンプル針組立体１０を示す。針組立体１０の基本的外側部材にはハウジング１２と、患者内に挿入する第１の穿刺針１４と、ハウジング１２の反対側端部の第２の穿刺針１５とを含み、第２の穿刺針は真空容器１６に穿刺して血液サンプルを収集する。ハウジング１２は第２の穿刺針１５に近接したねじ部１８を有し、容器ホルダー１９の前端の内ねじ２０をねじこんでホルダー１９を取付ける。真空容器１６をホルダー１９内に滑動させ、第２の穿刺針１５は容器１６の前端の貫通可能ストッパ２１を貫通する。上述の型式の多サンプル血液収集装置概要は周知である。

第２，４図は針組立体１０の詳細を示す。ハウジング１２は前端部２４と後端部２５とを有し、好適な例では両端部を別部材として製造し、部品交換を容易にすると共にハウジング内に室を形成するのを可能にする。前端部２４は好適な例では円筒形とし大きな穴部が内方に本体の一部内を延長する。この穴部は組立後にハウジング１２内の室２８となる。後端部内に小さな穴部２９を形成しほゞ穿刺針１４を嵌合する寸法とする。穿刺針１４は穴部２９内に挿入し、内方端は僅に室２８内に入り、室に連通する。穿刺針１４の尖端は端部２５から外方に突出する。穿刺針の位置ぎめ後接着剤等によつて固着できる。

ハウジングの前端部２４に多数の表手方向のリブ３１を形成して外方に延長する穿刺針を囲む。図示しない針シールドが通常穿刺針の外方延長部を囲み、同様に内部リブを有する。針シールドと針組立体との間の係合リブによつて使用者は針組立体を管ホルダーに対する収納取出が容易になる。室１８を囲む前端部の一部３４は平滑で好適な例で半透明又は透明とし、使用者がハウジング内を見得るようにする。多くの場合は前端部全部、できれば後端部も半透明又は透明材料製とし、製造を容易にし、使用材料の種類を最小にする。半透明剛性合成樹脂が最も好適な材料である。使用者が室内を見るための各種のシールした窓、ポート等とすることもできる。この種窓又はポートをシールし、針が血管内に入つた時に室２８に入る血液が漏洩しないようにする。前端部２４に環状フランジ３５を設けてハウジングの２部分を組立に際して接合する面を形成する。所要の固着手段、例えば接着剤等を使用してハウジングの両部分を固着する。

後端部２５には短い突出部３６を設け、ほゞ円筒形とする。この突出部はこの実施例では第２の穿刺針１５の内方端の支持の補強部とする。後端部の反対側端部には外ねじ１８を前述の通りに形成して管ホルダに対する連結装置とする。穴部38がハウジングの後端部内を延長する。この穴部の寸法は第２の穿刺針１５の直径を受ける寸法とし、第２の穿刺針の内方端３９は室２８内に突出し、

前後端部を結合した時に室２８に液連通する。第２の穿刺針１５は穴部３８内に接着剤等によつて固着する。大きな穴部４０が後端部２５内に短い寸法だけ延長し、穴部３８に連通する。第２の穿刺針１５の外方延長部を囲んでスリーブ弁４１を滑動可能とする。スリーブ弁４１は厚壁部４２と薄壁部４２と薄壁部の端部のフランジ４５とを有する。このスリーブ弁はフランジ４５と薄壁部とが穴部４０内に滑動して入り、フランジ４５がハウジングの後端部の内壁に接触する位置とする。更に厚壁部４２にキヤビテイ部４６を設ける。スリーブ弁４１の内径はキヤビテイ部を除いて第２の穿刺針１５の外径に嵌合させる。キヤビテイ46の内径はスリーブの内径より大とし、穿刺針の外径よりも大とする。両内径の機能上の差は後述の使用説明で明らかにする。

第４図に示す通り、第２の穿刺針１５の外方延長部側壁に２個の孔48，50を設ける。弾性スリーブ弁４１の定常条件では孔48，50を覆う。両孔共にスリーブの緊密な嵌合の内径で覆うこともできるがハウジング内の室に近い孔４８のみを覆うのが好適である。スリーブ弁４１は定常位置で孔４８上に気密接触を行なう。同時にキヤビテイ４６は孔５０を囲み、弁は孔５０に対して気密接触でない。

第２の穿刺針１５の内腔５１内にガス透過性液不透過性の多孔性部材５２を置く。好適な例で、この部材は空気透過性血液不透過性の多孔性プラグとする。プラグ５２は孔48，50間のスペースに置く。それ故、第２の穿刺針１５を通る血液は多孔性プラグ５２の血液不透過特性によつて妨害され、第２の穿刺針の尖端から血液が流出しない。多孔性プラグ５２の空気透過特性によつて室２８内及び第２の穿刺針内のエアは自由に流れて第２の穿刺針の尖端から流出する。

ハウジングの後端部と前端部の接合を容易にするために、環状フランジ５４をハウジングの後端部に設ける。ハウジング内の所要の流体流を確実にするために、エラストマーのリング５５を図示の例ではフランジ35，54間に介挿する。前端部と後端部との組合せに際してフランジ35，54を所要の固着手段、例えば接着剤等によつて固着する。

スリーブ弁４１は薄壁部４４が後述する通り弁を滑動させた時に後端部２５に向けて圧縮可能とする。スリーブ弁４１の厚壁部はキヤビテイ46を有し、薄壁部のように軸線方向には圧縮されない。更にキヤビテイ４６はスリーブ弁を後端部に向けて内方に滑動した時に両孔48，50を共に連通する長さとする。スリーブ弁を製造するには各種の材料を使用できるがエラストマー材料が好適である。

多孔性プラグ５２に関しては、多孔性材料、例えば焼結ポリエチレンの平均孔径約１０ミクロンの材料とする。

本発明の作動説明の前に穿刺針の他の実施例を第３図に示す。図示の例では多サンプル針組立体６０は第２図に示したと同様の素子を有し、同様の特性を有するため、同じ符号に添字αを付して同様の素子を示す。第２図の実施例では前後別の穿刺針を使用したが第３図の例では１本の、好適な例では一体の穿刺針６１をハウジング１２α内を貫通させる。第１の穿刺針部分14αは前端部24αから外方に延長させる。第２の穿刺針部15αは後端部25αから外方に延長させる。共通流体出口孔６２は穿刺針６１の中央部に形成して室28αに連通させる。第３図の例では血液は横孔６２を通つてスリーブ弁が閉鎖した時に室28α内に充満する。これによつて使用者は血管穿刺が有効に行なわれたことを知る目視表示となる。

第５図は本発明針組立体１０又は６０が多サンプルホルダー１９に接続された状態を示す。前端部２４から延長する穿刺針１４が血管穿刺手順間に患者P内に挿入される。この時に針組立体は定常静止状態にあり、スリーブ弁は横孔４８上に液不通過接触となる。定常静脈圧では患者からの血液は穿刺針１４内に押出されてハウジングの前端部２４を経て室２８に入る。流入血液は最初に室２８内にあつた空気を多孔性プラグ５２を通つて排出する。プラグ５２は空気透過性、血液不透過

性である。空気は第２の穿刺針の開放端から出る。血液は第１の穿刺針１４を通つて流れ第２図に示す内部開口３０又は第３図に示す横孔６２を経て室２８に充満する。少なくとも前端部２４又はその一部例えば壁部３４が半透明であるため、針組立体の使用者は血液が室２８に流入すれば認識できる。使用者が室内の血液を見れば、血管穿刺が行なわれた表示となる。反対に、穿刺針１４を患者内に穿刺しても室２８内の血液が見えなければ、血管穿刺が不十分であることを示す。この特性によつて、使用者は血管穿刺の表示を見るまではホルダー１９内の第２の穿刺針１５に真空血液収集容器を取付ける必要はない。血液不透過プラグ52とスリーブ弁４１とが第２の穿刺針からの血液流を防ぐため、第２の穿刺針から血液が流れることはない。使用者が血管穿刺に満足すれば、真空血液収集容器１６をホルダー１９内に滑動させて第２の穿刺針１５は貫通可能ストツパ２１を貫通する。この組合せを第６図に示す。

第６図は真空血液収集容器１６をホルダー１９内に完全に挿入し、第２の穿刺針１５は貫通可能ストツパ２１を貫通して先端部が血液収集容器内に入り血液を供給する状態にある。穿刺針１５が貫通可能ストツパ２１を貫通する時に弾性のスリーブ弁４１は穿刺針の外面に沿つて滑動し、後端部２５に圧縮される。圧縮されたスリーブ弁４１の拡大図を第７図に示す。図示の通り、薄壁部44は穴部４０内でアコーデイオン状に圧縮されて針組立体の後端部に押圧される。厚壁部４２はこれに対して圧縮又は畳まれず、単に後端部２５に向けて滑動する。厚壁部４２の滑動によつてキヤピテイー４６は両横孔48，50上となり、何れの孔も液を通さないブロックとならない。この結果、第２の穿刺針１５内の血液は血液不透過性プラグ５２によつてブロックされていたが、この障害物を廻つて供給される。即ち、第７図に示す通り、血液は横孔48，キヤピテイー46を通つて流れ、プラグ５２をバイパスする。血液はキヤピテイーから横孔５０を経て第２の穿刺針の内腔５１に戻つて連続流となる。第２の穿刺針の開放端を流出した血液は血液収集容器内に収集される。

血液が血液収集容器内に充満すれば、充満した容器はホルダー１９から取外し、この間穿刺針14は患者の血管内に穿刺された状態を保つ。血液収集容器を取外せば同時に滑動可能スリーブ４１に対する圧縮力もなくなり、スリーブは外方に滑動して第４図の位置に戻る。この位置は弁閉鎖位置であり、第２の穿刺針１５からの血液流出を防ぐ。このスリーブ弁の動きは自動的に血液が第２の穿刺針から流出するのを防ぐ。特に真空血液収集容器の交換間は血液の漏洩が生ずることはない。それ故、血液は患者の血管から室２８に流れ、次の血液収集容器がホルダーに挿入され、滑動可能の弁の内方圧縮運動が上述の通りに繰返される。多サンプル血液の収集が終れば、穿刺針１４を患者から取外し、全部の針組立体を廃棄する。

本発明は各種の変型が可能である。第８，９図に示す実施例は弁閉鎖の間は穿刺針からの血液の流出を防ぎ、空気は通過して排気目的を達する。第８図の実施例では多サンプル針組立体７０は大部分前の実施例と同様であるが、穿刺針７１は血液収集容器の貫通可能ストツパ７２を穿刺し、１個のみの横孔７４を設ける。この横孔の穿刺針71での位置は針組立体の後端部７５から著しく離れ、穿刺針の開放端７６に近い。ガス透過性液不透過性の多孔性プラグ７８を内腔７９内の横孔７４と開放端７６との間とする。スリーブ弁８０は前述のスリーブ弁４１とほゞ同様であるがいくらか長くして横孔７４を液不通過に接触する。更にスリーブ弁８０には前述のスリーブ弁４１に記したキヤピテイーを必要としない。更に、スリーブ弁80は図示の例では厚壁部８１と薄壁部８２とを設けたが、好適な例示であり、スリーブの厚さは全体を均等とすることもできる。

スリーブ８０が第８図の位置即ち閉位置にある時は針組立体内のエアは空気透過性プラグ７８を通つて流れ、血液はプラグを通らない。更に、スリーブ８０が有効に横孔７４を閉鎖するため、血液は流出しない。第９図はスリーブ弁８０の圧縮位置を示し、第７図と同様である。針７１は貫通

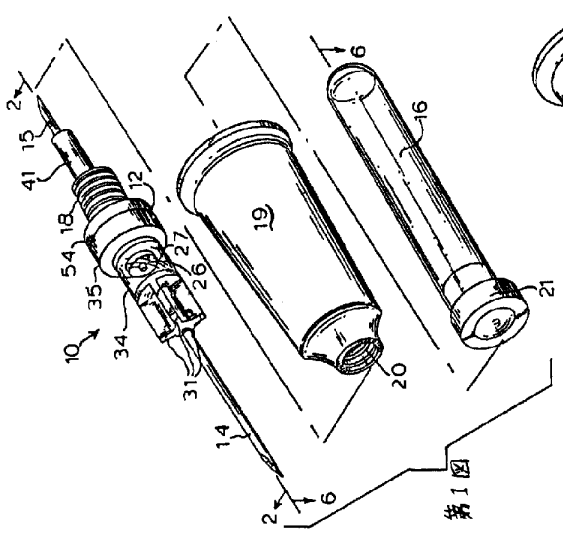
可能ストッパ７２内に穿刺し、横孔７４は血液収集容器内にある。スリーブ弁８０は滑動して針組立体の後端部７５に向けて圧縮される。横孔７４が露出したため、内腔７９内の血液は横孔７４を通つて直接血液収集容器内に流出する。第９図に示す通り、血液はプラグ７８を通らずに分流して横孔７４に流れ、穿刺針の開放端からは流れない。血液収集容器が充満すれば容器はホルダーから取外し、スリーブ弁８０は滑動して第８図に示す位置に戻る。これによつて血液収集容器の交換間に血液が穿刺針から流出するのを防ぐ。

上述した通り、本発明による多サンプル針組立体は中を通る血液等の液の流れを制御する。多サンプル収集過程間の血液収集容器の交換の間に血液が組立体外に漏洩するのを防ぐ。更に、本発明は使用者に対する目視表示を行ない、血液収集のために血管内に穿刺された時に直に認識し得る。上述の特性は針組立体を多サンプル収集用として有効に使用するために貢献する。

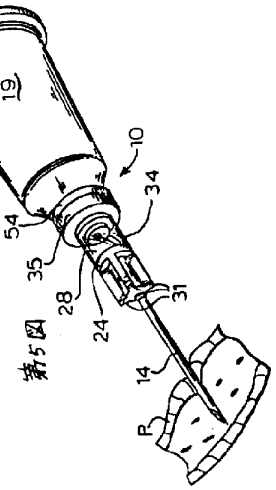
4.〔図面の簡単な説明〕

第１図は本発明の多サンプル針組立体と真空容器のホルダーと真空血液収集容器とを患者からの血液収集に使用する斜視図、第２図は第１図の２－２線に沿う多サンプル針組立体の拡大断面図、第３図は多サンプル針組立体の他の実施例を示す拡大断面図、第４図は第２図又は第３図の実施例の血流を遮断する定常閉位置とした弁部分を示す拡大断面図、第５図はホルダを連結した針組立体を患者に穿刺した斜視図、第６図は第１図の６－６線に沿い各部の使用間の組立状態を示す断面図、第７図は弁が開位置であり血液が穿刺針を流れる拡大断面図、第８図は本発明の別の実施例の第４図と同様の弁閉鎖位置を示す断面図、第９図は第８図の実施例の弁開位置を示す断面図である。

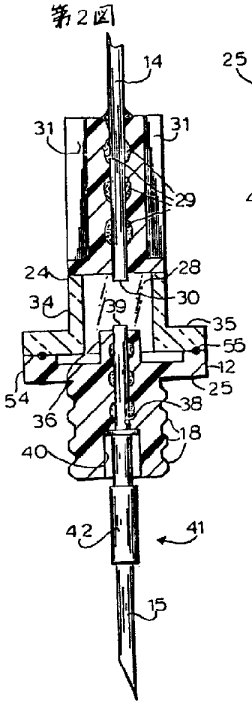
１０ … 多サンプル針組立体
１２ … ハウジング
１４，１５ … 穿刺針
１６ … 真空血液収集容器
１９ … 容器ホルダー
２４ … 前端部
２５ … 後端部
２８ … 室
４１ … スリーブ弁
４２ … 厚壁部
４４ … 薄壁部
４６ … キャビティー
４８，５０ … 横孔
５２ … 多孔性プラグ



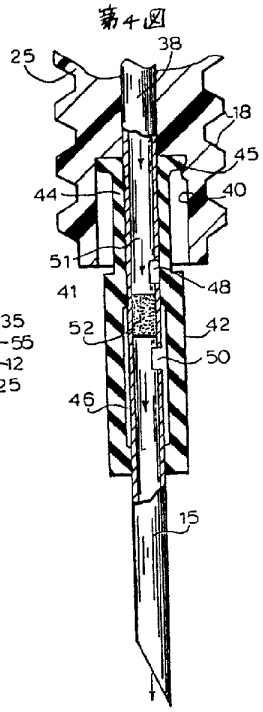
第1図



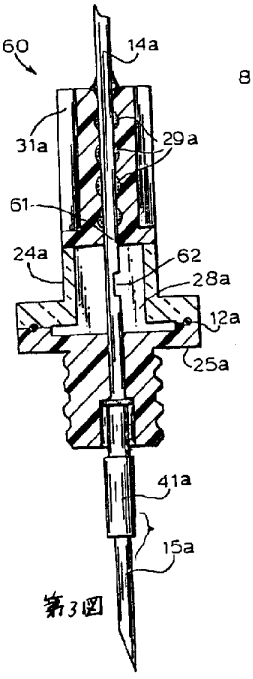
第5図



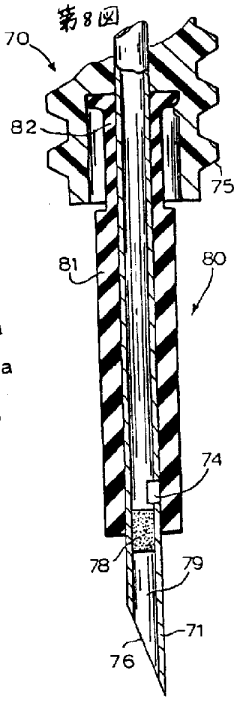
第2図



第4図

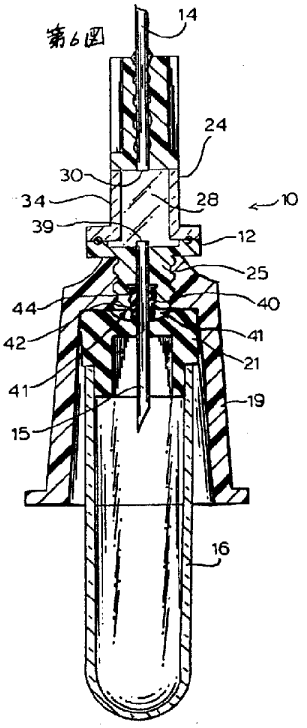


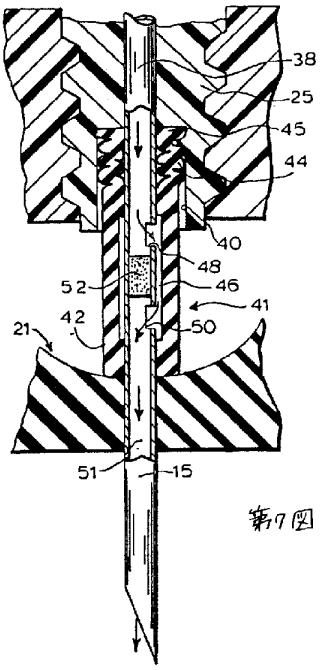
第3図



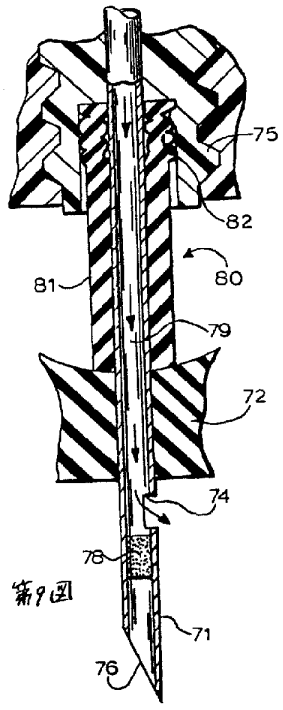
第8図

第6図


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第7図


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第9図

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wrap up close

(57) [Summary]
An apparatus includes a pre-sample reservoir, a flow dividing mechanism and a flow meterin g mechanism. The flow diverting mechanism includes an inlet port couplable to the lumen-defi ning device to receive bodily fluid from the patient, a first outlet port fluidly couplable to the p re-sample reservoir, and a second outlet port fluidly couplable to the sample reservoir. and an exit port. The flow diverter mechanism defines a first fluid flow path and a second fluid flow p ath configured to place the first outlet port and the second outlet port in fluid communication with the inlet port, respectively. The flow metering mechanism meters flow of a predetermine d volume of bodily fluid through the first fluid flow path to the pre-sample reservoir, meters fl ow of a second volume of bodily fluid through the second fluid flow path to the sample reserv oir, It is configured to display a volume indicator associated with the volume and the second v olume.
[Selection drawing] Fig. 2

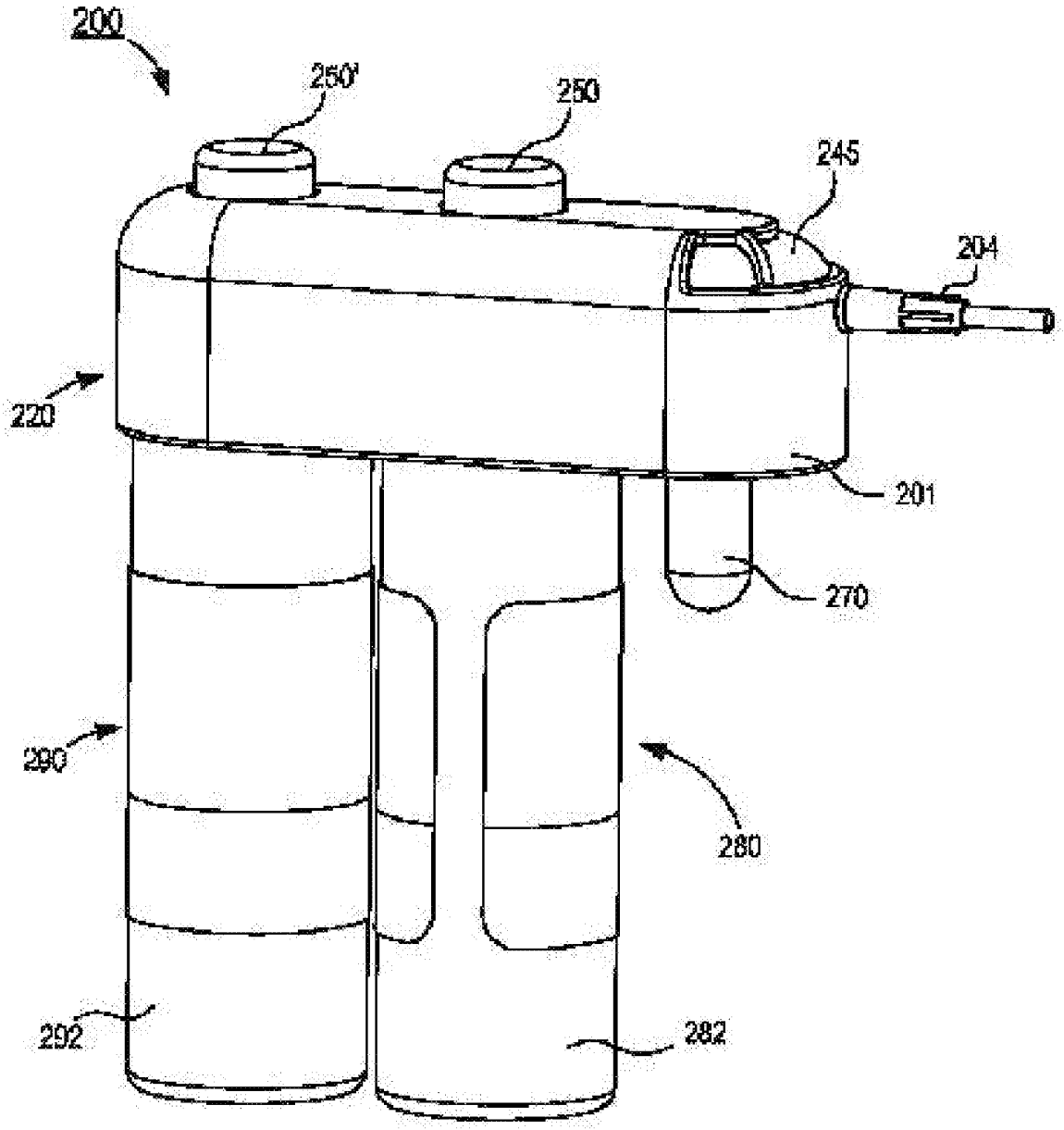


FIG. 2

The scope of the claims open

1. An apparatus for
obtaining a bodily fluid sample from a patient, comprising a
pre-sample reservoir configured to receive a first volume of bodily fluid withdrawn from the

patient; an

inlet port; A flow diverting mechanism including an outlet port and a second outlet port, whe rein the inlet port is configured to be coupled to a lumen defining device to receive bodily fluid from a patient, and the first outlet port is connected to the flow diverting mechanism. and the second outlet port is configured to fluidly couple the sample reservoir to the flow diverting me chanism, the flow diverting mechanism configured to fluidly couple the pre-sample reservoir t o the first outlet port. a first fluid flow path configured to place a in fluid communication with t he inlet port; and a second fluid flow path configured to place the second outlet port in fluid c ommunication with the inlet port. and a flow metering mechanism in fluid communication with

said first fluid flow path and said second fluid flow path, wherein a first volume of bodily fluid passes through said first fluid flow path. configured to meter flow into a pre-sample reservoir and meter flow of a second volume of bodily fluid through said second fluid flow path into said sample reservoir; and a flow metering mechanism configured to display an associated volume indicator.

2. A

first volume of said bodily fluid flows in said first fluid flow path during a first period of time, and a second volume of said bodily fluid flows in said second volume of fluid during a second period of time after said first period of time. 2. The device of claim 1, which flows in a two-flui d flow path.

3. The apparatus of claim

1, wherein the first volume of bodily fluid comprises contaminants present on the skin and t he second volume of bodily fluid is substantially free of contaminants present on the skin. .

4.

The apparatus of claim 1, wherein said pre-sample reservoir is at least partially defined by a portion of said flow divider mechanism.

5.

The apparatus of claim 1, wherein said volume indicator is a visual indicator.

6.

The flow diverting mechanism includes a moveable member configured to move through the second outlet port to place the sample reservoir in fluid communication with the second fluid f low path. Item 1. The device according to item 1.

7.

The apparatus of claim 6, wherein said flow metering mechanism is at least partially dispose d within a portion of said movable member.

8. The

flow diverting mechanism fluidly isolates the pre-sample reservoir and at least a portion of t he first fluid flow path when the first volume of blood is disposed within the pre-sample reserv oir. 2. The device of claim 1, wherein the device comprises:

9.

The flow diverter mechanism includes a third outlet port configured to fluidly couple a secon d sample reservoir to the flow diverter mechanism, the third outlet port being in fluid commun ication with the inlet port. 2. The device of claim 1, defining a third fluid flow path configured t o be positioned in the .

10.

A flow controller defining a first lumen and a second lumen, the first configuration placing th e first fluid flow path in fluid communication with the inlet port. and a second configuration in which the second lumen places the second fluid flow path in fluid communication with the inle t port, further comprising a flow controller configured to move between Apparatus as describe d.

11. The method of claim 10,

wherein the flow controller is configured to move from the first configuration to the second c onfiguration after the first volume of bodily fluid is placed in the pre-sample reservoir. Apparat us as described.

12.

An apparatus for obtaining a bodily fluid sample from a patient, comprising a

pre-sample reservoir configured to receive a first volume of bodily fluid withdrawn from the patient, an

inlet port, a first outlet port and a second outlet. A flow diverting mechanism comprising a p ort, wherein the inlet port is configured to be coupled to a lumen defining device to receive bo dily fluid from a patient, and the first outlet port directs the pre-sample reservoir to the flow d iverting mechanism. a flow diverting mechanism configured for fluid coupling, wherein the sec ond outlet port is configured to fluidly couple a sample reservoir to the flow diverting mechani sm; and a flow diverting mechanism disposed at least partially within the flow diverting mech anism

. a flow controller, wherein the flow controller defines at least a portion of a fluid flow path b etween the inlet port and the first outlet port in a first configuration; a flow controller configur ed to move between a second configuration defining at least a portion of a fluid flow path bet ween the port;

a first configuration of a movable member movably coupled to the flow diverting mechanism, wherein the sample reservoir is fluidly isolated from a fluid flow path between the inlet port a nd the second outlet port; a reservoir configured to move through the second outlet port betw een a second configuration in fluid communication with the fluid flow path between the inlet p ort and the second outlet port, the sample reservoir a movable member configured to receive a second volume of bodily fluid withdrawn from the patient when the flow controller is in its se cond configuration and the movable member is in its second configuration.

13. The apparatus of claim 12,

wherein the first volume of bodily fluid comprises contaminants present on the skin and the second volume of bodily fluid is substantially free of contaminants present on the skin. .

14.

The apparatus of claim 12, wherein the flow controller rotates between its first configuration and its second configuration relative to the flow diverter mechanism.

15.

The apparatus of claim 12, wherein said flow controller moves in linear motion relative to sai d flow diverter mechanism.

16. The apparatus of claim 12,

wherein the flow controller is configured to fluidly isolate the pre-sample reservoir when in it s second configuration.

17.

The apparatus of claim 12, wherein said movable member includes a piercing member config ured to pierce a portion of said sample reservoir when in its second configuration.

18. The apparatus of claim 12

, wherein said movable member is coupled to a biasing member configured to at least tempo rarily maintain said movable member in its first configuration.

19.

The apparatus of claim 12, wherein said flow diverter mechanism includes a third outlet port configured to fluidly couple a second sample reservoir to said flow diverter mechanism.

20. The

movable member is a first movable member, the device

is a second movable member, and the second sample reservoir is defined between the inlet p ort and the third outlet port. a first configuration fluidly isolated from the fluid flow path; and the second sample.

a reservoir configured to move through the third outlet port between a second configuration in fluid communication with the fluid flow path defined between the inlet port and the third outle t port; A second movable member configured to receive a third volume of bodily fluid withdra wn from the patient when the flow controller is in its second configuration and the second mo vable member is in its second configuration. 20. The device of Claim 19, further comprising a member.

21.

An apparatus for obtaining a bodily fluid sample from a patient, the

flow diverting mechanism comprising a pre-sample reservoir configured to receive a first vol ume of bodily fluid withdrawn from the patient, a

housing and a distribution member. said housing defining a first opening and a second openi ng, said first opening being in fluid communication with said pre-sample reservoir, said distrib ution member being disposed at least partially within said housing; and defining a fluid flow p ath in fluid communication with the second opening, wherein the distribution member is confi gured to be in fluid communication with the flow path and physically and fluidly coupled to a s ample reservoir. and an

inlet port configured to be coupled to a lumen-defining device to receive bodily fluid from the patient, the flow controller being rotatably coupled to the flow diversion mechanism, and a flo w controller configured to move between a first configuration in which the inlet port is in fluid communication with the first opening and a second configuration in which the inlet port is in fl uid communication with the second opening; Equipment to equip.

22. The apparatus of claim 21,

wherein the first volume of bodily fluid comprises contaminants present on the skin and the second volume of bodily fluid is substantially free of contaminants present on the skin. .

[Claim 23]

22. The apparatus of claim 21, wherein said pre-sample reservoir is at least partially defined by a portion of said distribution member.

24. The method of claim 21,

wherein the coupling portion includes a piercing member configured to pierce a portion of th e sample reservoir to place the sample reservoir in fluid communication with the fluid flow pat h. Apparatus as described.

25. Said

piercing of said portion of said sample reservoir by said piercing member causes bodily fluids from said patient to enter said sample reservoir through said inlet port and said flow path whe n said flow controller is in its second configuration. 25. The device of claim 24, which initiates inward flow.

26.

The first volume of bodily fluid is a first predetermined volume of bodily fluid, the fluid flow p ath is configured to receive a second predetermined volume of bodily fluid, and the second pr edetermined volume of bodily fluid is a sample volume. 22. Apparatus according to claim 21, r elated to volume.

27.

The apparatus of claim 26, wherein said sample volume is between about 10 milliliters and a bout 50 milliliters.

28.

The apparatus of claim 26, wherein said sample volume is approximately 30 milliliters.

[Claim 29]

said flow diverter mechanism including a seal member, said seal member forming a substant ially fluid tight seal with a surface of said flow controller and a surface of said housing when s aid flow controller is coupled to said flow diverter mechanism; Disposed between the housing and the flow controller, the seal member defines a first opening and a second opening, the firs t opening of the seal member substantially flush with the first opening of the housing. and wh erein said second opening of said seal member is substantially coaxial with said second openi ng of said housing.

The apparatus described in .

30.

A method of obtaining a predetermined sample volume of bodily fluid from a patient using a flow metering transfer device, wherein the flow metering transfer device is selectively placed i n fluid communication with a pre-sample reservoir and a sample reservoir. and a flow meterin g mechanism configured to meter the flow of bodily fluid from the patient to the pre-sample r eservoir and to the sample reservoir; A method comprising: establishing fluid communication between the patient

and the port of the flow metering transfer device; establishing fluid communication between the

port and the pre-sample reservoir;

metering a flow of bodily fluid transferred to a pre-sample reservoir; and

via said flow metering mechanism of said flow metering transfer device, a pre-sample volum e of bodily fluid disposed within said pre-sample reservoir to a predetermined pre-sample of b odily fluid.

fluidly isolating the pre-sample reservoir from the port to confine a pre-sample volume of th e bodily fluid within the pre-sample reservoir

; metering

a flow of bodily fluid transferred from the patient to the sample reservoir; and

via the flow metering mechanism of the flow metering transfer device disposed within the sa mple reservoir. and C. verifying that the obtained sample volume of bodily fluid is a predeterm ined sample volume of bodily fluid.

[Claim 31]

The flow metering transfer device has a first configuration in which fluid communication is es tablished between the patient and the pre-sample reservoir, and a second configuration in whi ch fluid communication is established between the patient and the sample reservoir. 31. The method of claim 30, including a flow controller configured to move between.

32.

The method of claim 30, wherein said bodily fluid is blood.

33. The method of claim 32

, wherein the sample reservoir comprises at least one of an aerobe medium or an anaerobe medium.

34.

The method of claim 30, wherein said predetermined pre-sample volume is between about 1 milliliter and about 10 milliliters.

35.

The method of claim 30, wherein said predetermined sample volume is between about 20 mi lliliters and about 60 milliliters.

36.

The method of claim 30, wherein said predetermined sample volume is approximately 60 mil

liliters.

37. verified that

said sample reservoir is a first sample reservoir, said sample volume is a first sample volum e, and said first sample volume within said first sample reservoir is said predetermined sampl e volume;

subsequently establishing fluid communication between the port and a second sample reservo ir;

metering the flow of bodily fluid transferred from the patient to the second sample reservoir ; verifying, via a metering mechanism, that a second sample volume of bodily fluid disposed within the second sample reservoir is the predetermined sample volume of bodily fluid;

31. The method of claim 30, further comprising:

38. The method of claim 37, wherein

said first sample volume and said second sample volume collectively equal between about 2 0 milliliters and about 60 milliliters.

39.

After verifying that said second sample volume in said second sample reservoir is said prede termined sample volume, establishing fluid communication between said port and a third sam ple reservoir

; metering a flow of bodily fluid transferred from a patient to said third sample reservoir; an d a third sample volume of bodily fluid

disposed within said third sample reservoir via said flow metering mechanism of said flow m etering transfer device. 38. The method of claim 37, further comprising verifying that is the pr edetermined sample volume of bodily fluid.

40.

The method of claim 39, wherein said first sample volume, said second sample volume and s aid third sample volume collectively equal between about 30 milliliters and about 60 milliliter s.

41.

The method of claim 39, wherein said first sample volume, said second sample volume and s aid third sample volume collectively equal approximately 60 milliliters.

detailed description open —

Description: CROSS-REFERENCE TO RELATED APPLICATIONS

[

1001] This application is entitled "Sterile Bodily-Fluid Collection Device and Method", filed De

c. 4, 2012. and Methods),” the disclosure of which is hereby incorporated by reference in its e ntirety. [1002] Embodiments described herein relate generally to the parenteral procurement of bodily fluid samples, and more particularly to microbial or other external sources of bodily f luids, such as those present on the skin. Devices and methods for obtaining bodily fluid sampl es parenterally with reduced contamination from contaminants. BACKGROUND ART [0003]

[1003] Health care practitioners routinely perform various types of microbiological tests on pa tients using parenterally obtained bodily fluids. In some cases, a patient sample (eg, bodily flu id) is tested for the presence of one or more potentially unwanted microorganisms, such as ba cteria, fungi or yeast (eg, Candida). Microbial testing may involve culturing patient samples in one or more sterile containers containing media that promote microbial growth, real-time diag nostics and/or molecular PCR-based techniques. Generally, when such microorganisms are pre sent in a patient sample, they will multiply in the culture medium over time. After a variable a mount of time (eg, hours to days), automated continuous monitoring can detect organism gro wth. Such automated monitoring can detect carbon dioxide produced by the growth of organis ms. The medium can then be tested for the presence of microorganisms. The presence of mic roorganisms in the medium indicates the presence of the same microorganisms in the patient sample, which in turn indicates the presence of the same microorganisms in the patient's bodi ly fluid from which the sample was obtained. Therefore, if it is determined that microorganism s are present in the culture medium, the patient is administered one or more antibiotics or ot her treatments specifically designed to treat or otherwise eliminate the undesirable microorga nisms from the patient. may be prescribed.

[0004]

[1004] However, patient samples can be contaminated during acquisition and/or otherwise pr one to false positive results. One process by which contamination of patient samples can occu r is microbes from the body surface (e.g., microbes present on the skin) that are removed dur ing needle insertion into the patient's body and subsequently transferred to the culture mediu m with the patient sample.) by transfer. Surface microbes and/or other unwanted external mi crobes may be removed either directly or through removed tissue debris, hair follicles, sweat glands and other skin appendage structures. Another possible source of contamination comes from the person who draws the patient sample. For example, doctors, phlebotomists, nurses, etc. may transfer contaminants from their bodies (eg, fingers, arms, etc.) to patient samples and/or to equipment containing patient samples. To further elaborate, the instruments and/or devices used during the patient sample acquisition process (e.g., patient to needle, needle/tu

be to sample container, etc.) can each introduce potential points of contamination. It often co ntains multiple fluid interfaces. Use of such instruments and/or devices typically involves man ual intervention to connect and/or fluidly couple various interfaces. Because these interfaces a re pre-assembled and non-sterilized as a single, fluidly coupled system, the user (e.g., physici an, phlebotomist, etc.) and/or other sources of contamination (e.g., ambient air, hospital roo m contaminants on table and counter surfaces, microorganisms transferred from linens or clot hing, etc.) may be introduced into the patient sample. In some cases, these contaminants can grow in the culture medium and ultimately result in a positive microbial test result, thereby fal sely indicating the presence of such organisms in the body.

[0005]

[1005] In some cases, false positive and/or false negative results may result from a given vol ume of patient sample. For example, by overfilling volume-sensitive blood culture bottles, as noted in the instructions for use and/or warning labels from the manufacturers of such culture bottles and associated automated continuous monitoring microbial detection systems, can lea d to false positive results. On the other hand, as another example, insufficient patient sample volume in culture medium can lead to false negative results. As an example, in a study condu cted by the Mayo Clinic entitled "Optimized Pathogen Detection with 30- Compared to 20-Millil iter Blood Culture Draws", published in the December 2011 issue of the Journal of Clinical Micr obiology, 20 milliliters (mL) of A patient sample volume allows detection of the presence of ap proximately 80% of bacteremia present in a patient sample, a patient sample volume of 40 m L allows detection of approximately 88% of bacteremia, and a patient sample volume of 60 m L allows detection of approximately 88% of bacteremia. Approximately 99% of bacteremia ca n be detected by sample volume.

[0006]

[1006] Such inaccurate results as a result of contamination, insufficient patient sample volum e, etc. are a problem when trying to diagnose or treat a suspected disease or condition. For e xample, a false negative result from a microbiological test can lead to misdiagnosis and/or del ay in treatment of a patient's illness, which in some cases can lead to death of the patient. Co nversely, a false-positive result from a microbiological test can lead to the patient receiving on e or more antimicrobial therapies unnecessarily, thereby causing serious side effects in the pa tient, including death, for example. Together, this can result in unnecessary burden and expen se to the health care system due to prolonged hospitalization of the patient and/or other com plications associated with the wrong treatment. In addition, the use of diagnostic imaging equ ipment due to these false positive results also increases the cost and unnecessary exposure of high doses of radiation associated with various imaging procedures (e.g., CT scans) to long-te rm patient health. It is also problematic from a patient safety perspective, as it has many kno wn adverse effects.

[1007

] Thus, for example, reducing microbial contamination in bodily fluid test samples by minimizi

ng exposure to non-sterile conditions and/or other external sources of contamination around patient samples and/or fluid interfaces. There is a need for a sterile "one-piece" bodily fluid co llection device and method. Further, such fluid collection devices provide visual, calculated, or must include means for accurately weighing, measuring, and/or otherwise assessing body flui ds transferred from the patient to the sample reservoir or culture medium, which can be other wise communicated. It is

SUMMARY OF THE INVENTION [

1008

] The present invention provides a non-toxic method for treating a body fluid sample by reduc ing contamination from microorganisms external to the body fluid source, such as microorgani sms present on the skin and/or other undesirable external contaminants. An orally acquired d evice is described. In some embodiments, a device for obtaining a bodily fluid sample from a patient includes a pre-sample reservoir, a flow diversion mechanism and a flow metering mec hanism. The pre-sample reservoir is configured to receive a first volume of bodily fluid withdra wn from the patient. The flow diverting mechanism includes an inlet port, a first outlet port an d a second outlet port and defines a first fluid flow path and a second fluid flow path. An inlet port can be coupled to the lumen-defining device to receive bodily fluid from the patient. A fir st outlet port and a second outlet port are configured to fluidly couple the pre-sample reservoi r and the sample reservoir, respectively, to the flow diverting mechanism. The first fluid flow p ath is configured to place the first outlet port in fluid communication with the inlet port and th e second fluid flow path is configured to place the second outlet port in fluid communication w ith the inlet port. is configured to A flow metering mechanism is in fluid communication with t he first fluid flow path and the second fluid flow path. A flow metering mechanism meters a fl ow of a first volume of bodily fluid through the first fluid flow path into the pre-sample reservo ir and a second volume of bodily fluid through the second fluid flow path into the sample reser voir. is configured to The flow metering mechanism is configured to display volume indicators associated with the first volume and the second volume.

BRIEF DESCRIPTION OF THE DRAWINGS

[0009]

FIG. 1 is a schematic diagram of a bodily fluid collection device according to an embodiment; 2 is a perspective view of a bodily fluid collection device according to an embodiment; FIG. 3 is an exploded perspective view of the bodily fluid collection device of FIG. 2; FIG. 4 is a side cross-sectional view taken along line X 1 -X 1 of FIG. 3 of a housing included in the bodily fluid c ollection device of FIG. 2;

5 is a cross-sectional view taken along line X 2 -X 2 of FIG. 3 of a movable member included i n the bodily fluid collection device of FIG. 2 ;

6 is a cross-sectional view taken along line X 3 -X 3 of FIG. 3 of the flow controller included in the bodily flui d collection device of FIG. 2;

7 is a cross-sectional view taken along line X 4 -X 4 of FIG. 3 of the flow controller included in the bodily flui

d collection device of FIG. 2;

8 is a top view of the bodily fluid collection device of FIG. 2 in a first configuration; FIG.

9 is a cross-sectional view taken along line X 5 -X 5 of FIG. 8 of the body fluid collection device of FIG. 2 in t he first configuration;

10 is a top view of the bodily fluid collection device of FIG. 2 in a second configuration; FIG.

11 is line X 6 -X 6 of FIG. 10 of the body fluid collection device of FIG. 2 in a second configuration; 1 is a cross-sec tional view taken along .

12 is a cross-sectional view taken along line X 6 -X 6 of FIG. 10 of the bodily fluid collection device of FIG. 2 in a third configuration;

13 is a cross-sectional view taken along line X 6 -X 6 of FIG. 10 of the bodily fluid collection device of FIG. 2 in a fourth configuration;

14 is a perspective view of a bodily fluid collection device according to an embodiment; FIG.

15 is a side cross-sectional view taken along line X 7 -X 7 of the bodily fluid collection device of FIG. 14; FI G.

16 is a perspective view of a bodily fluid collection device according to an embodiment; FIG.

17 is an exploded perspective view of a flow diverting mechanism included in the body fluid co llection device of FIG. 16; FIG.

18 along line X 8 -X 8 of FIG. 16 of a distribution member included in the bodily fluid collection device of FIG. 16; is a side cross-sectional view taken out.

19 is a top view of the bodily fluid collection device of FIG. 16 in a first configuration; FIG.

20 is a cross-sectional view taken along line X 9 -X 9 of FIG. 19 of the partial bodily fluid collection device of FIG. 16 in the first configuration;

21 is a top view of the bodily fluid collection device of FIG. 16 in a second configuration; FIG.

22 is a cross-sectional view taken along line X 10 -X 10 of FIG. 21 of the bodily fluid collection device of FI G. 16 in a second configuration;

FIG. 23 is a perspective view of a bodily fluid collection device according to an embodiment; F igure 24 is a cross-sectional view taken along line X11 - X11

of a portion of the bodily fluid collection device of Figure 23 in a first configuration ; 25 is a cr oss-sectional view taken along line X 11 -X 11 of the bodily fluid collection device of FIG. 23, in a second config uration; FIG. FIG. 26 is a perspective view of a bodily fluid collection device according to an emb odiment; 27 is an exploded perspective view of a flow diverting mechanism included in the bo dily fluid collection device of FIG. 26; FIG. 28 is a cross-sectional view taken along line X 13 - X 13 of FIG. 27 of a distribution member included in the bodily fluid collection device of FIG. 27;

29 is a cross-sectional view taken along line X 14 -X 14 of FIG. 27 of a coupling member included in the bod ily fluid collection device of FIG. 26;

30 is a cross-sectional view taken along line X 15 -X 15 of FIG. 27 of the dial included in the bodily fluid collection device of FIG. 26;

31 is a cross-sectional view taken along line X 16 -X 16 of FIG. 27 of the valve included in the bodily fluid collection device of FIG. 26;

32 is a cross-sectional view taken along line X 12 -X 12 of the bodily fluid collection device of FIG. 26 in the first configuration; FIG.

33 is a cross-sectional view taken along line X 12 -X 12 of the bodily fluid collection device of FIG. 26 in a second configuration; FIG.

34 is a perspective view of a bodily fluid collection device according to an embodiment; FIG.

35 is an exploded perspective view of a flow diverting mechanism included in the bodily fluid collection device of FIG. 34; FIG.

36 is a cross-sectional view taken along line X 17 -X 17 of a distribution member included in the flow diverting mechanism of FIG. 35; FIG.

37 is a top view of a portion of the bodily fluid collection device of FIG. 34 in a first configuration; FIG.

38 is a cross-sectional view taken along line X 18 -X 18 of the partial bodily fluid collection device of FIG. 37 in the first configuration; FIG.

39 is a top view of the bodily fluid collection device of FIG. 33 in a second configuration; FIG.

Figure 40 is a cross-sectional view taken along line X19 - X19

of Figure 39 of the body fluid collection device of Figure 33 in a second configuration ; 41 is a perspective view of a bodily fluid collection device in a first configuration according to embodiments; FIG. 42 is an exploded perspective view of a portion of the bodily fluid collection device of FIG. 41; FIG. 43 is a cross-sectional view taken along line X 20 -X 20 of the bodily fluid collection device of FIG. 41 in the first configuration; FIG. Figure 44 is a cross-sectional view taken along line X20 - X20 of the bodily fluid collection device of Figure 41 in a second configuration ; Figure 45 is a cross-sectional view taken along line X20 - X20 of the body fluid collection device of Figure 41 in a third configuration ; Figure 46 is a perspective view of a bodily fluid collection device in a first configuration according to an embodiment; 47 is an exploded perspective view of a portion of the bodily fluid collection device of FIG. 45; FIG. 48 shows the distribution member included in the bodily fluid collection device of FIG. 46, line X of FIG. 47. FIG.

Figure 21 is a side sectional view taken along 21 - X21 ;

49 is a side sectional view taken along line X 22 -X 22 of FIG. 47 of a movable member included in the bodil

y fluid collection device of FIG. 46;
50 is a top view of the bodily fluid collection device of FIG. 46 in a first configuration; FIG. Fig ure 51 is a cross-sectional view taken along line X23 - X23
of Figure 50 of the partial bodily fluid collection device of Figure 46 in the first configuration ; 52 is a top view of the bodily fluid collection device of FIG. 46 in a second configuration; FIG. Figure 53 is a cross-sectional view taken along line X24 - X24 of Figure 52 of the body fluid coll ection device of Figure 46 in a second configuration ; FIG. 54 is a perspective view of a bodily fluid collection device according to an embodiment; 55 is a top view of the bodily fluid collecti on device of FIG. 54; FIG. FIG. 56 is a flowchart illustrating a method of obtaining bodily fluid samples with reduced contamination using a collection device according to embodiments; DET AILED DESCRIPTION OF THE INVENTION [0010]

[1063] Described herein are devices for obtaining bodily fluid samples parenterally with reduc ed contamination from microorganisms external to the bodily fluid source, such as microorgan isms present on the skin and/or other undesirable external contaminants. It is In some embod iments, a device for obtaining a bodily fluid sample from a patient includes a pre-sample reser voir, a flow diversion mechanism and a flow metering mechanism. The pre-sample reservoir is configured to receive a first volume of bodily fluid withdrawn from the patient. The flow diverti ng mechanism includes an inlet port, a first outlet port and a second outlet port and defines a first fluid flow path and a second fluid flow path. An inlet port can be coupled to the lumen-def ining device to receive bodily fluid from the patient. A first outlet port and a second outlet por t are configured to fluidly couple the pre-sample reservoir and the sample reservoir, respectiv ely, to the flow diverting mechanism. The first fluid flow path is configured to place the first ou tlet port in fluid communication with the inlet port and the second fluid flow path is configured to place the second outlet port in fluid communication with the inlet port. is configured to A flo w metering mechanism is in fluid communication with the first fluid flow path and the second f luid flow path. A flow metering mechanism meters a flow of a first volume of bodily fluid throu gh the first fluid flow path into the pre-sample reservoir and a second volume of bodily fluid th rough the second fluid flow path into the sample reservoir. is configured to The flow metering mechanism is configured to display volume indicators associated with the first volume and the second volume.
[0011]
[1064] In some embodiments, an apparatus for obtaining a bodily fluid sample from a patient

includes a pre-sample reservoir, a flow diversion mechanism, a flow controller, and a movable member. The pre-sample reservoir is configured to receive a first volume of bodily fluid withdrawn from the patient. The flow diverting mechanism includes an inlet port, a first outlet port and a second outlet port. The inlet port is couplable to the lumen-defining device to receive bodily fluid from the patient. A first outlet port fluidly couples the pre-sample reservoir to the flow diverter mechanism and a second outlet port fluidly couples the sample reservoir to the flow diverter mechanism. A flow controller is disposed at least partially within the flow diverting mechanism and comprises a first configuration in which the flow controller defines at least a portion of a fluid flow path between the inlet port and the first outlet port; is movable between a second configuration that defines at least a portion of the fluid flow path between the inlet port and the second outlet port. The movable member is movably coupled to the flow diverting mechanism in a first configuration in which the sample reservoir is fluidly isolated from the fluid flow path between the inlet port and the second outlet port; It is movable through the second outlet port to and from a second configuration in fluid communication with the fluid flow path between the outlet port. The sample reservoir is configured to receive a second volume of bodily fluid withdrawn from the patient when the flow controller is in its second configuration and the movable member is in its second configuration.

[1065

] In some embodiments, a device for obtaining a bodily fluid sample from a patient includes a pre-sample reservoir, a flow diversion mechanism and a flow controller. The pre-sample reservoir is configured to receive a first volume of bodily fluid withdrawn from the patient. The flow diverting mechanism includes a housing and a distribution member. The housing has a first opening in fluid communication with the pre-sample reservoir.

defines a portion and a second opening. A distribution member defines a fluid passageway disposed at least partially within the housing and in fluid communication with the second opening. The distribution member includes a coupling portion configured to be in fluid communication with the flow path and physically and fluidly coupled to the sample reservoir. The flow controller includes an inlet port configured to be coupled to the lumen defining device to receive bodily fluid from the patient. A flow controller is rotatably coupled to the flow diverter mechanism and is movable between a first configuration in which the inlet port is in fluid communication with the first opening and a second configuration in which the inlet port is in fluid communication with the second opening. is.

[0013]

[1066] In some embodiments, a flow diverting mechanism including an inlet port configured to be selectively placed in fluid communication with the pre-sample reservoir and the sample reservoir, and bodily fluid from the patient to the pre-sample reservoir. and a flow metering mechanism configured to meter flow into a sample reservoir comprising the steps of: establishing fluid communication between a patient and an inlet port of the flow metering transfer device; including. Fluid communication is then established between the port and the pre-sample re

servoir. A flow of bodily fluid transferred from the patient to the pre-sample reservoir is meter ed. The method includes verifying, via a flow metering mechanism of the flow metering transf er device, that a pre-sample volume of bodily fluid disposed within a pre-sample reservoir is a first pre-sample volume of bodily fluid. With the pre-sample volume disposed within the pre-s ample reservoir, the pre-sample reservoir is fluidly isolated from the port to seal the pre-samp le volume of bodily fluid within the pre-sample reservoir. With the pre-sample reservoir fluidly isolated, the method includes establishing fluid communication between the port and the sam ple reservoir. A flow of bodily fluid transferred from the patient to the sample reservoir is met ered. The method includes verifying, via the flow metering mechanism of the flow metering tr ansfer device, that the sample volume of bodily fluid disposed within the sample reservoir is a first sample volume of bodily fluid.

[0014]

[1067] In some embodiments, an apparatus includes a flow diversion mechanism and a flow c ontroller. The flow diverting mechanism can define an inlet port, a first outlet port, a second o utlet port and a third outlet port. a first outlet port fluidly coupled to the pre-sample reservoir, a second outlet port fluidly coupled to the first sample reservoir, a third outlet port fluidly cou pled to the second sample reservoir; etc. All of the fluid reservoirs can be fluidly isolated from each other. The flow controller includes various fluid channels, which can allow fluid movemen t in specified directions and can be configured to be operatively coupled to the flow diverting mechanism. In use, the flow controller can allow bodily fluid flow into the pre-sample reservoi r when the flow diverter mechanism is in the first configuration. The flow diverter mechanism can be moved to a second configuration, in which the flow controller can allow bodily fluid flo w to enter the first sample reservoir. In addition, the flow diverter mechanism can then be mo ved to the third configuration so that the flow controller can allow bodily fluid flow to enter the second sample reservoir.

[0015]

[1068] In some embodiments, the bodily fluid collection device allows a second volume of bod ily fluid to flow into the first sample reservoir and/or a third volume of bodily fluid to flow into the second sample reservoir. previously, it can be configured to selectively divert a first predet ermined volume of bodily fluid to a pre-sample reservoir. In this way, the second and/or third volume of bodily fluid can be used for diagnosis or other testing, while the presence of microo rganisms from the body surface or other microbial sources external to the patient from whom the sample is obtained. A first volume of bodily fluid that may contain is isolated. In some em bodiments, the bodily fluid collection device can include additional sample reservoirs (eg, 3, 4, 5, 6 or more) depending on the analysis and/or testing protocols to be performed.

[1069

] In some embodiments, the bodily fluid collection device is configured such that an appropria te volume of bodily fluid is collected from the patient and/or transferred to a predetermined pr e-sample reservoir and/or sample reservoir.

Flow metering can be included to ensure that the A bodily fluid collection device can be config ured to automatically divert and/or control fluid flow after a metered volume of bodily fluid ha s been collected. For example, once a first metric pre-sample volume has been collected, the f low diverter mechanism can be configured to divert body fluid flow to a first sample reservoir, and then divert the flow after the first metric sample volume has been collected. The mechani sm can be configured to divert body fluid flow to a second sample reservoir, and so on. In so me embodiments, the bodily fluid collection device includes a metered volume display, such a s a liquid crystal display (LCD), to provide a visual indication of how much bodily fluid has bee n collected in each predetermined individual sample reservoir. can be provided to the user. In some embodiments, multiple displays can be provided to allow for customized pre-sample an d/or sample volume collection.

[1070

] As used in this specification and the appended claims, the singular forms "a, an" and "the" r efer to the plural unless the context clearly dictates otherwise. including referents of Thus, for example, the term "(a) member" is intended to mean a single member or combination of me mbers, and "(a) material" is intended to mean one or more materials or combinations thereof. intended to mean

[1071

] As used herein, "bodily fluid" includes, but is not limited to, blood, cerebrospinal fluid, urine, bile, lymph, saliva, synovial fluid, serous fluid, pleural fluid, amniotic fluid, etc., or any combin ation thereof. , can include any fluid obtained from the patient's body.

[0019]

[1072] As used herein, the terms "first predetermined amount," "first amount," and "first volu me" are configured to be received or contained by a first reservoir or a pre-sample reservoir. s tate the amount of body fluid The terms "first amount" and "first volume" do not explicitly stat e a predetermined amount, but unless explicitly stated otherwise, the first amount may be a fi rst predetermined amount. should be understood.

[1073

] As used herein, the terms "second volume" and "second volume" describe the amount of bo dily fluid configured to be received or contained by a second reservoir or sample reservoir. . T he second amount can be any suitable amount of bodily fluid and it need not be a predetermi ned amount. Conversely, when so explicitly stated, the second volume received and contained by the second reservoir or sample reservoir may be the second predetermined volume.

[1074

] As used herein, the term "set" can refer to a single feature comprising multiple features or multiple parts. For example, when referring to a set of walls, the set of walls can be considere d a single wall with separate portions, or the set of walls can be considered multiple walls. Si milarly, an integrally constructed article can include a set of walls. Such a set of walls can incl ude, for example, multiple portions that are discontinuous from each other. A set of walls can

also be made from multiple articles that are manufactured separately and later joined togethe r (eg, via welding, adhesives, or any suitable method).

[0022]

[1075] As used herein, the terms "proximal" and "distal" refer to directions toward and away f rom, respectively, a user placing the device in contact with a patient. Thus, for example, the e nd of the device that first contacts the patient's body would be the distal end, and the opposit e end of the device (eg, the end of the device being operated by the user) would be the proxi mal end of the device. becomes.

[1076

] As used herein, the terms "about," "approximately," and "substantially," when used in conne ction with numerical values, are nominally indicative of the value so defined. is intended to m ean that the value In other words, the terms about, approximately and substantially when use d in connection with numerical values generally include the indicated value plus or minus a giv en tolerance.

nothing. For example, in some cases a suitable tolerance may be ±10% of the indicated valu e, thus about 0.5 includes 0.45 and 0.55; 11, and about 1000 includes 900-1100. In other ca ses, a suitable tolerance may be plus or minus an acceptable percentage of the last significant digits of the indicated value. For example, a suitable tolerance might be ±10% of the last sign ificant digit, so approximately 10.1 includes 10.09 and 10.11, and approximately 25 includes 24.5 and 25.5. including. Such variations may result from manufacturing tolerances or other p ractical considerations (eg, tolerances associated with measurement equipment, acceptable h uman error, etc.).

[0024]

[1077] When describing the relationship between a given volume of bodily fluid and a collecte d volume of bodily fluid, it should be understood that these values include suitable tolerances such as those set forth above. For example, when stating that a collected volume of bodily flui d is substantially equal to a predetermined volume of bodily fluid, the collected volume and th e predetermined volume are nominally equal within suitable tolerances. In some cases, tolera nce can be determined by the intended use of the collected volume of bodily fluid. For exampl e, in some cases, blood culture assays are performed when the collected volume of blood is wi thin 1.0% to 5.0% of the manufacturer's (or evidence-based best practice) recommended vol ume. It can be about 99% accurate. As an example, the manufacturer's recommended volum e for the body fluid assay is 10 milliliters (mL) (ie total volume is 40 ml to 60 ml) ± 5%. Thu s, a collection volume of 10.5 mL provides results with greater than about 99% confidence, an d a collection volume of 11 mL provides results with less than about 99% confidence. In other cases suitable tolerances are 0.1%, 0.5%, 1.0%, 2.0%, 3.0%, 4.0%, 5.0%, 6.0% , 7.0%, 8. 0%, 9.0%, 10.0% or any fractional value therebetween. In still other cases, the tolerance can exceed 10.0%. Accordingly, any of the embodiments described herein may be any suitable flo w rate configured to meter the flow rate of body fluid and/or otherwise measure the volume o

f body fluid within suitable tolerances. It can include and/or be used with measurement mech anisms and/or devices. Additionally, flow metering mechanisms and/or devices can be arrange d to minimize or eliminate tolerance build-up that can result from a combination of inaccurate measurements, human error, and the like.

[0025]

[1078] FIG. 1 is a schematic illustration of a portion of a bodily fluid collection device 100, acc ording to an embodiment. In general, the bodily fluid collection device 100 (also referred to h erein as a "fluid collection device" or "collection device") allows for the withdrawal of bodily flu id from a patient, wherein a first portion or a first portion of the withdrawn bodily fluid is so th at a quantity separates from a second portion or volume and/or a third portion or volume of t he withdrawn bodily fluid used as a biological sample, such as to be tested for medical diagno stic and/or therapeutic purposes configured to be shunted. In other words, as described in mo re detail herein, the collection device 100 can transfer a first predetermined volume of bodily f luid to a pre-sample collection reservoir, second and third volumes of bodily fluid (or, in some i mplementations, 4th, 5th, etc.) to one or more sample collection reservoirs (eg, sample reser voirs) fluidly isolated from the pre-sample reservoir.

[1079

] The collection device 100 includes a flow diverter mechanism 120 , a flow controller 140 , a pre-sample reservoir 170 , a first sample reservoir 180 , and a second sample reservoir 190 t hat is different from the first sample reservoir 180 . The flow diverting mechanism 120 include s an inlet port 121 and at least two outlet ports, such as a first outlet port 125 and a second o utlet port 126, as shown in FIG. In some embodiments, flow diverter 120 can include a set of exit ports equal to the total number of pre-sample and sample reservoirs. For example, if coll ection device 100 has one pre-sample and four sample reservoirs, flow diverter 120 may inclu de five outlet ports. In some embodiments, a flow divider

Mechanism 120 can be operably coupled to an actuator (not shown in FIG. 1) that can facilitat e movement of flow diverter mechanism 120 between configurations. Inlet port 121 is configu red to be fluidly coupled to a medical device that defines a pathway X for withdrawing and/or transporting bodily fluid from a patient to collection device 100 . For example, entry port 121 can be fluidly coupled to a needle or other lumen defining device (eg, flexible sterile tubing). As such, the flow diverting mechanism 120 can receive bodily fluid from the patient via a nee dle or any other lumen defining device.

[1080

] The first outlet port 125 of the flow diverter mechanism 120 may be fluidly coupled to the pr e - sample reservoir 170 . In some embodiments, pre-sample reservoir 170 is integrally forme d with first outlet port 125 and/or part of flow diverter mechanism 120 . In other embodiment s, the pre-sample reservoir 170 is attached via adhesives, resistance fits, mechanical fastener s, any number of mating recesses, threaded connections and/or any other suitable connection or combination thereof. , can be mechanically and/or fluidly coupled to the flow diverting mec

hanism 120 . Similarly, pre-sample reservoir 170 can be physically (e.g., mechanically) couple d to flow diverting mechanism 120 such that the volume defined by pre-sample reservoir 170 is the flow diverting mechanism. 120 in fluid communication with a first outlet port 125 . In st ill other embodiments, the pre-sample reservoir 170 is operably coupled to the first outlet por t 125 of the flow diverting mechanism 120 via an intervening structure (not shown in FIG. 1) such as flexible sterile tubing. can be done. More particularly, the intervening structure can de fine a lumen configured to place the pre-sample reservoir 170 in fluid communication with the first outlet port 125 .

[1081

] The pre-sample reservoir 170 is configured to receive and contain a first predetermined volu me of bodily fluid. In some embodiments, the pre-sample reservoir 170 stores a first volume of bodily fluid (which may be the same as or different from the first volume of bodily fluid), a second volume of bodily fluid that is subsequently withdrawn from the patient, and a second v olume of bodily fluid. /or configured to receive in a fluidly isolated manner from the third volu me. Pre-sample reservoir 170 is described in "Systems and Methods for Parenterally Procuring Bodily-Fluid Samples with Reduced Contamination", which is incorporated herein by reference in its entirety. It can be any suitable reservoir for containing bodily fluids, such as the pre-sa mple reservoir described in detail in US Pat. No. 8,197,420.

[0029]

[1082] In some embodiments, the second outlet port 126 of the flow diverting mechanism 12 0 is fluidly coupled to a lumen defining device that can be coupled to the first sample reservoi r 180 and the second sample reservoir 190. is configured to Optionally, in other embodiments, the second outlet port 126 of the flow diverter 120 can be coupled to the first sample reservoi r 180, and the flow diverter 120 was coupled to the second sample reservoir 190 (Fig. (not sh own) can have a third exit port. In some embodiments, the first sample reservoir 180 can be i ntegrally formed with the second outlet port 126 and/or part of the flow diverting mechanism 120 . In other embodiments, the first sample reservoir 180 is mechanically coupled or operabl y coupled to the second outlet port 126 via intervening structures such as those described ab ove with respect to the pre-sample reservoir 170. can be combined. First sample reservoir 18 0 is configured to receive and contain a second volume of bodily fluid. For example, the secon d volume of bodily fluid can be the amount withdrawn from the patient following the withdraw al of the first pre-sample volume. In some embodiments, first sample reservoir 180 is configu red to contain a second volume of bodily fluid such that the second volume is fluidly isolated f rom the first volume of pre-sample bodily fluid.

[1083

] First sample reservoir 180 and second sample reservoir 190 may be, for example,
It can be any suitable sterile reservoir for containing bodily fluids, including a sample reservoi r as described in the incorporated '420 patent. In some embodiments, the second volume can be any suitable volume of bodily fluid and it need not be a predetermined volume. In other e

mbodiments, the transfer of bodily fluid to the first sample reservoir 180 and/or the second sa mple reservoir 190 can be metered or the like such that the second volume is a second predet ermined volume.

[1084

] The second sample reservoir 190 can be any suitable sample reservoir. In some embodiment s, the second sample reservoir 190 can be substantially similar to the first sample reservoir 1 80 described above. A second sample reservoir 190 can be fluidly coupled to the second outle t port 126 as described above. The fluidic coupling of the second outlet port 126 to the second sample reservoir 190 can be substantially similar to the fluidic coupling of the second outlet p ort 126 to the first sample reservoir 180, as detailed above. Accordingly, such portions are not described in further detail herein and should be considered substantially similar unless explicit ly described to the contrary. Additionally, additional outlet ports and sample reservoirs of flow diverter 120 (not shown in FIG. 1) may be substantially similar to second outlet port 126 and first sample reservoir 180 .

[0032]

[1085] In some embodiments, the pre-sample reservoir 170, the first sample reservoir 180 a nd the second sample reservoir 190 can be similarly coupled to (or formed with) the flow dive rting mechanism 120. FIG. In other embodiments, pre-sample reservoir 170 , first sample res ervoir 180 and second sample reservoir 190 need not be similarly coupled to flow diverting m echanism 120 . For example, in some embodiments, the pre-sample reservoir 170 can be inte grally formed with the flow diverting mechanism 120 (eg, the first outlet port 124) and the fir st sample reservoir 180 and/or the second sample reservoir 190. can be operably coupled to f low diverting mechanism 120 (eg, second outlet port 126) via an intervening structure such a s flexible sterile tubing or any combination thereof.

[0033]

[1086] In some embodiments, the collection device 100 includes an actuator (not shown in FI G. 1) and a first fluid flow path 142, a second fluid flow path 144 and optionally (not shown in FIG. 1). and a flow controller 140 that defines additional fluid flow paths. In some embodimen ts, an actuator may be included in or otherwise operably coupled to the flow diverting mechan ism 120 . As such, actuators can be configured to control fluid movement (eg, between differe nt configurations) within flow controller 140 . For example, the actuator may be movable betw een a first position corresponding to a first configuration of flow controller 140, a second positi on different from the first position corresponding to a second configuration of flow controller 1 40, and so on. In some embodiments, the actuator can be configured to move in one directio n. For example, an actuator can be moved from its first position to its second position, but ca nnot be moved from its second position to its first position. Similarly, the actuator can be mov ed from its second position to its third position, but cannot be moved from its third position ba ck to its second position. In this manner, flow controller 140 is prevented from moving to its s econd or third configuration before its first configuration, thus directing a first volume of bodil

y fluid to pre-sample reservoir 170 for medical diagnosis. and/or sample reservoirs 180 and/o r 190 designed to contain a second and/or third volume of withdrawn fluid used as a biological sample, such as for testing for therapeutic purposes. It is necessary not to be directed to

[0034]

[1087] The flow controller 140 has a first fluid flow path 142 fluidly coupling the inlet port 121 to the first outlet port 125 when in the first configuration and a second fluid flow path 142 wh en in the second configuration. 144 is configured to fluidly couple inlet port 121 to second outl et port 126 . In some embodiments, actuators such as those described above are incorporate d into the flow controller 14

0 can be configured to move in translation between the first and second configurations, and o ptionally between the third or fourth configuration. For example, in some embodiments, flow c ontroller 140 may be in a first configuration when in a distal position relative to collection devi ce 100 . In such embodiments, the actuator can be actuated to move flow controller 140 proxi mally to a proximal position relative to collection device 100, thereby placing flow controller 1 30 in the second configuration. In other embodiments, the actuator can be actuated to move t he flow controller 140 between the first and second configurations, or optionally between the t hird or fourth configurations, in a rotary motion. .

[1088

] Thus, when the flow controller 140 is in the first configuration, the second outlet port 126 (a nd optionally an additional outlet port coupled to the sample reservoir) is fluidly routed from t he inlet port 121. isolated to Similarly, first outlet port 125 is fluidly isolated from inlet port 12 1 when flow controller 140 is in the second configuration. Optionally, first outlet port 125 and second outlet port 126 are fluidly isolated from inlet port 121 when flow controller 140 is in a third configuration (not shown in FIG. 1). Thus, the flow controller 140 can direct or divert a fi rst volume of bodily fluid through the first outlet port 125 to the pre-sample fluid reservoir 17 0 when in the first configuration and in the second configuration. A second volume of bodily fl uid can then be directed or diverted to the first sample fluid reservoir 180 via the second outl et port 126 .

[0036]

[1089] In some embodiments, at least a portion of the actuator can be operably coupled to th e pre-sample fluid reservoir 170. As shown in FIG. In this manner, the actuator (or at least a portion of the actuator) causes or otherwise facilitates the creation of a vacuum within the "pr e-sample" fluid reservoir 170, thereby causing the flow diverter mechanism 120 to assume its first configuration. At some point, it can be configured to initiate flow through the bodily fluid collection device 100 and into the pre-sample fluid reservoir 170 . Actuators may be any suita ble mechanism for driving bodily fluid flow into collection device 100, such as, for example, ro tating discs, plungers, slides, dials, buttons, handles, levers, and/or any other suitable mecha nism or combination thereof. can include Examples of suitable actuators are described in more detail herein with reference to specific embodiments.

[0037]

[1090] In some embodiments, the flow diverter mechanism 120 is configured such that the flow of the second volume of bodily fluid is transported through the flow diverter mechanism 120 to the first sample fluid reservoir 180 and/or to the second sample fluid reservoir 190. can be configured such that a first volume of bodily fluid needs to be transported to the pre-sample fluid reservoir 170 before allowing for . In this manner, the flow diverting mechanism 120 can be used by a healthcare professional to collect a first predetermined amount of bodily fluid (e.g., a pre-sample) before collecting a second amount and/or a third amount of bodily fluid (e.g., a sample). can be characterized as requiring compliance with respect to Similarly, the flow diverter mechanism 120 can be used by a medical practitioner to transfer a second volume of bodily fluid, i.e., a sample, into a first sample fluid reservoir without first diverting the first volume of bodily fluid, i.e., a pre-sample, into a pre-sample reservoir 170. It can be configured to prevent collection within 180 . In this manner, a healthcare professional may (intentionally or not) add a first volume of bodily fluid that is more likely to contain surface microbes and/or other undesirable external contaminants into the bodily fluid sample used for analysis. (either unintentionally or unintentionally). In other embodiments, the fluid collection device 100 need not include mandatory compliance features or components.

[1091

] In some embodiments, the flow diverter mechanism 120 can have a fourth configuration (not shown in FIG. 1) that is different from the first, second, and third configurations. When in the fourth configuration, the flow diverter mechanism 120 can simultaneously fluidly isolate the inlet port 121 from the first outlet port 125, the second outlet port 126 and, optionally, the third outlet port. Therefore, the shunting

When mechanism 120 is in its fourth configuration, body fluid is prevented from flowing from inlet port 121 to pre-sample fluid reservoir 170, first sample fluid reservoir 180 and second sample fluid reservoir 190. FIG. In use, for example, the flow diverter mechanism 120 is placed (eg, manually or automatically) in a first configuration such that bodily fluid can flow from the inlet port 121 to the pre-sample fluid reservoir 170 . actuated and then moved to a second configuration such that bodily fluids can flow from inlet port 121 to first sample fluid reservoir 180 and, optionally, bodily fluids can flow from inlet port 121 to second sample fluid reservoir 190 It can be moved to a third configuration so that it can be used, and then moved to a fourth configuration so as to stop the flow of bodily fluids into and/or through the flow diverting mechanism 120 . In this manner, the device is effectively "cleaned" such that any residual bodily fluids within the device 100 are prevented from becoming contaminated and/or otherwise exposing medical personnel and/or patients to potentially hazardous fluids. Locked" and self-contained in the fourth form. This optional safety feature can prevent possible exposure to bodily fluid samples that may be infected with pathogens such as HIV, Hepatitis C, and the like.

[0039]

[1092] In some embodiments, one or more portions of the collection device 100 are disposed

within a housing (not shown in FIG. 1). For example, in some embodiments, at least a portion of one or more of flow diverting mechanism 120, first pre-sample reservoir 170 and sample reservoirs 180 and 190 can be disposed within the housing. In such embodiments, at least a portion of the flow diverter mechanism 120 is configured so that the user can activate the flow controller 140 to control the flow of bodily fluid from the patient (e.g., vein) to the collection device 100. Accessible through the housing. Examples of suitable housings are described in more detail herein with reference to specific embodiments.

[0040]

[1093] In some embodiments, the collection device 100 can optionally include one or more flow metering devices that can meter the flow of bodily fluid through the collection device. For example, a flow metering device can be in fluid communication with the first fluid flow path 142 and/or the second fluid flow path 144 to meter the flow of bodily fluid therethrough. In other embodiments, a flow metering device can be in fluid communication with and/or otherwise disposed in first port 125 and/or second port 126 . The flow metering device can be configured to provide the user with an indication related to the predetermined volume being transferred to the pre-sample reservoir 170, the first sample reservoir 180 and/or the second sample reservoir 190, such as an indicator (For example, electrical signal output devices such as dials, displays, colors, tactile output devices, wireless radio signals, Bluetooth radio signals, etc.). In some embodiments, a flow metering device can be operably coupled to an actuator, such as, for example, those described above. In such embodiments, the flow metering device operates an actuator to move flow controller 140 between its first configuration and its second configuration based on the desired volume of bodily fluid that has flowed through the flow metering device. may be operable as such. Thus, using the flow metering device, a desired volume of bodily fluid is transferred to the pre-sample reservoir 170, the first sample reservoir 180 and/or the second sample reservoir 190, thereby providing an insufficient volume, such as in microbiological testing, for example on patient samples. can ensure that incorrect and/or erroneous results can be prevented.

[0041]

[1094] Referring now to FIGS. Includes reservoir 290 . As further described herein, the collection device 200 is used to deliver a bodily fluid stream that is substantially free of extracorporeal microbes, such as microbes present on the skin and/or other undesirable external contaminants. It can be moved between a first configuration, a second configuration and a third configuration. collection de

Vise 200 may be of any suitable shape, size or configuration. For example, while sample reservoirs 280 and/or 290 are shown oriented perpendicular to housing 201 in FIGS. 2-13, collection device 200 is oriented planar to housing 201. It can have sample reservoirs 280 and/or 290, such as or arranged conically with respect to housing 201 .

[0042]

[1095] The flow diverter mechanism 220 includes a housing 201 and movable members 250 a

nd 250'. As shown in FIGS. 2-4, housing 201 is coupled to pre-sample reservoir 270 , first sa mple reservoir 280 and second sample reservoir 290 . Housing 201 includes an inlet port 221, a first outlet port 230, a second outlet port 231, a third outlet port 232, and an internal flow p ath 235 that can define a fluid flow path for collecting bodily fluids from a patient. stipulated. Inlet port 221 can be selectively placed in fluid communication with internal flow path 235 . M ore specifically, inlet port 221 defines an inlet lumen 202 that can be placed in fluid communic ation with internal flow path 235 . Inlet port 221 is thus part of housing 201 such that internal flow path 235 can be placed in fluid communication with a space substantially outside housing 201 via inlet lumen 202 . extends from Inlet port 221 can be fluidly coupled to a medical devi ce (not shown) that defines a fluid flow path for drawing bodily fluid from a patient and/or tra nsporting it to collection device 200 . For example, entry port 221 can be fluidly coupled to a needle or other lumen defining device (eg, flexible sterile tubing) directly or indirectly via ada pter 204 . Similarly, inlet lumen 202 defined by inlet port 221 is arranged to be in fluid comm unication with the lumen defined by the lumen-defining device when the lumen-defining devic e is coupled to inlet port 221 . . More specifically, when the lumen defining device is positione d within a portion of a patient's body (e.g., within a patient's vein or spinal space), the interior passageway 235 of the housing 201 is aligned with that portion of the patient's body. It can b e arranged in fluid communication with the portion.

[0043]

[1096] The internal passageway 235 defined by the housing 201 is a central lumen that exten ds along the length of the housing 201 and is used for venipuncture (fluid access) as describe d herein. (other methods employed to enable the patient to be placed in fluid communication with the patient's bodily fluids). Internal channels 235 form fluid flow paths that transport bod ily fluids between inlet port 221 and first, second, and third outlet ports 230 , 231 , and 232 . More specifically, when the internal flow path 235 is placed in fluid communication with a pati ent (eg, via a medical device coupled to the inlet port 221), the first outlet port 230, the seco nd outlet port 231 are and third outlet port 232 are selectively placed in fluid communication with internal flow path 235 to allow bodily fluids to flow into at least one of pre-sample reserv oir 270 , first sample reservoir 280 or second sample reservoir 290 . can be allowed to flow. I n some embodiments, bodily fluid is prevented from flowing to second outlet port 231 and thir d outlet port 232 before a predetermined volume of bodily fluid has been collected in pre-sam ple reservoir 270 . In some embodiments, the second outlet port 231 and the third outlet port 232 can be placed in fluid communication with the internal flow path 235 at the same time. In some embodiments, the second outlet port 231 and the third outlet port 232 can be arranged in fluid communication with the internal flow path 235 sequentially.

[0044]

[1097] Movable members 250, 250' are actuated (eg, moved) by a user from first and second positions relative to housing 201 to direct fluid flow to first sample reservoir 280 and second s ample reservoir. 290. Movable members 250 and 250 ’ are substantially identical and therefor

e will be described with respect to a single movable member 250 . As shown in FIG. 5, movea ble member 250 includes a boss 251 defining an interior cavity 252 , an inlet port 253 , a first outlet port 254 , and lumen 25 fluidly coupled to interior cavity 252 .

and a piercing member 255 defining 6. Inlet port 253 and outlet port 254 extend through the wall of boss 251 that defines interior chamber 252 of movable member 250 . Movable membe r 250 is positioned within support 257 (see FIG. 4) of housing 201 such that boss 251 is dispo sed within bore 258 (see FIG. 4) and at least a portion of movable member 250 is disposed wi thin annular chamber 260 (see FIG. 4). configured to be attached to the Optionally, a biasing member 259 (eg, a spring) can be disposed within the annular chamber 260 to return the mo vable member 250 to its first position after actuation by the user. In some embodiments, mov able member 250, annular chamber 260, bore 258 or boss 251 are configured to retain mova ble member 250 in a second position (e.g., depressed position) after being actuated by a user. A mechanical locking mechanism can be included.

[0045]

[1098] As described herein, in the first configuration, the movable member 250 is arranged to be spaced apart from the internal channel 235. As shown in FIG. In such configurations, a flui d flow path cannot be established between a portion of the patient's body (eg, a vein, spinal c avity, etc.) and sample reservoirs 280 and/or 290 . In other words, when movable member 25 0 is in its first configuration, first sample reservoir 280 and second sample reservoir 290 are fl uidly isolated from internal flow path 235 defined by housing 201 . Movable member 250 can be actuated by a user to move movable member 250 from the first configuration to the secon d configuration and into alignment with internal channel 235 . The force applied by the user m ay be sufficient to deform (eg, compress) biasing member 259, thereby inserting piercing me mber 255 into sample reservoirs 280 and/or 290. can be done. In the second configuration, in let port 253 and outlet port 254 are substantially aligned with internal flow path 235 to place i nternal cavity 252 in fluid communication with internal flow path 235 . Thus, when movable m ember 250 is in the second configuration, a fluid flow path is established between internal cha nnel 235 , internal cavity 252 , lumen 256 of piercing member 255 and sample reservoir 280 . In other words, in such a configuration, bodily fluids flow from the patient (eg, veins, spinal s paces, etc.) through the flow diverting mechanism 220 into the first sample reservoir 280 an d/or the second sample reservoir 280, as described in further detail herein. It can flow into th e sample reservoir 290 .

[0046]

[1099] The pre-sample reservoir 270 can be any suitable reservoir for containing bodily fluids, such as, for example, a single-use disposable collection tube, a vacuum-assisted collection tub e, and the like. Pre-sample reservoir 270 is configured to be fluidly coupled in any suitable ma nner (either directly or via an intervening structure such as sterile flexible tubing) to first outl et port 230 of collection device 200. . For example, in some embodiments, a portion of pre-sa mple reservoir 270 can form a friction fit within a portion of first outlet port 230 . In other em

bodiments, pre-sample reservoir 270 can be coupled to first outlet port 230 via threaded coup ling, adhesives, snap fits, mechanical fasteners and/or any other suitable coupling method. . I n some embodiments, pre-sample reservoir 270 can be integrally formed with housing 201 . P re-sample reservoir 270 is subjected to a negative pressure condition (vacuum condition) that can enable bodily fluid to be drawn into pre-sample reservoir 270 via vacuum suction from inl et port 221 through outlet port 230 (pre-sample reservoir 270) can be configured to be maint ained internally. Pre-sample reservoir 270 is configured to contain a first volume of bodily flui d, where the first volume of bodily fluid can be a predetermined volume or an unquantified vol ume, thereby is fluidly isolated from a second and/or a third volume of bodily fluid subsequent ly withdrawn from the patient.

[

1100] Sample reservoirs 280 and/or 290 may be single-use disposable collection tubes, vacuu m driven collection tubes, sample reservoirs such as those described in the '420 patent incorp orated herein by reference above, or the like. It can be any suitable reservoir for containing b odily fluids, including: In some embodiments, sample reservoirs 280 and/or 290 include, for e xample

It can be substantially similar or identical to known sample containers, such as the Vacutainer ®. Sample reservoirs 280 and 290 include sample vessels 282 and 292, respectively, and vac uum seals 284 and 294, respectively. A vacuum seal 284 or 294 can allow bodily fluid to be dr awn into the sample container 282 or 292, respectively, from the internal channel 235 via vac uum suction into the sample container 282 or 292, respectively. state). Sample containers 28 0 and/or 290 are fluidically connected in any suitable manner (directly or via an intervening st ructure such as sterile flexible tubing) to second and third outlet ports 231 and 232, respectiv ely, of collection device 200. It can be configured to be coupled. Sample reservoirs 280 and/or 290 can be moved relative to exit ports 231 and/or 232 so as to be placed in fluid communica tion with exit ports 231 and/or 232 . Sample reservoirs 280 and 290 can be configured to con tain a second volume or a third volume of bodily fluid. The second or third amount of bodily fl uid can be a predetermined amount or an unquantified amount, whereby the second or third amount of bodily fluid is the first amount of bodily fluid withdrawn from the patient. fluidly isol ated from In some configurations, sample reservoirs 280 and/or 290 may be coupled to collec tion device 200 by being integrally formed with housing 201, similar to pre-sample reservoir 2 70, and are therefore not discussed in detail herein. not described in In some cases, the samp le reservoirs 280 and/or 290 can be transparent so that the user has visual feedback to confir m the flow of bodily fluid into the sample reservoirs 280 and/or 290. can be done.

[0048]

[1101] In some embodiments, sample reservoirs 280 and 290 and flow diverter mechanism 2 20 (and/or portions of collection device 200 other than sample reservoirs 280 and 290) are in dependently formed (e.g., integrally formed) and bonded together during the manufacturing p rocess, for example. In some cases, sample reservoirs 280 and 290 can be coupled to flow div

erter mechanism 220 in a substantially sterile or sealed environment (eg, filled with ethylene oxide or the like). Accordingly, the interface between sample reservoirs 280 and 290 and flow diverter 220 is substantially sterile prior to use. Further, collection device 200 can be transpor ted and/or stored pre-assembled, such as to maintain a substantially sterile interface between sample reservoirs 280 and 290 and flow diverting mechanism 220 .

[0049]

[1102] As shown in FIGS. First member 241 is configured to be disposed within recess 266 (s ee, eg, FIG. 4) of housing 201 and is made of, for example, titanium, graphite, pyrolytic carbo n, polyester, polycarbonate, polyurethane, or the like. , elastomeric materials, etc., that are bi ocompatible. In some embodiments, second member 245 acts as an actuator to move first m ember 241 from the first configuration to the second configuration. More specifically, once the first member 241 is positioned within the recess 266, the second member 245 is moved betw een the first and second positions to move the flow controller 240 from the first configuration to the second configuration. It can be moved between two forms. In some embodiments, hou sing 201 can selectively restrict movement of second member 245 from its first position to its second position. In some embodiments, the housing 201 can be configured to prevent movem ent of the second member 245 moved to the second position. In other words, housing 201 ca n include a locking mechanism that prevents second member 245 from moving back from the second position to the first position. Second member 245 and/or housing 201 may also includ e mechanical detents and/or other indicators that provide visual or tactile feedback to ensure correct positioning of second member 245. is.

[1103

] The first member 241 is used for venipuncture (and/or other methods of accessing a patien t's bodily fluids).

A plurality of channels can be included to direct fluid flow subsequent to the . For example, as shown in FIGS. 6 and 7, first member 241 includes first channel 242 and second channel 244 . When the second member 245 is in the first position (see, for example, FIGS. 8 and 9), the f low controller 240 is arranged in the first configuration and the first channel 242 connects the inlet port 221 from the internal channel 235. Fluid communication is established between inlet port 221 and first outlet port 230 while being fluidly isolated. When the second member 245 i s in the second position (see, eg, FIGS. 10-13), the flow controller 240 is disposed in the seco nd configuration and the second flow path 244 connects the inlet port 221 to the first outlet p ort 230. Fluid communication is established between the inlet port 221 and the internal chann el 235 while being fluidly isolated from the . The position of the additional second member 24 5 corresponding to the flow path of the additional first member 241 and/or the configuration o f the flow controller 240 to further direct/isolate the fluid flow between the patient and the coll ection device 200. can be included. For example, the second member 245 can have a third po sition corresponding to a third configuration of the flow controller 240 that substantially preve nts fluid flow between the patient and the collection device 200 as a whole. In other words, in

some embodiments, after all bodily fluid samples have been removed from the patient, movin g the dial to the third position substantially seals the sample within the collection device 200 f rom the external environment. can be done.

[0051]

[1104] In operation, the collection device 200 can be used to collect bodily fluids (eg, blood) f rom a patient with reduced contamination from microorganisms present on the skin and/or ot her undesirable external contaminants. can. For example, inlet port 221 of collection device 2 00 is fluidly coupled via adapter 204 to a needle or other lumen defining device (eg, flexible st erile tubing). Following venipuncture (or other fluid access method), second member 245 is ro tated until it reaches the first position, as shown in FIGS. Alternatively, the second member 2 45 can be preset to the first position and the collection device 200 is otherwise sealed to main tain the vacuum within the pre-sample reservoir 270 and the sterility of the collection device 200. can do. For example, inlet port 221 and/or adapter 204 can include a valve that opens w hen collection device 200 is coupled to a needle or other lumen defining device.

[0052]

[1105] As described above, when the second member 245 is in the first position, the flow con troller 240 is disposed in the first configuration and the first passageway 242 of the first mem ber 241 connects the inlet port 221 to the internal passageway. Fluid communication is establi shed between inlet port 221 and first outlet port 230 while being fluidly isolated from 235 . Fu rther, the first sample reservoir 280 and the second sample reservoir 290 are fluidly isolated f rom the inlet port 221 in the first configuration and are located in a portion of the patient's bo dy (eg, a vein), as indicated by arrows AA in FIG. and a pre-sample reservoir 270 are defined. As described above, the fluid reservoirs used in collection device 200, such as pre-sample res ervoir 270 and sample reservoirs 280 and 290, are exposed to a negative pressure (i.e., the p ressure of the body part from which collection device 200 is used to draw bodily fluids). press ure less than the fluid pressure), thereby establishing fluid communication between a portion of the patient's body (e.g., a vein) and pre-sample reservoir 270, the negative pressure within pre-sample reservoir 270 causes , the pressure differential between the pre-sample reservoir 270 and that portion of the patient's body causes fluid to be drawn into the pre-sample reserv oir 270 . In this first configuration, flow controller 240 also fluidly isolates pre-sample reservoi r 270 from internal flow path 235 . Thus, a first volume (predetermined or unquantified) of bo dily fluid can be received in pre-sample reservoir 270 (for example) immediately after venipun cture and isolated from subsequent samples. Thus, with the collection device 200, a first volu me of bodily fluid most likely to contain surface microorganisms and/or other undesirable exte rnal contaminants may be diagnosed or affected by the contaminants. Subsequent volumes of bodily fluid samples collected and used for other tests can be uncontaminated.

[0053]

[1106] Following collection of the body fluid pre-sample volume in the pre-sample reservoir 2 70,

, the second member 245 can be rotated until it reaches a second position as shown in FIGS. When the second member 245 is in the second position, the flow controller 240 is placed in th e second configuration and the second flow path 244 of the first member 241 enters the first outlet port 230 (i.e., the pre-sample reservoir 270). Fluid communication is established betwe en inlet port 221 and internal channel 235 while being fluidly isolated from port 221 . In other words, in the second configuration, the flow controller 240 provides flow between a portion of the patient's body (eg, a vein) and the internal flow path 235 via the second flow path 244, as indicated by arrow BB in FIG. establish a fluid flow path in the

[0054]

[1107] With flow controller 240 in the second configuration, movable member 250 and/or 25 0' is actuated (i.e., depressed) by a user from a first position to a second position to move the patient's body. Fluid communication can be established between a portion (eg, a vein) and the first sample reservoir 280 and/or the second sample reservoir 290 . More specifically, movable member 250 moves from its first position to its second configuration such that piercing memb er 255 pierces vacuum seal 284 of first sample reservoir 280, as indicated by arrow CC in FI G. The piercing member 255 passes through the exit port 231 so that it can be opened and pl aced inside the sample container 282 . When in the second position, inlet port 253 and outlet port 254 of movable member 250 are substantially aligned with and in fluid communication wi th internal channel 235 such that bodily fluids flow from internal channel 235 to the movable member. It can flow into the internal cavity 252 of 250 and out of the lumen 256 of the pierci ng member 255 into the first sample reservoir 280 . A pressure differential between sample r eservoir 280 (eg, vacuum or negative pressure) and internal channel 235 draws bodily fluid in to sample reservoir 280 . In other words, in the second configuration, movable member 250 e stablishes a fluid flow path between internal flow path 235 and first sample reservoir 280, as i ndicated by arrow DD in FIG. Once a desired amount of bodily fluid (eg, a second amount) ha s been collected in first sample reservoir 280, the user releases movable member 250 such th at biasing member 259 returns the button to its first position. can be enabled to move to Whe n movable member 250 returns to its first position, piercing member 255 is removed from firs t sample reservoir 280 and seal 284 (e.g., a self sealing septum) opens first sample reservoir 280 to internal flow. It is fluidly isolated from channel 235 .

[0055]

[1108] Similarly, while the flow controller 240 is in the second configuration, the movable me mber 250' is actuated (depressed) by a user from its first position to its second position, as in dicated by arrow EE in FIG.)be able to. Thus, in a manner similar to the movable member 25 0 and the first sample reservoir 280 described above, a portion of the patient's body (eg, a ve in) and the second sample reservoir 290 (via the exit port 232). Fluid communication is establ ished. In other words, in the second configuration, movable member 250' establishes a fluid fl ow path between internal flow path 235 and second sample reservoir 290, as indicated by arr ow FF in FIG. Once a desired amount of bodily fluid (eg, a third amount) has been collected in

second sample reservoir 290, the user releases movable member 250' such that biasing mem ber 259' causes button 250' to move to its third position. It can be allowed to move back to o ne position. Although shown and described as being a sequential process, the order and/or se quencing of filling is not necessary (i.e., sample reservoir 280 may not necessarily fill before s ample reservoir 290, etc.). . In other words, when the flow controller 240 is moved to the sec ond configuration, the first sample reservoir 280 and the second sample reservoir 290 (and a ny additional sample reservoirs) are activated in any order at the same time (eg, simultaneou sly) and/or Or they can be filled in overlapping time intervals. For example, a user can initiate filling of the first sample reservoir 280, and then after the first sample reservoir 280 is partiall y filled, the user presses the movable member 250' to Filling of the second sample reservoir 2 90 can begin while the first sample reservoir 280 finishes filling. Additionally, adjustment of th e volume of bodily fluid collected in sample reservoirs 280 and/or 290 can be achieved by mo ving member 2

It can be enabled by repeatedly actuating (inserting) 50 and/or 250'. As noted above, the sec ond member 245 can have a third position corresponding to the third configuration of the flow controller 240, thereby substantially reducing fluid flow between the patient and the collection device 200 as a whole. to substantially seal the sample within the collection device 200 from t he external environment.

[1109

] Although not shown in FIGS. 2-13, the collection device 200 meters the volume of bodily flui d transferred to the pre-sample reservoir 270, the first sample reservoir 280 and/or the secon d sample reservoir 290. A flow metering device or the like can be included that can be configu red to. For example, in some embodiments, first member 241 of flow controller 240 can includ e a flow metering device in fluid communication with first flow path 242 and second flow path 244 . In other embodiments, a flow metering device can be positioned within the internal cavi ty 252 of the moveable member 250 and/or 250'. Accordingly, the volume of the bodily fluid s ample transferred to and placed in the first sample reservoir 280 and the second sample reser voir 290 may be such that the volume of the bodily fluid sample placed in each sample reserv oir 280 and 290 is e.g. It can be metered and/or controlled to have a predetermined volume, such as 30 mL.

[0057]

[1110] Although the collection device 200 is shown and described as including a first sample r eservoir 280 and a second sample reservoir 290, other embodiments may include any number of pre-sample reservoirs and/or sample reservoirs. can contain. For example, Figures 14 and 15 show a collection device 300 according to embodiments. As shown, some aspects of the co llection device 300 may be substantially similar to corresponding aspects of the collection devi ce 200 described above with reference to FIGS. 2-13. Accordingly, similar aspects are not des cribed in further detail herein.

[0058]

[1111] As shown in Figs. A fourth sample reservoir 390' is included. Pre-sample reservoir 370 may be substantially similar to pre-sample reservoir 270 described in detail above. In some e mbodiments, sample reservoirs 380, 380', 390 and 390' can be substantially similar to sample reservoirs 280 and 290 described in detail above. In some embodiments, sample reservoirs 3 80, 380', 390 and 390' can have substantially the same shape and size, eg, contain substanti ally the same medium. In other embodiments, sample reservoirs 380, 380', 390 and 390' can have substantially the same shape and size and contain one of aerobic or anaerobe media. ca n be done. For example, in some embodiments, the first sample reservoir 380 and the third s ample reservoir 390 can contain an aerobic culture medium, and the second sample reservoir 380' and the fourth sample reservoir 390' can contain an anaerobe culture medium. A culture medium can be included. In other embodiments, sample reservoirs 380, 380', 390 and 390' m ay each contain aerobic or anaerobe media in any arrangement or combination.

[0059]

[1112] The flow diverter mechanism 320 includes a housing 301 and a set of moveable memb ers 350, 350', 350'' and 350'''. Movable members 350, 350', 350'' and 350''' are substantially similar to movable member 250 described above with reference to FIG. 5, for example. Accor dingly, movable members 350, 350', 350'' and 350''' are positioned in a first position relative t o housing 301 such that they are placed in fluid communication with sample reservoirs 380, 3 80', 390 and 390', respectively. and a second position. The housing 301 is in fluid communicat ion with an inlet port 321 , a first outlet port 330 configured to be arranged in fluid communic ation with a pre-sample reservoir 370 , and a first sample reservoir 380 .

a second outlet port 331 configured to be arranged to be in fluid communication with a secon d sample reservoir 380' and a third outlet port 332 configured to be arranged in fluid commun ication with a third sample reservoir 390'; and a fifth outlet port 334 configured to be placed i n fluid communication with a fourth sample reservoir 390'. Further, housing 301 can be selecti vely placed in fluid communication with inlet port 321 and outlet ports 331 , 332 , 333 and 33 4 in a manner similar to that described above with respect to interior passageway 235 of hous ing 201 . An internal channel 335 is defined.

[1113

] The flow controller 340 is substantially similar to the flow controller 240 described above, e g, with reference to FIGS. 6-13. Accordingly, the flow controller 340 is rotated between the fir st and second configurations to provide a portion of the fluid flow path between the patient an d the pre-sample reservoir 370 or the sample reservoirs 380, 380', 390 and 390'. can be sele ctively defined. In this manner, a user can operate collection device 300 in a manner similar t o that described above with respect to collection device 200 in FIGS. 8-13. Thus, a first volum e of bodily fluid can be transferred to and placed in pre-sample reservoir 370, and subsequent volumes of bodily fluid can be transferred to and placed in sample reservoirs 380, 380', 390 a nd 390'. can be placed.

[0061]

[1114] FIGS. 16-22 illustrate a collection device 400 according to an embodiment. Collection device 400 includes flow diverter mechanism 420, flow controller 440 and sample reservoirs 480, 480', 490 and 490'. As further described herein, the collection device 400 can be moved between first, second, third, fourth and fifth configurations to, for example, collect microorganisms and/or microorganisms present on the skin. or a body fluid stream that is substantially free of extracorporeal microorganisms, such as other undesirable external contaminants. Collection device 400 may be of any suitable shape, size or configuration. For example, although sample reservoirs 480, 480', 490 and 490' are shown oriented perpendicular to housing 401 in FIGS. It is possible to have the sample reservoirs 480, 480', 490 and 490' oriented in a plane, arranged conically with respect to the housing 401, or the like.

[0062]

[1115] The sample reservoirs 480, 480', 490 and 490' are substantially similar or identical in form and function to the sample reservoirs 280 and/or 290 of the collection device 200; No details are given. As described above, the sample reservoirs 480, 480', 490 and 490' are negative pressure conditions that can allow fluid to be drawn from the patient into the sample reservoirs 480, 480', 490 and 490' via suction. (vacuum state) is maintained. In some embodiments, sample reservoirs 480 and 480′ can be aerobe culture bottles, sample reservoirs 490 and 490′ can be anaerobe culture bottles, and collection device 400 can be used to Thus, multiple aerobic and multiple anaerobic blood culture samples can be collected from a single venipuncture. As described in further detail herein, sample reservoirs 480, 480', 490 and 490' are each arranged in fluid communication with at least a portion of flow diverting mechanism 420 to receive a volume of bodily fluid sample. can do. The volume of the bodily fluid sample can be either predetermined or unquantified. Further, once a desired volume of bodily fluid has been placed within sample reservoirs 480, 480', 490, 490', each sample reservoir 480, 480', 490 and 490' will be displaced as described in further detail herein. can be fluidly isolated from at least a portion of flow diverting mechanism 420 .

[1116

] Flow diverting mechanism 420 includes housing 401 and distribution member 429 . Housing 401 of flow diverter mechanism 420 is physically and fluidly coupled to distribution member 429 to provide patient-to-body flow.

It provides and/or defines a set of fluid flow paths for collecting liquid. Housing 401 defines a recess 466 and a set of exit openings 403 . Recess 466 is configured to receive seal member 441 included in flow controller 440, as described in further detail herein. The set of outlet openings 403 is configured to define a different fluid flow path, each of which is in fluid communication with a different portion of the distribution member 429, a first outlet opening 403a, a second outlet opening 403b. , a third exit opening 403c, a fourth exit opening 403d and a fifth exit opening 403e. More specifically, distribution member 429 includes at least a portion of pre-sample reservoir 470 in fluid communication with first outlet opening 403a and a first channel 435a in fluid communication with second outlet opening 403b. , a second channel 435b in flui

d communication with the third outlet opening 403, a third channel 435c in fluid communicati on with the fourth outlet opening 403d, and a third channel 435c in fluid communication with the fifth outlet opening 403e. defines and/or forms four channels 435;

[0064]

[1117] As shown in FIGS. Pre-sample reservoir 470 is configured to contain bodily fluids such as, for example, blood, plasma, urine, and the like. A first outlet opening 403a of housing 401 can be substantially aligned with an open portion of pre-sample reservoir 470 to allow pre-sa mple reservoir 470 to receive the flow of bodily fluid from the patient. For example, pre-sampl e reservoir 470 can receive and contain a first amount or first volume of bodily fluid, where th e first amount of bodily fluid can be a predetermined amount or an unquantified amount. Addi tionally, the arrangement of the flow diverter mechanism 420 may be such that the pre-sampl e reservoir 470 may be configured to allow fluid from the flow paths 435a, 435b, 435c and 43 5d and/or subsequent volumes of bodily fluid withdrawn from the patient, as described in furt her detail herein. can be maintained in a systematically isolated manner. Although pre-sample reservoirs 270 and 370 are described above as maintaining a negative pressure, pre-sample r eservoir 470 does not maintain a negative pressure (vacuum) and therefore uses other mecha nisms such as gravity for example. can be used to draw bodily fluid into the pre-sample reser voir 470 .

[0065]

[1118] Channels 435a-435d extend radially from the center of distribution member 429 such that each channel 435a, 435b, 435c and 435d is fluidly isolated from pre-sample reservoir 47 0 and the other channels. are placed in In this manner, channels 435a, 435b, 435c and 435d are fluid flow channels between first and second ends substantially aligned with outlet openin gs 403b, 403c, 403d and 403e, respectively. can be oriented and/or otherwise defined. As sho wn in FIGS. 17 and 18, the distribution member 429 includes a first outlet port 431 positioned at the second end of the first flow path 435a and a second outlet port 431 positioned at the se cond end of the second flow path 435b. defining a second outlet port 432, a third outlet port 4 33 positioned at the second end of the third flow path 435c, and a fourth outlet port 434 posit ioned at the second end of the fourth flow path 435d; are doing. Further, the distribution me mber 429 includes a first piercing member 455a, a second piercing member 455b, a third pier cing member 455c and a fourth piercing member 455d, which are the first outlet port 431, th e second outlet port 432, the third It is physically and fluidly coupled to outlet port 433 and fo urth outlet port 434, respectively. Thus, as described in further detail herein, piercing member s 455a-355d can be used to pierce the vacuum seals of sample reservoirs 480, 480', 490 and 490', thereby allowing bodily fluids to flow. Flow can be started. Although not shown in Figure s 17 and 18, sample reservoirs 480, 480', 490 and 490' are in fluid communication with outlet ports 431, 432, 433 and 434, respectively. can be physically coupled (either directly or via an intervening structure, such as a sterile flexible tube) to a portion of distribution member 429 i n any suitable manner that can allow the can.

[0066]

[1119] The flow controller 440 includes a dial 445 and a seal member 441 . C
Lel member 441 is positioned within recess 466 of housing 401 (see, eg, FIG. 20). More particularly, coupling flow controller 440 to housing 401 such that seal member 441 is positioned between and in contact with the surface of housing 401 defining recess 466 and the surface of dial 445 . can be done. In addition, seal member 441 may be positioned against the surface of housing 401 defining dial 445 and recess 466 when flow controller 440 is coupled to housing 401, as described in further detail herein. can be sized and shaped to form a substantially fluid-tight seal with. The sealing member 441 is made of, for example, silicone, polylactic acid, polyglycolic acid, polylactic-co-glycolic acid (PLGA), polyanhydride, polyorthoester, polyetherester, polycaprolactone, polyesteramide, poly(butyric acid).), poly(valeric acid), polyurethanes, nylons, polyesters, polycarbonates, polyacrylates, polymers of ethylene-vinyl acetate and other acyl-substituted cellulose acetates, polystyrene, polyvinyl chloride, polyvinyl fluoride, poly(vinylimidazole), chloro It can be made from any material that is biocompatible, such as sulfonate polyolefins, polyethylene oxides and/or mixtures and copolymers thereof.

[0067]

[1120] As shown in FIG. 17, the sealing member 441 defines a set of openings 444 through which the flow of bodily fluids can be directed following venipuncture (or other method of accessing bodily fluids). . For example, the set of openings 444 defined by the seal member 441 includes a first opening 444a, a second opening 444b, a third opening 444c, a fourth opening 444d and a fifth opening 444e. The arrangement of the sealing member 441 is such that when the sealing member 441 is arranged in the recess 446, the first opening 444a, the second opening 444b, the third opening 444c, the fourth opening 444d, and the fifth opening 444e are , the first outlet opening 403a, the second outlet opening 403b, the third outlet opening 403c, the fourth outlet opening 403d and the fifth outlet opening 403e of the housing 401, respectively. is.

[0068]

[1121] The dial 445 of the flow controller 440 is rotatably coupled to the housing 401 and is movable between a first position, a second position, a third position, a fourth position and a fifth position relative to the housing 401. . Dial 445 includes an entry port 421 that defines lumen 402 . Inlet port 421 can be fluidly coupled to a medical device (not shown) that defines a fluid flow path for withdrawing and/or transporting bodily fluid from the patient's body to collection device 400 . For example, entry port 421 can be fluidly coupled to a needle or other lumen defining device (eg, flexible sterile tubing) either directly or indirectly via adapter 404 . Similarly, inlet lumen 402 defined by inlet port 421 is arranged to be in fluid communication with the lumen defined by the lumen-defining device when the lumen-defining device is coupled to inlet port 421 . be. Inlet port 421 thus connects to pre-sample reservoir 470, first sample reservoir 480, second sample reservoir 480', third sample reservoir 490 and fourth sample reservoir 490, as described in further detail herein. ' can be configured to be selectively placed in fluid

communication with a patient.

[0069]

[1122] As described above, the dial 445 is movable between a first position, a second positio n, a third position, a fourth position, and a fifth position. When the dial 445 is in the first posit ion, the flow controller 440 is arranged in a first configuration, aligning the inlet port 421 subs tantially with the first opening 444 a of the seal member 441 and the first outlet opening 403 a of the housing 401 . can be combined. Thus, the first opening 444a of the seal member 441 fluidly isolates the inlet port 421 from the outlet openings 403b, 403c, 403d and 403e, thereb y fluidly isolating the inlet port 421 from the flow paths 435a-335d. Fluid communication is es tablished between the inlet port 421 and the first outlet opening 403a while isolating to the fir st outlet port 403a. When the first outlet port 403a is aligned with the open portion of the pre -sample reservoir 470, the first opening 444a and the first outlet port 403a are aligned. Mouth opening 403 a establishes fluid communication between inlet port 421 and pre-sample reservoir 470 . When the dial 445 is rotated (or driven) to the second position, the flow contro ller 440 is placed in the second configuration and the second outlet opening 444b connects th e inlet port 421 to the outlet openings 403a, 403c, 403d and 403e. Fluid communication is est ablished between inlet port 421 and second outlet opening 403b while being fluidly isolated fr om. When the second outlet opening 403b is aligned with the first end of the first flow path 4 35a, the second opening 444b and the second outlet opening 403b are between the inlet port 421 and the first flow path 435a. establish fluid communication with the

[0070]

[1123] The collection device 400 operates similarly when the dial 445 is rotated to the third, f ourth and fifth positions. Thus, when inlet lumen 402 is placed in fluid communication with a p atient (eg, via a medical device coupled to inlet port 421), first outlet port 430, second outlet port 431, third outlet Port 432, fourth outlet port 433, and fifth outlet port 434 are selectively placed in fluid communication with inlet lumen 402 so that all body fluids are present in at lea st one of pre-sample reservoirs 470 or sample. It can be enabled to flow into one or more of r eservoirs 480, 480'490 and 490'. In some embodiments, additional seal outlet openings and/o r additional dials 445 corresponding to the configuration of the flow controller 440 are provide d to further direct/isolate fluid flow between the patient and the collection device 400. Can inc lude location. For example, dial 445 can have a sixth position corresponding to a sixth configu ration of flow controller 440 that substantially prevents fluid flow between the patient and coll ection device 400 as a whole. In other words, in some embodiments, after all bodily fluid sam ples have been removed from the patient, dial 445 may be moved to the sixth position to sub stantially seal the sample within collection device 400 from the external environment. can.

[0071]

[1124] In some embodiments, until after a predetermined volume of bodily fluid has been coll ected in the pre-sample reservoir 470, the bodily fluid does not flow to the outlet ports associ ated with the sample reservoir (eg, outlet ports 431-434). prevented. In some embodiments,

the exit ports associated with the sample reservoirs (eg, exit ports 431-434) can be placed in fluid communication with the entrance lumen 402 only sequentially (eg, exit ports 431-434). 431 must be in fluid communication with the inlet lumen 402 before the outlet port 432, etc.). In some embodiments, outlet ports associated with subsequent sample reservoirs (eg, outlet ports 432-434) are placed in fluid communication with inlet lumen 402 only after a defined vol ume of bodily fluid has been collected. can be placed. In some embodiments, the outlet ports associated with the sample reservoirs (eg, outlet ports 431-434) can be arranged in fluid com munication with the inlet lumen 402 in any random manner without any order preference. (e g, outlet port 434 can be in fluid communication with inlet lumen 402 before outlet port 431, outlet port 432 can be in fluid communication with inlet lumen 402 before outlet port 433, et c.)).

[0072]

[1125] In some embodiments, the housing 401 can selectively restrict movement of the dial 4 45 from its first position to its second, third, fourth and fifth positions. . In some embodiment s, housing 401 can be configured to prevent movement of dial 445 moved to the fifth positio n. In other words, housing 401 may include a locking mechanism that prevents dial 445 from moving back from the fifth position to the first position. Dial 445 and/or housing 401 may also include mechanical detents and/or other detents that provide visual or tactile feedback to ens ure correct positioning of dial 445 relative to exit openings 403a-403e of housing 401. It is als o possible to include an indicator.

[0073]

[1126] In operation, the collection device 400 can be used to collect bodily fluids (eg, blood, p lasma, urine, etc.) from a patient with reduced contamination. For example, entry port 421 of collection device 400 can be fluidly coupled to a needle or other lumen defining device (eg, fle xible sterile tubing). Following venipuncture (or other method of accessing bodily fluids), dial 445 is actuated (or turned) until it reaches the first position, as shown in FIGS. Alternatively, dial 445 can be preset to the first position and collection device 400 can be otherwise sealed t o maintain sterility of collection device 400 . For example, inlet port 421 can include a valve t hat opens when collection device 400 is coupled to a needle or other lumen defining device.

[0074]

[1127] As described above, when the dial 445 is in the first position, the flow controller 440 is disposed in the first configuration, and the first opening 444a of the seal member 441 connect s the inlet port 421 to the four flow paths 435a through 435a. Fluid communication is establis hed between inlet port 421 (contained within housing 401) and first outlet port 430 while bein g fluidly isolated from 335d. Further, sample reservoirs 480, 480', 490 and 490' are fluidly isol ated from inlet port 421 in the first configuration and are part of the patient's body (e.g., A flu id flow path is defined between the vein) and the pre-sample reservoir 470 . In this first confi guration, bodily fluid passes from that portion of the patient's body through the inlet lumen 4 02 of the inlet port 421, the first opening 444a of the seal member 441, the first outlet port 4

30, and into the pre-sample reservoir 470 (for example, by gravity, vacuum, etc.). In the firs t form, flow controller 440 also fluidly isolates pre-sample reservoir 470 from channels 435a-3 35d. Accordingly, a first volume (predetermined or unquantified) of bodily fluid can be receive d in pre-sample reservoir 470 immediately after venipuncture and isolated from subsequent s amples. Thus, with the collection device 400, a first volume of bodily fluid most likely to conta in surface microorganisms and/or other undesirable external contaminants may be diagnosed or affected by the contaminants. Subsequent volumes of bodily fluid samples collected and us ed for other tests can be uncontaminated.

[0075]

[1128] Following the collection of the bodily fluid pre-sample into the pre-sample reservoir 47 0, the dial 445 can be actuated (rotated) until it reaches the second position, as shown in FIG S. When dial 445 is in the second position, flow controller 440 is disposed in the second config uration, and second opening 444b of seal member 441 fluidly isolates pre-sample reservoir 47 0 from inlet port 421 while allowing inlet port 421 to flow. Establish fluid communication betw een 421 and channel 435a. In other words, in the second configuration, flow controller 440 es tablishes a fluid flow path between a portion of the patient's body (eg, a vein) and flow path 4 35a, as indicated by arrow HH in FIG. With the flow controller 440 in the second configuratio n, the sample reservoir 480 is actuated by the user from the first configuration to the second configuration (e.g., by pushing the piercing member 455a) into a portion of the patient's body (e.g., A vein) and the first sample reservoir 480 can be in fluid communication.

[0076]

[1129] As described above, the piercing member 455a is positioned inside the sample reservo ir 480 by piercing the vacuum seal of the sample reservoir 480 by moving the sample reservoi r 480 to the second configuration. In this second configuration, a portion of the patient's body (eg, a vein) is exposed to a vacuum suction force from the sample reservoir 480 due to the ne gative pressure (vacuum) within the sample reservoir 480 . A pressure differential between th e sample reservoir 480 (eg, vacuum or negative pressure) and that portion of the patient's bo dy draws fluid into the sample reservoir 480 . Bodily fluid passes from that portion of the pati ent's body through the inlet lumen 402 of the inlet port 421, the second opening 444b of the seal member 441, the second outlet opening 403b of the housing 401, and into the first flow path 435a. flow in. Vacuum suction draws the flow of bodily fluid through first channel 435a a nd into sample reservoir 480 via second outlet port 431 and piercing member 455a.

. In other words, in the second configuration, flow controller 440 establishes a fluid flow path between inlet port 421 and sample reservoir 480 . Once a desired amount of bodily fluid (eg, a second amount) has been collected in sample reservoir 480, the user actuates (rotates) flow controller 440 to a third position and/or rotates sample reservoir 480 to its The first sample re servoir 480 can be isolated from the channel 435a by moving it back to the first configuration. When sample reservoir 480 returns to the first configuration, piercing member 455a is remov ed from sample reservoir 480 and a seal (eg, self-sealing membrane) in sample reservoir 480

isolates first sample reservoir 480 from flow path 435a. Filling of the other sample reservoirs i s done similarly with the flow controller 440 positioned in the third, fourth and fifth configurati ons, respectively.

[0077]

[1130] It should be noted that the order and/or sequencing of filling is not necessary (ie, sam ple reservoir 480 does not necessarily need to be filled before sample reservoir 490, etc.). In other words, first sample reservoir 480 and second sample reservoir 490 (and any additional sample reservoirs) can be filled in any order. For example, the user can start filling the first sa mple reservoir 480, and then after the first sample reservoir 480 is partially filled, the user ca n fill the second sample reservoir 490. . Further, adjustment of the volume of bodily fluid colle cted in sample reservoirs 480 and/or 490 can be enabled by repeated filling of sample reservo irs 480 and/or 490 . However, in other embodiments, the order of filling is such that the secon d sample reservoir cannot be accessed until it is verified that a specified amount of bodily flui d has been placed in the first reservoir. It can be operated mechanically. As described above, t he dial 445 can substantially prevent fluid flow between the patient and the collection device 400 as a whole, substantially sealing the sample within the collection device 400 from the ext ernal environment. A sixth position for a sixth configuration of the flow controller 440 can be provided.

[0078]

[1131] The collection device 400 includes a set of four sample reservoirs (eg, a first sample re servoir 480, a second sample reservoir 480', a third reservoir 490 and a fourth reservoir 490') and/or to which other Although shown and described above as being coupled in a manner, in o ther embodiments the collection device may include and/or be coupled to any suitable numbe r of sample reservoirs. For example, Figures 23-25 show a collection device 500 according to an embodiment. As shown, some aspects of the collection device 500 can be substantially sim ilar to corresponding aspects of the collection device 500 described above with reference to FI GS. 16-22. Accordingly, similar aspects are not described in further detail herein.

[1132

] The collection device 500 includes a flow diverter mechanism 520 , a flow controller 540 , a f irst sample reservoir 580 and a second sample reservoir 590 . Sample reservoirs 580 and 590 can be substantially similar to the sample reservoirs described in detail above. In some embo diments, sample reservoirs 580 and 590 can have substantially the same shape and size and contain substantially the same medium. In other embodiments, sample reservoirs 580 and 59 0 can have substantially the same shape and size and can contain one of an aerobe medium o r an anaerobe medium. In still other embodiments, first sample reservoir 580 can have a first size that is substantially larger than the size of second sample reservoir 590 .

[0080]

[1133] As shown in FIGS. Housing 501 of flow diverter mechanism 520 is physically and fluidl y coupled to distribution member 529 to provide a set of fluid flow paths for collecting bodily f

luids from a patient and/or

stipulates. As described above with respect to housing 401, housing 501 can define a recess a nd first, second, and third outlet openings 503a, 503b, and 503c. The recess is configured to r eceive a seal member 541 included in flow controller 540, as described in detail above. First o utlet opening 503a, second outlet opening 503b and third outlet opening 503c correspond to f irst outlet opening 403a, second outlet opening 403b and third outlet opening 403c defined by housing 401, respectively. They can be substantially similar in form and function. Similarly, di stribution member 529 includes pre-sample reservoir 470 , first flow channel 435 a and secon d flow channel 435 a that are substantially similar to pre-sample reservoir 470 , first flow cha nnel 435 a and second flow channel 435 b included in flow diverter member 429 . Two flow pa ths 435b are defined. Thus, pre-sample reservoir 570 is in fluid communication with first outle t opening 503a, first channel 535a is in fluid communication with second outlet opening 503b, and as described above with respect to flow diverter mechanism 420; The second flow path 5 35b is in fluid communication with the third outlet opening 503c. As shown in FIG. 25, distribu tion member 529 is in fluid communication with first outlet port 531, which is in fluid commun ication with first channel 535a and first piercing member 555a, and second channel 535b, wit h second piercing member 555b. A second outlet port 532 is defined. As described above, pier cing members 555a and 555b can be used to pierce the vacuum seals of sample reservoirs 58 0 and 590, thereby initiating bodily fluid flow, as described in further detail herein. can do.

[0081]

[1134] The flow controller 540 includes a dial 545 and a seal member 541 . The seal member 541 is positioned within the recess of the housing 501 as described above. Thus, when flow co ntroller 540 is coupled to housing 501, seal member 541 forms a substantially fluid-tight seal with the surface of dial 545 and the surface of housing 501 that defines the recess. As shown in FIGS. 24 and 25, seal member 541 is substantially configured with first outlet opening 503 a, second outlet opening 503b and third outlet opening 503c, respectively, as described in det ail above with respect to seal member 441. defines a first opening 544a, a second opening 54 4b and a third opening 544c, which are aligned with each other.

[0082]

[1135] The dial 545 of the flow controller 540 may be substantially similar in form and functio n to the dial 445 while having a suitable size to be coupled to the housing 501 . Accordingly, d ial 545 may be rotatably coupled to housing 501 and movable relative to housing 501 betwee n first, second and third positions. Dial 545 includes an entry port 521 defining lumen 502 tha t defines a fluid flow path for withdrawing and/or transporting bodily fluid from a patient to col lection device 500. Medical device (not shown) can be fluidly coupled to In this way, inlet port 521 can be configured to selectively locate pre-sample reservoir 570 , first sample reservoir 5 80 and second sample reservoir 590 . More specifically, when the dial 545 is in the first positio n, the flow controller 540 is arranged in the first configuration and the inlet port 521 communi cates with the first opening 544a of the seal member 541 and the first outlet opening 503a of

the housing 501. is substantially aligned with Thus, as described in detail above with respect t o collection device 400, first opening 544a of seal member 541 establishes fluid communicatio n between inlet port 521 and first outlet opening 503a, and thus the inlet port. 521 is placed i n fluid communication with pre-sample reservoir 570 . Similarly, when the dial 545 is turned (or driven) to the second position, the flow controller 540 is placed in the second configuratio n and the second outlet opening 544b is connected to the inlet port 521 and the second outlet opening 503b. , thus establishing fluid communication with the first flow path 535a, and when the dial 545 is turned to the third position, the flow controller 540 is disposed in the third conf iguration, and the third outlet opening 544c communicates with the inlet port. Fluid communic ation is established between 521 and the third outlet opening 503c and thus the second flow path 535a. Thus, the collection device 500 is applied to the pre-sample 570 as described in de tail above with respect to the collection device 400 .

It can be used to transfer second and third volumes of bodily fluid to reservoir 580 and secon d sample reservoir 590, respectively.

[1136

] Figures 26-33 show a collection device 600 according to an embodiment. Collection device 6 00 includes flow diverter mechanism 620, flow controller 640 and sample reservoirs 680, 68 0', 690 and 690'. As further described herein, the collection device 600 can be moved betwee n first, second, third, fourth and fifth configurations to, for example, collect microorganisms a nd/or microorganisms present on the skin. A fluid stream can be delivered that is substantiall y free of extracorporeal microorganisms, such as or other undesirable external contaminants. Collection device 600 may be of any suitable shape, size or configuration. For example, aspect s and/or portions of collection device 600 may be similar in form and/or function to correspon ding aspects and/or portions of any of collection devices 100, 200, 300, 400 and/or 500 descr ibed above. . Accordingly, such similar aspects and/or parts will not be described in further de tail herein. By way of example, in some embodiments sample reservoirs 680, 680′, 690 and 6 90′ of collection device 600 are similar to sample reservoirs 480, 480′, 490 and 490′ included in collection device 400 of FIGS. may be substantially similar and/or the same in form and/or function as each.

[0084]

[1137] The flow diverting mechanism 620 includes a distribution member 629 and a set of co upling members 637a, 637b, 637c and 637d (see, eg, FIG. 27). Distribution member 629 is in fluid communication with coupling members 637a, 637b, 637c and 637d and is configured to provide and/or define a set of fluid flow paths for collecting bodily fluid from a patient. As sho wn in FIGS. 27 and 28, distribution member 629 includes a first outlet port 630 in fluid comm unication with pre-sample reservoir 670, a second outlet port 631 in fluid communication with first coupling member 637a; A third outlet port 632 in fluid communication with the second co upling portion 637b, a fourth outlet port 633 in fluid communication with the third coupling po rtion 637c, and a fifth outlet in fluid communication with the fourth coupling portion 637d. def

ines and/or forms a port 634;

[0085]

[1138] As shown in FIG. Pre-sample reservoir 670 is configured to contain bodily fluids such a s, for example, blood, plasma, urine, and the like. For example, the pre-sample reservoir 670 can receive and contain a first amount or volume of bodily fluid from a patient, where the first amount of bodily fluid can be a predetermined amount or an unquantified amount. Additionall y, the arrangement of flow diverter mechanism 620 and flow controller 640 allows pre-sample reservoir 670 to follow coupling portions 637a, 637b, 637c and 637d and/or bodily fluids with drawn from the patient, as described in further detail herein. It may be maintained fluidly isol ated from the volume. Thus, outlet ports 631, 632, 633 and 634 direct fluid flow paths betwe en flow controller 640 and coupling members 637a, 637b, 637c and 637d, respectively, as des cribed in further detail herein. may be attached and/or otherwise defined. In some embodime nts, the arrangement of first exit port 630 and pre-sample reservoir 670 can be substantially similar in form and function to pre-sample reservoirs 470 and/or 570 . Accordingly, pre-sampl e reservoir 670 will not be described in further detail herein.

[0086]

[1139] As shown in FIG. 29, the first coupling member 637a defines a channel 638a that is flu idly coupled to the piercing member 655a. Coupling member 637a can be physically and fluidl y coupled to distribution member 629, as described above. For example, channel 638a can re ceive a portion of distribution member second outlet port 631 and coupling member 637a can be physically and fluidly coupled thereto. In some embodiments, the surface of the second out let port 631 forms a substantially fluid-tight seal (e.g., fluid-tight seal) with the inner surface of the coupling portion 637a that defines the flow path 638a.

(e.g., a friction fit) that can form a substantially hermetic seal. The piercing member 655a of t he coupling portion 637a can be substantially similar in form and function to the piercing me mber 455a included in the collection device 400 of FIGS. 16-22. Accordingly, piercing member 655a will not be further described herein. The second coupling member 637b, the third coupli ng member 637c and the fourth coupling member 637d are similarly arranged. Accordingly, th e second coupling member 637b, the third coupling member 637c and the fourth coupling me mber 637d each include piercing members 655b, 655c and 655d respectively and define chan nels 638b, 638c and 638d respectively. As described in further detail herein, first coupling me mber 637a, second coupling member 637b, third coupling member 637c and fourth coupling member 637d are used to connect flow diverting mechanism 620 to first sample reservoir 68 0, It can be selectively placed in fluid communication with each of the second sample reservoi r 680', the third sample reservoir 690 and the fourth sample reservoir 690'.

[0087]

[1140] The flow controller 640 includes a dial 645 and a seal member 641, as shown in FIGS. A dial 645 of flow controller 640 is rotatably disposed within distribution member 629 (see FI GS. 32 and 33) and is movable between first, second, third and fourth positions. . Dial 645 inc

ludes an inlet port 621, a first outlet port 647 and a second outlet port 648, each in fluid com munication with interior space 646 (see, eg, FIG. 30). Interior space 646 is configured to rece ive a portion of seal member 641, as described in further detail herein. Inlet port 621 can be f luidly coupled to a medical device (not shown) that defines a fluid flow path for drawing bodily fluid from a patient and/or transporting it to collection device 600 . For example, inlet port 62 1 may be fluidly coupled to a needle or other lumen-defining device (e.g., flexible sterile tubin g) directly or indirectly via an adapter 604 (see, e.g., FIGS. 26 and 27). can do. First outlet po rt 647 is in fluid communication with pre-sample reservoir 670 . For example, first outlet port 647 can be rotatably disposed within first outlet port 630 of distribution member 629 . When dial 645 is in its first, second, third and fourth positions respectively, second outlet port 648 is connected to second outlet port 631, third outlet port 632, fourth outlet port 633 and It can b e selectively placed in fluid communication with the fifth outlet port 634 . Thus, the interior sp ace 646 of the dial 645 is divided into a pre-sample reservoir 670, a first sample reservoir 68 0, a second sample reservoir 680', a third sample reservoir 690 and a fourth sample reservoir, as described in further detail herein. It can be selectively placed in fluid communication with t he sample reservoir 690'.

[0088]

[1141] At least a portion of the sealing member 641 of the flow controller 640 is rotatably dis posed within an interior space 646 of the dial 645 and is movable between a first position and a second position. Further, seal member 641 can be sized and shaped such that an outer surf ace of seal member 641 forms a substantially fluid-tight seal with an inner surface of dial 645 that defines at least a portion of interior space 646 . As shown in FIG. 31, the sealing member 641 defines a first flow path 642 and a second flow path 644. As shown in FIG. When seal me mber 641 is in its first position within interior space 646 , passage 642 fluidly isolates inlet po rt 621 from second outlet port 648 while allowing inlet port 621 and first outlet port 647 to co mmunicate with each other. establish fluid communication therebetween. Similarly, when seal member 641 is in its second position within interior space 646 , second flow path 644 fluidly is olates inlet port 621 from first outlet port 647 while allowing inlet port 621 and second outlet port 647 to flow through inlet port 621 and second outlet port 647 . Establish fluid communica tion with outlet port 648 . Collection device 600 operates similarly when dial 645 is rotated wit hin dispensing member 629 to second, third and fourth positions. Accordingly, when inlet port 621 is placed in fluid communication with a patient (e.g., via a medical device coupled to inlet port 621 and/or adapter 604), first outlet port 630 of distribution member 629; 2 outlet port 631 , third outlet port 632 , fourth outlet port 633 and fifth outlet port 634 are in fluid commu nication with inlet port 621 .

to allow bodily fluids to flow into pre-sample reservoir 670, first sample reservoir 680, second sample reservoir 680', third sample reservoir 690 and fourth sample reservoir 690', respectiv ely. can be

[1142

] In operation, the collection device 600 can be used to collect bodily fluids (eg, blood, plasm a, urine, etc.) from a patient with reduced contamination. For example, entry port 621 of colle ction device 600 can be fluidly coupled to a needle or other lumen defining device (eg, flexible sterile tubing). Following venipuncture (or other method of accessing bodily fluids), the seal m ember can be actuated (or rotated) to its first position, as shown in FIG. Alternatively, the sea l member 641 can be preset in the first position and the collection device 600 can be otherwis e sealed to maintain the sterility of the collection device 600 . When seal member 641 is in its first position, flow controller 640 causes inlet port 621 and a first outlet port of distribution me mber 629 to flow through inlet port 621 from coupling members 637a, 637b, 637c and 637d while fluidly isolating inlet port 621 from coupling members 637a, 637b, 637c and 637d. 630 t o establish fluid communication. Thus, in a manner similar to that described above with respe ct to collection device 400, as indicated by arrow II in FIG. It can be transferred into pre-sam ple reservoir 670 via first exit port 630 of member 629 .

[0090]

[1143] Following collection of the bodily fluid pre-sample within pre-sample reservoir 670, sea l member 641 may be actuated (rotated) relative to dial 645 from its first position to its secon d position. Similarly, dial 645 can be actuated (or rotated) until it reaches the second position relative to distribution member 629, as shown in FIG. When seal member 641 and dial 645 ar e in their second positions, flow controller 640 is disposed in a second configuration and secon d flow path 644 of seal member 641 fluidly isolates pre-sample reservoir 670 from inlet port 6 21 . while establishing fluid communication between inlet port 621 and channel 638a of first c oupling member 637a. With flow controller 640 in its second configuration, sample reservoir 6 80 is actuated by a user from its first configuration to its second configuration (e.g., by pushin g piercing member 655a) to force a portion of the patient's body (e.g., , vein) and the first sa mple reservoir 680 . By moving the sample reservoir 680 to the second configuration, as desc ribed in detail above, the piercing member 655 a is positioned inside the sample reservoir 680 piercing the vacuum seal of the sample reservoir 680 . In this second configuration, that porti on of the patient's body (eg, a vein) is exposed to a vacuum suction force from the sample re servoir 680 due to the negative pressure (vacuum) within the sample reservoir 680 . Thus, as shown by arrows JJ in FIG. 33, body fluid is directed from that portion of the patient's body th rough inlet port 621, second channel 644, second outlet port 631 and channel 638a and throu gh the piercing member of first coupling member 637a. It can be forced through 655a into th e first sample reservoir 680.

[0091]

[1144] Once a desired volume of bodily fluid (eg, a second amount) has been collected in sam ple reservoir 680, the user may actuate (rotate) flow controller 640 to a third position and/or can be moved back to its first configuration to isolate the first sample reservoir 680 from the s econd flow path 644 . When the sample reservoir 680 returns to the first configuration, the pi ercing member 655a is removed from the sample reservoir 680 and the seal (eg, self-sealing

membrane) of the sample reservoir 680 fluidly removes the first sample reservoir 680 from th e flow path 635a. isolate to Filling of the other sample reservoirs is similarly performed with t he flow controller 640 positioned in the third, fourth and fifth configurations, respectively.

[1145

] Figures 34-40 show a collection device 700 according to an embodiment. The collection devi ce 700 includes a flow diverter 720, a flow controller 740 and sample reservoirs 780 and 780. 90 (although there are holders for four sample reservoirs, only two sample reservoirs are incl uded in the figure for clarity, and as part of the collection device 700 additional sample reserv oirs (e.g. 5th, 6th, etc.). As further described herein, the collection device 700 can be moved between first, second, third, fourth and fifth configurations to, for example, collect microorgan isms and/or microorganisms present on the skin. A bodily fluid stream can be delivered that is substantially free of extracorporeal microorganisms, such as other undesirable external conta minants. Collection device 700 may be of any suitable shape, size or configuration. For examp le, aspects and/or portions of collection device 700 may be substantially similar in form and/o r function to corresponding aspects and/or portions of any of collection devices 100, 200, 300, 400, 500 and/or 600 described above. can be similar to Accordingly, such similar aspects and/ or parts will not be described in further detail herein. By way of example, in some embodimen ts, sample reservoirs 780 and 790 of collection device 700 are substantially similar and/or sim ilar in form and function to sample reservoirs 480 and 490, respectively, included in collection device 400 of FIGS. or may be the same.

[0093]

[1146] The flow diverter mechanism 720 includes a housing 701, a distribution member 729 a nd a base plate 771. As shown in FIG. As described above with respect to collection device 40 0, housing 701 has a first outlet opening 703a, a second outlet opening 703b, a second outlet opening 703a, a second outlet opening 703b, and a second outlet opening 703a, each configu red to be in fluid communication with a different portion of distribution member 729. It define s three exit openings 703c, a fourth exit opening 703d and a fifth exit opening 703e. More spe cifically, distribution member 729 includes at least a portion of pre-sample reservoir 770 in flu id communication with first outlet opening 703a and a first fluid chamber 735a in fluid commu nication with second outlet opening 703b. , a second fluid chamber 735b in fluid communicati on with the third outlet opening 703b, a third fluid chamber 735c in fluid communication with the fourth outlet opening 703d, and a second fluid chamber 735c in fluid communication with the fifth outlet opening 703e. defines and/or forms four fluid chambers 735d. Additionally, ho using 701 defines a recess 766 configured to movably receive at least a portion of flow control ler 740, as described further herein.

[0094]

[1147] As shown in FIG. Pre-sample reservoir 770 is configured to contain bodily fluids such a s, for example, blood, plasma, urine, and the like. The first outlet opening 703a of the housin g 701 is substantially aligned with the open portion of the pre-sample reservoir 770 so that th

e pre-sample reservoir 770 can receive the flow of bodily fluid from the patient, as described i n detail above. be able to. More specifically, distribution member 729 includes a set of walls 7 36 that can, for example, divide the interior space of distribution member 729 into portions a nd/or spaces that are fluidly isolated from one another. For example, as shown in FIG. 36, a s et of walls 736 divides the interior space of distribution member 729 into pre-sample reservoir 770, first fluid chamber 735a, second fluid chamber 735b, third fluid chamber 735c and fourth fluid chamber 735c. It can be divided into chambers 735d. In some embodiments, wall 736 ca n equally define and/or form pre-sample reservoir 770 and fluid chambers 735a-735d. In othe r embodiments, pre-sample reservoir 770 can define a space that is different than the space d efined by fluid chambers 735a-735d.

[0095]

[1148] The distribution member 729 is in fluid communication with the first piercing member 755a, the second piercing member 755b, respectively, with the first fluid chamber 735a, the s econd fluid chamber 735b, the third fluid chamber 735c and the fourth fluid chamber 735d. , a third piercing member 755c and a fourth piercing member 755d. Thus, piercing members 7 55a-355d can be used to pierce sample reservoirs 780 and 790 (and corresponding sample re servoirs not shown in FIGS. 34-40), as described in further detail herein. , thereby initiating b odily fluid flow.

[1149

] The flow controller 740 of the collection device 700 includes a dial 745 and a seal member 7 41 . Seal member 741 is positioned within recess 766 of housing 701 (see, eg, FIGS. 38 and 40). More particularly, coupling flow controller 740 to housing 701 such that seal member 741 is positioned between and in contact with the surface of housing 701 defining recess 766 and the surface of dial 745 . can be done. Seal member 741 may be configured to form a substant ially fluid-tight seal with the surface of dial 745 and the surface of housing 701 defining recess 766, as described in detail above. As shown in FIG. 35, the sealing member 741 defines a first opening 744a, a second opening 744b, a third opening 744c, a fourth opening 744d and a fift h opening 744e. The arrangement of the sealing member 741 is such that when the sealing m ember 741 is arranged in the recess 766, the first opening 744a, the second opening 744b, th e third opening 744c, the fourth opening 744d, and the fifth opening 744e are formed. , the fi rst outlet opening 703a, the second outlet opening 703b, the third outlet opening 703c, the fo urth outlet opening 703d and the fifth outlet opening 703e of the housing 701, respectively. i s.

[0097]

[1150] The dial 745 of the flow controller 740 is rotatably coupled to the housing 701 and is movable relative to the housing 701 between a first position, a second position, a third positio n, a fourth position, and a fifth position. be. Dial 745 includes an entry port 721 that connects entry port 721 to a medical device (either directly or indirectly via adapter 704) that defines a fluid flow path for withdrawing bodily fluid from a patient and/or transporting it to collection d

evice 700.) can be fluidly coupled. Inlet port 721 thus connects to pre-sample reservoir 770, first sample reservoir 780, second sample reservoir 780', third sample reservoir 790 and fourt h sample reservoir 790, as described in further detail herein. ' can be configured to be selectiv ely placed in fluid communication with a patient. When dial 745 is in the first position, flow co ntroller 740 is disposed in a first configuration, aligning inlet port 721 substantially with first o pening 744 a of seal member 741 and first outlet opening 703 a of housing 701 . can be comb ined. Thus, the first opening 744a of the seal member 741 fluidly isolates the inlet port 721 fr om the outlet openings 703b, 703c, 703d and 703e, thereby fluidly isolating the inlet port 721 from the fluid chambers 735a-335d. Fluid communication is established between the inlet port 721 and the first outlet opening 703a while isolating to the first outlet port 703a. When the di al 745 is turned (or driven) to the second position, the flow controller 740 is placed in the sec ond configuration and the second outlet opening 744b connects the inlet port 721 to the pre-s ample reservoir 770 and the fluid chambers 735b-735b. Fluid communication is established b etween inlet port 721 and second outlet opening 703b while being fluidly isolated from 735d. Collection device 700 operates similarly when dial 745 is turned to the third, fourth and fifth p ositions. Accordingly, inlet port 721 is in fluid communication with the patient (eg, via a medic al device coupled to inlet port 721).

[1151

] In some embodiments, housing 701 selectively limits movement of dial 745 from its first pos ition to its second, third, fourth and fifth positions. be able to. In some other embodiments, th e housing 701 can be configured to prevent movement of the dial moved to the fifth position. In other words, housing 701 can include a locking mechanism that prevents dial 745 from mo ving back from the fifth position to the first position. This feature allows flow chambers 735a-735d and/or

This reduces the risk that bodily fluids collected in pull reservoirs 780 and 790 are contaminat ed from bodily fluids contained in pre-sample reservoir 770 (which has a high risk of containin g surface-bound microorganisms and/or other undesirable external contaminants). can be red uced. This locking mechanism can also protect medical personnel from exposure to blood-bor ne pathogens in patient samples, which may include HIV, hepatitis C, and the like. Dial 745 an d/or housing 701 may also have mechanical detents that provide visual or tactile feedback to ensure correct alignment of dial 745 with respect to exit port 703a and exit openings 703a-70 3d in housing 701. and/or other indicators may also be included.

[0099]

[1152] Similar to the embodiment of the collection device 400 shown in FIGS. The pre-sample reservoir 770 can contain bodily fluids such as, for example, blood, plasma, urine, and the lik e. Pre-sample reservoir 770 is configured to be fluidly coupled to first outlet port 703a of colle ction device 700 (located within housing 701). During operation of the collection device 700, when the flow controller 740 is in the first position, body fluid flows from a portion of the patie nt's body (eg, a vein) through the inlet port 721, into the pre-sample reservoir 770, into the s

eal member 741. is drawn into the opening for the pre-sample reservoir 744a and the first exi t port 703a located at . Pre-sample reservoir 770 is configured to contain a first volume of flui d to be drawn from a patient, where the first volume of bodily fluid can be a predetermined vo lume or an unquantified volume. Thereby the first volume of bodily fluid is fluidly isolated fro m a second and/or third and/or fourth and/or fifth volume of bodily fluid subsequently withdra wn from the patient.

[0100]

[1153] In operation, the collection device 700 can be used to collect bodily fluids (eg, blood, p lasma, urine, etc.) from a patient with reduced contamination. For example, entry port 721 of collection device 700 can be fluidly coupled to a needle or other lumen defining device (eg, fle xible sterile tubing). Following venipuncture, dial 745 is turned until it reaches the first positio n, as shown in FIGS. Alternatively, the dial 745 can be preset in the first position and the colle ction device 700 can be otherwise sealed to maintain the sterility of the collection device 700, as described above. With the dial 745 in the first position, the flow controller 740 is placed in a first configuration and the first outlet opening 744a of the seal member 741 fluidly connects the inlet port 721 from the four sample flow paths 735a-735d. While in isolation, fluid commu nication is established between inlet port 721 (contained within housing 701) and first outlet port 741 . In this first configuration, bodily fluids are directed from that portion of the patien t's body, as indicated by arrows KK in FIG. through and into the pre-sample reservoir 770 defi ned by the distribution member 770 . Accordingly, as described in detail above, a first volume (predetermined or unquantified) of bodily fluid can be received in pre-sample reservoir 770 im mediately after venipuncture and segregated from subsequent samples.

[0101]

[1154] Following the collection of the bodily fluid pre-sample within the pre-sample reservoir 770, the dial 745 can be actuated (or rotated) until it reaches the second position, as shown i n FIGS. When dial 745 is in the second position, flow controller 740 is placed in a second confi guration, and second outlet opening 744 a of seal member 741 fluidly isolates pre-sample res ervoir 770 from inlet port 721 while allowing inlet port 721 to flow. Fluid communication is est ablished between port 721 and first fluid chamber 735a. Once the first fluid chamber 735a is f illed with bodily fluid, the flow controller 740 can be moved to the third position to isolate and seal the first flow path 735a from the external environment. Additionally, the sample reservoir 780 is actuated from the first configuration to the second configuration to transfer bodily fluid from the first fluid chamber 735a to the sample reservoir 780.

can be sent. For example, sample reservoir 780 may be user or automatically actuated from a first configuration to a second configuration (pressing piercing member 755a) to allow a portio n of the patient's body (e.g., a vein) to move between sample reservoir 780 and sample reser voir 780. can establish fluid communication with the As described above, moving the sample r eservoir 780 to the second configuration causes the piercing member 755a to pierce the vacu um seal of the sample reservoir 780 and be positioned inside the sample reservoir 780 . In a

second configuration, that portion of the patient's body (eg, a vein) is subjected to vacuum su ction from the sample reservoir 780 due to the negative pressure (vacuum) existing within th e sample reservoir 780 in some embodiments. Thus, as indicated by arrow LL in FIG. 40, bodil y fluids flow from that portion of the patient's body through inlet port 721, second outlet open ing 744b in seal member 741, second outlet opening 703b in housing 701, second It flows int o the first sample reservoir 780 through the fluid chamber 735b.

[1155

] Once a desired amount of bodily fluid (eg, a second amount) has been collected in sample r eservoir 780, the user may actuate (rotate) flow controller 740 to a third position and/or The sample reservoir 780 can be moved back to its first configuration to isolate the first sample re servoir 780 from the inlet port 721 . When the sample reservoir 780 returns to the first config uration, the piercing member 755a is removed from the sample reservoir 780 and the seal (e g, self-sealing membrane) of the sample reservoir 780 allows the first sample reservoir 780 to enter the second fluid chamber 735b and the exterior. Fluid isolation from the environment. Fi lling of the other sample reservoirs is done in the same manner with the flow controller 740 in the third, fourth and fifth configurations respectively.

[0103]

[1156] In some embodiments, the collection device 700 can be configured such that there is no set of walls 736 separating the different fluid chambers 735a-735d within the distribution member 729 (detailed in FIG. 16). (see cross section). In such embodiments, the distribution member 729 is divided between the pre-sample reservoir 770 and the associated fluid chamb er 735 (ie, the fluid chamber is not separated into four separate portions by wall 736). In suc h embodiments, the user can fill all four sample reservoirs at once by actuating (rotating) dial 745 to either the second, third, fourth or fifth position. can be done.

[0104]

[1157] Any of the embodiments described herein can be used, for example, to meter (e.g., qu antify) the flow of bodily fluid into a pre-sample reservoir and/or a sample reservoir. Can be u sed with metering devices. In some cases, laboratory standard practice limits the exact inocul ation volume of bodily fluids (e.g., blood samples) due to the fact that fill volumes are judged visually by clinicians and/or phlebotomists and are therefore subject to human error. Consiste nt compliance is not ensured. The volume indicator on the blood collection bottle is difficult to read when held, and the fact that the collection bottle is not held upright during the withdraw al procedure contributes to the inaccurate volume of the bodily fluid sample received from the patient. could be a factor. Insufficient sample volume (eg, less than the manufacturer's recom mendation) can reduce the sensitivity of the culture test and lead to false-negative results. In addition, briefing materials and instructions for certain types of test supplies and equipment (e.g., blood culture bottles designed for use with automated microbial detection systems prod uced by manufacturers such as Becton Dickinson of Franklin Lakes, NJ). Filling volumes in exc ess of the manufacturer's recommendations, as indicated in the literature, may result in false

positives. Thus, flow metering and volume display capabilities allow laboratory technicians an d/or medical personnel (e.g., phlebotomists) to transfer sample reservoirs to incubators or oth er laboratories, depending on how the sample needs to be processed. The volume of bodily flu id collected in each individual sample reservoir can be verified prior to placement within the te sting device. The laboratory technician and/or phlebotomist may also provide accurate volume tric information (e.g., in medical records, databases, spreadsheets, etc.) for clinician evaluatio n when results are received.

), which helps reduce the likelihood of misinterpretation of false negative and/or false positive results.

[1158

] By way of example, FIGS. 41-45 illustrate a collection device 800 that can include one or mo re metering devices. Collection device 800 includes flow diverter mechanism 820 , flow contro ller 840 , display 875 and sample reservoir 880 . As further described herein, the collection de vice 800 can be moved between first, second and third configurations to remove, for example, microorganisms present on the skin and/or other undesirable external contaminants, and the l ike. , can deliver a body fluid stream that is substantially free of extracorporeal microorganis ms. Collection device 800 may be of any suitable shape, size or configuration. For example, as pects and/or portions of collection device 600 may be similar in form and/or function to corres ponding aspects and/or portions of any of collection devices 100, 200, 300, 400, 500, 600 an d/or 700 described above. can be substantially similar. Accordingly, such similar aspects and/o r parts will not be described in further detail herein. By way of example, in some embodiment s, sample reservoir 880 of collection device 800 is substantially similar and/or identical in for m and function to sample reservoir 480 included in collection device 400 of FIGS. could be.

[0106]

[1159] As shown in FIGS. 41-43, the flow diverter mechanism 820 includes an actuator portio n 822 (eg, a first portion), an intermediate portion 823 (eg, a second portion) and a coupling portion 824 (eg, a third portion). including. Actuator portion 822 of flow diverter mechanism 8 20 is substantially cylindrical including a set of actuator walls that define interior space 806 . More specifically, actuator portion 822 has a first end that is substantially closed and an oppos ite end that is substantially open to allow access to interior space 806 . a side second end. As such, actuator portion 822 can movably receive at least a portion of flow controller 840, as de scribed in further detail herein. Actuator portion 822 further includes inlet port 821 and outlet port 831 . Inlet port 821 is fluidly connected (either directly or indirectly via adapter 804) to a medical device that defines a fluid flow path for withdrawing bodily fluid from a patient and/or transporting it to collection device 800, as described in detail above. can be linked together.

[0107]

[1160] The outlet port 831 of the actuator portion 822 may be selectively positioned to place a portion of the interior space 806 of the actuator portion 822 in fluid communication with the interior space 807 defined by the intermediate portion 823. As shown in FIG. 43, intermediate

portion 823 is positioned between actuator portion 822 and coupling portion 824 . Although n ot shown in FIGS. 41-45, intermediate portion 823 can include a metering device that can be configured to meter a volume of bodily fluid transferred to sample reservoir 880, for example. For example, in some embodiments, a flow metering device can be fluidly coupled to outlet po rt 831 to meter the flow of bodily fluid therethrough. As shown in FIGS. 41 and 42, the interm ediate portion 823 includes a display 875 that provides a user with visual indicators and/or inf ormation related to the volume of bodily fluid that has flowed through the outlet port 831, for example. can provide. In other embodiments, the flow metering device may be placed at any other suitable location within or along the flow diverter 820 .

[1161

] The coupling portion 824 can be physically and fluidly coupled to the intermediate portion 82 3 . For example, in some embodiments, coupling portion 824 is partially disposed within interi or space 807 of intermediate portion 823 and attached thereto at least temporarily via a fricti on fit, press fit, snap fit, threaded connection, adhesive, or the like. can be linked together. Co upling portion 824 is configured to receive a portion of sample reservoir 880, as described in detail above, so that it can puncture the vacuum seal of sample reservoir 880, thereby initiati ng bodily fluid flow. includes a piercing member 855 that can be used to

[1162

] The flow controller 840 of the collection device 800 is disposed at least partially within the in terior space 806 defined by the actuator portion 822 and is movable between first, second an d third configurations. is. As shown in FIGS. 42 and 43, the flow controller 840 includes a mov able member 850 having a first sealing member 861, a second sealing member 862 and a thir d sealing member 863, and a biasing member 859 (eg, a spring or the like). including. Seal m embers 861 , 862 and 863 are in contact with the inner surface of actuator portion 822 that d efines interior space 806 . Accordingly, as described in further detail herein, each of the seal members 861, 862 and 863 has an inner surface that can, for example, divide the interior spa ce 806 of the actuator portion 822 into fluidly isolated portions; A fluid-tight seal can be form ed.

[0110]

[1163] The movable member 850 is movable within the interior space 806 between a first pos ition, a second position and a third position. The arrangement of movable member 850 is such that seal members 861, 862 and 863 selectively move within interior space 806 as movable m ember 850 moves between its first, second and third positions. It can be. More specifically, th e first sealing member 861 can move simultaneously with the movable member 850 as the m ovable member 850 moves between its first, second and third positions. A second seal memb er 862 and a third seal member 863 can be fixedly coupled to each other (eg, positioned at a fixed distance from each other) and slidably disposed about a portion of the movable member 850, which This causes movable member 850 to move from its first position (see, eg, FIG. 4 3) to its first position while second sealing member 862 and third sealing member 863 remain

in a substantially fixed position relative to actuator portion 822 . It may be possible to move t o two positions (see, eg, FIG. 44). For example, as movable member 850 moves between its f irst and second positions, second sealing member 862 and third sealing member 863 can rem ain in a substantially fixed position, thereby providing an inlet port. Port 821 is located on a fir st side of second sealing member 862 and exit port 831 is located on a second side of second sealing member 862 opposite the first side. Thus, when movable member 850 is in its first po sition (FIG. 43) and its second position (FIG. 44), inlet port 821 is in contact with first sealing member 861, as described in further detail herein. is in fluid communication with a portion of the interior space 806 defined between the second seal member 862 and the exit port is in th e interior space 806 defined between the second seal member 862 and the third seal member 863. in fluid communication with the part.

[0111]

[1164] The arrangement of the flow controller 840 is such that the first sealing member 861 moves relative to the second sealing member 862 and the third sealing member 863 when th e movable member 850 moves from its first position to its second position. , can be Movemen t of first seal member 861 relative to second seal member 862 can enlarge the space defined therebetween, thereby forming and/or otherwise defining pre-sample reservoir 870 . can do. I n addition, seal members 861 and 862 form a substantially fluid-tight seal with the inner surf ace of actuator portion 822 such that pre-sample reservoir 870 defined between first seal me mber 861 and second seal member 862 is , are fluidly isolated from the rest of the interior sp ace 806 . Thus, inlet port 821 can be in fluid communication with pre-sample reservoir 870 w hen moveable member 850 moves from its first position to its second position. As movable m ember 850 moves from its second position (see, eg, FIG. 44) to its third position (see, eg, FI G. 45), a portion of movable member 850 contacts third sealing member 863. , the first sealin g member 861 , the second sealing member 862 and the third sealing member 863 can be m oved substantially simultaneously within the interior space 806 . Accordingly, both the inlet po rt 821 and the outlet port 831 provide fluid communication to the portion of the interior space 806 defined between the second sealing member 862 and the third sealing member 863, as d escribed in further detail herein. A second sealing member 862 can be moved relative to the i nlet port 821 in communication.

[0112]

[1165] In operation, the collection device 800 can be used to collect bodily fluids (eg, blood, p lasma, urine, etc.) from a patient with reduced contamination. For example, entry port 821 of collection device 800 can be fluidly coupled to a needle or other lumen defining device (eg, fle xible sterile tubing). With inlet port 821 coupled to the lumen defining device, flow controller 840 can be moved from its first configuration to its second configuration. Thus, a user can app ly a force to move movable member 850 from its first position to its second position, as indica ted by arrow MM in FIG. As described above, the first sealing member 861 moves simultaneou sly with the movable member 850, thereby enlarging the space defined between the first seali

ng member 861 and the second sealing member 862, thereby A sample reservoir 870 is form ed and/or defined. First sealing member 861 and second sealing member 862 form a substant ially fluid-tight seal with the inner surface of actuator portion 822 that defines interior space 8 06 such that first sealing member 861 and second sealing member 862 are in contact with ea ch other. A negative pressure is created in the pre-sampling reservoir 870 by the increase in v olume between . Accordingly, once fluid communication is established between a portion of th e patient's body (eg, a vein) and the pre-sample reservoir 870 (eg, via inlet port 821 in FIG. 4 4), indicated by arrows NN in FIG. As such, the negative pressure differential between pre-sa mple reservoir 870 and that portion of the patient's body draws fluid into pre-sample reservoir 870 through inlet port 821 . In this first configuration, flow controller 840 also fluidly isolates pre-sample reservoir 870 from outlet port 831 . Accordingly, a first volume (predetermined or unquantified) of bodily fluid can be received in pre-sample reservoir 870 (for example) immed iately after venipuncture and isolated from subsequent samples. In this manner, the collection device 800 can be used to collect surface microorganisms and/or other undesirable A first vol ume of bodily fluid most likely to contain an external contaminant contaminates a subsequent volume of bodily fluid sample collected and used for diagnosis or other testing that may be aff ected by the contaminant can be prevented. In some embodiments, the metering device can meter a volume of bodily fluid placed in pre-sample reservoir 870 and present a value associa ted with that volume on display 875 .

[0113]

[1166] Following collection of the body fluid pre-sample volume in pre-sample reservoir 870, moveable member 850 is moved from its second position to its third position, as indicated by arrow OO in FIG. It can be arranged in a third configuration. As described above, when movab le member 850 moves from its second position to its third position, a portion of movable mem ber 850 is placed in contact with third sealing member 863 . Accordingly, the movable membe r 850 moves the first sealing member 861 , the second sealing member 862 and the third seal ing member 863 substantially simultaneously within the interior space 806 . Accordingly, the s econd sealing member 862 is positioned such that both the inlet port 821 and the outlet port 831 are in fluid communication with the portion of the interior space 806 defined between the second sealing member 862 and the third sealing member 863 . It can be moved relative to p ort 821 . Furthermore, because the volume of body fluid is fluidly isolated within the pre-sam ple reservoir 870, movement of the second seal member 862 and the third seal member 863 i n the direction of the first seal member 861 is restricted (i.e., body fluid is a substantially inco mpressible fluid). Thus, the pre-sample volume of bodily fluid is sequestered within pre-sampl e reservoir 870 and the space defined between second sealing member 862 and third sealing member 863 is separated by inlet port 821 and outlet port 821 . 831 defines a fluid flow path. Further, flow controller 840 is positioned such that when in its third configuration, first sealing member 861 is in contact with biasing member 859 such that at least a portion of the force ex erted by the user on movable member 850 is The biasing member 859 is operable to deform,

compress, bend and/or otherwise reconfigure. Accordingly, the biasing member 859 acts agai nst the first sealing member 861 to resist movement of the flow controller 840 from its secon d configuration to its third configuration, as described in further detail herein. can affect

[1167

] As described in detail above, piercing member 855 provides a vacuum seal for sample reser voir 880.

The sample reservoir 880 can be positioned relative to the collection device 800 such that the hole is pierced and placed inside the sample reservoir. A pressure differential between the sa mple reservoir 880 (eg, vacuum or negative pressure) and that part of the body draws body fl uid into the sample reservoir 880 . In other words, in the second configuration, flow controller 840 and flow diverter mechanism 820 direct body fluid from the patient through inlet port 82 1, second sealing member 862, and third sealing member 863, as indicated by arrow PP in FI G. through the portion of the interior space 806 defined therebetween, and the exit port 831 of the actuator portion 822, through the piercing member 855 of the intermediate portion 823 and the coupling portion 824, and into the sample reservoir 880; Establish a fluid flow path. A s discussed above, a metering device (not shown) can meter the volume of bodily fluid transfe rred, for example, through outlet port 831 and can present a value associated with the volum e of bodily fluid on display 875 .

[0115]

[1168] Once a desired volume of bodily fluid (eg, a second amount) has been collected in the sample reservoir 880, the user can remove and/or reduce the force applied to the movable m ember 850, thereby , a biasing member 859 can move the first sealing member 861 and the movable member 850 from their third position toward their second position. Further, due to th e substantially incompressible nature of the bodily fluid disposed within pre-sample reservoir 870, movement of first sealing member 861 transfers force through the volume of bodily flui d, thereby increasing second sealing member 862 and third sealing member 862. Seal memb ers 863 are moved from their third position toward their second position. In some embodimen ts, the biasing member 859 is operable to move the second seal member 862 relative to the a ctuator portion 822, for example, to a fourth position where the inlet port 821 can be substan tially blocked. The resulting force can be applied to the first sealing member 861 . Accordingl y, inlet port 821 can be fluidly isolated from interior space 806 of actuator portion 822 . Additi onally, the piercing member 855 can be removed from the sample reservoir 880 and a seal (e g, a self-sealing membrane) can fluidly isolate the bodily fluid sample from the space outside t he sample reservoir 880 . Subsequent filling of the sample reservoir is similarly accomplished by placing piercing member 855 into the sample reservoir and moving flow controller 840 to t he third configuration to allow bodily fluid to flow from the patient into the sample reservoir. c an be done.

[0116]

[1169] FIGS. 46-53 illustrate a collection device 900 according to an embodiment. Collection

device 900 includes flow diverter mechanism 920, flow controller 940 and sample reservoirs 9 80, 980', 990 and 990'. As further described herein, the collection device 900 can be moved b etween first, second, third, fourth and fifth configurations to, for example, collect microorgani sms and/or microorganisms present on the skin. or a body fluid stream that is substantially fr ee of extracorporeal microorganisms, such as other undesirable external contaminants. Collec tion device 900 may be of any suitable shape, size or configuration. For example, aspects an d/or portions of collection device 900 may be corresponding aspects and/or portions and confi gurations and/or of any of collection devices 100, 200, 300, 400, 500, 600, 700 and/or 800 d escribed above. They may be substantially similar in function. Accordingly, such similar aspect s and/or parts will not be described in further detail herein. By way of example, in some embo diments, sample reservoirs 980, 980', 990 and 990' of collection device 900 are similar to sa mple reservoirs 680, 680', 690 and 690 included in collection device 600 of FIGS. ' can be sub stantially similar and/or the same in form and function.

[1170

] The flow diverter mechanism 920 includes a housing 901, a distribution member 929 and m ovable members 950a, 950b, 950c and 950d. Housing 901 is physically and fluidly coupled to distribution member 929 to provide and/or define a set of fluid flow paths for collecting bodily fluids from a patient. Housing 901 may be included in a flow metering device and/or otherwis e (e.g., electrically and/or mechanically) as described in further detail herein.

and a set of displays 975' (eg, liquid crystal displays (LCDs), etc.) that can be coupled togethe r. Housing 901 defines recess 966, exit openings 903a, 903b, 903c, 903d, 903e and movable member openings 950a, 950b, 950c, 950d (also referred to herein as "openings"). Recess 966 is configured to receive seal member 941 included in flow controller 940, as described in furth er detail herein. First outlet opening 903a, second outlet opening 903b, third outlet opening 9 03c, fourth outlet opening 903d and fifth outlet opening 903e are each in fluid communication with different portions of distribution member 929. It is configured to define different fluid flo w paths. More specifically, distribution member 929 includes at least a portion of pre-sample r eservoir 970 in fluid communication with first outlet opening 903a and a first channel 935a in fluid communication with second outlet opening 903b. , a second passageway 935b in fluid co mmunication with the third outlet opening 903b, a third passageway 935c in fluid communicat ion with the fourth outlet opening 903d, and a second passageway 935c in fluid communicatio n with the fifth outlet opening 903e. defines and/or forms four channels 935;

[0118]

[1171] As shown in FIGS. Pre-sample reservoir 970 is configured to contain bodily fluids such as, for example, blood, plasma, urine, and the like. As described in detail above with respect t o pre-sample reservoir 470 in FIGS. 16-22, first outlet opening 903a of housing 901 is pre-mo unted to allow pre-sample reservoir 970 to receive a flow of bodily fluid from the patient. It ca n be substantially aligned with the open portion of sample reservoir 970 . Channels 935a-935 d extend radially from the center of distribution member 929 and are arranged such that each

channel 935a, 935b, 935c and 935d is fluidly isolated from pre-sample reservoir 970 and the other channels. ing. Thus, channels 935a, 935b, 935c and 935d have first ends defining openi ngs substantially aligned with outlet openings 903b, 903c, 930d and 903e, respectively, and movable members 950a, 950b, A fluid flow path may be directed and/or otherwise defined bet ween the second ends defining openings or ports configured to receive 950c and 950d, respec tively. Although distribution member 929 is shown in FIGS. 47 and 48 as including channels 9 35a-935d that are substantially closed, in other embodiments, with respect to distribution me mber 429 of FIGS. Channels 935a-935d can be substantially open as shown and described ab ove. Accordingly, distribution member 929 of collection device 900 can function substantially s imilar to distribution member 429 of collection device 400 .

[0119]

[1172] Movable members 950a, 950b, 950c and 950d are movably disposed in respective ope nings 905a, 905b, 905c and 905d of housing 901 and corresponding openings defined by the second end of distribution member 929. be. Although not shown in FIGS. 46-53, in some emb odiments moveable members 950a, 950b, 950c and 950d are biased members, as described i n detail above with respect to moveable members 250 and 250′ of collection device 200. etc. can be operatively coupled. Thus, movable members 950a, 950b, 950c and 950d are actuated (moved) by a user from first and second positions relative to housing 901 and distribution me mber 929 to direct fluid flow to a first sample. It can be directed into each of reservoir 980, se cond fluid reservoir 980', third fluid reservoir 990 and fourth sample reservoir 990'. Movable members 950a, 950b, 950c and 950d are substantially identical and therefore will be describe d with respect to a single movable member 950 in FIG. Additionally, some portions of movable member 950 may be substantially similar to movable members 250 and 350 described above. Accordingly, some portions of movable member 950 are not described in further detail herein. Movable member 950 defines an internal cavity 952 in fluid communication with inlet port 953 and piercing member 955 . The piercing member is substantially similar to that detailed abov e. The inlet port 953 extends through a set of walls that define the interior space 952 of the movable member 950 with corresponding passages 935a, 935b, 935c.

Alternatively, an internal chamber 952 is defined for selective placement in fluid communicatio n with 935d.

[1173

] As shown in FIG. The flow metering mechanism 967 can be, for example, a wheel or the like that can include a set of spokes or fins. In this manner, bodily fluid can enter inlet port 953 of movable member 950 and flow past flow metering device 967 , thereby allowing flow meterin g device 967 to rotate relative to movable member 950 . Accordingly, the rotational features o f the flow metering device 967 may be usable in determining the volume of bodily fluid transf erred to the interior space 952 of the movable member 950, the volumetric flow rate, and the like. Although not shown in FIGS. 46-53, flow control mechanism 967 of movable member 95 0 is operably coupled to display 975 ′ of housing 901 . Accordingly, as bodily fluids are transfe

rred to sample reservoirs 980, 980', 990 and/or 990', for example, volumetric information rel ated to the flow of bodily fluids can be presented on display 975'. In this way, a user can oper ate the collection device 900 to collect a bodily fluid sample from a patient, e.g. One can be vi sualized.

[0121]

[1174] The flow controller 940 of the collection device 900 includes a dial 945 and a seal me mber 941 . Seal member 941 is disposed within recess 966 of housing 901 . More particularly, flow controller 940 is coupled to housing 901 such that seal member 941 is positioned betwee n and in contact with the surface of housing 901 defining recess 966 and the surface of dial 9 45 . be able to. As described in detail herein, sealing member 941 can be configured to form a substantially fluid-tight seal with the surface of dial 945 and the surface of housing 901 defini ng recess 966 . As shown in FIG. 47, the sealing member 941 defines a first opening 944a, a second opening 944b, a third opening 944c, a fourth opening 944d and a fifth opening 944e. As for the arrangement of the sealing member 941, when the sealing member 941 is arrange d in the recess 966, the first opening 944a, the second opening 944b, the third opening 944c, the fourth opening 944d, and the fifth opening 944e are opened. , the first outlet opening 903 a, the second outlet opening 903b, the third outlet opening 903c, the fourth outlet opening 90 3d and the fifth outlet opening 903e of the housing 901, respectively. is.

[0122]

[1175] The dial 945 of the flow controller 940 is rotatably coupled to the housing 901 and is movable relative to the housing 901 between a first position, a second position, a third positio n, a fourth position, and a fifth position. be. Dial 945 includes an entry port 921 that connects entry port 921 to a medical device (either directly or indirectly via adapter 904) that defines a fluid flow path for drawing bodily fluid from a patient and/or transporting it to collection devic e 900.) can be fluidly coupled. Inlet port 921 thus connects to pre-sample reservoir 970, first sample reservoir 980, second sample reservoir 980', third sample reservoir 990 and fourth sa mple reservoir 990, as described in further detail herein. ' can be configured to be selectively placed in fluid communication with a patient. configuring dial 945 to rotate through first, seco nd, third, fourth and fifth positions in a manner substantially similar to that described above w ith respect to dial 445 of collection device 400; , and therefore will not be described in further detail here.

[1176

] As shown, the dial 945 can further include a display 975 that can be configured to present v olumetric information related to the flow of bodily fluids. For example, although not shown in FIGS. 46-53, a dial may be a flow metering device included in movable member 950
967, can include flow metering devices and the like. Thus, the flow metering device can, for e xample, meter the flow of bodily fluid through inlet port 921 such that volumetric information associated with the flow of bodily fluid through inlet port 921 is presented on display 975 of di al 945. , may be operatively coupled to the display 975 .

[1177

] In operation, the collection device 900 can be used to collect bodily fluids (eg, blood, plasm a, urine, etc.) from a patient with reduced contamination. For example, entry port 921 of colle ction device 900 can be fluidly coupled to a needle or other lumen defining device (eg, flexible sterile tubing). Following venipuncture (or other method of accessing bodily fluids), dial 945 is actuated (or turned) until it reaches the first position, as shown in FIGS. Alternatively, dial 94 5 can be preset to the first position and collection device 900 can be otherwise sealed to main tain sterility of collection device 900 .

[0125]

[1178] As described above, when the dial 945 is in the first position, the flow controller 940 is disposed in the first configuration, and the first opening 944a of the seal member 941 connect s the inlet port 921 to the four flow paths 935a to 935a. Fluid communication is established b etween inlet port 921 (contained within housing 901) and first outlet port 930 while being flui dly isolated from 335d. Further, sample reservoirs 980, 980', 990 and 990' are fluidly isolated from inlet port 921 in the first configuration and are part of the patient's body (e.g., A fluid flo w path is defined between the vein) and the pre-sample reservoir 970 . In this first configurati on, bodily fluids are forced (e.g., by gravity, vacuum, etc.) from that portion of the patient's b ody through inlet port 921, first opening 944a in seal member 941, and first outlet port 903a i n housing 901. through and into the pre-sample reservoir 970 . In the first form, flow controll er 940 also fluidly isolates pre-sample reservoir 970 from flow paths 935a-935d. Accordingly, a first volume (predetermined or unquantified) of bodily fluid can be received in pre-sample re servoir 970 immediately after venipuncture and isolated from subsequent samples. In this wa y, using the collection device 900, a first volume of bodily fluid most likely to contain surface microorganisms and/or other undesirable contaminants may be diagnosed or otherwise affect ed by the contaminant. Subsequent amounts of bodily fluid samples collected and used for tes ting can be avoided from contaminating. Additionally, the display 975 can present information received from a flow control mechanism (not shown) related to, for example, the volume of b odily fluid transferred to the pre-sample reservoir 970 . Thus, a precise volume of bodily fluid can be transferred to and fluidly isolated within the pre-sample reservoir.

[0126]

[1179] Following the collection of the bodily fluid pre-sample within the pre-sample reservoir 970, the dial 945 can be actuated (or rotated) until it reaches the second position, as shown i n FIGS. When the dial 945 is in the second position, the flow controller 940 is disposed in the second configuration, and the second opening 944b of the seal member 941 fluidly isolates th e pre-sample reservoir 970 from the inlet port 921 while allowing the inlet port 921 to flow. Fl uid communication is established between 921 and channel 935a. With flow controller 940 in t he second configuration, movable member 950a is actuated (i.e., depressed) by a user from a first position to a second position to allow patient (eg, vein) and first sample reservoir 880 to move. can establish fluid communication between the More specifically, as indicated by arrow

RR in FIG. to be placed in the first sample reservoir 980 .

[1180

] While in the second position, the inlet port 953 of the movable member 950 is substantially aligned with and in fluid communication with the first flow path 935a, thereby allowing body fl uid to flow through the first flow path 935a. can flow from into the internal cavity 952 of the working member 950 and out of the piercing member 955 into the first sample reservoir 980 . Sample reservoir 980 (e.g. vacuum or negative pressure)

) and the first channel 935 a draws bodily fluid into the sample reservoir 980 . In other words, in the second configuration, flow controller 940 and movable member 950a establish a fluid fl ow path between inlet port 921 of dial 945 and first sample reservoir 980, as indicated by arr ow SS in FIG. In addition, flow of bodily fluids through movable member 950 a causes flow m etering mechanism 967 to rotate relative to movable member 950 . Thus, rotation of flow met ering mechanism 967 may be usable in determining the volume of bodily fluid sample transfer red to sample reservoir 980 . Additionally, display 975 ′ can present information received from flow control mechanism 967 related to, for example, the volume of bodily fluid transferred to sample reservoir 980 . Therefore, a precise volume of bodily fluid can be transferred to the sa mple reservoir 980 . For example, in some cases, collection device 900 is used to collect three sample volumes of 20 mL each in first sample reservoir 980, second sample reservoir 980', an d third sample reservoir 990 (i.e., a total of 60 mL of sample volume is collected).

[0128]

[1181] Once a desired volume of bodily fluid (eg, a second amount) has been collected in the first sample reservoir 980, the user releases the movable member 950 to cause the biasing m ember (not shown) to It can be allowed to move back to the first position. When movable me mber 950 returns to its first position, piercing member 955 is removed from first sample reser voir 980 and a seal (eg, a self-sealing membrane) fluidly disconnects first sample reservoir 98 0 from internal flow path 935 . isolate to Using the collection device 900, transfer the second sample volume to the second sample reservoir 980' and the third sample volume to the third sample by rotating the dial 945 to its third, fourth and fifth positions, respectively. A fourth sa mple volume can be similarly transferred to reservoir 990 to fourth sample reservoir 990'.

[0129]

[1182] In some cases, the fluid collection device 900 allows the clinician and/or phlebotomist to open the package containing the fluid collection device 900, remove only the housing 901 (including the dispensing member 929), and remove the housing 901. It can be carried by the patient's bedside. The clinician and/or phlebotomist performs a venipuncture (or employs any other method of accessing the patient's bodily fluids) into a portion of the patient's body (e.g., a vein) using any standardized technique be able to. Following venipuncture, the clinician an d/or phlebotomist can collect the total blood volume required for all samples. For example, a c linician and/or phlebotomist can collect a 2.5 mL pre-sample diversion volume and a 10 mL sa mple volume for each of the four sample reservoirs, whereby the collected bodily fluid (e.g., b

lood) totals 42.5 mL. Following collection of a desired amount of bodily fluid, the hypodermic needle can be removed from that portion of the patient's body (e.g., a vein) and the clinician and/or phlebotomist can access the housing 901 (which contains the bodily fluid). can be plac ed on top of 4-pack (or 2-pack) pre-sterilized sample reservoirs with the membrane tops pre-placed in custom trays that match the shape of housing 901. By using such pre-sterilized pack s of sample reservoirs, the clinician does not have to perform the process step of "wiping" the sample reservoir tops with a sterilant, thereby, for example, sterilizing the reservoir tops. Red uced potential for contamination if inappropriate and/or insufficient. A clinician and/or phlebot omist can then trigger automatic inoculation of a sample reservoir containing bodily fluid with precise volume control. In some embodiments, after inoculation of the sample reservoirs is co mplete, the entire device 900 with volume information displayed for each individual sample re servoir can be sent to a laboratory for analysis. In other embodiments, sample reservoirs 980 and/or 990 are individually

[1183

] The collection device 900, with reference to FIGS.

Although shown and described as including 975 and 975', in other embodiments the collection device can include any suitable flow metering mechanism with any suitable output indicator. F or example, Figures 54 and 55 show a flow diverter 1020 and a flow controller 1040 according to embodiments. Flow diverter 1020 and flow controller 1040 may be substantially similar in f orm and function to flow diverter 920 and flow controller 940, respectively. Accordingly, simila r parts will not be described further herein. However, flow diverter 1020 and flow controller 10 40 may differ in the placement of set of displays 1075 . For example, flow diverting mechanis m 1020 includes housing 1001 configured to movably receive a set of movable members 1050 a, 1050b, 1050c and 1050d, each of which can include a flow metering mechanism, as describ ed above with respect to movable member 950. include. Accordingly, movable members 1050 a, 1050b, 1050c and 1050d can be used to determine the precise volume of bodily fluid that i s transported through them. As shown in FIG. 55, the display 1075 of the housing 1001 provi des a first illumination for a small volume (eg, 5 mL), a second illumination associated with an intermediate volume (eg, 20 mL), and an acceptable and/or large volume. A set of three light s can be included, including a third light associated with (eg, 40 mL). In this manner, when th e flow of bodily fluid is transferred through the flow controller 1040 and the flow diverter mec hanism 1020, for example into the first movable member 1050a, the flow metering mechanis m contained therein can send a signal or the like to the display. , the display is operable to illu minate the first light, the second light and/or the third light according to the volume of bodily fluid transferred through the movable member 1050 .

[0131]

[1184] In other embodiments, movable members 1050a, 1050b, 1050c, and 1050d can be m oved from a first position to a second position, a third position, or a fourth position relative to housing 1001 . In such embodiments, their positions can be associated with, for example, the

intended volume of bodily fluid to be transferred to the sample reservoir. For example, in som e embodiments, a user can actuate (eg, move) movable member 1050a from its first position to its second position. In such embodiments, the second position can be associated with, for e xample, a small volume (eg, 10 mL) of bodily fluid to be transferred to the sample reservoir. I n some embodiments, housing 1001 and/or moveable member 1050a can temporarily hold m oveable member 1050a in a second position until a low volume of sample has been transferre d to the sample reservoir. , locks, fasteners, protrusions, recesses, and the like. Further, when positioned in the second position, display 1075 is configured to illuminate a first illumination a ssociated with the smaller volume to indicate to the user the preset volume of bodily fluid to b e transferred to the sample reservoir. can do. Once a desired volume of bodily fluid has been t ransferred to and fluidly isolated within the sample reservoir, the flow diverter mechanism 102 0 can be configured to automatically return the movable member 1050a to its first position. I n this manner, flow diverter mechanism 1020 and flow controller 1040 can be physically and fl uidly coupled to any number of sample reservoirs and used to transfer precise volumes of bod ily fluid to each sample reservoir.

[0132]

[1185] FIG. 56 is a flowchart illustrating a method 1190 of obtaining a predetermined sample volume of bodily fluid from a patient using a flow metering transfer device. A flow metering tr ansfer device can be any of the transfer devices described herein (also referred to herein as a "collection device"). By way of example, in some embodiments the transfer device can be the collection device 900 described above with reference to FIGS. 46-53. Thus, the transfer devic e includes an inlet port configured to be selectively placed in fluid communication with a patie nt, a pre-sample reservoir and a sample reservoir, and fluid flow from the patient to the pre-s ample reservoir and to the sample reservoir. and a flow metering mechanism configured to m eter the flow of bodily fluid. The method 1190 includes, at 1191, establishing fluid communica tion between a patient and a port of a flow metering transfer device. For example, the port m ay be connected to a needle or other lumen-defining device (e.g., a flexible

A needle or other lumen-defining device can be inserted into the patient's body (eg, a venipun cture event or other method of accessing bodily fluids).

[1186

] With the port in fluid communication with the patient, at 1192, fluid communication is establ ished between the port and the pre-sample reservoir. In some embodiments, the flow meterin g transfer device can include a flow controller or the like (eg, flow controller 940 included in c ollection device 900) that provides fluid communication between the port and the pre-sample reservoir. It can be actuated and/or manipulated (eg rotated) to an established position (eg fir st position). In some embodiments, actuation of the flow controller may cause the flow contro ller and flow diversion mechanism to collectively define at least a portion of a fluid flow path b etween the port and the pre-sample reservoir. In some embodiments, the pre-sample reservoi r can include negative pressure or the like that can initiate the flow of bodily fluid from the pat

ient to the pre-sample reservoir. In other embodiments, bodily fluid flow can be initiated in an y other suitable manner (eg, gravity, etc.).

[0134]

[1187] At 1193, the flow of bodily fluid transferred from the patient to the pre-sample reservo ir is metered. For example, in some embodiments, the port has a flow control mechanism that can meter the flow of bodily fluid through the port (eg, in a manner similar to that described a bove with respect to flow control mechanism 967 of collection device 900). can contain. Thus, a pre-sample volume of bodily fluid is transferred to the pre-sample reservoir. The method 11 90 includes, at 1194, verifying, via the flow metering mechanism of the flow metering transfer device, that the pre-sample volume of bodily fluid disposed within the pre-sample reservoir is a predetermined pre-sample volume of bodily fluid. For example, the flow metering mechanis m can include and/or be operably coupled to a display or the like (eg, display 975 and/or 975′ of collection device 900). The flow metering mechanism can be configured to present volumet ric information on a display, as described above.

[0135]

[1188] Once the pre-sample volume of bodily fluid is disposed within the pre-sample reservoi r, at 1195, the pre-sample reservoir is fluidly isolated from the port to seal the pre-sample vol ume of bodily fluid within the pre-sample reservoir. For example, in some cases, the flow cont roller and/or flow diverter mechanism can be actuated (or rotated) from a first position and/or configuration to a second position and/or configuration. When the flow controller and/or flow diverter mechanism are in the second configuration, the pre-sample reservoir is fluidly isolate d from the space outside the pre-sample reservoir. In some embodiments, when the flow cont roller and/or flow diversion mechanism is driven to its second position and/or configuration, at 1196 fluid communication is established between the port and the sample reservoir. For exam ple, in some embodiments, the flow metering transfer device can include a piercing member (e.g., movable member 950) configured to pierce a portion of the sample reservoir (e.g., me mbrane, etc.) etc. Thus, when the flow controller and/or flow diverter mechanism is in its sec ond position and/or second configuration, the perforation of that portion of the sample reserv oir places the sample reservoir in fluid communication with the port. As noted above, the sam ple reservoir can contain, for example, a negative pressure or the like that can initiate the flo w of bodily fluid from the patient to the sample reservoir.

[0136]

[1189] At 1197, the flow of bodily fluid transferred from the patient to the pre-sample reservo ir is metered. For example, as described above, the port may include a flow control mechanis m capable of metering the flow of bodily fluid through the port (eg, in a manner similar to tha t described above with respect to flow control mechanism 967 of collection device 900). can b e done. In some embodiments, the flow control mechanism can be included in a movable me mber, such as, for example, movable member 950 in FIG. A sample volume of bodily fluid is t hus transferred to the sample reservoir. The method 1190 includes, at 1198, removing the bo

dy disposed within the sample reservoir via the flow metering mechanism of the flow meterin g transfer device.

This includes verifying that the sample volume of liquid is a predetermined sample volume of volume. For example, as described above, a display or the like can be configured to present v olumetric information.

[0137]

[1190] In this manner, a predetermined pre-sample volume of bodily fluid is collected, which may include, for example, externally present microorganisms. For example, in some embodim ents, the predetermined pre-sample volume is about 0.1 mL, about 0.3 mL, about 0.5 mL, ab out 1.0 mL, about 2.0 mL, about 3.0 mL, about 4.0 mL, It can be about 5.0 mL, about 10 mL, about 20 mL, about 50 mL, and/or any volume or volume fraction value therebetween. In oth er embodiments, the pre-sample volume can be greater than 50 mL or 0.1 mL. In other embo diments, the predetermined pre-sample volume can be between about 2 mL and about 5 mL. In one embodiment, the predetermined pre-sample volume can be approximately 3 mL. Additi onally, by collecting the predetermined pre-sample volume, the predetermined sample volume disposed within the one or more sample reservoirs can be substantially free of externally pres ent microorganisms. In some embodiments, the predetermined sample volume can be betwee n 10 mL and 60 mL. In other embodiments, the predetermined sample volume can be betwee n 30 mL and 60 mL. In still other embodiments, the predetermined sample volume can be 60 mL. Although described above as transferring a sample volume of bodily fluid to a single samp le reservoir, in other embodiments, a flow metering transfer device can be used to transfer a given sample volume to two or more sample reservoirs. For example, in some embodiments, a predetermined pre-sample volume of bodily fluid can be collected in and fluidly isolated with in a pre-sample reservoir, as described above. A predetermined sample volume into a first sa mple reservoir, a predetermined sample volume into a second sample reservoir, and a predete rmined sample volume into a third sample reservoir using a flow metering transfer device whil e the pre-sample volume is fluidly isolated. can be transferred to In such a case, the predeter mined sample volume can be, for example, 20 mL, so that the total sample volume placed in t he first, second and third reservoirs is 60 mL.

[0138]

[1191] Various embodiments of the bodily fluid collection devices described herein enable coll ection of two (or more) sets of bodily fluid (e.g., blood) samples from a single venipuncture. c an do. The current standard of care is to perform some tests (e.g., blood cultures) on separat e, independent samples (e.g., via two separate venipunctures, via catheter + venipuncture, a nd/or combinations thereof). They are asked to do so by obtaining it from a fluid access point. Embodiments described herein can facilitate obtaining multiple samples for a given diagnostic test (e.g., blood culture test) from a single bodily fluid access point (e.g., venipuncture); Ther eby, the annual number of venipunctures required to obtain these samples can be reduced by a factor of two. This is advantageous for both patients and medical personnel alike. Reducing

the number of venipunctures (and/or other blood access procedures) significantly reduces the risk of needlestick injuries to health care workers and reduces patient-related complications resulting from these procedures (e.g., hematoma, thrombosis, phlebitis, infection, etc.) can be reduced. Further, reducing the number of fluid access procedures (eg, venipuncture) reduces the supply utilization, labor and waste associated with these procedures. The cost reductions realized by the healthcare system are significant, as are patient concerns for improved sample integrity resulting in more accurate patient diagnoses that inform treatment plan development and implementation, as well as more efficient resource consumption. presents an opportunity to promote improved outcomes in The bodily fluid collection device also greatly reduces the incidence of false positives from post-collection analysis. The fluid collection devices described herein can also streamline the fluid collection process, reducing the number of manual steps and "touch points", thereby reducing the chances of external contamination. The devices described herein can also minimize the risk of needle stick injury and infection to the laboratory technician and/or phlebotomist.

[1192

] In some embodiments, the bodily fluid collection devices described herein (eg, 100, 200, 300, 400, 500, 600, 700, 800 and 900) are sterile saturated.

It may include and/or be formed in part from a composite material (eg, housing 401). Current standards rely on medical personnel to place individual antiseptic materials (eg, isopropyl alcohol swabs) on top of individual sample reservoirs (eg, 480, 480', 490 and 490'). To ensure compliance with this protocol, (for example) the device 400 may include antiseptic material disposed within the device 400 so that the housing 401, as shown in FIG. 2 pack), the first point of contact from the top of housing 401 and sample reservoirs 480, 480', 490, 490' is the disinfectant material. In this way, the tops of the sample reservoirs 480, 480', 490, 490' are ensured that proper disinfection is applied before bodily fluids are inoculated into the sample reservoirs.

[0140]

[1193] While various embodiments have been particularly shown and described, various changes in form and detail can be made. For example, although dial 445 (actuator) is shown and described with reference to FIGS. 19-22 as rotating in a single direction, in other embodiments, dial 445 (actuator) rotates in a first direction. and a second direction opposite the first direction. In such embodiments, rotation in the second direction can be configured to move the collection device through any number of configurations. In other embodiments, rotation of the actuator in the second direction can be restricted. In some embodiments, the dial can include a mechanical stop or lock to fluidly isolate the first volume of bodily fluid received from the patient (ie, the contaminated sample). In other words, when the first reservoir (pre-sample reservoir) is filled with a predetermined volume of bodily fluid and the user rotates the dial (actuator) to start drawing in additional sample, the dial (actuator) is turned to (It cannot be moved back to establish fluid communication with the first sample volume (contained within the pre-s

ample reservoir).

[0141]

[1194] While several embodiments have been described above, it should be understood that t hey have been presented by way of example only and not limitation. Although various embodi ments have been described as including combinations of particular features and/or component s, any combination or sub-combination of any feature and/or component from any of the emb odiments described herein may be described. Other embodiments with combinations are possi ble. For example, with reference to FIGS. 34-40, although collection device 700 is shown and described as having a first, second, third, fourth or fifth configuration, other implementations are possible. In form, the collection devices described herein can have more or fewer forms. F urther, while the collection device 200 is shown and described with reference to FIGS. 2-13 as having a vacuum-assisted collection tube as the pre-sample reservoir 270, in other embodime nts, the collection device 200 includes a dispensing member. The collection device 400 of the embodiment presented in FIGS. 16-22 can have chambers housed in a housing 201 similar to the collection device 400 of the embodiment presented in FIGS. It is possible.

[0142]

[1195] It is also possible to vary the specific arrangement of the various components. For exa mple, the sizes and specific shapes of various components may differ from the illustrated emb odiments while still providing functionality as described herein. More specifically, the sizes and shapes of the various components can be specifically selected for the desired flow rate of bodil y fluid flow into the fluid reservoir. For example, although flow metering mechanism 967 is sp ecifically shown in FIG. 49, any of the collection devices described herein can be used with an y suitable flow metering mechanism. For example, in some embodiments, the collection devic e includes a flow metering mechanism and/or, for example, pressure sensors, voltage sensor s, optical sensors, velocity sensors, flow meters, strain gauges, valves, turbines, floats, displa cement analysis, Density Analysis, Gravimetric Analysis, Optical Analysis, Ultrasound Analysis, Thermal Analysis, Doppler Analysis, Electromagnetic Field (emf) Analysis, Reflection Analysis, Obstacle Analysis, Area Analysis, Venturi Analysis, Coriolis Analysis, Visual Analysis and/or an y other suitable sensor, analysis and/or

(e.g., applying and/or using Boyle's law, the ideal gas law, force calculations (force = mass x acceleration), etc., as examples), other Any mechanism, device or method can be included.

drawing open —

[Fig. 1]

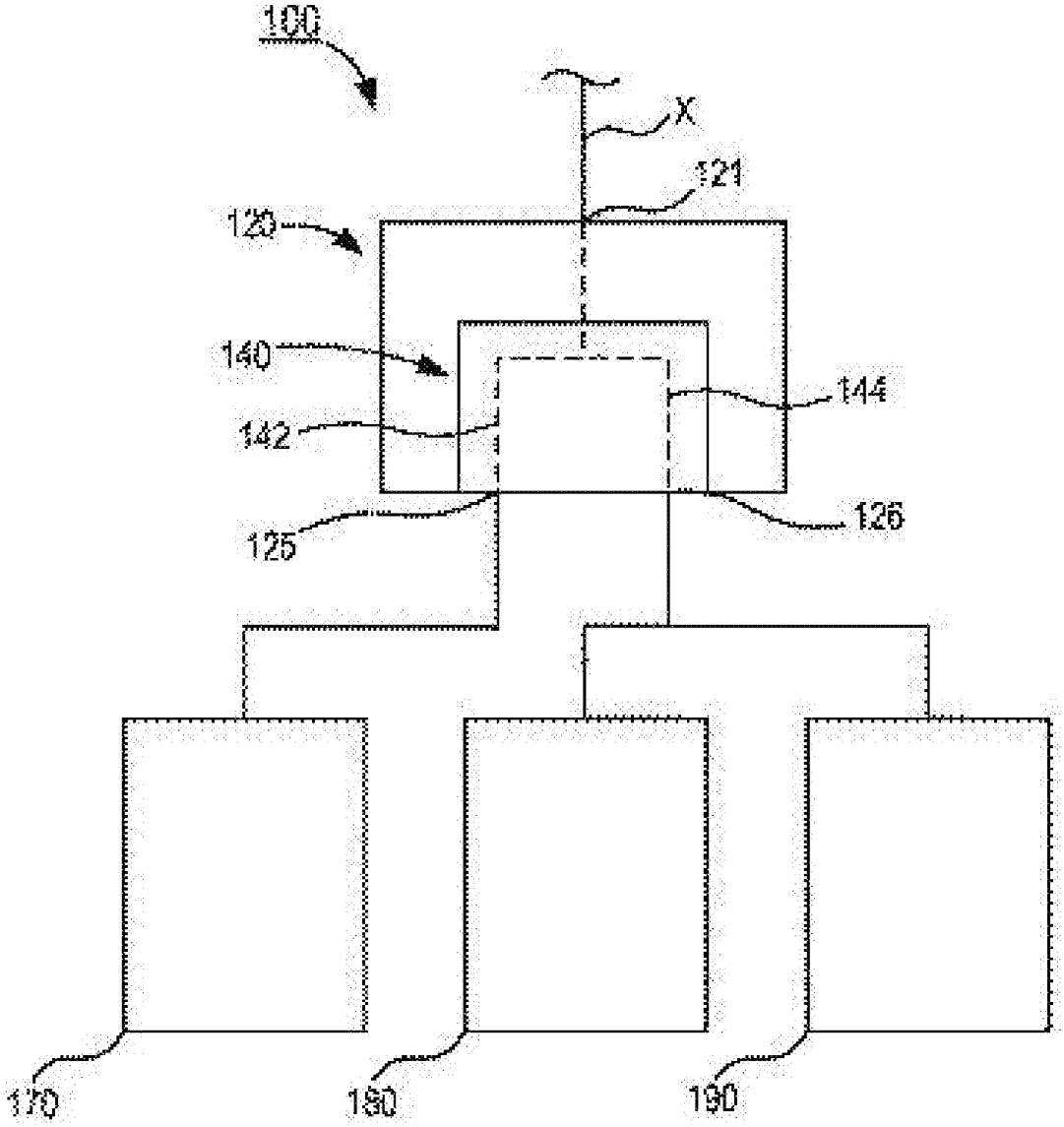


FIG. 1

[Figure 2]

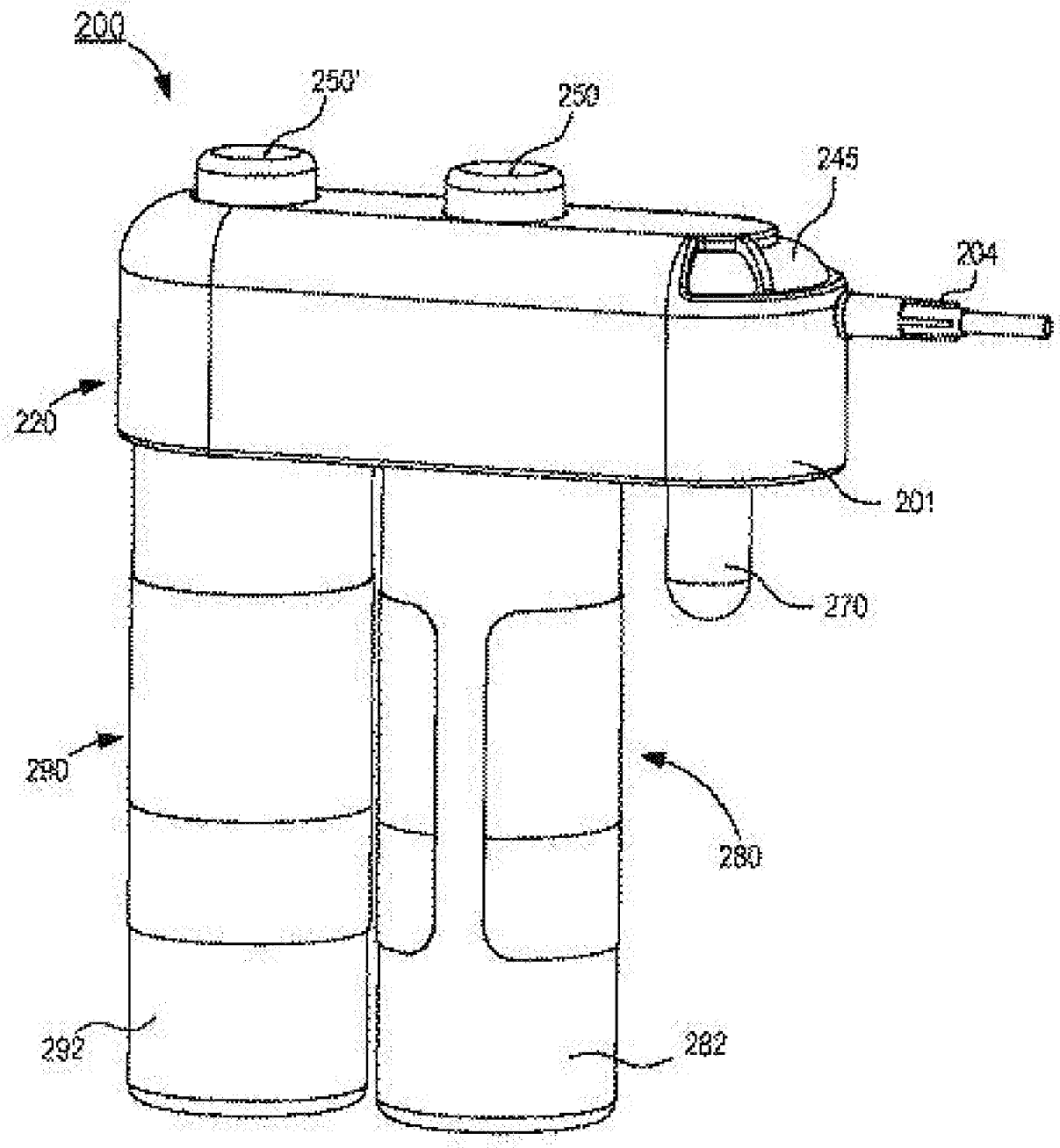
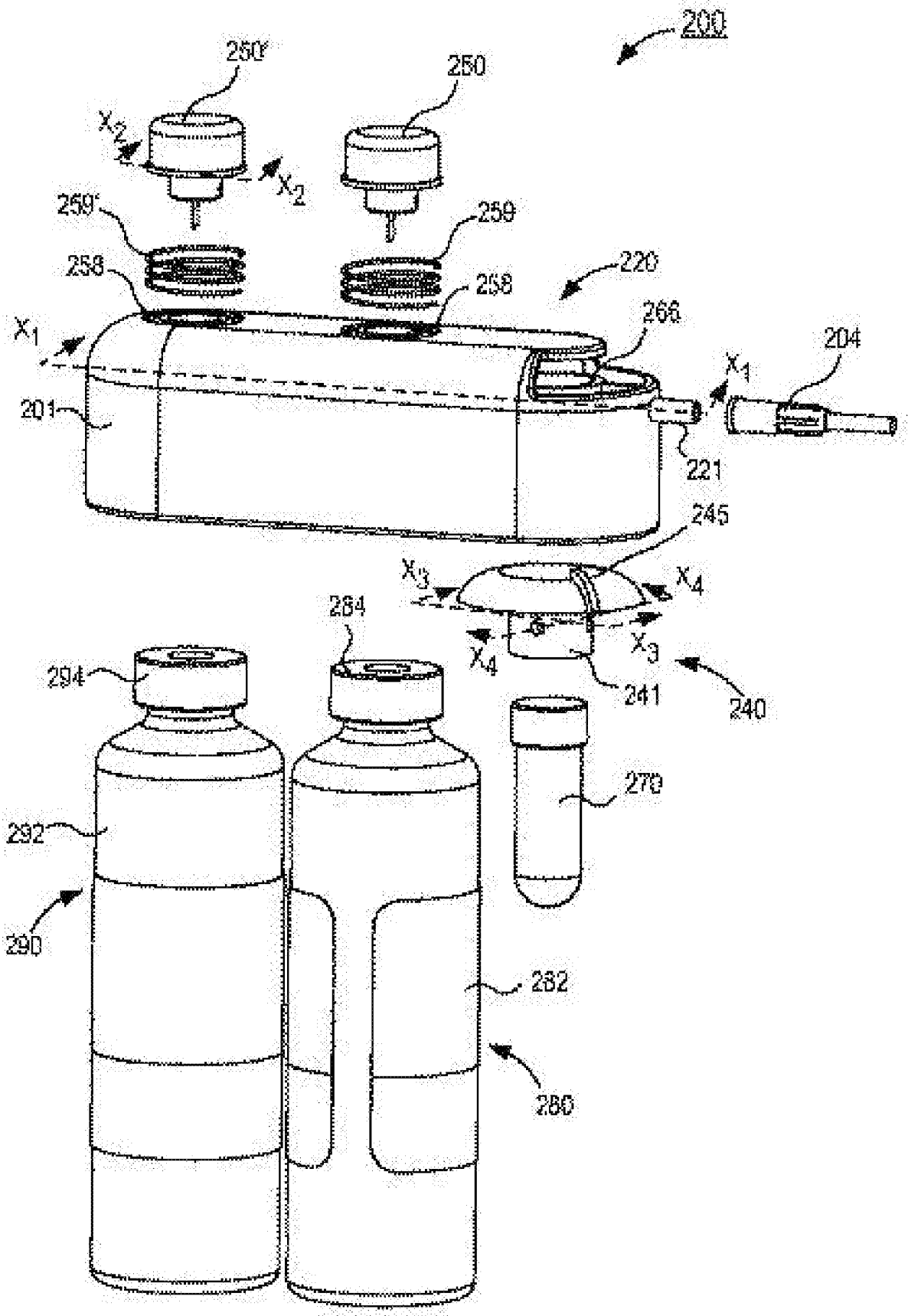


FIG. 2

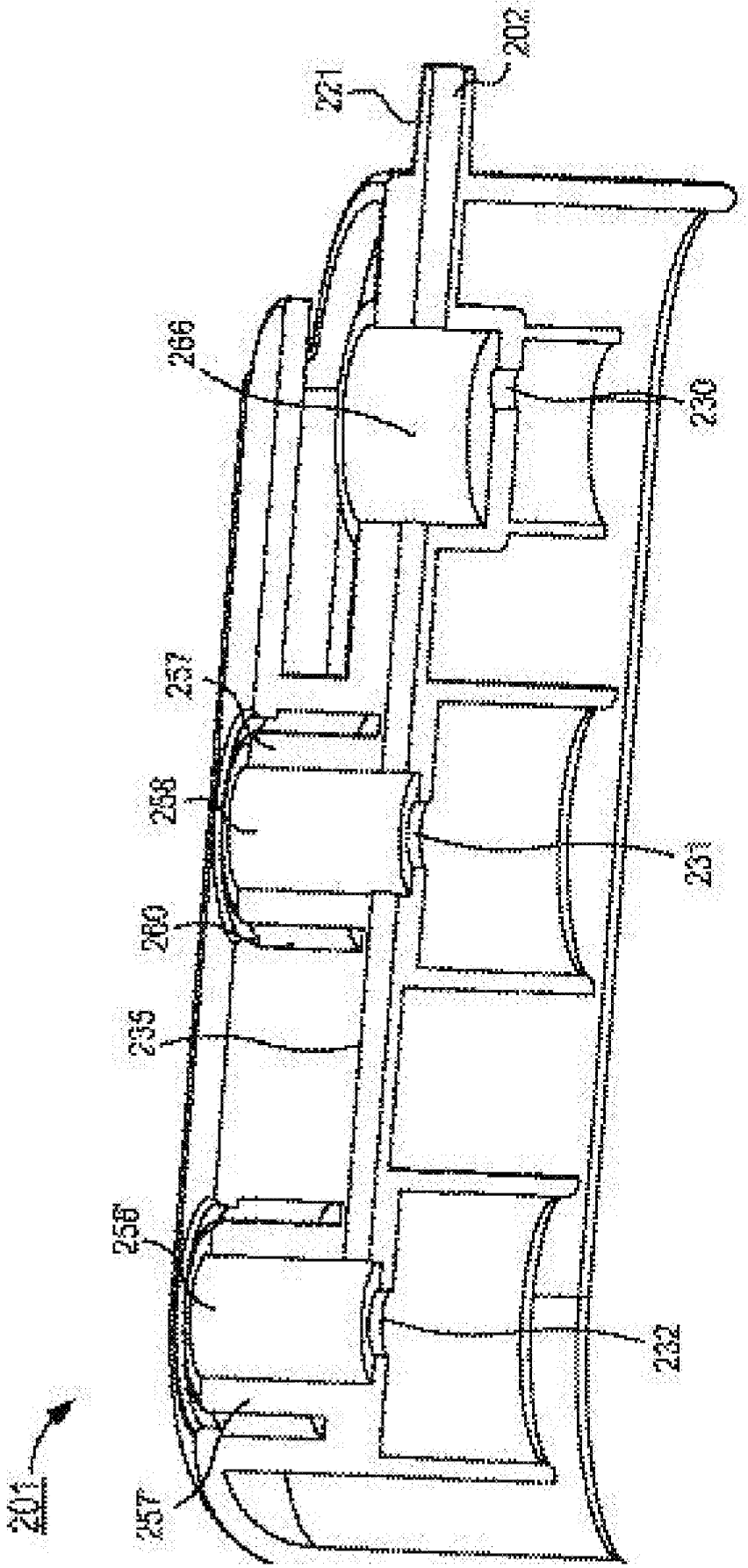
[Figure 3]


200
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250
X_2
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259'
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X_1
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[Figure 4]

FIG. 3

FIG. 4



[Figure 5]

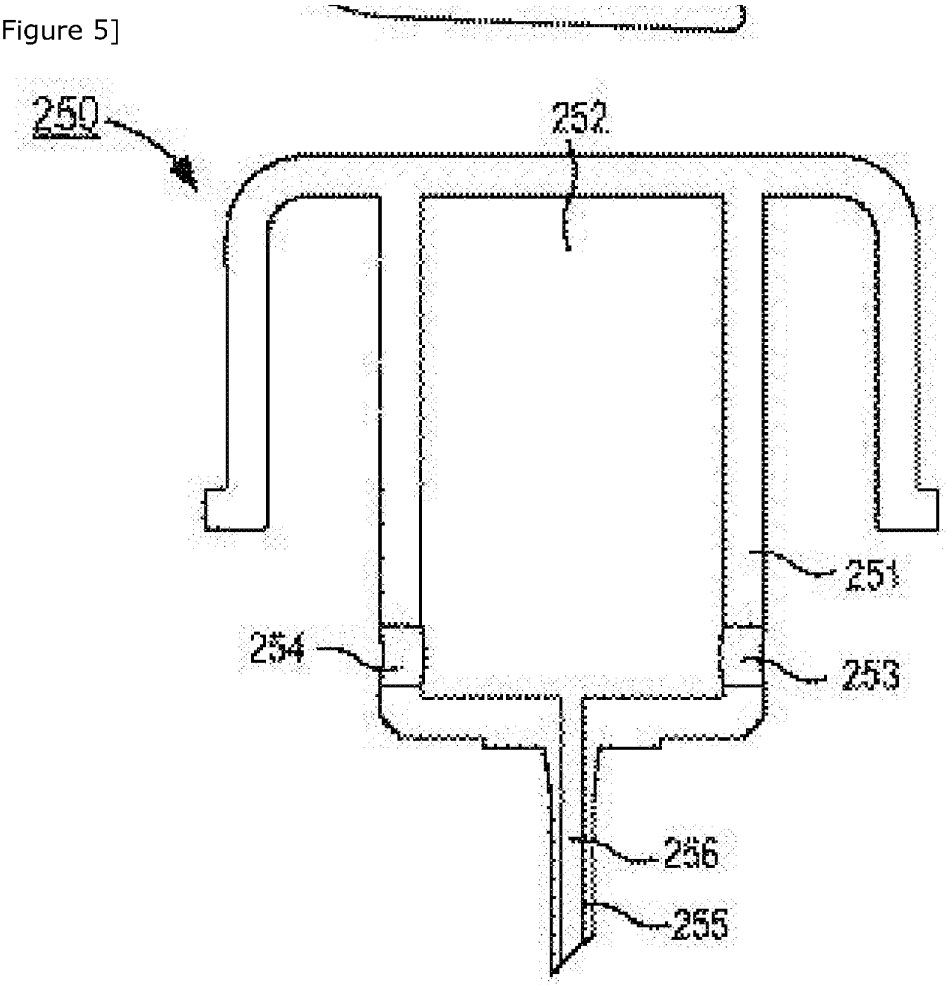


FIG. 5

[Fig. 6]

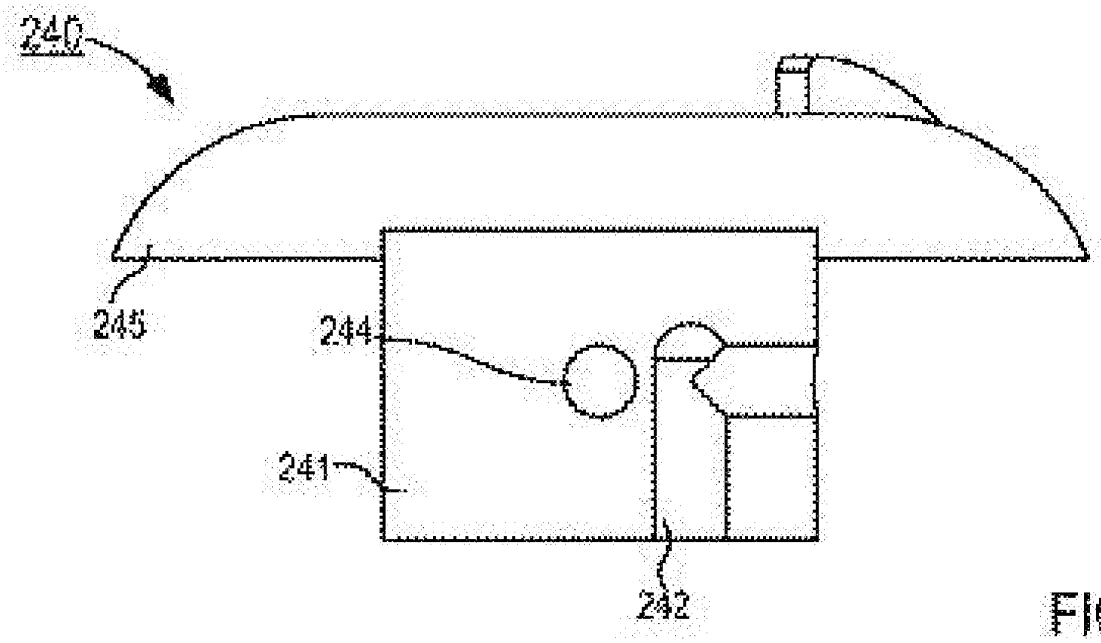


FIG. 6

[Fig. 7]

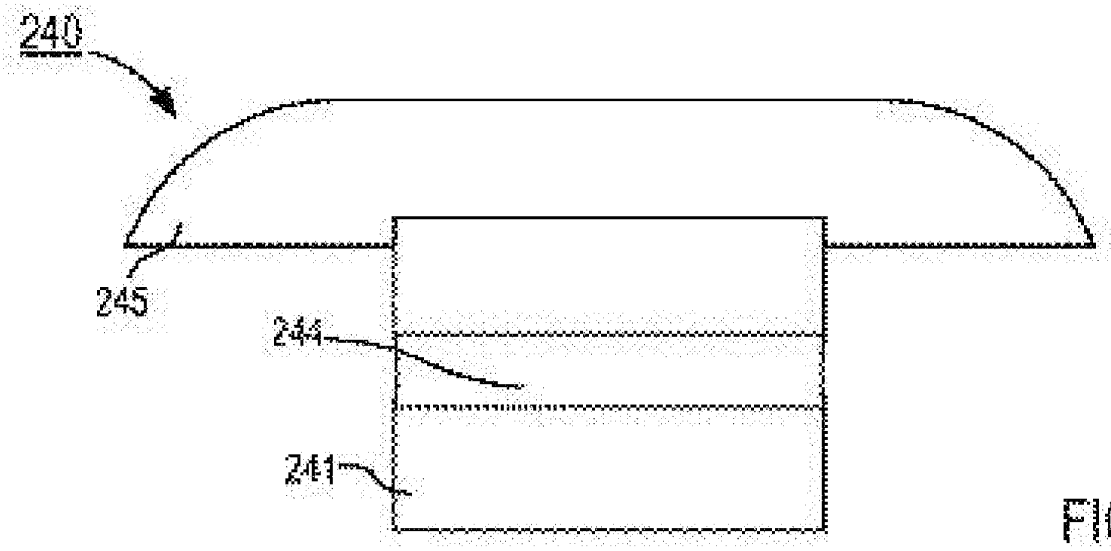


FIG. 7

[Fig. 8]

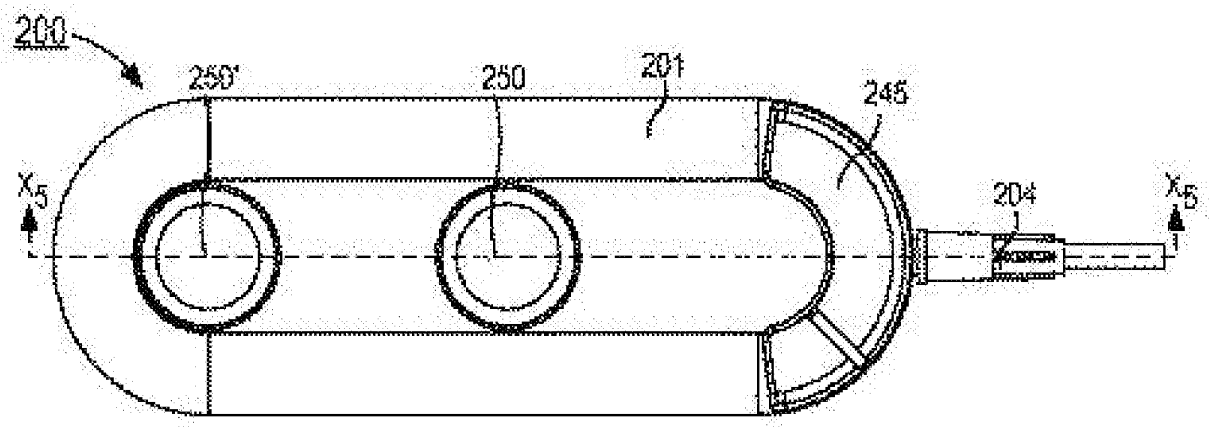


FIG. 8

[Fig. 9]

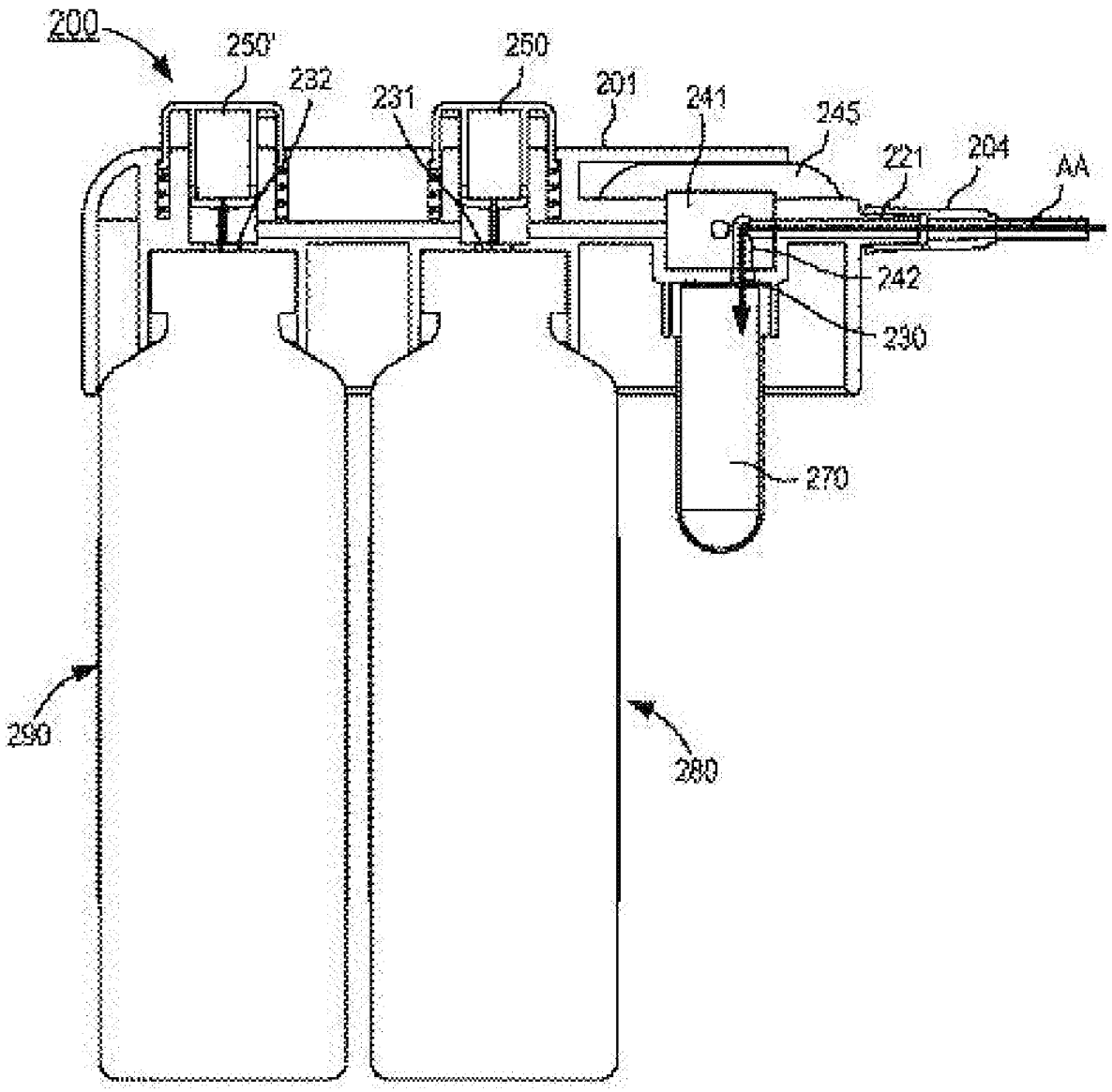


FIG. 9

[Fig. 10]

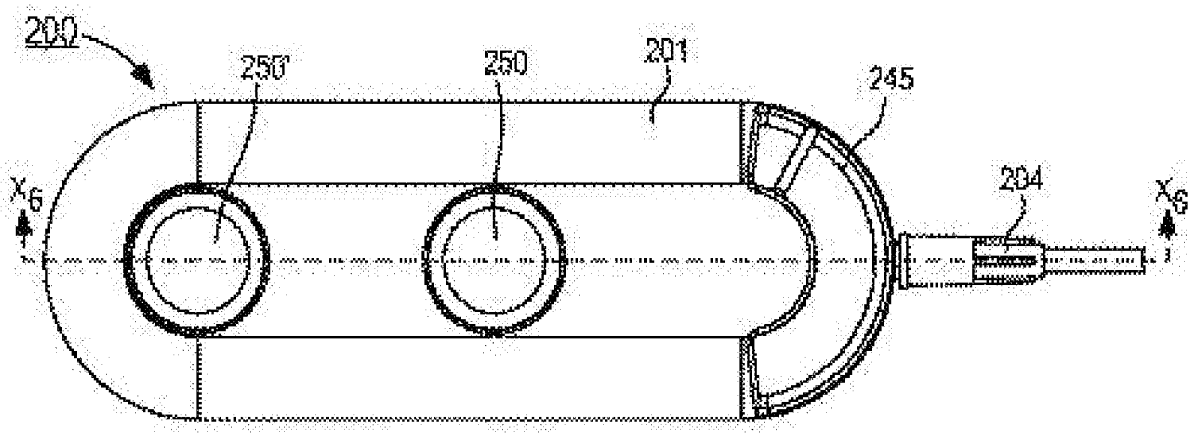


FIG. 10

[Fig. 11]

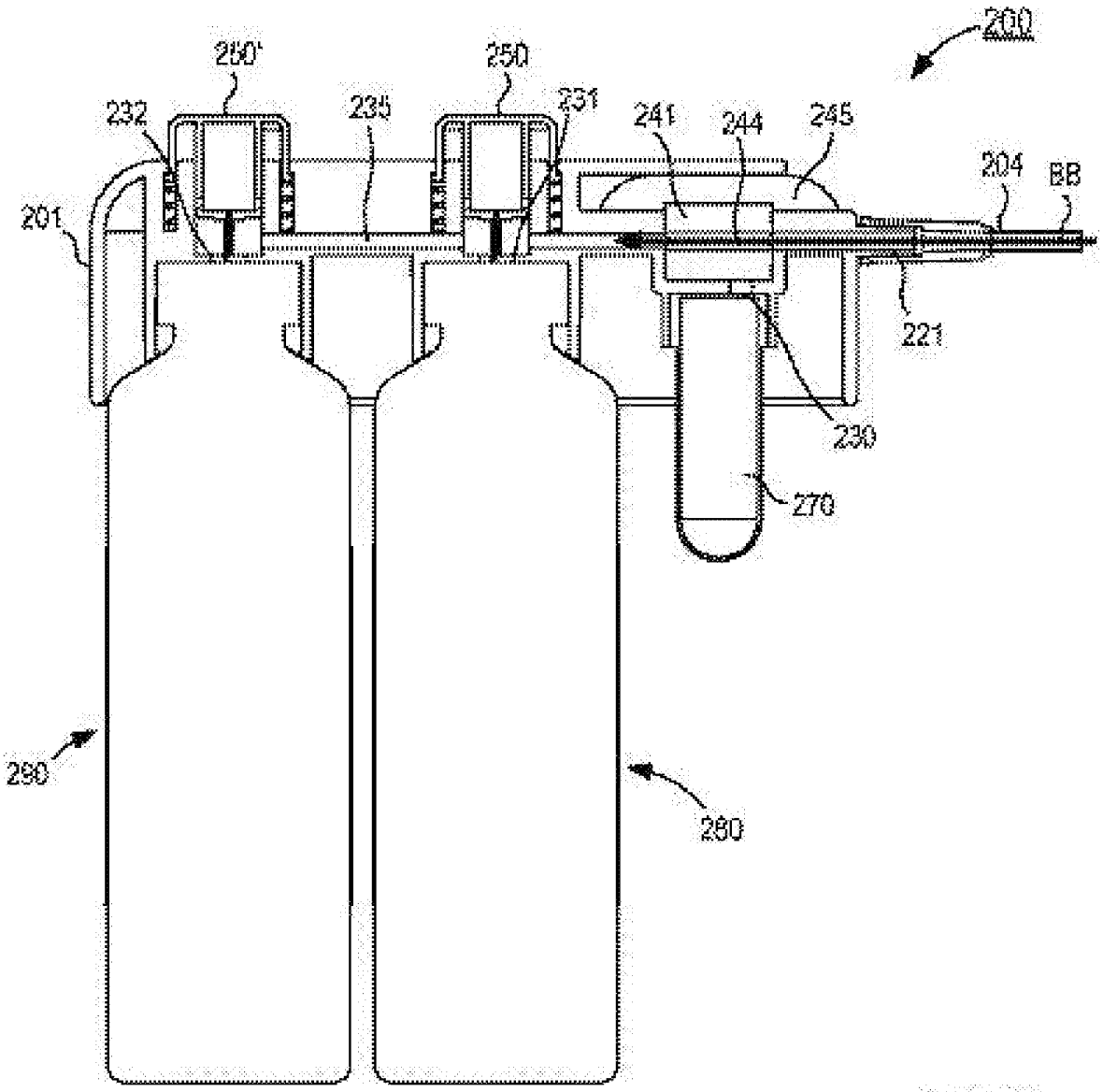

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FIG. 11

[Fig. 12]

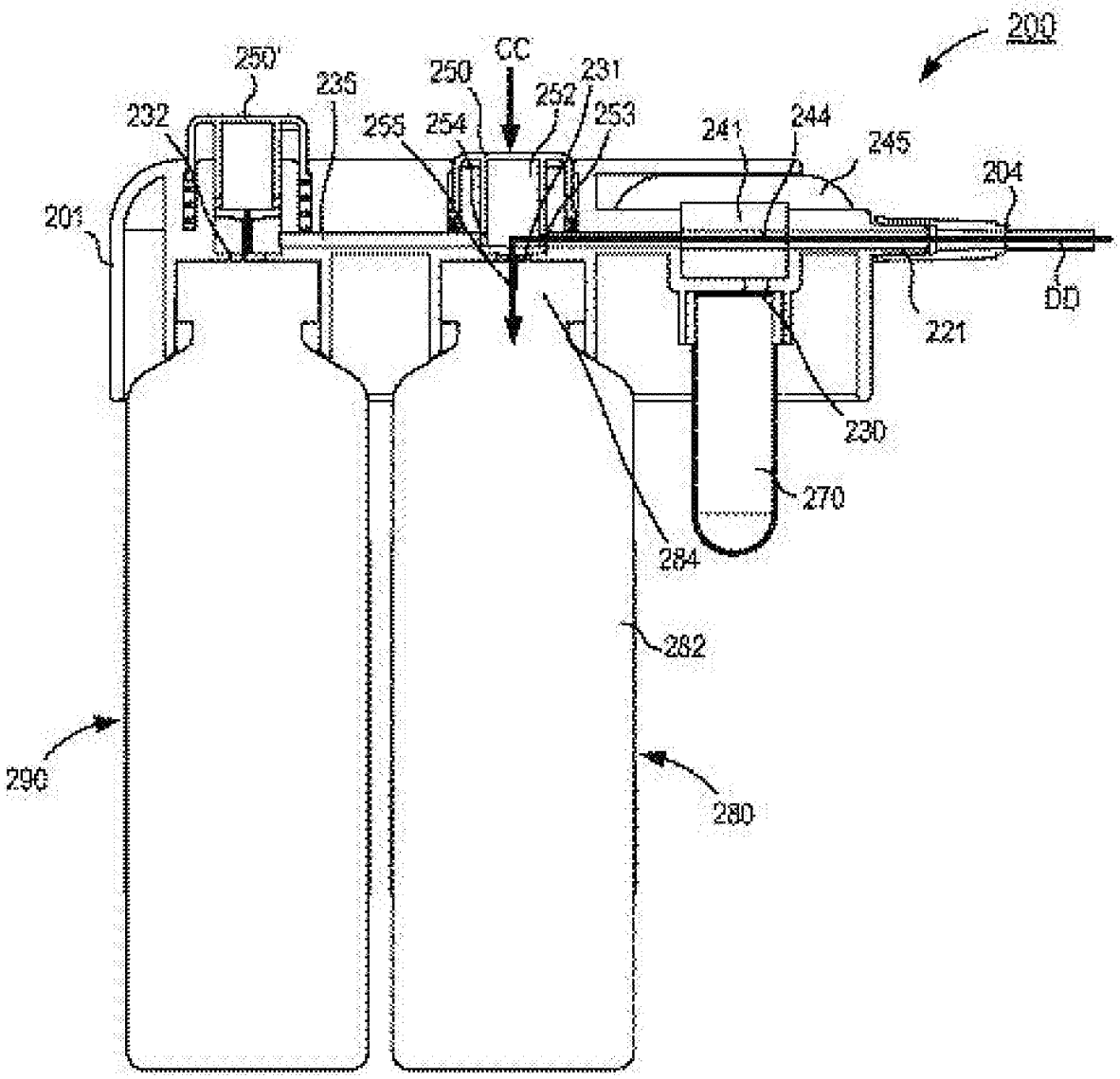

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FIG. 12

[Fig. 13]

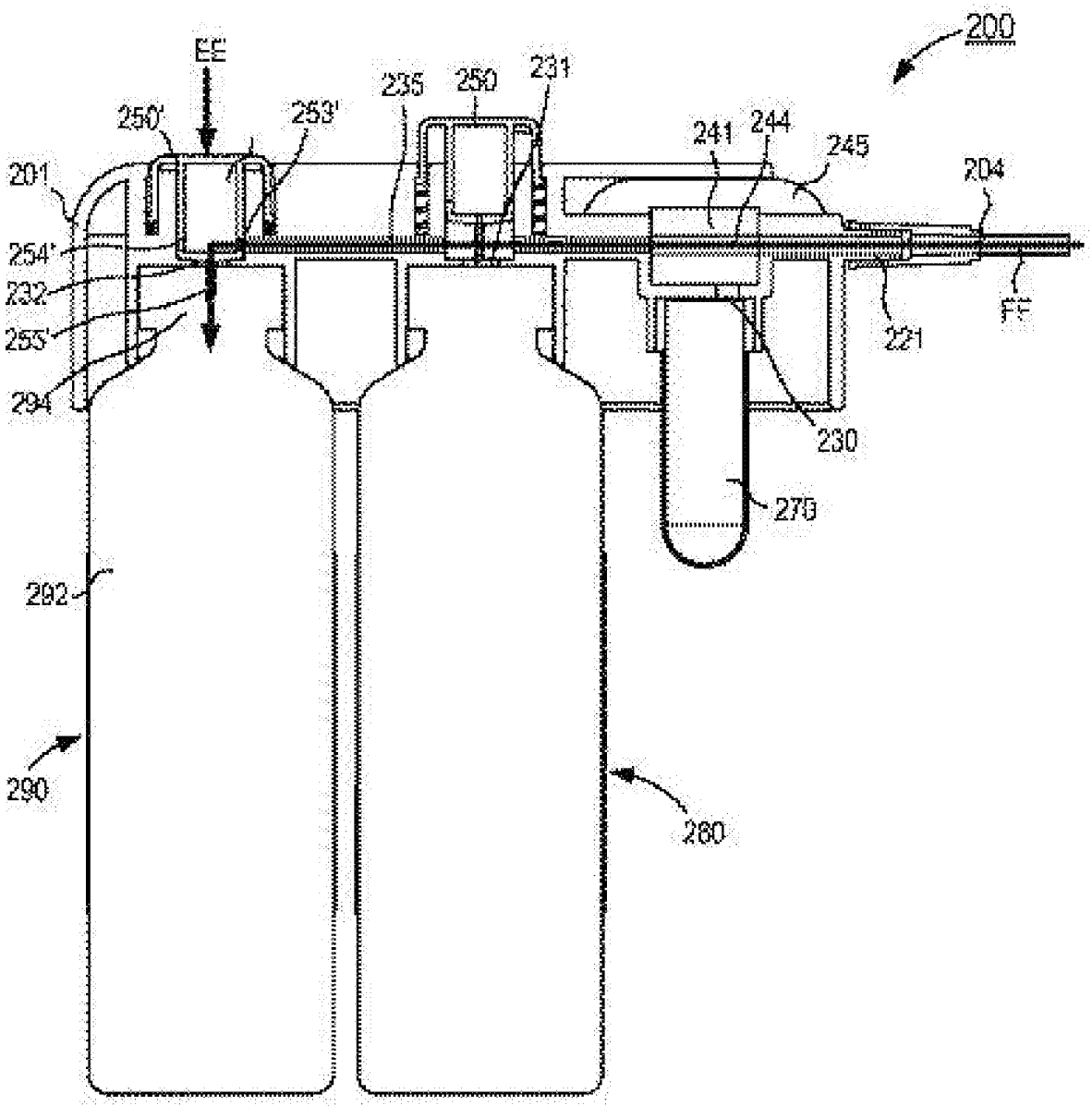

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FIG. 13

[Fig. 14]

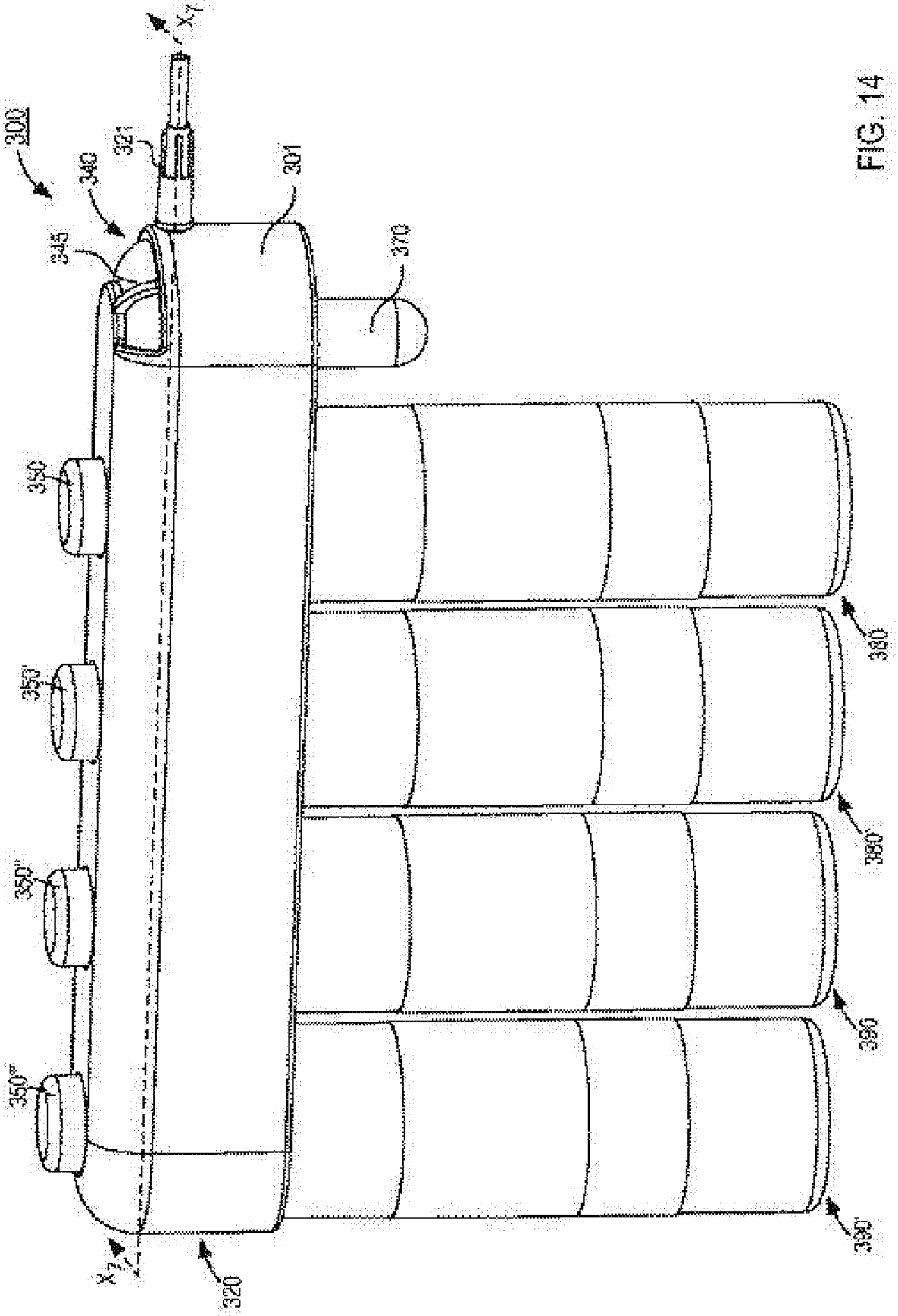
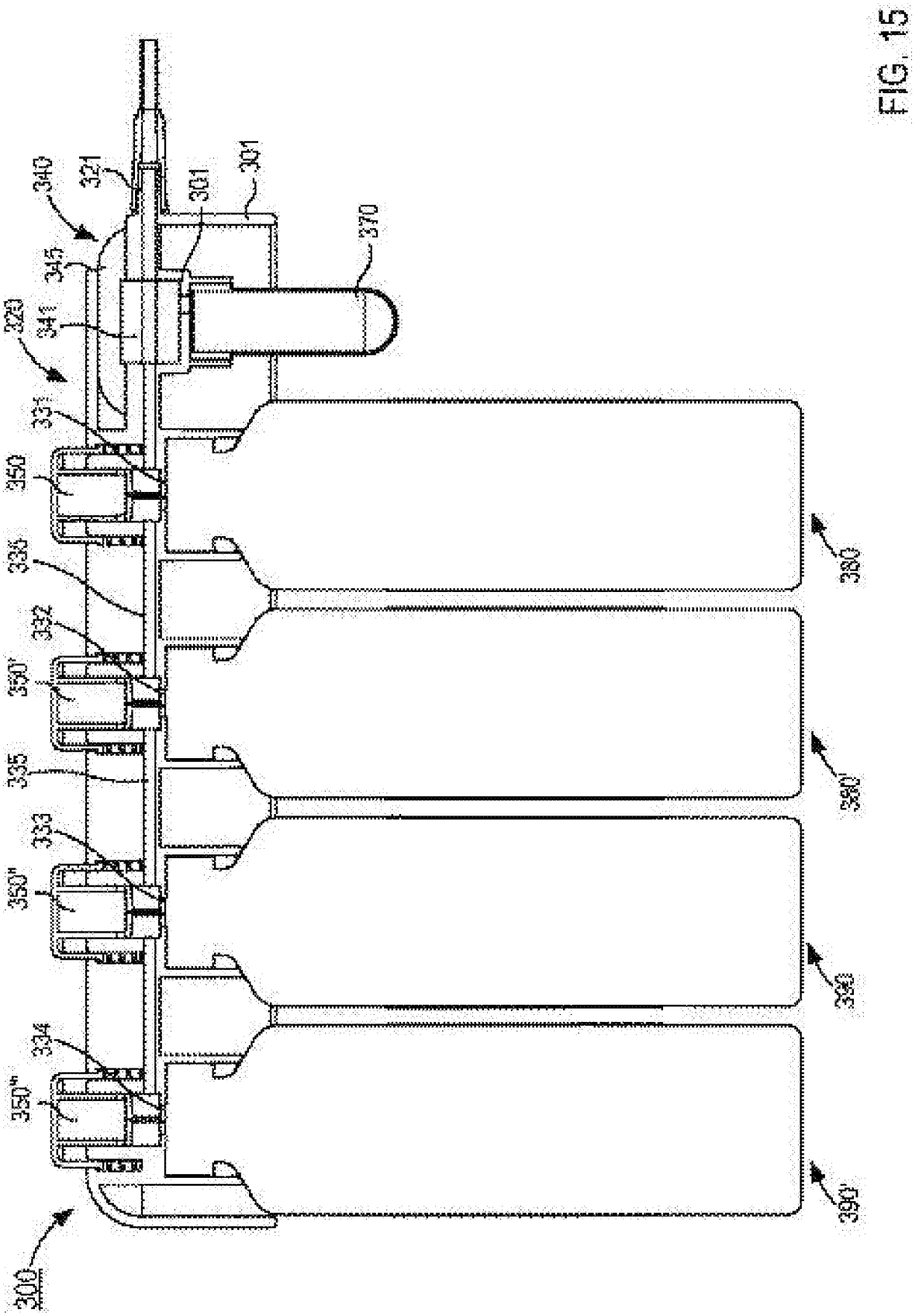
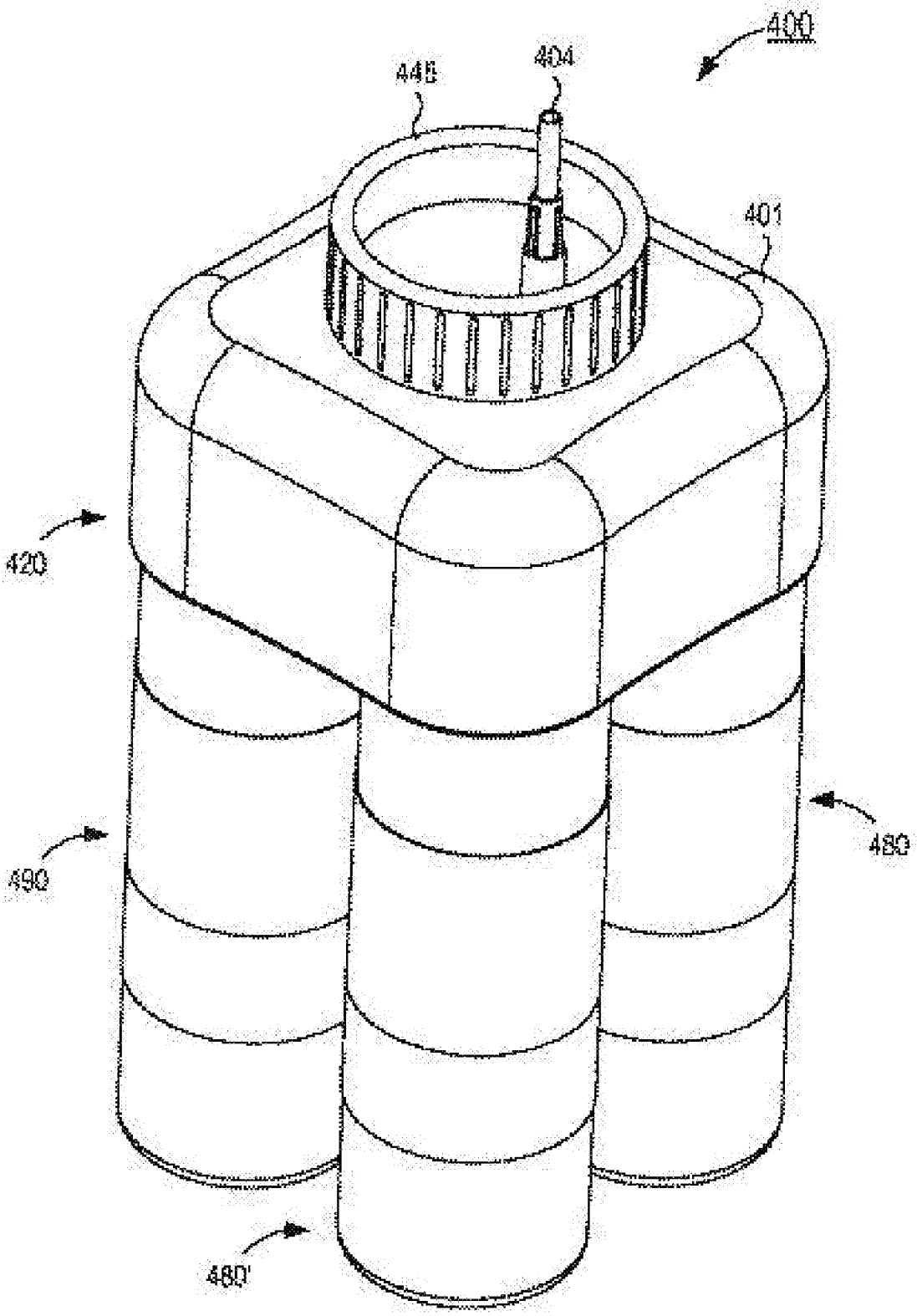

300
321
340
345
301
370
350
350'
350"
350"'
360
360'
380
380'
320
X_1
X_2
Z_2

FIG. 14

[Fig. 15]

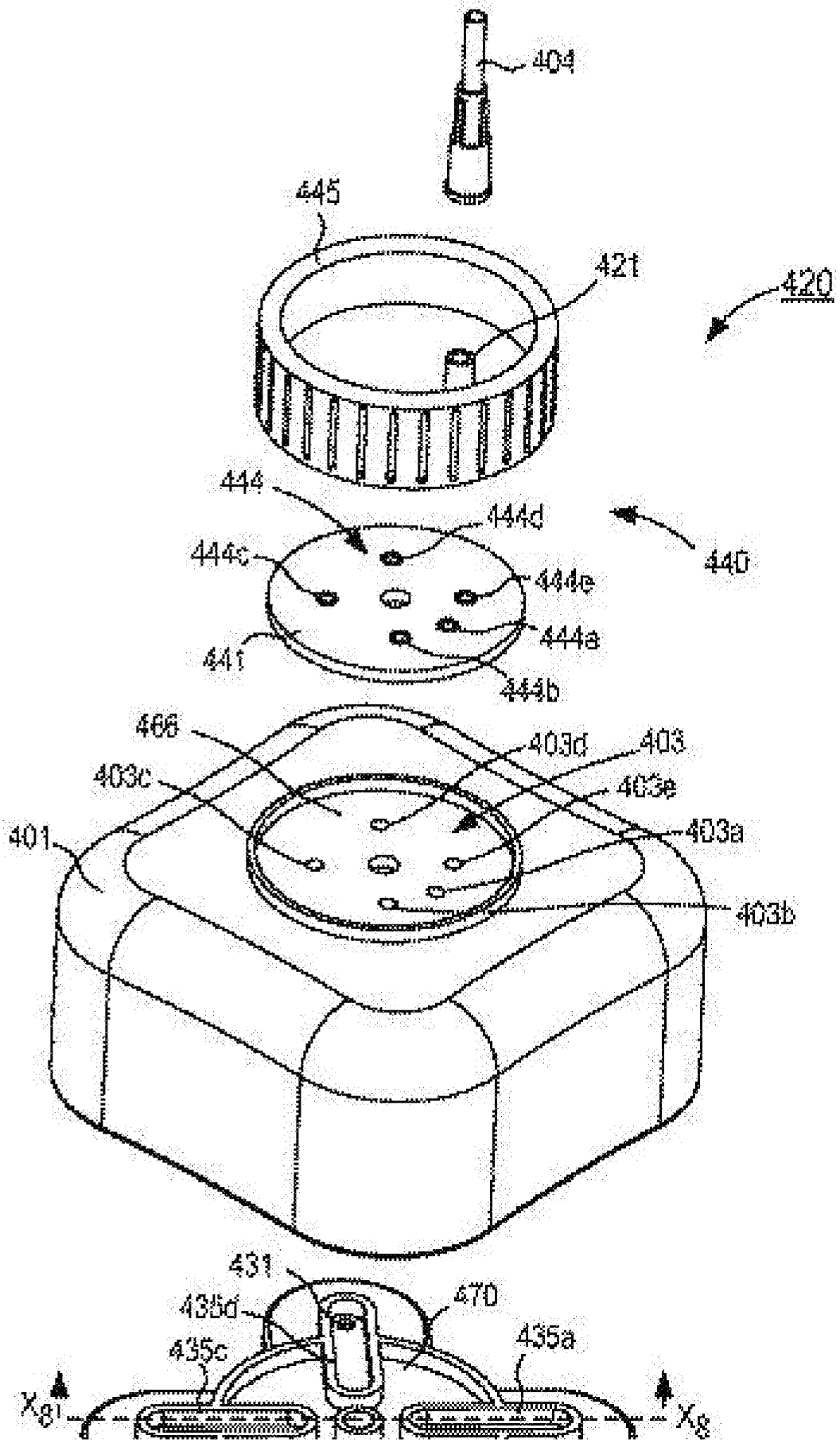

FIG. 15
340
321
301
301
370
345
343
223
333
350
335
332
350'
335
333
350"
334
350"
300
380
380'
380
390'

[Fig. 16]


400
404
445
401
420
490
480
480'

[Fig. 17]

FIG. 16


404
445
421
420
444
444d
444c
444e
440
444a
441
444b
466
403d
403
403c
403e
401
403a
403b
431
470
435d
435a
435c
X81
X8

[Fig. 18]

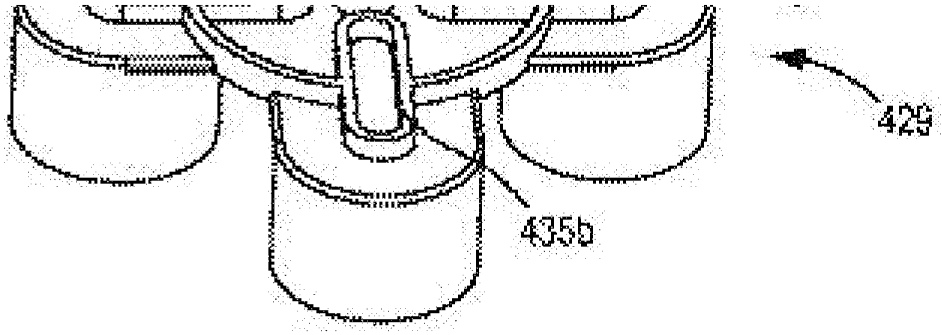


FIG. 17

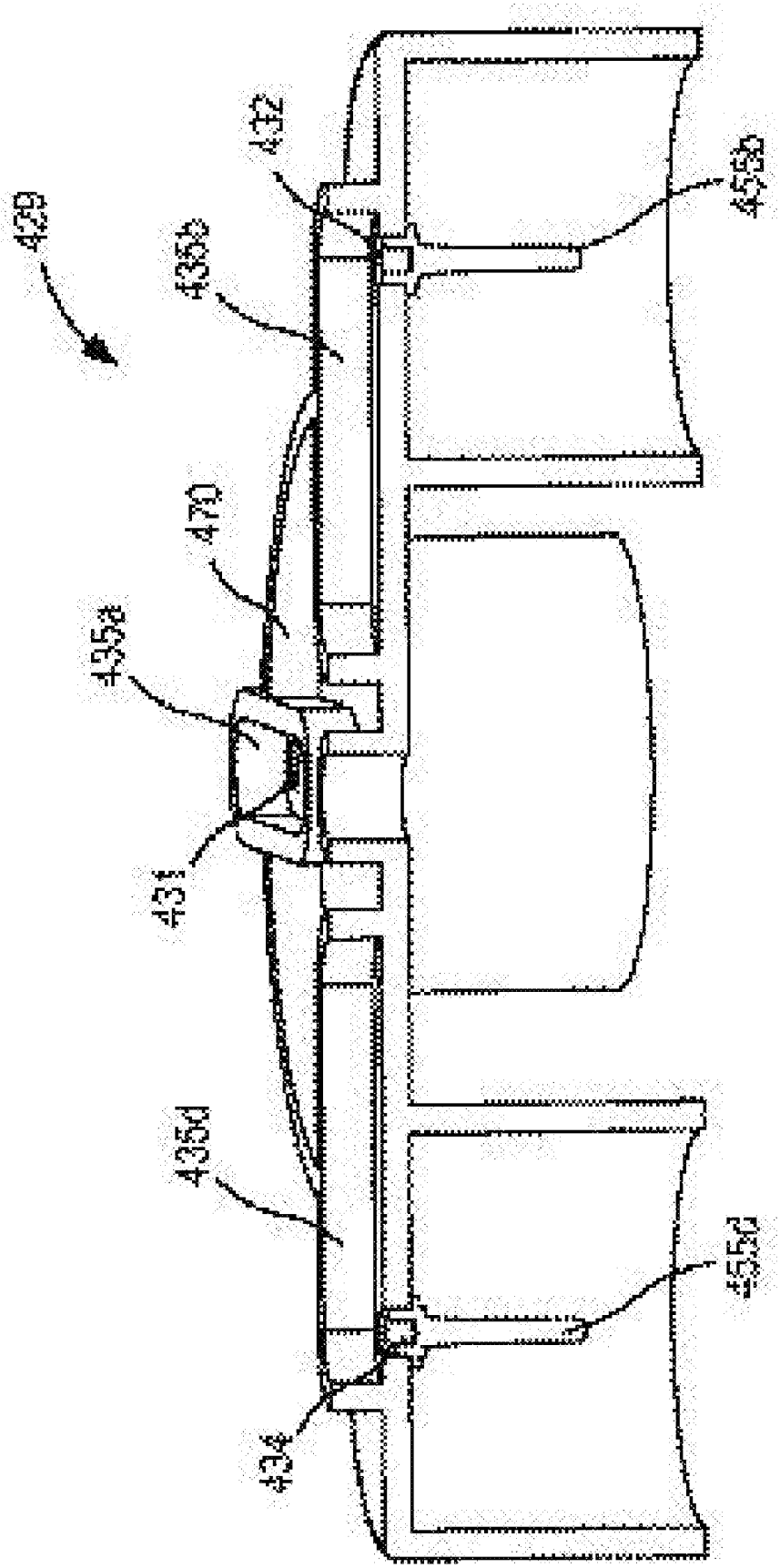


FIG. 18

[Fig. 19]

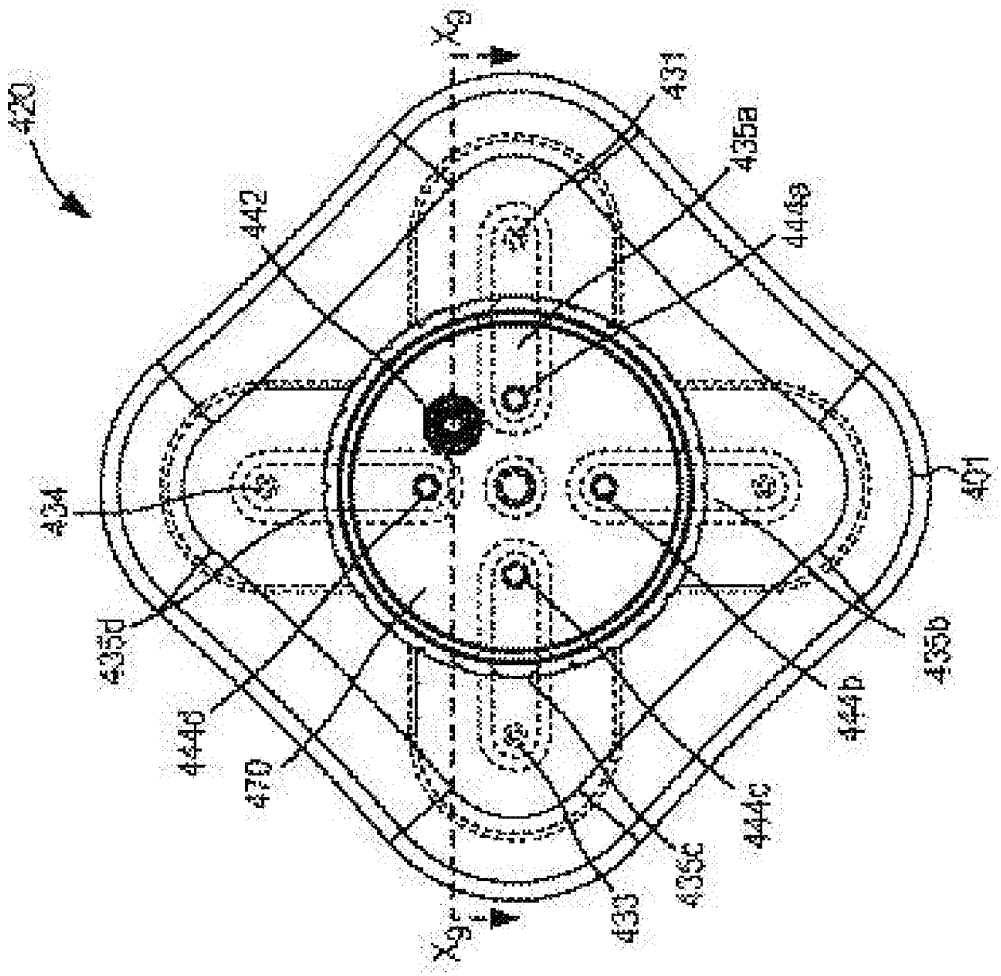


FIG. 19

[Fig. 20]

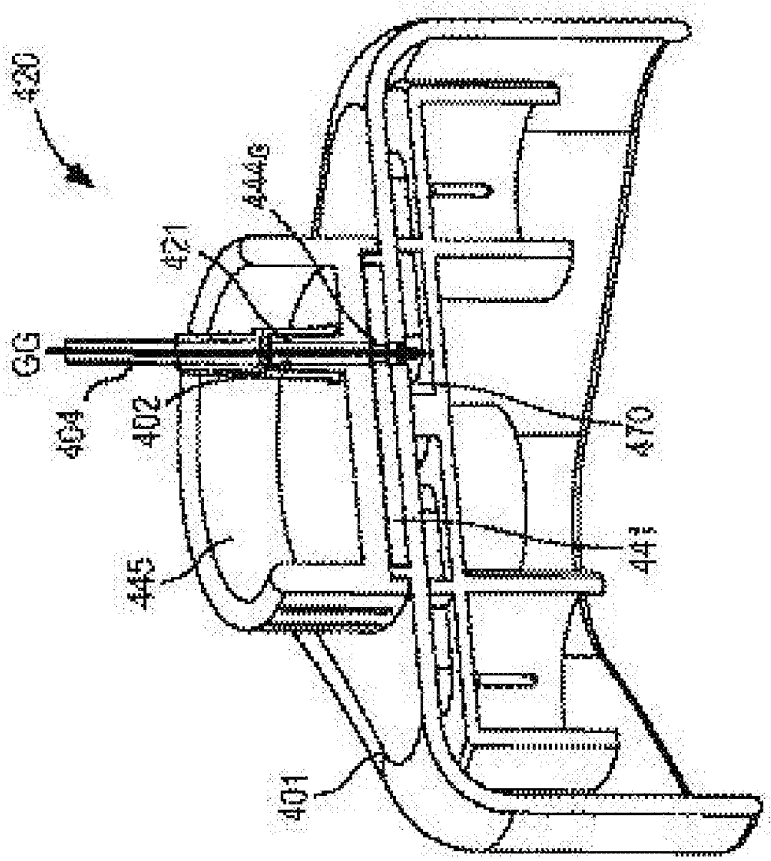


FIG. 20

[Fig. 21]

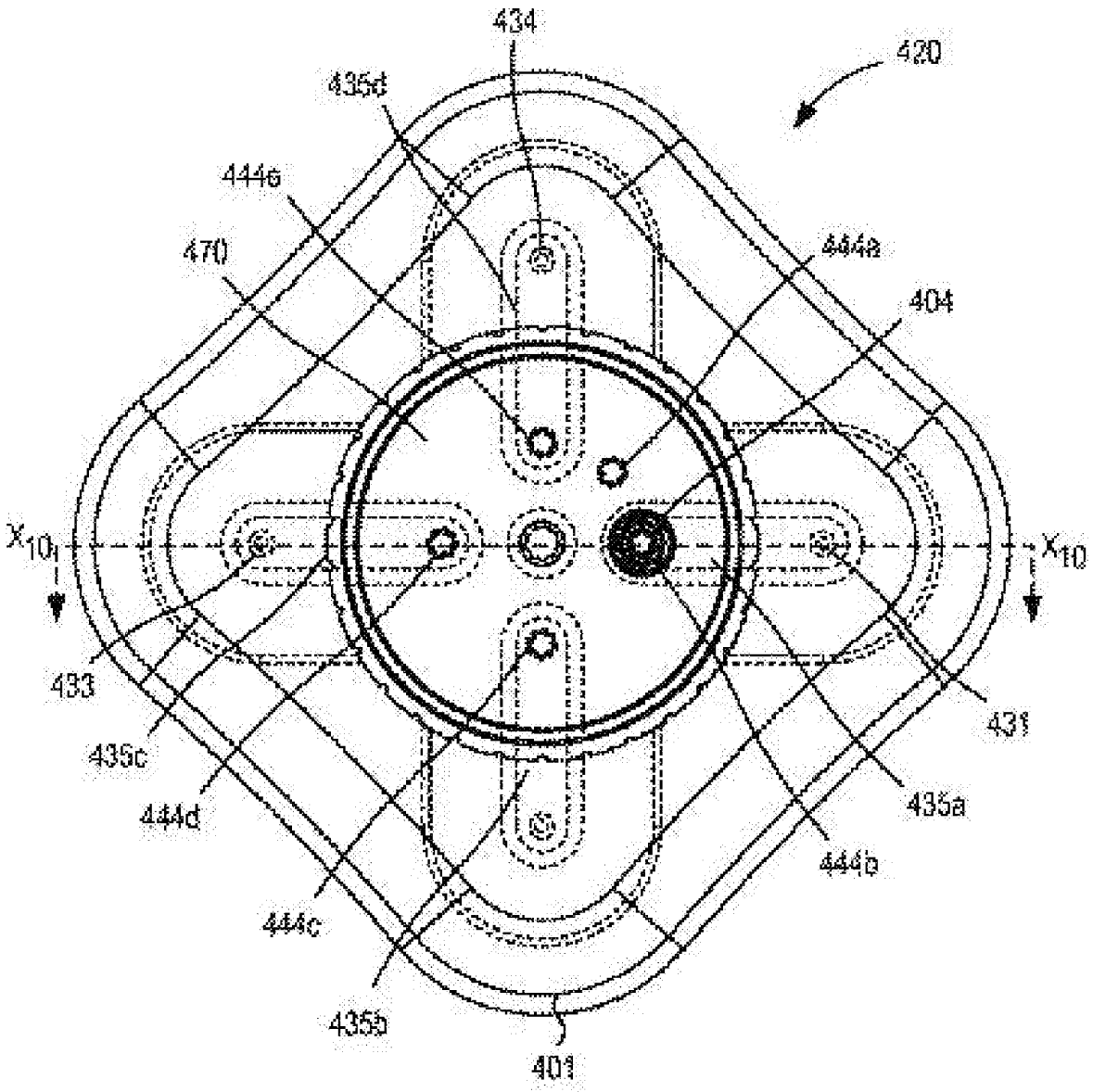
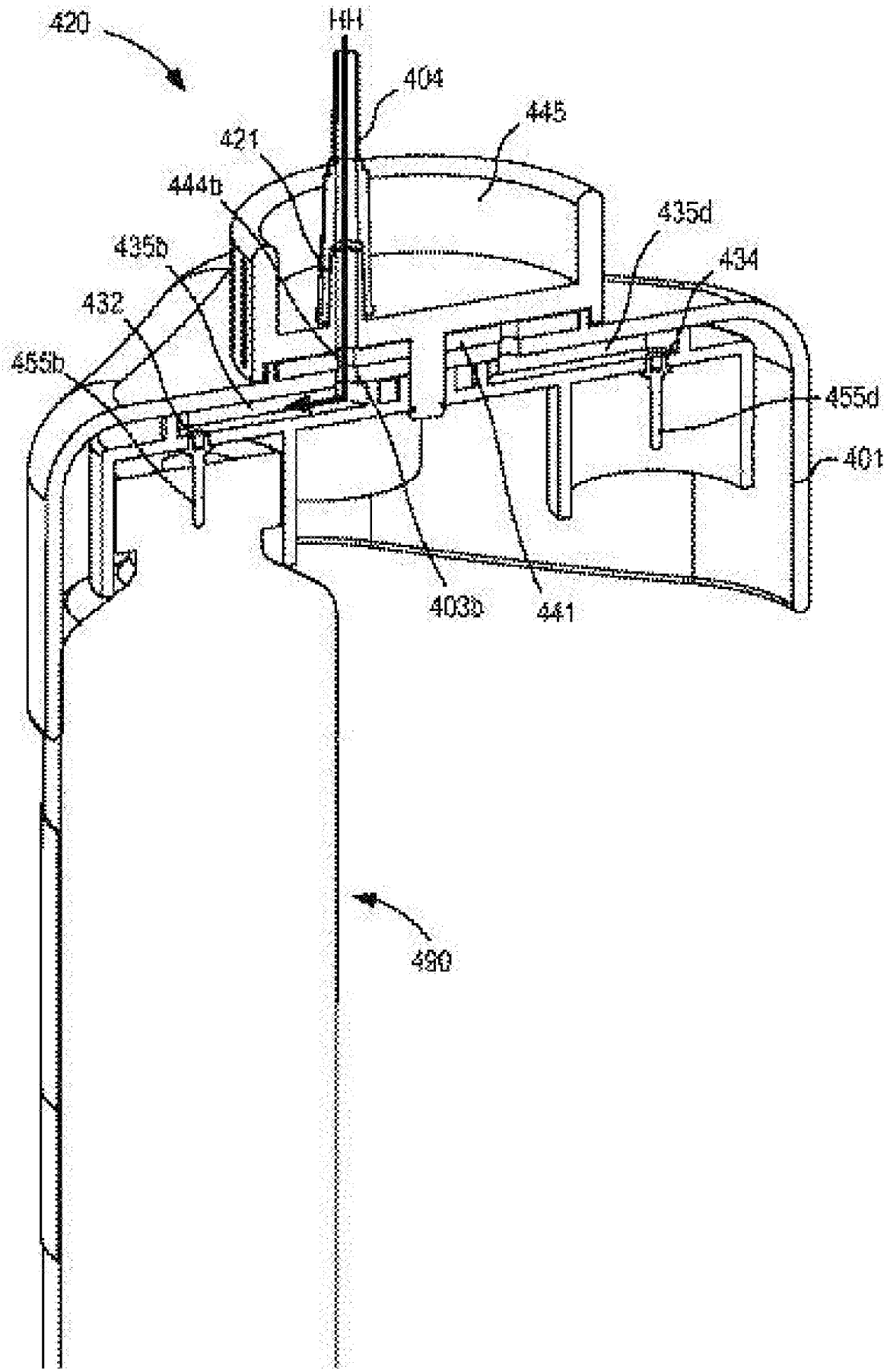

434
420
435d
444e
470
444a
404
X_{10}
X_{10}
433
439c
444d
431
435a
444b
444c
435b
401

FIG. 21

[Fig. 22]


420
HH
404
445
421
444b
435d
435b
434
432
455b
455d
401
403b
441
490

[Fig.23]

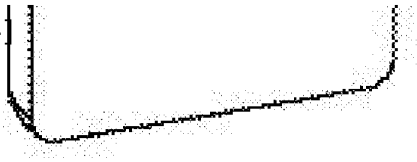
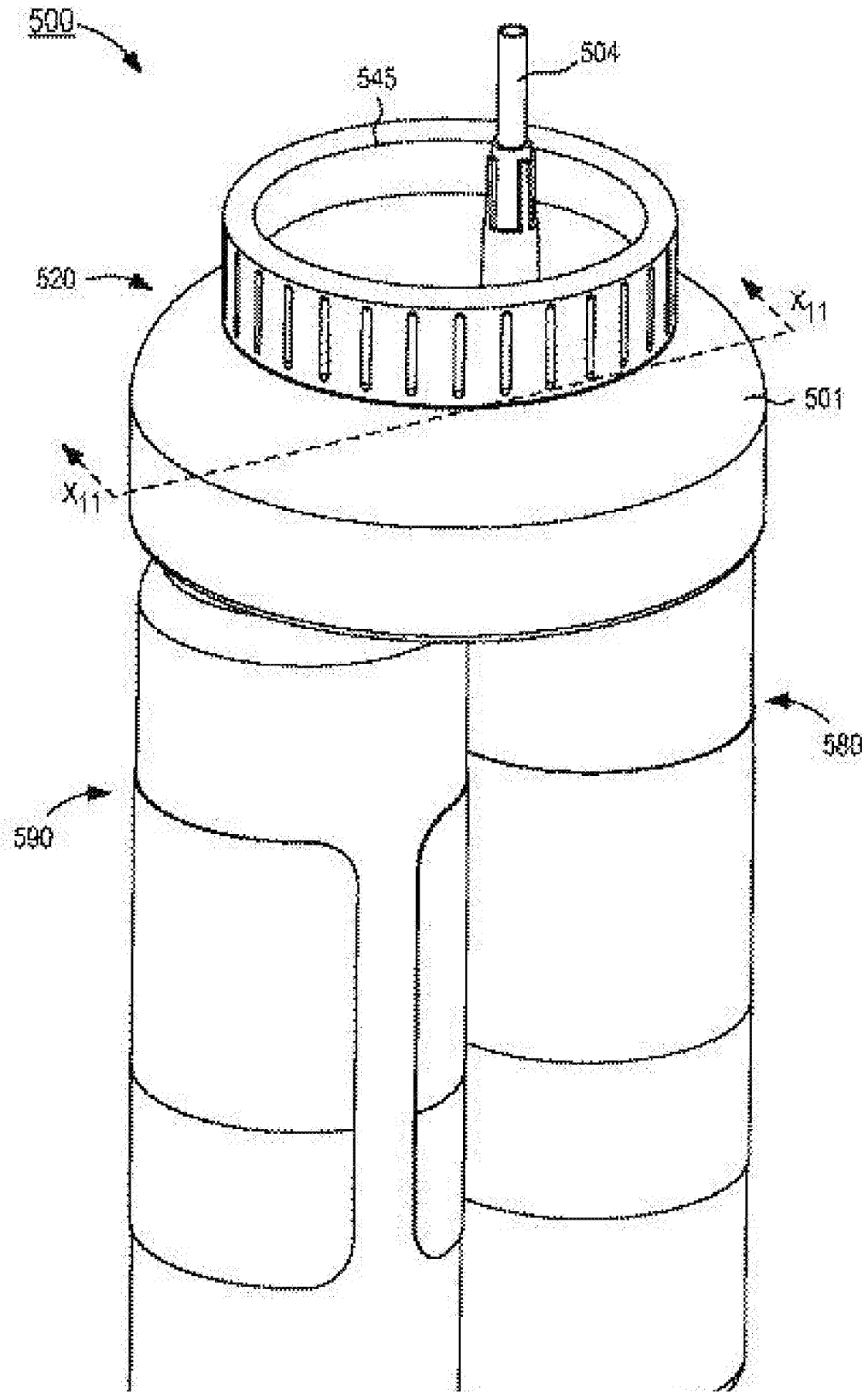


FIG. 22


500
504
545
520
X_{11}
501
X_{11}
590
590

[Fig.24]

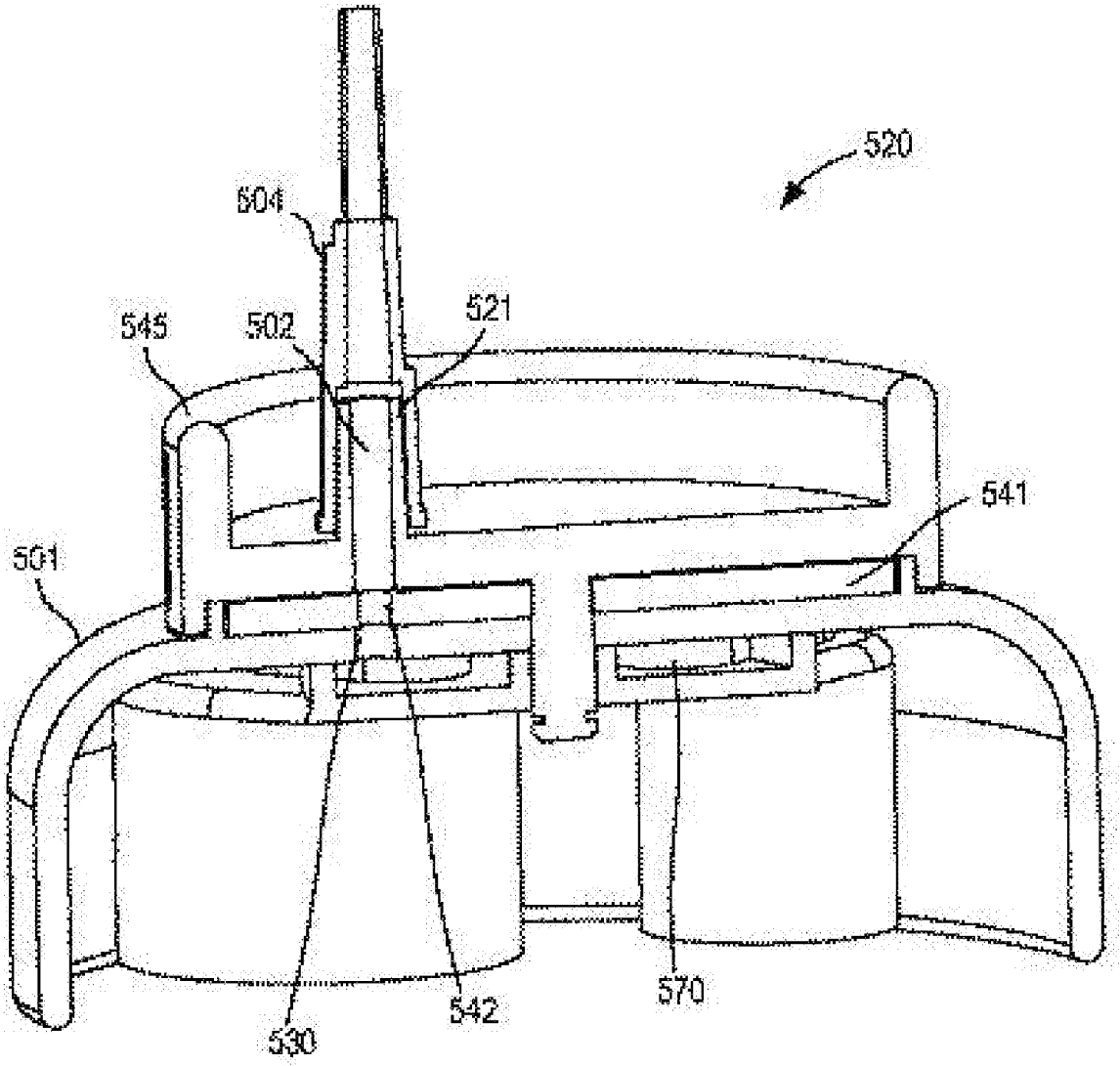
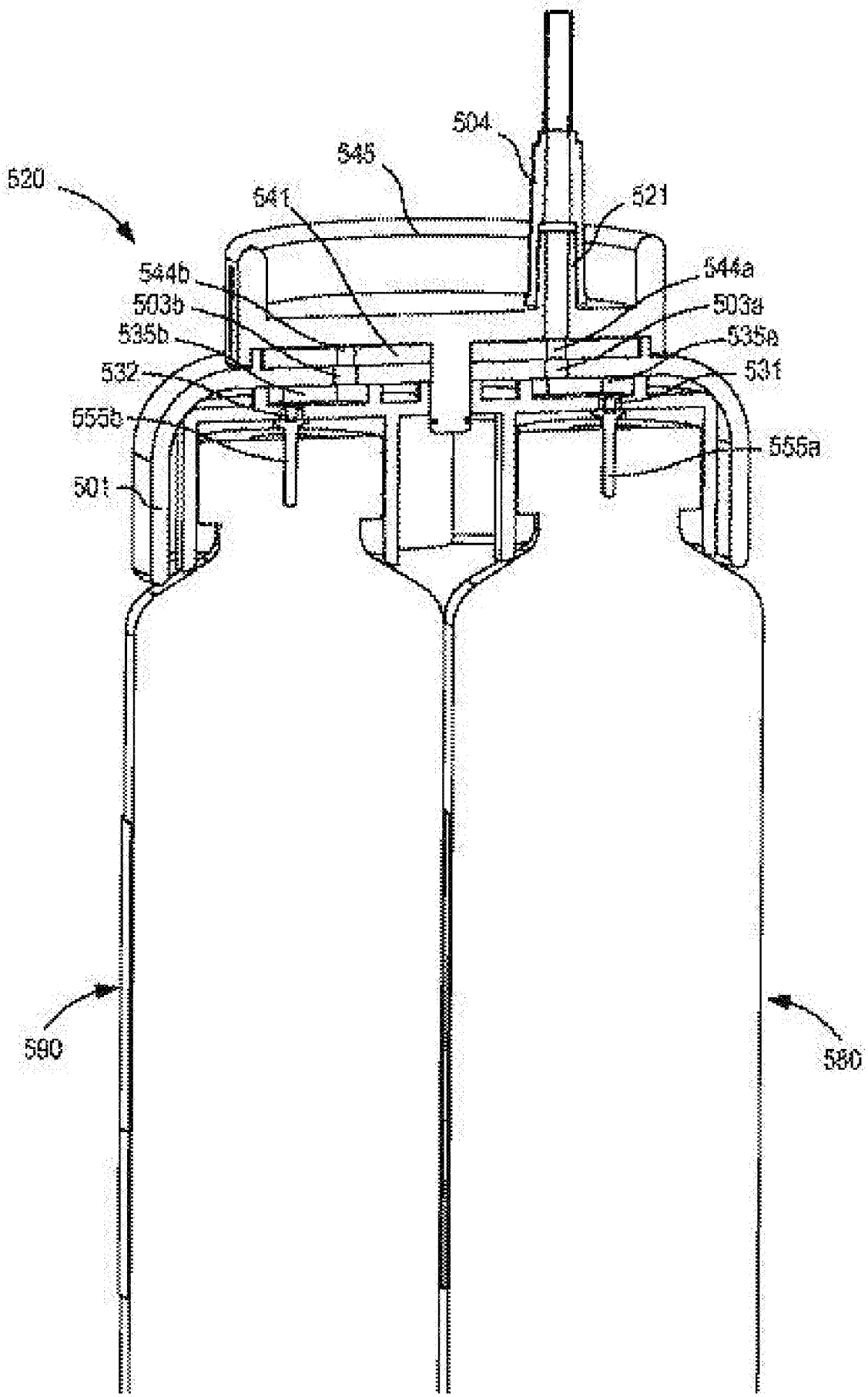


FIG. 24

[Fig.25]


504
545
520
541
521
544b
544a
503b
503a
535b
535a
532
531
555b
555a
501
590
580

[Fig.26]

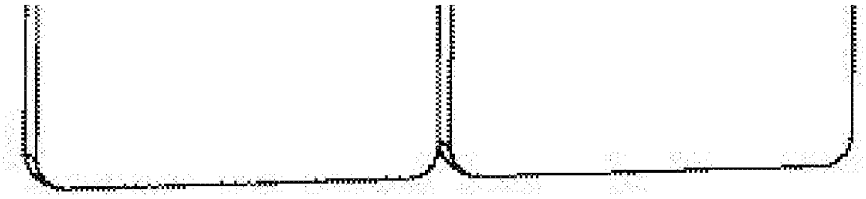
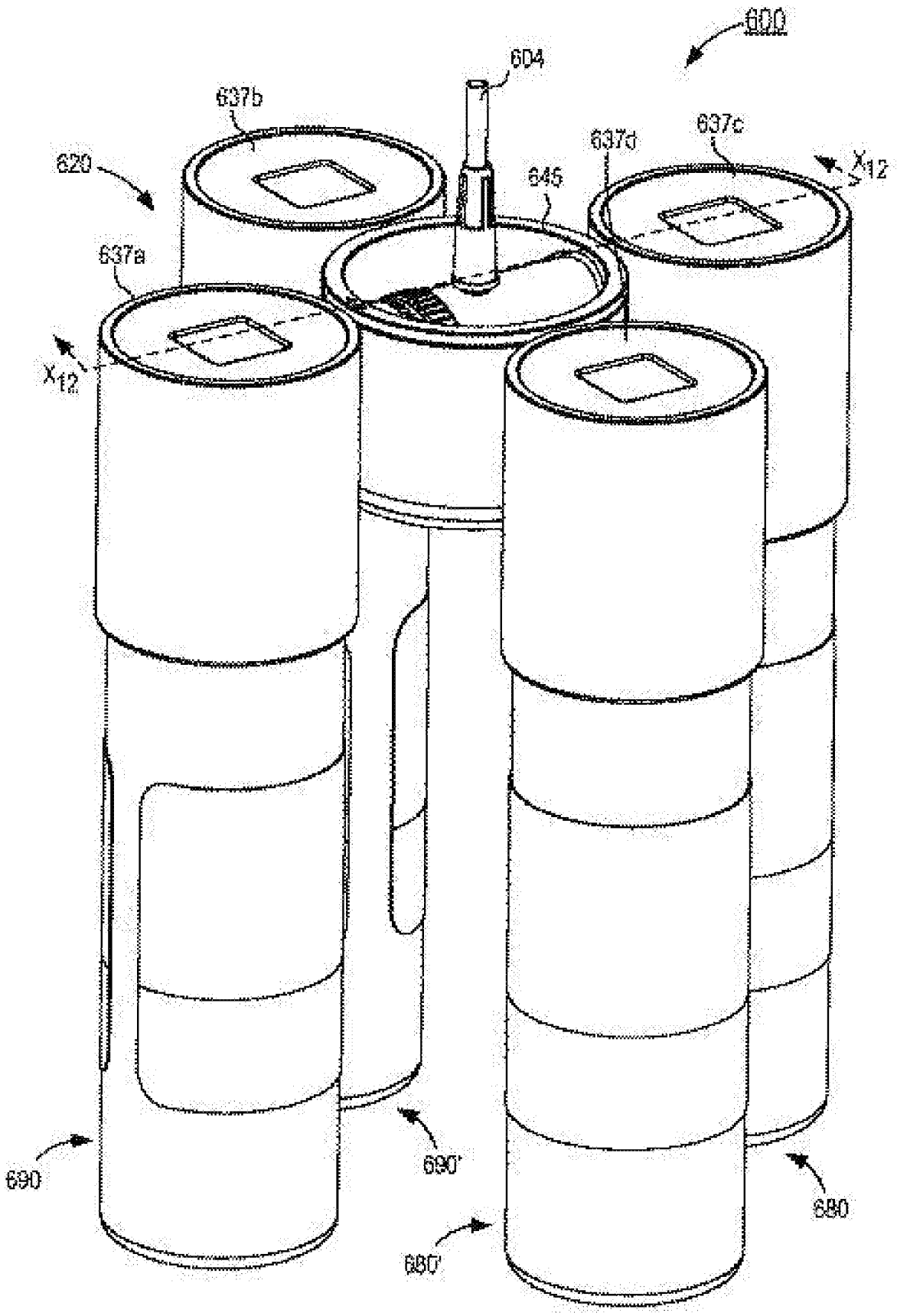


FIG. 25


600
604
637b
637d
637c
620
645
637a
X12
X12
690
690'
680
680'

[Fig.27]

FIG. 26

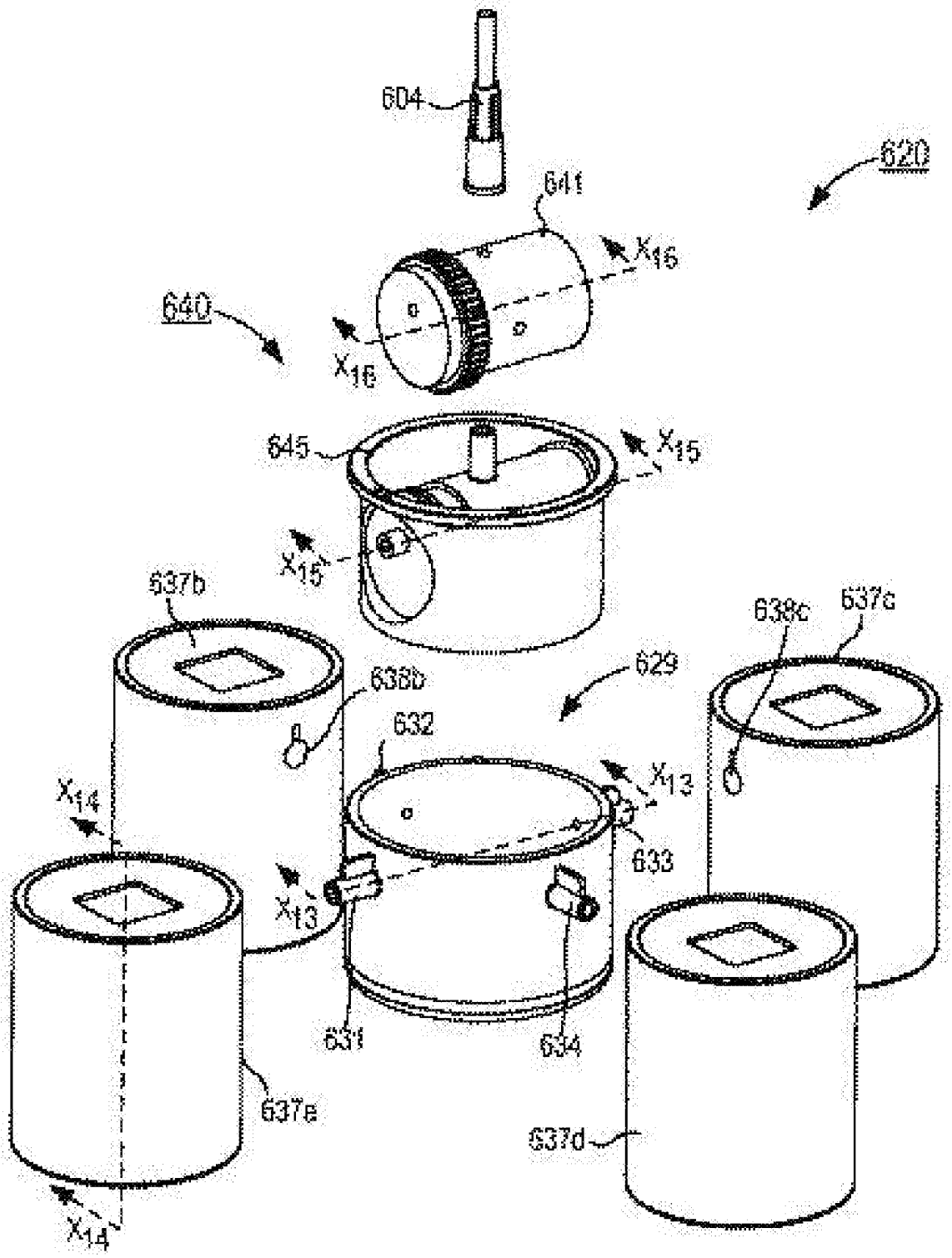

604
620
641
X_{16}
640
X_{16}
645
X_{15}
X_{15}
637b
638c
637c
638b
629
632
X_{13}
X_{14}
633
X_{13}
631
634
637e
637d
X_{14}

FIG. 27

[Fig.28]

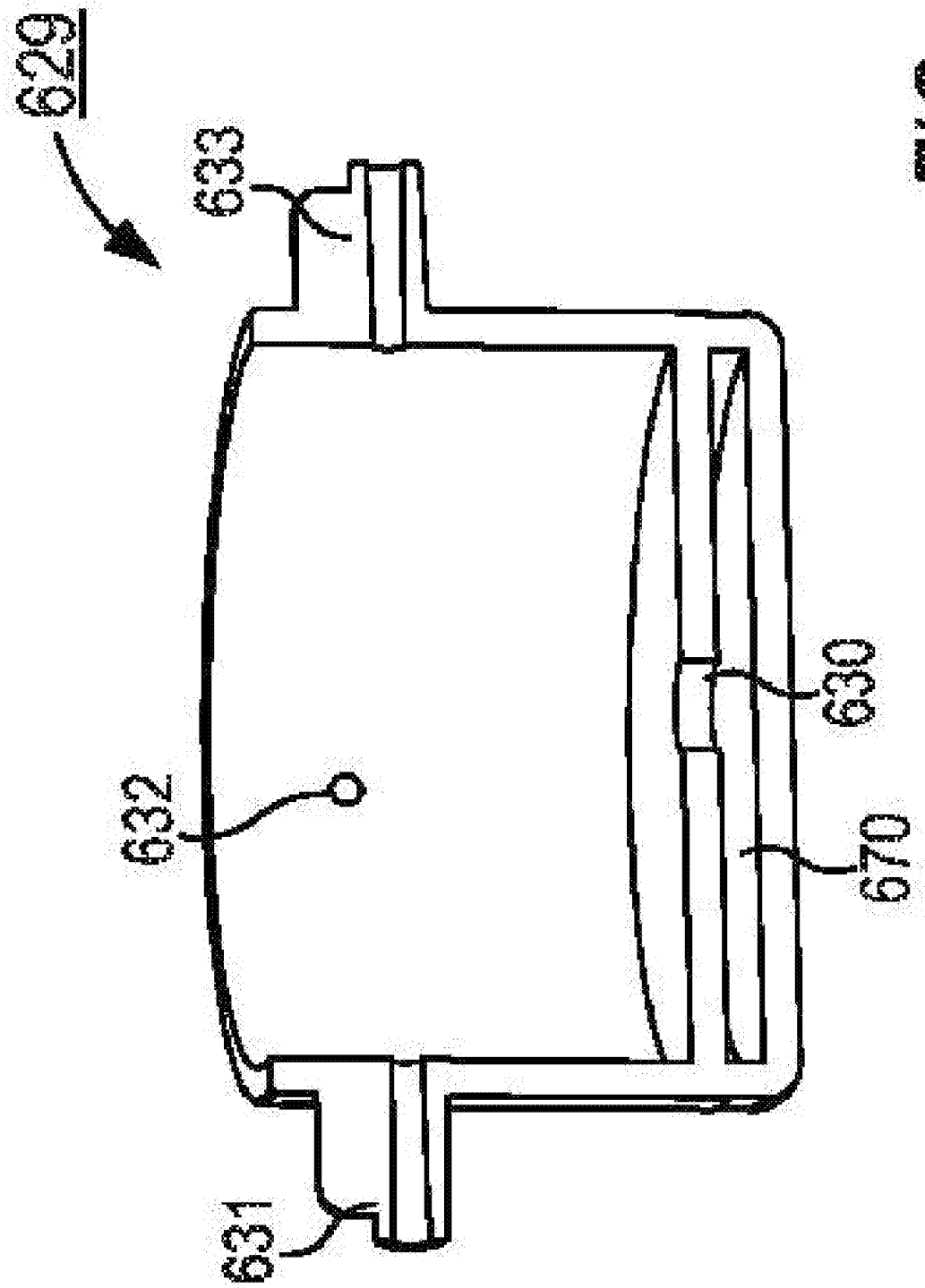


FIG. 28

[Fig.29]

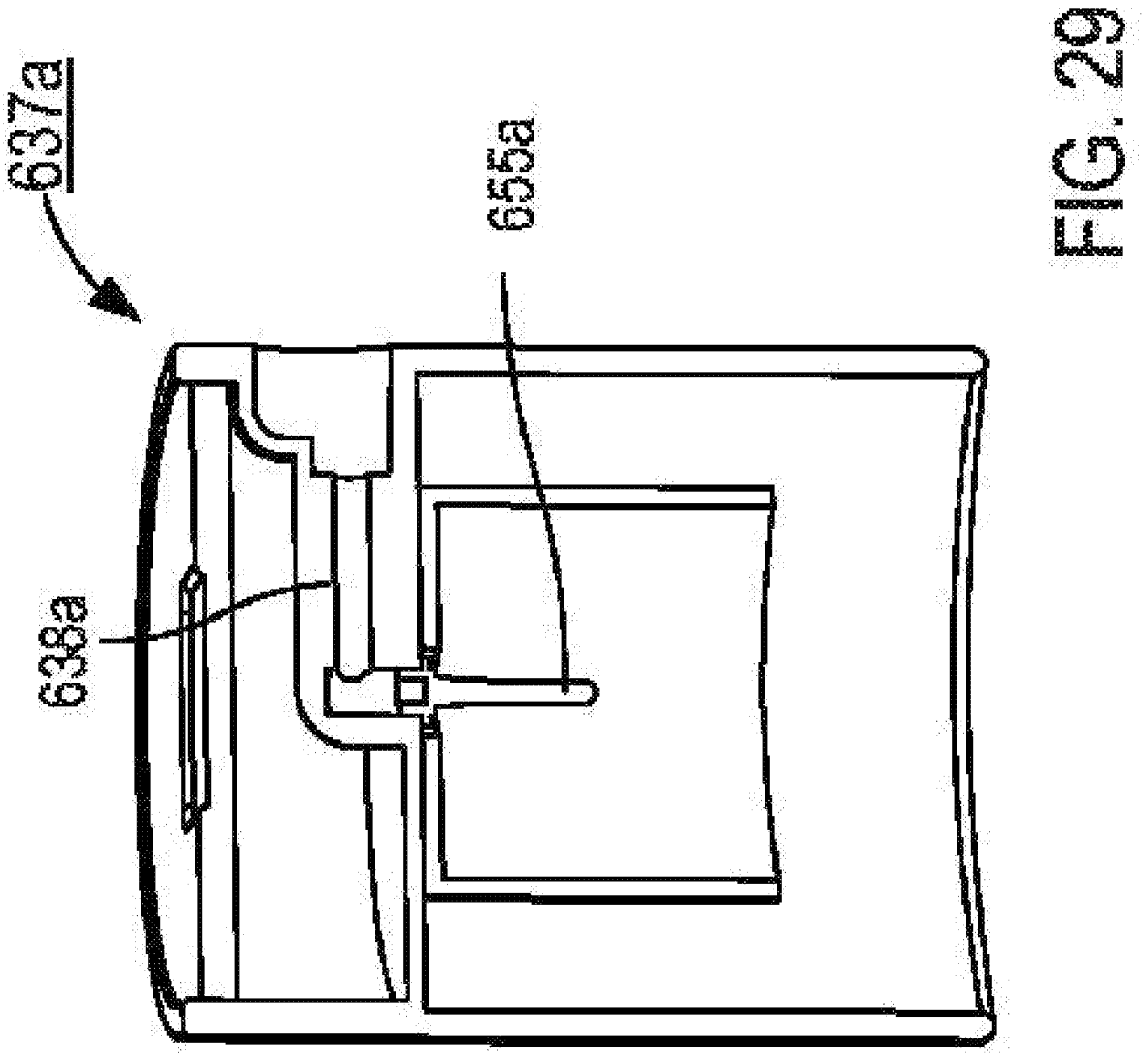
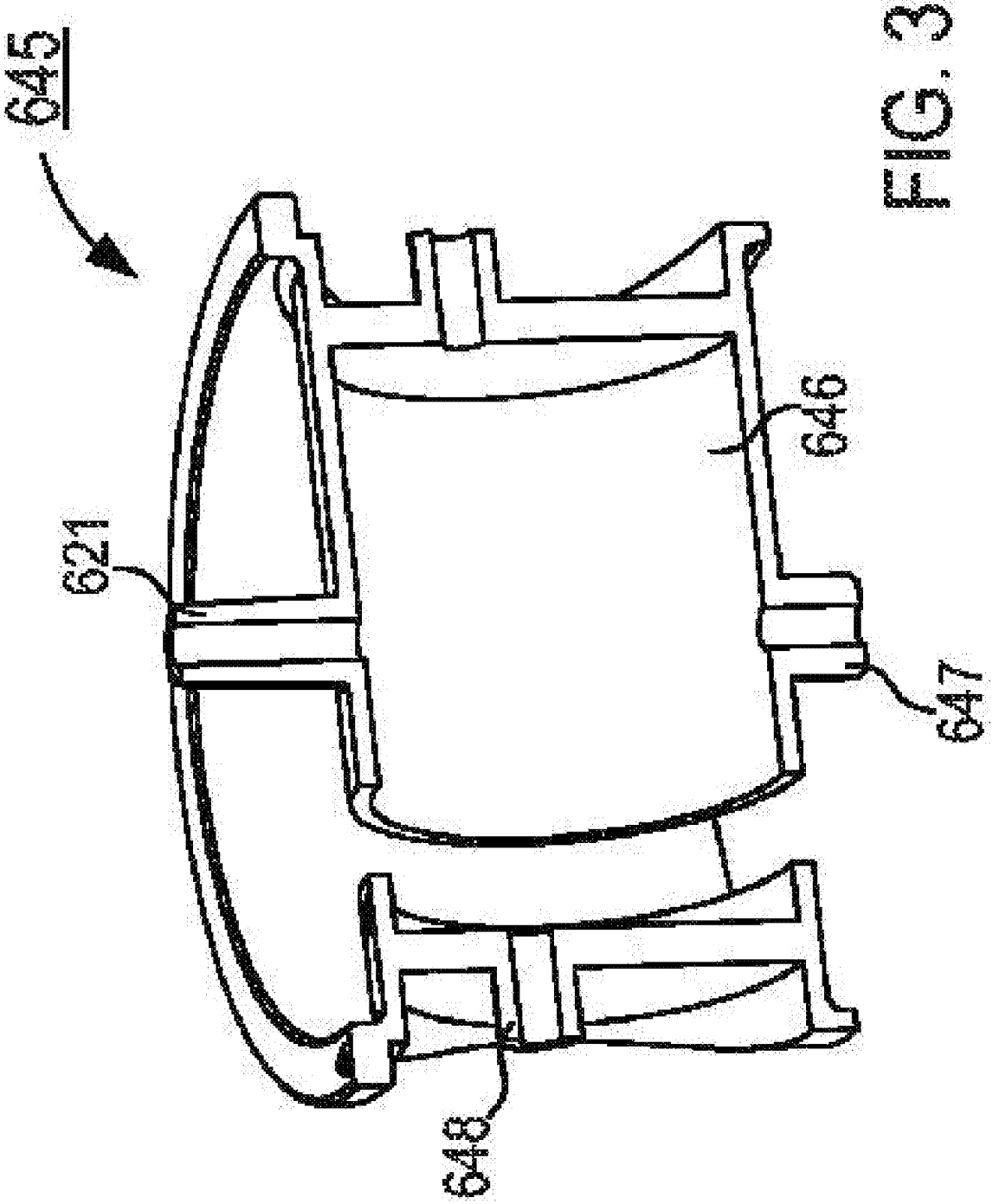


FIG. 29

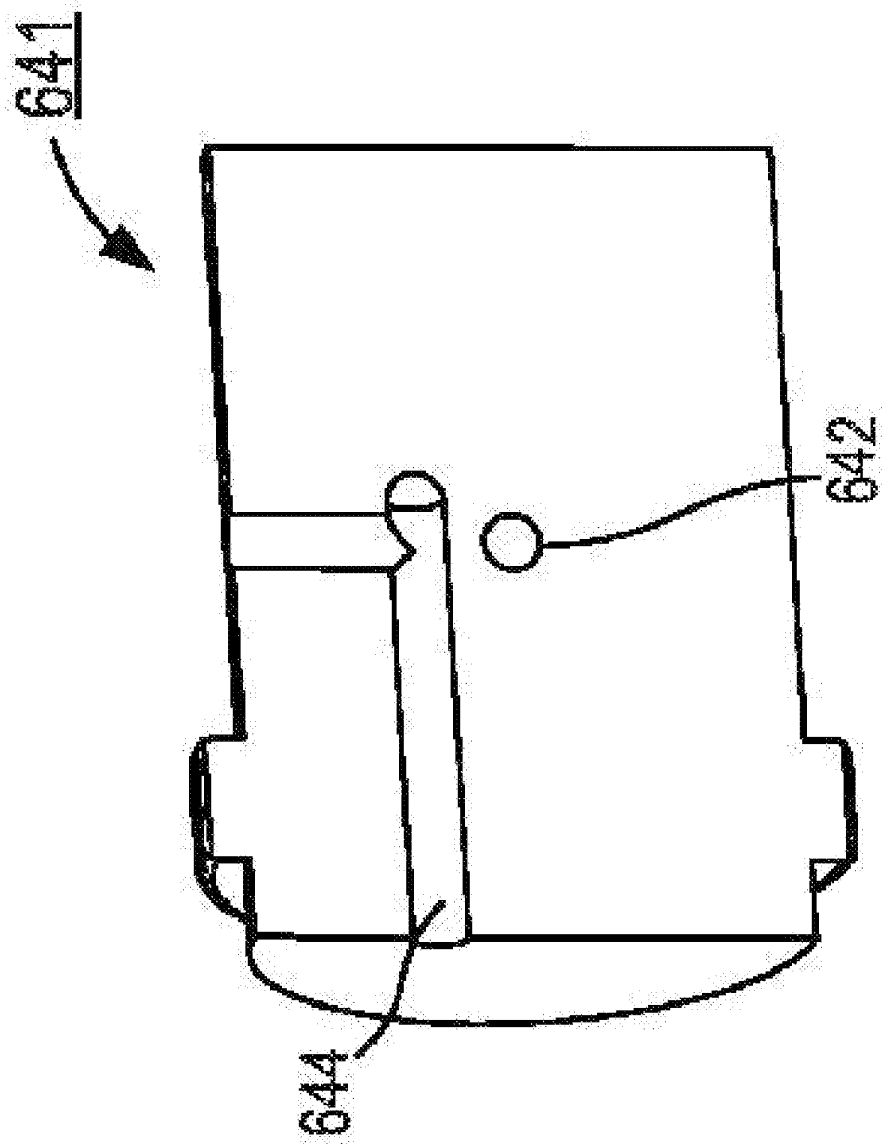
[Fig. 30]

FIG. 30



[Fig. 31]

FIG. 31



[Fig. 32]

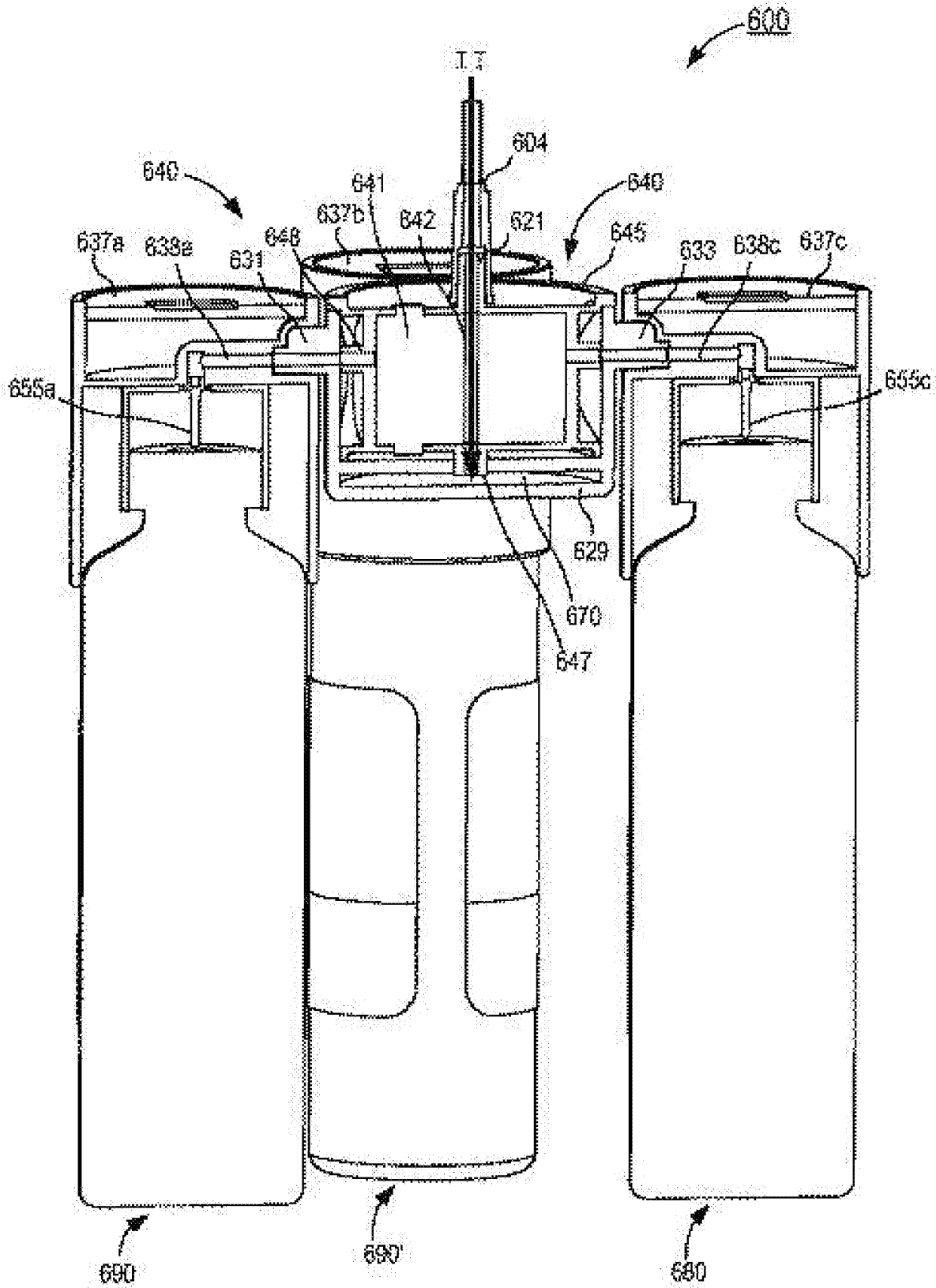

600
I
I
604
640
641
637b
642
621
640
645
637a
638a
631
648
633
638c
637c
655a
655c
629
670
647
690
690'
680

FIG. 32

[Fig. 33]

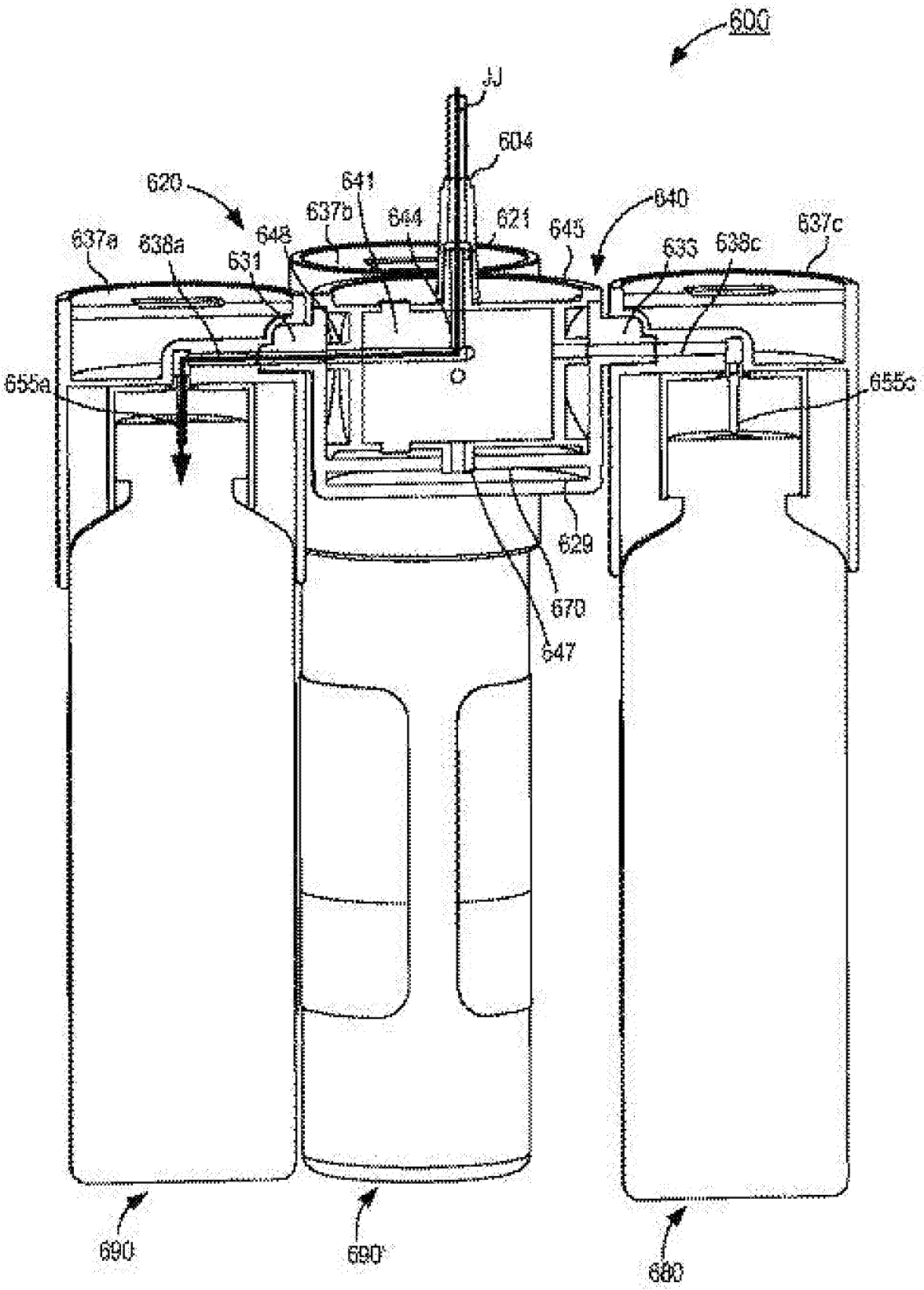
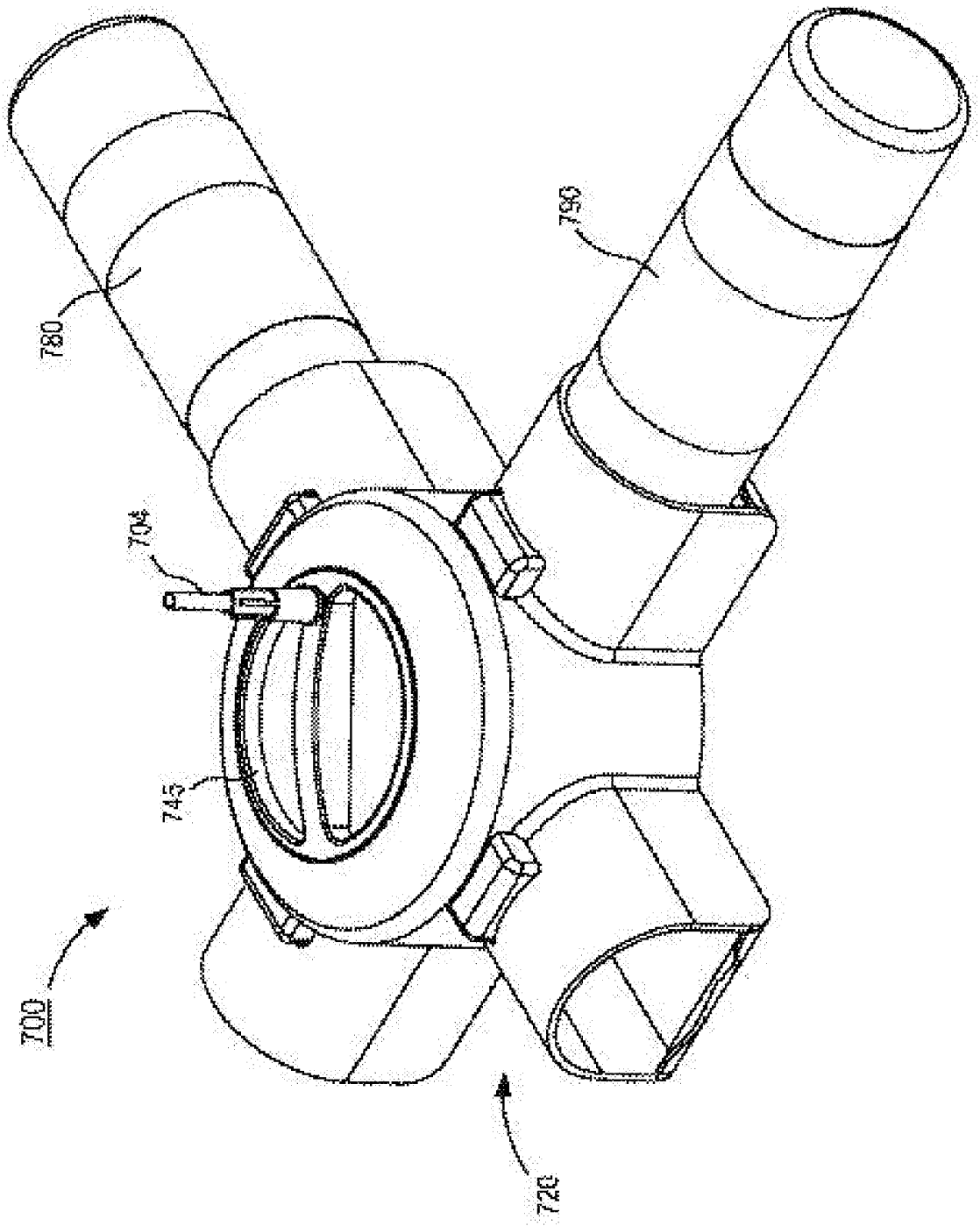

600
JJ
604
620
641
637b
644
621
645
640
637a
638a
648
631
633
638c
637c
655a
655c
629
670
647
690
690
680

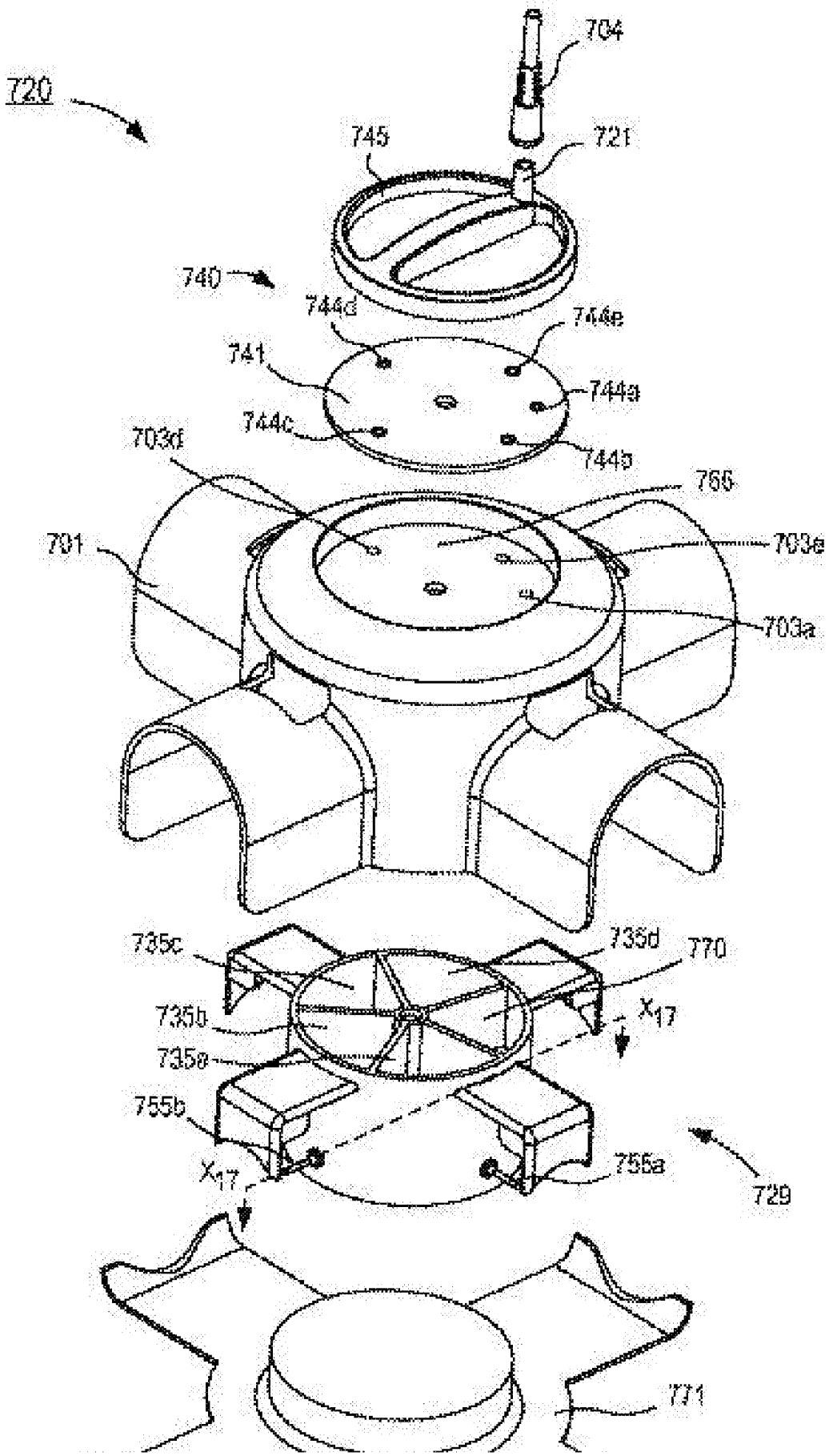
FIG. 33

[Fig. 34]

FIG. 34



[Fig.35]


720
704
745
721
740
744d
744e
741
744a
744c
744b
703f
766
701
703e
703a
735c
735d
770
735b
X_{17}
735a
755b
X_{17}
755a
729
771

[Fig. 36]

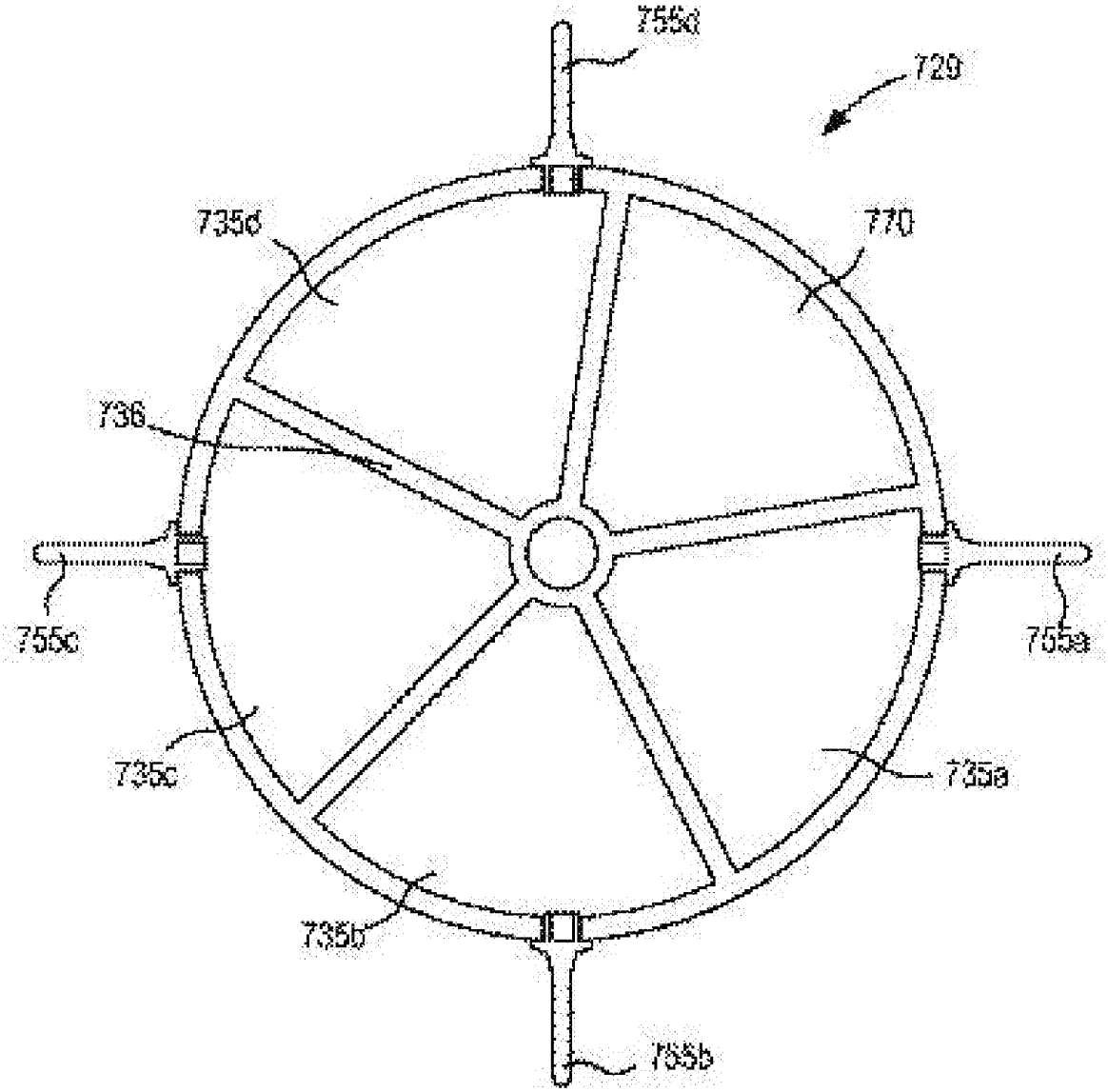


FIG. 36

[Fig. 37]

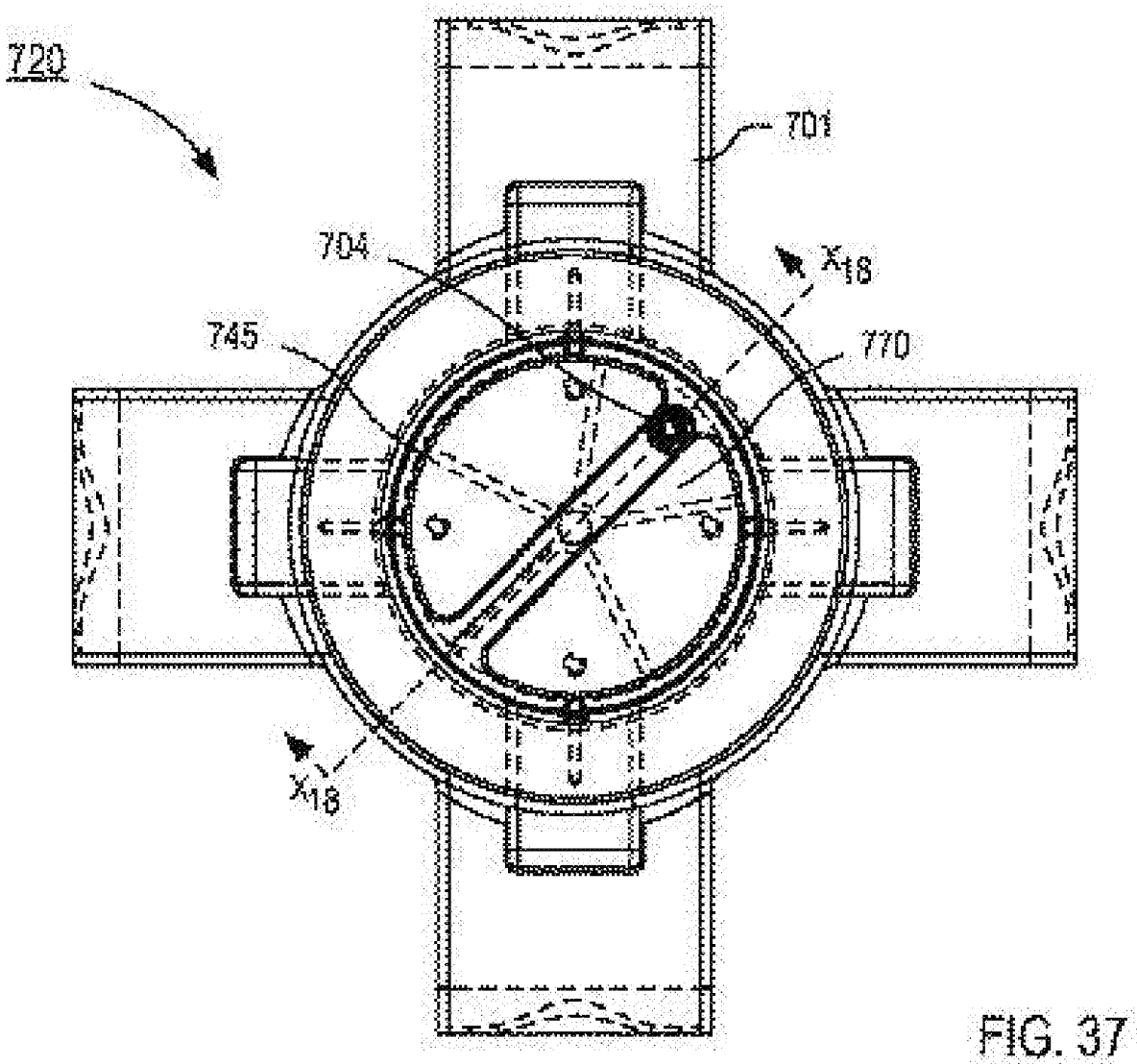


FIG. 37

[Fig. 38]

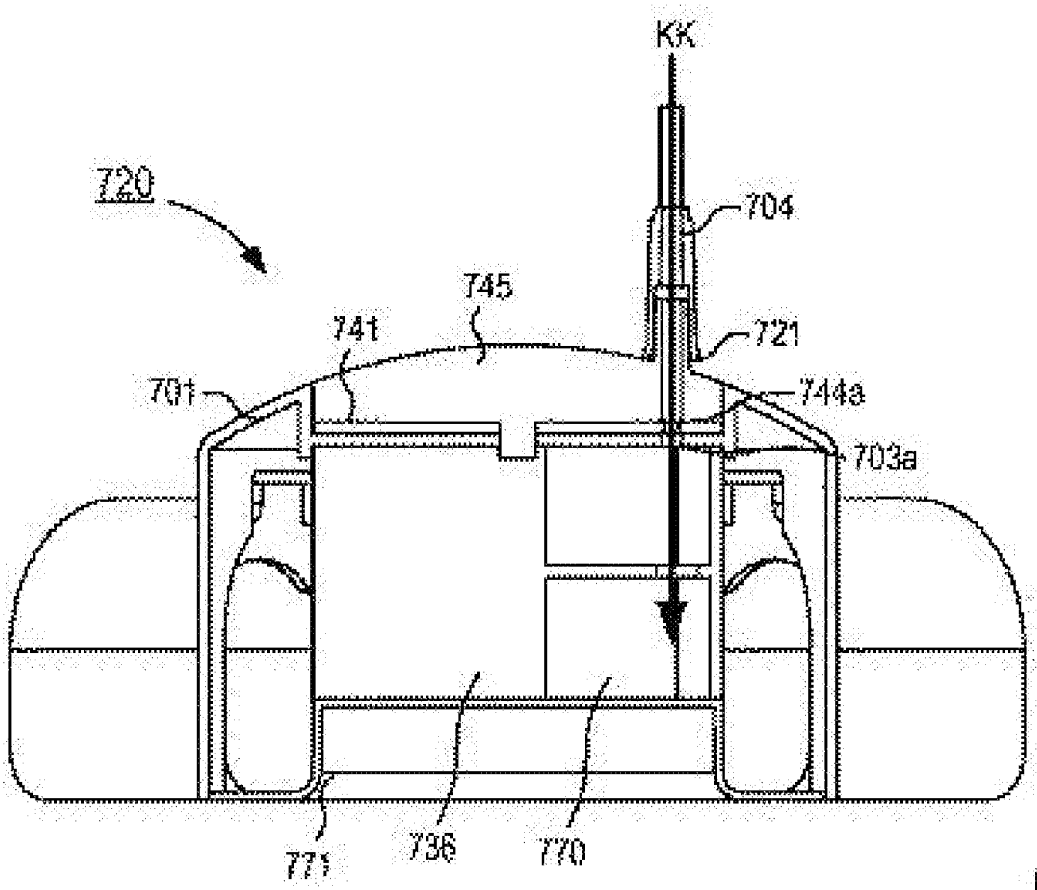


FIG. 38

[Fig.39]

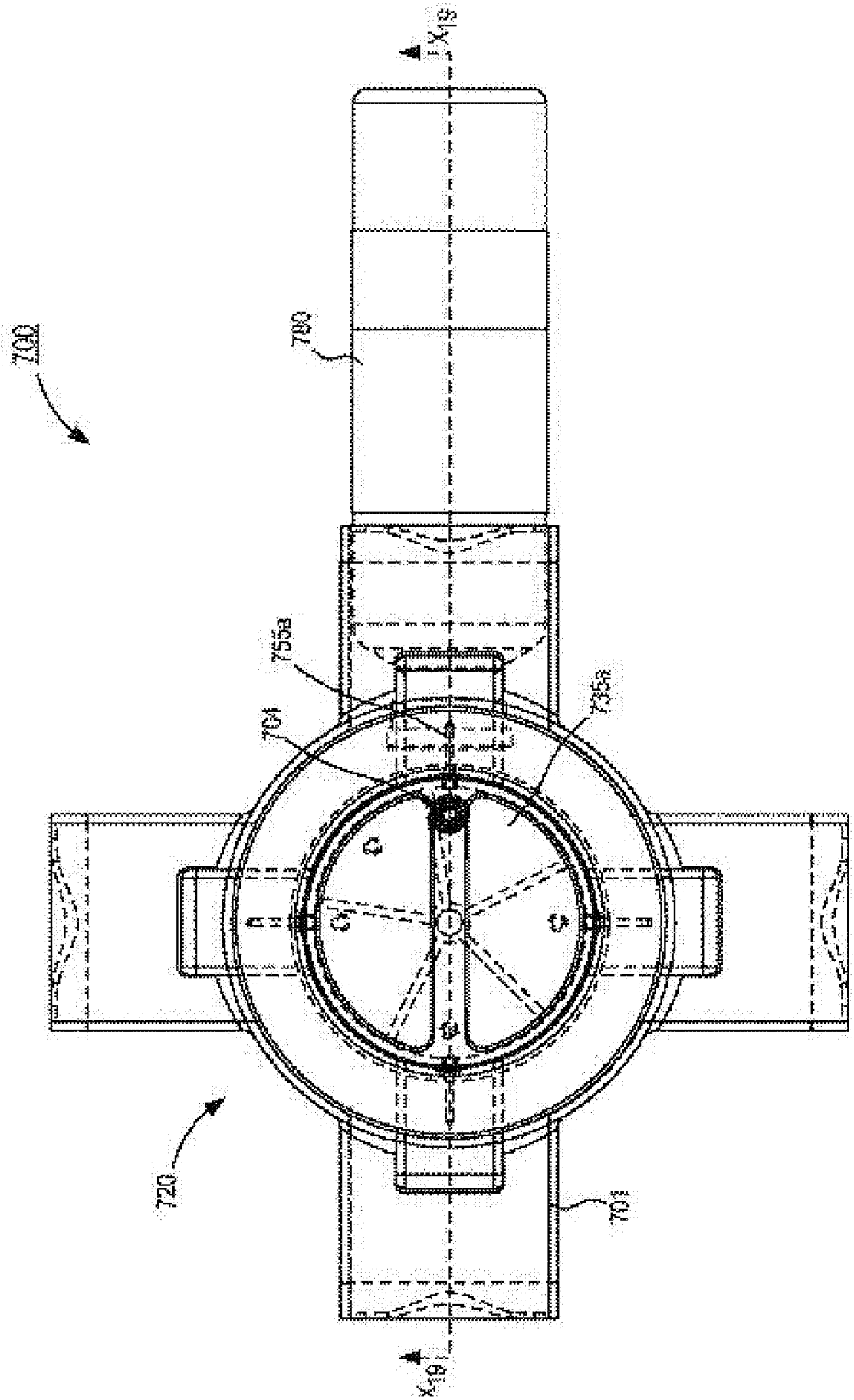


FIG. 39

[Fig. 40]

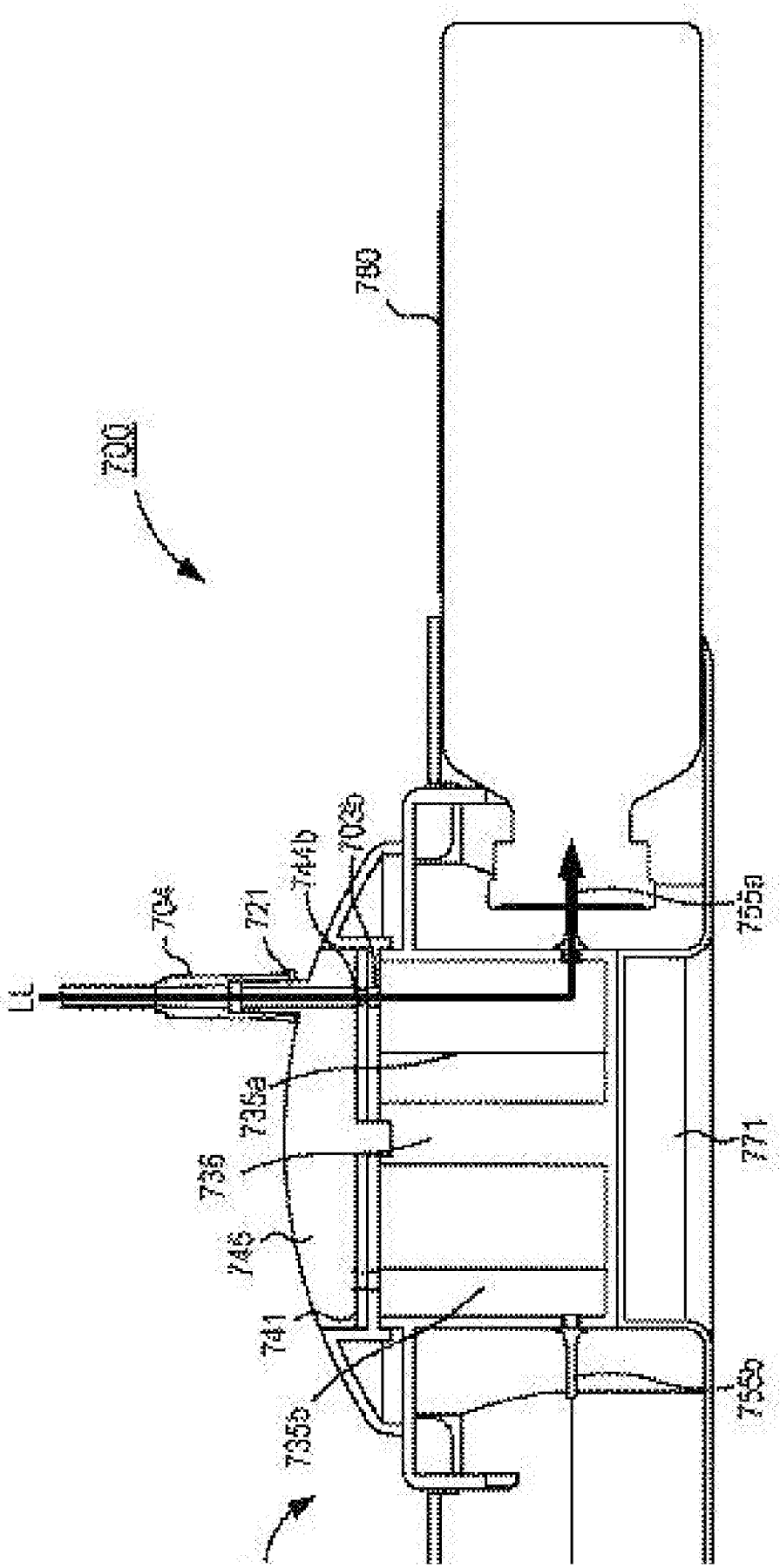
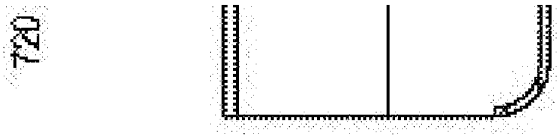
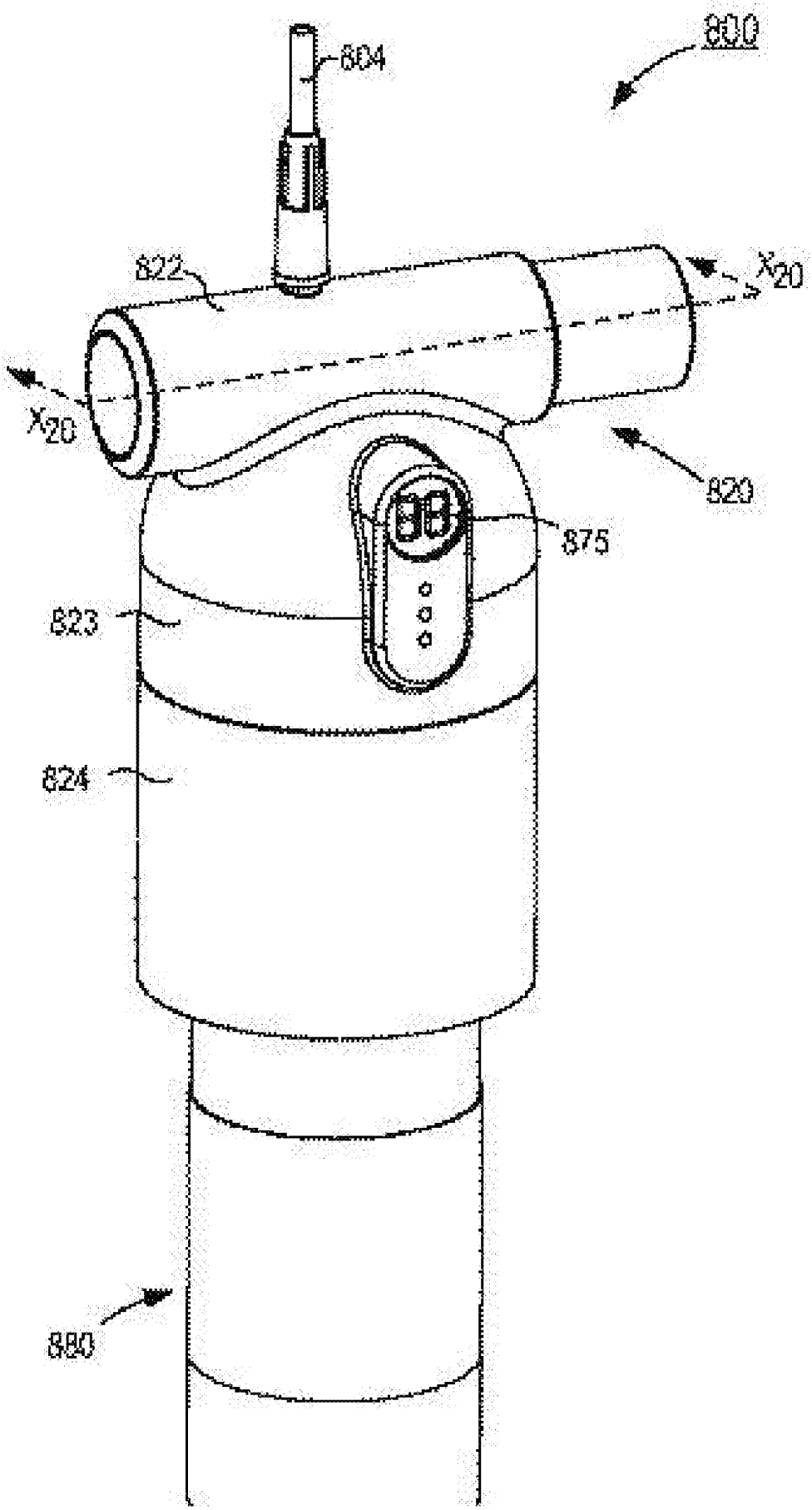

700
793
LL
704a
721
744b
703a
755a1
735a
735
746
741
735b
771
755b

FIG. 40

[Fig. 41]




800
804
822
X20
X20
820
875
823
824
880

[Fig. 42]

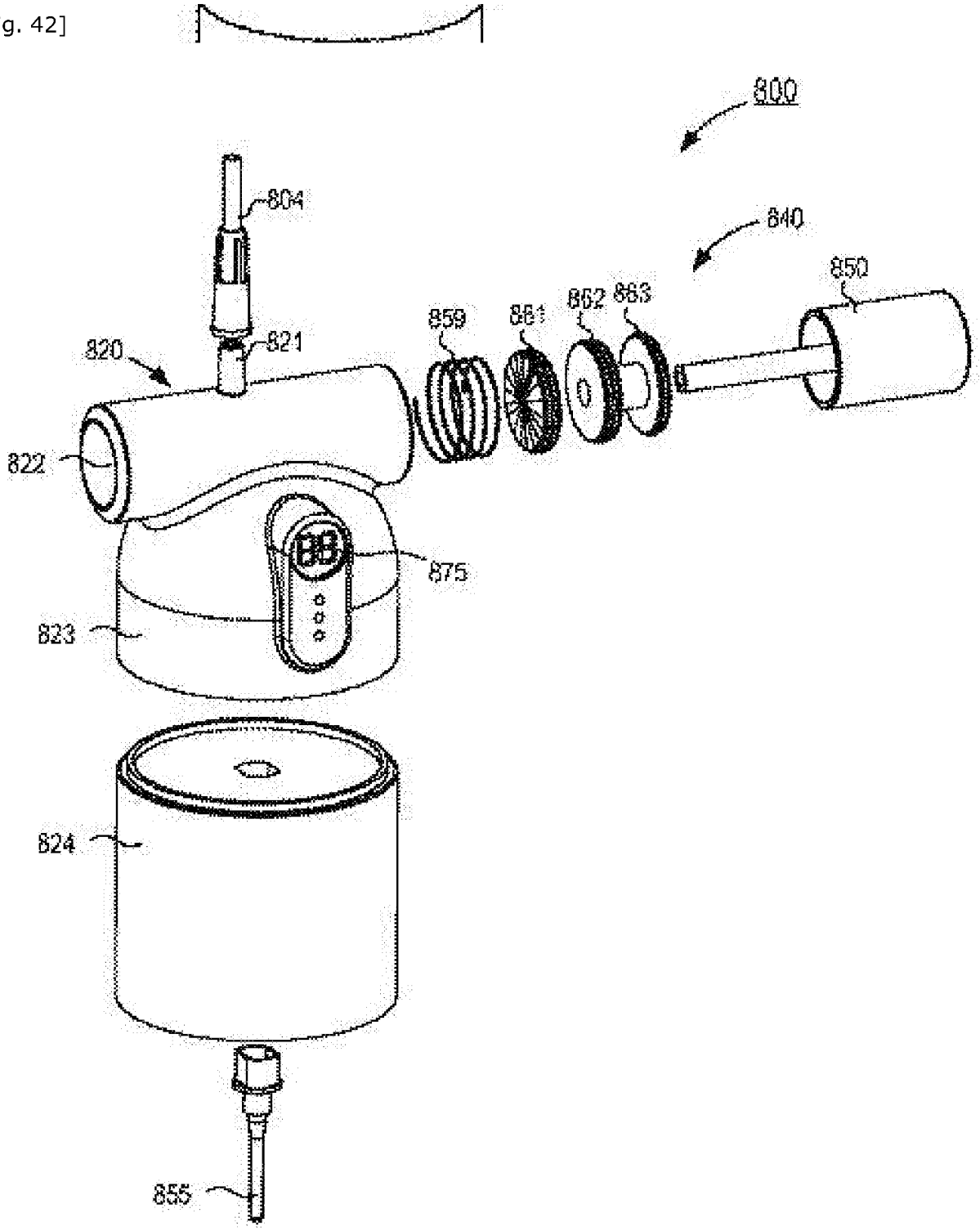
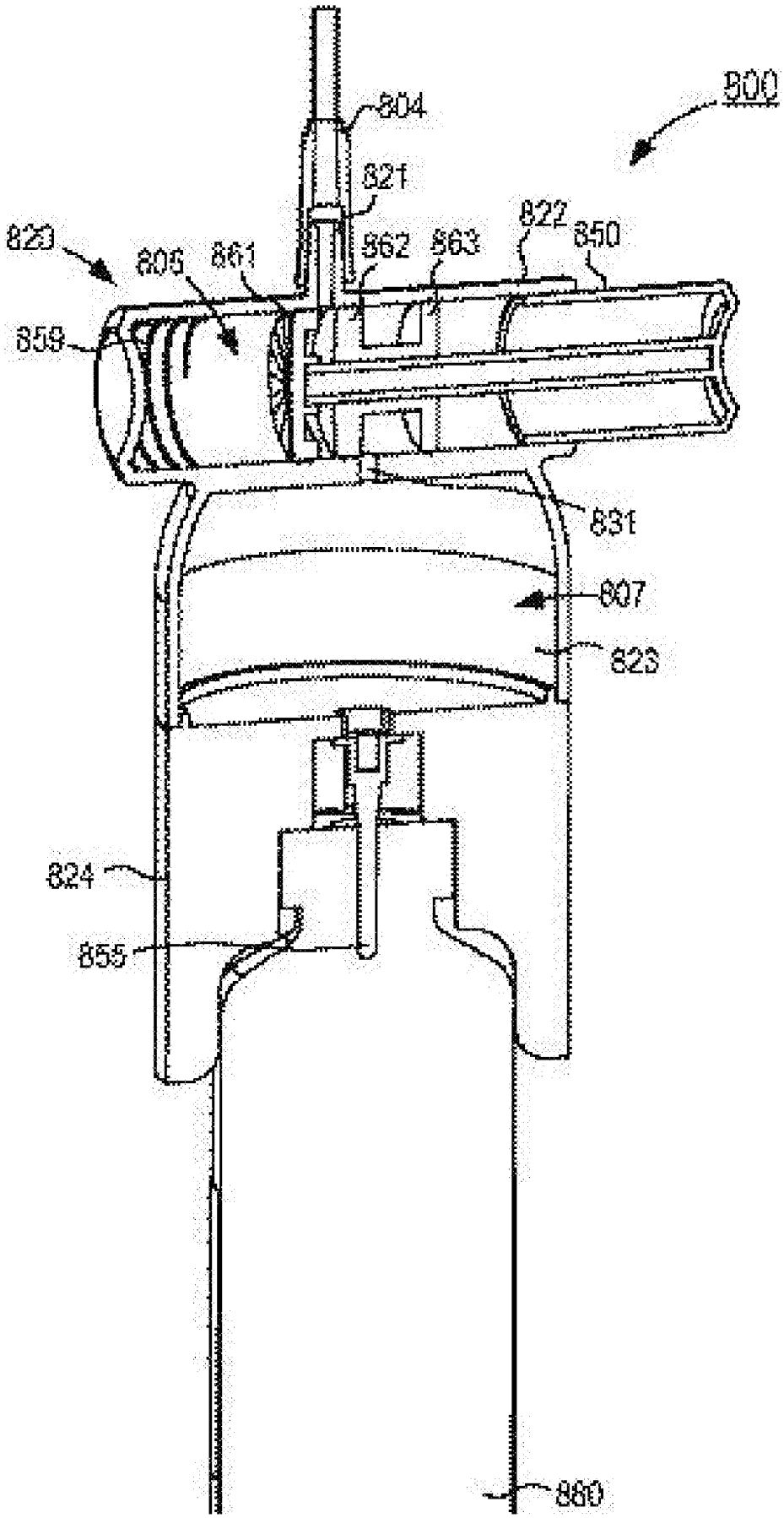


FIG. 42

[Fig. 43]


800
804
821
822
850
820
805
861
862
863
859
831
807
823
824
855
860

[Fig. 44]

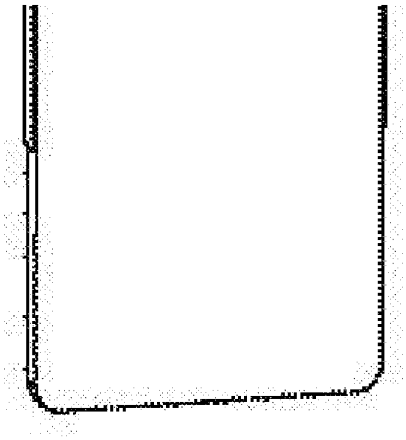
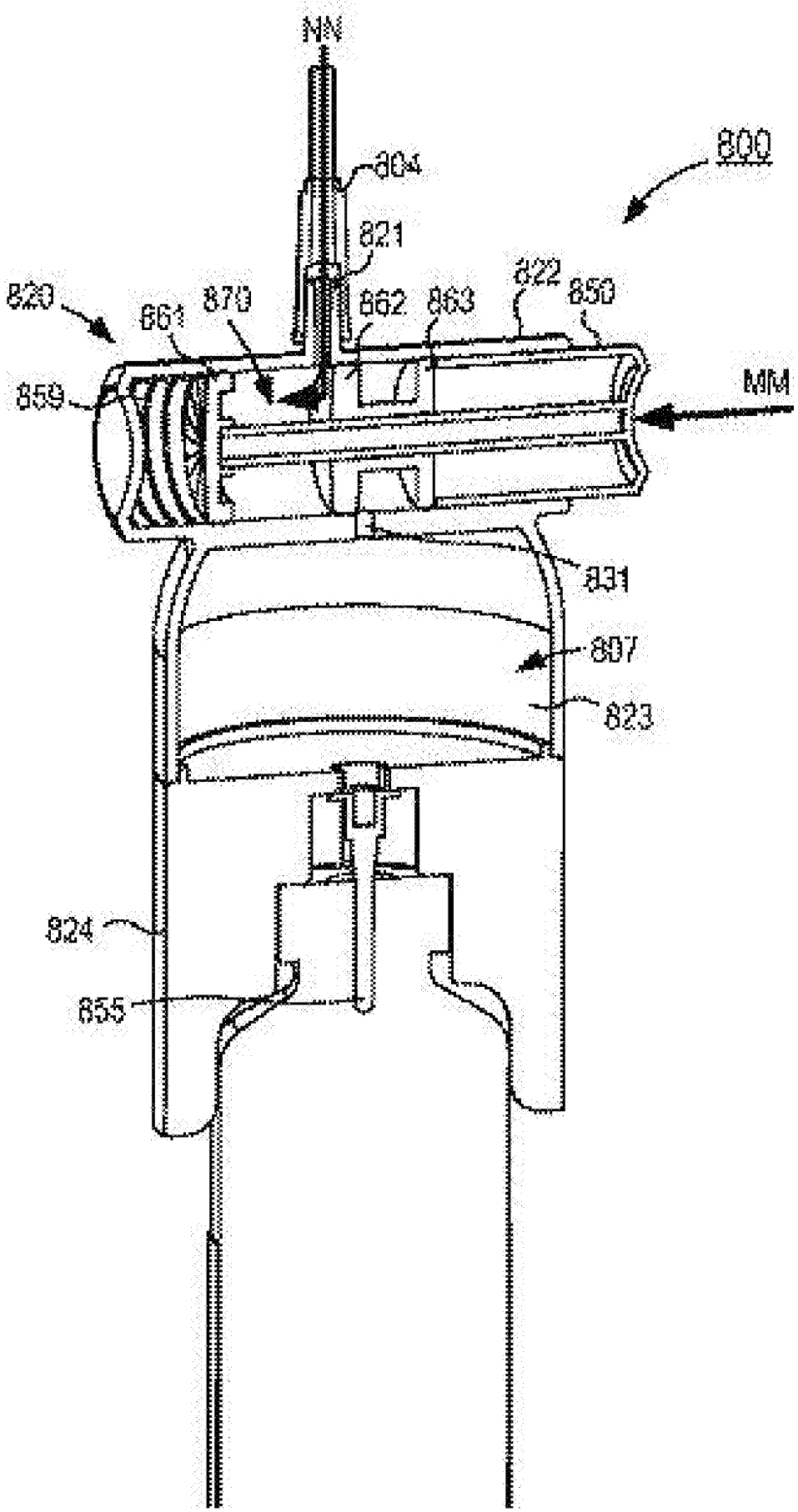


FIG. 43


NN
800
804
821
822
850
820
661
870
862
863
859
MM
831
807
823
824
855

[Fig. 45]

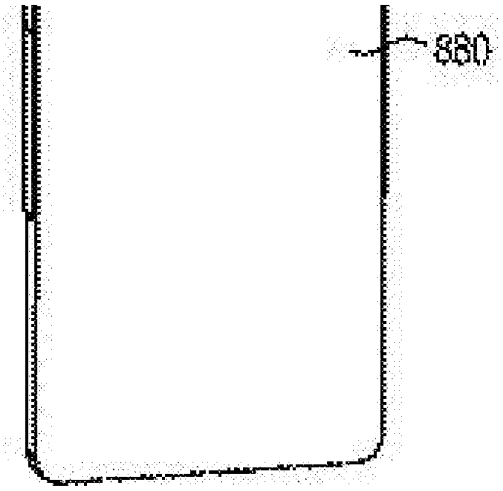
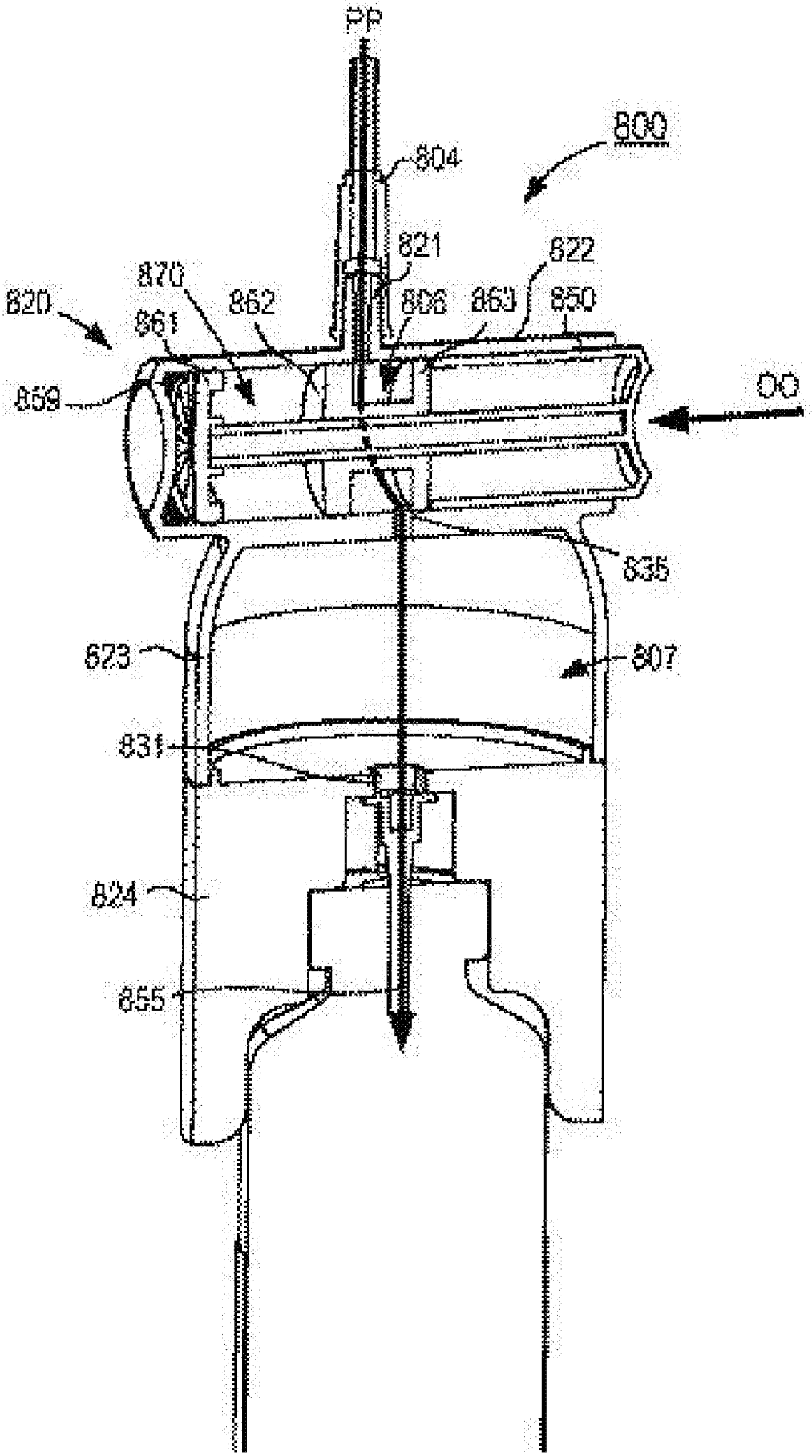


FIG. 44


PP
800
804
821
822
870
820
861
862
806
863
850
859
00
835
823
807
831
824
855

[Fig. 46]

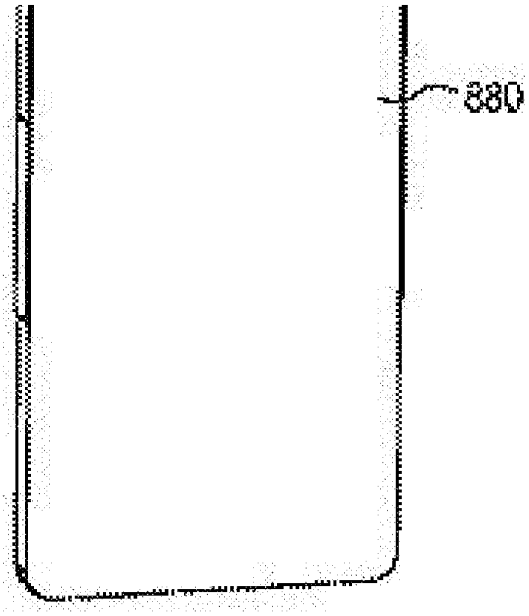
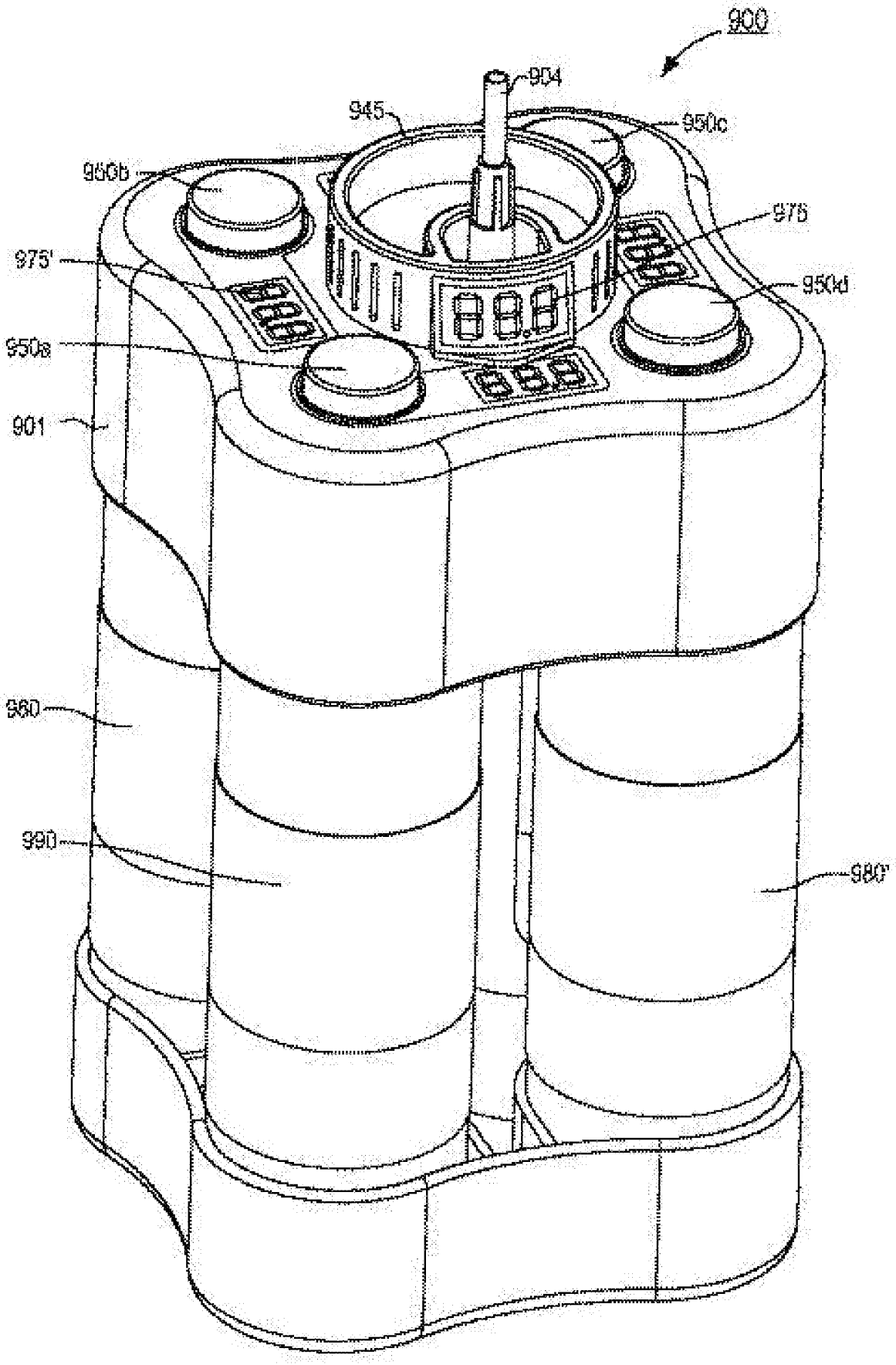
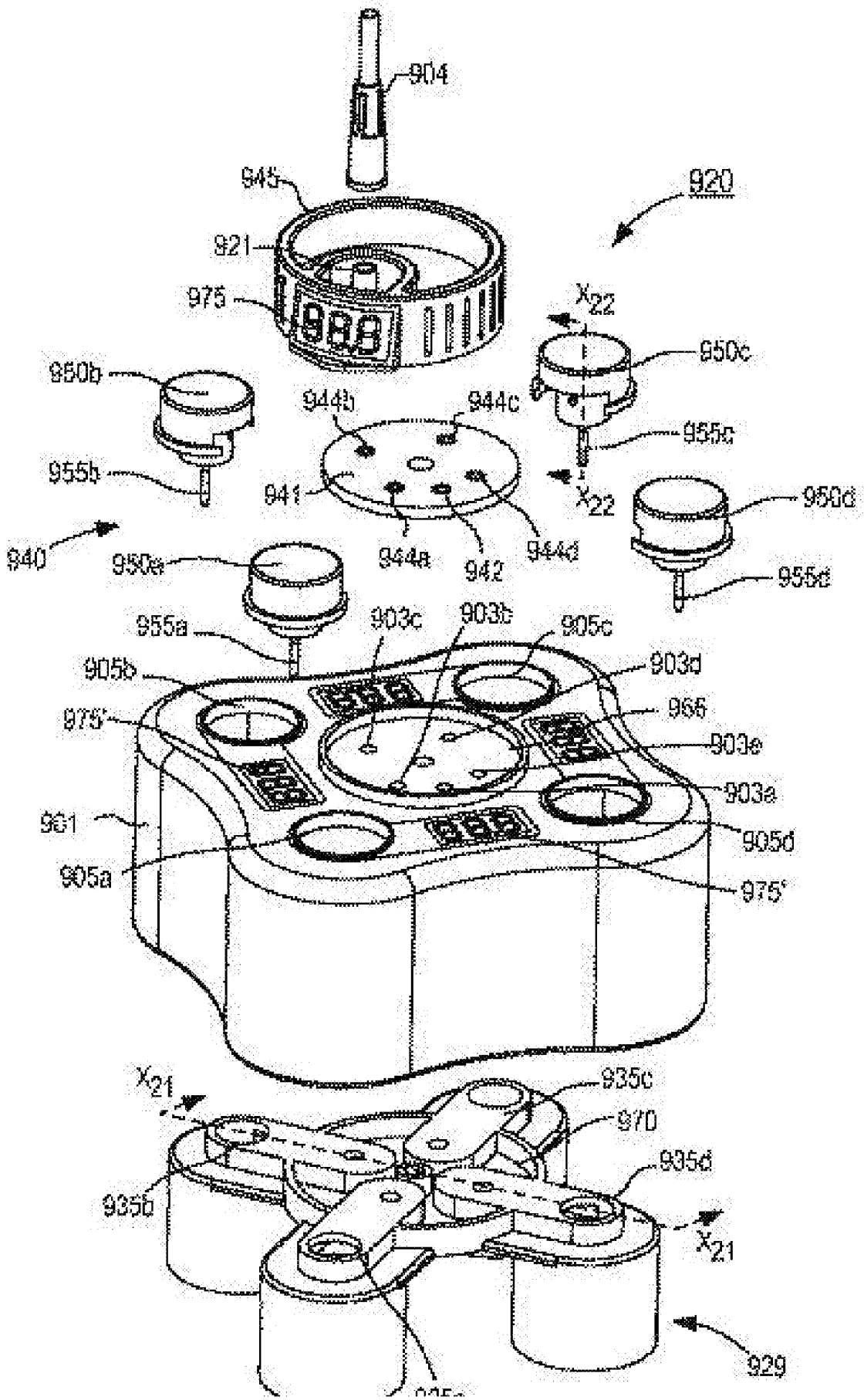


FIG. 45


900
904
945
950c
950b
975
975'
950d
950a
901
960
990
980'

[Fig. 46]


904
945
920
921
975
X22
950c
950b
944b
944c
955c
955b
941
X22
950d
940
944a
942
944d
950a
955d
955a
903c
903b
905c
905b
903d
975'
966
903e
903a
961
905d
905a
975'
X21
935c
970
935d
935b
X21
929

[Fig. 48]

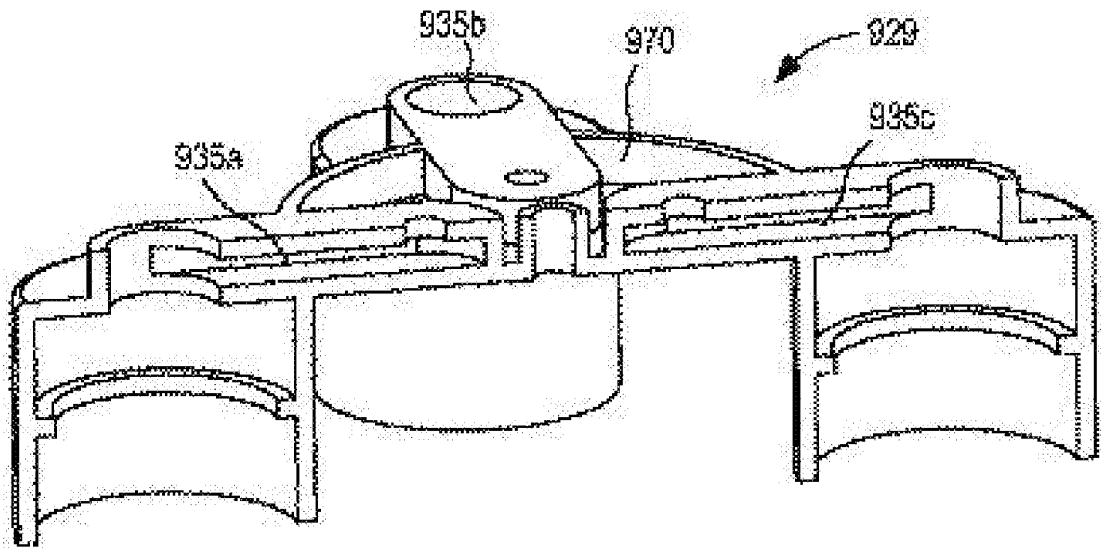


FIG. 48

[Fig. 49]

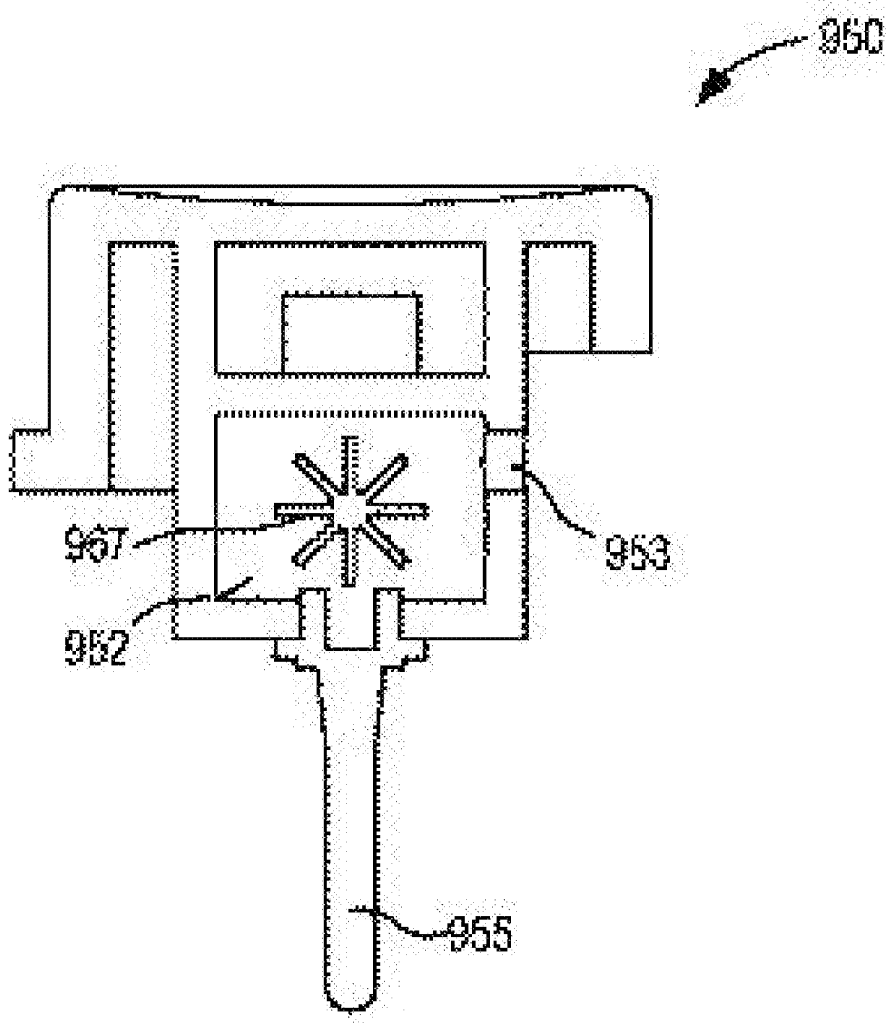


FIG. 49

[Fig. 50]

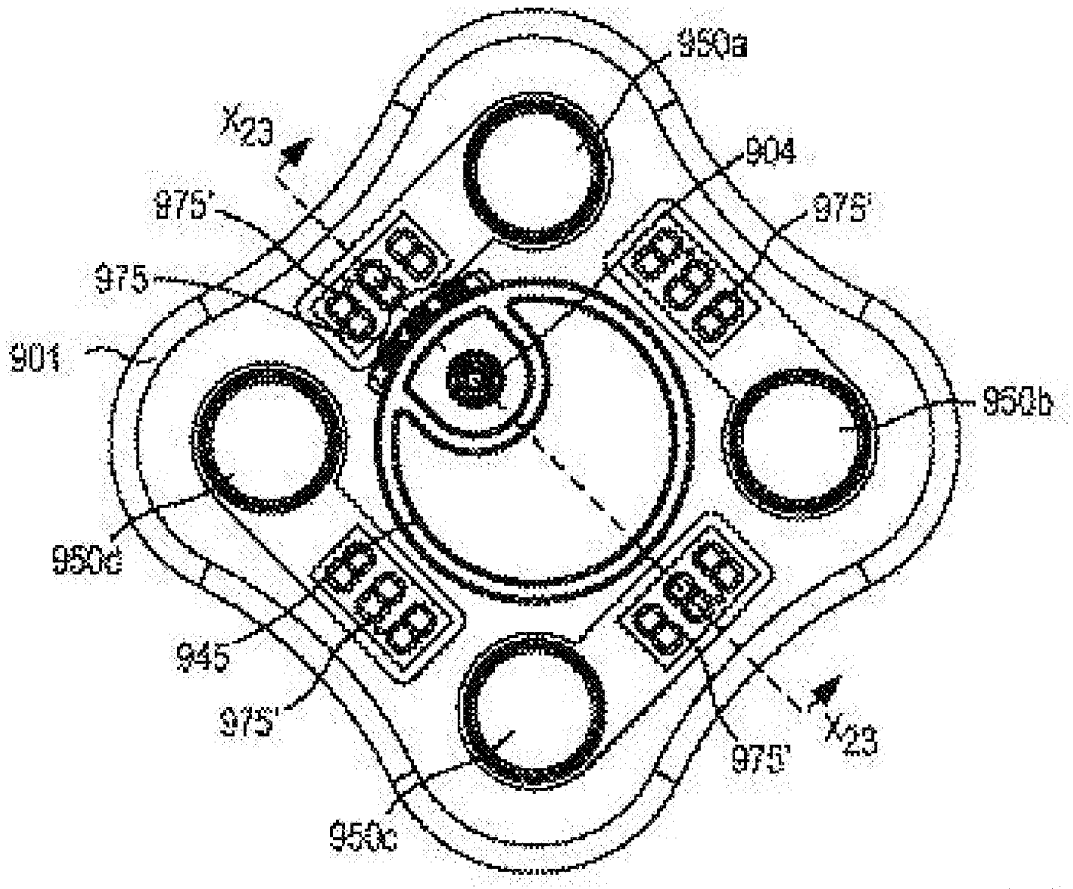


FIG. 50

[Fig. 51]

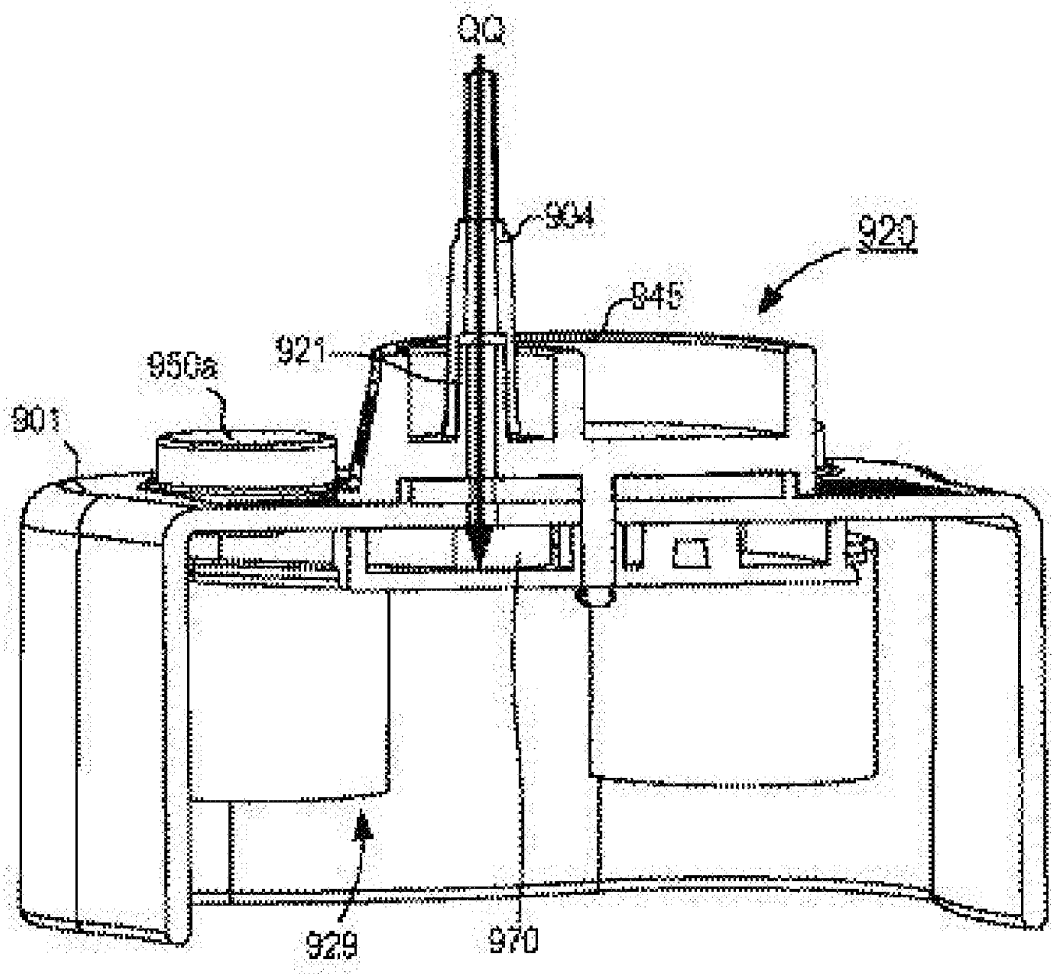


FIG. 51

[Fig. 52]

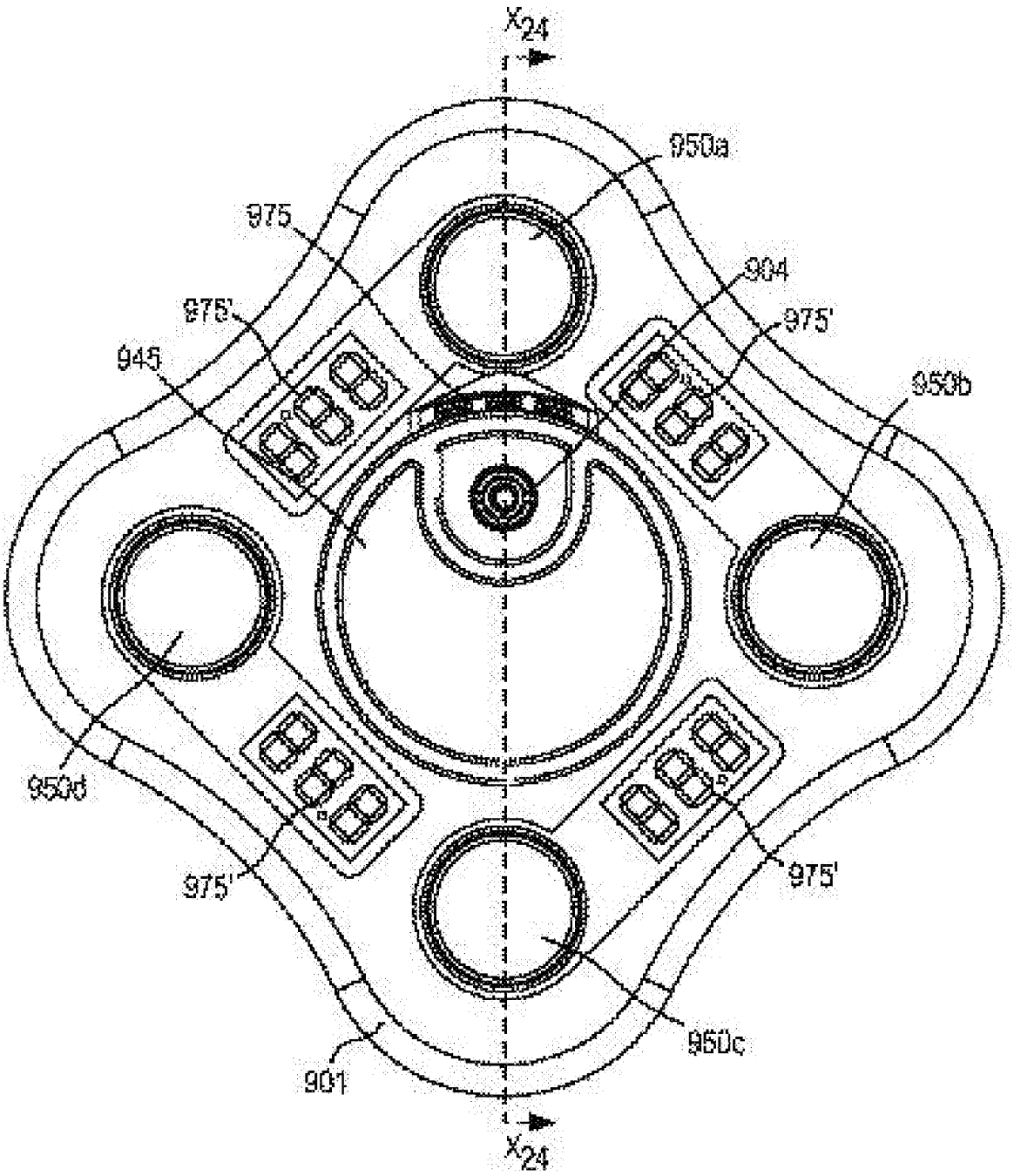
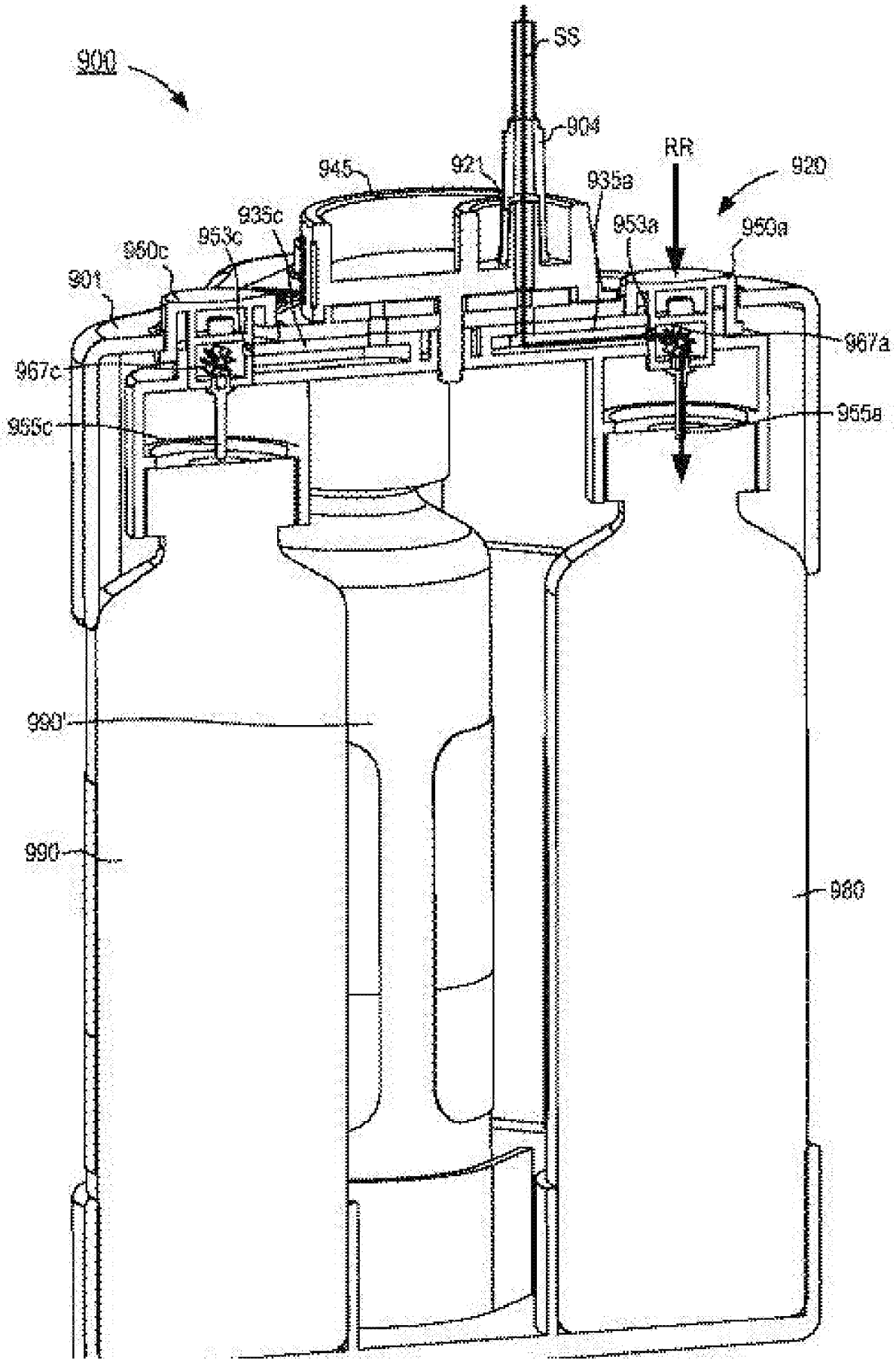
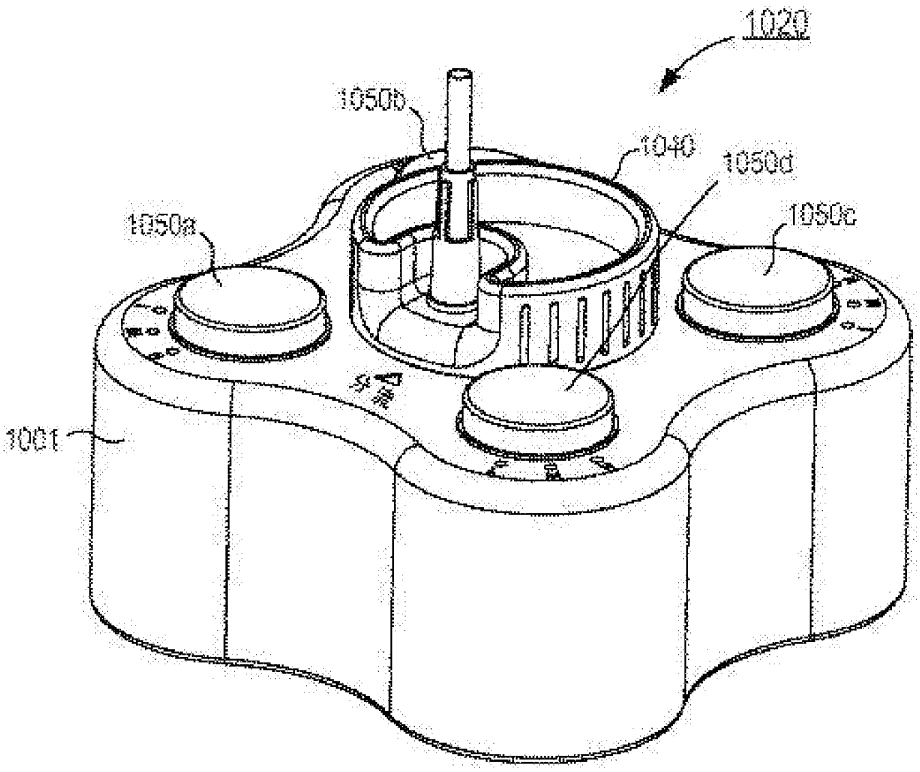


FIG. 52

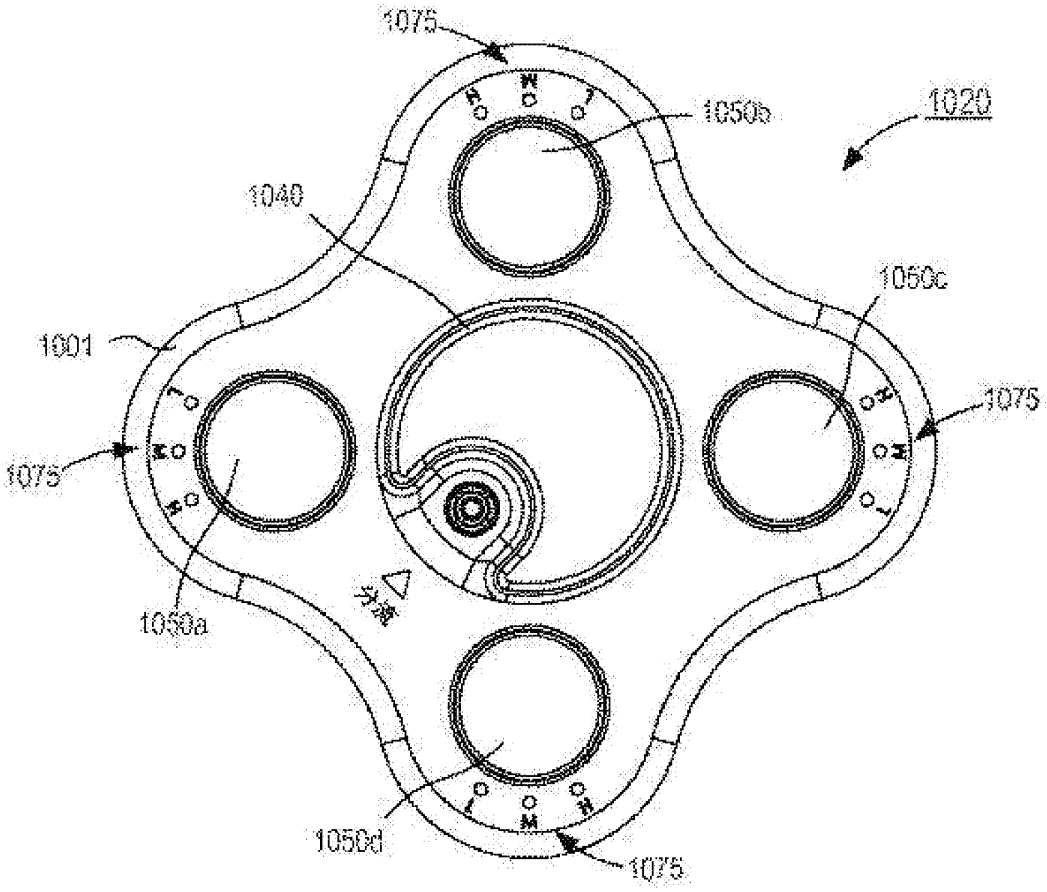
[Fig. 53]


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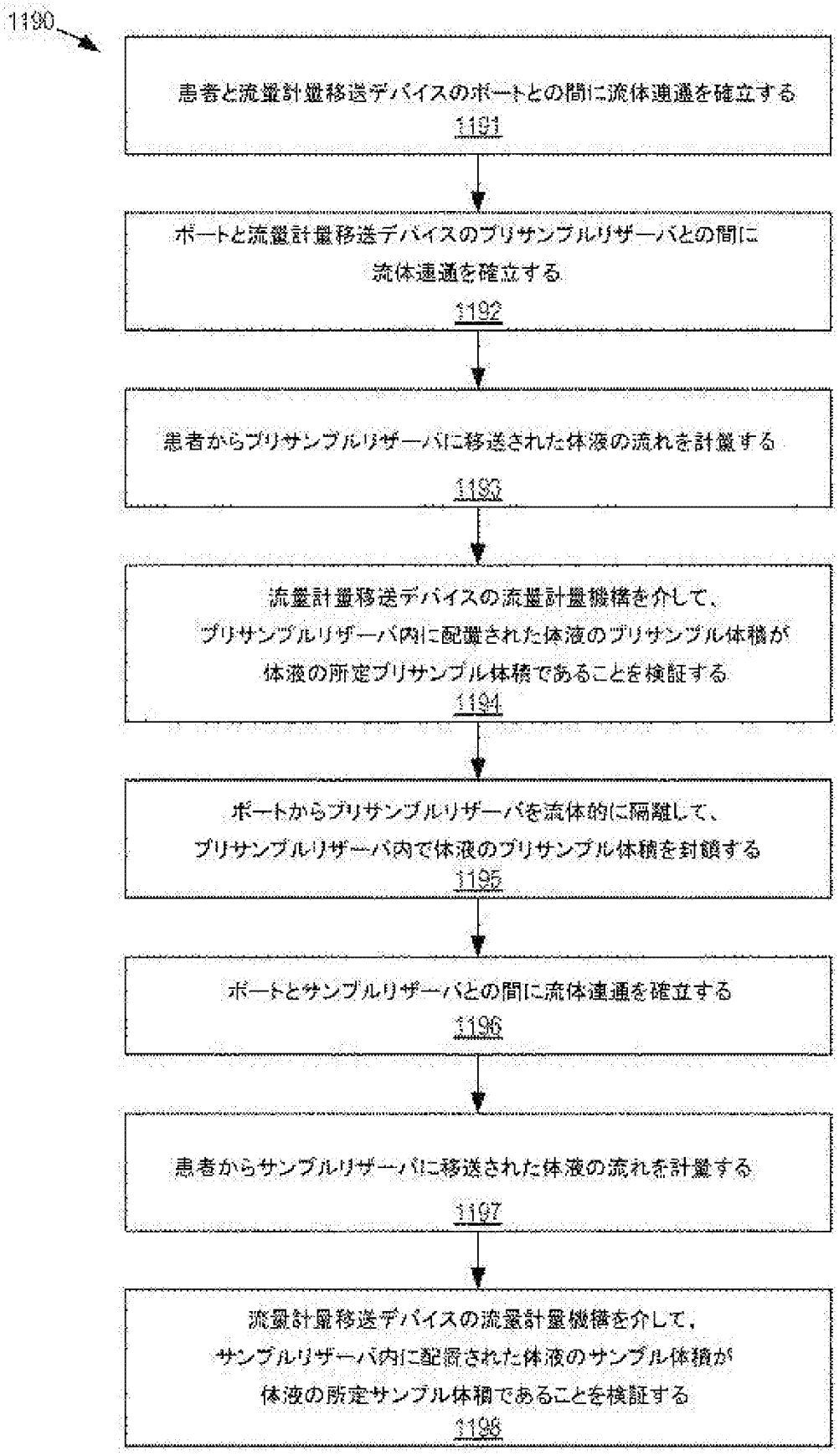
[Fig. 54]



[Fig. 55]



[Fig. 56]


1190
患者と流量計量移送デバイスのポートとの間に流体連通を確立する
1191
ポートと流量計量移送デバイスのプリサンプルリザーバとの間に
流体連通を確立する
1192
患者からプリサンプルリザーバに移送された体液の流れを計量する
1193
流量計量移送デバイスの流量計量機構を介して、
プリサンプルリザーバ内に配置された体液のプリサンプル体積が
体液の所定プリサンプル体積であることを検証する
1194
ポートからプリサンプルリザーバを流体的に隔離して、
プリサンプルリザーバ内で体液のプリサンプル体積を封鎖する
1195
ポートとサンプルリザーバとの間に流体連通を確立する
1196
患者からサンプルリザーバに移送された体液の流れを計量する
1197
流量計量移送デバイスの流量計量機構を介して、
サンプルリザーバ内に配置された体液のサンプル体積が
体液の所定サンプル体積であることを検証する
1198

search report open —

[International search report]

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2013/073080

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61B 5/155 (2014.01)
USPC - 600/575
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC(8) - A61B 5/00, 5/15, 5/153, 5/155; A61M 39/22; A61J 1/05; G01N 1/10, 1/14, 1/18 (2014.01)
USPC - 422/559; 435/294.1; 600/573, 575, 576, 577, 578; 604/248, 409

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
CPC - A61B 5/1405, 5/1427, 5/1438, 5/150251; A61M 39/223 (2013.01)

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
PatBase, Google Patents, Google Scholar,

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,097,842 A (BONN) 24 March 1992 (24.03.1992) entire document	12, 15, 16, 18
Y		1-11, 13, 14, 17, 19-29
X	US 2008/0145933 A1 (PATTON) 19 June 2008 (19.06.2008) entire document	30-41
Y		3, 13, 17, 22, 24, 25,
Y	US 2005/0148993 A1 (MATHIAS et al) 07 July 2005 (07.07.2005) entire document	1-11
Y	WO 2005/068011 A1 (MEHLHORN) 28 July 2005 (28.06.2005) entire document	14, 21-29
Y	US 3,848,581 A (CINQUALBRE et al) 19 November 1974 (19.11.1974) entire document	9, 19, 20

☐ Further documents are listed in the continuation of Box C. ☐

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
06 February 2014	18 FEB 2014
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer: Blaine R. Copenheaver PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

Form PCT/ISA/210 (second sheet) (July 2009)

drawing open

Representative drawing 1 2 3 Four Five 6 7 8 9 ...

Magnify and Rotate

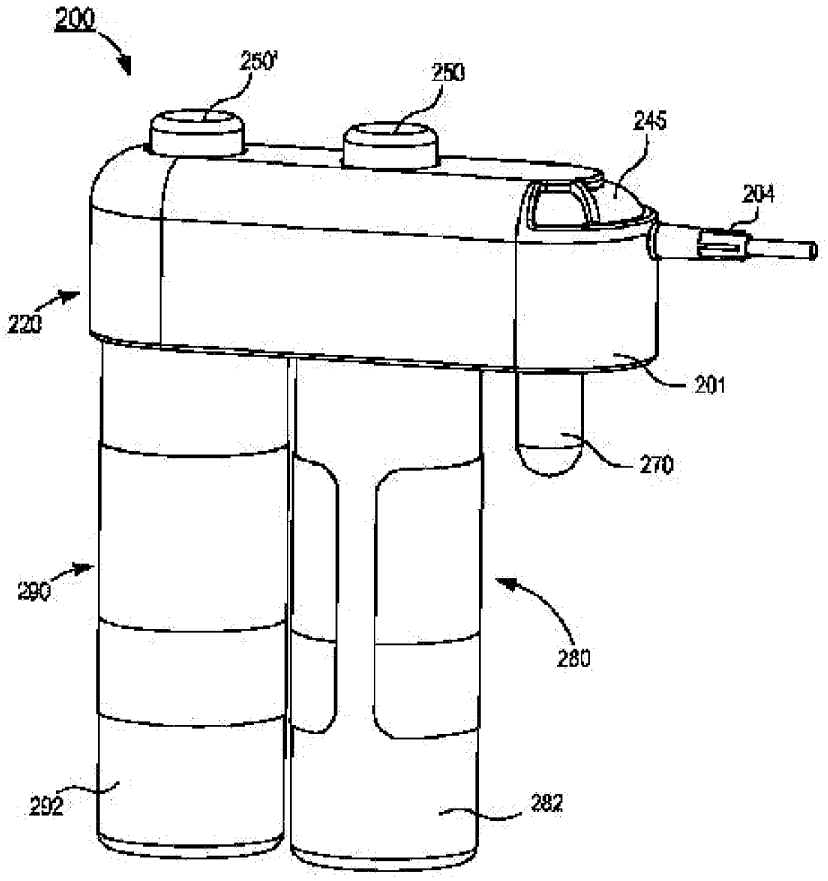


FIG. 2

Representative drawing

1 / 1 display

Copyright JPO and INPIT (P0200)

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(51)Int.Cl.			F I			テーマコード（参考）
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A61B	5/15	(2006.01)	A61B	5/14	300H	

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(87)国際公開番号　WO2014/089186
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最終頁に続く

(54)【発明の名称】滅菌体液収集デバイス及び方法

(57)【要約】
装置は、プリサンプルリザーバ、分流機構及び流量計量機構を含む。分流機構は、患者から体液を受け取るように内腔規定デバイスに結合可能な入口ポートと、プリサンプルリザーバに流体的に結合可能な第１出口ポートと、サンプルリザーバに流体的に結合可能な第２出口ポートと、を有する。分流機構は、第１出口ポート及び第２出口ポートをそれぞれ入口ポートに流体連通するように配置するように構成された第１流体流路及び第２流路を規定する。流量計量機構は、体液の所定体積の第１流体流路を通るプリサンプルリザーバへの流れを計量し、体液の第２体積の第２流体流路を通るサンプルリザーバへの流れを計量し、所定体積及び第２体積に関連する体積インジケータを表示するように構成される。
【選択図】図２

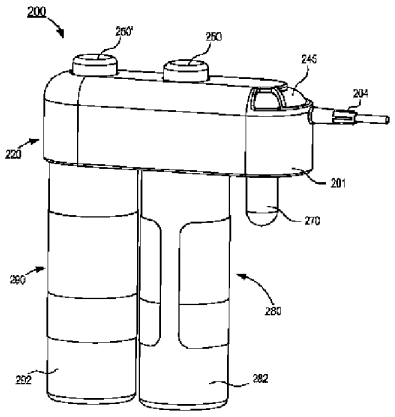


FIG. 2

【特許請求の範囲】
【請求項１】
患者から体液サンプルを取得する装置であって、
前記患者から抜き取られる体液の第１体積を受け取るように構成されたプリサンプルリザーバと、
入口ポート、第１出口ポート及び第２出口ポートを含む分流機構であって、前記入口ポートが、患者から体液を受け取るように内腔規定デバイスに結合されるように構成され、前記第１出口ポートが、前記分流機構に前記プリサンプルリザーバを流体的に結合するように構成され、前記第２出口ポートが、前記分流機構にサンプルリザーバを流体的に結合するように構成され、前記分流機構が、前記第１出口ポートを前記入口ポートに流体連通するように配置するように構成された第１流体流路と、前記第２出口ポートを前記入口ポートに流体連通するように配置するように構成された第２流体流路と、を規定する、分流機構と、
前記第１流体流路及び前記第２流体流路に流体連通する流量計量機構であって、体液の第１体積の前記第１流体流路を通る前記プリサンプルリザーバ内への流れを計量し、体液の第２体積の前記第２流体流路を通る前記サンプルリザーバ内への流れを計量するように構成され、前記第１体積及び前記第２体積に関連する体積インジケータを表示するように構成された流量計量機構と、を備える装置。
【請求項２】
前記体液の第１体積が、第１期間中に前記第１流体流路内で流れ、前記体液の第２体積が、前記第１期間の後、第２期間中に前記第２流体流路内で流れる、請求項１に記載の装置。
【請求項３】
前記体液の第１体積が、皮膚に存在する汚染物質を含み、前記体液の第２体積には、皮膚に存在する汚染物質が実質的にない、請求項１に記載の装置。
【請求項４】
前記プリサンプルリザーバが、前記分流器機構の一部によって少なくとも部分的に規定される、請求項１に記載の装置。
【請求項５】
前記体積インジケータが視覚的インジケータである、請求項１に記載の装置。
【請求項６】
前記分流機構が、前記第２出口ポートを通って移動して前記サンプルリザーバを前記第２流体流路に流体連通するように配置するように構成された可動部材を含む、請求項１に記載の装置。
【請求項７】
前記流量計量機構が、前記可動部材の一部の中に少なくとも部分的に配置される、請求項６に記載の装置。
【請求項８】
前記分流機構が、前記血液の第１体積が前記プリサンプルリザーバ内に配置されると、前記プリサンプルリザーバ及び前記第１流体流路の少なくとも一部を流体的に隔離するように構成される、請求項１に記載の装置。
【請求項９】
前記分流機構が、第２サンプルリザーバを前記分流機構に流体的に結合するように構成された第３出口ポートを含み、前記第３出口ポートを前記入口ポートに流体連通するように配置するように構成された第３流体流路を規定する、請求項１に記載の装置。
【請求項１０】
第１内腔及び第２内腔を規定する流量コントローラであって、前記第１内腔が前記第１流体流路を前記入口ポートに流体連通するように配置する第１形態と、前記第２内腔が前記第２流体流路を前記入口ポートに流体連通するように配置する第２形態との間で移動するように構成された流量コントローラをさらに備える、請求項１に記載の装置。

【請求項１１】
前記流量コントローラが、前記体液の第１体積が前記プリサンプルリザーバ内に配置された後、前記第１形態から前記第２形態に移動するように構成される、請求項１０に記載の装置。
【請求項１２】
患者から体液サンプルを取得する装置であって、
前記患者から抜き取られる体液の第１体積を受け取るように構成されたプリサンプルリザーバと、
入口ポート、第１出口ポート及び第２出口ポートを含む分流機構であって、前記入口ポートが、患者から体液を受け取るように内腔規定デバイスに結合されるように構成され、前記第１出口ポートが前記プリサンプルリザーバを前記分流機構に流体的に結合するように構成され、前記第２出口ポートが、サンプルリザーバを前記分流機構に流体的に結合するように構成される、分流機構と、
前記分流機構内に少なくとも部分的に配置された流量コントローラであって、前記流量コントローラが前記入口ポートと前記第１出口ポートとの間に流体流路の少なくとも一部を規定する第１形態と、前記流量コントローラが前記入口ポートと前記第２出口ポートとの間に流体流路の少なくとも一部を規定する第２形態との間で移動するように構成された流量コントローラと、
前記分流機構に移動可能に結合された可動部材であって、前記サンプルリザーバが前記入口ポートと前記第２出口ポートとの間の流体流路から流体的に隔離される第１形態と、前記サンプルリザーバが前記入口ポートと前記第２出口ポートとの間の前記流体流路に流体連通する第２形態との間で、前記第２出口ポートを通して移動するように構成され、前記サンプルリザーバが、前記流量コントローラがその第２形態にあり、前記可動部材がその第２形態にある時、前記患者から抜き取られる体液の第２体積を受け取るように構成される、可動部材と、を含む装置。
【請求項１３】
前記体液の第１体積が、皮膚に存在する汚染物質を含み、前記体液の第２体積には、皮膚に存在する汚染物質が実質的にない、請求項１２に記載の装置。
【請求項１４】
前記流量コントローラが、前記分流機構に対してその第１形態とその第２形態との間で回転する、請求項１２に記載の装置。
【請求項１５】
前記流量コントローラが、前記分流機構に対して線形運動で移動する、請求項１２に記載の装置。
【請求項１６】
前記流量コントローラが、その第２形態にある時に、前記プリサンプルリザーバを流体的に隔離するように構成される、請求項１２に記載の装置。
【請求項１７】
前記可動部材が、その第２形態にある時、前記サンプルリザーバの一部を穿孔するように構成された穿孔部材を含む、請求項１２に記載の装置。
【請求項１８】
前記可動部材が、前記可動部材をその第１形態で少なくとも一時的に維持するように構成された付勢部材に結合されている、請求項１２に記載の装置。
【請求項１９】
前記分流機構が、第２サンプルリザーバを前記分流機構に流体的に結合するように構成された第３出口ポートを含む、請求項１２に記載の装置。
【請求項２０】
前記可動部材が第１可動部材であり、前記装置が、
第２可動部材であって、前記第２サンプルリザーバが前記入口ポートと前記第３出口ポートとの間に規定された流体流路から流体的に隔離される第１形態と、前記第２サンプル

リザーバが前記入口ポートと前記第３出口ポートとの間に規定された前記流体流路に流体連通する第２形態との間で、前記第３出口ポートを通して移動するように構成され、前記第２サンプルリザーバが、前記流量コントローラがその第２形態にあり、前記第２可動部材がその第２形態にある時、前記患者から抜き取られる体液の第３体積を受け取るように構成される、第２可動部材をさらに含む、請求項１９に記載の装置。

【請求項２１】

患者から体液サンプルを取得する装置であって、

前記患者から抜き取られる体液の第１体積を受け取るように構成されたプリサンプルリザーバと、

ハウジング及び分配部材を含む分流機構であって、前記ハウジングが第１開口部及び第２開口部を規定し、前記第１開口部が前記プリサンプルリザーバに流体連通しており、前記分配部材が、前記ハウジング内に少なくとも部分的に配置され、かつ前記第２開口に流体連通している流体流路を規定し、前記分配部材が、前記流路に流体連通しかつサンプルリザーバに物理的にかつ流体的に結合されるように構成された結合部分を含む、分流機構と、

前記患者から体液を受け取るように内腔規定デバイスに結合されるように構成された入口ポートを含む流量コントローラであって、前記分流機構に回転可能に結合され、かつ前記入口ポートが前記第１開口部に流体連通する第１形態と、前記入口ポートが前記第２開口部に流体連通する第２形態との間で移動するように構成された流量コントローラと、を備える装置。

【請求項２２】

前記体液の第１体積が、皮膚に存在する汚染物質を含み、前記体液の第２体積には、皮膚に存在する汚染物質が実質的にない、請求項２１に記載の装置。

【請求項２３】

前記プリサンプルリザーバが、前記分配部材の一部によって少なくとも部分的に規定される、請求項２１に記載の装置。

【請求項２４】

前記結合部分が、前記サンプルリザーバの一部を穿孔して前記サンプルリザーバを前記流体流路に流体連通するように配置するように構成された穿孔部材を含む、請求項２１に記載の装置。

【請求項２５】

前記穿孔部材による前記サンプルリザーバの前記一部の前記穿孔が、前記流量コントローラがその第２形態にある時、体液の前記患者から前記入口ポート及び前記流路を通る前記サンプルリザーバ内への流れを開始する、請求項２４に記載の装置。

【請求項２６】

前記体液の第１体積が、体液の第１所定体積であり、前記流体流路が、体液の第２所定体積を受け取るように構成され、前記体液の第２所定体積がサンプル体積に関連する、請求項２１に記載の装置。

【請求項２７】

前記サンプル体積が、約１０ミリリットルと約５０ミリリットルとの間である、請求項２６に記載の装置。

【請求項２８】

前記サンプル体積が約３０ミリリットルである、請求項２６に記載の装置。

【請求項２９】

前記分流機構がシール部材を含み、前記流量コントローラが前記分流機構に結合された時に、前記シール部材が、前記流量コントローラの表面及び前記ハウジングの表面と実質的流体密封シールを形成するように、前記ハウジングと前記流量コントローラとの間に配置され、前記シール部材が第１開口部及び第２開口部を規定し、前記シール部材の前記第１開口部が、前記ハウジングの前記第１開口部と実質的に同軸であり、前記シール部材の前記第２開口部が、前記ハウジングの前記第２開口部と実質的に同軸である、請求項２１

に記載の装置。
【請求項３０】
流量計量移送デバイスを用いて患者から体液の所定サンプル体積を取得する方法であって、前記流量計量移送デバイスが、プリサンプルリザーバ及びサンプルリザーバに流体連通するように選択的に配置されるように構成された入口ポートを含む分流機構と、前記患者からの体液の前記プリサンプルリザーバへの流れ及び前記サンプルリザーバへの流れを計量するように構成された流量計量機構とを含む、方法であり、
前記患者と前記流量計量移送デバイスの前記ポートとの間に流体連通を確立するステップと、
前記ポートと前記プリサンプルリザーバとの間に流体連通を確立するステップと、
前記患者から前記プリサンプルリザーバに移送された体液の流れを計量するステップと、
前記流量計量移送デバイスの前記流量計量機構を介して、前記プリサンプルリザーバ内に配置された体液のプリサンプル体積が体液の所定プリサンプル体積であることを検証するステップと、
前記プリサンプルリザーバを前記ポートから流体的に隔離して、前記プリサンプルリザーバ内で前記体液のプリサンプル体積を封鎖するステップと、
前記ポートと前記サンプルリザーバとの間に流体連通を確立するステップと、
前記患者から前記サンプルリザーバに移送された体液の流れを計量するステップと、
前記流量計量移送デバイスの前記流量計量機構を介して、前記サンプルリザーバ内に配置された体液のサンプル体積が体液の所定サンプル体積であることを検証するステップと、を含む方法。
【請求項３１】
前記流量計量移送デバイスが、前記患者と前記プリサンプルリザーバとの間に流体連通が確立される第１形態と、前記患者と前記サンプルリザーバとの間に流体連通が確立される第２形態との間で移動するように構成された流量コントローラを含む、請求項３０に記載の方法。
【請求項３２】
前記体液が血液である、請求項３０に記載の方法。
【請求項３３】
前記サンプルリザーバが、好気性菌用培地又は嫌気性菌用培地のうちの少なくとも一方を含む、請求項３２に記載の方法。
【請求項３４】
前記所定プリサンプル体積が、約１ミリリットルと約１０ミリリットルとの間である、請求項３０に記載の方法。
【請求項３５】
前記所定サンプル体積が、約２０ミリリットルと約６０ミリリットルとの間である、請求項３０に記載の方法。
【請求項３６】
前記所定サンプル体積が約６０ミリリットルである、請求項３０に記載の方法。
【請求項３７】
前記サンプルリザーバが第１サンプルリザーバであり、前記サンプル体積が第１サンプル体積であり、
前記第１サンプルリザーバ内の前記第１サンプル体積が前記所定サンプル体積であることを検証した後、前記ポートと第２サンプルリザーバとの間に流体連通を確立するステップと、
前記患者から前記第２サンプルリザーバに移送された体液の流れを計量するステップと、
前記流量計量移送デバイスの前記流量計量機構を介して、前記第２サンプルリザーバ内に配置された体液の第２サンプル体積が体液の前記所定サンプル体積であることを検証す

るステップと、をさらに含む、請求項３０に記載の方法。
【請求項３８】
前記第１サンプル体積及び前記第２サンプル体積が、まとめて、約２０ミリリットルと約６０ミリリットルとの間に等しい、請求項３７に記載の方法。
【請求項３９】
前記第２サンプルリザーバ内の前記第２サンプル体積が前記所定サンプル体積であることを検証した後、前記ポートと第３サンプルリザーバとの間に流体連通を確立するステップと、
前記患者から前記第３サンプルリザーバに移送された体液の流れを計量するステップと、
前記流量計量移送デバイスの前記流量計量機構を介して、前記第３サンプルリザーバ内に配置された体液の第３サンプル体積が体液の前記所定サンプル体積であることを検証するステップと、をさらに含む、請求項３７に記載の方法。
【請求項４０】
前記第１サンプル体積、前記第２サンプル体積及び前記第３サンプル体積が、まとめて、約３０ミリリットルと約６０ミリリットルとの間に等しい、請求項３９に記載の方法。
【請求項４１】
前記第１サンプル体積、前記第２サンプル体積及び前記第３サンプル体積が、まとめて、約６０ミリリットルに等しい、請求項３９に記載の方法。
【発明の詳細な説明】
【技術分野】
【０００１】
関連出願の相互参照
[1001] 本出願は、２０１２年１２月４日に出願された「滅菌体液収集デバイス及び方法（Sterile Bodily-Fluid Collection Device and Methods）」と題する米国仮特許出願第６１，７３３，１９９号に対する優先権及びその利益を主張し、その出願の開示内容は、全体として参照により本明細書に組み込まれる。
【０００２】
[1002] 本明細書に記載する実施形態は、概して体液サンプルの非経口的獲得（parenteral procurement）に関し、より詳細には、皮膚に存在する微生物等、体液源の外部の微生物又は他の汚染物質からの汚染を低減して、体液サンプルを非経口的に獲得するデバイス及び方法に関する。
【背景技術】
【０００３】
[1003] 医療従事者は、日常的に、非経口的に取得された体液を用いて患者に対してさまざまなタイプの微生物検査を行う。場合によっては、患者サンプル（例えば、体液）は、細菌、真菌又は酵母菌（例えば、カンジダ）等、１種又は複数種の望ましくない可能性がある微生物が存在するか検査される。微生物検査は、微生物増殖を促進する培地を収容する１つ又は複数の滅菌容器において患者サンプルを培養すること、リアルタイム診断及び／又は分子ＰＣＲに基づく手法を含む場合がある。一般に、こうした微生物が患者サンプルに存在する場合、それら微生物は、培地において経時的に繁殖する。可変時間（例えば数時間から数日間）の後、自動化された連続モニタリングにより、生物体の成長を検出することができる。こうした自動化モニタリングは、生物体の増殖によって生成される二酸化炭素を検出することができる。そして、培地に対して、微生物が存在するか検査することができる。培地に微生物が存在する場合、それは、患者サンプルに同じ微生物が存在することを示唆し、それはさらに、サンプルを取得した患者の体液に同じ微生物が存在することを示唆する。従って、培地に微生物が存在すると判断された場合、患者は、患者から望ましくない微生物を処置するか又は他の方法で除去するように特に設計された１種あるいは複数種の抗生物質又は他の処置が処方される可能性がある。
【０００４】

[1004] しかしながら、患者サンプルは、獲得中に汚染される可能性がり、及び／又は、他の方法で偽陽性結果が出やすい可能性がある。患者サンプルの汚染が発生する可能性がある１つの過程は、患者の体内への針の挿入中に取り除かれ後に患者サンプルとともに培地に移送された体表からの微生物（例えば、皮膚に存在する微生物）の移送による。体表微生物及び／又は他の望ましくない外部微生物は、直接、又は取り除かれた組織片、毛包、汗腺及び他の皮膚付属器構造を介して取り除かれる可能性がある。別のあり得る汚染源は、患者サンプルを抜き取る人から来る。例えば、医師、瀉血専門医、看護師等が、自身の身体（例えば、指、腕等）から患者サンプルに及び／又は患者サンプルを収容している機器に汚染物質を移送する可能性がある。さらに詳述すると、患者サンプル獲得プロセス（例えば、患者から針、針／管からサンプル容器等）の間に使用される機器及び／又はデバイスは、各々が有り得る汚染の箇所を生じさせる可能性がある複数の流体インタフェースを含むことが多い。こうした機器及び／又はデバイスの使用は、通常、さまざまなインタフェースを接続し及び／又は流体的に結合するための手作業による介入を含む。これらのインタフェースは、単一の流体的に結合されたシステムとして事前に組み立てられかつ滅菌されないため、使用者（例えば、医師、瀉血専門医等）及び／又は他の汚染源（例えば、周囲空気、病室のテーブル及びカウンタの表面の汚染物質、リネン又は衣類から移送された微生物等）を介して患者サンプルに導入される可能性がある。場合によっては、こうした汚染物質は、培地で生育し、最終的に陽性の微生物検査結果をもたらす可能性があり、それにより、体内におけるこうした微生物の存在を誤って示す。

【０００５】

[1005] 場合によっては、偽陽性結果及び／又は偽陰性結果は、患者サンプルの所定体積に起因する可能性がある。例えば、体積に影響されやすい血液培養ボトルを過充填することにより、こうした培養ボトル及び関連する自動連続モニタリング微生物検出システムの製造業者からの使用説明書及び／又は警告ラベルにおいて注記されているように、偽陽性結果に至る可能性がある。一方、別の例として、培地内における患者サンプルの体積が不十分であることにより、偽陰性結果がもたらされる可能性がある。例として、Journal of Clinical Microbiologyの２０１１年１２月号に記載された「Optimized Pathogen Detection with 30- Compared to 20-Milliliter Blood Culture Draws」と題するMayo Clinicによって行われた研究において、２０ミリリットル（ｍＬ）の患者サンプル体積により、患者サンプルに存在する菌血症の約８０％の存在を検出することができ、４０ｍＬの患者サンプル体積により、菌血症の約８８％を検出することができ、６０ｍＬの患者サンプル体積により、菌血症の約９９％を検出することができる。

【０００６】

[1006] 汚染、不十分な患者サンプル体積等の結果としてのこうした不正確な結果は、疑いのある病気又は健康状態を診断するか又は治療しようとする時に問題である。例えば、微生物検査からの偽陰性結果により、患者の病気が誤診され及び／又は治療が遅れることになる可能性があり、それによって場合によっては、患者の死に至る可能性がある。逆に、微生物検査からの偽陽性結果により、患者が１つ又は複数の抗微生物療法を不必要に受けることになる可能性があり、それにより、例えば死を含む患者の深刻な副作用が引き起こされるとともに、患者の入院の期間の延長及び／又は間違った治療に関連する他の合併症のために医療制度に対する不必要な負担及び出費がもたらされる可能性がある。さらに、これらの偽陽性結果に起因する診断撮像機器の使用はまた、コストとともに、種々の撮像処置（例えば、ＣＴスキャン）に関連する高濃度放射線の不必要な照射が長期の患者の健康に対して多くの既知の悪影響を及ぼすため、患者の安全性の観点からも問題である。

【０００７】

[1007] 従って、例えば、患者サンプル及び／又は流体インタフェースの周囲の非滅菌状態及び／又は他の外部汚染源への暴露を最小限にすることにより、体液検査サンプルにおける微生物汚染を低減する、滅菌「一体型」体液収集デバイス及び方法が必要とされている。さらに、こうした体液収集デバイスが、患者サンプルを実質的にリアルタイムに（例えば、患者のベッドわきで）獲得している医療従事者に視覚的に、計算された方法で、又

は他の方法で通信することができる、患者からサンプルリザーバ又は培地に移送された体液の体液を正確に計量し、測定し、及び／又は、他の方法で評価する手段を含むことが必要とされている。

【発明の概要】

【０００８】

[1008] 本明細書では、皮膚に存在する微生物及び／又は他の望ましくない外部汚染物質等、体液源の外部の微生物からの汚染を低減して体液サンプルを非経口的に獲得するデバイスについて記載されている。いくつかの実施形態では、患者から体液サンプルを取得する装置は、プリサンプルリザーバ、分流機構及び流量計量機構を含む。プリサンプルリザーバは、患者から抜き取られる体液の第１体積を受け取るように構成されている。分流機構は、入口ポート、第１出口ポート及び第２出口ポートを含み、第１流体流路及び第２流体流路を規定している。入口ポートを、患者から体液を受け取るように内腔規定デバイスに結合することができる。第１出口ポート及び第２出口ポートは、プリサンプルリザーバ及びサンプルリザーバそれぞれを分流機構に流体的に結合するように構成されている。第１流体流路は、第１出口ポートを入口ポートに流体連通するように配置するように構成され、第２流体流路は、第２出口ポートを入口ポートに流体連通するように配置するように構成されている。流量計量機構は、第１流体流路及び第２流体流路に流体連通している。流量計量機構は、体液の第１体積の第１流体流路を通るプリサンプルリザーバ内への流れを計量し、体液の第２体積の第２流体流路を通るサンプルリザーバ内への流れを計量するように構成されている。流量計量機構は、第１体積及び第２体積に関連する体積インジケータを表示するように構成されている。

【図面の簡単な説明】

【０００９】

【図１】実施形態による体液収集デバイスの概略図である。

【図２】実施形態による体液収集デバイスの斜視図である。

【図３】図２の体液収集デバイスの組立分解斜視図である。

【図４】図２の体液収集デバイスに含まれるハウジングの図３の線X_1－X_1に沿って取り出された側断面図である。

【図５】図２の体液収集デバイスに含まれる可動部材の図３の線X_2－X_2に沿って取り出された断面図である。

【図６】図２の体液収集デバイスに含まれる流量コントローラの図３の線X_3－X_3に沿って取り出された断面図である。

【図７】図２の体液収集デバイスに含まれる流量コントローラの図３の線X_4－X_4に沿って取り出された断面図である。

【図８】第１形態にある図２の体液収集デバイスの上面図である。

【図９】第１形態にある図２の体液収集デバイスの図８の線X_5－X_5に沿って取り出された断面図である。

【図１０】第２形態にある図２の体液収集デバイスの上面図である。

【図１１】第２形態にある図２の体液収集デバイスの図１０の線X_6－X_6に沿って取り出された断面図である。

【図１２】第３形態にある図２の体液収集デバイスの図１０の線X_6－X_6に沿って取り出された断面図である。

【図１３】第４形態にある図２の体液収集デバイスの図１０の線X_6－X_6に沿って取り出された断面図である。

【図１４】実施形態による体液収集デバイスの斜視図である。

【図１５】図１４の体液収集デバイスの線X_7－X_7に沿って取り出された側断面図である。

【図１６】実施形態による体液収集デバイスの斜視図である。

【図１７】図１６の体液収集デバイスに含まれる分流機構の組立分解斜視図である。

【図１８】図１６の体液収集デバイスに含まれる分配部材の図１６の線X_8－X_8に沿っ

て取り出された側断面図である。
【図１９】第１形態にある図１６の体液収集デバイスの上面図である。
【図２０】第１形態にある図１６の一部体液収集デバイスの図１９の線X_9－X_9に沿って取り出された断面図である。
【図２１】第２形態にある図１６の体液収集デバイスの上面図である。
【図２２】第２形態にある図１６の体液収集デバイスの図２１の線X_{10}－X_{10}に沿って取り出された断面図である。
【図２３】実施形態による体液収集デバイスの斜視図である。
【図２４】第１形態にある、図２３の体液収集デバイスの一部の線X_{11}－X_{11}に沿って取り出された断面図である。
【図２５】第２形態にある、図２３の体液収集デバイスの線X_{11}－X_{11}に沿って取り出された断面図である。
【図２６】実施形態による体液収集デバイスの斜視図である。
【図２７】図２６の体液収集デバイスに含まれる分流機構の組立分解斜視図である。
【図２８】図２７の体液収集デバイスに含まれる分配部材の図２７の線X_{13}－X_{13}に沿って取り出された断面図である。
【図２９】図２６の体液収集デバイスに含まれる結合部材の図２７の線X_{14}－X_{14}に沿って取り出された断面図である。
【図３０】図２６の体液収集デバイスに含まれるダイヤルの図２７の線X_{15}－X_{15}に沿って取り出された断面図である。
【図３１】図２６の体液収集デバイスに含まれる弁の図２７の線X_{16}－X_{16}に沿って取り出された断面図である。
【図３２】第１形態にある図２６の体液収集デバイスの線X_{12}－X_{12}に沿って取り出された断面図である。
【図３３】第２形態にある図２６の体液収集デバイスの線X_{12}－X_{12}に沿って取り出された断面図である。
【図３４】実施形態による体液収集デバイスの斜視図である。
【図３５】図３４の体液収集デバイスに含まれる分流機構の組立分解斜視図である。
【図３６】図３５の分流機構に含まれる分配部材の線X_{17}－X_{17}に沿って取り出された断面図である。
【図３７】第１形態にある図３４の体液収集デバイスの一部の上面図である。
【図３８】第１形態にある図３７の一部体液収集デバイスの線X_{18}－X_{18}に沿って取り出された断面図である。
【図３９】第２形態にある図３３の体液収集デバイスの上面図である。
【図４０】第２形態にある図３３の体液収集デバイスの図３９の線X_{19}－X_{19}に沿って取り出された断面図である。
【図４１】実施形態による第１形態にある体液収集デバイスの斜視図である。
【図４２】図４１の体液収集デバイスの一部の組立分解斜視図である。
【図４３】第１形態にある図４１の体液収集デバイスの線X_{20}－X_{20}に沿って取り出された断面図である。
【図４４】第２形態にある図４１の体液収集デバイスの線X_{20}－X_{20}に沿って取り出された断面図である。
【図４５】第３形態にある図４１の体液収集デバイスの線X_{20}－X_{20}に沿って取り出された断面図である。
【図４６】実施形態による第１形態にある体液収集デバイスの斜視図である。
【図４７】図４５の体液収集デバイスの一部の組立分解斜視図である。
【図４８】図４６の体液収集デバイスに含まれる分配部材の図４７の線X_{21}－X_{21}に沿って取り出された側断面図である。
【図４９】図４６の体液収集デバイスに含まれる可動部材の図４７の線X_{22}－X_{22}に沿って取り出された側断面図である。

【図５０】第１形態にある図４６の体液収集デバイスの上面図である。
【図５１】第１形態にある図４６の一部体液収集デバイスの図５０の線$X_{23}-X_{23}$に沿って取り出された断面図である。
【図５２】第２形態にある図４６の体液収集デバイスの上面図である。
【図５３】第２形態にある図４６の体液収集デバイスの図５２の線$X_{24}-X_{24}$に沿って取り出された断面図である。
【図５４】実施形態による体液収集デバイスの斜視図である。
【図５５】図５４の体液収集デバイスの上面図である。
【図５６】実施形態による収集デバイスを用いて、汚染を低減して体液サンプルを取得する方法を示すフローチャートである。
【発明を実施するための形態】
【００１０】
[1063] 本明細書では、皮膚に存在する微生物及び／又は他の望ましくない外部汚染物質等、体液源の外部の微生物からの汚染を低減して体液サンプルを非経口的に獲得するデバイスについて記載されている。いくつかの実施形態では、患者から体液サンプルを取得する装置は、プリサンプルリザーバ、分流機構及び流量計量機構を含む。プリサンプルリザーバは、患者から抜き取られる体液の第１体積を受け取るように構成されている。分流機構は、入口ポート、第１出口ポート及び第２出口ポートを含み、第１流体流路及び第２流体流路を規定している。入口ポートを、患者から体液を受け取るように内腔規定デバイスに結合することができる。第１出口ポート及び第２出口ポートは、プリサンプルリザーバ及びサンプルリザーバそれぞれを分流機構に流体的に結合するように構成されている。第１流体流路は、第１出口ポートを入口ポートに流体連通するように配置するように構成され、第２流体流路は、第２出口ポートを入口ポートに流体連通するように配置するように構成されている。流量計量機構は、第１流体流路及び第２流体流路に流体連通している。流量計量機構は、体液の第１体積の第１流体流路を通るプリサンプルリザーバ内への流れを計量し、体液の第２体積の第２流体流路を通るサンプルリザーバ内への流れを計量するように構成されている。流量計量機構は、第１体積及び第２体積に関連する体積インジケータを表示するように構成されている。
【００１１】
[1064] いくつかの実施形態では、患者から体液サンプルを取得する装置は、プリサンプルリザーバ、分流機構、流量コントローラ及び可動部材を含む。プリサンプルリザーバは、患者から抜き取られる体液の第１体積を受け取るように構成されている。分流機構は、入口ポート、第１出口ポート及び第２出口ポートを含む。入口ポートは、患者から体液を受け取るように内腔規定デバイスに結合可能である。第１出口ポートは、プリサンプルリザーバを分流機構に流体的に結合し、第２出口ポートは、サンプルリザーバを分流機構に流体的に結合する。流量コントローラは、分流機構内に少なくとも部分的に配置され、流量コントローラを、流量コントローラが入口ポートと第１出口ポートとの間に流体流路の少なくとも一部を規定する第１形態と、流量コントローラが入口ポートと第２出口ポートとの間に流体流路の少なくとも一部を規定する第２形態との間で移動させることができる。可動部材は、分流機構に移動可能に結合され、サンプルリザーバが入口ポートと第２出口ポートとの間の流体流路から流体的に隔離される第１形態と、サンプルリザーバが入口ポートと第２出口ポートとの間の流体流路に流体連通する第２形態との間で、第２出口ポートを通して移動可能である。サンプルリザーバは、流量コントローラがその第２形態にあり、可動部材がその第２形態にある時、患者から抜き取られる体液の第２体積を受け取るように構成されている。
【００１２】
[1065] いくつかの実施形態では、患者から体液サンプルを取得する装置は、プリサンプルリザーバ、分流機構及び流量コントローラを含む。プリサンプルリザーバは、患者から抜き取られる体液の第１体積を受け取るように構成されている。分流機構は、ハウジング及び分配部材を含む。ハウジングは、プリサンプルリザーバに流体連通している第１開口

部と第２開口部とを規定している。分配部材は、ハウジング内に少なくとも部分的に配置され、かつ第２開口に流体連通している流体流路を規定している。分配部材は、流路に流体連通しかつサンプルリザーバに物理的にかつ流体的に結合されるように構成された結合部分を含む。流量コントローラは、患者から体液を受け取るように内腔規定デバイスに結合されるように構成された入口ポートを含む。流量コントローラは、分流機構に回転可能に結合され、かつ入口ポートが第１開口部に流体連通する第１形態と、入口ポートが第２開口部に流体連通する第２形態との間で移動可能である。

【００１３】

[1066] いくつかの実施形態では、プリサンプルリザーバ及びサンプルリザーバに流体連通するように選択的に配置されるように構成された入口ポートを含む分流機構と、患者からの体液のプリサンプルリザーバへの流れ及びサンプルリザーバへの流れを計量するように構成された流量計量機構とを有する流量計量移送デバイスを用いる方法は、患者と流量計量移送デバイスの入口ポートとの間に流体連通を確立するステップを含む。そして、ポートとプリサンプルリザーバとの間に流体連通が確立される。患者からプリサンプルリザーバに移送された体液の流れが計量される。本方法は、流量計量移送デバイスの流量計量機構を介して、プリサンプルリザーバ内に配置された体液のプリサンプル体積が体液の第１プリサンプル体積であることを検証するステップを含む。プリサンプルリザーバ内にプリサンプル体積が配置された状態で、プリサンプルリザーバがポートから流体的に隔離されて、プリサンプルリザーバ内で体液のプリサンプル体積が封鎖される。プリサンプルリザーバが流体的に隔離された状態で、本方法は、ポートとサンプルリザーバとの間に流体連通を確立するステップを含む。患者からサンプルリザーバに移送された体液の流れが計量される。本方法は、流量計量移送デバイスの流量計量機構を介して、サンプルリザーバ内に配置された体液のサンプル体積が体液の第１サンプル体積であることを検証するステップを含む。

【００１４】

[1067] いくつかの実施形態では、装置は、分流機構及び流量コントローラを含む。分流機構は、入口ポート、第１出口ポート、第２出口ポート及び第３出口ポートを規定することができる。第１出口ポートは、プリサンプルリザーバに流体的に結合され、第２出口ポートは、第１サンプルリザーバに流体的に結合され、第３出口ポートは、第２サンプルリザーバに流体的に結合され、等である。流体リザーバのすべてを、互いから流体的に隔離することができる。流量コントローラはさまざまな流体チャネルを含み、流体チャネルは、指定された方向における流体移動を可能にすることができ、分流機構に動作可能に結合されるように構成され得る。使用時、分流機構が第１形態にある時、流量コントローラは、体液の流れがプリサンプルリザーバに入るのを可能にすることができる。分流機構を第２形態に移動させることができ、そこでは、流量コントローラは、体液の流れが第１サンプルリザーバに入るのを可能にすることができる。さらに、分流機構を、その後、第３形態に移動させることができ、それにより、流量コントローラは、体液の流れが第２サンプルリザーバに入るのを可能にすることができる。

【００１５】

[1068] いくつかの実施形態では、体液収集デバイスを、体液の第２体積の第１サンプルリザーバ内への流れ及び／又は体液の第３体積の第２サンプルリザーバ内への流れを可能にする前に、体液の第１の所定体積をプリサンプルリザーバに選択的に分流させるように構成することができる。このように、体液の第２体積及び／又は第３体積を、診断又は他の検査に使用することができ、一方で、体表又はサンプルを獲得する患者の外部の他の微生物源からの微生物を含む可能性がある体液の第１体積が隔離される。いくつかの実施形態では、体液収集デバイスは、行われる分析プロトコル及び／又は検査プロトコルに応じて追加のサンプルリザーバ（例えば、３、４、５、６以上）を含むことができる。

【００１６】

[1069] いくつかの実施形態では、体液収集デバイスは、体液の適切な体積が患者から収集され及び／又は所定のプリサンプルリザーバ及び／又はサンプルリザーバに移送される

のを確実にするために、流量計量を含むことができる。体液収集デバイスを、体液の計量された体積が収集された後に、流体流を自動的に分流させ及び／又は制御するように構成することができる。例えば、第１計量プリサンプル体積が収集されると、分流機構を、体液流を第１サンプルリザーバに分流させるように構成することができ、その後、第１計量サンプル体積が収集された後、分流機構を、体液流を第２サンプルリザーバに分流させるように構成することができ、等である。いくつかの実施形態では、体液収集デバイスは、例えば液晶ディスプレイ（ＬＣＤ）等の計量された体積のディスプレイを含み、どれだけの体液が各所定の個々のサンプルリザーバ内に収集されたかの視覚的指示を使用者に提供することができる。いくつかの実施形態では、カスタマイズされたプリサンプル及び／又はサンプル体積収集を可能にするように、複数のディスプレイを設けることができる。

【００１７】

[1070] 本明細書及び添付の特許請求の範囲で用いる単数形「１つの（a、an）」及び「その（the）」は、文脈に明示的に述べられていない限り、複数の指示対象を含む。従って、例えば、「（１つの）部材」という用語は、単一部材又は部材の組合せを意味するように意図され、「（１つの）材料」は、１つあるいは複数の材料又はそれらの組合せを意味するように意図されている。

【００１８】

[1071] 本明細書で用いる「体液」は、限定されないが、血液、髄液、尿、胆汁、リンパ液、唾液、滑液、漿液、胸膜液、羊水等又はそれらのあらゆる組合せを含む、患者の体内から得られるあらゆる流体を含むことができる。

【００１９】

[1072] 本明細書で用いる「第１の所定量」、「第１量」及び「第１体積」という用語は、第１リザーバ又はプリサンプルリザーバによって受け取られるか又は収容されるように構成された体液の量を述べる。「第１量」及び「第１体積」という用語は、所定量を明示的に述べないが、明示的に異なるように述べられていない限り、第１量は第１の所定量であることが理解されるべきである。

【００２０】

[1073] 本明細書で用いる「第２量」及び「第２体積」という用語は、第２リザーバ又はサンプルリザーバによって受け取られるか又は収容されるように構成された体液の量を述べる。第２量を、体液のあらゆる好適な量とすることができ、それは所定量である必要はない。逆に、そのように明示的に述べられる場合、第２リザーバ又はサンプルリザーバによって受け取られかつ収容される第２量は、第２の所定量であり得る。

【００２１】

[1074] 本明細書で用いる「組」という用語は、複数の機構又は複数の部品を含む単一の機構を指すことができる。例えば、壁の組と言う場合、壁の組を、別個の部分を含む１つの壁とみなすことができ、又は壁の組を、複数の壁とみなすことができる。同様に言えば、一体的に構成された物品は一組の壁を含むことができる。こうした一組の壁は、例えば、互いに不連続である複数の部分を含むことができる。一組の壁を、別個に製造され、後に（例えば、溶接、接着剤又はあらゆる好適な方法を介して）互いに接合される複数の物品から製造することも可能である。

【００２２】

[1075] 本明細書で用いる「近位」及び「遠位」という用語は、デバイスを患者に接触するように配置する使用者に対してそれぞれ近い方の方向及び離れる方向を指す。従って、例えば、患者の身体に最初に接触するデバイスの端部は遠位端となり、デバイスの反対側の端部（例えば、使用者が操作しているデバイスの端部）はデバイスの近位端となる。

【００２３】

[1076] 本明細書で用いる「約」、「およそ」及び「実質的に」という用語は、数値と関連して用いられる場合、そのように定義される値が名目上示されている値であることを意味するように意図されている。言い換えれば、約、およそ及び実質的にという用語は、数値に関連して用いられる場合、概して、示されている値プラスマイナス所与の許容差を含

む。例えば、場合によっては、好適な許容差は、示されている値の±１０％である可能性があり、従って、約０．５は０．４５及び０．５５を含み、約１０は９～１１を含み、約１０００は９００～１１００を含む。他の場合では、好適な許容差は、プラスマイナス示されている値の最後の有効数字の許容可能な割合であり得る。例えば、好適な許容差は、最後の有効数字の±１０％である可能性があり、従って、約１０．１は１０．０９及び１０．１１を含み、およそ２５は２４．５及び２５．５を含む。こうした変動は、製造公差又は他の実際的な考慮事項（例えば、測定器具に関連する公差、許容可能な人的ミス等）からもたらされ得る。

【００２４】

[1077] 体液の所定体積と体液の収集された体積との関係について述べる場合、それらの値は、上述したものの等の好適な許容差を含むことが理解されるべきである。例えば、体液の収集された体積が体液の所定体積と実質的に等しいと述べる場合、収集された体積及び所定体積は、名目上、好適な許容差の範囲内で等しい。場合によっては、許容差を、体液の収集された体積の意図された使用によって求めることができる。例えば、場合によっては、血液培養のアッセイは、血液の収集された体積が製造業者の（又はエビエンスに基づく最適な実践）推奨体積の１．０％から５．０％の範囲内である時、約９９％正確であり得る。例として、体液のアッセイに対する製造業者の推奨体積は、約９９％の信頼度のために、合計４本又は６本の収集ボトルが使用される場合、１本のサンプル収集ボトル当り１０ミリリットル（ｍＬ）（すなわち、総体積は４０ｍｌ～６０ｍｌ）±５％であり得る。従って、１０．５ｍＬの収集体積により、約９９％を超える信頼度での結果が提供され、１１ｍＬの収集体積により、約９９％未満の信頼度の結果が提供される。他の場合では、好適な許容差は、０．１％、０．５％、１．０％、２．０％、３．０％、４．０％、５．０％、６．０％、７．０％、８．０％、９．０％、１０．０％又はそれらの間のあらゆる分数値であり得る。さらに他の場合では、許容差は１０．０％を上回る可能性がある。従って、本明細書に記載する実施形態のいずれも、好適な許容差の範囲内で体液の流量を計量し及び／又は体液の体積を他の方法で測定するように構成されたあらゆる好適な流量測定機構及び／又はデバイスを含み及び／又はそれとともに使用することができる。さらに、流量計量機構及び／又はデバイスを、不正確な測定、人的ミス等の組合せからもたらされる可能性がある公差の蓄積を最小限にするか又はなくすように配置することができる。

【００２５】

[1078] 図１は、実施形態による体液収集デバイス１００の一部の概略図である。概して、体液収集デバイス１００（本明細書では、「流体収集デバイス」又は「収集デバイス」とも呼ぶ）は、患者から体液を抜き取ることを可能にし、その際、抜き取られた体液の第１部分又は第１量が、医療診断及び／又は治療の目的で検査されるため等、生物学的サンプルとして使用される、抜き取られた体液の第２部分あるいは体積及び／又は第３部分あるいは体積から離れるように分流されるように構成されている。言い換えれば、本明細書においてより詳細に記載するように、収集デバイス１００は、体液の第１の所定体積をプリサンプル収集リザーバに、体液の第２体積及び第３体積（又は、いくつかの実施形態では、第４、第５等）を、プリサンプルリザーバから流体的に隔離された１つ又は複数のサンプル収集リザーバ（例えば、サンプルリザーバ）に移送するように構成されている。

【００２６】

[1079] 収集デバイス１００は、分流機構１２０、流量コントローラ１４０、プリサンプルリザーバ１７０、第１サンプルリザーバ１８０、及び第１サンプルリザーバ１８０とは異なる第２サンプルリザーバ１９０を含む。分流機構１２０は、図１に示すように、入口ポート１２１と、第１出口ポート１２５及び第２出口ポート１２６等、少なくとも２つの出口ポートとを含む。いくつかの実施形態では、分流機構１２０は、プリサンプルリザーバ及びサンプルリザーバの総数に等しい一組の出口ポートを含むことができる。例えば、収集デバイス１００が１つのプリサンプル及び４つのサンプリリザーバを有する場合、分流機構１２０は５つの出口ポートを含むことができる。いくつかの実施形態では、分流機

構１２０を、複数の形態の間の分流機構１２０の移動を容易にすることができる（図１には示さない）アクチュエータに動作可能に結合することができる。入口ポート１２１は、患者から体液を抜き取り及び／又は収集デバイス１００に輸送するための経路Ｘを規定している医療デバイスに流体的に結合されるように構成されている。例えば、入口ポート１２１を、針又は他の内腔規定デバイス（例えば、可撓性滅菌管）に流体的に結合することができる。このように、分流機構１２０は、針又は他のあらゆる内腔規定デバイスを介して患者から体液を受け取ることができる。

【００２７】

[1080] 分流機構１２０の第１出口ポート１２５を、プリサンプルリザーバ１７０に流体的に結合することができる。いくつかの実施形態では、プリサンプルリザーバ１７０は、第１出口ポート１２５及び／又は分流機構１２０の一部と一体的に形成されている。他の実施形態では、プリサンプルリザーバ１７０を、接着剤、抵抗嵌め（resistance fit）、機械的締結具、あらゆる数の嵌合凹部、ねじ結合及び／又は他のあらゆる好適な結合あるいはその組合せを介して、分流機構１２０に機械的に及び／又は流体的に結合することができる。同様に言えば、プリサンプルリザーバ１７０を、分流機構１２０に物理的に（例えば、機械的に）結合することができ、それにより、プリサンプルリザーバ１７０によって規定される内部空間（volume）が分流機構１２０の第１出口ポート１２５に流体連通する。さらに他の実施形態では、プリサンプルリザーバ１７０を、可撓性滅菌管等の（図１には示さない）介在構造を介して、分流機構１２０の第１出口ポート１２５に動作可能に結合することができる。より詳細には、介在構造は、プリサンプルリザーバ１７０を、第１出口ポート１２５に流体連通するように配置するように構成された内腔を規定することができる。

【００２８】

[1081] プリサンプルリザーバ１７０は、体液の第１の所定体積を受け取りかつ収容するように構成されている。いくつかの実施形態では、プリサンプルリザーバ１７０は、体液の第１体積を、患者から後に抜き取られる（体液の第１体積と同じである場合もあれば異なる場合もある）体液の第２体積及び／又は第３体積から流体的に隔離するように収容するように構成されている。プリサンプルリザーバ１７０は、全体として参照により本明細書に組み込まれる、「汚染を低減して体液サンプルを非経口的に獲得するシステム及び方法（Systems and Methods for Parenterally Procuring Bodily-Fluid Samples with Reduced Contamination）」と題する米国特許第８，１９７，４２０号に詳細に記載されているプリサンプルリザーバ等、体液を収容するあらゆる好適なリザーバであり得る。

【００２９】

[1082] いくつかの実施形態では、分流機構１２０の第２出口ポート１２６は、第１サンプルリザーバ１８０及び第２サンプルリザーバ１９０に結合することができる内腔規定デバイスに流体的に結合されるように構成されている。任意選択的に、他の実施形態では、分流機構１２０の第２出口ポート１２６を、第１サンプルリザーバ１８０に結合することができ、分流機構１２０は、第２サンプルリザーバ１９０に結合された（図示せず）第３出口ポートを有することができる。いくつかの実施形態では、第１サンプルリザーバ１８０を、第２出口ポート１２６及び／又は分流機構１２０の一部と一体的に形成することができる。他の実施形態では、第１サンプルリザーバ１８０を、プリサンプルリザーバ１７０に関して上述したような介在構造を介して、第２出口ポート１２６に機械的に結合し、又は第２出口ポート１２６に動作可能に結合することができる。第１サンプルリザーバ１８０は、体液の第２体積を受け取りかつ収容するように構成されている。例えば、体液の第２体積は、第１プリサンプル体積の抜取りに続いて患者から抜き取られた量であり得る。いくつかの実施形態では、第１サンプルリザーバ１８０は、第２体積がプリサンプル体液の第１体積から流体的に隔離されるように、体液の第２体積を収容するように構成されている。

【００３０】

[1083] 第１サンプルリザーバ１８０及び第２サンプルリザーバ１９０は、例えば、上で

参照により組み込んだ‘４２０特許に記載されているようなサンプルリザーバを含む、体液を収容するあらゆる好適な滅菌リザーバであり得る。いくつかの実施形態では、第２体積を、体液のあらゆる好適な体積とすることができ、それは所定体積である必要はない。他の実施形態では、第１サンプルリザーバ１８０及び／又は第２サンプルリザーバ１９０への体液の移送を、第２体積が第２の所定体積であるように、計量等することができる。

【００３１】

[1084] 第２サンプルリザーバ１９０は、あらゆる好適なサンプルリザーバであり得る。いくつかの実施形態では、第２サンプルリザーバ１９０は、上述した第１サンプルリザーバ１８０と実質的に同様であり得る。第２サンプルリザーバ１９０を、上述したように、第２出口ポート１２６に流体的に結合することができる。第２出口ポート１２６の第２サンプルリザーバ１９０への流体的結合は、詳細に上述したように、第２出口ポート１２６の第１サンプルリザーバ１８０への流体的結合と実質的に同様であり得る。従って、こうした部分については、本明細書ではそれ以上詳細には記載せず、明示的に異なるように記載されていない限り、実質的に同様であるとみなすべきである。さらに、（図１には示さない）分流機構１２０の追加の出口ポート及びサンプルリザーバは、第２出口ポート１２６及び第１サンプルリザーバ１８０と実質的に同様であり得る。

【００３２】

[1085] いくつかの実施形態では、プリサンプルリザーバ１７０、第１サンプルリザーバ１８０及び第２サンプルリザーバ１９０を、分流機構１２０に同様に結合する（又はともに形成する）ことができる。他の実施形態では、プリサンプルリザーバ１７０、第１サンプルリザーバ１８０及び第２サンプルリザーバ１９０は、分流機構１２０に同様に結合される必要はない。例えば、いくつかの実施形態では、プリサンプルリザーバ１７０を、分流機構１２０（例えば、第１出口ポート１２４）と一体的に形成することができ、第１サンプルリザーバ１８０及び／又は第２サンプルリザーバ１９０を、可撓性滅菌管又はそのあらゆる組合せ等の介在構造を介して、分流機構１２０（例えば、第２出口ポート１２６）に動作可能に結合することができる。

【００３３】

[1086] いくつかの実施形態では、収集デバイス１００は、（図１には示さない）アクチュエータと、第１流体流路１４２、第２流体流路１４４及び任意選択的に（図１には示さない）追加の流体流路を規定する流量コントローラ１４０と、をさらに含むことができる。いくつかの実施形態では、アクチュエータを、分流機構１２０に含めるか又は他の方法で動作可能に結合することができる。このように、アクチュエータを、流量コントローラ１４０内の（例えば、異なる形態の間の）流体移動を制御するように構成することができる。例えば、アクチュエータは、流量コントローラ１４０の第１形態に対応する第１位置、流量コントローラ１４０の第２形態に対応する、第１位置とは異なる第２位置等の間で移動可能であり得る。いくつかの実施形態では、アクチュエータを、単方向に移動するように構成することができる。例えば、アクチュエータを、その第１位置からその第２位置に移動させることができるが、その第２位置からその第１位置に移動させることはできない。同様に、アクチュエータを、その第２位置から第３位置に移動させることができるが、その第３位置からその第２位置に戻るように移動させることはできない。このように、流量コントローラ１４０は、その第１形態の前にその第２形態又は第３形態に移動することが防止され、従って、体液の第１量がプリサンプルリザーバ１７０に向けられ、医療診断及び／又は治療の目的での検査のため等、生物学的サンプルとして使用される抜き取られた流体の第２体積及び／又は第３体積を収容するように設計されたサンプルリザーバ１８０及び／又は１９０に向けられないことが必要である。

【００３４】

[1087] 流量コントローラ１４０は、第１形態にある時、第１流体流路１４２が入口ポート１２１を第１出口ポート１２５に流体的に結合し、第２形態にある時、第２流体流路１４４が入口ポート１２１を第２出口ポート１２６に流体的に結合するように構成されている。いくつかの実施形態では、上述したようなアクチュエータを、流量コントローラ１４

０を第１形態及び第２形態、任意選択的に第３形態又は第４形態の間で、並進運動で移動させるように構成することができる。例えば、いくつかの実施形態では、流量コントローラ１４０は、収集デバイス１００に対して遠位位置にある時に第１形態であり得る。こうした実施形態では、アクチュエータを、流量コントローラ１４０を収集デバイス１００に対して近位位置まで近位方向に移動させ、それにより流量コントローラ１３０を第２形態に配置するように作動させることができる。他の実施形態では、アクチュエータを、流量コントローラ１４０を第１形態及び第２形態又は任意選択的に第３形態あるいは第４形態の間で、回転運動で移動するように作動させることも可能である。

【００３５】

[1088] 従って、流量コントローラ１４０が第１形態にある時、第２出口ポート１２６（及び任意選択的に、サンプルリザーバに結合された追加の出口ポート）は、入口ポート１２１から流体的に隔離される。同様に、流量コントローラ１４０が第２形態にある時、第１出口ポート１２５は入口ポート１２１から流体的に隔離される。任意選択的に、流量コントローラ１４０が（図１には示さない）第３形態にある場合、第１出口ポート１２５及び第２出口ポート１２６は、入口ポート１２１から流体的に隔離される。このように、流量コントローラ１４０は、第１形態にある時、体液の第１量を、第１出口ポート１２５を介してプリサンプル流体リザーバ１７０に仕向け又は分流させることができ、第２形態にある時、体液の第２量を、第２出口ポート１２６を介して第１サンプル流体リザーバ１８０に仕向け又は分流させることができる。

【００３６】

[1089] いくつかの実施形態では、アクチュエータの少なくとも一部を、プリサンプル流体リザーバ１７０に動作可能に結合することができる。このように、アクチュエータ（又はアクチュエータの少なくとも一部）を、「プリサンプル」流体リザーバ１７０内における真空の発生を引き起こすか又は他の方法で促進し、それにより、分流機構１２０がその第１形態にある時、体液の収集デバイス１００を通りプリサンプル流体リザーバ１７０に入る流れを開始するように構成することができる。アクチュエータは、例えば、回転ディスク、プランジャ、スライド、ダイヤル、ボタン、ハンドル、レバー及び／あるいは他のあらゆる好適な機構又はそれらの組合せ等、収集デバイス１００内への体液の流れを駆動するあらゆる好適な機構を含むことができる。好適なアクチュエータの例については、本明細書において具体的な実施形態を参照してより詳細に記載する。

【００３７】

[1090] いくつかの実施形態では、分流機構１２０を、体液の第２量の流れが分流機構１２０を通って第１サンプル流体リザーバ１８０に及び／又は第２サンプル流体リザーバ１９０に輸送されるのを可能にする前に、体液の第１量をプリサンプル流体リザーバ１７０に輸送する必要があるように構成することができる。このように、分流機構１２０を、医療従事者による、体液の第２量及び／又は第３量（例えば、サンプル）を収集する前に体液の第１の所定量（例えば、プリサンプル）を収集することに関するコンプライアンスを必要とするものとして特徴付けることができる。同様に言えば、分流機構１２０を、医療従事者が、体液の第１量、すなわちプリサンプルをプリサンプルリザーバ１７０に最初に分流させることなく、体液の第２量すなわちサンプルを第１サンプル流体リザーバ１８０内に収集するのを防止するように構成することができる。このように、医療従事者は、体表微生物及び／又は他の望ましくない外部汚染物質を含む可能性がより高い体液の第１量を、分析に使用される体液サンプル内に（意図的であっても無意図的であっても）含めることが防止される。他の実施形態では、流体収集デバイス１００は、強制的コンプライアンスの特徴又は構成要素を含む必要はない。

【００３８】

[1091] いくつかの実施形態では、分流機構１２０は、第１形態、第２形態及び第３形態とは異なる（図１には示さない）第４形態を有することができる。第４形態にある時、分流機構１２０は、入口ポート１２１を、第１出口ポート１２５、第２出口ポート１２６及び任意選択的に第３出口ポートから同時に流体的に隔離することができる。従って、分流

機構１２０がその第４形態にある時、入口ポート１２１からプリサンプル流体リザーバ１７０、第１サンプル流体リザーバ１８０及び第２サンプル流体リザーバ１９０に体液が流れることが防止される。使用時、例えば、分流機構１２０を、体液が入口ポート１２１からプリサンプル流体リザーバ１７０に流れることができるように分流機構１２０を第１形態に配置するように（例えば、手動で又は自動的に）作動させ、その後、体液が入口ポート１２１から第１サンプル流体リザーバ１８０に流れることができるように第２形態まで移動させ、任意選択的に、体液が入口ポート１２１から第２サンプル流体リザーバ１９０に流れることができるように第３形態に移動させることができ、その後、体液の分流機構１２０内への及び／又はそこを通る流れを停止させるように第４形態に移動させることができる。このように、デバイスは、デバイス１００内のいかなる残留体液も汚染され及び／又は他の方法で医療従事者及び／又は患者をあり得る危険な流体にさらすことが防止されるように、有効に「ロックされ」かつ第４形態で自己完結する。この任意選択的な安全機能により、ＨＩＶ、Ｃ型肝炎等の病原体が感染している可能性がある体液サンプルへのあり得る暴露を防止することができる。

【００３９】

[1092] いくつかの実施形態では、収集デバイス１００の１つ又は複数の部分は、（図１には示さない）ハウジング内に配置されている。例えば、いくつかの実施形態では、分流機構１２０、第１プリサンプルリザーバ１７０並びにサンプルリザーバ１８０及び１９０のうちの１つ又は複数の少なくとも一部を、ハウジング内に配置することができる。こうした実施形態では、分流機構１２０の少なくとも一部は、使用者が、患者（例えば、静脈）から収集デバイス１００への体液の流れを制御するように流量コントローラ１４０を作動させることができるように、ハウジングを通してアクセス可能である。好適なハウジングの例については、本明細書において具体的な実施形態を参照してより詳細に記載する。

【００４０】

[1093] いくつかの実施形態では、収集デバイス１００は、任意選択的に、収集デバイスを通して体液の流れを計量することができる１つ又は複数の流量計量デバイスを含むことができる。例えば、流量計量デバイスは、第１流体流路１４２及び／又は第２流体流路１４４に流体連通してそこを通る体液の流れを計量することができる。他の実施形態では、流量計量デバイスは、第１ポート１２５及び／又は第２ポート１２６に流体連通し及び／又は他の方法でそこに配置されることが可能である。流量計量デバイスは、プリサンプルリザーバ１７０、第１サンプルリザーバ１８０及び／又は第２サンプルリザーバ１９０に移送されている所定体積に関連する指示を使用者に提供するように構成することができるインジケータ等（例えば、ダイヤル、ディスプレイ、色、触覚出力デバイス、ワイヤレス無線信号、Bluetooth（登録商標）無線信号等の電気信号出力デバイス）を含むことができる。いくつかの実施形態では、流量計量デバイスを、例えば、上述したもののようなアクチュエータ等に動作可能に結合することができる。こうした実施形態では、流量計量デバイスは、流量計量デバイスを通して流れた体液の所望の体積に基づいて、流量コントローラ１４０をその第１形態とその第２形態との間で移動させるようにアクチュエータを作動させるように、動作可能であり得る。従って、流量計量デバイスを用いて、体液の所望の体積がプリサンプルリザーバ１７０、第１サンプルリザーバ１８０及び／又は第２サンプルリザーバ１９０に移送され、それにより、例えば患者サンプルに対する微生物検査等において不十分な、不正確な及び／又は誤った結果を防止することができることを確実にすることができる。

【００４１】

[1094] ここで図２～図１３を参照すると、収集デバイス２００は、分流機構２２０、流量コントローラ２４０、プリサンプルリザーバ２７０、第１サンプルリザーバ２８０、及び第１サンプルリザーバ２８０とは異なる第２サンプルリザーバ２９０を含む。本明細書においてさらに記載するように、収集デバイス２００を、例えば皮膚に存在する微生物及び／又は他の望ましくない外部汚染物質等、体外の微生物が実質的にない体液の流れを送出するために、第１形態、第２形態及び第３形態の間で移動させることができる。収集デ

バイス２００は、いかなる好適な形状、サイズ又は構成でもあり得る。例えば、図２～図１３ではサンプルリザーバ２８０及び／又は２９０がハウジング２０１に対して垂直に向けられているように示されているが、収集デバイス２００は、ハウジング２０１に対して平面に向けられているか又はハウジング２０１に対して円錐状に配置されている等のサンプルリザーバ２８０及び／又は２９０を有することができる。

【００４２】

[1095] 分流機構２２０は、ハウジング２０１及び可動部材２５０及び２５０’を含む。図２～図４に示すように、ハウジング２０１は、プリサンプルリザーバ２７０、第１サンプルリザーバ２８０及び第２サンプルリザーバ２９０に結合されている。ハウジング２０１は、入口ポート２２１、第１出口ポート２３０、第２出口ポート２３１、第３出口ポート２３２を含み、患者から体液を収集するための流体流路を規定することができる内部流路２３５を規定している。入口ポート２２１を、内部流路２３５に流体連通するように選択的に配置することができる。より具体的には、入口ポート２２１は、内部流路２３５に流体連通するように配置することができる入口内腔２０２を規定している。このように、入口ポート２２１は、内部流路２３５を、入口内腔２０２を介してハウジング２０１の実質的に外側の空間に流体連通するように配置することができるように、ハウジング２０１の一部から延在している。入口ポート２２１を、患者から体液を抜き取り及び／又は収集デバイス２００に輸送するための流体流路を規定する（図示せず）医療デバイスに流体的に結合することができる。例えば、入口ポート２２１を、アダプタ２０４を介して直接又は間接的に針又は他の内腔規定デバイス（例えば、可撓性滅菌管）に流体的に結合することができる。同様に言えば、入口ポート２２１によって規定された入口内腔２０２は、内腔規定デバイスが入口ポート２２１に結合された時に内腔規定デバイスによって規定される内腔に流体連通するように配置される。さらに詳述すると、内腔規定デバイスが患者の身体の一部の中に（例えば、患者の静脈又は脊椎腔内に）配置されると、ハウジング２０１の内部流路２３５を、患者の身体のその部分に流体連通するように配置することができる。

【００４３】

[1096] ハウジング２０１によって規定される内部流路２３５は、ハウジング２０１の長さに沿って延在する中心内腔であり、それを、本明細書に記載するように静脈穿刺（体液へのアクセスを可能にするために採用される他の方法）に続いて患者の体液に流体連通するように配置することができる。内部流路２３５は、入口ポート２２１と第１出口ポート２３０、第２出口ポート２３１及び第３出口ポート２３２との間で体液を移送する流体流経路を形成する。より具体的には、内部流路２３５が（例えば、入口ポート２２１に結合された医療デバイスを介して）患者に流体連通するように配置されると、第１出口ポート２３０、第２出口ポート２３１及び第３出口ポート２３２を、内部流路２３５に流体連通するように選択的に配置して、体液がプリサンプルリザーバ２７０、第１サンプルリザーバ２８０又は第２サンプルリザーバ２９０のうちの少なくとも１つに流れ込むのを可能にすることができる。いくつかの実施形態では、体液は、体液の所定体積がプリサンプルリザーバ２７０内に収集される前に、第２出口ポート２３１及び第３出口ポート２３２に流れるのが防止される。いくつかの実施形態では、第２出口ポート２３１及び第３出口ポート２３２を、同時に内部流路２３５に流体連通するように配置することができる。いくつかの実施形態では、第２出口ポート２３１及び第３出口ポート２３２を、逐次内部流路２３５に流体連通するように配置することができる。

【００４４】

[1097] 可動部材２５０、２５０’は、使用者によって、ハウジング２０１に対して第１位置及び第２位置から作動（例えば、移動）させて、流体流を第１サンプルリザーバ２８０及び第２サンプルリザーバ２９０内に向けるように構成されている。可動部材２５０及び２５０’は、実質的に同じであり、従って、単一の可動部材２５０に関して記載する。図５に示すように、可動部材２５０は、内部空洞２５２を規定するボス２５１と、入口ポート２５３と、第１出口ポート２５４と、内部空洞２５２に流体的に結合された内腔２５

６を規定する穿孔部材２５５とを含む。入口ポート２５３及び出口ポート２５４は、可動部材２５０の内部チャンバ２５２を規定するボス２５１の壁を通って延在している。可動部材２５０は、ボス２５１がボア２５８（図４参照）内に配置され、可動部材２５０の少なくとも一部が環状チャンバ２６０内に配置されるように、ハウジング２０１の支持体２５７（図４参照）に取り付けられるように構成されている。任意選択的に、可動部材２５０を使用者が作動させた後にその第１位置に戻すように、付勢部材２５９（例えば、ばね）を環状チャンバ２６０内に配置することができる。いくつかの実施形態では、可動部材２５０、環状チャンバ２６０、ボア２５８又はボス２５１は、使用者によって作動された後に可動部材２５０を第２位置（例えば、押下位置）で保持するように構成された機械的係止機構を含むことができる。

【００４５】

[1098] 本明細書に記載するように、第１形態では、可動部材２５０は、内部流路２３５から間隔を空けて配置されるように配置されている。こうした形態では、患者の身体の一部（例えば、静脈、脊椎腔等）とサンプルリザーバ２８０及び／又は２９０との間に、流体流路を確立することができない。言い換えれば、可動部材２５０がその第１形態にある時、第１サンプルリザーバ２８０及び第２サンプルリザーバ２９０は、ハウジング２０１によって規定される内部流路２３５から流体的に隔離される。可動部材２５０を、使用者により、可動部材２５０を第１形態から第２形態にかつ内部流路２３５と整列するように移動させるように作動させることができる。使用者によってかけられる力は、付勢部材２５９を変形させる（例えば、圧縮する）のに十分である可能性があり、それにより、穿孔部材２５５をサンプルリザーバ２８０及び／又は２９０内に挿入することができる。第２形態では、入口ポート２５３及び出口ポート２５４は、内部流路２３５と実質的に位置合せされて、内部空洞２５２を内部流路２３５に流体連通するように配置する。従って、可動部材２５０が第２形態にある場合、内部流路２３５と、内部空洞２５２と、穿孔部材２５５の内腔２５６と、サンプルリザーバ２８０との間に流体流経路が確立される。言い換えれば、こうした形態では、本明細書においてさらに詳細に記載するように、体液は、患者（例えば、静脈、脊椎腔等）から分流機構２２０を通って、第１サンプルリザーバ２８０及び／又は第２サンプルリザーバ２９０内に流れ込むことができる。

【００４６】

[1099] プリサンプルリザーバ２７０は、例えば、単回使用使い捨て収集チューブ、真空による収集チューブ等、体液を収容するあらゆる好適なリザーバであり得る。プリサンプルリザーバ２７０は、収集デバイス２００の第１出口ポート２３０に（直接、又は滅菌可撓性管等の介在構造を介して）あらゆる好適な方法で流体的に結合されるように構成されている。例えば、いくつかの実施形態では、プリサンプルリザーバ２７０の一部は、第１出口ポート２３０の一部の中に摩擦嵌めを形成することができる。他の実施形態では、プリサンプルリザーバ２７０を、ねじ結合、接着剤、スナップフィット、機械的締結具及び／又は他のあらゆる好適な結合方法を介して、第１出口ポート２３０に結合することができる。いくつかの実施形態では、プリサンプルリザーバ２７０を、ハウジング２０１と一体的に形成することができる。プリサンプルリザーバ２７０を、体液を、真空吸引を介して入口ポート２２１から出口ポート２３０を通りプリサンプルリザーバ２７０に引き込むのを可能にすることができる負圧状態（真空状態）を（プリサンプルリザーバ２７０の）内部で維持するように構成することができる。プリサンプルリザーバ２７０は、体液の第１量を収容するように構成されており、そこでは、体液の第１量は所定量であることも未定量であることも可能であり、それにより、体液の第１量は、患者から後に抜き取られる体液の第２量及び／又は第３量から流体的に隔離される。

【００４７】

[1100] サンプルリザーバ２８０及び／又は２９０は、単回使用使い捨て収集チューブ、真空による収集チューブ、上記参照により本明細書に組み込まれる‘４２０特許に記載されているようなサンプルリザーバ等を含む、体液を収容するあらゆる好適なリザーバであり得る。いくつかの実施形態では、サンプルリザーバ２８０及び／又は２９０は、例えば

Vacutainer（登録商標）等、既知のサンプル容器と実質的に同様であるか又は同じであり得る。サンプルリザーバ２８０及び２９０は、それぞれサンプル容器２８２及び２９２を含み、それぞれ真空シール２８４及び２９４を含む。真空シール２８４又は２９４は、サンプル容器２８２又は２９２それぞれ内部に、真空吸引を介して内部流路２３５からサンプル容器２８２又は２９２それぞれに体液が引き込まれるのを可能にすることができる負圧状態（真空状態）を維持する。サンプル容器２８０及び／又は２９０を、収集デバイス２００の第２出口ポート２３１及び第３出口ポート２３２それぞれに（直接、又は滅菌可撓管等の介在構造を介して）あらゆる好適な方法で流体的に結合されるように構成することができる。サンプルリザーバ２８０及び／又は２９０を、出口ポート２３１及び／又は２３２に流体連通するように配置するように、出口ポート２３１及び／又は２３２に対して移動させることができる。サンプルリザーバ２８０及び２９０を、体液の第２量又は第３量を収容するように構成することができる。体液の第２量又は第３量は、所定量であることも未定量であることも可能であり、それにより、体液の第２量又は第３量は、患者から抜き取られる体液の第１量から流体的に隔離される。いくつかの構成では、サンプルリザーバ２８０及び／又は２９０を、プリサンプルリザーバ２７０と同様にハウジング２０１と一体的に形成することによって収集デバイス２００に結合することができ、従って、それらについてはここでは詳細に記載しない。場合によっては、サンプルリザーバ２８０及び／又は２９０を透明とすることができ、それにより、使用者は、サンプルリザーバ２８０及び／又は２９０内への体液の流れを確認するように視覚的フィードバックを得ることができる。

【００４８】

[1101] いくつかの実施形態では、サンプルリザーバ２８０及び２９０と分流機構２２０（及び／又はサンプルリザーバ２８０及び２９０以外の収集デバイス２００の部分）とは、独立して形成され（例えば、一体的に形成されず）例えば製造プロセス中に合わせて結合される。場合によっては、サンプルリザーバ２８０及び２９０を、実質的に滅菌又は密封環境（例えば、エチレンオキシド等で充填された環境）で分流機構２２０に結合することができる。従って、サンプルリザーバ２８０及び２９０と分流機構２２０との間のインタフェースは、使用前に実質的に滅菌される。さらに、収集デバイス２００を、サンプルリザーバ２８０及び２９０と分流機構２２０との間に実質的滅菌インタフェースを維持するため等、事前組立式に輸送及び／又は保管することができる。

【００４９】

[1102] 図６及び図７に示すように、流量コントローラ２４０は、第１部材２４１及び第２部材２４５を含む。第１部材２４１は、ハウジング２０１の凹部２６６（例えば、図４を参照）内に配置されるように構成され、第１部材２４１を、例えば、チタン、グラファイト、熱分解炭素、ポリエステル、ポリカーボネート、ポリウレタン、エラストマー材料等、生体適合性であるあらゆる材料から作製することができる。いくつかの実施形態では、第２部材２４５は、第１部材２４１を第１形態から第２形態に移動させるアクチュエータとしての役割を果たす。より具体的には、第１部材２４１が凹部２６６内に配置されると、第２部材２４５を、第１位置と第２位置との間で移動させて、流量コントローラ２４０を第１形態と第２形態との間で移動させることができる。いくつかの実施形態では、ハウジング２０１は、第２部材２４５のその第１位置からその第２位置への移動を選択的に制限することができる。いくつかの実施形態では、ハウジング２０１を、第２位置に移動した第２部材２４５の移動を防止するように構成することができる。言い換えれば、ハウジング２０１は、第２部材２４５が第２位置から第１位置に戻るように移動するのを防止する係止機構を含むことができる。第２部材２４５及び／又はハウジング２０１はまた、第２部材２４５の正確な位置決めを確実にするように視覚的フィードバック又は触覚フィードバックを提供する機械的戻り止め及び／又は他のインジケータを含むことも可能である。

【００５０】

[1103] 第１部材２４１は、静脈穿刺（及び／又は患者の体液にアクセスする他の方法）

に続いて流体流を方向付ける複数のチャネルを含むことができる。例えば、図６及び図７に示すように、第１部材２４１は第１流路２４２及び第２流路２４４を含む。第２部材２４５が第１位置にある時（例えば、図８及び図９を参照）、流量コントローラ２４０は第１形態に配置され、第１流路２４２は、入口ポート２２１を内部流路２３５から流体的に隔離しながら、入口ポート２２１と第１出口ポート２３０との間に流体連通を確立する。第２部材２４５が第２位置にある時（例えば、図１０～図１３を参照）、流量コントローラ２４０は第２形態に配置され、第２流路２４４は、入口ポート２２１を第１出口ポート２３０から流体的に隔離しながら、入口ポート２２１と内部流路２３５との間に流体連通を確立する。患者と収集デバイス２００との間で流体流をさらに方向付ける／隔離するように、追加の第１部材２４１の流路及び／又は流量コントローラ２４０の形態に対応する追加の第２部材２４５の位置を含めることができる。例えば、第２部材２４５は、患者と収集デバイス２００との間の流体流を全体的に実質的に防止する、流量コントローラ２４０の第３形態に対応する第３位置を有することができる。言い換えれば、いくつかの実施形態では、すべての体液サンプルが患者から取り出された後に、収集デバイス２００内のサンプルを外部環境から実質的に封止するように、ダイヤルを第３位置に移動させることができる。

【００５１】

[1104] 動作時、収集デバイス２００を使用して、皮膚に存在する微生物及び／又は他の望ましくない外部汚染物質からの汚染を低減して、患者から体液（例えば、血液）を収集することができる。例えば、収集デバイス２００の入口ポート２２１は、アダプタ２０４を介して針又は他の内腔規定デバイス（例えば、可撓性滅菌管）に流体的に結合される。静脈穿刺（又は他の体液アクセス方法）に続いて、第２部材２４５を、図８及び図９に示すように第１位置に達するまで回転させる。別法として、第２部材２４５を第１位置に事前設定することができ、収集デバイス２００を、プリサンプルリザーバ２７０内の真空及び収集デバイス２００の無菌状態を保持するように他の方法で封止することができる。例えば、入口ポート２２１及び／又はアダプタ２０４は、収集デバイス２００が針又は他の内腔規定デバイスに結合された時に開放される弁を含むことができる。

【００５２】

[1105] 上述したように、第２部材２４５が第１位置にある時、流量コントローラ２４０は第１形態に配置され、第１部材２４１の第１流路２４２は、入口ポート２２１を内部流路２３５から流体的に隔離しながら、入口ポート２２１と第１出口ポート２３０との間に流体連通を確立する。さらに、第１サンプルリザーバ２８０及び第２サンプルリザーバ２９０は、第１形態では入口ポート２２１から流体的に隔離され、図９において矢印ＡＡによって示すように、患者の身体の一部（例えば、静脈）とプリサンプルリザーバ２７０との間に流体流路が規定される。上述したように、プリサンプルリザーバ２７０並びにサンプルリザーバ２８０及び２９０等、収集デバイス２００で使用される流体リザーバを、負圧（すなわち、収集デバイス２００が体液を抜き取るために使用されている身体の部分の流体圧力未満の圧力）を規定し、それにより、患者の身体の一部（例えば、静脈）とプリサンプルリザーバ２７０との間に流体連通が確立されると、プリサンプルリザーバ２７０内の負圧により、プリサンプルリザーバ２７０と患者の身体のその部分との間の圧力差によってプリサンプルリザーバ２７０内に体液が引き込まれるようになる。この第１形態では、流量コントローラ２４０はまた、プリサンプルリザーバ２７０を内部流路２３５から流体的に隔離する。従って、体液の第１量（所定量又は未定量）を、（例えば）静脈穿刺の直後にプリサンプルリザーバ２７０内に受け取り、後続するサンプルから隔離することができる。このように、収集デバイス２００を用いて、体表微生物及び／又は他の望ましくない外部汚染物質を含む可能性が最も高い体液の第１量が、診断又は汚染物質によって影響を受ける可能性がある他の検査のために収集され使用される体液サンプルの後続する量を汚染しないようにすることができる。

【００５３】

[1106] プリサンプルリザーバ２７０内における体液プリサンプルの体積の収集に続いて

、第２部材２４５を、図１０及び図１１に示すような第２位置に達するまで、回転させることができる。第２部材２４５が第２位置にある時、流量コントローラ２４０は第２形態に配置され、第１部材２４１の第２流路２４４は、第１出口ポート２３０（すなわち、プリサンプルリザーバ２７０）を入口ポート２２１から流体的に隔離しながら、入口ポート２２１と内部流路２３５との間に流体連通を確立する。言い換えれば、第２形態では、流量コントローラ２４０は、図１１において矢印ＢＢによって示すように第２流路２４４を介して、患者の身体の一部（例えば、静脈）と内部流路２３５との間に流体流路を確立する。

【００５４】

[1107] 流量コントローラ２４０が第２形態にある状態で、可動部材２５０及び／又は２５０’を使用者が第１位置から第２位置に作動させて（すなわち、押下して）、患者の身体の一部（例えば静脈）と第１サンプルリザーバ２８０及び／又は第２サンプルリザーバ２９０との間に流体連通を確立することができる。より具体的には、可動部材２５０は、その第１位置からその第２形態に移動して、図１２において矢印ＣＣによって示すように、穿孔部材２５５が第１サンプルリザーバ２８０の真空シール２８４に穴をあけサンプル容器２８２内部に配置されことが可能であるように、穿孔部材２５５が出口ポート２３１を通過するようにする。第２位置にある時、可動部材２５０の入口ポート２５３及び出口ポート２５４は、内部流路２３５と実質的に位置合せされかつそれに流体連通し、それにより、体液が、内部流路２３５から可動部材２５０の内部空洞２５２内に、かつ穿孔部材２５５の内腔２５６から出て第１サンプルリザーバ２８０内に流れることができる。サンプルリザーバ２８０（例えば、真空又は負圧）と内部流路２３５との圧力差により、体液がサンプルリザーバ２８０内に引き込まれる。言い換えれば、第２形態では、図１２において矢印ＤＤによって示すように、可動部材２５０は、内部流路２３５と第１サンプルリザーバ２８０との間に流体流路を確立する。第１サンプルリザーバ２８０に体液の所望の量（例えば、第２量）が収集されると、使用者は、可動部材２５０を解放して、付勢部材２５９がボタンをその第１位置に戻るように移動させるのを可能にすることができる。可動部材２５０がその第１位置に戻ると、穿孔部材２５５は第１サンプルリザーバ２８０から取り除かれ、シール２８４（例えば、自己封止膜（self sealing septum））が、第１サンプルリザーバ２８０を内部流路２３５から流体的に隔離する。

【００５５】

[1108] 同様に、流量コントローラ２４０が第２形態にある間、図１３において矢印ＥＥによって示すように、可動部材２５０’を、使用者がその第１位置から第２位置に作動させる（押下する）ことができる。このように、上述した可動部材２５０及び第１サンプルリザーバ２８０と同様の方法で、患者の身体の一部（例えば、静脈）と第２サンプルリザーバ２９０との間に（出口ポート２３２を介して）流体連通が確立される。言い換えれば、第２形態では、可動部材２５０’は、図１３において矢印ＦＦによって示すように、内部流路２３５と第２サンプルリザーバ２９０との間に流体流路を確立する。第２サンプルリザーバ２９０内に体液の所望の量（例えば、第３量）が収集されると、使用者は、可動部材２５０’を解放して、付勢部材２５９’がボタン２５０’をその第１位置に戻るように移動させるのを可能にすることができる。逐次プロセスであるものとして示しかつ記載しているが、充填の順序及び／又は順序付けは必ずしも必要ではない（すなわち、サンプルリザーバ２８０は、必ずしもサンプルリザーバ２９０より前に充填されなくてもよい、等）。言い換えれば、流量コントローラ２４０が第２形態に移動すると、第１サンプルリザーバ２８０及び第２サンプルリザーバ２９０（及び任意の追加のサンプルリザーバ）を、あらゆる順序で、同じ時点で（例えば、同時に）及び／又は一部が重なる時間間隔で充填することができる。例えば、使用者は、第１サンプルリザーバ２８０への充填を開始することができ、その後、第１サンプルリザーバ２８０が部分的に充填された後、使用者は、可動部材２５０’を押下して、第１サンプルリザーバ２８０が充填を終了している間に、第２サンプルリザーバ２９０への充填を開始するようにすることができる。さらに、サンプルリザーバ２８０及び／又は２９０内に収集された体液の体積の調整を、可動部材２

５０及び／又は２５０’を繰り返し作動させる（挿入する）ことによって可能にすることができる。上述したように、第２部材２４５は、流量コントローラ２４０の第３形態に対応する第３位置を有することができ、それにより、患者と収集デバイス２００との間の流体流を全体的に実質的に防止して、収集デバイス２００内のサンプルを外部環境から実質的に封止することができる。

【００５６】

[1109] 図２～図１３には示さないが、収集デバイス２００は、プリサンプルリザーバ２７０、第１サンプルリザーバ２８０及び／又は第２サンプルリザーバ２９０に移送される体液の体積を計量するように構成することができる流量計量デバイス等を含むことができる。例えば、いくつかの実施形態では、流量コントローラ２４０の第１部材２４１は、第１流路２４２及び第２流路２４４に流体連通している流量計量デバイスを含むことができる。他の実施形態では、流量計量デバイスを、可動部材２５０及び／又は２５０’の内部空洞２５２内に配置することができる。従って、第１サンプルリザーバ２８０及び第２サンプルリザーバ２９０に移送されかつその中に配置される体液サンプルの体積を、各サンプルリザーバ２８０及び２９０内に配置される体液サンプルの体積が例えば１０ｍＬ、２０ｍＬ、３０ｍＬ等の所定体積であるように、計量し及び／又は制御することができる。

【００５７】

[1110] 収集デバイス２００は、第１サンプルリザーバ２８０及び第２サンプルリザーバ２９０を含むものとして示されかつ記載されているが、他の実施形態では、あらゆる数のプリサンプルリザーバ及び／又はサンプルリザーバを含むことができる。例えば、図１４及び図１５は、実施形態による収集デバイス３００を示す。図示するように、収集デバイス３００のいくつかの態様は、図２～図１３を参照して上述した収集デバイス２００の対応する態様に実質的に同様であり得る。従って、同様の態様については本明細書ではそれ以上詳細には記載しない。

【００５８】

[1111] 図１４及び図１５に示すように、収集デバイス３００は、分流機構３２０、流量コントローラ３４０、プリサンプルリザーバ３７０、第１サンプルリザーバ３８０、第２サンプルリザーバ３８０’、第３サンプルリザーバ３９０及び第４サンプルリザーバ３９０’を含む。プリサンプルリザーバ３７０は、詳細に上述したプリサンプルリザーバ２７０と実質的に同様であり得る。いくつかの実施形態では、サンプルリザーバ３８０、３８０’、３９０及び３９０’は、詳細に上述したサンプルリザーバ２８０及び２９０と実質的に同様であり得る。いくつかの実施形態では、サンプルリザーバ３８０、３８０’、３９０及び３９０’は、実質的に同じ形状及びサイズを有することができ、例えば、実質的に同じ培地を含むことができる。他の実施形態では、サンプルリザーバ３８０、３８０’、３９０及び３９０’は、実質的に同じ形状及びサイズを有することができ、好気性菌用培地又は嫌気性菌用培地のうちの一方を含むことができる。例えば、いくつかの実施形態では、第１サンプルリザーバ３８０及び第３サンプルリザーバ３９０は好気性菌用培地を含むことができ、第２サンプルリザーバ３８０’及び第４サンプルリザーバ３９０’は嫌気性菌用培地を含むことができる。他の実施形態では、サンプルリザーバ３８０、３８０’、３９０及び３９０’は、各々、好気性菌用培地又は嫌気性菌用培地をあらゆる配置又は組合せで含むことができる。

【００５９】

[1112] 分流機構３２０は、ハウジング３０１と一組の可動部材３５０、３５０’、３５０’’及び３５０’’’とを含む。可動部材３５０、３５０’、３５０’’及び３５０’’’は、例えば、図５を参照して上述した可動部材２５０と実質的に同様である。従って、可動部材３５０、３５０’、３５０’’及び３５０’’’を、サンプルリザーバ３８０、３８０’、３９０及び３９０’それぞれに流体連通して配置されるように、ハウジング３０１に対して第１位置と第２位置との間で移動させることができる。ハウジング３０１は、入口ポート３２１と、プリサンプルリザーバ３７０に流体連通するように配置されるように構成された第１出口ポート３３０と、第１サンプルリザーバ３８０に流体連通する

ように配置されるように構成された第２出口ポート３３１と、第２サンプルリザーバ３８０’に流体連通するように配置されるように構成された第３出口ポート３３２と、第３サンプルリザーバ３９０’に流体連通するように配置されるように構成された第４出口ポート３３３と、第４サンプルリザーバ３９０’に流体連通するように配置されるように構成された第５出口ポート３３４とを含む。さらに、ハウジング３０１は、ハウジング２０１の内部流路２３５に関して上述したものと同様の方法で、入口ポート３２１並びに出口ポート３３１、３３２、３３３及び３３４に流体連通するように選択的に配置することができる内部流路３３５を規定している。

【００６０】

[1113] 流量コントローラ３４０は、例えば、図６～図１３を参照して上述した流量コントローラ２４０と実質的に同様である。従って、流量コントローラ３４０を、第１形態と第２形態との間で回転させて、患者とプリサンプルリザーバ３７０又はサンプルリザーバ３８０、３８０’、３９０及び３９０’との間に流体流路の一部を選択的に規定することができる。このように、使用者は、図８～図１３において収集デバイス２００に関して上述したものと同様の方法で、収集デバイス３００を操作することができる。従って、体液の第１体積をプリサンプルリザーバ３７０に移送しかつその中に配置することができ、体液の後続する体積を、サンプルリザーバ３８０、３８０’、３９０及び３９０’に移送しかつその中に配置することができる。

【００６１】

[1114] 図１６～図２２は、実施形態による収集デバイス４００を示す。収集デバイス４００は、分流機構４２０、流量コントローラ４４０並びにサンプルリザーバ４８０、４８０’、４９０及び４９０’を含む。本明細書においてさらに記載するように、収集デバイス４００を、第１形態、第２形態、第３形態、第４形態及び第５形態の間で移動させて、例えば、皮膚に存在する微生物及び／又は他の望ましくない外部汚染物質等、体外の微生物が実質的にない体液の流れを送出することができる。収集デバイス４００は、あらゆる好適な形状、サイズ又は構成であり得る。例えば、図１６～図２２において、サンプルリザーバ４８０、４８０’、４９０及び４９０’がハウジング４０１に対して垂直に向けられて示されているが、収集デバイス４００は、ハウジング４０１に対してあらゆる好適な平面において向けられ、又はハウジング４０１に対して円錐状に配置される等のサンプルリザーバ４８０、４８０’、４９０及び４９０’を有することができる。

【００６２】

[1115] サンプルリザーバ４８０、４８０’、４９０及び４９０’は、収集デバイス２００のサンプルリザーバ２８０及び／又は２９０と形態及び機能が実質的に同様であるか又は同じであり、従って、本明細書では詳細には記載しない。上述したように、サンプルリザーバ４８０、４８０’、４９０及び４９０’は、吸引を介して患者からサンプルリザーバ４８０、４８０’、４９０及び４９０’に体液を引き込むのを可能にすることができる負圧状態（真空状態）を維持する。いくつかの実施形態では、サンプルリザーバ４８０及び４８０’を好気性菌用培養ボトルとすることができ、サンプルリザーバ４９０及び４９０’を嫌気性菌用培養ボトルとすることができ、収集デバイス４００を用いて、１回の静脈穿刺から複数の好気性菌用血液培養サンプル及び複数の嫌気性菌用血液培養サンプルを収集することができる。本明細書においてさらに詳細に記載するように、サンプルリザーバ４８０、４８０’、４９０及び４９０’を、各々、体液サンプルのある体積を受け取るように分流機構４２０の少なくとも一部に流体連通するように配置することができる。体液サンプルの体積は、所定量でも未定量であり得る。さらに、サンプルリザーバ４８０、４８０’、４９０、４９０’内に体液の所望の体積が配置されると、本明細書においてさらに詳細に記載するように、各サンプルリザーバ４８０、４８０’、４９０及び４９０’を、分流機構４２０の少なくとも一部から流体的に隔離することができる。

【００６３】

[1116] 分流機構４２０は、ハウジング４０１及び分配部材４２９を含む。分流機構４２０のハウジング４０１は、分配部材４２９に物理的にかつ流体的に結合され、患者から体

液を収集する一組の流体流経路を提供し及び／又は規定している。ハウジング４０１は、凹部４６６及び一組の出口開口部４０３を規定している。凹部４６６は、本明細書においてさらに詳細に記載するように、流量コントローラ４４０に含まれるシール部材４４１を受け入れるように構成されている。出口開口部４０３の組は、各々が、分配部材４２９の異なる部分に流体連通している異なる流体流路を規定するように構成されている、第１出口開口部４０３ａ、第２出口開口部４０３ｂ、第３出口開口部４０３ｃ、第４出口開口部４０３ｄ及び第５出口開口部４０３ｅを含む。より具体的には、分配部材４２９は、第１出口開口部４０３ａに流体連通しているプリサンプルリザーバ４７０の少なくとも一部と、第２出口開口部４０３ｂに流体連通している第１流路４３５ａ、第３出口開口部４０３に流体連通している第２流路４３５ｂ、第４出口開口部４０３ｄに流体連通している第３流路４３５ｃ及び第５出口開口部４０３ｅに流体連通している第４流路４３５とを規定し及び／又は形成している。

【００６４】

[1117] 図１７及び図１８に示すように、分配部材４２９は、プリサンプルリザーバ４７０の少なくとも一部を規定するチャンバ又は空間を規定している。プリサンプルリザーバ４７０は、例えば、血液、血漿、尿等の体液を収容するように構成されている。ハウジング４０１の第１出口開口部４０３ａを、プリサンプルリザーバ４７０が患者から体液の流れを受け取るのを可能にするように、プリサンプルリザーバ４７０の開放部分と実質的に位置合せすることができる。例えば、プリサンプルリザーバ４７０は、体液の第１量又は第１体積を受け取りかつ収容することができ、ここで、体液の第１量は、所定量でも未定量でもあり得る。さらに、分流機構４２０の配置を、本明細書においてさらに詳細に記載するように、プリサンプルリザーバ４７０が流路４３５ａ、４３５ｂ、４３５ｃ及び４３５ｄ並びに／又は患者から抜き取られた体液の後続する体積から流体的に隔離して維持されるというものとすることができる。プリサンプルリザーバ２７０及び３７０を、負圧を維持するものとして上述しているが、プリサンプルリザーバ４７０は、負圧状態（真空状態）を維持せず、従って、例えば重力等の他の機構を用いて、体液をプリサンプルリザーバ４７０内に引き込むことができる。

【００６５】

[1118] 流路４３５ａ～４３５ｄは、分配部材４２９の中心から放射状に延在し、各流路４３５ａ、４３５ｂ、４３５ｃ及び４３５ｄがプリサンプルリザーバ４７０及び他の流路から流体的に隔離されるように配置されている。このように、流路４３５ａ、４３５ｂ、４３５ｃ及び４３５ｄは、出口開口部４０３ｂ、４０３ｃ、４０３ｄ及び４０３ｅそれぞれと実質的に位置合せされる第１端部と第２端部との間で流体流路を方向付け及び／又は他の方法で規定することができる。図１７及び図１８に示すように、分配部材４２９は、第１流路４３５ａの第２端部に配置された第１出口ポート４３１と、第２流路４３５ｂの第２端部に配置された第２出口ポート４３２と、第３流路４３５ｃの第２端部に配置された第３出口ポート４３３と、第４流路４３５ｄの第２端部に配置された第４出口ポート４３４とを規定している。さらに、分配部材４２９は、第１穿孔部材４５５ａ、第２穿孔部材４５５ｂ、第３穿孔部材４５５ｃ及び第４穿孔部材４５５ｄを含み、それらは、第１出口ポート４３１、第２出口ポート４３２、第３出口ポート４３３及び第４出口ポート４３４それぞれに、物理的にかつ流体的に結合されている。従って、本明細書においてさらに詳細に記載するように、穿孔部材４５５ａ～３５５ｄを用いて、サンプルリザーバ４８０、４８０’、４９０及び４９０’の真空シールに穴をあけることができ、それにより、体液の流れを開始することができる。図１７及び図１８には示さないが、サンプルリザーバ４８０、４８０’、４９０及び４９０’を、サンプルリザーバ４８０、４８０’、４９０及び４９０’が出口ポート４３１、４３２、４３３及び４３４それぞれに流体連通するように配置されるのを可能にすることができるあらゆる好適な方法で、分配部材４２９の一部に（直接、又は滅菌可撓性管等の介在構造を介して）物理的に結合することができる。

【００６６】

[1119] 流量コントローラ４４０は、ダイヤル４４５及びシール部材４４１を含む。シー

ル部材４４１は、ハウジング４０１の凹部４６６内に配置される（例えば、図２０を参照）。より詳細には、流量コントローラ４４０を、シール部材４４１が凹部４６６を規定するハウジング４０１の表面とダイヤル４４５の表面との間にかつそれらと接触して配置されるように、ハウジング４０１に結合することができる。さらに、シール部材４４１は、本明細書においてさらに詳細に記載するように、流量コントローラ４４０がハウジング４０１に結合された時、シール部材４４１が、ダイヤル４４５の表面及び凹部４６６を規定するハウジング４０１の表面と実質的流体密封シールを形成するような、サイズ及び形状を有することができる。シール部材４４１を、例えば、シリコーン、ポリ乳酸、ポリグリコール酸、ポリ乳酸－グリコール酸共重合体（ＰＬＧＡ）、ポリ酸無水物、ポリオルトエステル、ポリエーテルエステル、ポリカプロラクトン、ポリエステルアミド、ポリ（酪酸）、ポリ（吉草酸）、ポリウレタン、ナイロン、ポリエステル、ポリカーボネート、ポリアクリレート、エチレンービニルアセテート及び他のアシル置換セルロースアセテートのポリマー、ポリスチレン、ポリ塩化ビニル、ポリフッ化ビニル、ポリ（ビニルイミダゾール）、クロロスルホネートポリオレフィン、ポリエチレンオキシド並びに／又はそれらの混合物及びコポリマー等、生体適合性であるあらゆる材料から作製することができる。

【００６７】

[1120] 図１７に示すように、シール部材４４１は、静脈穿刺（又は体液にアクセスする他の方法）に続いて体液の流れを方向付けることができる一組の開口部４４４を規定している。例えば、シール部材４４１によって規定される一組の開口部４４４は、第１開口部４４４ａ、第２開口部４４４ｂ、第３開口部４４４ｃ、第４開口部４４４ｄ及び第５開口部４４４ｅを含む。シール部材４４１の配置は、シール部材４４１が凹部４４６内に配置された時、第１開口部４４４ａ、第２開口部４４４ｂ、第３開口部４４４ｃ、第４開口部４４４ｄ及び第５開口部４４４ｅが、ハウジング４０１の第１出口開口部４０３ａ、第２出口開口部４０３ｂ、第３出口開口部４０３ｃ、第４出口開口部４０３ｄ及び第５出口開口部４０３ｅそれぞれと実質的に位置合せされる、というものである。

【００６８】

[1121] 流量コントローラ４４０のダイヤル４４５は、ハウジング４０１に回転可能に結合され、かつハウジング４０１に対する第１位置、第２位置、第３位置、第４位置及び第５位置の間で移動可能である。ダイヤル４４５は、内腔４０２を規定する入口ポート４２１を含む。入口ポート４２１を、患者の体内から体液を抜き取り及び／又は収集デバイス４００に輸送するための流体流経路を規定する（図示せず）医療デバイスに流体的に結合することができる。例えば、入口ポート４２１を、針又は他の内腔規定デバイス（例えば、可撓性滅菌管）に直接又はアダプタ４０４を介して間接的に流体的に結合することができる。同様に言えば、入口ポート４２１によって規定される入口内腔４０２は、内腔規定デバイスが入口ポート４２１に結合された時、内腔規定デバイスによって規定される内腔に流体連通するように配置される。このように、入口ポート４２１を、本明細書においてさらに詳細に記載するように、プリサンプルリザーバ４７０、第１サンプルリザーバ４８０、第２サンプルリザーバ４８０’、第３サンプルリザーバ４９０及び第４サンプルリザーバ４９０’を、患者に流体連通するように選択的に配置するように構成することができる。

【００６９】

[1122] 上述したように、ダイヤル４４５は、第１位置、第２位置、第３位置、第４位置及び第５位置の間で移動可能である。ダイヤル４４５が第１位置にある時、流量コントローラ４４０は第１形態で配置され、入口ポート４２１を、シール部材４４１の第１開口部４４４ａ及びハウジング４０１の第１出口開口部４０３ａと実質的に位置合せすることができる。このように、シール部材４４１の第１開口部４４４ａは、入口ポート４２１を出口開口部４０３ｂ、４０３ｃ、４０３ｄ及び４０３ｅから流体的に隔離し、それにより入口ポート４２１を流路４３５ａ～３３５ｄから流体的に隔離しながら、入口ポート４２１と第１出口開口部４０３ａとの間に流体連通を確立する。第１出口ポート４０３ａがプリサンプルリザーバ４７０の開放部分と位置合せされると、第１開口部４４４ａ及び第１出

口開口部４０３ａは、入口ポート４２１とプリサンプルリザーバ４７０との間に流体連通を確立する。ダイヤル４４５が第２位置まで回転した（又は駆動された）時、流量コントローラ４４０は第２形態に配置され、第２出口開口部４４４ｂは、入口ポート４２１を出口開口部４０３ａ、４０３ｃ、４０３ｄ及び４０３ｅから流体的に隔離しながら、入口ポート４２１と第２出口開口部４０３ｂとの間に流体連通を確立する。第２出口開口部４０３ｂが第１流路４３５ａの第１端部と位置合せされると、第２開口部４４４ｂ及び第２出口開口部４０３ｂは、入口ポート４２１と第１流路４３５ａとの間に流体連通を確立する。

【００７０】

[1123] 収集デバイス４００は、ダイヤル４４５が第３位置、第４位置及び第５位置まで回転した時、同様に作用する。従って、入口内腔４０２が（例えば、入口ポート４２１に結合された医療デバイスを介して）患者に流体連通するように配置されると、第１出口ポート４３０、第２出口ポート４３１、第３出口ポート４３２、第４出口ポート４３３及び第５出口ポート４３４を、入口内腔４０２に流体連通するように選択的に配置して、体液のすべてがプリサンプルリザーバ４７０のうちの少なくとも１つ、又はサンプルリザーバ４８０、４８０’４９０及び４９０’のうちの１つあるいは複数に流れ込むのを可能にすることができる。いくつかの実施形態では、患者と収集デバイス４００との間で流体流をさらに方向付け／隔離するために、追加のシール出口開口部及び／又は流量コントローラ４４０の形態に対応する追加のダイヤル４４５の位置を含めることができる。例えば、ダイヤル４４５は、患者と収集デバイス４００との間の流体流を全体として実質的に防止する、流量コントローラ４４０の第６形態に対応する第６位置を有することができる。言い換えれば、いくつかの実施形態では、すべての体液サンプルが患者から取り出された後、収集デバイス４００内のサンプルを外部環境から実質的にシールするようにダイヤル４４５を第６位置に移動させることができる。

【００７１】

[1124] いくつかの実施形態では、プリサンプルリザーバ４７０内に体液の所定体積が収集される後まで、体液は、サンプルリザーバに関連する出口ポート（例えば、出口ポート４３１～４３４）に流れるのが防止される。いくつかの実施形態では、サンプルリザーバに関連する出口ポート（例えば、出口ポート４３１～４３４）を、逐次的にのみ、入口内腔４０２に流体連通するように配置することができる（例えば、出口ポート４３１は、出口ポート４３２の前に入口内腔４０２に流体連通しなければならない、等）。いくつかの実施形態では、後続するサンプルリザーバに関連する出口ポート（例えば、出口ポート４３２～４３４）を、体液の確定された体積が収集された後にのみ、入口内腔４０２に流体連通するように配置することができる。いくつかの実施形態では、サンプルリザーバに関連する出口ポート（例えば、出口ポート４３１～４３４）を、いかなる順序の優先もなくあらゆるランダムな方法で入口内腔４０２に流体連通するように配置することができる（例えば、出口ポート４３４は、出口ポート４３１の前に入口内腔４０２に流体連通することができ、出口ポート４３２は、出口ポート４３３の前に入口内腔４０２に流体連通することができる等）。

【００７２】

[1125] いくつかの実施形態では、ハウジング４０１は、ダイヤル４４５のその第１位置からその第２位置、第３位置、第４位置及び第５位置への移動を選択的に制限することができる。いくつかの実施形態では、ハウジング４０１を、第５位置まで移動したダイヤル４４５の移動を防止するように構成することができる。言い換えれば、ハウジング４０１は、ダイヤル４４５が第５位置から第１位置に戻るように移動するのを防止する係止機構を含むことができる。ダイヤル４４５及び／又はハウジング４０１は又はウジング４０１の出口開口部４０３ａ～４０３ｅに対するダイヤル４４５の正確な位置決めを確実にするように視覚的フィードバック又は触覚フィードバックを提供する、機械的戻り止め及び／又は他のインジケータを含むことも可能である。

【００７３】

[1126] 動作時、収集デバイス４００を用いて、汚染を低減して患者から体液（例えば、血液、血漿、尿等）を収集することができる。例えば、収集デバイス４００の入口ポート４２１を、針又は他の内腔規定デバイス（例えば、可撓性滅菌管）に流体的に結合することができる。静脈穿刺（又は体液にアクセスする他の方法）に続いて、図１９及び図２０に示すように、ダイヤル４４５が第１位置に達するまで駆動される（又は回される）。別法として、ダイヤル４４５を第１位置に事前設定することができ、収集デバイス４００を、収集デバイス４００の無菌状態を維持するように他の方法で封止することができる。例えば、入口ポート４２１は、収集デバイス４００が針又は他の内腔規定デバイスに結合されると開放する弁を含むことができる。

【００７４】

[1127] 上述したように、ダイヤル４４５が第１位置にある時、流量コントローラ４４０は第１形態に配置され、シール部材４４１の第１開口部４４４ａは、入口ポート４２１を４つの流路４３５ａ～３３５ｄから流体的に隔離しながら、（ハウジング４０１内に含まれる）入口ポート４２１と第１出口ポート４３０との間で流体連通を確立する。さらに、サンプルリザーバ４８０、４８０’、４９０及び４９０’は、第１形態では入口ポート４２１から流体的に隔離されており、図２０において矢印ＧＧによって示すように、患者の身体の一部（例えば、静脈）とプリサンプルリザーバ４７０との間に、流体流路が規定される。この第１形態では、体液は、患者の身体のその部分から入口ポート４２１の入口内腔４０２、シール部材４４１の第１開口部４４４ａ、第１出口ポート４３０を通り、プリサンプルリザーバ４７０内に（例えば、重力、真空等により）流れ込む。第１形態では、流量コントローラ４４０はまた、プリサンプルリザーバ４７０を流路４３５ａ～３３５ｄから流体的に隔離する。従って、体液の第１量（所定量又は未定量）を、静脈穿刺の直後にプリサンプルリザーバ４７０内に受け取り、後続するサンプルから隔離することができる。このように、収集デバイス４００を用いて、体表微生物及び／又は他の望ましくない外部汚染物質を含む可能性が最も高い体液の第１量が、診断又は汚染物質によって影響を受ける可能性がある他の試験に対して収集され使用される体液サンプルの後続する量を汚染しないようにすることができる。

【００７５】

[1128] プリサンプルリザーバ４７０内への体液プリサンプルの収集に続き、図２１及び図２２に示すように、ダイヤル４４５を、第２位置に達するまで作動させる（回転させる）ことができる。ダイヤル４４５が第２位置にある時、流量コントローラ４４０は第２形態に配置され、シール部材４４１の第２開口部４４４ｂは、プリサンプルリザーバ４７０を入口ポート４２１から流体的に隔離しながら、入口ポート４２１と流路４３５ａとの間に流体連通を確立する。言い換えれば、第２形態では、図２２において矢印ＨＨによって示すように、流量コントローラ４４０は、患者の身体の一部（例えば、静脈）と流路４３５ａとの間に流体流路を確立する。流量コントローラ４４０が第２形態にある状態で、サンプルリザーバ４８０を、使用者が、第１形態から第２形態に作動させて（例えば、穿孔部材４５５ａを押して）患者の身体の一部（例えば、静脈）と第１サンプルリザーバ４８０との間に流体連通を確立することができる。

【００７６】

[1129] 上述したように、サンプルリザーバ４８０を第２形態に移動させることにより、穿孔部材４５５ａが、サンプルリザーバ４８０の真空シールに穴をあけでサンプルリザーバ４８０の内側に配置される。この第２形態では、患者の身体の一部（例えば、静脈）が、サンプルリザーバ４８０内の負圧状態（真空）によるサンプルリザーバ４８０からの真空吸引力にさらされる。サンプルリザーバ４８０（例えば、真空又は負圧）と患者の身体のその部分との圧力差により、サンプルリザーバ４８０内に体液が引き込まれる。体液は、患者の身体のその部分から、入口ポート４２１の入口内腔４０２、シール部材４４１の第２開口部４４４ｂ、ハウジング４０１の第２出口開口部４０３ｂを通って、第１流路４３５ａ内に流れ込む。真空吸引により、体液の流れが第１流路４３５ａを通って、第２出口ポート４３１及び穿孔部材４５５ａを介してサンプルリザーバ４８０内に引き込まれる

。言い換えれば、第２形態では、流量コントローラ４４０は、入口ポート４２１とサンプルリザーバ４８０との間に流体流路を確立する。サンプルリザーバ４８０内に体液の所望の量（例えば、第２量）が収集されると、使用者は、流量コントローラ４４０を第３位置まで作動させ（回転させ）、及び／又はサンプルリザーバ４８０をその第１形態に戻るように移動させて、第１サンプルリザーバ４８０を流路４３５ａから隔離することができる。サンプルリザーバ４８０が第１形態に戻ると、穿孔部材４５５ａはサンプルリザーバ４８０から取り除かれ、サンプルリザーバ４８０のシール（例えば、自己封止膜）が、第１サンプルリザーバ４８０を流路４３５ａから隔離する。他のサンプルリザーバの充填は、流量コントローラ４４０が第３形態、第４形態及び第５形態それぞれに配置されて同様に行われる。

【００７７】

[1130] 充填の順序及び／又は順序付けは必ずしも必要ではない（すなわち、サンプルリザーバ４８０は必ずしもサンプルリザーバ４９０の前に充填されなくてもよい等）ことに留意されたい。言い換えれば、第１サンプルリザーバ４８０及び第２サンプルリザーバ４９０（及び任意の追加のサンプルリザーバ）をあらゆる順序で充填することができる。例えば、使用者は、第１サンプルリザーバ４８０の充填を開始することができ、その後、第１サンプルリザーバ４８０が部分的に充填された後、使用者は第２サンプルリザーバ４９０を充填することができる。さらに、サンプルリザーバ４８０及び／又は４９０内に収集された体液の体積の調整を、サンプルリザーバ４８０及び／又は４９０の繰り返される充填によって可能とすることができる。しかしながら、他の実施形態では、充填の順序を、体液の指定された量が第１リザーバ内に配置されたことが確認されるまで、第２サンプルリザーバにアクセスすることができない等のように、機械的に操作することができる。上述したように、ダイヤル４４５は、患者と収集デバイス４００との間の流体流を全体として実質的に防止して、収集デバイス４００内のサンプルを外部環境から実質的に封止することができる、流量コントローラ４４０の第６形態に対する第６位置を有することができる。

【００７８】

[1131] 収集デバイス４００を、４つのサンプルリザーバの組（例えば、第１サンプルリザーバ４８０、第２サンプルリザーバ４８０’、第３リザーバ４９０及び第４リザーバ４９０’）を含み及び／又はそれらに他の方法で結合しているものとして上に示し記載しているが、他の実施形態では、収集デバイスは、あらゆる好適な数のサンプルリザーバを含むことができ及び／又はそれらに結合され得る。例えば、図２３～図２５は、実施形態による収集デバイス５００を示す。図示するように、収集デバイス５００のいくつかの態様は、図１６～図２２を参照して上述した収集デバイス５００の対応する態様と実質的に同様であり得る。従って、同様の態様については本明細書ではそれ以上詳細には記載しない。

【００７９】

[1132] 収集デバイス５００は、分流機構５２０、流量コントローラ５４０、第１サンプルリザーバ５８０及び第２サンプルリザーバ５９０を含む。サンプルリザーバ５８０及び５９０は、詳細に上述したサンプルリザーバと実質的に同様であり得る。いくつかの実施形態では、サンプルリザーバ５８０及び５９０は、実質的に同じ形状及びサイズを有することができ、実質的に同じ培地を含むことができる。他の実施形態では、サンプルリザーバ５８０及び５９０は、実質的に同じ形状及びサイズを有することができ、好気性菌用培地又は嫌気性菌用培地のうちの一方を含むことができる。さらに他の実施形態では、第１サンプルリザーバ５８０は、第２サンプルリザーバ５９０のサイズより実質的に大きい第１サイズを有することができる。

【００８０】

[1133] 図２４及び図２５に示すように、分流機構５２０は、ハウジング５０１及び分配部材５２９を含む。分流機構５２０のハウジング５０１は、分配部材５２９に物理的にかつ流体的に結合されており、患者から体液を収集する一組の流体流経路を提供し及び／又

は規定している。ハウジング４０１に関して上述したように、ハウジング５０１は、凹部と、第１出口開口部５０３ａ、第２出口開口部５０３ｂ及び第３出口開口部５０３ｃとを規定することができる。凹部は、詳細に上述したように、流量コントローラ５４０に含まれるシール部材５４１を受け入れるように構成されている。第１出口開口部５０３ａ、第２出口開口部５０３ｂ及び第３出口開口部５０３ｃは、ハウジング４０１によって規定された第１出口開口部４０３ａ、第２出口開口部４０３ｂ及び第３出口開口部４０３ｃそれぞれと形態及び機能が実質的に同様であり得る。同様に、分配部材５２９は、分流部材４２９に含まれるプリサンプルリザーバ４７０、第１流路４３５ａ及び第２流路４３５ｂと実質的に同様である、プリサンプルリザーバ４７０、第１流路４３５ａ及び第２流路４３５ｂを規定している。従って、分流機構４２０に関して上述したように、プリサンプルリザーバ５７０は、第１出口開口部５０３ａに流体連通しており、第１流路５３５ａは、第２出口開口部５０３ｂに流体連通しており、第２流路５３５ｂは、第３出口開口部５０３ｃに流体連通している。図２５に示すように、分配部材５２９は、第１流路５３５ａ及び第１穿孔部材５５５ａに流体連通している第１出口ポート５３１と、第２流路５３５ｂ及び第２穿孔部材５５５ｂに流体連通している第２出口ポート５３２とを規定している。上述したように、穿孔部材５５５ａ及び５５５ｂを用いて、本明細書においてさらに詳細に記載するように、サンプルリザーバ５８０及び５９０の真空シールに穴をあけることができ、それにより、体液の流れを開始することができる。

【００８１】

[1134] 流量コントローラ５４０は、ダイヤル５４５及びシール部材５４１を含む。シール部材５４１は、上述したように、ハウジング５０１の凹部内に配置される。このように、流量コントローラ５４０がハウジング５０１に結合されると、シール部材５４１は、ダイヤル５４５の表面及び凹部を規定するハウジング５０１の表面と実質的流体密封シールを形成する。図２４及び図２５に示すように、シール部材５４１は、シール部材４４１に関して詳細に上述したように、第１出口開口部５０３ａ、第２出口開口部５０３ｂ及び第３出口開口部５０３ｃそれぞれと実質的に位置合せされる、第１開口部５４４ａ、第２開口部５４４ｂ及び第３開口部５４４ｃを規定している。

【００８２】

[1135] 流量コントローラ５４０のダイヤル５４５は、ハウジング５０１に結合されるのに好適なサイズを有していながら、ダイヤル４４５と形態及び機能が実質的に同様であり得る。従って、ダイヤル５４５を、ハウジング５０１に回転可能に結合し、ハウジング５０１に対して第１位置、第２位置及び第３位置の間で移動可能とすることができる。ダイヤル５４５は、内腔５０２を規定する入口ポート５２１を含み、入口ポート５２１を、患者から体液を抜き取り及び／又は収集デバイス５００に輸送するための流体流経路を規定する医療デバイス（図示せず）に流体的に結合することができる。このように、入口ポート５２１を、プリサンプルリザーバ５７０、第１サンプルリザーバ５８０及び第２サンプルリザーバ５９０を選択的に配置するように構成することができる。より詳細には、ダイヤル５４５が第１位置にある時、流量コントローラ５４０は第１形態に配置され、入口ポート５２１は、シール部材５４１の第１開口部５４４ａ及びハウジング５０１の第１出口開口部５０３ａと実質的に位置合せされる。このように、収集デバイス４００に関して詳細に上述したように、シール部材５４１の第１開口部５４４ａは、入口ポート５２１と第１出口開口部５０３ａとの間に流体連通を確立し、従って、入口ポート５２１を、プリサンプルリザーバ５７０に流体連通するように配置する。同様に、ダイヤル５４５が第２位置まで回される（又は駆動される）と、流量コントローラ５４０は第２形態に配置され、第２出口開口部５４４ｂは、入口ポート５２１と第２出口開口部５０３ｂ、従って第１流路５３５ａとの間に流体連通を確立し、ダイヤル５４５が第３位置まで回されると、流量コントローラ５４０は第３形態に配置され、第３出口開口部５４４ｃは、入口ポート５２１と第３出口開口部５０３ｃ、従って第２流路５３５ａとの間に流体連通を確立する。このように、収集デバイス４００に関して詳細に上述したように、収集デバイス５００を、プリサンプル５７０に体液の第１体積を移送するために使用し、その後、第１サンプルリ

ザーバ５８０及び第２サンプルリザーバ５９０それぞれに体液の第２体積及び第３体積を移送するために使用することができる。

【００８３】

[1136] 図２６～図３３は、実施形態による収集デバイス６００を示す。収集デバイス６００は、分流機構６２０、流量コントローラ６４０並びにサンプルリザーバ６８０、６８０’、６９０及び６９０’を含む。本明細書においてさらに記載するように、収集デバイス６００を、第１形態、第２形態、第３形態、第４形態及び第５形態の間で移動させて、例えば、皮膚に存在する微生物及び／又は他の望ましくない外部汚染物質等、体外の微生物が実質的ない体液の流れを送出することができる。収集デバイス６００は、あらゆる好適な形状、サイズ又は構成であり得る。例えば、収集デバイス６００の態様及び／又は部分は、上述した収集デバイス１００、２００、３００、４００及び／又は５００のいずれかの対応する態様及び／又は部分と形態及び／又は機能が同様であり得る。従って、こうした同様の態様及び／又は部分については、本明細書ではそれ以上詳細には記載しない。例として、いくつかの実施形態では、収集デバイス６００のサンプルリザーバ６８０、６８０’、６９０及び６９０’は、図１６～図２２の収集デバイス４００に含まれるサンプルリザーバ４８０、４８０’、４９０及び４９０’それぞれと形態及び／又は機能が実質的に同様であり及び／又は同じであり得る。

【００８４】

[1137] 分流機構６２０は、分配部材６２９並びに一組の結合部材６３７ａ、６３７ｂ、６３７ｃ及び６３７ｄを含む（例えば、図２７を参照）。分配部材６２９は、結合部材６３７ａ、６３７ｂ、６３７ｃ及び６３７ｄに流体連通しており、患者から体液を収集する一組の流体流経路を提供し及び／又は規定するように構成されている。図２７及び図２８に示すように、分配部材６２９は、プリサンプルリザーバ６７０に流体連通している第１出口ポート６３０と、第１結合部材６３７ａに流体連通している第２出口ポート６３１と、第２結合部分６３７ｂに流体連通している第３出口ポート６３２と、第３結合部分６３７ｃに流体連通している第４出口ポート６３３と、第４結合部分６３７ｄに流体連通している第５出口ポート６３４とを規定し及び／又は形成している。

【００８５】

[1138] 図２８に示すように、分配部材６２９は、プリサンプルリザーバ６７０の少なくとも一部を規定するチャンバ又は空間を規定している。プリサンプルリザーバ６７０は、例えば、血液、血漿、尿等の体液を収容するように構成されている。例えば、プリサンプルリザーバ６７０は、患者から体液の第１量又は第１体積を受け取りかつ収容することができ、そこでは、体液の第１量は所定量でも未定量でもあり得る。さらに、分流機構６２０及び流量コントローラ６４０の配置は、本明細書においてさらに詳細に記載するように、プリサンプルリザーバ６７０が結合部分６３７ａ、６３７ｂ、６３７ｃ及び６３７ｄ並びに／又は患者から抜き取られる体液の後続する体積から流体的に隔離されて維持されるというものであり得る。このように、出口ポート６３１、６３２、６３３及び６３４は、本明細書においてさらに詳細に記載するように、流量コントローラ６４０と結合部材６３７ａ、６３７ｂ、６３７ｃ及び６３７ｄそれぞれとの間に流体流路を方向付け及び／又は他の方法で規定することができる。いくつかの実施形態では、第１出口ポート６３０及びプリサンプルリザーバ６７０の配置は、プリサンプルリザーバ４７０及び／又は５７０と形態及び機能が実質的に同様であり得る。従って、プリサンプルリザーバ６７０について、本明細書ではそれ以上詳細には記載しない。

【００８６】

[1139] 図２９に示すように、第１結合部材６３７ａは、穿孔部材６５５ａに流体的に結合されている流路６３８ａを規定している。上述したように、結合部材６３７ａを、分配部材６２９に物理的にかつ流体的に結合することができる。例えば、流路６３８ａは、分配部材の第２出口ポート６３１の一部を受け入れて、結合部材６３７ａをそれに物理的にかつ流体的に結合することができる。いくつかの実施形態では、第２出口ポート６３１の表面は、流路６３８ａを規定する結合部分６３７ａの内面と実質的流体密封シール（例え

ば、実質的気密シールを形成することができる摩擦嵌め）を形成することができる。結合部分６３７ａの穿孔部材６５５ａは、図１６～図２２の収集デバイス４００に含まれる穿孔部材４５５ａと形態及び機能が実質的に同様であり得る。従って、穿孔部材６５５ａについては本明細書ではそれ以上記載しない。第２結合部材６３７ｂ、第３結合部材６３７ｃ及び第４結合部材６３７ｄは同様に配置される。従って、第２結合部材６３７ｂ、第３結合部材６３７ｃ及び第４結合部材６３７ｄは各々、穿孔部材６５５ｂ、６５５ｃ及び６５５ｄそれぞれを含み、各々、流路６３８ｂ、６３８ｃ及び６３８ｄそれぞれを規定している。本明細書においてさらに詳細に記載するように、第１結合部材６３７ａ、第２結合部材６３７ｂ、第３結合部材６３７ｃ及び第４結合部材６３７ｄを用いて、分流機構６２０を、第１サンプルリザーバ６８０、第２サンプルリザーバ６８０’、第３サンプルリザーバ６９０及び第４サンプルリザーバ６９０’それぞれに流体連通するように選択的に配置することができる。

【００８７】

[1140] 図３０及び図３１に示すように、流量コントローラ６４０は、ダイヤル６４５及びシール部材６４１を含む。流量コントローラ６４０のダイヤル６４５は、分配部材６２９内に回転可能に配置され（図３２及び図３３を参照）、第１位置、第２位置、第３位置及び第４位置の間で移動可能である。ダイヤル６４５は、各々が内部空間６４６に流体連通している入口ポート６２１、第１出口ポート６４７及び第２出口ポート６４８を含む（例えば、図３０を参照）。内部空間６４６は、本明細書においてさらに詳細に記載するように、シール部材６４１の一部を受け入れるように構成されている。入口ポート６２１を、患者から体液を抜き取り及び／又は収集デバイス６００に輸送するための流体流経路を規定する（図示せず）医療デバイスに流体的に結合することができる。例えば、入口ポート６２１を、針又は他の内腔規定デバイス（例えば、可撓性滅菌管）に直接又はアダプタ６０４（例えば、図２６及び図２７を参照）を介して間接的に流体的に結合することができる。第１出口ポート６４７は、プリサンプルリザーバ６７０に流体連通している。例えば、第１出口ポート６４７を、分配部材６２９の第１出口ポート６３０内に回転可能に配置することができる。ダイヤル６４５が、その第１位置、第２位置、第３位置及び第４位置にそれぞれある時、第２出口ポート６４８を、第２出口ポート６３１、第３出口ポート６３２、第４出口ポート６３３及び第５出口ポート６３４に流体連通するように選択的に配置することができる。このように、本明細書においてさらに詳細に記載するように、ダイヤル６４５の内部空間６４６を、プリサンプルリザーバ６７０、第１サンプルリザーバ６８０、第２サンプルリザーバ６８０’、第３サンプルリザーバ６９０及び第４サンプルリザーバ６９０’に流体連通するように選択的に配置することができる。

【００８８】

[1141] 流量コントローラ６４０のシール部材６４１の少なくとも一部が、ダイヤル６４５の内部空間６４６内に回転可能に配置され、第１位置と第２位置との間で移動可能である。さらに、シール部材６４１は、シール部材６４１の外面が、内部空間６４６の少なくとも一部を規定するダイヤル６４５の内面と実質的流体密封シールを形成するようなサイズ及び形状を有することができる。図３１に示すように、シール部材６４１は、第１流路６４２及び第２流路６４４を規定している。シール部材６４１が内部空間６４６内でその第１位置にある時、流路６４２は、入口ポート６２１を第２出口ポート６４８から流体的に隔離しながら、入口ポート６２１と第１出口ポート６４７との間に流体連通を確立する。同様に、シール部材６４１が内部空間６４６内でその第２位置にある時、第２流路６４４は、入口ポート６２１を第１出口ポート６４７から流体的に隔離しながら、入口ポート６２１と第２出口ポート６４８との間に流体連通を確立する。収集デバイス６００は、ダイヤル６４５が分配部材６２９内で第２位置、第３位置及び第４位置まで回転する時に同様に作用する。従って、入口ポート６２１が（例えば、入口ポート６２１及び／又はアダプタ６０４に結合された医療デバイスを介して）患者に流体連通するように配置されると、分配部材６２９の第１出口ポート６３０、第２出口ポート６３１、第３出口ポート６３２、第４出口ポート６３３及び第５出口ポート６３４を、入口ポート６２１に流体連通す

るように選択的に配置して、体液がプリサンプルリザーバ６７０、第１サンプルリザーバ６８０、第２サンプルリザーバ６８０’、第３サンプルリザーバ６９０及び第４サンプルリザーバ６９０’それぞれの中に流れ込むのを可能にすることができる。

【００８９】

[1142] 動作時、収集デバイス６００を用いて、汚染を低減して患者から体液（例えば、血液、血漿、尿等）を収集することができる。例えば、収集デバイス６００の入口ポート６２１を、針又は他の内腔規定デバイス（例えば、可撓性滅菌管）に流体的に結合することができる。静脈穿刺（又は体液にアクセスする他の方法）に続き、図３２に示すように、シール部材をその第１位置になるまで作動（又は回転）させることができる。別法として、シール部材６４１を第１位置に事前設定することができ、収集デバイス６００を、収集デバイス６００の無菌状態を維持するように他の方法で封止することができる。シール部材６４１がその第１位置にある時、流量コントローラ６４０は、入口ポート６２１を結合部材６３７ａ、６３７ｂ、６３７ｃ及び６３７ｄから流体的に隔離しながら、入口ポート６２１と分配部材６２９の第１出口ポート６３０との間に流体連通を確立する。従って、図３２において矢印ＩＩによって示すように、収集デバイス４００に関して上述したものと同様の方法で、体液を、患者から入口ポート６２１、第１流路６４２、ダイヤル６４５の第１出口ポート６４７、分配部材６２９の第１出口ポート６３０を介してプリサンプルリザーバ６７０内に移送することができる。

【００９０】

[1143] プリサンプルリザーバ６７０内における体液プリサンプルの収集に続いて、シール部材６４１をダイヤル６４５に対してその第１位置からその第２位置に作動させる（回転させる）ことができる。同様に、図３３に示すように、ダイヤル６４５を、それが分配部材６２９に対して第２位置に達するまで作動させる（又は回転させる）ことができる。シール部材６４１及びダイヤル６４５がその第２位置にある時、流量コントローラ６４０は第２形態に配置され、シール部材６４１の第２流路６４４は、プリサンプルリザーバ６７０を入口ポート６２１から流体的に隔離しながら、入口ポート６２１と第１結合部材６３７ａの流路６３８ａとの間に流体連通を確立する。流量コントローラ６４０が第２形態にある状態で、サンプルリザーバ６８０を、使用者によりその第１形態から第２形態に作動させて（例えば、穿孔部材６５５ａを押して）、患者の身体の一部（例えば、静脈）と第１サンプルリザーバ６８０との間に流体連通を確立することができる。詳細に上述したように、サンプルリザーバ６８０を第２形態に移動させることにより、穿孔部材６５５ａが、サンプルリザーバ６８０の真空シールに穴をあけてサンプルリザーバ６８０の内側に配置される。この第２形態では、患者の身体のその部分（例えば、静脈）が、サンプルリザーバ６８０内の負圧状態（真空）のためにサンプルリザーバ６８０からの真空吸引力にさらされる。従って、図３３において矢印ＪＪによって示すように、体液を、患者の身体のその部分から入口ポート６２１、第２流路６４４、第２出口ポート６３１及び流路６３８ａ並びに第１結合部材６３７ａの穿孔部材６５５ａを通って第１サンプルリザーバ６８０内に強制的に流すことができる。

【００９１】

[1144] サンプルリザーバ６８０内に体液の所望の体積（例えば、第２量）が収集されると、使用者は、流量コントローラ６４０を第３位置まで作動させ（回転させ）及び／又はサンプルリザーバ６８０をその第１形態に戻るように移動させて、第１サンプルリザーバ６８０を第２流路６４４から隔離することができる。サンプルリザーバ６８０が第１形態に戻ると、穿孔部材６５５ａは、サンプルリザーバ６８０から取り除かれ、サンプルリザーバ６８０のシール（例えば、自己封止膜）が、第１サンプルリザーバ６８０を流路６３５ａから流体的に隔離する。他のサンプルリザーバの充填は、流量コントローラ６４０が第３形態、第４形態及び第５形態それぞれに配置されている状態で同様に行われる。

【００９２】

[1145] 図３４～図４０は、実施形態による収集デバイス７００を示す。収集デバイス７００は、分流機構７２０、流量コントローラ７４０並びにサンプルリザーバ７８０及び７

９０を含む（４つのサンプルリザーバに対してホルダが存在するが、明確にするために図では２つのサンプルリザーバのみが含まれており、収集デバイス７００の一部として、追加のサンプルリザーバ（例えば、第５、第６等）を含めることができる）。本明細書においてさらに記載するように、収集デバイス７００を第１形態、第２形態、第３形態、第４形態及び第５形態の間で移動させて、例えば、皮膚に存在する微生物及び／又は他の望ましくない外部汚染物質等、体外の微生物が実質的にない体液の流れを送出することができる。収集デバイス７００は、あらゆる好適な形状、サイズ又は構成であり得る。例えば、収集デバイス７００の態様及び／又は部分は、上述した収集デバイス１００、２００、３００、４００、５００及び／又は６００のいずれかの対応する態様及び／又は部分と形態及び／又は機能が実質的に同様であり得る。従って、こうした同様の態様及び／又は部分については、本明細書ではそれ以上詳細に記載しない。例として、いくつかの実施形態では、収集デバイス７００のサンプルリザーバ７８０及び７９０は、図１６～図２２の収集デバイス４００に含まれるサンプルリザーバ４８０及び４９０それぞれと形態及び機能が実質的に同様及び／又は同じであり得る。

【００９３】

[1146] 分流機構７２０は、ハウジング７０１、分配部材７２９及びベースプレート７７１を含む。収集デバイス４００に関して上述したように、ハウジング７０１は、各々、分配部材７２９の異なる部分に流体連通しているように構成されている、第１出口開口部７０３ａ、第２で出口開口部７０３ｂ、第３出口開口部７０３ｃ、第４出口開口部７０３ｄ及び第５出口開口部７０３ｅを規定している。より具体的には、分配部材７２９は、第１出口開口部７０３ａに流体連通しているプリサンプルリザーバ７７０の少なくとも一部と、第２出口開口部７０３ｂに流体連通している第１流体チャンバ７３５ａ、第３出口開口部７０３ｂに流体連通している第２流体チャンバ７３５ｂ、第４出口開口部７０３ｄに流体連通している第３流体チャンバ７３５ｃ、第５出口開口部７０３ｅに流体連通している第４流体チャンバ７３５ｄとを規定し及び／又は形成している。さらに、本明細書においてさらに記載するように、ハウジング７０１は、流量コントローラ７４０の少なくとも一部を移動可能に受け入れるように構成された凹部７６６を規定している。

【００９４】

[1147] 図３６に示すように、分配部材７２９は、プリサンプルリザーバ７７０の少なくとも一部を形成するチャンバ又は空間を規定している。プリサンプルリザーバ７７０は、例えば、血液、血漿、尿等の体液を収容するように構成されている。ハウジング７０１の第１出口開口部７０３ａを、詳細に上述したように、プリサンプルリザーバ７７０が患者から体液の流れを受け取ることができるように、プリサンプルリザーバ７７０の開放部分と実質的に位置合せすることができる。さらに詳述すると、分配部材７２９は一組の壁７３６を含み、それらは、例えば、分配部材７２９の内部空間を互いに流体的に隔離されている部分及び／又は空間に分割することができる。例えば、図３６に示すように、一組の壁７３６は、分配部材７２９の内部空間を、プリサンプルリザーバ７７０、第１流体チャンバ７３５ａ、第２流体チャンバ７３５ｂ、第３流体チャンバ７３５ｃ及び第４流体チャンバ７３５ｄに分割することができる。いくつかの実施形態では、壁７３６は、プリサンプルリザーバ７７０及び流体チャンバ７３５ａ～７３５ｄを等しく規定し及び／又は形成することができる。他の実施形態では、プリサンプルリザーバ７７０は、流体チャンバ７３５ａ～７３５ｄによって規定される空間とは異なる空間を規定することができる。

【００９５】

[1148] 分配部材７２９は、第１流体チャンバ７３５ａ、第２流体チャンバ７３５ｂ、第３流体チャンバ７３５ｃ及び第４流体チャンバ７３５ｄそれぞれに流体連通している、第１穿孔部材７５５ａ、第２穿孔部材７５５ｂ、第３穿孔部材７５５ｃ及び第４穿孔部材７５５ｄをさらに含む。従って、穿孔部材７５５ａ～３５５ｄを用いて、本明細書においてさらに詳細に記載するように、サンプルリザーバ７８０及び７９０（並びに図３４～図４０には示さない対応するサンプルリザーバ）に穴をあけることができ、それにより、体液の流れを開始することができる。

【００９６】

[1149] 収集デバイス７００の流量コントローラ７４０は、ダイヤル７４５及びシール部材７４１を含む。シール部材７４１は、ハウジング７０１の凹部７６６内に配置される（例えば、図３８及び図４０を参照）。より詳細には、シール部材７４１が、凹部７６６を規定するハウジング７０１の表面とダイヤル７４５の表面との間にかつそれらと接触して配置されるように、流量コントローラ７４０をハウジング７０１に結合することができる。シール部材７４１を、詳細に上述したように、ダイヤル７４５の表面及び凹部７６６を規定するハウジング７０１の表面と実質的流体密封シールを形成するように構成することができる。図３５に示すように、シール部材７４１は、第１開口部７４４ａ、第２開口部７４４ｂ、第３開口部７４４ｃ、第４開口部７４４ｄ及び第５開口部７４４ｅを規定している。シール部材７４１の配置は、シール部材７４１が凹部７６６内に配置された時、第１開口部７４４ａ、第２開口部７４４ｂ、第３開口部７４４ｃ、第４開口部７４４ｄ及び第５開口部７４４ｅが、ハウジング７０１の第１出口開口部７０３ａ、第２出口開口部７０３ｂ、第３出口開口部７０３ｃ、第４出口開口部７０３ｄ及び第５出口開口部７０３ｅそれぞれと実質的に位置合せされる、というものである。

【００９７】

[1150] 流量コントローラ７４０のダイヤル７４５は、ハウジング７０１に回転可能に結合され、ハウジング７０１に対して第１位置、第２位置、第３位置、第４位置及び第５位置の間で移動可能である。ダイヤル７４５は入口ポート７２１を含み、入口ポート７２１を、患者から体液を抜き取り及び／又は収集デバイス７００に輸送するための流体流経路を規定する医療デバイスに（直接又はアダプタ７０４を介して間接的に）流体的に結合することができる。このように、入口ポート７２１を、本明細書においてさらに詳細に記載するように、プリサンプルリザーバ７７０、第１サンプルリザーバ７８０、第２サンプルリザーバ７８０’、第３サンプルリザーバ７９０及び第４サンプルリザーバ７９０’を患者に流体連通するように選択的に配置するように構成することができる。ダイヤル７４５が第１位置にある時、流量コントローラ７４０は第１形態に配置され、入口ポート７２１を、シール部材７４１の第１開口部７４４ａ及びハウジング７０１の第１出口開口部７０３ａと実質的に位置合せすることができる。このように、シール部材７４１の第１開口部７４４ａは、入口ポート７２１を出口開口部７０３ｂ、７０３ｃ、７０３ｄ及び７０３ｅから流体的に隔離し、それにより入口ポート７２１を流体チャンバ７３５ａ～３３５ｄから流体的に隔離しながら、入口ポート７２１と第１出口開口部７０３ａとの間に流体連通を確立する。ダイヤル７４５が第２位置まで回される（又は駆動される）と、流量コントローラ７４０は第２形態に配置され、第２出口開口部７４４ｂは、入口ポート７２１をプリサンプルリザーバ７７０及び流体チャンバ７３５ｂ～７３５ｄから流体的に隔離しながら、入口ポート７２１と第２出口開口部７０３ｂとの間に流体連通を確立する。収集デバイス７００は、ダイヤル７４５が第３位置、第４位置及び第５位置まで回される時、同様に作用する。従って、入口ポート７２１が（例えば、入口ポート７２１に結合された医療デビスを介して）患者に流体連通するように配置されると、体液のすべてがプリサンプルリザーバ７７０、第１サンプルリザーバ７８０又は第２サンプルリザーバ７９０（又はそれらに結合された他の任意の流体リザーバ）内に流れ込むことができるように、第１出口開口部７０３ａ、第２出口開口部７０３ｂ、第３出口開口部７０３ｃ、第４出口開口部７０３ｄ及び第５出口開口部７０３ｅを入口ポート７２１に流体連通するように選択的に配置することができる。

【００９８】

[1151] いくつかの実施形態では、ハウジング７０１は、ダイヤル７４５のその第１位置からその第２位置、第３位置、第４位置及び第５位置への移動を選択的に制限することができる。いくつかの他の実施形態では、ハウジング７０１を、第５位置まで移動したダイヤルの移動を防止するように構成することができる。言い換えれば、ハウジング７０１は、ダイヤル７４５が第５位置から第１位置に戻るように移動するのを防止する係止機構を含むことができる。この特徴により、流量チャンバ７３５ａ～７３５ｄ並びに／又はサン

プルリザーバ７８０及び７９０内に収集された体液が（表面に結合された微生物及び／又は他の望ましくない外部汚染物質を含むリスクが高い）プリサンプルリザーバ７７０内に収容された体液から汚染されるリスクを低減することができる。この係止機構により、医療従事者を、ＨＩＶ、Ｃ型肝炎等を含む可能性がある患者サンプル内の血液媒介病原体にさらされることから保護することも可能である。ダイヤル７４５及び／又はハウジング７０１は又はウジング７０１における出口ポート７０３ａ及び出口開口部７０３ａ～７０３ｄに対するダイヤル７４５の正確な位置合せを確実にするように視覚的フィードバック又は触覚フィードバックを提供する、機械的戻り止め及び／又は他のインジケータも含むことができる。

【００９９】

[1152] 図１６～図２２に示す収集デバイス４００の実施形態と同様に、収集デバイス７００は、分配部材７２９内に収容されるチャンバであるプリサンプルリザーバ７７０を含む。プリサンプルリザーバ７７０は、例えば、血液、血漿、尿等の体液を収容することができる。プリサンプルリザーバ７７０は、（ハウジング７０１内に位置する）収集デバイス７００の第１出口ポート７０３ａに流体的に結合されるように構成されている。収集デバイス７００の動作中、流量コントローラ７４０が第１位置にある時、体液は、患者の身体の一部（例えば、静脈）から、入口ポート７２１を介して、プリサンプルリザーバ７７０、シール部材７４１内に位置するプリサンプルリザーバ７４４ａ用の開口部及び第１出口ポート７０３ａ内に引き込まれる。プリサンプルリザーバ７７０は、患者から抜き取られる流体の第１量を収容するように構成され、そこでは、体液の第１量は、所定量であることも未定量であることも可能であり、それにより、体液の第１量は、患者から後に抜き取られる体液の第２量及び／又は第３量及び／又は第４量及び／又は第５量から流体的に隔離される。

【０１００】

[1153] 動作時、収集デバイス７００を用いて、汚染を低減して患者から体液（例えば、血液、血漿、尿等）を収集することができる。例えば、収集デバイス７００の入口ポート７２１を、針又は他の内腔規定デバイス（例えば、可撓性滅菌管）に流体的に結合することができる。静脈穿刺に続き、図３７及び図３８に示すように、ダイヤル７４５が第１位置に達するまで回される。別法として、上述したように、ダイヤル７４５を第１位置で事前設定することができ、収集デバイス７００の無菌状態を維持するように、収集デバイス７００を他の方法で封止することができる。ダイヤル７４５が第１位置にある状態で、流量コントローラ７４０は第１形態に配置され、シール部材７４１の第１出口開口部７４４ａは、入口ポート７２１を４つのサンプル流路７３５ａ～７３５ｄから流体的に隔離しながら、（ハウジング７０１内に含まれる）入口ポート７２１と第１出口ポート７４１との間に流体連通を確立する。この第１形態では、体液は、図３８において矢印ＫＫによって示すように、患者の身体のその部分から、入口ポート７２１、シール部材７４１の第１出口開口部７４４ａ、ハウジング７０１の第１出口ポート７０３ａを通って、分配部材７７０によって規定されたプリサンプルリザーバ７７０内に流れ込む。従って、詳細に上述したように、体液の第１量（所定量又は未定量）を、静脈穿刺の直後にプリサンプルリザーバ７７０内に受け取り、後続するサンプルから隔離することができる。

【０１０１】

[1154] プリサンプルリザーバ７７０内における体液プリサンプルの収集に続き、ダイヤル７４５を、図３９及び図４０に示すように第２位置に達するまで作動させる（又は回転させる）ことができる。ダイヤル７４５が第２位置にある時、流量コントローラ７４０は第２形態に配置され、シール部材７４１の第２出口開口部７４４ａは、プリサンプルリザーバ７７０を入口ポート７２１から流体的に隔離しながら、入口ポート７２１と第１流体チャンバ７３５ａとの間に流体連通を確立する。第１流体チャンバ７３５ａに体液が充填されると、流量コントローラ７４０を第３位置に移動させて、第１流路７３５ａを外部環境から隔離し封止することができる。さらに、サンプルリザーバ７８０を第１形態から第２形態に作動させて、体液を第１流体チャンバ７３５ａからサンプルリザーバ７８０に移

送することができる。例えば、サンプルリザーバ７８０を使用者が又は自動的に第１形態から第２形態に作動させて（穿孔部材７５５ａを押して）、患者の身体の一部（例えば、静脈）とサンプルリザーバ７８０との間に流体連通を確立することができる。上述したように、サンプルリザーバ７８０を第２形態まで移動させることにより、穿孔部材７５５ａがサンプルリザーバ７８０の真空シールに穴をあけ、サンプルリザーバ７８０の内側に配置される。第２形態では、患者の身体のその部分（例えば、静脈）は、幾つかの実施形態ではサンプルリザーバ７８０内部に存在する負圧状態（真空）によりサンプルリザーバ７８０からの真空吸引にさらされる。従って、図４０において矢印ＬＬによって示すように、体液は、患者の身体のその部分から、入口ポート７２１、シール部材７４１の第２出口開口部７４４ｂ、ハウジング７０１の第２出口開口部７０３ｂ、第２流体チャンバ７３５ｂを通って第１サンプルリザーバ７８０内に流れ込む。

【０１０２】

[1155] サンプルリザーバ７８０内に体液の所望の量（例えば、第２量）が収集されると、使用者は、流量コントローラ７４０を第３位置まで作動させ（回転させ）及び／又はサンプルリザーバ７８０をその第１形態に戻るように移動させて、第１サンプルリザーバ７８０を入口ポート７２１から隔離することができる。サンプルリザーバ７８０が第１形態に戻ると、穿孔部材７５５ａはサンプルリザーバ７８０から取り除かれ、サンプルリザーバ７８０のシール（例えば、自己封止膜）が、第１サンプルリザーバ７８０を第２流体チャンバ７３５ｂ及び外部環境から流体的に隔離する。他のサンプルリザーバの充填は、流量コントローラ７４０が第３形態、第４形態及び第５形態それぞれにある状態で同じ方法で行われる。

【０１０３】

[1156] いくつかの実施形態では、収集デバイス７００を、分配部材７２９内で異なる流体チャンバ７３５ａ～７３５ｄを分離する一組の壁７３６が存在しないように構成することができる（図１６における詳細な断面図を参照）。こうした実施形態では、分配部材７２９は、プリサンプルリザーバ７７０と結合された流体チャンバ７３５との間で分割される（すなわち、流体チャンバは、壁７３６によって４つの別個の部分に分離されない）。こうした実施形態では、使用者は、ダイヤル７４５を第２位置、第３位置、第４位置又は第５位置のいずれかに作動（回転）させることによって、一度に４つのサンプルリザーバすべてを充填することができる。

【０１０４】

[1157] 本明細書に記載する実施形態のうちのいずれも、例えば、プリサンプルリザーバ及び／又はサンプルリザーバ内への体液の流れを計量する（例えば、定量化する）ために使用することができる計量デバイスと使用することができる。場合によっては、検査標準実施により、充填体積が臨床医及び／又は瀉血専門医によって視覚的に判断され従って人的ミスを受けやすいという事実により、体液（例えば、血液試料）の正確な接種体積との一貫したコンプライアンスが確保されない。血液収集ボトルの体積インジケータは、保持されている時に読み取ることが困難であり、収集ボトルは引込み処置の間、直立して保持されないという事実が、患者から受け取られた体液サンプルの不正確な体積の要因となる可能性がある。サンプル体積が不十分である（例えば、製造業者の推奨未満である）ことにより、培養検査の感度が低下し、偽陰性結果に至る可能性がある。さらに、所定タイプの検査供給品及び装置（例えば、Franklin Lakes、NJのBecton Dickinson等の製造業者によって生成される自動微生物検出システムと使用するように設計された血液培養ボトル）に対する概要資料及び使用説明書において指示されているように、製造業者の推奨を上回る充填体積は、偽陽性をもたらす可能性がある。従って、流量計量及び体積表示機能により、検査技師及び／又は医療従事者（例えば、瀉血専門医）は、サンプルがいかに処理される必要があるかに応じて、サンプルリザーバをインキュベータに又は他の研究室検査機器内に配置する前に各個々のサンプルリザーバ内に収集される体液の体積を確認することができる。検査技師及び／又は瀉血専門医はまた、結果が受け取られる時に臨床医が評価するための正確な体積情報を（例えば、診療記録、データベース、スプレッドシート等に

）記録することも可能であり、それにより、偽陰性結果及び／又は偽陽性結果の誤った解釈の可能性を低減するのに役立つ。

【０１０５】

[1158] 例として、図４１～図４５は、１つ又は複数の計量デバイスを含むことができる収集デバイス８００を示す。収集デバイス８００は、分流機構８２０、流量コントローラ８４０、ディスプレイ８７５及びサンプルリザーバ８８０を含む。本明細書においてさらに記載するように、収集デバイス８００を第１形態、第２形態及び第３形態の間で移動させて、例えば、皮膚に存在する微生物及び／又は他の望ましくない外部汚染物質等、体外の微生物が実質的にない体液の流れを送出することができる。収集デバイス８００は、あらゆる好適な形状、サイズ又は構成であり得る。例えば、収集デバイス６００の態様及び／又は部分は、上述した収集デバイス１００、２００、３００、４００、５００、６００及び／又は７００のいずれかの対応する態様及び／又は部分と形態及び／又は機能が実質的に同様であり得る。従って、こうした同様の態様及び／又は部分については、本明細書ではそれ以上詳細に記載しない。例として、いくつかの実施形態では、収集デバイス８００のサンプルリザーバ８８０は、図１６～図２２の収集デバイス４００に含まれるサンプルリザーバ４８０と形態及び機能が実質的に同様であり及び／又は同じであり得る。

【０１０６】

[1159] 図４１～図４３に示すように、分流機構８２０は、アクチュエータ部分８２２（例えば、第１部分）、中間部分８２３（例えば、第２部分）及び結合部分８２４（例えば、第３部分）を含む。分流機構８２０のアクチュエータ部分８２２は、内部空間８０６を規定する一組のアクチュエータ壁を含む実質的に円筒状である。より具体的には、アクチュエータ部分８２２は、実質的に閉鎖されている第１端部と、内部空間８０６へのアクセスを可能にするように実質的に開放されている、第１端部と反対側の第２端部とを含む。このように、アクチュエータ部分８２２は、本明細書においてさらに詳細に記載するように、流量コントローラ８４０の少なくとも一部を移動可能に受け入れることができる。アクチュエータ部分８２２は、入口ポート８２１及び出口ポート８３１をさらに含む。入口ポート８２１を、詳細に上述したように、患者から体液を抜き取り及び／又は収集デバイス８００に輸送するための流体流経路を規定する医療デバイスに（直接又はアダプタ８０４を介して間接的に）流体的に結合することができる。

【０１０７】

[1160] アクチュエータ部分８２２の出口ポート８３１は、アクチュエータ部分８２２の内部空間８０６の一部を、中間部分８２３によって規定される内部空間８０７に流体連通するように選択的に配置することができる。図４３に示すように、中間部分８２３は、アクチュエータ部分８２２と結合部分８２４との間に配置されている。図４１～図４５には示さないが、中間部分８２３は、例えばサンプルリザーバ８８０に移送される体液の体積を計量するように構成することができる計量デバイスを含むことができる。例えば、いくつかの実施形態では、流量計量デバイスを出口ポート８３１に流体的に結合して、そこを通る体液の流れを計量することができる。図４１及び図４２に示すように、中間部分８２３はディスプレイ８７５を含み、ディスプレイ８７５は、例えば、出口ポート８３１を通って流れた体液の体積に関連する視覚的インジケータ及び／又は情報を使用者に提供することができる。他の実施形態では、流量計量デバイスを、分流機構８２０内の又はそれに沿った他のあらゆる好適な位置に配置することができる。

【０１０８】

[1161] 結合部分８２４を、中間部分８２３に物理的にかつ流体的に結合することができる。例えば、いくつかの実施形態では、結合部分８２４を、中間部分８２３の内部空間８０７内に部分的に配置し、それに、摩擦嵌め、圧入、スナップフィット、ねじ結合、接着剤等を介して少なくとも一時的に結合することができる。結合部分８２４は、詳細に上述したように、サンプルリザーバ８８０の一部を受け入れるように構成されており、サンプルリザーバ８８０の真空シールに穴をあけ、それにより体液の流れを開始することができるように使用することができる穿孔部材８５５を含む。

【０１０９】

[1162] 収集デバイス８００の流量コントローラ８４０は、アクチュエータ部分８２２によって規定された内部空間８０６内に少なくとも部分的に配置され、第１形態、第２形態及び第３形態の間で移動可能である。図４２及び図４３に示すように、流量コントローラ８４０は、第１シール部材８６１、第２シール部材８６２及び第３シール部材８６３を有する可動部材８５０と、付勢部材８５９（例えば、ばね等）とを含む。シール部材８６１、８６２及び８６３は、内部空間８０６を規定するアクチュエータ部分８２２の内面と接触している。従って、本明細書においてさらに詳細に記載するように、シール部材８６１、８６２及び８６３は各々、例えばアクチュエータ部分８２２の内部空間８０６を流体的に隔離された部分に分割することができる内面と、実質的流体密封シールを形成することができる。

【０１１０】

[1163] 可動部材８５０は、内部空間８０６内で第１位置、第２位置及び第３位置の間で移動可能である。可動部材８５０の配置は、可動部材８５０がその第１位置、第２位置及び第３位置の間で移動する際に、シール部材８６１、８６２及び８６３が内部空間８０６内で選択的に移動する、というものであり得る。より具体的には、可動部材８５０がその第１位置、第２位置及び第３位置の間で移動する際、第１シール部材８６１を可動部材８５０と同時に移動させることができる。第２シール部材８６２及び第３シール部材８６３を、互いに固定して結合し（例えば、互いに固定距離で配置し）、可動部材８５０の一部の周囲に摺動可能に配置することができ、それにより、可動部材８５０は、第２シール部材８６２及び第３シール部材８６３がアクチュエータ部分８２２に対して実質的固定位置にあり続ける間に、その第１位置（例えば、図４３を参照）からその第２位置（例えば、図４４を参照）に移動することを可能にすることができる。例えば、可動部材８５０がその第１位置と第２位置との間で移動する際、第２シール部材８６２及び第３シール部材８６３は、実質的固定位置にあり続けることができ、それにより、入口ポート８２１は第２シール部材８６２の第１側に配置され、出口ポート８３１は、第２シール部材８６２の第１側とは反対側の第２側に配置される。従って、本明細書においてさらに詳細に記載するように、可動部材８５０がその第１位置（図４３）及びその第２位置（図４４）にある時、入口ポート８２１は、第１シール部材８６１と第２シール部材８６２との間に規定された内部空間８０６の部分に流体連通しており、出口ポートは、第２シール部材８６２と第３シール部材８６３との間に規定された内部空間８０６の部分に流体連通している。

【０１１１】

[1164] 流量コントローラ８４０の配置は、可動部材８５０がその第１位置からその第２位置に移動した時に、第１シール部材８６１が第２シール部材８６２及び第３シール部材８６３に対して移動する、というものであり得る。第２シール部材８６２に対する第１シール部材８６１の移動により、それらの間に規定された空間が拡大することが可能であり、それにより、プリサンプルリザーバ８７０を形成し及び／又は他の方法で規定することができる。さらに、シール部材８６１及び８６２がアクチュエータ部分８２２の内面と実質的流体密封シールを形成していることにより、第１シール部材８６１と第２シール部材８６２との間に規定されたプリサンプルリザーバ８７０は、内部空間８０６の他の部分から流体的に隔離される。従って、可動部材８５０がその第１位置からその第２位置に移動する時、入口ポート８２１はプリサンプルリザーバ８７０に流体連通することができる。可動部材８５０がその第２位置（例えば、図４４を参照）からその第３位置（例えば、図４５を参照）まで移動する時、可動部材８５０の一部は第３シール部材８６３と接触して、内部空間８０６内で第１シール部材８６１、第２シール部材８６２及び第３シール部材８６３を実質的に同時に移動させることができる。従って、本明細書においてさらに詳細に記載するように、入口ポート８２１及び出口ポート８３１の両方が、第２シール部材８６２と第３シール部材８６３との間に規定された内部空間８０６の部分に流体連通するように、第２シール部材８６２を入口ポート８２１に対して移動させることができる。

【０１１２】

[1165] 動作時、収集デバイス８００を用いて、汚染を低減して患者から体液（例えば、血液、血漿、尿等）を収集することができる。例えば、収集デバイス８００の入口ポート８２１を、針又は他の内腔規定デバイス（例えば、可撓性滅菌管）に流体的に結合することができる。入口ポート８２１が内腔規定デバイスに結合された状態で、流量コントローラ８４０をその第１形態からその第２形態に移動させることができる。このように、使用者は、図４４において矢印ＭＭによって示すように、可動部材８５０をその第１位置からその第２位置に移動させるように力をかけることができる。上述したように、第１シール部材８６１は、可動部材８５０と同時に移動し、それによって、第１シール部材８６１と第２シール部材８６２との間に規定された空間が拡大し、それにより、プリサンプルリザーバ８７０が形成され及び／又は規定される。第１シール部材８６１及び第２シール部材８６２が、内部空間８０６を規定するアクチュエータ部分８２２の内面と実質的流体密封シールを形成していることにより、第１シール部材８６１と第２シール部材８６２との間の容積の増大によって、プリサンプリリザーバ８７０内に負圧がもたらされる。従って、患者の身体の一部（例えば、静脈）とプリサンプルリザーバ８７０との間に（例えば、図４４における入口ポート８２１を介して）流体連通が確立されると、図４４において矢印ＮＮによって示すように、プリサンプルリザーバ８７０と患者の身体のその部分との間の負圧の差により、入口ポート８２１を通してプリサンプルリザーバ８７０内に体液が引き込まれる。この第１形態では、流量コントローラ８４０はまた、プリサンプルリザーバ８７０を出口ポート８３１から流体的に隔離する。従って、体液の第１量（所定量又は未定量）を、（例えば）静脈穿刺の直後にプリサンプルリザーバ８７０内に受け取り、後続するサンプルから隔離することができる。このように、収集デバイス８００を用いて、体表微生物及び／又は他の望ましくない外部汚染物質を含む可能性が最も高い体液の第１量が、診断又は汚染物質によって影響を受ける可能性がある他の検査のために収集されかつ使用される体液サンプルの後続する量を汚染するのを防止することができる。いくつかの実施形態では、計量デバイスは、プリサンプルリザーバ８７０内に配置された体液の体積を計量し、その体積に関連する値をディスプレイ８７５に提示することができる。

【０１１３】

[1166] プリサンプルリザーバ８７０内における体液プリサンプルの体積の収集に続き、図４５において矢印ＯＯによって示すように、可動部材８５０をその第２位置からその第３位置に移動させて、流量コントローラを第３形態に配置することができる。上述したように、可動部材８５０がその第２位置からその第３位置に移動すると、可動部材８５０の部分は、第３シール部材８６３と接触するように配置される。従って、可動部材８５０は、内部空間８０６内で、第１シール部材８６１、第２シール部材８６２及び第３シール部材８６３を実質的に同時に移動させる。従って、入口ポート８２１及び出口ポート８３１両方が、第２シール部材８６２と第３シール部材８６３との間に規定された内部空間８０６の部分に流体連通するように、第２シール部材８６２を、入口ポート８２１に対して移動させることができる。さらに、体液の体積がプリサンプルリザーバ８７０内で流体的に隔離されているため、第２シール部材８６２及び第３シール部材８６３の第１シール部材８６１の方向における移動が制限される（すなわち、体液は実質的に非圧縮性流体である）。このように、体液のプリサンプル体積は、プリサンプルリザーバ８７０内で封鎖（sequester）され、第２シール部材８６２と第３シール部材８６３との間に規定された空間は、入口ポート８２１と出口ポート８３１との間に流体流路を規定する。さらに、流量コントローラ８４０の配置は、その第３形態にある時、第１シール部材８６１が付勢部材８５９と接触するように配置され、使用者により可動部材８５０にかけられる力の少なくとも一部が、付勢部材８５９を変形させ、圧縮し、屈曲させ及び／又は他の方法で再構成するように動作可能である、というものである。従って、付勢部材８５９は、本明細書においてさらに詳細に記載するように、第１シール部材８６１に対して、流量コントローラ８４０のその第２形態からその第３形態への移動に抵抗する反力を及ぼすことができる。

【０１１４】

[1167] 詳細に上述したように、穿孔部材８５５が、サンプルリザーバ８８０の真空シー

ルに穴をあけてサンプルリザーバ内部に配置されるように、サンプルリザーバ８８０を収集デバイス８００に対して配置することができる。サンプルリザーバ８８０（例えば、真空又は負圧）と身体のその部分との間の圧力差により、体液がサンプルリザーバ８８０内に引き込まれる。言い換えれば、第２形態では、流量コントローラ８４０及び分流機構８２０は、図４５において矢印ＰＰによって示すように、体液を、患者から、入口ポート８２１、第２シール部材８６２と第３シール部材８６３との間に規定された内部空間８０６の部分、及びアクチュエータ部分８２２の出口ポート８３１を通って、中間部分８２３及び結合部分８２４の穿孔部材８５５を通って、サンプルリザーバ８８０内に引き込むことができるように、流体流路を確立する。上述したように、（図示せず）計量デバイスが、例えば出口ポート８３１を通して移送される体液の体積を計量することができ、体液の体積に関連する値をディスプレイ８７５に提示することができる。

【０１１５】

[1168] サンプルリザーバ８８０内に体液の所望の体積（例えば、第２量）が収集されると、使用者は、可動部材８５０にかけられた力を取り除き及び／又は低減することができ、それにより、付勢部材８５９が、第１シール部材８６１及び可動部材８５０をそれらの第３位置からそれらの第２位置に向かって移動させることができる。さらに、プリサンプルリザーバ８７０内に配置された体液が実質的に非圧縮性であることにより、第１シール部材８６１の移動が、体液の体積を通して力を移送し、第２シール部材８６２及び第３シール部材８６３をそれらの第３位置からそれらの第２位置に向かって移動させる。いくつかの実施形態では、付勢部材８５９は、第２シール部材８６２をアクチュエータ部分８２２に対して例えば入口ポート８２１を実質的に遮断することができる第４位置に移動させるように作用可能であり得る力を、第１シール部材８６１にかけることができる。従って、入口ポート８２１を、アクチュエータ部分８２２の内部空間８０６から流体的に隔離することができる。さらに、穿孔部材８５５をサンプルリザーバ８８０から取り除くことができ、シール（例えば、自己封止膜）が、体液サンプルをサンプルリザーバ８８０の外側の空間から流体的に隔離することができる。後続するサンプルリザーバの充填を、穿孔部材８５５をサンプルリザーバ内に配置し、流量コントローラ８４０を第３形態まで移動させて体液が患者からサンプルリザーバに流れるのを可能にすることによって、同様に行うことができる。

【０１１６】

[1169] 図４６～図５３は、実施形態による収集デバイス９００を示す。収集デバイス９００は、分流機構９２０、流量コントローラ９４０及びサンプルリザーバ９８０、９８０’、９９０及び９９０’を含む。本明細書においてさらに記載するように、収集デバイス９００を、第１形態、第２形態、第３形態、第４形態及び第５形態の間で移動させて、例えば、皮膚に存在する微生物及び／又は他の望ましくない外部汚染物質等、体外の微生物が実質的にない体液の流れを送出することができる。収集デバイス９００は、あらゆる好適な形状、サイズ又は構成であり得る。例えば、収集デバイス９００の態様及び／又は部分は、上述した収集デバイス１００、２００、３００、４００、５００、６００、７００及び／又は８００のいずれかの対応する態様及び／又は部分と形態及び／又は機能が実質的に同様であり得る。従って、こうした同様の態様及び／部分については、本明細書ではそれ以上詳細に記載しない。例として、いくつかの実施形態では、収集デバイス９００のサンプルリザーバ９８０、９８０’、９９０及び９９０’は、図２６～図３３の収集デバイス６００に含まれる、サンプルリザーバ６８０、６８０’、６９０及び６９０’と形態及び機能が実質的に同様であり及び／又は同じであり得る。

【０１１７】

[1170] 分流機構９２０は、ハウジング９０１、分配部材９２９並びに可動部材９５０ａ、９５０ｂ、９５０ｃ及び９５０ｄを含む。ハウジング９０１は、分配部材９２９に物理的にかつ流体的に結合されており、患者から体液を収集する一組の流体流経路を提供し及び／又は規定している。ハウジング９０１は、本明細書においてさらに詳細に記載するように、流量計量デバイスに含め及び／又は他の方法で（例えば、電気的に及び／又は機械

的に）結合することができる一組のディスプレイ９７５’（例えば、液晶ディスプレイ（ＬＣＤ）等）を含む。ハウジング９０１は、凹部９６６、出口開口部９０３ａ、９０３ｂ、９０３ｃ、９０３ｄ、９０３ｅ及び（本明細書において「開口」とも呼ぶ）可動部材開口９５０ａ、９５０ｂ、９５０ｃ、９５０ｄを規定している。凹部９６６は、本明細書においてさらに詳細に記載するように、流量コントローラ９４０に含まれるシール部材９４１を受け入れるように構成されている。第１出口開口部９０３ａ、第２出口開口部９０３ｂ、第３出口開口部９０３ｃ、第４出口開口部９０３ｄ及び第５出口開口部９０３ｅは、各々、分配部材９２９の異なる部分に流体連通している異なる流体流路を規定するように構成されている。より具体的には、分配部材９２９は、第１出口開口部９０３ａに流体連通しているプリサンプルリザーバ９７０の少なくとも一部と、第２出口開口部９０３ｂに流体連通している第１流路９３５ａ、第３出口開口部９０３ｂに流体連通している第２流路９３５ｂ、第４出口開口部９０３ｄに流体連通している第３流路９３５ｃ、第５出口開口部９０３ｅに流体連通している第４流路９３５とを規定し及び／又は形成している。

【０１１８】

[1171] 図４７及び図４８に示すように、分配部材９２９は、プリサンプルリザーバ９７０の少なくとも一部を規定するチャンバ又は空間を規定している。プリサンプルリザーバ９７０は、例えば、血液、血漿、尿等の体液を収容するように構成されている。図１６～図２２においてプリサンプルリザーバ４７０に関して詳細に上述したように、プリサンプルリザーバ９７０が患者から体液の流れを受け取るのを可能にするように、ハウジング９０１の第１出口開口部９０３ａを、プリサンプルリザーバ９７０の開放部分と実質的に位置合せすることができる。流路９３５ａ～９３５ｄは、分配部材９２９の中心から放射状に延在し、各流路９３５ａ、９３５ｂ、９３５ｃ及び９３５ｄがプリサンプルリザーバ９７０及び他の流路から流体的に隔離されるように配置されている。このように、流路９３５ａ、９３５ｂ、９３５ｃ及び９３５ｄは、出口開口部９０３ｂ、９０３ｃ、９３０ｄ及び９０３ｅそれぞれと実質的に位置合せされた開口を規定する第１端部と、可動部材９５０ａ、９５０ｂ、９５０ｃ及び９５０ｄそれぞれを受け入れるように構成された開口又はポートを規定する第２端部との間で、流体流路を方向付け及び／又は他の方法で規定することができる。図４７及び図４８において、分配部材９２９は、実質的に閉鎖されている流路９３５ａ～９３５ｄを含むものとして示されているが、他の実施形態では、図１７及び図１８の分配部材４２９に関して上に示しかつ記載したように、流路９３５ａ～９３５ｄを実質的に開放することができる。従って、収集デバイス９００の分配部材９２９は、収集デバイス４００の分配部材４２９と実質的に同様に機能することができる。

【０１１９】

[1172] 可動部材９５０ａ、９５０ｂ、９５０ｃ及び９５０ｄは、ハウジング９０１の開口９０５ａ、９０５ｂ、９０５ｃ及び９０５ｄそれぞれと、分配部材９２９の第２端部によって規定される対応する開口とに移動可能に配置される。図４６～図５３には示さないが、いくつかの実施形態では、可動部材９５０ａ、９５０ｂ、９５０ｃ及び９５０ｄを、収集デバイス２００の可動部材２５０及び２５０’に関して詳細に上述したように、付勢部材等に動作可能に結合することができる。このように、可動部材９５０ａ、９５０ｂ、９５０ｃ及び９５０ｄを、使用者が、ハウジング９０１及び分配部材９２９に対して第１位置及び第２位置から作動させ（移動させ）て、流体流を第１サンプルリザーバ９８０、第２流体リザーバ９８０’、第３流体リザーバ９９０及び第４サンプルリザーバ９９０’それぞれの中に仕向けることができる。可動部材９５０ａ、９５０ｂ、９５０ｃ及び９５０ｄは、実質的に同じであり、従って、図４９において単一の可動部材９５０に関して記載する。さらに、可動部材９５０のいくつかの部分は、上述した可動部材２５０及び３５０と実質的に同様であり得る。従って、可動部材９５０のいくつかの部分については、本明細書においてそれ以上詳細に説明しない。可動部材９５０は、入口ポート９５３及び穿孔部材９５５に流体連通している内部空洞９５２を規定している。穿孔部材は、詳細に上述したものと実質的に同様である。入口ポート９５３は、一組の壁を通して延在し、一組の壁は、可動部材９５０の内部空間９５２を対応する流路９３５ａ、９３５ｂ、９３５ｃ

又は９３５ｄに流体連通するように選択的に配置するように内部チャンバ９５２を規定している。

【０１２０】

[1173] 図４９に示すように、可動部材９５０は、内部空間９５２内に回転可能に配置されかつ入口ポート９５３と実質的に直接流体連通している流量制御機構９６７を含む。流量計量機構９６７は、例えば、一組のスポーク又はフィンを含むことができるホイール等であり得る。このように、体液は、可動部材９５０の入口ポート９５３に入り、流量計量デバイス９６７を通過して流れることができ、それにより、流量計量デバイス９６７が可動部材９５０に対して回転することができる。従って、流量計量デバイス９６７の回転の特徴は、可動部材９５０の内部空間９５２に移送される体液の体積、体積流量等を求める際に使用可能であり得る。図４６～図５３には示さないが、可動部材９５０の流量制御機構９６７は、ハウジング９０１のディスプレイ９７５’に動作可能に結合される。従って、体液が、例えばサンプルリザーバ９８０、９８０’、９９０及び／又は９９０’に移送される際、体液の流れに関連する体積情報をディスプレイ９７５’に提示することができる。このように、使用者は、患者から体液サンプルを収集するように収集デバイス９００を操作することができ、例えばサンプルリザーバ９８０に移送される体液サンプルの正確な体積を求めるためにディスプレイ９７５’の少なくとも１つを視覚化することができる。

【０１２１】

[1174] 収集デバイス９００の流量コントローラ９４０は、ダイヤル９４５及びシール部材９４１を含む。シール部材９４１は、ハウジング９０１の凹部９６６内に配置される。より詳細には、シール部材９４１が、凹部９６６を規定するハウジング９０１の表面とダイヤル９４５の表面との間にかつそれらと接触するように配置されるように、流量コントローラ９４０をハウジング９０１に結合することができる。本明細書において詳細に記載するように、シール部材９４１を、ダイヤル９４５の表面及び凹部９６６を規定するハウジング９０１の表面と実質的流体密封シールを形成するように構成することができる。図４７に示すように、シール部材９４１は、第１開口部９４４ａ、第２開口部９４４ｂ、第３開口部９４４ｃ、第４開口部９４４ｄ及び第５開口部９４４ｅを規定している。シール部材９４１の配置は、シール部材９４１が凹部９６６内に配置されると、第１開口部９４４ａ、第２開口部９４４ｂ、第３開口部９４４ｃ、第４開口部９４４ｄ及び第５開口部９４４ｅが、ハウジング９０１の第１出口開口部９０３ａ、第２出口開口部９０３ｂ、第３出口開口部９０３ｃ、第４出口開口部９０３ｄ及び第５出口開口部９０３ｅそれぞれと実質的に位置合せされる、というものである。

【０１２２】

[1175] 流量コントローラ９４０のダイヤル９４５は、ハウジング９０１に回転可能に結合され、ハウジング９０１に対して第１位置、第２位置、第３位置、第４位置及び第５位置の間で移動可能である。ダイヤル９４５は入口ポート９２１を含み、入口ポート９２１を、患者から体液を抜き取り及び／又は収集デバイス９００に輸送するための流体流経路を規定する医療デバイスに（直接又はアダプタ９０４を介して間接的に）流体的に結合することができる。このように、入口ポート９２１を、本明細書においてさらに詳細に記載するように、プリサンプルリザーバ９７０、第１サンプルリザーバ９８０、第２サンプルリザーバ９８０’、第３サンプルリザーバ９９０及び第４サンプルリザーバ９９０’を患者に流体連通するように選択的に配置するように構成することができる。ダイヤル９４５を、収集デバイス４００のダイヤル４４５に関して上述したものと実質的に同様な方法で、第１位置、第２位置、第３位置、第４位置及び第５位置を通して回転するように構成することができ、従って、それについては本明細書においてそれ以上詳細に記載しない。

【０１２３】

[1176] 図示するように、ダイヤル９４５は、体液の流れに関連する体積情報を提示するように構成することができるディスプレイ９７５をさらに含むことができる。例えば、図４６～図５３には示さないが、ダイヤルは、可動部材９５０に含まれる流量計量デバイス

９６７等、流量計量デバイス等を含むことができる。このように、流量計量デバイスは、例えば入口ポート９２１を通る体液の流れを計量することができ、入口ポート９２１を通る体液の流れに関連する体積情報がダイヤル９４５のディスプレイ９７５に提示されるように、ディスプレイ９７５に動作可能に結合され得る。

【０１２４】

[1177] 動作時、収集デバイス９００を用いて、汚染を低減して患者から体液（例えば、血液、血漿、尿等）を収集することができる。例えば、収集デバイス９００の入口ポート９２１を、針又は他の内腔規定デバイス（例えば、可撓性滅菌管）に流体的に結合することができる。静脈穿刺（又は、体液にアクセスする他の方法）に続き、図５０及び図５１に示すように、ダイヤル９４５は、第１位置に達するまで駆動される（又は回される）。別法として、ダイヤル９４５を第１位置に事前設定することができ、収集デバイス９００の無菌状態を維持するように、収集デバイス９００を他の方法で封止することができる。

【０１２５】

[1178] 上述したように、ダイヤル９４５が第１位置にある時、流量コントローラ９４０は第１形態に配置され、シール部材９４１の第１開口部９４４ａは、入口ポート９２１を４つの流路９３５ａ～３３５ｄから流体的に隔離しながら、（ハウジング９０１内に含まれる）入口ポート９２１と第１出口ポート９３０との間に流体連通を確立する。さらに、サンプルリザーバ９８０、９８０’、９９０及び９９０’は、第１形態では入口ポート９２１から流体的に隔離されており、図５１において矢印ＱＱによって示すように、患者の身体の一部（例えば、静脈）とプリサンプルリザーバ９７０との間に、流体流路が規定される。この第１形態では、体液は、（例えば、重力、真空等により）、患者の身体のその部分から、入口ポート９２１、シール部材９４１の第１開口部９４４ａ、ハウジング９０１の第１出口ポート９０３ａを通って、プリサンプルリザーバ９７０内に流れ込む。第１形態では、流量コントローラ９４０はまた、流路９３５ａ～９３５ｄからプリサンプルリザーバ９７０を流体的に隔離する。従って、体液の第１量（所定量又は未定量）を、静脈穿刺の直後にプリサンプルリザーバ９７０内に受け取り、後続するサンプルから隔離することができる。このように、収集デバイス９００を用いて、体表微生物及び／又は他の望ましくない汚染物質を含む可能性が最も高い体液の第１量が、診断又は汚染物質によって影響を受ける可能性がある他の検査に対して収集されかつ使用される体液サンプルの後続する量を汚染しないようにすることができる。さらに、ディスプレイ９７５は、例えば、プリサンプルリザーバ９７０に移送される体液の体積に関連する、（図示せず）流量制御機構から受け取られる情報を提示することができる。従って、体液の正確な体積を、プリサンプルリザーバに移送し、かつその中で流体的に隔離することができる。

【０１２６】

[1179] プリサンプルリザーバ９７０内における体液プリサンプルの収集に続き、図５２及び図５３に示すように、ダイヤル９４５を、第２位置に達するまで作動させる（又は回転させる）ことができる。ダイヤル９４５が第２位置にある時、流量コントローラ９４０は第２形態に配置され、シール部材９４１の第２開口部９４４ｂは、プリサンプルリザーバ９７０を入口ポート９２１から流体的に隔離しながら、入口ポート９２１と流路９３５ａとの間に流体連通を確立する。流量コントローラ９４０が第２形態にある状態で、可動部材９５０ａを、使用者が第１位置から第２位置に作動させて（すなわち押下して）、患者（例えば、静脈）と第１サンプルリザーバ８８０との間に流体連通を確立することができる。より具体的には、図５３において矢印ＲＲによって示すように、可動部材９５０は、その第１位置からその第２位置に移動して、穿孔部材９５５が、第１サンプルリザーバ９８０の真空シールを通過して第１サンプルリザーバ９８０内に配置されるようにする。

【０１２７】

[1180] 第２位置にある間、可動部材９５０の入口ポート９５３は、第１流路９３５ａと実質的に位置合せされかつ流体連通し、それにより、体液が、第１流路９３５ａから稼働部材９５０の内部空洞９５２内に入り、穿孔部材９５５から出て第１サンプルリザーバ９８０に入るように流れることができる。サンプルリザーバ９８０（例えば、真空又は負圧

）と第１流路９３５ａとの圧力差により、サンプルリザーバ９８０内に体液が引き込まれる。言い換えれば、第２形態では、図５３において矢印ＳＳによって示すように、流量コントローラ９４０及び可動部材９５０ａは、ダイヤル９４５の入口ポート９２１と第１サンプルリザーバ９８０との間に流体流路を確立する。さらに、体液の可動部材９５０ａを通る流れにより、可動部材９５０に対して流量計量機構９６７が回転する。従って、流量計量機構９６７の回転は、サンプルリザーバ９８０に移送される体液サンプルの体積を求める際に使用可能であり得る。さらに、ディスプレイ９７５’は、例えば、サンプルリザーバ９８０に移送される体液の体積に関連する、流量制御機構９６７から受け取られる情報を提示することができる。従って、体液の正確な体積をサンプルリザーバ９８０に移送することができる。例えば、場合によっては、収集デバイス９００を用いて、第１サンプルリザーバ９８０、第２サンプルリザーバ９８０’及び第３サンプルリザーバ９９０の各々に２０ｍＬの３つのサンプル体積を収集する（すなわち、合計６０ｍＬのサンプル体積が収集される）ことができる。

【０１２８】

[1181] 第１サンプルリザーバ９８０内に体液の所望の体積（例えば、第２量）が収集されると、使用者は、可動部材９５０を解放して、（図示せず）付勢部材がその第１位置に戻るように移動するのを可能にすることができる。可動部材９５０がその第１位置に戻ると、穿孔部材９５５は、第１サンプルリザーバ９８０から取り除かれ、シール（例えば、自己封止膜）が、第１サンプルリザーバ９８０を内部流路９３５から流体的に隔離する。収集デバイス９００を用いて、ダイヤル９４５をその第３位置、第４位置及び第５位置までそれぞれ回転させることにより、第２サンプル体積を第２サンプルリザーバ９８０’に、第３サンプル体積を第３サンプルリザーバ９９０に、第４サンプル体積を第４サンプルリザーバ９９０’に、同様に移送することができる。

【０１２９】

[1182] 場合によっては、体液収集デバイス９００により、臨床医及び／又は瀉血専門医は、体液収集デバイス９００を収容するパッケージを開封し、（分配部材９２９を含む）ハウジング９０１のみを取り出し、ハウジング９０１を患者のベッドわきに持って行くことができる。臨床医及び／又は瀉血専門医は、あらゆる標準化技法を用いて患者の身体の一部（例えば、静脈）に対して静脈穿刺を行う（又は、患者の体液にアクセスする他のあらゆる方法を採用する）ことができる。静脈穿刺に続き、臨床医及び／又は瀉血専門医は、すべてのサンプルに対して必要な総血液体積を収集することができる。例えば、臨床医及び／又は瀉血専門医は、２．５ｍＬプリサンプル分流体積及び４つのサンプルリザーバの各々に対して１０ｍＬサンプル体積を収集することができ、それにより、収集された体液（例えば、血液）は合計４２．５ｍＬになる。体液の所望の量の収集に続き、皮下注射針を患者の身体のその部分（例えば、静脈）から取り除くことができ、臨床医及び／又は瀉血専門医は、（体液を収容している）ハウジング９０１を、膜頂部がハウジング９０１の形状に一致するカスタムトレイ内に事前に配置された状態で、４パック（又は２パック）の事前滅菌されたサンプルリザーバの上に配置することができる。サンプルリザーバのこうした事前滅菌されたパックを使用することにより、臨床医は、滅菌剤を用いてサンプルリザーバの頂部を「拭く」プロセスステップを行う必要がなく、それにより、例えば、リザーバ頂部の滅菌が不適切及び／又は不十分である場合に、汚染の可能性が低減する。そして、臨床医及び／又は瀉血専門医は、体液を含むサンプルリザーバの自動接種を正確な体積制御で起動させることができる。いくつかの実施形態では、サンプルリザーバの接種が完了した後、各個々のサンプルリザーバに対して体積情報が表示されているデバイス９００全体を、分析のために研究室に送ることができる。他の実施形態では、サンプルリザーバ９８０及び／又は９９０を個々に取り除き、分析のために研究室に送ることができる。

【０１３０】

[1183] 収集デバイス９００を、図４６～図５３を参照して、収集デバイスの一部を通して移送される体液の体積に関する体積データを提示することができる一組のディスプレイ

９７５及び９７５’を含むものとして示し記載しているが、他の実施形態では、収集デバイスは、あらゆる好適な出力インジケータを有するあらゆる好適な流量計量機構を含むことができる。例えば、図５４及び図５５は、実施形態による分流機構１０２０及び流量コントローラ１０４０を示す。分流機構１０２０及び流量コントローラ１０４０は、分流機構９２０及び流量コントローラ９４０それぞれと形態及び機能が実質的に同様であり得る。従って、同様の部分については本明細書ではそれ以上記載しない。しかしながら、分流機構１０２０及び流量コントローラ１０４０は、一組のディスプレイ１０７５の配置が異なる可能性がある。例えば、分流機構１０２０は、可動部材９５０に関して上述したよう、各々が流量計量機構を含むことができる一組の可動部材１０５０ａ、１０５０ｂ、１０５０ｃ及び１０５０ｄを移動可能に受け入れるように構成されるハウジング１００１を含む。従って、可動部材１０５０ａ、１０５０ｂ、１０５０ｃ及び１０５０ｄを用いて、それらを通して移送される体液の正確な体積を求めることができる。図５５に示すように、ハウジング１００１のディスプレイ１０７５は、小さい体積（例えば、５ｍＬ）の第１照明、中間の体積（例えば、２０ｍＬ）に関連する第２照明、及び許容可能な及び／又は大きい体積（例えば、４０ｍＬ）に関連する第３照明を含む３つの照明の組を含むことができる。このように、体液の流れが流量コントローラ１０４０及び分流機構１０２０を通して、例えば第１可動部材１０５０ａ内に移送される際、その中に含まれる流量計量機構は、信号等をディスプレイに送信することができ、ディスプレイは、可動部材１０５０を通して移送される体液の体積に従って第１照明、第２照明及び／又は第３照明を点灯するように動作可能である。

【０１３１】

[1184] 他の実施形態では、可動部材１０５０ａ、１０５０ｂ、１０５０ｃ及び１０５０ｄを、ハウジング１００１に対して第１位置から第２位置、第３位置又は第４位置に移動させることができる。こうした実施形態では、それらの位置を、例えば、サンプルリザーバに移送される体液の意図された体積に関連付けることができる。例えば、いくつかの実施形態では、使用者は、可動部材１０５０ａをその第１位置からその第２位置に作動させる（例えば、移動させる）ことができる。こうした実施形態では、第２位置を、例えば、サンプルリザーバに移送される体液の小さい体積（例えば、１０ｍＬ）に関連付けることができる。いくつかの実施形態では、ハウジング１００１及び／又は可動部材１０５０ａは、サンプルの低い体積量がサンプルリザーバに移送されるまで、可動部材１０５０ａを第２位置で一時的に保持することができる、戻り止め、ロック、留め具、突起、凹部等を含むことができる。さらに、第２位置に配置されると、ディスプレイ１０７５を、サンプルリザーバに移送される体液の事前設定された体積を使用者に示すように、小さい体積に関連する第１照明を照明するように構成することができる。体液の所望の体積がサンプルリザーバに移送されかつその中で流体的に隔離されると、分流機構１０２０を、可動部材１０５０ａをその第１位置に自動的に戻すように構成することができる。このように、分流機構１０２０及び流量コントローラ１０４０を、あらゆる数のサンプルリザーバに物理的にかつ流体的に結合し、各サンプルリザーバに体液の正確な体積を移送するように使用することができる。

【０１３２】

[1185] 図５６は、流量計量移送デバイスを用いて患者から体液の所定サンプル体積を取得する方法１１９０を示すフローチャートである。流量計量移送デバイスは、（本明細書において「収集デバイス」とも呼ぶ）本明細書に記載する移送デバイスのいずれでもあり得る。例として、いくつかの実施形態では、移送デバイスは、図４６～図５３を参照して上述した収集デバイス９００であり得る。従って、移送デバイスは、患者に流体連通するように選択的に配置されるように構成された入口ポートと、プリサンプルリザーバ及びサンプルリザーバと、患者からプリサンプルリザーバへの体液の流れ及びサンプルリザーバへの体液の流れを計量するように構成された流量計量機構とを含むことができる。方法１１９０は、１１９１において、患者と流量計量移送デバイスのポートとの間に流体連通を確立することを含む。例えば、ポートを針又は他の内腔規定デバイス（例えば、可撓性滅

菌管）に流体的に結合することができ、針又は他の内腔規定デバイスを、患者の体内に挿入することができる（例えば、静脈穿刺事象又は体液にアクセスする他の方法）。

【０１３３】

[1186] ポートが患者に流体連通している状態で、１１９２において、ポートとプリサンプルリザーバとの間の流体連通を確立する。いくつかの実施形態では、流量計量移送デバイスは流量コントローラ等（例えば、収集デバイス９００に含まれる流量コントローラ９４０等）を含むことができ、それを、ポートとプリサンプルリザーバとの間に流体連通を確立する位置（例えば、第１位置）まで作動させ及び／又は操作する（例えば、回転させる）ことができる。いくつかの実施形態では、流量コントローラの作動により、流量コントローラ及び分流機構は、ポートとプリサンプルリザーバとの間の流体流路の少なくとも一部をまとめて規定するようにすることができる。いくつかの実施形態では、プリサンプルリザーバは、患者からプリサンプルリザーバへの体液の流れを開始することができる負圧等を含むことができる。他の実施形態では、体液の流れを、他のあらゆる好適な方法（例えば、重力等）で開始することができる。

【０１３４】

[1187] １１９３において、患者からプリサンプルリザーバに移送された体液の流れを計量する。例えば、いくつかの実施形態では、ポートは、（例えば、収集デバイス９００の流量制御機構９６７に関して上述したものと同様の方法で）ポートを通過する体液の流れを計量することができる流量制御機構を含むことができる。従って、体液のプリサンプル体積がプリサンプルリザーバに移送される。方法１１９０は、１１９４において、流量計量移送デバイスの流量計量機構を介して、プリサンプルリザーバ内に配置された体液のプリサンプル体積が体液の所定プリサンプル体積であることを検証することを含む。例えば、流量計量機構は、ディスプレイ等（例えば、収集デバイス９００のディスプレイ９７５及び／又は９７５’）を含むことができ、及び／又はディスプレイ等に動作可能に結合され得る。流量計量機構を、上述したように、ディスプレイに体積情報を提示するように構成することができる。

【０１３５】

[1188] プリサンプルリザーバ内に体液のプリサンプル体積が配置されると、１１９５において、プリサンプルリザーバをポートから流体的に隔離して、プリサンプルリザーバ内で体液のプリサンプル体積を封鎖する。例えば、場合によっては、流量コントローラ及び／又は分流機構を、第１位置及び／又は第１形態から第２位置及び／又は第２形態に作動させる（又は回転させる）ことができる。流量コントローラ及び／又は分流機構が第２形態にある場合、プリサンプルリザーバは、プリサンプルリザーバの外部の空間から流体的に隔離される。いくつかの実施形態では、流量コントローラ及び／又は分流機構がその第２位置及び／又は第２形態に駆動されると、１１９６において、ポートとサンプルリザーバとの間に流体連通を確立する。例えば、いくつかの実施形態では、流量計量移送デバイスは、サンプルリザーバの一部（例えば、膜等）を穿孔するように構成された穿孔部材を含むことができる、可動部材（例えば可動部材９５０）等を含むことができる。従って、流量コントローラ及び／又は分流機構がその第２位置及び／又は第２形態にある時、サンプルリザーバのその部分の穿孔により、サンプルリザーバがポートに流体連通するように配置される。上述したように、サンプルリザーバは、例えば、患者からサンプルリザーバへの体液の流れを開始することができる負圧等を含むことができる。

【０１３６】

[1189] １１９７において、患者からプリサンプルリザーバに移送された体液の流れを計量する。例えば、上述したように、ポートは、（例えば、収集デバイス９００の流量制御機構９６７に関して上述したものと同様の方法で）ポートを通過する体液の流れを計量することができる流量制御機構を含むことができる。いくつかの実施形態では、流量制御機構を、例えば、図４９の可動部材９５０等の可動部材等に含めることができる。従って、体液のサンプル体積がサンプルリザーバに移送される。方法１１９０は、１１９８において、流量計量移送デバイスの流量計量機構を介して、サンプルリザーバ内に配置された体

液のサンプル体積が体積の所定サンプル体積であることを検証することを含む。例えば、上述したように、ディスプレイ等を、体積情報を提示するように構成することができる。

【０１３７】

[1190] このように、例えば外部に存在する微生物を含む可能性がある、体液の所定プリサンプル体積が収集される。例えば、いくつかの実施形態では、所定プリサンプル体積は、約０．１ｍＬ、約０．３ｍＬ、約０．５ｍＬ、約１．０ｍＬ、約２．０ｍＬ、約３．０ｍＬ、約４．０ｍＬ、約５．０ｍＬ、約１０ｍＬ、約２０ｍＬ、約５０ｍＬ及び／又はそれらの間のあらゆる体積あるいは体積の分数値であり得る。他の実施形態では、プリサンプル体積は、５０ｍＬを超えるか又は０．１ｍＬであり得る。他の実施形態では、所定プリサンプル体積は、約２ｍＬと約５ｍＬとの間であり得る。一実施形態では、所定プリサンプル体積は約３ｍＬであり得る。さらに、所定プリサンプル体積を収集することにより、１つ又は複数のサンプルリザーバ内に配置された所定サンプル体積に、外部に存在する微生物が実質的にないようにすることができる。いくつかの実施形態では、所定サンプル体積は、１０ｍＬと６０ｍＬとの間であり得る。他の実施形態では、所定サンプル体積は、３０ｍＬと６０ｍＬとの間であり得る。さらに他の実施形態では、所定サンプル体積は６０ｍＬであり得る。体液のサンプル体積を単一のサンプルリザーバに移送するものとして上述したが、他の実施形態では、流量計量移送デバイスを用いて、所定サンプル体積を２つ以上のサンプルリザーバに移送することができる。例えば、いくつかの実施形態では、上述したように、体液の所定プリサンプル体積を、プリサンプルリザーバに収集しかつその中で流体的に隔離することができる。プリサンプル体積が流体的に隔離されている状態で、流量計量移送デバイスを用いて、所定サンプル体積を第１サンプルリザーバに、所定サンプル体積を第２サンプルリザーバに、所定サンプル体積を第３サンプルリザーバに移送することができる。こうした場合、所定サンプル体積を例えば２０ｍＬにすることができ、それにより、第１リザーバ、第２リザーバ及び第３リザーバ内に配置される総サンプル体積は６０ｍＬとなる。

【０１３８】

[1191] 本明細書に記載した体液収集デバイスのさまざまな実施形態により、１回の静脈穿刺から２つ（又はそれより多く）の組の体液（例えば、血液）サンプルを収集するのを可能にすることができる。現標準治療では、いくつかの検査（例えば、血液培養）を、（例えば、２回の別個の静脈穿刺を介して、カテーテル＋静脈穿刺及び／又はそれらの組合せを介して）サンプルを別個の独立した体液アクセス点から獲得して行うように求められている。本明細書に記載する実施形態により、単一の体液アクセス点（例えば、静脈穿刺）から所定の診断検査（例えば、血液培養検査）のための複数のサンプルの獲得を容易にすることができ、それにより、これらのサンプルの獲得に必要な静脈穿刺の年間の数を１／２低減させることができる。これは、患者及び医療従事者両方に同様に有利である。静脈穿刺（及び／又は他の血液アクセス処置）の数が低減することにより、大幅に、医療従事者に対する針刺し損傷のリスクを低減させ、これらの処置からもたらされる患者に関連する合併症（例えば、血腫、血栓症、静脈炎、感染症等）を低減させることができる。さらに、体液アクセス処置（例えば、静脈穿刺）の数を低減させることにより、これらの処置に関連する供給品の利用、労力及び廃棄物が低減する。医療制度によって実現されるコストの削減は、重要であり、より効率的な資源の消費とともに、治療計画の展開及び実施を通知するより正確な患者診断をもたらすサンプルの完全性の改善のために患者の転帰の改善を促進する機会を示す。体液収集デバイスはまた、収集後分析からの偽陽性の発生も大幅に低減させる。本明細書に記載する体液収集デバイスはまた、体液収集プロセスを効率化し、手作業によるステップ及び「接触点」の数を低減させ、それにより外部汚染の機会を低減させることも可能である。本明細書に記載するデバイスはまた、検査技師及び／又は瀉血専門医に対する針刺し損傷及び感染のリスクを最小限にすることができる。

【０１３９】

[1192] いくつかの実施形態では、本明細書に記載した体液収集デバイス（例えば、１００、２００、３００、４００、５００、６００、７００、８００及び９００）は、消毒飽

和材料（例えば、ハウジング４０１）を含み及び／又はそれから部分的に形成され得る。現標準は、医療従事者が個々の消毒材料（例えば、イソプロピルアルコール綿棒）を個々のサンプルリザーバ（例えば、４８０、４８０’、４９０及び４９０’）の頂部に配置することに依存する。このプロトコルとのコンプライアンスを確保するために、（例えば）デバイス４００は、デバイス４００内に配置された消毒材料を含むことができ、それにより、図１６に示すように、ハウジング４０１が４パック（又は２パック）のボトルの頂部に配置された時、ハウジング４０１及びサンプルリザーバ４８０、４８０’、４９０、４９０’の頂部からの最初の接触点は、消毒材料である。このように、サンプルリザーバ４８０、４８０’、４９０、４９０’の頂部は、体液がサンプルリザーバ内に接種される前に適切な消毒が適用されることが保証される。

【０１４０】

[1193] さまざまな実施形態について特に示し記載したが、形態及び詳細のさまざまな変更を行うことができる。例えば、ダイヤル４４５（アクチュエータ）を、図１９～図２２を参照して、単一方向に回転するものとして示し記載しているが、他の実施形態では、ダイヤル４４５（アクチュエータ）を、第１方向と第１方向とは反対の第２方向とに回転させることができる。こうした実施形態では、第２方向における回転を、収集デバイスを、あらゆる数の形態を通して移動させるように構成することができる。他の実施形態では、アクチュエータの第２方向における回転を制限することができる。いくつかの実施形態では、ダイヤルは、患者から受け取られる体液の第１体積（すなわち、汚染されたサンプル）を流体的に隔離するように機械的止め具又はロックを含むことができる。言い換えれば、第１リザーバ（プリサンプルリザーバ）に体液の所定体積が充填され、使用者が、追加のサンプルの引込みを開始するようにダイヤル（アクチュエータ）を回転させると、ダイヤル（アクチュエータ）を、（プリサンプルリザーバ内に収容された）第１サンプル体積との流体連通を確立するように戻るように移動させることはできない。

【０１４１】

[1194] いくつかの実施形態について上述したが、それらは、限定としてではなく単に例として提示されていることが理解されるべきである。さまざまな実施形態を、特定の特徴及び／又は構成要素の組合せを含むものとして記載したが、本明細書に記載した実施形態のいずれかからのいずれの特徴及び／又は構成要素のいかなるコンビネーション又はサブコンビネーションを有する他の実施形態が可能である。例えば、図３４～図４０を参照して、収集デバイス７００を、第１形態、第２形態、第３形態、第４形態又は第５形態を有するものとして示し記載しているが、他の実施形態では、本明細書に記載した収集デバイスは、それより多いか又は少ない形態を有することができる。さらに、収集デバイス２００を、図２～図１３を参照して、プリサンプルリザーバ２７０として真空による収集チューブを有するものとして示し記載しているが、他の実施形態では、収集デバイス２００は、分配部材４２９内に収容されたチャンバであるプリサンプルリザーバ４７０を含む、図１６～図２２に提示した実施形態の収集デバイス４００に類似するハウジング２０１内に収容されたチャンバを有することができ、その逆も可能である。

【０１４２】

[1195] さまざまな構成要素の具体的な構成を変更することも可能である。例えば、さまざまな構成要素のサイズ及び具体的な形状は、依然として本明細書に記載するような機能を提供しながら、図示する実施形態とは異なり得る。より具体的には、さまざまな構成要素のサイズ及び形状を、体液流の流体リザーバ内への所望の流量に対して具体的に選択することができる。例えば、図４９において流量計量機構９６７を特に示すが、本明細書に記載した収集デバイスのいずれも、あらゆる好適な流量計量機構とともに使用することができる。例えば、いくつかの実施形態では、収集デバイスは、流量計量機構、及び／又は、例えば、圧力センサ、電圧センサ、光センサ、速度センサ、流量計、歪みゲージ、弁、タービン、浮き、変位分析、密度分析、重量分析、光学分析、超音波分析、熱分析、ドップラ分析、電磁場（ｅｍｆ）分析、反射分析、障害物分析、面積分析、ベンチュリ分析、コリオリ分析、視覚分析並びに／又は他のあらゆる好適なセンサ、分析及び／あるいは計

算（例えば、一例としてボイルの法則、理想気体法則、力計算（力＝質量×加速度）等を適用し及び／又は使用する）等、体液の体積特徴を測定するように構成された、他のあらゆる機構、デバイス又は方法を含むことができる。

【図１】

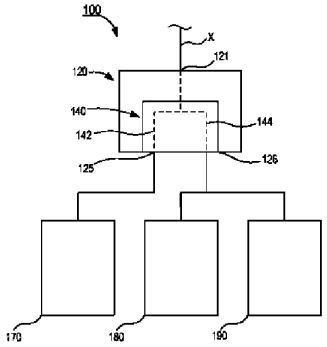


FIG. 1

【図２】

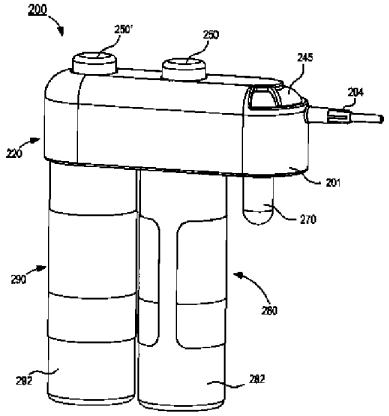


FIG. 2

【図３】

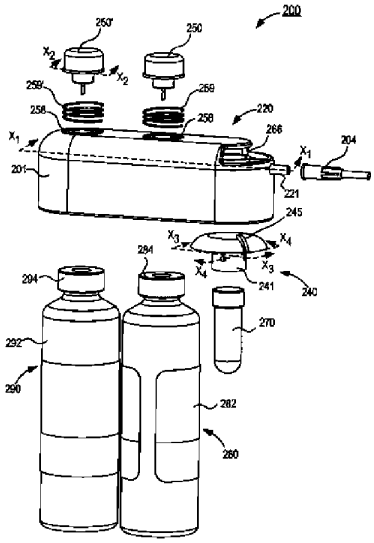


FIG. 3

【図４】

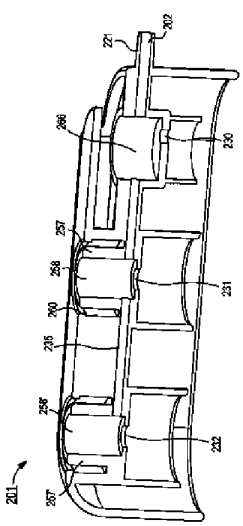


FIG. 4

【図５】

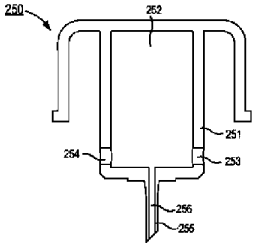


FIG. 5

【図６】

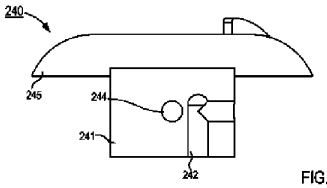


FIG. 6

【図７】

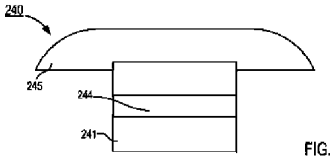


FIG. 7

【図８】

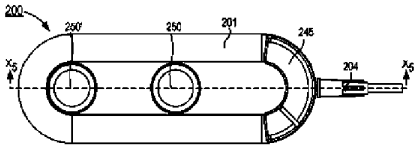


FIG. 8

【図９】

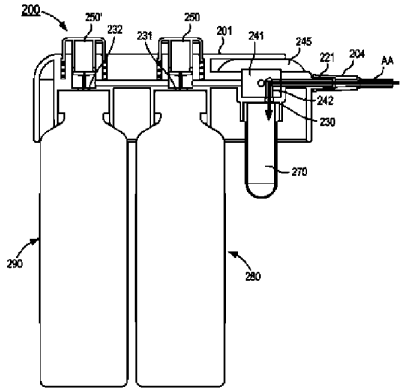


FIG. 9

【図１０】

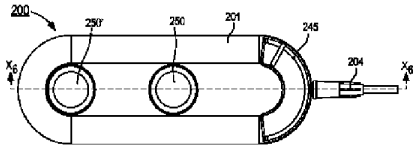


FIG. 10

【図１１】

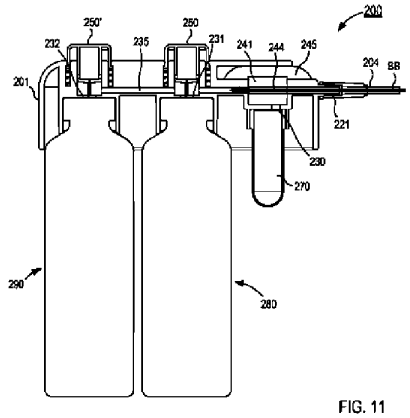


FIG. 11

【図１２】

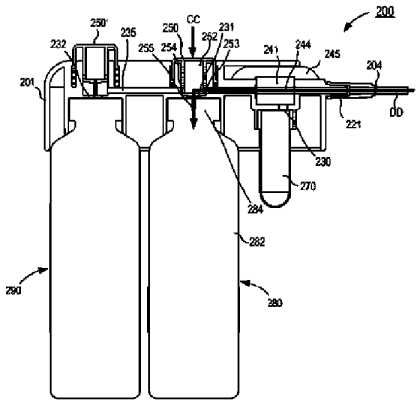


FIG. 12

【図１３】

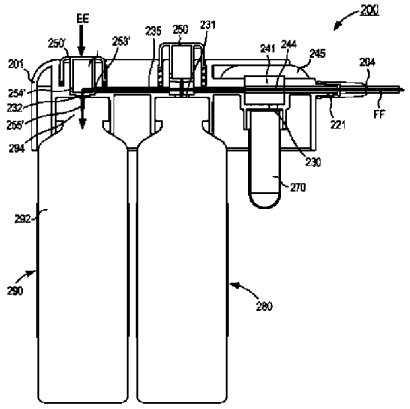


FIG. 13

【図１４】

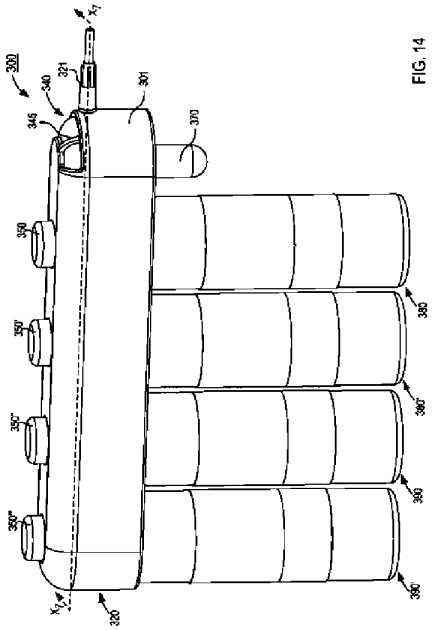


FIG. 14

【図１５】

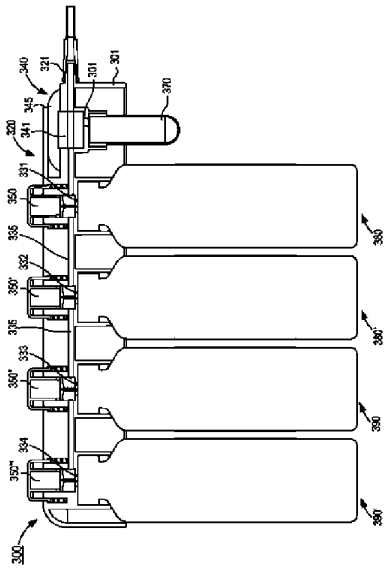


FIG. 15

【図１６】

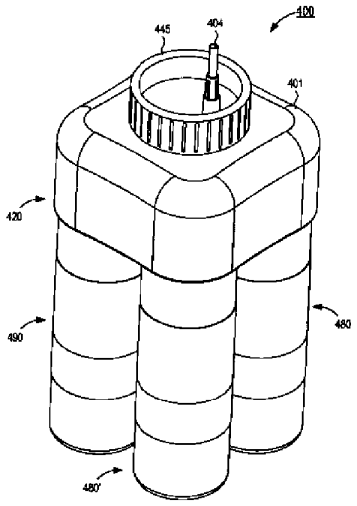


FIG. 16

【図１７】

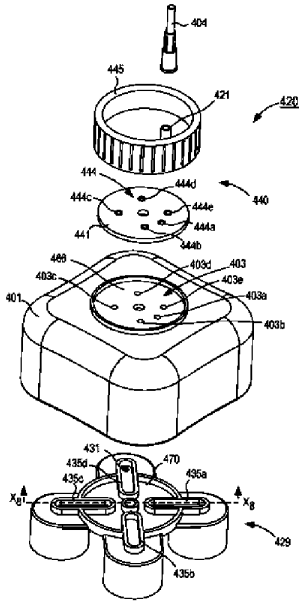


FIG. 17

【図１８】

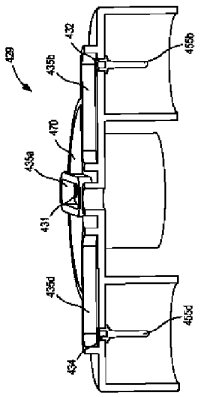


FIG. 18

【図１９】

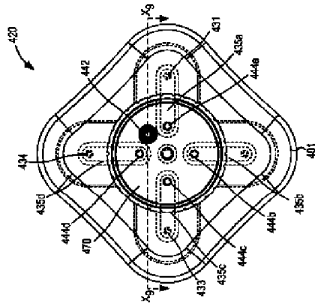


FIG. 19

【図２０】

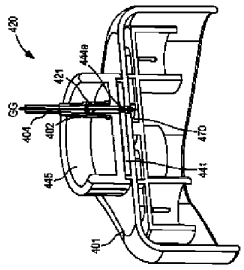


FIG. 20

【図２１】

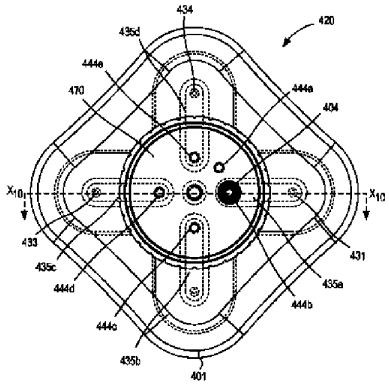


FIG. 21

【図２２】

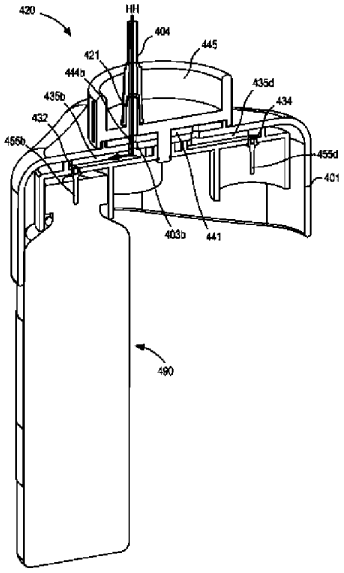


FIG. 22

【図２３】

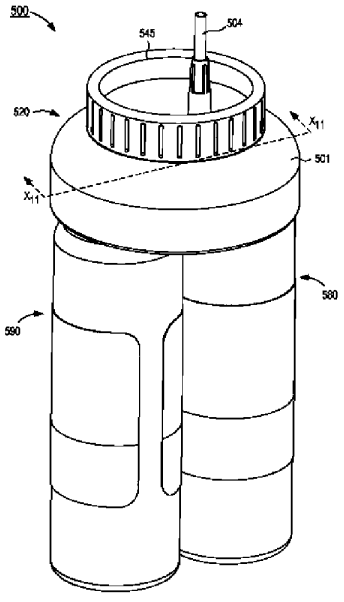


FIG. 23

【図２４】

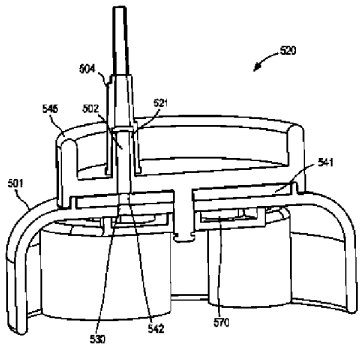


FIG. 24

【図２５】

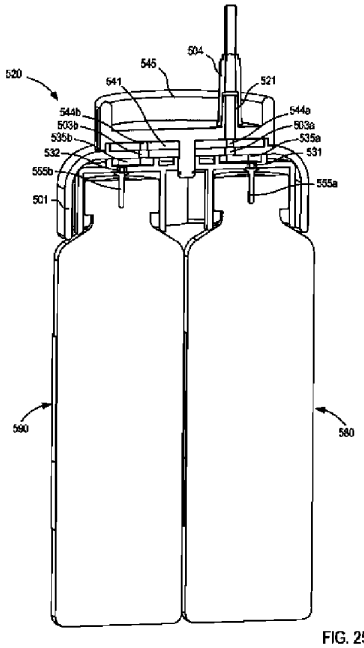


FIG. 25

【図２６】

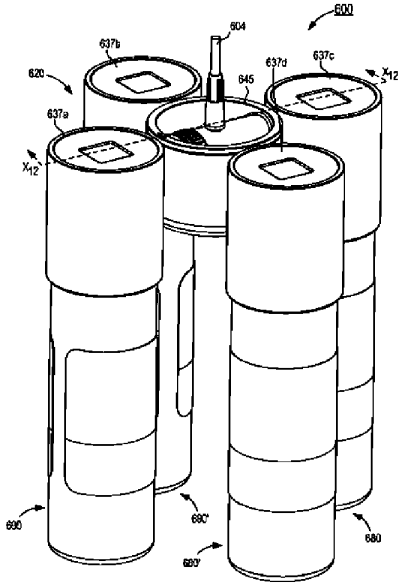


FIG. 26

【図２７】

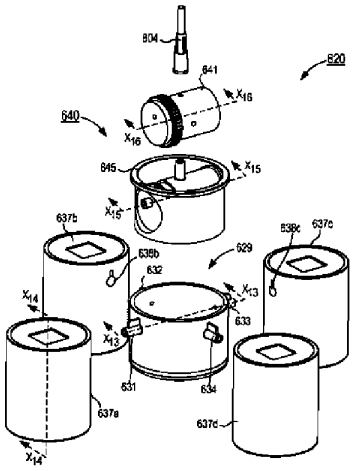


FIG. 27

【図２８】

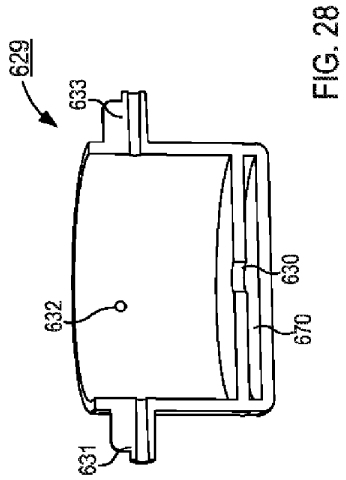


FIG. 28

【図２９】

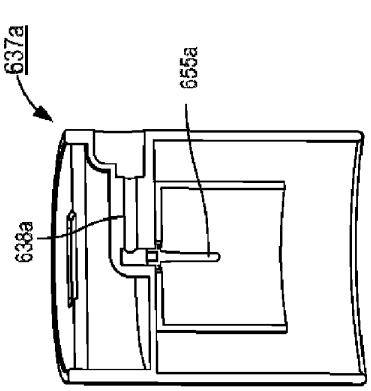


FIG. 29

【図３０】

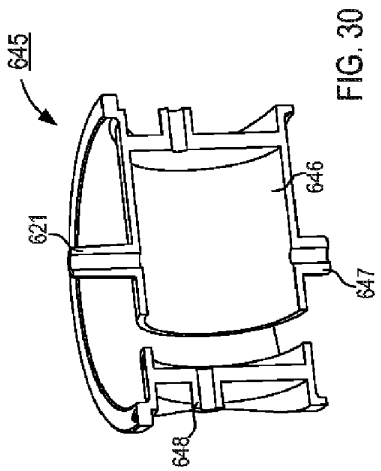


FIG. 30

【図３１】

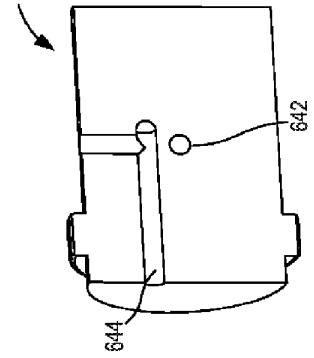


FIG. 31

【図３２】

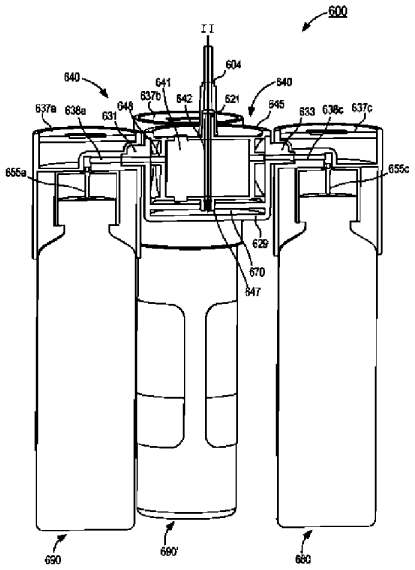


FIG. 32

【図３３】

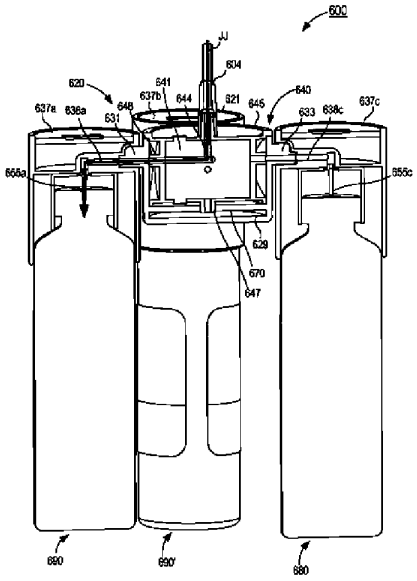


FIG. 33

【図３４】

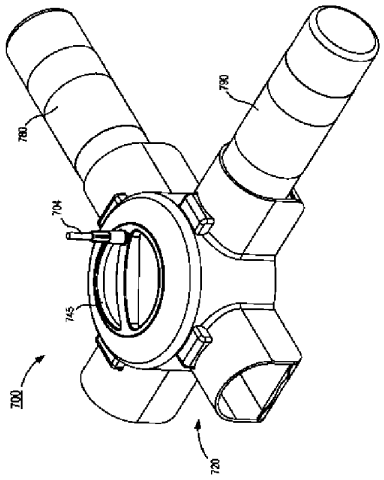


FIG. 34

【図３５】

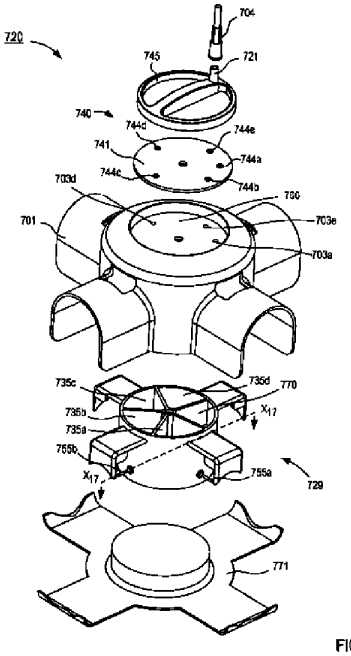


FIG. 35

【図３６】

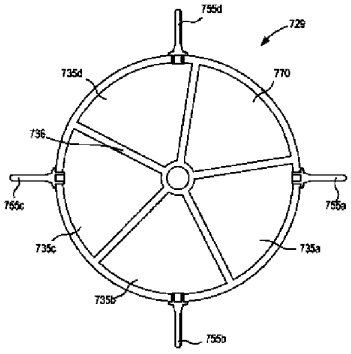


FIG. 36

【図３７】

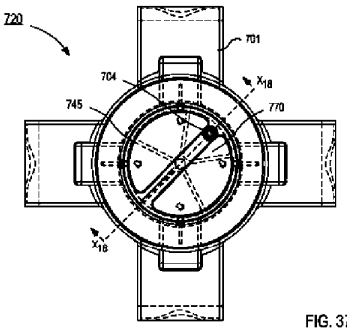


FIG. 37

【図３８】

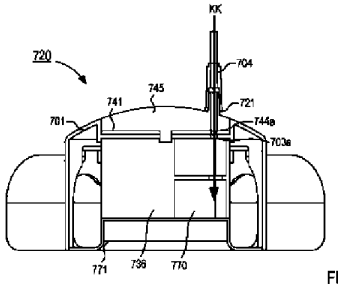


FIG. 38

【図３９】

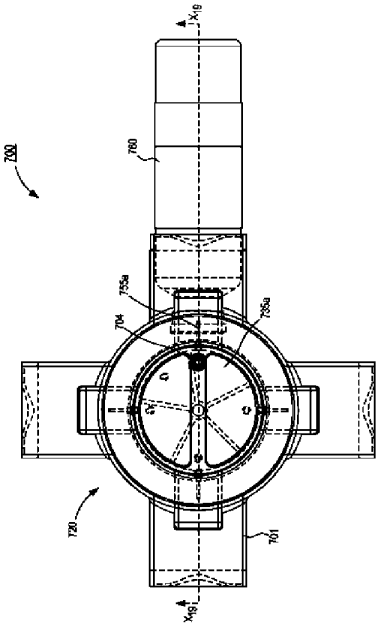


FIG. 39

【図４０】

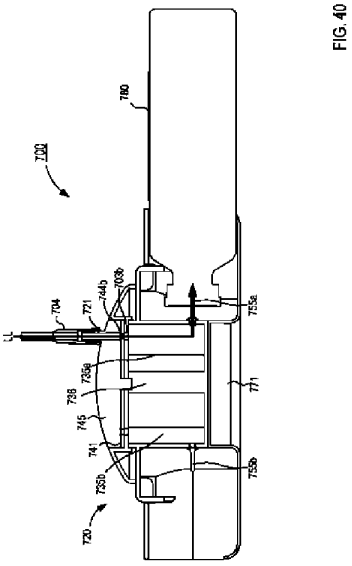


FIG. 40

【図４１】

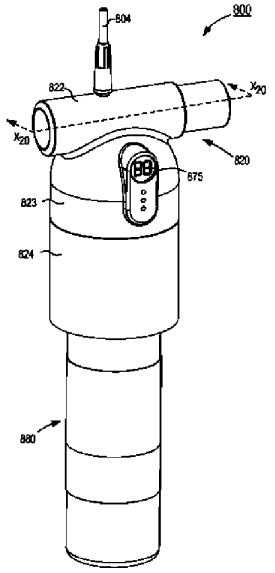


FIG. 41

【図４２】

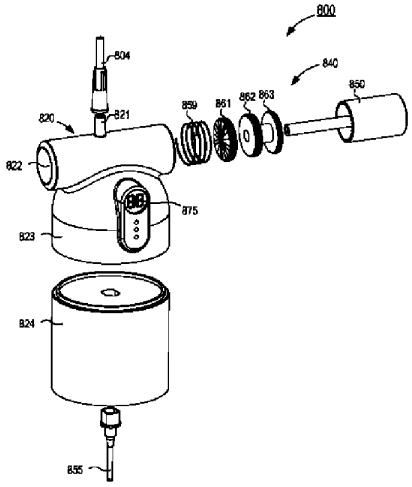


FIG. 42

【図４３】

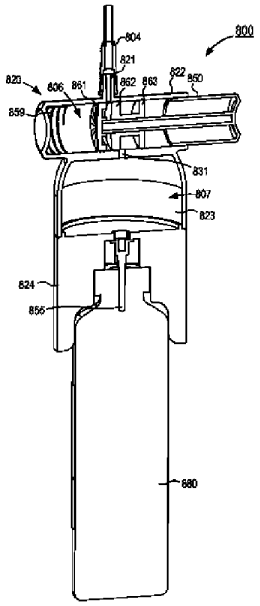


FIG. 43

【図４４】

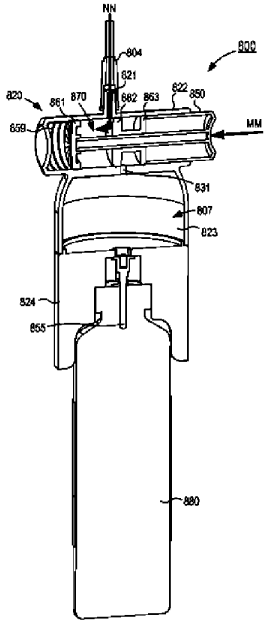


FIG. 44

【図４５】

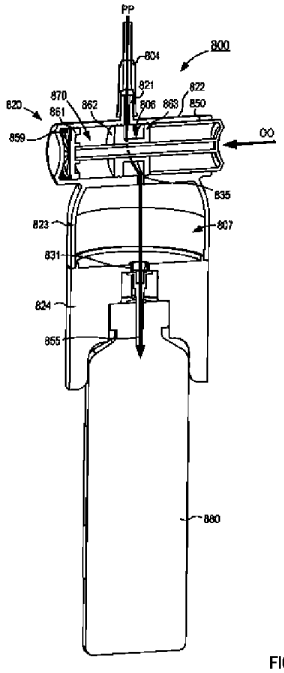


FIG. 45

【図４６】

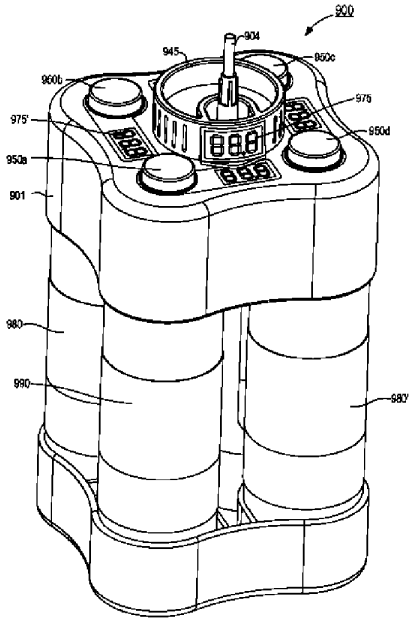


FIG. 46

【図４７】

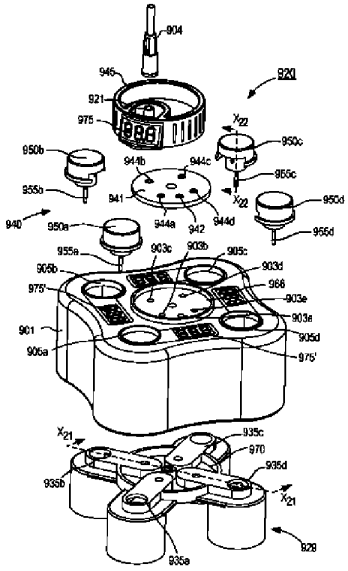


FIG. 47

【図４８】

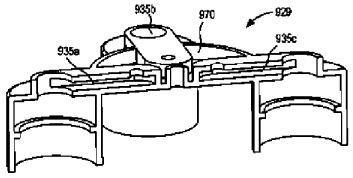


FIG. 48

【図４９】

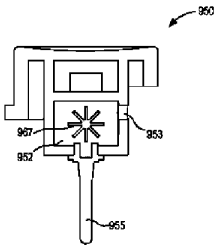


FIG. 49

【図５０】

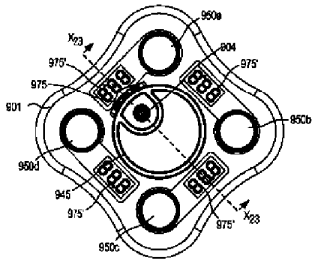


FIG. 50

【図５１】

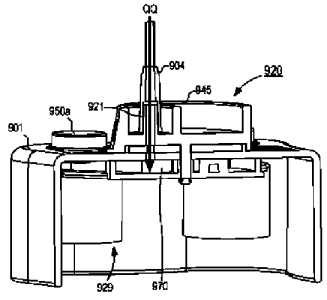


FIG. 51

【図５２】

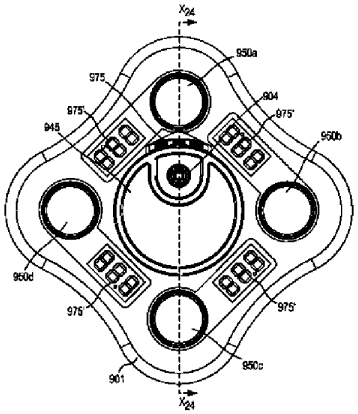


FIG. 52

【図５３】

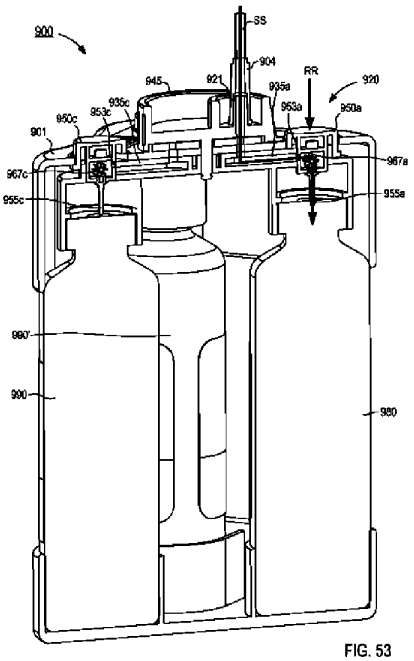
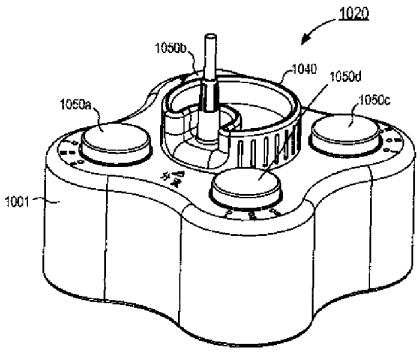
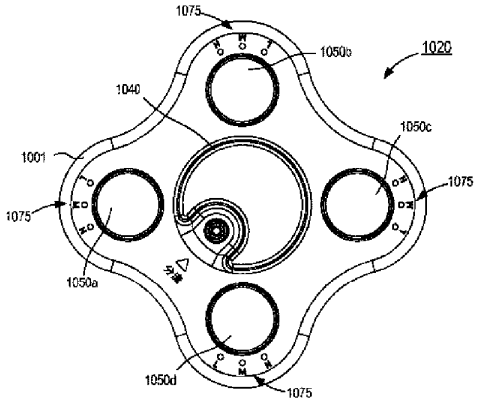


FIG. 53

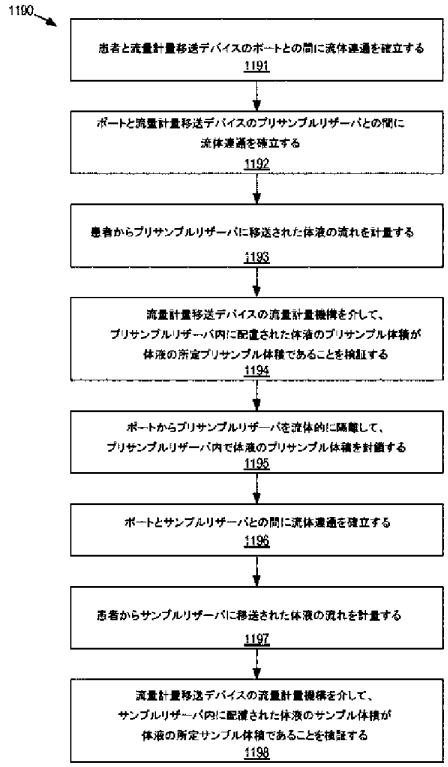
【図５４】



【図５５】



【図５６】


1190
患者と流量計量移送デバイスのポートとの間に流体連通を確立する
1191
ポートと流量計量移送デバイスのプリサンプルリザーバとの間に
流体連通を確立する
1192
患者からプリサンプルリザーバに移送された体液の流れを計量する
1193
流量計量移送デバイスの流量計量機構を介して、
プリサンプルリザーバ内に配置された体液のプリサンプル体積が
体液の所定プリサンプル体積であることを検証する
1194
ポートからプリサンプルリザーバを流体的に隔離して、
プリサンプルリザーバ内で体液のプリサンプル体積を封鎖する
1195
ポートとサンプルリザーバとの間に流体連通を確立する
1196
患者からサンプルリザーバに移送された体液の流れを計量する
1197
流量計量移送デバイスの流量計量機構を介して、
サンプルリザーバ内に配置された体液のサンプル体積が
体液の所定サンプル体積であることを検証する
1198

【国際調査報告】

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2013/073060

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61B 5/155 (2014.01)
USPC - 600/575
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
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USPC - 422/559; 435/294.1; 600/573, 575, 576, 577, 578; 604/248, 409

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Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
PatBase, Google Patents, Google Scholar,

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X – Y	US 5,097,842 A (BONN) 24 March 1992 (24.03.1992) entire document	12, 15, 16, 18 – 1-11, 13, 14, 17, 19-29
X – Y	US 2008/0145933 A1 (PATTON) 19 June 2008 (19.06.2008) entire document	30-41 – 3, 13, 17, 22, 24, 25,
Y	US 2005/0148893 A1 (MATHIAS et al) 07 July 2005 (07.07.2005) entire document	1-11
Y	WO 2005/068011 A1 (MEHLHORN) 28 July 2005 (28.06.2005) entire document	14, 21-29
Y	US 3,848,581 A (CINQUALBRE et al) 19 November 1974 (19.11.1974) entire document	9, 19, 20

☐ Further documents are listed in the continuation of Box C. ☐

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
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"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
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Date of the actual completion of the international search	Date of mailing of the international search report
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Literature display help

1 / 1 display

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(32))[Priority date] October 15, 1981 (33) [Country claiming priority] United States of America (US) 72) [Inventor] [Name] Edward El Nagyant (72) [Inventor] [Name] Josef Kaufmann (74

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wrap up close —

(57) [Abstract] Since this gazette is application data before electronic filing, abstract data is n ot recorded.

The scope of the claims open —

Claims:

(1) a housing having a forward end and a rearward end; a sample collection chamber within s aid housing; and a first open passageway at said forward end and in fluid communication with said sample collection chamber. a first puncture needle extending outwardly from said first op en passageway for insertion into a collection source; and a second puncture needle at said rea rward end in fluid communication with said sample collection chamber. a sample collection de vice for collecting one or more liquid samples from a collection source and discharging into a n egative pressure vessel for collection, comprising: an open passageway in said second open p assageway; a second piercing needle extending into the sample collection chamber to a point spaced from the first open passageway, the second piercing needles mutually extending into t he sample collection chamber; having spaced apart first and second openings, the first and se cond openings providing fluid communication between the sample collection chamber and the lumen of the second puncture needle; from a first position that closes the opening of and ope ns the second opening to a second position that opens the first opening along the second pun cture needle so as to be able to reciprocate the sample collection a gas permeable, liquid imp ermeable, annular porous plug positioned within the chamber, wherein liquid is introduced int o the sample collection chamber when the first puncture needle is engaged with the collection source; all of the gas is pushed out and flows into the second puncture needle through the firs t and second openings, and when the second puncture needle receives the negative pressure

container, the annular porous plug is closed on both sides thereof. The action of the differentia l pressure moves toward the second opening passage to open the first opening and into the s ample collection chamber to the second opening located on the negative pressure side of the annular porous plug. A sample collection device, wherein residual gas is expelled so that the li quid in the sample collection chamber can be collected into the negative pressure container th rough the second puncture needle.

(2) The sample collection device according to claim 1, wherein the annular porous plug is mad e of sintered polyethylene, open-cell foamed polyethylene, or porous polyethylene.A sample c ollection device which is a member made from any of the group consisting of ethylene, porous polyfluorocarbon, and mixtures thereof.

(3) In the sample collection device according to claim 1, a third opening provided in a portion of the second puncture needle extending outward from the housing and the second puncture needle a resilient sleeve extending over the distal end of the sample collection chamber oppos ite the sample collection chamber, wherein the sleeve extends into the third opening when the negative pressure container is penetrated by the second puncture needle; A sample collection device, characterized in that it closes the

(4) The sample collection device of claim 1, having a resilient sleeve slidably engaging said se cond puncture needle at an end opposite said sample collection chamber. and said needle-eng aging surface on the inside of said sleeve has a plurality of longitudinally extending grooves, s aid needle-engaging grooves being gas permeable and liquid impermeable. A sample collectio n device characterized by:

(5) A sample collection device as claimed in claim 1, wherein said housing includes means for connecting a support for a vacuum vessel.

(6) A sample-collecting device according to claim 5, wherein a support for a negative pressure vessel is connected to said housing.

(7) The sample collection device of claim 3, wherein said housing includes means for connecti ng a support for a vacuum vessel.

(8) The sample collection device of claim 1, wherein said housing includes a device for observi ng the contents of said sample collection chamber.

(9) A sample collection device according to claim 8, wherein the device for observing the cont ents is a transparent housing wall adjacent to the sample collection chamber.

(10) The collection device of claim 1, comprising a resilient sleeve slidingly engaging the punc ture needle at the end of the puncture needle opposite the sample collection chamber, The ne edle-engaging surface on the inside of the sleeve forms a stepped inner surface, and a portion of the longitudinal region of the surface sealingly engages the outer surface of the associated second needle. forming an internal bore of small diameter for mating, and another portion of t he lengthwise region of the stepped inner surface forms an air passageway with the mating o uter surface of the second puncture needle. A sample collection device characterized by formi ng a large diameter internal aperture.

detailed description open —

DETAILED DESCRIPTION OF THE INVENTION

The present invention relates to a device for collecting a liquid sample such as blood from a p atient. More particularly, the invention relates to needle assemblies for collecting one or more liquid samples from such patients. The device of the present invention employs an introductio n chamber with transparent or translucent walls to allow observation of whether the needle in question is in close proximity to the proper position. The introduction chamber has therein a r eciprocating plug formed of a material which provides an obstruction wall for the liquid receive d and an exhaust passageway for the gas pushed out by the liquid sample received in the intr oduction chamber. incorporated.

When the stopper initially receives the sample liquid, it reciprocates to prevent the liquid sam ple from being expelled while at the same time causing gas to be expelled by the liquid sampl e. Then, as the liquid sample is discharged into one or more of the vacuum collection vessels, the plug is assembled to continuously discharge the collected sample through the one or more vacuum collection vessels. It reciprocates in cooperation with vent holes in the discharge are a. In the case where multiple samples are continuously collected and discharged into multiple vacuum vessels, the assembly may be used with the discharge opening of the device during t he exchange period of the vacuum collection vessel in preparation for the next sample dischar ge. It includes a cooperating flexible sleeve.

As noted above, it is desirable to provide a mechanism for informing the user of such a needle assembly that the venous needle has penetrated the patient's vein from which a blood sample is to be collected. Venous placement is often difficult when collecting blood from a patient and there may be inadequate blood flow to the collection container for other reasons. thisIn such c ases, it is beneficial to be able to quickly perceive the entry of the needle into the vein and th e flow of blood into the needle assembly. Upon such sensing of needle entry, a negative press ure collection container is inserted into the collection assembly in accordance with well-known blood sampling techniques during a single sample collection procedure.

One of the problems encountered during the venipuncture step is air pockets found in various needle assemblies for one or more blood samplings. When a venipuncture is performed and a negative pressure collection container is not yet attached to the opposite end of the needle as sembly, under normal atmospheric conditions blood will always flow through the needle due to the pool of air remaining inside the needle assembly. It does not necessarily flow into the asse mbly. Thus, once the venipuncture is accomplished, blood flow is not initiated simply by the o bstruction of an air pocket within the needle assembly.

In accordance with the present invention, by contrast, the use of a porous plug within the coll ection chamber forces air out of the collection chamber so that the collection chamber receive s the collected blood sample. In addition, the plug initially evacuates expelled air during the a cceptance period of the procedure for receiving the sample, and the needle assembly to disch arge the sample to the vacuum collection container when the vacuum container is attached to the needle assembly. is positioned within the collection chamber to cooperate with an outlet in the negative pressure puncture needle. For example, in one embodiment for a single sample c ollection procedure of the present invention, the assembly of the present invention vents expe lled air as the sample is introduced, and a negative pressure vessel is attached to the assembl y for evacuation of the negative pressure puncture. A porous plug that moves to open a passa geway in the assembly in response to the differential pressure to expel the introduced sample into the vacuum collection vessel when the needle penetrates into the vacuum collection vess el. have.

Another embodiment of the invention has a flexible sleeve that covers the exit opening of the negative pressure needle. The flexible sleeve is arranged to evacuate air from the third evacu ation outlet in the evacuation needle during sample introduction. The flexible sleeve then flexe s and moves to cover the third discharge outlet when the negative pressure blood collection c ontainer is inserted into the assembly as it is penetrated by the negative pressure puncture n eedle. Once one sample is obtained in the negative pressure blood collection device and the n egative pressure container is removed from the assembly, the flexible sleeve is then held neg ative until the negative pressure container is attached for a second sample collection. It cover s the exit opening of the pressure puncture needle. As is well known to those skilled in the ar t, this procedure is repeated to collect the required number of samples into separate negative pressure blood collection containers.

Considering the use of porous plugs in blood collection devices of the type described herein, p rior U.S. Ser. William N. Eldvidge, inventor (assigned to the same person) in "Blood Sampling Assembly Having Vein Entry Indicator" states that an air pool can be perceived by the user thr ough a venous needle. He knew he was preventing the desired flow of blood to the point. The Eldridge invention includes a porous plug that mates with a one-way valve that allows air insid e the needle assembly to pass out of this vent during the initial stages of the blood collection procedure. The vent prevents the passage of blood until the user adheres the blood collection device to the needle assembly. Upon contact with the negative pressure of the negative press ure blood collection container, a separate one-way valve opens to carry blood from the patien t's vein through the needle assembly and into the collection container.

Although the Eldridge invention recognized the use of a porous material to vent the displaced air while receiving blood, there remains room for improvement of such devices, particularly th e present invention. Related. That is, the plug of the present invention does not reciprocate a nd act merely as a vent, but acts as a valve mechanism itself without a separate and complex structure to provide valve action. That is, the plug of the present invention cooperates with a

d reciprocally engages the blood introduction chamber to vent air from the introduction cham ber, but not to expel the blood sample, but not the blood introduced when the assembly is ad hered to the negative pressure blood collection container. move to expel the

Next, description will be made with reference to the drawings. In the drawings, the same part s are denoted by the same reference numerals. Fig. 1 shows the housing12 shows the basic e xternal components of the needle assembly 10 including a first needle 14 for insertion into a p atient and a second needle 15 subjected to negative pressure at the opposite end of the housi ng 12; ing. A second puncture needle 15 is adapted to be inserted into a negative pressure co ntainer 16 for collecting a blood sample. Housing 12 includes a threaded portion 25 having thr eads 18 adjacent a second puncture needle 15 into which a container support 19 is threaded by an inner combination thread 20 provided at its forward end. The vacuum container 16 is in serted into the container support 19 so that the second puncture needle 15 penetrates the sto pper 21 at the front end of the vacuum container 16 . Such general aspects of sample collecti on vessels are well known to those skilled in the art.

Description will be made with reference to FIG. Housing 12 preferably has a forward end 24 a nd a rearward end 25 which are separable for insertion of a porous plug 27 therein. Forward e nd 24 is preferably cylindrical and has a large mouth opening 28 for reciprocatingly receiving a porous plug 27 therein. The opposite end of this portion is provided with a small port 29 for receiving the first puncture needle 14 therein. In this embodiment the small port 29 extends t o a smaller small diameter conduit 30 which communicates the ports 29 and 28 with each oth er. A stepped portion 33 for receiving the first puncture needle 14 in a contacting state is form ed at the junction of the mouth hole 29 and the conduit 30 . The first puncture needle 14 may be secured within the aperture 29 by a suitable adhesive. Those skilled in the art will recogniz e that the conduit 30 is not an essential element for this construction, but merely a preferred form. Further, the diameter of conduit 30 can be varied to regulate the flow rate of fluid passi ng therethrough.

The forward end 24 of the housing also includes a number of longitudinal ribs 31 surrounding the outwardly extending first needle. A sheath (not shown) having internal ribs that mate with ribs 31 substantially covers the outwardly extending first puncture needle. Interlocking ribs be tween the puncture needle armor and the needle assembly facilitate insertion and removal of the armor from the needle assembly by the user. Forward end 24 also includes an annular flan ge 32 which serves as a mating surface when the two portions of the housing are joined into an assembly. Again, an adhesive or similar suitable fastening material can be used to secure t he two parts of the housing and assembly.

Rear end 25 includes a slightly protruding cylindrical portion 40 sized to fit inside port 28 of th e forward end. Opposite this rearward end, external threads 18 are provided at 26 on rearwar d end 25, as previously described in connection with the tube support. An aperture 70 similar to aperture 29 at the forward end of the housing extends through the rearward end of the hou sing. The aperture 70 is sized to match the diameter of the second puncture needle 15 and a

ain the second puncture needle is secured to the aperture 70 by a suitable material such as a n adhesive. An annular flange 46 is provided corresponding to the annular flange 32 to join th e two ends 24 and 25 of the housing together. It will be appreciated that the flanges 32 and 4 6 may be secured by a suitable securing material such as adhesive when the two portions of t he housing are assembled with the plug 27 positioned therein. A mouth opening 28 in forward end 24 defines a tubular chamber 50 for receiving the liquid sample to be collected.

Annular wall 88 at the forward end of tubular chamber 50 is made of a translucent or transpar ent material to allow viewing of the contents of tubular chamber 50 and to inform the user of the device that the puncture needle has reached the vein. It is preferably formed of Those skil led in the art will appreciate that from a manufacturing standpoint, the entire front end of the needle assembly is preferably made of a transparent material such as a hard thermoplastic. H owever, a sealed window, port or other device for observing the contents of tubular chamber 50 by the user of the device is within the scope of the invention.

The porous plug 27 is reciprocally mounted in the orifice 28 and has an inner orifice 72 for rec iprocating engagement with the forward end of the puncture needle 15 which is subjected to negative pressure. As is well known, the porous plug 27 is an opening.The bore 28 is cylindric al in shape, the diameter of which engages the wall of the tubular chamber 50 in a fluid-tight manner, and the action of the differential pressure on the opposite surface thereof causes the plug 27 to reciprocate within the bore 28. It is defined so that it can be done.

The porous plug 27 is made of a so-called gas-permeable, liquid-impermeable material which allows the passage of gas, eg air, but not the passage of liquid, eg blood. Examples of materia ls that may be used to form the porous plug 27 include sintered polyethylene, open cell foame d polyethylene, and other similar moldable polymeric materials such as porous polypropylene and porous polyfluorocarbon.

As shown in FIG. 2, negative pressure needle 15 includes a notch 74 adjacent end 84 thereof. In this regard, depending on the positioning of the porous plug 27, the notch 74 communicate s between the tubular chamber 50 and the lumen of the second piercing needle 15 so that the end 84 of the porous plug 27 is not blocked by the plug. or deformed or otherwise closed. An additional notch or opening 76 is provided to provide communication between the rearward en d 51 of tubular chamber 50 and second puncture needle 15 . Further, as shown in FIG. 2, a thi rd notch or opening 78 is provided which provides communication between the atmosphere, t he peripheral region of the assembly of the present invention, and the lumen of the second pu ncture needle 15 .

Next, description will be made with reference to FIG. A needle assembly connected to support 19 is shown. A first puncture needle 14 is shown being inserted into a patient P during venipu ncture. When first puncture needle 14 enters patient P's vein, blood flows from the vein throu gh first puncture needle 14 and small bore conduit 30 into tubular chamber 50 . When blood e nters tubular chamber 50 , the air in tubular chamber 50 is forced out of tubular chamber 50 t hrough porous plug 27 , but blood does not pass through porous plug 27 due to the characte

stics of porous plug 27 . Air that has passed through plug 27 passes from tubular chamber 50 through notches 74 and 76 and further through the lumen of second puncture needle 15 and external notch 78 to the flexible tube covering the outer end of negative pressure puncture ne edle 15 . 2, into the area 82 (FIG. 2) between the flange 92 of the armor 80 and the end face 106 of the end 25 of the housing. The plug 27 now remains in the position shown in FIG. 2 ov er the orifice or notch 74. FIG. Further here a blood sample taken from patient P is located in tubular chamber 50 .

Referring now to FIG. 3, the assembly is shown having support 19 attached to hub portion 26 of rear housing 25. As shown in FIG. Negative pressure blood collection container 16 is shown fitted into support 19 with a resilient plug pierced by the end or point 100 of negative pressur e puncture needle 15 . Penetration of puncture needle 15 into plug 21 creates a vacuum that draws any air remaining in tubular chamber 50 away from the inner region of vacuum contain er 16 and notch 74 and Withdraw through porous plug 27 by communicating 76 through the l umen of puncture needle 15 . As plug 27 becomes occluded by blood, a differential pressure i s created between upper tubular chamber 50 and lower tubular chamber 51, causing plug 27 to move downward toward the plane of extension 40 as shown in FIG.

This movement causes plug 27 to uncover opening or notch 74 . Any residual air trapped in th e lower tubular chamber 51 during this movement passes through the notch 76 and aids the movement of the plug 27 . When the notch 74 is uncovered, communication is provided betwe en the tubular chamber 50 and the negative pressure container 16 through the lumen of the n egative pressure puncture needle 15 . On the other hand, the insertion of the vacuum vessel 16 into the support 19 and the penetration of the puncture needle 15 through the plug 21 by t he point 100 causes the armor 80 to be pulled upwards, as shown in FIG. 26 to a position wh ere it engages the bottom surface 106 . Thus, the blood sample that has been drawn from the patient P's vein and contained in the tubular chamber 50 moves into the negative pressure col lection container 16 . Once the sample has been withdrawn into container 16 , container 16 is removed from support 19 thereby returning armor 80 to a position covering notch 78 and ove r end 100 of negative pressure puncture needle 15 . In this manner, the first puncture needle 14 remains in the vein without leaking blood, allowing a plurality of needles to be inserted int o the vein.Allows for continuous mounting of container 16 into support 19 for receiving a bloo d sample.

Referring now to FIG. 4, there is shown another embodiment in which notch 78 is not used in negative pressure puncture needle 15a. Identical parts in this device are designated by the sa me reference numerals with the suffix a. In this embodiment, puncture needle 15a has flange 108 instead of air passage or opening 78 which is always positioned adjacent surface 106a of extension 26a and in gas-tight closed engagement. A sleeve 90 is formed. As shown in FIG. 6, the sleeve 90 is positioned in sliding engagement over the puncture needle 15a. However, sle eve 90 has a plurality of internal grooves 94 where points 95 inside the grooves actually enga ge the outer surface of puncture needle 15a. The groove thus provides gas communication b

tween the puncture needle end 100a and the upper end of the sleeve 90 where air leaks betw een the adjacent surface of the flange 108 of the sleeve 90 and the surface 106a of the exten sion 26a. The grooves 94 are sized to allow passage of gas but not liquid. It will be appreciate d that the upper surface of flange 108 may similarly include grooves to provide ventilation bet ween end 100a and the atmosphere.

Yet another example of the invention which provides a single blood sample collection assembl y is shown in FIG. As shown in this assembly, no special sleeve 80 is used and puncture needl e 15b does not have a third notch or opening such as notch 78 in the embodiment shown in F IG. . Thus, when puncture needle 14 is inserted into a patient's vein, fluid communication is p rovided between the vein and tubular chamber 50 and a sample is collected in tubular chamb er 50 . The device does not allow the blood sample to flow through the porous plug 27 as in t he embodiment shown in FIG. However, the air forced out by the blood sample entering tubul ar chamber 50 passes through air permeable plug 27, notches 74, 76, the lumen of puncture needle 15, and exits end 100b of negative pressure puncture needle 15b. be done. When a su pport is mounted on extension 26b and point 100b of puncture needle 15b is inserted through the plug into negative pressure blood collection container 16, tubular chamber 50 above and t ubular chamber 51 below plug 27 are closed. A differential pressure is created between them which causes the plug 27 to move downward and open the notch 74 . This provides fluid com munication between the tubular chamber 50 and the vacuum vessel 16 for single sample colle ction into the vacuum vessel 16 . Since no further samples are collected by this assembly in t his embodiment, the puncture needle 14 is removed from the patient P's vein and the assemb ly is discarded as the required single sample has been collected into the vacuum container.

Another multiple sampling embodiment similar to that shown in FIG. 4 is shown in FIGS. 8a a nd 8b, in which air is communicated between point 100c of negative pressure puncture needle 15c and the atmosphere. In this embodiment, the inner diameter of sleeve 110 is stepped, an d the surface of sleeve 110 and puncture needle 15 combined with the small inner diameter 1 14 of sleeve 110 in close contact with the outer surface of puncture needle 15c. provides a lar ge inner diameter 116 that forms a vent passageway 118 for the . Thus, in the position shown in Figure 8a, ventilation occurs between the end 100c of the puncture needle 15c and the atm osphere through the passageway 118, and in the position shown in Figure 8b, the passagewa y 118 is closed preventing all ventilation.

As will be appreciated from the foregoing, in accordance with the present invention, a blood c ollection needle assembly is provided for collecting single or multiple samples incorporating a device that indicates venous penetration to its user. be. In addition, the device of the present i nvention with a porous plug having a simple form which is permeable to gas but impermeable to liquid and has the function of a valve is very simple and inexpensive to manufacture. It is p articularly suitable for mass production as will be appreciated by those skilled in the art.

Brief description of the drawing

open —

BRIEF DESCRIPTION OF THE DRAWINGS FIG.
1 is a perspective view of a sample collection needle assembly, a support for a negative press ure container and a negative pressure blood collection container used to obtain a blood sampl e from a patient.
2 is an enlarged cross-sectional view taken along line 2--2 of FIG. 1 showing one embodiment of the present invention; FIG.
3 is an enlarged cross-sectional view along line 3--3 of FIG. 1; FIG.
FIG. 4 is a partial sectional view similar to FIG. 2 showing the present invention.Fig. 3 shows another embodiment of the light;
FIG. 5 is a perspective view of a needle assembly inserted into a patient and connected to a s upport to allow the user to visualize venous entry;
6 is a cross-sectional view along line 6--6 of FIG. 4; FIG.
FIG. 7 is a view similar to FIG. 2 but an enlarged cross-sectional view of a single sampling ne edle assembly illustrating another embodiment of the present invention;
Figure 8a is an enlarged partial cross-sectional view of a single sampling needle assembly sho wing another embodiment of the present invention;
Figure 8b is the embodiment of Figure 8a in the closed, non-vented position.
DESCRIPTION OF SYMBOLS 10... Needle assembly 12... Housing
14... First puncture needle 15... Second puncture needle 16
... Negative pressure container 19... Support member 24
... Front end 25... Rear end
27... Annular shape Porous plug 29 First opening
50 Sample collection chamber 70 Second opening
74 First opening 76 Second opening
78 Third opening 80 Flexible sleeve
94 Groove 114 Small inner diameter
116 Large inner diameter

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⑲ 日本国特許庁（JP）　　⑪ 特許出願公開

⑫ 公開特許公報（A）　　昭58—67238

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明　　細　　書

1.〔発明の名称〕

試料採集装置

2.〔特許請求の範囲〕

(1)　前方端および後方端を有するハウジングと；該ハウジングの中にある試料採集室と；前記前方端にあり前記試料採集室と液体的に連通する第1の開口通路と；採集源の中に挿入するために前記第1の開口通路から外方へ向つて伸長する第1の穿刺針と；前記後方端にあり前記試料採集室と流体的に連通する第2の開口通路と；から構成され採集源から1つ又はそれ以上の液体試料を採集し負圧容器の中へ排出して採集するための試料採集装置において、前記第2の開口通路の中にあり前記試料採集室の中へ前記第1の開口通路から間隔を置いた点まで伸長する第2の穿刺針を有し、該第2の穿刺針は前記試料採集室の中へ伸長する部分に互に離間する第1および第2の開口部を有し、該第1および第2の開口部は前記試料採集室と前記第2の穿刺針の管腔の間を流体的に連通し、前記第1の開口部を閉鎖し前記第2の開口部を開口する第1の位置から前記第1の開口部を開口する第2の位置まで前記第2の穿刺針に沿つて往復動可能に前記試料採集室の中に置かれた気体透過性で液体不透可性の環状多孔質栓を有し、前記第1の穿刺針が前記採集源と係合すると液体が前記試料採集室の中へその中の気体を全て押し出して流入し前記第1および第2の開口部を通じて前記第2の穿刺針へ出てまた前記第2の穿刺針が負圧容器を受け入れると前記環状多孔質栓はその両側の差圧の作用によつて前記第2の開口通路に向つて移動して前記第1の開口部を閉口し、前記環状多孔質栓の負圧側に位置する前記第2の開口部へ前記試料採集室に残留する気体を押し出して前記試料採集室の中の液体を前記第2の穿刺針を通じて前記負圧容器の中へ採集できるようになつていることを特徴とする試料採集装置。

(2)　特許請求の範囲第1項に記載の試料採集装置において、前記環状多孔質栓が、焼結ポリエチレン、開放セル型発泡ポリエチレン、多孔性ポリ

(1)　　(2)

エチレン、多孔性ポリフルオロカーボン、及びこれらの混合物、より成る群のいづれかにより作られた部材である試料採集装置。

(3) 特許請求の範囲第1項に記載の試料採集装置において、前記第2の穿刺針の前記ハウジングから外方へ伸長する部分に設けられた第3の開口部と前記第2の穿刺針の前記試料採集室とは反対側の端末部の上に伸長する弾力のあるスリーブとを有し、負圧容器が前記第2の穿刺針によつて貫入されると前記スリーブが前記第3の開口部を閉鎖することを特徴とする試料採集装置。

(4) 特許請求の範囲第1項に記載の試料採集装置において、前記試料採集室とは反対側の端末部において前記第2の穿刺針と滑動的に係合する弾力のあるスリーブを有し、該スリーブの内側の前記穿刺針に係合する面は複数個の縦方向に伸長する溝部を有し、前記穿刺針と係合した前記溝部が気体透過性で液体不透過性であることを特徴とする試料採集装置。

(5) 特許請求の範囲第1項に記載の試料採集装

(3)

置において、前記ハウジングが負圧容器用支持具を接続するための装置を有することを特徴とする試料採集装置。

(6) 特許請求の範囲第5項に記載の試料採集装置において、負圧容器用支持具が前記ハウジングに接続されることを特徴とする試料採集装置。

(7) 特許請求の範囲第3項に記載の試料採集装置において、前記ハウジングが負圧容器用支持具を接続するための装置を含むことを特徴とする試料採集装置。

(8) 特許請求の範囲第1項に記載の試料採集装置において、前記ハウジングが前記試料採集室の内容物を観察するための装置を有することを特徴とする試料採集装置。

(9) 特許請求の範囲第8項に記載の試料採集装置において前記内容物を観察するための装置が前記試料採集室に隣接した透明なハウジング壁であることを特徴とする試料採集装置。

(10) 特許請求の範囲第1項に記載の採集装置において前記穿刺針の前記試料採集室とは反対側の

(4)

端部で前記穿刺針と滑動的に係合する弾力のあるスリーブを有し、該スリーブの内側の前記穿刺針に係合する面は段付きの内側表面を形成し、該面の長さ方向領域の一部は組み合わされる前記第2の穿刺針の外側表面と密閉的に係合するために小さな径の内部口孔を形成しており、前記段付きの内側表面の長さ方向領域の他の一部は組み合わされる前記第2の穿刺針の外側表面と共に空気通路を形成する大口径の内部口孔を形成することを特徴とする試料採集装置。

3.〔発明の詳細な説明〕

本発明は患者から血液の如き液体試料を採集するための装置に関する。特に本発明はそのような患者から1つあるいは複数の液体試料を採集するための針組み立て体に関する。本発明の装置は問題となる針が適正な位置に近接したか否かを観察できるような透明あるいは半透明の壁を有する導入室を用いている。再に導入室は、受け入れた液体に対しては障害壁となりその導入室に受け入れられた液体試料によつて押し出される気体に対し

(5)

ては排気通路となる材料で形成される往復動する栓をその中に組み込んでいる。

その栓は試料液体を最初に受け入れるとその液体試料が排出されるのを防ぎながら同時にその液体試料によつて気体が排気するように往復動する。次いで液体試料が1つあるいは複数の負圧採集容器に排出される時にその栓は採集された試料を1つあるいはそれ以上の負圧採集容器へ連続的に排出して通過させるように組み立て体の排出領域にある通気孔との協働作用で往復動する。複数の試料を採集し続けて複数個の負圧容器へ排出する場合において、その組立体は次の試料の排出に備えての負圧採集容器の交換期間の間にその装置の排出開口部と協働する可撓性スリーブを包含する。

上述の如くそのような針組立体の使用者に静脈針が血液試料を採集する患者の静脈に貫入した事を知らせる機構を備えることが望ましい。患者から血液を採集する際に往々にして静脈に定置することは困難でありまた他の理由によつて採集容器への血液の流れが適正でないことがある。このよ

(6)

うな場合に静脈の中へ針が入り血液が針組み立て体の中へ流入することを迅速に知覚できることは有益である。針が入つたことをこのように知覚すると単一試料採集の手順中の周知の血液試料採集手法に従つて負圧採集容器が採集組み立て体の中へ挿入される。

静脈穿刺段階で起こる問題の１つは１つあるいは複数の血液試料採取のための種々の針組み立て体において見い出される空気の溜りである。静脈穿刺がなされ負圧採集容器がまだ針組み立て体の反対側端部に取り付けられていない時には、通常の大気圧条件下では針組み立て体の内側に残留する空気の溜りのために血液は常に針組み立て体の中へ流入するとは限らない。したがつて静脈穿刺が完遂されても、単に針組み立て体の中の空気溜りの妨害によつて血液の流れは開始されない。

本発明によれば、対照的に採集室内の多孔質栓の使用によつてその栓が採集された血液試料を採集室が受け入れるように採集室から空気を押し出す。更にこの栓は試料を受け入れるための手順の

受け入れ期間において最初は押し出された空気を排気し、負圧容器が針組み立て体に取り付けられるとその試料を負圧採集容器へ排出するように針組み立て体の負圧穿刺針における出口と協働するように採集室の中に配置されている。例えば本発明の単一試料採集手順用の１つの実施態様において本発明の組み立て体は試料が導入されると押し出された空気を通気し、負圧容器が組み立て体に取り付けられ排出用負圧穿刺針が負圧採集容器の中へ貫入するとその導入された試料を負圧採集容器の中へ排出するために差圧に応答して組み立て体の通路を開口するために移動する多孔質の栓を有する。

本発明の他の実施態様は負圧穿刺針の排出開口部を覆う可撓性スリーブを有する。可撓性スリーブは試料導入中に排出穿刺針における第３の排出出口から空気を排出するように配置される。続いてこの可撓性袖部は負圧血液採集容器が負圧穿刺針によつて貫入されるように組み立て体の中へ挿入されるとたわみかつ移動しこの第３の排出出口

を塞う。一旦１つの試料を負圧血液採集装置の中に得て組み立て体から負圧容器が取り外されると、可撓性スリーブは次に第２の試料採集のために負圧容器が取り付けられるまでは負圧穿刺針の排出開口部を被つている。当業者には周知であるがこの手順は必要とされる数の試料を別々の負圧血液採集容器の中へ採集するために繰り返される。

ここに記載する種類の血液採集装置における多孔質栓の使用について考えてみると、先願である１９７８年６月１５日に出願された米国出願番号９１５,６７０の「静脈穿刺表示付血液採集組み立て体」（Blood Sampling Assembly Having Vein Entry Indicator）において発明者（譲受人は本願と同一人）ウイリアム・エヌ・エルドリッジ（William N. Eldvidge）は空気の溜りが静脈針を通つて使用者が知覚し得る点まで流れる望ましい血液の流れを防げていることを認識していた。エルドリッジの発明においては１方向性弁と結合する多孔質栓を備えておりその１方向性弁は針組み立て体の内側の空気を血液採集手順の

最初の段階でこの通気装置の外へ通過させる。この通気装置は使用者が血液採集装置を針組み立て体に接着させるまで血液の通過を防止する。負圧血液採集容器の負圧と接すると分離された１方向性弁が開き患者の静脈から血液を運び針組み立て体を通して採集容器へ血液を入れる。

エルドリッジの発明は血液を受け入れている間に押しのけられた空気を通気させる多孔質材料の使用を認識していたがそのような装置の改良する余地は残されており、特にその余地は本発明に関連する。すなわち本発明の栓は往復動し単に通気口として作用するのではなく弁作用を提供するような分離されたまた複雑な構造を持たずにそれ自身が弁機構として作用する。すなわち本発明の栓は血液導入室と協働して往復動的に係合し導入室から空気は通気するが血液試料は排出せず組み立て体が負圧血液採集容器と接着した時に導入した血液を排出するように移動する。

次に図面を参照し説明する。なお図面において同一部分は同一符号で示す。第１図はハウジング

１２、患者の中へ挿入するための第１の穿刺針１４およびハウジング１２の反対端にある負圧を受ける第２の穿刺針１５を包含する針組み立て体１０の基本的な外部構成要素を示している。第２の穿刺針１５は血液試料を採集するための負圧容器１６の中へ挿入されるようになつている。ハウジング１２は容器支持具１９がその前方端に設けられている内側の組み合わせねじ２０によつてねじ込まれる第２の穿刺針１５に隣接するねじ１８を有するねじ部２５を包含する。負圧容器１６は第２の穿刺針１５が負圧容器１６の前方端にあるストツパ２１を貫通するように容器支持具１９の中へ挿入される。試料採集容器のこのような一般的な態様は当業者には周知である。

第２図を参照し説明する。ハウジング１２は前方端２４および後方端２５を有しこれら両端は多孔質の栓２７を挿入するために分離できることが好ましい。前方端２４は円筒状であるのが好ましくその中に多孔質の栓２７を往復運動可能に受け入れるように大きな口孔２８を有する。この部分

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入あるいは針状組み立て体からの脱着を容易にする。前方端２４はまたハウジングの２つの部分を接合して組立体にするとき接合面としての役割を果す環状のフランジ３２を包含する。ここでもハウジングおよび組み立て体の２つの部分を固定するために接着剤あるいは類似の適当な固定材料を用いることができる。

後方端２５は前方端の口孔２８の内側に適合するように寸法を定められた少し突き出た円筒部４０を包含している。この後方端の反対側には管支持体の連結機構で前述したように外ねじ１８が後方端２５の符号２６の部分に設けられている。ハウジングの前方端における口孔２９と同様の口孔７０がハウジングの後方端を通つて伸長している。口孔７０は第２の穿刺針１５の直径と適合するように寸法を定められておりここにおいても例えば接着剤の如き適当な材料によつて第２の穿刺針が口孔７０に固定される。ハウジングの２つの端部２４および２５を組合わせるにあたり環状フランジ３２に対応し環状フランジ４６が設けられ

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の反対端にはその中に第１の穿刺針１４を受け入れるための小さな口孔２９が設けられている。本実施例においては小さな口孔２９は口孔２９と口孔２８を互いに連通させるさらに小さな小口径導管３０まで伸長している。口孔２９と導管３０の接合点には第１の穿刺針１４を接する状態で受け入れるための段付部３３が形成されている。第１の穿刺針１４は適宜な接着剤によつて口孔２９の中に固定されても良い。この構造に対しては導管３０は必須の要素ではなく単に好ましい形態に過ぎないことは当業者には周知であろう。更に導管３０の直径はその中を通過する流体の流量を調節するために変えることができる。

ハウジングの前方端２４はまた外側に向つて伸長する第１の穿刺針を包囲する多数の縦方向のリブ３１を包含している。リブ３１と組み合わされるリブを内部に有する鎧装（図示せず）が外側に向つて伸長する第１の穿刺針をほぼ被つている。穿刺針の鎧装と針状組み立て体の間の組み合わされるリブは使用者の鎧装の針状組み立て体への挿

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ている。ハウジングの２つの部分をその中に位置定めされた栓２７とともに組み立てる際にフランジ３２および４６が例えば接着剤の如き適当な固定材料によつて固定できることは理解されるであろう。前方端２４の口孔２８は採集する液体試料を受け入れるための管状室５０を形成する。

管状室５０の内容物を観察するためにまた本装置の使用者に穿刺針が静脈に到達したことを知らせるために、管状室５０を形成する前方端の環状壁８８は半透明あるいは透明な材料で形成されるのが好ましい。製造面から考えれば針状組み立て体の前方端全体が熱可塑性硬質樹脂の如き透明な材料で作られるのが好ましいことは当業者に理解されるであろう。しかしながら本装置の使用者が管状室５０の内容物を観察するための密閉された窓、口孔あるいは他の装置も本発明の範囲にある。

多孔質栓２７は口孔２８の中に往復運動可能に取り付けられまた負圧を受ける穿刺針１５の前方端と往復運動可能に嵌入させるための内側の口孔７２を有している。多孔質栓２７は周知の如く口

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孔２８に従つて円筒形の形状をしておりその径は管状室５０の壁と液体密封的に係合するがまたその反対面との差圧の作用によつて口孔２８の中で栓２７が往復動することができるように定められている。

多孔質栓２７は例えば空気の如き気体の通過は許すが例えば血液の如き液体の通過は許さないいわゆる気体透過性・液体不透過性材料でできている。多孔質栓２７を形成するために用いられる材料の例として焼結ポリエチレンや開放セル型の発泡ポリエチレンや他の同様な型成形可能な重合体物質例えば多孔のポリプロピレンや多孔のポリフルオロカーボン等がある。

第２図に示すように負圧穿刺針１５はその端部８４に隣接した切り欠き７４を包含する。この点において多孔質栓２７の位置定めに依存するが切り欠き７４が管状室５０と第２の穿刺針１５の管腔の間を連通するので多孔質栓２７の端部８４は栓で塞がれるかあるいは変形させるか又は他の方法により閉じられる。付加的な切り欠きすなわち

開口７６が管状室５０の後方端５１と第２の穿刺針１５の間を連通するために設けられている。更に第２図に示されるように大気すなわち本発明の組み立て体の外周領域と第２の穿刺針１５の管腔の間を連通させる第３の切り欠きすなわち開口７８が設けられている。

つぎに第５図を参照し説明する。支持具１９に連結されている針状組み立て体が図示されている。静脈穿刺中の患者Ｐの中に挿入されている第１の穿刺針１４が示されている。第１の穿刺針１４が患者Ｐの静脈に入ると血液は静脈から第１の穿刺針１４および小口径導管３０を経て管状室５０の中へ流入する。血液が管状室５０に流入すると管状室５０の中の空気は多孔質栓２７を通じて管状室５０から押し出されるが血液は多孔質栓２７の特性によつて多孔質栓２７を通過しない。栓２７を通過した空気は管状室５０から切り欠き７４および７６を経てさらに第２の穿刺針１５の管腔および外部切り欠き７８を通つて負圧穿刺針１５の外側端部を被つている柔軟な鎧装８０のフランジ

９２とハウジングの端部２５の端面１０６の間の領域８２（第２図）の中へ押し出される。ここにおいて栓２７はオリフイスすなわち切り欠き７４を覆つて第２図に示す位置に留つている。更にここにおいて患者Ｐから採集された血液試料は管状室５０の中に位置している。

次に第３図を参照すると、組み立て体が後方ハウジング２５のハブ部２６に取り付けられた支持具１９を有するのが示されている。負圧穿刺針１５の端部すなわち点１００によつて貫通された弾力性の栓を有し支持具１９の中に嵌入されている負圧の血液採集容器１６が示されている。穿刺針１５が栓２１に貫入することによつて真空状態が作り出されるがこの真空すなわち負圧は管状室５０の中に残留しているすべての空気を、負圧容器１６の内部領域と切り欠き７４および７６を穿刺針１５の管腔を通じて連通することによつて、多孔質栓２７を通して引き抜く。栓２７が血液によつて閉塞されるため上部管状室５０と下部管状室５１の間に差圧が生じ栓２７は第３図に示すよ

うに延長部４０の面に向つて下方へ移動する。

この移動によつて栓２７は開口すなわち切り欠き７４の覆いを取り除く。この移動の間に下部管状室５１の中に閉じ込められていた残留空気は全て切り欠き７６を通りプラグ２７の運動を助長する。切り欠き７４の被覆が取り除かれると負圧穿刺針１５の管腔を通じて管状室５０と負圧容器１６の間の流通がもたらされる。一方、負圧容器１６の支持具１９の中への挿入および穿刺針１５の点１００による栓２１への貫通によつて第３図に示すように鎧装８０は鎧装８０の上側フランジ９２が軸頭２６の底面１０６と係合する位置まで上方へ移動する。このように患者Ｐの静脈から抜かれ管状室５０に収納されていた血液試料は負圧採集容器１６の中へ移動する。試料が容器１６の中へ引き抜かれたならば容器１６は支持具１９から取り外されこれによつて鎧装８０は切り欠き７８を塞ぎかつ負圧穿刺針１５の端部１００を覆う位置まで戻る。このように第１の穿刺針１４は血液を漏洩することなく静脈の中に留つて複数の

血液試料を受け入れるために容器１６を支持具１９の中へ連続して取り付けることを可能にする。

次に第４図を参照すると、負圧穿刺針１５ａに切り欠き７８が用いられていない別の実施態様が示されている。この装置では同一の部分は添字ａを付した同一符号で示してある。本実施態様においては、穿刺針１５ａには空気通路すなわち開口７８に代つてそのフランジ１０８が常に延長部２６ａの表面１０６ａと隣接して気体は密閉しないように閉じて係合して位置するようなスリーブ９０が形成されている。第６図に示されるようにスリーブ９０は穿刺針１５ａの上に摺動式に係合するように配置されている。しかしながらスリーブ９０は溝の内側の点９５が穿刺針１５ａの外側面と実際に係合する複数の内部溝９４を有する。したがつて溝は穿刺針端部１００ａとスリーブ９０の上側端部の間の気体連通を提供しそこにおいて空気はスリーブ９０のフランジ１０８の隣接面と延長部２６ａの表面１０６ａの間を漏洩する。溝９４は気体は通過させ液体は通過させないよう

な寸法に定められる。フランジ１０８の上方面も同様に端部１００ａと大気の間の通気作用を提供する溝を包含可能なことは理解されるであろう。

単一血液試料採集組み立て体を提供する本発明の更に他の例を第７図に示す。この組み立て体に示されるように特殊なスリーブ８０は使用されておらずかつ穿刺針１５ｂは第２図に示される実施態様における切り欠き７８のような第３の切り欠きすなわち開口を有していない。したがつて穿刺針１４が患者の静脈に挿入されると静脈と管状室５０の間に液体的連通がもたらされ管状室５０の中に試料が採集される。本装置は第２図に示される実施態様のように血液試料は多孔質栓２７を通つて流れない。しかしながら血液試料が管状室５０に入ることによつて押し出された空気は空気透過性栓２７を通り更に切り欠き７４，７６、穿刺針１５の管腔を通つて負圧穿刺針１５ｂの端部１００ｂから排出される。支持具が延長部２６ｂの上に取り付けられ穿刺針１５ｂの点１００ｂが栓を通つて負圧血液採集容器１６の中へ挿入され

ると栓２７の上方の管状室５０と下方の管状室５１の間に差圧が生じそれによつて栓２７は下方へ移動して切り欠き部７４を開口する。これによつて負圧容器１６の中への単一試料採集のための管状室５０と負圧容器１６の間の液体の連通が提供される。この実施態様においてはこの組み立て体によつて更に試料を採集しないので穿刺針１４は患者Ｐの静脈から取り外され組み立て体は必要とする１個の試料が負圧容器の中に採集されたので捨てられる。

負圧穿刺針１５ｃの点１００ｃと大気の間で空気を流通させる第４図に示す態様と類似の他の複数試料採集の実施態様を第８ａおよび８ｂ図に示す。本実施態様においては袖部１１０の内径は段付きになつており、穿刺針１５ｃの外側表面と密着する袖部１１０の小さな内側の径１１４と組み合わされる袖部１１０の表面と穿刺針１５の間の通気通路１１８を形成する大きな内側の径１１６を提供する。したがつて第８ａ図に示す位置においては穿刺針１５ｃの端部１００ｃと大気の間で

通路１１８を通じて通気が起こり、第８ｂ図に示す位置においては通路１１８は閉じられてすべての通気を妨げる。

上述のことから理解されるように本発明においては血液採集針組み立て体はその使用者に静脈への針入を示す装置を組み込んだ単一あるいは複数の試料を採集するために提供されるものである。更に気体を通過させ液体を通過させず弁の機能を有する単純な形態を有する多孔質栓をした本発明の装置は非常に簡素化され製造するに廉価である。当業者に理解されるように特に大量生産に適している。

4.〔図面の簡単な説明〕

第１図は試料採集針組み立て体、負圧容器用支持体および患者からの血液試料を得るために用いる負圧血液採集容器の斜視図。

第２図は本発明の１つの実施態様を示す第１図の線２－２に沿つた拡大断面図。

第３図は第１図の線３－３に沿つた拡大断面図。

第４図は第２図に類似の部分断面図にして本発

明の他の実施態様を示す。

第５図は患者に挿入され使用者が静脈への針入を視覚できるように支持体に連結された針組み立て体の斜視図。

第６図は第４図の線６－６に沿つた断面図。

第７図は第２図に類似の図面であるが本発明の他の実施態様を示す単一試料採集針組み立て体の拡大断面図。

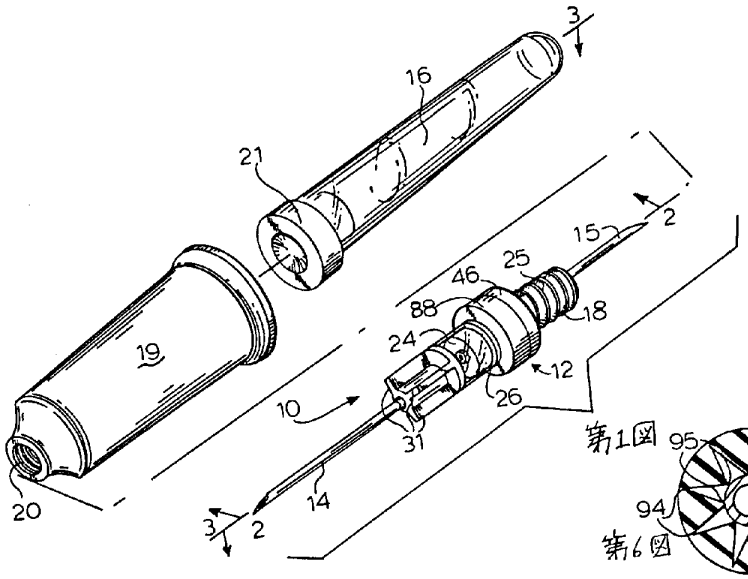
第８ａ図は本発明の他の実施態様を示す単一試料採集針組み立て体の部分拡大断面図。

第８ｂ図は閉鎖されて非通気位置にある第８ａ図の実施態様。

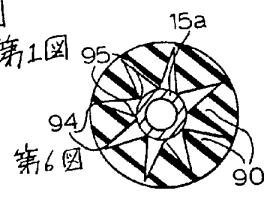
１０……針組み立て体、１２……ハウジング、
１４……第１の穿刺針、１５……第２の穿刺針、
１６……負圧容器、　１９……支持具、
２４……前方端、　２５……後方端、
２７……環状多孔質栓、２９……第１の口孔、
５０……試料採集室、　７０……第２の口孔、
７４……第１の開口部、７６……第２の開口部、
７８……第３の開口部、８０……可撓性スリーブ、
９４……溝、　１１４……小さな内側口径、
１１６……大きな内側口径

特許出願人　ベクトン・ディッキンソン・アンド・カンパニー

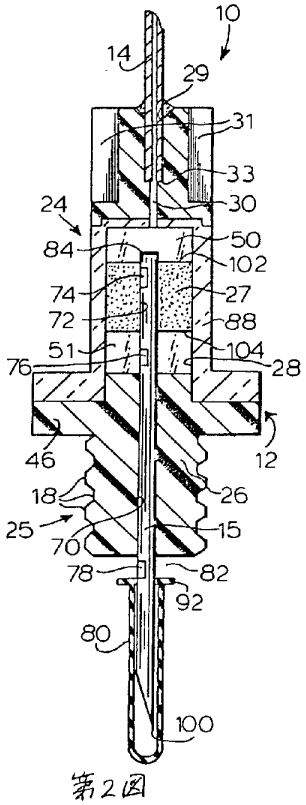
代理人　弁理士　湯浅恭三（外４名）



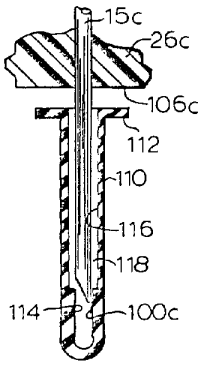
第1図



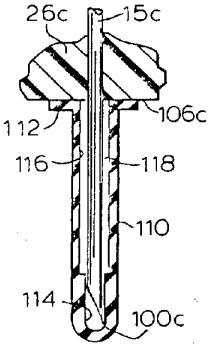
第6図



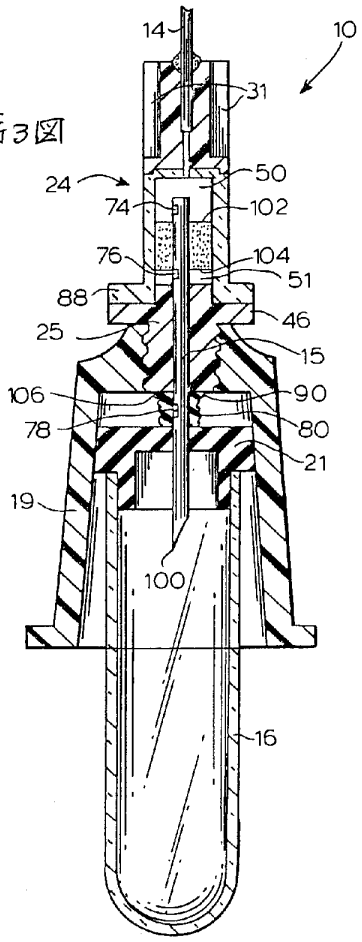
第2図



第8a図

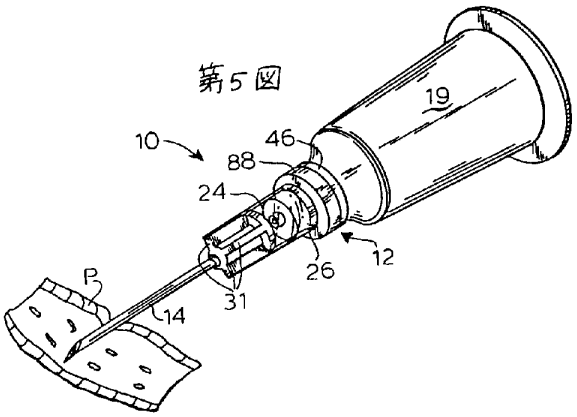


第8b図

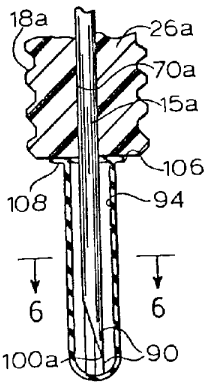


第3図

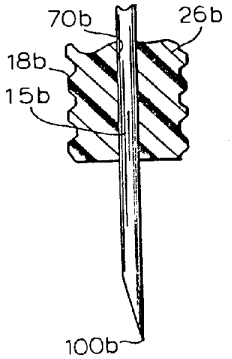
第5図


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第4図


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第7図


70b
26b
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Letter to the Editor

Quality control of bacterial contamination of blood components: the feasibility of diversion system testing

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Quality controls and retrospective investigations indicate that the majority of bacterial strains isolated from platelet concentrates (PC) derives from bacterial flora contaminating the skin[1,2], while about 50% of cases of bacterial contamination of red cell concentrates (RCC) are caused by transitory episodes of asymptomatic bacteraemia in the donor[3]. For the recipient, the risk of receiving PC contaminated by bacteria is 10-1,000 higher than the combined risk of receiving product contaminated by viruses such as HBV, HCV and HIV. The available epidemiological data show that 1: 2-3,000 PC can be contaminated by bacteria and that the risk of severe sepsis is about 1 case for every 1:50,000 platelet transfusions[1]. The risk of severe sepsis from transfusion of RCC is estimated to be about 1:500,000[4]. In the United States bacterial contamination of blood components is the second cause, after human error, of transfusion-related deaths[2].

The recognized preventive measures include: careful selection of the donor in order to avoid periods of possible bacteraemia (recent dental procedures or diarrhoea), scrupulous disinfection of the venipuncture site with appropriate disinfectants not contaminated by bacteria, diversion – for diagnostic purposes – of the first millilitres of donated blood. Widespread use of pathogen inactivation is currently only available for plasma. Assessment of microbiological contamination of blood components by automated culture systems is increasing and is the subject of considerable debate.

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Microbiological cultures of blood components have two aims: to avoid assigning contaminated blood components and to control the quality of the process of producing the blood components themselves. Given the low prevalence of potentially contaminated blood components, preventive bacteriological screening should include all blood components produced: this is an onerous and demanding strategy. Again, in consideration of the low prevalence of contamination, the efficacy of the bacteriological controls on samples can be challenged. Nevertheless, statistically and epidemiologically interesting results can be obtained from co-operation among centres which share the same investigation methods and aims.

We analyzed the technical feasibility of a study on microbiological contamination, using a simple system of diversion into a satellite bag, which allows the blood component to be sampled without compromising its clinical usefulness.

The system allows samples of the contents of the primary bag to be analysed, so the results are applicable to all the blood components produced by fractionating that unit of whole blood, or to conserve the satellite bag in the same conditions as those of the blood component to test, thus exactly reproducing the times and methods of storing the component.

Triple or quadruple bags with SAG-M are used. After having carried out the fractionation and having detached the plasma bag, the SAG-M is allowed to flow into the bag with the red blood cells. After mixing, about 20 mL of the product are allowed to flow into the bag containing SAG-M. This bag is then destined fro sampling for microbiological tests.

We used this system to investigate microbial contamination of RCC. The satellite bags were stored in the blood bank in the same conditions as those used for

the RCC to be transfused. The samples were taken in a sterile environment, under a laminar flow hood, on day + 16 of storage (this being the mean time of use of RCC in our centre) and on day + 42 (expiry date). The cultures were carried out with the MiniVITAL system (BioMerieux SA, Marcy- l'Etoile, France).

The presence of aerobic and anaerobic bacteria and mycetes was investigated. The sampling was carried out using two blood culture bottles with 5 mL of sample in each bottle. Overall, 340 cultures were set up for 170 units of RCC. One blood culture was positive for *Micrococcus spp.*, a saprophytic skin contaminant, weakly pathogenic for humans. This positive culture was found in the group of samples taken on day + 42. Our results, indicating a higher than expected percentage of contamination, support the fact that the most prevalent type of contamination is that from the skin; the data are also of interest with the aim of controlling the production process of blood components[5]. It goes without saying that the number of investigations carried out is too low to attribute any statistical significance to the results.

We believe that it would be worthwhile building a multicentre collaboration on the basis of our methodological approach and in the light of our results.

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Espacenet

Bibliographic data: WO2011162772 (A1) — 2011-12-29

BLOOD DRAWING DEVICE WITH FLASH DETECTION

Inventor(s): FISCHEL LLOYD [US]; BROWN LEROY [US] ± (FISCHEL, LLOYD, ; BROWN, LEROY)

Applicant(s): CLEARVIEW PATIENT SAFETY TECHNOLOGIES LLC [US]; FISCHEL LLOYD [US]; BROWN LEROY [US] ± (CLEARVIEW PATIENT SAFETY TECHNOLOGIES, LLC, ; FISCHEL, LLOYD, ; BROWN, LEROY)

Classification: - **international:** ***A61M5/36***
- **cooperative:** **A61B5/15003 (EP)**; **A61B5/150213 (EP)**; **A61B5/150389 (EP)**; **A61B5/150496 (EP)**; **A61B5/150572 (EP)**; **A61B5/150732 (EP)**; **A61B5/15074 (EP)**; **A61B5/150992 (EP)**; **A61B5/1545 (EP)**; A61B5/150473 (EP)

Application number: WO2010US40030 20100625 Global Dossier

Priority number(s): US20100822931 20100624

Abstract of WO2011162772 (A1)

A device for drawing fluid from a lumen, and particularly blood from a blood vessel, is disclosed. The device may provide indication of the entry of an intravenous cannula into the lumen. The device may include a guide tube for receiving a blood sample container and which may be connected to a needle for drawing blood from a lumen. A rear cannula may extend into the guide tube from the well. A flexible sleeve may be mounted on a barb connected to the guide tube. The flexible sleeve may extend into the guide tube from the well and surround at least a tip portion of the rear cannula. A venting member may be provided between the interior of the sleeve and the ambient.

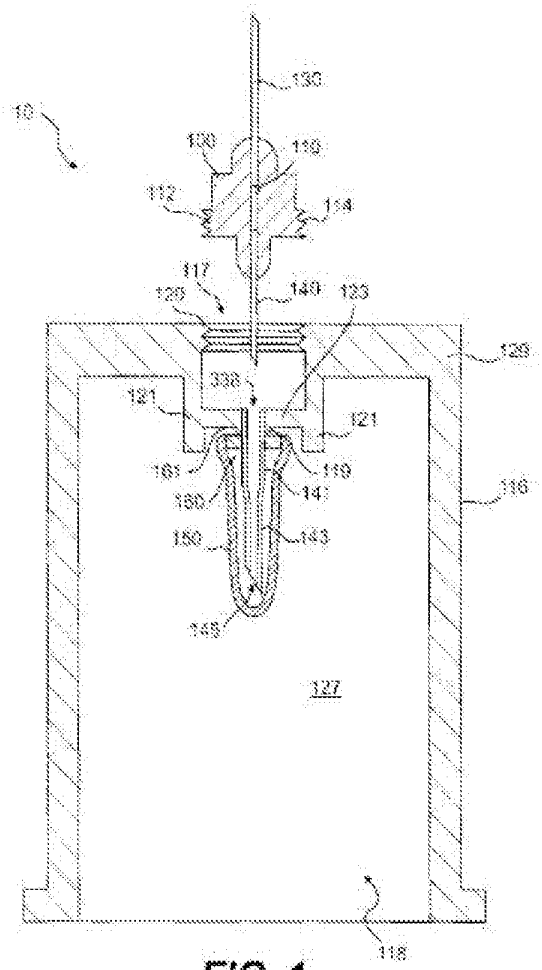

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FIG. 1

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12/822,931 24 June 2010 (24.06.2010) US

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(54) Title: BLOOD DRAWING DEVICE WITH FLASH DETECTION

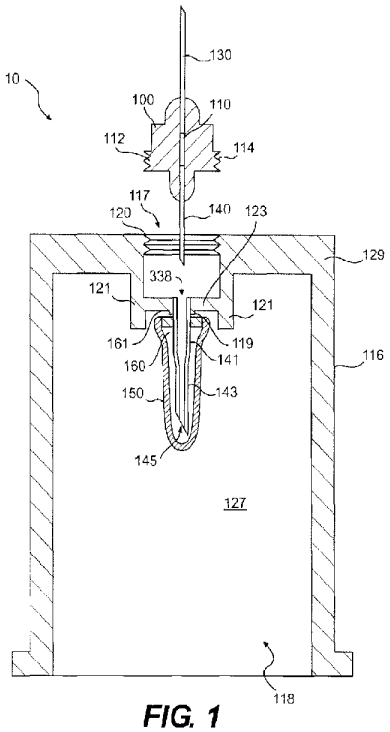


FIG. 1

(57) Abstract: A device for drawing fluid from a lumen, and particularly blood from a blood vessel, is disclosed. The device may provide indication of the entry of an intravenous cannula into the lumen. The device may include a guide tube for receiving a blood sample container and which may be connected to a needle for drawing blood from a lumen. A rear cannula may extend into the guide tube from the well. A flexible sleeve may be mounted on a barb connected to the guide tube. The flexible sleeve may extend into the guide tube from the well and surround at least a tip portion of the rear cannula. A venting member may be provided between the interior of the sleeve and the ambient.

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BLOOD DRAWING DEVICE WITH FLASH DETECTION

FIELD OF THE INVENTION

[0001] The present invention relates to an apparatus for drawing bodily fluids, and particularly blood, from an animal.

BACKGROUND OF THE INVENTION

[0002] Intravenous blood collection assemblies have long been used to draw bodily fluids, such as blood, from patients. With respect to drawing blood in particular, the vessel or lumen from which the blood is drawn is often rather small and or not visible. If the needle tip is not in communication with the interior of the blood vessel during the procedure, the procedure is likely to be unsuccessful, causing error, undermining the integrity of the specimen, and the patient may be harmed additionally by the penetration of delicate underlying structures. Accordingly, confirmation of accurate placement of the needle tip into a blood vessel is desirable for blood drawing procedures.

[0003] Past intravenous blood collection assemblies have included mechanisms for indicating when a needle tip is in communication with the interior of a blood vessel. These needle kits have included a transparent portion in the needle body from which the presence of blood can be observed. The observation of blood in the needle body is known as "flash." Flash detection has been less than satisfactory for many such collection assemblies. In some instances, the flow of blood into the transparent portion of the needle body is impeded by air backpressure in the needle, and thus flash confirmation is not visible or delayed. This delay can impede the determination of the precise moment at which the needle tip enters the blood vessel, which may cause the healthcare worker inserting the needle to miss or perforate the vessel and penetrate into delicate surrounding structures. In other instances, while flash occurs, the visual indication of flash is not easily detected because the amount of flash is small or obscured due to the positioning of the collection assembly. Accordingly, there is a need

for a blood-drawing device that provides flash relatively rapidly and to an extent that a user may readily detect it.

[0004] There are also many needles that are currently used that do not provide for flash detection. It would be advantageous to be able to retrofit such needles so that they may be used to draw blood and provide detection of flash.

SUMMARY OF THE INVENTION

[0005] Responsive to the foregoing challenges, Applicant has developed a guide tube assembly for connection to a device for drawing fluid from a lumen, comprising: a guide tube (116) having an open end (118) and a well (117); a flexible sleeve (150, 151) having an interior space in fluid communication with the well (117) and extending into the guide tube (116); one or more passages (332, 334, 336, 338) extending through the guide tube (116) which are in fluid communication with the flexible sleeve (150) interior space; and a venting member (160) connected to the guide tube (116) or incorporated into the flexible sleeve (150, 151), said venting member in fluid communication with the one or more passages (332, 334, 336, 338) and disposed between the flexible sleeve (150, 151) interior space and an ambient.

[0006] It is to be understood that both the foregoing general description and the following detailed description are exemplary and explanatory only, and are not restrictive of the invention as claimed.

BRIEF DESCRIPTION OF THE DRAWINGS

[0007] In order to assist the understanding of this invention, reference will now be made to the appended drawings, in which like reference characters refer to like elements.

[0008] Figure 1 is a side view in cross-section of a blood drawing needle and guide tube having a venting member in accordance with a first embodiment of the present invention prior to connection with a blood drawing needle.

[0009] Figure 2 is a side view in cross-section of the guide tube shown in Figure 1

after connection to the blood drawing needle.

[0010] Figure 3 is a side view in cross-section of a guide tube having a venting member in accordance with an second embodiment of the present invention prior to connection with a blood drawing needle.

[0011] Figure 4 is an end view of the raised dimple surface of a well bottom wall provided in the guide tube in accordance with an alternative embodiment of the invention shown in Figures 1-3.

[0012] Figure 5 is an end view of the raised radial line surface of a well bottom wall provided in the guide tube in accordance with an alternative embodiment of the invention shown in Figures 1-3.

[0013] Figure 6 is a side view in cross-section of a blood drawing device with a guide tube having a venting member located in a guide tube opening in accordance with a third embodiment of the present invention.

[0014] Figure 7 is a side view in cross-section of a blood drawing device with a guide tube having a venting member located in a guide tube opening with well bottom extensions surrounding the venting member in accordance with a fourth embodiment of the present invention.

[0015] Figure 8 is a side view in cross-section of a blood drawing device with a guide tube having a venting member and viewing window located in a guide tube side wall in accordance with a fifth embodiment of the present invention.

[0016] Figure 9 is a side view in cross-section of a blood drawing device with a guide tube having a venting member and viewing window located in a guide tube side wall in accordance with a sixth embodiment of the present invention.

[0017] Figure 10 is a side view in cross-section of a blood drawing device with a guide tube having a venting member located in a guide tube opening in accordance with a seventh embodiment of the present invention.

[0018] Figure 11 is a side view in cross-section of a blood drawing device with a guide tube having a venting member located in a guide tube opening and a viewing

window located in a guide tube side wall in accordance with an eighth embodiment of the present invention.

[0019] Figure 12 is a side view in cross-section of a blood drawing device with a guide tube having a venting member located in a guide tube opening surrounded by well bottom extensions and having a viewing window located in a guide tube side wall in accordance with a ninth embodiment of the present invention.

[0020] Figure 13 is a side view in cross-section of a blood drawing device with a guide tube having a venting member located in a guide tube opening with well bottom extensions surrounding the venting member in accordance with a tenth embodiment of the present invention.

[0021] Figure 14 is a side view in cross-section of a blood drawing device with a guide tube having a sealing membrane in a guide tube well and a venting member and viewing window located in a guide tube side wall in accordance with an eleventh embodiment of the present invention.

[0022] Figure 15 is a side view in cross-section of a blood drawing device with a guide tube having a venting member and viewing window located in a guide tube side wall in accordance with a twelfth embodiment of the present invention.

[0023] Figure 16 is a side view in cross-section of a blood drawing device with a guide tube having a venting member located in a guide tube well in accordance with a thirteenth embodiment of the present invention.

[0024] Figure 17 is a side view in cross-section of a blood drawing device with a guide tube having a venting member located in a sleeve tubulation and a viewing window located in a guide tube side wall in accordance with a fourteenth embodiment of the present invention.

[0025] Figure 18 is a side view in cross-section of a blood drawing device with a guide tube having an air-permeable sleeve and a viewing window located in a guide tube side wall in accordance with a fifteenth embodiment of the present invention.

[0026] Figure 19 is a side view in cross-section of a blood drawing device with a

guide tube having a sleeve with a venting portion and a viewing window located in a guide tube side wall in accordance with a sixteenth embodiment of the present invention.

[0027] Figure 20 is a side view in cross-section of a blood drawing device with a guide tube having a venting member located in a sleeve tubulation and a viewing window located in a guide tube side wall in accordance with a seventeenth embodiment of the present invention.

[0028] Figure 21 is a side view in cross-section of a blood drawing device with a guide tube having an air-permeable sleeve and a viewing window located in a guide tube side wall in accordance with an eighteenth embodiment of the present invention.

[0029] Figure 22 is a side view in cross-section of a blood drawing device with a guide tube having a sleeve with a venting portion and a viewing window located in a guide tube side wall in accordance with a ninteenth embodiment of the present invention.

[0030] Figure 23 is a side view in partial cross-section of a first Luer-adapter type butterfly needle attachment which may be used to connect with the guide tubes shown in Figures 1-22.

[0031] Figure 24 is a side view in cross-section of a second butterfly needle attachment that may be used to directly connect to the guide tubes shown in Figures 1-22.

DETAILED DESCRIPTION OF EMBODIMENTS OF THE INVENTION

[0032] Reference will now be made in detail to a first embodiment of the present invention, an example of which is illustrated in the accompanying drawings. With reference to Figs. 1 and 2, a guide tube **116** is shown. The guide tube **116** is provided for connection to a central body **100** which may include one or more constituent elements, such as a threaded connector **112** with interlocking threads **114** or other connection means, for connecting the central body to the guide tube. The threaded connector **112** may be integrally formed with, or connected to the central body using

adhesive, male-female interfaces, threaded interfaces, or any other connection means. It is appreciated that the guide tube **116** may be connected to the central body **100** by any connection means, including without limitation the threaded interfaces shown, male-female interfaces, pressure-fit connectors, slot and key connectors, snap-on connectors, and the like. The type of connection between the guide tube **116** and the central body **100** is not intended to be limiting to the scope or use of any of the present embodiments of the invention.

[0033] A fluid passage **110** within the central body **100** may communicate with, and in the embodiment shown, be connected to the front cannula **130** and the first rear cannula **140**, respectively, using adhesive, threaded interfaces, pressure fit, or other connection means. Alternatively, the central body **100** may be integrally formed with the front and/or first rear cannulae **130** and **140**. It is further appreciated the front and first rear cannulae **130** and **140** may be formed of a continuous material and eliminate the need to fluid passage **110**. It is also appreciated that the front and/or rear cannulae may be transparent or translucent, in whole or part, to provide flash detection in alternative embodiments of the present invention. If included, the fluid passage **110** may be defined by the opening within the central body between the front and rear cannulae when the cannulae are directly connected to the central body. The fluid passage **110** may be adapted to receive a sufficient amount of fluid to allow observation of the fluid (*i.e.*, "flash") from outside the blood-drawing device **10**. At the same time, the fluid passage **110** may have a sufficiently small volume so as to rapidly fill with fluid during the use of the blood-drawing device.

[0034] Preferably, the central body **100** may be constructed of plastic material suitable for medical use. Further, in any embodiment of the present invention, all, or portions, of the central body **100** may be transparent, translucent, connected to transparent or translucent I.V. tubing, or otherwise adapted to permit detection of fluids passing through the central body and/or I.V. tubing from a vantage point outside of the blood-drawing device **10**. For example, with reference to Fig. 1, the central body **100**

may include a transparent wall that is adapted to permit the observation of "flash" when it occurs. In an alternate embodiment of the present invention, the side wall of the central body **100** also may be adapted to magnify or otherwise enhance the detection of fluid passing through the central body, although it is appreciated that a magnifying or enhancement feature is not necessarily required.

[0035] It is further appreciated that the front cannula **130** may be replaced with or connected to a flexible butterfly connection tube **182** that is part of a butterfly needle **180** as shown in Fig. 23. When connected to a flexible butterfly connection tube **182**, the front cannula **130** extending from the central body **100** may be eliminated and replaced with a Luer-adapter including a female connector **102** and male connector **103** which is connected via the butterfly connection tube **182** to a butterfly cannula **184** which substitutes for the front cannula **130**. The flexible butterfly connection tube **182** may be translucent or transparent when combined with the embodiments shown in Figs. 1-22 so that the "flash" of blood that enters the device **10** may be visible first in the butterfly connection tube. In a further alternative, shown in Fig. 24 and applicable to the embodiments shown in Figs. 1-22, the female connector **102** of the Luer-adapter may connect directly to a specially formed mating male connector **103** integrally formed with the guide tube **116.** It is appreciated that the placement of the male and female connectors could be reversed or replaced with other connector types in alternative embodiments of the invention.

[0036] With renewed reference to Figs. 1-2, the front cannula **130** may extend from the front end of the central body **100** and terminate at a tapered or pointed end **132** which is adapted to be inserted into a lumen. The first rear cannula **140** may extend from the rear of the central body **100** and terminate at a tapered or pointed end.

[0037] A generally cylindrical guide tube **116** is adapted to be connected to the central body **100**. Preferably, the guide tube **116** may be made in whole or part of transparent or translucent material that permits viewing of the interior space of the guide tube. The guide tube **116** may include a substantially closed end **129**, an open

end **118** at one end communicating with an interior opening **127**, and a well **117** at the opposite end defined in part by a well bottom wall **123**. The open end **118** may be adapted to receive a blood or fluid sample container. The upper edge of the well **117** may include threads or other connection means **120** adapted to mate with the threads **114** of the threaded connector **112** provided on the central body **100**.

[0038] The well bottom wall **123** may include a centrally located opening through which a second rear cannula **141** extends towards the guide tube open end **118**. The second rear cannula **141** may be sufficiently fastened to the well bottom wall **123** by any means such that the application of pressure from a fluid sample container pressed against the second rear cannula will not dislodge the second rear cannula. The guide tube **116** may extend coaxially with the second rear cannula **141** sufficiently beyond the tapered end **145** to provide some degree of protection against inadvertent "needle sticks" by a user of the blood-drawing device **10** as well as to guide the reception of a fluid sample container.

[0039] The bottom surface of the well bottom wall **123** located within the interior of the guide tube **116** may include a shoulder **119** against which a venting member **160** may be disposed. The shoulder **119** may create an air space **161** between the bottom surface of the well **117** and the venting member **160**. In one alternative embodiment of the invention, shown in Fig. 4, the shoulder **119** may be replaced by or incorporate a surface having raised dimples **217**, or in another alternative embodiment, as shown in Fig. 5, the shoulder may be replaced by or incorporate a surface having raised radial lines **219**, or some other surface which both supports the venting member **160** and provides for air flow between the venting member and the interior of the guide tube **116**. In still other alternative embodiments of the present invention, an air-permeable spacer may be provided between the venting member **160** and the bottom surface of the well bottom wall **123** to provide the required air flow in place of any raised features on the bottom of the well bottom wall.

[0040] The second rear cannula **141** may include a stepped diameter **143** or other

narrowing feature that results in the second rear cannula having a narrower diameter at the pointed end **145** compared with the end extending from the well **117**. The end of the second rear cannula **141** nearest to the well **117** may have a diameter sufficient to receive the first rear cannula **140** within it. In alternative embodiments of the invention, the second rear cannula **141** may have a uniform diameter over its entire length.

[0041] One or more well bottom extensions **121** may also extend from the well bottom wall **123** into the guide tube opening **118** adjacent to the venting member **160**. The well bottom extensions **121** may surround the venting member **160** in whole or in part and may be formed so as to leave an air space for air to flow from the interior of the sleeve **150** through the venting member **160** to the ambient in the guide tube interior opening **127**. The well bottom extensions **121** may be semi-circular, or prong shaped, and surround the venting member **160**. Further, the well bottom extensions **121** may extend into the guide tube **116** a distance sufficient to protect the venting member **160** from being impacted against, damaged or dislodged by, the stopper of a container inserted into the guide tube. The well bottom extensions **121** may be formed of plastic material which is integral with the rest of the guide tube **116** and well bottom wall **123**. The well bottom extensions **121** may also contact the venting member **160** and/or flexible sleeve **150** so as to assist in retaining the sleeve and venting member in the guide tube **116**.

[0042] The venting member **160** may be constructed out of any material which is capable of substantially preventing blood from passing through it while permitting air to vent through it. Preferably, for purposes of ease of manufacturing, the venting member **160** may be formed as a stamped disk with a central opening from a sheet of venting member material for the embodiment shown in Figs. 1-2.

[0043] The venting member **160** may be constructed of any of a number of materials that provide the desired level of porosity, which may include, but are not limited to sintered, layered, rolled, foamed, perforated, or impregnated, hydrophyllic/hydrophobic compositions, porous polyethylene, porous polypropylene,

porous polyfluorocarbon, absorbent paper, materials impregnated with dilute Russell Viper venom molded fiber, fiberglass, felt, granular starch, cellulose, polyacrylamide gel, hydrogel, a molded admixture of porous hydrophobic/hydrophyllic granules and sufficiently low density silicone, molded open cell polyurethane, and like polymeric materials. Examples of materials that may be used to construct the venting (i.e., porous) member **160** are discussed in U.S. Patent No. 4,207,870 to Eldridge, and U.S. Patent No. 4,340,068 to Kaufman, each of which are hereby incorporated by reference.

[0044] The venting member **160** (*i.e.*, a means for venting air) may be inserted over the second rear cannula **141** and pressed against or near to the rear portion of the well bottom wall **123**. The venting member **160** may form a seal against the second rear cannula **141** that is sufficient to prevent blood from escaping past the venting member. In the embodiments of the present invention, the venting member **160** may be gas, and particularly air, permeable, but at least partially, and preferably wholly, impermeable to a liquid, such as blood. Preferably, the venting member **160** may be substantially porous for gas constituents less than about 5 microns in size, and substantially non-porous for liquid constituents about 5 microns or greater in size, however, it is appreciated that these approximate sizes should not be limiting for the invention.

[0045] For each of the embodiments discussed in connection with Figs. 3-24, the venting member **160** may be constructed in accordance with the description of the venting members described in connection with the embodiment of the invention described in connection with Figs. 1-2.

[0046] A flexible sleeve **150** may be disposed over and around the second rear cannula **141**. The sleeve **150** may isolate the second rear cannula **141** from the ambient, wherein the ambient includes any space outside of the sleeve **150**, irrespective of whether or not the space is contained within the guide tube **116** or any other structure. The flexible sleeve **150** may be stretched over all or part of the side wall of the venting member **160**, or in alternate embodiments, otherwise contact the venting member **160**. The flexible sleeve **150** may be made of a shape memory

material, such as elastic rubber or elastomeric silicone or latex, or the like, which will return to the shape shown in Fig. 1 as long as no other structure obstructs it. Examples of materials that may be used to construct the flexible sleeve **150** are discussed in U.S. Patent No. 3,877,465 to Miyake, U.S. Patent No. 5,086,780 to Schmitt, U.S. Patent No. 6,110,160 to Farber, U.S. Patent No. 6,533,760 to Leong, U.S. Patent Pub. No. US 2002/0004647 A1 to Leong, and U.S. Patent Pub. No. US 2003/0078544 A1 to Chen, each of which is hereby incorporated by reference. It is appreciated that any suitable material may be used for the flexible sleeve without departing from the intended scope of the present invention.

[0047] The flexible sleeve **150**, also known as a multiple sample sleeve, may preferably be transparent or translucent such that the presence of blood within the flexible sleeve may be visually detected. When the flexible sleeve **150** is transparent or translucent in any of the embodiments shown in Figs. 1-24, the guide tube **116** may also be transparent or translucent so that the "flash" of blood may be visible through both the guide tube and the flexible sleeve to the person drawing blood. The length of the flexible sleeve **150** may be sufficient to accommodate the second rear cannula **141** but not so long as to present serious risk of the second rear cannula piercing the side wall of the flexible sleeve when a fluid sample container is pushed into the guide tube **116**.

[0048] Prior to using the device **10** to draw blood, the central body **100** may be connected to the guide tube **116** at the threaded end **112** as shown in Fig. 2, in which like reference characters refer to like elements. When so connected, the combination of the guide tube **116** with a venting member **160** and the flexible sleeve **150** may be used to effectively "retrofit" a non-venting blood drawing device to become a venting blood drawing device. It is appreciated that each of the embodiments of the present invention shown in Figs. 1-24 may be used to retrofit existing non-venting blood drawing devices to become devices which vent air without substantially venting blood. The well **117** may be designed to provide sufficient space to accommodate the rear portion of

the central body **100** of a conventional or known blood drawing device within it to provide retro-fitting.

[0049] The function of the first embodiment of the blood-drawing device **10** will now be described with reference to Figs. 1-2. With reference to Figs. 1-2, the tapered end **132** of the front cannula **130** (or some extension thereof) may be inserted into a fluid containing body lumen prior to the insertion of a fluid sample container into the guide tube **116**. In a preferred embodiment of the present invention, the front cannula **130** is inserted into a lumen containing a visually detectable fluid, such as blood. At the time that the front cannula **130** is inserted into the body lumen, it is assumed that the internal passages within the blood-drawing device (*i.e.*, the passage through the front cannula **130**, the fluid passage **110**, the passage through the rear cannula **140**, and the space inside the flexible sleeve **150**) may be filled with atmospheric air or some other gas. When the front cannula **130** establishes communication with the fluid in the body lumen, fluid pressure in the lumen may force the fluid through the front cannula **130** towards the fluid passage **110**.

[0050] The flow of fluid through the front cannula may begin to compress the air in the fluid passage **110**, the rear cannula **140**, the second rear cannula **141**, and the space between the rear cannulae and the flexible sleeve **150**, driving the air towards the venting member **160**. Air within the blood drawing device **10** that would otherwise prevent or slow the flow of blood into it, may vent through the flexible sleeve **150** and the venting member **160** to the ambient within the guide tube **116**. The air may vent from the venting member **160** through the air space **161** that may be created by the shoulder **119** or the dimples **217** (Fig. 4) or radial lines **219** (Fig. 5). As a result, there may be insufficient air pressure within the fluid passage **110** to resist the flow of the fluid, where it may be detected or observed as "flash" by a user.

[0051] Blood that flows into the blood drawing device may be viewed either through the central body **100**, the butterfly connection tube **182** (in embodiments that use a butterfly needle) or through a transparent or translucent flexible sleeve **150** and/or a

transparent or translucent guide tube **116**. The visual detection of blood indicates positive vein entry, known as flash. It is appreciated that "flash" may be detected at any point along the device that includes a transparent or translucent member, which may include, but not be limited to, a transparent or translucent cannula, central body, I.V. tubing, flexible sleeve, or other constituent member.

[0052] Once flash is detected, a fluid sample container may be pressed into the open end **118** of the guide tube **116**, the second rear cannula **141** may pierce the flexible sleeve **150**, and the flexible sleeve is pushed back towards the base of the second rear cannula. As shown in Fig. 2, the first rear cannula **140** may slide into the second rear cannula **141** and the second rear cannula may extend into the guide tube **116** a distance which is sufficient to pierce the stopper provided on the top of a fluid sample container. The one or more well bottom extensions **121** may prevent the fluid sample container from crushing, dislodging or otherwise damaging the venting member **160**. A sample of blood may then be received in the fluid sample container.

[0053] An alternative embodiment of the present invention is shown in Fig. 3, in which like reference characters refer to like elements in the other drawing figures. The embodiment shown in Fig. 3 differs from that shown in Figs. 1-2 in that the second rear cannula **141** is truncated. In this embodiment the first rear cannula **140** is of sufficient length to pierce a fluid sample container. It is also appreciated that the second rear cannula **141** could be replaced with an integral portion of the well bottom wall **123** shaped to receive the venting member **160**. In all other respects the embodiment shown in Fig. 3 operates like the embodiment shown in Figs. 1-2.

[0054] With reference to Fig. 6, another embodiment of the present invention is shown in which all reference characters refer to like elements shown in the previous drawing figures. The well bottom wall upper surface **125** may prevent blood from flowing into the well **117** when the central body **100** is seated against the well bottom wall **123**.

[0055] With continued reference to Fig. 6, the second rear cannula **141** may have a

venting member **160** disposed about it at a base portion against the inner end wall of the guide tube **116**. The venting member **160** may have a base **300** and a barb portion **302**. The base **300** may be adhered to the end wall of the guide tube **116**, pressure fit onto the second cannula **141**, or otherwise fixed into position within the guide tube **116** without being directly connected to the central body **100** or any element of the central body, such as the first rear cannula **140**. The venting member **160** base **300** may be defined in part by an annular recess which separates the base from the barb portion **302** that is adapted to have the open end of a flexible sleeve **150** mounted thereon. Alternatively, the venting member **160** need not have any annular recess so long as the flexible sleeve **150** has a base portion **300** which provides an air path for air to flow from inside the flexible sleeve **150** to the interior of the guide tube **116**. The air path may be provided in whole or in part by well bottom wall **123** features such as dimples **217** (Fig. 4), radial lines **219** (Fig. 5) or the like. The embodiment shown in Fig. 6, as well as the embodiments of the invention shown in Figs. 1-5 and 7-24, may be used to retrofit an existing and non-air venting needle central body **100** into an air venting blood drawing device after being connected to the guide tube **116**.

[0056] With continued reference to Fig. 6, when the front cannula **130** (or butterfly cannula **184** with respect to Figs. 23-24) is introduced to a lumen, such as a vein, to draw fluid, such as blood, the blood may readily flow through the front cannula, the first rear cannula **140**, the second rear cannula **141** and into the interior of the flexible sleeve **150**. Air within the blood drawing device **10** that would otherwise prevent or slow the flow of blood into it, may vent through the flexible sleeve **150** and the venting member **160** through the venting member base **300** to the ambient within the guide tube **116**. The venting member base **300** may provide a surface for air to escape from the venting member **160**. Blood that flows into the blood drawing device may be viewed either through the central body **100**, the butterfly connection tube **182** (in embodiments that use a butterfly needle) or through a transparent or translucent flexible sleeve **150** and transparent or translucent guide tube **116**. The visual detection of blood indicates

positive vein entry, known as flash. Once flash is detected, a fluid sample container may be pressed into the open end **118** of the guide tube **116**, the second rear cannula **141** may pierce the flexible sleeve **150** and the flexible sleeve is pushed back towards the base of the second rear cannula. The shape of the venting member **160** with a wide base **300** and barb portion **302** may be such as to withstand the force of a fluid sample container being inserted into the guide tube and against the venting member without the venting member being crushed or otherwise damaged. This is necessary so that multiple sample containers can be filled with blood without the risk of leakage past a damaged venting member.

[0057] With reference to Fig. 7, another embodiment of the present invention is shown in which all reference characters refer to like elements shown in the previous drawing figures. The embodiment shown in Fig. 7 is identical in all respects to that shown in Fig. 6 with the following exception. With respect to Fig. 7, one or more well bottom extensions **121** may extend from the well bottom wall **123**. The well bottom extensions **121** may surround the venting member **160** in whole or in part and may be formed so as to leave an air space for air to flow from the interior of the sleeve **150** through the venting member **160** to the ambient in the guide tube opening **118**. The well bottom extensions **121** may be semi-circular or prong shaped and surround the venting member **160**. Further, the well bottom extensions **121** may extend into the guide tube **116** a distance sufficient to protect the venting member **160** from being impacted against, damaged or dislodged by, the stopper of a container inserted into the guide tube. The well bottom extensions **121** may be formed of plastic material which is integral with the rest of the guide tube **116** and well bottom wall **123**. The well bottom extensions **121** may also be used to secure the venting member **160** and more particularly, the base portion **300** of the venting member so that the venting member is retained in place without the need to use an adhesive or other connection means to the guide tube **116**.

[0058] With reference to Fig. 8, another embodiment of the present invention is

shown in which all reference characters refer to like elements shown in the previous drawing figures. As noted above with respect to Figs. 6-7, the well bottom wall upper surface **125** may prevent blood from flowing into the well **117** when the central body **100** is seated against the well bottom wall **123**.

[0059] With continued reference to Fig. 8, the flexible sleeve **150** may be mounted or fitted onto a sleeve connector **330** which is integrally formed with the guide tube **116** within the guide tube opening **118**. A sleeve connector passage **332** may extend through the sleeve connector **330** and connect with a lateral passage **334** that extends from the sleeve connector passage **332** to a guide tube aperture **342** located along the guide tube outer wall. The guide tube aperture **342** may have a venting member **160** disposed in it, and an optional viewing window **340** disposed in it. The viewing window **340** may be transparent or translucent and may permit blood to be viewed by a user through the viewing window so as to detect flash. The viewing window **340** may be disposed next to, circumferentially about, or within the venting member **160** without departing from the intended scope of the invention. In fact, the viewing window **340** and the venting member **160** may be disposed in separate apertures in alternative embodiments. The viewing window **340** also may be unnecessary if flash is detected elsewhere, such as through a translucent or transparent butterfly connection tube, central body, flexible sleeve and/or guide tube.

[0060] The blood drawing device shown in Fig. 8 may be used as follows. The central body **100** may be connected to the guide tube **116** such that the rear portion of the central body seals against the well bottom wall upper surface **125**. Such sealing is not required in this or any other embodiments discussed, but is preferred to limit the amount of blood that may flow into the well space **117** if the central body **100** is disconnected from the guide tube **116**.

[0061] Once the central body **100** is connected to the guide tube **116**, the front cannula **130** or butterfly cannula **184** may be introduced into a lumen, such as a vein, to draw fluid, such as blood. The blood may readily flow through the front cannula **130**,

the first rear cannula **140**, the second rear cannula **141** and into the interior of the flexible sleeve **150**. Air within the blood drawing device **10** that would otherwise prevent or slow the flow of blood into it, may vent through the flexible sleeve **150**, the sleeve connector passage **332**, the lateral passage **334**, and the venting member **160** to the ambient outside the guide tube **116**. Blood that flows into the blood drawing device may be viewed either through the central body **100**, the butterfly connection tube **182** (in embodiments that use a butterfly needle), through a transparent or translucent flexible sleeve **150** and transparent or translucent guide tube **116**, or through the optional viewing window **340**. The visual detection of blood indicates positive vein entry, known as flash. Once flash is detected, a fluid sample container may be pressed into the open end **118** of the guide tube **116**, the second rear cannula **141** may pierce the flexible sleeve **150** and the flexible sleeve is pushed back towards the base of the second rear cannula.

[0062] With reference to Fig. 9, another embodiment of the present invention is shown in which all reference characters refer to like elements shown in the previous drawing figures. The embodiment shown in Fig. 9 is identical in all respects to that shown in Fig. 8 with the following exception. With respect to Fig. 9, a well passage **336** extends from the well **117** to the aperture **342**. Air may vent from the rear cannula **140** up through the second rear cannula **141** and into the well **117**. The air may then flow through the well passage **336** and the venting member **160**. Blood may fill the well passage **336** and the aperture **340**. Blood may be viewed either through the central body **100**, the butterfly connection tube **182** (in embodiments that use a butterfly needle), through a transparent or translucent flexible sleeve **150** and transparent or translucent guide tube **116**, or through the optional viewing window **340**.

[0063] With reference to Fig. 10, another embodiment of the present invention is shown in which all reference characters refer to like elements shown in the previous drawing figures. A venting member **160** may be disposed against the well bottom wall **123** of the guide tube **116**. The venting member **160** base portion **300** may be adhered

to the well bottom wall of the guide tube **116**, pressure fit onto the cannula **140**, or otherwise fixed into position. A central well opening **338** may extend through the venting member **160** and the well bottom wall **123** to permit air and blood to flow into the well **117**. Alternatively, the central well opening **338** may be reduced in diameter so that the cannula **140** seals against the well bottom wall **123** and/or the venting member **160**. The venting member **160** may have a base **300** separated from a barb portion **302** by an annular recess. The barb portion **302** may be adapted to have an open end of a flexible sleeve **150** mounted thereon. Alternatively, the venting member **160** need not have any annular recess so long as the flexible sleeve **150** has a base portion **300** which provides an air path for air to flow from inside the flexible sleeve **150** to the interior of the guide tube **116**. The air path may be provided in whole or in part by well bottom wall **123** features such as dimples **217** (Fig. 4), radial lines **219** (Fig. 5) or the like.

[0064] With continued reference to Fig. 10, when the front cannula **130** or butterfly cannula **184** is introduced to a lumen, such as a vein, to draw fluid, such as blood, the blood may readily flow through the front cannula, the first rear cannula **140** and into the interior of the flexible sleeve **150**. Air within the blood drawing device **10** that would otherwise prevent or slow the flow of blood into it, may vent through the flexible sleeve **150** and the venting member **160** through the venting member base **300** to the ambient within the guide tube **116**. The venting member base **300** may provide a surface for air to escape from the venting member **160**. Blood that flows into the blood drawing device may be viewed either through the central body **100**, the butterfly connection tube **182** (in embodiments that use a butterfly needle) or through a transparent or translucent flexible sleeve **150** and transparent or translucent guide tube **116**. The visual detection of blood indicates positive vein entry, known as flash. Once flash is detected, a fluid sample container may be pressed into the open end **118** of the guide tube **116**, the rear cannula **140** may pierce the flexible sleeve **150** and the flexible sleeve is pushed back towards the base of the second rear cannula.

[0065] With reference to Fig. 11, another embodiment of the present invention is shown in which all reference characters refer to like elements shown in the previous drawing figures. The embodiment shown in Fig. 11 is identical in all respects to that shown in Fig. 10 with the following exception. With respect to Fig. 11, a well passage **336** extends from the well **117** to the aperture **342**. After air vents through the venting member **160**, blood may flow from the rear cannula **140** up through the central well opening **338** and into the well **117**. The blood may then flow through the well passage **336** and to the viewing window **340**. Blood may be viewed either through the central body **100**, the butterfly connection tube **182** (in embodiments that use a butterfly needle), through a transparent or translucent flexible sleeve **150** and transparent or translucent guide tube **116**, or through the optional viewing window **340**. The well **117** may be formed with sufficient space to permit blood to flow to the viewing window without creating significant air back-pressure in the well passage **336** and aperture **342**.

[0066] With reference to Fig. 12, another embodiment of the present invention is shown in which all reference characters refer to like elements shown in the previous drawing figures. The embodiment shown in Fig. 12 is identical in all respects to that shown in Fig. 11 with the following exception. With respect to Fig. 12, one or more well bottom extensions **121** may extend from the well bottom wall **123**. The well bottom extensions **121** may surround the venting member **160** in whole or in part and may be formed so as to leave an air space for air to flow from the interior of the sleeve **150** through the venting member **160** to the ambient in the guide tube opening **118**. The well bottom extensions **121** may be semi-circular or prong shaped and surround the venting member **160**. Further, the well bottom extensions **121** may extend into the guide tube **116** a distance sufficient to protect the venting member **160** from being impacted against, damaged or dislodged by, the stopper of a container inserted into the guide tube. The well bottom extensions **121** may be formed of plastic material which is integral with the rest of the guide tube **116** and well bottom wall **123**. The well bottom extensions **121** may also be used to secure the venting member **160** and more

particularly, the base portion **300** of the venting member so that the venting member is retained in place without the need to use an adhesive or other connection means to the guide tube **116**.

[0067] With reference to Fig. 13, another embodiment of the present invention is shown in which all reference characters refer to like elements shown in the previous drawing figures. The embodiment shown in Fig. 13 is identical in all respects to that shown in Fig. 10 with the following two exceptions. With respect to Fig. 13, one or more well bottom extensions **121** may extend from the well bottom wall **123**. The well bottom extensions **121** may surround the venting member **160** in whole or in part and may be formed so as to leave an air space for air to flow from the interior of the sleeve **150** through the venting member **160** to the ambient in the guide tube opening **118**. The well bottom extensions **121** may be semi-circular or prong shaped and surround the venting member **160**. Further, the well bottom extensions **121** may extend into the guide tube **116** a distance sufficient to protect the venting member **160** from being impacted against, damaged or dislodged by, the stopper of a container inserted into the guide tube. The well bottom extensions **121** may be formed of plastic material which is integral with the rest of the guide tube **116** and well bottom wall **123**. The well bottom extensions **121** may also be used to secure the venting member **160** and more particularly, the base portion **300** of the venting member so that the venting member is retained in place without the need to use an adhesive or other connection means to the guide tube **116**. Further, in Fig. 13 the central body **100** may be connected to the guide tube **116** such that the rear portion of the central body seals against the well bottom wall upper surface **125**. Such sealing is not required in this or any other embodiments discussed, but is preferred to limit the amount of blood that may flow into the well space **117** if the central body **100** is disconnected from the guide tube **116**.

[0068] With reference to Fig. 14, another embodiment of the present invention is shown in which all reference characters refer to like elements shown in the previous drawing figures. The well bottom wall **123** may have a sealing membrane **310** made of

material similar to or the same as the flexible sleeve **150** which may prevent blood from flowing into the well **117** when the cannula **140** is inserted through and/or withdrawn from it.

[0069] With continued reference to Fig. 14, the flexible sleeve **150** may be mounted or fitted onto a sleeve connector **330** which is integrally formed with the guide tube **116** within the guide tube interior opening **127**. A central well opening **338** may extend through the sleeve connector **330** and connect with a lateral passage **334** that extends from the central well opening **338** to a guide tube aperture **342** located along the guide tube outer wall. The guide tube aperture **342** may have a venting member **160** disposed in it, and an optional viewing window **340** disposed in it. The viewing window **340** may be transparent or translucent and may permit blood to be viewed by a user through the viewing window so as to detect flash. The viewing window **340** may be disposed next to, circumferentially about, or within the venting member **160** without departing from the intended scope of the invention. In fact, the viewing window **340** and the venting member **160** may be disposed in separate apertures in alternative embodiments. The viewing window **340** also may be unnecessary if flash is detected elsewhere, such as through a translucent or transparent butterfly connection tube, central body, flexible sleeve and/or guide tube. The blood drawing device shown in Fig. 14 may be used in the same manner as that described above in connection with Fig. 8.

[0070] With reference to Fig. 15, another embodiment of the present invention is shown in which all reference characters refer to like elements shown in the previous drawing figures. The embodiment shown in Fig. 15 is identical in all respects to that shown in Fig. 9 with the following exception. With respect to Fig. 15, the central well opening **338** is defined by the well bottom wall **123** and the sleeve connector **330**. The second rear cannula (shown in Fig. 9) is not provided. When the front cannula **130** is introduced to the vein of a patient air may vent from the rear cannula **140** up through the central well opening **338** and into the well **117**. The air may then flow through the well passage **336** and the venting member **160**. After the air is vented, blood may fill

the well passage **336** and the aperture **340**. Blood may be viewed either through the central body **100**, the butterfly connection tube **182** (in embodiments that use a butterfly needle), through a transparent or translucent flexible sleeve **150** and transparent or translucent guide tube **116**, or through the optional viewing window **340**.

[0071] With reference to Fig. 16, another embodiment of the present invention is shown in which all reference characters refer to like elements shown in the previous drawing figures. The flexible sleeve **150** may be mounted or fitted onto a sleeve connector **330** which is integrally formed with the guide tube **116** within the guide tube opening **118**. A central well opening **338** may extend through the sleeve connector **330** and connect with a well **117**. A venting member **160** which may be a flexible membrane or other porous material may be disposed along the interior of the well bottom wall **123** so as to provide a blood barrier between the central well opening **338** and the well **117**. A well passage **336** may extend from the well **117** to the outside of the guide tube **116** outer wall. One or more raised features **344** may be provided adjacent to the end of the well passage **336** to assist a user in tactically sensing the location of the well passage so as not to block it with the user's fingers or hand.

[0072] The blood drawing device shown in Fig. 16 may be used as follows. The central body **100** may be connected to the guide tube **116** such that the rear cannula **140** extends through the venting member **160**. Once the central body **100** is connected to the guide tube **116**, the front cannula **130** or butterfly cannula **184** (in alternative embodiments that utilize a butterfly needle) may be introduced into a lumen, such as a vein, to draw fluid, such as blood. The blood may readily flow through the front cannula **130**, the rear cannula **140** and into the interior of the flexible sleeve **150**. Air within the blood drawing device **10** that would otherwise prevent or slow the flow of blood into it, may vent through the flexible sleeve **150**, the central well opening **338**, the venting member **160** and the well passage **336** to the ambient outside the guide tube **116**. Blood that flows into the blood drawing device may be viewed either through the central body **100**, the butterfly connection tube **182** (in embodiments that use a butterfly

needle), or through a transparent or translucent flexible sleeve **150** and transparent or translucent guide tube **116**. The visual detection of blood indicates positive vein entry, known as flash. Once flash is detected, a fluid sample container may be pressed into the open end **118** of the guide tube **116**, the second rear cannula **141** may pierce the flexible sleeve **150** and the flexible sleeve is pushed back towards the base of the second rear cannula.

[0073] With reference to Fig. 17, another embodiment of the present invention is shown in which all reference characters refer to like elements shown in the previous drawing figures. The flexible sleeve **150** may be mounted or fitted onto a sleeve connector **330** which is integrally formed with the guide tube **116** within the guide tube opening **118**. A central well opening **338** may be defined by a second rear cannula **141** and provide fluid communication between the interior of a flexible sleeve **150** and a well **117** provided in the guide tube **116**. A well passage **336** may extend from the well **117** to a guide tube aperture **342** located along the guide tube **116** outer wall. The guide tube aperture **342** may have a viewing window **340** disposed in it. The viewing window **340** may be transparent or translucent and may permit blood to be viewed by a user through the viewing window so as to detect flash. The flexible sleeve **150** may include a side tubulation **154** in which a venting member **160** is inserted.

[0074] The blood drawing device shown in Fig. 17 may be used as follows. The central body **100** may be connected to the guide tube **116**. Once the central body **100** is connected to the guide tube **116**, the front cannula **130** or butterfly cannula **184** may be introduced into a lumen, such as a vein, to draw fluid, such as blood. The blood may readily flow through the front cannula **130**, the first rear cannula **140**, the second rear cannula **141** and into the interior of the flexible sleeve **150**. Air within the blood drawing device **10** that would otherwise prevent or slow the flow of blood into it, may vent through the venting member **160** provided in the side tubulation **154** in the flexible sleeve **150** to the ambient inside the guide tube **116**. Blood that flows into the blood drawing device may be viewed either through the central body **100**, the butterfly

connection tube **182** (in embodiments that use a butterfly needle), through a transparent or translucent flexible sleeve **150** and transparent or translucent guide tube **116**, or through the optional viewing window **340**. The viewing window **340** may be unnecessary if flash is detected elsewhere, such as through a translucent or transparent butterfly connection tube, central body, flexible sleeve and/or guide tube.

[0075] With reference to Fig. 18, another embodiment of the present invention is shown in which all reference characters refer to like elements shown in the previous drawing figures. The embodiment shown in Fig. 18 is identical in all respects to that shown in Fig. 17 with the following exception. In Fig. 18, an air-permeable, blood impermeable flexible sleeve **151** replaces the flexible sleeve **150** shown in Fig. 17. The air-permeable, blood-impermeable sleeve **151** serves as a venting member.

[0076] The air-permeable, completely or partially blood-impermeable flexible sleeve **151** may be constructed of a material that is largely air-permeable, but partially, largely or entirely impermeable to blood. The air-permeable sleeve **151** may be used to isolate the rear cannula **140** of a blood drawing device from the ambient in the same manner as conventional sleeve may isolate rear cannulae. During a blood drawing procedure using a device not equipped with a means for venting air from the sleeve, blood from a lumen may be slowed or prevented from entering the device due to air back pressure in the device. In these devices the air in the device may be trapped because there is no vent provided. In the present embodiment, an air-permeable sleeve **151** replaces a conventional sleeve in the guide tube **116**. The air-permeable sleeve **151** may provide a pathway to vent air from the device interior, through the sleeve wall, to the ambient. As the air is vented, the blood filling the device may contact the air-permeable sleeve **151**. However, the air-permeable sleeve **151** may prevent or retard the flow of blood through its wall because the pore size of the air-permeable sleeve may be large enough to allow the passage of air, but too small to allow much or any blood to pass. This air passage-blood blockage may permit blood to fill the needle and/or the sleeve **151** more readily because there is reduced or no air back pressure inhibiting the flow of blood into

the blood drawing device. As a result, a blood drawing device equipped with the air-permeable sleeve **151** may indicate flash (the visual indication of blood flow into the needle) more readily. The air-permeable sleeve **151** may be used with conventional needle drawing or infusion sets (such as butterfly needles), hypodermic needles, or the like, to enhance flash indication.

[0077] The air-permeable sleeve **151** may be made of any suitable material that is completely or at least partially air-permeable and substantially blood impermeable, such as for example, low density polyethylene or low density rubber. One example of a method of making such material is described in U.S. Patent No. 5,641,442. A second example may be made of crumbed material of sufficiently low density/high flexibility to allow the required flexibility in spite of the use of thermal binders like polyethylene. Low density material such as low density silicone may be sifted using a #80 mesh and mixed with #100 mesh low density polyethylene. This mixture may be heated at approximately 280° F and injected into a cavity mold to form the selectively porous sleeve **151**.

[0078] An air-permeable sleeve may be constructed of porous material formed from the combination of a hydrophobic porous material with a hydrophilic porous agent. The hydrophobic porous material, for example, may be a polymeric matrix of either thermoplastic resins such as polyvinyl chloride or copolymers thereof, or synthetic or natural thermosetting rubber-like polymers. In a second example, the polymeric matrix may be rubber-like polymers combined with additives such as anti-degradants, cross-linking agents, cure inhibitors, platinum and other type catalysts, inert fillers, or like materials used to compound thermosetting compounds, and intimately mixed with a hydrophilic porous agent such as silica hydrogel, precipitated hydrated silica, for example such as that sold under the trademark Hi-Sil from PPG Industries, or polyacrylamide gel, cross-linked homopolymer of acrylamide, for example such as that sold under the trademark Agrosoake from Agrosoake International, inert fillers and/or water or solvent soluble porosics. In a third example, the polymeric matrix may be

made of a synthetic or natural thermosetting polymer or copolymer, such as those that may be made in accordance with the methods disclosed in U.S. Patent No. 4,548,835 to Takahashi, et al. and U.S. Patent No. 4,153,760 to Sundberg et al, for example, each of which is hereby incorporated by reference.

[0079] The porous agent may be prepared by polymerizing acrylamide in the presence of an aqueous sodium carbonate to produce a partially hydrolyzed, lightly cross-linked, polyacrylamide gel in accordance with the method disclosed in U.S. Patent No. 3,022,279 to Proffitt, for example, which is hereby incorporated by reference. The polyacrylamide gel may be produced in bead or granular form using an inverse suspension polymerization method for water-soluble monomer, which is disclosed in U.S. Patent No. 2,982,749 to Friedrich et al., for example, and which is hereby incorporated by reference.

[0080] In one embodiment, for example, the hydrophilic granules may be added to the hydrophobic material in sufficient quantities to create a hydrophilic/hydrophobic porous material. The porosity of the hydrophobic material may be manifested by a network of voids/pores extending throughout the matrix or binder, between neighboring particles of the dispersed filler and portions of the polymeric matrix, which may be achieved by the shrinking of the swollen hydrophilic granules during the dehydration/curing phase. The resultant degree of porosity may be controlled by the amount of water or water substitute added to the polymeric matrix binder material during the mixing phase, the vulcanization of the polymeric matrix (such as for example, under hydrostatic conditions in a steam autoclave to a state of cure using the pressurized steam as a source of heat), the proportion and size of the hydrophilic granules added, the duration of the mixing phase, and the wall thickness of the elastomeric sleeve. The hydrophilic granules may be mixed with a normally hydrophobic binder (and water or a water substitute may be added to control porosity) in a mixing type extruder.

[0081] When this material is formed into an air-permeable flexible sleeve **151**, water-

based liquids such as blood may rapidly soak into the pores/voids containing the granular material, causing the granules to swell and seal the pores/voids contained within the polymeric matrix. Thus, the air-permeable flexible sleeve, which is initially permeable to air, may become relatively impermeable to liquids, such as blood, due to the swelling of the moisture reactive granules entrapped within the pores/voids within the polymeric matrix.

[0082] With reference to Fig. 19, another embodiment of the present invention is shown in which all reference characters refer to like elements shown in the previous drawing figures. The embodiment shown in Fig. 19 is identical in all respects to that shown in Fig. 17 with the following exception.

[0083] In the embodiment shown in Fig. 19, a portion of the flexible sleeve **150** may be made to be porous to air. A challenge associated with making the flexible porous sleeve **150** shown in Fig. 19 is that many methods of making a material porous may render the material less flexible. For example, porous "soaker" hoses are made by mixing ground rubber with a thermoplastic such as polyethylene which allows the ground rubber to be "sintered" or stuck together by melting the polyethylene. The addition of the polyethylene makes the hose much stiffer than a plain rubber hose. The same may be true when making a fully porous multiple sample sleeve as shown in Fig. 18 – the resulting sleeve may be less flexible than required. As a result, one solution is to restrict the porous portion of the flexible sleeve **150** to the area near but not all the way at the open end of the sleeve as shown in Fig. 19, so that air can vent from the sleeve while still permitting the open end of the sleeve and the closed end of the sleeve to be made of relatively more flexible material which does not vent. This way the open end of the sleeve may be flexible enough to be stretched over the sleeve connector **330** and the closed end of the sleeve may be flexible enough to be pierced by the second rear cannula **141** without breaking apart while reverting to its original shape after being compressed by the vacuum tube after its removal. This ability to maintain the sleeve's compressibility and "memory" function may be important to the proper functioning of the

sleeve.

[0084] With reference to Fig. 19, the flexible sleeve **150** may be made of a first type of flexible sleeve material which does not substantially vent air (i.e., is the air-impermeable portion of the sleeve) such as the material described in U.S. Patent No. 3,877,465 to Miyake, for example, and of a second type of flexible sleeve material that makes up the venting member **160** which is air-permeable and completely or partially blood-impermeable (i.e., the air-permeable blood-impermeable portion of the sleeve) and formed as a venting port or wall portion added to or incorporated or integrated into the sleeve **150**. The venting member **160** may be of any shape or size suitable for permitting air to vent from the interior of the sleeve **150** while completely or substantially preventing the passage of blood. The venting member **160** may be made of some flexible material other than just air, meaning that the venting member **160** is not merely an opening, but rather a second type of material having numerous small air passages as distinguished from the first type of material that makes up the flexible sleeve **150** or a single larger opening or hole in the first type of material.

[0085] In the embodiment of the invention shown in Fig. 19, the venting member **160** may be constructed of a material that is largely air-permeable, but partially, largely, or entirely impermeable to blood, and preferably made of similar or the same material as used to construct the sleeve **151** shown in Figure 18. Preferably, the venting member **160** may be provided as near to the open end of the flexible sleeve **150** as is practically possible, however, in alternative embodiments, the venting member may be placed in alternate locations closer to or near the closed end of the flexible sleeve **150**.

[0086] The porous venting member **160** shown in Fig. 19 could be achieved by forming a part of the sleeve wall by partially hydrating an absorbent such as polyacrylamide gel with water and mixing it with a heat cured injection molding silicone. When subjected to the typical curing temperatures of 120-200° degrees Celsius the water may convert to steam once the sleeve is ejected from the mold. This may create an open cell structure which contains granules of polyacrylamide. These granules may

be processed further during a post cure phase where the granules are further dehydrated with heated dry air. This drying process may create open spaces around each granule which allows air to escape. These same granules absorb water and swell when exposed to blood, thereby sealing the venting portion to prevent leakage. With particular reference to Fig. 19, the resulting porous blood-impermeable air-permeable ring shaped venting member **160** can be inserted into sleeve molds where transparent silicone can be injected adjacent to both edges of the venting port, thus bonding the venting portion with the transparent, more flexible body portion material of the sleeve.

[0087] With reference to Figs. 20-22, three other embodiments of the present invention are shown in which all reference characters refer to like elements shown in the previous drawing figures. The embodiments shown in Figs. 20-22 are identical in all respects to those shown in Figs. 17-19, respectively, with the following exception. With respect to Figs. 20-22, the central well opening **338** is defined by the well bottom wall **123** and the sleeve connector **330**. The second rear cannula (shown in Figs. 17-19) is not provided. When the front cannula **130** is introduced to the vein of a patient air may vent from the rear cannula **140** through the venting members **160** or air-permeable, blood-impermeable flexible sleeve **151** shown in Figs. 20-22. After the air is vented, blood may fill the well passage **336** and the aperture **340**. Blood may be viewed either through the central body **100**, the butterfly connection tube **182** (in embodiments that use a butterfly needle), through a transparent or translucent flexible sleeve **150** and transparent or translucent guide tube **116**, or through the optional viewing window **340**. As noted above, the size of the well **117** may be sufficient to permit blood to fill the aperture **342** without developing sufficient air back-pressure to prevent such filling.

[0088] It is appreciated that the embodiments of the invention shown in Figs. 1-24 may be altered as follows without departing from the intended scope of the invention. The shoulder **119**, the dimples **217** and the radial lines **219** on the bottom of the well **117** could be replaced by a shoulder, raised dimples or raised radial lines on the surface of the venting member **160** closest to the well bottom wall **123**. Accordingly, the

illustrations provided in Figs. 1, 4 and 5 of the shoulder **119**, the dimples **217** and the radial lines **219** are intended to also illustrate such features as they may be provided on a venting member.

[0089] With regard to Figs. 23-24, the butterfly needle **180** may be connected to the Luer-type hub **102** via a butterfly connection tube **182**. The butterfly needle **180** may include a butterfly (*i.e.*, front) cannula **184** and one or more wings **186**. The butterfly cannula **184** may be inserted directly into the body lumen for blood collection. Flash may be observed in the transparent or translucent butterfly connection tube **182**, in which case the central body **100** need not be transparent or translucent (although it could be).

[0090] With continued reference to Figs. 23-24, known butterfly needles may use a butterfly connection tube **182** approximately 12 or more inches in length. This length of tubing is used so as to provide a sufficiently long column of air to permit flash observation when the blood-drawing device **10** is not provided with an air vent. Specifically, when a butterfly connection tube is used without an air vent, the flow of fluid through the butterfly needle may compress the volume of air in the butterfly connection tube **182**, the fluid passage **110**, the rear cannula **140**, and the space between the rear cannula and the flexible sleeve **150**. Because there is no vent provided, as blood flows into the device, the air in the device exerts an increasing level of backpressure on the blood, which may prevent blood flow and flash detection. The inclusion of a butterfly connection tube approximately 12 inches in length or greater increases the relative volume of air in the blood collection device. The increased volume of air in the device may permit flash detection before the air backpressure in the device rises to a level that prevents further blood flow into the device and could frustrate flash detection. Butterfly connection tubes of this length may be coiled in packaging, and retain some coil memory after they are removed from their packaging. Previously coiled butterfly connection tubes may resist being straightened for use and have an inherent bias towards returning to their coiled shape. Accordingly, manipulation of a

butterfly needle attached to a previously coiled butterfly connection tube may be difficult due to the connection tube's tendency to recoil. This action can be the cause of accidental needle sticks for the healthcare worker and the patient. Furthermore, the coil memory of the tubing may make handling generally difficult for lumen insertion, and/or maintenance of the needle in the lumen.

[0091] The butterfly connection tube **182** used in the devices shown in Figs. 23-24 may be less than approximately 12 inches in length, and more preferably, may be only a few inches in length as a result of the inclusion of a venting member **160** in the blood-drawing device **10**. The inclusion of the venting member **160** may obviate the need for a relatively long column of air in the butterfly connection tube that otherwise may be needed to indicate flash. The use of a shortened butterfly connection tube **182** may also obviate the need to coil the tube prior to use, thereby eliminating the issues associated with coil memory in the tube, as well as make it possible to use rigid or semi-rigid connection tubes that may better enable placement of the front cannula into the body lumen.

[0092] Each of the embodiments of the present invention shown in all of the afore-noted figures may also utilize a transparent or translucent flexible sleeve **150** to provide flash detection. An example of a transparent sleeve is disclosed in U.S. Patent No. 3,886,930 to Ryan, which is hereby incorporated by reference. Use of a transparent or translucent sleeve **150** may make it unnecessary for the central body **100** or other elements of the device to be constructed of transparent or translucent material because the flash may be detected through the wall of the sleeve itself and thereby allow for the retrofitting of known blood-drawing devices to provide air venting and flash detection without other modification of the device. Use of a transparent or translucent sleeve **150** may also obviate the need to have discreet front and rear cannulae **130** and **140**. The front and rear cannulae may be constructed from a single integral piece of material because in this embodiment of the invention there may be no need to view flash in the central body **100**.

[0093] Each of the embodiments of the invention described above may also be modified such that the porous member **160** includes or is constructed of any one or more of a number of substances that may permit air venting, and limit and reduce blood seepage, but not completely prevent blood seepage through the particular porous structure. For example, hydrophilic and/or hydrophobic substances such as polyethylene and granular starch, cellulose, polyacrylamide gel, or the like may be used. Such substances are known in the art, and may be used to permit gas (*e.g.*, air) to flow through them, but absorb or block liquid substances. Accordingly, a porous member comprised of these materials may be used to permit the air in a blood drawing device to vent past it until it is contacted by a liquid, such as blood, at which time the blood may be absorbed.

[0094] Similarly, glass powder or fiber may be used to simulate clotting, or a clotting agent, such as dilute Russell Viper Venom, may be used to permit air venting with little or reduced blood seepage. Russell Viper Venom is known in the art as a clotting agent. A porous member **160** impregnated with a clotting agent or simulating clotting agent may be used to permit the air in a blood drawing device to vent until it is contacted by blood, at which time the blood may clot or act as clotted and reduce further blood seepage through the porous member. As a result, use of hydrophilic and/or clotting agents in the previously described porous member may permit improved blood flow into a blood drawing device and flash detection.

[0095] It will be apparent to those skilled in the art that variations and modifications of the present invention can be made without departing from the scope or spirit of the invention. For example, the shape, size, and material selection for the various components of the blood-drawing device may be changed without departing from the intended scope of the invention and appended claims. It is further appreciated that forming one or more elements of the apparatus embodiments of the present invention integrally as opposed to separately is intended to fall within the scope of the invention and appended claims.

WHAT IS CLAIMED IS:

1. A guide tube assembly for connection to a device for drawing fluid from a lumen, comprising:

a guide tube (116) having an open end (118) and a well (117);

a flexible sleeve (150, 151) having an interior space in fluid communication with the well (117) and extending into the guide tube (116);

one or more passages (332, 334, 336, 338) extending through the guide tube (116) which are in fluid communication with the flexible sleeve (150) interior space; and

a venting member (160) connected to the guide tube (116) or incorporated into the flexible sleeve (150, 151), said venting member in fluid communication with the one or more passages (332, 334, 336, 338) and disposed between the flexible sleeve (150, 151) interior space and an ambient.

2. The guide tube assembly of Claim 1, wherein:

the guide tube (116) has an interior opening (127) and a substantially closed end (129);

the well (117) is defined by a well bottom wall (123) and is formed in the substantially closed end (129) of the guide tube (116);

one of the one or more passages is a central well opening (338) extending from the well (117) to the guide tube interior opening (127);

the venting member (160) is connected to the guide tube (116) within the guide tube interior opening (127);

the flexible sleeve (150) is mounted on the venting member (160) and extends into the guide tube interior opening (127), said sleeve defining an interior space; and

one or more well bottom extensions (121) extend into the guide tube interior opening (127) adjacent to the venting member (160).

3. The guide tube of Claim 2 wherein the venting member (160) has a base (300) exposed to the ambient and a barb portion (302) adapted to receive the flexible sleeve (150).

4. The guide tube of Claim 3 wherein the venting member (160) is adhered to the well bottom wall (123).

5. The guide tube of Claim 3 wherein the venting member (160) contacts raised dimples (217) provided on the well bottom wall (123).

6. The guide tube of Claim 3 wherein the venting member (160) contacts a raised shoulder (119) provided on the well bottom wall (123).

7. The guide tube of Claim 3 wherein the venting member (160) contacts raised radial lines (219) provided on the well bottom wall (123).

8. The guide tube of Claim 2 wherein the central well opening (338) is defined by a rear cannula (141) connected to the guide tube (116) and extending into the guide tube interior opening (127).

9. The guide tube of Claim 8 wherein the rear cannula (141) has a stepped diameter (143).

10. The guide tube of Claim 2 further comprising a well bottom wall (123) upper surface (125) adapted to seal against a central body (100) of a blood drawing device (10).

11. The guide tube of Claim 2 wherein the one or more well bottom extensions (121) are adapted to retain the venting member (160) by a frictional fit.

12. The guide tube of Claim 2 wherein the one or more well bottom extensions (121) extend an equal to greater distance into the guide tube interior opening (127) than the venting member (160).

13. The guide tube of Claim 2 further comprising:

a well passage (336) extending from the well (117) to an aperture (342) provided in a side wall of the guide tube (116); and

a viewing window (344) disposed in the aperture (342).

14. The guide tube of Claim 2 wherein the guide tube (116) and the flexible sleeve (150) are transparent or translucent.

15. The guide tube assembly of Claim 1, wherein:

the guide tube (116) has an interior opening (127) and a substantially closed end (129);

the well (117) is defined by a well bottom wall (123) and is formed in the substantially closed end (129) of the guide tube (116);

one of the one or more passages is a central well opening (338) extending from the well (117) to the guide tube interior opening (127);

the venting member (160) is connected to the guide tube (116) within the guide tube interior opening (127), said venting member having a base (300) and a barb portion (302); and

the flexible sleeve (150) is mounted on the venting member (160) and extends into the guide tube interior opening (127), said sleeve defining an interior space and being mounted on said venting member so that the base (300) of the venting member is exposed to an ambient.

16. The guide tube of Claim 15 wherein the venting member (160) is adhered to the well bottom wall (123).

17. The guide tube of Claim 15 wherein the central well opening (338) is defined by a rear cannula (141) connected to the guide tube (116) and extending into the guide tube interior opening (127).

18. The guide tube of Claim 17 wherein the rear cannula (141) has a stepped diameter (143).

19. The guide tube of Claim 15 further comprising a well bottom wall (123) upper surface (125) adapted to seal against a central body (100) of a blood drawing device (10).

20. The guide tube of Claim 15 further comprising:

a well passage (336) extending from the well (117) to an aperture (342) provided in a side wall of the guide tube (116); and

a viewing window (344) disposed in the aperture (342).

21. The guide tube of Claim 15 wherein the guide tube (116) and the flexible sleeve

(150) are transparent or translucent.

22. The guide tube assembly of Claim 1 further comprising:

a sleeve connector (330) extending from a well bottom wall (123) into a guide tube interior opening (127), and wherein

the guide tube (116) has a substantially closed end (129);

the well (117) is defined by the well bottom wall (123) and is formed in the substantially closed end (129) of the guide tube (116);

one of the one or more passages is a central well opening (338) extending from the well (117) to the guide tube interior opening (127) through the sleeve connector (330);

the flexible sleeve (150) is mounted on the sleeve connector (330) and extends into the guide tube interior opening (127), said sleeve defining an interior space; and

the one or more passages (332, 334, 336, 338) connect the sleeve interior space with an aperture (342) provided in a wall of the guide tube (116).

23. The guide tube of Claim 22 wherein the venting member (160) is disposed in the aperture (342).

24. The guide tube of Claim 23 further comprising a viewing window (340) disposed in the aperture (342).

25. The guide tube of Claim 24 wherein the viewing window (340) is disposed within the venting member (160).

26. The guide tube of Claim 24 wherein the viewing window (340) is disposed about the venting member (160).

27. The guide tube of Claim 24 wherein the viewing window (340) is disposed adjacent to the venting member (160).

28. The guide tube of Claim 22 further comprising a viewing window (340) disposed in the aperture (342).

29. The guide tube of Claim 22 further comprising:

a second aperture in the guide tube (116) wall communicating with the one or

more passages (332, 334, 336, 338); and

a viewing window (340) disposed in the second aperture.

30. The guide tube of Claim 22 wherein the central well opening (338) is defined by a rear cannula (141) connected to the guide tube (116) and extending into the guide tube interior opening (127).

31. The guide tube of Claim 30 wherein the rear cannula (141) has a stepped diameter (143).

32. The guide tube of Claim 22 further comprising a well bottom wall (123) upper surface (125) adapted to seal against a central body (100) of a blood drawing device (10).

33. The guide tube of Claim 22 further comprising a sealing membrane (310) disposed in the well (117) along the well bottom wall (123).

34. The guide tube of Claim 22 wherein the one or more passages (332, 334, 336, 338) communicate with the well (117).

35. The guide tube of Claim 22 wherein the venting member (160) is disposed in the well (117) along the well bottom wall (123).

36. The guide tube of Claim 22 wherein the aperture (340) is surrounded by one or more raised features (344) on the wall of the guide tube (116).

37. The guide tube of Claim 22 wherein the venting member (160) is disposed in a tubulation (154) provided in the side wall of the flexible sleeve (150).

38. The guide tube of Claim 37 further comprising a viewing window (340) disposed in the aperture (342).

39. The guide tube of Claim 37 wherein the central well opening (338) is defined by a rear cannula (141) connected to the guide tube (116) and extending into the guide tube interior opening (127).

40. The guide tube of Claim 39 wherein the rear cannula (141) has a stepped diameter (143).

41. The guide tube of Claim 22 wherein the venting member (160) comprises an air-

permeable sleeve (151) or is integrated into a portion of the flexible sleeve (150).

42. The guide tube of Claim 41 further comprising a viewing window (340) disposed in the aperture (342).

43. The guide tube of Claim 41 wherein the central well opening (338) is defined by a rear cannula (141) connected to the guide tube (116) and extending into the guide tube interior opening (127).

44. The guide tube of Claim 43 wherein the rear cannula (141) has a stepped diameter (143).

45. The guide tube of Claim 22 wherein the guide tube (116) and the flexible sleeve (150) are transparent or translucent.

46. The device of Claims 2, 15 and 22 wherein the venting member (160) is permeable to air and impermeable to blood.

47. The device of Claim 1, further comprising:

a first connector (103) of a Luer-adapter connected to the guide tube (116); and

a butterfly needle (180) connected to the first connector of the Luer-adapter by a second connector (102).

48. The device of Claim 1, further comprising:

a first connector (103) of a Luer-adapter integrally formed in an end of the guide tube (116) opposite the guide tube open end (118); and

a butterfly needle (180) connected to the first connector of the Luer-adapter by a second connector (102).

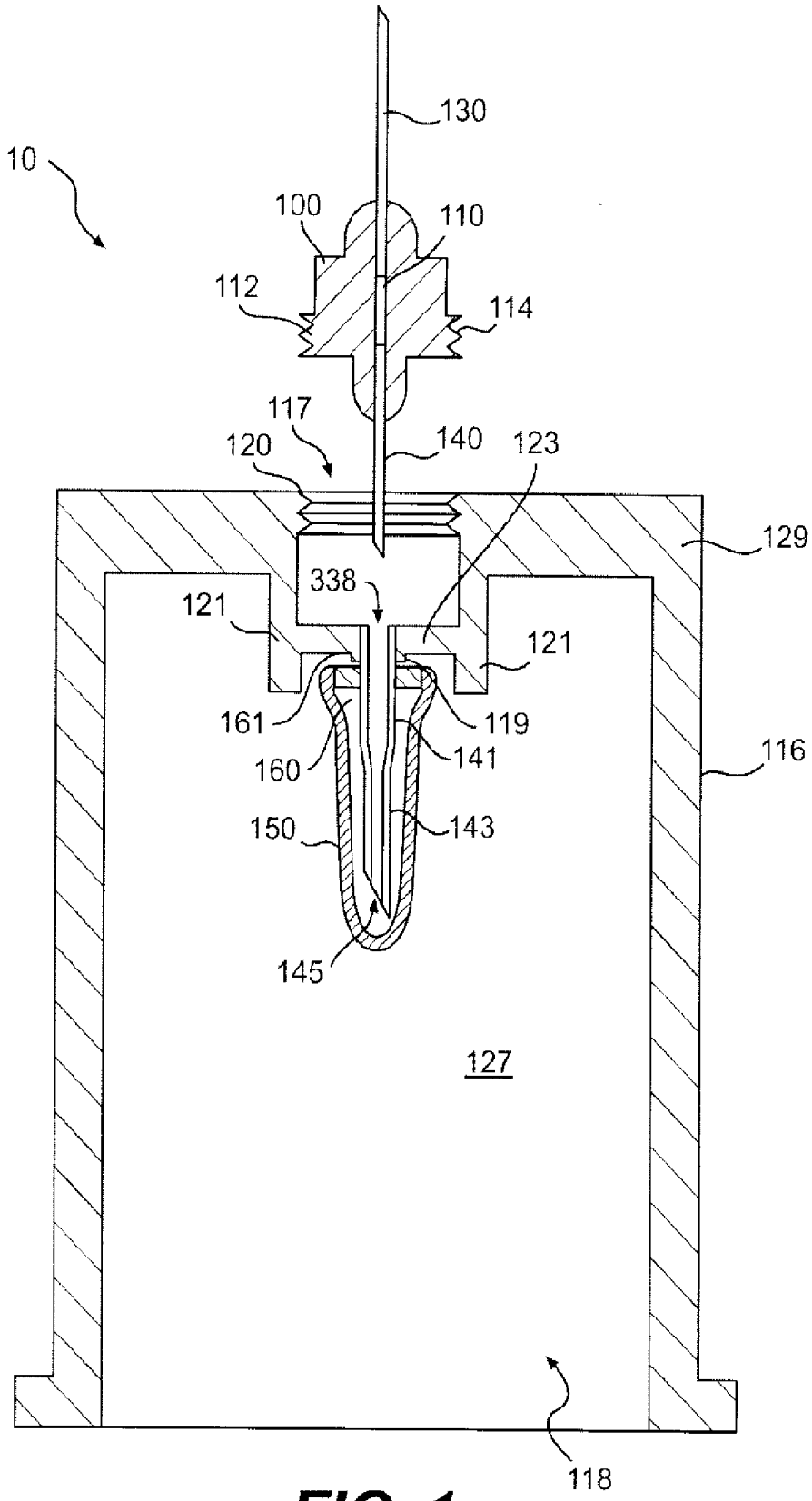

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FIG. 1

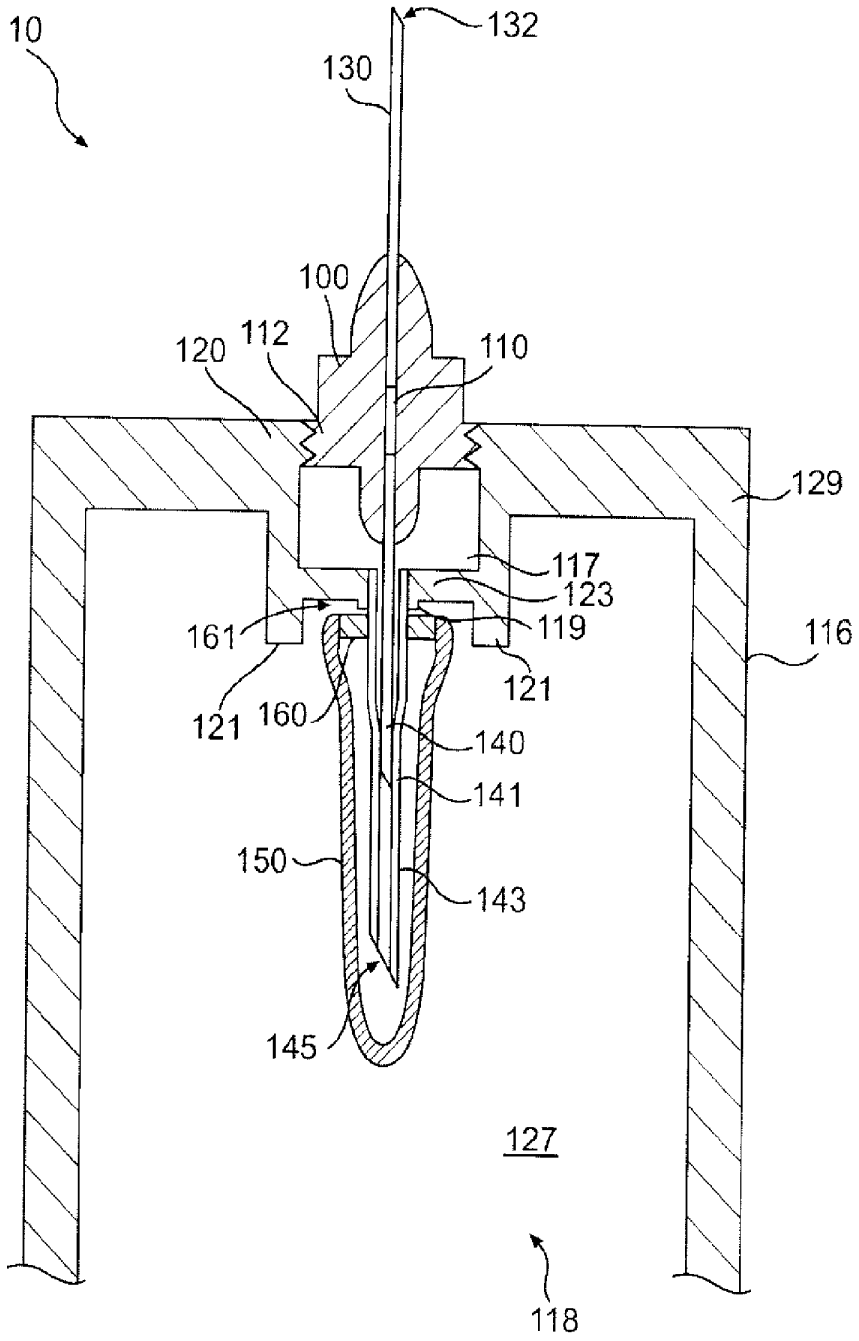

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FIG. 2

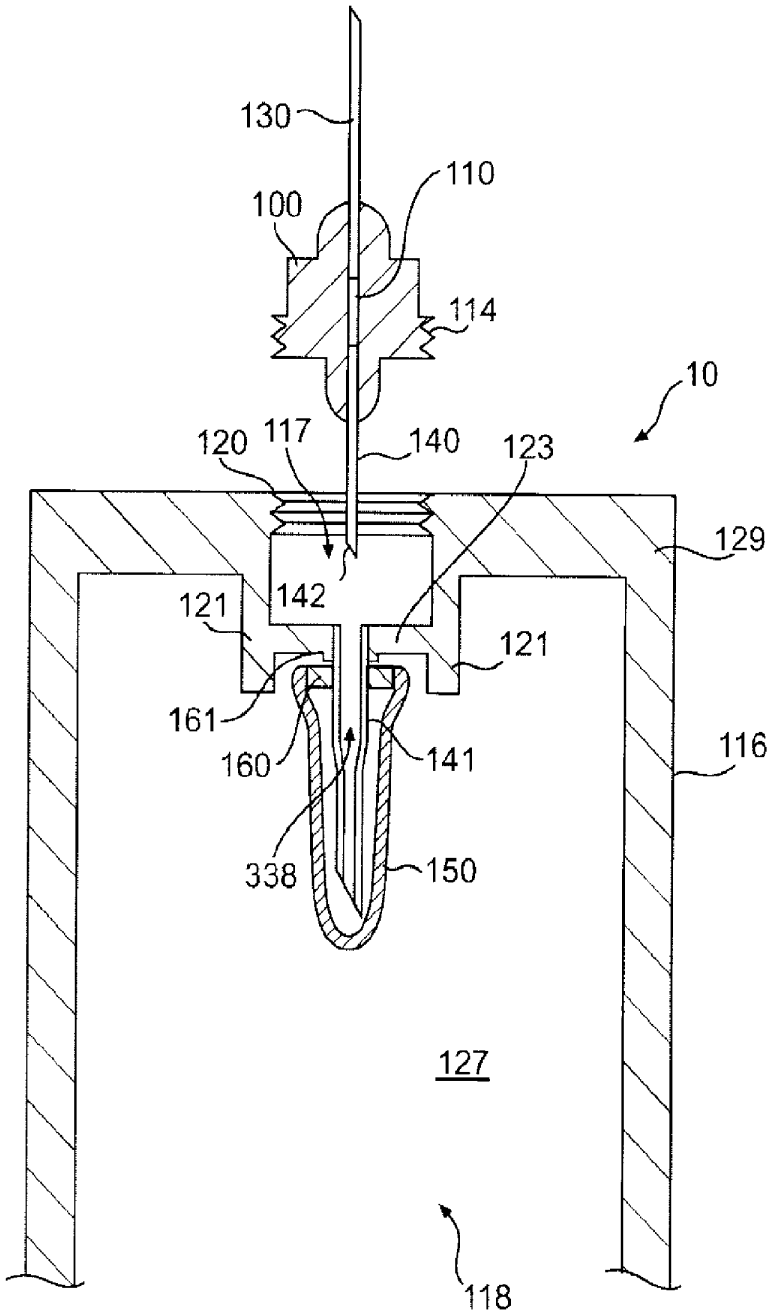


FIG. 3

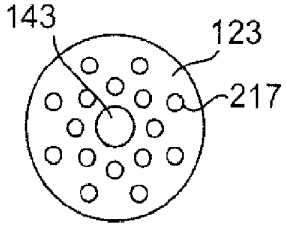


FIG. 4

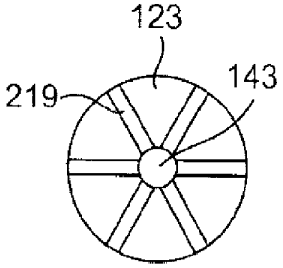


FIG. 5

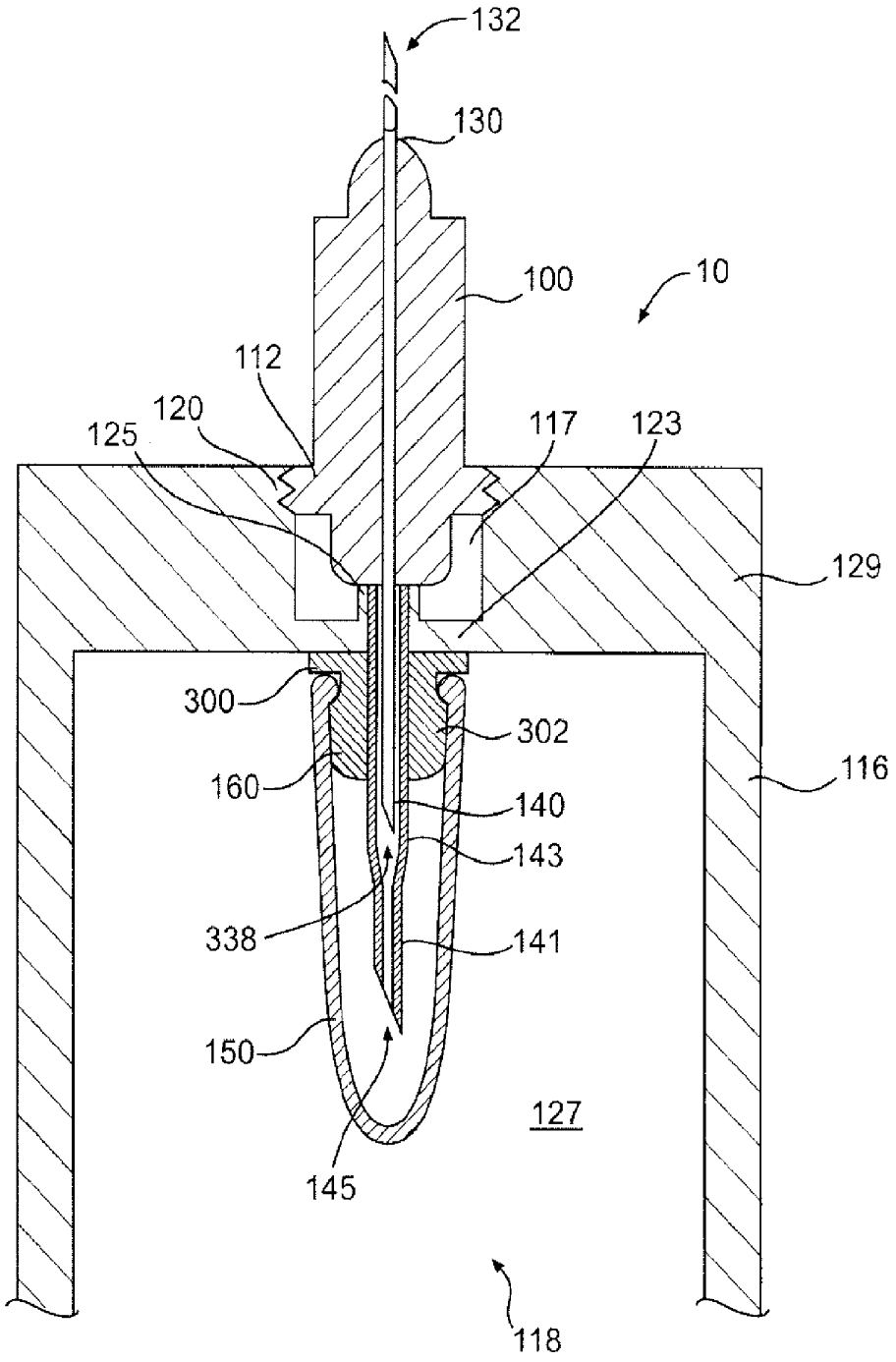

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FIG. 6

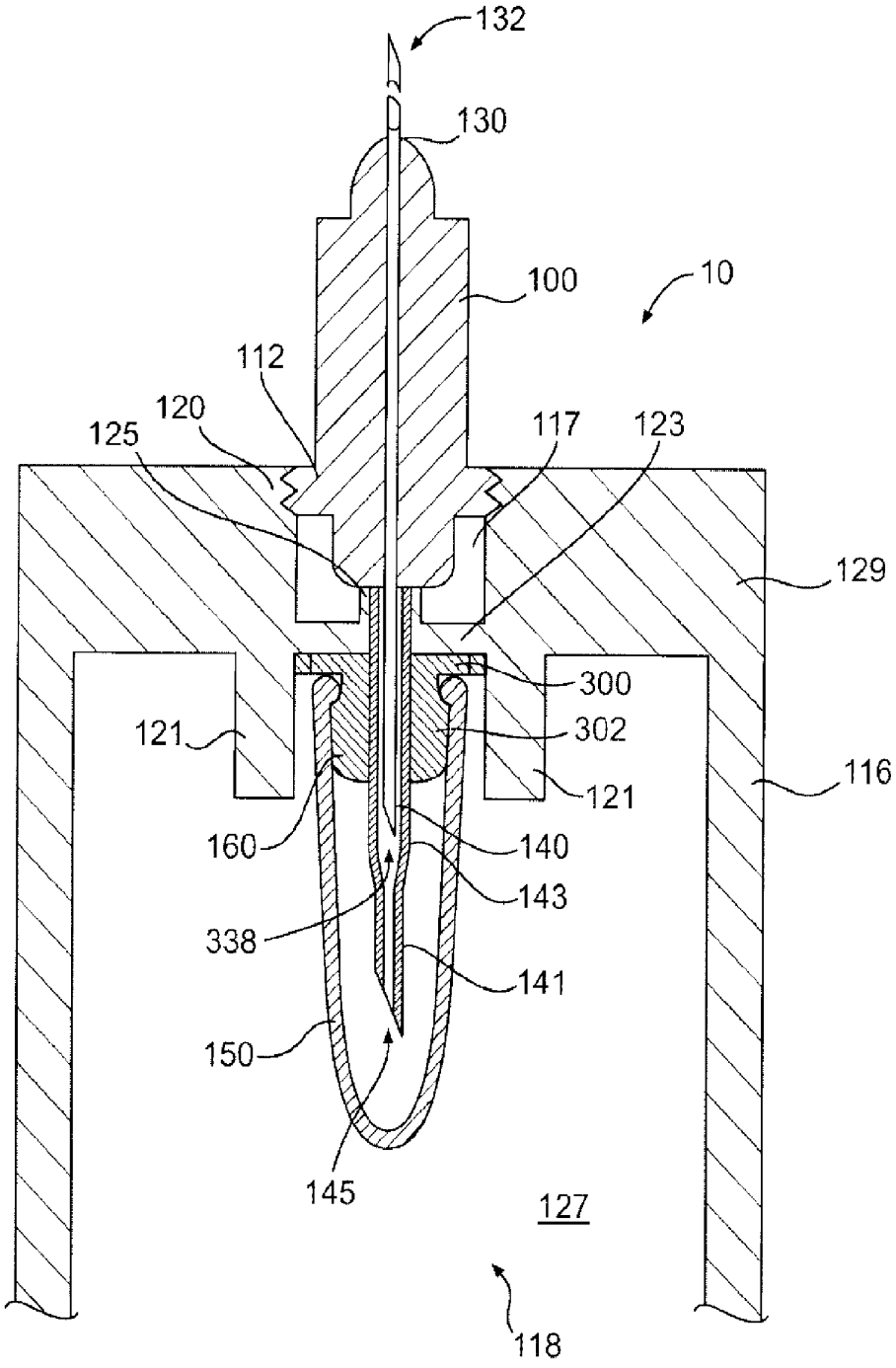

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FIG. 7

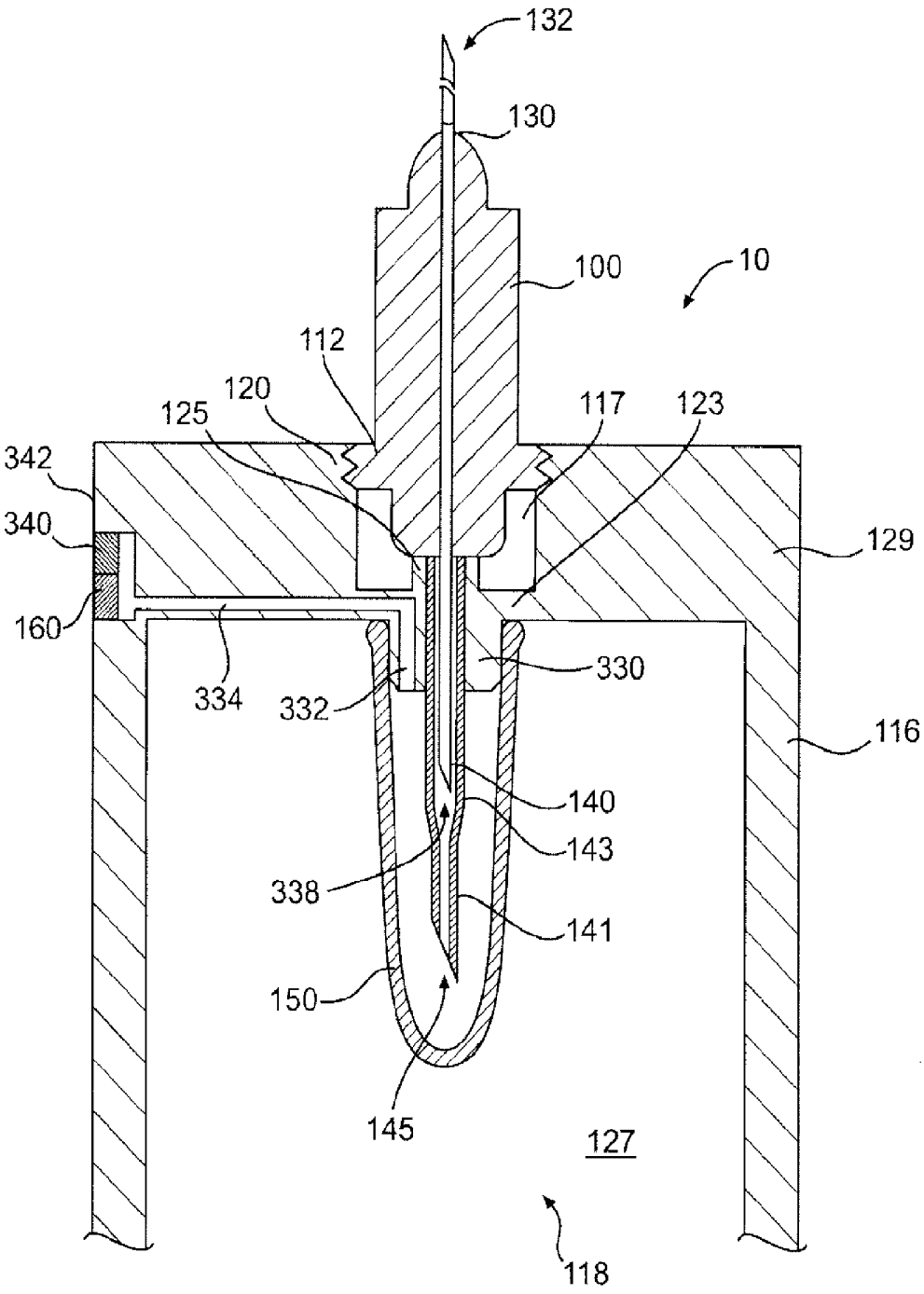

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FIG. 8

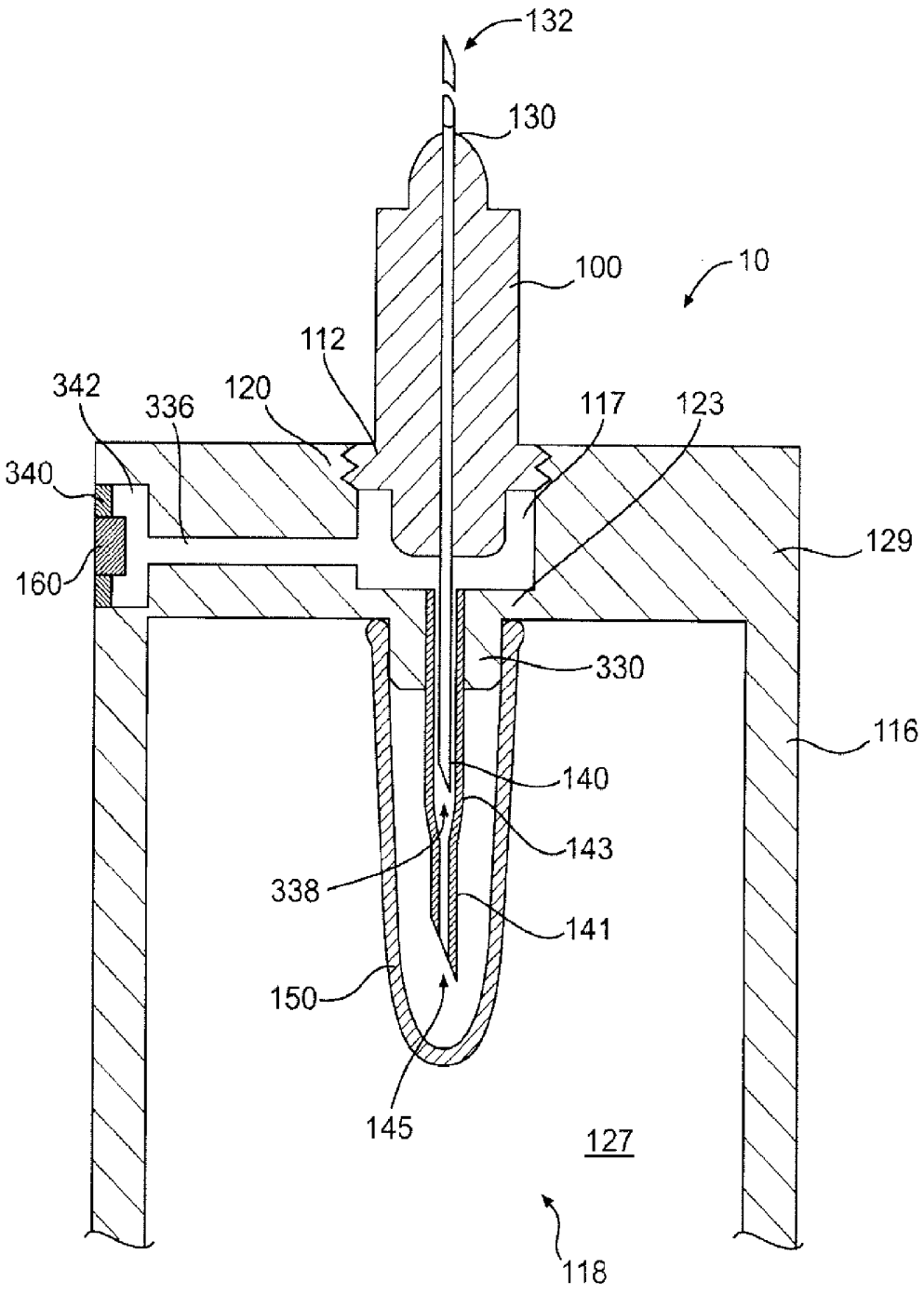

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FIG. 9

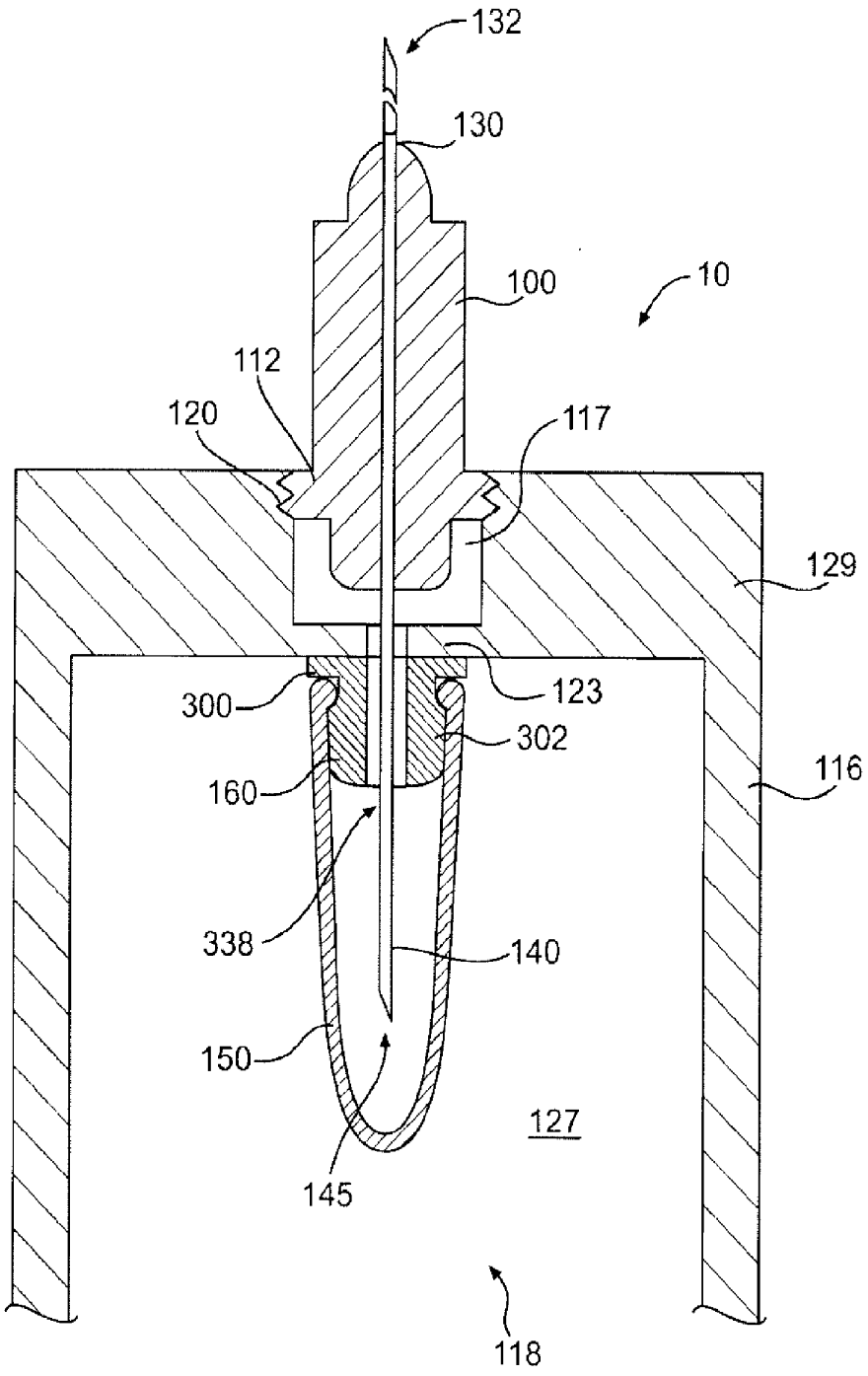

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FIG. 10

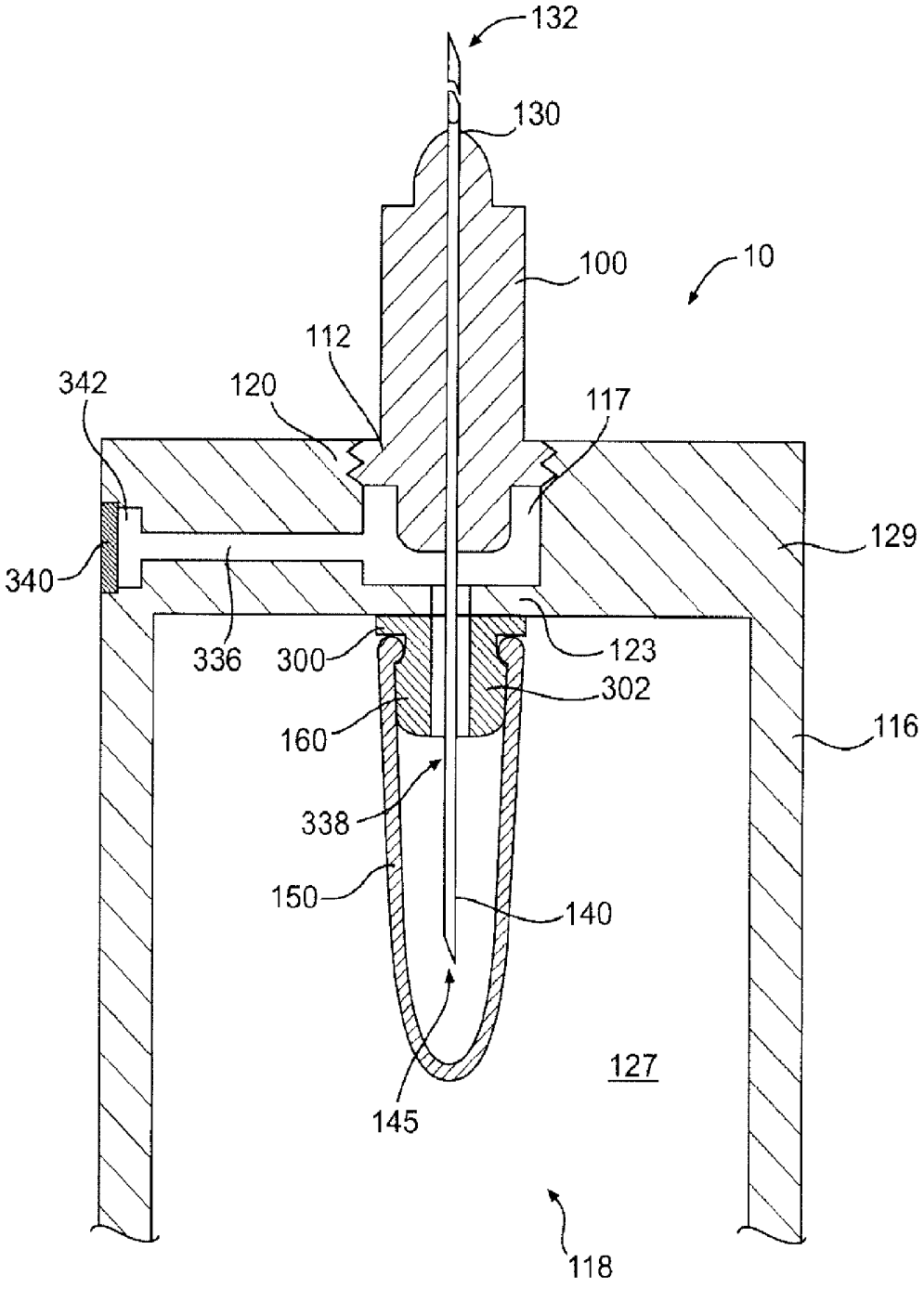

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FIG. 11

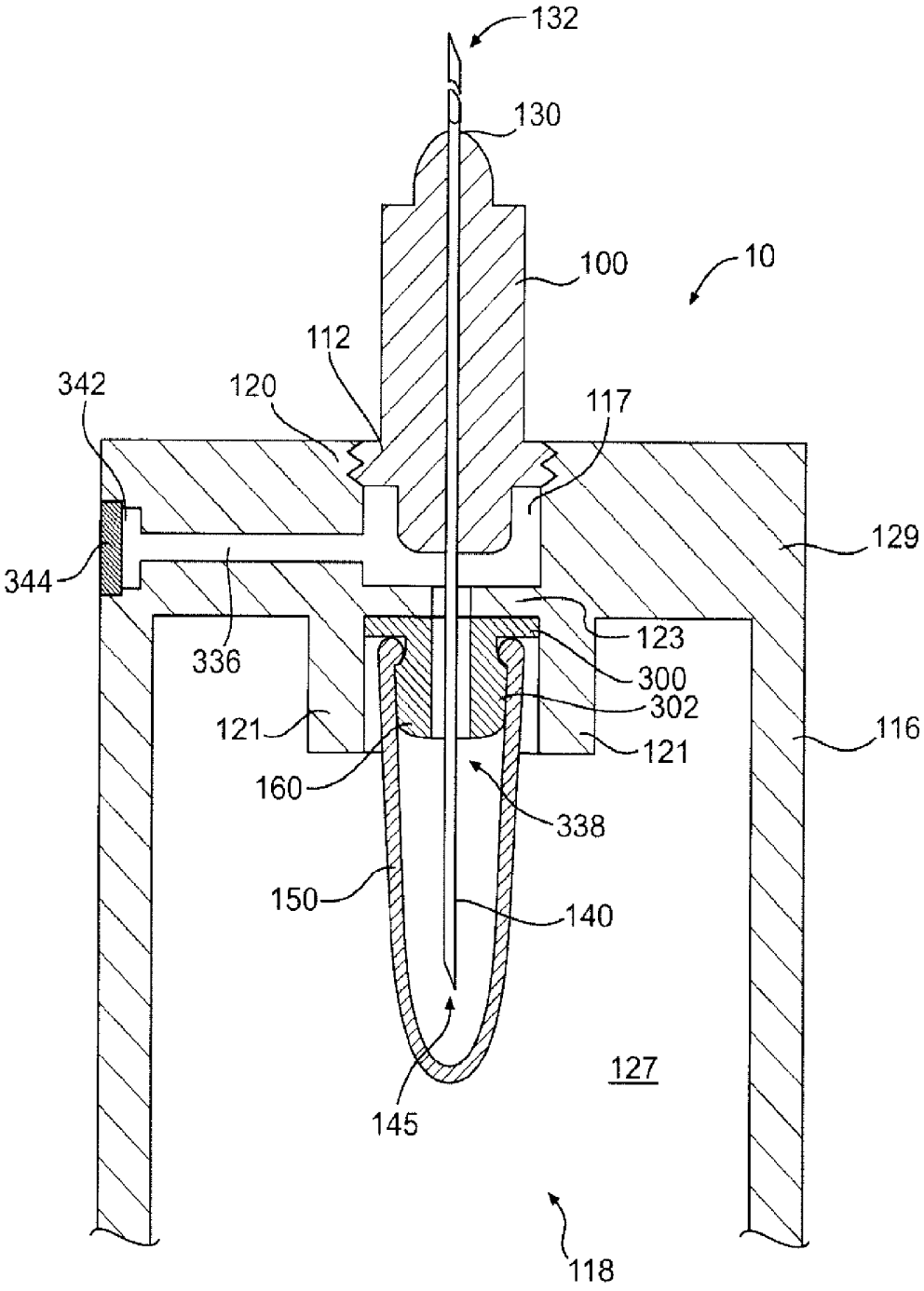

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FIG. 12

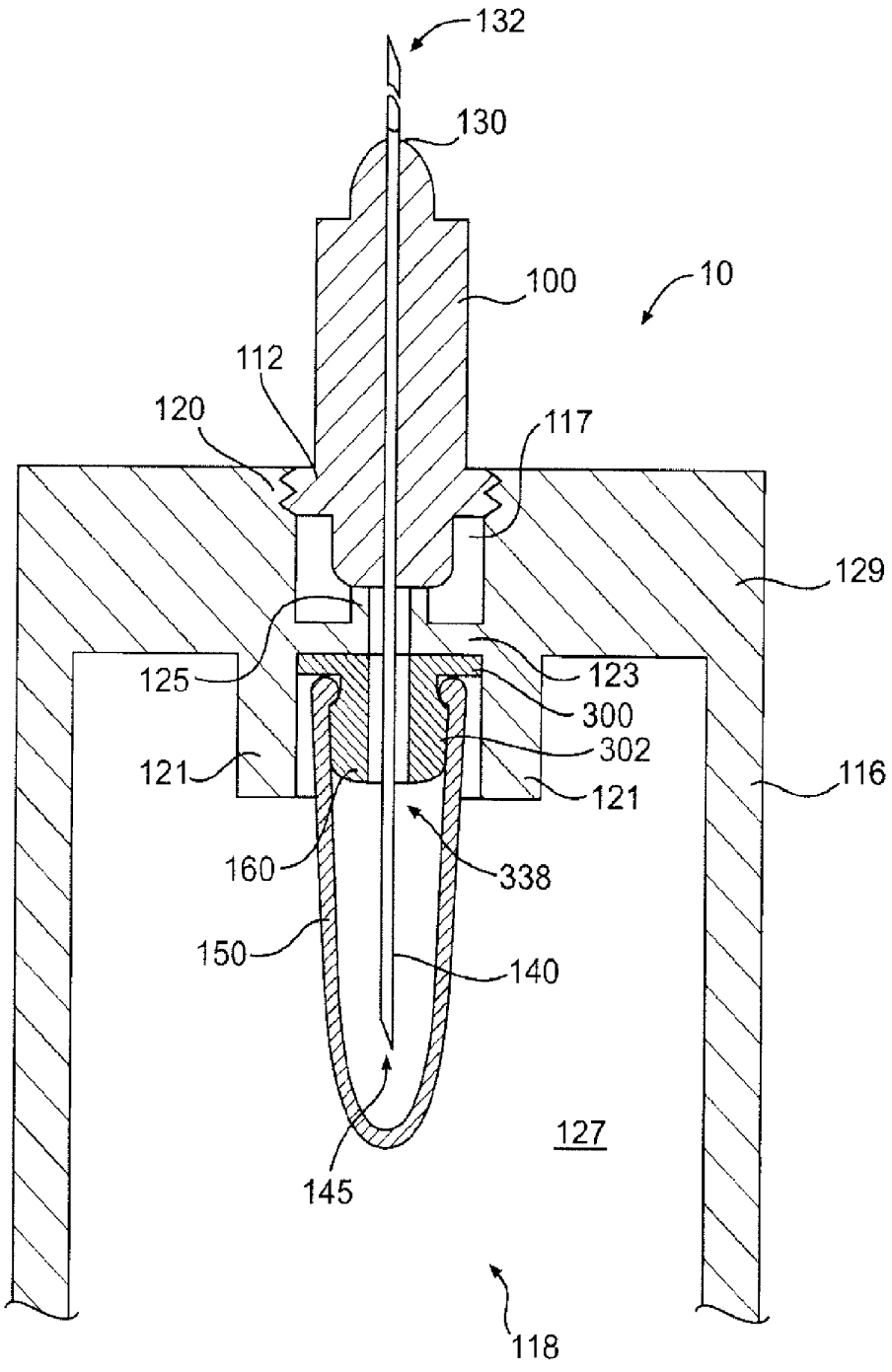

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FIG. 13

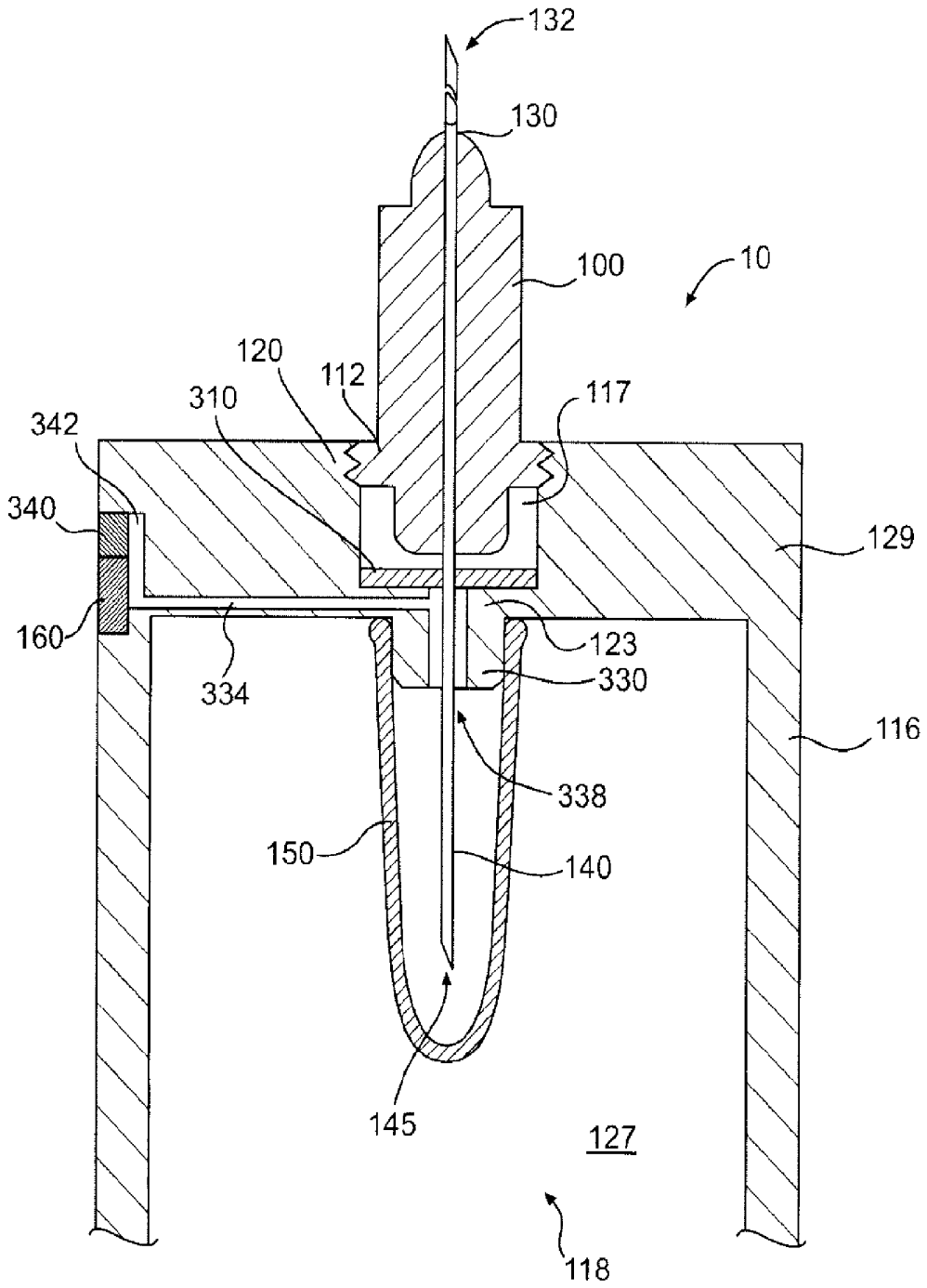

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FIG. 14

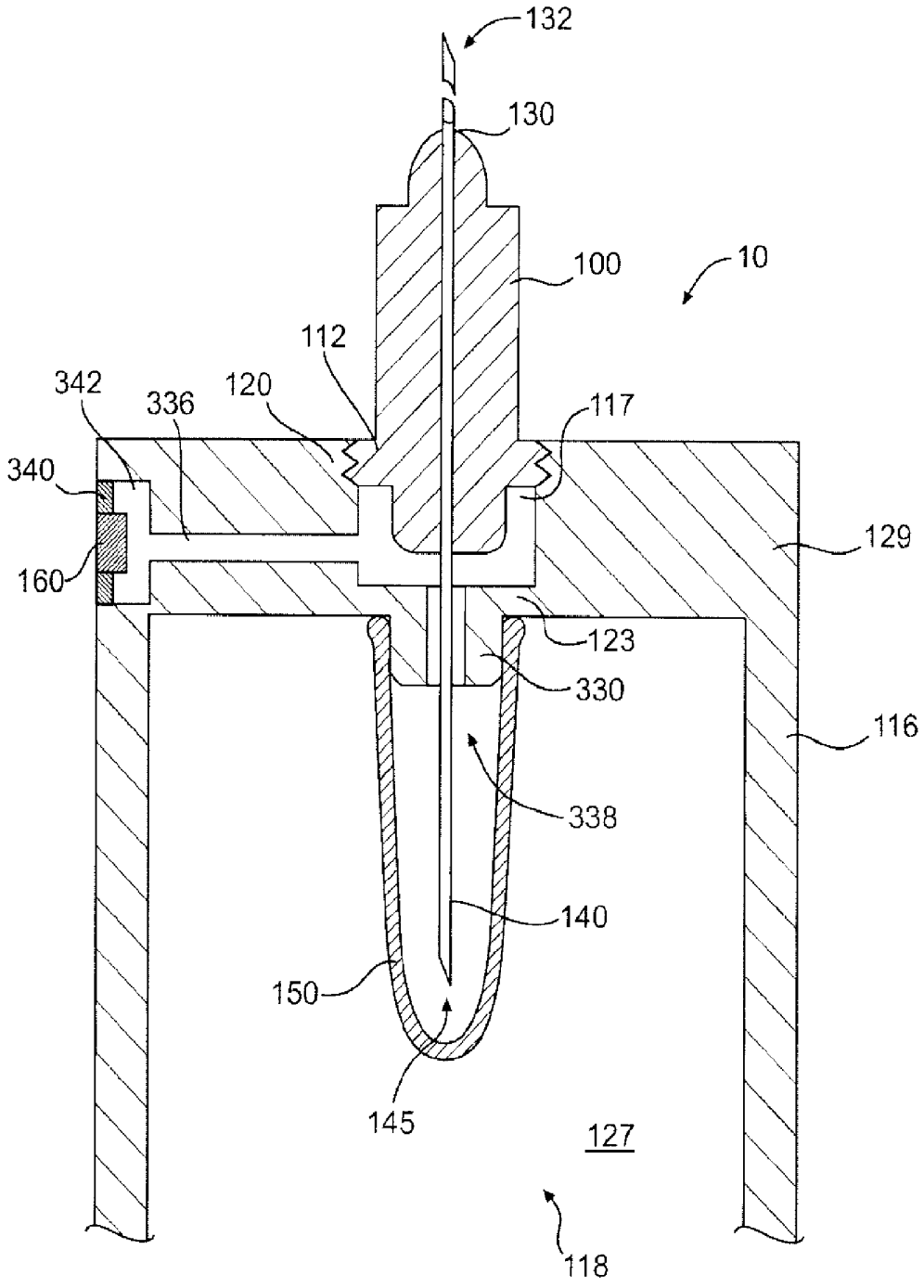

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FIG. 15

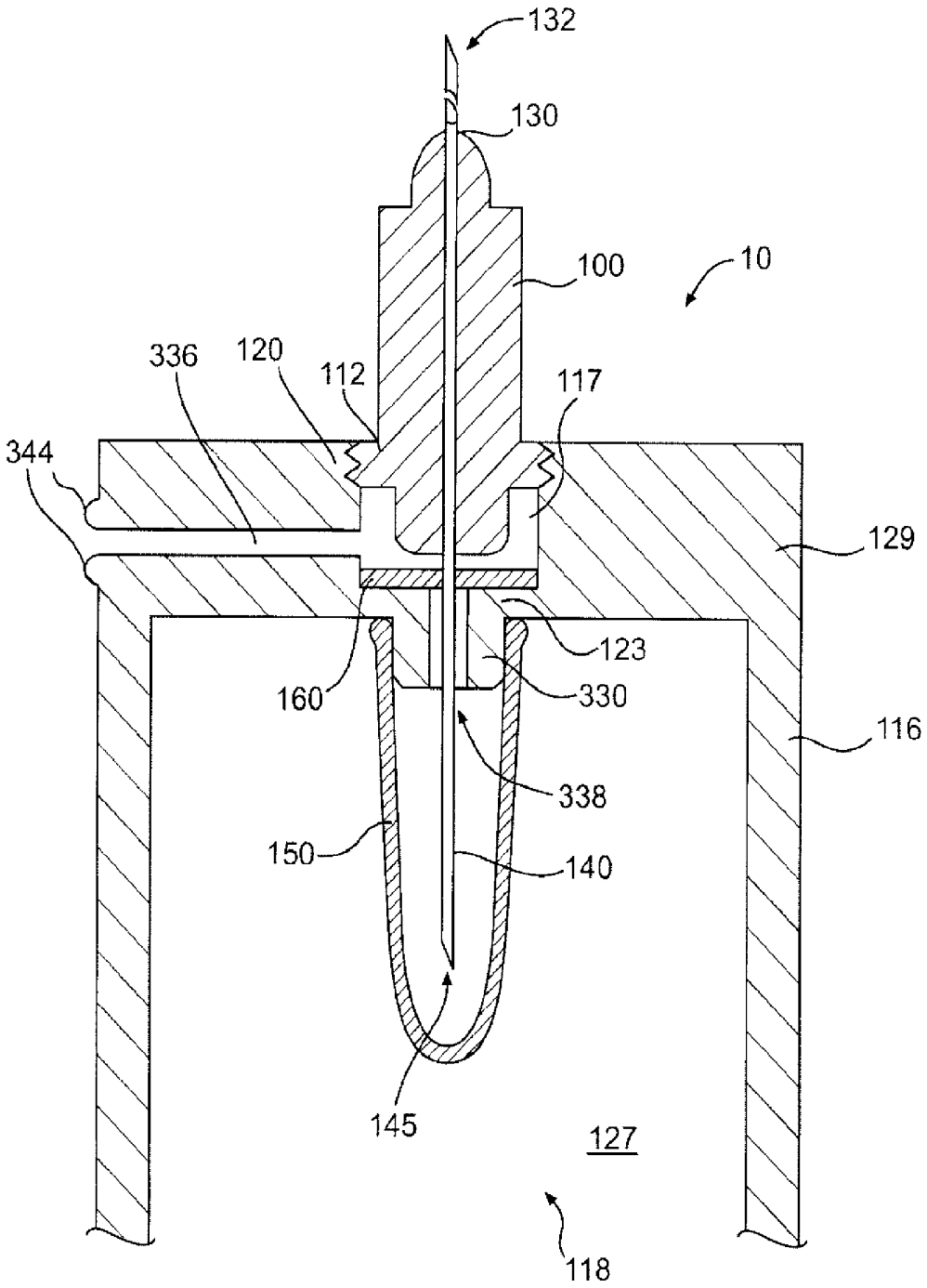

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FIG. 16

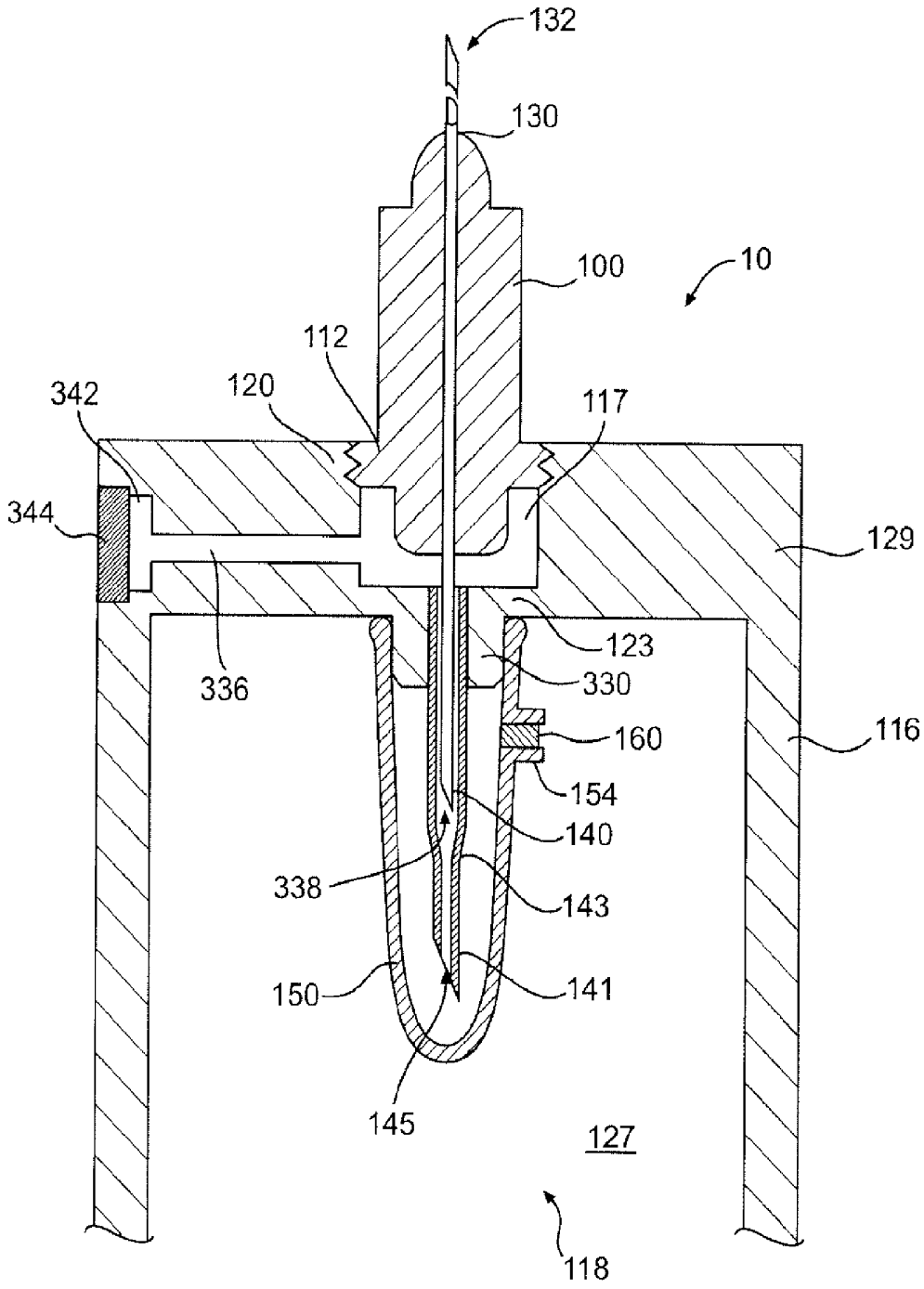

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FIG. 17

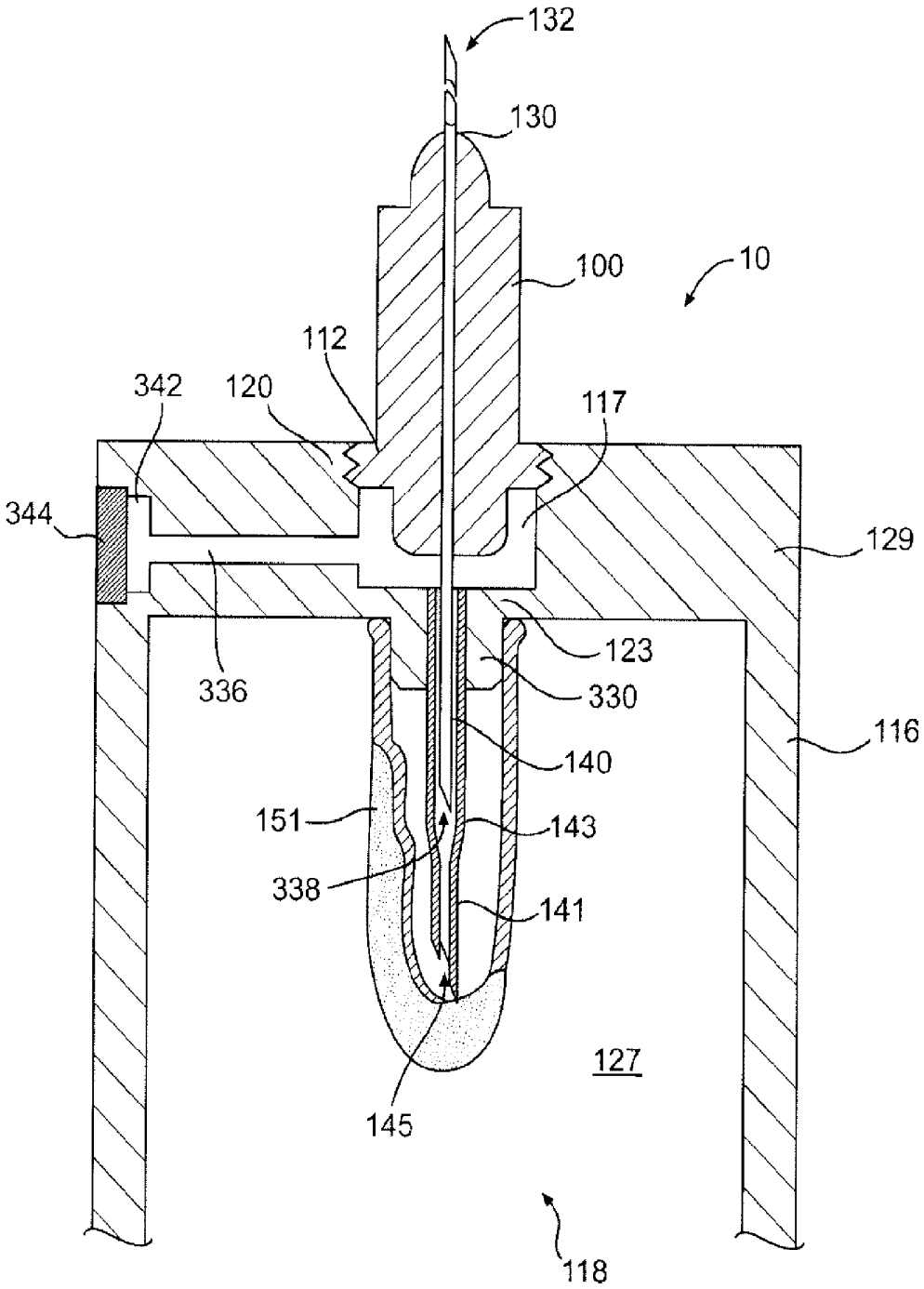

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FIG. 18

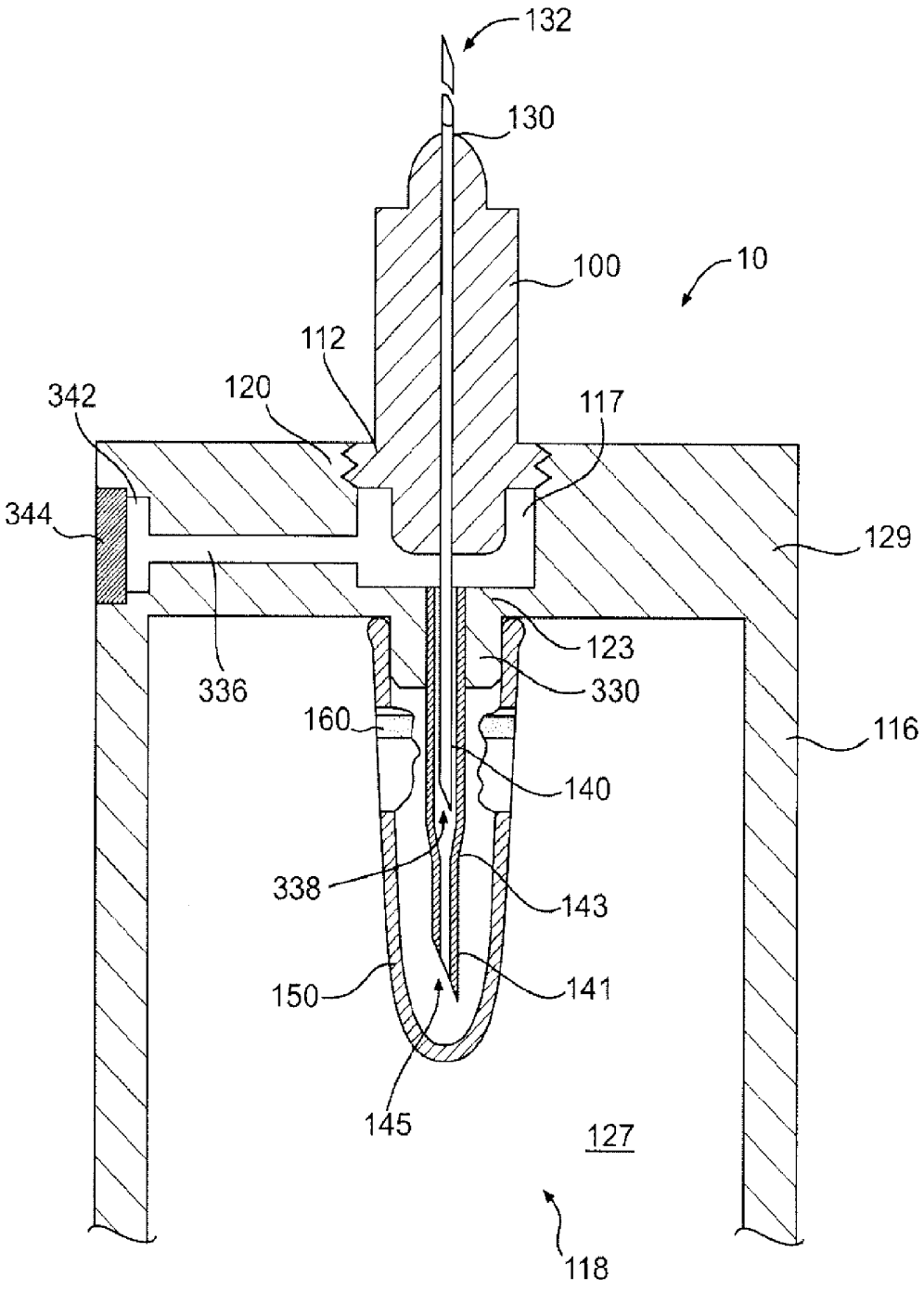

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FIG. 19

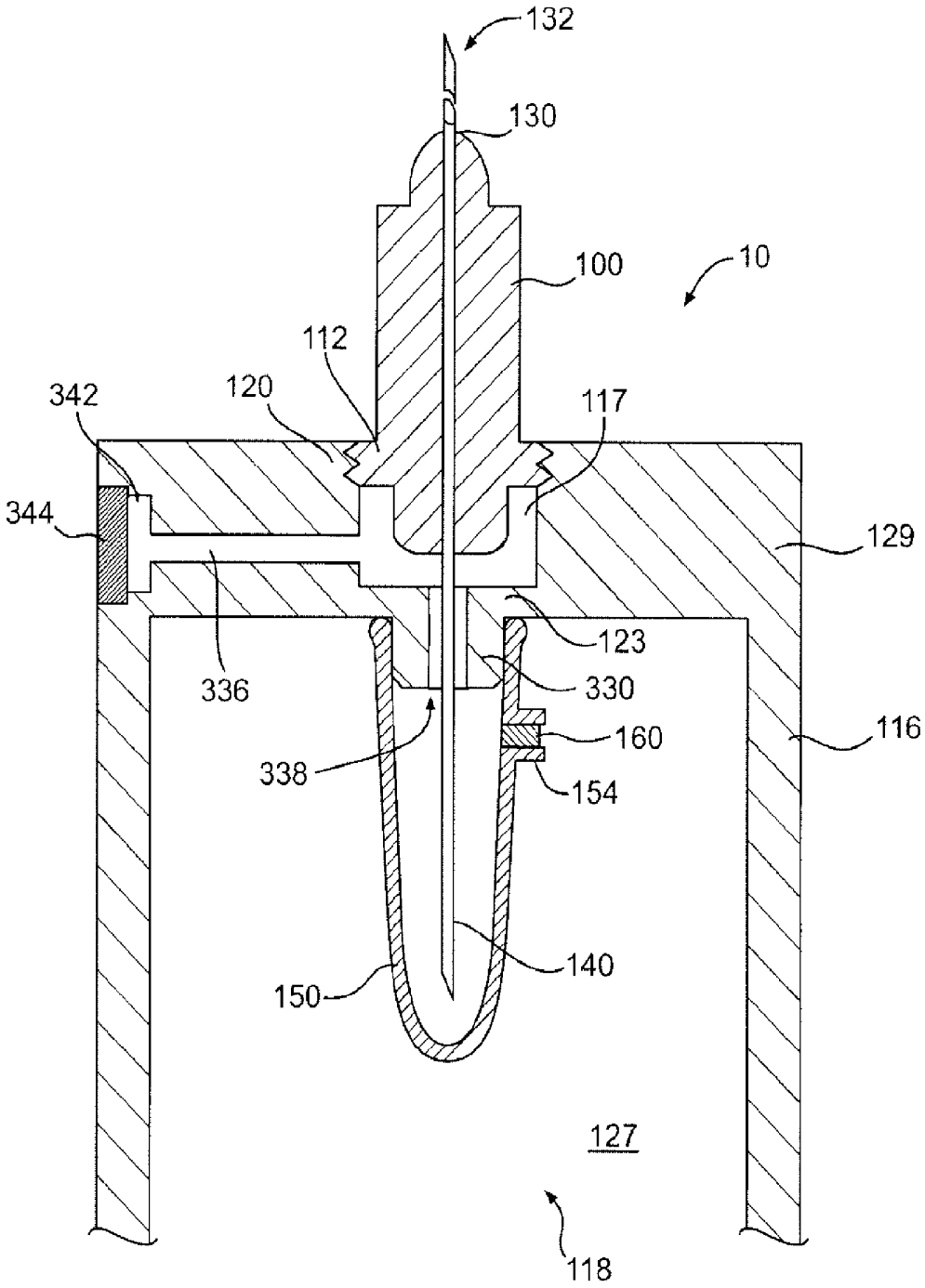

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FIG. 20

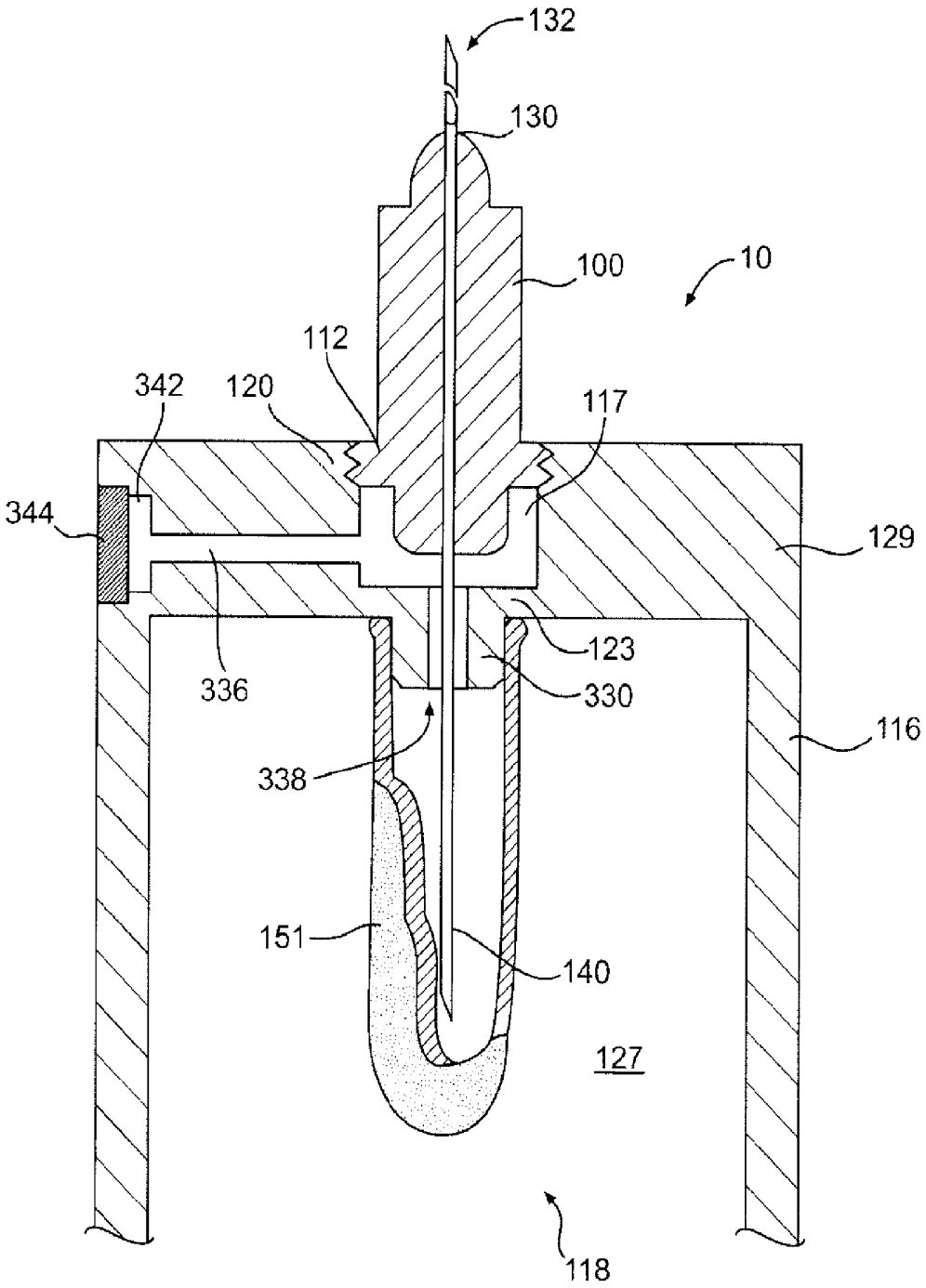

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FIG. 21

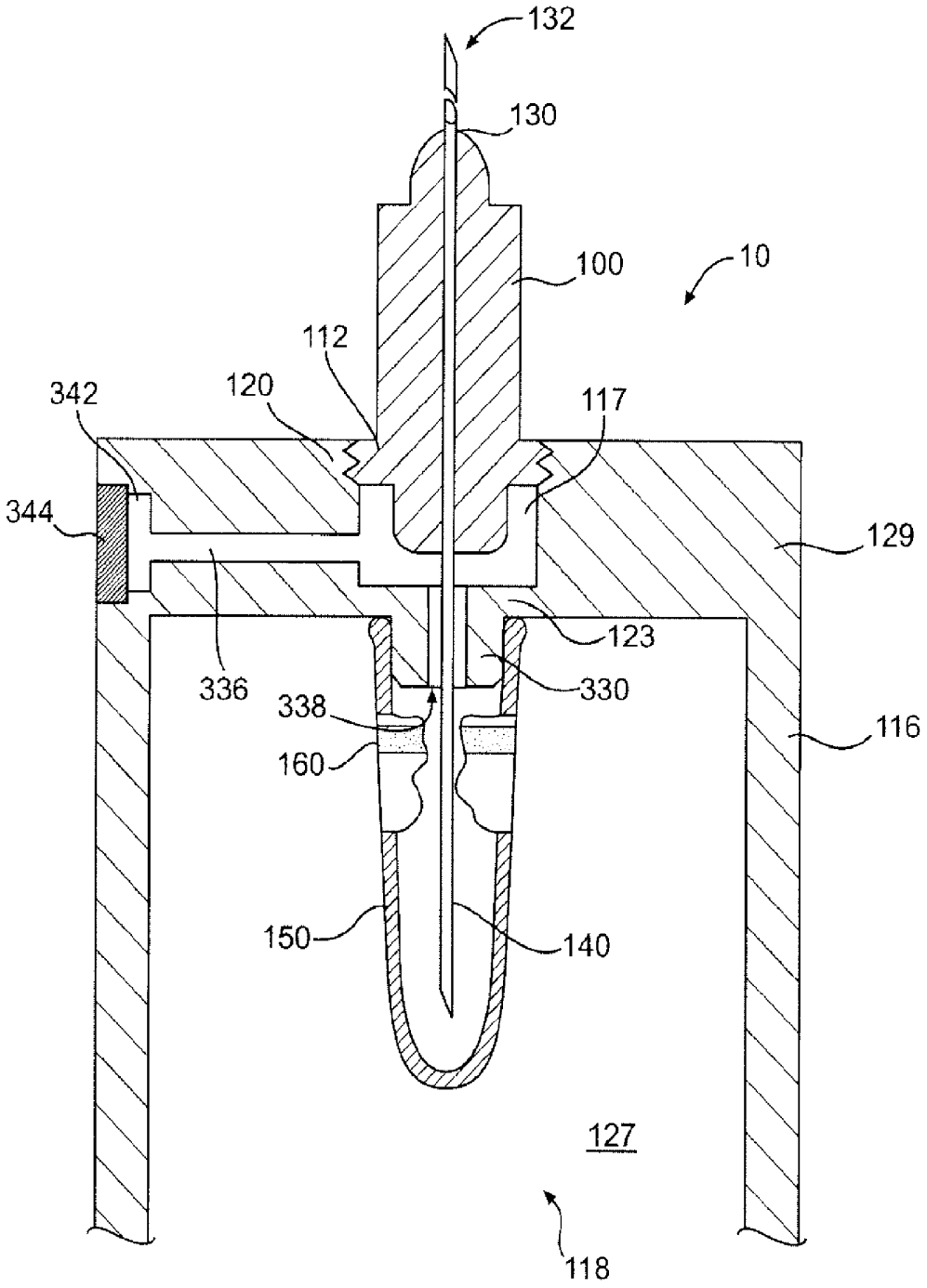

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FIG. 22

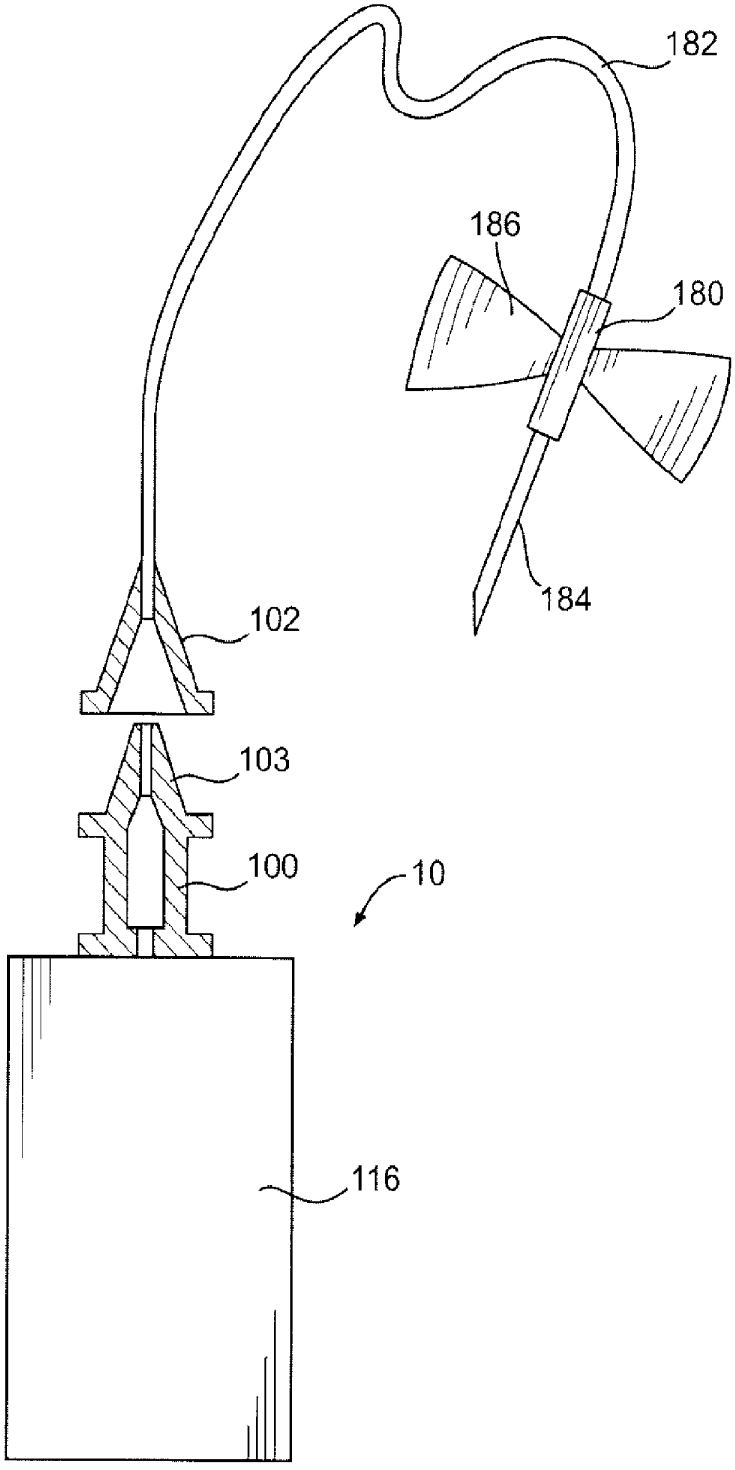


FIG. 23

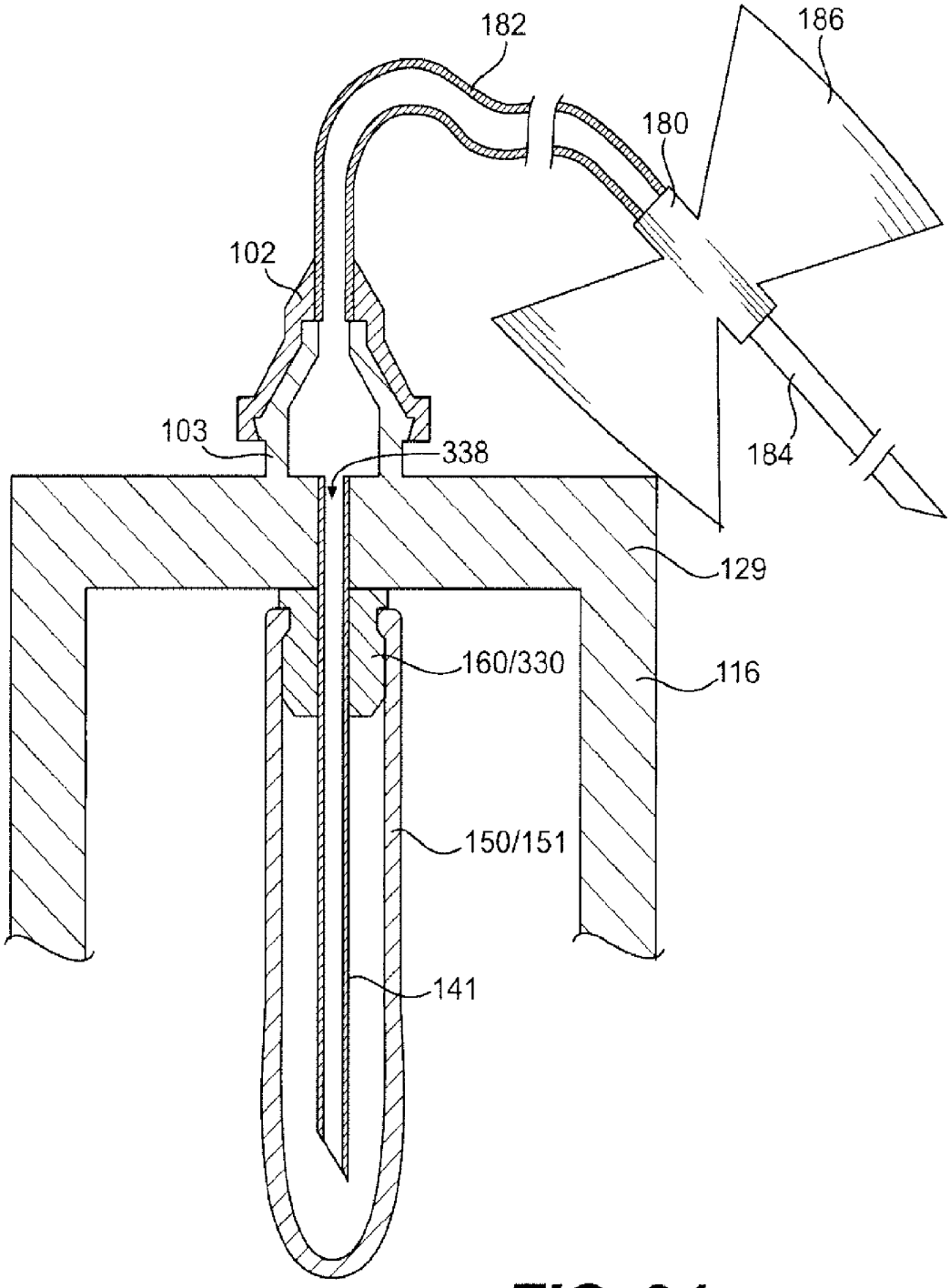


FIG. 24

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2010/040030

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61M 5/36 (2010.01)
USPC - 604/122
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC(8) - A61M 5/36, 5/178 (2010.01)
USPC - 604/122, 164

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
MicroPatent, Freepatentsonline, Google

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2008/0086085 A1 (BROWN) 10 April 2008 (10.04.2008) entire document	1-48
Y	US 2003/0153874 A1 (TAL) 14 August 2003 (14.08.2003) entire document	1-48
Y	EP0 440 479 B1 (VAN HEUGTEN) 07 August 1991 (07.08.1991) entire document	2-14

☐ Further documents are listed in the continuation of Box C. ☐

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
12 August 2010	30 AUG 2010
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer: Blaine R. Copenheaver PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

Form PCT/ISA/210 (second sheet) (July 2009)

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Literature display help

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Patent 5789869

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(19) [Country of issue] Japan Patent Office (JP)
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(11) [Patent number] Patent No. 5789869 (P5789869)
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(45) [Date of Issue] October 7, 2015 (2015.10.7)
(54) [Title of Invention] Auxiliary Plate for Polishing Pad and Equipped with Auxiliary Plate for Polishing Pad Polishing Apparatus
(51) [International Patent Classification]
B24B 37/12 (2012.01)
[FI]
B24B 37/04 A
[Number of Claims] 11
[Total Number of Pages] 21
(21) [Application Number] Patent Application 2011-165360 (P2011-165360)
(22) [Application date] July 28, 2011 (2011.7.28)
(65) [Publication number] JP-A-2013-27951 (P2013-27951A) (43) [Publication date] 2013 February 7, 2013 (February 7, 2013) [Date of request for examination] June 25, 2014 (June 25,

2014) [Matters to be stated regarding results of research commissioned by the government] (report by applicant) commissioned by the government Patent application related to research results (FY2010 Ministry of Economy, Trade and Industry "Strategic Fundamental Technology Advancement Support Project" commissioned research, patent application subject to Article 1 9 of the Industrial Technology Enhancement Act) (73) [Patentee] [Identification number] 599 096053

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[Name] Eiji Suzuki
[Examiner] Takashi Kameda
(56) [References] [Reference] Japanese Patent Application
Laid- Open No. 08- 118231 (JP, A) [Reference] JP-A-07-328915 (JP, A) (58) [Field investigate d] (Int.Cl., DB name) B24B 37/12 H01L 21/304

The scope of the claims open ----

(57) [Scope of Claims]
[Claim 1] A

polishing pad auxiliary plate mounted on a rotating surface plate of a polishing apparatus for detachably attaching a polishing pad to the rotating surface plate, wherein

:

a first fixing means for fixing the lower auxiliary plate to the rotating surface plate; and

a pad supporting surface on which the polishing pad is superposed and fixed. an upper auxiliary plate superimposed on the upper surface of the lower auxiliary plate;

second fixing means for fixing the upper auxiliary plate to the lower auxiliary plate;

the lower auxiliary plate and the upper side; positioning means for aligning the center axis of the auxiliary plate with respect to each other

, and the lower auxiliary plate is fixed to the rotating surface plate of the polishing apparatus by the first fixing means. By removing the upper auxiliary plate from the lower auxiliary plate held and fixed to the rotating surface plate, the polishing pad can be rotated while being fixed to the pad supporting surface of the upper auxiliary plate. The upper auxiliary plate can be removed from the surface plate, and the removed upper auxiliary plate can be fixed and attached again to the lower auxiliary plate while being aligned by the positioning means, and ,

the fixing force between the lower auxiliary plate and the upper auxiliary plate by the second fixing means is smaller than the fixing force between the rotating platen and the lower auxiliary plate by the first fixing means;

Auxiliary plate for a polishing pad, characterized in that :

[Claim 2]

2. The auxiliary plate for a polishing pad according to claim 1 , wherein said positioning means is located inside the outer peripheral surfaces of said lower auxiliary plate and said upper auxiliary plate.

3. The positioning

means

includes an engaging projection provided on one of the lower auxiliary plate and the upper auxiliary plate and protruding toward the other, and the lower auxiliary plate and the upper auxiliary plate. 3. An auxiliary plate for a polishing pad according to claim 2 , wherein said auxiliary plate for a polishing pad comprises an engaging concave portion provided on the other side thereof and with which said engaging convex portion is engaged .

4. The polishing pad according to claim 3

, wherein said engaging projections and said engaging recesses are formed with engaging portions located on the outer peripheral portions of said lower auxiliary plate and said upper auxiliary plate. Auxiliary plate. 5. An annular engagement in which the engaging portions of the engaging protrusion and the engaging recess extend continuously in the circumferential direction of the lower auxiliary plate and the upper auxiliary plate and are fitted to each other. 5. The auxiliary plate for a polishing pad according to claim 4 , comprising an outer peripheral surface and an engaging inner peripheral surface . 6. At a plurality of locations on the circumference of the outer peripheral portions of the lower auxiliary plate and the upper auxiliary plat

e, the lower auxiliary plate and the upper auxiliary plate are overlapped on one side toward th e other. The engaging concave portion that opens and the engaging convex portion that protr udes toward one side of the other of the mutual overlapping surfaces of the lower auxiliary pl ate and the upper auxiliary plate are formed at positions corresponding to each other. wherein said engaging portion is formed by fitting said engaging convex portion into said engaging con cave portion.

5. The polishing pad auxiliary plate according to 4 .

7.

The engaging protrusions projecting from a plurality of locations on the circumference of one of the lower auxiliary plate and the upper auxiliary plate toward the other are formed of an el astic material, and The engagement portion is formed by engaging the tip of the engagement projection with the engagement recess provided in the outer peripheral surface of the other of the side auxiliary plate and the upper auxiliary plate. 5. The polishing pad auxiliary plate acco rding to claim 4 .

8. A polishing pad auxiliary plate according to claim 3

, wherein said engaging projections and said engaging recesses are provided on the central axes of said lower auxiliary plate and said upper auxiliary plate. 9. An outer peripheral surfac e of said engaging projection and an inner peripheral surface of said engaging recess are form ed with screw grooves for engaging with each other, and said engaging projection and said en gaging portion constituting said positioning means are formed with thread grooves for engagi ng with each other. 9. The auxiliary plate for a polishing pad according to claim 8 , wherein sai d second fixing means is formed by screwing with said mating recess . 10. The engaging pro jection provided on one of the lower auxiliary plate and the upper auxiliary plate is formed of t he same material as one of the lower auxiliary plate and the upper auxiliary plate. The auxilia ry plate for a polishing pad according to any one of claims 3 , 4 , 5 , 6 , 8 and 9 .

11. The auxiliary plate for a polishing pad according to any one of claims 1 to 10 is mounted o n the upper surface of a rotating surface plate, and a protective member is provided on the ou ter peripheral side of the rotating surface plate with a gap

therebetween . 11. The positioning means according to any one of claims 1 to 10 , wherein t he positioning means is disposed on the inner peripheral side of the outer peripheral end faces of the rotating platen and the polishing pad auxiliary plate. 2. A polishing apparatus comprisin g the polishing pad auxiliary plate according to 1 or 2 above.

detailed description open —

Description: BACKGROUND OF THE INVENTION 1.

Field of the Invention The present invention relates to the polishing of substrates such as silicon wafers, semiconductor substrates, glass substrates, etc., which are workpieces requiring high flatness accuracy. It relates to a related technique, and more particularly to a technique that makes it possible to reuse a polishing pad used in polishing the surface of such a substrate.

is. 2.

Description of the Related Art As is well known, in manufacturing a semiconductor, a polishing process is performed to flatten the surface of a substrate such as a silicon wafer, a semiconductor substrate, a glass substrate, or the like. Such a polishing process generally involves fixing a disc-shaped polishing pad made of a resin material or the like directly on a rotating surface plate of a polishing apparatus with a double-sided tape, and supplying a polishing liquid containing abrasive grains to the polishing pad. Polishing is performed by rotating the substrates relative to each other. [0003] Polishing pads for carrying out such a polishing process are made of foamed or non-foamed urethane or the like, as described in Japanese Patent Application Laid-Open No. 2002-11630 (Patent Document 1). A resin pad is used. Further, in many cases, the polishing surface of such a polishing pad is provided with grooves such as concentric circles, grids, or radial grooves, or the bubbles of foamed resin are opened. [0004] By the way, when performing a polishing process using a polishing pad, when changing the type of substrate to be polished, the polishing pad used for the polishing process is peeled off from the rotating platen and replaced with another polishing pad. sometimes you have to. Also, for example, when a polishing pad that has deteriorated due to polishing is to be re-processed, such as by grooving the surface, with another processing device for the purpose of reusing the polishing pad, the polishing pad is removed from the rotating platen. Needs to be pulled off. [0005]

However, since the thin disk-shaped polishing pad is firmly fixed to the rotating surface plate

of the polishing apparatus with an adhesive tape, when the polishing pad is peeled off from th e rotating surface plate, Damage such as bending, breaking, wrinkling, and tearing is likely to occur. Therefore, due to such damage, there is often a problem that such polishing pads cann ot be reused and must be discarded even though their service life has not expired.

[0006]

Moreover, the work of peeling off the polishing pad from the rotating surface plate while payi ng close attention not to damage it requires skill and caution, and there is also the problem of placing a heavy burden on the operator. In addition, since it takes a considerable amount of ti me to peel off the polishing pad from the rotating surface plate, the polishing apparatus, whic h is expensive and valuable equipment, must be stopped for a long time, which shortens the o peration time of the equipment. There was also the problem that the

[0007]

Therefore, the present inventor previously described in Japanese Patent Application Laid-Ope n No. 2010-214579 (Patent Document 2) that an auxiliary plate is attached to the back surfac e of the polishing pad, and the polishing pad is rotated by the polishing apparatus through thi s auxiliary plate. We proposed a polishing pad with an auxiliary plate that is fixed to the surfa ce plate with double-sided tape. With such a polishing pad with auxiliary plate, since the polis hing pad is attached to and detached from the rotating surface plate while being supported by the auxiliary plate, damage to the polishing pad during attachment and detachment is reinforc ed by the auxiliary plate. Therefore, it is possible to attach and detach the polishing pad to an d from the rotating platen with good workability while preventing the polishing pad from being damaged.

[0008]

However, as a result of further studies and studies by the present inventors, it has been foun d that it is difficult to say that the polishing pad with an auxiliary plate proposed in Patent Doc ument 2 is easily compatible with all polishing apparatuses. rice field.

[0009]

That is, when the polishing pad is overlaid and fixed to the rotating surface plate, it is necess ary to align the center of the polishing pad with the rotation center of the rotating surface plat e. Accuracy is required for center alignment. If the number of attachment/detachment of the polishing pad to/from the rotating platen increases by adopting the auxiliary plate as describe d above, it becomes more difficult and labor-intensive to align the center position when attach ing the polishing pad to the rotating platen. big is big

It becomes a problem. Further, in the polishing pad with auxiliary plate proposed in Patent D ocument 2, in order to detachably attach the auxiliary plate while aligning the center of the au xiliary plate with respect to the rotary surface plate, the following are provided between the a uxiliary plate and the rotary surface plate

:

For example, fixing means such as an outer peripheral ring may be provided on the outer peri

pheral surface of the rotating surface plate. On the other hand, in some polishing apparatuse s, a protective cover or the like is attached to the outer peripheral side of the rotary platen, so that the space on the outer peripheral side of the rotary platen is extremely narrow. Therefor e, if such an outer peripheral ring were to be adopted, and a polishing device with a narrow sp ace on the outer peripheral side of the rotating surface plate was used, there was a possibility that the polishing device would need to be modified. of.

[Prior Art Documents]

[Patent Documents]

[0011]

[Patent Document 1] Japanese Unexamined Patent Application Publication No. 2002-11630 [P atent Document 2] Japanese Unexamined Patent Application Publication No. 2010-214579 [Su mmary of the Invention] [Problems to be Solved by the Invention] SUMMARY OF THE INVEN TION It is an object of the present invention to provide a polishing pad which can be easily att ached to and detached from a rotating surface plate while sufficiently securing the fixing force of the polishing pad to the rotating surface plate . For a polishing pad with a novel structure, which can prevent damage to the polishing pad when the polishing pad is removed from the r otating platen, and which can be advantageous for reuse of the polishing pad, for example. To provide an auxiliary plate. [0013]

In addition, according to the present invention, the work of aligning the center when mounti ng the polishing pad on the rotating surface plate can be performed easily and accurately, and the labor burden can be reduced. Another object of the present invention is to provide an auxi liary plate for a polishing pad with an improved structure, which can be easily and advantageo usly applied to a rotating surface plate in a polishing machine without requiring any special m odification. A further object of the present invention is to provide a polishing apparatus havin g such a novel polishing pad auxiliary plate

. Means for Solving the Problems In order to solve the above problems, a first aspect of the present invention relating to an auxiliary plate for a polishing pad is: (A) mounted on a rotatin g surface plate of a polishing apparatus; A polishing pad auxiliary plate for detachably attachi ng a pad to the rotary platen, comprising: (B) a lower auxiliary plate disposed on the upper s urface of the rotary platen; and (C) the lower auxiliary plate. and (D) a pad supporting surfac e on which the polishing pad is superimposed and fixed, which is superimposed on the upper s urface of the lower auxiliary plate. (E) a second fixing means for fixing the upper auxiliary plat e to the lower auxiliary plate; The lower auxiliary plate is held in a fixed state by the first fixin

g means to the rotating surface plate of the polishing apparatus, and is fixed to the rotating s urface plate. Further, by removing the upper auxiliary plate from the lower auxiliary plate, the polishing pad can be removed from the rotating surface plate while being fixed to the pad sup porting surface of the upper auxiliary plate. At the same time, it is possible to attach the remo ved upper auxiliary plate to the lower auxiliary plate by fixing it again in a state of being align ed by the positioning means.

and the fixing force between the lower auxiliary plate and the upper auxiliary plate by the sec ond fixing means is stronger than the fixing force between the rotating platen and the lower a uxiliary plate by the first fixing means. It features a smaller auxiliary plate for the polishing pa d. In the polishing pad auxiliary plate constructed according to the present invention, the pol ishing pad is composed of the upper auxiliary plate and the upper auxiliary plate

.

It is fixedly attached to the rotating surface plate via the lower auxiliary plate. Thereby, the u pper auxiliary plate can be removed from the lower auxiliary plate while the lower auxiliary pl ate is fixed to the rotating surface plate, and the polishing pad can be removed from the rotati ng surface plate while being fixed to the upper auxiliary plate. becomes possible. Therefore, in a state in which the polishing pad is reinforced and protected by the upper auxiliary plate, t he polishing pad can be removed from the rotating surface plate while preventing damage to t he polishing pad, and the thin polishing pad can be easily handled

.

becomes. For example, when the polishing pad is repeatedly attached and detached when the object to be polished or the polishing conditions are changed, or when the worn polishing pad is detached and reattached after reprocessing, the attachment and detachment of the polishin g pad to and from the rotating platen and the polishing are difficult. It is also possible to easil y perform operations such as reproduction processing for pads. Moreover, since the lower au xiliary plate still fixed to the rotating surface plate and the upper auxiliary plate removed toge ther with the polishing pad are aligned with each other by the positioning means, the position on the rotating surface plate can be easily adjusted

.

The attachment and detachment work of the polishing pad, which requires alignment, can be performed more easily. In particular, since the positioning means is provided between the low er auxiliary plate and the upper auxiliary plate, there is no need to apply special processing or the like to the rotating surface plate. In addition, it is possible to prevent such positioning me ans from protruding to the outer peripheral side of the rotating surface plate. applicable witho ut In the polishing pad auxiliary plate according to the first aspect of the present invention

,

, the fixing force between the lower auxiliary plate and the upper auxiliary plate by the seco nd fixing means is smaller than the fixing force between the rotating platen and the lower aux iliary plate by the first fixing means; A certain aspect is employed . According to the first aspe ct , the fixing forces of the first and second fixing means are mutually adjusted, so that the up per auxiliary plate to which the polishing pad is fixed can be rotated

. This makes it easier to remove the lower auxiliary plate that is still fixed to the surface plate. In short, there is no need for a special operation or the like to keep the lower auxiliary plate fi xed to the rotating platen, and the polishing pad can be attached to the upper supporting plat e while the lower auxiliary plate remains fixed to the rotating platen. It becomes possible to e asily remove the plate from the rotating surface plate while it is fixed to the plate. According t o a second aspect of the present invention , in the polishing pad auxiliary plate according to the first aspect, the positioning means is arranged on the inner peripheral side of the outer pe ripheral surfaces of the lower auxiliary plate and the upper auxiliary plate . It is located and pr ovided. [0022] In the polishing pad auxiliary plate of this aspect, the projection of the upper and lower auxiliary plates to the outer peripheral side of the positioning means is completely a voided. Therefore, for example, even when the outer diameter of the upper and lower auxiliar y plates is set to be the same as or slightly smaller than the outer diameter of the rotating sur face plate, the supporting surface of the polishing pad can be secured sufficiently large and th e It is possible to prevent the positioning means from protruding to the outer peripheral side, and even if a protective cover or the like is installed on the outer peripheral side of the rotatin g surface plate, it will not become an obstacle when applying the polishing pad auxiliary plate according to the present invention. Avoided.

A third

aspect of the present invention is the polishing pad auxiliary plate according to the second a spect, wherein the positioning means is provided on one of the lower auxiliary plate and the u pper auxiliary plate and on the other . It is composed of an engaging projection projecting to ward and an engaging recess provided in the other of the lower auxiliary plate and the upper auxiliary plate with which the engaging projection is engaged. In the polishing pad auxiliary pl ate of this aspect, it is possible to easily obtain a mechanically large positioning force based on the mutual engagement between the engaging projections and the engaging recesses. Furt her, by adjusting the shape, size, number, etc. of the engaging projections and engaging rece sses, it is possible to easily set the direction and acting force of the positioning action with a l arge degree of freedom.

A fourth aspect

of the present invention is the auxiliary plate for a polishing pad according to the third aspec t, wherein the engaging projections and the engaging recesses are located on the outer perip heries of the lower auxiliary plate and the upper auxiliary plate . It is formed with an engagin g portion located in the portion. In the polishing pad auxiliary plate of this aspect, the engag ement outer peripheral surface of the engagement projection and the engagement recess are positioned in the outer peripheral portion away from the center of the polishing pad auxiliary plate and are engaged with each other in a concave-convex manner . By forming the engage ment inner peripheral surface of the upper and lower auxiliary plates, the relative positioning accuracy, particularly the radial positioning accuracy, can be improved. As shown in the sixth and seventh aspects below, the engaging outer peripheral surface of the engaging convex por tion and the engaging inner peripheral surface of the engaging concave portion are arranged around the center of the polishing pad auxiliary plate. It may extend in the circumferential dir ection along the outer peripheral edge of the polishing pad auxiliary plate, or it may extend on the circumference like the engaging protrusions and engaging recesses formed on the outer p eripheral portion of the polishing pad auxiliary plate. It may be in a partially positioned form. A fifth aspect of the present invention is the auxiliary plate for a polishing pad according to t he fourth aspect, wherein the engaging portions of the engaging projections and the engaging recesses correspond to the lower auxiliary plate and the It is composed of an annular engagin g outer peripheral surface and an engaging inner peripheral surface that extend continuously i n the circumferential direction of the upper auxiliary plate and are fitted to each other. [0028]

In the polishing pad auxiliary plate of this aspect, more preferably, the engaging concave por tion and the engaging convex portion are formed with an annular inner and outer peripheral e ngaging surface that spreads around the central axis of the polishing pad auxiliary plate. Ther efore, when the upper auxiliary plate is attached to the lower auxiliary plate, it is not necessar y to align the upper auxiliary plate with each other in the circumferential direction, and the wo rk can be performed easily and quickly. A sixth aspect of the present invention is a polishing pad auxiliary plate according to the fourth aspect, wherein the lower auxiliary plate and the u pper auxiliary plate are provided at a plurality of locations on the periphery of the outer perip heral portions of the lower auxiliary plate and the upper auxiliary plate

. The engaging recess opening toward the other on one of the overlapping surfaces of the low er auxiliary plate and the upper auxiliary plate, and the other of the mutually overlapping surf

aces of the lower auxiliary plate and the upper auxiliary plate and the engaging projection pro jecting toward one side are formed at positions corresponding to each other, and the engaging portion is formed by fitting the engaging projection into the engaging recess. is. In the polishi ng pad auxiliary plate of this mode, the mutual positioning of the upper and lower auxiliary p lates can be easily realized not only in the direction perpendicular to the axis but also in the ci rcumferential direction around the central axis. In a seventh aspect of the present invention , in the polishing pad auxiliary plate according to the fourth aspect, the outer peripheral portio n of one of the lower auxiliary plate and the upper auxiliary plate has a plurality of points on t he circumference of the other . The engaging convex portion protruding toward the upper auxi liary plate is formed of an elastic material, and engages with the engaging concave portion pr ovided in an opening on the outer peripheral surface of the other of the lower auxiliary plate a nd the upper auxiliary plate. The engaging portion is configured by engaging the tip of the en gaging projection.

In the polishing pad auxiliary plate of this aspect, it is possible to form the engaging portions so as to be exposed on the outer peripheral surfaces of the upper and lower auxiliary plates . can be confirmed. In addition, in this aspect, the engagement state of the engagement portio n can be stably maintained by utilizing the elasticity of the engagement convex portion. An ei ghth
aspect of
the present invention is the polishing pad auxiliary plate according to the third aspect, where in the engaging projections and the engaging recesses are located at the centers of the lower auxiliary plate and the upper auxiliary plate . It is provided on the shaft. In the polishing pad auxiliary plate of this aspect, the engaging projections and the engaging recesses are formed on the central axis of the upper and lower auxiliary plates .

By providing this, it becomes possible to align the central axes of the upper and lower auxiliar y plates with one engaging portion. Further, when the engaging projections and the engaging recesses provided on the central axis are aligned with each other, it is not necessary to align t he upper and lower auxiliary plates with each other in the circumferential direction. can be ea sily brought into engagement. According to a ninth aspect of the present invention , in the p olishing pad auxiliary plate according to the eighth aspect, the outer peripheral surface of the engaging projection and the inner peripheral surface of the engaging recess are screwed toget

her

. A groove is formed, and the second fixing means is formed by screwing the engaging project ion and the engaging recess that constitute the positioning means. [0036] In the polishing p ad auxiliary plate of this mode, the fixing force between the upper auxiliary plate and the low er auxiliary plate can be obtained by the positioning means. Therefore, it is possible to config ure the second fixing means only by such positioning means, or to configure the fixing force b etween the upper and lower auxiliary plates by the second fixing means as an auxiliary means by the positioning means. A tenth aspect of the present invention is the third , fourth , fifth , sixth , eighth and ninth

2. In the polishing pad auxiliary plate according to any one of the above aspects, the engagin g projection provided on one of the lower auxiliary plate and the upper auxiliary plate is arran ged between the lower auxiliary plate and the upper auxiliary plate. It is made of the same m aterial as the one. In the polishing pad auxiliary plate of this aspect, it is possible to prevent the support characteristics of the polishing pad of the auxiliary plates superimposed one on to p of the other from greatly differing locally at the portions where the engaging projections are formed

.

. Therefore, when a pressing force acts on the surface of the polishing pad during pad polishin g, the pressure reaction force and the elasticity of the polishing pad are reduced at the format ion portions of the engaging convex portions and the engaging concave portions of the upper and lower auxiliary plates that support the polishing pad. It is possible to reduce or avoid defe cts such as polishing accuracy caused by local differences in such characteristics. Further, ac cording to the present invention, the auxiliary plate for a polishing pad according to any one o f the first to tenth aspects of the present invention is mounted on the upper surface of a rotati ng platen, and is attached to the outer peripheral side of the rotating platen

. A polishing apparatus in which a protective member is arranged with a gap in between, and the positioning means is provided on the inner peripheral side of the outer peripheral end surf aces of the rotating platen and the polishing pad auxiliary plate, Characterized by EFFECTS OF THE INVENTION By adopting the polishing pad auxiliary plate structured according to the pre sent invention or using the polishing apparatus structured according to the present invention, the polishing pad can be prevented from being damaged and polished. can be easily removed from and attached to the rotating surface plate, and positioning of the polishing pad on the ro tating surface plate can be performed easily and accurately. [Brief Description of the Drawings]

FIG. 1 is a vertical cross-sectional view showing the essential parts of a polishing apparatus e quipped with a polishing pad auxiliary plate according to a first embodiment of the present inv ention;

2 is an explanatory view of a longitudinal section showing a state in which the polishing pad is removed in the polishing apparatus shown in FIG. 1; FIG.

FIG. 3 is a vertical cross-sectional view showing a main part of a polishing apparatus equipped with a polishing pad auxiliary plate according to a second embodiment of the present inventio n;

4 is an explanatory view of a longitudinal section showing a state in which the polishing pad is removed in the polishing apparatus shown in FIG. 3; FIG.

FIG. 5 is a vertical cross-sectional view showing the essential parts of a polishing apparatus e quipped with a polishing pad auxiliary plate according to a third embodiment of the present in vention;

6 is an explanatory view of a longitudinal section showing a state in which the polishing pad is removed in the polishing apparatus shown in FIG. 5; FIG.

FIG. 7 is a vertical cross-sectional view showing a main part of a polishing apparatus equipped with a polishing pad auxiliary plate according to a fourth embodiment of the present inventio n;

8 is an explanatory view of a longitudinal section showing a state in which the polishing pad is removed in the polishing apparatus shown in FIG. 7; FIG.

FIG. 9 is a vertical cross-sectional view showing a main part of a polishing apparatus equipped with a polishing pad auxiliary plate according to a fifth embodiment of the present invention;

10 is a side view of a lower auxiliary plate that constitutes the polishing pad auxiliary plate sh own in FIG. 9; FIG.

11 is a plan view of the lower auxiliary plate shown in FIG. 10; FIG.

FIG. 12 is a longitudinal sectional view showing the essential parts of a polishing apparatus eq uipped with a polishing pad auxiliary plate according to a sixth embodiment of the present inv ention;

FIG. 13 is a vertical cross-sectional view showing the essential parts of a polishing apparatus equipped with a polishing pad auxiliary plate according to a seventh embodiment of the prese nt invention;

FIG. 14 is a vertical cross-sectional view showing a main part of a polishing apparatus equipp ed with a polishing pad auxiliary plate according to an eighth embodiment of the present inve ntion;

FIG. 15 is an explanatory view of a longitudinal section showing a state in which a polishing p ad auxiliary plate according to a ninth embodiment of the present invention is removed;
FIG. 16 is an explanatory view of a longitudinal section showing a state in which a polishing p ad auxiliary plate is removed according to a tenth embodiment of the present invention;
FIG. 17 is an explanatory view of a longitudinal section showing a state in which a polishing p ad auxiliary plate according to an eleventh embodiment of the present invention is removed;
FIG. 18 is an explanatory view of a longitudinal section showing a state in which a polishing p ad auxiliary plate according to a twelfth embodiment of the present invention is removed;
FIG. 19 is an explanatory view of a longitudinal section showing a state in which a polishing p ad auxiliary plate according to a thirteenth embodiment of the present invention is removed;
FIG. 20 is an explanatory view of a longitudinal section showing a state in which a polishing p ad auxiliary plate according to a fourteenth embodiment of the present invention is positione d;
FIG. 21 is an explanatory view of a longitudinal section showing a state in which a polishing p ad auxiliary plate according to a fifteenth embodiment of the present invention is positioned;
FIG. 22 is an explanatory view of a longitudinal section showing a state in which a polishing p ad auxiliary plate according to a sixteenth embodiment of the present invention is removed;
DETAILED DESCRIPTION OF THE INVENTION Embodiments of the present invention will be de scribed
below

with reference to the drawings. First, FIGS. 1 and 2 show a polishing pad auxiliary plate 10 a s a first embodiment of the present invention. This polishing pad auxiliary plate 10 is used by being attached to a rotary surface plate 14 of a polishing apparatus 12, and a polishing pad 1 6 is detachably attached to the rotary surface plate 14. As shown in FIG.
The polishing apparatus is used ,

for example, as a CMP apparatus as described in Japanese Patent Application Laid-Open No. 2010-141155, for example. A rotating shaft extending vertically is rotatably supported by the main body of the apparatus fixedly installed above, and a disk-shaped rotating platen 14 is fix ed to the upper end of the rotating shaft. The rotating surface plate 14 has a flat upper surfac e 18 extending horizontally, and the upper surface 18 serves as a support surface for the polis hing pad 16 . The rotating shaft is connected to the rotating output shaft of an electric motor, and the driving force of the electric motor is transmitted so that the rotating shaft and thus th e rotating surface plate 14 are rotated about the central axis. there is A nozzle for supplying p olishing slurry is arranged above the upper surface 18 supporting the polishing pad 16, and a wafer or the like to be polished (an object to be polished) is held and rotated while being mov ed to the polishing pad 16. A polishing head is provided for polishing by pressing. In such a polishing apparatus, the polishing pad auxiliary plate 10 mounted on the rotating platen 14
is

includes a lower auxiliary plate 20 and an upper auxiliary plate 22 . A lower auxiliary plate 20 is fixed to the upper surface 18 of the rotating platen 14 by first fixing means 24 , and an upp er auxiliary plate 22 is attached to the upper surface of the lower auxiliary plate 20 . It is fixe d by two fixing means 26 . That is, the lower auxiliary plate 20 and the upper auxiliary plate 2 2 are overlapped and fixed to each other via the second fixing means 26, thereby forming the polishing pad auxiliary plate 10 having a two-layer structure as a whole. , and is attached to t he upper surface 18 of the rotating surface plate 14 by the first fixing means 24 .

Each of the lower auxiliary plate 20 and the upper

auxiliary plate 22 has a thin, substantially circular flat plate shape, and has a flat front surfa ce (upper surface) and a rear surface (lower surface). These upper and lower auxiliary plates 22 and 20 are desirably made of a harder material than the polishing pad 16 to which it is att ached, or having a higher member rigidity than the polishing pad 16 . Although it depends on the method of use, as will be described later, the lower auxiliary plate 20 can be used without being repeatedly attached and detached after being attached to the rotary surface plate 14, w hile the upper auxiliary plate 22 can be attached and detached after being attached to the rot ary surface plate 14. is expected to be repeated, it is desirable that at least the upper auxiliar y plate 22 should have higher member rigidity than the polishing pad 16 .

[0046]

Of course, the upper auxiliary plate 22 supports the polishing pad 16 and provides the stren gth, rigidity, and rigidity required for various treatments such as polishing, cleaning, and re-gr ooving of the polishing pad surface, in addition to polishing by the polishing device 12 . Any m aterial that satisfies shape stability and accuracy may be used, and its material and thickness are not limited. In particular, not only the lower auxiliary plate 20 but also the upper auxiliary plate 22 alone bears the supporting strength and rigidity of the polishing pad 16. Since the lo wer surface is supported by the rotating surface plate 14 by being superimposed on each othe r and used, the strength and rigidity of the single unit are not required so much. Therefore, in addition to metals such as stainless steel, synthetic resins, fiber-reinforced resins, and the like can be employed as materials for forming the lower auxiliary plate 20 and the upper auxiliary plate 22 . In particular, synthetic resin materials are lighter than metal materials and easier to process and handle. . In order to obtain a stable supporting force over the entire polishing p ad 16, it is desirable to set the outer diameter dimension of the upper auxiliary plate 22 to be equal to or larger than the outer diameter dimension of the polishing pad 16,

and

It is desirable to set the outer diameter of the lower auxiliary plate 20 to be equal to or larger than the outer diameter of the upper auxiliary plate 22, and set the outer diameter of the low er auxiliary plate 20 to be equal to or smaller than the outer diameter of the rotating surface plate 12. should be set to In particular, as shown in FIGS. 1 and 2, the outer diameters of the lower auxiliary plate 20 and the upper auxiliary plate 22 are made substantially the same, and the outer diameter of the rotating surface plate 14 to be mounted is also substantially the sa

me. By doing so, it becomes possible to ensure a sufficiently large support area for the polishi ng pad 16 . As a result, the polishing pad 16 having approximately the same size as the rotati ng surface plate 14 can be attached to the rotating surface plate 14 with approximately the sa me supporting force over the entirety thereof.

[0048]

Furthermore, as the first fixing means 24 and the second fixing means 26, the lower auxiliar y plate 20 and the upper auxiliary plate 22 are fixed to the upper surface 18 of the rotating pl aten 14 against the external force exerted during polishing. It is not particularly limited as lon g as it can be held at. Specifically, an adhesive, a pressure-sensitive adhesive, or a double-sid ed tape having an adhesive or a pressure-sensitive adhesive attached to both sides of a base sheet may be employed as the first and second fixing means 24, 26. In addition, negative pre ssure suction using negative pressure air or the like, or magnetic suction using a permanent magnet or an electromagnet can be employed. In addition, it is desirable that the fixing mean s made of adhesive or the like apply substantially uniform fixing force over substantially the e ntire surface of the flat overlapping surfaces of the lower auxiliary plate 20 and the upper auxi liary plate 22. Adhesive strength can be obtained, and problems such as locally different supp ort characteristics of the polishing pad 16 on the surface of the polishing pad auxiliary plate 1 0 can be avoided.

For example ,

the fixing force can be turned ON/OFF by negative pressure suction or an electromagnet. au xiliary

It is desirable to set the fixing force of the upper auxiliary plate 22 to the lower auxiliary plate 20 by the second fixing means 26 to be smaller than the fixing force of the plate 20 . As a res ult, when the upper auxiliary plate 22 is peeled off from the lower auxiliary plate 20 and remo ved, the lower auxiliary plate 20 can be easily left fixed on the rotating surface plate 14.例文帳 に追加 The specific realization of such a difference in adhesion force is achieved by differentiati ng the adhesion means itself such as the material of the adhesive and pressure-sensitive adh esive, as well as the adhesion area and the condition of the adhesion surface (surface roughn ess, presence or absence of plasma treatment, etc.) can also be realized by making the .

Further, the surface (upper surface) of the upper auxiliary plate 22 serves as a

polishing pad supporting surface, and the polishing pad 16 is superimposed and mounted th ereon. As such a polishing pad 16, conventionally known various types of polishing pads can b e employed. The back surface of the polishing pad 16 is fixed to the surface of the upper auxil iary plate 22 using a conventionally known adhesive tape or suitable adhesive for attaching th e polishing pad.

It is desirable that the fixing means for fixing

the polishing pad 16 to the upper auxiliary plate 22 has a larger fixing force than the second fixing means 26 described above. As a result, when the upper auxiliary plate 22 is removed fr om the lower auxiliary plate 20 with the polishing pad 16 still fixed, the polishing pad 16 does

not move from the upper auxiliary plate 22 even if the upper auxiliary plate 22 is bent or the l ike. It is possible to effectively prevent the peeling off. The outer diameter of the polishing p ad 16 is generally a standard value, but in many cases it is set equal to or smaller than the ou ter diameter of the upper surface 18 of the rotating surface plate 14 to which it is attached . [0053]

Further, for example, at least one of between the upper surface 18 of the rotating surface pl ate 14 and the lower auxiliary plate 20, between the lower auxiliary plate 20 and the upper au xiliary plate 22, and between the upper auxiliary plate 22 and the polishing pad 16 A suitable cushioning layer may be provided. By providing such a cushion layer, it becomes possible to a chieve uniform polishing efficiency over the entire surface of the workpiece when polishing wit h the polishing pad 16 .

[0054]

As such a cushion layer, for example, a resin sheet, an elastomer sheet, a rubber sheet, or t he like to which a certain degree of compressibility is imparted by foaming can be suitably em ployed. A cushion layer can also be configured by the first fixing means 24 , the second fixing means 26 , and the means for fixing the polishing pad 16 to the upper auxiliary plate 22 . In o rder to prevent local distortion on the support surface of the polishing pad 16, the cushion lay er is formed so as to have a size and a constant thickness over substantially the entire suppor t area of the polishing pad 16. is desirable. Positioning means 28 are provided between the l ower auxiliary plate 20 and the upper auxiliary plate 22 that constitute the polishing pad auxil iary plate 10 to align the centers of the plates with each other

.

In the present embodiment, a circular stepped surface 30 is formed on the outer peripheral p ortion of the lower auxiliary plate 20 and extends around the central axis of the lower auxiliar y plate 20 over the entire circumference. By reducing the thickness of the lower auxiliary plat e 20 on the outer peripheral side of the stepped surface 30, the notch cross-sectional shape t hat opens to the outer peripheral surface of the lower auxiliary plate 20 continues to the entir e circumference in the circumferential direction. An annular engaging recess 32 that extends i nward is formed integrally with the lower auxiliary plate 20 so as to protrude therefrom.

[0056]

On the other hand, in the present embodiment, a circular stepped surface 34 is formed on th e outer peripheral portion of the upper auxiliary plate 22 so as to extend around the central a xis of the upper auxiliary plate 22 over the entire circumference. Since the thickness of the up per auxiliary plate 22 is increased on the outer peripheral side of the stepped surface 34, an a nnular engagement continuously extends along the outer peripheral edge of the upper auxiliar y plate 22 along the entire circumference in the circumferential direction. A mating projection 36 is integrally formed so as to protrude from the upper auxiliary plate 22 . Incidentally, the e

ngaging convex portion 36 and the engaging concave portion 32 may be formed on either of t he upper and lower auxiliary plates 22 and 20 .

The stepped surface 30 and the engaging recess 32 of the lower auxiliary plate 20 are aligne d with the stepped surface 34 and the engaging projection 36 of the upper auxiliary plate 22 . It constitutes an engagement outer peripheral surface and an engagement inner peripheral su rface. When the upper auxiliary plate 22 is superimposed on the lower auxiliary plate 20, the engaging convex portion 36 is fitted into the engaging concave portion 32, and the stepped su rface 34 is superimposed on the stepped surface 30 in the radial direction. is formed. As a res ult, the engaging concave portion 32 and the engaging convex portion 36 constitute the positi oning means 28, and the lower auxiliary plate 20 and the upper side support plate 20 are alig ned in the radial direction with their central axes aligned with each other. Auxiliary plates 22 a re superimposed. In addition, the positioning means 28 is positioned on the inner peripheral si de of the outer peripheral surfaces of the upper and lower auxiliary plates 22 and 20, thereby preventing the upper and lower auxiliary plates 22 and 20 and the polishing apparatus 12 fro m becoming large. . In the polishing apparatus 12 provided with the polishing pad auxiliary plate 10 having such a structure, the upper and lower auxiliary plates 22 are mounted on the upper surface 18 of the rotating platen 14 as shown in FIG

.

, 20 is fixedly attached, and the polishing pad 16 is fixedly supported on the upper surface of the upper auxiliary plate 22. Then, the rotating platen 14 is driven to rotate, and the substrat e or the like is processed. CMP (Chemical Mechanical Polishing) is applied to objects. The polis hing apparatus 12 can exhibit the following special technical effects by being provided with th e polishing pad auxiliary plate 10 having a specific structure.

[0059]

First, as shown in FIG. 2, while the polishing pad 16 is fixed to the upper surface of the uppe r auxiliary plate 22, the upper auxiliary plate 22 is fixed to the rotating surface plate 14 by th e first fixing means 24. By removing the side auxiliary plate 20, the polishing pad 16 can be r emoved from the rotating surface plate 14. - 特許庁 Even when the surface (polishing surface) of the polishing pad 16 is removed from the rotating platen 14 and cleaned or reprocessed, th e polishing pad 16 can be kept fixed to the upper surface of the upper auxiliary plate 22 . As a result, the upper auxiliary plate 22 provides reinforcement not only when the polishing pad 16 is attached to and detached from the rotating surface plate 14, when the polishing pad 16 is c leaned and reprocessed, but also when the polishing pad 16 is transported or stored. By this a ction, the polishing pad 16 can be prevented from being bent or damaged, and the polishing p ad 16 can be kept in good condition.

Further

, even when the polishing pad 16 is removed from the rotating surface plate 14 together wit h the upper auxiliary plate 22 , the lower auxiliary plate 20 remains on the upper surface 18 o

f the rotating surface plate 14 . When the polishing pad 16 is again mounted on the rotating p laten 14, the positioning means 28 provided between the upper auxiliary plate 22 and the low er auxiliary plate 20 moves the upper auxiliary plate 22 and thus the polishing pad 16 to the l ower auxiliary plate. The center axis of the plate 20 and thus the rotating platen 14 can be ali gned with high accuracy and easily.

[0061]

Here, since the engaging concave portion 32 and the engaging convex portion 36 constitutin g the positioning means 28 are overlapped with almost no gap in a mutually fitted state, the s upport characteristics of the polishing pad 16 are improved. can be prevented from adversely affecting Of the outer peripheral portions of the upper and lower auxiliary plates 22 and 20, p articularly in the present embodiment, an engaging portion, in other words, a positioning mea ns 28, is formed on the outer peripheral edge portion, and the diameter of the polishing pad 1 6 that serves as the main region for polishing is formed. Since it is out of the middle part in th e direction, even if there is a slight gap between the engaging concave portion 32 and the eng aging convex portion 36, the supporting characteristics of the polishing pad 16 are such that a serious problem occurs in the polishing characteristics. can be avoided. Moreover, the engagi ng concave portion 32 and the engaging convex portion 36 constituting the positioning means 28 are formed on the superimposed surfaces of the upper and lower auxiliary plates 22 and 2 0, in other words, on the outer circumferences of the rotating surface plate 14 and the polishi ng pad auxiliary plate 10

.

Since it is formed on the inner peripheral side of the end face, the upper and lower auxiliary pl ates 22 and 20 can be prevented from projecting onto the outer peripheral surface. Therefore, as shown in FIGS. 1 and 2, for example, even when the protective member 38 is installed clos e to the outer peripheral side of the rotating surface plate 14 in the polishing apparatus 12, th e protective member 38 cannot be protected. Polishing provided with upper and lower auxiliar y plates 22, 20 provided with positioning means 28 while avoiding interference

A device 12 is made possible. Furthermore, as described above, while preventing damage to the polishing pad 16, the polishing pad 16 can be quickly attached to and detached from the r otating platen 14 with accurate positioning accuracy

.

The operating time of the expensive polishing equipment is not unnecessarily limited for such work, and the operating efficiency of the polishing equipment can be improved, and thus the production efficiency of substrates and the like (polishing work efficiency) can be improved.

In addition, since the polishing pad 16 can be easily attached to and detached from the rotati ng surface

plate 14, the reuse of the polishing pad 16 can be realized on a practical level without specia l skill or knowledge. That is, for example, the polishing pad 16 once removed from the rotatin g platen 14 can be reused when changing the type of the object to be polished such as a subs

trate, or the polishing pad 16 can be re-processed by another processing device such as surfa ce grooving as a countermeasure against deterioration. It is also possible to consider reusing t he polishing pad 16 once removed from the rotating surface plate 14 after reprocessing at a p ractical level. Although the first embodiment of the present invention has been described ab ove, the specific structure of the present invention should not be construed as limited by the fi rst embodiment

.

A plurality of other embodiments of the present invention having different positioning means between the upper and lower auxiliary plates 22 and 20 are illustrated below, but these embo diments are not intended to limit the configuration of the present invention. In the following e mbodiments, members and parts having the same structure as in the first embodiment are de noted by the same reference numerals as those in the first embodiment in the corresponding parts in each figure. , their detailed description is omitted. 3 and 4 show a polishing apparat us 42 provided with a polishing pad auxiliary plate 40 as a second embodiment of the present invention

.

In this polishing pad auxiliary plate 40, an engaging recess 44 is formed by an annular groov e continuously extending in the circumferential direction on the outer peripheral portion of the upper surface of the lower auxiliary plate 20. As shown in FIG . On the other hand, on the out er peripheral portion of the lower surface of the upper auxiliary plate 22, an engagement conv ex portion 46 is formed by an annular protrusion extending continuously in the circumferential direction. The engaging projection 46 may be formed integrally with the upper auxiliary plate 22, or may be formed separately as illustrated. That is, in this embodiment, an annular circu mferential groove 48 that opens in the lower surface of the upper auxiliary plate 22 and exten ds in the circumferential direction is formed. block is fitted and fixed at one end in the axial di rection to form an engagement convex portion 46 . The engaging concave portion 44 of the l ower auxiliary plate 20 and the engaging convex portion 46 of the upper auxiliary plate 22 are both formed at corresponding radial positions around the central axis

.

are overlapped, the engagement projections 46 are fitted into the engagement recesses 44, t hereby aligning the upper and lower auxiliary plates 22 and 20 with each other in the radial di rection. In the present embodiment, two side walls of the engaging recess 44 of the lower aux iliary plate 20 and the inner and outer peripheral surfaces of the engaging protrusion 46 of th e upper auxiliary plate 20 are superimposed on each other in the corresponding radial directio n. A pair of inner and outer engagement surfaces are provided. 5 and 6 show a polishing ap paratus 52 provided with a polishing pad auxiliary plate 50 as a third embodiment of the pres ent invention

. [0070]

In this polishing pad auxiliary plate 50, the lower auxiliary plate 20 has a stepped surface 54 as a circular engagement inner peripheral surface extending all around the central axis on the outer peripheral portion thereof. By increasing the thickness of the lower auxiliary plate 20 on the outer peripheral side of the stepped surface 54, an annular shape continuously extends al ong the outer peripheral edge of the lower auxiliary plate 20 along the entire circumference in the circumferential direction. The engaging convex portion 56 of
It is formed integrally with the side auxiliary plate 20 . On the other hand, on the outer perip heral portion of the upper auxiliary plate 22, there is formed a stepped surface 58 as a circula r engagement outer peripheral surface extending all around the central axis
.
Since the thickness of the upper auxiliary plate 22 is reduced on the outer peripheral side of t he step surface 58, the upper auxiliary plate 22 has a notched cross-sectional shape that ope ns to the outer peripheral surface and extends continuously along the entire circumference in the circumferential direction. An annular engaging recess 60 is formed integrally with the upp er auxiliary plate 22 .
Further, the step surface 54 of the lower auxiliary plate 20 is formed with
female threads, while the step surface 58 of the upper auxiliary plate 22 is formed with male threads. Then, the female thread of the stepped surface 54 of the lower auxiliary plate 20 is s crewed with the male thread of the stepped surface 58 of the upper auxiliary plate 22 so that the stepped surface 54 of the lower auxiliary plate 20 and the stepped surface 58 of the upper auxiliary plate 22 are screwed together. are superimposed on each other in the radial directio n, the upper auxiliary plate 22 is superimposed on the upper surface of the lower auxiliary pla te 20 . Further, in such a superimposed state, the screwing structure of the stepped surfaces 58, 54 of the upper and lower auxiliary plates 22, 20 constitutes a second fixing means 62 for detachably fixing the upper and lower auxiliary plates 22, 20. . The direction of the male and female threads in such a threaded structure is set in consideration of the rotational reaction fo rce exerted on the rotating surface plate 14 of the polishing device 12 during polishing so that the screws do not loosen
.
It is desirable that
FIGS.
7 and 8 show a polishing apparatus 66 having a polishing pad auxiliary plate 64 as a fourth embodiment of the present invention.
[0075]
In this polishing pad auxiliary plate 64 , a cylindrical engaging convex portion 68 projecting upward is formed at the central portion of the upper surface of the lower auxiliary plate 20 . T

he engaging projection 68 may be formed integrally with the lower auxiliary plate 20, or may be formed separately as shown in the drawing. That is, in this embodiment, a circular fitting r ecess 70 is formed on the central axis of the lower auxiliary plate 20, and a cylindrical block f ormed separately from the fitting recess 70 is provided. An engaging convex portion 68 is for med by being fitted and fixed at one end in the axial direction. On the other hand, in the centr al portion of the lower surface of the upper auxiliary plate 22, there is formed a bottomed circ ular engaging recess 72 that opens to the lower surface on the central axis. Incidentally, the e ngaging convex portion 68 and the engaging concave portion 72 may be formed on either of t he upper and lower auxiliary plates 22 and 20. As shown in FIG. When the upper and lower auxiliary plates 22 and 20 are superimposed, the engaging convex portion 68 is fitted into the engaging concave portion 72, thereby aligning the upper and lower auxiliary plates 22 and 20 with each other in the radial direction

.

It is designed to be In this embodiment, the engagement outer peripheral surface and the eng agement inner peripheral surface are formed by the outer peripheral surface of the engaging protrusion 68 of the lower auxiliary plate 20 and the inner peripheral surface of the engaging recess 72 of the upper auxiliary plate 22. It is configured.

FIG.

9 shows a polishing apparatus 76 provided with a polishing pad auxiliary plate 74 as a fifth e mbodiment of the present invention.

[0078]

In this polishing pad auxiliary plate 74 , a cylindrical engaging convex portion 78 projecting upward is formed on the outer peripheral portion of the upper surface of the lower auxiliary pl ate 20 . This engaging projection 78 may be formed integrally with the lower auxiliary plate 2 0, or may form a fitting recess in the lower auxiliary plate 20 like the engaging projection in t he fourth embodiment. Alternatively, a separate pin or the like may be fixed by press-fitting o r the like. Also, as shown in FIGS. 10 and 11, a plurality of such engaging projections 78 are f ormed independently of each other at the outer peripheral portion of the lower auxiliary plate 20 at predetermined intervals in the circumferential direction. Particularly preferably, the plura lity of engaging protrusions 78 are formed at regular intervals in the circumferential direction and positioned on the same circle on the central axis.

On the other hand, on the outer peripheral portion of the lower surface of the upper auxiliar y plate 22, bottomed circular engagement grooves are provided at positions corresponding to the formation positions of the plurality of engaging projections 78 on the lower auxiliary plate 20, respectively . A concave portion 80 is formed to open downward. Incidentally, the engagin g convex portion 78 and the engaging concave portion 80 may be formed on either of the upp er and lower auxiliary plates 22 and 20. As shown in FIG. When the upper and lower auxiliar y plates 22 and 20 are superimposed, the engaging convex portions 78 are fitted into the eng

aging concave portions 80, respectively, so that the upper and lower auxiliary plates 22 and 20 are positioned radially relative to each other

.

are designed to be matched. In the present embodiment, the outer circumferences of the lower auxiliary plate 20 and the upper auxiliary plate 22 are formed by the outer circumference of the engagement projection 78 of the lower auxiliary plate 20 and the inner circumference of the engagement recess 80 of the upper auxiliary plate 22 . An engaging outer peripheral surface and an engaging inner peripheral surface located in a portion are configured. In particular, as in this embodiment, by adopting positioning means consisting of a plurality of engaging projections 78 and engaging recesses 80 independent in the circumferential direction, the superimposed upper and lower auxiliary plates 22, 20 can be diametrically aligned

.

Mutual positioning is possible not only in the direction but also in the circumferential direction. Instead of the plurality of independent engaging recesses 80 formed in the upper auxiliary plate 22 ,

a circumferential groove continuously extending circularly in the circumferential direction around the central axis of the upper auxiliary plate 22 may be employed. Alternatively, as shown in the sixth embodiment of the present invention in FIG. 12, a circular stepped surface 82 is formed around the central axis of the outer peripheral portion of the upper auxiliary plate 22 and extends over the entire circumference. By making the thickness dimension of the outer peripheral side smaller than 82, it is also possible to form an annular engagement concave portion 83 that has a notched cross-sectional shape that opens to the outer peripheral surface of the upper auxiliary plate 22 and that extends continuously all around in the circumferential direction. It is possible.

[0083]

In this way, in the upper auxiliary plate 22, the engaging surfaces of the engaging projections 78 of the lower auxiliary plate 20 are formed continuously over the entire circumference, so that when the upper and lower auxiliary plates 20 and 22 are superimposed, the upper and lower auxiliary plates 20 and 22 can be overlapped. Since it is no longer necessary to align the auxiliary plates 20 and 22 with each other in the circumferential direction, the mounting work can be easily performed.

FIG.

13 shows a polishing pad auxiliary plate 84 as a seventh embodiment of the present invention.

In this polishing pad auxiliary plate 84, the upper portion of the outer peripheral surface of the lower auxiliary plate 20 and the lower portion of the outer peripheral surface of the upper

auxiliary plate 22 are each provided with a small diameter portion. By superimposing the upper and lower auxiliary plates 22 and 20, the small diameter portions of the upper and lower auxiliary plates 22 and 20 form an annular ring that extends across the entire circumference i

n the circumferential direction by widening a predetermined width across the upper and lower auxiliary plates 22 and 20. A shaped receiving recess 86 is formed. A groove-shaped engagi ng recess 88 is formed at the lower end of the small diameter portion of the lower auxiliary pl ate 20

.

The engagement recess 88 opens to the outer peripheral surface of the lower auxiliary plate 2 0 at the bottom surface of the accommodation recess 86 . Here, the bottom surface of the acc ommodation recess 86 refers to an annular surface extending over the upper and lower auxili ary plates 22 and 20 and extending in the vertical direction in FIG. On the other hand, a plate -shaped engaging projection 90 made of an elastic material is attached to the small-diameter portion of the upper auxiliary plate 22 that constitutes the accommodation recess 86 so that it s proximal end is fixed by a fixing pin 92 . The engaging protrusions 90 are accommodated in accommodation recesses 86 formed on the outer peripheral surfaces of the upper and lower a uxiliary plates 22 , 20 and extend from the upper auxiliary plate 22 onto the outer peripheral surface of the lower auxiliary plate 20 . there is An engaging claw portion 94 formed at the tip portion of the engaging projection portion 90 is engaged with an engaging recess portion 88 f ormed in the small diameter portion of the lower auxiliary plate 20, and the engaging projecti on portion 90 is locked. It is held in a locked state based on elasticity.

Furthermore, a plurality of such engaging projections 90 are provided on the outer periphera l surfaces of the upper and lower auxiliary plates 22 and 20 at predetermined intervals in the circumferential direction . And attached to the outer peripheral surface of the upper auxiliary plate 22

Each of the engaging projections 90 is elastically pressed against the outer peripheral surface of the lower auxiliary plate 20, thereby forming positioning means for positioning the upper a nd lower auxiliary plates 22, 20 relative to each other on the central axis. Further, by engagin g the engaging claw portion 94 of the engaging convex portion 90 with the engaging concave portion 88, a fixing means is also configured to hold the upper and lower auxiliary plates 22 a nd 20 in a superimposed state and apply a fixing force. there is Instead of the engaging prot rusions 90 having the engaging claws 94 that engage with the engaging recesses 88 as descri bed above, for example, an eighth embodiment of the present invention shown in FIG

.

In addition, a connecting plate 100 extending across the upper and lower auxiliary plates 22 a nd 20 and superimposed on the bottom surface of the housing recess 86 is adopted, and both ends of the connecting plate 100 are connected to one of the upper and lower auxiliary plates 22 and 20. It is also possible to fix to the outer peripheral surface of the by connecting pins 1 02 , 102 . At least one of the connecting pins 102, 102 is detachable from the lower auxiliary plate 20 or the upper auxiliary plate 22, so that the connection of the upper and lower auxiliar y plates 22, 20 by the connecting plate 100 can be released. , the attachment and detachmen

t of the upper auxiliary plate 22 to which the polishing pad 16 is fixed with respect to the lowe r auxiliary plate 20 is permitted. The first fixing means 24 and the second fixing means 26 m ade of double-faced tape or the like shown in the first to eighth embodiments are used when r emoving the upper and lower auxiliary plates 22 and 20 and the rotating surface plate 14

.

In addition, it is desirable to be held on the fixing surface on the side of a specific member. Th is facilitates handling of the upper and lower auxiliary plates 22, 20 and the first and second fi xing means 24, 26 in a detached state. In addition, the fixing surfaces on which the first and second fixing means 24 and 26 remain are determined by making the fixing force of both surf aces of the first fixing means and the second fixing means 24 and 26 themselves different fro m each other. It is possible to set by differentiating the surface roughness, material, etc. of th e fixed upper and lower auxiliary plates 22 and 20 and the rotating platen 14 from each other. In particular, it

is desirable that the first fixing means 24 is held on the fixing surface on the side of the lowe r auxiliary plate 20 when the lower auxiliary plate 20 is removed. becomes easier. On the othe r hand, as shown in FIG. 2 in the first embodiment, the second fixing means 26 is held on the fixing surface on the side of the upper auxiliary plate 22 when the upper auxiliary plate 22 is r emoved. Alternatively, it may remain on the upper surface of the lower auxiliary plate 20 as in the ninth embodiment of the present invention shown in FIG. By holding the second fixing me ans 26 on the fixing surface on the side of the upper auxiliary plate 22, the removed upper au xiliary plate 22 can be attached to the rotating surface plate of the device for reprocessing suc h as grooving of the polishing pad 16. At the time of mounting, it is also possible to use the se cond fixing means 26 held by the upper auxiliary plate 22 for mounting. On the other hand, b y holding the second fixing means 26 on the fixing surface of the lower auxiliary plate 20, whe n mounting another upper auxiliary plate 22 with another polishing pad 16 mounted thereon t o the lower auxiliary plate 20, It is also possible to attach using the second fixing means 26 h eld by the lower auxiliary plate 20 .

Further, the engaging recesses 32, 44, 60, 72, 80, (83), 88 and the engaging projections 36, 46, 56,

70, 78, 90 shown in the first to seventh embodiments may be provided on opposite sides of the lower auxiliary plate 20 side and the upper auxiliary plate 22 side. For example, as the te nth embodiment of the present invention is shown in FIG. The stepped surface 30 and the eng aging recess 32 may be formed on the upper auxiliary plate 22 , while the stepped surface 34 and the engaging convex portion 36 forming the inner peripheral surface of the engagement may be formed on the lower auxiliary plate 20 . It is possible.

[0092]

Furthermore, the engaging recesses 32, 44, 60, 72, 80, (83) and the engaging protrusions 3 6, 46, 56, 70, 78 shown in the first to sixth embodiments are overlapped with each other. It is also possible to form an inclination angle with respect to the outer peripheral surface of the en

gaging projection and the inner peripheral surface of the engaging recess for positioning the u pper and lower auxiliary plates 22 and 20 by using the upper and lower auxiliary plates 22 an d 20 as shown in FIG. For example, as an eleventh embodiment of the present invention is sh own in FIG. On the other hand, while the engaging convex portion 36 is tapered in the incline d direction in which it gradually tapers in the projecting direction,

A stepped surface 30 serving as an engaging outer peripheral surface of an engaging recess 3 2 formed in the outer peripheral portion of the upper auxiliary plate 22 can be tapered at an i nclination direction and an inclination angle corresponding to the stepped surface 34 . As a re sult, the operation of fitting the engaging convex portion 36 into the engaging concave portio n 32 and overlapping the upper and lower auxiliary plates 22, 20 can be further facilitated by using the tapers provided on both the stepped surfaces 34, 30 as guide surfaces. It becomes possible to do it easily. Incidentally, as shown in the twelfth embodiment of the invention sh own in FIG. 18 and the thirteenth embodiment of the invention shown in FIG

.

Even when adopting a plurality of projection-shaped engaging projections 78 formed independ ently in the direction and a plurality of hole-shaped engaging recesses 80 formed at respectiv e corresponding positions of the upper auxiliary plate 22, the engagement A tapered portion 1 04 having a tapered shape can be formed by giving an inclination angle to the outer periphera l surface of the projecting tip portion of the convex portion 78 . In FIG. 19, an engagement pi n 106 formed separately is press-fitted into a fitting hole 105 formed in the lower auxiliary pla te 20 to form the engagement convex portion 78. The lower end of the locking pin 106 also h as a tapered portion 104 similar to the upper end. As a result, the locking pin 106 has no dire ctivity and is easy to handle, and the operation of press-fitting it into the fitting hole 105 is als o facilitated.

[0094]

Further, in the fourteenth embodiment of the present invention shown in FIG. 20, a straddle between the upper and lower auxiliary plates 22, 20 is used as a kind of positioning means for aligning the central axis of the upper and lower auxiliary plates 22, 20 in a superimposed stat e. A locating sleeve 108 is thus shown fitted over. The positioning sleeve 108 has an inner dia meter that is the same as or slightly larger than the outer diameter of the upper and lower au xiliary plates 22 and 20, which are disk-shaped and have substantially the same outer diamet er. formed. Such a positioning sleeve 108 is used when superimposing the upper and lower au xiliary plates 22 and 20, and by superimposing the upper and lower auxiliary plates 22 and 20 within the positioning sleeve 108, the central axes of the upper and lower auxiliary plates 22 and 20 are aligned. They can be axially superimposed and secured to each other with a secon d securing means 26 . Therefore, the positioning sleeve 108 can be removed after the upper a nd lower auxiliary plates 22 and 20 are superimposed and fixed to each other, thereby positio ning the upper and lower auxiliary plates 22 and 20 so as to protrude on the outer peripheral surface. It is possible to attach them to each other without means and in precise alignment.

[0095]

Furthermore, in the fifteenth embodiment of the present invention shown in FIG. 21, a slit-shaped engagement groove 110 is formed extending across the overlapping direction when the upper and lower auxiliary plates 22 and 20 are overlapped. ing. The engaging grooves 110 are open to the outer peripheral surfaces of the upper and lower auxiliary plates 22 and 20 and have a predetermined depth radially inward. It is A plate-shaped engaging plate 112 is fitted into the engaging groove 110 from the opening of the outer peripheral surface, so that the upper and lower auxiliary plates 22 and 20 are positioned by the engaging plate 112 and is in a connected state. Although the engaging plate 112 is formed separately from the upper and lower auxiliary plates 22 and 20, it may be formed integrally with one of the upper and lower auxiliary plates 22 and 20 so as to protrude toward the other. . In that case, the engagement groove 110 is formed only in the other auxiliary plate.

Furthermore, in the sixteenth embodiment of the present invention shown in FIG. 22 ,

a fitting recess 114 is formed as an engaging recess opening in the lower surface of the upper auxiliary plate 22 . In particular, in this embodiment, the fitting recess 114 is formed as an annular groove extending continuously in the circumferential direction around the central axis of the upper auxiliary plate 22 . On the other hand, the lower auxiliary plate 20 has a fitting convex portion 116 as an engaging convex portion that protrudes upward on the upper surface that overlaps with the upper auxiliary plate 22 . In addition, in this embodiment, the fitting protrusion 116 is formed as an annular protrusion corresponding to the fitting recess 114 . When the upper and lower auxiliary plates 22 and 20 are superimposed, the fitting convex portion 116 is positioned so as to enter the fitting concave portion 114 .

[0097]

The fitting projection 116 has a hollow structure, and the inside of the fitting projection 116 is provided with an external space.

A fluid reservoir 118 is formed which is sealed between them. Further, at least the inner peripheral wall and the outer peripheral wall of the wall portion of the fitting convex portion 116 that defines the fluid reservoir 118 are bulged and deformable in the radial direction. Specifically, for example, by forming the fitting convex portion 116 with a rubber elastic material or the like, it is possible to realize an inner peripheral wall that can bulge radially inward and an outer peripheral wall that can bulge radially outward. be. Further, the lower auxiliary plate 22 is formed with a fluid passage 120 that communicates with the fluid reservoir 118 and extends radially outward and opens to the outer peripheral surface

.

A pressure screw 122 is screwed into the end opening. In addition, a sealed area composed of the fluid passage 120 and the fluid reservoir 118 sealed by the pressurizing screw 122 is filled with an incompressible fluid such as oil.

Thus

, by screwing the pressure screw 122, the internal pressure of the fluid reservoir 118 can be

increased through the fluid passage 120, and the inner and outer peripheral walls of the fluid reservoir 118 can be expanded outward. As a result, the fitting convex portion 116 is expande d and pressed against the inner surface of the fitting concave portion 114, so that the upper a nd lower auxiliary plates 22 and 20 can be positioned by mutual frictional force and the like, a nd can also exert a fixing force. there is

When removing the upper auxiliary plate 22 from the lower auxiliary plate 20 ,

the pressure screw 122 is rotated in the direction of loosening and moved to the outer perip heral side of the lower auxiliary plate 20, whereby the fluid reservoir 118 is removed. , the pr essing force of the fitting protrusion 116 against the fitting recess 114 can be released.

[0101]

In addition, although not listed individually, the present invention can be implemented with v arious changes, modifications, improvements, etc. based on the knowledge of those skilled in the art. It is also possible to attach an O-ring or a sealing material to the portion to prevent fo reign matter from entering the overlapping surfaces of the upper and lower auxiliary plates.

In addition to the auxiliary plates 20 and 22 having the two-layer structure described above, i t

is also possible to add additional auxiliary plates in a laminated state and fixed by fixing mea ns. By adopting the auxiliary plate of the third layer in this way, it becomes possible to realize an elastic support state or to dispose of the intermediate layer.

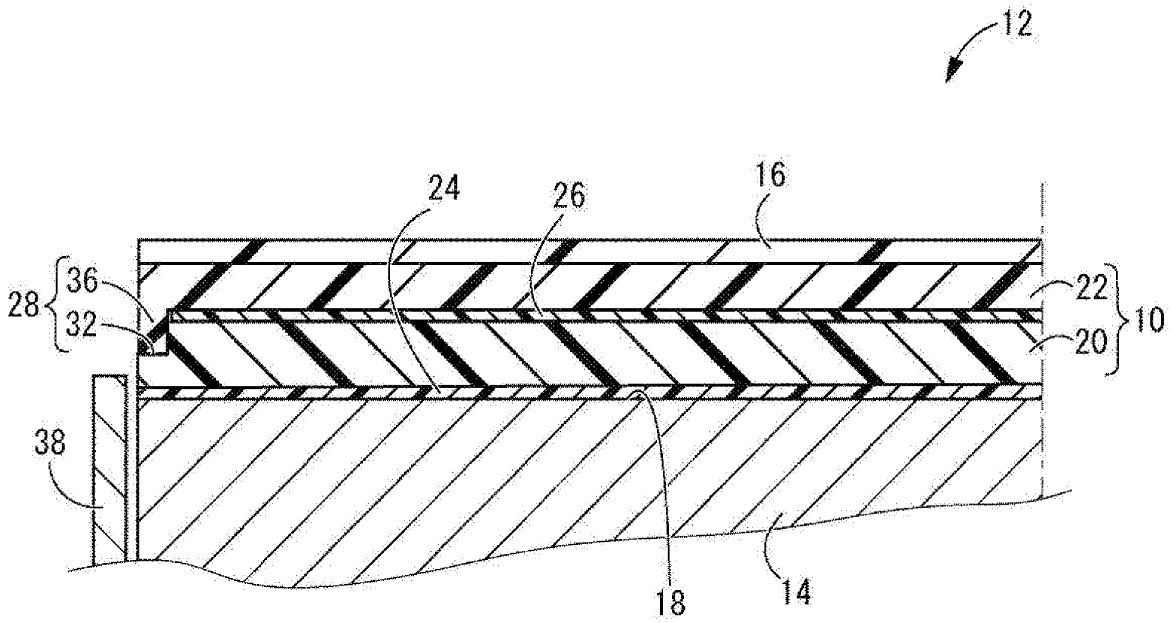
[Description of Reference Symbols]

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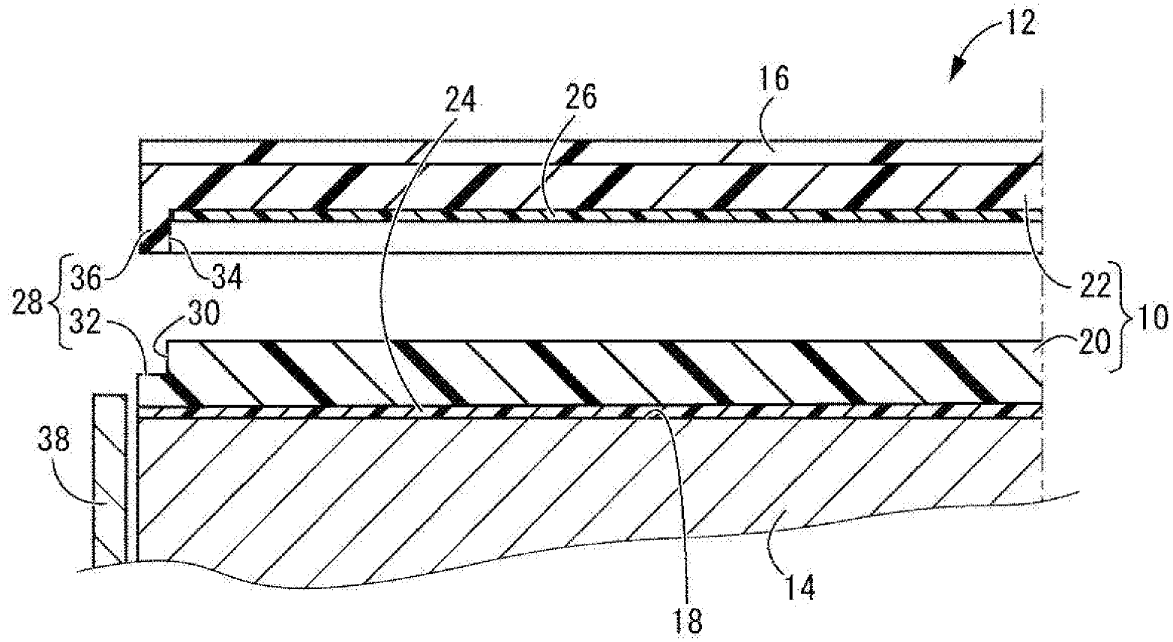
, 40, 50, 64, 74, 84: polishing pad auxiliary plate, 12, 42, 52, 66, 76: polishing device, 14: ro tating platen, 16: polishing pad, 18: upper surface, 20: lower auxiliary plate, 22: upper auxili ary plate, 24: first fixing means, 26, 62: second fixing means, 28: positioning means, 30, 58: step surface (engagement outer circumference surface), 32, 44, 60, 72, 80, 88: engagement concave portion, 34, 54: step surface (engagement inner peripheral surface), 36, 46, 56, 68, 78, 90: engagement convex portion, 38: Protective member

drawing open —

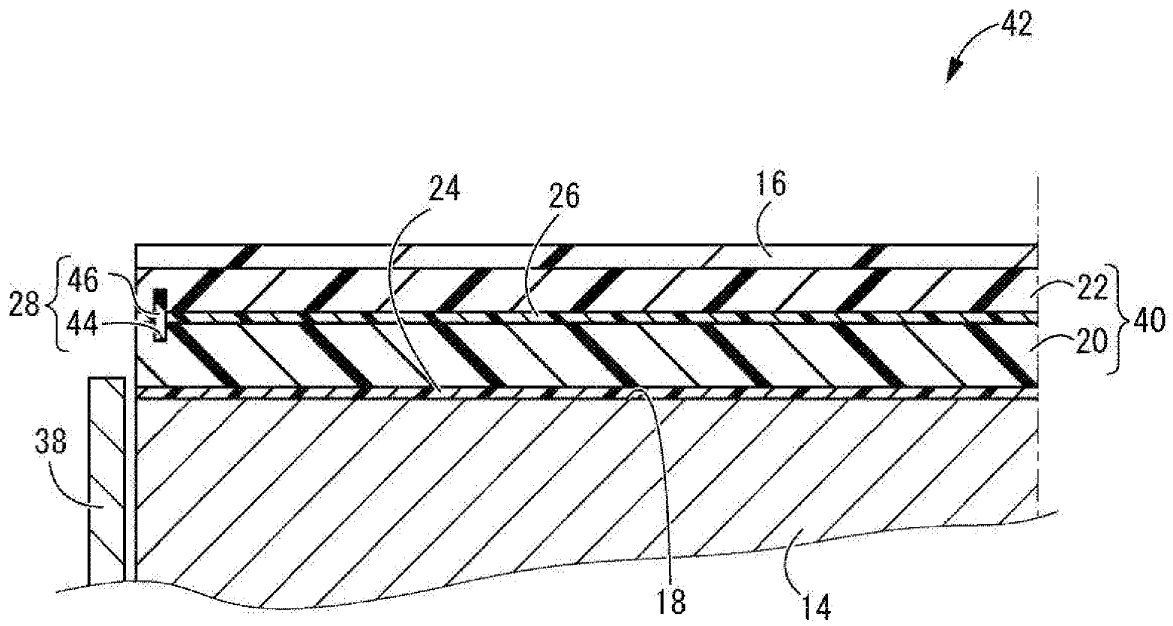
[Fig. 1]



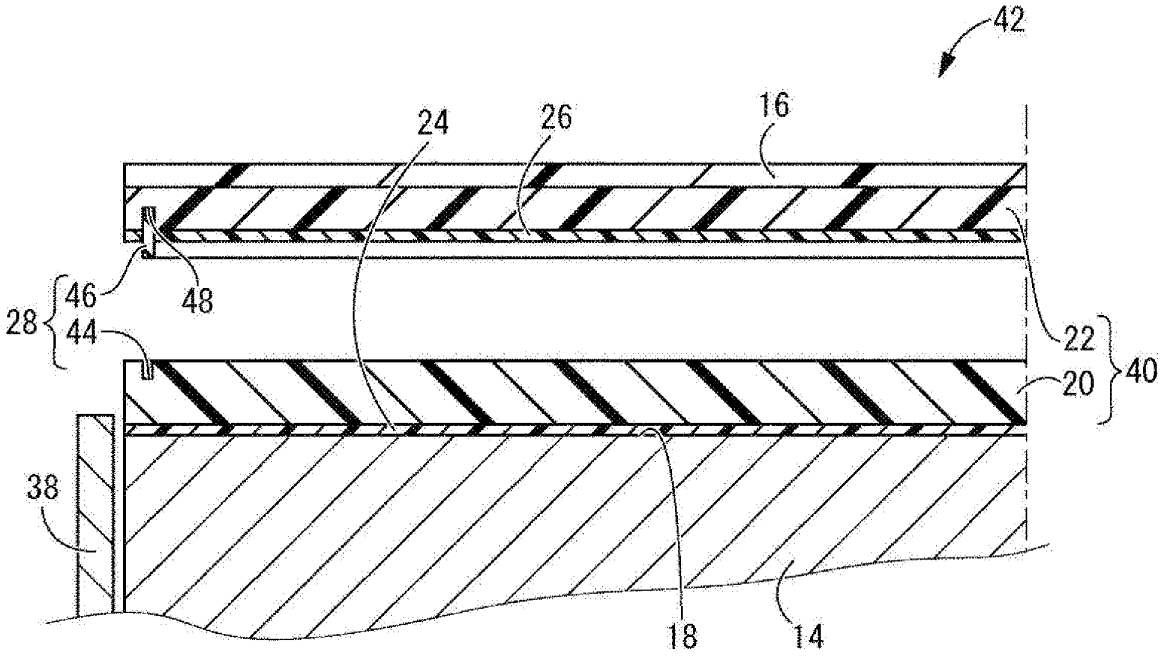
[Figure 2]



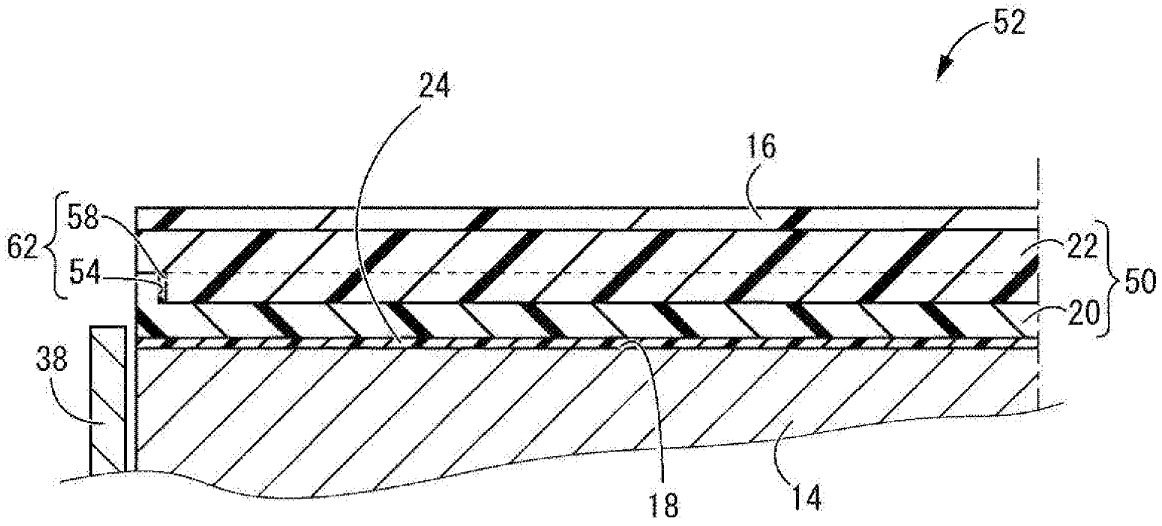
[Figure 3]



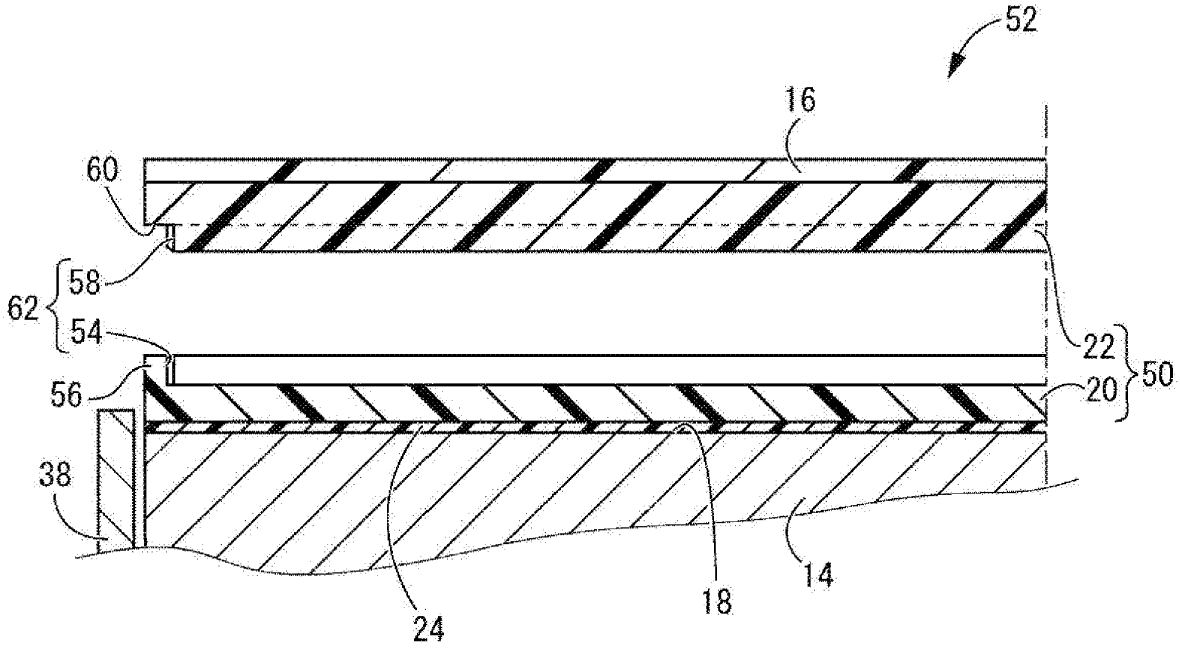
[Figure 4]



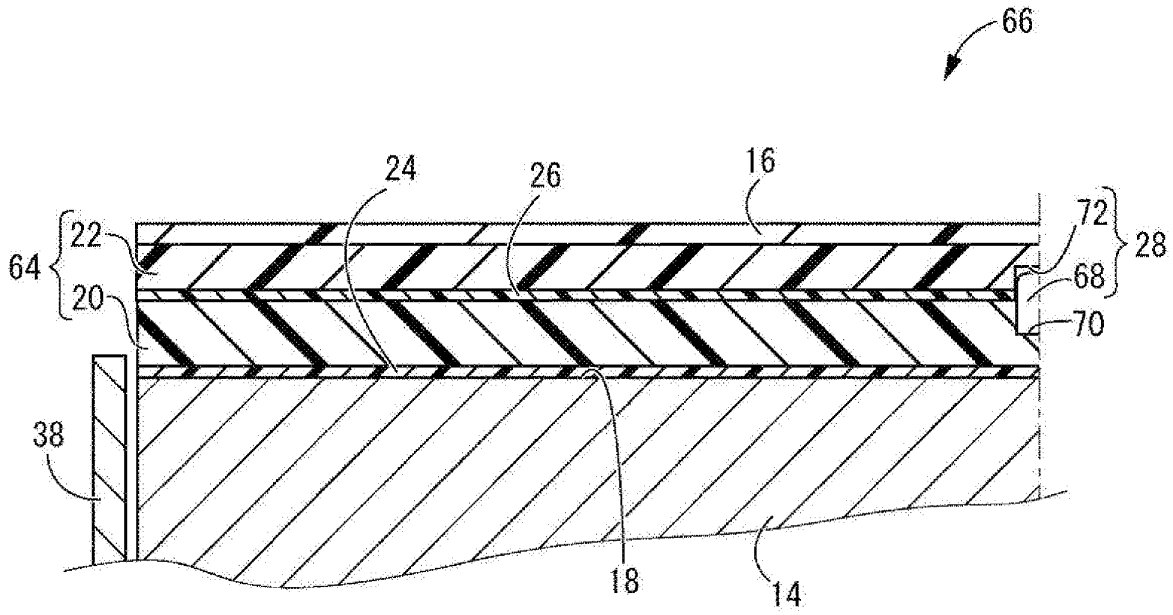
[Figure 5]


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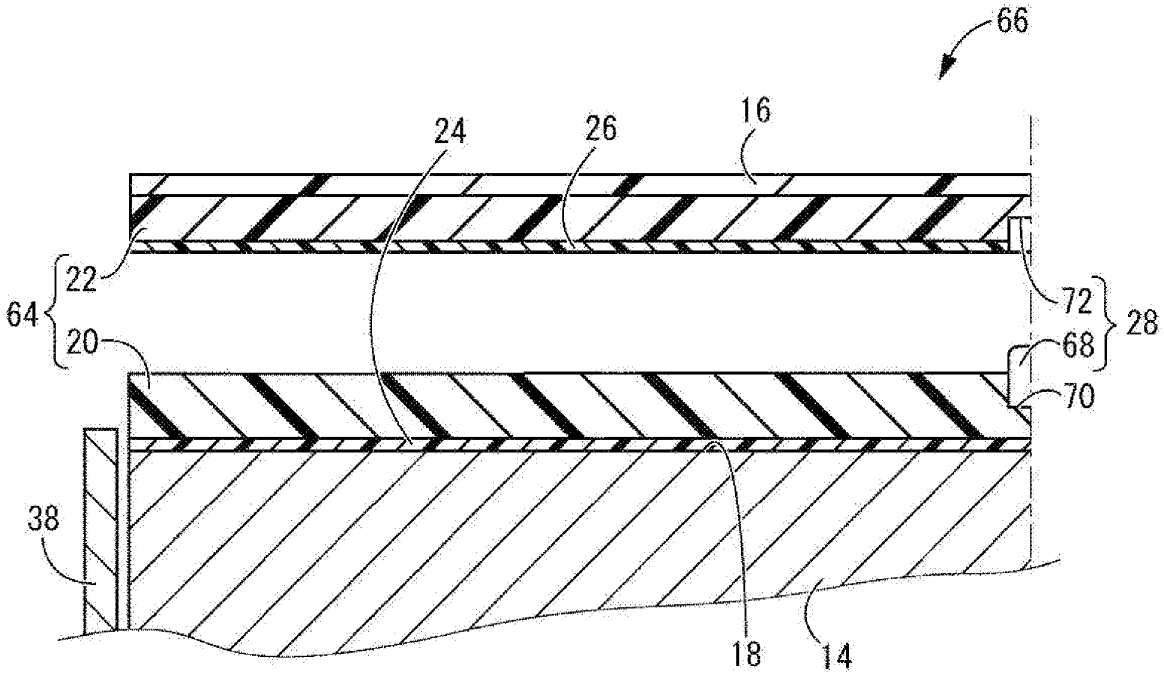
[Fig. 6]


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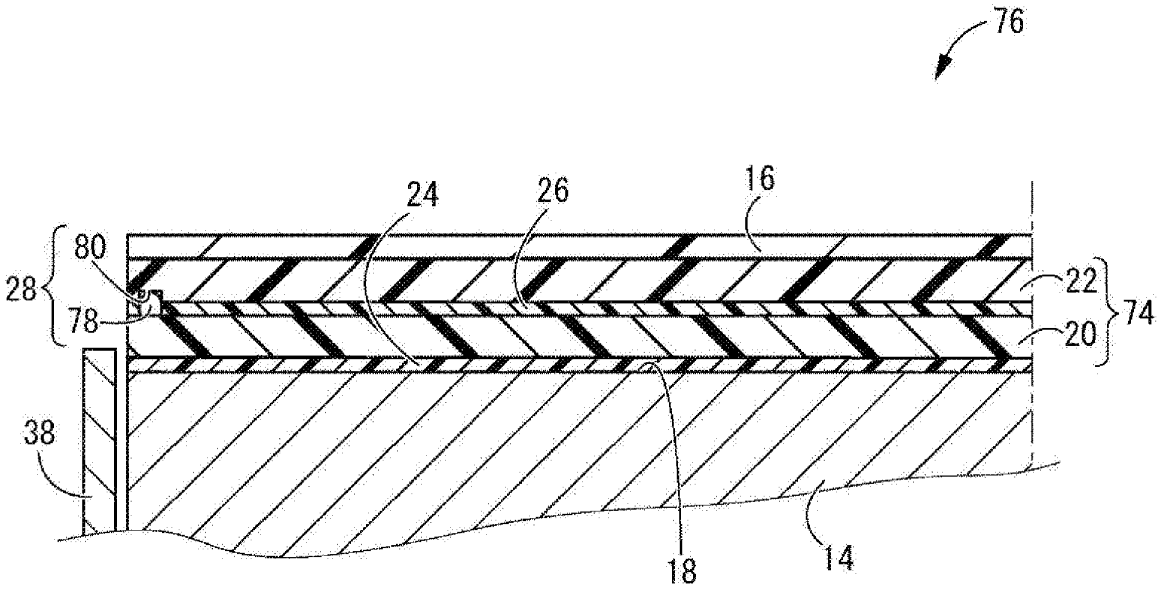
[Fig. 7]


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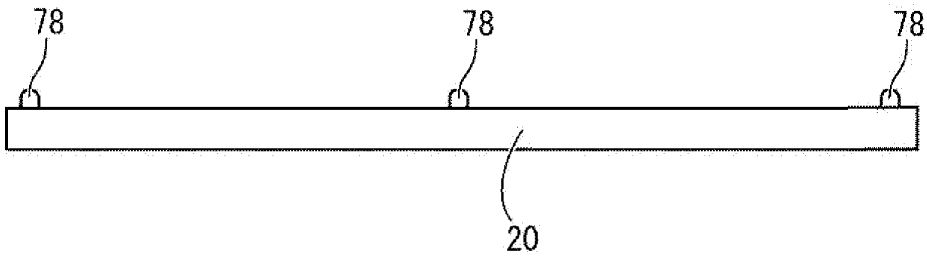
[Fig. 8]


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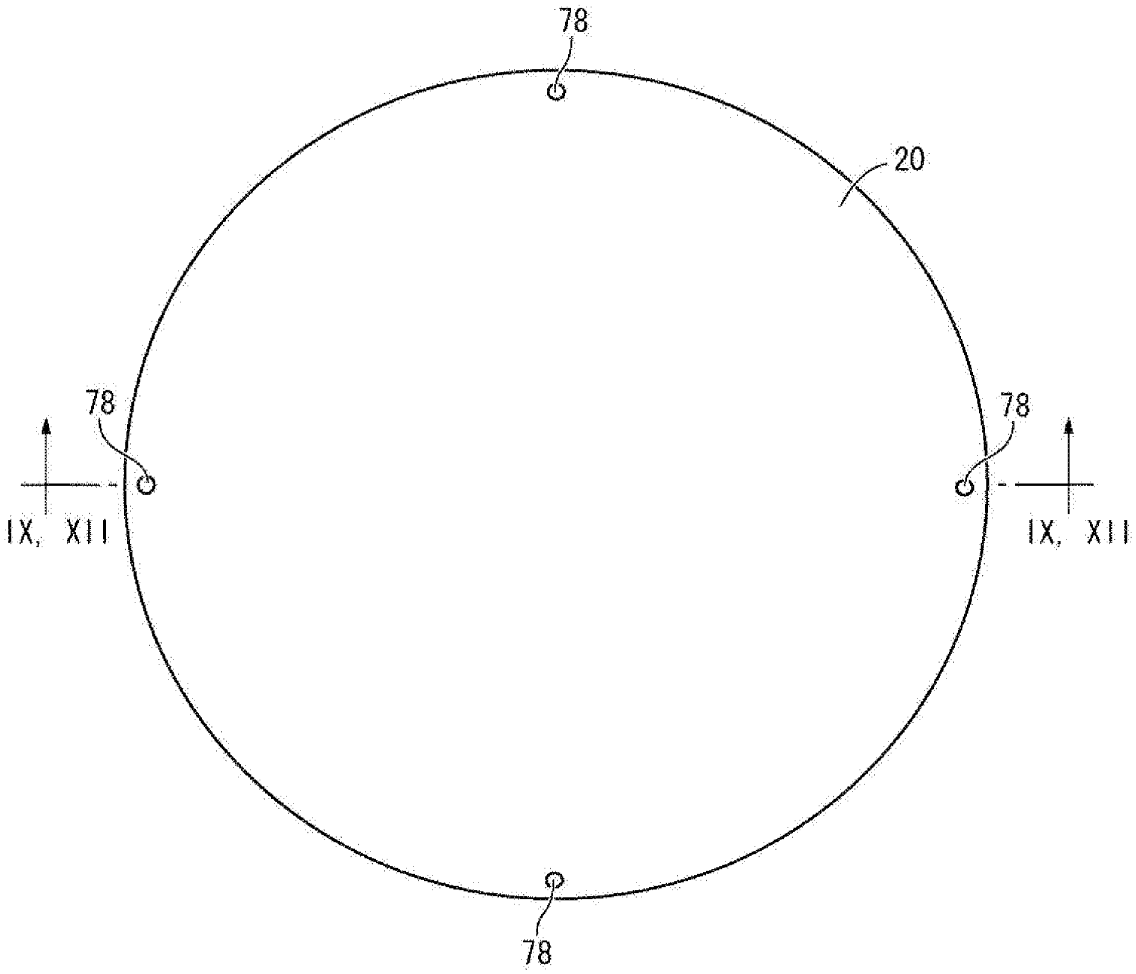
[Fig. 9]



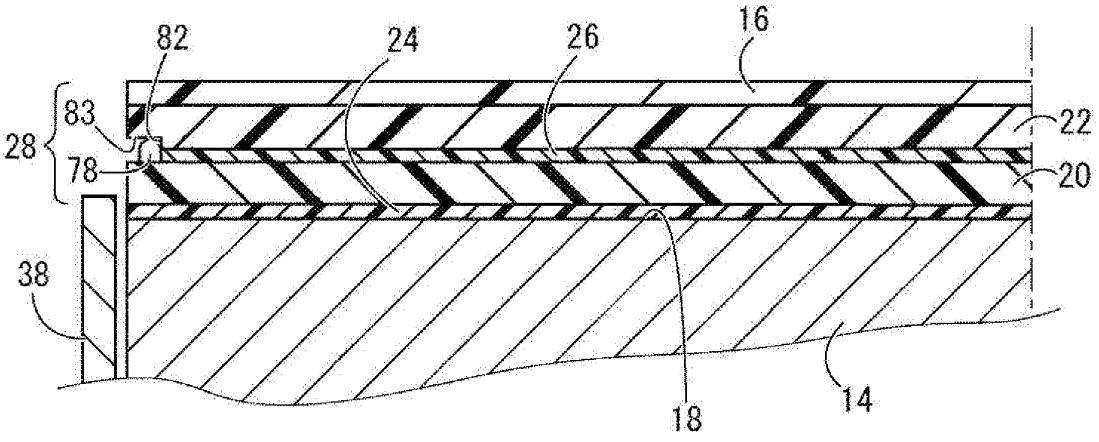
[Fig. 10]



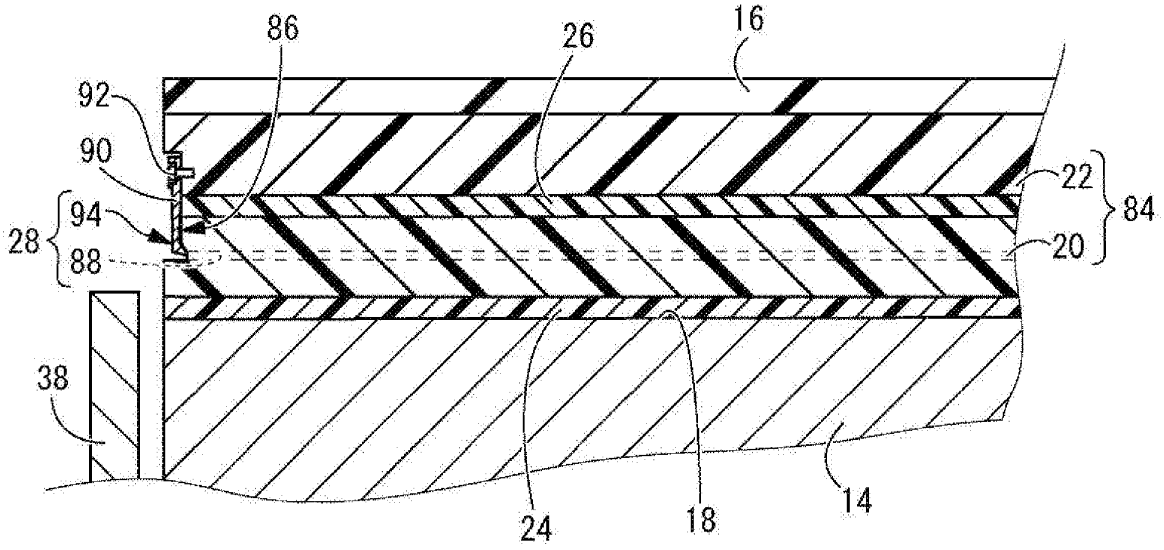
[Fig. 11]



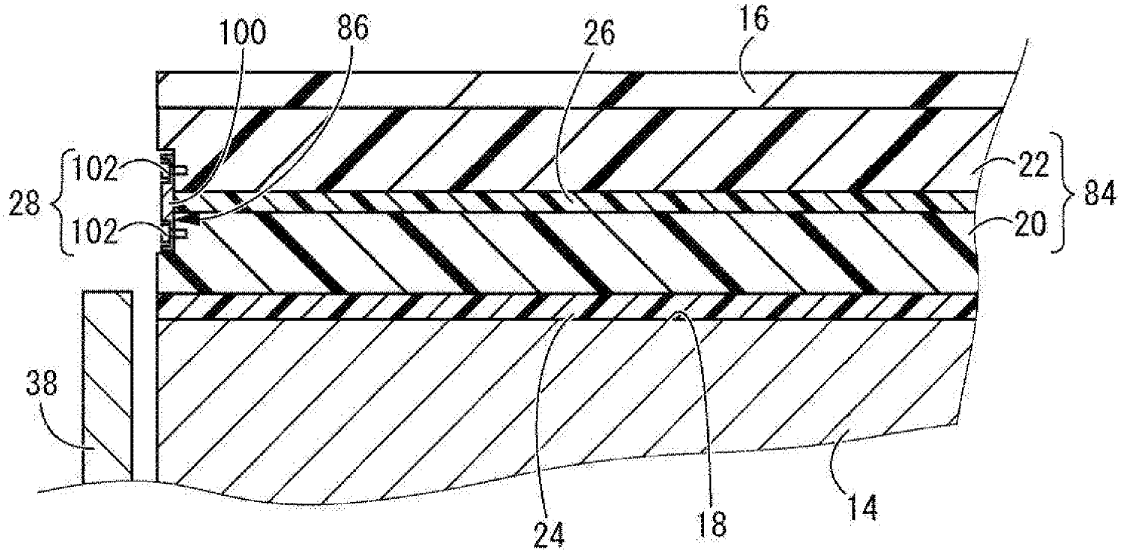
[Fig. 12]



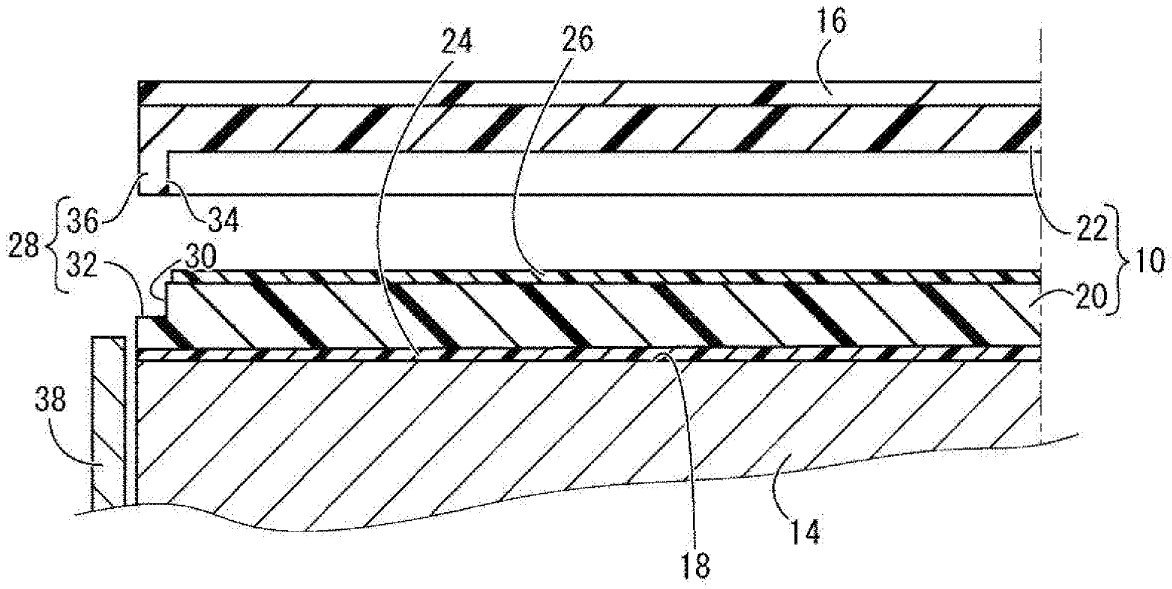
[Fig. 13]


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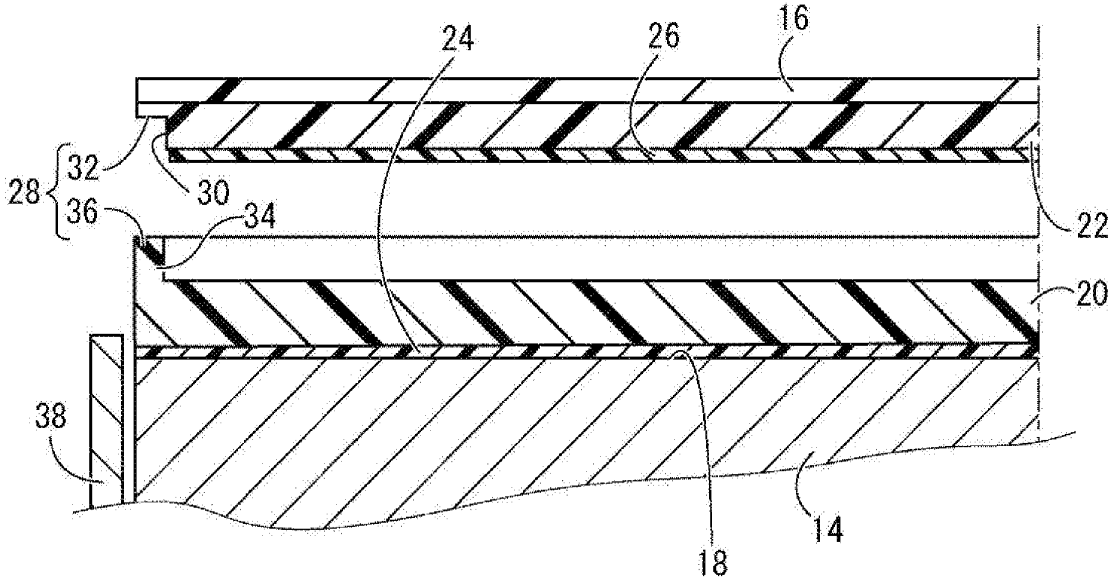
[Fig. 14]


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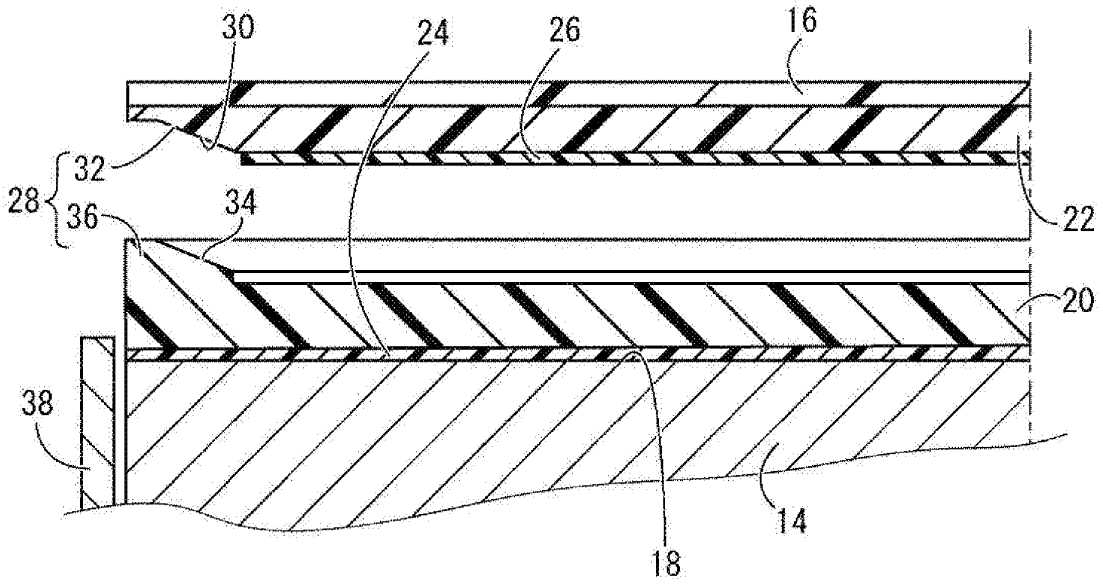
[Fig. 15]


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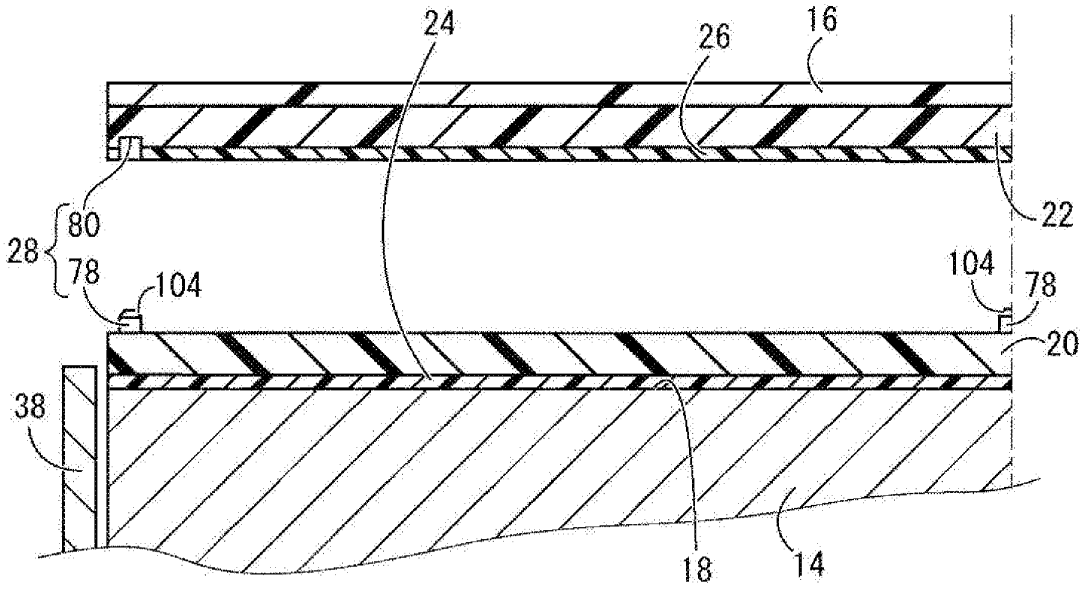
[Fig. 16]


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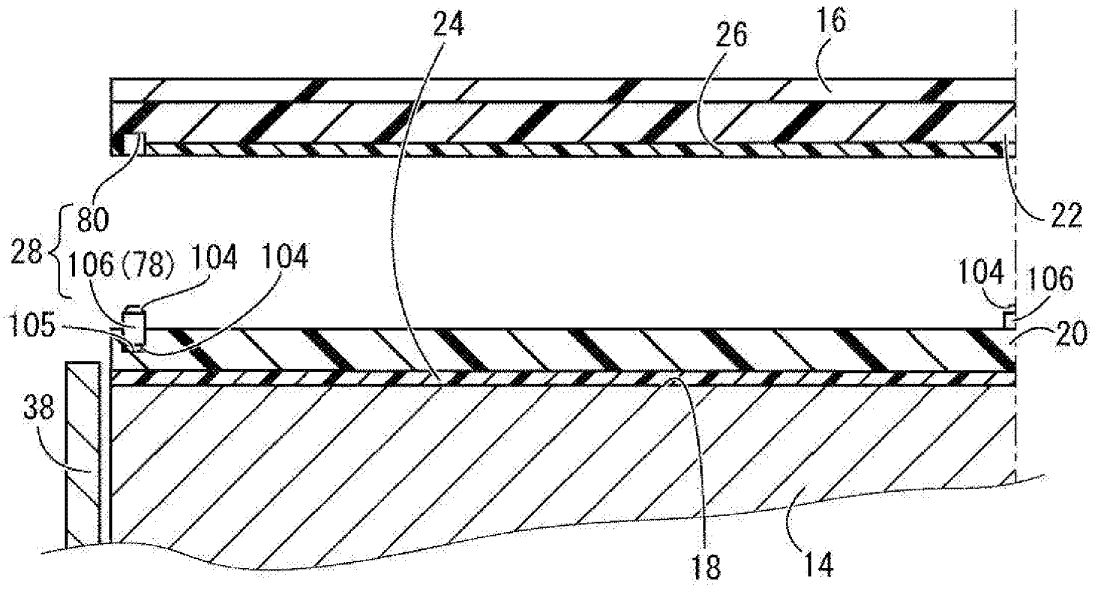
[Fig. 17]


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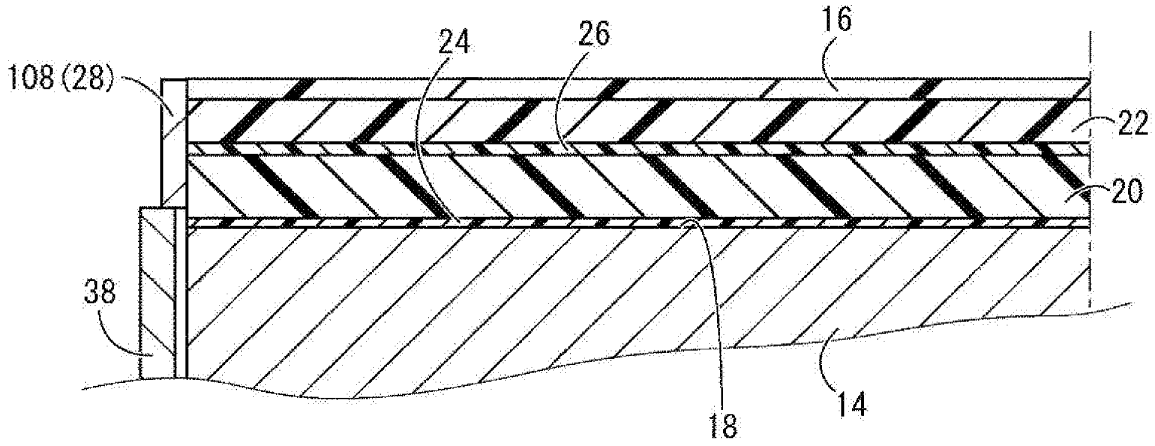
[Fig. 18]


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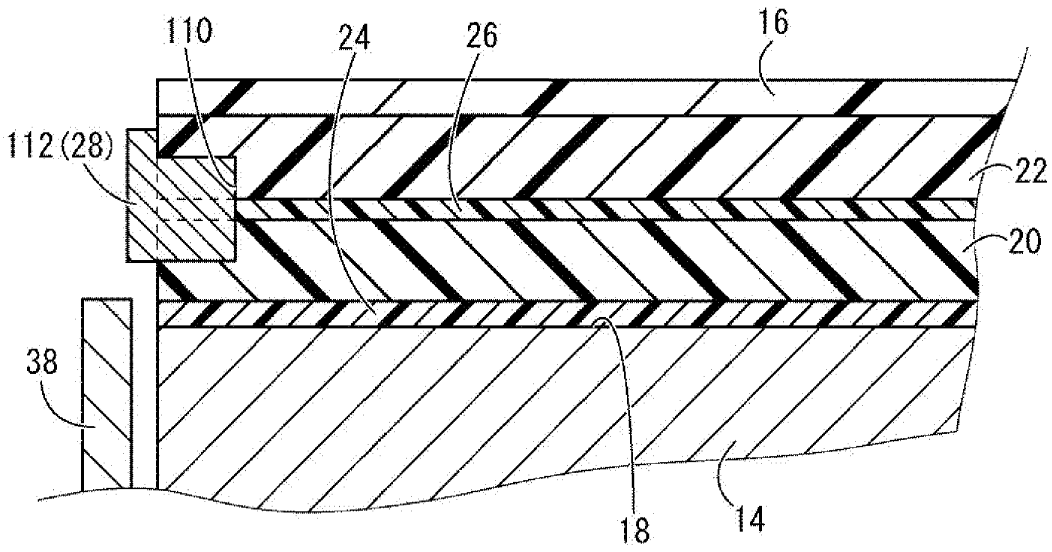
[Fig. 19]


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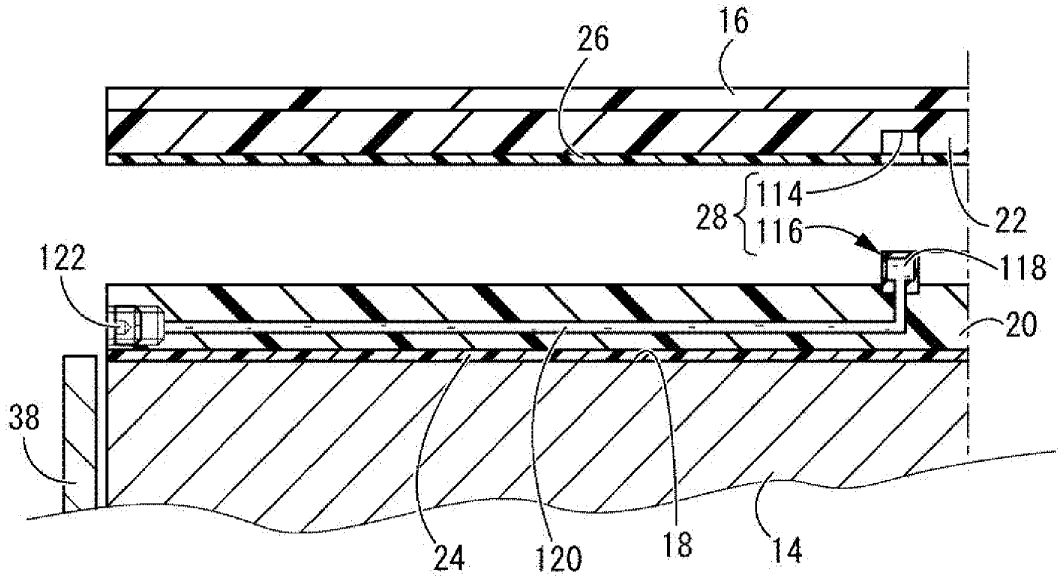
[Fig. 20]


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[Fig. 21]



[Fig. 22]



drawing open —

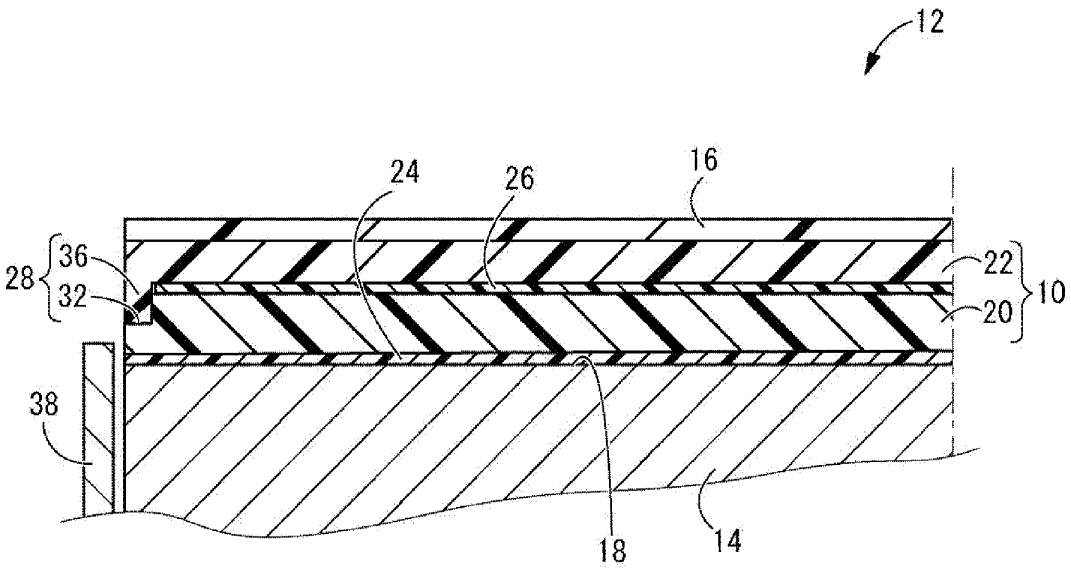


Figure 1

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Patent 5789869

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(45) [Date of Issue] October 7, 2015 (2015.10.7)
(54) [Title of Invention] Auxiliary Plate for Polishing Pad and Equipped with Auxiliary Plate for Polishing Pad Polishing Apparatus
(51) [International Patent Classification]
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[FI]
B24B 37/04 A
[Number of Claims] 11
[Total Number of Pages] 21
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(22) [Application date] July 28, 2011 (2011.7.28)
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2014) [Matters to be stated regarding results of research commissioned by the government] (report by applicant) commissioned by the government Patent application related to research results (FY2010 Ministry of Economy, Trade and Industry "Strategic Fundamental Technology Advancement Support Project" commissioned research, patent application subject to Article 1 9 of the Industrial Technology Enhancement Act) (73) [Patentee] [Identification number] 599 096053

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[Name] Or name] Mie Nakane
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[Name] Tatsutoshi Suzuki
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[Name] Eiji Suzuki
[Examiner] Takashi Kameda
(56) [References] [Reference] Japanese Patent Application
Laid- Open No. 08- 118231 (JP, A) [Reference] JP-A-07-328915 (JP, A) (58) [Field investigate d] (Int.Cl., DB name) B24B 37/12 H01L 21/304

The scope of the claims open ----

(57) [Scope of Claims]
[Claim 1] A

polishing pad auxiliary plate mounted on a rotating surface plate of a polishing apparatus for detachably attaching a polishing pad to the rotating surface plate, wherein

:

a first fixing means for fixing the lower auxiliary plate to the rotating surface plate; and

a pad supporting surface on which the polishing pad is superposed and fixed. an upper auxiliary plate superimposed on the upper surface of the lower auxiliary plate;

second fixing means for fixing the upper auxiliary plate to the lower auxiliary plate;

the lower auxiliary plate and the upper side; positioning means for aligning the center axis of the auxiliary plate with respect to each other

, and the lower auxiliary plate is fixed to the rotating surface plate of the polishing apparatus by the first fixing means. By removing the upper auxiliary plate from the lower auxiliary plate held and fixed to the rotating surface plate, the polishing pad can be rotated while being fixed to the pad supporting surface of the upper auxiliary plate. The upper auxiliary plate can be removed from the surface plate, and the removed upper auxiliary plate can be fixed and attached again to the lower auxiliary plate while being aligned by the positioning means, and ,

the fixing force between the lower auxiliary plate and the upper auxiliary plate by the second fixing means is smaller than the fixing force between the rotating platen and the lower auxiliary plate by the first fixing means;

Auxiliary plate for a polishing pad, characterized in that :

[Claim 2]

2. The auxiliary plate for a polishing pad according to claim 1 , wherein said positioning means is located inside the outer peripheral surfaces of said lower auxiliary plate and said upper auxiliary plate.

3. The positioning

means

includes an engaging projection provided on one of the lower auxiliary plate and the upper auxiliary plate and protruding toward the other, and the lower auxiliary plate and the upper auxiliary plate. 3. An auxiliary plate for a polishing pad according to claim 2 , wherein said auxiliary plate for a polishing pad comprises an engaging concave portion provided on the other side thereof and with which said engaging convex portion is engaged .

4. The polishing pad according to claim 3

, wherein said engaging projections and said engaging recesses are formed with engaging portions located on the outer peripheral portions of said lower auxiliary plate and said upper auxiliary plate. Auxiliary plate. 5. An annular engagement in which the engaging portions of the engaging protrusion and the engaging recess extend continuously in the circumferential direction of the lower auxiliary plate and the upper auxiliary plate and are fitted to each other. 5. The auxiliary plate for a polishing pad according to claim 4 , comprising an outer peripheral surface and an engaging inner peripheral surface . 6. At a plurality of locations on the circumference of the outer peripheral portions of the lower auxiliary plate and the upper auxiliary plat

e, the lower auxiliary plate and the upper auxiliary plate are overlapped on one side toward th e other. The engaging concave portion that opens and the engaging convex portion that protr udes toward one side of the other of the mutual overlapping surfaces of the lower auxiliary pl ate and the upper auxiliary plate are formed at positions corresponding to each other. wherein said engaging portion is formed by fitting said engaging convex portion into said engaging con cave portion.

5. The polishing pad auxiliary plate according to 4 .

7.

The engaging protrusions projecting from a plurality of locations on the circumference of one of the lower auxiliary plate and the upper auxiliary plate toward the other are formed of an el astic material, and The engagement portion is formed by engaging the tip of the engagement projection with the engagement recess provided in the outer peripheral surface of the other of the side auxiliary plate and the upper auxiliary plate. 5. The polishing pad auxiliary plate acco rding to claim 4 .

8. A polishing pad auxiliary plate according to claim 3

, wherein said engaging projections and said engaging recesses are provided on the central axes of said lower auxiliary plate and said upper auxiliary plate. 9. An outer peripheral surfac e of said engaging projection and an inner peripheral surface of said engaging recess are form ed with screw grooves for engaging with each other, and said engaging projection and said en gaging portion constituting said positioning means are formed with thread grooves for engagi ng with each other. 9. The auxiliary plate for a polishing pad according to claim 8 , wherein sai d second fixing means is formed by screwing with said mating recess . 10. The engaging pro jection provided on one of the lower auxiliary plate and the upper auxiliary plate is formed of t he same material as one of the lower auxiliary plate and the upper auxiliary plate. The auxilia ry plate for a polishing pad according to any one of claims 3 , 4 , 5 , 6 , 8 and 9 .

11. The auxiliary plate for a polishing pad according to any one of claims 1 to 10 is mounted o n the upper surface of a rotating surface plate, and a protective member is provided on the ou ter peripheral side of the rotating surface plate with a gap

therebetween . 11. The positioning means according to any one of claims 1 to 10 , wherein t he positioning means is disposed on the inner peripheral side of the outer peripheral end faces of the rotating platen and the polishing pad auxiliary plate. 2. A polishing apparatus comprisin g the polishing pad auxiliary plate according to 1 or 2 above.

detailed description open —

Description: BACKGROUND OF THE INVENTION 1.

Field of the Invention The present invention relates to the polishing of substrates such as silicon wafers, semiconductor substrates, glass substrates, etc., which are workpieces requiring high flatness accuracy. It relates to a related technique, and more particularly to a technique that makes it possible to reuse a polishing pad used in polishing the surface of such a substrate.

is. 2.

Description of the Related Art As is well known, in manufacturing a semiconductor, a polishing process is performed to flatten the surface of a substrate such as a silicon wafer, a semiconductor substrate, a glass substrate, or the like. Such a polishing process generally involves fixing a disc-shaped polishing pad made of a resin material or the like directly on a rotating surface plate of a polishing apparatus with a double-sided tape, and supplying a polishing liquid containing abrasive grains to the polishing pad. Polishing is performed by rotating the substrates relative to each other. [0003] Polishing pads for carrying out such a polishing process are made of foamed or non-foamed urethane or the like, as described in Japanese Patent Application Laid-Open No. 2002-11630 (Patent Document 1). A resin pad is used. Further, in many cases, the polishing surface of such a polishing pad is provided with grooves such as concentric circles, grids, or radial grooves, or the bubbles of foamed resin are opened. [0004] By the way, when performing a polishing process using a polishing pad, when changing the type of substrate to be polished, the polishing pad used for the polishing process is peeled off from the rotating platen and replaced with another polishing pad. sometimes you have to. Also, for example, when a polishing pad that has deteriorated due to polishing is to be re-processed, such as by grooving the surface, with another processing device for the purpose of reusing the polishing pad, the polishing pad is removed from the rotating platen. Needs to be pulled off. [0005]

However, since the thin disk-shaped polishing pad is firmly fixed to the rotating surface plate

of the polishing apparatus with an adhesive tape, when the polishing pad is peeled off from th e rotating surface plate, Damage such as bending, breaking, wrinkling, and tearing is likely to occur. Therefore, due to such damage, there is often a problem that such polishing pads cann ot be reused and must be discarded even though their service life has not expired.

[0006]

Moreover, the work of peeling off the polishing pad from the rotating surface plate while payi ng close attention not to damage it requires skill and caution, and there is also the problem of placing a heavy burden on the operator. In addition, since it takes a considerable amount of ti me to peel off the polishing pad from the rotating surface plate, the polishing apparatus, whic h is expensive and valuable equipment, must be stopped for a long time, which shortens the o peration time of the equipment. There was also the problem that the

[0007]

Therefore, the present inventor previously described in Japanese Patent Application Laid-Ope n No. 2010-214579 (Patent Document 2) that an auxiliary plate is attached to the back surfac e of the polishing pad, and the polishing pad is rotated by the polishing apparatus through thi s auxiliary plate. We proposed a polishing pad with an auxiliary plate that is fixed to the surfa ce plate with double-sided tape. With such a polishing pad with auxiliary plate, since the polis hing pad is attached to and detached from the rotating surface plate while being supported by the auxiliary plate, damage to the polishing pad during attachment and detachment is reinforc ed by the auxiliary plate. Therefore, it is possible to attach and detach the polishing pad to an d from the rotating platen with good workability while preventing the polishing pad from being damaged.

[0008]

However, as a result of further studies and studies by the present inventors, it has been foun d that it is difficult to say that the polishing pad with an auxiliary plate proposed in Patent Doc ument 2 is easily compatible with all polishing apparatuses. rice field.

[0009]

That is, when the polishing pad is overlaid and fixed to the rotating surface plate, it is necess ary to align the center of the polishing pad with the rotation center of the rotating surface plat e. Accuracy is required for center alignment. If the number of attachment/detachment of the polishing pad to/from the rotating platen increases by adopting the auxiliary plate as describe d above, it becomes more difficult and labor-intensive to align the center position when attach ing the polishing pad to the rotating platen. big is big

It becomes a problem. Further, in the polishing pad with auxiliary plate proposed in Patent D ocument 2, in order to detachably attach the auxiliary plate while aligning the center of the au xiliary plate with respect to the rotary surface plate, the following are provided between the a uxiliary plate and the rotary surface plate

:

For example, fixing means such as an outer peripheral ring may be provided on the outer peri

pheral surface of the rotating surface plate. On the other hand, in some polishing apparatuse s, a protective cover or the like is attached to the outer peripheral side of the rotary platen, so that the space on the outer peripheral side of the rotary platen is extremely narrow. Therefor e, if such an outer peripheral ring were to be adopted, and a polishing device with a narrow sp ace on the outer peripheral side of the rotating surface plate was used, there was a possibility that the polishing device would need to be modified. of.

[Prior Art Documents]

[Patent Documents]

[0011]

[Patent Document 1] Japanese Unexamined Patent Application Publication No. 2002-11630 [P atent Document 2] Japanese Unexamined Patent Application Publication No. 2010-214579 [Su mmary of the Invention] [Problems to be Solved by the Invention] SUMMARY OF THE INVEN TION It is an object of the present invention to provide a polishing pad which can be easily att ached to and detached from a rotating surface plate while sufficiently securing the fixing force of the polishing pad to the rotating surface plate . For a polishing pad with a novel structure, which can prevent damage to the polishing pad when the polishing pad is removed from the r otating platen, and which can be advantageous for reuse of the polishing pad, for example. To provide an auxiliary plate. [0013]

In addition, according to the present invention, the work of aligning the center when mounti ng the polishing pad on the rotating surface plate can be performed easily and accurately, and the labor burden can be reduced. Another object of the present invention is to provide an auxi liary plate for a polishing pad with an improved structure, which can be easily and advantageo usly applied to a rotating surface plate in a polishing machine without requiring any special m odification. A further object of the present invention is to provide a polishing apparatus havin g such a novel polishing pad auxiliary plate

. Means for Solving the Problems In order to solve the above problems, a first aspect of the present invention relating to an auxiliary plate for a polishing pad is: (A) mounted on a rotatin g surface plate of a polishing apparatus; A polishing pad auxiliary plate for detachably attachi ng a pad to the rotary platen, comprising: (B) a lower auxiliary plate disposed on the upper s urface of the rotary platen; and (C) the lower auxiliary plate. and (D) a pad supporting surfac e on which the polishing pad is superimposed and fixed, which is superimposed on the upper s urface of the lower auxiliary plate. (E) a second fixing means for fixing the upper auxiliary plat e to the lower auxiliary plate; The lower auxiliary plate is held in a fixed state by the first fixin

g means to the rotating surface plate of the polishing apparatus, and is fixed to the rotating s urface plate. Further, by removing the upper auxiliary plate from the lower auxiliary plate, the polishing pad can be removed from the rotating surface plate while being fixed to the pad sup porting surface of the upper auxiliary plate. At the same time, it is possible to attach the remo ved upper auxiliary plate to the lower auxiliary plate by fixing it again in a state of being align ed by the positioning means.

and the fixing force between the lower auxiliary plate and the upper auxiliary plate by the sec ond fixing means is stronger than the fixing force between the rotating platen and the lower a uxiliary plate by the first fixing means. It features a smaller auxiliary plate for the polishing pa d. In the polishing pad auxiliary plate constructed according to the present invention, the pol ishing pad is composed of the upper auxiliary plate and the upper auxiliary plate

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It is fixedly attached to the rotating surface plate via the lower auxiliary plate. Thereby, the u pper auxiliary plate can be removed from the lower auxiliary plate while the lower auxiliary pl ate is fixed to the rotating surface plate, and the polishing pad can be removed from the rotati ng surface plate while being fixed to the upper auxiliary plate. becomes possible. Therefore, in a state in which the polishing pad is reinforced and protected by the upper auxiliary plate, t he polishing pad can be removed from the rotating surface plate while preventing damage to t he polishing pad, and the thin polishing pad can be easily handled

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becomes. For example, when the polishing pad is repeatedly attached and detached when the object to be polished or the polishing conditions are changed, or when the worn polishing pad is detached and reattached after reprocessing, the attachment and detachment of the polishin g pad to and from the rotating platen and the polishing are difficult. It is also possible to easil y perform operations such as reproduction processing for pads. Moreover, since the lower au xiliary plate still fixed to the rotating surface plate and the upper auxiliary plate removed toge ther with the polishing pad are aligned with each other by the positioning means, the position on the rotating surface plate can be easily adjusted

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The attachment and detachment work of the polishing pad, which requires alignment, can be performed more easily. In particular, since the positioning means is provided between the low er auxiliary plate and the upper auxiliary plate, there is no need to apply special processing or the like to the rotating surface plate. In addition, it is possible to prevent such positioning me ans from protruding to the outer peripheral side of the rotating surface plate. applicable witho ut In the polishing pad auxiliary plate according to the first aspect of the present invention

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, the fixing force between the lower auxiliary plate and the upper auxiliary plate by the seco nd fixing means is smaller than the fixing force between the rotating platen and the lower aux iliary plate by the first fixing means; A certain aspect is employed . According to the first aspe ct , the fixing forces of the first and second fixing means are mutually adjusted, so that the up per auxiliary plate to which the polishing pad is fixed can be rotated

. This makes it easier to remove the lower auxiliary plate that is still fixed to the surface plate. In short, there is no need for a special operation or the like to keep the lower auxiliary plate fi xed to the rotating platen, and the polishing pad can be attached to the upper supporting plat e while the lower auxiliary plate remains fixed to the rotating platen. It becomes possible to e asily remove the plate from the rotating surface plate while it is fixed to the plate. According t o a second aspect of the present invention , in the polishing pad auxiliary plate according to the first aspect, the positioning means is arranged on the inner peripheral side of the outer pe ripheral surfaces of the lower auxiliary plate and the upper auxiliary plate . It is located and pr ovided. [0022] In the polishing pad auxiliary plate of this aspect, the projection of the upper and lower auxiliary plates to the outer peripheral side of the positioning means is completely a voided. Therefore, for example, even when the outer diameter of the upper and lower auxiliar y plates is set to be the same as or slightly smaller than the outer diameter of the rotating sur face plate, the supporting surface of the polishing pad can be secured sufficiently large and th e It is possible to prevent the positioning means from protruding to the outer peripheral side, and even if a protective cover or the like is installed on the outer peripheral side of the rotatin g surface plate, it will not become an obstacle when applying the polishing pad auxiliary plate according to the present invention. Avoided.

A third

aspect of the present invention is the polishing pad auxiliary plate according to the second a spect, wherein the positioning means is provided on one of the lower auxiliary plate and the u pper auxiliary plate and on the other . It is composed of an engaging projection projecting to ward and an engaging recess provided in the other of the lower auxiliary plate and the upper auxiliary plate with which the engaging projection is engaged. In the polishing pad auxiliary pl ate of this aspect, it is possible to easily obtain a mechanically large positioning force based on the mutual engagement between the engaging projections and the engaging recesses. Furt her, by adjusting the shape, size, number, etc. of the engaging projections and engaging rece sses, it is possible to easily set the direction and acting force of the positioning action with a l arge degree of freedom.

A fourth aspect

of the present invention is the auxiliary plate for a polishing pad according to the third aspec t, wherein the engaging projections and the engaging recesses are located on the outer perip heries of the lower auxiliary plate and the upper auxiliary plate . It is formed with an engagin g portion located in the portion. In the polishing pad auxiliary plate of this aspect, the engag ement outer peripheral surface of the engagement projection and the engagement recess are positioned in the outer peripheral portion away from the center of the polishing pad auxiliary plate and are engaged with each other in a concave-convex manner . By forming the engage ment inner peripheral surface of the upper and lower auxiliary plates, the relative positioning accuracy, particularly the radial positioning accuracy, can be improved. As shown in the sixth and seventh aspects below, the engaging outer peripheral surface of the engaging convex por tion and the engaging inner peripheral surface of the engaging concave portion are arranged around the center of the polishing pad auxiliary plate. It may extend in the circumferential dir ection along the outer peripheral edge of the polishing pad auxiliary plate, or it may extend on the circumference like the engaging protrusions and engaging recesses formed on the outer p eripheral portion of the polishing pad auxiliary plate. It may be in a partially positioned form. A fifth aspect of the present invention is the auxiliary plate for a polishing pad according to t he fourth aspect, wherein the engaging portions of the engaging projections and the engaging recesses correspond to the lower auxiliary plate and the It is composed of an annular engagin g outer peripheral surface and an engaging inner peripheral surface that extend continuously i n the circumferential direction of the upper auxiliary plate and are fitted to each other. [0028]

In the polishing pad auxiliary plate of this aspect, more preferably, the engaging concave por tion and the engaging convex portion are formed with an annular inner and outer peripheral e ngaging surface that spreads around the central axis of the polishing pad auxiliary plate. Ther efore, when the upper auxiliary plate is attached to the lower auxiliary plate, it is not necessar y to align the upper auxiliary plate with each other in the circumferential direction, and the wo rk can be performed easily and quickly. A sixth aspect of the present invention is a polishing pad auxiliary plate according to the fourth aspect, wherein the lower auxiliary plate and the u pper auxiliary plate are provided at a plurality of locations on the periphery of the outer perip heral portions of the lower auxiliary plate and the upper auxiliary plate

. The engaging recess opening toward the other on one of the overlapping surfaces of the low er auxiliary plate and the upper auxiliary plate, and the other of the mutually overlapping surf

aces of the lower auxiliary plate and the upper auxiliary plate and the engaging projection pro jecting toward one side are formed at positions corresponding to each other, and the engaging portion is formed by fitting the engaging projection into the engaging recess. is. In the polishi ng pad auxiliary plate of this mode, the mutual positioning of the upper and lower auxiliary p lates can be easily realized not only in the direction perpendicular to the axis but also in the ci rcumferential direction around the central axis. In a seventh aspect of the present invention , in the polishing pad auxiliary plate according to the fourth aspect, the outer peripheral portio n of one of the lower auxiliary plate and the upper auxiliary plate has a plurality of points on t he circumference of the other . The engaging convex portion protruding toward the upper auxi liary plate is formed of an elastic material, and engages with the engaging concave portion pr ovided in an opening on the outer peripheral surface of the other of the lower auxiliary plate a nd the upper auxiliary plate. The engaging portion is configured by engaging the tip of the en gaging projection.

In the polishing pad auxiliary plate of this aspect, it is possible to form the engaging portions so as to be exposed on the outer peripheral surfaces of the upper and lower auxiliary plates . can be confirmed. In addition, in this aspect, the engagement state of the engagement portio n can be stably maintained by utilizing the elasticity of the engagement convex portion. An ei ghth
aspect of
the present invention is the polishing pad auxiliary plate according to the third aspect, where in the engaging projections and the engaging recesses are located at the centers of the lower auxiliary plate and the upper auxiliary plate . It is provided on the shaft. In the polishing pad auxiliary plate of this aspect, the engaging projections and the engaging recesses are formed on the central axis of the upper and lower auxiliary plates .

By providing this, it becomes possible to align the central axes of the upper and lower auxiliar y plates with one engaging portion. Further, when the engaging projections and the engaging recesses provided on the central axis are aligned with each other, it is not necessary to align t he upper and lower auxiliary plates with each other in the circumferential direction. can be ea sily brought into engagement. According to a ninth aspect of the present invention , in the p olishing pad auxiliary plate according to the eighth aspect, the outer peripheral surface of the engaging projection and the inner peripheral surface of the engaging recess are screwed toget

her

. A groove is formed, and the second fixing means is formed by screwing the engaging project ion and the engaging recess that constitute the positioning means. [0036] In the polishing p ad auxiliary plate of this mode, the fixing force between the upper auxiliary plate and the low er auxiliary plate can be obtained by the positioning means. Therefore, it is possible to config ure the second fixing means only by such positioning means, or to configure the fixing force b etween the upper and lower auxiliary plates by the second fixing means as an auxiliary means by the positioning means. A tenth aspect of the present invention is the third , fourth , fifth , sixth , eighth and ninth

2. In the polishing pad auxiliary plate according to any one of the above aspects, the engagin g projection provided on one of the lower auxiliary plate and the upper auxiliary plate is arran ged between the lower auxiliary plate and the upper auxiliary plate. It is made of the same m aterial as the one. In the polishing pad auxiliary plate of this aspect, it is possible to prevent the support characteristics of the polishing pad of the auxiliary plates superimposed one on to p of the other from greatly differing locally at the portions where the engaging projections are formed

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. Therefore, when a pressing force acts on the surface of the polishing pad during pad polishin g, the pressure reaction force and the elasticity of the polishing pad are reduced at the format ion portions of the engaging convex portions and the engaging concave portions of the upper and lower auxiliary plates that support the polishing pad. It is possible to reduce or avoid defe cts such as polishing accuracy caused by local differences in such characteristics. Further, ac cording to the present invention, the auxiliary plate for a polishing pad according to any one o f the first to tenth aspects of the present invention is mounted on the upper surface of a rotati ng platen, and is attached to the outer peripheral side of the rotating platen

. A polishing apparatus in which a protective member is arranged with a gap in between, and the positioning means is provided on the inner peripheral side of the outer peripheral end surf aces of the rotating platen and the polishing pad auxiliary plate, Characterized by EFFECTS OF THE INVENTION By adopting the polishing pad auxiliary plate structured according to the pre sent invention or using the polishing apparatus structured according to the present invention, the polishing pad can be prevented from being damaged and polished. can be easily removed from and attached to the rotating surface plate, and positioning of the polishing pad on the ro tating surface plate can be performed easily and accurately. [Brief Description of the Drawings]

FIG. 1 is a vertical cross-sectional view showing the essential parts of a polishing apparatus e quipped with a polishing pad auxiliary plate according to a first embodiment of the present inv ention;

2 is an explanatory view of a longitudinal section showing a state in which the polishing pad is removed in the polishing apparatus shown in FIG. 1; FIG.

FIG. 3 is a vertical cross-sectional view showing a main part of a polishing apparatus equipped with a polishing pad auxiliary plate according to a second embodiment of the present inventio n;

4 is an explanatory view of a longitudinal section showing a state in which the polishing pad is removed in the polishing apparatus shown in FIG. 3; FIG.

FIG. 5 is a vertical cross-sectional view showing the essential parts of a polishing apparatus e quipped with a polishing pad auxiliary plate according to a third embodiment of the present in vention;

6 is an explanatory view of a longitudinal section showing a state in which the polishing pad is removed in the polishing apparatus shown in FIG. 5; FIG.

FIG. 7 is a vertical cross-sectional view showing a main part of a polishing apparatus equipped with a polishing pad auxiliary plate according to a fourth embodiment of the present inventio n;

8 is an explanatory view of a longitudinal section showing a state in which the polishing pad is removed in the polishing apparatus shown in FIG. 7; FIG.

FIG. 9 is a vertical cross-sectional view showing a main part of a polishing apparatus equipped with a polishing pad auxiliary plate according to a fifth embodiment of the present invention;

10 is a side view of a lower auxiliary plate that constitutes the polishing pad auxiliary plate sh own in FIG. 9; FIG.

11 is a plan view of the lower auxiliary plate shown in FIG. 10; FIG.

FIG. 12 is a longitudinal sectional view showing the essential parts of a polishing apparatus eq uipped with a polishing pad auxiliary plate according to a sixth embodiment of the present inv ention;

FIG. 13 is a vertical cross-sectional view showing the essential parts of a polishing apparatus equipped with a polishing pad auxiliary plate according to a seventh embodiment of the prese nt invention;

FIG. 14 is a vertical cross-sectional view showing a main part of a polishing apparatus equipp ed with a polishing pad auxiliary plate according to an eighth embodiment of the present inve ntion;

FIG. 15 is an explanatory view of a longitudinal section showing a state in which a polishing p ad auxiliary plate according to a ninth embodiment of the present invention is removed;
FIG. 16 is an explanatory view of a longitudinal section showing a state in which a polishing p ad auxiliary plate is removed according to a tenth embodiment of the present invention;
FIG. 17 is an explanatory view of a longitudinal section showing a state in which a polishing p ad auxiliary plate according to an eleventh embodiment of the present invention is removed;
FIG. 18 is an explanatory view of a longitudinal section showing a state in which a polishing p ad auxiliary plate according to a twelfth embodiment of the present invention is removed;
FIG. 19 is an explanatory view of a longitudinal section showing a state in which a polishing p ad auxiliary plate according to a thirteenth embodiment of the present invention is removed;
FIG. 20 is an explanatory view of a longitudinal section showing a state in which a polishing p ad auxiliary plate according to a fourteenth embodiment of the present invention is positione d;
FIG. 21 is an explanatory view of a longitudinal section showing a state in which a polishing p ad auxiliary plate according to a fifteenth embodiment of the present invention is positioned;
FIG. 22 is an explanatory view of a longitudinal section showing a state in which a polishing p ad auxiliary plate according to a sixteenth embodiment of the present invention is removed;
DETAILED DESCRIPTION OF THE INVENTION Embodiments of the present invention will be de scribed
below

with reference to the drawings. First, FIGS. 1 and 2 show a polishing pad auxiliary plate 10 a s a first embodiment of the present invention. This polishing pad auxiliary plate 10 is used by being attached to a rotary surface plate 14 of a polishing apparatus 12, and a polishing pad 1 6 is detachably attached to the rotary surface plate 14. As shown in FIG.
The polishing apparatus is used ,

for example, as a CMP apparatus as described in Japanese Patent Application Laid-Open No. 2010-141155, for example. A rotating shaft extending vertically is rotatably supported by the main body of the apparatus fixedly installed above, and a disk-shaped rotating platen 14 is fix ed to the upper end of the rotating shaft. The rotating surface plate 14 has a flat upper surfac e 18 extending horizontally, and the upper surface 18 serves as a support surface for the polis hing pad 16 . The rotating shaft is connected to the rotating output shaft of an electric motor, and the driving force of the electric motor is transmitted so that the rotating shaft and thus th e rotating surface plate 14 are rotated about the central axis. there is A nozzle for supplying p olishing slurry is arranged above the upper surface 18 supporting the polishing pad 16, and a wafer or the like to be polished (an object to be polished) is held and rotated while being mov ed to the polishing pad 16. A polishing head is provided for polishing by pressing. In such a polishing apparatus, the polishing pad auxiliary plate 10 mounted on the rotating platen 14
is

includes a lower auxiliary plate 20 and an upper auxiliary plate 22 . A lower auxiliary plate 20 is fixed to the upper surface 18 of the rotating platen 14 by first fixing means 24 , and an upp er auxiliary plate 22 is attached to the upper surface of the lower auxiliary plate 20 . It is fixe d by two fixing means 26 . That is, the lower auxiliary plate 20 and the upper auxiliary plate 2 2 are overlapped and fixed to each other via the second fixing means 26, thereby forming the polishing pad auxiliary plate 10 having a two-layer structure as a whole. , and is attached to t he upper surface 18 of the rotating surface plate 14 by the first fixing means 24 .

Each of the lower auxiliary plate 20 and the upper

auxiliary plate 22 has a thin, substantially circular flat plate shape, and has a flat front surfa ce (upper surface) and a rear surface (lower surface). These upper and lower auxiliary plates 22 and 20 are desirably made of a harder material than the polishing pad 16 to which it is att ached, or having a higher member rigidity than the polishing pad 16 . Although it depends on the method of use, as will be described later, the lower auxiliary plate 20 can be used without being repeatedly attached and detached after being attached to the rotary surface plate 14, w hile the upper auxiliary plate 22 can be attached and detached after being attached to the rot ary surface plate 14. is expected to be repeated, it is desirable that at least the upper auxiliar y plate 22 should have higher member rigidity than the polishing pad 16 .

[0046]

Of course, the upper auxiliary plate 22 supports the polishing pad 16 and provides the stren gth, rigidity, and rigidity required for various treatments such as polishing, cleaning, and re-gr ooving of the polishing pad surface, in addition to polishing by the polishing device 12 . Any m aterial that satisfies shape stability and accuracy may be used, and its material and thickness are not limited. In particular, not only the lower auxiliary plate 20 but also the upper auxiliary plate 22 alone bears the supporting strength and rigidity of the polishing pad 16. Since the lo wer surface is supported by the rotating surface plate 14 by being superimposed on each othe r and used, the strength and rigidity of the single unit are not required so much. Therefore, in addition to metals such as stainless steel, synthetic resins, fiber-reinforced resins, and the like can be employed as materials for forming the lower auxiliary plate 20 and the upper auxiliary plate 22 . In particular, synthetic resin materials are lighter than metal materials and easier to process and handle. . In order to obtain a stable supporting force over the entire polishing p ad 16, it is desirable to set the outer diameter dimension of the upper auxiliary plate 22 to be equal to or larger than the outer diameter dimension of the polishing pad 16,

and

It is desirable to set the outer diameter of the lower auxiliary plate 20 to be equal to or larger than the outer diameter of the upper auxiliary plate 22, and set the outer diameter of the low er auxiliary plate 20 to be equal to or smaller than the outer diameter of the rotating surface plate 12. should be set to In particular, as shown in FIGS. 1 and 2, the outer diameters of the lower auxiliary plate 20 and the upper auxiliary plate 22 are made substantially the same, and the outer diameter of the rotating surface plate 14 to be mounted is also substantially the sa

me. By doing so, it becomes possible to ensure a sufficiently large support area for the polishi ng pad 16 . As a result, the polishing pad 16 having approximately the same size as the rotati ng surface plate 14 can be attached to the rotating surface plate 14 with approximately the sa me supporting force over the entirety thereof.

[0048]

Furthermore, as the first fixing means 24 and the second fixing means 26, the lower auxiliar y plate 20 and the upper auxiliary plate 22 are fixed to the upper surface 18 of the rotating pl aten 14 against the external force exerted during polishing. It is not particularly limited as lon g as it can be held at. Specifically, an adhesive, a pressure-sensitive adhesive, or a double-sid ed tape having an adhesive or a pressure-sensitive adhesive attached to both sides of a base sheet may be employed as the first and second fixing means 24, 26. In addition, negative pre ssure suction using negative pressure air or the like, or magnetic suction using a permanent magnet or an electromagnet can be employed. In addition, it is desirable that the fixing mean s made of adhesive or the like apply substantially uniform fixing force over substantially the e ntire surface of the flat overlapping surfaces of the lower auxiliary plate 20 and the upper auxi liary plate 22. Adhesive strength can be obtained, and problems such as locally different supp ort characteristics of the polishing pad 16 on the surface of the polishing pad auxiliary plate 1 0 can be avoided.

For example ,

the fixing force can be turned ON/OFF by negative pressure suction or an electromagnet. au xiliary

It is desirable to set the fixing force of the upper auxiliary plate 22 to the lower auxiliary plate 20 by the second fixing means 26 to be smaller than the fixing force of the plate 20 . As a res ult, when the upper auxiliary plate 22 is peeled off from the lower auxiliary plate 20 and remo ved, the lower auxiliary plate 20 can be easily left fixed on the rotating surface plate 14.例文帳 に追加 The specific realization of such a difference in adhesion force is achieved by differentiati ng the adhesion means itself such as the material of the adhesive and pressure-sensitive adh esive, as well as the adhesion area and the condition of the adhesion surface (surface roughn ess, presence or absence of plasma treatment, etc.) can also be realized by making the .

Further, the surface (upper surface) of the upper auxiliary plate 22 serves as a

polishing pad supporting surface, and the polishing pad 16 is superimposed and mounted th ereon. As such a polishing pad 16, conventionally known various types of polishing pads can b e employed. The back surface of the polishing pad 16 is fixed to the surface of the upper auxil iary plate 22 using a conventionally known adhesive tape or suitable adhesive for attaching th e polishing pad.

It is desirable that the fixing means for fixing

the polishing pad 16 to the upper auxiliary plate 22 has a larger fixing force than the second fixing means 26 described above. As a result, when the upper auxiliary plate 22 is removed fr om the lower auxiliary plate 20 with the polishing pad 16 still fixed, the polishing pad 16 does

not move from the upper auxiliary plate 22 even if the upper auxiliary plate 22 is bent or the l ike. It is possible to effectively prevent the peeling off. The outer diameter of the polishing p ad 16 is generally a standard value, but in many cases it is set equal to or smaller than the ou ter diameter of the upper surface 18 of the rotating surface plate 14 to which it is attached . [0053]

Further, for example, at least one of between the upper surface 18 of the rotating surface pl ate 14 and the lower auxiliary plate 20, between the lower auxiliary plate 20 and the upper au xiliary plate 22, and between the upper auxiliary plate 22 and the polishing pad 16 A suitable cushioning layer may be provided. By providing such a cushion layer, it becomes possible to a chieve uniform polishing efficiency over the entire surface of the workpiece when polishing wit h the polishing pad 16 .

[0054]

As such a cushion layer, for example, a resin sheet, an elastomer sheet, a rubber sheet, or t he like to which a certain degree of compressibility is imparted by foaming can be suitably em ployed. A cushion layer can also be configured by the first fixing means 24 , the second fixing means 26 , and the means for fixing the polishing pad 16 to the upper auxiliary plate 22 . In o rder to prevent local distortion on the support surface of the polishing pad 16, the cushion lay er is formed so as to have a size and a constant thickness over substantially the entire suppor t area of the polishing pad 16. is desirable. Positioning means 28 are provided between the l ower auxiliary plate 20 and the upper auxiliary plate 22 that constitute the polishing pad auxil iary plate 10 to align the centers of the plates with each other

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In the present embodiment, a circular stepped surface 30 is formed on the outer peripheral p ortion of the lower auxiliary plate 20 and extends around the central axis of the lower auxiliar y plate 20 over the entire circumference. By reducing the thickness of the lower auxiliary plat e 20 on the outer peripheral side of the stepped surface 30, the notch cross-sectional shape t hat opens to the outer peripheral surface of the lower auxiliary plate 20 continues to the entir e circumference in the circumferential direction. An annular engaging recess 32 that extends i nward is formed integrally with the lower auxiliary plate 20 so as to protrude therefrom.

[0056]

On the other hand, in the present embodiment, a circular stepped surface 34 is formed on th e outer peripheral portion of the upper auxiliary plate 22 so as to extend around the central a xis of the upper auxiliary plate 22 over the entire circumference. Since the thickness of the up per auxiliary plate 22 is increased on the outer peripheral side of the stepped surface 34, an a nnular engagement continuously extends along the outer peripheral edge of the upper auxiliar y plate 22 along the entire circumference in the circumferential direction. A mating projection 36 is integrally formed so as to protrude from the upper auxiliary plate 22 . Incidentally, the e

ngaging convex portion 36 and the engaging concave portion 32 may be formed on either of t he upper and lower auxiliary plates 22 and 20 .

The stepped surface 30 and the engaging recess 32 of the lower auxiliary plate 20 are aligne d with the stepped surface 34 and the engaging projection 36 of the upper auxiliary plate 22 . It constitutes an engagement outer peripheral surface and an engagement inner peripheral su rface. When the upper auxiliary plate 22 is superimposed on the lower auxiliary plate 20, the engaging convex portion 36 is fitted into the engaging concave portion 32, and the stepped su rface 34 is superimposed on the stepped surface 30 in the radial direction. is formed. As a res ult, the engaging concave portion 32 and the engaging convex portion 36 constitute the positi oning means 28, and the lower auxiliary plate 20 and the upper side support plate 20 are alig ned in the radial direction with their central axes aligned with each other. Auxiliary plates 22 a re superimposed. In addition, the positioning means 28 is positioned on the inner peripheral si de of the outer peripheral surfaces of the upper and lower auxiliary plates 22 and 20, thereby preventing the upper and lower auxiliary plates 22 and 20 and the polishing apparatus 12 fro m becoming large. . In the polishing apparatus 12 provided with the polishing pad auxiliary plate 10 having such a structure, the upper and lower auxiliary plates 22 are mounted on the upper surface 18 of the rotating platen 14 as shown in FIG

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, 20 is fixedly attached, and the polishing pad 16 is fixedly supported on the upper surface of the upper auxiliary plate 22. Then, the rotating platen 14 is driven to rotate, and the substrat e or the like is processed. CMP (Chemical Mechanical Polishing) is applied to objects. The polis hing apparatus 12 can exhibit the following special technical effects by being provided with th e polishing pad auxiliary plate 10 having a specific structure.

[0059]

First, as shown in FIG. 2, while the polishing pad 16 is fixed to the upper surface of the uppe r auxiliary plate 22, the upper auxiliary plate 22 is fixed to the rotating surface plate 14 by th e first fixing means 24. By removing the side auxiliary plate 20, the polishing pad 16 can be r emoved from the rotating surface plate 14. - 特許庁 Even when the surface (polishing surface) of the polishing pad 16 is removed from the rotating platen 14 and cleaned or reprocessed, th e polishing pad 16 can be kept fixed to the upper surface of the upper auxiliary plate 22 . As a result, the upper auxiliary plate 22 provides reinforcement not only when the polishing pad 16 is attached to and detached from the rotating surface plate 14, when the polishing pad 16 is c leaned and reprocessed, but also when the polishing pad 16 is transported or stored. By this a ction, the polishing pad 16 can be prevented from being bent or damaged, and the polishing p ad 16 can be kept in good condition.

Further

, even when the polishing pad 16 is removed from the rotating surface plate 14 together wit h the upper auxiliary plate 22 , the lower auxiliary plate 20 remains on the upper surface 18 o

f the rotating surface plate 14 . When the polishing pad 16 is again mounted on the rotating p laten 14, the positioning means 28 provided between the upper auxiliary plate 22 and the low er auxiliary plate 20 moves the upper auxiliary plate 22 and thus the polishing pad 16 to the l ower auxiliary plate. The center axis of the plate 20 and thus the rotating platen 14 can be ali gned with high accuracy and easily.

[0061]

Here, since the engaging concave portion 32 and the engaging convex portion 36 constitutin g the positioning means 28 are overlapped with almost no gap in a mutually fitted state, the s upport characteristics of the polishing pad 16 are improved. can be prevented from adversely affecting Of the outer peripheral portions of the upper and lower auxiliary plates 22 and 20, p articularly in the present embodiment, an engaging portion, in other words, a positioning mea ns 28, is formed on the outer peripheral edge portion, and the diameter of the polishing pad 1 6 that serves as the main region for polishing is formed. Since it is out of the middle part in th e direction, even if there is a slight gap between the engaging concave portion 32 and the eng aging convex portion 36, the supporting characteristics of the polishing pad 16 are such that a serious problem occurs in the polishing characteristics. can be avoided. Moreover, the engagi ng concave portion 32 and the engaging convex portion 36 constituting the positioning means 28 are formed on the superimposed surfaces of the upper and lower auxiliary plates 22 and 2 0, in other words, on the outer circumferences of the rotating surface plate 14 and the polishi ng pad auxiliary plate 10

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Since it is formed on the inner peripheral side of the end face, the upper and lower auxiliary pl ates 22 and 20 can be prevented from projecting onto the outer peripheral surface. Therefore, as shown in FIGS. 1 and 2, for example, even when the protective member 38 is installed clos e to the outer peripheral side of the rotating surface plate 14 in the polishing apparatus 12, th e protective member 38 cannot be protected. Polishing provided with upper and lower auxiliar y plates 22, 20 provided with positioning means 28 while avoiding interference

A device 12 is made possible. Furthermore, as described above, while preventing damage to the polishing pad 16, the polishing pad 16 can be quickly attached to and detached from the r otating platen 14 with accurate positioning accuracy

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The operating time of the expensive polishing equipment is not unnecessarily limited for such work, and the operating efficiency of the polishing equipment can be improved, and thus the production efficiency of substrates and the like (polishing work efficiency) can be improved. In addition, since the polishing pad 16 can be easily attached to and detached from the rotati ng surface

plate 14, the reuse of the polishing pad 16 can be realized on a practical level without specia l skill or knowledge. That is, for example, the polishing pad 16 once removed from the rotatin g platen 14 can be reused when changing the type of the object to be polished such as a subs

trate, or the polishing pad 16 can be re-processed by another processing device such as surfa ce grooving as a countermeasure against deterioration. It is also possible to consider reusing t he polishing pad 16 once removed from the rotating surface plate 14 after reprocessing at a p ractical level. Although the first embodiment of the present invention has been described ab ove, the specific structure of the present invention should not be construed as limited by the fi rst embodiment

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A plurality of other embodiments of the present invention having different positioning means between the upper and lower auxiliary plates 22 and 20 are illustrated below, but these embo diments are not intended to limit the configuration of the present invention. In the following e mbodiments, members and parts having the same structure as in the first embodiment are de noted by the same reference numerals as those in the first embodiment in the corresponding parts in each figure. , their detailed description is omitted. 3 and 4 show a polishing apparat us 42 provided with a polishing pad auxiliary plate 40 as a second embodiment of the present invention

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In this polishing pad auxiliary plate 40, an engaging recess 44 is formed by an annular groov e continuously extending in the circumferential direction on the outer peripheral portion of the upper surface of the lower auxiliary plate 20. As shown in FIG . On the other hand, on the out er peripheral portion of the lower surface of the upper auxiliary plate 22, an engagement conv ex portion 46 is formed by an annular protrusion extending continuously in the circumferential direction. The engaging projection 46 may be formed integrally with the upper auxiliary plate 22, or may be formed separately as illustrated. That is, in this embodiment, an annular circu mferential groove 48 that opens in the lower surface of the upper auxiliary plate 22 and exten ds in the circumferential direction is formed. block is fitted and fixed at one end in the axial di rection to form an engagement convex portion 46 . The engaging concave portion 44 of the l ower auxiliary plate 20 and the engaging convex portion 46 of the upper auxiliary plate 22 are both formed at corresponding radial positions around the central axis

.

are overlapped, the engagement projections 46 are fitted into the engagement recesses 44, t hereby aligning the upper and lower auxiliary plates 22 and 20 with each other in the radial di rection. In the present embodiment, two side walls of the engaging recess 44 of the lower aux iliary plate 20 and the inner and outer peripheral surfaces of the engaging protrusion 46 of th e upper auxiliary plate 20 are superimposed on each other in the corresponding radial directio n. A pair of inner and outer engagement surfaces are provided. 5 and 6 show a polishing ap paratus 52 provided with a polishing pad auxiliary plate 50 as a third embodiment of the pres ent invention

. [0070]

In this polishing pad auxiliary plate 50, the lower auxiliary plate 20 has a stepped surface 54 as a circular engagement inner peripheral surface extending all around the central axis on the outer peripheral portion thereof. By increasing the thickness of the lower auxiliary plate 20 on the outer peripheral side of the stepped surface 54, an annular shape continuously extends al ong the outer peripheral edge of the lower auxiliary plate 20 along the entire circumference in the circumferential direction. The engaging convex portion 56 of
It is formed integrally with the side auxiliary plate 20 . On the other hand, on the outer perip heral portion of the upper auxiliary plate 22, there is formed a stepped surface 58 as a circula r engagement outer peripheral surface extending all around the central axis
.
Since the thickness of the upper auxiliary plate 22 is reduced on the outer peripheral side of t he step surface 58, the upper auxiliary plate 22 has a notched cross-sectional shape that ope ns to the outer peripheral surface and extends continuously along the entire circumference in the circumferential direction. An annular engaging recess 60 is formed integrally with the upp er auxiliary plate 22 .
Further, the step surface 54 of the lower auxiliary plate 20 is formed with
female threads, while the step surface 58 of the upper auxiliary plate 22 is formed with male threads. Then, the female thread of the stepped surface 54 of the lower auxiliary plate 20 is s crewed with the male thread of the stepped surface 58 of the upper auxiliary plate 22 so that the stepped surface 54 of the lower auxiliary plate 20 and the stepped surface 58 of the upper auxiliary plate 22 are screwed together. are superimposed on each other in the radial directio n, the upper auxiliary plate 22 is superimposed on the upper surface of the lower auxiliary pla te 20 . Further, in such a superimposed state, the screwing structure of the stepped surfaces 58, 54 of the upper and lower auxiliary plates 22, 20 constitutes a second fixing means 62 for detachably fixing the upper and lower auxiliary plates 22, 20. . The direction of the male and female threads in such a threaded structure is set in consideration of the rotational reaction fo rce exerted on the rotating surface plate 14 of the polishing device 12 during polishing so that the screws do not loosen
.
It is desirable that
FIGS.
7 and 8 show a polishing apparatus 66 having a polishing pad auxiliary plate 64 as a fourth embodiment of the present invention.
[0075]
In this polishing pad auxiliary plate 64 , a cylindrical engaging convex portion 68 projecting upward is formed at the central portion of the upper surface of the lower auxiliary plate 20 . T

he engaging projection 68 may be formed integrally with the lower auxiliary plate 20, or may be formed separately as shown in the drawing. That is, in this embodiment, a circular fitting r ecess 70 is formed on the central axis of the lower auxiliary plate 20, and a cylindrical block f ormed separately from the fitting recess 70 is provided. An engaging convex portion 68 is for med by being fitted and fixed at one end in the axial direction. On the other hand, in the centr al portion of the lower surface of the upper auxiliary plate 22, there is formed a bottomed circ ular engaging recess 72 that opens to the lower surface on the central axis. Incidentally, the e ngaging convex portion 68 and the engaging concave portion 72 may be formed on either of t he upper and lower auxiliary plates 22 and 20. As shown in FIG. When the upper and lower auxiliary plates 22 and 20 are superimposed, the engaging convex portion 68 is fitted into the engaging concave portion 72, thereby aligning the upper and lower auxiliary plates 22 and 20 with each other in the radial direction

.

It is designed to be In this embodiment, the engagement outer peripheral surface and the eng agement inner peripheral surface are formed by the outer peripheral surface of the engaging protrusion 68 of the lower auxiliary plate 20 and the inner peripheral surface of the engaging recess 72 of the upper auxiliary plate 22. It is configured.

FIG.

9 shows a polishing apparatus 76 provided with a polishing pad auxiliary plate 74 as a fifth e mbodiment of the present invention.

[0078]

In this polishing pad auxiliary plate 74 , a cylindrical engaging convex portion 78 projecting upward is formed on the outer peripheral portion of the upper surface of the lower auxiliary pl ate 20 . This engaging projection 78 may be formed integrally with the lower auxiliary plate 2 0, or may form a fitting recess in the lower auxiliary plate 20 like the engaging projection in t he fourth embodiment. Alternatively, a separate pin or the like may be fixed by press-fitting o r the like. Also, as shown in FIGS. 10 and 11, a plurality of such engaging projections 78 are f ormed independently of each other at the outer peripheral portion of the lower auxiliary plate 20 at predetermined intervals in the circumferential direction. Particularly preferably, the plura lity of engaging protrusions 78 are formed at regular intervals in the circumferential direction and positioned on the same circle on the central axis.

On the other hand, on the outer peripheral portion of the lower surface of the upper auxiliar y plate 22, bottomed circular engagement grooves are provided at positions corresponding to the formation positions of the plurality of engaging projections 78 on the lower auxiliary plate 20, respectively . A concave portion 80 is formed to open downward. Incidentally, the engagin g convex portion 78 and the engaging concave portion 80 may be formed on either of the upp er and lower auxiliary plates 22 and 20. As shown in FIG. When the upper and lower auxiliar y plates 22 and 20 are superimposed, the engaging convex portions 78 are fitted into the eng

aging concave portions 80, respectively, so that the upper and lower auxiliary plates 22 and 20 are positioned radially relative to each other

.

are designed to be matched. In the present embodiment, the outer circumferences of the lower auxiliary plate 20 and the upper auxiliary plate 22 are formed by the outer circumference of the engagement projection 78 of the lower auxiliary plate 20 and the inner circumference of the engagement recess 80 of the upper auxiliary plate 22 . An engaging outer peripheral surface and an engaging inner peripheral surface located in a portion are configured. In particular, as in this embodiment, by adopting positioning means consisting of a plurality of engaging projections 78 and engaging recesses 80 independent in the circumferential direction, the superimposed upper and lower auxiliary plates 22, 20 can be diametrically aligned

.

Mutual positioning is possible not only in the direction but also in the circumferential direction. Instead of the plurality of independent engaging recesses 80 formed in the upper auxiliary plate 22 ,

a circumferential groove continuously extending circularly in the circumferential direction around the central axis of the upper auxiliary plate 22 may be employed. Alternatively, as shown in the sixth embodiment of the present invention in FIG. 12, a circular stepped surface 82 is formed around the central axis of the outer peripheral portion of the upper auxiliary plate 22 and extends over the entire circumference. By making the thickness dimension of the outer peripheral side smaller than 82, it is also possible to form an annular engagement concave portion 83 that has a notched cross-sectional shape that opens to the outer peripheral surface of the upper auxiliary plate 22 and that extends continuously all around in the circumferential direction. It is possible.

[0083]

In this way, in the upper auxiliary plate 22, the engaging surfaces of the engaging projections 78 of the lower auxiliary plate 20 are formed continuously over the entire circumference, so that when the upper and lower auxiliary plates 20 and 22 are superimposed, the upper and lower auxiliary plates 20 and 22 can be overlapped. Since it is no longer necessary to align the auxiliary plates 20 and 22 with each other in the circumferential direction, the mounting work can be easily performed.

FIG.

13 shows a polishing pad auxiliary plate 84 as a seventh embodiment of the present invention.

In this polishing pad auxiliary plate 84, the upper portion of the outer peripheral surface of the lower auxiliary plate 20 and the lower portion of the outer peripheral surface of the upper

auxiliary plate 22 are each provided with a small diameter portion. By superimposing the upper and lower auxiliary plates 22 and 20, the small diameter portions of the upper and lower auxiliary plates 22 and 20 form an annular ring that extends across the entire circumference i

n the circumferential direction by widening a predetermined width across the upper and lower auxiliary plates 22 and 20. A shaped receiving recess 86 is formed. A groove-shaped engagi ng recess 88 is formed at the lower end of the small diameter portion of the lower auxiliary pl ate 20

.

The engagement recess 88 opens to the outer peripheral surface of the lower auxiliary plate 2 0 at the bottom surface of the accommodation recess 86 . Here, the bottom surface of the acc ommodation recess 86 refers to an annular surface extending over the upper and lower auxili ary plates 22 and 20 and extending in the vertical direction in FIG. On the other hand, a plate -shaped engaging projection 90 made of an elastic material is attached to the small-diameter portion of the upper auxiliary plate 22 that constitutes the accommodation recess 86 so that it s proximal end is fixed by a fixing pin 92 . The engaging protrusions 90 are accommodated in accommodation recesses 86 formed on the outer peripheral surfaces of the upper and lower a uxiliary plates 22 , 20 and extend from the upper auxiliary plate 22 onto the outer peripheral surface of the lower auxiliary plate 20 . there is An engaging claw portion 94 formed at the tip portion of the engaging projection portion 90 is engaged with an engaging recess portion 88 f ormed in the small diameter portion of the lower auxiliary plate 20, and the engaging projecti on portion 90 is locked. It is held in a locked state based on elasticity.

Furthermore, a plurality of such engaging projections 90 are provided on the outer periphera l surfaces of the upper and lower auxiliary plates 22 and 20 at predetermined intervals in the circumferential direction . And attached to the outer peripheral surface of the upper auxiliary plate 22

Each of the engaging projections 90 is elastically pressed against the outer peripheral surface of the lower auxiliary plate 20, thereby forming positioning means for positioning the upper a nd lower auxiliary plates 22, 20 relative to each other on the central axis. Further, by engagin g the engaging claw portion 94 of the engaging convex portion 90 with the engaging concave portion 88, a fixing means is also configured to hold the upper and lower auxiliary plates 22 a nd 20 in a superimposed state and apply a fixing force. there is Instead of the engaging prot rusions 90 having the engaging claws 94 that engage with the engaging recesses 88 as descri bed above, for example, an eighth embodiment of the present invention shown in FIG

.

In addition, a connecting plate 100 extending across the upper and lower auxiliary plates 22 a nd 20 and superimposed on the bottom surface of the housing recess 86 is adopted, and both ends of the connecting plate 100 are connected to one of the upper and lower auxiliary plates 22 and 20. It is also possible to fix to the outer peripheral surface of the by connecting pins 1 02 , 102 . At least one of the connecting pins 102, 102 is detachable from the lower auxiliary plate 20 or the upper auxiliary plate 22, so that the connection of the upper and lower auxiliar y plates 22, 20 by the connecting plate 100 can be released. , the attachment and detachmen

t of the upper auxiliary plate 22 to which the polishing pad 16 is fixed with respect to the lowe r auxiliary plate 20 is permitted. The first fixing means 24 and the second fixing means 26 m ade of double-faced tape or the like shown in the first to eighth embodiments are used when r emoving the upper and lower auxiliary plates 22 and 20 and the rotating surface plate 14

.

In addition, it is desirable to be held on the fixing surface on the side of a specific member. Th is facilitates handling of the upper and lower auxiliary plates 22, 20 and the first and second fi xing means 24, 26 in a detached state. In addition, the fixing surfaces on which the first and second fixing means 24 and 26 remain are determined by making the fixing force of both surf aces of the first fixing means and the second fixing means 24 and 26 themselves different fro m each other. It is possible to set by differentiating the surface roughness, material, etc. of th e fixed upper and lower auxiliary plates 22 and 20 and the rotating platen 14 from each other. In particular, it

is desirable that the first fixing means 24 is held on the fixing surface on the side of the lowe r auxiliary plate 20 when the lower auxiliary plate 20 is removed. becomes easier. On the othe r hand, as shown in FIG. 2 in the first embodiment, the second fixing means 26 is held on the fixing surface on the side of the upper auxiliary plate 22 when the upper auxiliary plate 22 is r emoved. Alternatively, it may remain on the upper surface of the lower auxiliary plate 20 as in the ninth embodiment of the present invention shown in FIG. By holding the second fixing me ans 26 on the fixing surface on the side of the upper auxiliary plate 22, the removed upper au xiliary plate 22 can be attached to the rotating surface plate of the device for reprocessing suc h as grooving of the polishing pad 16. At the time of mounting, it is also possible to use the se cond fixing means 26 held by the upper auxiliary plate 22 for mounting. On the other hand, b y holding the second fixing means 26 on the fixing surface of the lower auxiliary plate 20, whe n mounting another upper auxiliary plate 22 with another polishing pad 16 mounted thereon t o the lower auxiliary plate 20, It is also possible to attach using the second fixing means 26 h eld by the lower auxiliary plate 20 .

Further, the engaging recesses 32, 44, 60, 72, 80, (83), 88 and the engaging projections 36, 46, 56,

70, 78, 90 shown in the first to seventh embodiments may be provided on opposite sides of the lower auxiliary plate 20 side and the upper auxiliary plate 22 side. For example, as the te nth embodiment of the present invention is shown in FIG. The stepped surface 30 and the eng aging recess 32 may be formed on the upper auxiliary plate 22 , while the stepped surface 34 and the engaging convex portion 36 forming the inner peripheral surface of the engagement may be formed on the lower auxiliary plate 20 . It is possible.

[0092]

Furthermore, the engaging recesses 32, 44, 60, 72, 80, (83) and the engaging protrusions 3 6, 46, 56, 70, 78 shown in the first to sixth embodiments are overlapped with each other. It is also possible to form an inclination angle with respect to the outer peripheral surface of the en

gaging projection and the inner peripheral surface of the engaging recess for positioning the u pper and lower auxiliary plates 22 and 20 by using the upper and lower auxiliary plates 22 an d 20 as shown in FIG. For example, as an eleventh embodiment of the present invention is sh own in FIG. On the other hand, while the engaging convex portion 36 is tapered in the incline d direction in which it gradually tapers in the projecting direction,

A stepped surface 30 serving as an engaging outer peripheral surface of an engaging recess 3 2 formed in the outer peripheral portion of the upper auxiliary plate 22 can be tapered at an i nclination direction and an inclination angle corresponding to the stepped surface 34 . As a re sult, the operation of fitting the engaging convex portion 36 into the engaging concave portio n 32 and overlapping the upper and lower auxiliary plates 22, 20 can be further facilitated by using the tapers provided on both the stepped surfaces 34, 30 as guide surfaces. It becomes possible to do it easily. Incidentally, as shown in the twelfth embodiment of the invention sh own in FIG. 18 and the thirteenth embodiment of the invention shown in FIG

.

Even when adopting a plurality of projection-shaped engaging projections 78 formed independ ently in the direction and a plurality of hole-shaped engaging recesses 80 formed at respectiv e corresponding positions of the upper auxiliary plate 22, the engagement A tapered portion 1 04 having a tapered shape can be formed by giving an inclination angle to the outer periphera l surface of the projecting tip portion of the convex portion 78 . In FIG. 19, an engagement pi n 106 formed separately is press-fitted into a fitting hole 105 formed in the lower auxiliary pla te 20 to form the engagement convex portion 78. The lower end of the locking pin 106 also h as a tapered portion 104 similar to the upper end. As a result, the locking pin 106 has no dire ctivity and is easy to handle, and the operation of press-fitting it into the fitting hole 105 is als o facilitated.

[0094]

Further, in the fourteenth embodiment of the present invention shown in FIG. 20, a straddle between the upper and lower auxiliary plates 22, 20 is used as a kind of positioning means for aligning the central axis of the upper and lower auxiliary plates 22, 20 in a superimposed stat e. A locating sleeve 108 is thus shown fitted over. The positioning sleeve 108 has an inner dia meter that is the same as or slightly larger than the outer diameter of the upper and lower au xiliary plates 22 and 20, which are disk-shaped and have substantially the same outer diamet er. formed. Such a positioning sleeve 108 is used when superimposing the upper and lower au xiliary plates 22 and 20, and by superimposing the upper and lower auxiliary plates 22 and 20 within the positioning sleeve 108, the central axes of the upper and lower auxiliary plates 22 and 20 are aligned. They can be axially superimposed and secured to each other with a secon d securing means 26 . Therefore, the positioning sleeve 108 can be removed after the upper a nd lower auxiliary plates 22 and 20 are superimposed and fixed to each other, thereby positio ning the upper and lower auxiliary plates 22 and 20 so as to protrude on the outer peripheral surface. It is possible to attach them to each other without means and in precise alignment.

[0095]

Furthermore, in the fifteenth embodiment of the present invention shown in FIG. 21, a slit-shaped engagement groove 110 is formed extending across the overlapping direction when the upper and lower auxiliary plates 22 and 20 are overlapped. ing. The engaging grooves 110 are open to the outer peripheral surfaces of the upper and lower auxiliary plates 22 and 20 and have a predetermined depth radially inward. It is A plate-shaped engaging plate 112 is fitted into the engaging groove 110 from the opening of the outer peripheral surface, so that the upper and lower auxiliary plates 22 and 20 are positioned by the engaging plate 112 and is in a connected state. Although the engaging plate 112 is formed separately from the upper and lower auxiliary plates 22 and 20, it may be formed integrally with one of the upper and lower auxiliary plates 22 and 20 so as to protrude toward the other. . In that case, the engagement groove 110 is formed only in the other auxiliary plate.

Furthermore, in the sixteenth embodiment of the present invention shown in FIG. 22 ,

a fitting recess 114 is formed as an engaging recess opening in the lower surface of the upper auxiliary plate 22 . In particular, in this embodiment, the fitting recess 114 is formed as an annular groove extending continuously in the circumferential direction around the central axis of the upper auxiliary plate 22 . On the other hand, the lower auxiliary plate 20 has a fitting convex portion 116 as an engaging convex portion that protrudes upward on the upper surface that overlaps with the upper auxiliary plate 22 . In addition, in this embodiment, the fitting protrusion 116 is formed as an annular protrusion corresponding to the fitting recess 114 . When the upper and lower auxiliary plates 22 and 20 are superimposed, the fitting convex portion 116 is positioned so as to enter the fitting concave portion 114 .

[0097]

The fitting projection 116 has a hollow structure, and the inside of the fitting projection 116 is provided with an external space.

A fluid reservoir 118 is formed which is sealed between them. Further, at least the inner peripheral wall and the outer peripheral wall of the wall portion of the fitting convex portion 116 that defines the fluid reservoir 118 are bulged and deformable in the radial direction. Specifically, for example, by forming the fitting convex portion 116 with a rubber elastic material or the like, it is possible to realize an inner peripheral wall that can bulge radially inward and an outer peripheral wall that can bulge radially outward. be. Further, the lower auxiliary plate 22 is formed with a fluid passage 120 that communicates with the fluid reservoir 118 and extends radially outward and opens to the outer peripheral surface

.

A pressure screw 122 is screwed into the end opening. In addition, a sealed area composed of the fluid passage 120 and the fluid reservoir 118 sealed by the pressurizing screw 122 is filled with an incompressible fluid such as oil.

Thus

, by screwing the pressure screw 122, the internal pressure of the fluid reservoir 118 can be

increased through the fluid passage 120, and the inner and outer peripheral walls of the fluid reservoir 118 can be expanded outward. As a result, the fitting convex portion 116 is expande d and pressed against the inner surface of the fitting concave portion 114, so that the upper a nd lower auxiliary plates 22 and 20 can be positioned by mutual frictional force and the like, a nd can also exert a fixing force. there is

When removing the upper auxiliary plate 22 from the lower auxiliary plate 20 ,

the pressure screw 122 is rotated in the direction of loosening and moved to the outer perip heral side of the lower auxiliary plate 20, whereby the fluid reservoir 118 is removed. , the pr essing force of the fitting protrusion 116 against the fitting recess 114 can be released.

[0101]

In addition, although not listed individually, the present invention can be implemented with v arious changes, modifications, improvements, etc. based on the knowledge of those skilled in the art. It is also possible to attach an O-ring or a sealing material to the portion to prevent fo reign matter from entering the overlapping surfaces of the upper and lower auxiliary plates.

In addition to the auxiliary plates 20 and 22 having the two-layer structure described above, i t

is also possible to add additional auxiliary plates in a laminated state and fixed by fixing mea ns. By adopting the auxiliary plate of the third layer in this way, it becomes possible to realize an elastic support state or to dispose of the intermediate layer.

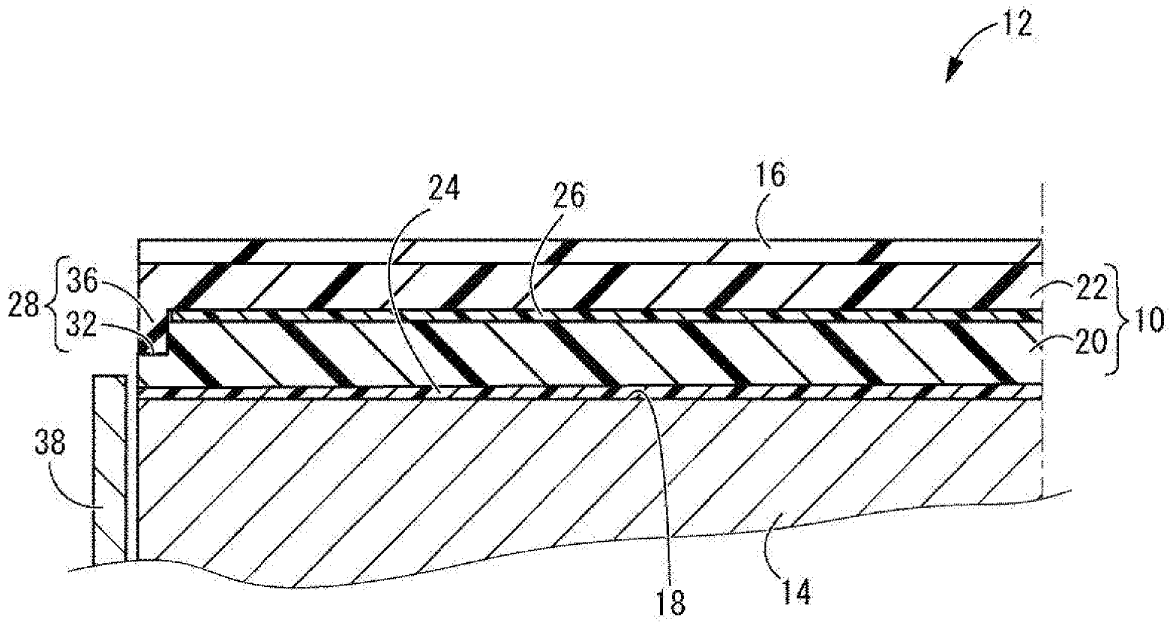
[Description of Reference Symbols]

10

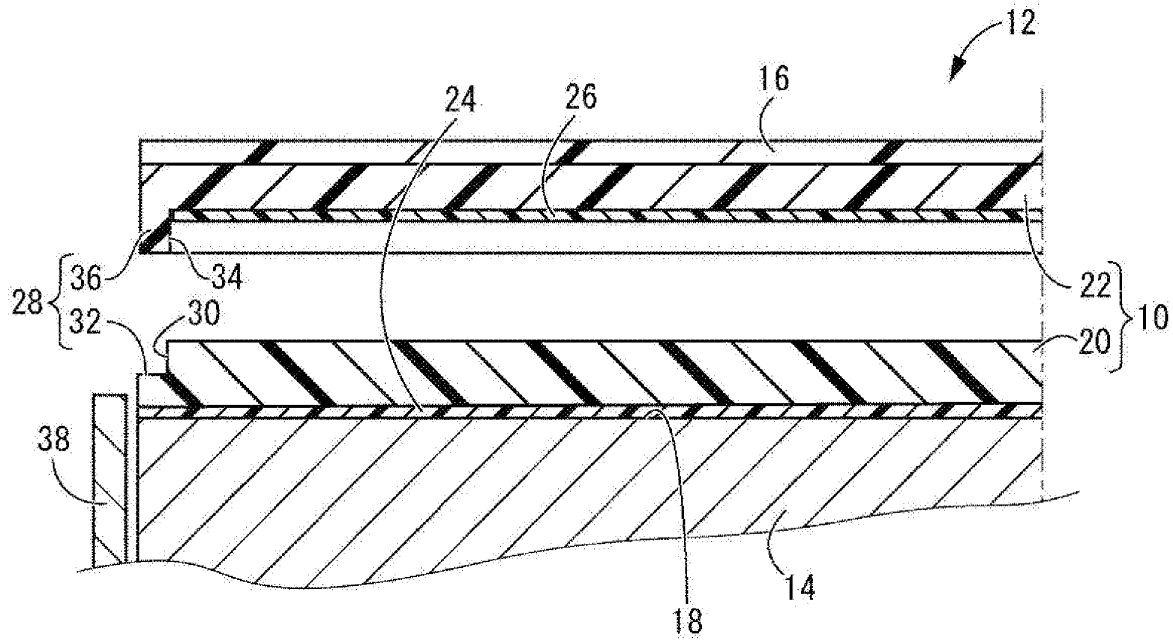
, 40, 50, 64, 74, 84: polishing pad auxiliary plate, 12, 42, 52, 66, 76: polishing device, 14: ro tating platen, 16: polishing pad, 18: upper surface, 20: lower auxiliary plate, 22: upper auxili ary plate, 24: first fixing means, 26, 62: second fixing means, 28: positioning means, 30, 58: step surface (engagement outer circumference surface), 32, 44, 60, 72, 80, 88: engagement concave portion, 34, 54: step surface (engagement inner peripheral surface), 36, 46, 56, 68, 78, 90: engagement convex portion, 38: Protective member

drawing open —

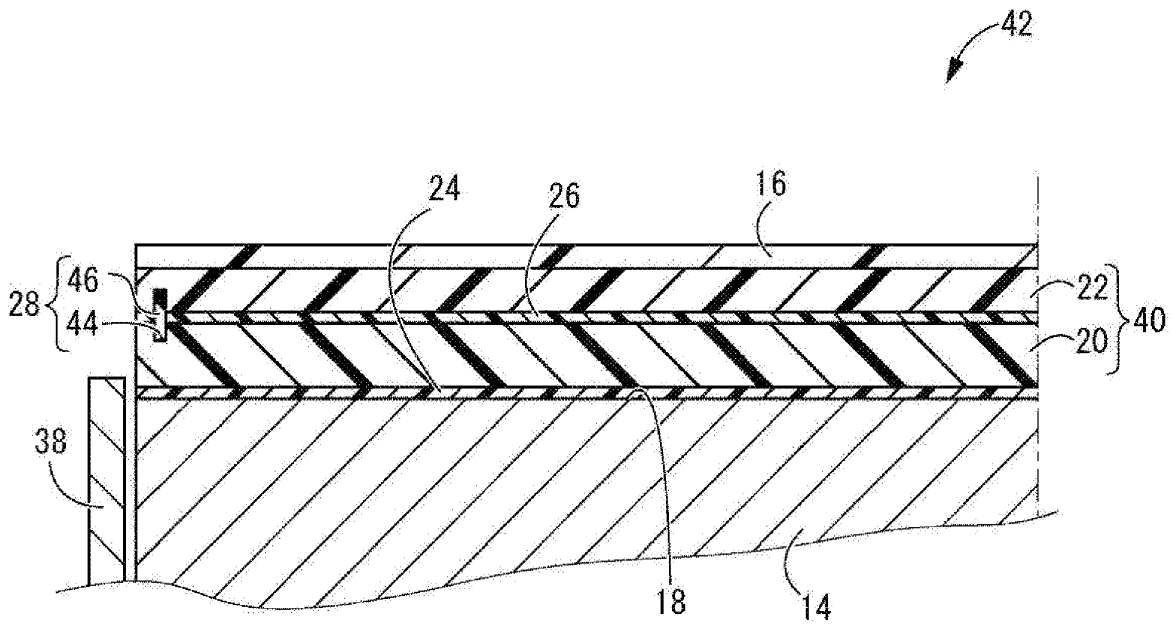
[Fig. 1]



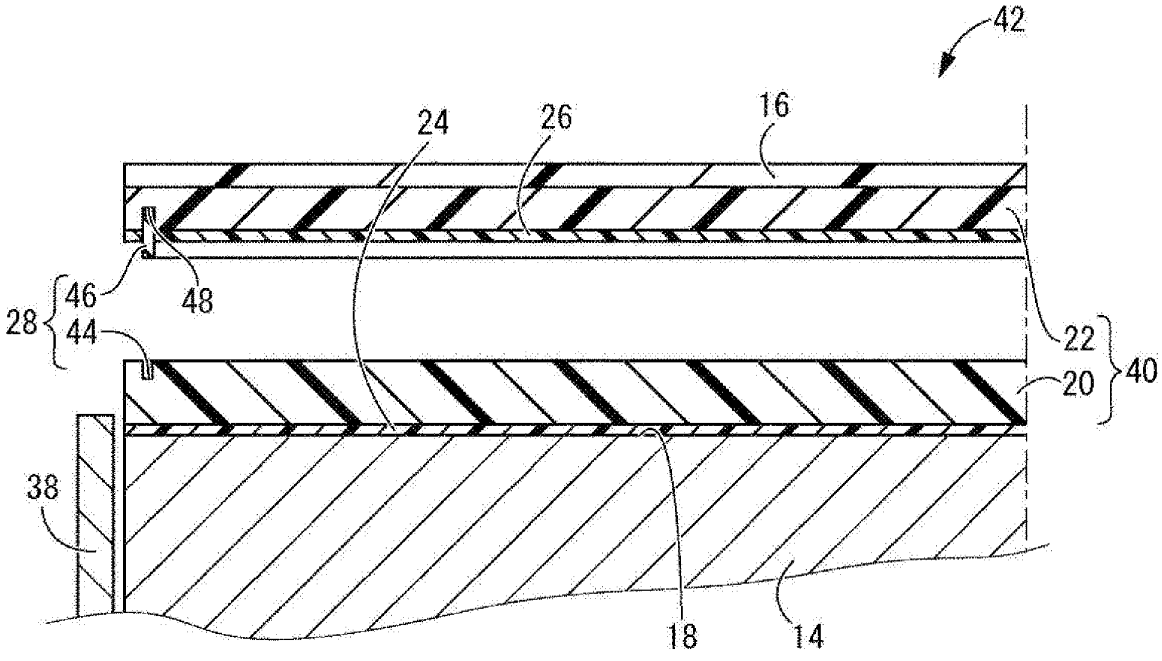
[Figure 2]



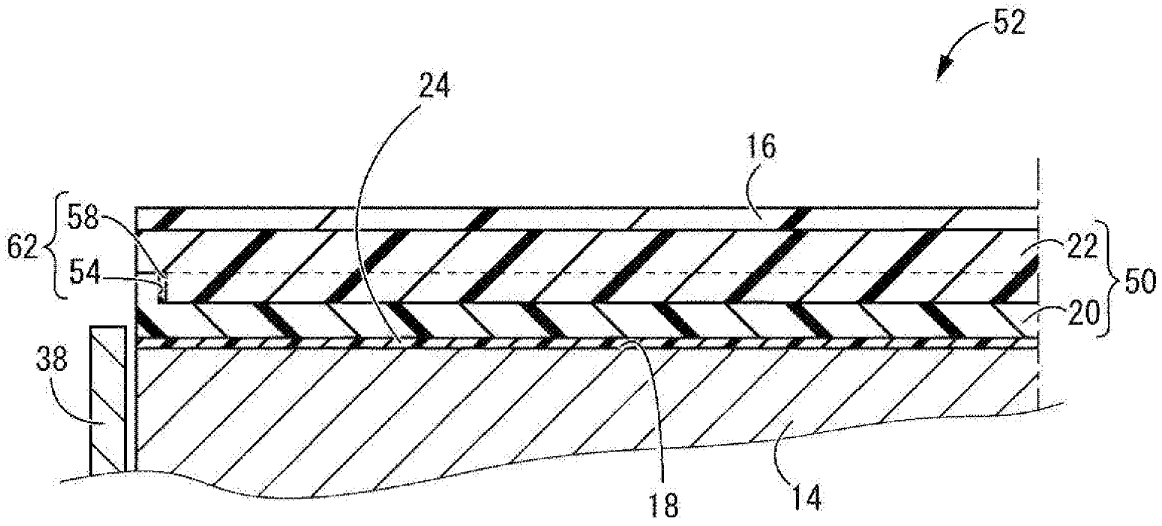
[Figure 3]



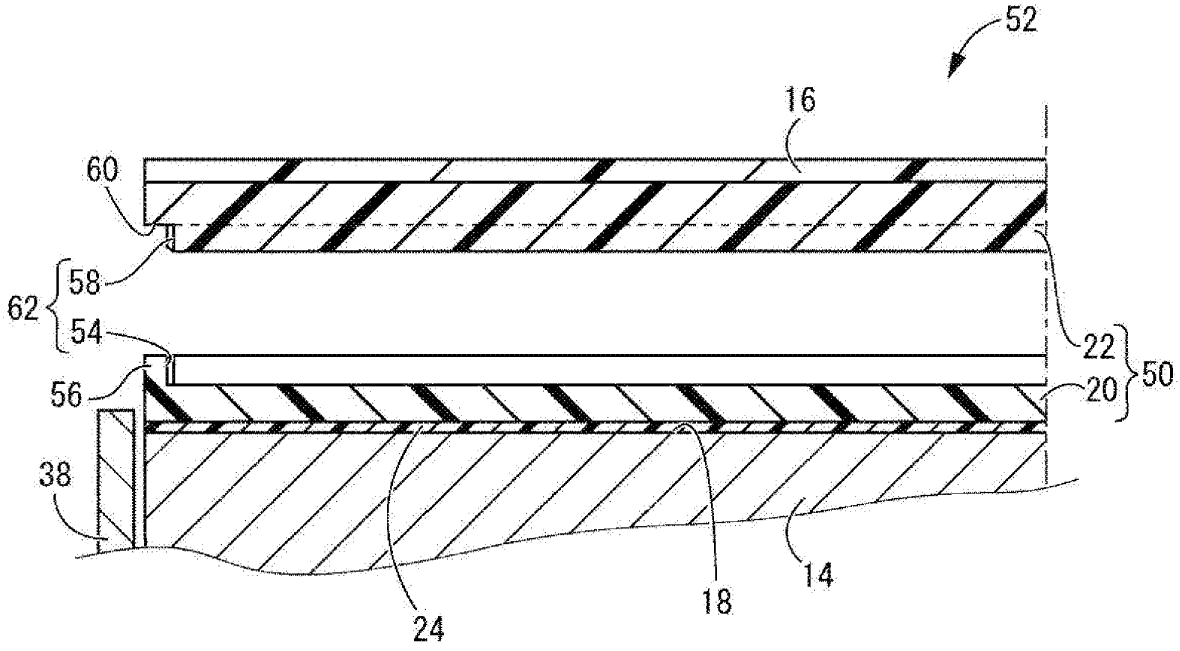
[Figure 4]



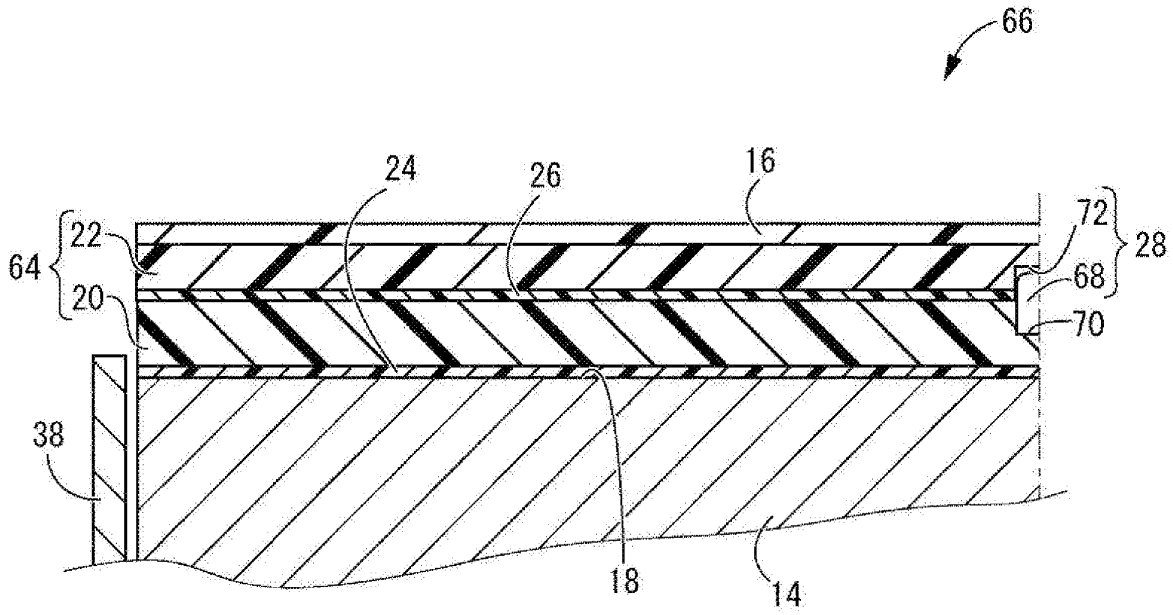
[Figure 5]


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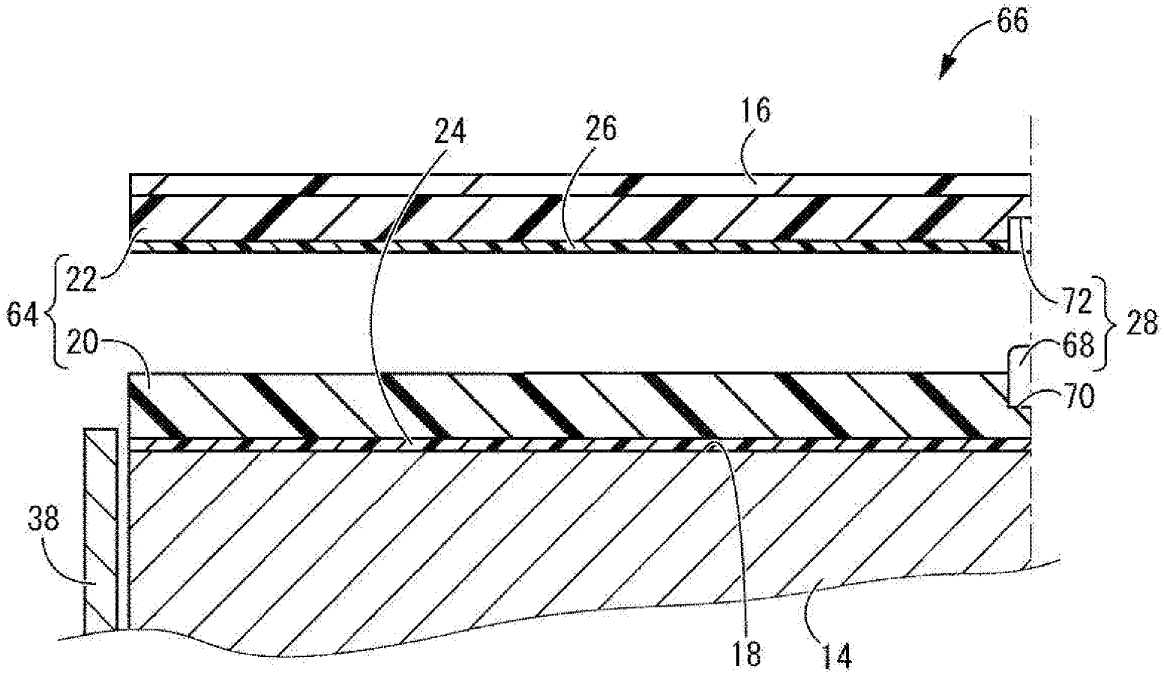
[Fig. 6]


52
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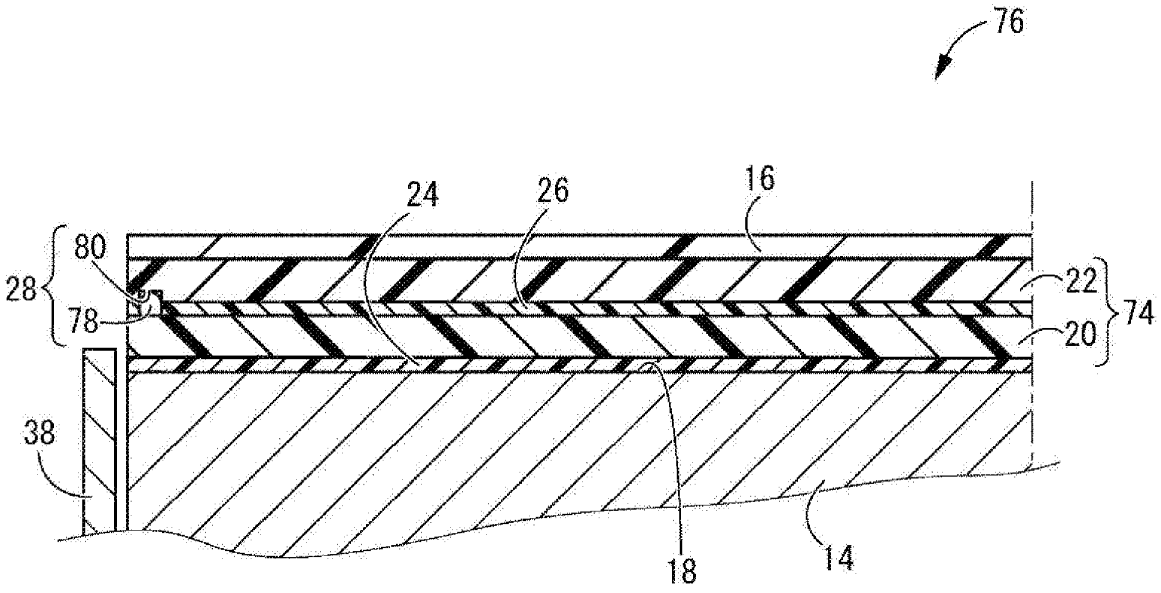
[Fig. 7]


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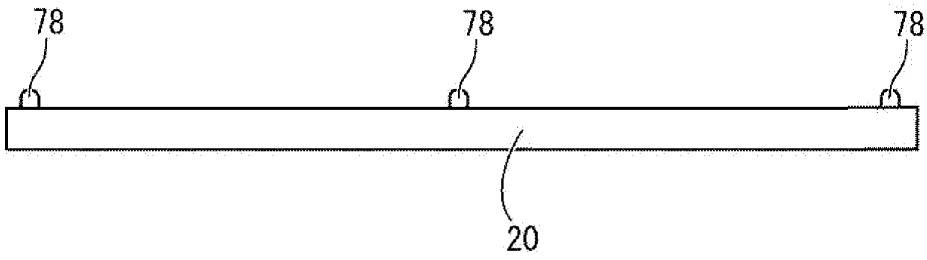
[Fig. 8]


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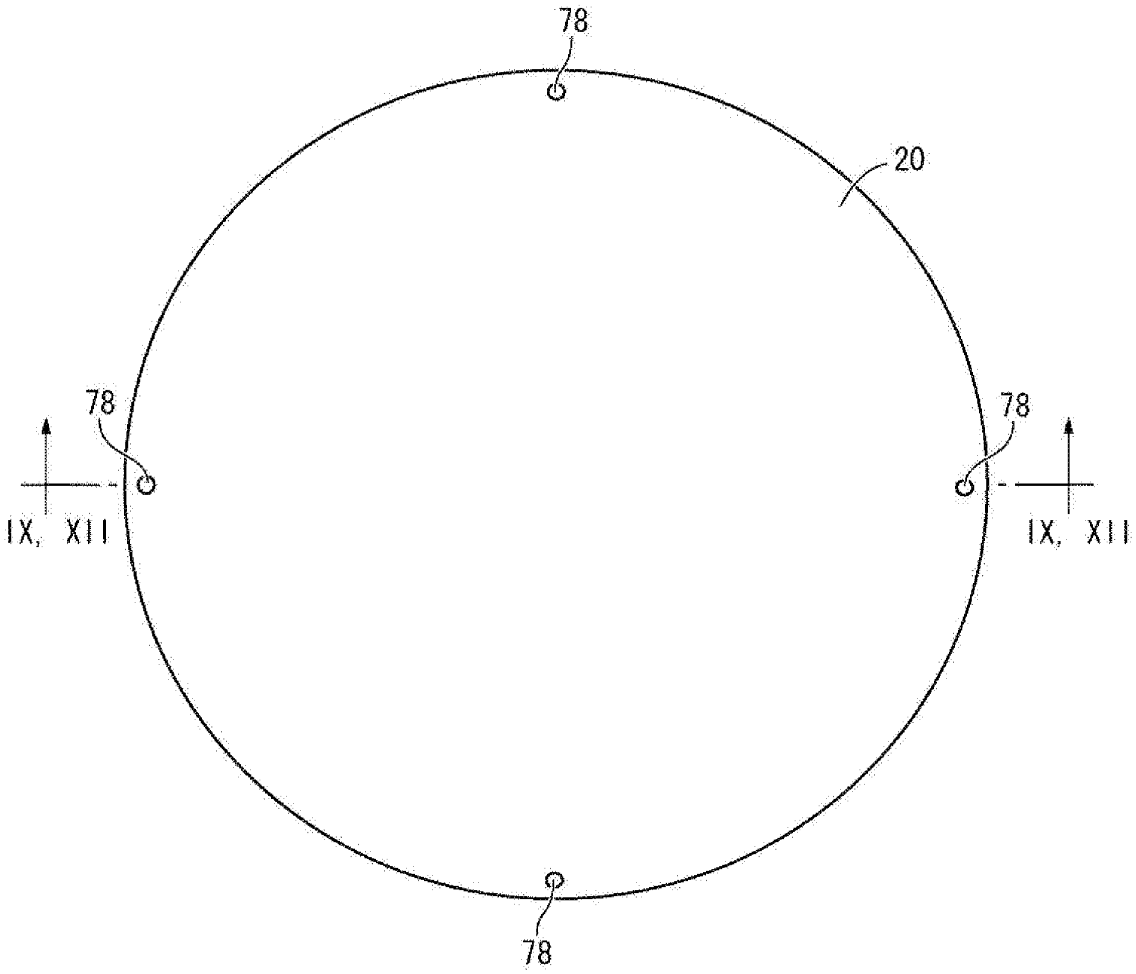
[Fig. 9]



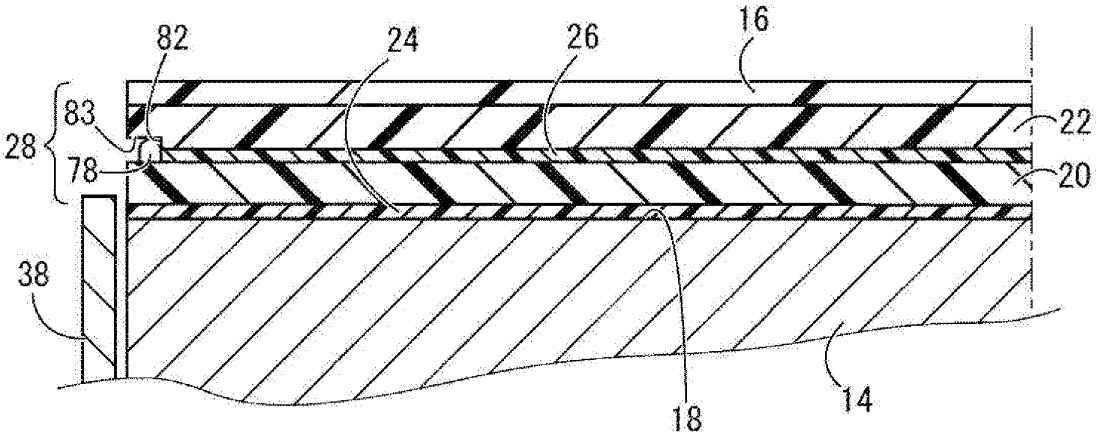
[Fig. 10]



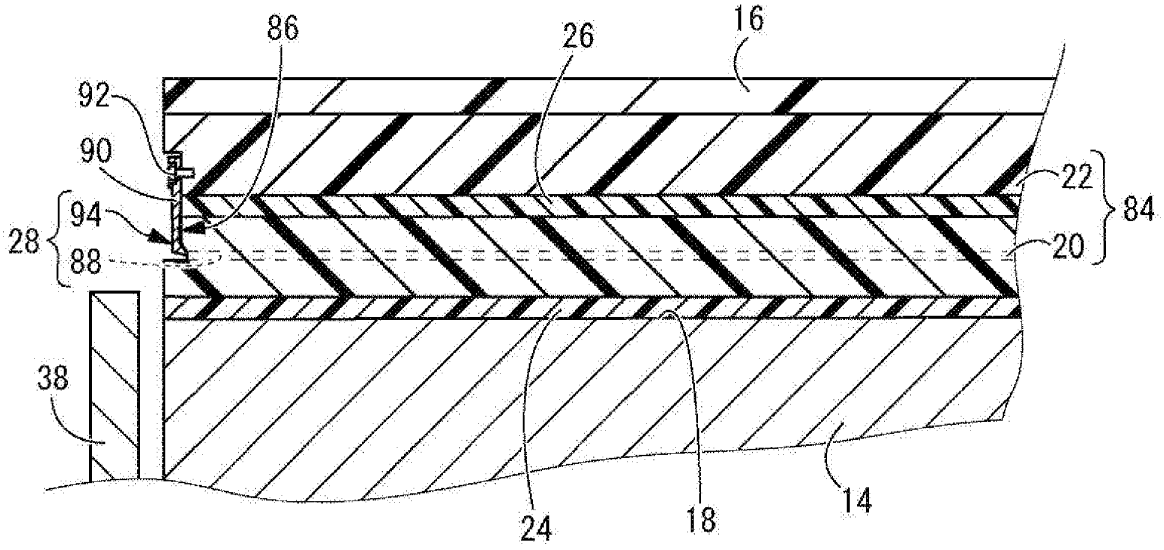
[Fig. 11]



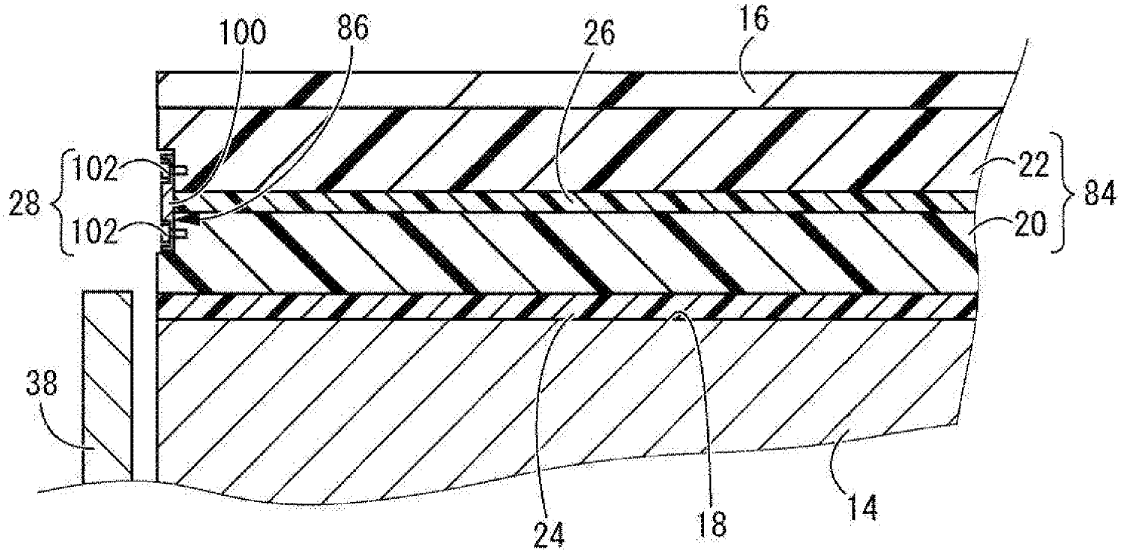
[Fig. 12]



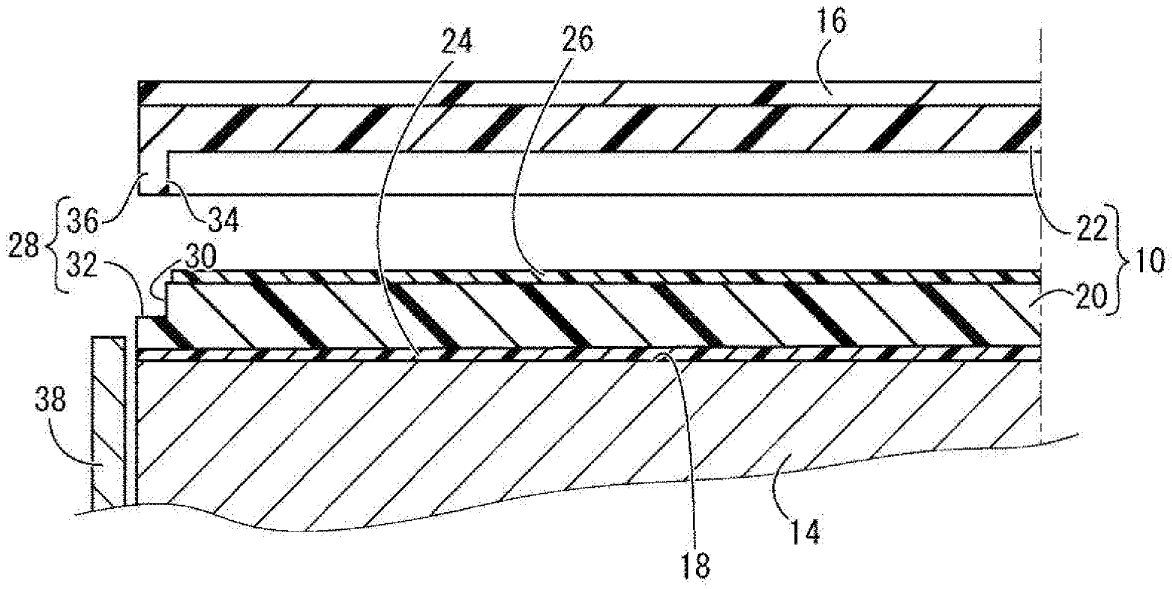
[Fig. 13]


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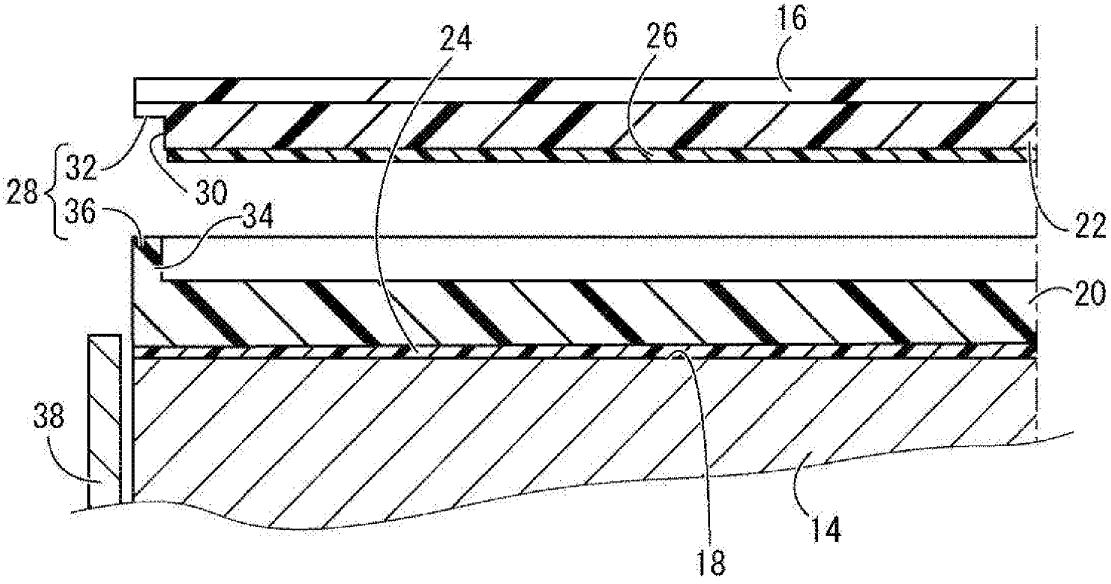
[Fig. 14]


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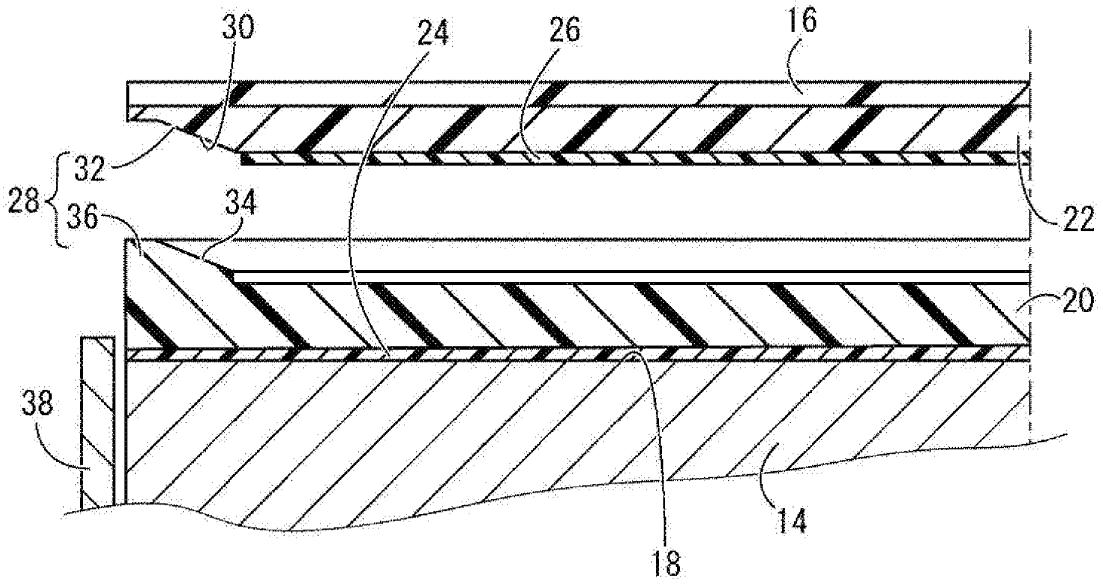
[Fig. 15]


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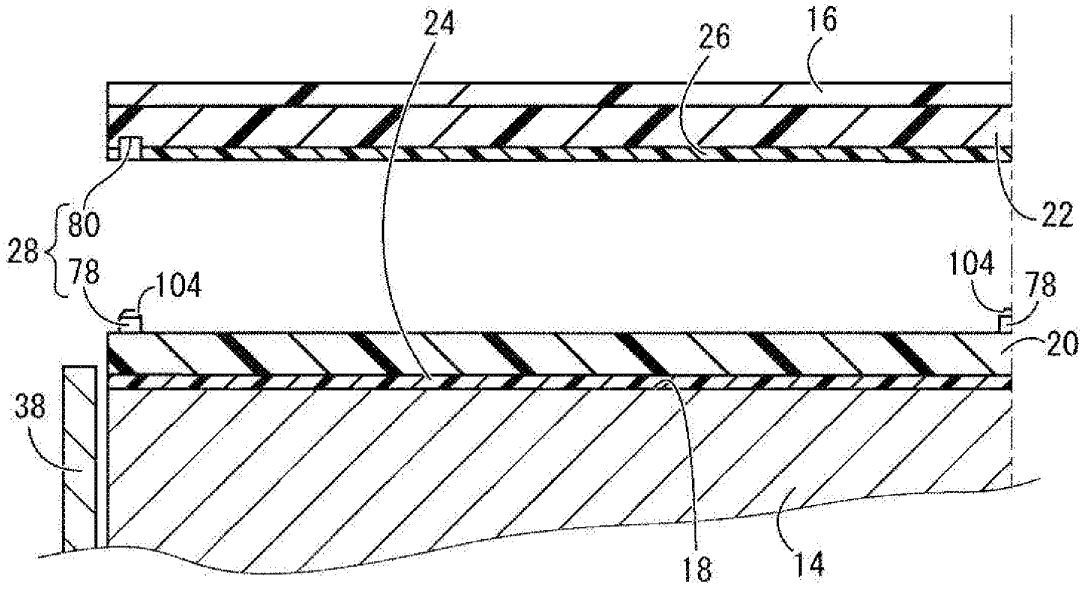
[Fig. 16]


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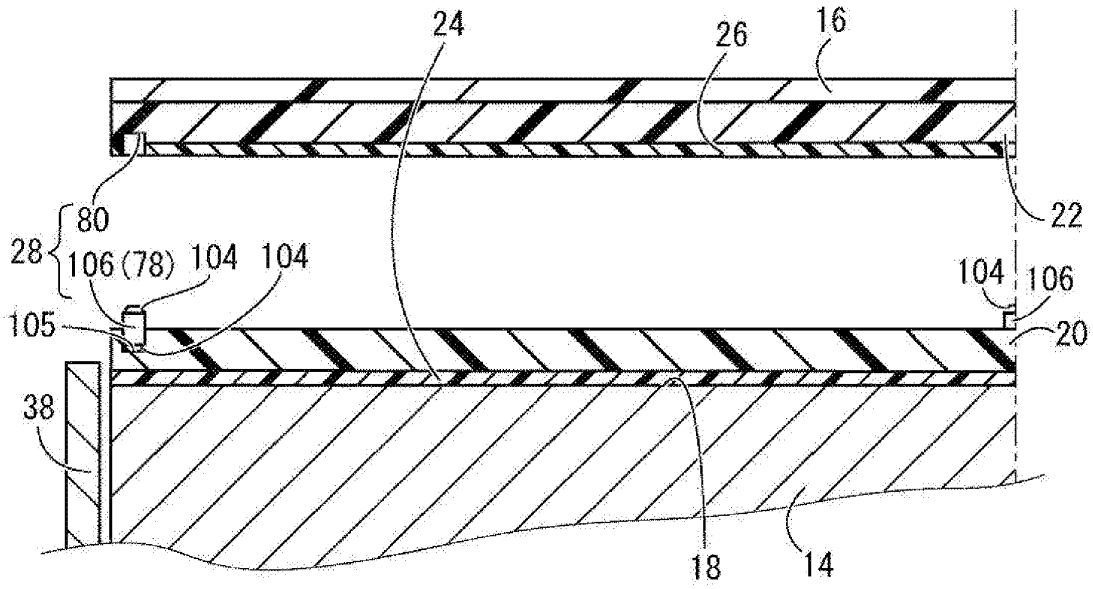
[Fig. 17]


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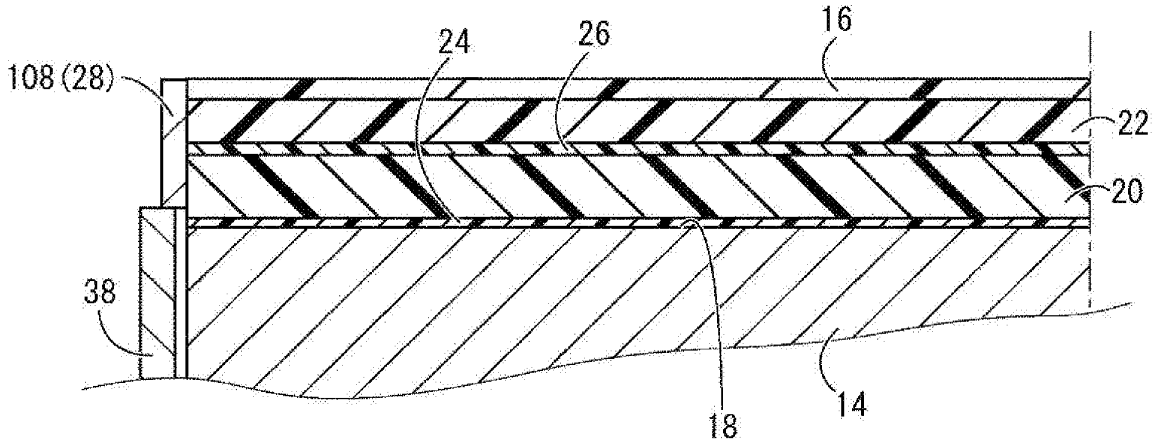
[Fig. 18]


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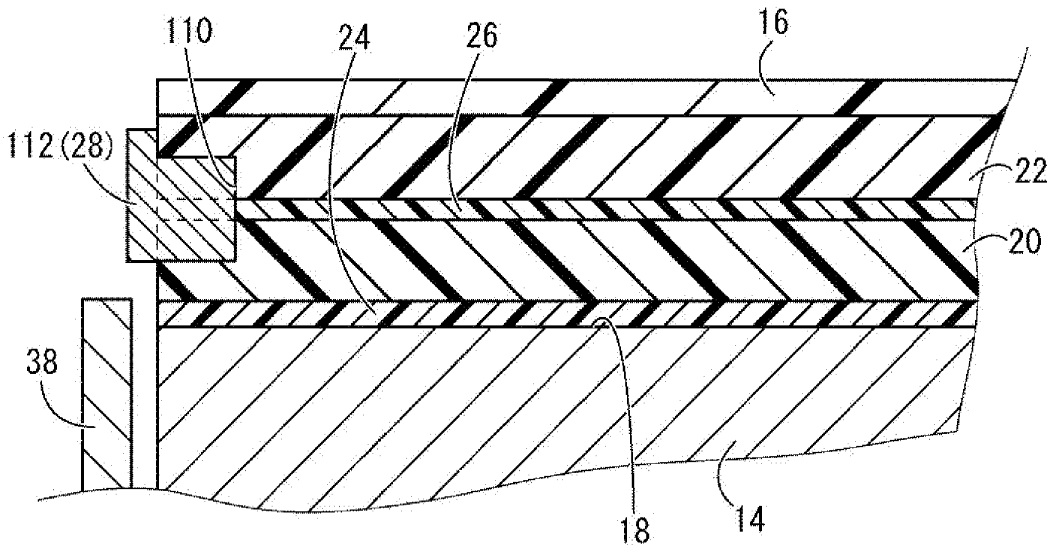
[Fig. 19]


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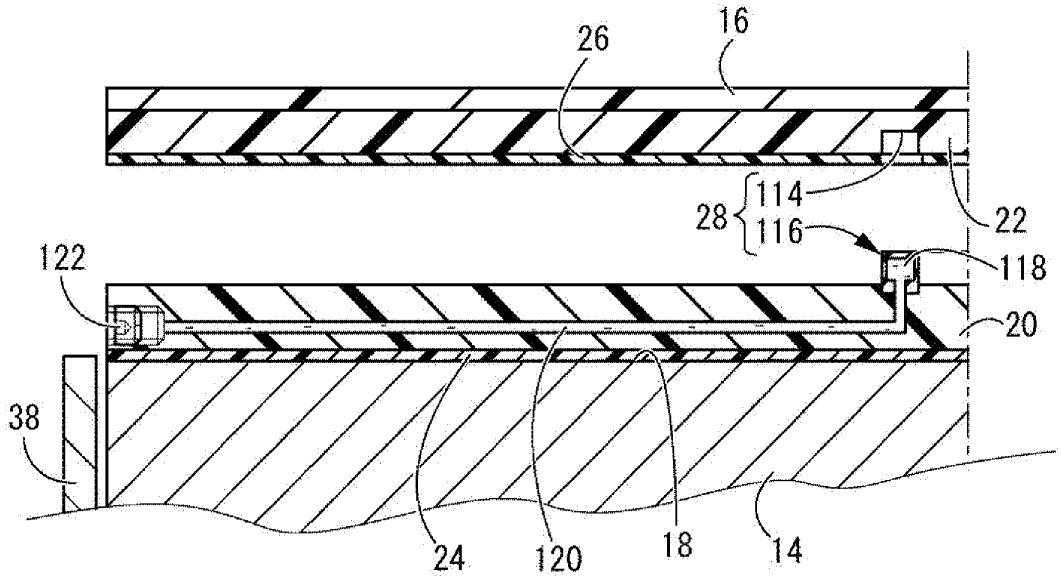
[Fig. 20]


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[Fig. 21]



[Fig. 22]



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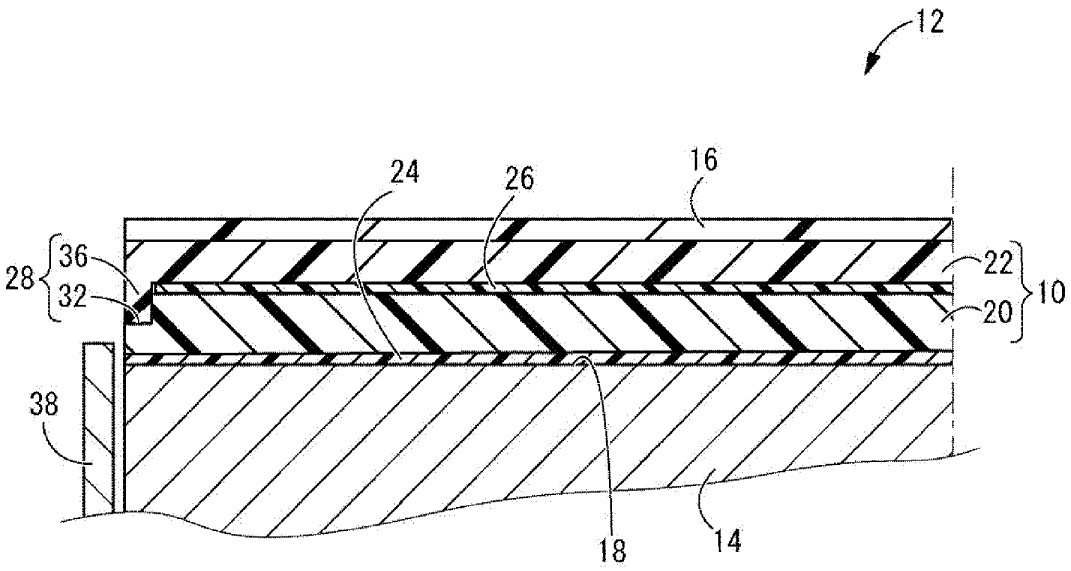


Figure 1

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最終頁に続く

(54)【発明の名称】研磨パッド用補助板および研磨パッド用補助板を備えた研磨装置

(57)【特許請求の範囲】
【請求項１】
研磨装置の回転定盤に装着されて、研磨パッドを該回転定盤に対して着脱可能に取り付ける研磨パッド用補助板において、
前記回転定盤の上面に重ね合わされて配される下側補助板と、
該下側補助板を該回転定盤に固着する第一の固着手段と、
前記研磨パッドが重ね合わされて固着されるパッド支持面を備えており、該下側補助板の上面に重ね合わされて配される上側補助板と、
該上側補助板を該下側補助板に固着する第二の固着手段と、
該下側補助板と該上側補助板とを相互に位置決めして中心軸を合わせる位置決め手段とを、有しており、前記研磨装置の前記回転定盤に対して前記下側補助板が前記第一の固着手段による固着状態に保持されて、該回転定盤に固着された該下側補助板から前記上側補助板を取り外すことにより、該上側補助板の前記パッド支持面に固着されたままの状態で前記研磨パッドを該回転定盤から取り外すことが可能とされていると共に、取り外した該上側補助板を該下側補助板に対して前記位置決め手段による位置合わせ状態で再び固着せしめて取り付けることが可能とされており、且つ、
前記第二の固着手段による前記下側補助板と前記上側補助板との固着力が、前記第一の固着手段による前記回転定盤と該下側補助板との固着力よりも小さくされていることを特徴とする研磨パッド用補助板。
【請求項２】

前記位置決め手段が、前記下側補助板および前記上側補助板の外周面よりも内周側に位置して設けられている請求項１に記載の研磨パッド用補助板。

【請求項３】

前記位置決め手段が、

前記下側補助板と前記上側補助板との一方に設けられて他方に向かって突出する係合凸部と、該下側補助板と前記上側補助板との他方に設けられて該係合凸部が係合せしめられる係合凹部とによって構成されている請求項２に記載の研磨パッド用補助板。

【請求項４】

前記係合凸部および前記係合凹部が、前記下側補助板および前記上側補助板の外周部分に位置する係合部をもって形成されている請求項３に記載の研磨パッド用補助板。

【請求項５】

前記係合凸部および前記係合凹部における前記係合部が、前記下側補助板および前記上側補助板の周方向に連続して延びて相互に嵌め合わされる環状の係合外周面および係合内周面によって構成されている請求項４に記載の研磨パッド用補助板。

【請求項６】

前記下側補助板および前記上側補助板の外周部分における周上の複数箇所において、前記下側補助板と前記上側補助板との相互の重ね合わせ面の一方において他方に向かって開口する前記係合凹部と、該下側補助板と前記上側補助板との相互の重ね合わせ面の他方において一方に向かって突出する前記係合凸部とが、互いに対応する位置に形成されており、該係合凹部に対する該係合凸部の嵌まり込みによって前記係合部が構成されている請求項４に記載の研磨パッド用補助板。

【請求項７】

前記下側補助板と前記上側補助板との一方の外周部分における周上の複数箇所から他方に向かって突出する前記係合凸部が弾性材によって形成されており、該下側補助板と前記上側補助板との他方における外周面に開口して設けられた前記係合凹部に対して該係合凸部の先端が係合されることにより前記係合部が構成されている請求項４に記載の研磨パッド用補助板。

【請求項８】

前記係合凸部および前記係合凹部が、前記下側補助板および前記上側補助板の中心軸上に設けられている請求項３に記載の研磨パッド用補助板。

【請求項９】

前記係合凸部の外周面と前記係合凹部の内周面とにおいて互いに螺合するねじ溝が形成されており、前記位置決め手段を構成する該係合凸部と該係合凹部との螺合により前記第二の固着手段が構成されている請求項８に記載の研磨パッド用補助板。

【請求項１０】

前記下側補助板と前記上側補助板との一方に設けられた前記係合凸部が、該下側補助板と該上側補助板との一方と同じ材質で形成されている請求項３，４，５，６，８，９の何れか１項に記載の研磨パッド用補助板。

【請求項１１】

請求項１～１０の何れか１項に記載の研磨パッド用補助板が回転定盤の上面に装着されると共に、該回転定盤の外周側に隙間を隔てて保護部材が配設されており、該回転定盤および該研磨パッド用補助板の外周端面よりも内周側に位置して、前記位置決め手段が設けられていることを特徴とする請求項１～１０の何れか１項に記載の研磨パッド用補助板を備えた研磨装置。

【発明の詳細な説明】

【技術分野】

【０００１】

本発明は、シリコンウエハや半導体基板、ガラス基板等のような高い平坦加工精度が要求される被加工物である基板を対象とする研磨に関連する技術に係り、特に、かかる基板の表面を研磨する際に用いられる研磨パッドの再使用を実現可能とする技術に関するもの

である。

【背景技術】

【０００２】

良く知られているように、半導体の製造に際しては、構成材となるシリコンウエハや半導体基板、ガラス基板等の基板の表面を平坦化する研磨処理が行われている。かかる研磨処理は、一般に、樹脂材等からなる円板形状の研磨パッドを研磨装置の回転定盤の上に両面テープで直接固定し、砥粒を含んだ研磨液を供給しつつ、研磨パッドと基板を相対的に回転運動させて研磨を行うことによって実施されている。

【０００３】

そして、このような研磨処理を実施するための研磨パッドとしては、特開２００２－１１６３０号公報（特許文献１）等に記載されているように、発泡又は無発泡のウレタン等からなる樹脂パッドが採用されている。また、かかる研磨パッドの研磨表面には、多くの場合、同心円状や格子状、放射状等の溝加工が施されたり、発泡樹脂の気泡が開口される等している。

【０００４】

ところで、研磨パッドを用いた研磨加工を行う場合には、研磨対象である基板の品種切り替え等に際して、研磨加工に使用する研磨パッドを回転定盤から引き剥がして別の研磨パッドに交換しなければならない場合がある。また、例えば、研磨加工に伴って劣化した研磨パッドを、その再使用等を目的として、別の加工装置で表面溝入れ等の再加工するような場合等においても、研磨パッドを回転定盤から引き剥がすことが必要となる。

【０００５】

ところが、薄肉円板形状の研磨パッドは、研磨装置の回転定盤に対して粘着テープで強固に固着されていることから、この研磨パッドを回転定盤から引き剥がす際に、研磨パッドに対して曲がりや折れ、シワ、破れ等の損傷が発生し易い。それ故このような損傷が原因で、かかる研磨パッドを、寿命がきていないにもかかわらず、再使用できずに廃棄せざるを得なくなることが多いという問題があった。

【０００６】

しかも、損傷しないように細心の注意を払いつつ研磨パッドを回転定盤から引き剥がす作業は、熟練と注意を要することから作業者に大きな負担をかけるという問題もあった。加えて、研磨パッドを回転定盤から引き剥がす作業に相当の時間が必要となることから、高価で貴重な設備である研磨装置を長時間に亘って停止させなければならず、設備の稼働時間が制限されてしまうという問題もあった。

【０００７】

そこで、本発明者は、先に特開２０１０－２１４５７９号公報（特許文献２）において、研磨パッドの裏面に補助板を取り付け、この補助板を介して、研磨パッドを研磨装置の回転定盤に対して両面テープ等で固着するようにした補助板付き研磨パッドを提案した。かかる補助板付き研磨パッドでは、研磨パッドが補助板で支持されたままの状態を保ちつつ回転定盤に対して着脱されることから、着脱に際しての研磨パッドの損傷が補助板で補強される。それ故、研磨パッドの損傷を防止しつつ、回転定盤に対して研磨パッドを良好な作業性をもって着脱することが可能となる。

【０００８】

ところが、本発明者が更なる研究と検討を重ねたところ、特許文献２で提案した補助板付き研磨パッドでは、必ずしも全ての研磨装置への対応が容易であると言い難いことがわかった。

【０００９】

すなわち、研磨パッドを回転定盤に重ね合わせて固着する際には、研磨パッドの中心を回転定盤の回転中心に位置合わせする必要があり、特に研磨表面に溝等が施された研磨パッドでは中心位置合わせに精度が要求される。そして、上述の如き補助板を採用することで回転定盤に対する研磨パッドの着脱回数が増加すると、より一層、研磨パッドを回転定盤に装着する際の中心位置合わせの作業が難しくて労力負担が大きいということが大きな

問題となるのである。

【００１０】

また、特許文献２で提案した補助板付き研磨パッドでは、補助板を回転定盤に対して中心位置合わせしつつ着脱可能に取り付けるために、補助板と回転定盤との間において、例えば回転定盤の外周面上に外周リングなどの固着手段が設けられる場合がある。一方、研磨装置のなかには、回転定盤の外周側に保護カバー等が装着されて、回転定盤の外周側のスペースが非常に狭くなっているものもある。それ故、仮に、そのような外周リングを採用しようとした場合に、たまたま回転定盤の外周側のスペースが狭い研磨装置を用いる際には、研磨装置の改造などが必要となるおそれもあったのである。

【先行技術文献】

【特許文献】

【００１１】

【特許文献１】特開２００２－１１６３０号公報

【特許文献２】特開２０１０－２１４５７９号公報

【発明の概要】

【発明が解決しようとする課題】

【００１２】

本発明は上述の如き事情を背景として為されたものであり、回転定盤に対する研磨パッドの固着力を充分に確保しつつ、回転定盤に対する研磨パッドの着脱を容易に行うことを可能と為し、特に回転定盤から研磨パッドを取り外すに際しての研磨パッドの損傷を防止することが出来て、例えば研磨パッドの再利用の実現にも有利とされ得る、新規な構造の研磨パッド用補助板を提供することにある。

【００１３】

それに加えて、本発明は、研磨パッドを回転定盤に装着する際の中心合わせの作業を容易に且つ精度良く行うことが出来て、労力負担も軽減され得ると共に、従来の各種仕様の研磨装置における回転定盤にも特別な改造を必要とすることなく容易に且つ有利に適用され得る、改良された構造の研磨パッド用補助板を提供することも、目的とする。

【００１４】

さらに、本発明は、かかる新規な構造とされた研磨パッド用補助板を備えた研磨装置を提供することも、目的とする。

【課題を解決するための手段】

【００１５】

かかる課題を解決するために、研磨パッド用補助板に関する本発明の第一の態様は、（Ａ）研磨装置の回転定盤に装着されて、研磨パッドを該回転定盤に対して着脱可能に取り付ける研磨パッド用補助板において、（Ｂ）前記回転定盤の上面に重ね合わされて配される下側補助板と、（Ｃ）該下側補助板を該回転定盤に固着する第一の固着手段と、（Ｄ）前記研磨パッドが重ね合わされて固着されるパッド支持面を備えており、該下側補助板の上面に重ね合わされて配される上側補助板と、（Ｅ）該上側補助板を該下側補助板に固着する第二の固着手段と、（Ｆ）該下側補助板と該上側補助板とを相互に位置決めして中心軸を合わせる位置決め手段とを、有しており、前記研磨装置の前記回転定盤に対して前記下側補助板が前記第一の固着手段による固着状態に保持されて、該回転定盤に固着された該下側補助板から前記上側補助板を取り外すことにより、該上側補助板の前記パッド支持面に固着されたままの状態で前記研磨パッドを該回転定盤から取り外すことが可能とされていると共に、取り外した該上側補助板を該下側補助板に対して前記位置決め手段による位置合わせ状態で再び固着せしめて取り付けることが可能とされており、且つ、前記第二の固着手段による前記下側補助板と前記上側補助板との固着力が、前記第一の固着手段による前記回転定盤と該下側補助板との固着力よりも小さくされている研磨パッド用補助板を特徴とする。

【００１６】

本発明に従う構造とされた研磨パッド用補助板では、研磨パッドを、上側補助板および

下側補助板を介して、回転定盤に固着して装着することとなる。これにより、下側補助板を回転定盤に固着したまま、下側補助板から上側補助板を取り外すことが出来、研磨パッドを上側補助板に固着されたままの状態で回転定盤から取り外すことが可能となる。

【００１７】

それ故、研磨パッドが上側補助板で補強および保護された状態で、研磨パッドの損傷を防止しつつ、研磨パッドを回転定盤から取り外すことが出来、薄肉の研磨パッドの取り扱いも容易となる。そして、例えば研磨対象物や研磨条件の変更等に際して研磨パッドの着脱を繰り返す際や、磨耗した研磨パッドを取り外して再生処理後に再装着する際などにおいて、回転定盤への研磨パッドの着脱や研磨パッドに対する再生処理等の作業を容易に行うことも可能となる。

【００１８】

しかも、回転定盤に固着されたままの下側補助板と、研磨パッドと共に取り外される上側補助板とが、位置決め手段により相互に中心軸合わせされることから、回転定盤への位置合わせが必要となる研磨パッドの着脱作業を一層容易に行うことができる。特に、かかる位置決め手段が、下側補助板と上側補助板との間に設けられていることから、回転定盤に対して特別な加工等を施す必要がない。また、かかる位置決め手段が、回転定盤よりも外周側に大きく突出することが回避され得、例えば回転定盤の外周側に保護カバー等が設けられている研磨装置などにも、特別な改造を施すことなく適用可能とされる。

【００１９】

上記本発明の第一の態様に係る研磨パッド用補助板においては、前記第二の固着手段による前記下側補助板と前記上側補助板との固着力が、前記第一の固着手段による前記回転定盤と該下側補助板との固着力よりも小さくされている態様が、採用されている。

【００２０】

このような第一の態様に従えば、第一及び第二の固着手段における固着力を相互に調整して設定したことにより、研磨パッドが固着されたままの上側補助板を、回転定盤に固着されたままの下側補助板から取り外す作業が一層容易となる。要するに、下側補助板を回転定盤に対して固着状態に保つための特別な操作等を必要とすることなく、下側補助板を回転定盤への固着状態に残しつつ研磨パッドを上側補助板に固着されたままの状態で回転定盤から容易に取り外すことが可能になる。

【００２１】

本発明の第二の態様は、前記第一の態様に係る研磨パッド用補助板において、前記位置決め手段が、前記下側補助板および前記上側補助板の外周面よりも内周側に位置して設けられているものである。

【００２２】

本態様の研磨パッド用補助板では　位置決め手段における上下補助板の外周側への突出が完全に回避される。それ故、例えば上下補助板の外径寸法を回転定盤の外径寸法と同じか僅かに小さく設定して装着する場合でも、研磨パッドの支持面を十分に大きく確保しつつ、回転定盤から外周側に位置決め手段が突出することを回避することが出来、回転定盤の外周側に保護カバー等が設置されていても、本発明に係る研磨パッド用補助板の適用に際して障害となることが回避される。

【００２３】

本発明の第三の態様は、前記第二の態様に係る研磨パッド用補助板において、前記位置決め手段が、前記下側補助板と前記上側補助板との一方に設けられて他方に向かって突出する係合凸部と、該下側補助板と前記上側補助板との他方に設けられて該係合凸部が係合せしめられる係合凹部とによって構成されているものである。

【００２４】

本態様の研磨パッド用補助板では、係合凸部と係合凹部との相互係合作用に基づいて、機械的に大きな位置決め力を容易に得ることが可能となる。また、係合凸部や係合凹部の形状や大きさ、数などを調節することにより、位置決め作用の方向や作用力を大きな自由度で容易に設定することも可能となる。

【００２５】
本発明の第四の態様は、前記第三の態様に係る研磨パッド用補助板において、前記係合凸部および前記係合凹部が、前記下側補助板および前記上側補助板の外周部分に位置する係合部をもって形成されているものである。
【００２６】
本態様の研磨パッド用補助板では、研磨パッド用補助板の中央から離れた外周部分に位置して、相互に凹凸嵌合せしめられる係合凸部の係合外周面と係合凹部の係合内周面とを形成することにより、上下補助板の相対的な位置決め精度、特に径方向の位置決め精度の向上が図られ得る。なお、後述の第六及び第七の態様にも示されているように、係合凸部の係合外周面および係合凹部の係合内周面は、研磨パッド用補助板の中心周りで研磨パッド用補助板の外周縁部に沿って周方向に延びる形態であっても良いし、研磨パッド用補助板の外周部分に形成された係合凸部と係合凹部のように周上で部分的に位置する形態であっても良い。
【００２７】
本発明の第五の態様は、前記第四の態様に係る研磨パッド用補助板において、前記係合凸部および前記係合凹部における前記係合部が、前記下側補助板および前記上側補助板の周方向に連続して延びて相互に嵌め合わされる環状の係合外周面および係合内周面によって構成されているものである。
【００２８】
本態様の研磨パッド用補助板において、より好適には、研磨パッド用補助板の中心軸回りに広がる環状の係合内外周面をもって係合凹部と係合凸部が形成されることとなり、それによって、上側補助板の下側補助板への装着時に周方向での相互の位置合わせが必要なくなり、容易且つ速やかに作業することが可能となる。
【００２９】
本発明の第六の態様は、前記第四の態様に係る研磨パッド用補助板であって、前記下側補助板および前記上側補助板の外周部分における周上の複数箇所において、前記下側補助板と前記上側補助板との相互の重ね合わせ面の一方において他方に向かって開口する前記係合凹部と、該下側補助板と前記上側補助板との相互の重ね合わせ面の他方において一方に向かって突出する前記係合凸部とが、互いに対応する位置に形成されており、該係合凹部に対する該係合凸部の嵌まり込みによって前記係合部が構成されているものである。
【００３０】
本態様の研磨パッド用補助板では、上下補助板の相互の位置合わせを軸直角方向だけでなく中心軸回りの周方向でも容易に実現することが可能となる。
【００３１】
本発明の第七の態様は、前記第四の態様に係る研磨パッド用補助板において、前記下側補助板と前記上側補助板との一方の外周部分における周上の複数箇所から他方に向かって突出する前記係合凸部が弾性材によって形成されており、該下側補助板と前記上側補助板との他方における外周面に開口して設けられた前記係合凹部に対して該係合凸部の先端が係合されることにより前記係合部が構成されているものである。
【００３２】
本態様の研磨パッド用補助板では、上下補助板の外周面上に係合部を露出させて形成することが可能であり、それによって係合部の係合状態を目視等で容易に確認することが可能となる。また、本態様では、係合凸部の弾性を利用して係合部における係合状態が安定して保たれ得る。
【００３３】
本発明の第八の態様は、前記第三の態様に係る研磨パッド用補助板において、前記係合凸部および前記係合凹部が、前記下側補助板および前記上側補助板の中心軸上に設けられているものである。
【００３４】
本態様の研磨パッド用補助板では、上下補助板の中心軸上に係合凸部および係合凹部を

設けたことにより、一つの係合部によって上下補助板の中心軸合わせを行うことが可能になる。また、中心軸上に設けられた係合凸部と係合凹部の相互の位置合わせに際しては、上下補助板の周方向での相互の位置合わせが必要なく、それら係合凸部と係合凹部を容易に係合状態とすることも可能になる。

【００３５】

本発明の第九の態様は、前記第八の態様に係る研磨パッド用補助板において、前記係合凸部の外周面と前記係合凹部の内周面とにおいて互いに螺合するねじ溝が形成されており、前記位置決め手段を構成する該係合凸部と該係合凹部との螺合により前記第二の固着手段が構成されているものである。

【００３６】

本態様の研磨パッド用補助板では、位置決め手段により、上側補助板と下側補助板との固着力を得ることができる。それ故、かかる位置決め手段のみによって第二の固着手段を構成したり、第二の固着手段による上下補助板間の固着力を位置決め手段で補助的に構成することも可能となる。

【００３７】

本発明の第十の態様は、前記第三，四，五，六，八，九の何れかの態様に係る研磨パッド用補助板において、前記下側補助板と前記上側補助板との一方に設けられた前記係合凸部が、該下側補助板と該上側補助板との一方と同じ材質で形成されているものである。

【００３８】

本態様の研磨パッド用補助板では、上下で重ね合わされた補助板における研磨パッドの支持特性が、係合凸部の形成部分で局所的に大きく異なることを防止することが可能となる。それ故、パッド研磨加工に際して押圧力が研磨パッド表面に作用した際、かかる研磨パッドを支持している上下補助板における係合凸部や係合凹部の形成部位において、押圧反力や研磨パッド弾性などの特性が局部的に異なることに起因する研磨精度などの不具合を軽減乃至は回避することが可能になる。

【００３９】

さらに、本発明は、前記第一～十の何れかの態様に記載の本発明に係る研磨パッド用補助板が回転定盤の上面に装着されると共に、該回転定盤の外周側に隙間を隔てて保護部材が配設されており、該回転定盤および該研磨パッド用補助板の外周端面よりも内周側に位置して、前記位置決め手段が設けられている研磨装置も、特徴とする。

【発明の効果】

【００４０】

本発明に従う構造とされた研磨パッド用補助板を採用し、または本発明に従う構造とされた研磨装置を用いることによって、研磨パッドの損傷を防止しつつ、研磨パッドを回転定盤から容易に取り外したり装着したりすることが可能となるのであり、研磨パッドの装着に際しての回転定盤への位置合わせも容易に且つ精度良く行うことが可能となる。

【図面の簡単な説明】

【００４１】

【図１】本発明の第一の実施形態としての研磨パッド用補助板を装着した研磨装置の要部を示す縦断面図。

【図２】図１に示された研磨装置において研磨パッドを取り外した状態を示す縦断面の説明図。

【図３】本発明の第二の実施形態としての研磨パッド用補助板を装着した研磨装置の要部を示す縦断面図。

【図４】図３に示された研磨装置において研磨パッドを取り外した状態を示す縦断面の説明図。

【図５】本発明の第三の実施形態としての研磨パッド用補助板を装着した研磨装置の要部を示す縦断面図。

【図６】図５に示された研磨装置において研磨パッドを取り外した状態を示す縦断面の説明図。

【図７】本発明の第四の実施形態としての研磨パッド用補助板を装着した研磨装置の要部を示す縦断面図。
【図８】図７に示された研磨装置において研磨パッドを取り外した状態を示す縦断面の説明図。
【図９】本発明の第五の実施形態としての研磨パッド用補助板を装着した研磨装置の要部を示す縦断面図。
【図１０】図９に示された研磨パッド用補助板を構成する下側補助板の側面図。
【図１１】図１０に示された下側補助板の平面図。
【図１２】本発明の第六の実施形態としての研磨パッド用補助板を装着した研磨装置の要部を示す縦断面図。
【図１３】本発明の第七の実施形態としての研磨パッド用補助板を装着した研磨装置の要部を示す縦断面図。
【図１４】本発明の第八の実施形態としての研磨パッド用補助板を装着した研磨装置の要部を示す縦断面図。
【図１５】本発明の第九の実施形態としての研磨パッド用補助板を取り外した状態を示す縦断面の説明図。
【図１６】本発明の第十の実施形態としての研磨パッド用補助板を取り外した状態を示す縦断面の説明図。
【図１７】本発明の第十一の実施形態としての研磨パッド用補助板を取り外した状態を示す縦断面の説明図。
【図１８】本発明の第十二の実施形態としての研磨パッド用補助板を取り外した状態を示す縦断面の説明図。
【図１９】本発明の第十三の実施形態としての研磨パッド用補助板を取り外した状態を示す縦断面の説明図。
【図２０】本発明の第十四の実施形態としての研磨パッド用補助板を位置決めした状態を示す縦断面の説明図。
【図２１】本発明の第十五の実施形態としての研磨パッド用補助板を位置決めした状態を示す縦断面の説明図。
【図２２】本発明の第十六の実施形態としての研磨パッド用補助板を取り外した状態を示す縦断面の説明図。
【発明を実施するための形態】
【００４２】
以下、本発明の実施形態について、図面を参照しつつ説明する。先ず、図１～２には、本発明の第一の実施形態としての研磨パッド用補助板１０が示されている。この研磨パッド用補助板１０は、研磨装置１２の回転定盤１４に装着されて用いられ、回転定盤１４に対して研磨パッド１６を着脱可能に取り付けるようになっている。
【００４３】
研磨装置は、例えば特開２０１０－１４１１５５号公報等に記載されているように例えばＣＭＰ装置として用いられるものであって、基本構造は周知であるが要部を説明すると、先ず基礎ベース上に固定設置された装置本体によって鉛直方向に延びる回転軸が回転可能に支持されており、この回転軸の上端部に円盤形状の回転定盤１４が固設されている。かかる回転定盤１４は、水平方向に広がる平坦な上面１８を有しており、この上面１８が研磨パッド１６の支持面とされている。また、回転軸には、電気モータの回転出力軸が連結されており、電気モータの駆動力が伝達されることで回転軸ひいては回転定盤１４が中心軸回りに回転駆動されるようになっている。なお、研磨パッド１６を支持する上面１８の上方には、研磨用スラリを供給するノズルが配置されると共に、研磨対象（被研磨物）であるウェハ等を保持して回転させつつ研磨パッド１６に押し付けることで研磨加工を施す研磨ヘッドが配設されている。
【００４４】
このような研磨装置において、その回転定盤１４に装着された研磨パッド用補助板１０

は、下側補助板２０および上側補助板２２を含んでいる。そして、回転定盤１４の上面１８に対して、下側補助板２０が第一の固着手段２４で固着されており、更に、下側補助板２０の上面に対して、上側補助板２２が第二の固着手段２６で固着されている。即ち、下側補助板２０と上側補助板２２は、第二の固着手段２６を介して相互に重ね合わされて固着されることにより、全体として二層構造とされた研磨パッド用補助板１０を構成しており、第一の固着手段２４により回転定盤１４の上面１８に取り付けられている。

【００４５】

下側補助板２０および上側補助板２２は、何れも、薄肉の略円形平板形状とされており、平坦な表面（上面）と裏面（下面）を有している。これらの上下補助板２２，２０は、装着される研磨パッド１６よりも硬質材料であるものや、研磨パッド１６よりも部材剛性が大きいものが望ましい。使用方法にもよるが、後述するように下側補助板２０は回転定盤１４への取り付け後に着脱を繰り返さない使用も可能である一方、上側補助板２２は回転定盤１４への取り付け後に着脱を繰り返すことが予定されることから、少なくとも上側補助板２２は、研磨パッド１６よりも部材剛性が大きいものを採用することが望ましい。

【００４６】

尤も、上側補助板２２は、研磨パッド１６を支持せしめて、研磨装置１２による研磨加工の他、研磨パッド表面へのドレッシング、清掃、再溝入などの各種の処理に際して要求される強度や剛性、形状安定性及び精度を満足するものであれば良く、その材質や厚さ寸法は限定されるものでない。特に、下側補助板２０だけでなく上側補助板２２も、それ単体で、研磨パッド１６の支持強度や剛性等を負うものでなく、例えば研磨加工に際しては研磨装置１２の回転定盤１４の上に重ね合わされて使用されることで、回転定盤１４で下面を支持されるものであることから、単体での強度や剛性がそれ程迄に要求されるものでない。それ故、ステンレス鋼等の金属の他、合成樹脂や繊維強化樹脂等も、下側補助板２０や上側補助板２２の形成材料として採用され得る。特に、合成樹脂材は金属材に比して軽量で加工や取扱いが容易であり、例えばポリカーボネート等は、厚さ寸法精度の安定性や温度変化に対する低歪み特性にも優れているといった利点がある。

【００４７】

また、研磨パッド１６の全体に亘って安定した支持力を得るためには、上側補助板２２の外径寸法を研磨パッド１６の外径寸法の値以上に設定することが望ましく、且つ下側補助板２０の外径寸法を上側補助板２２の外径寸法の値以上に設定することが望ましく、更に下側補助板２０の外径寸法を回転定盤１２の外径寸法の値以下に設定することが望ましい。特に、図１，２に示されているように、下側補助板２０および上側補助板２２の外径寸法を略同じにすると共に、装着される回転定盤１４の外径寸法とも略同じとすることにより、研磨パッド１６の支持面積を十分に大きく確保することが可能になる。これにより、回転定盤１４と略同じ大きさの研磨パッド１６を、その全体に亘って略同じ支持力をもって回転定盤１４に装着することが可能となる。

【００４８】

更にまた、第一の固着手段２４および第二の固着手段２６としては、研磨に際して及ぼされる外力に対抗して、回転定盤１４の上面１８へ下側補助板２０および上側補助板２２を固着状態に保持し得るものであればよく、特に限定されるものでない。具体的には、接着剤や粘着剤、または基材シートの両面に接着剤や粘着剤が付着等された両面テープなどが、第一及び第二の固着手段２４，２６として採用され得るが、その他、負圧エア等を利用した負圧吸引や、永久磁石又は電磁石を利用した磁力吸引なども採用可能である。また、これらの接着剤等からなる固着手段は、下側補助板２０や上側補助板２２において平坦な重ね合わせ面の略全面に亘って略均一に固着力を及ぼすことが望ましく、それによって、大きな固着力を得ることが出来ると共に、研磨パッド用補助板１０の表面において研磨パッド１６の支持特性が局所的に異なる不具合等を回避できる。

【００４９】

例えば負圧吸引や電磁石では固着力をＯＮ／ＯＦＦできるが、接着剤等のように一定の固着力が及ぼされる場合には、第一の固着手段２４による回転定盤１４に対する下側補助

板２０の固着力に比して、第二の固着手段２６により下側補助板２０に対する上側補助板２２の固着力が小さくなるように設定されることが望ましい。これにより、上側補助板２２を下側補助板２０から引き剥がして取り外す際、下側補助板２０を回転定盤１４上に固着せしめたまま残置させておくことが容易に実現可能となる。このような固着力の相違の具体的な実現は、接着剤や粘着剤の材質など固着手段そのものを相互に異ならせる他、固着面積や固着面の状態（面粗さやプラズマ等の処理有無など）を相互に異ならせること等によっても実現可能である。

【００５０】

さらに、上側補助板２２の表面（上面）は研磨パッド支持面となっており、研磨パッド１６が重ね合わされて取り付けられている。かかる研磨パッド１６は、従来から公知の各種の研磨パッドを採用することが出来る。そして、この研磨パッド１６の裏面が、上側補助板２２の表面に対して、研磨パッド貼付用として従来公知の粘着テープや適当な接着剤等を利用して固着されている。

【００５１】

なお、研磨パッド１６の上側補助板２２への固着手段は前述の第二の固着手段２６よりも、大きな固着力を設定することが望ましい。これにより、研磨パッド１６が固着されたままの状態で上側補助板２２を下側補助板２０から取り外す際に、上側補助板２２が湾曲等しても研磨パッド１６が上側補助板２２から予期せずに剥がれることが効果的に防止され得る。

【００５２】

また、研磨パッド１６の外径寸法は、一般に規格値とされるが、多くの場合、装着される回転定盤１４の上面１８の外径寸法と同じか小さく設定される。

【００５３】

さらに、例えば回転定盤１４の上面１８と下側補助板２０との間、下側補助板２０と上側補助板２２との間、上側補助板２２と研磨パッド１６との間の少なくとも一つにおいて、適当なクッション層を設けても良い。このようなクッション層を設けることにより、研磨パッド１６による研磨加工に際して、被加工物に対する研磨効率の全面に亘る均一化を図ることが可能となる。

【００５４】

かかるクッション層としては、例えば発泡によってある程度の圧縮性が付与された樹脂シートや、エラストマーシート、ゴムシート等が好適に採用され得る。また、第一の固着手段２４や第二の固着手段２６、研磨パッド１６の上側補助板２２への固着手段によって、クッション層を構成することも可能である。なお、クッション層は、研磨パッド１６の支持面における局部的な歪を防止するために、研磨パッド１６の支持領域の略全体に亘る大きさをもって一定厚さで存在するように、形成されることが望ましい。

【００５５】

また、研磨パッド用補助板１０を構成する下側補助板２０と上側補助板２２との間には、相互に位置決めして中心軸を合わせる位置決め手段２８が設けられている。本実施形態では、下側補助板２０の外周部分に、下側補助板２０の中心軸回りで全周に亘って延びる円形の段差面３０が形成されている。そして、この段差面３０よりも外周側では下側補助板２０の厚さ寸法が小さくされることで、下側補助板２０の外周面に開放する切欠断面形状をもって周方向の全周に連続して延びる環状の係合凹部３２が、下側補助板２０に突出して一体形成されている。

【００５６】

一方、本実施形態では、上側補助板２２の外周部分には、上側補助板２２の中心軸回りで全周に亘って延びる円形の段差面３４が形成されている。そして、この段差面３４よりも外周側では上側補助板２２の厚さ寸法が大きくされることで、上側補助板２２の外周端縁に沿って周方向の全周に連続して延びる環状の係合凸部３６が、上側補助板２２に突出して一体形成されている。なお、係合凸部３６および係合凹部３２は、上下補助板２２，２０のどちらに形成されていても良い。

【００５７】
上述の下側補助板２０の段差面３０および係合凹部３２は、上側補助板２２の段差面３４および係合凸部３６に対して相互に位置合わせされており、本実施形態において係合外周面および係合内周面を構成している。そして、下側補助板２０に上側補助板２２が重ね合わされる際、係合凹部３２に係合凸部３６が嵌まり込み、段差面３０に段差面３４が径方向で重ね合わされ、係合部が形成される。これにより、係合凹部３２と係合凸部３６とによって位置決め手段２８が構成されており、中心軸が相互に一致させられて径方向で位置合わせされた状態で、下側補助板２０と上側補助板２２が重ね合わされるようになっている。なお、位置決め手段２８は、上下補助板２２，２０の外周面よりも内周側に位置して設けられ、それにより、上下補助板２２，２０、ひいては研磨装置１２が大型化しないようにしている。

【００５８】
このような構造とされた研磨パッド用補助板１０を備えた研磨装置１２にあっては、図１に示されているように、回転定盤１４の上面１８に上下の補助板２２，２０からなる研磨パッド用補助板１０を固着せしめて装着すると共に、上側補助板２２の上面に研磨パッド１６を固着支持せしめた状態で、回転定盤１４を回転駆動させて基板等の被加工物に対してＣＭＰ（化学機械研磨）を施すようにされる。そして、かかる研磨装置１２は、特定構造の研磨パッド用補助板１０を備えていることにより、以下の如き特別な技術的効果を発揮し得る。

【００５９】
先ず、図２に示されているように、研磨パッド１６を上側補助板２２の上面に固着させたままで、上側補助板２２を、第一の固着手段２４により回転定盤１４に固着された下側補助板２０から取り外すことにより、研磨パッド１６を回転定盤１４から取り外すことが出来る。そして、回転定盤１４から取り外して研磨パッド１６の表面（研磨面）をクリーニングや再加工等する場合でも、研磨パッド１６を上側補助板２２の上面に固着させたままで行うことが出来る。これにより、回転定盤１４に対する研磨パッド１６の着脱の際や、研磨パッド１６のクリーニングや再加工の際などは勿論、研磨パッド１６の移送時や保存時等においても、上側補助板２２による補強作用により研磨パッド１６の曲がりや損傷を防止できて、研磨パッド１６を良好な状態に保つことが出来る。

【００６０】
また、研磨パッド１６を上側補助板２２と共に回転定盤１４から取り外した際にも、回転定盤１４の上面１８には下側補助板２０が残置される。そして、研磨パッド１６を再び回転定盤１４に装着する際、上側補助板２２と下側補助板２０との間に設けられた位置決め手段２８により、上側補助板２２ひいては研磨パッド１６が下側補助板２０ひいては回転定盤１４に対して高精度に且つ容易に中心軸合わせされ得る。

【００６１】
ここにおいて、かかる位置決め手段２８を構成する係合凹部３２と係合凸部３６は、相互に嵌合された状態で殆ど隙間なく重ね合わされるようになっていることから、研磨パッド１６の支持特性への悪影響が防止され得る。また、上下補助板２２，２０の外周部分のうち特に本実施形態では外周端縁部に係合部、言い換えると位置決め手段２８が形成されており、研磨パッド１６において研磨用の主たる領域となる径方向中間部分を外れていることから、係合凹部３２と係合凸部３６の嵌合部分に多少の隙間があっても、研磨特性に大きな問題が発生する程の研磨パッド１６の支持特性への悪影響が回避され得る。

【００６２】
しかも、位置決め手段２８を構成する係合凹部３２と係合凸部３６は、上下補助板２２，２０の重ね合わせ面、換言すると、回転定盤１４および研磨パッド用補助板１０の外周端面よりも内周側に形成されており、上下補助板２２，２０の外周面上への突出が回避され得る。それ故、例えば図１，２に示されているように、研磨装置１２において回転定盤１４の外周側に近接して保護部材３８が設置されている場合でも、そのような保護部材３８への干渉を回避しつつ、位置決め手段２８を備えた上下補助板２２，２０を備えた研磨

装置１２が実現可能とされる。

【００６３】

さらに、上述のように研磨パッド１６の損傷を防止しつつ、正確な位置合わせ精度で速やかに研磨パッド１６を回転定盤１４に対して着脱することが出来る結果、研磨パッド１６の着脱等の作業のために高価な研磨設備の稼働時間が不必要に制限されることがなくなり、研磨設備の稼働効率の向上ひいては基板等の生産効率（研磨作業効率）の向上が達成され得る。

【００６４】

また、研磨パッド１６の回転定盤１４に対する着脱が容易に実現されることから、特別な熟練や知識がなくとも研磨パッド１６の再利用が実用レベルで実現可能となる。即ち、例えば、基板等の被研磨物の品種切り替え等に際して一旦回転定盤１４から外した研磨パッド１６を再利用したり、劣化対策として別の加工装置で表面溝入れ等の再加工するのに一旦回転定盤１４から取り外した研磨パッド１６を再加工後に再利用したりすることなども、実用化レベルで検討することが可能となるのである。

【００６５】

以上、本発明の第一の実施形態について説明してきたが、本発明の具体的構造はかかる第一の実施形態によって限定的に解釈されるものでない。上下補助板２２，２０間において別構造の位置決め手段を備えた、本発明の別の実施形態の複数を以下に例示するが、これらの実施形態も本発明の構成を限定的に示すものでない。なお、以下の実施形態において、第一の実施形態と同様な構造とされた部材および部位については、それぞれ、第一の実施形態と同一の符号を各図中の対応する部位に記載することにより、それらの詳細な説明を省略する。

【００６６】

図３～４には、本発明の第二の実施形態としての研磨パッド用補助板４０を備えた研磨装置４２が示されている。

【００６７】

この研磨パッド用補助板４０においては、下側補助板２０の上面の外周部分を周方向に連続して延びる円環形状の溝によって係合凹部４４が形成されている。一方、上側補助板２２の下面の外周部分には、周方向に連続して延びる円環形状の突起によって係合凸部４６が形成されている。この係合凸部４６は、上側補助板２２に一体形成されていても良いが、図示されているように、別体形成されていても良い。即ち、本実施形態では、上側補助板２２の下面に開口して周方向に延びる円環形状の周溝４８が形成されており、この周溝４８に対して、別体形成された円環形状のブロックが軸方向一端側で嵌め込まれて固着されることにより係合凸部４６が形成されている。

【００６８】

下側補助板２０の係合凹部４４と、上側補助板２２の係合凸部４６は、何れも中心軸回りで対応する径方向位置に形成されており、上下補助板２２，２０が重ね合わされた際、係合凹部４４に対して係合凸部４６が嵌め入れられることにより、上下補助板２２，２０が相互に径方向で位置合わせされるようになっている。なお、本実施形態では、下側補助板２０の係合凹部４４における両側壁面と、上側補助板の係合凸部４６における内外周面との、各対応する径方向の重ね合わせ面によって、二組の係合内周面および係合外周面が構成されている。

【００６９】

図５～６には、本発明の第三の実施形態としての研磨パッド用補助板５０を備えた研磨装置５２が示されている。

【００７０】

この研磨パッド用補助板５０においては、下側補助板２０の外周部分には、中心軸回りで全周に亘って延びる円形の係合内周面としての段差面５４が形成されている。そして、この段差面５４よりも外周側では下側補助板２０の厚さ寸法が大きくされることで、下側補助板２０の外周端縁に沿って周方向の全周に連続して延びる環状の係合凸部５６が、下

側補助板２０に一体形成されている。

【００７１】

一方、上側補助板２２の外周部分には、中心軸回りで全周に亘って延びる円形の係合外周面としての段差面５８が形成されている。そして、この段差面５８よりも外周側では上側補助板２２の厚さ寸法が小さくされることで、上側補助板２２の外周面に開放する切欠断面形状をもって周方向の全周に連続して延びる環状の係合凹部６０が、上側補助板２２に一体形成されている。

【００７２】

さらに、下側補助板２０の段差面５４には雌ねじが形成されている一方、上側補助板２２の段差面５８には雄ねじが形成されている。そして、下側補助板２０の段差面５４の雌ねじに対して上側補助板２２の段差面５８の雄ねじを螺合させて、下側補助板２０の段差面５４と上側補助板２２の段差面５８とを径方向に重ね合わせることにより、下側補助板２０の上面に上側補助板２２が重ね合わされるようになっている。また、かかる重ね合わせ状態下では、上下補助板２２，２０の段差面５８，５４の螺着構造により、上下補助板２２，２０を取り外し可能に固着する第二の固着手段６２が構成されている。

【００７３】

なお、このような螺着構造における雌雄ねじは、研磨装置１２の回転定盤１４に対して及ぼされる研磨時の回転反力を考慮して、ねじが緩まないようにねじ方向が設定されることが望ましい。

【００７４】

図７～８には、本発明の第四の実施形態としての研磨パッド用補助板６４を備えた研磨装置６６が示されている。

【００７５】

この研磨パッド用補助板６４においては、下側補助板２０の上面の中央部分で上方に向かって突出する円柱形状の係合凸部６８が形成されている。この係合凸部６８は、下側補助板２０に一体形成されていても良いが、図示されているように、別体形成されていても良い。即ち、本実施形態では、下側補助板２０の中心軸上に円形の嵌着凹所７０が形成されており、この嵌着凹所７０に対して、別体形成された円柱形状のブロックが軸方向一端側で嵌め込まれて固着されることにより係合凸部６８が形成されている。一方、上側補助板２２の下面の中央部分には、中心軸上で下面に開口する有底円形の係合凹部７２が形成されている。なお、係合凸部６８および係合凹部７２は上下補助板２２，２０のどちらに形成されていても良い。

【００７６】

そして、上下補助板２２，２０が重ね合わされた際、係合凹部７２に対して係合凸部６８が嵌め入れられることにより、上下補助板２２，２０が相互に径方向で位置合わせされるようになっている。なお、本実施形態では、下側補助板２０の係合凸部６８の外周面と上側補助板２２の係合凹部７２の内周面とによって、係合外周面と係合内周面とが構成されている。

【００７７】

図９には、本発明の第五の実施形態としての研磨パッド用補助板７４を備えた研磨装置７６が示されている。

【００７８】

この研磨パッド用補助板７４においては、下側補助板２０の上面の外周部分で上方に向かって突出する円柱形状の係合凸部７８が形成されている。この係合凸部７８は、下側補助板２０に一体形成されていても良いし、前記第四の実施形態における係合凸部のように下側補助板２０に嵌着凹所を形成して別体のピンなどを圧入等で固着しても良い。また、図１０～１１に示されているように、かかる係合凸部７８は、下側補助板２０の外周部分で周方向で所定距離を隔てて互いに独立して複数形成されている。特に好適には、周方向で等間隔に且つ中心軸上の同一円上に位置して、それら複数の係合凸部７８が形成される。

【００７９】
一方、上側補助板２２の下面の外周部分には、下側補助板２０における複数の係合凸部７８の形成位置に対して各対応する位置に、それぞれ、有底円形の係合凹部８０が下方に向かって開口して形成されている。なお、係合凸部７８および係合凹部８０は上下補助板２２，２０のどちらに形成されていても良い。
【００８０】
そして、上下補助板２２，２０が重ね合わされた際、係合凹部８０に対してそれぞれ係合凸部７８が嵌め入れられることにより、上下補助板２２，２０が相互に径方向で位置合わせされるようになっている。なお、本実施形態では、下側補助板２０の係合凸部７８の外周面と上側補助板２２の係合凹部８０の内周面とによって、下側補助板２０および上側補助板２２の外周部分に位置する係合外周面と係合内周面とが構成されている。
【００８１】
特に本実施形態のように、周方向で独立した複数の係合凸部７８と係合凹部８０とからなる位置決め手段を採用することにより、重ね合わされた上下補助板２２，２０を径方向だけでなく周方向においても相互に位置決めすることが可能となる。
【００８２】
なお、上側補助板２２に形成される独立した複数の係合凹部８０に代えて、上側補助板２２の中心軸回りで周方向に連続して円形に延びる周溝を採用したり、或いは図１２における本発明の第六の実施形態に示されているように、上側補助板２２の外周部分を中心軸回りで全周に亘って延びる円形の段差面８２を形成し、この段差面８２よりも外周側の厚さ寸法を小さくすることで、上側補助板２２の外周面に開放する切欠断面形状をもって周方向の全周に連続して延びる環状の係合凹部８３を形成することも可能である。
【００８３】
このように上側補助板２２において、下側補助板２０の係合凸部７８の係合面を全周に亘って連続して形成することにより、上下補助板２０，２２の重ね合わせに際して、上下補助板２０，２２を相互に周方向で位置合わせする必要がなくなって装着作業を容易に行うことが可能となる。
【００８４】
図１３には、本発明の第七の実施形態としての研磨パッド用補助板８４が示されている。
【００８５】
この研磨パッド用補助板８４においては、下側補助板２０の外周面の上側部分と、上側補助板２２の外周面の下側部分とに、それぞれ小径部が設けられている。そして、これら上下補助板２２，２０が重ね合わされることにより、それぞれの小径部によって、上下補助板２２，２０間に跨がって所定幅で広がって周方向の全周に亘って延びる円環形状の収容凹所８６が形成されている。
【００８６】
また、下側補助板２０の小径部下端には、溝状の係合凹部８８が形成されている。この係合凹部８８は、収容凹所８６の底面において、下側補助板２０の外周面に開口せしめられている。ここで、収容凹所８６の底面とは、収容凹所８６を構成する面のうち、上下補助板２２，２０に跨り、図１３の上下方向に広がる環状の面を指す。一方、収容凹所８６を構成する上側補助板２２の小径部には、弾性材からなる板状の係合凸部９０が、その基端部において固定ピン９２で固定されて取り付けられるている。この係合凸部９０は、上下補助板２２，２０の外周面に形成された収容凹所８６に収容配置されており、上側補助板２２から下側補助板２０の外周面上に延び出している。そして、係合凸部９０の先端部分に形成された係合爪部９４が、下側補助板２０の小径部に形成された係合凹部８８に対して係止され、係合凸部９０の弾性に基づいて係止状態に保持されるようになっている。
【００８７】
更にまた、このような係合凸部９０が、上下補助板２２，２０の外周面上で周方向に所定距離を隔てて複数設けられている。そして、上側補助板２２の外周面に取り付けられた

各係合凸部９０が、下側補助板２０の外周面に対して弾性的に押し付けられることで、上下補助板２２，２０が中心軸上で相互に位置決めする位置決め手段が構成されている。また、係合凸部９０の係合爪部９４が係合凹部８８に係止されることにより、上下補助板２２，２０を重ね合わせ状態に保持せしめて固着力を及ぼす固着手段も構成されている。

【００８８】

なお、上述の如き係合凹部８８に係合する係合爪部９４を備えた係合凸部９０に代えて、例えば図１４に示された本発明の第八の実施形態のように、上下補助板２２，２０間に跨がって延びて収容凹所８６の底面に重ね合わされる連結板１００を採用し、かかる連結板１００の両端部分を上下補助板２２，２０の各一方の外周面に対して連結ピン１０２，１０２で固着することも可能である。なお、連結ピン１０２，１０２の少なくとも一方は下側補助板２０又は上側補助板２２に対して着脱可能とされることにより、上下補助板２２，２０の連結板１００による連結が解除可能とされて、研磨パッド１６が固着された上側補助板２２の下側補助板２０に対する着脱が許容されることとなる。

【００８９】

また、第一～八の実施形態に示された両面テープ等からなる第一の固着手段２４や第二の固着手段２６は、上下補助板２２，２０や回転定盤１４を取り外す際に、特定の部材側の固着面に保持されることが望ましい。これにより、取り外した状態での上下補助板２２，２０や第一及び第二の固着手段２４，２６の取り扱いが容易となるからである。なお、第一及び第二の固着手段２４，２６が何れの固着面に残るかは、第一の固着手段や第二の固着手段２４，２６自体における両面の固着力を相互に異ならせる他、固着される上下補助板２２，２０や回転定盤１４の面粗度や材質等を相互に異ならせることなどによって設定することが可能である。

【００９０】

特に、第一の固着手段２４は、下側補助板２０を取り外す際に下側補助板２０側の固着面に保持されることが望ましく、それによって回転定盤１４の上面１８のメンテナンスが容易となる。一方、第二の固着手段２６は、第一の実施形態における図２に示されているように、上側補助板２２を取り外す際に上側補助板２２側の固着面に保持されるようになっていても良いし、例えば図１５に示す本発明の第九の実施形態のように、下側補助板２０の上面に残るようにしても良い。なお、第二の固着手段２６を上側補助板２２側の固着面に保持させることにより、研磨パッド１６の溝入れなどの再加工用装置の回転定盤に対して、取り外した上側補助板２２を装着する際に、上側補助板２２に保持された第二の固着手段２６を利用して取り付けることも可能となる。一方、第二の固着手段２６を下側補助板２０側の固着面に保持させることにより、別の研磨パッド１６を装着した別の上側補助板２２を下側補助板２０に装着する際に、下側補助板２０に保持された第二の固着手段２６を利用して取り付けることも可能となる。

【００９１】

また、第一～七の実施形態に示された係合凹部３２，４４，６０，７２，８０，（８３），８８と係合凸部３６，４６，５６，７０，７８，９０は、下側補助板２０側と上側補助板２２側とにおいて相互に反対側に設けられていても良い。例えば本発明の第十の実施形態が図１６に示されているように、第一の実施形態として図１～２に示された研磨パッド用補助板１０に対して、その係合外周面を構成する段差面３０と係合凹部３２とを上側補助板２２に形成する一方、係合内周面を構成する段差面３４と係合凸部３６とを下側補助板２０に形成することも可能である。

【００９２】

更にまた、第一～六の実施形態に示された係合凹部３２，４４，６０，７２，８０，（８３）と係合凸部３６，４６，５６，７０，７８において、相互に重ね合わされて上下補助板２２，２０を位置決めする係合凸部の外周面と係合凹部の内周面とに対して傾斜角を付すことも可能である。例えば本発明の第十一の実施形態が図１７に示されているように、下側補助板２０の外周部分に突出形成した係合凸部３６の係合内周面としての段差面３４に対して、係合凸部３６が突出方向で次第に先細となる傾斜方向のテーパを付す一方、

上側補助板２２の外周部分に形成した係合凹部３２の係合外周面としての段差面３０に対して、段差面３４に対応する傾斜方向および傾斜角度のテーパを付すことができる。これにより、係合凸部３６を係合凹部３２に嵌め入れて上下補助板２２，２０を重ね合わせる作業を、両段差面３４，３０に付されたテーパを案内面として利用することで、一層容易に行うことが可能となる。

【００９３】

因みに、図１８に記載の本発明の第十二の実施形態や、図１９に記載の本発明の第十三の実施形態に示されているように、下側補助板２０の周方向で独立して複数形成される突起形状の係合凸部７８と、上側補助板２２の各対応する位置に形成される複数の穴形状の係合凹部８０とを採用する場合でも、係合凸部７８の突出先端部分の外周面に対して傾斜角を付して、先細形状のテーパ部１０４を形成することができる。なお、図１９では、下側補助板２０に形成された嵌着穴１０５に対して、別体形成された係止ピン１０６が圧入等で固着されて係合凸部７８が構成されており、かかる係止ピン１０６の下端にも、上端と同様なテーパ部１０４が付されている。これにより、係止ピン１０６に方向性が無くなって取り扱いが容易となると共に、嵌着穴１０５への圧入作業も容易となる。

【００９４】

また、図２０に示された本発明の第十四の実施形態では、上下補助板２２，２０の重ね合わせ状態で中心軸を合わせる位置決め手段の一種として、それら上下補助板２２，２０間に跨がって外挿される位置決めスリーブ１０８が示されている。この位置決めスリーブ１０８は、互いに略同じ外径寸法の円板形状とされた上下補助板２２，２０の外径寸法と同じか僅かに大きな内径寸法を有しており、金属材や合成樹脂材によって形成されている。このような位置決めスリーブ１０８を、上下補助板２２，２０の重ね合わせに際して用いて、位置決めスリーブ１０８内で上下補助板２２，２０を重ね合わせるとにより、上下補助板２２，２０を中心軸合わせしつつ軸方向に重ね合わせて、第二の固着手段２６で相互に固着することができる。それ故、上下補助板２２，２０を重ね合わせて相互に固着せしめた後で、位置決めスリーブ１０８を取り外すことが出来るのであり、それによって、上下補助板２２，２０を、外周面上に突出する位置決め手段を有しない状態で且つ正確な位置合わせ状態で相互に固着することが可能となる。

【００９５】

更にまた、図２１に示された本発明の第十五の実施形態では、上下補助板２２，２０の重ね合わせ状態で重ね合わせ方向に跨がって延びるスリット状の係合溝１１０が形成されている。この係合溝１１０は、上下補助板２２，２０の外周面に開口して径方向内方に所定深さを有しており、上下補助板２２，２０の周方向で互いに独立して複数設けられている。そして、かかる係合溝１１０に対して、外周面の開口部からプレート形状の係合板１１２が嵌め入れられることにより、かかる係合板１１２で上下補助板２２，２０が相互に位置決めされると共に、相互に連結状態とされている。なお、かかる係合板１１２は、上下補助板２２，２０と別体形成されているが、例えば上下補助板２２，２０の何れか一方において他方に向かって突出する形状をもって一体形成されていても良い。その場合には、係合溝１１０は、当該他方の補助板にだけ形成されることとなる。

【００９６】

さらに、図２２に示された本発明の第十六の実施形態では、上側補助板２２の下面に開口する係合凹部としての嵌合凹部１１４が形成されている。特に本実施形態では、かかる嵌合凹部１１４が、上側補助板２２の中心軸回りで周方向に連続して延びる環状溝として形成されている。一方、下側補助板２０には、上側補助板２２に重ね合わされる上面において上方に突出する係合凸部としての嵌合凸部１１６が形成されている。なお、本実施形態では、かかる嵌合凸部１１６が、嵌合凹部１１４に対応する環状凸部として形成されている。そして、上下補助板２２，２０の重ね合わせ状態で、嵌合凸部１１６が嵌合凹部１１４に入り込んで位置せしめられるようになっている。

【００９７】

また、嵌合凸部１１６は中空構造とされており、嵌合凸部１１６の内部において外部空

間に対して密閉された流体溜１１８が形成されている。更に、この流体溜１１８を画成する嵌合凸部１１６の壁部は、少なくとも内周壁と外周壁が径方向に向かって膨出変形可能にされている。具体的には、例えば嵌合凸部１１６をゴム弾性体などで形成することによって、径方向内方に膨出可能な内周壁と径方向外方に膨出可能な外周壁とが実現可能である。

【００９８】

更にまた、下側補助板２２には、流体溜１１８に連通して、径方向外方に延び出し外周面に開口する流体通路１２０が形成されていると共に、この流体通路１２０の外周端開口部に加圧ねじ１２２がねじ込まれている。また、加圧ねじ１２２で封止された流体通路１２０と流体溜１１８からなる密閉領域には、オイルなどの非圧縮性流体が充填されている。

【００９９】

これにより、加圧ねじ１２２をねじ込むことにより、流体通路１２０を通じて流体溜１１８の内圧を上昇させて、流体溜１１８の内周壁および外周壁を外方に膨出させることが出来る。その結果、嵌合凸部１１６が拡張されて、嵌合凹部１１４の内面に押し付けられ、相互の摩擦力等によって上下補助板２２，２０を相互に位置決めすると共に固着力も及ぼし得るようになっている。

【０１００】

なお、上側補助板２２を下側補助板２０から取り外すに際しては、加圧ねじ１２２を緩ませる方向に回転操作して下側補助板２０の外周側に移動させることにより、流体溜１１８の圧力を低下させて嵌合凸部１１６の嵌合凹部１１４への押し付け力を解除することができる。

【０１０１】

その他、一々列挙はしないが、本発明は当業者の知識に基づいて種々なる変更，修正，改良などを加えて実施することが可能であり、例えば、係合凸部と係合凹部の係合部分にＯリングやシール材を装着して上下補助板の重ね合わせ面等への異物の侵入を防止することも可能である。

【０１０２】

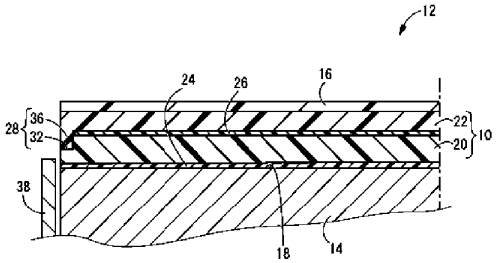
また、上述の二層構造の補助板２０，２２に加えて、更に補助板を積層状態で且つ固着手段で固着せしめて追加することも可能である。このように第三層の補助板を採用することで、弾性支持状態を実現したり、或いは中間層を使い捨てする等の態様も可能となる。

【符号の説明】

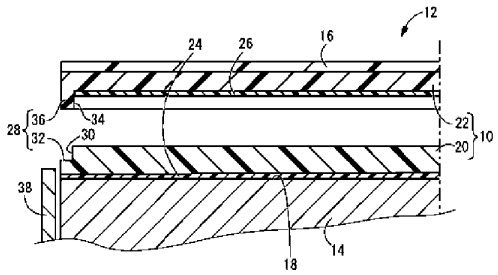
【０１０３】

１０，４０，５０，６４，７４，８４：研磨パッド用補助板、１２，４２，５２，６６，７６：研磨装置、１４：回転定盤、１６：研磨パッド、１８：上面、２０：下側補助板、２２：上側補助板、２４：第一の固着手段、２６，６２：第二の固着手段、２８：位置決め手段、３０，５８：段差面（係合外周面）、３２，４４，６０，７２，８０，８８：係合凹部、３４，５４：段差面（係合内周面）、３６，４６，５６，６８，７８，９０：係合凸部、３８：保護部材

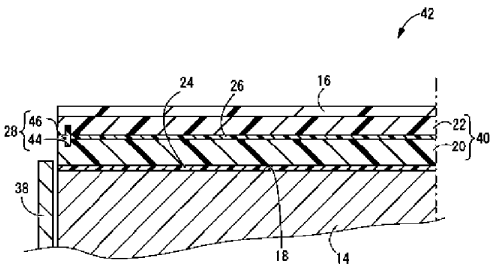
【図１】



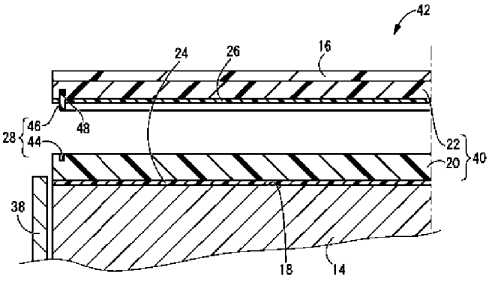
【図２】



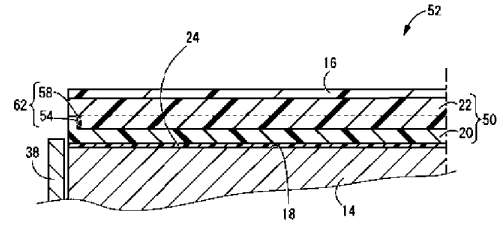
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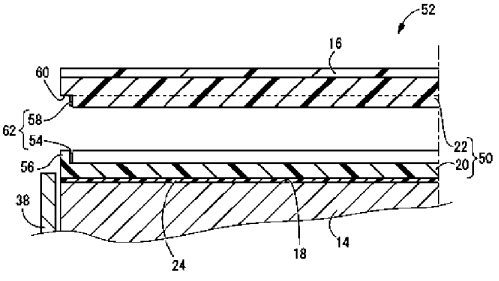
【図４】



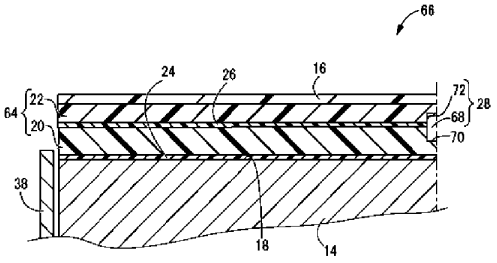
【図５】



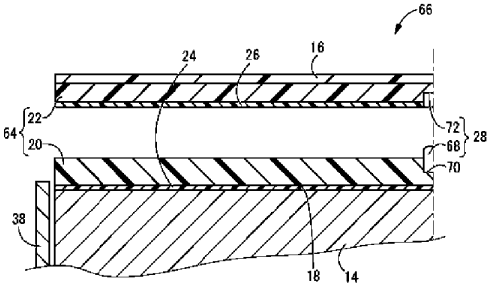
【図６】



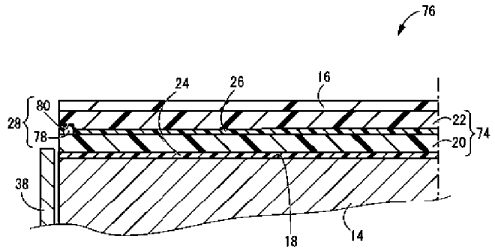
【図７】



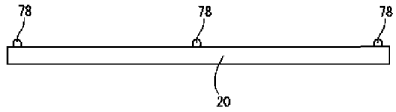
【図８】



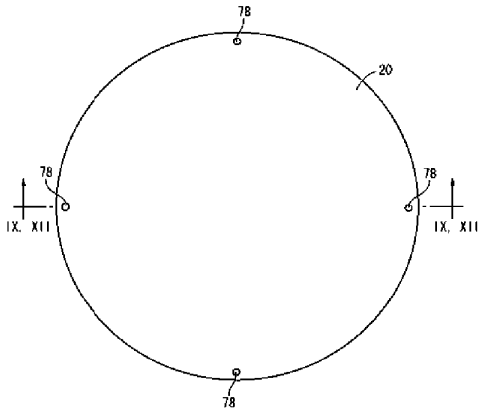
【図９】



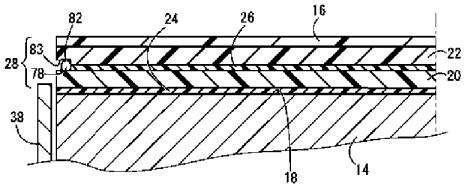
【図１０】



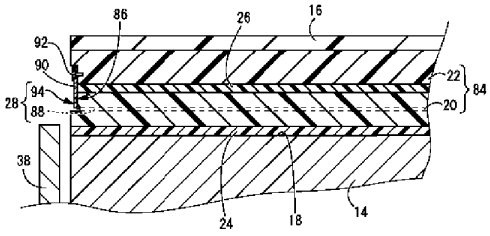
【図１１】



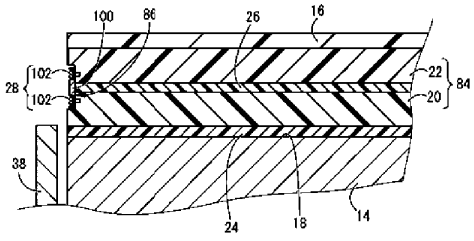
【図１２】



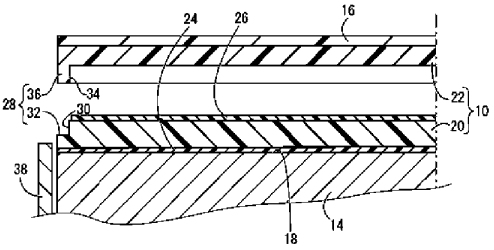
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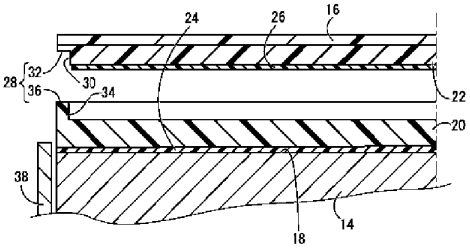
【図１４】



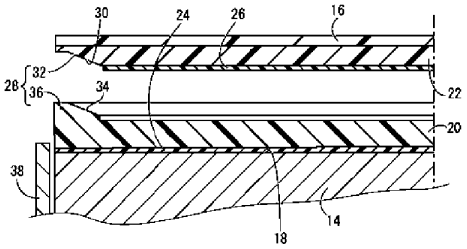
【図１５】



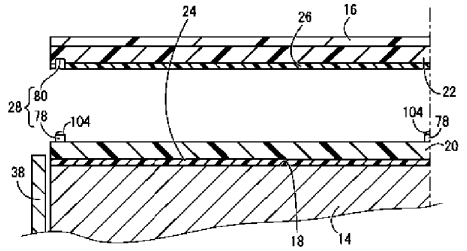
【図１６】



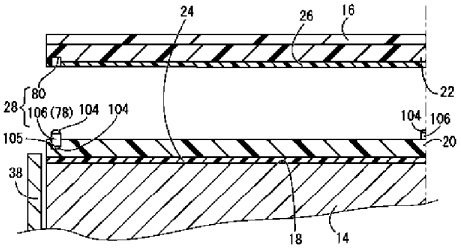
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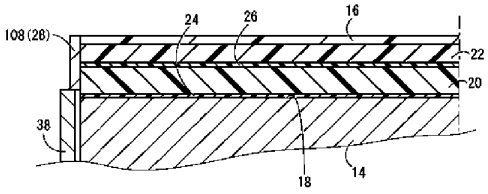
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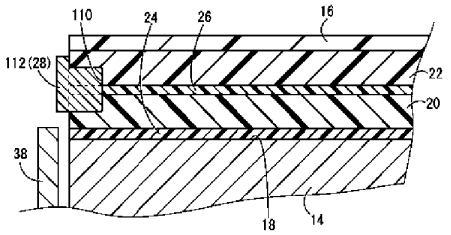
【図１９】



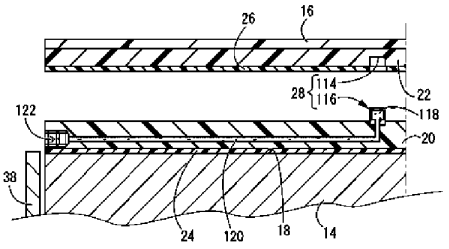
【図２０】



【図２１】



【図２２】



フロントページの続き

(56)参考文献 特開平０８－１１８２３１（ＪＰ，Ａ）
特開平０７－３２８９１５（ＪＰ，Ａ）

(58)調査した分野(Int.Cl.，ＤＢ名)
Ｂ２４Ｂ　３７／１２
Ｈ０１Ｌ　２１／３０４

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Application No.	Ref.	Date
22 181 212.6 - 1122	KUR-19212-P-EP	28.09.2023
Applicant: Kurin, Inc.		

Communication pursuant to Article 94(3) EPC

The examination of the above-identified application has revealed that it does not meet the requirements of the European Patent Convention for the reasons enclosed herewith. If the deficiencies indicated are not rectified the application may be refused pursuant to Article 97(2) EPC.

You are invited to file your observations and in sofar as the deficiencies are such as to be rectifiable, to correct the indicated deficiencies within a period

of 4 months

from the notification of this communication, this period being computed in accordance with Rules 126(2) and 131(2) and (4) EPC. One set of amendments to the description, claims and drawings is to be filed within the said period on separate sheets (R. 50(1) EPC).

If filing amendments, you must identify them and indicate the basis for them in the application as filed. Failure to meet either requirement may lead to a communication from the Examining Division requesting that you correct this deficiency (R. 137(4) EPC).

In case you withdraw the application within the above-mentioned period, the examination fee will be refunded at a rate of 50% (Art. 11(b) RFees).

Failure to comply with this invitation in due time will result in the application being deemed to be withdrawn (Art. 94(4) EPC).

Registered Letter

Nielsen, Michael
Primary Examiner
For the Examining Division

Enclosure(s): 3 page/s reasons (EPO Form 2906)

The examination is being carried out on the **following application documents**

Description, Pages

1, 2, 4-46	as originally filed	
3, 3a, 3b	filed in electronic form on	19-05-2023

Claims, Numbers

1-8	filed in electronic form on	19-05-2023

Drawings, Sheets

1/69-69/69	as originally filed

1). The applicants arguments with regard to neither of the documents cited hinting to "a chamber connected with the inlet port and the outlet port, and configured to collect a first portion of the blood sample, **the chamber including a material that is air permeable and blood impermeable**" are agreed upon.

Applicants arguments with regard support for the claims on file, their novelty and inventiveness are likewise agreed upon.

Therefore:

2). The applicant should **bring the description into conformity** with the claims of the present divisional application (Article 84 EPC). In particular should features that are present in the independent claim not be referred to as options in the form of e.g. "in some instances", "in some embodiments", "in a preferred embodiment", "in one implementation" and so forth, but be clearly identified as forming part of the invention. T**his applies to the description as a whole**, not only to the introductory part. The "Summary of The Invention" should likewise be amended, i.e. **recitation of superseded claims and subject-matter be removed or adapted** to the wording of the claims on file.

Anything referred to as "**embodiment**" or "**implementation**" and which is not covered by the claims on file should be **excised or clearly referred to as examples not covered by the invention**. This throughout the description and drawings.

- The technical field of the invention (Rule 42(1)(a) EPC; Guidelines F-II.4.2) must correspond to the amended set of claims.

- The summary of the invention (Rule 42(1)(c) EPC; Guidelines F-II.4.5) must correspond to the amended set of claims. Where appropriate, statements such as "The invention is set out in the appended set of claims" or "The invention is as defined in claim X" may be used instead of repeating the claims verbatim.
- **Embodiments which are no longer covered by the claims must be** deleted, unless they can reasonably be considered to be useful for highlighting specific aspects of the amended subject-matter. If this is the case, they must be clearly marked as not being part of the present invention (T 1808/06 and Guidelines F-IV, 4.3)]:
  - Any combinations of features which do not fall under the scope of the amended independent claims must be clearly marked as not being part of the present invention.
  - Statements such as "The following examples/aspects/embodiments X, Y, Z are not according to the invention and are present for illustration purposes only" may be used **at the start of the description or in the list of figures**.
- The technical features of the independent claims may not be presented as optional in the description. Where they precede a feature of an independent claim, terms such as "for example", "may", "can", "exemplary", "optionally", "preferably" and the like must be removed.
- The **"claim-like" clauses** in paragraphs [0014] to [0023] and at pages 43 to 46 **must be deleted prior to grant**. Claim-like clauses are clauses present in the description which use claim language such as "according to the preceding clause" or "characterised in that" (Guidelines F-IV, 4.4). Claim-like clauses include examples, embodiments or aspects which are presented as claim-like clauses. The simple conversion of these clauses into separate optional features will not be admitted either.

3). The unit inches expressed in paragraphs [0099], [00115] and [00156] does not meet the requirements of Rule 49(10) EPC and should be replaced by the appropriate SI unit (see Guidelines F-II, Annex, 2). The present expression should, however, be retained in parentheses after the replacement expression.

4). Care should be taken during revision, especially of the introductory portion and any statements of problem or advantage, not to add subject-matter which extends beyond the content of the application as originally filed (Articles 76(1) and 123(2) EPC).

5). Any information the applicant may wish to submit concerning the subject-matter of the invention, for example further details of its advantages or of the problem it solves, and for which there is no basis in the application as filed, should be confined to the letter of reply and not be incorporated into the application (Articles 76(1) and 123(2) EPC and the Guidelines H-V, 2.2 to 2.5).

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REGISTRY OF MEDICAL TECHNOLOGISTS
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THE STANDARD CLOTTING TIME

A METHOD BASED ON THE USE OF WHOLE VENOUS BLOOD IN CAPILLARY TUBES

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In 1955, Mayer[1] described a method for testing the coagulation time of whole blood that was later referred to as the *standard clotting time*.[2] The method was reported to be reliable and to reveal a rather narrow range of normal values, as compared with the more widely used Lee-White technic for clotting time, and with the now almost abandoned capillary method for clotting time. In the course of investigating possible clotting abnormalities in patients with prostatic cancer,[5] we re-evaluated the method, particularly because its claimed normal range of 11.9 ± 0.9 min. was based merely on values obtained from 40 healthy, fasting men, in the age group of 25 to 35 years.

MATERIALS AND METHODS

Because Mayer's procedure as outlined in 1957 was followed in detail,[2] it will not be described fully. It is necessary to note, however, that the No. 19 gage stainless steel needle was replaced by the Becton, Dickinson and Company No. 20 sterile disposable needle. With this method, venous blood is drawn and diverted by a special adapter to 3 capillary tubes, which are maintained at a temperature of 21 C. in a water bath. The end point is obtained by means of breaking off each capillary tube in succession and observing a fibrin clot. The average value determined from the 3 tubes represents the standard clotting time. It differs considerably from the ordinarily performed capillary clotting time because of the use of venous blood, with minimal admixture of tissue thromboplastin, and because the temperature is controlled. The test is readily performed by 1 technologist, and it is possible to examine 2 patients at the same time. Although it is of necessity performed at the bedside and requires minutes rather than seconds, the total time of performance is comparable to that of other coagulation tests if preparation of blood samples and reagents is considered. The following groups of persons, who were generally in a postprandial state, were examined:

1. Fifty-three women in the age group of 17 to 60 years.
2. Fifteen healthy men, 25 to 50 years of age.
3. Thirty healthy employees in the age group of 60 to 80 years, to serve as controls for patients with prostatic cancer.
4. Twenty-two men with cancer of the prostate gland, in the age group of 60 to 80 years.
5. Twelve persons on 2 different occasions, 1 to 12 months apart, in order to determine the standard deviation of the test.
6. Thirty-six outpatients maintained on anticoagulants (Coumadin) over a period of 1 year, for comparison of the standard clotting time with Quick's 1-stage prothrombin time.[4]
7. Twenty-five persons with miscellaneous cases who were investigated because of a history of a suspected bleeding tendency, for comparison with the clotting time (Lee-White) for whole blood, and a battery of other screening tests for blood coagulation.[4]

Received, July 2, 1962; revision received, September 14; accepted for publication November 14.

Dr. Meissner is Associate Pathologist at the Rhode Island Hospital, and Assistant Professor at Tufts University Medical School. Mrs. Moehring is Medical Technologist at the Rhode Island Hospital.

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RESULTS

1. Fifty-three healthy women (17 to 60 years) manifested a normal value of 11.2, with a standard deviation from the mean of ±1.1 min.

2. Fifteen healthy men (25 to 50 years) manifested normal values of 11.1 ± 1.1 min.

3. Thirty healthy male employees (60 to 80 years of age), with 42 determinations manifested normal values of 10.1 ± 1.3 min.

4. Twenty-two men (44 determinations) with cancer of the prostate gland manifested an average value of 10.5 ± 1.5 min. These men were also in the age group of 60 to 80 years.

5. Twelve controls taken on 2 different occasions (1 to 12 months apart) revealed a standard deviation from the mean of ±1.0 min.

6. One hundred thirty-nine determinations of the standard clotting time and also the prothrombin time on 36 patients being treated with anticoagulants revealed a poor correlation between these 2 tests. For the prothrombin activity in the so-called therapeutic range of from 20 to 30 per cent, the values in the standard clotting time ranged from 10.2 to 21.0 min. (Fig. 1). Prothrombin activity of less than 20 per cent revealed a range in the standard clotting time of 11.5 to 23.5 min.; values of prothrombin activity of more than 30 per cent manifested in the standard clotting time a range of 10.5 to 18.4 min. If, conversely, the therapeutic range of the standard clotting time is considered, which, according to Mayer and Connell[3] is between 15 and 20 min., the corresponding prothrombin activities revealed a range of 16 to 49 per cent (Fig. 1); taking values of the standard clotting time of less than 15 min., the range of the corresponding prothrombin activity varied from 15 to 70 per cent, and similarly, in values above 20 min., the variation of prothrombin activity was between 15 and 24 per cent.

7. Comparison of the standard clotting time with the clotting time for whole blood, and other screening tests, revealed that the standard clotting time was within the normal range whenever the clotting time for whole blood (Lee-White) was less than 20 min., with the following exceptions: 3 instances of patients treated with salicylates in whom the clotting time for whole blood was normal and the standard clotting time moderately prolonged (less than 20 min.); 3 other persons with a history of minor bleeding dif-

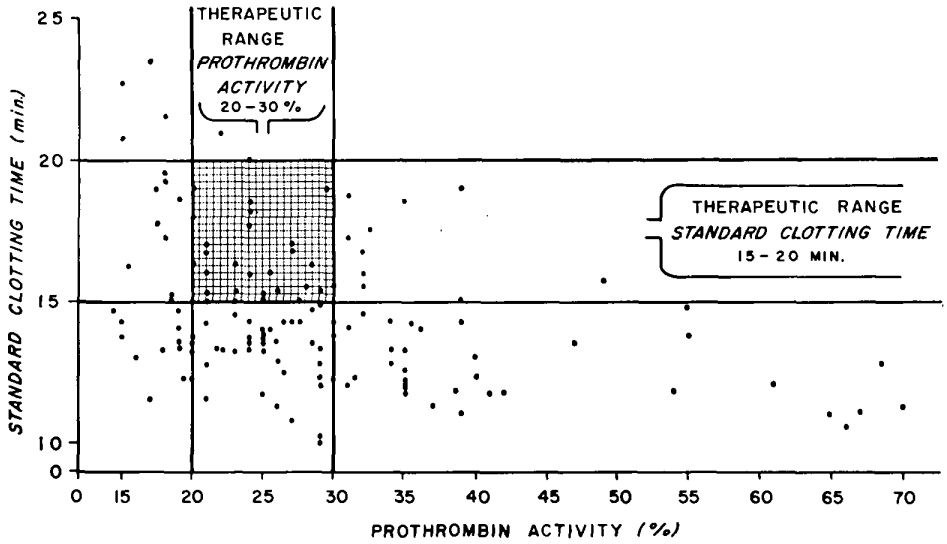


FIG. 1. A scattergram of the standard clotting time (min.) and prothrombin activity (per cent) of 139 determinations on 36 patients being treated with anticoagulants. Except for the *cross-hatched area*, there is no consistent correlation between the 2 tests.

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ficulty in whom the standard clotting time revealed a slight prolongation, in the range of from 15 to 20 min., whereas tests for other phases in blood coagulation, including the thromboplastin generation test, were normal. In addition, a patient with hemophilia A manifested a great prolongation of the standard clotting time, as well as the clotting time of the whole blood. There were 2 patients in whom, for unexplained reasons, the clotting time was less than normal, 9:00 and 7:33 min. One of these, a 34-year-old woman, had pulmonary coccidioidomycosis with multiple segmental pulmonary resections; her only other abnormality was a slightly positive tourniquet and petechiometer test. The other person, a 68-year-old man, is a patient with probable cirrhosis of the liver.

COMMENTS

We have found the standard clotting time a reliable and reproducible test for coagulation of whole blood. The normal range of values corresponds well with the figures reported by Mayer and Connell, except in the older age group, for whom the values are slightly less (approximately 1 min.).

The observation made by Mayer and Connell that there is poor correlation between the standard clotting time and the 1-stage prothrombin time is confirmed. The controversy[7] concerning which of the 2 tests more adequately represents a response to anticoagulation therapy is not resolved by our study; its resolution would require a very close clinical follow-up over a long period of time, which is not feasible for a study based on outpatients. According to Rapaport and Ames,[6] a Factor IX deficiency that is not measured by the prothrombin time does not seem to be the explanation. The standard clotting time may prove valuable whenever a discrepancy is encountered between 1 type of test, such as the 1-stage prothrombin time, and the clinical manifestations in anticoagulated patients. We also found that it may be a helpful procedure in evaluating a "borderline" prolonged clotting time, although it is by no means a substitute for detailed investigation of the patient with a history of definite bleeding. We have not determined whether or not values lower than normal (excluding faulty venipuncture) indicate a state of hypercoagulability. The greatest value of the test results from the fact that the normal range is rather narrow, as stated by Mayer and Connell.

SUMMARY

A re-evaluation of the standard clotting time, using several control groups, demonstrates that it is a reproducible test for coagulation of whole blood. It may be regarded as an additional useful test in the evaluation of an abnormal clotting time for whole blood, of patients with bleeding problems, and of patients being treated with anticoagulants.

SUMMARIO IN INTERLINGUA

Un re-evaluation del tempore standard de coagulation, utilisante plure gruppos de controlo, demonstra que illo es un reproducibile test pro le coagulation de sanguine total. Illo pote esser reguardate como un test additional de utilitate in le evalutation de anormal tempores de coagulation in sanguines total ab patientes con problemas hemorrhagic e ab patientes sub tractamento con anticoagulantes.

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27500 7590 09/17/2024

PILLSBURY WINTHROP SHAW PITTMAN LLP (CV)
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EXAMINER	
NGUYEN, HUONG Q	

ART UNIT	PAPER NUMBER
3791	

NOTIFICATION DATE	DELIVERY MODE
09/17/2024	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Docket_IP@pillsburylaw.com

Office Action Summary	Application No. 17/893,079	Applicant(s) ROGERS et al.	
	Examiner Huong Q NGUYEN	Art Unit 3791	AIA (FITF) Status Yes

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☑ Responsive to communication(s) filed on 01/19/2024.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☐ This action is **FINAL.** 2b) ☑ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5) ☑ Claim(s) 1-4,6-7 and 32-41 is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6) ☐ Claim(s) _____ is/are allowed.

7) ☑ Claim(s) 1-4,6-7 and 32-41 is/are rejected.

8) ☐ Claim(s) _____ is/are objected to.

9) ☐ Claim(s) _____ are subject to restriction and/or election requirement

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to **PPHfeedback@uspto.gov.**

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☑ The drawing(s) filed on 8/22/02022 is/are: a)☐ accepted or b)☑ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a)☐ All b)☐ Some** c)☐ None of the:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☑ Notice of References Cited (PTO-892)

2) ☑ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date _____.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____.

4) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/19/2024 has been entered.

Claims 1-4, 6-7, and 32-41 remain pending and under prosecution.

Notice of Pre-AIA or AIA Status

The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "junction" in **Claims 3-4 and 40-41** must be shown *with element numbers* or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing

should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Interpretation

The following is a quotation of 35 U.S.C. 112(f):

> (f) Element in Claim for a Combination. – An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

The following is a quotation of pre-AIA 35 U.S.C. 112, sixth paragraph:

> An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

The claims in this application are given their broadest reasonable interpretation using the plain meaning of the claim language in light of the specification as it would be understood by one of ordinary skill in the art. The broadest reasonable interpretation of a claim element

(also commonly referred to as a claim limitation) is limited by the description in the specification when 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, is invoked.

As explained in MPEP § 2181, subsection I, claim limitations that meet the following three-prong test will be interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph:

(A) the claim limitation uses the term "means" or "step" or a term used as a substitute for "means" that is a generic placeholder (also called a nonce term or a non-structural term having no specific structural meaning) for performing the claimed function;

(B) the term "means" or "step" or the generic placeholder is modified by functional language, typically, but not always linked by the transition word "for" (e.g., "means for") or another linking word or phrase, such as "configured to" or "so that"; and

(C) the term "means" or "step" or the generic placeholder is not modified by sufficient structure, material, or acts for performing the claimed function.

Use of the word "means" (or "step") in a claim with functional language creates a rebuttable presumption that the claim limitation is to be treated in accordance with 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph. The presumption that the claim limitation is interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, is rebutted when the claim limitation recites sufficient structure, material, or acts to entirely perform the recited function.

Absence of the word "means" (or "step") in a claim creates a rebuttable presumption that the claim limitation is not to be treated in accordance with 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph. The presumption that the claim limitation is not interpreted under

35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, is rebutted when the claim limitation recites function without reciting sufficient structure, material or acts to entirely perform the recited function.

Claim limitations in this application that use the word "means" (or "step") are being interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, except as otherwise indicated in an Office action. Conversely, claim limitations in this application that do not use the word "means" (or "step") are not being interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, except as otherwise indicated in an Office action.

No elements are interpreted under 112(f).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112(a):

> (a) IN GENERAL.—The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention.

The following is a quotation of the first paragraph of pre-AIA 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3-4 and 40-41 are rejected under 35 U.S.C. 112(a) or 35 U.S.C. 112 (pre-AIA), first paragraph, as failing to comply with the written description requirement. The claim(s) contains

subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor or a joint inventor, or for applications subject to pre-AIA 35 U.S.C. 112, the inventor(s), at the time the application was filed, had possession of the claimed invention.

The above claims recite a junction connecting the inlet port, sampling channel, and the chamber. However, as the instant invention appears to be drawn to the embodiment in Figure 24 and said junction has not been identified in Figure 24 per the drawing objection above, it is unclear that applicant has proper support for the embodiment of Figure 24 with the moving part having a first and second position along with said junction as claimed. If support exists for said junction, applicant is requested to point out portions of the disclosure showing said support.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a)(1) the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention.

Claim(s) 1-4, 6-7, 32, 34-38, and 40-41 is/are rejected under 35 U.S.C. 102(a)(1) as being anticipated by Percarpio (US Pat No. 4106497 – cited by applicant).

In regard to Claim 1, Percarpio discloses a device comprising:

an inlet port (corresponding to location of needle 22) for receiving a blood sample, best seen in Figure 3 (Col.2: 58-Col.3: 23);

an outlet port 42, 44 (central passageway, opening -- Col.2: 58-Col.3: 23) – Figure 3;

a chamber (one channel) 92 connected with the inlet port and the outlet port, and configured to collect a first portion of the blood sample ("by capturing the blood within the indicator area including channels 92, there is no danger of contamination of blood being collected into chamber 32 and ultimately into an evacuated container through the passageway interconnected with rear needle 50" – Col.4: 16-39) – Figure 3,

the chamber including a material 90 that is air permeable (due to vents) and blood impermeable ("film of water expansible material 90… Three spaced channels 92 are formed in the film to provide air passageways for facilitating venting of the assembly and flow of blood into the indicator area where film 90 is located. The number of channels is a matter of choice. Thereafter, expansion of the film due to contact with the liquid closes channels 92 and locks the blood into the area of the location of the film" – Col.4: 16-39) – Figure 3;

a sampling channel 28 (extends through valve 78) connected with the inlet port and configured to convey a subsequent portion of the blood sample to the outlet port while bypassing the chamber – after blood is collected in channel 92 and the water expansible material forming the from expands to close channel 92 and stops the blood flow to channel 92, tube 94 is then advanced in holder 62 until the pointed end 54 of needle 50 pierces the stopper 96 and enters the evacuated tube…The difference in pressure caused by the vacuum within tube 94 causes the flaps of check valve 82 and 84 to separate permitting flow of blood through

the check valve 78 and through passageway 42 and communicating needle 50 into the evacuated tube 94 for blood collection purposes (Col.5: 1-47), best seen in Figure 4; and

a housing (defined by hub 26 and adapter 40) that fully encloses the inlet port, the outlet port, the chamber, and the sampling channel, best seen in Figure 3.

2. (Previously Presented) The device in accordance with claim 1, wherein the material is configured to seal upon contact with the first portion of the blood sample (Col.4: 16-39; Col.5: 1-47).

3. (Previously Presented) The device in accordance with claim 1, further comprising a junction 32 connecting the inlet port (corresponding to location of needle 22) and the sampling channel 28 and the chamber 92, best seen in Figure 3.

4. (Previously Presented) The device in accordance with claim 3, wherein the junction 32 is configured to convey the subsequent portion of the blood sample to the outlet port 42, 44 while bypassing the chamber 92 (Col.4: 16-39; Col.5: 1-47).

6. (Previously Presented) The device in accordance with claim 1, wherein the device is configured with a moving part – 78 check valve with flaps 82, 84 – that is movable from a first position (closed) to a second position (open) to allow blood to bypass the chamber 92 and go through the sampling channel 28 – "The difference in pressure caused by the vacuum within tube 94 causes the flaps of check valve 82 and 84 to separate permitting flow of blood through

the check valve 78 and through passageway 42 and communicating needle 50 into the evacuated tube 94 for blood collection purposes" (Col.5: 1-47), best seen in Figure 2 and 4.

7. (Previously Presented) The device in accordance with claim 6, the moving part 78, 82, 84 further configured to move from the first position to the second position after the first portion of blood flows into the chamber 92 – "tube 94 is then advanced in holder 62 until the pointed end 54 of needle 50 pierces the stopper 96 and enters the evacuated tube…The difference in pressure caused by the vacuum within tube 94 causes the flaps of check valve 82 and 84 to separate permitting flow of blood through the check valve 78 and through passageway 42 and communicating needle 50 into the evacuated tube 94 for blood collection purposes" (Col.5: 1-47).

32. (Previously Presented) The device in accordance with claim 6, wherein the moving part 78, 82, 84 is an inner chamber housing, best seen in Figure 3-4.

In regard to Claim 34, Percarpio discloses a device comprising:

an inlet port (corresponding to location of needle 22) for receiving a blood sample, best seen in Figure 3 (Col.2: 58-Col.3: 23);

an outlet port 42, 44 (central passageway, opening -- Col.2: 58-Col.3: 23) – Figure 3;

a chamber (one channel) 92 connected with the inlet port and the outlet port, and configured to collect a first portion of the blood sample ("by capturing the blood within the indicator area including channels 92, there is no danger of contamination of blood being

collected into chamber 32 and ultimately into an evacuated container through the passageway interconnected with rear needle 50" – Col.4: 16-39) – Figure 3,

the chamber including an air permeable blood barrier due to vents ("Three spaced channels 92 are formed in the film to provide air passageways for facilitating venting of the assembly and flow of blood into the indicator area where film 90 is located. The number of channels is a matter of choice – Col.4: 16-39) – Figure 3;

a sampling channel 28 (extends through valve 78) connected with the inlet port and the outlet port, the sampling channel and chamber configured to convey a subsequent portion of the blood sample through the sampling channel to the outlet port – after blood is collected in channel 92 and the water expansible material forming the from expands to close channel 92 and stops the blood flow to channel 92, tube 94 is then advanced in holder 62 until the pointed end 54 of needle 50 pierces the stopper 96 and enters the evacuated tube…The difference in pressure caused by the vacuum within tube 94 causes the flaps of check valve 82 and 84 to separate permitting flow of blood through the check valve 78 and through passageway 42 and communicating needle 50 into the evacuated tube 94 for blood collection purposes (Col.5: 1-47), best seen in Figure 4; and

a housing (defined by hub 26 and adapter 40) that fully encloses the inlet port, the outlet port, the chamber, and the sampling channel, best seen in Figure 3.

35. (Previously Presented) The device in accordance with claim 34, wherein the air permeable blood barrier is configured to seal upon contact with the first portion of the blood sample (Col.4: 16-39; Col.5: 1-47).

36. (Previously Presented) The device in accordance with claim 34, wherein the device is configured with a moving part – 78 check valve with flaps 82, 84 – that is movable from a first position (closed) to a second position (open) to allow blood to bypass the chamber 92 and go through the sampling channel 28 – "The difference in pressure caused by the vacuum within tube 94 causes the flaps of check valve 82 and 84 to separate permitting flow of blood through the check valve 78 and through passageway 42 and communicating needle 50 into the evacuated tube 94 for blood collection purposes" (Col.5: 1-47), best seen in Figure 2 and 4.

37. (Previously Presented) The device in accordance with claim 36, the moving part 78, 82, 84 further configured to move from the first position to the second position after the first portion of blood flows into the chamber 92 -- after blood is collected in channel 92 and the water expansible material forming the from expands to close channel 92 and stops the blood flow to channel 92, tube 94 is then advanced in holder 62 until the pointed end 54 of needle 50 pierces the stopper 96 and enters the evacuated tube…The difference in pressure caused by the vacuum within tube 94 causes the flaps of check valve 82 and 84 to separate permitting flow of blood through the check valve 78 and through passageway 42 and communicating needle 50 into the evacuated tube 94 for blood collection purposes (Col.5: 1-47), best seen in Figure 4.

38. (Previously Presented) The device in accordance with claim 36, wherein the moving part 78, 82, 84 is an inner chamber housing, best seen in Figure 3-4.

40. (Previously Presented) The device in accordance with claim 34, further comprising a junction 32 connecting the inlet port (corresponding to location of needle 22) and the sampling channel 28 and the chamber 92, best seen in Figure 3.

41. (Previously Presented) The device in accordance with claim 40, wherein the junction 32 is configured to convey the subsequent portion of the blood sample to the outlet port 42, 44 while bypassing the chamber 92, best seen in Figure 3-4.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries for establishing a background for determining obviousness under 35 U.S.C. 103 are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.

3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims the examiner presumes that the subject matter of the various claims was commonly owned as of the effective filing date of the claimed invention(s) absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and effective filing dates of each claim that was not commonly owned as of the effective filing date of the later invention in order for the examiner to consider the applicability of 35 U.S.C. 102(b)(2)(C) for any potential 35 U.S.C. 102(a)(2) prior art against the later invention.

Claim(s) 33 and 39 is/are rejected under 35 U.S.C. 103 as being unpatentable over Percarpio in view of Kaufman (US Pat No. 4312362).

Percarpio discloses the invention above but do not expressly disclose the device further comprising a locking mechanism configured to maintain the moving part in the first until the chamber is filled, providing force to overcome the locking mechanism to enable movement of the moving part to the second position.

Kaufman teach that it is well-known in the art to provide a blood sampling device comprising a locking mechanism that maintain the moving part 26 in the first position (so that hole 48 is free) which allows air to escape (similar to in Percarpio), and then providing force to overcome the locking mechanism to enable movement of the moving part to the second position (to free hole 49), which enables collection of the blood into evacuated tube 16 when said tube is connected also similarly to Percarpio, best seen in Figure 2 and 7 (Col.6: 44-Col.7: 50). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention of filing to modify Percarpio such that the device further comprising a locking

mechanism configured to maintain the moving part in the first until the chamber is filled, providing force to overcome the locking mechanism to enable movement of the moving part to the second position as taught by Kaufman to effectively maintain the moving part in the first position until the chamber is filled, providing force to overcome the locking mechanism to enable movement of the moving part to the second position.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on nonstatutory double patenting provided the reference application or patent either is shown to be commonly owned with the

examined application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. See MPEP § 717.02 for applications subject to examination under the first inventor to file provisions of the AIA as explained in MPEP § 2159. See MPEP § 2146 *et seq.* for applications not subject to examination under the first inventor to file provisions of the AIA. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

The USPTO Internet website contains terminal disclaimer forms which may be used. Please visit www.uspto.gov/patent/patents-forms. The filing date of the application in which the form is filed determines what form (e.g., PTO/SB/25, PTO/SB/26, PTO/AIA/25, or PTO/AIA/26) should be used. A web-based eTerminal Disclaimer may be filled out completely online using web-screens. An eTerminal Disclaimer that meets all requirements is auto-processed and approved immediately upon submission. For more information about eTerminal Disclaimers, refer to www.uspto.gov/patents/process/file/efs/guidance/eTD-info-I.jsp.

Claims 1 and 34 are rejected on the ground of nonstatutory double patenting as being unpatentable over claim 5 of U.S. Patent No. 9820682.

Although the claims at issue are not identical, they are not patentably distinct from each other because both recite a device comprising: an inlet port for receiving a blood sample; an outlet port; a chamber connected with the inlet port and the outlet port, and configured to collect a first portion of the blood sample, the chamber including a material that is an air permeable blood barrier; a sampling channel connected with the inlet port and the outlet port, the sampling channel and chamber configured to convey a subsequent portion of the blood

sample through the sampling channel to the outlet port while bypassing the chamber; and a housing that houses and defines the inlet port, the outlet port, the chamber, and the sampling channel.

Claims 1 and 34 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 10010282.

Although the claims at issue are not identical, they are not patentably distinct from each other because both recite a device comprising: an inlet port for receiving a blood sample; an outlet port; a chamber connected with the inlet port and the outlet port, and configured to collect a first portion of the blood sample, the chamber including a material that is an air permeable blood barrier; a sampling channel connected with the inlet port and the outlet port, the sampling channel and chamber configured to convey a subsequent portion of the blood sample through the sampling channel to the outlet port while bypassing the chamber; and a housing that fully encloses the inlet port, the outlet port, the chamber, and the sampling channel.

Claim 1 and 34 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1 and 18 of U.S. Patent No. 10143412.

Although the claims at issue are not identical, they are not patentably distinct from each other because both recite a device comprising: an inlet port for receiving a blood sample; an outlet port; a chamber connected with the inlet port and the outlet port, and configured to collect a first portion of the blood sample, the chamber including a material that is an air

permeable blood barrier; a sampling channel connected with the inlet port and the outlet port, the sampling channel and chamber configured to convey a subsequent portion of the blood sample through the sampling channel to the outlet port while bypassing the chamber; and a housing that fully encloses the inlet port, the outlet port, the chamber, and the sampling channel.

Claim 1 and 34 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1, 3, and 20-21 of U.S. Patent No. 11185266.

Although the claims at issue are not identical, they are not patentably distinct from each other because both recite a device comprising: an inlet port for receiving a blood sample; an outlet port; a chamber connected with the inlet port and the outlet port, and configured to collect a first portion of the blood sample, the chamber including a material that is an air permeable blood barrier; a sampling channel connected with the inlet port and the outlet port, the sampling channel and chamber configured to convey a subsequent portion of the blood sample through the sampling channel to the outlet port while bypassing the chamber; and a housing that fully encloses the inlet port, the outlet port, the chamber, and the sampling channel.

Claim 1 and 34 are rejected on the ground of nonstatutory double patenting as being unpatentable over claim 1 of U.S. Patent No. 10827964.

Although the claims at issue are not identical, they are not patentably distinct from each other because both recite a device comprising: an inlet port for receiving a blood sample; an

outlet port; a chamber connected with the inlet port and the outlet port, and configured to collect a first portion of the blood sample, the chamber including a material that is an air permeable blood barrier; a sampling channel connected with the inlet port and the outlet port, the sampling channel and chamber configured to convey a subsequent portion of the blood sample through the sampling channel to the outlet port while bypassing the chamber; and a housing that fully encloses the inlet port, the outlet port, the chamber, and the sampling channel.

Claim 1 and 34 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-2 and 8-9 of U.S. Patent No. 11311219.

Although the claims at issue are not identical, they are not patentably distinct from each other because both recite a device comprising: an inlet port for receiving a blood sample; an outlet port; a chamber connected with the inlet port and the outlet port, and configured to collect a first portion of the blood sample, the chamber including a material that is an air permeable blood barrier; a sampling channel connected with the inlet port and the outlet port, the sampling channel and chamber configured to convey a subsequent portion of the blood sample through the sampling channel to the outlet port while bypassing the chamber; and a housing that fully encloses the inlet port, the outlet port, the chamber, and the sampling channel.

Response to Arguments

Applicant's arguments with respect to claim(s) above have been considered but are moot because the new ground of rejection does not rely on any reference applied in the prior rejection of record for any teaching or matter specifically challenged in the argument.

Regarding the Drawing objections and 112(a) rejection, it is submitted that the mention of "a pathway" to the sampling channel 2422 in paragraph 0142 does not necessarily indicate a junction as recited in claims 3-4 and 40-41. As previously noted, Figure 24 does not clearly show said structure, the specification does not describe said structure in relation to said embodiment, and the specific reference to a junction in Figure 17A is not relevant as said figure does not apply to the instant embodiment. Therefore, said objections and rejections are maintained.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Huong Q NGUYEN whose telephone number is (571)272-8340. The examiner can normally be reached on 10 am - 6 pm.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert (Tse) Chen can be reached at 5712723672. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H.Q.N/
Examiner, Art Unit 3791

/RENE T TOWA/
Primary Examiner, Art Unit 3791

Notice of References Cited	Application/Control No. 17/893,079	Applicant(s)/Patent Under Reexamination ROGERS et al.	
	Examiner Huong Q NGUYEN	Art Unit 3791	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date YYYY-MM-DD	Name	CPC Classification	US Classification
*	A	US-4312362-A	1982-01-26	Kaufman; Joseph	A61B5/15003	600/584
	B					
	C					
	D					
	E					
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Dates in YYYY-MM-DD format are publication dates. Classifications may be US or foreign.

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (01-22)
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

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Filing Date	2022-08-22
First Named Inventor	Gino KANG
Art Unit	3791
Examiner Name	NGUYEN, HUONG Q
Attorney Docket Number	069366-0572192_KUR3C02US

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	1	S5825146	JP		1983-02-15	BECTON DICKINSON CO		☒

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Examiner Signature	/H Q NGUYEN/	Date Considered	09/06/2024

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☐ See attached certification statement.

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☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Benjamin F. Hudson/	Date (YYYY-MM-DD)	2024-04-23
Name/Print	Benjamin F. Hudson	Registration Number	71,474

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

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	1	European Patent Office; Communication pursuant to Article 94(3) EPC, dated Oct. 31, 2018; 11 pages.	☐
	2	European Patent Application No. EP19200766.4 extended European Search Report dated Dec. 2, 2019, 11 pages.	☐
	3	Communication Under Rule 71(3) EPC dated Apr. 22, 2020 for EP application No. 17840467.9. 125 pages.	☐
	4	Japanese Patent Office, Notice of Reasons for Rejection dated Jun. 15, 2021, Application No. JP 2019-534792, 6 pages.	☐
	5	Japanese Patent Office, Notice of Reasons for Rejection for JP Application No. JP 2020-118498 date Aug. 10, 2021.	☐
	6	Japanese Patent Office, Notice of Reasons for Rejection, Japanese patent application No. JP2018-523384, dated Jul. 23, 2019, 5 pages.	☐

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8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /H.Q.N/

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (01-22)
Approved for use through 05/31/2024. OMB 0651-0031
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT
(Not for submission under 37 CFR 1.99)

Application Number	17893079
Filing Date	2022-08-22
First Named Inventor	Gino KANG
Art Unit	3791
Examiner Name	NGUYEN, HUONG Q
Attorney Docket Number	069366-0572192_KUR3C02US

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Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	6126643		2000-10-03	VAILLANCOUERT VINCENT L	
	2	9764891		2017-09-19	AVILES VICTOR M	
	3	5147329		1992-09-15	BRANNON JAMES K	
	4	5518005		1996-05-21	BRANNON JAMES K	
	5	62845767		2019-05-09	BREWER MICHAEL	

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	1	20150314105		2015-11-05	GASPARYAN LEVON	

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	2	20150359473		2015-12-17	GARRETT CHAD	
	3	20160262677		2016-09-15	EBETSBERGER FRANZ	
	4	20160325085		2016-11-10	CHELAK TODD	
	5	20070031283		2007-02-08	DAVIS CHARLES Q	
	6	20190365303		2019-12-05	BULLINGTON GREGORY J	
	7	20180297303		2018-10-18	SEKIGUCHI TAKUMI	
	8	20190175087		2019-06-13	BULLINGTON GREGORY J	
	9	20210145336		2021-05-20	ROGERS BOBBY E	
	10	20060009713		2006-01-12	FLAHERTY PATRICE	

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	1	S5643474	JP		1981-10-12	TORAY INDUSTRIES		☐
	2	1996005875	WO		1996-02-29	BAXTER INT		☒
	3	104107054	CN		2014-10-22	BECTON DICKINSON CO		☒
	4	104981203	CN		2015-10-14	MAGNOLIA MEDICAL TECHNOLOGIES INC		☒
	5	1717280	CN		2006-01-04	SECR DEFENCE		☒
	6	2015150742	WO		2015-10-08	UNIV HULL		☒

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	1	Office Action (Non-Final Rejection) dated 04/25/2023 for US App. 16838017 (pages 1-20).	☐
	2	Office Action (Final Rejection) dated 01/29/2024 for US App. 16838017 (pages 1-44).	☐
	3	"Membrane Definition & Meaning," Merriam-Webster, Merriam-Webster, 22 Apr. 2009, www.merriam-webster.com/dictionary/ membrane. (Year: 2009).	☐

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	4	Office Action (Advisory Action) dated 02/09/2024 for US App. 16838017 (pages 1-6).	☐
	5	Office Action (Non-Final Rejection) dated 04/16/2024 for US App. 16838017 (pages 1-19).	☐
	6	Office Action (Non-Final Rejection) dated 05/21/2024 for IL App. 286812 (pages 1-3).	☐
	7	First Office Action (Non-Final Rejection) dated 01/16/2024 for JP App. 2021-558648 (pages 1-6).	☐
	8	First Office Action (Non-Final Rejection) dated 09/27/2023 for CN App. 202080000666.0 (pages 1-11).	☐
	9	Second Office Action (Non-Final Rejection dated 04/28/2024 for CN App. 202080000666.0 (pages 1-11).	☐
	10	European Patent Office, Extended European Search Report for European Patent Application 21818838.1-1122, dated April 22, 2024, 11 pages.	☐
	11	Australian Patent Office, Examination Report No. 1 for for Australian Patent Application 2021202622, dated March 18, 2022, 3 pages.	☐
	12	European Patent Office, Extended European Search Report for European Patent Application 23155927.9-1122, dated July 26, 2023, pages 1-8.	☐
	13	Office Action (Non-Final Rejection) mailed 10/04/2023 for US Application No. 17538900 (1-47).	☐
	14	First Office Action (Non-Final Rejection) dated 08-03-2023 for CN Application No. 202010300942.7. 21 pages.	☐

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	15	Office Action (Non-Final Rejection) dated 02/21/2023 for US Application No. 17893079, pages 1-32.	☐
	16	Office Action (Final Rejection) dated 07/19/2023 for US Application No. 17893079, pages 1-21.	☐
	17	Advisory Action dated 09/29/2023 for US Application 17893079, pages 1-24.	☐
	18	European Patent Office, Examination Report for European Patent Application 22181212.6-1122, dated September 28, 2023, pages 1-5.	☐
	19	European Patent Office, Extended European Search Report for European Patent Application 20781928.5-1122 dated October 28, 2022, pages 1-10.	☐
	20	Rule 70(a) Communication for European Application No. 20781928.5-1122 dated November 15, 2022, 1 page.	☐
	21	International Search Report and Written Opinion dated 19 March 2020 for PCT application no. PCT/US2020/023617. pages.	☐
	22	International Search Report and Written Opinion dated 28 September 2021 for PCT application no. PCT/ US2021/035294. 7 pages.	☐
	23	European Patent Office, Extended European Search Report for European Patent Application 22181212.6-1122 dated October 24, 2022, pages 1-10.	☐
	24	Australian Patent Office, Australian Examination Report No. 1 for Application No. 2021120 622 dated March 18, 2022, 3 pages.	☐
	25	Notice of Allowance mailed 03-01-2023; Attorney Docket No. 069366-0572419_KUR2D01AU. 3 pages.	☐

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	Examiner Name	NGUYEN, HUONG Q
	Attorney Docket Number	069366-0572192_KUR3C02US

	26	First Office Action dated 11/24/2021 for IL Application No. 286030, pages 1-3.	☐
	27	Notice of Allowance mailed 01-29-2023; Attorney Docket No. 069366-0572425_KUR2D01IL. 87 pages.	☐
	28	Office Action (Non-Final Rejection) dated 08/10/2021 for Japanese Application No. 2020-118498, pages 1-7.	☐
	29	Office Action (Non-Final Rejection) dated 03/28/2022 for Japanese Application No. 2020-118498, pages 1-3.	☐
	30	Office Action (Non-Final Rejection) dated 09/01/2022 for Japanese Application No. 2020-118498, pages 1-4.	☐
	31	Notice of Allowance mailed 04-04-2023; Attorney Docket No. 069366-0572230_KUR2D02JP. 6 pages.	☐
	32	Rule 71(3) Communication and Text for Grant mailed 08/31/2022 for European Application No. 19200766.4-1122. 189 pages.	☐
	33	Office Action (Non-Final Rejection) mailed 01/21/2022 for Israeli Application No. 267684. 3 pages.	☐
	34	Notice of Allowance mailed 02-14-2023; Attorney Docket No. 069366-0572429_KUR3N01IL. 122 pages.	☐
	35	Office Action (Non-Final Rejection) mailed 11/29/2022 for Application No. 2021-214177, pages 1-3.	☐
	36	Notice of Allowance mailed 06-20-2023; Attorney Docket No. 069366-0572231_KUR3D01JP. 6 pages.	☐

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	Filing Date	2022-08-22
	First Named Inventor	Gino KANG
	Art Unit	3791
	Examiner Name	NGUYEN, HUONG Q
	Attorney Docket Number	069366-0572192_KUR3C02US

	37	Office Action (Non-Final Rejection) mailed 11/4/2022 for Application No. 17094692, pages 1-50.	☐
	38	Notice of Allowance mailed 04-20-2023; Attorney Docket No. 069366-0572169_KUR4C01US. 36 pages.	☐
	39	Office Action (Non-Final Rejection) mailed 08/04/2022 for Application No. 16819033, pages 1-35.	☐
	40	Notice of Allowance mailed 11-28-2022; Attorney Docket No. 069366-0572168_KUR4002US. 9 pages.	☐
	41	JP Office Action mailed 02/27/2024; Attorney Docket No. 069366-0575273_KUR2D03JP. 11 pages.	☐
	42	Office Action (Non-Final Rejection) dated 01/25/2024 for IL App. 302893 (pages 1-3).	☐
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	44	JP Notice of Allowance mailed 06-20-2023; Attorney Docket No. 069366-0572231_KUR3D01JP. 6 pages.	☐
	45	Office Action (Non-Final Rejection) dated 10/04/2023 for US App. No. 17538990 (pages 1-47)	☐
	46	Notice of Allowance mailed 09-14-2023; Attorney Docket No. 069366-0574152_KUR2D02IL. 90 pages.	☐
	47	Notice of Allowance mailed 09-08-2023; Attorney Docket No. 069366-0574153_KUR2C04US. 35 page.	☐

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	Attorney Docket Number	069366-0572192_KUR3C02US

	48	Office Action (Final Rejection) dated 08/25/2023 for US App. No. 18113710 (pages 1-50)	☐
	49	European Patent Office, Extended European Search Report for European Patent Application 20197213.0-1132, dated Dec. 9, 2020, 6 pages.	☐
	50	Examination Report No. 1 dated Apr. 29, 2020, for Australian Patent Application No. 2016297849. 3 pages.	☐

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EXAMINER SIGNATURE

Examiner Signature	/H Q NGUYEN/	Date Considered	09/06/2024

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /H.Q.N/

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	Art Unit	3791
	Examiner Name	NGUYEN, HUONG Q
	Attorney Docket Number	069366-0572192_KUR3C02US

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Benjamin F. Hudson/	Date (YYYY-MM-DD)	2024-06-27
Name/Print	Benjamin F. Hudson	Registration Number	71,474

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

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5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

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Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

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	Attorney Docket Number	069366-0572192_KUR3C02US

	1	Notice of Allowance mailed 07-04-2024; Attorney Docket No. 069366-0572164_KUR7N01JP. 9 pages.	☐
	2	Office Action mailed 05-21-2024; Attorney Docket No. 069366-0572161_KUR7N01IL. 6 pages.	☐
	3	European Patent Office, Examination Report for European Patent Application 20781928.5, dated July 31, 2024, pages 1-6.	☐

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EXAMINER SIGNATURE

Examiner Signature	/H Q NGUYEN/	Date Considered	09/06/2024

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☐ See attached certification statement.

☒ A certification statement is not submitted herewith.

FEE

☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

COPIES

☐ An identification of an earlier application pursuant to 37 CFR 1.98 (d) (1) is attached.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Benjamin F. Hudson/	Date (YYYY-MM-DD)	2024-08-26
Name/Print	Benjamin F. Hudson	Registration Number	71,474

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	First Named Inventor	Gino KANG
	Art Unit	3791
	Examiner Name	NGUYEN, HUONG Q
	Attorney Docket Number	069366-0572192_KUR3C02US

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	2	10299713		2019-05-28	PATTON RICHARD G	
	3	10265007		2019-04-23	BULLINGTON GREGORY	
	4	11395612		2022-07-26	BULLINGTON GREGORY J	
	5	10881343		2021-01-05	BULLINGTON GREGORY J	
	6	10596315		2020-03-24	BULLINGTON GREGORY J	
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	9	11737693		2023-08-29	BULLINGTON GREGORY J	
	10	11439332		2022-09-13	BULLINGTON GREGORY J	
	11	11589843		2023-02-28	BULLINGTON GREGORY J	
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	5	20220304664		2022-09-29	HAMMER JEREMY	
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	1	European Patent Application No. EP23155927.9 extended European Search Report dated Jul. 26, 2023, 8 pages.	☐
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Bacterial Contamination of Platelets for Transfusion: Recent Advances and Issues

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- Bacterial contamination of blood products has emerged as a serious problem in transfusion medicine in the past 20 years and is second only to ABO-mismatch in causing transfusion-associated death.
- Data from 1985 - 1999 showed that 11% (77/694) of transfusion-associated fatalities reported to the FDA were caused by bacterially contaminated products leading to sepsis.
- As platelets are stored at room temperature, and in a large volume of plasma and a bag that allows oxygen diffusion, it is platelet products that are the most frequently implicated in transfusion-associated fatalities due to bacterial contamination.

The transfusion medicine community has attempted to reduce the amount of bacterial contamination in the blood supply by several methods including improved skin disinfection prior to donation, removal of the skin plug with diversion of the first 10 cc of the collection, ongoing donor screening, and analysis/culture of the donated product. Even with these measures in place, several fatalities due to septic reactions associated with transfusion have occurred and been reported. At the time of this writing, the exact "residual risk" of bacterial contamination is not known.

While packed red blood cell units can be contaminated by bacteria, the fact that they are *not* stored at room temperature and are not in a medium containing a large amount of plasma, leads the incidence of sepsis following transfusion of these units to be much less frequent. For a discussion of pRBC bacterial contamination, the first 3 references are recommended to the reader.[1-3] Below, the authors focus on the risks, strategies, and regulations regarding bacterial contamination of platelet products and its mitigation.

Estimates of Prevalence and Incidence

Prior to routine culturing of platelet units, which became universal following implementation AABB Standard 5.1.5.1 (discussed in more detail below), the estimated numbers of bacterially contaminated units, transfusion-associated septic reactions and deaths were usually made retrospectively based on reported or published reactions and sequelae.

By 2000, it was generally held that between 1:1,000 and 1:4,000 units[3-8] were contaminated with bacteria; the estimate of 1:2,000 to 3,000 became commonly accepted. Sepsis due to bacterial contamination was less common and estimated to occur in 1:20,000 to 1:85,000 units.[8] Estimates at the number of deaths due to this transfusion related complication were more difficult to elucidate.

In 2001, Yomtovian and colleagues estimated that 500 to 750 "severe and possibly fatal" events occurred annually.[4] Other estimates of this figure are more on the order of 100 to 150 deaths per year.[9,10] (The estimated risk of bacterially contaminated red cell units was significantly lower (approximately 1:500,000)[11] and approximately 10 to 1,000 times greater than the combined risk of transfusing HIV, HBV, HCV, and HTLV.[11]

Sources of Bacterial Contamination

Occult donor bacteremia and contamination of the product during collection have been the main avenues for entry of bacteria and have been the focus of prevention efforts. Gram-positive skin flora, introduced to the unit during collection, are the most common contaminates identified in retrospective analysis of platelet units.[12] Three reporting systems have suggested that 70% of contaminates isolated were gram-positive bacteria, while 80% of fatalities due to transfusion-related sepsis were caused by gram-negative organisms.[13-15] This finding was also observed in a recent review of the American Red Cross (ARC) experience with pretransfusion culturing of apheresis-derived platelets (ADP) between March and December 2004 (discussed in detail below).[16] This data showed that gram-positive organisms are implicated in approximately 4/5 of the cases. Gram-negative bacteria comprise the other 20%; however, they account for 40% of deaths due to septic transfusion reactions. Burns and colleagues recently published an extensive list of primary reports of clinically significant sepsis attributed to platelet transfusion from a PubMed literature search of all published cases.[17]

Due to the clinical significance of bacterial contamination, much effort has been made over the years to improve disinfection of skin at the phlebotomy site including the discontinuation of "green soap." Additionally, diversion of the skin plug produced by the needle as it passes through the skin, away from the bag into a pouch used for other viral testing, has been instituted nationwide in the United States. Despite these efforts, bacterial contamination of products continued(s) to be observed and skin flora continued(s) to be the most frequently cultured organisms.

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Asymptomatic donor bacteremia is the reason seemingly healthy volunteers may be allowed to donate while infectious, leading to bacterial contamination of blood products. In this case, even stringent donor screening will not catch this potential source of bacterial contamination. There are many examples of donors who unknowingly donate blood while bacteremic. For example, a case of transfusion associated *Staphylococcus aureus* platelet contamination has been reported in a blood donor who had undergone a tooth extraction 3 hours prior to donation, and was likely the result of transient bacteremia.[12] Haimowitz and colleagues discovered *Streptococcus bovis* at 11.4 hours after incubation of a platelet product donated by an asymptomatic female. After being informed of the result and despite negative follow up blood cultures, she underwent colonoscopy and a 3 cm mass was noted and removed.[18] Jafari and colleagues reported a case of *Salmonella* sepsis transmitted via platelet transfusion to 2 recipients from an asymptomatic donor who upon retrospective questioning reported that he had fever, abdominal pain, diarrhea, and hematochezia 13 days *prior* to donation. The donor owned a pet boa constrictor. The snake was thought to have been colonized with *Salmonella* and the original source of the infection.[19] Finally, there have been several cases of pRBC transfusion-associated *Yersinia enterolitica* septicemia in which many of the donors retrospectively reported diarrhea in the days preceding donation.[20]

An Open Letter to the Blood Community and AABB Standard 5.1.5.1

Physicians concerned that the risk from infected units was too high and that there were technologies that could address the issue at least in part wrote an "open letter" to the transfusion medicine community urging implementation of a method to stem this complication.[21] In 2003, AABB Standard 5.1.5.1 was released after considerable discussion, debate, and a public comment period. To be implemented within 1 year, the Standard read, "The blood bank or transfusion service shall have methods to limit and detect bacterial contamination in all platelet components."

At that time and presently, there were no FDA-approved tests for unit-by-unit bacteria screening at the time and point of transfusion. In addition, it was known that more than 15 tests *could* be used but none met "optimal" criteria including sensitivity and specificity, cost:efficacy, and logistical considerations affecting product supply and outdating. Thus, AABB was in an unenviable position of introducing a standard without guidance (at that time) as to *how* to implement it. **Table 1** below (adapted from reference 22) lists the tests capable of detecting bacteria and some comments regarding each.

Clinical Relevance

Typically at the time of collection, the level of contamination is relatively low (between 1 to 10 colony forming units (CFU)/mL.[23] However, once the product is inoculated, the bacteria can proliferate to levels of 10^6/mL or greater.[3] This amount of bacteria transfused during a short period of time can cause bacteremia, fever, chills, hypotension, nausea, vomiting, diarrhea, and oliguria, which may progress to sepsis and ultimately multi-system organ failure and death. Alternatively, the transfusion of contaminated cellular blood products may produce no symptoms or long-term clinical consequences. The severity of the reaction depends on: 1) the species of bacteria present, 2) the inoculum, 3) the rate of bacterial propagation, and 4) underlying disease, leukocyte count, the status of the immune system, and receipt of concomitant antibiotics in the recipient.[3] Gram-negative bacteria tend to cause more severe reactions due to the presence of endotoxin produced by these organisms. While causing only one-fifth of the cases, gram-negative bacteria have been reported to account for 40% of deaths due to septic transfusion reactions.[12,16]

Table 1_Description of Tests Capable of Detecting Bacteria

Methodology	Comments
Culture-based methodology: BacT/ALERT 3D Automated Microbial Detection System (bioMérieux, Durham, NC)	Detects CO_2 production by bacteria; FDA approved for quality control; Semi-closed system; Detects 5-10 CFU/mL (12-26 hr incubation);4 mL required
Culture-based methodology: (Pall eBDS, Pall Corporation, East Hills, NY)	Measures O_2 consumption by bacteria; FDA approved for quality control; Completely closed system; Requires 5-6 mL (concentrated to 2-3 mL)
DNA/RNA-based amplification and non-amplification, Chemiluminescence systems	Highly sensitive and specific; Requires highly conserved target by all bacteria or multiple primers and large inoculum; In experimental use only
Tests detecting changes in metabolic parameters or physical elements (glucose concentration, pH, platelet swirling)	Low sensitivity and specificity; Platelet concentration of the sample can affect results; Can be used at point of issue; Validation and QC difficult
Flow or static cytometry: (Scansystem, Hemosystem, Marseilles, France [laser-based, solid-phase cytometry])	Recently approved in Europe; Rapid (30 hr incubation and 90 min test time); Acceptable sensitivity and specificity; Requires reagent antibody to highly conserved common antigen or multiple reagent antibodies; 3 mL required
Bacterial cell wall component detection systems: (Platelet PGD test, Verax Biomedical, Worcester, MA)	Rapid (20 minutes); Lateral flow format; Sensitivity (10^3 to 10^4) in preliminary trial; 0.5 mL required; In experimental use only
Dielectrophoretic method: (Cell Analysis, Slough, United Kingdom)	Recently approved in Europe; Rapid (30 min); Sensitivity (10^3 to 10^5) in preliminary trial; 1 mL required
Gram stain	Requires a high level of contamination; Low sensitivity at lower concentrations; Can be used at point of issue; Validation and QC difficult
Endotoxin detection	Requires a high level of contamination; Low sensitivity at lower concentrations

Adapted from Reference 22.

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Strategies for the Mitigation of Contaminated Blood Products

As previously stated, detection strategies show variable sensitivity and specificity. Measuring abnormal glucose concentrations, low pH, microscopic examination of gram-stained specimens, and platelet swirling characteristics have been less useful due to low sensitivity and specificity. However, these methods have the advantage of being able to be used at the time and point of transfusion, are less expensive and use equipment commonly available.

Automated culture-based systems used for years in the hospital setting for detection of bacteremia in blood cultures obtained from patients were implemented by many of the nation's blood collection systems. Principally, they detect CO_2 generation or O_2 consumption by bacteria. Some of the limitations of culture-based systems are relatively insensitive at low levels of bacterial contamination causing false negative results, long incubation times for slow-growing bacteria, false positive results, high cost and the need for capital investment.[24-26] Holme and colleagues have recently shown that modifications to the Pall eBDS system have attempted to minimize these limitations.[29] While feasible for apheresis-derived platelets (ADP), culture based methods are not considered feasible for each whole blood-derived platelet (WBP) unit at the time of collection because of the high cost. Thus, those centers and services that used ADP could comply more easily and effectively with the new standard than those who used WBP, and converting entire systems from ADP to WBP was in-and-of-itself costly and met with resistance due to standard of care, cost, and availability concerns.

Apheresis Derived (ADP) Versus Whole Blood Derived Platelets (WBP)

Even before the implementation of Standard 5.1.5.1, the use of ADP had increased (52% to 99% of total transfused products per Ness and colleagues from 1987-1998) likely in part due to concern by some authorities about bacterial contamination.[8] Indeed, Ness and colleagues concluded that the rate of septic transfusion reactions due to WBP was 5.39 times higher than ADP (95% CI, 1.89, 12.9). Dykstra and colleagues found that the rate of bacterial contamination in ADP and WBP was identical (P=1.0); however, when platelet concentrates were pooled, the risk increased by 5 fold.[7]

Despite the apparent advantages of using ADP, maintaining adequate inventories and simultaneously providing adequate bacterial contamination testing is still a challenge due to the time it takes for the culture. Many experts have considered the effect and possibility of extending the expiration date to 7 days. In order to have a licensed 7 day ADP, clinical tests of the platelets, storage and medium will be required as will demonstration of bacteria detection and an acceptable rate of "residual risk." In order to allow the use of WBP with cost effective and optimal bacterial detection performance, 2 alternatives can be considered, but both are in clinical development and thus are not available. These include: 1) a 5 or 7 day "pooled and stored" WBP where a culture-based system could be used as a single test on a pre-storage pooled product, and 2) the approval of a effective test that could be used at the point and time of transfusion and which would be rapid enough for most clinical situations.

Residual Risk in "Tested" Components

Despite the strategies described above, bacterial contamination continues to be observed, although markedly reduced, and fatal consequences have been reported. As there was no standardized or required system in place to determine the true incidence of the morbidity and mortality caused by septic platelet units prior to the implementation of AABB Standard 5.1.5.1, it is impossible to determine with accuracy the effect of the standard in terms of percent improvement or reduction in adverse events. Some relevant data are available however.

From March 1, 2004 through December 31, 2004, approximately 350,000 units from 87,000 voluntary donors at 36 regional centers were cultured by the American Red Cross. Two hundred nineteen were initially positive, 67 were confirmed on re-sampling for an overall confirmed positive rate of 0.019% or 1:5,234 as compared to published reports of 1:2,000 to 3,000. Initially, 4 to 5 mL from each unit was transferred through a sterile docking device at least 24 hours after collection and used to inoculate BacT/ALERT BPA aerobic culture bottles. Confirmation of a positive blood culture bottle was performed by taking a new sample from product, inoculating a new BacT/ALERT aerobic culture bottle and if positive, performing bacterial isolation and identification. Eighty percent of the confirmed positive cases were gram-positive bacteria, mainly *Staphylococcus* (46.3%) and *Streptococcus* (26.9%) species. Serratia was the most commonly isolated gram-negative bacteria (n=4). Seventy-two percent of gram-negative organisms were identified within the first 12 hours of inoculation (personal communication; ARC). No patient transfused with an unconfirmed positive product had a septic transfusion reaction.

Three fatal cases and 2 non-fatal cases of transfusion-associated sepsis in platelet recipients have occurred since the standard was adopted. The first 2 cases were reported in MMWR.[27] The first case was that of a 74-year-old man who received 1 pool of 5 platelet concentrates. The pooled unit was tested by a pH method and found to be acceptable. After a hypotensive reaction, *S. aureus* was cultured from both the patient's blood and the platelet bag and by pulsed-field gel electrophoresis (PFGE) were identical. The second case was a 79-year-old man who was transfused a single platelet pheresis unit. The unit was tested by an automated culture system using a standard method. One hour after transfusion the patient had shortness of breath, chills, and fever. *S. lugdenensis* was cultured from both the patient's blood and the platelet bag and by PFGE were identical. The final case of fatality [presented to the Advisory Committee on Blood Safety (1/25/2005)] was a premature infant who received 2 doses of a single platelet pheresis. The unit was tested by a manual culture. The patient had symptoms consistent with sepsis. The platelet unit was then recultured and found to be growing *Serratia marcescens*. The patient's cultures were negative, but the cultures were taken after antibiotic therapy was initiated. One of the non-fatal cases was a BacT/ALERT failure of an apheresis platelet unit.[16]

Using numbers that are estimates only, and recognizing the limitations therein, a residual risk figure may be on the order of 3 to 6 fatal cases per year following the administration of approximately 2 million platelet doses per year (*The reader is asked to note that the true number of transfused platelet doses per year in the United States has not been established with certainty. While as many as 9 million units are given, the proportion of ADP vs. WBP is not known, nor is the number of WBP pooled into a dose*). Therefore, an incidence figure of approximately 1 fatality per approximately 500,000 tested doses may be posited. This is

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likely to be grossly inaccurate due to the lack of validated data, suboptimal test methods for WBP, and reporting and assumptions used. If one uses the figures given earlier in this report of 100 to 150 deaths annually (pre-standard implementation) and a residual as high as 6, then the improvement has been about 95%. Again, this number is a gross estimate, which will likely be revised with the collection of additional data. Though the "improvement rate" seems excellent, a residual risk of fatality incidence of 1:500,000 may be judged unacceptable by some, and thus other means of improving upon this complication may be warranted.

Pathogen Reduction (Inactivation)

Pathogen reduction is the term given to a number of technologies that prevent pathogens from replicating and thus prevent them from causing disease following transfusion. Methods under investigation (some are in use in Europe) use a variety of compounds including methylene blue, riboflavin and solvent-detergent treatment. In addition, a number of photodynamic processes use psoralen-based chemicals followed by ultraviolet light to inactivate bacteria and viruses by preventing replication and transcription of nucleic acids. This latter method has been extensively tested for bacterial reduction in platelet products. Gram-positive and gram-negative bacteria have been shown in three preclinical trials to be sensitive to pathogen inactivation (reviewed in reference 28). The main disadvantage of pathogen inactivation is that no method is equally effective for all organisms and these methods may be especially ineffective for spore-forming organisms.[28] The advantage is that this is a proactive method for bacterial reduction and has the potential to be as effective for known pathogens as it is for emerging pathogens.

Ongoing Issues

Bacterial contamination of blood products was, and may continue to be, a serious health risk to transfusion recipients. While we believe substantial improvement has been made, though difficult to accurately quantify, some level of residual risk appears to exist. Systems to help quantify this residual risk need to be implemented and/or strengthened. In addition, there is some evidence to suggest that the implementation of Standard 5.1.5.1 has caused a significant reduction in platelet availability, delay in their release to hospital transfusion services, and/or a declination in WBP use which may have added to the overall cost of platelet provision and transfusion. In order to address these issues, rapid and cost-effective tests need to be developed and approved for use at the time and point of transfusion. Alternatively, and with the use of a validated bacterial detection test, prestorage pooling may be "allowed" and thus lead to a state of equipoise between ADP and WBP safety and therefore use. An effective method or methods for bacterial detection and limitation will likely allow the extension of either ADP or pooled and stored WBP to 7 or perhaps even 8 days, thus likely improving the logistical and availability issues currently surrounding this valuable human resource. Finally, the adoption of pathogen reduction technologies in Europe and their approval in the United States may abrogate any residual or evolving risk.

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פ.ק 13

תאריך: ז' שבט תשפ"ג
29/01/2023
מספרכם: 1000-016-01

לכבוד
כץ, פרזנטי ושות'
דרך אבא הלל 14,
רמת גן, מיקוד 52506

א. ג. נ.,

הנדון: **<u>הודעה לפני קיבול בקשת פטנט מספר 286030</u>**

סימוכין: מכתבכם מיום 25/08/2022

לתשומת לבכם: מקום בו הנכם מופנים ל"חוק", הכוונה היא לחוק הפטנטים, התשכ"ז – 1967. מקום בו הנכם מופנים ל"תקנות", הכוונה היא לתקנות הפטנטים (נוהלי הרשות, סדרי דין, מסמכים ואגרות), התשכ"ח – 1968. בהתאם לחוזר רשם 035/2017 – פטנטים **לא ניתן להשהות פרסום בקשות פטנט לפי סעיף 26 לחוק.**

<u>הודעה זו מבוססת על המסמכים הבאים:</u>

שרטוטים מתאריך: 01/09/2021
פרטי הבקשה מתאריך: 01/09/2021
תביעות מתאריך: 25/08/2022

<u>מענה לטיעוני המבקש</u>

מערכת התביעות המוצעת מתקבלת.

<u>הריני להודיעכם כי בחינת הבקשה הנ"ל הושלמה לפי הוראות סעיף 48ו(ג)(1) ו- (2) לחוק.</u>

<u>תשלום אגרת קיבול</u>

1. הבקשה תתקבל בהתאם לסעיף 26 לחוק לאחר תשלום אגרת הקיבול.
2. יש לשלם את האגרה תוך 3 חודשים מתאריך הודעה זו.
3. סכום האגרה נכון למועד הודעה זו הינו 764.00 ש"ח. הסכום כפוף לעדכונו על פי המדד בהתאם לתקנה 6א.

<u>הפניה בפירוט למסמך הבכורה</u>

לפי הוראות **סעיף 20 לחוזר הרשם 034/2017-פטנטים** במידה ופירוט הבקשה מכיל הפניה למסמך בכורה באמצעות הביטוי "incorporated by reference" ובמידה וחלפו 14 חודשים ממועד דין הקדימה (אם נדרש) לא ניתן עוד להוסיף דבר מתוך מסמך הבכורה והמבקש לא יכול להסתמך על האמור במסמך הבכורה, לצורך סעיפים 12 ו-13 לחוק.

<u>עדכון רשימות האסמכתאות והפרסומים לפי סעיף 18א לחוק</u>

לתשומת לבכם, בהתאם להוראות פרק ג' בחוזר רשם 035/2017-פטנטים חובת המבקש לעדכן את הרשות בכל שינוי שחל ברשימת הפרסומים בהתאם לסעיף 18 לחוק נמשכת עד קיבול הבקשה.

באם ברצונכם להחזיר את הבקשה לבחינה בעקבות שינוי ברשימת הפרסומים שהתרחש לאחר תשובתכם להודעת הליקויים האחרונה, עליכם להגיש בקשה לבחינה חוזרת בה עליכם לציין מהו השינוי ברשימת הפרסומים ומתי נודע על שינוי זה.

בקשה לבחינה חוזרת יש להגיש באמצעות פניה ל-"בקשה לתיקונים לאחר פ.ק. 13".

<u>הגשת בקשות חלוקה</u>

בהתאם להוראות סעיף 24(א) לחוק זכאי המבקש כל עוד לא קובלה הבקשה לדרוש את חלוקת הבקשה לבקשות אחדות. לפיכך, באם ברצונכם להגיש בקשות חלוקה מבקשה זו עליכם לעשות זאת בטרם מועד הקיבול. לא נוכל להכיר בבקשות שיוגשו לאחר מועד הקיבול של הבקשה הנוכחית כבקשות חלוקה לעניין סעיף 24(ג) לחוק.

<u>בדיקה פורמלית</u>

להודעה הנוכחית מצורף העתק פירוט הבקשה המעודכן - אם נפלו טעויות נא להודיע עליהן לרשות לפני מועד תשלום אגרת הקיבול.

לצורך אימות פרטי הפרסום בהתאם לסעיף 26 לחוק ניתן לעיין בנסח הבקשה באתר הרשות בקישור הבא:

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ניתן לעיין בפרטי תיק הבקשה באתר הרשות בקישור:

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בכבוד רב

אלברט אקרמן
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ראש צוות: מוריה שלמה לוי

claims

1. A blood device connected with a blood sampling system comprising:

a patient needle for accessing a blood sample from a patient and a sample needle that is sealed,

an inlet port connected with the patient needle to receive the blood sample from the patient;

a chamber connected with the inlet port and having a vent

comprising an air permeable blood barrier, wherein the chamber for receiving a first portion of the blood sample prior to the sample needle is unsealed;

a sampling channel having a proximal end connected with the inlet port, wherein the sampling channel for conveying a second portion of the blood sample once the sample needle is unsealed;

an outlet port connected with a distal end of the sampling channel for conveying the second portion of the blood sample to the sample needle; and

a housing that houses and defines the inlet port, the outlet port, the chamber, and the sampling channel.

2. The blood device in accordance with claim 1, wherein the chamber is at ambient air pressure, and wherein the chamber receives the first portion of the blood sample by blood pressure of the patient overcoming the ambient air pressure in the chamber.

3. The blood device in accordance with claim 1, wherein the sampling channel causes the second portion of the blood sample to bypass the first portion of blood in the chamber and exit the outlet port for conveyance to a blood collection device.

4. The blood device in accordance with claim 1, wherein the air permeable blood barrier includes an air permeable material that seals upon contact with blood.

BLOOD SAMPLE OPTIMIZATION SYSTEM AND BLOOD CONTAMINANT SEQUESTRATION DEVICE AND METHOD

ABSTRACT

Blood sample optimization systems and methods are described that reduce or eliminate contaminates in collected blood samples, which in turn reduces or eliminates false positive readings in blood cultures or other testing of collected blood samples. A blood sample optimization system can include a blood sequestration device located between a patient needle and a sample needle. The blood sequestration device can include a sequestration chamber for sequestering an initial, potentially contaminated aliquot of blood, and may further include a sampling channel that bypasses the sequestration chamber to convey likely uncontaminated blood between the patient needle and the sample needle after the initial aliquot of blood is sequestered in the sequestration chamber.

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit of priority of U.S. Non-Provisional Application Serial No. 15/140,443, filed on April 27, 2016 and titled "BLOOD SAMPLE OPTIMIZATION SYSTEM AND BLOOD CONTAMINANT SEQUESTRATION DEVICE AND METHOD" and U.S. Non-Provisional Application Serial No. 15/140,448, filed on April 27, 2016 and titled "BLOOD SAMPLE OPTIMIZATION SYSTEM AND BLOOD CONTAMINANT SEQUESTRATION DEVICE AND METHOD", both of which claim priority to U.S. Provisional Application Serial No. 62/196,797, filed on July 24, 2015 and titled "BLOOD CULTURE IMPROVEMENT SYSTEM AND METHOD"; U.S. Provisional Application Serial No. 62/238,636, filed on October 7, 2015 and titled "BLOOD SEQUESTRATION SYSTEM FOR NON-CONTAMINATED BLOOD SAMPLING"; and U.S. Provisional Application Serial No. 62/318,194, filed on April 4, 2016 and titled "BLOOD SAMPLE OPTIMIZATION SYSTEM AND BLOOD CONTAMINANT

SEQUESTRATION DEVICE AND METHOD," the disclosures of which are incorporated by reference in their entirety.

BACKGROUND

[0002] Bacteraemia is the presence of microorganisms in the blood. Sepsis, on the other hand, is bacteraemia in the presence of clinical symptoms and signs such as fever, tachycardia, tachypnea and hypotension. Bacteraemia and sepsis are associated with a high mortality and an increased incidence and duration of hospital stay and associated costs. Many bacteraemias, sepsis, fungaemias and other pathogens actually occur within a hospital or other healthcare settings with catheters and venipunctures being a source of contamination as potential carriers of these pathogens.

[0003] Blood cultures are the standard test used to detect microbial pathogens related to bacteraemia and sepsis in a patient's blood. The term blood culture refers to a single venipuncture, either from a peripheral site or central or arterial line, with the blood inoculated into one or more blood culture bottles or containers. One bottle is considered a blood culture where two or more are considered a set. Multiple sets may be obtained from multiple venipunctures and are associated with different sites on the patient.

[0004] These methods allow for microbial identification and susceptibility testing to be performed, which is a critical component to managing sepsis, however the lack of rapid results and decreased sensitivity for fastidious pathogens has led to the development of improved systems and adjunctive molecular or proteomic testing.

[0005] Collection of blood samples for conducting blood cultures is a critical component of modern patient care and can either positively affect the patient outcome by providing an accurate diagnosis, or can adversely affect the outcome by prolonging unnecessary antimicrobial therapy, the length of hospital stays, and increasing costs.

[0006] One outcome of collection of blood cultures is contamination. Blood culture contamination can lead to a false positive culture result and/or significant increase in healthcare related costs. Sources of blood culture contamination include improper skin

antisepsis, improper collection tube disinfection, and contamination of the initial blood draw which may then skew results.

[0007] Blood culture collection kits generally consist of a "butterfly" set, infusion set, or other type of venipuncture device as offered by companies like BD, Smiths, B. Braun and others, and aerobic and anaerobic blood culture bottles. Various different bottles are also available depending on the test requirements. These bottles are specifically designed to optimize recovery of both aerobic and anaerobic organisms. In conventional kits, a bottle used is known generally as a "Vacutainer," which is a blood collection tube formed of a sterile glass or plastic tube with a closure that is evacuated to create a vacuum inside the tube to facilitate the draw of a predetermined volume of liquid such as blood.

[0008] False positive blood cultures are typically a result of poor sampling techniques. They cause the use of antibiotics when not needed, increasing hospital costs and patient anxiety. Blood cultures are drawn from a needlestick into the skin, and then a Vacutainer is attached to capture a sample of blood. Contamination may occur from improper or incomplete disinfection of the skin area in and around the puncture site. It may also occur from the coring of the skin by the needle during insertion, with the cored skin cells and any associated contamination being pulled into the sample.

[0009] Blood flow through a hypodermic needle is laminar, and as such, a velocity gradient can be developed over the flow tube as a pressure drop is applied to the hypodermic needle. Either forceful aspiration of blood, or using a very small hypodermic needle, can cause lysis and a release of potassium from the red blood cells, thereby rendering the blood samples abnormal.

[0010] In other instances, some patients have delicate veins that can collapse under a pressure drop or vacuum, particularly as applied by a syringe's plunger that is drawn too quickly for the patient's condition. Since such condition is impossible to know beforehand, such vein collapses are a risk and very difficult to control.

[0011] Various strategies have been implemented to decrease blood culture contamination rates, e.g. training staff with regard to aseptic collection technique, feedback

with regard to contamination rates and implementation of blood culture collection kits. Although skin antisepsis can reduce the burden of contamination, 20% or more of skin organisms are located deep within the dermis and are unaffected by antisepsis. Changing needles before bottle inoculation is not advisable as it increases the risk to acquire needle stick injuries without decreasing contamination rates.

[0012] Some conventional systems and techniques for reducing blood culture contamination include discarding the initial aliquot of blood taken from central venous catheters, venipunctures, and other vascular access systems. However, these systems require the user to mechanically manipulate an intravascular device, or require a complex series of steps that are difficult to ensure being followed.

SUMMARY

[0013] This document presents systems and methods for reducing blood culture contamination, lysing of cells, and vein collapse. In some implementations, a system and method can eliminate user variability in disinfection, and also eliminate the risk of skin cells getting into the blood culture sample. The systems and methods disclosed herein do not require a change in existing clinical processes, other than to potentially indicate when a vacutainer or other blood collection device (i.e., syringe) should be attached for drawing contaminant-free blood samples.

[0014] In some implementations of the systems and methods disclosed herein the withdrawal of blood is accomplished passively by use of the patient's own blood pressure, thereby reducing the risk of vein collapse and eliminating any additional user steps over current practice. The systems and methods can be applied to accommodate short-path direct stick or butterfly venipuncture systems. They can also be used with samples drawn through a catheter.

[0015] In one aspect, a blood sequestration device is presented. The blood sequestration device includes an inlet port and an outlet port. The blood sequestration device further includes a sequestration chamber connected with the inlet port, the sequestration chamber having a vent comprising an air permeable blood barrier. The blood sequestration

device further includes a sampling channel having a proximal end connected with the inlet port and a distal end connected with the outlet port.

[0016] In another aspect, a blood sequestration device connected with a blood sampling pathway is described. The blood sampling pathway has a patient needle and a sample collection device. The blood sequestration device includes an inlet port connected with the patient needle, and a sequestration chamber connected with the inlet port, the sequestration chamber having a vent comprising an air permeable blood barrier. The blood sequestration device further includes a sampling channel having a proximal end connected with the inlet port, and an outlet port connected with a distal end of the sampling channel and with the sample collection device.

[0017] In yet another aspect, a blood sequestration device connected with a blood sampling system is described. The blood sampling system includes a patient needle for accessing a blood sample from a patient, and a sample needle that is sealed and adapted for receiving an evacuated blood collection tube. The blood sequestration device includes an inlet port connected with the patient needle to receive the blood sample from the patient. The blood sequestration device further includes a sequestration chamber connected with the inlet port and having a vent comprising an air permeable blood barrier, the sequestration chamber for receiving and sequestering a first portion of the blood sample prior to the sample needle being unsealed by the evacuated blood collection tube. The blood sequestration device further includes a sampling channel having a proximal end connected with the inlet port, the sampling channel for conveying a subsequent portion of the blood sample once the sample needle is unsealed by the evacuated blood collection tube. The blood sequestration device further includes an outlet port connected with a distal end of the sampling channel for conveying the subsequent portion of the blood sample to the sample needle.

[0018] In yet another aspect, a blood sample optimization system is disclosed and described. The blood sample optimization system includes a blood sampling system for accessing and acquiring one or more samples of a patient's blood, and a blood sequestration device for receiving and sequestering a first portion of the one or more samples of the

patient's blood which might be contaminated by a venipuncture process and which could result in a false positive identification of a pathogen in the patient's blood.

[0019] The blood sampling system includes a patient needle configured for a venipuncture of a patient to access a sample of blood of a patient, a blood sampling pathway connected with the patient needle for conveying the sample of blood, and a sample needle configured for receiving an evacuated blood collection container to collect and contain a subsequent portion of the sample of blood.

[0020] In yet another aspect, a blood sequestration device is disclosed and described. In some implementations, the blood sequestration device can include an inlet port, an outlet port connected with the inlet port, and a sequestration chamber connected with the inlet port. The sequestration chamber can have a vent comprising an air permeable blood barrier.

[0021] The blood sequestration device is connected along the blood sampling pathway between the patient needle and the sample needle, and includes an inlet port for receiving the sample of blood. The blood sequestration device further includes a sequestration chamber connected with the inlet port for receiving a first amount of the sample of blood, the sequestration chamber having a vent comprising an air permeable blood barrier for sequestering at least a first portion of the first amount of the sample of blood. The blood sequestration device may further include a sampling channel having a proximal end connected with the inlet port, the sampling channel conveying a subsequent amount of the sample of blood to the evacuated blood collection container upon the sequestration chamber sequestering at least the first portion of the first amount of the sample of blood. The blood sequestration device further includes an outlet port connected with a distal end of the sampling channel, the outlet port for outputting the subsequent amount of the sample of blood.

[0022] The details of one or more embodiments are set forth in the accompanying drawings and the description below. Other features and advantages will be apparent from the description and drawings, and from the claims.

BRIEF DESCRIPTION OF THE DRAWINGS

[0023] These and other aspects will now be described in detail with reference to the following drawings.

[0024] FIG. 1 illustrates a blood sample optimization system.

[0025] FIG. 2 illustrates a blood sample optimization system in accordance with an alternative implementation.

[0026] FIG. 3 illustrates a blood sample optimization system in accordance with another alternative implementation.

[0027] FIG. 4 illustrates a blood sample optimization system in accordance with another alternative implementation.

[0028] FIG. 5 illustrates a blood sample optimization system in accordance with another alternative implementation.

[0029] FIG. 6 illustrates a blood sample optimization system in accordance with an alternative implementation.

[0030] FIG. 7 is a flowchart of a method for optimizing a quality of a blood culture.

[0031] FIGS. 8A – 8E illustrate a blood sequestration system for non-contaminated blood sampling, in accordance with some implementations.

[0032] FIG. 9 illustrates a pathway splitter for use in a blood sequestrations system.

[0033] FIGS. 10A – 10D illustrate a blood sequestration system for non-contaminated blood sampling, in accordance with alternative implementations.

[0034] FIGS. 11A – 11E illustrate a blood sequestration system for non-contaminated blood sampling, in accordance with other alternative implementations.

[0035] FIGS. 12A-12D illustrate a blood sample optimization system including a blood sequestration device in accordance with yet other alternative implementations.

[0036] FIGS. 13A-13D illustrate a blood sample optimization system 1300 in accordance with yet another alternative implementations.

[0037] FIGS. 14A-14E illustrate yet another implementation of a blood sampling system to sequester contaminates of an initial aliquot or sample to reduce false positives in blood cultures or tests performed on a patient's blood sample.

[0038] FIGS. 15A-15G illustrate a blood sequestration device and method of using the same, in accordance with yet another implementation.

[0039] FIGS. 16A-16D illustrate a blood sequestration device in accordance with yet another implementation.

[0040] FIGS. 17A – 17E illustrate a bottom member of a housing for a blood sequestration device.

[0041] FIGS. 18A – 18F illustrate a top member of a housing for a blood sequestration device.

[0042] FIGS. 19A and 19B illustrate a blood sequestration device having a top member mated with a bottom member.

[0043] FIG. 20 shows a blood sample optimization system including a blood sequestration device.

[0044] FIG. 21 illustrates a non-vented blood sequestration device using a wicking material chamber.

[0045] FIGS. 22A and 22B illustrate a material makeup of a filter for sequestering blood in a sequestration chamber of a blood sequestration device.

[0046] FIGS. 23A and 23B illustrate another implementation of a blood sequestration device that uses a vacuum force from a blood collection device.

[0047] Like reference symbols in the various drawings indicate like elements.

DETAILED DESCRIPTION

[0048] This document describes blood sample optimization systems and methods for reducing or eliminating contaminates in collected blood samples, which in turn reduces or eliminates false positive readings in blood cultures or other testing of collected blood samples. In some implementations, a blood sample optimization system includes a patient needle for vascular access to a patient's bloodstream, a sample needle for providing a blood sample to a blood collection container, such as an evacuated blood collection container or tube like a Vacutainer™ or the like, or other sampling device, and a blood sequestration device located between the patient needle and the sample needle. The blood sequestration device includes a sequestration chamber for sequestering an initial, potentially contaminated aliquot of blood, and may further include a sampling channel that bypasses the sequestration chamber to convey likely uncontaminated blood between the patient needle and the sample needle after the initial aliquot of blood is sequestered in the sequestration chamber.

[0049] FIG. 1 illustrates a blood sample optimization system in accordance with some implementations. The system includes a patient needle 1 to puncture the skin of a patient to access the patient's vein and blood therein. The system further includes a sample needle (i.e., a resealably closed needle for use with Vacutainers™ or the like) 5, which may be contained within and initially sealed by a resealable boot 10, a Luer activated valve, or another collection interface or device. The resealable boot 10 can be pushed aside or around the sample needle 5 by application of a Vacutainer™ bottle (not shown) for drawing the patient's blood. The system can further include a low volume chamber 30 that leads to the sample needle 5, but also includes an orifice or one or more channels 45 that lead to a sequestration chamber 55 formed by a housing 50.

[0050] The sequestration chamber 55 is a chamber, channel, pathway, lock, or other structure for receiving and holding a first aliquot of the patient's blood, which may be in a predetermined or measured amount, depending on a volume of the sequestration chamber 55. The first draw of blood typically contains or is more susceptible to containing organisms that cause bacteraemia and sepsis or other pathogens than subsequent blood draws. The sequestration chamber 55 can be a vessel encased in a solid housing, formed in or defined by

the housing itself, or can be implemented as tubing or a lumen. The sequestration chamber 55, regardless how formed and implemented, may have a predetermined volume. In some implementations, the predetermined volume may be based on a volume of the patient needle, i.e. ranging from less than the volume of the patient needle to any volume up to or greater than 20 times or more of the volume of the patient needle. The predetermined volume of the sequestration chamber 55 may also be established to economize or minimize an amount of blood to be sequestered and disposed of.

[0051] The sequestration chamber 55 can be formed, contained or housed in a chamber housing 50, and can be made of plastic, rubber, steel, aluminum or other suitable material. For example, the sequestration chamber 55 could be formed of flexible tubing or other elastomeric materials. The sequestration chamber 55 further includes an air permeable blood barrier 20 that allows air to exit the sequestration chamber 55. As used herein the term "air permeable blood barrier" means an air permeable but substantially blood impermeable substance, material, or structure. Examples may include hydrophobic membranes and coatings, a hydrophilic membrane or coating combined with a hydrophobic membrane or coating, mesh, a filter, a mechanical valve, antimicrobial material, or any other means of allowing air to be displaced from the sequestration chamber 55 as it is filled with blood. In various exemplary embodiments, an air permeable blood barrier may be formed by one or more materials that allow air to pass through until contacted by a liquid, such material then becomes completely or partially sealed to prevent or inhibit the passage of air and/or liquid. In other words, prior to contact with liquid, the material forms a barrier that is air permeable. After contact with a liquid, the material substantially or completely prevents the further passage of air and/or liquid.

[0052] The orifice or channel 45 can be any desired length, cross-sectional shape or size, and/or can be formed to depart from the low volume chamber 30 at any desired angle or orientation. The orifice or channel 45 may also include a one-way flap or valve 60 that maintains an initial aliquot of blood sample within the sequestration chamber 55. In some specific implementations, the orifice or channel 45 can include a "duck bill" or flapper valve 60, or the like, for one-way flow of blood from low volume chamber 30 to the sequestration chamber 55. The air permeable blood barrier 20 can also be constructed of a material that

allows air to exit but then seals upon contact with blood, thereby not allowing external air to enter sequestration chamber 55. This sealing would eliminate the need for a valve.

[0053] Valve 60 can be any type of valve or closing mechanism. Chamber 30 is designed to hold virtually no residual blood, and can be designed to be adapted to hold or allow pass-through of a particular volume or rate of blood into sequestration chamber 55. Likewise, sequestration chamber 55 may also include any type of coating, such as an anti-microbial coating, or a coating that aids identification and/or diagnosis of components of the first, sequestered blood draw.

[0054] Housing 50 and 40 can be formed of any suitable material, including plastic, such as acrylonitrile butadiene styrene (ABS) or other thermoplastic or polymeric material, rubber, steel, or aluminum. The air permeable blood barrier 20 can include a color-providing substance, or other signaling mechanism, that is activated upon contact with blood from the initial blood draw, or when air displacement is stopped, or any combination of events with blood in the sequestration chamber 55. The air permeable barrier may also include an outer layer such as a hydrophobic membrane or cover that inhibits or prevents the inadvertent or premature sealing of the filter by an external fluid source, splash etc. Sequestration chamber 55 can also be translucent or clear to enable a user to visually confirm the chamber is filled.

[0055] FIG. 2 illustrates a blood sample optimization system in accordance with some alternative implementations. In the implementation shown in FIG. 2, a sequestration chamber 55, or waste chamber, surrounds the patient needle 1, with an open-ended cuff or housing connected with the waste chamber and encircling the sample needle housing base and housing. The patient needle 1 and sample needle 5 are connected together by a boot 56, which forms a continuous blood draw channel therethrough. The boot 56 includes a single orifice or channel leading from the blood draw channel into sequestration chamber 55. The device can include more than one single orifice or channel, in other implementations. Each orifice or channel can include a one-way valve, and can be sized and adapted for predetermined amount of blood flow.

[0056] The sequestration chamber 55 includes an air permeable blood barrier. The filter can further include a sensor or indicator to sense and/or indicate, respectively, when a

predetermined volume of blood has been collected in the sequestration chamber 55. That indication will alert a user to attach an evacuated blood collection tube or bottle, such as a Vacutainer™ to the sample needle 5. The housing for the sequestration chamber 55 can be any size or shape, and can include any type of material to define an interior space or volume therein. The interior space is initially filled only with air, but can also be coated with an agent or substance, such as a decontaminate, solidifying agent, or the like. Once evacuated blood collection tube is attached to the sample needle 5, blood will flow automatically into the patient needle 1, through the blood draw channel and sample needle 5, and into the bottle. The sample needle 5 is covered by a resealable boot, coating or membrane that seals the sample needle when a blood collection bottle is not attached thereon or thereto.

[0057] FIG. 3 illustrates a blood sample optimization system in accordance with some alternative implementations. In the implementation shown, a sample needle 5 is surrounded by a resealable boot or membrane, and is further connected with a patient needle 1. A blood flow channel is formed through the sample needle and the patient needle. The connection between the sample needle and patient needle includes a "T" or "Y" connector 102, which includes a channel, port or aperture leading out from the main blood flow channel to a sequestration chamber 104.

[0058] The T or Y connector 102 may include a flap or one-way valve, and have an opening that is sized and adapted for a predetermined rate of flow of blood. The sequestration chamber 104 can be formed from tubing, or be formed by a solid housing, and is initially filled with air. The sequestration chamber 104 will receive blood that flows out of a patient automatically, i.e. under pressure from the patient's own blood pressure. The sequestration chamber 104 includes an air permeable blood barrier 106, preferably at the distal end of tubing that forms the sequestration chamber 104, and which is connected at the proximal end to the T or Y connector 102. The T or Y connector 102 can branch off at any desired angle for most efficient blood flow, and can be formed so as to minimize an interface between the aperture and channel and the main blood flow channel, so as to minimize or eliminate mixing of the initial aliquot of blood with main blood draw samples.

[0059] In some alternative implementations, the sample needle may be affixed to a tubing of any length, as shown in FIG. 4, connecting at its opposite end to the T or Y connector 102. The sequestration chamber 104 can be any shape or volume so long as it will contain a predetermined amount of blood sample in the initial aliquot. The T or Y connector 102 may also include an opening or channel that is parallel to the main blood flow channel. The air permeable blood barrier may further include an indicator 107 or other mechanism to indicate when a predetermined amount of blood has been collected in the sequestration chamber, or when air being expelled reaches a certain threshold, i.e. to zero. The tubing can also include a clip 109 that can be used to pinch off and prevent fluid flow therethrough.

[0060] Once the air permeable blood barrier and primary chamber are sealed the initial aliquot of blood is trapped in the sequestration chamber 104, an evacuated blood collection tube, such as a Vacutainer™ bottle may be attached to the sample needle 5 to obtain the sample. The blood collection tube can be removed, and the sample needle 5 will be resealed. Any number of follow-on blood collection tubes can then be attached for further blood draws or samples. Upon completion of all blood draws, the system can be discarded, with the initial aliquot of blood remaining trapped in the sequestration chamber 104.

[0061] FIG. 5 illustrates a blood sample optimization system in accordance with some alternative implementations. In the implementation shown, a sample needle 5 is connected with a patient needle by tubing. A "T" or "Y" connector 120 is added along the tubing at any desired location, and includes an aperture, port or channel leading to a sequestration chamber 204, substantially as described above.

[0062] FIG. 6 illustrates a blood sample optimization system in accordance with some alternative implementations, in which a sequestration chamber 304, formed as a primary collection channel, receives an initial aliquot of blood, and is provided adjacent to the blood sampling channel. The sequestration chamber 304 can encircle the blood sampling channel, the patient needle 1, and/or the sample needle 5. The primary collection channel can include a T or Y connector 120, or other type of aperture or channel. The sequestration chamber 304 includes an air permeable blood barrier, which can also include an indicator of being contacted by a fluid such as blood, as described above.

[0063] In some implementations, either the patient needle 1 or the sample needle 5, or both, can be replaced by a Luer lock male or female connector. However, in various implementations, the connector at a sample needle end of the blood sample optimization system is initially sealed to permit the diversion of the initial aliquot of blood to the sequestration chamber, which is pressured at ambient air pressure and includes the air outlet of the air permeable blood barrier. In this way, the system passively and automatically uses a patient's own blood pressure to overcome the ambient air pressure of the sequestration chamber to push out air through the air permeable blood barrier and displace air in the sequestration chamber with blood.

[0064] FIG. 7 is a flowchart of an exemplary method for optimizing the quality of a blood culture. At 702, a clinician places a needle into a patient's vein. At 704, blood then flows into a sequestration chamber, pushing the air in the sequestration chamber out of the sequestration chamber through an air permeable blood barrier. In some implementations, the volume of the sequestration chamber is less than 0.1 to more than 5 cubic centimeters (cc's), or more. The sequestration chamber is sized and adapted to collect a first portion of a blood sample, which is more prone to contamination than secondary and other subsequent portion of the blood sample or subsequent draws. Since the sequestration chamber has an air-permeable blood barrier through which air can be displaced by blood pushed from the patient's vein, such blood will naturally and automatically flow into the sequestration chamber before it is drawn into or otherwise enters into a Vacutainer or other bottle for receiving and storing a blood sample.

[0065] When the sequestration chamber fills, the blood will gather at or otherwise make contact with the air permeable blood barrier, which will inhibit or prevent blood from passing therethrough. At 706, when the blood comes into contact with the entire internal surface area of the air permeable blood barrier, the air permeable blood barrier is then closed and air no longer flows out or in. At 708, the clinician may be provided an indictor or can see the full chamber, to indicate the evacuated blood collection tube, such as a Vacutainer™ can be attached. The indicator can include visibility into the primary chamber to see whether it is full, the blood barrier changing color, for example, or other indicator. The fill time of

the sequestration chamber may be substantially instantaneous, so such indicator, if present, may be only that the sequestration chamber is filled.

[0066] Prior to an evacuated blood collection tube being attached, communication between the needle, sampling channel, and the sequestration chamber is restricted by the sealing of the sequestration chamber blood barrier thereby not permitting air to reenter the system through the sequestration. Sealing the communication path could also be accomplished with a mechanical twist or other movement, a small orifice or tortuous pathway, eliminating the need for a separate valve or mechanical movement or operation by the clinician. At 710, once the evacuated blood collection tube is removed, the self-sealing membrane closes the sample needle, and at 712, additional subsequent evacuated blood collection tubes may be attached. Once samples have been taken, at 714 the device is removed from the patient and discarded.

[0067] FIGS. 8A – 8E illustrate an exemplary blood sample optimization system 800 for non-contaminated blood sampling, in accordance with some implementations. The blood sample optimization system 800 includes an inlet port 802 that can be connected to tubing, a patient needle (or both), or other vascular or venous access device, and a pathway splitter 804 having a first outlet to a sequestration chamber tubing 806 and a second outlet to sample collection tubing 808. One or both of the sequestration chamber tubing 806 and the sample collection tubing 808 can be formed of tubing. In some implementations, the sequestration chamber tubing 806 is sized so as to contain a particular volume of initial blood sample. The sample collection tubing 808 will receive a blood sample once the sequestration chamber tubing 806 is filled. The sample collection tubing 808 can be connected to a Vacutainer™ base or housing 810, or other blood sample collection device.

[0068] The blood sequestration system 800 further includes a blood sequestration device 812 which, as shown in more detail in FIGS. 8B – 8D, includes a housing 818 that includes a sampling channel 820 defining a pathway for the non-contaminated sample collection tubing 808 or connected at either end to the non-contaminated sample collection tubing 808. The sampling channel 820 can be curved through the housing 818 so as to better

affix and stabilize the housing 818 at a location along the non-contaminated sample collection tubing 808.

[0069] The blood sequestration device 812 further includes a sequestration chamber 822 connected with the sequestration chamber tubing 806 or other chamber. The sequestration chamber 822 terminates at an air permeable blood barrier 824. The air permeable blood barrier 824 can also include a coloring agent that turns a different color upon full contact with blood, as an indicator that the regular collection of blood samples (i.e. the non-contaminated blood samples) can be initiated. Other indicators may be used, such as a small light, a sound generation mechanism, or the like. In some implementations, the air permeable blood barrier is positioned at a right angle from the direction of sequestration chamber 822, but can be positioned at any distance or orientation in order to conserve space and materials used for the housing 818. The housing 818 and its contents can be formed of any rigid or semi-rigid material or set of materials.

[0070] FIG. 9 illustrates a pathway splitter 900 for use in a blood sequestrations system, such as those shown in FIGS. 8A – 8E, for example. The pathway splitter 900 includes an inlet port 902, a main line outlet port 904, and a sequestration channel outlet port 906. The inlet port 902 can be connected to main tubing that is in turn connected to a patient needle system, or directly to a patient needle. The main line outlet port 904 can be connected to main line tubing to a blood sampling system, such as a vacutainer base or housing, or directly to such blood sampling system. The sequestration channel outlet port 906 can be connected to sequestration tubing for receiving and sequestering a first sample of blood, up to a measured amount or predetermined threshold. Alternatively, the sequestration channel outlet port 906 can be connected to a sequestration chamber. The sequestration channel outlet port 906 is preferably 20-70 degrees angled from the main line outlet port 904, which in turn is preferably in-line with the inlet port 902. Once the predetermined amount of initial blood sample is sequestered in the sequestration tubing or chamber, in accordance with mechanisms and techniques described herein, follow-on blood samples will flow into the inlet port 902 and directly out the main line outlet port 904, without impedance.

[0071] FIGS. 10A – 10D illustrate a blood sequestration device 1000 in accordance with alternative implementations. The blood sequestration device 1000 includes an inlet port 1002, a main outlet port 1004, and a sequestration channel port 1006. The inlet port 1002 can be connected to a patient needle or related tubing. The main outlet port 1004 can be connected to a blood sample collection device such as a Vacutainer, associated tubing, or a Luer activated valve, or the like. The sequestration channel port 1006 splits off from the main outlet port 1004 to a sequestration chamber 1008. In some implementations, the sequestration chamber 1008 is formed as a helical channel within a housing or other container 1001.

[0072] The sequestration chamber 1008 is connected at the distal end to an air permeable blood barrier 1010, substantially as described above. Air in the sequestration chamber 1008 is displaced through the air permeable blood barrier 1010 by an initial aliquot of blood that is guided into the sequestration channel port 1006. Once the sequestration chamber 1008 is filled, further blood draws through the main outlet port 1004 can be accomplished, where these samples will be non-contaminated.

[0073] FIGS. 11A – 11E illustrate a blood sequestration device 1100 in accordance with other alternative implementations. The blood sequestration device 1100 includes an inlet port 1102, similar to the inlet ports described above, a main outlet port 1104, and a sequestration channel port 1106 that splits off from the main outlet port 1104 and inlet port 1102. The sequestration channel port is connected to a sequestration chamber 1108. In the implementation shown in FIGS. 11A – 11E, the blood sequestration device includes a base member 1101 having a channel therein, which functions as the sequestration chamber 1108. The channel can be formed as a tortuous path through the base member 1101, which is in turn shaped and formed to rest on a limb of a patient.

[0074] A portion of the sequestration chamber 1108 can protrude from the base member or near a top surface of the base member, just before exiting to an air permeable blood barrier 1110, to serve as a blood sequestration indicator 1109. The indicator 1109 can be formed of a clear material, or a material that changes color when in contact with blood.

[0075] In some implementations, the blood sequestration device 1100 can include a blood sampling device 1120 such as a normally closed needle, Vacutainer™ shield or other collection device. The blood sampling device 1120 can be manufactured and sold with the blood sequestration device 1100 for efficiency and convenience, so that a first aliquot of blood that may be contaminated by a patient needle insertion process can be sequestered. Thereafter, the blood sampling device 1120 can draw non-contaminated blood samples to reduce the risk of false positive testing and ensure a non-contaminated sample.

[0076] FIGS. 12A-12D illustrate a blood sample optimization system 1200 in accordance with yet other alternative implementations. The system 1200 includes a blood sequestration device 1202 for attaching to a blood sampling device 1204, such as a Vacutainer™ or other collection and sampling device. The blood sequestration device 1202 is configured and arranged to receive, prior to a Vacutainer™ container or vial being attached to a collection needle of the blood sampling device 1204, a first aliquot or amount of blood, and sequester that first aliquot or amount in a sequestration channel of the blood sequestration device 1202.

[0077] In some implementations, the blood sequestration device 1202 can include an inlet port 1212, a main outlet port, and a sequestration channel port. The inlet port 1212 can be connected to a patient needle or related tubing. The main outlet port 1214 can be connected to a normally closed needle or device to enable connection with an evacuated blood collection container or other collection device such as a Vacutainer™, associated tubing, luer connectors, syringe, a Luer activated valve, or the like. The sequestration channel port splits off from the main outlet port to a sequestration chamber 1218.

[0078] In some implementations, the sequestration chamber 1218 is formed as a channel within the body of a sequestration device 1202. The sequestration chamber 1218 can be a winding channel, such as a U-shaped channel, an S-shaped channel, a helical channel, or any other winding channel. The sequestration device 1202 can include a housing or other containing body, and one or more channels formed therein. As shown in FIGS. 12A and 12B, the sequestration device 1202 includes a main body 1206 and a cap 1208. The main body 1206 is formed with one or more cavities or channels, which are further formed with

one or more arms 1210 that extend from the cap 1208, and which abut the cavities or channels in the main body 1206 to form the primary collection port and main outlet port.

[0079] FIGS. 13A-13D illustrate a blood sample optimization system 1300 in accordance with yet other alternative implementations. The system 1300 includes a blood sequestration device 1302 for attaching to a blood sampling device 1304, such as a Vacutainer or other bodily fluid collection and sampling device. The blood sequestration device 1302 is configured and arranged to receive, prior to a Vacutainer container or vial being attached to a collection needle of the blood sampling device 1304, a first aliquot or amount of blood, and to sequester that first aliquot or amount of blood or other bodily fluid in a sequestration channel of the blood sequestration device 1302.

[0080] The blood sequestration device 1302 includes a housing 1301 having an inlet port 1314, a main outlet port 1312, and a sequestration channel port 1316. The inlet port 1314 can be connected to a patient needle or associated tubing. The main outlet port 1312 can be connected to a normally closed needle or device to enable connection with an evacuated blood collection container or other collection device such as a Vacutainer™, associated tubing, luer connectors, syringe, a Luer activated valve, or the like. The sequestration channel port 1316 splits off from the main inlet port 1314 to a sequestration chamber 1318.

[0081] In the implementation shown in FIGS. 13A-D, the sequestration chamber 1318 is formed as a cavity or chamber within housing 1301 or formed by walls that define housing 1301. The sequestration chamber 1318 can be a winding channel, such as a U-shaped channel, an S-shaped channel, a helical channel, or any other winding channel, that is defined by the cooperation and connection of housing 1301 with cap 1307 which cap 1307 can include a protrusion 1305 that provides one or more walls or directors for the winding channel in the sequestration chamber 1318. The protrusion 1305 from the cap 1307 can be straight or curved, and may have various channels, apertures or grooves embedded therein, and can extend from the cap 1307 any angle or orientation. When the cap 1307 is connected with the housing 1301 to complete the formation of the sequestration chamber 1318, the protrusion 1305 forms at least part of the winding channel to sequester a first aliquot or

amount of blood or other bodily fluid in a sequestration channel formed in the sequestration chamber 1318 and by the winding channel.

[0082] The sequestration chamber 1318 includes an air permeable blood barrier 1310, substantially as described above. Air in the sequestration chamber 1318 is displaced through the air permeable blood barrier 1310 by an initial aliquot of blood that is provided into the sequestration chamber 1318 by the blood pressure of the patient. Once the sequestration chamber 1318 is filled and the air in the sequestration chamber 1318 displaced, the blood pressure of the patient will be insufficient to drive or provide further blood into the blood sequestration device 1302, and in particular the outlet port 1312, until a force such as a vacuum or other pressure, such as provided by the blood sample collection device like Vacutainer is provided to draw out a next aliquot or amount of blood or bodily fluid. Further blood draws through the main outlet port 1312 can be accomplished, where these samples will be non-contaminated since any contaminants would be sequestered in the sequestration chamber 1318 with the first aliquot of blood.

[0083] FIGS. 14A-14E illustrate yet another implementation of a blood sampling system 1400 to sequester contaminates of an initial aliquot or sample to reduce false positives in blood cultures or tests performed on a patient's blood sample. The blood sampling system 1400 includes a blood sequestration device 1401 that can be connected between a blood sample collection device 1403 and a patient needle (not shown). The blood sample collection device 1403 can be a Vacutainer or the like. The blood sequestration device 1401 includes an inlet port 1402 that can be connected with a patient needle that is inserted into a patient's vascular system for access to and withdrawing of a blood sample. The inlet port 1402 may also be connected with tubing or other conduit that is in turn connected with the patient needle.

[0084] The inlet port 1402 defines an opening into the blood sequestration device 1401, which opening can be the same cross sectional dimensions as tubing or other conduit connected with the patient needle or the patient needle itself. For instance, the opening can be circular with a diameter of approximately 0.045 inches, but can have a diameter of between 0.01 inches or less to 0.2 inches or more. The blood sequestration device 1401

further includes an outlet port 1404, which defines an opening out of the blood sequestration device 1401 and to the blood sample collection device 1403. The outlet port 1404 may also be connected with tubing or other conduit that is in turn connected with the blood sequestration device 1403. The outlet port 1404 can further include a connector device such as a threaded cap, a Luer connector (male or female), a non threaded interference or glue joint fitting for attachment of various devices including but not limited to tubing, or the like.

[0085] The blood sequestration device 1401 further includes a sampling channel 1406 between the inlet port 1402 and the outlet port 1404, and which functions as a blood sample pathway once a first aliquot of blood has been sequestered. The sampling channel 1406 can be any sized, shaped or configured channel, or conduit. In some implementations, the sampling channel 1406 has a substantially similar cross sectional area as the opening of the inlet port 1402. In other implementations, the sampling channel 1406 can gradually widen from the inlet port 1402 to the outlet port 1404.

[0086] The blood sequestration device 1401 further includes a sequestration chamber 1408 that is connected to and split off or diverted from the sampling channel 1406 at any point between the inlet port 1402 and the outlet port 1404, but preferably from a proximal end of the sampling channel 1406 near the inlet port 1402. The sequestration chamber 1408 is at first maintained at atmospheric pressure, and includes an air outlet 1412 at or near a distal end of the sequestration chamber 1408 opposite the diversion point from the sampling channel 1406. The air outlet 1412 includes an air permeable blood barrier 1412. As shown in FIG. 14B, the air permeable blood barrier 1412 can be overlaid with a protective cover 1416. The protective cover 1416 can be sized and configured to inhibit a user from touching the air permeable blood barrier 1412 with their finger or other external implement, while still allowing air to exit the air permeable blood barrier 1412 as the air is displaced from the sequestration chamber 1408 by blood being forced into the sequestration chamber 1408 by a patient's own blood pressure. In addition the protective cover 1416 can be constructed to inhibit or prevent accidental exposure of the air permeable blood barrier to environmental fluids or splashes. This can be accomplished in a variety of mechanical ways including but not limited to the addition of a hydrophobic membrane to the protective cover.

[0087] As shown in FIGS. 14C and 14D, the sampling channel 1406 can be cylindrical or frusto-conical in shape, going from a smaller diameter to a larger diameter, to minimize a potential to lyse red blood cells. Likewise, the sampling channel 1406 is formed with a minimal amount of or no sharp turns or edges, which can also lyse red blood cells. The sampling channel 1406 splits off to the sequestration chamber 1408 near the inlet port 1402 via a diversion pathway 1409. The diversion pathway 1409 can have any cross-sectional shape or size, but is preferably similar to the cross-sectional shape of at least part of the inlet port 1402.

[0088] In some implementations, the sampling channel 1406 and the sequestration chamber 1408 are formed by grooves, channels, locks or other pathways formed in housing 1414. The housing 1414 can be made of plastic, metal or other rigid or semi-rigid material. The housing 1414 can have a bottom member that sealably mates with a top member. One or both of the bottom member and the top member can include the sampling channel 1406 and the sequestration chamber 1408, as well as the diversion pathway 1409, the inlet port 1402, and the outlet port 1404. In some other implementations, one or more of the diversion pathway 1409, the inlet port 1402, and/or the outlet port 1404 can be at least partially formed by a cap member that is connected to either end of the housing 1414. In some implementations, the top member and the bottom member, as well as the cap member(s), can be coupled together by laser welding, heat sealing, gluing, snapping, screwing, bolting, or the like. In other implementations, some or all of the interior surface of the diversion pathway 1409 and/or sequestration chamber 1408 can be coated or loaded with an agent or substance, such as a decontaminate, solidifying agent, or the like. For instance, a solidifying agent can be provided at the diversion pathway 1409 such that when the sequestration chamber 1408 is filled and the initial aliquot of blood backs up to the diversion pathway 1409, that last amount of sequestered blood could solidify, creating a barrier between the sequestration chamber 1408 and the sampling channel 1406.

[0089] FIGS. 15A-15G illustrate a blood sequestration device 1500. The blood sequestration device 1500 can be connected to a normally closed needle or device to enable connection with an evacuated blood collection container or other collection device such as a Vacutainer™, associated tubing, luer connectors, syringe, a Luer activated valve, or the like.

[0090] The blood sequestration device 1500 includes an inlet port 1502 that can be connected with a patient needle that is inserted into a patient's vascular system for access to and withdrawing of a blood sample. The inlet port 1502 may also be connected with tubing or other conduit that is in turn connected with the patient needle. The inlet port 1502 defines an opening into the blood sequestration device 1500, which opening may be the same cross sectional dimensions as tubing or other conduit connected with the patient needle or the patient needle itself. For instance, the opening can be circular with a diameter of approximately 0.045 inches, but can have a diameter of between 0.01 inches or less to 0.2 inches or more.

[0091] The inlet port 1502 can also include a sealing or fluid-tight connector or connection, such as threading or Luer fitting, or the like. In some implementations, tubing or other conduit associated with the patient needle can be integral with the inlet port 1502, such as by co-molding, gluing, laser weld, or thermally bonding the parts together. In this manner, the blood sequestration device 1500 can be fabricated and sold with the patient needle as a single unit, eliminating the need for connecting the patient needle to the blood sequestration device 1500 at the time of blood draw or sampling.

[0092] The blood sequestration device 1500 further includes an outlet port 1504, which defines an opening out of the blood sequestration device 1500 and to the blood sample collection device. The outlet port 1504 may also be connected with tubing or other conduit that is in turn connected with the blood sequestration device, and may also include a sealing or fluid-tight connector or connection, such as threading or Luer fitting, or the like. Accordingly, as discussed above, the blood sequestration device 1500 can be fabricated and sold with the patient needle and/or tubing and the blood sample collection device as a single unit, eliminating the need for connecting the patient needle and the blood sample collection device to the blood sequestration device 1500 at the time of blood draw or sampling.

[0093] The blood sequestration device 1500 further includes a sampling channel 1506 between the inlet port 1502 and the outlet port 1504, and which functions as a blood sample pathway once a first aliquot of blood has been sequestered. The sampling channel 1506 can be any sized, shaped or configured channel or conduit. In some implementations, the

sampling channel 1506 has a substantially similar cross sectional area as the opening of the inlet port 1502. In other implementations, the sampling channel 1506 can gradually widen from the inlet port 1502 to the outlet port 1504.

[0094] The blood sequestration device 1500 further includes a sequestration chamber 1508 that is connected to and split off or diverted from the sampling channel 1506 at any point between the inlet port 1502 and the outlet port 1504, but preferably from a proximal end of the sampling channel 1506 near the inlet port 1502. In some implementations, the diversion includes a Y-shaped junction. The sequestration chamber 1508 is preferably maintained at atmospheric pressure, and includes a vent 1510 at or near a distal end of the sequestration chamber 1508. The vent 1510 includes an air permeable blood barrier 1512. FIG. 15C illustrates the blood sequestration device 1500 with the sequestration chamber 1508 filled with a first aliquot or sample of blood from the patient.

[0095] The air permeable blood barrier 1512 can be covered with a protective cover 1516. The protective cover 1516 can be sized and configured to inhibit a user from touching the air permeable blood barrier 1512 with their finger or other external implement, while still allowing air to exit the air permeable blood barrier 1512 as the air is displaced from the sequestration chamber 1508 by blood being forced into the sequestration chamber 1508 by a patient's own blood pressure. The protective cover 1516 can be constructed to inhibit or prevent accidental exposure of the filter to environmental fluids or splashes. This can be accomplished in a variety of mechanical ways including but not limited to the addition of a hydrophobic membrane to the protective cover.

[0096] FIG. 15B is a perspective view of the blood sequestration device 1500 from the outlet port 1504 and top side of a housing 1501 of the blood sequestration device 1500 that includes the vent 1510, and illustrating an initial aliquot of blood filling sequestration chamber 1508 while the sampling channel 1506 is empty, before a sample collection device is activated. FIG. 15G is a perspective view of the blood sequestration device 1500 from the outlet port 1504 and bottom side of the housing 1501 of the blood sequestration device 1500, and illustrating the initial aliquot of blood filling sequestration chamber 1508 while the sampling channel 1506 is empty, before the sample collection device is activated. FIG. 15C

is another perspective view of the blood sequestration device 1500 from the inlet port 1502 and top side of a housing 1501 of the blood sequestration device 1500 that includes the vent 1510, and illustrating blood now being drawn through sampling channel 1506 while the sequestered blood remains substantially in the sequestration chamber 1508.

[0097] FIG. 15D is a cross section of the blood sequestration device 1500 in accordance with some implementations, showing the housing 1501 that defines the sampling channel 1506 and the sequestration chamber 1508. FIGS. 15E and 15F illustrate various form factors of a housing for a blood sequestration device, in accordance with one or more implementations described herein.

[0098] The sequestration chamber 1508 can have a larger cross-sectional area than the sampling channel 1506, and the cross-sectional area and length can be configured for a predetermined or specific volume of blood to be sequestered or locked. The sampling channel 1506 can be sized to be compatible with tubing for either or both of the patient needle tubing or the blood collection device tubing.

[0099] The housing 1501 can be formed of multiple parts or a single, unitary part. In some implementations, and as illustrated in FIG. 15D, the housing 1501 includes a top member 1520 and a bottom member 1522 that are mated together, one or both of which having grooves, channels, locks, conduits or other pathways pre-formed therein, such as by an injection molding process or by etching, cutting, drilling, etc. The top member 1520 can be connected with the bottom member 1522 by any mating or connection mechanism, such as by laser welding, thermal bonding, ultrasonic welding, gluing, using screws, rivets, bolts, or the like, or by other mating mechanisms such as latches, grooves, tongues, pins, flanges, or the like.

[00100] In some implementations, such as shown in FIG. 15D, the top member 1520 can include the grooves, channels, locks, conduits or other pathways, while the bottom member 1522 can include a protrusion 1524 that is sized and adapted to fit into at least one of the grooves, channels, locks or other pathways of the top member 1520. The protrusion 1524 can provide a surface feature, such as a partial groove or channel, for instance, to complete the formation of either the sampling channel 1506 and/or the sequestration chamber 1508. In

some implementations, the protrusion 1524 can be formed with one or more angled sides or surfaces for a tighter fit within the corresponding groove, channel, lock or other pathway. In yet other implementations, both the top member 1520 and the bottom member can include grooves, channels, locks or other pathways, as well as one or more protrusions 1524.

[00101] In some implementations, the sampling channel 1506 and the sequestration chamber 1508 are formed by grooves, channels, locks or other pathways formed in housing 1501. The housing 1501 can be made of any suitable material, including rubber, plastic, metal or other material. The housing 1501 can be formed of a clear or translucent material, or of an opaque or non-translucent material. In other implementations, the housing 1501 can be mostly opaque or non-translucent, while the housing surface directly adjacent to the sampling channel 1506 and/or the sequestration chamber 1508 is clear or translucent, giving a practitioner a visual cue or sign that the sequestration chamber 1508 is first filled to the extent necessary or desired, and/or then a visual cue or sign that the sequestered blood remains sequestered while a clean sample of blood is drawn through the sampling channel 1506. Other visual cues or signs of the sequestration can include, without limitation: the air permeable blood barrier 1512 turning a different color upon contact, saturation, or partial saturation with blood; a color-coded tab or indicator at any point along or adjacent to the sequestration chamber; an audible signal; a vibratory signal; or other signal.

[00102] After a venipuncture by a patient needle of a patient (not shown), which could gather a number of pathogens from the patient's skin, a first amount of the patient's blood with those pathogens will make its way into the input port 1502 blood sequestration device 1500 and flow into the sequestration chamber 1508 by following the path of least resistance, as the patient's own blood pressure overcomes the atmospheric pressure in the sequestration chamber 1508 to displace air therein through the air permeable blood barrier 1512. The patient's blood pressure will not be sufficient to overcome the air pressure that builds up in the sealed sampling channel 1506. Eventually, the sequestration chamber 1508, which has a predetermined volume, is filled with blood that displaces air through the air permeable blood barrier 1512. Once the blood hits the air permeable blood barrier, the blood interacts with the air permeable blood barrier 1512 material to completely or partially seal the vent 1510. A signal or indication may be provided that the practitioner can now utilize the Vacutainer

capsule or other blood sample collection device to acquire a next amount of the patient's blood for sampling. The blood in the sequestration chamber 1508 is now effectively sequestered in the sequestration chamber.

[00103] Upon filling the blood sequestration pathway 1508 but prior to use of the Vacutainer or other blood sample collection device, the patient's blood pressure may drive compression of the air in the sampling channel 1506, possibly resulting in a small amount of blood moving past the diversion point to the sequestration chamber 1508 and into the sampling channel 1506, queuing up the uncontaminated blood to be drawn through the sampling channel 1506.

[00104] FIGS. 16-19 illustrate yet another implementation of a blood sequestration device. FIGS. 16A-16D illustrate a blood sequestration device 1600 that can be connected between a blood sample collection device, such as an evacuated blood collection container like a Vacutainer™ (not shown), and a patient needle (not shown) and/or associated tubing. FIG. 17 illustrates a bottom member of the blood sequestration device, and FIG. 18 illustrates a top member of the blood sequestration device, which top member and bottom member can be mated together to form an input port, and output port, a sequestration chamber and a sampling channel, as explained more fully below. FIGS. 19A and B show the top member and bottom member mated together. It should be understood that FIGS. 16-19 illustrate one exemplary manner of constructing a blood sequestration device as described herein, and other forms of construction are possible.

[00105] Referring to FIGS. 16A – D, the blood sequestration device 1600 includes an inlet port 1602 that can be connected with a patient needle that is inserted into a patient's vascular system for access to and withdrawing of a blood sample. The inlet port 1602 may also be connected with tubing or other conduit that is in turn connected with the patient needle. The inlet port 1602 defines an opening into the blood sequestration device 1600, which opening can be the same cross sectional dimensions as tubing or other conduit connected with the patient needle or the patient needle itself. For instance, the opening can be circular with a diameter of approximately 0.045 inches, but can have a diameter of between 0.01 inches or less to 0.2 inches or more.

[00106] The inlet port 1602 can also include a sealing or fluid-tight connector or connection, such as threading or Luer fitting, or the like. In some implementations, tubing or other conduit associated with the patient needle can be integral with the inlet port 1602, such as by co-molding, gluing, laser weld, or thermally bonding the parts together. In this manner, the blood sequestration device 1600 can be fabricated and sold with the patient needle and/or tubing as a single unit, eliminating the need for connecting the patient needle to the blood sequestration device 1600 at the time of blood draw or sampling.

[00107] The blood sequestration device 1600 further includes an outlet port 1604, which defines an opening out of the blood sequestration device 1600 and to the blood sample collection device. The outlet port 1604 may also be connected with tubing or other conduit that is in turn connected with the blood sequestration device, and may also include a sealing or fluid-tight connector or connection, such as threading or Luer fitting, or the like. Accordingly, as discussed above, the blood sequestration device 1600 can be fabricated and sold with the patient needle and/or tubing and the blood sample collection device as a single unit, eliminating the need for connecting the patient needle and the blood sample collection device to the blood sequestration device 1600 at the time of blood draw or sampling.

[00108] The blood sequestration device 1600 further includes a sampling channel 1606 between the inlet port 1602 and the outlet port 1604, and a sequestration chamber 1608 that is connected to and split off or diverted from the sampling channel 1606 at any point between the inlet port 1602 and the outlet port 1604. The sampling channel 1606 functions as a blood sampling pathway once a first aliquot of blood has been sequestered in the sequestration chamber 1608. The sampling channel 1606 can be any sized, shaped or configured channel, or conduit. In some implementations, the sampling channel 1606 has a substantially similar cross sectional area as the opening of the inlet port 1602. In other implementations, the sampling channel 1606 can gradually widen from the inlet port 1602 to the outlet port 1604. The sequestration chamber 1608 may have a larger cross section to form a big reservoir toward the sequestration channel path so that the blood will want to enter the reservoir first versus entering a smaller diameter on the sampling channel 1606, as is shown more fully in FIGS. 17 and 19.

[00109] In some exemplary implementations, the diversion between the sampling channel 1606 and the sequestration chamber 1608 is by diverter junction 1607. Diverter junction 1607 may be a substantially Y-shaped, T-shaped, or U-shaped. In some preferred exemplary implementations, and as shown in FIG. 17A – 17B, the diverter junction 1607 is configured such that the flow out of the inlet port 1602 is preferentially directed toward the sequestration chamber 1608. The sequestration chamber 1608 may also include or form a curve or ramp to direct the initial blood flow toward and into the sequestration chamber 1608.

[00110] The sequestration chamber 1608 is preferably maintained at atmospheric pressure, and includes a vent 1610 at or near a distal end of the sequestration chamber 1608. The vent 1610 may include an air permeable blood barrier 1612 as described above.

[00111] The blood sequestration device 1600 can include a housing 1601 that can be formed of multiple parts or a single, unitary part. In some implementations, and as illustrated in FIGS. 17A – 17D and FIGS. 18A – 18F, the housing 1601 includes a top member 1620 and a bottom member 1622 that are mated together. The blood sequestration device 1600 can also include a gasket or other sealing member (not shown) so that when the top member 1620 is mechanically attached with the bottom member 1622, the interface between the two is sealed by the gasket or sealing member. The FIGS. 17A – 17D illustrate a bottom member 1622 of a housing for a blood sequestration device 1600. The bottom member 1622 can include grooves, channels, locks, conduits or other pathways pre-formed therein, such as by an injection molding process or by etching, cutting, drilling, etc., to form the sampling channel 1606, the sequestration chamber 1608, and diverter junction 1607.

[00112] The sequestration chamber 1608 may have a larger cross section than the sampling channel 1606 so that the blood will preferentially move into the sequestration chamber first versus entering a smaller diameter on the sampling channel 1606.

[00113] FIGS. 18A – 18F illustrate the top member 1620, which can be connected with the bottom member 1622 by any mating or connection mechanism, such as by laser welding, thermal bonding, gluing, using screws, rivets, bolts, or the like, or by other mating mechanisms such as latches, grooves, tongues, pins, flanges, or the like. The top member

1620 can include some or all of the grooves, channels, locks, conduits or other pathways to form the sampling channel 1606, the sequestration chamber 1608, and the diverter junction 1607. In yet other implementations, both the top member 1620 and the bottom member 1622 can include the grooves, channels, locks or other pathways.

[00114] In some implementations, the sampling channel 1606 and the sequestration chamber 1608 are formed by grooves, channels, locks or other pathways formed in housing 1601. The housing 1601 can be made of rubber, plastic, metal or any other suitable material. The housing 1601 can be formed of a clear or translucent material, or of an opaque or non-translucent material. In other implementations, the housing 1601 can be mostly opaque or non-translucent, while the housing surface directly adjacent to the sampling channel 1606 and/or the sequestration chamber 1608 may be clear or translucent, giving a practitioner a visual cue or sign that the sequestration chamber 1608 is first filled to the extent necessary or desired, and/or then a visual cue or sign that the sequestered blood remains sequestered while a clean sample of blood is drawn through the sampling channel 1606. Other visual cues or signs of the sequestration can include, without limitation: the air permeable blood barrier 1612 turning a different color upon contact, saturation, or partial saturation with blood; a color-coded tab or indicator at any point along or adjacent to the sequestration chamber; an audible signal; a vibratory signal; or other signal.

[00115] As shown in FIGS. 18A – 18F, the air permeable blood barrier 1612 can be covered with, or surrounded by, a protective member 1616. The protective member 1616 can be sized and configured to inhibit a user from touching the air permeable blood barrier 1612 with their finger or other external implement, while still allowing air to exit the air permeable blood barrier 1612 as the air is displaced from the sequestration chamber 1608. In some implementations, the protective member 1616 includes a protrusion that extends up from a top surface of the top member 1620 and around the air permeable blood barrier 1612. The protective cover 1616 can be constructed to inhibit or prevent accidental exposure of the filter to environmental fluids or splashes. This can be accomplished in a variety of mechanical ways including but not limited to the addition of a hydrophobic membrane to the protective cover.

[00116] In use, the blood sequestration device 1600 includes a sampling channel 1606 and a sequestration chamber 1608. Both pathways are initially air-filled at atmospheric pressure, but the sampling channel 1606 is directed to an output port 1604 that will be initially sealed by a Vacutainer or other such sealed blood sampling device, and the sequestration chamber 1608 terminates at a vent 1610 to atmosphere that includes an air permeable blood barrier 1612.

[00117] After a venipuncture by a patient needle of a patient (not shown), which could gather a number of pathogens from the patient's skin, a first amount of the patient's blood with those pathogens will pass through input port 1602 of blood sequestration device 1600. This initial volume of potentially contaminated blood will preferentially flow into the sequestration chamber 1608 by finding the path of least resistance. The patient's own blood pressure overcomes the atmospheric pressure in the vented sequestration chamber 1608 to displace air therein through the air permeable blood barrier 1612, but is not sufficient to overcome the air pressure that builds up in the sealed sampling channel 1606. In various exemplary embodiments, the sequestration chamber 1608 and sampling channel 1606 can be configured such that the force generated by the patient's blood pressure is sufficient to overcome any effect of gravity, regardless of the blood sequestration device's orientation.

[00118] Eventually, the sequestration chamber 1608 fills with blood that displaces air through the air permeable blood barrier 1612. Once the blood contacts the air permeable blood barrier, the blood interacts with the air permeable blood barrier 1612 material to completely or partially seal the vent 1610. A signal or indication may be provided that the practitioner can now utilize the Vacutainer or other blood sampling device.

[00119] Upon filling the blood sequestration pathway 1608 but prior to use of the Vacutainer or other blood sample collection device, the patient's blood pressure may drive compression of the air in the sampling channel 1606, possibly resulting in a small amount of blood moving past the diversion point into the sampling channel 1606, queuing up the uncontaminated blood to be drawn through the sampling channel 1606.

[00120] FIG. 19A is a side view, and FIG. 19B is a cross-sectional view, of the blood sequestration device 1600, illustrating the top member 1620 mated with the bottom member 1622.

[00121] FIG. 20 shows a blood sample optimization system 2000 that includes a patient needle 2002 for vascular access to a patient's bloodstream, a blood sample collection device 2004 to facilitate the collecting of one or more blood samples, and a conduit 2006 providing a fluid connection between the patient needle 2002 and the blood sample collection device 2004. In some implementations, the blood sample collection device 2004 includes a protective shield that includes a sealed collection needle on which a sealed vacuum-loaded container is placed, which, once pierced by the collection needle, draws in a blood sample under vacuum pressure or force through the conduit 2006 from the patient needle 2002.

[00122] The blood sample optimization system 2000 further includes a blood sequestration device 2008, located at any point on the conduit 2006 between the patient needle 2002 and the blood sample collection device 2004 as described herein.

[00123] FIG. 21 illustrates a non-vented blood sequestration device 2100 using a wicking material chamber. The blood sequestration device 2100 includes a housing 2101 that has a sampling channel 2104 that is at least partially surrounded or abutted by a sequestration chamber 2102 that is filled with a wicking material. An initial aliquot of blood is drawn in from the patient needle into the sampling channel 2104 where it is immediately wicked into the wicking material of the sequestration chamber 2102. The wicking material and/or sequestration chamber 2102 is sized and adapted to receive and hold a predetermined amount of blood, such that follow-on or later blood draws pass by the wicking material and flow straight through the sampling channel 2104 to a sampling device such as a Vacutainer. The wicking material can include a substance such as a solidifier, a decontaminate, or other additive.

[00124] As described herein, an air permeable blood barrier may be created using a wide variety of different structures and materials. As shown in FIGS. 22A and B, an air permeable blood barrier 2202 of a blood sequestration device 2200 can include a polymer bead matrix 2204, in which at least some beads are treated to make them hydrophilic. The

air permeable blood barrier 2202 further includes a self-sealing material 2206, such as carboxymethyl cellulose (CMC) or cellulose gum, or other sealing material. The air permeable blood barrier 2202 can further include voids 2208 that permit air flow before contact or during partial contact with a fluid such as blood. As shown in FIG. 22B, contact with a fluid causes the self-sealing material 2206 to swell and close off the voids 2208, occluding air flow through the voids 2208 and creating a complete or partial seal.

[00125] FIGS. 23A and B illustrate yet another implementation of a blood sequestration device 2300, having an inlet port 2302 to connect with a patient needle, an outlet port 2304 to connect with a blood sample collection device, a sequestration chamber 2306, and a sampling channel 2308 that bypasses the sequestration chamber 2306 once the sequestration chamber is filled to an initial aliquot of potentially contaminated blood to be sequestered. The sequestration chamber 2306 includes a hydrophobic plug 2312 at a distal end of the sequestration chamber 2306 that is farthest from the inlet port 2302. A vacuum or other drawing force applied from the outlet port 2304, such as from a Vacutainer or the like, draws in blood into the inlet port 2302 and directly into the sequestration chamber 2306, where the initial aliquot of blood will contact the hydrophobic plug 2312 and cause the initial aliquot of blood to back up into the sequestration chamber 2306 and be sequestered there. A small amount of blood may make its way into the sampling channel 2308, which is initially closed off by valve 2308. Upon release of the valve 2308, and under further force of the vacuum or other force, follow-on amounts of blood will flow into inlet port 2302, bypass the sequestration chamber 2306, and flow into and through sampling channel 2308 toward the outlet port 2304 and to the collection device.

[00126] The sampling channel 2308 can have any suitable geometry and can be formed of plastic tubing or any other suitable material. Valve 2308 can be a clip or other enclosing device to pinch, shunt, bend or otherwise close off the sampling channel before the initial aliquot of blood is sequestered in the sequestration chamber 2306.

[00127] Although a variety of embodiments have been described in detail above, other modifications are possible. Other embodiments may be within the scope of the following claims.

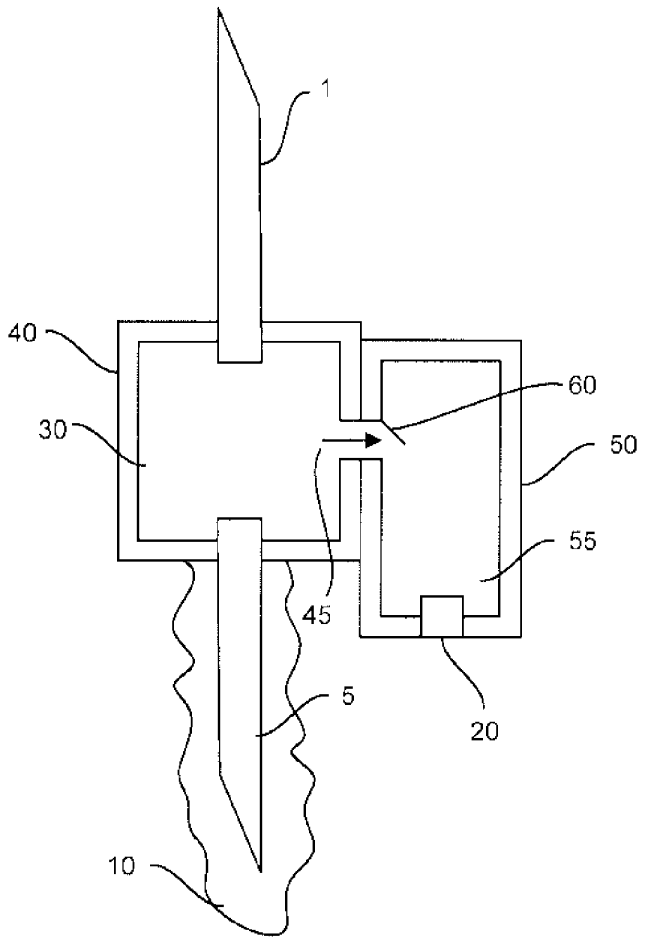


FIG. 1

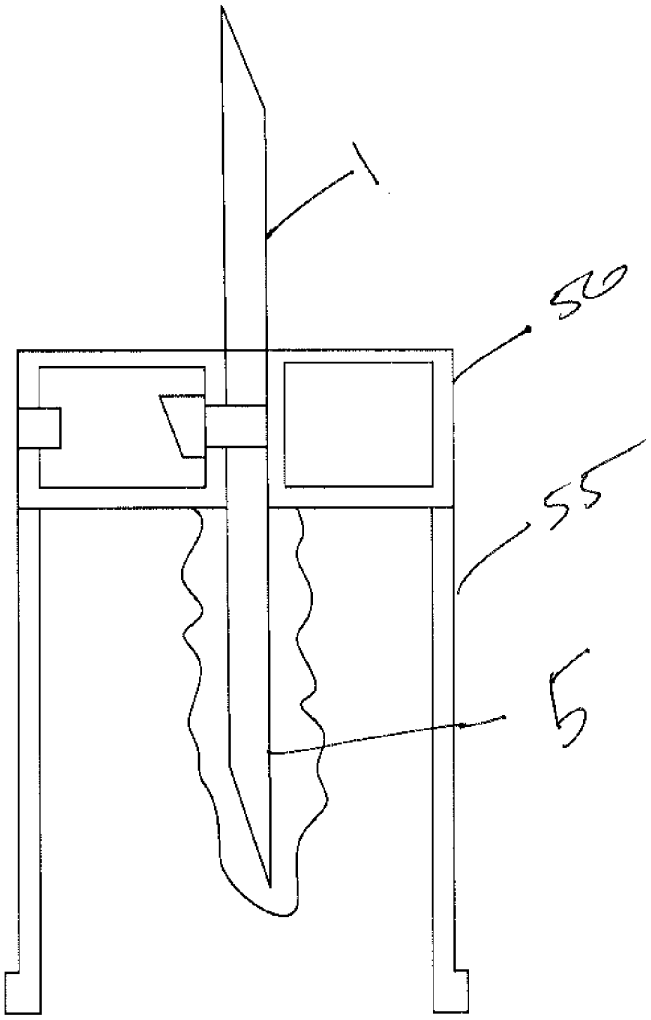


FIG. 2

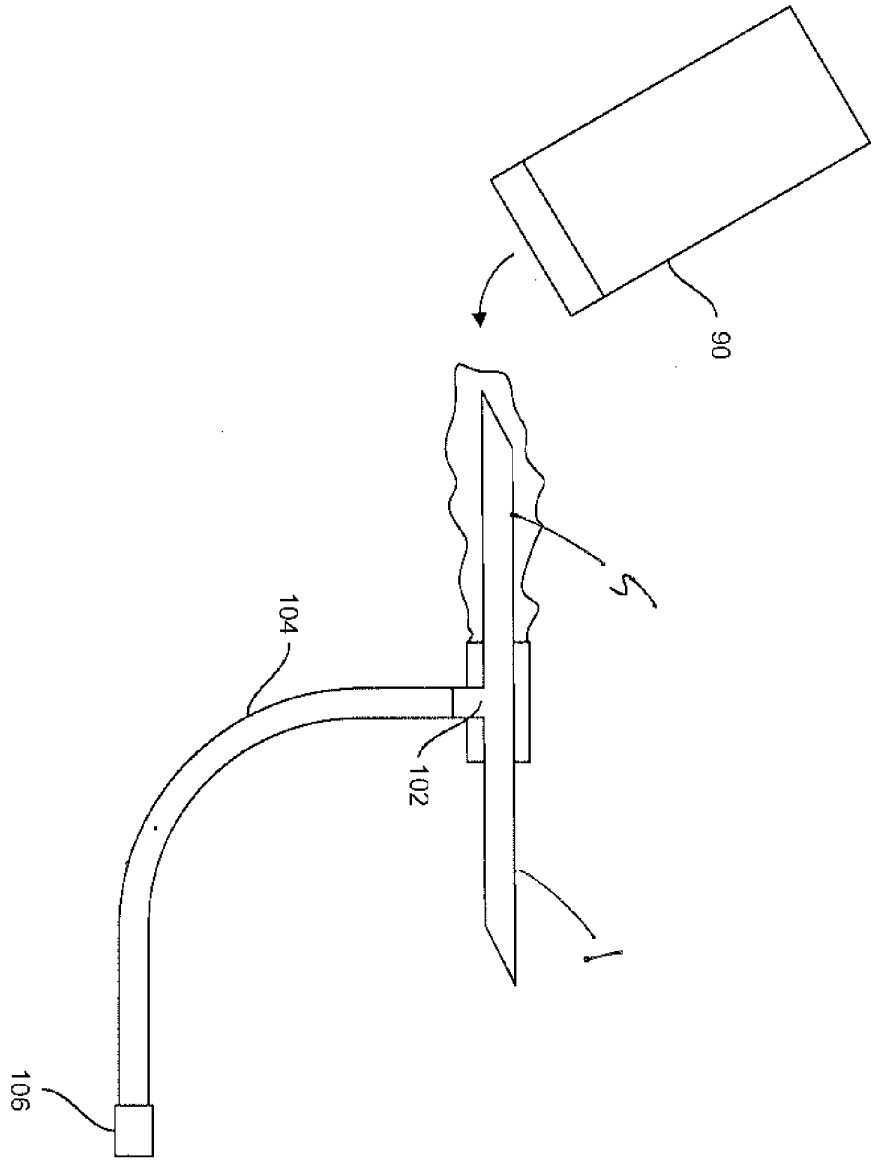


FIG. 3

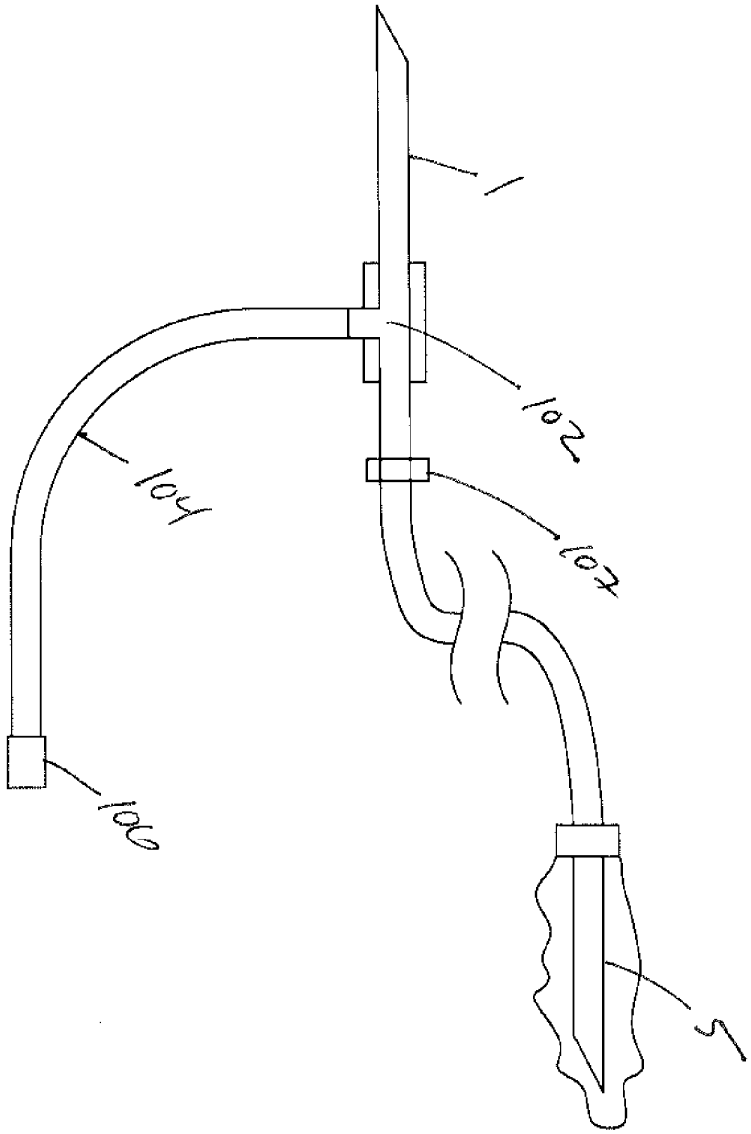


FIG. 4

FIG. 5

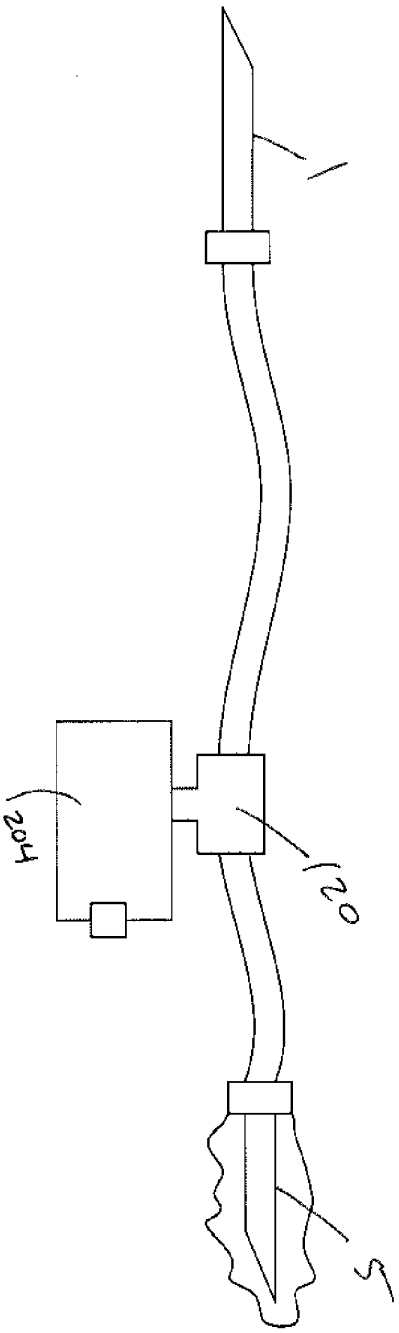
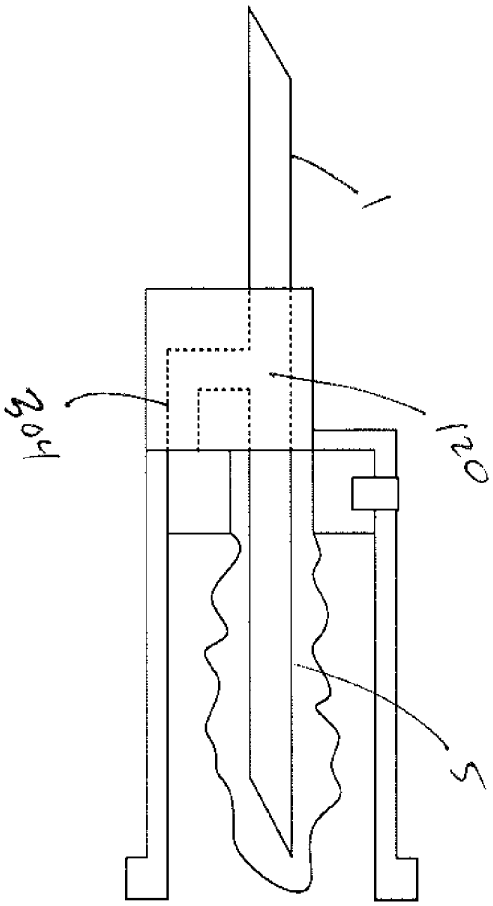


FIG. 6



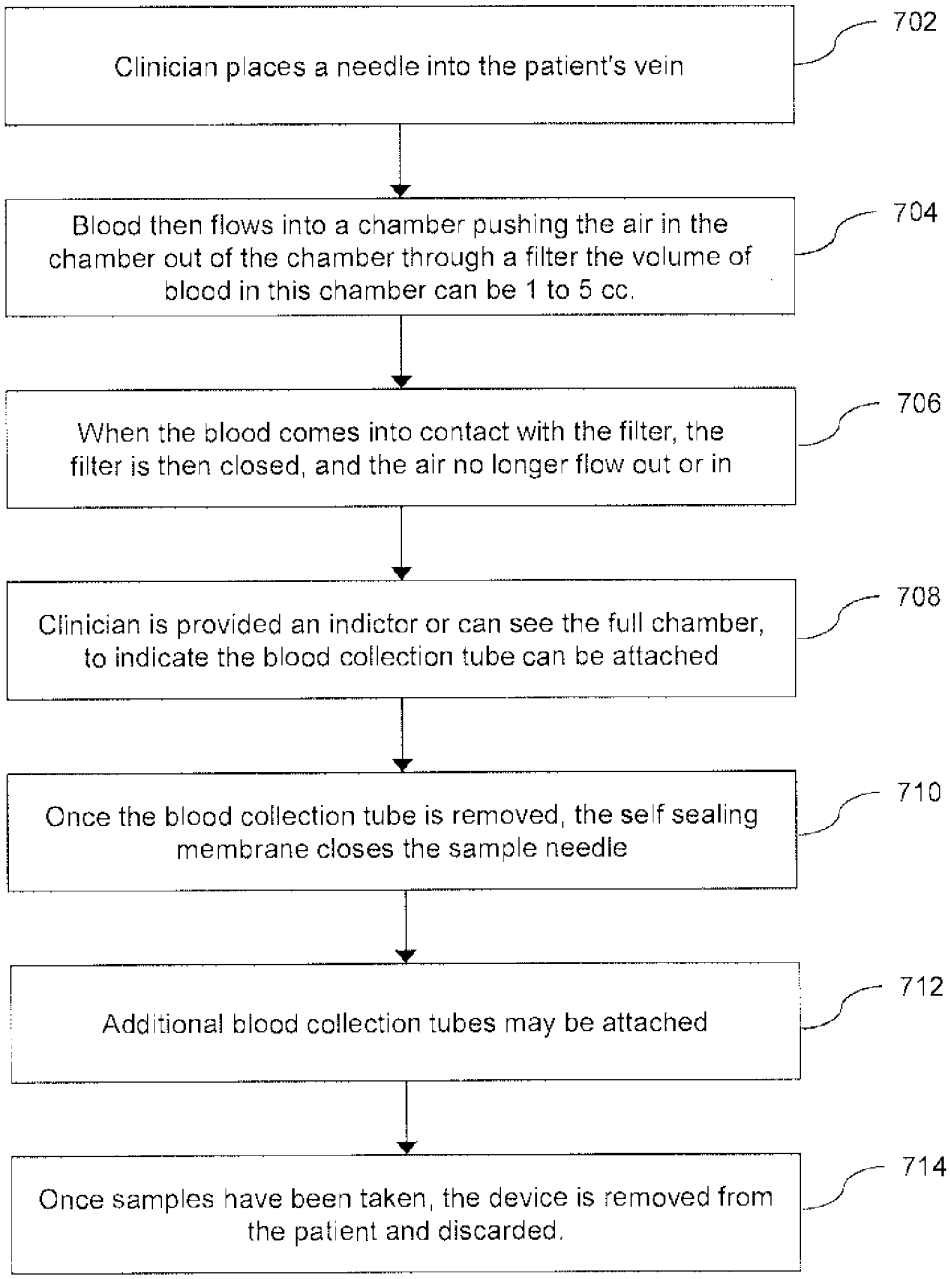

Clinician places a needle into the patient's vein
702
Blood then flows into a chamber pushing the air in the chamber out of the chamber through a filter the volume of blood in this chamber can be 1 to 5 cc.
704
When the blood comes into contact with the filter, the filter is then closed, and the air no longer flow out or in
706
Clinician is provided an indictor or can see the full chamber, to indicate the blood collection tube can be attached
708
Once the blood collection tube is removed, the self sealing membrane closes the sample needle
710
Additional blood collection tubes may be attached
712
Once samples have been taken, the device is removed from the patient and discarded.
714

FIG. 7

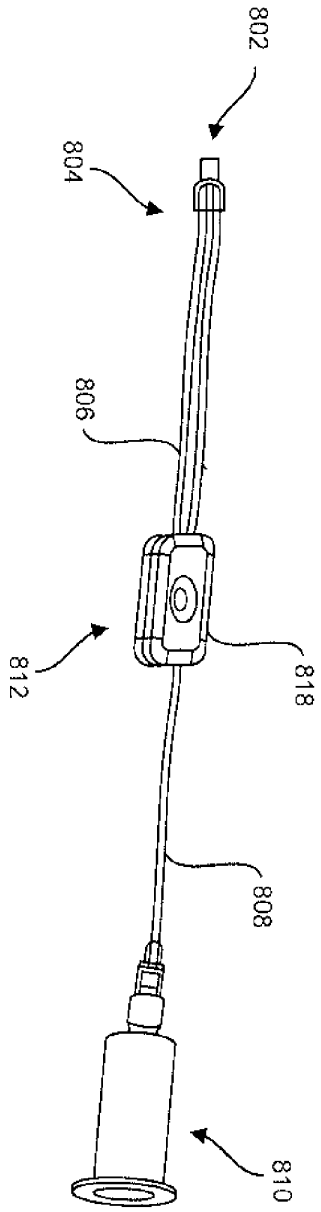


FIG. 8A

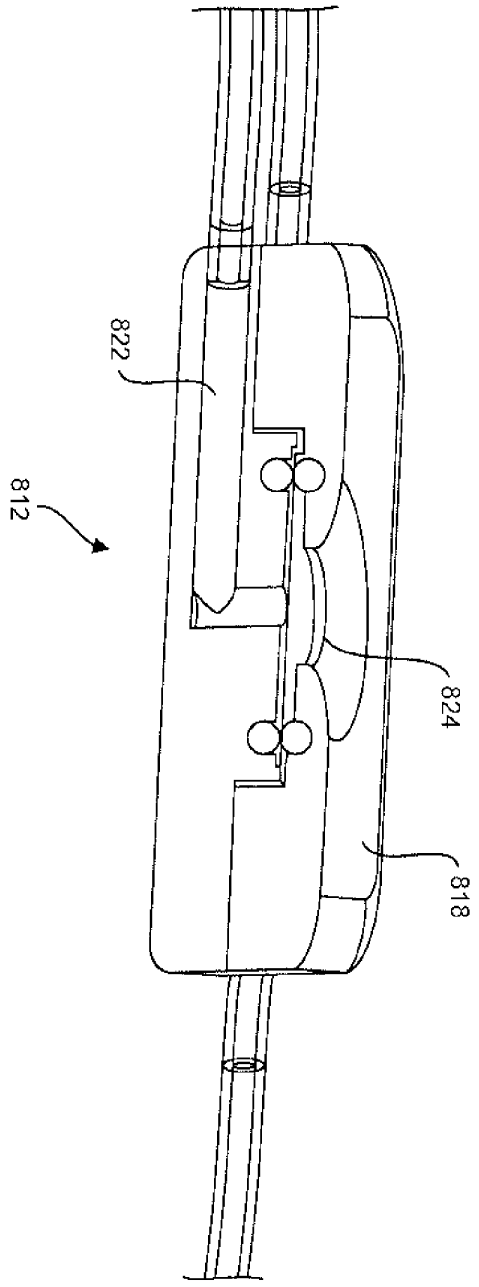


FIG. 8B

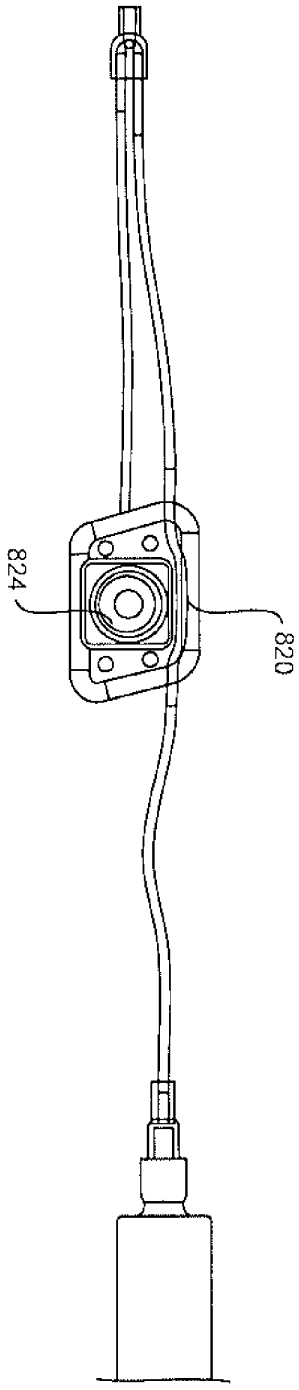


FIG. 8C

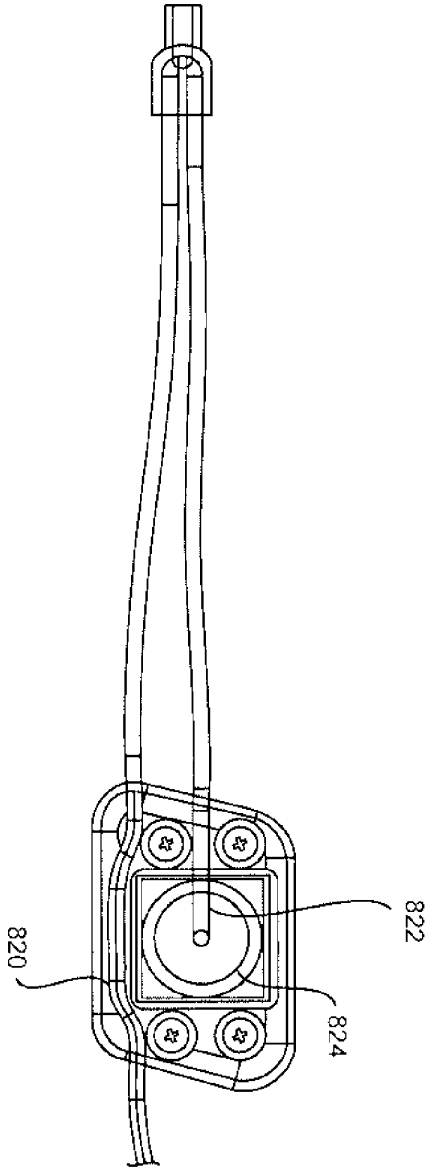


FIG. 8D

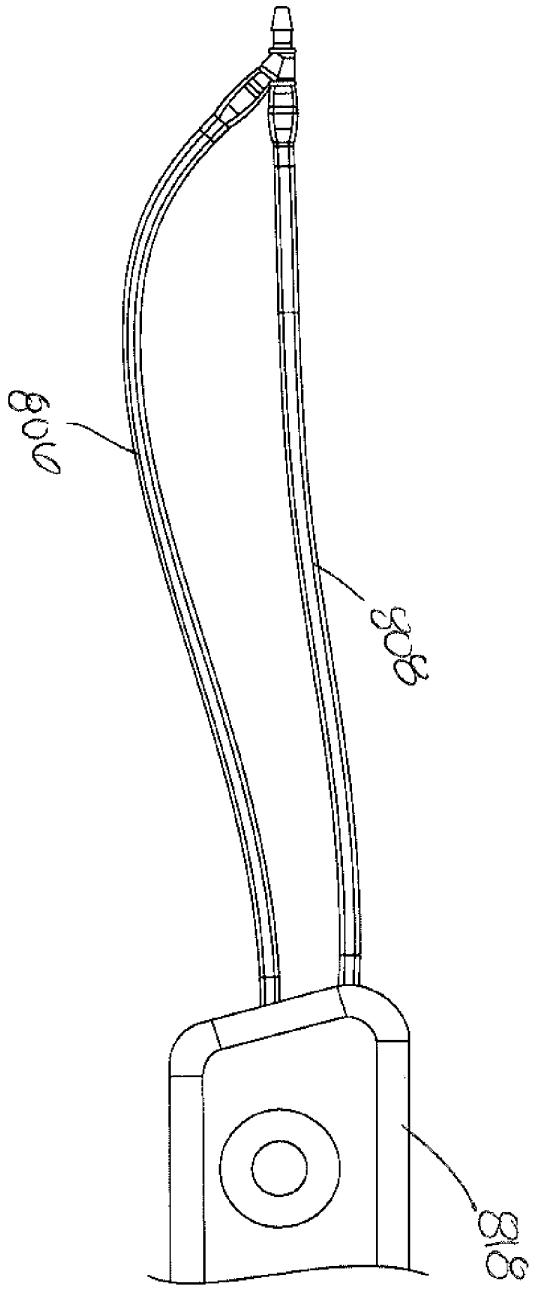


FIG. 8E

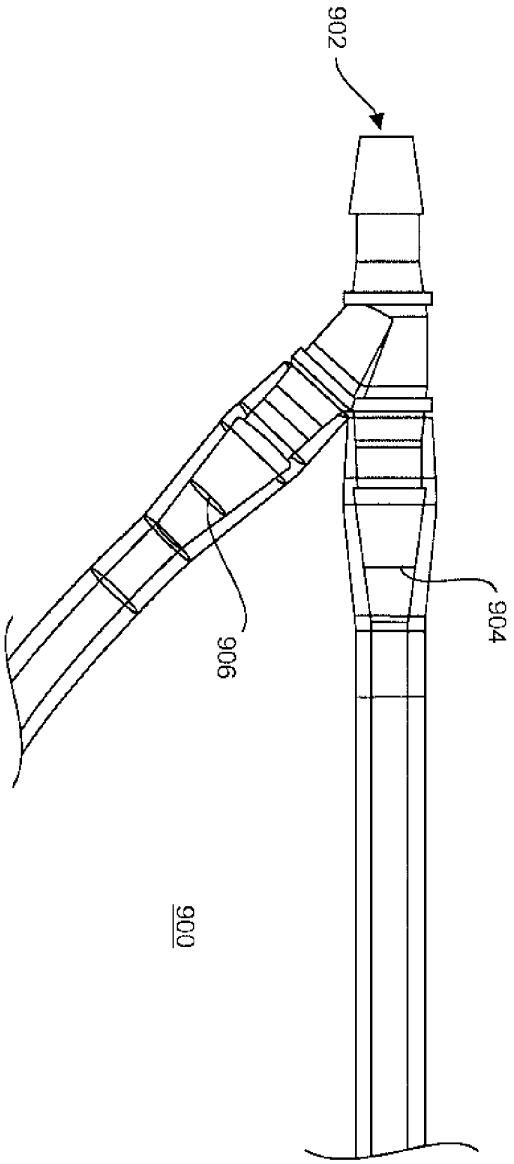


FIG. 9

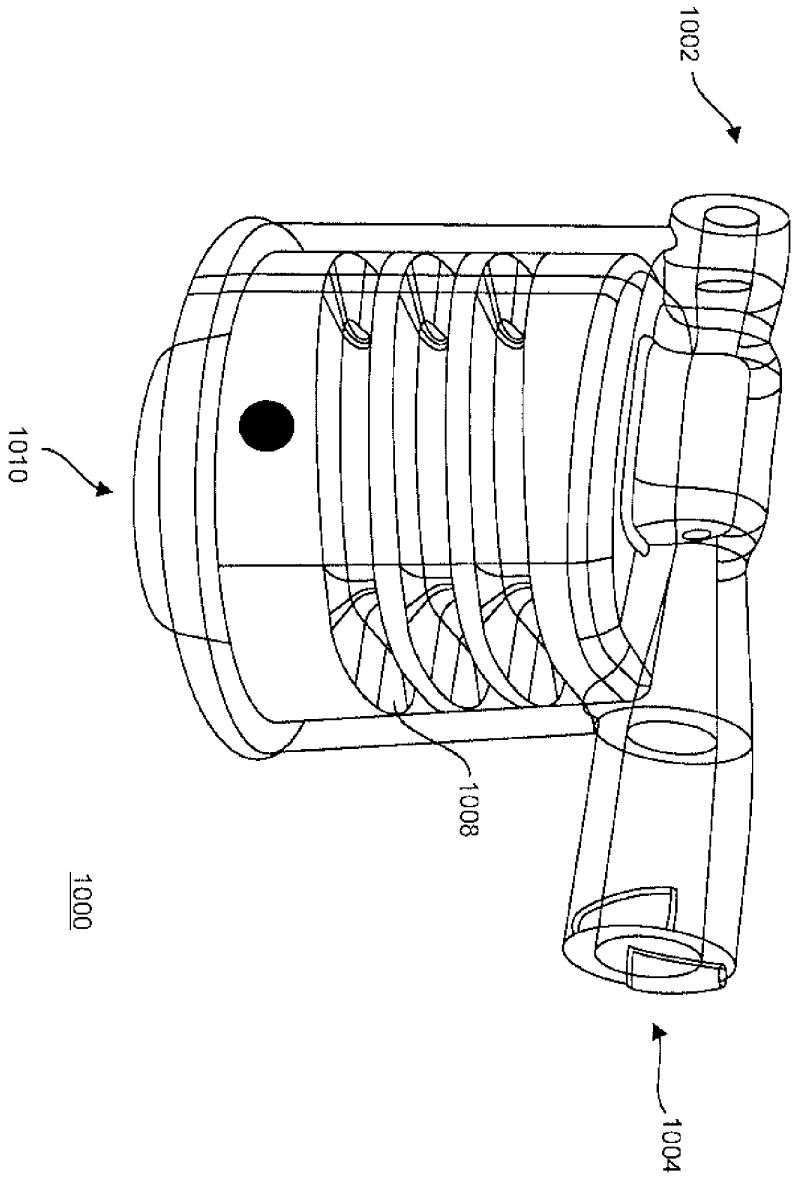


FIG. 10A

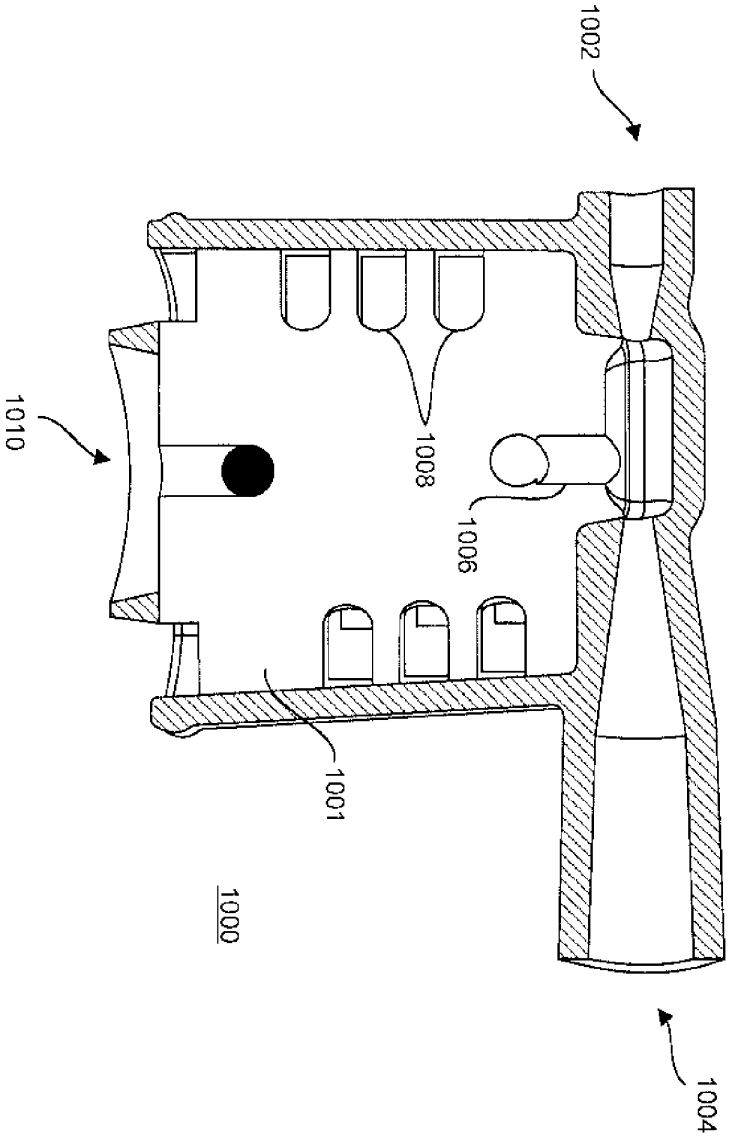


FIG. 10B

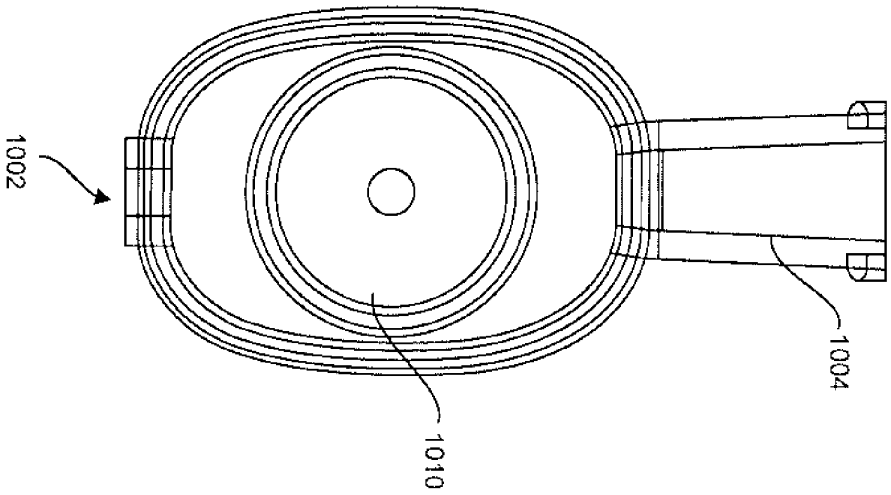


FIG. 10C

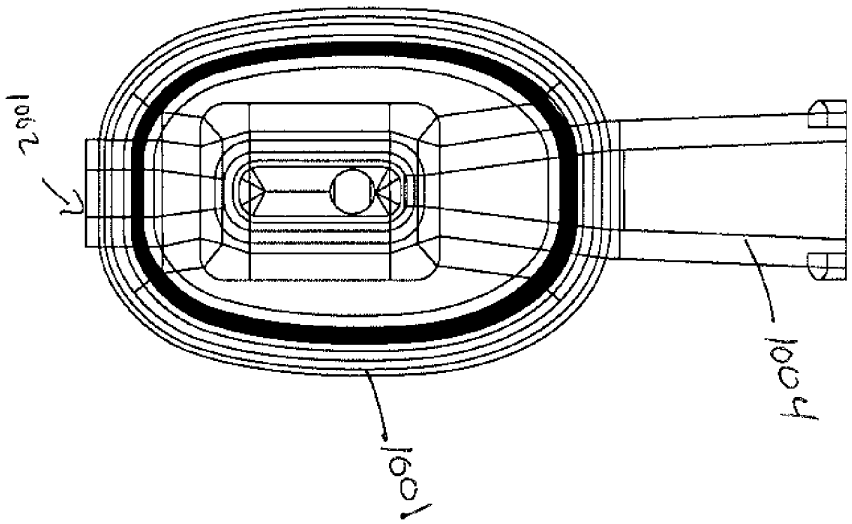


FIG. 10D

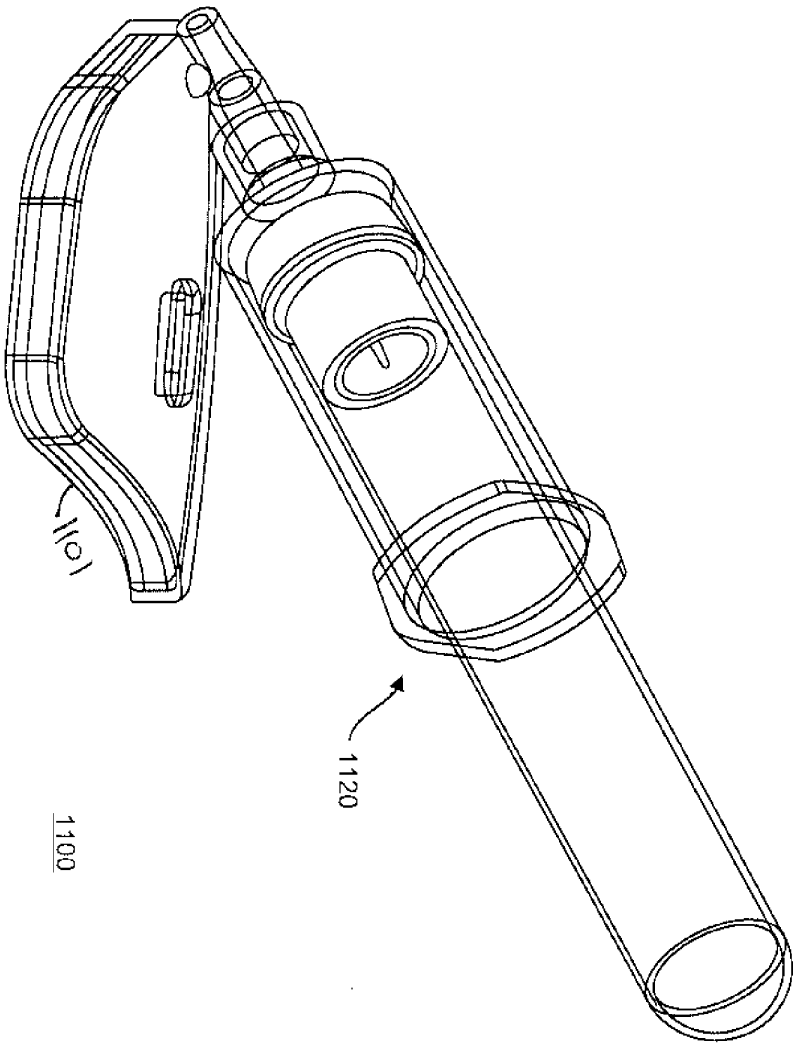


FIG. 11A

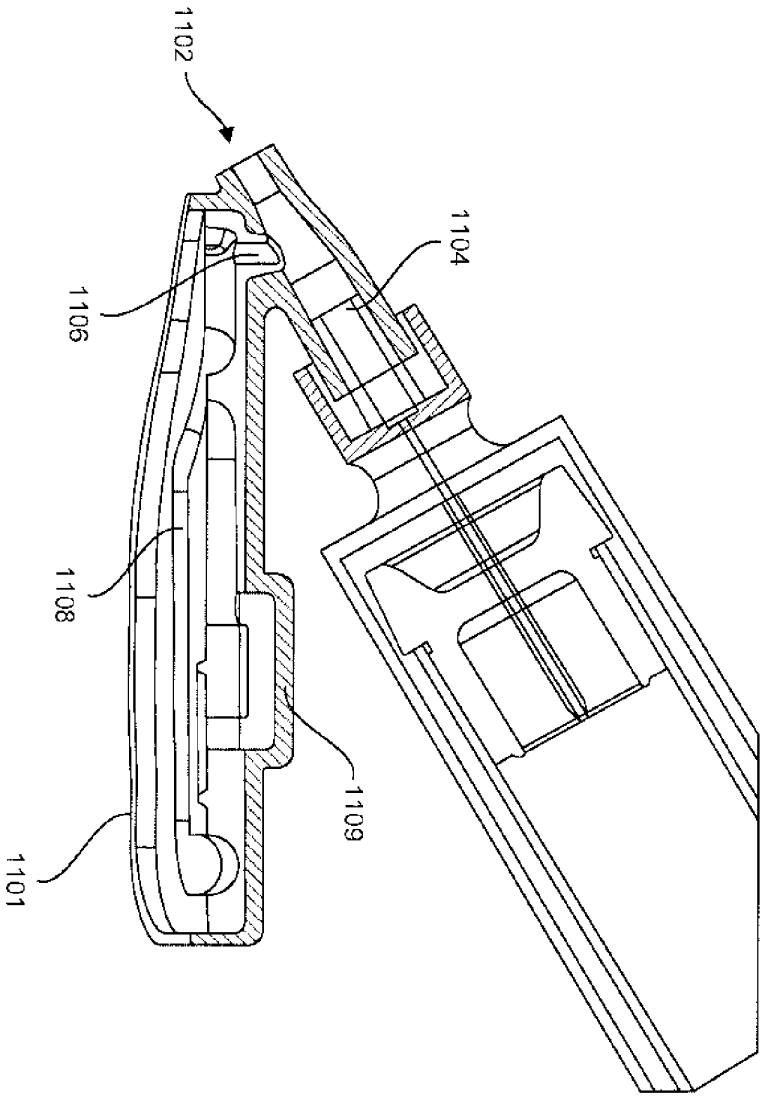


FIG. 11B

FIG. 11C

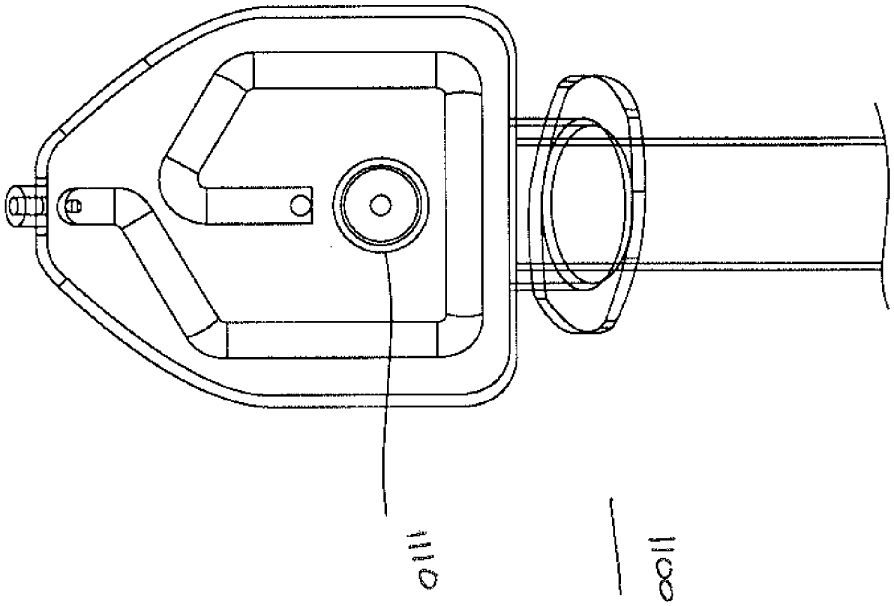
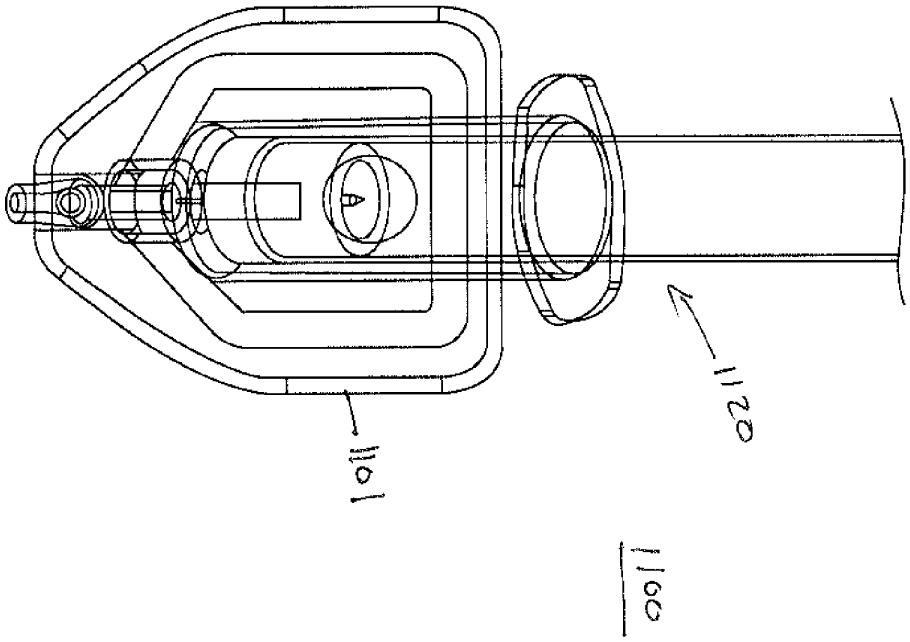


FIG. 11D



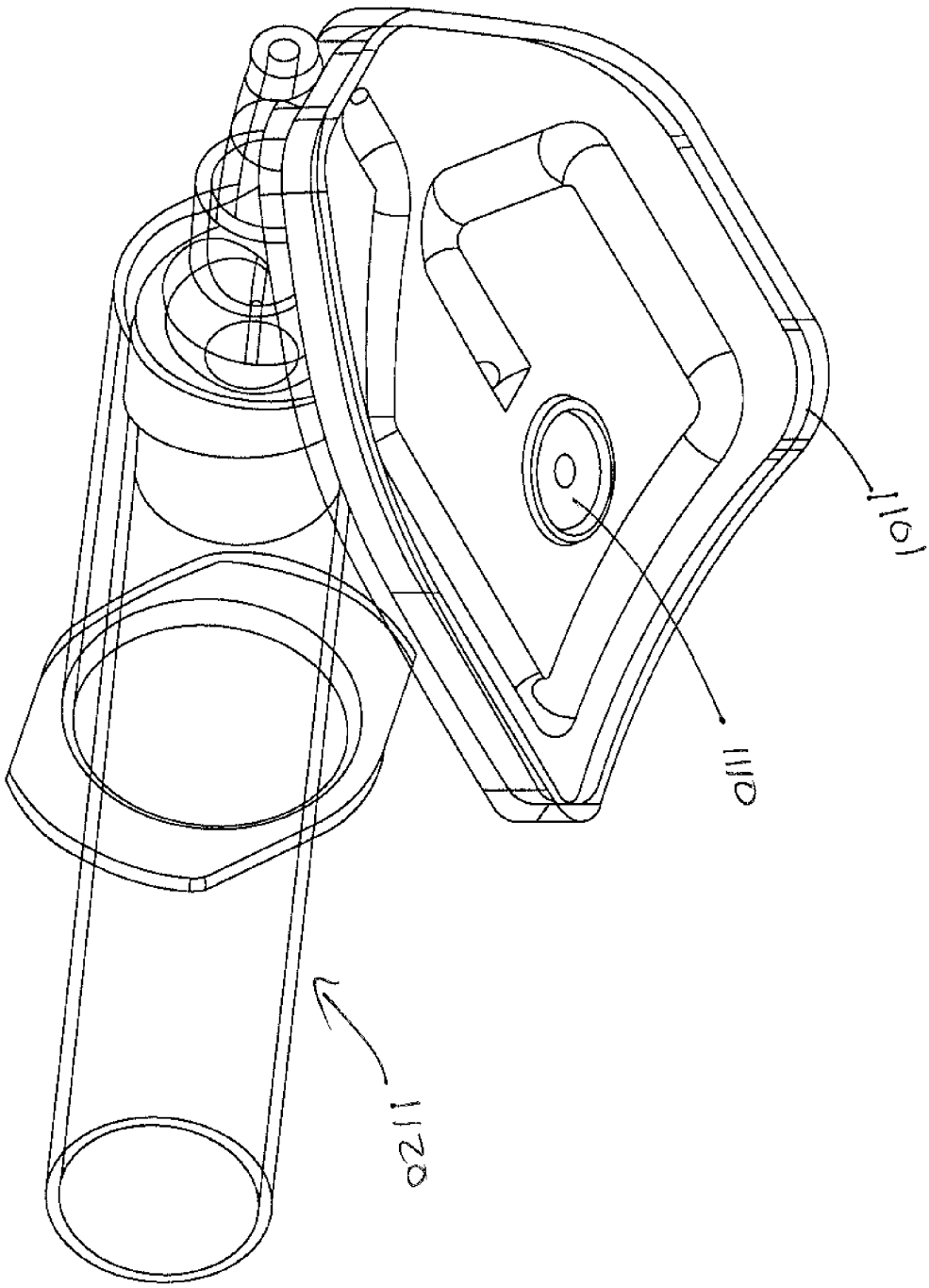


FIG. 11E

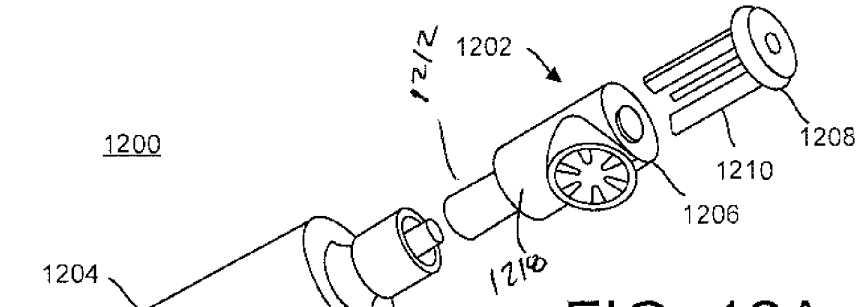


FIG. 12A

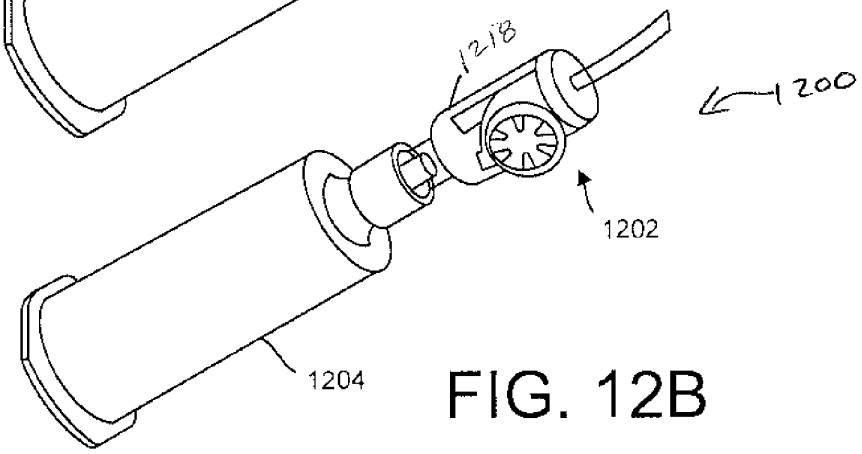


FIG. 12B

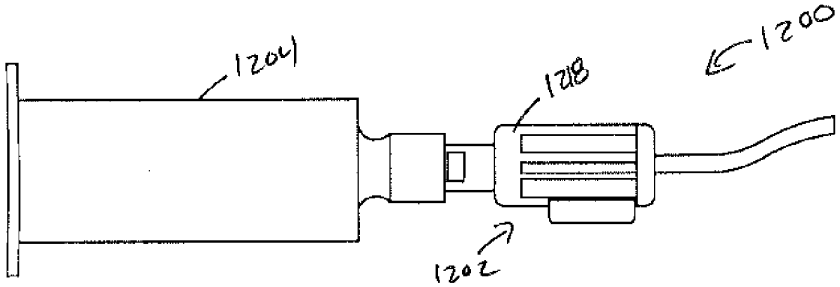


FIG. 12C

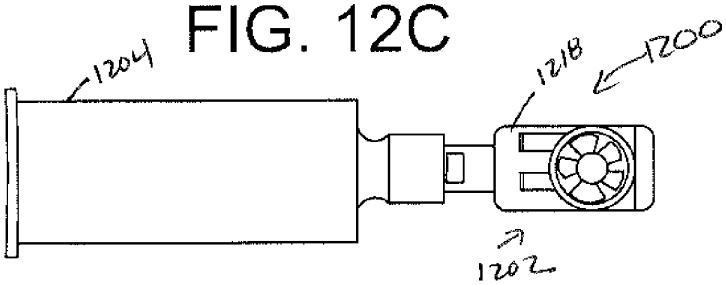


FIG. 12D

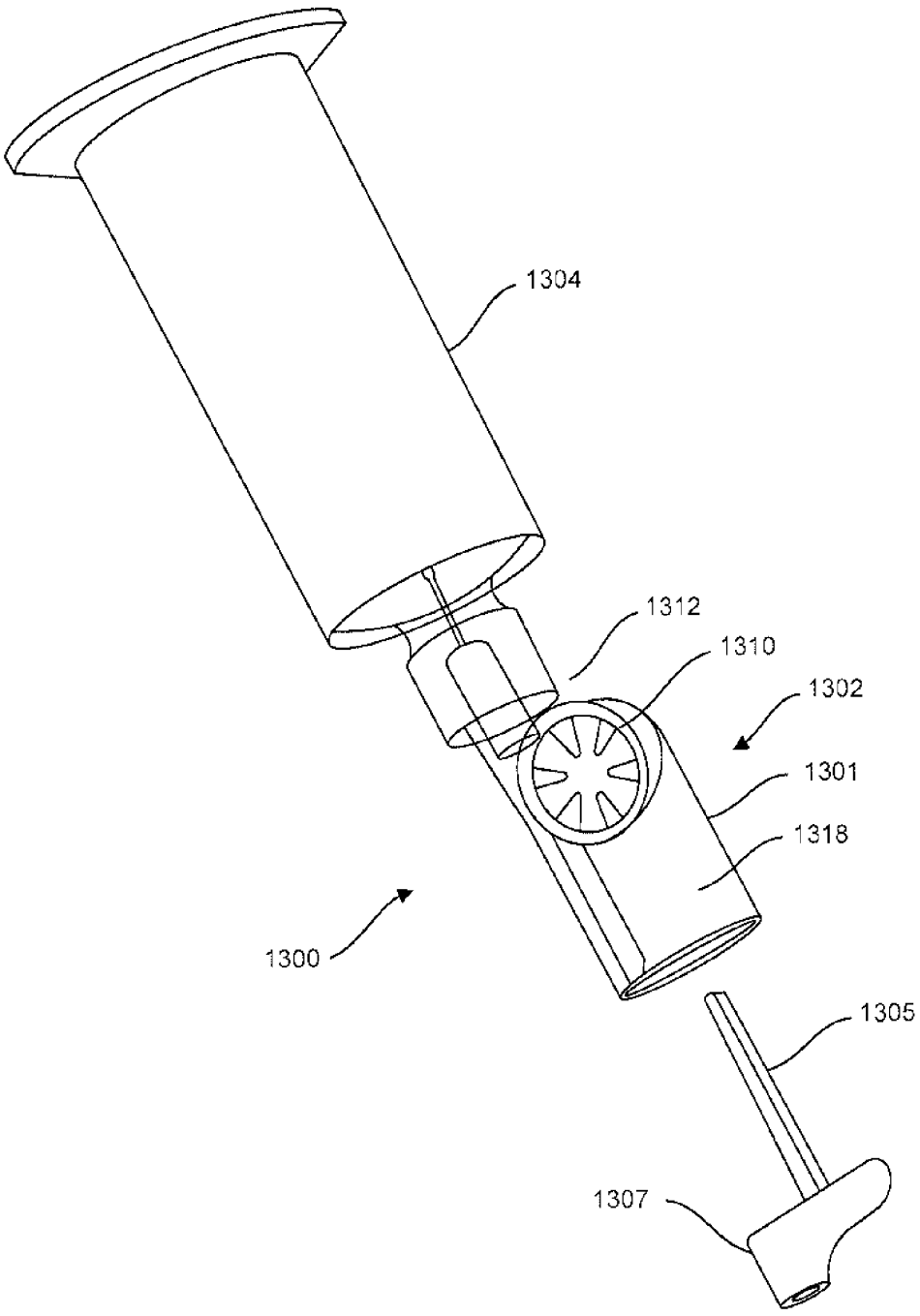


FIG. 13A

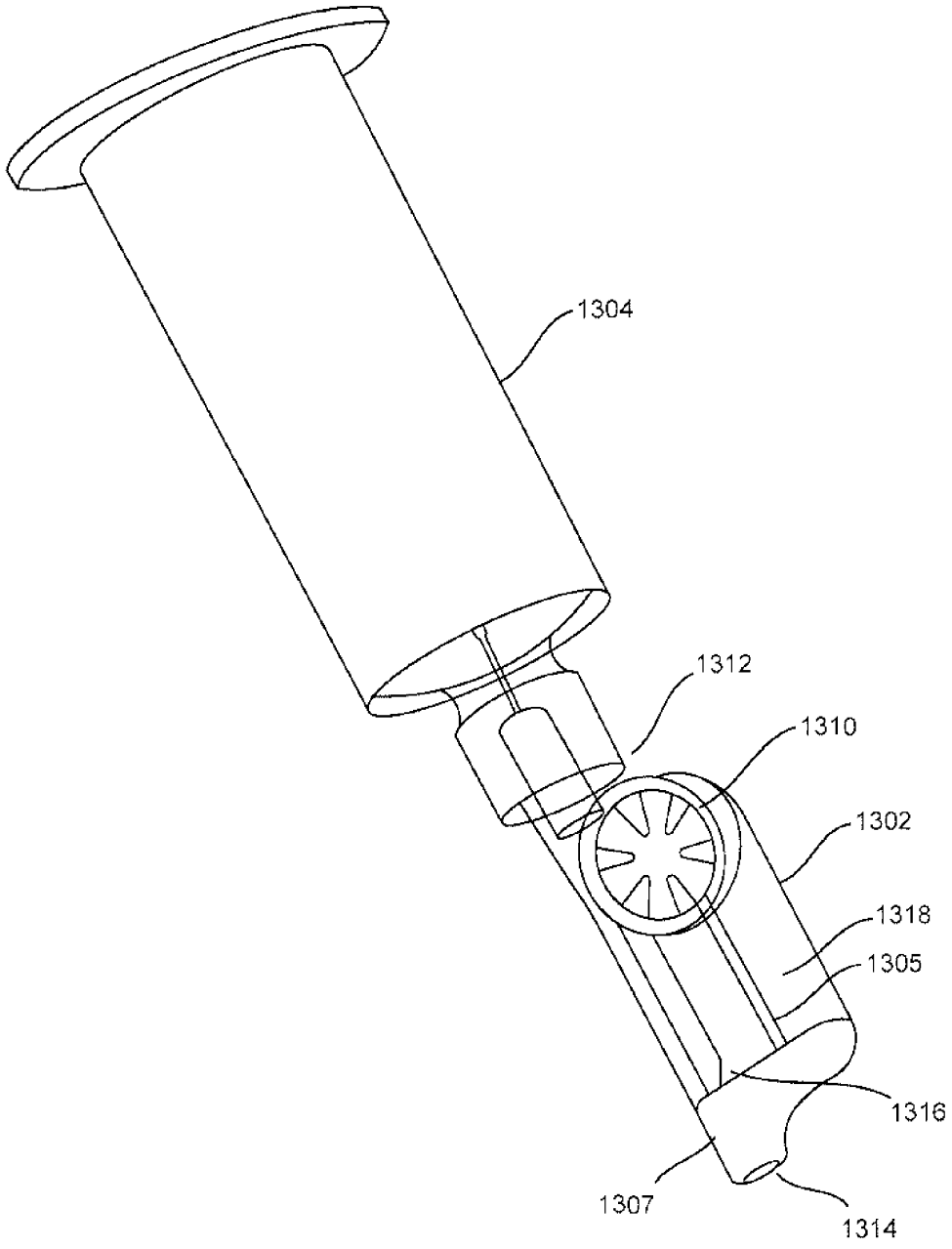


FIG. 13B

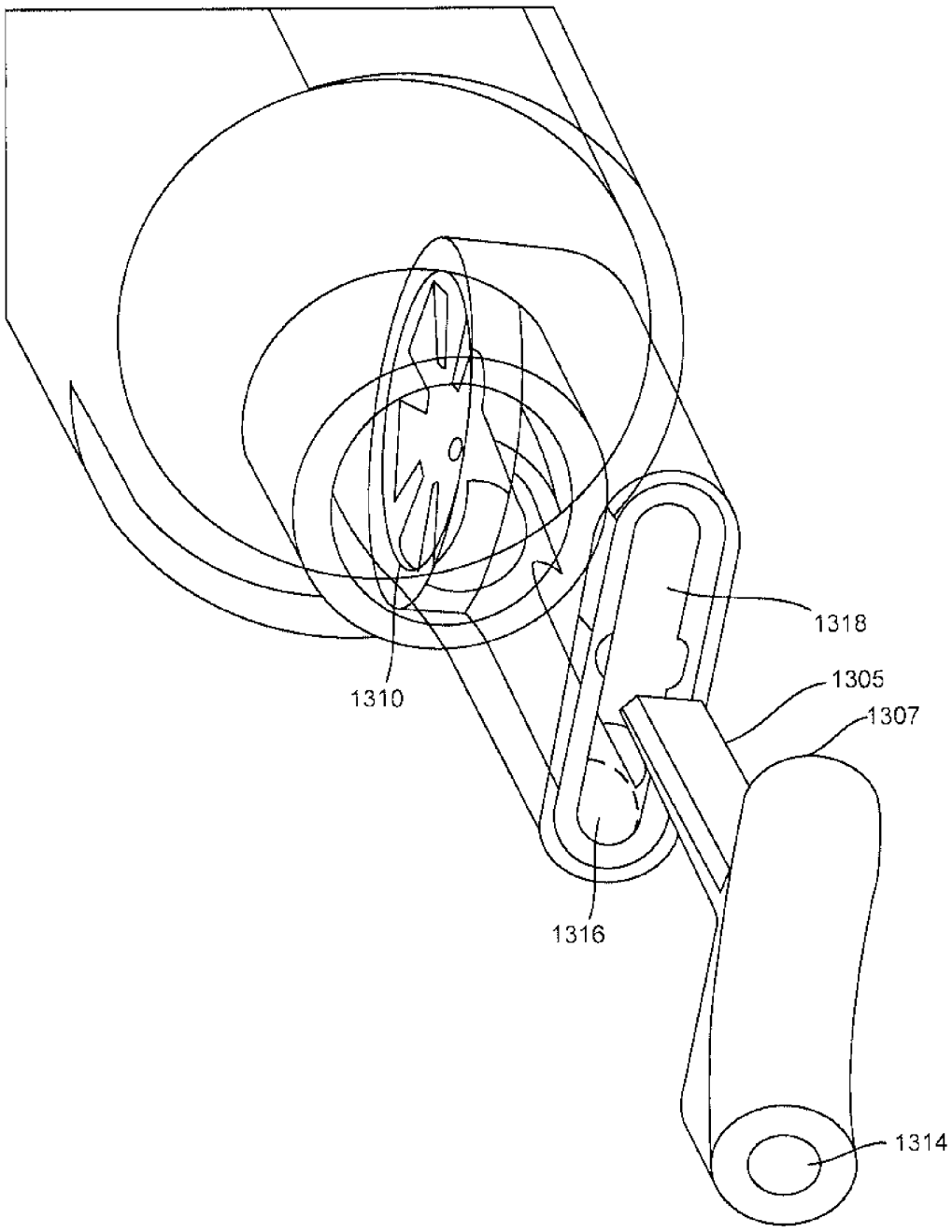


FIG. 13C

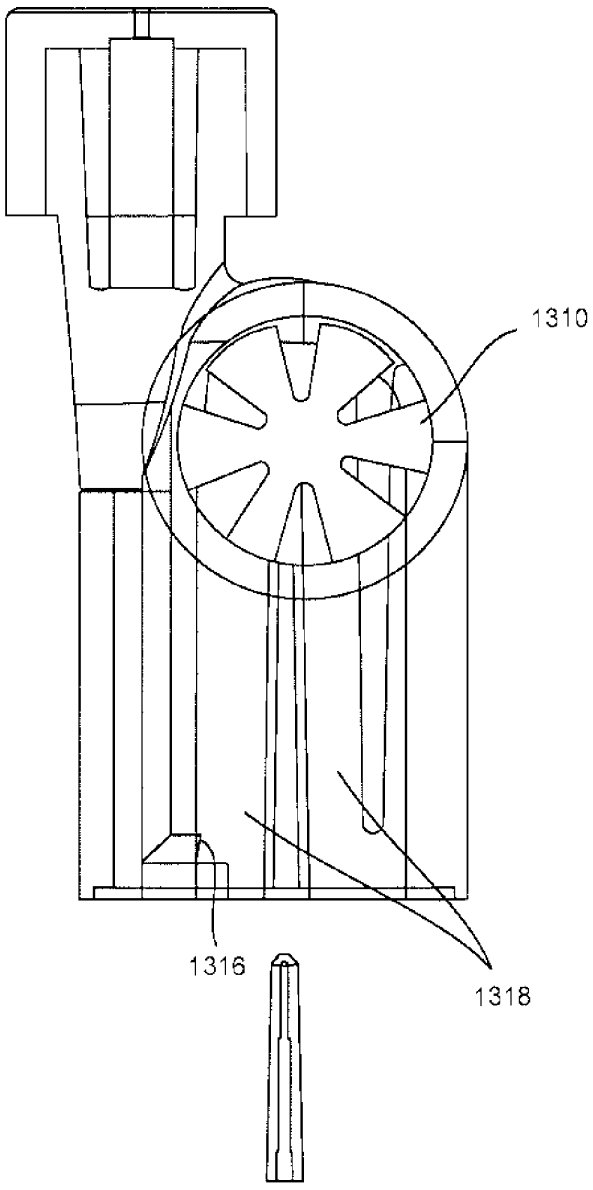


FIG. 13D

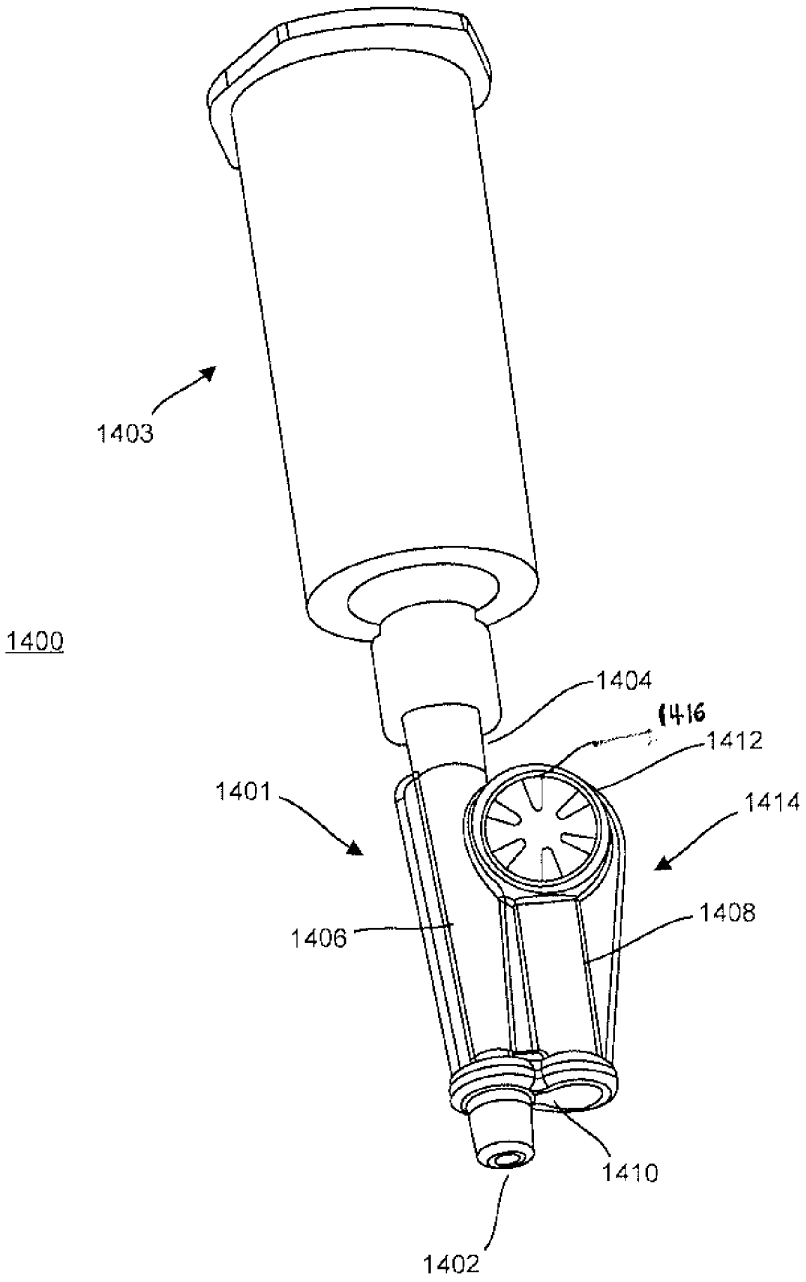


FIG. 14A

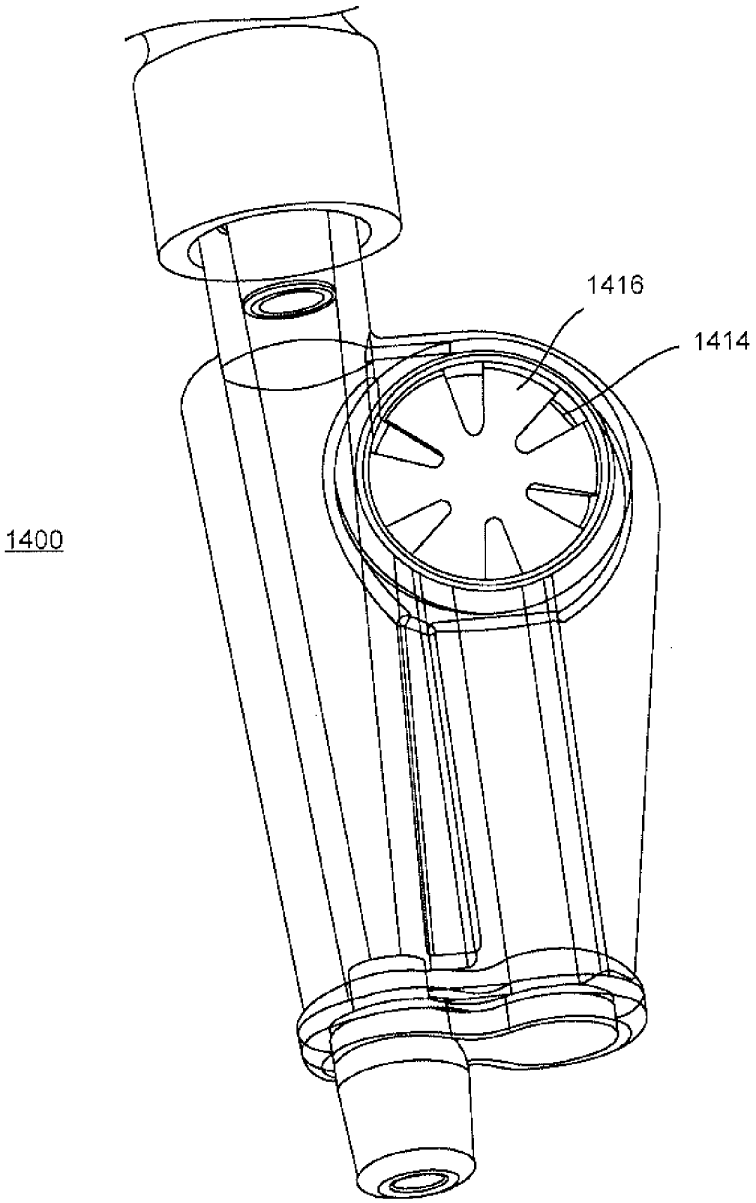


FIG. 14B

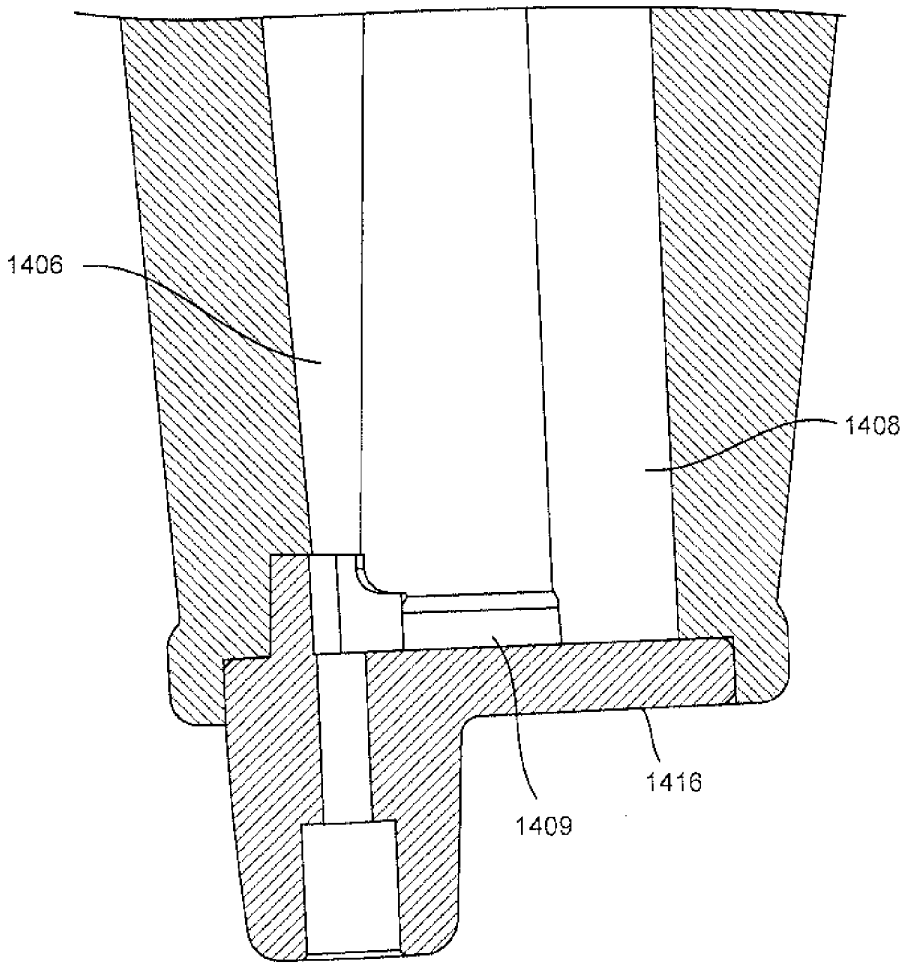


FIG. 14C

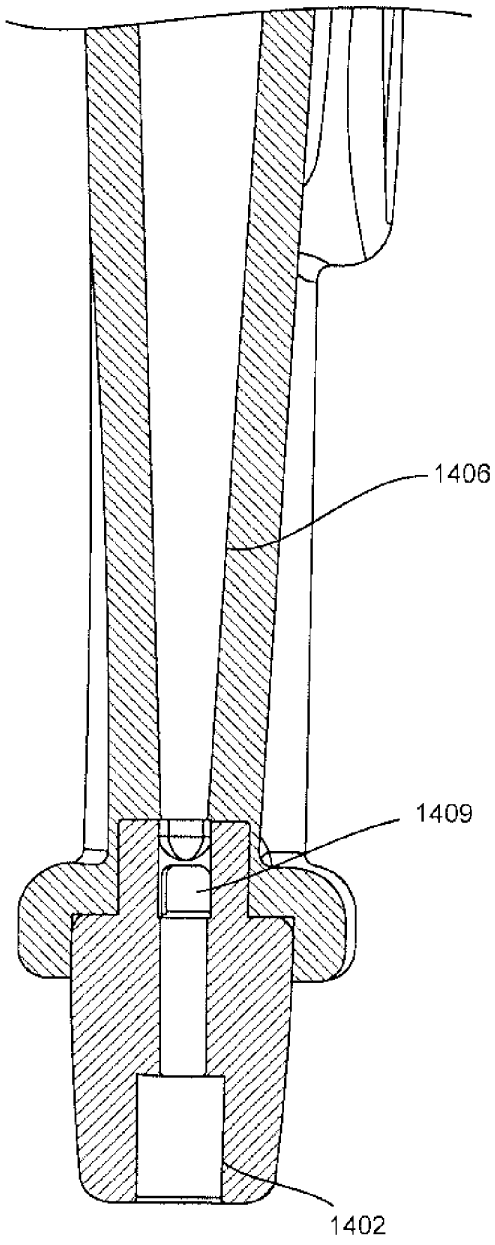


FIG. 14D

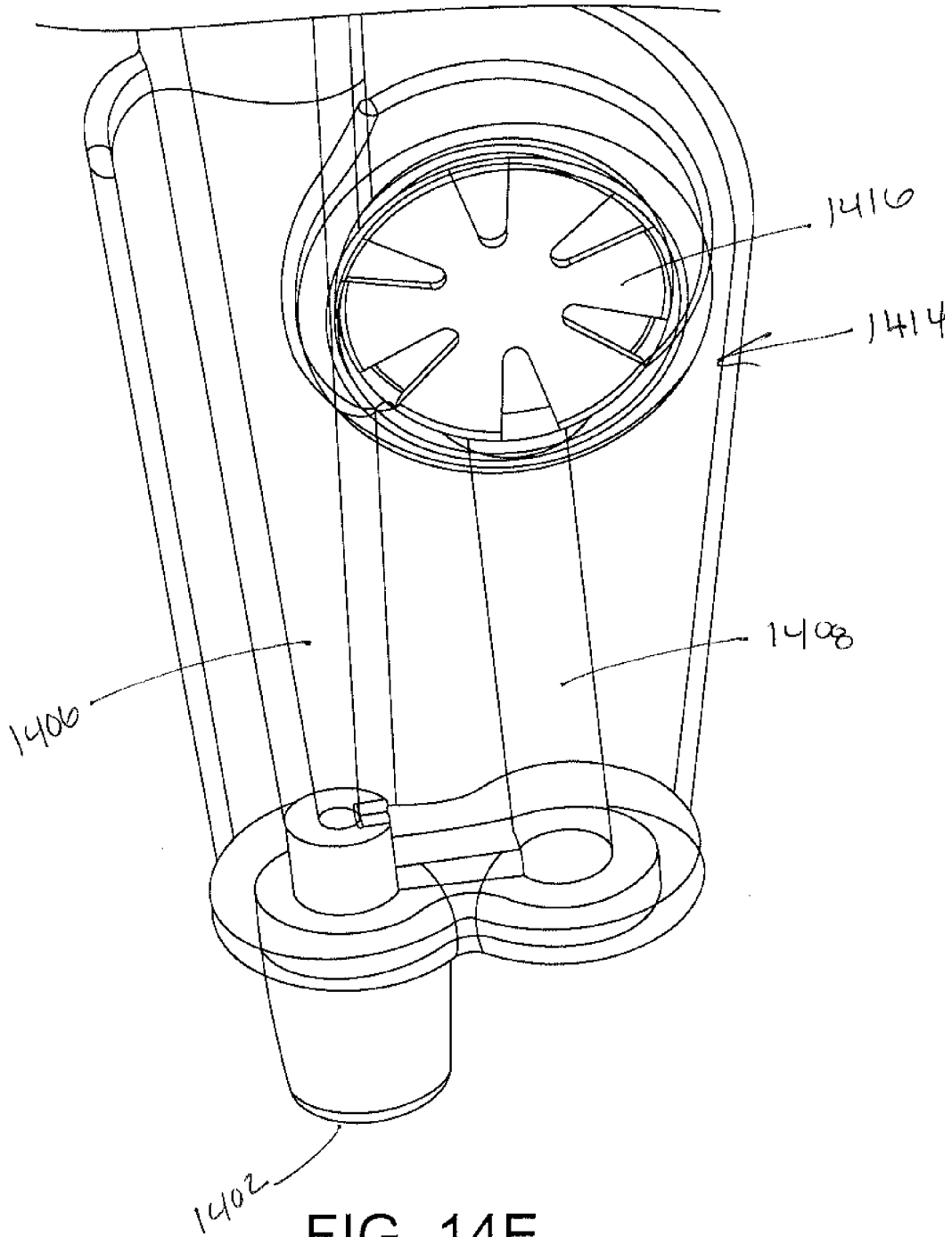


FIG. 14E

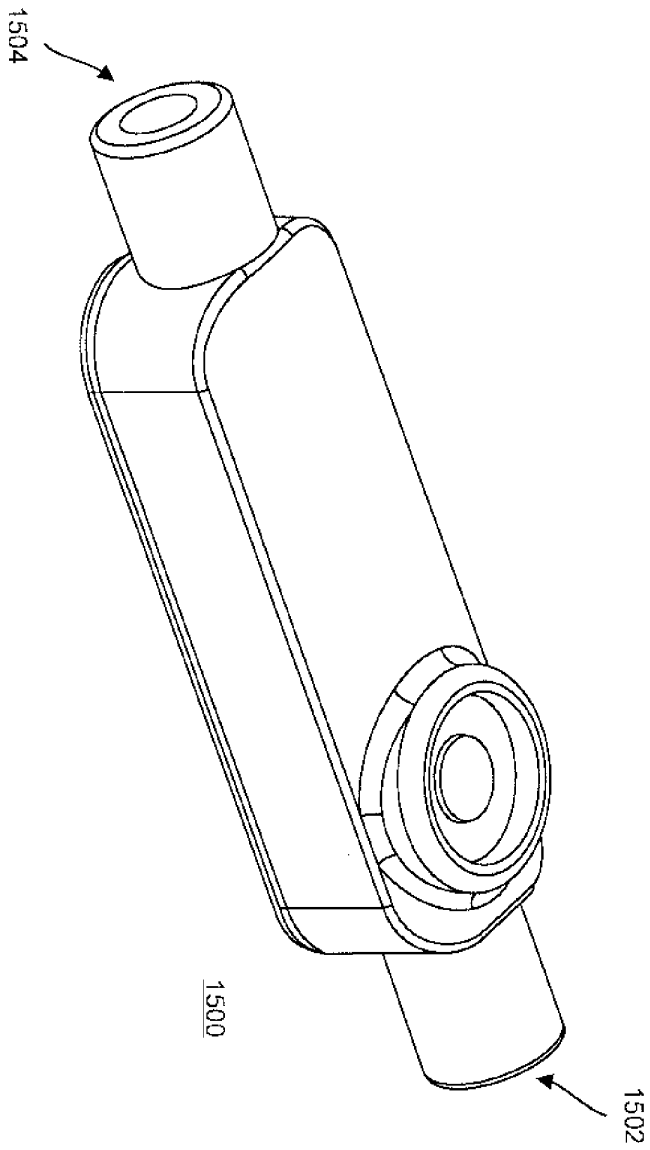


FIG. 15A

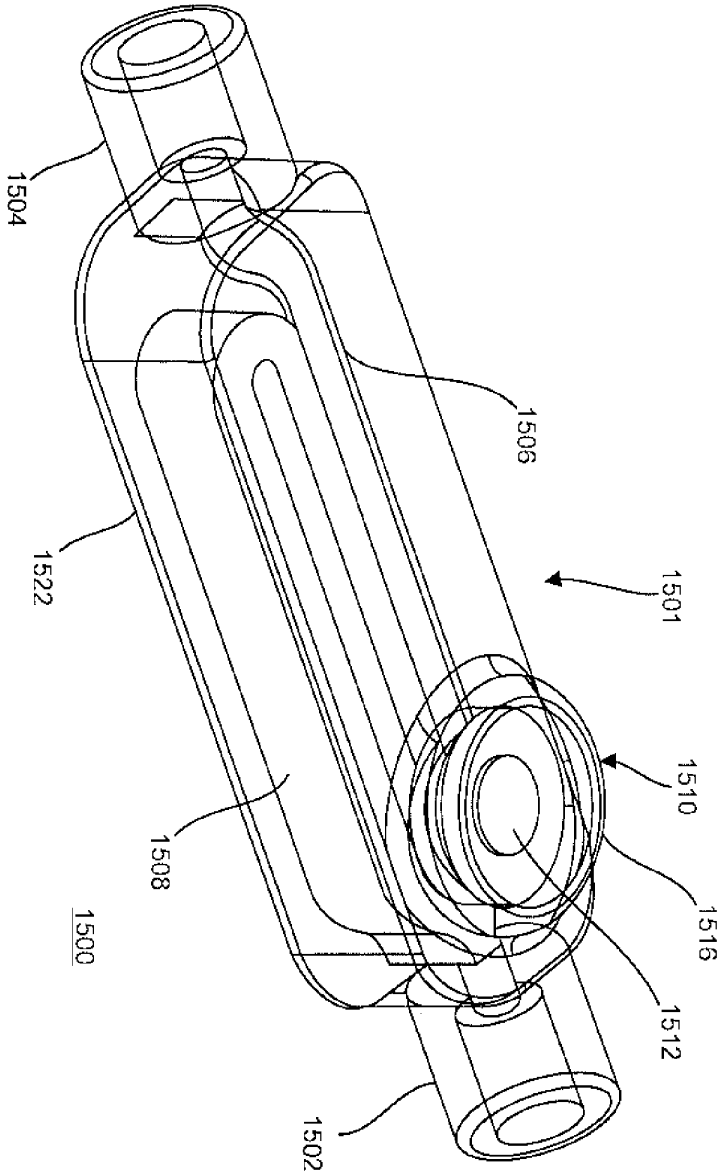


FIG. 15B

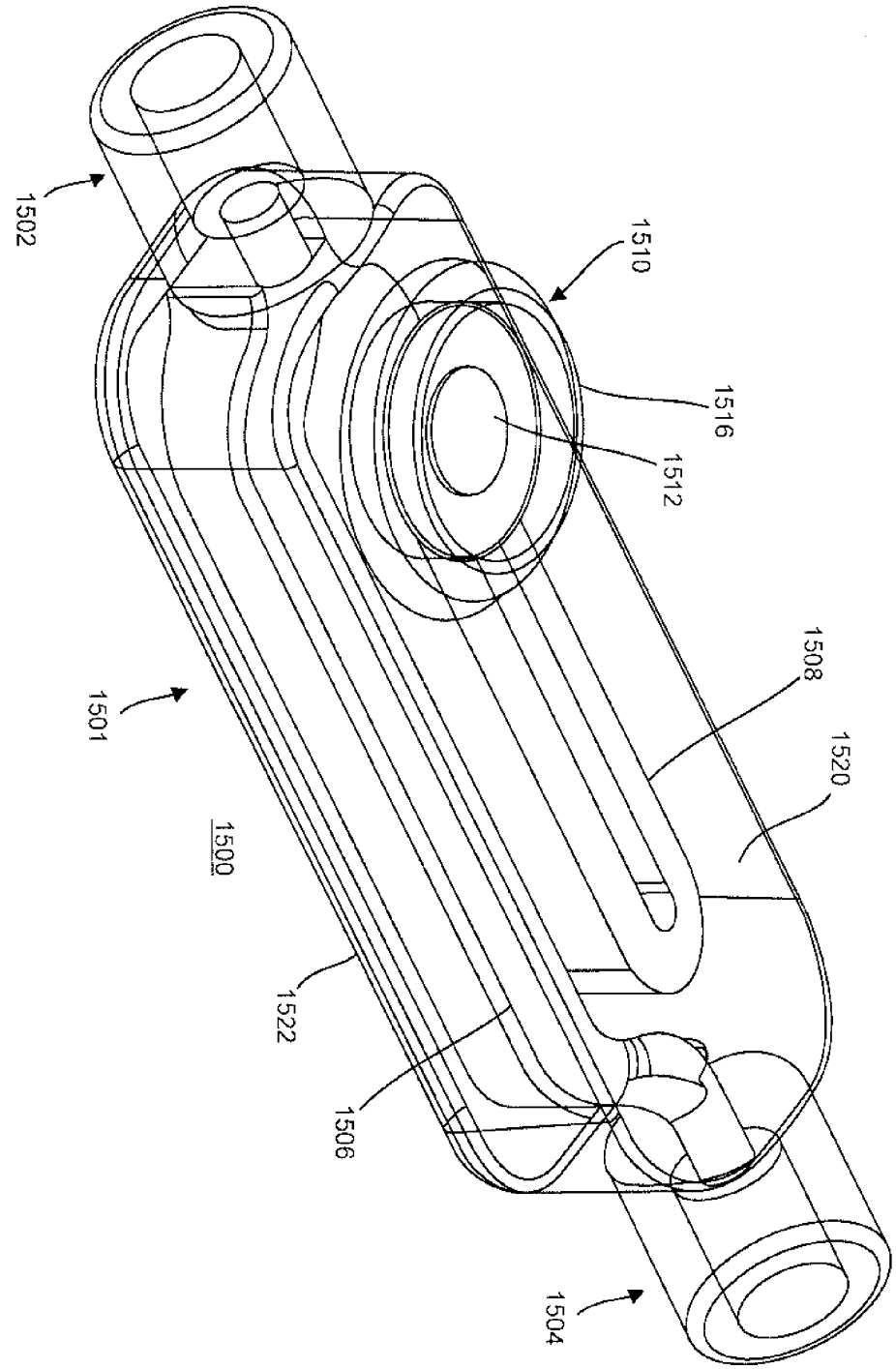


FIG. 15C

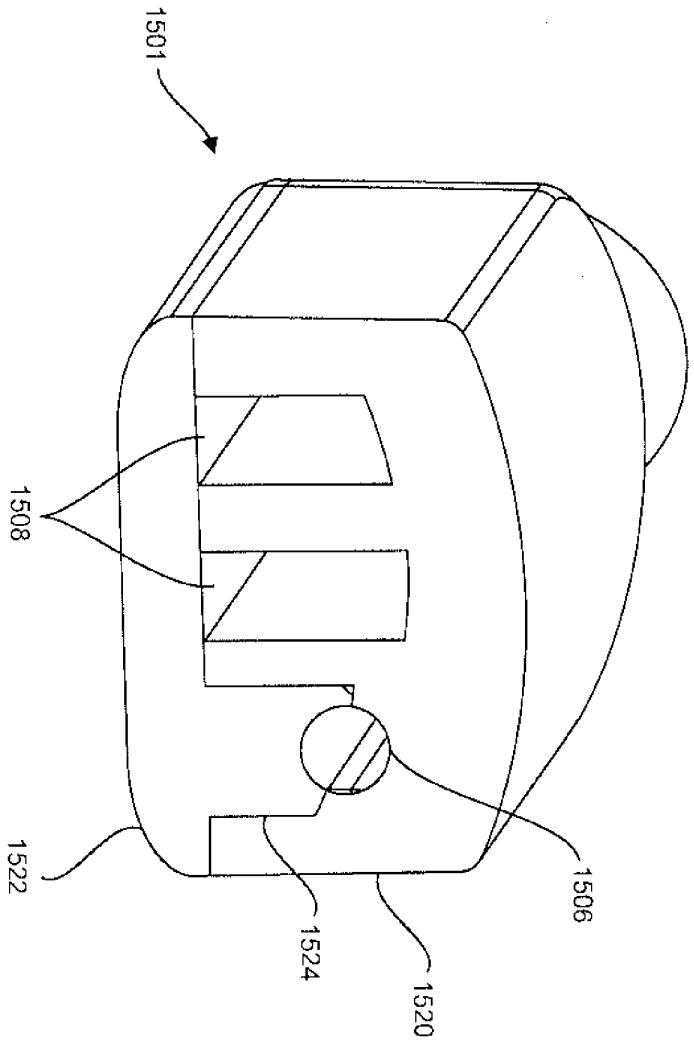


FIG. 15D

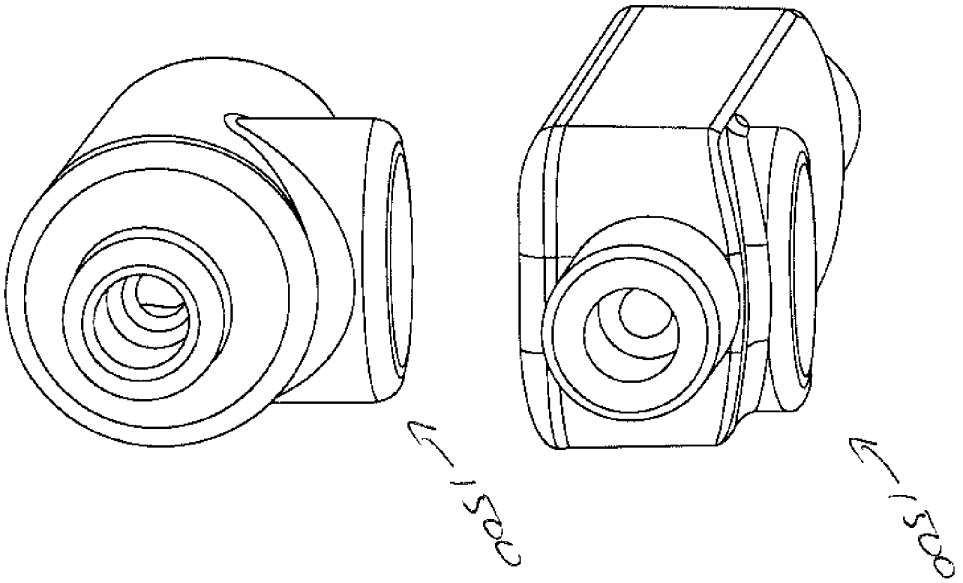


FIG. 15E

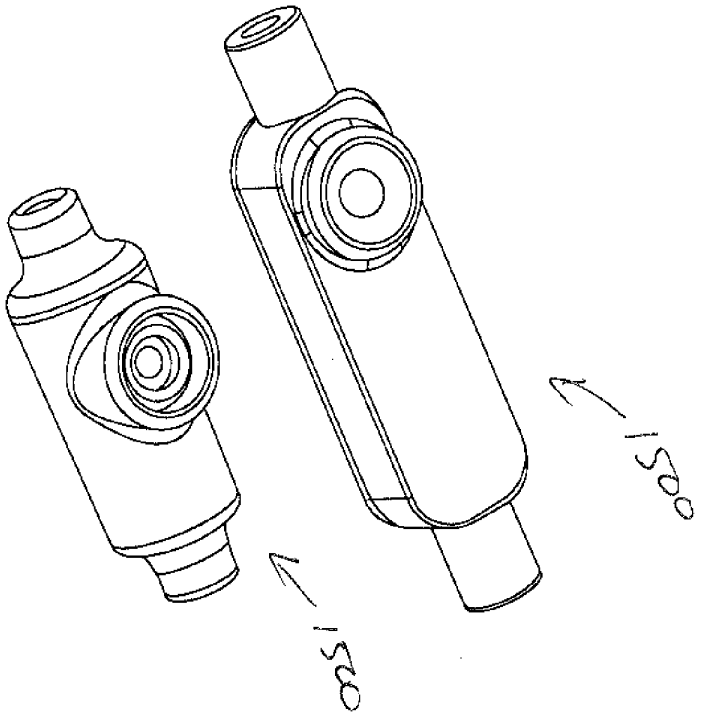


FIG. 15F

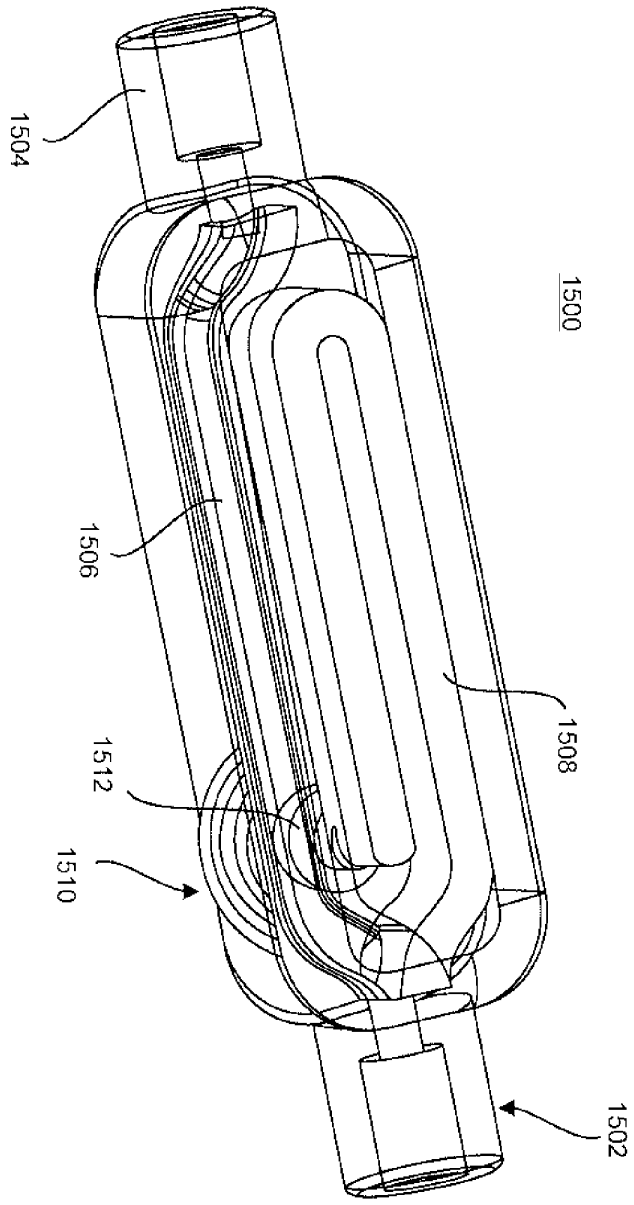


FIG. 15G



FIG. 16B

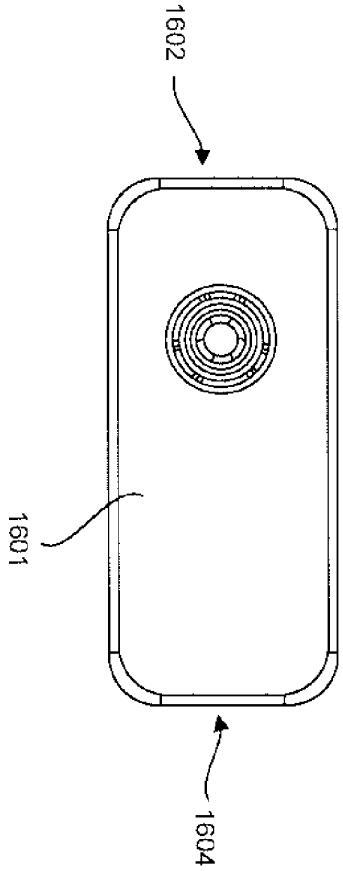


FIG. 16A

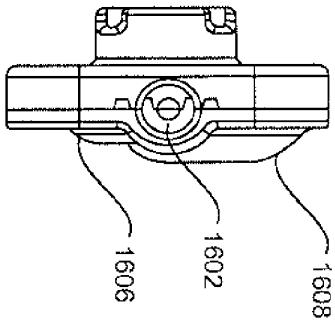


FIG. 16C

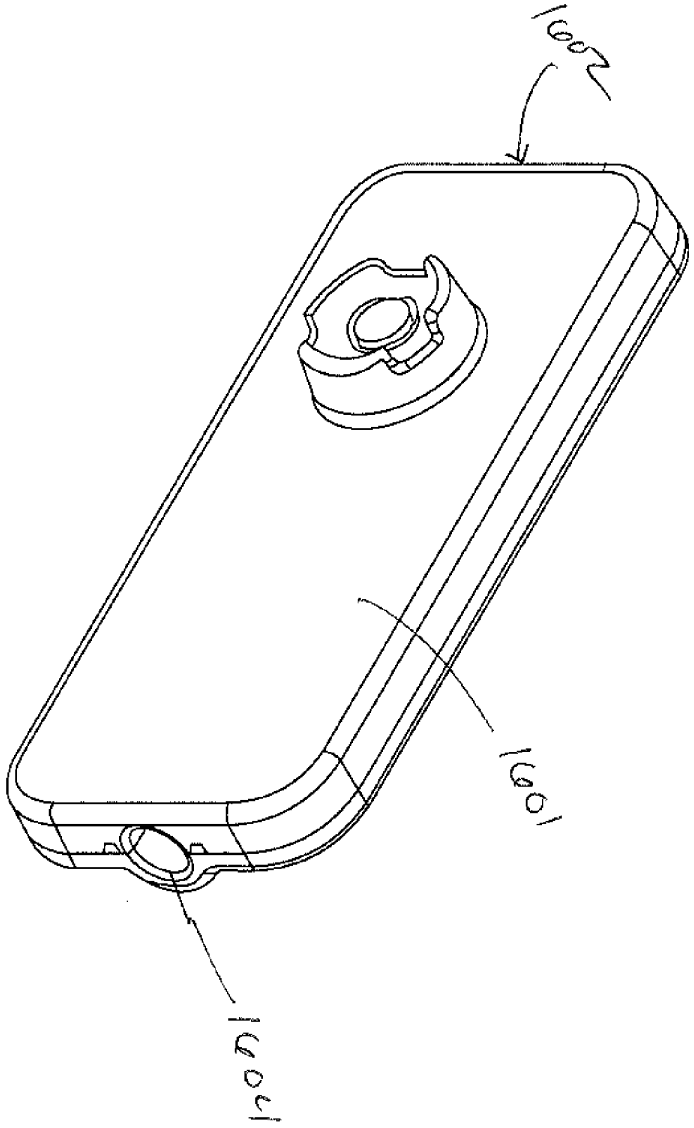


FIG. 16D

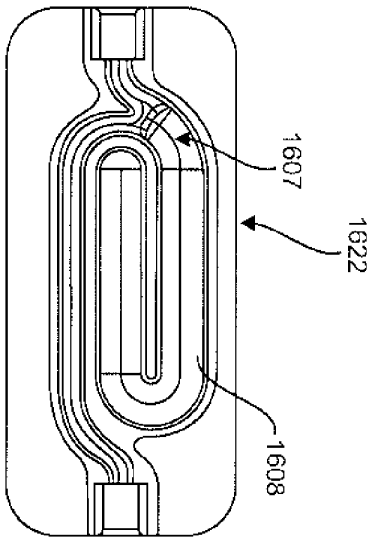


FIG. 17A

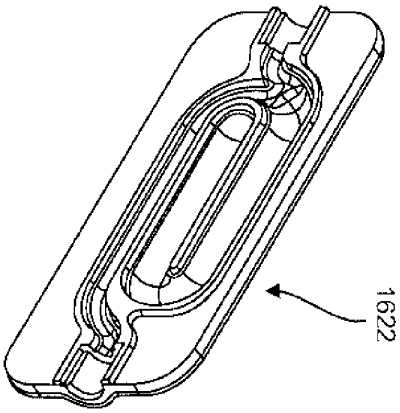


FIG. 17B

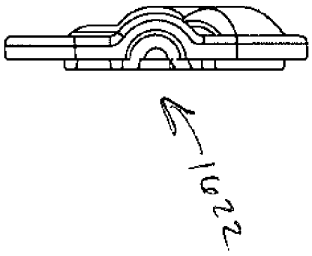


FIG. 17C

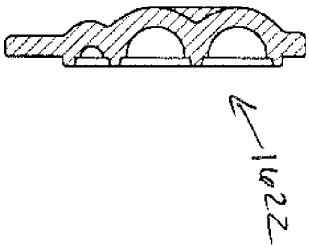


FIG. 17D

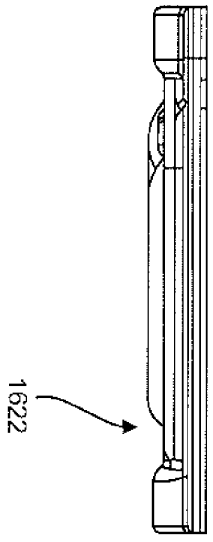


FIG. 17E

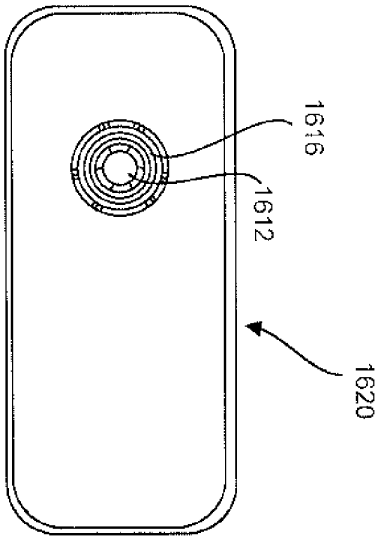


FIG. 18A

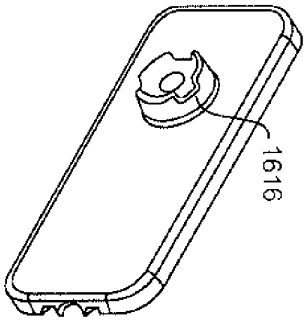


FIG. 18B

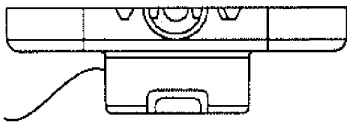


FIG. 18C

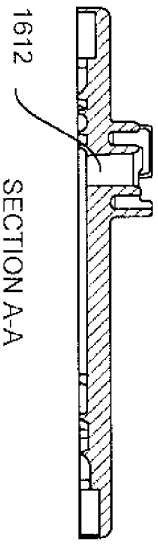


FIG. 18D

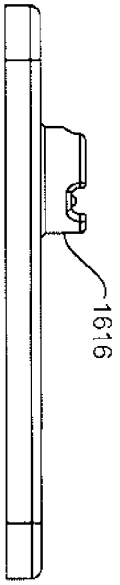


FIG. 18E

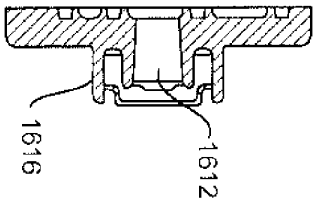


FIG. 18F

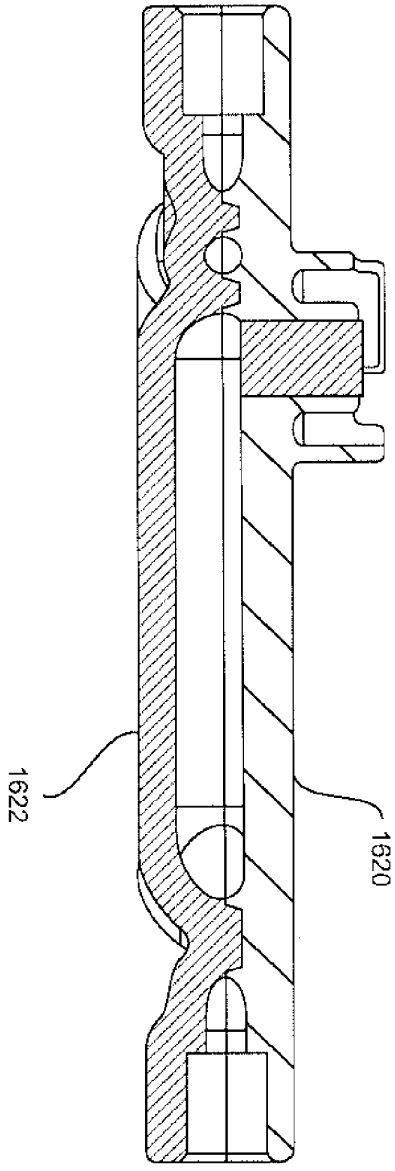


FIG. 19A

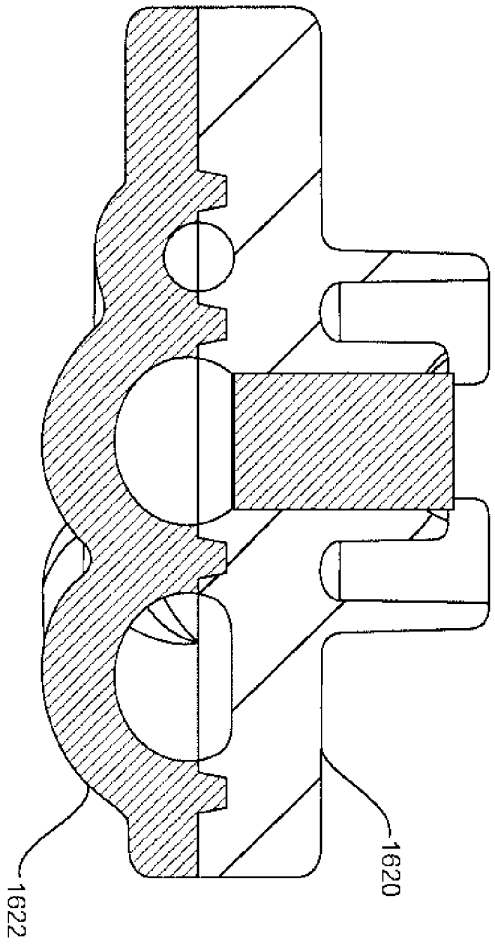


FIG. 19B

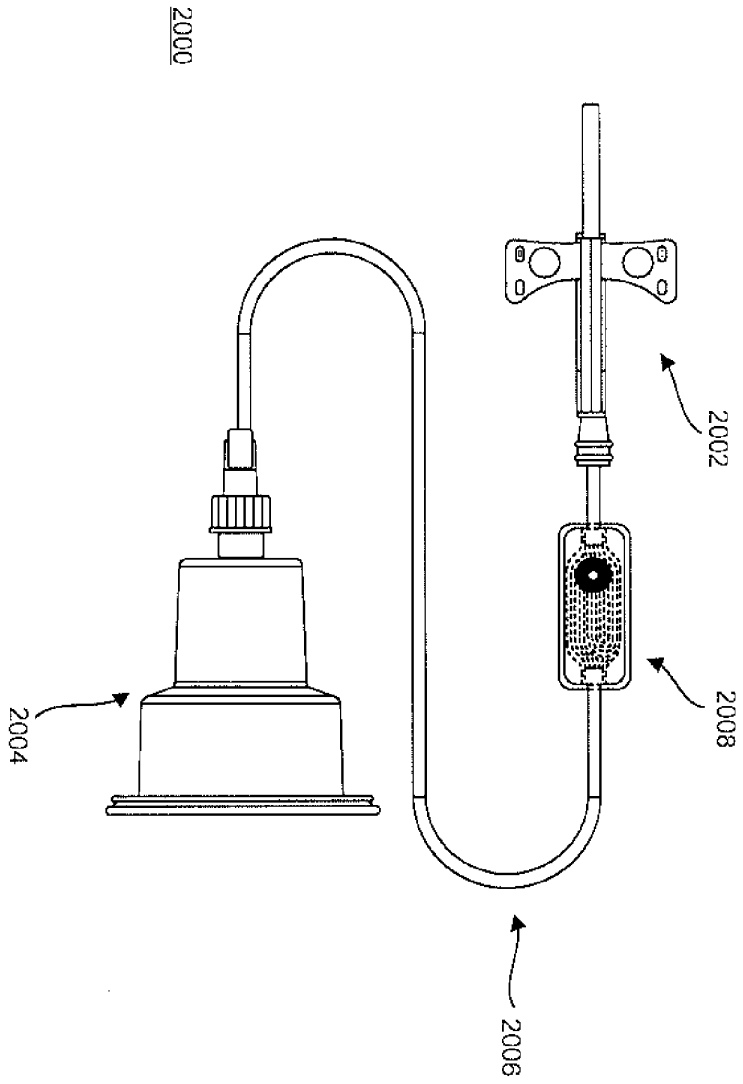


FIG. 20

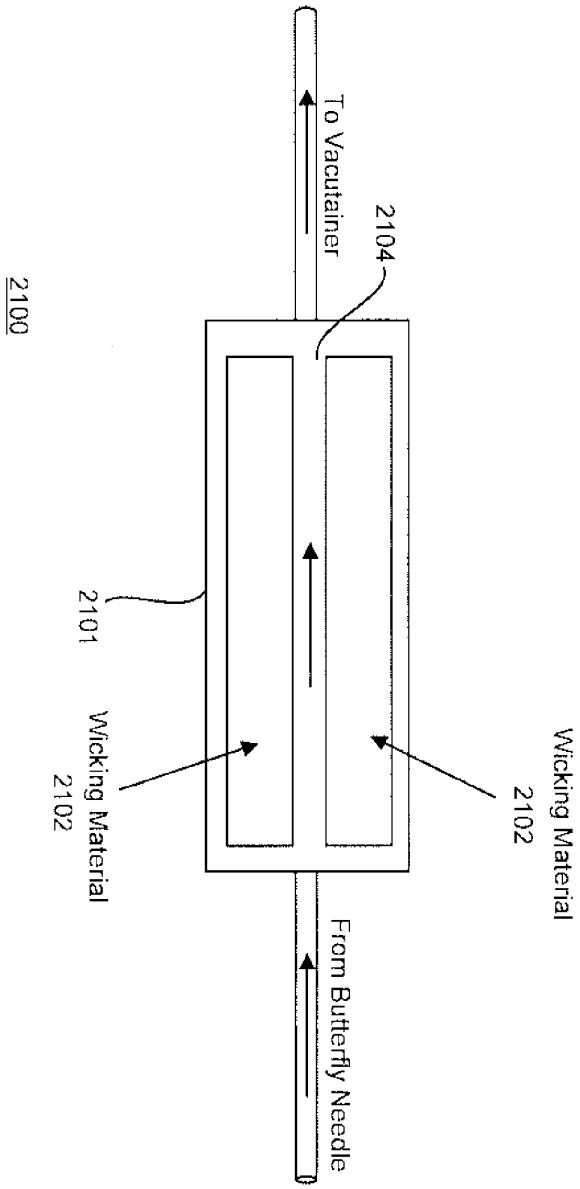

2100
To Vacutainer
2104
2101
Wicking Material
2102
Wicking Material
2102
From Butterfly Needle

FIG. 21

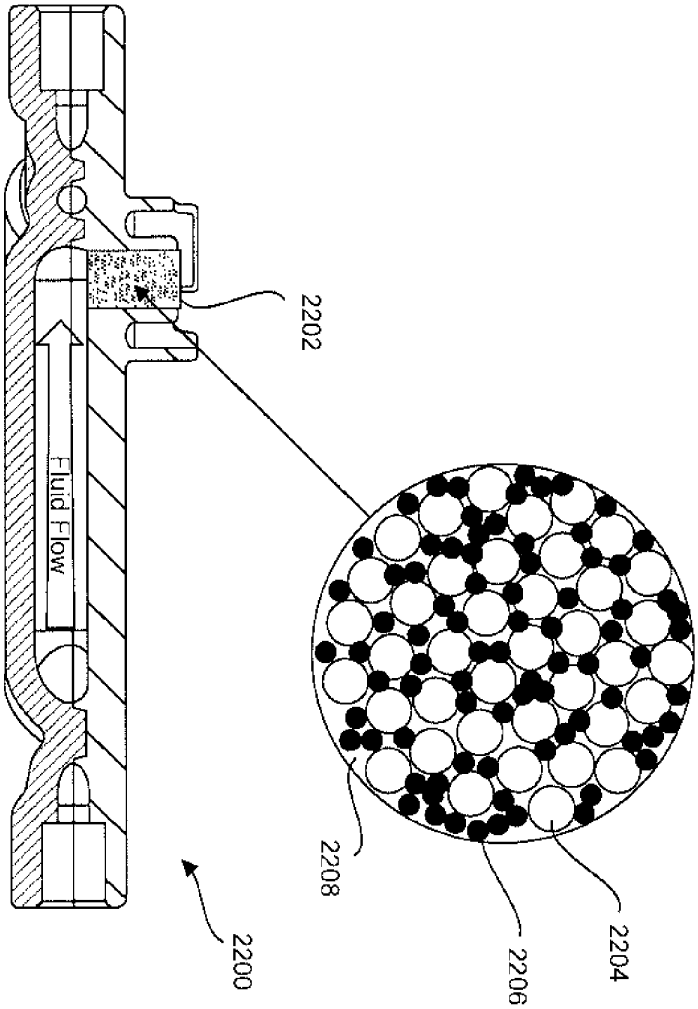


FIG. 22A

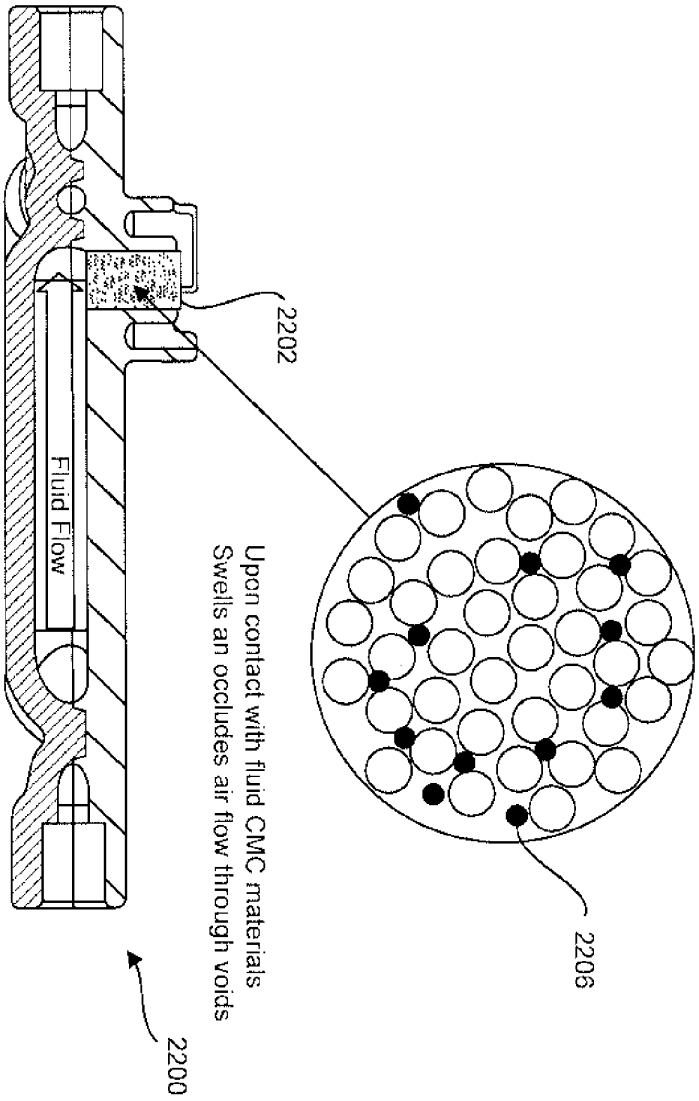

2202
Fluid Flow
Upon contact with fluid CMC materials
Swells an occludes air flow through voids
2206
2200

FIG. 22B

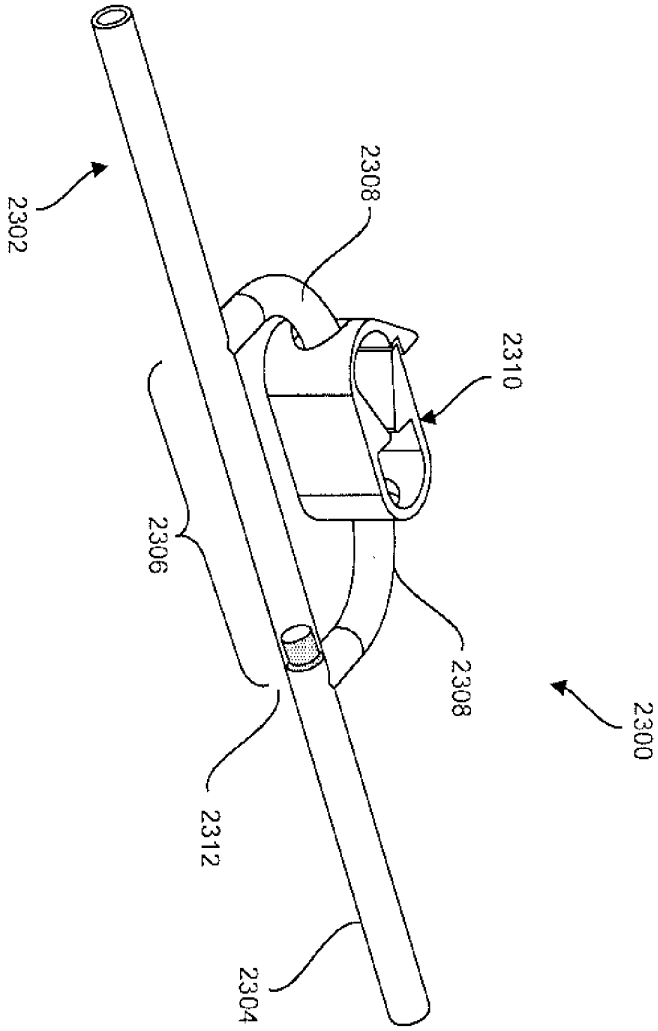


FIG. 23A

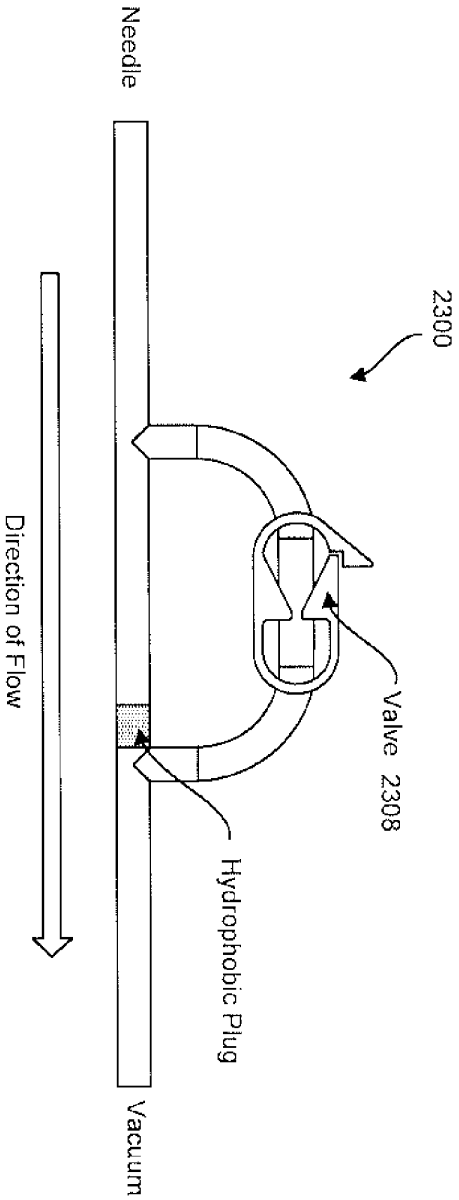

Needle
2300
Valve 2308
Hydrophobic Plug
Vacuum
Direction of Flow

FIG. 23B

(Translation)

Reference No.: D1163JP02 Letter No.: 309696 Mailing Date: June 20, 2023 1

Notice of Allowance

(Divisional)

Application Serial No.:	2021-214177
Drafting Date:	June 16, 2023
Examiner:	Naoya TAKAGI 3611 2Q00
Title of the Invention:	BLOOD SAMPLE OPTIMIZATION SYSTEM AND BLOOD CONTAMINANT SEQUESTRATION DEVICE AND METHOD
Number of Claims:	20
Applicant(s):	KURIN, INC.
Agent:	MURAKOSHI, Satoshi

A decision is hereby made to grant patent right to the above identified patent application on the ground that no cause for rejecting the application has been found in the examination.

This is to certify that all the above-referenced items are identical to the JPO's official record.
Certificated: June 19, 2023
Administrative Official of Ministry of Economy, Trade and Industry, Takashi SATO

Note: Applicant must pay Issue Fee within 30 days from the mailing date indicated above.

(Translation)

- Type of Application: Divisional Application
- Cited References: Yes
- Grace Period under Patent Act Article 30: No
- Amendment to Title of the Invention: No
- Deposit of Biological Material : N/A

(Translation)

Reference No.: D1163JP02 Letter No.: 309696 Mailing Date: June 20, 2023 3/E

Reference Information

Application Serial No.: 2021-214177

- FI

  A61B 5/15 200

- Search Fields (IPC, DB Name):

  A61B 5/15-5/157

- References Cited :

  Japanese Patent Application Publication No.2013-240628 (JP,A)
  Japanese Patent Application Publication No.2016-504075 (JP,A)
  International Patent Application Publication No.2014/058945 (WO,A1)
  US Patent Application Publication No.2005/0245885 (US,A1)

- Non-patent literatures:

特許査定

（分割）

特許出願の番号	特願２０２１－２１４１７７
起案日	令和　５年　６月１６日
特許庁審査官	▲高▼木　尚哉　３６１１　２Ｑ００
発明の名称	流体分流デバイス、及び流体分流サンプリングシステム
請求項の数	２０
特許出願人	クリン　インコーポレイテッド
代理人	村越　智史（ほか　４名）

この出願については、拒絶の理由を発見しないから、特許査定をします。

上記はファイルに記録されている事項と相違ないことを認証する。
認証日　令和 5年 6月19日　経済産業事務官　佐藤　隆

注意：この書面を受け取った日から３０日以内に特許料の納付が必要です。

・出願種別　分割
・参考文献　有
・特許法第３０条適用　無
・発明の名称の変更　無

・菌寄託

参考情報

特許出願の番号　特願２０２１－２１４１７７

・ＦＩ

Ａ６１Ｂ　５／１５　２００

・調査した分野（ＩＰＣ，ＤＢ名）

Ａ６１Ｂ　５／１５－５／１５７

・参考特許文献

特開２０１３－２４０６２８　（ＪＰ，Ａ）
特表２０１６－５０４０７５　（ＪＰ，Ａ）
国際公開第２０１４／０５８９４５　（ＷＯ，Ａ１）
米国特許出願公開第２００５／０２４５８８５　（ＵＳ，Ａ１）

・参考図書雑誌

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NOTICE OF ALLOWANCE AND FEE(S) DUE

27500 7590 11/28/2022

PILLSBURY WINTHROP SHAW PITTMAN LLP (CV)
ATTENTION: DOCKETING DEPARTMENT
P.O BOX 10500
McLean, VA 22102

EXAMINER	
ABOUELELA, MAY A	
ART UNIT	PAPER NUMBER
3791	

DATE MAILED: 11/28/2022

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/819,033	03/13/2020	Bobby E. ROGERS	069366-0572168_KUR4002US	6468

TITLE OF INVENTION: BLOOD CONTAMINANT SEQUESTRATION DEVICE WITH PASSIVE FLUID CONTROL JUNCTION

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	$600	$0.00	$0.00	$600	02/28/2023

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the ENTITY STATUS shown above. If the ENTITY STATUS is shown as SMALL or MICRO, verify whether entitlement to that entity status still applies.

If the ENTITY STATUS is the same as shown above, pay the TOTAL FEE(S) DUE shown above.

If the ENTITY STATUS is changed from that shown above, on PART B - FEE(S) TRANSMITTAL, complete section number 5 titled "Change in Entity Status (from status indicated above)".

For purposes of this notice, small entity fees are 1/2 the amount of undiscounted fees, and micro entity fees are 1/2 the amount of small entity fees.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Maintenance fees are due in utility patents issuing on applications filed on or after Dec. 12, 1980. It is patentee's responsibility to ensure timely payment of maintenance fees when due. More information is available at www.uspto.gov/PatentMaintenanceFees.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), by mail or fax, or via EFS-Web.

By mail, send to: Mail Stop ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

By fax, send to: (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

27500 7590 11/28/2022

PILLSBURY WINTHROP SHAW PITTMAN LLP (CV)
ATTENTION: DOCKETING DEPARTMENT
P.O BOX 10500
McLean, VA 22102

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being transmitted to the USPTO via EFS-Web or by facsimile to (571) 273-2885, on the date below.

(Typed or printed name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/819,033	03/13/2020	Bobby E. ROGERS	069366-0572168_KUR4002US	6468

TITLE OF INVENTION: BLOOD CONTAMINANT SEQUESTRATION DEVICE WITH PASSIVE FLUID CONTROL JUNCTION

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	$600	$0.00	$0.00	$600	02/28/2023

EXAMINER	ART UNIT	CLASS-SUBCLASS
ABOUELELA, MAY A	3791	600-573000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

❑ Change of correspondence address (or Change of Correspondence Address form PTO/AIA/122 or PTO/SB/122) attached.

❑ "Fee Address" indication (or "Fee Address" Indication form PTO/AIA/47 or PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list
(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,
(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 _____
2 _____
3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document must have been previously recorded, or filed for recordation, as set forth in 37 CFR 3.11 and 37 CFR 3.81(a). Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ❑ Individual ❑ Corporation or other private group entity ❑ Government

4a. Fees submitted: ❑Issue Fee ❑Publication Fee (if required) ❑Advance Order - # of Copies _____

4b. Method of Payment: *(Please first reapply any previously paid fee shown above)*

❑ Electronic Payment via EFS-Web ❑ Enclosed check ❑ Non-electronic payment by credit card (Attach form PTO-2038)

❑ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment to Deposit Account No. _____

5. **Change in Entity Status** (from status indicated above)

❑ Applicant certifying micro entity status. See 37 CFR 1.29

❑ Applicant asserting small entity status. See 37 CFR 1.27

❑ Applicant changing to regular undiscounted fee status.

NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.
NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.
NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature _____ Date _____

Typed or printed name _____ Registration No. _____

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/819,033	03/13/2020	Bobby E. ROGERS	069366-0572168_KUR4002US	6468

27500 7590 11/28/2022

PILLSBURY WINTHROP SHAW PITTMAN LLP (CV)
ATTENTION: DOCKETING DEPARTMENT
P.O BOX 10500
McLean, VA 22102

EXAMINER	
ABOUELELA, MAY A	

ART UNIT	PAPER NUMBER
3791	

DATE MAILED: 11/28/2022

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(Applications filed on or after May 29, 2000)

The Office has discontinued providing a Patent Term Adjustment (PTA) calculation with the Notice of Allowance.

Section 1(h)(2) of the AIA Technical Corrections Act amended 35 U.S.C. 154(b)(3)(B)(i) to eliminate the requirement that the Office provide a patent term adjustment determination with the notice of allowance. See Revisions to Patent Term Adjustment, 78 Fed. Reg. 19416, 19417 (Apr. 1, 2013). Therefore, the Office is no longer providing an initial patent term adjustment determination with the notice of allowance. The Office will continue to provide a patent term adjustment determination with the Issue Notification Letter that is mailed to applicant approximately three weeks prior to the issue date of the patent, and will include the patent term adjustment on the patent. Any request for reconsideration of the patent term adjustment determination (or reinstatement of patent term adjustment) should follow the process outlined in 37 CFR 1.705.

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

OMB Clearance and PRA Burden Statement for PTOL-85 Part B

The Paperwork Reduction Act (PRA) of 1995 requires Federal agencies to obtain Office of Management and Budget approval before requesting most types of information from the public. When OMB approves an agency request to collect information from the public, OMB (i) provides a valid OMB Control Number and expiration date for the agency to display on the instrument that will be used to collect the information and (ii) requires the agency to inform the public about the OMB Control Number's legal significance in accordance with 5 CFR 1320.5(b).

The information collected by PTOL-85 Part B is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 30 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450. Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Notice of Allowability	Application No. 16/819,033	Applicant(s) ROGERS et al.	
	Examiner MAY A ABOUELELA	Art Unit 3791	AIA (FITF) Status Yes

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☑ This communication is responsive to 11/04/2022.
   ☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

3. ☑ The allowed claim(s) is/are 1-23 . As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see **http://www.uspto.gov/patents/init_events/pph/index.jsp** or send an inquiry to **PPHfeedback@uspto.gov.**

4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

   Certified copies:

   a) ☐ All b) ☐ Some* c) ☐ None of the:

   1. ☐ Certified copies of the priority documents have been received.
   2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
   3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____ .

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____ .

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____.
3. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material _____.
4. ☑ Interview Summary (PTO-413), Paper No./Mail Date. 11/16/2022.
5. ☑ Examiner's Amendment/Comment
6. ☑ Examiner's Statement of Reasons for Allowance
7. ☐ Other _____.

/MAY A ABOUELELA/
Primary Examiner, Art Unit 3791

Notice of Pre-AIA or AIA Status

1. The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

Terminal Disclaimer

2. The terminal disclaimer filed on 11/17/2022 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of 17/094692, 17/538990, 11311219, 9820682, 10143412, 11185266 has been reviewed and is accepted. The terminal disclaimer has been recorded.

EXAMINER'S AMENDMENT

3. Authorization for this examiner's amendment was given in an interview with BENJAMIN F. HUDSON on 11/06/2022.

Claim 5 should be amended as follow:

5. (Currently Amended) The device in accordance with claim 1, wherein the junction includes one or more passive structures configured to inhibit ~~a~~ **the** return to the inlet path of any of the first portion of blood received by the chamber.

Allowable Subject Matter

4. Claims 1-23 are allowed.

5. The following is an examiner's statement of reasons for allowance: the most pertinent prior art Eldridge et al (4,207,870) teaches a device comprising; an inlet path;

an outlet path; a chamber connected to the inlet path; and a sampling channel connected between the inlet path and the outlet path, the sampling channel being configured to convey subsequent amounts of blood between the inlet path and the outlet path after the first amount of blood is received by the sequestration chamber.

The prior art does not teach, disclose and/or fairly suggest a chamber connected with the inlet path by a junction and being configured to receive a first portion of blood through the inlet path, the junction being configured to inhibit a return to the inlet path of any of the first portion of blood received by the chamber.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MAY A ABOUELELA whose telephone number is (571)270-7917. The examiner can normally be reached 8-5.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, JACQUELINE CHENG can be reached on 5712725596. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of published or unpublished applications may be obtained from Patent Center. Unpublished application information in Patent Center is available to registered users. To file and manage patent submissions in Patent Center, visit: https://patentcenter.uspto.gov. Visit https://www.uspto.gov/patents/apply/patent-center for more information about Patent Center and https://www.uspto.gov/patents/docx for information about filing in DOCX format. For additional questions, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/MAY A ABOUELELA/
Primary Examiner, Art Unit 3791

Examiner-Initiated Interview Summary	**Application No.** 16/819,033	**Applicant(s)** ROGERS et al.		
	Examiner MAY A ABOUELELA	**Art Unit** 3791	**AIA (First Inventor to File) Status** Yes	**Page** 1 of 1

All Participants (applicant, applicants representative, PTO personnel)	**Title**	**Type**
MAY A ABOUELELA	Primary Examiner	Telephonic
BENJAMIN F. HUDSON	Attorney of Record	

Date of Interview: 16 November 2022

Issues Discussed:

35 U.S.C. 112

Applicant and Examiner discussed the claims set mailed on 11/04/2022. Applicant and Examiner discussed the claim language with respect to the applied prior art and the disclosure. Applicant and Examiner discussed proposed claim amendments represented by the Examiner to overcome 112 rejection for claim 5. The Applicant has authorized the Examiner to amend the claims.

/MAY A ABOUELELA/ Primary Examiner, Art Unit 3791	

Applicant is reminded that a complete written statement as to the substance of the interview must be made of record in the application file. It is the applicants responsibility to provide the written statement, unless the interview was initiated by the Examiner and the Examiner has indicated that a written summary will be provided. See MPEP 713.04
Please further see:
MPEP 713.04
Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews, paragraph (b)
37 CFR § 1.2 Business to be transacted in writing

Applicant recordation instructions: It is not necessary for applicant to provide a separate record of the substance of interview.

Examiner recordation instructions: Examiners must summarize the substance of any interview of record. A complete and proper recordation of the substance of an interview should include the items listed in MPEP 713.04 for complete and proper recordation including the identification of the general thrust of each argument or issue discussed, a general indication of any other pertinent matters discussed regarding patentability and the general results or outcome of the interview, to include an indication as to whether or not agreement was reached on the issues raised.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/838,017	04/01/2020	Bobby E. ROGERS	069366-0572158_KUR7001US	1044

27500 7590 04/16/2024

PILLSBURY WINTHROP SHAW PITTMAN LLP (CV)
ATTENTION: DOCKETING DEPARTMENT
P.O BOX 10500
McLean, VA 22102

EXAMINER	
PORTILLO, JAIRO H	

ART UNIT	PAPER NUMBER
3791	

NOTIFICATION DATE	DELIVERY MODE
04/16/2024	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Docket_IP@pillsburylaw.com

Office Action Summary	Application No. 16/838,017	Applicant(s) ROGERS et al.	
	Examiner JAIRO H PORTILLO	Art Unit 3791	AIA (FITF) Status Yes

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☑ Responsive to communication(s) filed on 4/05/2024.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☐ This action is **FINAL.** 2b) ☑ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5) ☑ Claim(s) 1-4,6-9,14 and 16-18 is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6) ☐ Claim(s) _____ is/are allowed.

7) ☑ Claim(s) 1-4,6-9,14 and 16-18 is/are rejected.

8) ☐ Claim(s) _____ is/are objected to.

9) ☐ Claim(s) _____ are subject to restriction and/or election requirement

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to **PPHfeedback@uspto.gov.**

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a)☐ All b)☐ Some** c)☐ None of the:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)

2) ☑ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date _____.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____.

4) ☐ Other: _____.

DETAILED ACTION

Notice of Pre-AIA or AIA Status

The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/05/2024 has been entered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim(s) 1-3, 6-8, 14, and 16-17 is/are rejected under 35 U.S.C. 103 as being unpatentable over **Bullington et al (US 2019/0365303) ("Bullington").**

Regarding Claim 1, while Bullington teaches a device for optimizing a fluid sample collected by a fluid collection device from a fluid source (Abstract, [0134]-[0135] Figs. 9 and 10), the device comprising:

an inlet configured to connect with the fluid source ([0135] Figs. 9 and 10, inlet 512);

an outlet configured to connect with the fluid collection device ([0135] Figs. 9 and 10, outlet 516);

a sample path connected between the inlet and the outlet ([0135] Figs. 9 and 10, sample path 554), the sample path further having a resistive plug ([0141] Figs, 9 and 10, barrier 574); and

a chamber connected between the inlet and the outlet ([0135] , Figs. 9 and 10, fluid control device 500), the chamber having an air permeable fluid resistor proximate the outlet ([0050] fluid control device utilizes air permeable resistors, [0143] air permeable fluid resistor 515), the chamber being arranged to receive, when a pressure differential is applied between the inlet and the outlet, a first portion of the fluid sample from the fluid source to displace air therein through the air permeable fluid resistor and the outlet, such that upon receipt of the first portion of the fluid sample in the chamber, subsequent portions of the fluid sample can be conveyed by the sample path from the inlet to the outlet ([0136]-[0140] pressure differentials applied between the inlet and outlet to lead a first portion of the fluid sample into sequestration chamber 514, [0145] with subsequent portions following the sample path 554 to the outlet),

the resistive plug including a membrane that is pierceable ([0141] Figs, 9 and 10, barrier 574, pierceable by the piercing member); and

a piercing member configured to pierce the membrane ([0141] Figs. 9 and 10, piercing member 578),

wherein the device is configured such that, once the chamber fills with the first portion of the fluid sample, pressure is exerted against a diaphragm of the piercing member causing the diaphragm to stretch and the piercing member to contact the membrane ([0141]-[0142]),

Bullington fails to teach

wherein the device is configured such that, once the chamber fills with the first portion of the fluid sample, pressure is exerted against the *membrane* causing the *membrane* to stretch and contact the *piercing member*.

It would have been obvious to one of ordinary skill in the art, before the effective filing date of the claimed invention, that Bullington teaches a piercing member, a resistive plug including a membrane that is pierceable, and a piercing action due to pressure exertion wherein a component stretches to bring the piercing member into contact with a pierceable membrane, is the same mechanism as the instant invention. The difference between the inventions is what component is stretching to facilitate the piercing action. If one were to reverse the stretching action from occurring at the diaphragm 576 to instead occur at the barrier 574, the claim limitations would be taught. Examiner recognizes this as a design choice, specifically a reversal of parts [*In reGazda,* 219 F.2d 449, 104 USPQ 400 (CCPA 1955) (Prior art disclosed a clock fixed to the stationary steering wheel column of an automobile while the gear for winding the clock moves with steering wheel; mere reversal of such movement, so the clock moves with wheel, was held to be an obvious modification.).].

Regarding Claim 2, Bullington teaches the device in accordance with claim 1, further comprising a housing that houses and/or defines one or more of the inlet, the outlet, the sample path, and the chamber (*See Claim 1 Rejection,* housing of fluid control device 500).

Regarding Claim 3, Bullington teaches the device in accordance with claim 1, wherein the air permeable fluid resistor includes a material that seals upon contact with the first portion of the fluid sample ([0054] fluid resistor can perform this function by sealing upon contact with the first portion of the fluid sample).

Regarding Claim 6, Bullington teaches a device for optimizing a fluid sample collected by a fluid collection device from a fluid source (Abstract, [0134]-[0135] Figs. 9 and 10), the device comprising:

an inlet configured to connect with the fluid source ([0135] Figs. 9 and 10, inlet 512);

an outlet configured to connect with the fluid collection device ([0135] Figs. 9 and 10, outlet 516);

a sample path connected between the inlet and the outlet ([0135] Figs. 9 and 10, sample path 554), the sample path further having a resistive plug that is configured to inhibit at least a part of a first portion of the fluid sample from entering the sample path ([0141] Figs, 9 and 10, barrier 574 acts as resistive plug); and

a chamber connected between the inlet and the outlet ([0135] , Figs. 9 and 10, fluid control device 500), the chamber further having an air permeable fluid resistor proximate the outlet ([0050] fluid control device utilizes air permeable resistors, [0143] air permeable fluid resistor 515), the chamber being arranged to receive, when a pressure differential is applied between the inlet and the outlet, the first portion of the fluid sample from the fluid source to displace air therein through the air permeable fluid resistor and the outlet, such that upon receipt of the first portion of the fluid sample in the chamber, subsequent portions of the fluid sample can be forced through the resistive plug and conveyed by the sample path from the inlet to the outlet ([0136]-[0140] pressure differentials applied between the inlet and outlet to lead a first portion of the fluid sample into sequestration chamber 514, [0145] with subsequent portions following the sample path 554 to the outlet, after piercing, subsequent portions of the fluid sample can be forced through the resistive plug and conveyed by the sample path from the inlet to the outlet),

the resistive plug including a membrane that is pierceable ([0141] Figs, 9 and 10, barrier 574); and

a piercing member configured to pierce the membrane ([0141] Figs. 9 and 10, piercing member 578),

wherein the device is configured such that, once the chamber fills with the first portion of the fluid sample, pressure is exerted against a diaphragm of the piercing member causing the diaphragm to stretch and the piercing member to contact the membrane ([0141]-[0142]),

Bullington fails to teach

wherein the device is configured such that, once the chamber fills with the first portion of the fluid sample, pressure is exerted against the *membrane* causing the *membrane* to stretch and contact the *piercing member*.

It would have been obvious to one of ordinary skill in the art, before the effective filing date of the claimed invention, that Bullington teaches a piercing member, a resistive plug including a membrane that is pierceable, and a piercing action due to pressure exertion wherein a component stretches to bring the piercing member into contact with a pierceable membrane, is the same mechanism as the instant invention. The difference between the inventions is what component is stretching to facilitate the piercing action. If one were to reverse the stretching action from occurring at the diaphragm 576 to instead occur at the barrier 574, the claim limitations would be taught. Examiner recognizes this as a design choice, specifically a reversal of parts [*In reGazda,* 219 F.2d 449, 104 USPQ 400 (CCPA 1955) (Prior art disclosed a clock fixed to the stationary steering wheel column of an automobile while the gear for winding the clock moves with steering wheel; mere reversal of such movement, so the clock moves with wheel, was held to be an obvious modification.).].

Regarding Claim 7, Bullington teaches the device in accordance with claim 6, further comprising a housing that houses and/or defines one or more of the inlet, the outlet, the sample path, and the chamber (*See Claim 6 Rejection,* housing of fluid control device 500).

Regarding Claim 8, Bullington teaches the device in accordance with claim 6, wherein the air permeable fluid resistor includes a material that seals upon contact with the first portion of the fluid sample ([0054] fluid resistor can perform this function by sealing upon contact with the first portion of the fluid sample).

Regarding Claim 14, Bullington teaches a device for optimizing a fluid sample (Abstract, [0134]-[0135] Figs. 9 and 10), the device comprising:

an inlet ([0135] Figs. 9 and 10, inlet 512);

an outlet ([0135] Figs. 9 and 10, outlet 516);

a sample path connected between the inlet and the outlet ([0135] Figs. 9 and 10, sample path 554), and

a chamber connected between the inlet and the outlet ([0135] , Figs. 9 and 10, fluid control device 500), the chamber having an air permeable fluid resistor proximate the outlet ([0050] fluid control device utilizes air permeable resistors, [0143] air permeable fluid resistor 515), the chamber being arranged to receive, when a pressure differential is applied between the inlet and the outlet, a first portion of the fluid sample from the fluid source to displace air therein through the air permeable fluid resistor and the outlet, such that upon receipt of the first portion of the fluid sample in the chamber, subsequent portions of the fluid sample can be conveyed by the sample path from the inlet to the outlet ([0136]-[0140] pressure differentials applied between the inlet and outlet to lead a first portion of the fluid sample into sequestration chamber 514, [0145] with subsequent portions following the sample path 554 to the outlet),

wherein the sample path further includes a resistive plug that is configured to inhibit at least a part of the first portion of the fluid sample from entering the sample path during receipt of the first portion of the fluid sample in the chamber ([0141] Figs. 9 and 10, barrier 574 acts as resistive plug),

the resistive plug including a membrane that is pierceable ([0141] Figs, 9 and 10, barrier 574); and

a piercing member configured to pierce the membrane ([0141] Figs. 9 and 10, piercing member 578),

wherein the device is configured such that, once the chamber fills with the first portion of the fluid sample, pressure is exerted against a diaphragm of the piercing member causing the diaphragm to stretch and the piercing member to contact the membrane ([0141]-[0142]),

Bullington fails to teach

wherein the device is configured such that, once the chamber fills with the first portion of the fluid sample, pressure is exerted against the *membrane* causing the *membrane* to stretch and contact the *piercing member*.

It would have been obvious to one of ordinary skill in the art, before the effective filing date of the claimed invention, that Bullington teaches a piercing member, a resistive plug including a membrane that is pierceable, and a piercing action due to pressure exertion wherein a component stretches to bring the piercing member into contact with a pierceable membrane, is the same mechanism as the instant invention. The difference between the inventions is what component is stretching to facilitate the piercing action. If one were to reverse the stretching action from occurring at the diaphragm 576 to instead occur at the barrier 574, the claim limitations would be taught. Examiner recognizes this as a design choice, specifically a reversal of parts [*In reGazda,* 219 F.2d 449, 104 USPQ 400 (CCPA 1955) (Prior art disclosed a clock fixed to the stationary steering wheel column of an automobile while the gear for winding the clock moves with steering wheel; mere reversal of such movement, so the clock moves with wheel, was held to be an obvious modification.).].

Regarding Claim 16, Bullington teaches the device in accordance with claim 14, further comprising a housing that houses and/or defines one or more of the inlet, the outlet, the sample path, and the chamber (*See Claim 14 Rejection,* housing of fluid control device 500).

Regarding Claim 17, Bullington teaches the device in accordance with claim 14, wherein the air permeable fluid resistor includes a material that seals upon contact with the first portion of the fluid sample ([0054] fluid resistor can perform this function by sealing upon contact with the first portion of the fluid sample).

Claim(s) 4, 9, and 18 is/are rejected under 35 U.S.C. 103 as being unpatentable over **Bullington** in view of **Rogers et al (US 2017/0020428) ("Rogers").**

Regarding Claim 4, while Bullington teaches the device in accordance with claim 1, Bullington fails to teach wherein the chamber includes a tortuous path.

However Rogers teaches a device for optimizing a fluid sample collected by a fluid collection device from a fluid source (Abstract, [0072] Figs. 11A-11E) wherein a sequestration chamber includes a tortuous path ([0072]).

It would have been obvious to one of ordinary skill in the art, before the effective filing date of the claimed invention, to form the sequestration chamber of Bullington with a tortuous path as a simple substitution of one configuration for sequestration of a fluid sample for another configuration sequestration of a fluid sample to obtain predictable results of trapping initial contaminants.

Regarding Claim 9, while Bullington teaches the device in accordance with claim 6, Bullington fails to teach wherein the chamber includes a tortuous path.

However Rogers teaches a device for optimizing a fluid sample collected by a fluid collection device from a fluid source (Abstract, [0072] Figs. 11A-11E) wherein a sequestration chamber includes a tortuous path ([0072]).

It would have been obvious to one of ordinary skill in the art, before the effective filing date of the claimed invention, to form the sequestration chamber of Bullington with a tortuous path as a simple substitution of one configuration for sequestration of a fluid sample for another configuration sequestration of a fluid sample to obtain predictable results of trapping initial contaminants.

Regarding Claim 18, while Bullington teaches the device in accordance with claim 14, Bullington fails to teach wherein the chamber includes a tortuous path.

However Rogers teaches a device for optimizing a fluid sample collected by a fluid collection device from a fluid source (Abstract, [0072] Figs. 11A-11E) wherein a sequestration chamber includes a tortuous path ([0072]).

It would have been obvious to one of ordinary skill in the art, before the effective filing date of the claimed invention, to form the sequestration chamber of Bullington with a tortuous path as a simple substitution of one configuration for sequestration of a fluid sample for another configuration sequestration of a fluid sample to obtain predictable results of trapping initial contaminants.

Response to Arguments

Applicant's amendments filed 4/05/2024 with respect to the 35 USC 103 rejection have been fully considered, and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Bullington.

Applicant's arguments filed 4/05/2024 with respect to the 35 USC 103 rejection have been fully considered, but are not persuasive.

Applicant argues that Bullington teaches the opposite of the amended claim by having the needle move to puncture the membrane, rather than the membrane moving to be punctured by the piercing member. Redesigning Bullington to meet the claim language is not obvious as it would require a substantial redesign and change in the operation of Bullington's device. Examiner respectfully disagrees. Changing Bullington to meet the claim limitations merely requires a reversal of which membrane flexes upon receipt of the fluid sample. This does not require a change in operation as the system would still guide a first portion of the sample to a sequestration chamber, leading to a membrane flexing to enable a piercing action, the piercing action allowing the subsequent portion of the fluid sample to flow to the outlet. Further, a

substantial redesign is not needed as the only change required would be which membrane has the flexing property (barrier 574 instead of diaphragm 576).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAIRO H PORTILLO whose telephone number is (571)272-1073. The examiner can normally be reached M-F 9:00 am - 5:15 pm.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jacqueline Cheng can be reached on (571)272-5596. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of published or unpublished applications may be obtained from Patent Center. Unpublished application information in Patent Center is available to registered users. To file and manage patent submissions in Patent Center, visit: https://patentcenter.uspto.gov. Visit https://www.uspto.gov/patents/apply/patent-center for more information about Patent Center and https://www.uspto.gov/patents/docx for information about filing in DOCX format. For additional questions, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JAIRO H. PORTILLO/
Examiner
Art Unit 3791

/PUYA AGAHI/
Primary Examiner, Art Unit 3791

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT
(Not for submission under 37 CFR 1.99)

Application Number	16838017
Filing Date	2020-04-01
First Named Inventor	Bobby E. ROGERS
Art Unit	3791
Examiner Name	PORTILLO, JAIRO H
Attorney Docket Number	069366-0572158_KUR7001US

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	4416291		1983-11-22	KAUFMAN JOSEPH	
	2	10299713		2019-05-28	PATTON RICHARD G	
	3	10265007		2019-04-23	BULLINGTON GREGORY	
	4	11395612		2022-07-26	BULLINGTON GREGORY J	
	5	10881343		2021-01-05	BULLINGTON GREGORY J	
	6	10596315		2020-03-24	BULLINGTON GREGORY J	
	7	11660030		2023-05-30	BULLINGTON GREGORY J	
	8	11259727		2022-03-01	BULLINGTON GREGORY J	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /J.H.P/

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	9	11737693		2023-08-29	BULLINGTON GREGORY J	
	10	11439332		2022-09-13	BULLINGTON GREGORY J	
	11	11589843		2023-02-28	BULLINGTON GREGORY J	
	12	11612340		2023-03-28	BULLINGTON GREGORY J	
	13	11234626		2022-02-01	BULLINGTON GREGORY J	
	14	10624977		2020-04-21	BULLINGTON GREGORY J	
	15	11653863		2023-05-23	BULLINGTON GREGORY J	
	16	11419531		2022-08-23	BULLINGTON GREGORY J	
	17	11786155		2023-10-17	BULLINGTON GREGORY J	
	18	11789017		2023-10-17	BULLINGTON GREGORY J	

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Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20220151525		2022-05-19	BULLINGTON GREGORY J	
	2	20220151527		2022-05-19	BULLINGTON GREGORY J	
	3	20200289039		2020-09-17	BULLINGTON GREGORY J	
	4	20210275068		2021-09-09	MIAZGA JAY M	
	5	20220304664		2022-09-29	HAMMER JEREMY	
	6	20160073937		2016-03-17	BURKHOLZ JONATHAN KARL	

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Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] ¡	Kind Code[4]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T[5]
	1	S5825146	JP		1983-02-15	BECTON DICKINSON CO		☒

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	First Named Inventor	Bobby E. ROGERS
	Art Unit	3791
	Examiner Name	PORTILLO, JAIRO H
	Attorney Docket Number	069366-0572158_KUR7001US

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
	1	European Patent Application No. EP23155927.9 extended European Search Report dated Jul. 26, 2023, 8 pages.	☐
	2	JP Notice of Allowance mailed 06-20-2023; Attorney Docket No. 069366-0572231_KUR3D01JP. 6 pages.	☐
	3	Examination Report dated Sep. 28, 2023, for European Patent Application No. 22181212.6. 5 pages.	☐
	4	Office Action (Notice of Section 18) dated 12/20/2023 for IL App No. 309380 (pages 1-5).	☐
	5	JP Office Action mailed 02/27/2024; Attorney Docket No. 069366-0575273_KUR2D03JP. 11 pages.	☐

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EXAMINER SIGNATURE

Examiner Signature	/JAIRO H PORTILLO/	Date Considered	04/10/2024

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /J.H.P/

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
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	Art Unit	3791
	Examiner Name	PORTILLO, JAIRO H
	Attorney Docket Number	069366-0572158_KUR7001US

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Benjamin F. Hudson/	Date (YYYY-MM-DD)	2024-04-05
Name/Print	Benjamin F. Hudson	Registration Number	71,474

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /J.H.P/

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /J.H.P/

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Application Number	18/898,239
Filing Date	09/26/2024
First Named Inventor	Bobby E. Rogers
Art Unit	
Client Number	069366
Matter Number	0581370_KUR2C07US

GENERAL

Pursuant to 37 C.F.R. 1.97 and 1.98 and to the duty of disclosure set forth in 37 C.F.R. 1.56, the Examiner in charge of the above-identified application is requested to consider and make of record the references listed herewith. A copy of each listed reference, other than U.S. patents/applications and references cited in a parent application, is enclosed.

Although the information submitted herewith may be "material" to the Examiner's consideration of the subject application, this submission is not intended to constitute an admission that such information is "prior art" as to the claimed invention, nor is it intended to constitute an admission that such information is "analogous prior art".

In accordance with 37 C.F.R. 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made.

TIMING

In accordance with 37 CFR 1.97(b), this Information Disclosure Statement is being filed within three months of the filing of a national application other than a continued prosecution application under 37 CFR 1.53(d); within three months of the date of entry of the national stage as set forth in 37 CFR 1.491 in an international application; before the mailing of a first Office Action on the merits; or before the mailing of a first Office Action after the filing of a request for continued examination under 37 CFR 1.114.

CERTIFICATION STATEMENT

No certification statement is required. This Information Disclosure Statement is being filed in accordance with 37 CFR 1.97(b).

FEE

No fee is required. This Information Disclosure Statement is being filed in accordance with 37 CFR 1.97(b).

ADDITIONAL COMMENTS

SIGNATURE

Signature	/Benjamin F. Hudson/	**Date**	2024-09-27
Name	Benjamin F. Hudson	**Registration Number**	71,474

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/819,033	03/13/2020	Bobby E. ROGERS	KURIN4CIP	6468

158174 7590 08/04/2022

Kurin, Inc.
P.O. Box 371710
San Diego, CA 92137

EXAMINER	
ABOUELELA, MAY A	

ART UNIT	PAPER NUMBER
3791	

NOTIFICATION DATE	DELIVERY MODE
08/04/2022	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

eofficeaction@appcoll.com
jsnolan1@hotmail.com
kurin@virtualipsupport.com

PTOL-90A (Rev. 04/07)

Office Action Summary	Application No. 16/819,033	Applicant(s) ROGERS et al.	
	Examiner MAY A ABOUELELA	Art Unit 3791	AIA (FITF) Status Yes

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☑ Responsive to communication(s) filed on 03/13/2020.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☐ This action is **FINAL.** 2b) ☑ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5) ☑ Claim(s) 1-20 is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6) ☐ Claim(s) _____ is/are allowed.

7) ☑ Claim(s) 1-20 is/are rejected.

8) ☐ Claim(s) _____ is/are objected to.

9) ☐ Claim(s) _____ are subject to restriction and/or election requirement

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to **PPHfeedback@uspto.gov.**

Application Papers

10)☑ The specification is objected to by the Examiner.

11)☑ The drawing(s) filed on 06/01/2020 is/are: a)☑ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a)☐ All b)☐ Some** c)☐ None of the:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☑ Notice of References Cited (PTO-892)

2) ☑ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date _____.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____.

4) ☐ Other: _____.

Notice of Pre-AIA or AIA Status

1. The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on 06/24/2020, 07/03/2020 and 09/18/2020. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Specification

3. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Objections

4. Claim 11 is objected to because of the following informalities: the phrase "in inlet port" in line 2 should be amended to read –an inlet port--. Appropriate correction is required.

5. Claim 11 is objected to because of the following informalities: the phrase "the vent further being further configured to" in line 8 should be amended to read –the vent further being configured to--. Appropriate correction is required.

6. Claim 12 is objected to because of the following informalities: the phrase "it" in line 3 should be amended to read –air--. Appropriate correction is required.

7. Claim 13 is objected to because of the following informalities: the phrase "a return" in line 2 should be amended to read –the return--. Appropriate correction is required.

8. Claim 18 is objected to because of the following informalities: the phrase "a patient" in line 4 should be amended to read –the patient--. Appropriate correction is required.

9. Claim 18 is objected to because of the following informalities: the phrase "at subsequent" in line 8 should be amended to read –a subsequent--. Appropriate correction is required.

10. Claim 19 is objected to because of the following informalities: the phrase "a return" in line 3 should be amended to read –the return--. Appropriate correction is required.

Claim Interpretation

11. The following is a quotation of 35 U.S.C. 112(f):

> (f) Element in Claim for a Combination. – An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

The following is a quotation of pre-AIA 35 U.S.C. 112, sixth paragraph:

> An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

The claims in this application are given their broadest reasonable interpretation using the plain meaning of the claim language in light of the specification as it would be understood by one of ordinary skill in the art. The broadest reasonable interpretation of a claim element (also commonly referred to as a claim limitation) is limited by the description in the specification when 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, is invoked.

As explained in MPEP § 2181, subsection I, claim limitations that meet the following three-prong test will be interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph:

(A) the claim limitation uses the term "means" or "step" or a term used as a substitute for "means" that is a generic placeholder (also called a nonce term or a non-structural term having no specific structural meaning) for performing the claimed function;

(B) the term "means" or "step" or the generic placeholder is modified by functional language, typically, but not always linked by the transition word "for" (e.g., "means for") or another linking word or phrase, such as "configured to" or "so that"; and

(C) the term "means" or "step" or the generic placeholder is not modified by sufficient structure, material, or acts for performing the claimed function.

Use of the word "means" (or "step") in a claim with functional language creates a rebuttable presumption that the claim limitation is to be treated in accordance with 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph. The presumption that the claim limitation is interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, is rebutted when the claim limitation recites sufficient structure, material, or acts to entirely perform the recited function.

Absence of the word "means" (or "step") in a claim creates a rebuttable presumption that the claim limitation is not to be treated in accordance with 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph. The presumption that the claim limitation is not interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, is rebutted when the claim limitation recites function without reciting sufficient structure, material or acts to entirely perform the recited function.

Claim limitations in this application that use the word "means" (or "step") are being interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, except as otherwise indicated in an Office action. Conversely, claim limitations in this application that do not use the word "means" (or "step") are not being interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, except as otherwise indicated in an Office action.

This application includes one or more claim limitations that do not use the word "means," but are nonetheless being interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, because the claim limitation(s) uses a generic placeholder that is coupled with functional language without reciting sufficient structure to perform

the recited function and the generic placeholder is not preceded by a structural modifier. Such claim limitation(s) is/are:

Limitation "closure mechanism" in claim 12, the claim does not recite enough structure that corresponds to the claimed "closure mechanism", however the specification disclose (the closure mechanism 3710 is a raised portion that is raised from an outer surface of the housing, par.215, the closure mechanism simply defines a surface to interface with another object, such as a human fingertip, a cotton swab, a piece of tape, or any other object, to seal any vents, apertures, openings, holes, par.216, closure mechanism in the form of a cap 3180 to enclose and/or seal air-permeable blood barrier and/or air vent, par.219).

Because this/these claim limitation(s) is/are being interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, it/they is/are being interpreted to cover the corresponding structure described in the specification as performing the claimed function, and equivalents thereof.

If applicant does not intend to have this/these limitation(s) interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, applicant may: (1) amend the claim limitation(s) to avoid it/them being interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph (e.g., by reciting sufficient structure to perform the claimed function); or (2) present a sufficient showing that the claim limitation(s) recite(s) sufficient structure to perform the claimed function so as to avoid it/them being interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph.

Claim Rejections - 35 USC § 112

12. The following is a quotation of 35 U.S.C. 112(b):
(b) CONCLUSION.—The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.

The following is a quotation of 35 U.S.C. 112 (pre-AIA), second paragraph:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 18-20 are rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor or a joint inventor (or for applications subject to pre-AIA 35 U.S.C. 112, the applicant), regards as the invention.

Claim 18 recites the limitation "the patient needle" in line 10. There is insufficient antecedent basis for this limitation in the claim.

Claim 18 recites the limitation "the sample needle" in line 10. There is insufficient antecedent basis for this limitation in the claim.

Double Patenting

13. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory double patenting rejection is appropriate where the claims at issue are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s)

because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the reference application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

The USPTO internet Web site contains terminal disclaimer forms which may be used. Please visit http://www.uspto.gov/forms/. The filing date of the application will determine what form should be used. A web-based eTerminal Disclaimer may be filled out completely online using web-screens. An eTerminal Disclaimer that meets all requirements is auto-processed and approved immediately upon submission. For more information about eTerminal Disclaimers, refer to http://www.uspto.gov/patents/process/file/efs/guidance/eTD-info-I.jsp.

Claims 1-20 are provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claims 7-13 of co-pending Application No.17/094692, claims 1-20 of co-pending Application No.17/538990, claims 1-20 of U.S Patent Application

No.11311219, claims 1-16 of U.S Patent Application No. 9820682, claims 1-23 of U.S Patent Application No.10143412, and claims 1-2 of U.S Patent Application No. 11185266. Although the claims at issue are not identical, they are not patentably distinct from each other because the copending and patent applications and the instance application are claiming a common subject matter including: a blood sequestration device comprising; an inlet path; an outlet path; a sequestration chamber connected with the inlet path by a junction and being configured to receive a first portion of blood through the inlet path, the first blood portion is inhibited to return to the inlet path; and a sampling channel connected between the inlet path and the outlet path, the sampling channel being configured to convey subsequent amounts of blood between the inlet path and the outlet path.

This is a provisional nonstatutory double patenting rejection because the patentably indistinct claims have not in fact been patented.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MAY A ABOUELELA whose telephone number is (571)270-7917. The examiner can normally be reached 8-5.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, JACQUELINE CHENG can be reached on 5712725596. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of published or unpublished applications may be obtained from Patent Center. Unpublished application information in Patent Center is available to registered users. To file and manage patent submissions in Patent Center, visit: https://patentcenter.uspto.gov. Visit https://www.uspto.gov/patents/apply/patent-center for more information about Patent Center and https://www.uspto.gov/patents/docx for information about filing in DOCX format. For additional questions, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/MAY A ABOUELELA/
Primary Examiner, Art Unit 3791

Notice of References Cited	Application/Control No. 16/819,033	Applicant(s)/Patent Under Reexamination ROGERS et al.	
	Examiner MAY A ABOUELELA	Art Unit 3791	Page 1 of 4

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	CPC Classification	US Classification
*	A	US-20040073171-A1	04-2004	Rogers, Bobby E.	A61M39/26	604/164.13
*	B	US-9138572-B2	09-2015	Zeytoonian; Paul	A61M39/26	1/1
*	C	US-8568371-B2	10-2013	Siopes; William	A61M39/26	251/903
*	D	US-8540663-B2	09-2013	Davey; Christopher T.	A61M1/30	604/93.01
*	E	US-8523826-B2	09-2013	Layton, Jr.; Russell K.	A61M39/16	604/533
*	F	US-20160174888-A1	06-2016	Berthier; Erwin	A61B5/150503	600/573
*	G	US-8197420-B2	06-2012	Patton; Richard G.	A61B5/150503	600/573
*	H	US-4057050-A	11-1977	Sarstedt; Walter	A61B5/150351	604/125
*	I	US-20050240161-A1	10-2005	Crawford, Jamieson William McLean	A61B5/150572	604/264
*	J	US-20040147855-A1	07-2004	Marsden, Stewart	A61B5/150496	600/576
*	K	US-8864684-B2	10-2014	Bullington; Gregory J.	A61B10/0048	600/576
*	L	US-8535241-B2	09-2013	Bullington; Gregory	A61B10/0045	604/249
*	M	US-20130317391-A1	11-2013	Bullington; Gregory J.	A61B5/15003	600/578

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*	B	US-20030105414-A1	06-2003	Leong, Alvin Tan Chee	A61B5/15003	600/576
*	C	US-5749857-A	05-1998	Cuppy; Michael J.	A61M25/0606	604/161
*	D	US-9060724-B2	06-2015	Bullington; Gregory J.	A61B5/150221	1/1
*	E	US-9204864-B2	12-2015	Bullington; Gregory J.	A61B10/0096	1/1
*	F	US-20020004647-A1	01-2002	Leong, Alvin Tan Chee	A61B5/1545	604/168.01
*	G	US-3817240-A	06-1974	Ayres; Waldemar A.	A61B5/150221	600/584
*	H	US-3874367-A	04-1975	Ayres; Waldemar A.	A61B5/15003	600/577
*	I	US-3886930-A	06-1975	Ryan; George R.	A61B5/15003	600/584
*	J	US-4106497-A	08-1978	Percarpio; Edward P.	A61B5/150221	600/579
*	K	US-4154229-A	05-1979	Nugent; Edward L.	A61B5/150351	600/577
*	L	US-4207870-A	06-1980	Eldridge; William N.	A61B5/150732	604/167.03
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*	B	US-5520193-A	05-1996	Suzuki; Issei	A61B5/1545	604/126
*	C	US-20100057004-A1	03-2010	Christensen; Kelly D.	A61M39/22	604/122
*	D	US-20070088279-A1	04-2007	Shue; Ming-Jeng	A61M25/0693	604/168.01
*	E	US-20080145933-A1	06-2008	Patton; Richard G.	A61B5/154	435/379
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*	H	US-6569117-B1	05-2003	Ziv; David	A61M39/02	604/246
*	I	US-3741197-A	06-1973	Sanz; Manuel C.	A61B5/150267	600/583
*	J	US-20100010372-A1	01-2010	BROWN; LEROY R.	A61B5/15003	600/573
*	K	US-8603009-B2	12-2013	Tan; Alvin Chee Leong	A61B5/150664	600/573
*	L	US-20080319346-A1	12-2008	Crawford; Jamieson	A61B5/150389	600/576
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	Examiner MAY A ABOUELELA	Art Unit 3791	Page 4 of 4

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*	C	US-4444203-A	04-1984	Engelman; Allan	A61B5/150496	600/576
*	D	US-20070083162-A1	04-2007	O'Reagan; James	A61M39/26	604/167.03
*	E	US-6398743-B1	06-2002	Halseth; Thor R.	A61B5/15003	604/164.12
*	F	US-9022950-B2	05-2015	Bullington; Gregory	A61B5/150389	600/576
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Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (02-18)
Approved for use through 11/30/2020. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT
(Not for submission under 37 CFR 1.99)

Application Number	16819033
Filing Date	2020-03-13
First Named Inventor	Bobby E. ROGERS
Art Unit	3791
Examiner Name	
Attorney Docket Number	KURIN4CIP

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	4444203	A	1984-04-24	Engelman	
	2	6398743	B1	2002-06-04	Halseth et al.	

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	1	20070083162	A1	2007-04-12	O'Reagan et al.	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (**Not for submission under 37 CFR 1.99)**	Application Number	16819033
	Filing Date	2020-03-13
	First Named Inventor	Bobby E. ROGERS
	Art Unit	3791
	Examiner Name	
	Attorney Docket Number	KURIN4CIP

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
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Examiner Signature	/MAY A ABOUELELA/	Date Considered	05/18/2022

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[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	16819033
	Filing Date	2020-03-13
	First Named Inventor	Bobby E. ROGERS
	Art Unit	3791
	Examiner Name	
	Attorney Docket Number	KURIN4CIP

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

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See attached certification statement.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/JSN/	Date (YYYY-MM-DD)	2020-09-18
Name/Print	James Scott Nolan	Registration Number	53,393

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

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Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (02-18)
Approved for use through 11/30/2020. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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Application Number	16819033
Filing Date	2020-03-13
First Named Inventor	Bobby E. ROGERS
Art Unit	3791
Examiner Name	
Attorney Docket Number	KURIN4CIP

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Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	4349035	A	1982-09-14	Thomas et al.	
	2	5401262	A	1995-03-28	Karwoski et al.	

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Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20180271425	A1	2018-09-27	Kurin, Inc.	
	2	20180177445	A1	2018-06-28	Kurin, Inc.	
	3	20180353117	A1	2018-12-13	Magnolia Medical Technologies, Inc.	

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	1	International Search Report and Written Opinion dated 19 June 2020, for PCT application no. PCTUS2020/023617.	

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EXAMINER SIGNATURE

Examiner Signature	/MAY A ABOUELELA/	Date Considered	05/18/2022

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Signature	/JSN/	Date (YYYY-MM-DD)	2020-07-01
Name/Print	James S. Nolan	Registration Number	53,393

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Application Number	16819033
Filing Date	2020-03-13
First Named Inventor	Bobby E. ROGERS
Art Unit	3791
Examiner Name	
Attorney Docket Number	KURIN4CIP

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Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	10010282	B2	2018-07-03	Rogers et al.	
	2	10143412	B2	2018-12-04	Rogers et al.	
	3	3648684	A	1972-03-14	Barnwell et al.	
	4	3741197	A	1973-06-26	Sanz et al.	
	5	3817240	A	1974-06-18	Ayres	
	6	3874367	A	1975-04-01	Ayres	
	7	3886930	A	1975-06-03	Ryan	
	8	4056101	A	1977-11-01	Geissler et al.	

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	Examiner Name	
	Attorney Docket Number	KURIN4CIP

	9	4057050	A	1977-11-08	Sarstedt	
	10	4106497	A	1978-08-15	Percarpio	
	11	4154229	A	1979-05-15	Nugent	
	12	4207870	A	1980-06-17	Eldridge	
	13	4412548	A	1983-11-01	Hoch	
	14	4416290	A	1983-11-22	Lutkowski	
	15	4813433	A	1989-03-21	Downey	
	16	5222502	A	1993-06-29	Kurose	
	17	5520193	A	1996-05-28	Suzuki et al.	
	18	5749857	A	1998-05-12	Cuppy	
	19	6569117	B1	2003-05-27	Ziv et al.	

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	20	8070725	B2	2011-12-06	Christensen	
	21	8197420	B2	2012-06-12	Patton	
	22	8523826	B2	2013-09-03	Layton Jr.	
	23	8535241	B2	2013-09-17	Bullington et al.	
	24	8540663	B2	2013-09-24	Davey et al.	
	25	8568371	B2	2013-10-29	Siopes et al.	
	26	8603009	B2	2013-12-10	Tan et al.	
	27	8864684	B2	2014-10-21	Bullington et al.	
	28	9022951	B2	2015-05-05	Bullington et al.	
	29	9060724	B2	2015-06-23	Bullington et al.	
	30	9138572	B2	2015-09-22	Zeytoonian et al.	

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	31	9155495	B2	2015-10-13	Bullington et al.	
	32	9204864	B2	2015-12-08	Bullington et al.	
	33	9820682	B2	2017-11-21	Rogers et al.	

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	1	20020004647	A1	2002-01-10	Leong	
	2	20030105414	A1	2003-06-05	Leong	
	3	20030208151	A1	2003-11-06	Kraus et al.	
	4	20040054333	A1	2004-03-18	Theeuwes et al.	
	5	20040073171	A1	2004-04-15	Rogers et al.	
	6	20040147855	A1	2004-07-29	Marsden	

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	7	20050004524	A1	2005-01-06	Newby et al.	
	8	20050005635	A1	2005-01-13	Metais	
	9	20050007524	A1	2005-01-13	Luo et al.	
	10	20050240161	A1	2005-10-27	Crawford	
	11	20070088279	A1	2007-04-19	Shue et al.	
	12	20080145933	A1	2008-06-19	Patton	
	13	20080167577	A1	2008-07-10	Weilbacher et al.	
	14	20080319346	A1	2008-12-25	Crawford et al.	
	15	20090227953	A1	2009-09-10	Tan et al.	
	16	20100010372	A1	2010-01-14	Brown et al.	
	17	20100057004	A1	2010-03-04	Christensen et al.	

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	18	20130317391	A1	2013-11-28	Bullington et al.	
	19	20140039348	A1	2014-02-06	Bullington et al.	
	20	20140107564	A1	2014-04-17	Bullington et al.	
	21	20140155782	A1	2014-06-05	Bullington et al.	
	22	20140276578	A1	2014-09-18	Bullington et al.	
	23	20150246352	A1	2015-09-03	Bullington et al.	
	24	20150342510	A1	2015-12-03	Bullington et al.	
	25	20160017488	A1	2016-01-21	Kobayashi et al.	
	26	20160174888	A1	2016-06-23	Berthier et al.	
	27	20160361006	A1	2016-12-15	Bullington et al.	
	28	20170020427	A1	2017-01-26	Rogers et al.	

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	29	20170020428	A1	2017-01-26	Rogers et al.	
	30	20170065733	A1	2017-03-09	Bullington et al.	
	31	20180140240	A1	2018-05-24	Bullington et al.	
	32	20180177445	A1	2018-06-28	Rogers et al.	
	33	20180353117	A1	2018-12-13	Bullington et al.	
	34	20190159711	A1	2019-05-30	Rogers et al.	

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	1	1665986	EP	B1	2009-06-03	Bennett et al.		
	2	3324845	EP	A1	2018-05-30	Rogers et al.	Equivalent to WO2017/019552	
	3	3562397	EP	A1	2019-11-06	Rogers et al.	Equivalent to WO2018/125929	

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	4	3622890	EP	A1	2020-03-18	Rogers et al.		
	5	3622890	EP	A1	2019-10-01	Bobby E. Rogers		X
	6	2012016496	JP	A	2012-01-26	Akiyama et al.		☐
	7	2019534792	JP	A	2019-12-05	Seilinger et al.		☐
	8	2020000340	JP	A	2020-01-09	Omura et al.		☒
	9	5789869	JP	B2	2015-10-07	Suzuki, Tatsutoshi et al.		☒
	10	5825146	JP	B2	2015-12-02	Karasawa et al.		☒
	11	5867238	JP	B2	2016-02-24	Najiyanto et al.		☒
	12	6643474	JP	B2	2020-02-12	Rogers, et al.		☒
	13	H08257018	JP	A	1996-10-08	Higaki et al.		☒
	14	H09504726	JP	A	1997-05-13	Desecki et al.		☐

EFS Web 2.1.18

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.A.A/

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	16819033
	Filing Date	2020-03-13
	First Named Inventor	Bobby E. ROGERS
	Art Unit	3791
	Examiner Name	
	Attorney Docket Number	KURIN4CIP

	15	S5825146	JP	A	1983-02-15	Jiyosefu		☒
	16	S5867238	JP	A	1983-04-21	Edowaado et al.		☐
	17	2011162772	WO	A1	2011-12-29	Fischel et al.		☐
	18	2013181352	WO	A1	2013-12-05	Bullington et al.		☐
	19	2017019552	WO	A1	2017-02-02	Rogers et al.		☐
	20	2018125929	WO	A1	2018-07-05	Rogers et al.		☐
	21	9605875	WO	A1	1996-02-29	Desecki et al.		☐

If you wish to add additional Foreign Patent Document citation information please click the Add button Add

NON-PATENT LITERATURE DOCUMENTS Remove

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
	1	BULLINGTON, et al, Systems and Methods for Sample Collection with Reduced Hemolysis, Exhibit H in Provisional Application No. 62/517,681, dated 6/9/2017, 131 pages	
	2	Communication Under Rule 71(3) EPC dated 22 April 2020 for EP application no. 17840467.9	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.A.A/

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	16819033
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	Examiner Name	
	Attorney Docket Number	KURIN4CIP

	3	European Patent Application No. EP19200766.4 extended European Search Report dated December 2, 2019, 11 pages.	
	4	European Patent Office; Communication pursuant to Article 94(3) EPC; dated October 31, 2018.	
	5	Examination Report No. 1 dated 29 April 2020, for Australian Patent Application No. 2016297849.	
	6	International Search Report and Written Opinion for PCT/US16/43709, Dated October 19, 2016.	
	7	International Search Report/Written Opinion for PCT/US17/68569 dated 25 April 2018.	
	8	Japanese Patent Office, Notice of Reasons for Rejection, Japanese patent application number JP2018-523384, dated July 23, 2019.	

If you wish to add additional non-patent literature document citation information please click the Add button Add

EXAMINER SIGNATURE

Examiner Signature	/MAY A ABOUELELA/	Date Considered	05/18/2022

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.A.A/

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	16819033
	Filing Date	2020-03-13
	First Named Inventor	Bobby E. ROGERS
	Art Unit	3791
	Examiner Name	
	Attorney Docket Number	KURIN4CIP

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

See attached certification statement.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/JSN/	Date (YYYY-MM-DD)	2020-06-24
Name/Print	James S. Nolan	Registration Number	53393

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.A.A/

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.A.A/

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

NOTICE OF ALLOWANCE AND FEE(S) DUE

27500 7590 09/08/2023

PILLSBURY WINTHROP SHAW PITTMAN LLP (CV)
ATTENTION: DOCKETING DEPARTMENT
P.O BOX 10500
McLean, VA 22102

EXAMINER	
ABOUELELA, MAY A	
ART UNIT	PAPER NUMBER
3791	

DATE MAILED: 09/08/2023

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
18/113,710	02/24/2023	Bobby E. ROGERS	069366-0574153_KUR2C04US	2715

TITLE OF INVENTION: BLOOD SAMPLE OPTIMIZATION SYSTEM AND BLOOD CONTAMINANT SEQUESTRATION DEVICE AND METHOD

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	$480	$0.00	$0.00	$480	12/08/2023

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the ENTITY STATUS shown above. If the ENTITY STATUS is shown as SMALL or MICRO, verify whether entitlement to that entity status still applies.

If the ENTITY STATUS is the same as shown above, pay the TOTAL FEE(S) DUE shown above.

If the ENTITY STATUS is changed from that shown above, on PART B - FEE(S) TRANSMITTAL, complete section number 5 titled "Change in Entity Status (from status indicated above)".

For purposes of this notice, small entity fees are 40% the amount of undiscounted fees, and micro entity fees are 20% the amount of undiscounted fees.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Maintenance fees are due in utility patents issuing on applications filed on or after Dec. 12, 1980. It is patentee's responsibility to ensure timely payment of maintenance fees when due. More information is available at www.uspto.gov/PatentMaintenanceFees.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), by mail or fax, or via EFS-Web.

By mail, send to: Mail Stop ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

By fax, send to: (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications. **Because electronic patent issuance may occur shortly after issue fee payment, any desired continuing application should preferably be filed prior to payment of this issue fee in order not to jeopardize copendency.**

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

27500 7590 09/08/2023
PILLSBURY WINTHROP SHAW PITTMAN LLP (CV)
ATTENTION: DOCKETING DEPARTMENT
P.O BOX 10500
McLean, VA 22102

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being transmitted to the USPTO via EFS-Web or by facsimile to (571) 273-2885, on the date below.

(Typed or printed name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
18/113,710	02/24/2023	Bobby E. ROGERS	069366-0574153_KUR2C04US	2715

TITLE OF INVENTION: BLOOD SAMPLE OPTIMIZATION SYSTEM AND BLOOD CONTAMINANT SEQUESTRATION DEVICE AND METHOD

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	$480	$0.00	$0.00	$480	12/08/2023

EXAMINER	ART UNIT	CLASS-SUBCLASS
ABOUELELA, MAY A	3791	600-577000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

❑ Change of correspondence address (or Change of Correspondence Address form PTO/AIA/122 or PTO/SB/122) attached.

❑ "Fee Address" indication (or "Fee Address" Indication form PTO/AIA/47 or PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list
(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,
(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 _____
2 _____
3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document must have been previously recorded, or filed for recordation, as set forth in 37 CFR 3.11 and 37 CFR 3.81(a). Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ❑ Individual ❑ Corporation or other private group entity ❑ Government

4a. Fees submitted: ❑ Issue Fee ❑ Publication Fee (if required)

4b. Method of Payment: *(Please first reapply any previously paid fee shown above)*

❑ Electronic Payment via Patent Center or EFS-Web ❑ Enclosed check ❑ Non-electronic payment by credit card (Attach form PTO-2038)

❑ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment to Deposit Account No. _____

5. **Change in Entity Status** (from status indicated above)

❑ Applicant certifying micro entity status. See 37 CFR 1.29

NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.

❑ Applicant asserting small entity status. See 37 CFR 1.27

NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.

❑ Applicant changing to regular undiscounted fee status.

NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature _____ Date _____

Typed or printed name _____ Registration No. _____

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
18/113,710	02/24/2023	Bobby E. ROGERS	069366-0574153_KUR2C04US	2715

27500 7590 09/08/2023

PILLSBURY WINTHROP SHAW PITTMAN LLP (CV)
ATTENTION: DOCKETING DEPARTMENT
P.O BOX 10500
McLean, VA 22102

EXAMINER	
ABOUELELA, MAY A	
ART UNIT	PAPER NUMBER
3791	

DATE MAILED: 09/08/2023

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(Applications filed on or after May 29, 2000)

The Office has discontinued providing a Patent Term Adjustment (PTA) calculation with the Notice of Allowance.

Section 1(h)(2) of the AIA Technical Corrections Act amended 35 U.S.C. 154(b)(3)(B)(i) to eliminate the requirement that the Office provide a patent term adjustment determination with the notice of allowance. See Revisions to Patent Term Adjustment, 78 Fed. Reg. 19416, 19417 (Apr. 1, 2013). Therefore, the Office is no longer providing an initial patent term adjustment determination with the notice of allowance. The Office will continue to provide a patent term adjustment determination with the Issue Notification Letter that is mailed to applicant approximately three weeks prior to the issue date of the patent, and will include the patent term adjustment on the patent. Any request for reconsideration of the patent term adjustment determination (or reinstatement of patent term adjustment) should follow the process outlined in 37 CFR 1.705.

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

OMB Clearance and PRA Burden Statement for PTOL-85 Part B

The Paperwork Reduction Act (PRA) of 1995 requires Federal agencies to obtain Office of Management and Budget approval before requesting most types of information from the public. When OMB approves an agency request to collect information from the public, OMB (i) provides a valid OMB Control Number and expiration date for the agency to display on the instrument that will be used to collect the information and (ii) requires the agency to inform the public about the OMB Control Number's legal significance in accordance with 5 CFR 1320.5(b).

The information collected by PTOL-85 Part B is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 30 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450. Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

Notice of Allowability	Application No. 18/113,710	Applicant(s) ROGERS et al.	
	Examiner MAY A ABOUELELA	Art Unit 3791	AIA (FITF) Status Yes

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☑ This communication is responsive to 08/29/2023.
   ☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

3. ☑ The allowed claim(s) is/are 17-31 . As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see **http://www.uspto.gov/patents/init_events/pph/index.jsp** or send an inquiry to **PPHfeedback@uspto.gov.**

4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

   Certified copies:

   a) ☐ All b) ☐ Some* c) ☐ None of the:

   1. ☐ Certified copies of the priority documents have been received.
   2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
   3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____ .

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____ .

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☑ Notice of References Cited (PTO-892)
2. ☑ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____.
3. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material _____.
4. ☐ Interview Summary (PTO-413), Paper No./Mail Date. _____.
5. ☐ Examiner's Amendment/Comment
6. ☑ Examiner's Statement of Reasons for Allowance
7. ☑ Other A.NE.

/MAY A ABOUELELA/
Primary Examiner, Art Unit 3791

Notice of Pre-AIA or AIA Status

1. The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on 05/10/2023. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Allowable Subject Matter

3. Claims 17-31 are allowed.

4. The following is an examiner's statement of reasons for allowance: the most pertinent prior art Christensen et al (2010/0057004) teaches a device comprising: an inlet port for receiving a blood sample; an outlet port; a chamber connected with the inlet port and the outlet port, and configured to collect a first portion of the blood sample, the chamber including a material that is air permeable and blood impermeable.

The prior art does not teach, disclose and/or fairly suggest a sampling channel connected with the inlet port and configured to convey a subsequent portion of the blood sample to the outlet port while bypassing the chamber.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MAY A ABOUELELA whose telephone number is (571)270-7917. The examiner can normally be reached 8-5.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, JACQUELINE CHENG can be reached on 5712725596. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of published or unpublished applications may be obtained from Patent Center. Unpublished application information in Patent Center is available to registered users. To file and manage patent submissions in Patent Center, visit: https://patentcenter.uspto.gov. Visit https://www.uspto.gov/patents/apply/patent-center for more information about Patent Center and https://www.uspto.gov/patents/docx for information about filing in DOCX format. For additional questions, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/MAY A ABOUELELA/
Primary Examiner, Art Unit 3791

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT
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First Named Inventor	Bobby E. ROGERS
Art Unit	-
Examiner Name	
Attorney Docket Number	069366-0574153_KUR2C04US

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	Attorney Docket Number	069366-0574153_KUR2C04US

	22	2019534792A	JP		2019-12-05	プライメタルズ・テクノロジーズ・オーストリア・ゲーエムベーハー		☒
	23	H09504726A	JP		1997-05-13	BAXTER INT		☒
	24	9605875A1	WO		1996-02-29	BAXTER INT		☐
	25	2013181352A1	WO		2013-12-05	MAGNOLIA MEDICAL TECHNOLOGIES INC		☐
	26	2014058945	WO		2014-04-17	BULLINGTON GREGORY J		☐
	27	2017019552A1	WO		2017-02-02	KURIN INC		☐
	28	2018125929A1	WO		2018-07-05	KURIN INC		☐
	29	S5825146A	JP		1983-02-15	BECTON DICKINSON CO		☒
	30	S5867238A	JP		1983-04-21	BECTON DICKINSON CO		☒
	31	5643474	JP		2014-12-17	ヴェロシス，インク.		☒
	32	5825146B2	JP		2015-12-02	JVC KENWOOD CORP,		☒

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	18113710
	Filing Date	2023-02-24
	First Named Inventor	Bobby E. ROGERS
	Art Unit	-
	Examiner Name	
	Attorney Docket Number	069366-0574153_KUR2C04US

	33	2020000340A	JP		2020-01-09	TOSHO INC		☒
	34	2013240628	JP		2013-12-05	COVIDIEN LP		☒
	35	H02224742	JP		1990-09-06	SPACELABS INC		☒
	36	S5789869	JP		1982-06-04	BECTON DICKINSON CO		☒
	37	2005349196	JP		2005-12-22	BECTON DICKINSON CO		☒
	38	10243129	DE		2004-04-01	RITTER GMBH		☒
	39	7203008	DE		1972-05-10	IMMUNO AG FUER CHEM-MED PROD		☒
	40	10038026	DE		2001-02-22	ZIERDEN PETER		☒
	41	29913417	DE		2000-12-28	ZIERDEN PETER		☒
	42	10134913	DE		2003-02-20	HIBERNA AG		☒
	43	10134913C2	DE		2003-06-26	HIBERNA AG		☒

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	44	2541494	DE		1977-03-31	GUERRA LUIS A		☒
	45	2008101025	WO		2008-08-21	EDWARDS LIFESCIENCES CORP		☐
	46	0448795A2	EP		1991-10-02	BECTON DICKINSON CO		☐
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	48	2007033319A1	WO		2007-03-22	EDWARDS LIFESCIENCES CORP		☐

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Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T5
	1	International Search Report and Written Opinion dated Nov. 5, 2015, for PCT application No. PCT/US2015/035870. 6 pages.	
	2	International Search Report and VVritten Opinion dated 16 July 2020 for PCT application no. PCT/US2020/026276. 9 pages.	
	3	Bullington, et al., Systems and Methods for Sample Collection with Reduced Hemolysis, Exhibit H in U.S. Appl. No. 62/517,681, dated Jun. 9, 2017, 131 pages.	
	4	Communication Under Rule 71(3) EPC dated Apr. 22, 2020 for EP application No. 17840467.9. 125 pages.	

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	Attorney Docket Number	069366-0574153_KUR2C04US

	5	European Patent Application No. EP19200766.4 extended European Search Report dated Dec. 2, 2019, 11 pages.	
	6	European Patent Office, Extended European Search Report for European Patent Application 20197213.0-1132, dated Dec. 9, 2020, 6 pages.	
	7	European Patent Office; Communication pursuant to Article 94(3) EPC; dated Oct. 31, 2018; 11 pages.	
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	9	International Search Report and Written Opinion dated Jun. 19, 2020, for PCT application No. PCTUS2020/023617. 12 pages.	
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	11	International Search Report/Written Opinion for PCT/US17/68569 dated Apr. 25, 2018. 9 pages.	
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	16	De Korte, Dirk, et al. "Diversion of first blood volume results in a reduction of bacterial contamination for whole-blood collections." Vox sanguinis 83.1 (2002): 13-16.	
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EXAMINER SIGNATURE

Examiner Signature	/MAY A ABOUELELA/	Date Considered	08/31/2023

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

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	Examiner Name	
	Attorney Docket Number	069366-0574153_KUR2C04US

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

See attached certification statement.

The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Benjamin F. Hudson/	Date (YYYY-MM-DD)	2023-05-10
Name/Print	Benjamin F. Hudson	Registration Number	71,474

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

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China National Intellectual Property Administration

1110-11, A, Floor 11, Chengjian Plaza, 18 Beitaipingzhuang Road, Haidian District, Beijing 100088, PR China Beijing Pat SF Intellectual Property Agency Co Ltd	Issue Date: August 3, 2023

Application No. or patent No.: 202010300942.7 Issue serial No.: 2023080301552950

Applicant（s）: KURIN, INC.

Title of invention-creation: BLOOD OPTIMIZATION DEVICE

First Office Action

1 ☒ Upon the request of the applicant for substantive examination, the China National Intellectual Property Administration has performed the examination for the above-identified application for a patent for invention according to the provisions of Article 35.1 of the Patent Law.

☐ The China National Intellectual Property Administration itself has decided to perform the substantive examination for the above-identified application for a patent for invention according to the provisions of Article 35.2 of the Patent Law.

2 ☒ The applicant requested to designate the filing date of

March 13, 2020 in the Patent Office of US as the priority date;

March 19, 2020 in the Patent Office of US as the priority date.

3 ☐ After examination, the amendment submitted on_____is not in conformity with the provisions of Rule 51.1 of the Implementing Regulations of the Patent Law, so it has not been accepted.

4 ☐ Examination is made based on the Chinese text or translation of the international application as originally filed.

☒ Examination is made based on the following documents:

Drawings and abstract as filed on the filing date;

items 1-23 of claims and paragraphs 1-251 of description as filed on June 29, 2023.

5 ☒ This notification cited reference documents as follows:（its code will continue to be used in the future when examined.）

code	File No. or title	Publication date (or filing date of conflicting application)
1	US2018177445A1	20180628
2	US4349035A	19820914
3	US5401262A	19950328

6 The conclusion of the examination:

In regard to the Description:

☐ The subject matter of the application belongs to the objects mentioned in Article 5 of the Patent Law, for which no patent right shall be granted.

☐ The description is not in conformity with the provisions of Article 26.3 of the Patent Law.

☐ The description is not in conformity with the provisions of Article 33 of the Patent Law.

☐ The description is not in conformity with the provisions of Rule 17 of Implementing Regulations of the Patent Law.

☐

In regard to the Claims:

☐ Claims_____are not in conformity with the provisions of Article 2.2 of the Patent Law.
☐ Claims_____are not in conformity with the provisions of Article 9.1 of the Patent Law.
☒ Claims__1-4, 12, 18_____do not possess the novelty under Article 22.2 of the Patent Law.
☒ Claims__5-11, 13-17, 19-23_____do not possess the inventiveness under Article 22.3 of the Patent Law.
☐ Claims_____do not possess the practical applicability under Article 22.4 of the Patent Law
☐ Claims_____belong to the objects mentioned in Article 25 of the Patent Law, for which no patent right shall be granted.
☒ Claims__1, 12_____are not in conformity with the provisions of Article 26.4 of the Patent Law.
☐ Claims_____are not in conformity with the provisions of Article 31.1 of the Patent Law.
☒ Claim____19___is not in conformity with the provisions of Article 33 of the Patent Law.
☐ Claims_____are not in conformity with the provisions of Article 19 of the Patent Law.
☐ Claims_____are not in conformity with the provisions of Article 20 of the Patent Law.
☐ Claims_____are not in conformity with the provisions of Article 21 of the Patent Law.
☐ Claims_____are not in conformity with the provisions of Rule 22 of Implementing Regulations of the Patent Law.
☐ _____
☐ The application is not in conformity with the provisions of Article 26.5 of the Patent Law or with the provisions of Rule 26 of Implementing Regulations of the Patent Law.
☐ The application is not in conformity with the provisions of Article 20.1 of the Patent Law.
☐ The division application is not in conformity with the provisions of Rule 43.1 of Implementing Regulations of the Patent Law.

7. According to the above conclusion, the examiner deems that:
☐ The applicant shall amend the application documents as required by the text of Office Action.
☐ The applicant shall state the reason why the application can be accepted and amend the part that is indicated not to be in conformity with the provisions, otherwise the application will be rejected.
☒ No subject matter in the application is patentable, the application will be rejected if the applicant does not make a statement or the statement is not convincing.
☐ ___

8. The applicant shall pay attention to the following items:
(1) In accordance with the provisions of Article 37 of the Patent Law, the applicant shall submit the observations within __**4**___months from the date of receiving this notification. If the applicant, without any justified reason, fails to reply within the time limit, the application shall be deemed to have been withdrawn.
(2) The amendments to the application made by the applicant shall be in conformity with the provisions of Article 33 of the Patent Law. The amended text shall not go beyond the disclosure scope of the initial description and claims. The amendment should be in conformity with the provisions of Rule 51.3 of the Implementing Regulations of the Patent Law. The applicant shall make the amendment according to the request of this notification.
(3) Any observation and/or amended text shall be mailed or sent by hand to the Receiving Division of the Patent Office. Any document that is not mailed or sent by hand to the Receiving Division does not have legal effect.
(4) The applicant and/or his agent shall not go to the Patent Office to hold an interview with the examiner if no interview is arranged in advance.
(5) For an invention patent application that entered the substantive examination stage, if the applicant withdraws the application on his own initiative before the due date for responding to the first Office Action (except for the case that a response has already been filed), the applicant can request a refund of 50% of the substantive examination fee.

9. The text of the notification embraces __4__ pages, along with the enclosures herein:
☐ _____Copy(ies) of the cited references is enclosed in pages of _____.
☐ _____

Examiner: Examining Department:
Tel:

Text of the First Office Action

Application number: 202010300942.7

The present application relates to blood optimization device. The following examination opinions are now set forth.

Claim 19 does not comply with the provision under Article 33[1] of the Patent Law.

Claim 19 defines "the vent further comprises a cover that inhibits air from reentering the chamber after air has been displaced". It can be known from the disclosure contained in the original description that: "an air permeable blood barrier may be formed by one or more materials that allow air to pass through until contacted by a liquid, such material then becomes completely or partially sealed to prevent or inhibit the passage of air and/or liquid" (see paragraph [0070] of the description <*Translator's note: corresponding to paragraph [0067] of the English description provided by the former Chinese agency*>), "the air permeable blood barrier 1412 can be overlaid with a protective cover 1416. The protective cover 1416 can be sized and configured to inhibit a user from touching the air permeable blood barrier 1412 with their finger or other external implement, while still allowing air to exit the air permeable blood barrier 1412 as the air is displaced from the sequestration chamber 1408 by blood being forced into the sequestration chamber 1408 by a patient's own blood pressure. In addition the protective cover 1416 can be constructed to inhibit or prevent accidental exposure of the air permeable blood barrier to environmental fluids or splashes" (see the description, paragraph [0105] <*Translator's note:*

[1] Article 33 An applicant may amend his or its patent application documents, however, the amendment to the patent application documents for an invention or utility model may not go beyond the scope of disclosure contained in the original description and claims, and the amendment to the patent application documents for a design may not go beyond the scope of the disclosure as shown in the original drawings or photographs.

corresponding to paragraph [00102] of the English description provided by the former Chinese agency>). Accordingly, it is the air permeable blood barrier rather than the structure e.g., protective cover or cover, etc., that inhibits air from reentering the chamber after the air is displaced, and the protective cover or cover is to inhibit or prevent accidental exposure of the air permeable blood barrier to environmental fluids or splashes (see paragraphs [0105], [0115], [0136] of the description <*Translator's note: corresponding to paragraphs [00102], [00112], [00133] of the English description provided by the former Chinese agency*>). The limitation in claim 19 is not disclosed in the original application documents, nor can be directly and unambiguously determined from the original application documents. Therefore, claim 19 goes beyond the scope of disclosure contained in the original description and claims, and does not comply with the provision under Article 33 of the Patent Law.

Claims 1-4, 12, and 18 do not possess novelty prescribed under Article 22.2[2] of the Patent Law, and claims 5-11, 13-17, and 19-23 do not possess inventiveness prescribed under Article 22.3[3] of the Patent Law.

1. Claims 1 and 12 seek to protect a device. Reference 1 (US2018177445A1) discloses (see the description, paragraphs [0058]-[0170], and Figs. 1-30G): a blood sequestration device comprises an inlet port (see the description, paragraphs [0156], [0161]) and an outlet port (see the description, paragraphs [0159], [0161]), and a housing 3001 (see the description, paragraph [0161]), the housing 3001 comprising:

an inlet path 3002 (see the description, paragraph [0156], Fig. 30A)

[2] Article 22.2 Novelty means that, the invention or utility model does not form part of the prior art; nor has any entity or individual filed a patent application for the identical invention or utility model with the patent administrative department under the State Council before the filing date, and the content of the application is disclosed in patent application documents published or patent documents announced after the filing date.

[3] Article 22.3 Inventiveness means that, as compared with the prior art, the invention possesses prominent substantive features and represents a notable progress and that the utility model possesses substantive features and represents a progress.

(namely comprising an inlet port, an inlet path connected with the inlet port);

an outlet path 3004 (see the description, paragraph [0158], Fig. 30A) (namely comprising an outlet port, an outlet path connected with the outlet port);

a chamber 3008 (see the description, paragraph [0160], Fig. 30A) connected with the inlet path 3002 by a junction 3007 and being configured to receive a first portion of blood through the inlet path 3002 (see the description, paragraphs [0160], [0163]-[0164]), the junction 3007 being configured to inhibit a return to the inlet path 3002 of any of the first portion of blood received by the chamber 3008 (see the description, paragraphs [0061], [0067], [0156], [0160]-[0161]); and

a sampling channel 3006 connected between the inlet path 3002 and the outlet path 3004 (see the description, paragraphs [0159]-[0160]), the sampling channel 3006 being configured to convey subsequent amounts of blood between the inlet path 3002 and the outlet path 3004 after the first amount of blood is received by the chamber 3008 (see the description, paragraphs [0160]-[0170]).

As can be seen, Reference 1 has disclosed all the technical features of claim 1. Moreover, the technical solution disclosed by Reference 1 and the technical solution sought for protection in claim 1 belong to the same technical field, are used for solving the same technical problem, and can produce the same technical effect. Therefore, the technical solution sought for protection in claim 1 does not possess novelty.

2. Claim 20 seeks to protect a blood sample optimization system. Reference 1 (US2018177445A1) discloses (see the description, paragraphs [0058]-[0170], and Figs. 1-30G): a blood sample optimization system (see the description, paragraph [0156]) comprises a blood sampling system comprising:

the blood sequestration device 3000 includes an inlet path 3002 that can

be connected with a patient needle (namely the venipuncture apparatus) that is inserted into a patient's vascular system for access to and withdrawing of a blood sample (namely configuring the same for venipuncture of a patient to access a sample of blood of the patient);

the blood sequestration device 3000 includes a sampling channel 3006 (namely the blood sampling pathway connected with the venipuncture apparatus for conveying the sample of blood) between the inlet port 3002 and the outlet port 3004;

an outlet path 3004 (comprising a reservoir) for collecting a subsequent portion of the sample of blood; and

a device connected along the blood sampling pathway 3006 between the patient needle and the outlet path 3004 (comprising a reservoir), the device comprising:

an inlet path 3002 connected with the patient needle (see the description, paragraph [0156], Fig. 30A) (namely comprising an inlet port, an inlet path connected with the inlet port);

an outlet path 3004 (see the description, paragraph [0158], Fig. 30A) (namely comprising an outlet port, an outlet path connected with the outlet port);

a chamber 3008 (see the description, paragraph [0160], Fig. 30A) connected with the inlet path 3002 by a junction 3007 and being configured to receive a first portion of blood through the inlet path 3002 (see the description, paragraphs [0160], [0163]-[0164]), the junction 3007 being configured to inhibit a return to the inlet path 3002 of any of the first portion of blood received by the chamber 3008 (see the description, paragraphs [0061], [0067], [0156], [0160]-[0161]); and

a sampling channel 3006 connected between the inlet path 3002 and the outlet path 3004 (see the description, paragraphs [0159]-[0160]), the sampling channel 3006 being configured to convey subsequent amounts of blood between the inlet path 3002 and the outlet path 3004 after the first

amount of blood is received by the chamber 3008 (see the description, paragraphs [0160]-[0170]).

The differences of the technical solution sought for protection in claim 20 as compare with the contents disclosed by Reference 1 lie in: a reservoir configured for receiving an evacuated blood collection tube to collect a subsequent portion of the sample of blood; an outlet path connected with the sample needle. Based on the differences, it is determined that the technical problem to be practically solved by the present application is how to collect a sample. However, Reference 1 discloses in another embodiment: a reservoir configured for receiving an evacuated blood collection tube to collect a subsequent portion of the sample of blood; an outlet path connected with the sample needle 5 (see the description, paragraph [0065], Figs. 1, 7). The above differences are disclosed by another embodiment of Reference 1.

Thus, it is obvious for a person skilled in the art to obtain the technical solution sought for protection in claim 20 on the basis of Reference 1 in combination with routine technical means in the art. Therefore, the technical solution sought for protection in claim 20 does not possess prominent substantive features or represent notable progress, and does not possess inventiveness prescribed under Article 22.3 of the Patent Law.

3. Claims 2-4 refer to claim 1, claim 10 refers to claim 1, and claim 11 refers to claim 10. It is disclosed: the junction is angled from the inlet path toward the chamber (see the description, paragraph [0160], Figs. 17A, 30A); the junction has a cross-sectional area that is smaller than a cross-sectional area of the inlet path (see the description, paragraph [0160], Figs. 17A, 30A); the junction has a cross-sectional area that is larger than a cross-sectional area of the inlet path (see the description, paragraphs [0160], [0163], Figs. 17A, 30A); the chamber 3008 has a vent 3010 that allows air to be displaced by the first

portion of blood (see the description, paragraphs [0161], [0163]-[0165], Figs. 30A-D); the vent 3010 includes two or more vent apertures 3012 (see the description, paragraphs [0160]-[0161]). Therefore, where the claims referred to do not possess novelty, claims 2-4 and 10-11 do not possess novelty prescribed under Article 22.2 of the Patent Law, either.

4. Claim 5 refers to claim 1, claim 13 refers to claim 12, and claim 21 refers to claim 20. Reference 2 (US4349035A) discloses (see the description, line 20 in column 4 to line 7 in column 8, and Figs. 1-10): a blood collection assembly comprises a cannular 19 (comprising an inlet path) (see the description, lines 23-28 in column 4, Fig. 5), a valve 22 connected to a receptacle 21 (comprising a chamber) (see the description, lines 23-28 in column 4, Figs. 4-5); the purpose of valve 22 (namely one or more passive structures) is to operably open to allow blood to only flow into receptacle 21, but to operably close to prevent blood from backflowing out of the receptacle 21 toward the patient (namely passive structures configured to inhibit the return to the inlet path of any of the first portion of blood received by the chamber); valve 22 is an elastomeric material, such as rubber, which is substantially tubular in cross-section and which projects from stopper 25 a short distance into receptacle 21; at the far or distal end of valve 22, it tapers to a point; at the point of the tubular valve is a slit 28 which communicates with space 26; this slit serves as an operable passageway to open up to allow blood to flow into receptacle 21; when slit 28 is closed, it forms a liquid tight seal so as to prevent blood from flowing therethrough in that closed position; other configurations in this type valve may be employed, for example, a dome-shaped valve with an operable hole therein. Accordingly, partial of the additional technical features of claim 5 is disclosed by Reference 2. Moreover, the disclosed feature performs the same function in Reference 2 as in the present application, namely inhibiting backflow of the blood. Reference 2 provides a technical inspiration, based on which the person skilled in the art would easily envisage disposing

the junction of Reference 1 to have said structure, thereby inhibiting backflow of the blood. Therefore, where the claims referred to do not possess novelty, claims 5, 13, and 21 do not possess inventiveness prescribed under Article 22.3 of the Patent Law, either.

5. Claim 6 refers to claim 5, and claim 14 refers to claim 13. The additional features of claims 6 and 14 are disclosed by Reference 1: the valve 22 exhibits a conical shape (namely the feature “one or more passive structures include a conical baffle having a tapered end directed toward the chamber”) (see the description, lines 13-17 in column 5, and Figs. 4-5). Therefore, where the claims referred to do not possess inventiveness, claims 6 and 14 do not possess inventiveness prescribed under Article 22.3 of the Patent Law, either.

6. Claim 7 refers to claim 5, and claim 15 refers to claim 13. Reference 3 (US5401262A) discloses (see the description, line 9 in column 8 to line 53 in column 26, Figs. 1-15): a blood drainage device; the plurality of curved baffles 112a-112c (namely two or more staggered baffles) in the upper portion of the manometer chamber return spray and condensate to the water column, resulting in further effectiveness of fluid retention in the column. The disclosed feature performs the same function in Reference 3 as in the present application, namely retaining fluid. Reference 3 provides with a technical inspiration. In view of this, the remaining additional features belong to routine technical means easily envisaged by the person skilled in the art. Therefore, where the claims referred to do not possess inventiveness, claims 7 and 15 do not possess inventiveness prescribed under Article 22.3 of the Patent Law, either.

7. Claims 8 and 9 refer to claim 5, claims 16 and 17 refer to claim 13, and claim 22 refers to claim 21. The additional features of claims 8-9, 16-17, and 22 belong to routine technical means easily envisaged by the person skilled in the

art on the basis of valve 22 disclosed by Reference 2. Therefore, where the claims referred to do not possess inventiveness, claims 8-9, 16-17, and 22 do not possess inventiveness prescribed under Article 22.3 of the Patent Law, either.

8. Claim 18 refers to claim 12. The additional feature of claim 18 is disclosed by Reference 1 (*ibid*): the chamber 3008 has a vent 3010 that allows air to be displace by the first portion of blood, and the vent 3010 is further configured to close upon the chamber 3008 being filled with the first portion of blood. Therefore, where the claim referred to does not possess novelty, claim 18 does not possess novelty prescribed under Article 22.2 of the Patent Law, either.

9. Claim 23 refers to claim 20. The additional feature of claim 23 is disclosed by Reference 1 (*ibid*): the chamber 3008 has a vent 3010 that allows air to be displaced by the first portion of blood (see the description, paragraphs [0161], [0163]-[0165], Figs. 30A-D). Therefore, where the claim referred to does not possess inventiveness, claim 23 does not possess inventiveness prescribed under Article 22.3 of the Patent Law, either.

Claims 1 and 12 do not comply with the provision under Article 26.4[4] of the Patent Law.

The subject matter of claims 1 and 12 cannot clearly reflect the technical field to which the technical solutions sought for protection relate, with the result that the protection scope of claims 1 and 12 is unclear. Therefore, claims 1 and 12 do not comply with the provision under Article 26.4 of the Patent Law.

[4] Article 26.4 The claims shall be supported by the description and shall define the scope of the patent protection sought for in a clear and concise manner.

For the above reasons, no patent right can be granted for the present application. Moreover, the description of the present application does not disclose any other patentable substantive content. Therefore, the present application does not possess a prospect of grant even if the amendments would be made to the application documents. If the Applicant cannot present convincing causes within the time limit specified in the present office action, the present application will be rejected.

Moreover, pursuant to *Announcement on Suspending the Collection and Adjustment of Some Patent Charges* (No. 272) issued by China National Intellectual Property Administration, where an invention patent application that entered into the substantive examination phase is withdrawn on the Applicant's own initiative prior to expiration of the time limit for responding to the First Office Action (except the case where a response has been filed) from 1 August 2018, it is allowed to request a refund 50% of the substantive examination fee.

Should you have any questions on the examination opinions, you may feed back your opinions via the following ways: phone of the Examiner: 010-53962499, or phone on-duty: 010-53962356, or email address: sxbjzx_yijian@cnipa.gov.cn. Please note that the contents fed back through the email address should not have legal force and formal observation and/or amendment texts should be submitted to the Receiving Department of the Patent Office within the time limit specified.

Examiner: Peijie JIANG

Code: 30082386

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发文日：

2023 年 08 月 03 日

申请号：202010300942.7 **发文序号：2023080301552950**

申请人：酷睿有限公司

发明创造名称：具有被动流体控制接合部的血液污染物分离装置

第 一 次 审 查 意 见 通 知 书

1.☒应申请人提出的实质审查请求，根据专利法第 35 条第 1 款的规定，国家知识产权局对上述发明专利申请进行实质审查。

☐根据专利法第 35 条第 2 款的规定，国家知识产权局决定自行对上述发明专利申请进行审查。

2.☒申请人要求以其在：

US 专利局的申请日 2020 年 03 月 13 日为优先权日， US 专利局的申请日 2020 年 03 月 19 日为优先权日。

☒申请人已经提交了经原受理机构证明的第一次提出的在先申请文件的副本。

☐申请人尚未提交经原受理机构证明的第一次提出的在先申请文件的副本，根据专利法第 30 条的规定视为未要求优先权要求。

3.☐经审查，申请人于_____提交的修改文件，不符合专利法实施细则第 51 条第 1 款的规定，不予接受。

4.审查针对的申请文件：

☐原始申请文件。☐分案申请递交日提交的文件。☒下列申请文件：

申请日提交的说明书摘要、说明书附图； 2023 年 6 月 29 日提交的权利要求第 1-23 项、说明书第 1-251 段。

5.☐本通知书是在未进行检索的情况下作出的。

☒本通知书是在进行了检索的情况下作出的。

☒本通知书引用下列对比文件(其编号在今后的审查过程中继续沿用)：

编号	文 件 号 或 名 称	公开日期（或抵触申请的申请日）
1	US2018177445A1	2018-06-28
2	US4349035A	1982-09-14
3	US5401262A	1995-03-28

6.审查的结论性意见：

关于说明书：

☐申请的内容属于专利法第 5 条规定的不授予专利权的范围。
☐说明书不符合专利法第 26 条第 3 款的规定。
☐说明书不符合专利法第 33 条的规定。
☐说明书的撰写不符合专利法实施细则第 17 条的规定。
☐_____

关于权利要求书：

☐权利要求_____不符合专利法第 2 条第 2 款的规定。
☐权利要求_____不符合专利法第 9 条第 1 款的规定。
☒权利要求 1-4、12、18 不具备专利法第 22 条第 2 款规定的新颖性。
☒权利要求 5-11、13-17、19-23 不具备专利法第 22 条第 3 款规定的创造性。
☐权利要求_____不具备专利法第 22 条第 4 款规定的实用性。
☐权利要求_____属于专利法第 25 条规定的不授予专利权的范围。
☒权利要求 1、12 不符合专利法第 26 条第 4 款的规定。
☐权利要求_____不符合专利法第 31 条第 1 款的规定。
☒权利要求 19 不符合专利法第 33 条的规定。
☐权利要求_____不符合专利法实施细则第 19 条的规定。
☐权利要求_____不符合专利法实施细则第 20 条的规定。
☐权利要求_____不符合专利法实施细则第 21 条的规定。
☐权利要求_____不符合专利法实施细则第 22 条的规定。
☐_____

☐申请不符合专利法第 26 条第 5 款或者实施细则第 26 条的规定。
☐申请不符合专利法第 19 条第 1 款的规定。
☐分案申请不符合专利法实施细则第 43 条第 1 款的规定。

上述结论性意见的具体分析见本通知书的正文部分。

7.基于上述结论性意见，审查员认为：

☐申请人应当按照通知书正文部分提出的要求，对申请文件进行修改。
☐申请人应当在意见陈述书中论述其专利申请可以被授予专利权的理由，并对通知书正文部分中指出的不符合规定之处进行修改，否则将不能授予专利权。
☒专利申请中没有可以被授予专利权的实质性内容，如果申请人没有陈述理由或者陈述理由不充分，其申请将被驳回。
☐_____

8.申请人应注意下列事项：

(1) 根据专利法第 37 条的规定，申请人应在收到本通知书之日起的 4 个月内陈述意见，如果申请人无正当理由逾期不答复，其申请被视为撤回。

(2) 申请人对其申请的修改应当符合专利法第 33 条的规定，不得超出原说明书和权利要求书记载的范围，同时申请人对专利申请文件进行的修改应当符合专利法实施细则第 51 条第 3 款的规定，按照本通知书的要求进行修改。

(3) 申请人的意见陈述书和/或修改文本应邮寄或递交国家知识产权局专利局受理处，凡未邮寄或递交给受理处的文件不具备法律效力。

(4) 未经预约，申请人和/或代理师不得前来国家知识产权局专利局与审查员举行会晤。

(5) 对进入实质审查阶段的发明专利申请，在第一次审查意见通知书答复期限届满前（已提交答复意见的除外），主动申请撤回的，可以请求退还 50%的专利申请实质审查费。

9.本通知书正文部分共有 4 页，并附有下述附件：

☐引用的对比文件的复印件共_____份_____页。
☐_____



审查员：姜佩杰　　联系电话：010-53962499　　审查部门：专利审查协作北京中心

第 一 次 审 查 意 见 通 知 书

申请号:202010300942 7

本申请涉及血液优化装置，现提出如下的审查意见：

权利要求 19 不符合专利法第 33 条的规定

权利要求 19 中限定“通气口还包括盖，在空气被置换后，所述盖抑制空气重新进入所述腔室”，而通过原说明书中记载可知，“透气性血液屏障可以由一种或多种材料形成，该材料允许空气通过直到与液体接触，然后这种材料被完全或部分密封以防止或抑制空气和/或液体的通过”（参见说明书第 0070 段）；“透气性血液屏障 1412 可以覆盖有保护罩 1416。保护罩 1416 的尺寸和构造可以设定成禁止使用者通过其手指或其他外部器具触摸透气性血液屏障 1412，同时当由于血液借助患者自身的血压而被迫进入隔离室 1408 中而使空气从隔离室 1408 中排出时，仍允许空气离开透气性血液屏障 1412。另外，保护罩 1416 可被构造成抑制或防止透气性血液屏障对环境流体或飞溅物的意外暴露。”（参见说明书第 0105 段）；由此可知，空气被置换后，抑制空气重新进入腔室的是透气性血液屏障，而非保护罩或盖等结构，保护罩或盖是用于抑制或防止透气性血液屏障对环境流体或飞溅物的意外暴露（可参见说明书第 0105、0115、0136 段）。权利要求 9 的上述限定并未记载在原申请文件中，且不能由原申请文件直接的、毫无疑义确定得到，权利要求 9 超出了原说明书和权利要求书记载范围，不符合专利法第 33 条的规定。

权利要求 1-4、12、18 不符合专利法第 22 条第 2 款规定的新颖性；权利要求 5-11、13-17、19-23 不符合专利法第 22 条第 3 款规定的创造性

1.权利要求 1、12 请求保护一种装置，对比文件 1（US2018177445A1）公开了（说明书第 0058-0170 段，附图 1-30G）：一种血液隔离装置，包括具有入口端口（说明书第 0156、0161 段）和出口端口（说明书第 0159、0161 段）的壳体 3001（说明书第 0161 段），该壳体 3001 包含：

入口路径 3002（说明书第 0156 段，图 30A）（即包含入口端口，与入口端口连接的入口路径）；

出口路径 3004（说明书第 0158 段，图 30A）（即包含出口端口，与出口端口连接的出口路径）；

腔室 3008（说明书第 0160 段，图 30A），通过接合部 3007 与所述入口路径 3002 连接，并被构造成通过所述入口路径 3002 接收第一部分血液（说明书第 0160、0163-0164 段），所述接合部 3007 被构造为抑制由腔室 3008 接收的任何所述第一部分血液返回所述入口路径 3002（说明书第 0061、0067、0156、0160-0161 段）；以及

在入口路径 3002 和出口路径 3004 之间连接的采样通道 3006（说明书第 0159-0160 段），所述采样通道 3006 被构造为在第一量的血液被腔室 3008 接收之后在入口路径 3002 和出口路径 3004 之间输送后续量的血液（说明书第 0160-0170 段）。

由此可见，对比文件 1 已经公开了上述权利要求的全部技术特征，且对比文件 1 所公开的技术方案与该

权利要求所要求保护的技术方案属于同一技术领域，用于解决相同的技术问题，并能产生相同的技术效果，因此上述权利要求所要求保护的技术方案不具备新颖性。

2. 权利要求 20 请求保护一种血液样本优化系统，对比文件 1（US2018177445A1）公开了（说明书第 0058-0170 段，附图 1-30G）：一种血液样本优化系统（说明书第 0156 段），包括血液采样系统，包括：血液隔离装置 3000 包括入口路径 3002，该入口路径 3002 可以与患者针（即静脉穿刺设备）连接，该患者针插入患者的血管系统中以用于进入和抽出血液样品（即其构造成对患者进行静脉穿刺以获取患者的血液样本）。血液隔离装置 3000 包括从入口路径 3002 到出口路径 3004 的采样通道 3006（即与所述静脉穿刺设备连接的血液采样通路，用于输送所述血液样本）；出口路径 3004（包含储存器），以收集血液样本的后续部分；以及沿患者针和出口路径 3004（包含储存器）之间的血液采样通路 3006 连接的装置，该装置包括：

与患者针连接的入口路径 3002（说明书第 0156 段，图 30A）（即包含入口端口，与入口端口连接的入口路径）；

出口路径 3004（说明书第 0158 段，图 30A）（即包含出口端口，与出口端口连接的出口路径）；

腔室 3008（说明书第 0160 段，图 30A），通过接合部 3007 与所述入口路径 3002 连接，并被构造成通过所述入口路径 3002 接收第一部分血液（说明书第 0160、0163-0164 段），所述接合部 3007 被构造为抑制由腔室 3008 接收的任何所述第一部分血液返回所述入口路径 3002（说明书第 0061、0067、0156、0160-0161 段）；以及

在入口路径 3002 和出口路径 3004 之间连接的采样通道 3006（说明书第 0159-0160 段），所述采样通道 3006 被构造为在第一量的血液被腔室 3008 接收之后在入口路径 3002 和出口路径 3004 之间输送后续量的血液（说明书第 0160-0170 段）。

权利要求 20 所要求保护的技术方案与对比文件 1 公开的内容相比，其区别在于：储存器，其构造成用于接收抽空的采血管，以收集血液样本的后续部分；与样本针连接的出口路径，基于上述区别，本申请实际要解决的技术问题是：如何采集样本。但是对比文件 1 的另一实施例公开：储存器，其构造成用于接收抽空的采血管，以收集血液样本的后续部分；与样本针 5 连接的出口路径（说明书第 0065 段，图 1、7），上述区别被对比文件 1 的另一实施例公开。

由此可知，在对比文件 1 的基础上结合常规技术手段以获得该权利要求请求保护的技术方案对本领域技术人员来说是显而易见的，因此，该权利要求的技术方案不具备突出的实质性特点和显著的进步，不具备专利法第 22 条第 3 款规定的创造性。

3.权利要求 2-4 引用权利要求 1、权利要求 10 引用权利要求 1、权利要求 11 引用权利要求 10，接合部从入口路径朝向腔室成角度（说明书第 0160 段，图 17A、30A）；接合部的截面积小于入口路径的截面积（说明书第 0160 段，图 17A、30A）；接合部的截面积大于入口路径的截面积（说明书第 0160、0163 段，图

17A、30A）；腔室 3008 具有通气口 3010，所述通气口 3010 允许空气被所述第一部分血液置换（说明书第 0161、0163-0165 段，图 30A-D）；通气口 3010 包括两个或更多个通气孔 3012(说明书第 0160-0161 段）；因此，在其引用的权利要求不具备新颖性时，上述权利要求也不具备专利法第 22 条第 2 款规定的新颖性。

4.权利要求 5 引用权利要求 1，权利要求 13 引用权利要求 12，权利要求 21 引用权利要求 20，对比文件 2（US4349035A）公开（说明书第 4 栏第 20 行至第 8 栏第 7 行，图 1-10）：一种血液采集组件，包括管 19（包含入口路径）（参见说明书第 4 栏第 23-28 行，图 5），连接到容器 21（具有腔室）的阀 22（参见说明书第 4 栏第 23-28 行，图 4-5），阀 22（即一个或多个被动结构）的目的是可操作地打开以允许血液仅流入容器 21，但是可操作地关闭以防止血液从容器 21 向患者回流（即被动结构构造成抑制由腔室接收的任何第一部分血液返回到入口路径）。阀 22 是弹性体材料，例如橡胶，其横截面基本上是管状的并且从止动件 25 突出短距离到容器 21 中。在阀 22 的远端或远端处，它逐渐变细到一点。在管状阀的点处是与空间 26 连通的狭缝 28。该狭缝用作可操作通道以打开以允许血液流入容器 21；当狭缝 28 闭合时，其形成液密密封，以便防止血液在该闭合位置流过其中。在这种类型的阀中可以采用其他构造，例如，其中具有可操作孔的圆顶形阀。故部分附加特征 5 被对比文件 2 公开，且其在对比文件 2 中的所起的作用与其在本申请中所起的作用相同，都是用于抑制血液回流。对比文件 2 给出技术启示，在此基础上，本领域技术人员容易想到将对比文件 1 的接合部设置成具有上述结构，进而抑制血液回流。因此，在其引用的权利要求不具备新颖性时，上述权利要求也不具备专利法第 22 条第 3 款规定的创造性。

5.权利要求 6 引用权利要求 5，权利要求 14 引用权利要求 13，其附加特征被对比文件 1 公开：阀 22 程锥形（即一个或多个被动结构包括锥形挡板，所述锥形挡板具有指向所述腔室的锥形端）（参见说明书第 5 栏第 13-17 行，图 4-5），因此，在其引用的权利要求不具备创造性时，上述权利要求也不具备专利法第 22 条第 3 款规定的创造性。

6.权利要求 7 引用权利要求 5，权利要求 15 引用权利要求 13，对比文件 3（US5401262A）公开（说明书第 8 栏第 9 行至第 26 栏第 53 行，图 1-15）：一种血液引流装置，压力计腔室的上部中的多个弯曲挡板 112a-112c（即两个或更多个交错的挡板）将喷雾和冷凝物返回到水柱，从而进一步有效地保持柱中的流体。其在对比文件 3 中的作用与其在本申请中作用相同，都是用于流体潴留，对比文件 3 给出了技术启示，在此基础上，其余附加特征属于本领域技术人员容易想到的常规技术手段，因此，在其引用的权利要求不具备创造性时，上述权利要求也不具备专利法第 22 条第 3 款规定的创造性。

7.权利要求 8、9 引用权利要求 5，权利要求 16、17 引用权利要求 13，权利要求 22 引用权利要求 21，其附加特征属于本领域技术人员在对比文件 2 公开的阀 22 的基础上容易想到的常规技术手段，因此，在其引用的权利要求不具备创造性时，上述权利要求也不具备专利法第 22 条第 3 款规定的创造性。

8.权利要求 18 引用权利要求 12，其附加特征被对比文件 1 公开（参见同上）：腔室 3008 具有通气口

3010，所述通气口 3019 允许空气被所述第一部分血液置换，所述通气口 3010 进一步构造成在所述腔室 3008 中充满所述第一部分血液时关闭。因此，在其引用的权利要求不具备新颖性时，上述权利要求也不具备专利法第 22 条第 2 款规定的新颖性。

9.权利要求 23 引用权利要求 20，其附加特征被对本比文件 1 公开（参见同上）：腔室 3008 具有通气口 3010，所述通气口 3010 允许空气被所述第一部分血液置换（说明书第 0161、0163-0165 段，图 30A-D）；因此，在其引用的权利要求不具备创造性时，上述权利要求也不具备专利法第 22 条第 3 款规定的创造性。

权利要求 1,12 不符合专利法第 26 条第 4 款的规定

权利要求 1、12 主题名称未能清楚反映出请求保护的技术方案所涉及的技术领域，导致该权利要求的保护范围不清楚，不符合专利法第 26 条第 4 款的规定。

基于上述理由，本申请不能被授予专利权，而且本申请的说明书中也没有记载其它任何可获得专利权的实质性内容，因而即使对申请文件进行修改，本申请也不具备被授予专利权的前景。如果申请人不能在本通知书规定的答复期限内提出具有说服力的理由，本申请将被驳回。

另根据国家知识产权局《关于停征和调整部分专利收费的公告》（第 272 号）规定，对进入实质审查的发明专利申请，在第一次审查意见通知书答复期限前（已提交答复意见的除外）主动申请撤回的，可以请求退还 50%的专利申请实质审查费。

如您对审查意见存在疑问，可拨打审查员电话 010-53962499，或值班电话 010-53962356 ，也可通过邮箱 sxbjzx_yijian@cnipa.gov.cn 反馈意见。请注意：邮箱反馈的内容不具备法律效力，请将正式的意见陈述书和/或修改文本在规定期限内提交给专利局受理部门。

审查员姓名:姜佩杰
审查员代码:30082386

国 家 知 识 产 权 局

检 索 报 告

申请号：2020103009427	申请日：2020 年 04 月 16 日	首次检索
申请人：酷睿有限公司	最早的优先权日：2020 年 03 月 13 日	
权利要求项数：23	说明书段数：251+117	

审查员确定的 IPC 分类号：A61B 5/15,A61B 5/153

检索记录信息：US2004073171A1: 美局检索报告

US2018177445A1: 欧局检索报告

US2018271425A1: 欧局检索报告

US2018353117A1: 欧局检索报告

US4349035A: 欧局检索报告

US5401262A: 欧局检索报告

US2018177445A1: 3 VCN, /PN US2018177445 or us4349035 OR US5401246

相 关 专 利 文 献

类型	国别以及代码[11] 给出的文献号	代码[43]或[45] 给出的日期	IPC 分类号	相关的段落 和/或图号	涉及的权 利要求
X	US2018177445A1	2018-06-28	A61B5/15	说明书第 0058-0170 段，附图 1-30G	1-4、6、8-12、14、16-18、20、23
Y	US2018177445A1	2018-06-28	A61B5/15	说明书第 0058-0170 段，附图 1-30G	5、7、13、15、21、22
Y	US4349035A	1982-09-14	A61M1/00	说明书第 4 栏第 20 行至第 8 栏第 7 行，图 1-10	5、13、21、22
Y	US5401262A	1995-03-28	A61M1/00	说明书第 8 栏第 9 行至第 26 栏第 53 行，图 1-15	7、15

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A	US2004073171A1	2004-04-15	A61M5/178	全文	1-18、20-23
A	US2018271425A1	2018-09-27	A61B5/15	全文	1-18、20-23
A	US2018353117A1	2018-12-13	A61B5/15	全文	1-18、20-23

相 关 非 专 利 文 献					
类型	书名（包括版本号和卷号）	出版日期	作者姓名和出版者名称	相关页数	涉及的权利要求
类型	期刊或文摘名称 （包括卷号和期号）	发行日期	作者姓名和文章标题	相关页数	涉及的权利要求
类型	网址	网络发布日 或公开日	作者姓名和网页标题	相关部分	涉及的权利要求

表格填写说明事项：

1. 审查员实际检索领域的 IPC 分类号应当填写到大组和/或小组所在的分类位置。
2. 期刊或其它定期出版物的名称可以使用符合一般公认的国际惯例的缩写名称。
3. 相关文件的类型说明：

   X：单独影响权利要求的新颖性或创造性的文件；

   Y：与本检索报告中其他 Y 类文件组合后影响权利要求的创造性的文件；

   A：背景技术文件，即反映权利要求的部分技术特征或者有关的现有技术的文件；

   R：任何单位或个人在申请日向专利局提交的、属于同样的发明创造的专利或专利申请文件。

   P：中间文件，其公开日在申请的申请日与所要求的优先权日之间的文件，或者会导致需要核实该申请优先权的文件；

E：单独影响权利要求新颖性的抵触申请文件；

T：申请日或优先权日当天或之后公布的，可以对所要求保护发明的理论或原理提供清楚解释的文件，或者可显示出所要求保护发明的推理或事实不成立的文件；

L：除 X、Y、A、R、P、E 和 T 类文件之外的文件。

审 查 员：姜佩杰　　审查部门：专利审查协作北京中心
2023 年 08 月 01 日

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/893,079	08/22/2022	Bobby E. ROGERS	069366-0572192_KUR3C02US	6240

27500 7590 09/29/2023

PILLSBURY WINTHROP SHAW PITTMAN LLP (CV)
ATTENTION: DOCKETING DEPARTMENT
P.O BOX 10500
McLean, VA 22102

EXAMINER	
NGUYEN, HUONG Q	

ART UNIT	PAPER NUMBER
3791	

NOTIFICATION DATE	DELIVERY MODE
09/29/2023	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Docket_IP@pillsburylaw.com

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 17/893,079	**Applicant(s)** ROGERS et al.	
	Examiner Huong Q NGUYEN	**Art Unit** 3791	**AIA (FITF) Status** Yes

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 19 September 2023 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

NO NOTICE OF APPEAL FILED

1. ☑ The reply was filed after a final rejection. No Notice of Appeal has been filed. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114 if this is a utility or plant application. Note that RCEs are not permitted in design applications. The reply must be filed within one of the following time periods:
   a) ☐ The period for reply expires ____ months from the mailing date of the final rejection.
   b) ☑ The period for reply expires on: (1) the mailing date of this Advisory Action; or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
   c) ☐ A prior Advisory Action was mailed more than 3 months after the mailing date of the final rejection in response to a first after-final reply filed within 2 months of the mailing date of the final rejection.The current period for reply expires ____ months from the mailing date of *the prior Advisory Action* or SIX MONTHS from the mailing date of the final rejection, whichever is earlier.
   Examiner Note: If box 1 is checked, check either box (a), (b) or (c). ONLY CHECK BOX (b) WHEN THIS ADVISORY ACTION IS THE FIRST RESPONSE TO APPLICANTS FIRST AFTER-FINAL REPLY WHICH WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. ONLY CHECK BOX (c) IN THE LIMITED SITUATION SET FORTH UNDER BOX (c). See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) or (c) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendments filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   b) ☐ They raise the issue of new matter (see NOTE below);
   c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.
   NOTE: _____ (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☐ For purposes of appeal, the proposed amendment(s):(a)☐ will not be entered, or (b)☐ will be entered, and an explanation of how the new or amended claims would be rejected is provided below or appended.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____
9. ☐ The affidavit or other evidence filed after final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
10. ☐ The affidavit or other evidence filed after the date of filing the Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
11. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

12. ☐ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____.
13. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____
14. ☑ Other: See Continuation Sheet.

STATUS OF CLAIMS

15. The status of the claim(s) is (or will be) as follows:
    Claim(s) allowed:_____.
    Claim(s) objected to:_____.
    Claim(s) rejected:1-4,6-7 and 32-41.
    Claim(s) withdrawn from consideration:_____.

/DEVIN B HENSON/
Primary Examiner, Art Unit 3791

Continuation of REQUEST FOR RECONSIDERATION/OTHER 14. Other: Applicant contends that Cinqualbre et al does not disclose a housing “that houses and defines the inlet port, the outlet port, the chamber, and the sampling channel” because the test tubes are removable from the body of the device, as well as being external to the device. It is submitted that applicant is reading limitations into the claims. The term “houses” and “defines” is not limited to structural “enclosure.” The claims do not require that the chamber resides “completely within the housing.”
https://www.merriam-webster.com/dictionary/housing defines the term as simply “something that covers or protects, such as a support, e.g. frame, for mechanical parts.” It is submitted that this reading of the term “ houses” is a broad but reasonable interpretation to one of ordinary skill in the art. The term “defines” is even broader than “houses” and requires/implies even less structure. Therefore, it is submitted that because housing 1 structurally provides the recesses 4 in which test tubes 5 are disposed, the housing absolutely “houses” and “defines” the chamber (defined as test tube), in addition to the inlet, outlet, and sampling channel, as broadly as has been claimed. Though applicant contends that Cinqualbre et al is not a “blood separation device,” said term does not imply any particular structure or function that the prior art cannot support, as broadly as has been claimed. Therefore, the rejection is maintained.
In regard to the drawing objections and 112 rejections, it is submitted that the junction needs to be shown with element numbers in Figure 24, which provides for the other structures of the invention as claimed. Providing said drawing would obviate the 112 rejection.

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/893,079	08/22/2022	Bobby E. ROGERS	069366-0572192_KUR3C02US	6240

27500 7590 07/19/2023

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EXAMINER	
NGUYEN, HUONG Q	

ART UNIT	PAPER NUMBER
3791	

NOTIFICATION DATE	DELIVERY MODE
07/19/2023	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Docket_IP@pillsburylaw.com

Office Action Summary	Application No. 17/893,079	Applicant(s) ROGERS et al.	
	Examiner Huong Q NGUYEN	Art Unit 3791	AIA (FITF) Status Yes

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☑ Responsive to communication(s) filed on 05/22/2023.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☑ This action is **FINAL.** 2b) ☐ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5) ☑ Claim(s) 1-4,6-7 and 32-41 is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6) ☐ Claim(s) _____ is/are allowed.

7) ☑ Claim(s) 1-4,6-7 and 32-41 is/are rejected.

8) ☐ Claim(s) _____ is/are objected to.

9) ☐ Claim(s) _____ are subject to restriction and/or election requirement

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to **PPHfeedback@uspto.gov.**

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☑ The drawing(s) filed on 8/22/02022 is/are: a)☐ accepted or b)☑ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a)☐ All b)☐ Some** c)☐ None of the:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☑ Notice of References Cited (PTO-892)

2) ☑ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date _____.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____.

4) ☐ Other: _____.

DETAILED ACTION

This office action is responsive to the amendment filed 5/22/2023. Claims 1-4, 6-7, and 32-41 remain pending and under prosecution.

Notice of Pre-AIA or AIA Status

The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "junction" in **Claims 3-4 and 40-41** must be shown *with element numbers* or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the

filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Interpretation

The following is a quotation of 35 U.S.C. 112(f):

> (f) Element in Claim for a Combination. – An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

The following is a quotation of pre-AIA 35 U.S.C. 112, sixth paragraph:

> An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

The claims in this application are given their broadest reasonable interpretation using the plain meaning of the claim language in light of the specification as it would be understood by one of ordinary skill in the art. The broadest reasonable interpretation of a claim element (also commonly referred to as a claim limitation) is limited by the description in the specification when 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, is invoked.

As explained in MPEP § 2181, subsection I, claim limitations that meet the following three-prong test will be interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph:

(A) the claim limitation uses the term "means" or "step" or a term used as a substitute for "means" that is a generic placeholder (also called a nonce term or a non-structural term having no specific structural meaning) for performing the claimed function;

(B) the term "means" or "step" or the generic placeholder is modified by functional language, typically, but not always linked by the transition word "for" (e.g., "means for") or another linking word or phrase, such as "configured to" or "so that"; and

(C) the term "means" or "step" or the generic placeholder is not modified by sufficient structure, material, or acts for performing the claimed function.

Use of the word "means" (or "step") in a claim with functional language creates a rebuttable presumption that the claim limitation is to be treated in accordance with 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph. The presumption that the claim limitation is interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, is rebutted when the claim limitation recites sufficient structure, material, or acts to entirely perform the recited function.

Absence of the word "means" (or "step") in a claim creates a rebuttable presumption that the claim limitation is not to be treated in accordance with 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph. The presumption that the claim limitation is not interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, is rebutted when the claim limitation recites function without reciting sufficient structure, material or acts to entirely perform the recited function.

Claim limitations in this application that use the word "means" (or "step") are being interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, except as

otherwise indicated in an Office action. Conversely, claim limitations in this application that do not use the word "means" (or "step") are not being interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, except as otherwise indicated in an Office action.

No elements are interpreted under 112(f).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112(a):

> (a) IN GENERAL.—The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention.

The following is a quotation of the first paragraph of pre-AIA 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3-4 and 40-41 are rejected under 35 U.S.C. 112(a) or 35 U.S.C. 112 (pre-AIA), first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor or a joint inventor, or for applications subject to pre-AIA 35 U.S.C. 112, the inventor(s), at the time the application was filed, had possession of the claimed invention.

The above claims recite a junction connecting the inlet port, sampling channel, and the chamber. However, as the instant invention appears to be drawn to the embodiment in Figure 24 and said junction has not been identified in Figure 24 per the drawing objection above, it is unclear that applicant has proper support for the embodiment of Figure 24 with the moving part having a first and second position along with said junction as claimed. If support exists for said junction, applicant is requested to point out portions of the disclosure showing said support.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries for establishing a background for determining obviousness under 35 U.S.C. 103 are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.

3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims the examiner presumes that the subject matter of the various claims was commonly owned as of the effective filing date of the claimed invention(s) absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and effective filing dates of each claim that was not commonly owned as of the effective filing date of the later invention in order for the examiner to consider the applicability of 35 U.S.C. 102(b)(2)(C) for any potential 35 U.S.C. 102(a)(2) prior art against the later invention.

Claim(s) 1-4, 6-7, 32, 34-38, and 40-41 is/are rejected under 35 U.S.C. 103 as being unpatentable over Cinqualbre et al (US Pat No. 3848581) in view of Eldridge (US Pat No. 4207870).

In regard to Claim 1, Cinqualbre et al disclose a device comprising:

an inlet port 2 (on end of needle 3) for receiving a blood sample, best seen in Figure 4 (Col.3: 36-Col.4: 32);

an outlet port 4 (second recess 4 from the left for second to left test tube 5), best seen in Figure 4 (Col.3: 36-Col.4: 32);

a chamber 5 (first test tube on left) connected with the inlet port and the outlet port (test tube 5 is connected to second left recess 4 by length of main canal 2), and configured to collect a first portion of the blood sample, the chamber including a material that is blood impermeable (i.e. the body 1) as well as vent 9 that is air permeable, best seen in Figure 4 (Col.3: 36-Col.4: 32);

a sampling channel 8 (second left transverse channel 8 that leads to second left recess 4 – defined as the outlet above) connected with the inlet port and configured to convey a subsequent portion of the blood sample to the outlet port while bypassing the chamber – after a first left test tube 5 (defined as the chamber above) is filled with blood, a second left test tube 5 (that is connected to the outlet defined as second left recess 4) is filled with blood, thus bypassing the first test tube/chamber as defined; and

a housing 1 that houses and defines the inlet port, the outlet port, the chamber, and the sampling channel, best seen in Figure 4 (Col.3: 36-Col.4: 32).

However, Cinqualbre et al do not expressly disclose the chamber having a material is that blood impermeable as well as air permeable. Cinqualbre et al does disclose each chamber or test tube 5 is connected to air passage 9, which enables air to escape (i.e. is air permeable) and thus vent the device to enable filling of the test tube 5 with blood.

Eldridge teach an analogous fluid sampling device comprising a plug 42 that vents using a material that is blood impermeable as well as air permeable to prevent the blood from spilling as well as prevent backflow during sampling as an analogous means of providing the desired air flow, best seen in Figure 1 and 3 (Col.2: 57-Col.3: 62).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of filing to modify the venting means of Cinqualbre et al such that it is a material that is blood impermeable as well as air permeable as taught by Eldridge above to prevent the blood from spilling as well as preventing backflow of the blood from the test tube during sampling.

2. Eldridge discloses the material is configured to seal upon contact with the first portion of the blood sample, best seen in Figure 1 and 3 (Col.2: 57-Col.3: 62).

3. Cinqualbre et al disclose a junction 12 (associated the second valve member 11 on left) connecting the inlet port 2 and the sampling channel 8 and the chamber 5 (first test tube on left), best seen in Figure 4 (Col.3: 36-Col.4: 32).

4. Cinqualbre et al disclose wherein the junction 12 as defined is configured to convey the subsequent portion of the blood sample to the outlet port 4 (defined as second recess 4 from left for second to left test tube 5) while bypassing the chamber 5 (first test tube on left), best seen in Figure 4 (Col.3: 36-Col.4: 32).

6. Cinqualbre et al disclose wherein the device is configured with a moving part 11 (associated with first left test tube 5) that is movable from a first position (valve 11 in open position) to a second position (valve 11 in closed position) to allow blood to bypass the chamber 5 (first test tube on left) and go through the sampling channel 8 (associated with second to left test tube 5) – when valve 11 of first left test tube is in the closed position (relative to the chamber 5 – defined as first left test tube), the blood flow is prevented from flowing into the chamber and thus bypasses said chamber as defined and flows into the second to left test tube, defined as the sampling channel, best seen in Figure 4 (Col.3: 36-Col.4: 32).

7. Cinqualbre et al disclose the moving part 11 as defined further configured to move from the first position to the second position after the first portion of blood flows into the chamber 5 – after the chamber (first test tube on left 5) is sufficiently filled, the user can close the valve 11 to move it into the closed position so that the next test tube in the series can be

filled, defined as the sampling channel leading to the outlet port 4 (defined relative to the second to left test tube 5), best seen in Figure 4 (Col.3: 36-Col.4: 32).

32. Cinqualbre et al disclose wherein the moving part 11 is an inner chamber housing, best seen in Figure 4 (Col.3: 36-Col.4: 32).

In regard to Claim 34, Cinqualbre et al disclose a device comprising:

an inlet port 2 (on end of needle 3) for receiving a blood sample, best seen in Figure 4 (Col.3: 36-Col.4: 32);

an outlet port 4 (second recess 4 from the left for second to left test tube 5), best seen in Figure 4 (Col.3: 36-Col.4: 32);

a chamber 5 (first test tube on left) connected with the inlet port and the outlet port (test tube 5 is connected to second left recess 4 by length of main canal 2), and configured to collect a first portion of the blood sample, the chamber including a material that is blood impermeable (i.e. the body 1) as well as vent 9 that is air permeable, best seen in Figure 4 (Col.3: 36-Col.4: 32);

a sampling channel 8 (second left transverse channel 8 that leads to second left recess 4 – defined as the outlet above) connected with the inlet port and the outlet port, the sampling channel and chamber configured to convey a subsequent portion of the blood sample through the sampling channel to the outlet port – after a first left test tube 5 (defined as the chamber above) is filled with blood, a second left test tube 5 (that is connected to the outlet defined as second left recess 4) is filled with blood; and

a housing 1 that houses and defines the inlet port, the outlet port, the chamber, and the sampling channel, best seen in Figure 4 (Col.3: 36-Col.4: 32).

However, Cinqualbre et al do not expressly disclose the chamber having a material is that blood impermeable as well as air permeable. Cinqualbre et al does disclose each chamber or test tube 5 is connected to air passage 9, which enables air to escape (i.e. is air permeable) and thus vent the device to enable filling of the test tube 5 with blood.

Eldridge teach an analogous fluid sampling device comprising a plug 42 that vents using a material that is blood impermeable as well as air permeable to prevent the blood from spilling as well as prevent backflow during sampling as an analogous means of providing the desired air flow, best seen in Figure 1 and 3 (Col.2: 57-Col.3: 62).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of filing to modify the venting means of Cinqualbre et al such that it is a material that is blood impermeable as well as air permeable as taught by Eldridge above to prevent the blood from spilling as well as preventing backflow of the blood from the test tube during sampling.

35. Eldridge discloses the device in accordance with claim 34, wherein the air permeable blood barrier is configured to seal upon contact with the first portion of the blood sample, best seen in Figure 1 and 3 (Col.2: 57-Col.3: 62).

36. Cinqualbre et al disclose the device in accordance with claim 34, wherein the device is configured with a moving part 11 (associated with first left test tube 5) that is movable from a first position (valve 11 in open position) to a second position (valve 11 in closed position) to allow blood to bypass the chamber 5 (first test tube on left) and go through the sampling

channel 8 (associated with second to left test tube 5) – when valve 11 of first left test tube is in the closed position (relative to the chamber 5 – defined as first left test tube), the blood flow is prevented from flowing into the chamber and thus bypasses said chamber as defined and flows into the second to left test tube, defined as the sampling channel, best seen in Figure 4 (Col.3: 36-Col.4: 32).

37. Cinqualbre et al disclose the device in accordance with claim 36, the moving part further configured to move from the first position to the second position after the first portion of blood flows into the chamber 5 – after the chamber (first test tube on left 5) is sufficiently filled with blood, the user can close the valve 11 to move it into closed position so that the next test tube in the series can be filled, defined as the sampling channel leading to the outlet port 4 (defined relative to the second to left test tube 5), best seen in Figure 4 (Col.3: 36-Col.4: 32).

38. Cinqualbre et al disclose the device in accordance with claim 36, wherein the moving part 11 is an inner chamber housing, best seen in Figure 4 (Col.3: 36-Col.4: 32).

40. Cinqualbre et al disclose the device in accordance with claim 34, further comprising a junction 12 (associated the second valve member 11 on left) connecting the inlet port 2 and the sampling channel 8 and the chamber 5 (first test tube on left), best seen in Figure 4 (Col.3: 36-Col.4: 32).

41. Cinqualbre et al disclose the device in accordance with claim 40, wherein the junction 12 as defined is configured to convey the subsequent portion of the blood sample to the outlet port 4 (defined as second recess 4 from left for second to left test tube 5) while bypassing the chamber 5 (first test tube on left), best seen in Figure 4 (Col.3: 36-Col.4: 32).

Claim(s) 33 and 39 is/are rejected under 35 U.S.C. 103 as being unpatentable over Cinqualbre et al in view of Eldridge, further in view of Vaillancouert (US Pat No. 6126643).

Cinqualbre et al in view of Eldridge disclose the inventio above but do not expressly disclose a locking mechanism configured to maintain the moving part in the first position until the chamber is filled, providing force to overcome the locking mechanism to enable movement of the moving part to the second position.

Vaillancouert teach that it is well-known in the art to provide an analogous blood sampling device comprising a locking mechanism 24 that enables plunger 21 to be releasably locked relative to barrel 11 so that blood is selectively introduced into the syringe, best see n in Figure 4-5 (Col.4: 63-Col.5: 53). Vaillancouert also teaches that other suitable releasable locking means may also be used to secure the plunger 21 relative to the barrel 11 (Col.5: 8-9).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of filing to modify the invention of Cinqualbre et al in view of Eldridge such that there is a locking mechanism configured to selectively maintain the moving part in the first position until the chamber is filled, as taught by Vaillancouert, to effectively prevent the moving part (valve 11 of Cinqualbre et al) from prematurely closing the window 12 before blood sufficiently fills chamber 5 (defined as first test tube on left), which when combined with the user, would thus provide force to overcome the locking mechanism to enable movement of the moving part to the second position as desired. It is noted that the disclosure does not provide any detail into how force would overcome the locking mechanism other than as broadly as has been claimed.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on nonstatutory double patenting provided the reference application or patent either is shown to be commonly owned with the examined application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. See MPEP § 717.02 for applications subject to examination under the first inventor to file provisions of the AIA as explained in MPEP § 2159. See MPEP § 2146 *et seq.* for applications not subject to examination under the first inventor to file provisions of the AIA. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

The USPTO Internet website contains terminal disclaimer forms which may be used. Please visit www.uspto.gov/patent/patents-forms. The filing date of the application in which the form is filed determines what form (e.g., PTO/SB/25, PTO/SB/26, PTO/AIA/25, or PTO/AIA/26) should be used. A web-based eTerminal Disclaimer may be filled out completely online using web-screens. An eTerminal Disclaimer that meets all requirements is auto-processed and approved immediately upon submission. For more information about eTerminal Disclaimers, refer to www.uspto.gov/patents/process/file/efs/guidance/eTD-info-I.jsp.

Claims 1 and 34 are rejected on the ground of nonstatutory double patenting as being unpatentable over claim 5 of U.S. Patent No. 9820682.

Although the claims at issue are not identical, they are not patentably distinct from each other because both recite a device comprising: an inlet port for receiving a blood sample; an outlet port; a chamber connected with the inlet port and the outlet port, and configured to collect a first portion of the blood sample, the chamber including a material that is an air permeable blood barrier; a sampling channel connected with the inlet port and the outlet port, the sampling channel and chamber configured to convey a subsequent portion of the blood sample through the sampling channel to the outlet port while bypassing the chamber; and a housing that houses and defines the inlet port, the outlet port, the chamber, and the sampling channel.

Claims 1 and 34 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 10010282.

Although the claims at issue are not identical, they are not patentably distinct from each other because both recite a device comprising: an inlet port for receiving a blood sample; an outlet port; a chamber connected with the inlet port and the outlet port, and configured to collect a first portion of the blood sample, the chamber including a material that is an air permeable blood barrier; a sampling channel connected with the inlet port and the outlet port, the sampling channel and chamber configured to convey a subsequent portion of the blood sample through the sampling channel to the outlet port while bypassing the chamber; and a housing that houses and defines the inlet port, the outlet port, the chamber, and the sampling channel.

Claim 1 and 34 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1 and 18 of U.S. Patent No. 10143412.

Although the claims at issue are not identical, they are not patentably distinct from each other because both recite a device comprising: an inlet port for receiving a blood sample; an outlet port; a chamber connected with the inlet port and the outlet port, and configured to collect a first portion of the blood sample, the chamber including a material that is an air permeable blood barrier; a sampling channel connected with the inlet port and the outlet port, the sampling channel and chamber configured to convey a subsequent portion of the blood sample through the sampling channel to the outlet port while bypassing the chamber; and a housing that houses and defines the inlet port, the outlet port, the chamber, and the sampling channel.

Claim 1 and 34 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1, 3, and 20-21 of U.S. Patent No. 11185266.

Although the claims at issue are not identical, they are not patentably distinct from each other because both recite a device comprising: an inlet port for receiving a blood sample; an outlet port; a chamber connected with the inlet port and the outlet port, and configured to collect a first portion of the blood sample, the chamber including a material that is an air permeable blood barrier; a sampling channel connected with the inlet port and the outlet port, the sampling channel and chamber configured to convey a subsequent portion of the blood sample through the sampling channel to the outlet port while bypassing the chamber; and a housing that houses and defines the inlet port, the outlet port, the chamber, and the sampling channel.

Claim 1 and 34 are rejected on the ground of nonstatutory double patenting as being unpatentable over claim 1 of U.S. Patent No. 10827964.

Although the claims at issue are not identical, they are not patentably distinct from each other because both recite a device comprising: an inlet port for receiving a blood sample; an outlet port; a chamber connected with the inlet port and the outlet port, and configured to collect a first portion of the blood sample, the chamber including a material that is an air permeable blood barrier; a sampling channel connected with the inlet port and the outlet port, the sampling channel and chamber configured to convey a subsequent portion of the blood sample through the sampling channel to the outlet port while bypassing the chamber; and a

housing that houses and defines the inlet port, the outlet port, the chamber, and the sampling channel.

Claim 1 and 34 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-2 and 8-9 of U.S. Patent No. 11311219.

Although the claims at issue are not identical, they are not patentably distinct from each other because both recite a device comprising: an inlet port for receiving a blood sample; an outlet port; a chamber connected with the inlet port and the outlet port, and configured to collect a first portion of the blood sample, the chamber including a material that is an air permeable blood barrier; a sampling channel connected with the inlet port and the outlet port, the sampling channel and chamber configured to convey a subsequent portion of the blood sample through the sampling channel to the outlet port while bypassing the chamber; and a housing that houses and defines the inlet port, the outlet port, the chamber, and the sampling channel.

Response to Arguments

Applicant's arguments with respect to claim(s) above have been considered but are moot because the new ground of rejection does not rely on any reference applied in the prior rejection of record for any teaching or matter specifically challenged in the argument.

The previous Drawing objections and 112 rejections are moot in light of applicant's amendments.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Huong Q NGUYEN whose telephone number is (571)272-8340. The examiner can normally be reached on 10 am - 6 pm.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert (Tse) Chen can be reached at 5712723672. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

H.Q. NGUYEN
Examiner
Art Unit 3791

/DEVIN B HENSON/
Primary Examiner, Art Unit 3791

(Translation)

Reference No.: Letter No.: 150687 Mailing Date: April 4, 2023 1

Notice of Allowance

(Divisional)

Application Serial No.:	2020-118498
Drafting Date:	March 23, 2023
Examiner:	ISONO Koji 3411 2Q00
Title of the Invention:	BLOOD SAMPLE OPTIMIZATION SYSTEM AND BLOOD CONTAMINANT SEQUESTRATION DEVICE AND METHOD
Number of Claims:	15
Applicant(s):	KURIN, INC.
Agent:	MURAKOSHI, Satoshi

A decision is hereby made to grant patent right to the above identified patent application on the ground that no cause for rejecting the application has been found in the examination.

This is to certify that all the above-referenced items are identical to the JPO's official record.
Certificated: March 28, 2023
Administrative Official of Ministry of Economy, Trade and Industry, Takashi SATO

Note: Applicant must pay Issue Fee within 30 days from the mailing date indicated above.

(Translation)

- Type of Application: Divisional Application
- Cited References: Yes
- Grace Period under Patent Act Article 30: No
- Amendment to Title of the Invention: No
- Deposit of Biological Material : N/A

(Translation)

Reference No.: Letter No.: 150687 Mailing Date: April 4, 2023 /E

Reference Information

Application Serial No.: 2020-118498

- FI

  A61B 5/15 100 ,
  A61B 5/15 200

- Search Fields (IPC, DB Name):

  A61B 5/00-5/398

- References Cited :

US Patent Application Publication No.2008/0145933	(US,A1)
Japanese Patent Application Publication No.2001-000424	(JP,A)
Japanese Patent Application Publication No.H09-504726	(JP,A)
US Patent Application Publication No.2006/0009713	(US,A1)
Japanese Patent Application Publication No.S58-025146	(JP,A)
Japanese Patent Application Publication No.H02-224742	(JP,A)
US Patent Application Publication No.2011/0306899	(US,A1)

- Non-patent literatures:

特許査定

（分割）

特許出願の番号	特願２０２０－１１８４９８
起案日	令和　５年　３月２３日
特許庁審査官	磯野　光司　３４１１　２Ｑ００
発明の名称	血液サンプル最適化システム及び血液隔離装置
請求項の数	１０
特許出願人	クリン　インコーポレイテッド
代理人	村越　智史（ほか　４名）

この出願については、拒絶の理由を発見しないから、特許査定をします。

上記はファイルに記録されている事項と相違ないことを認証する。
認証日　令和 5年 3月28日　経済産業事務官　佐藤　隆

注意：この書面を受け取った日から３０日以内に特許料の納付が必要です。

・出願種別　分割
・参考文献　有
・特許法第３０条適用　無
・発明の名称の変更　無

・菌寄託

参考情報

特許出願の番号　特願２０２０－１１８４９８

・ＦＩ

Ａ６１Ｂ　５／１５　１００　，
Ａ６１Ｂ　５／１５　２００

・調査した分野（ＩＰＣ，ＤＢ名）

Ａ６１Ｂ　５／００－５／３９８

・参考特許文献

米国特許出願公開第２００８／０１４５９３３	（ＵＳ，Ａ１）
特開２００１－０００４２４	（ＪＰ，Ａ）
特表平０９－５０４７２６	（ＪＰ，Ａ）
米国特許出願公開第２００６／０００９７１３	（ＵＳ，Ａ１）
特開昭５８－０２５１４６	（ＪＰ，Ａ）
特開平０２－２２４７４２	（ＪＰ，Ａ）
米国特許出願公開第２０１１／０３０６８９９	（ＵＳ，Ａ１）

・参考図書雑誌

Japanese Patent Application No. 2020-118498
Your Ref: KURIN2JP-DIV2
Our Ref: TS/KRN-C0137JP03
October 13, 2022

Translation of "Notice of Reasons for Rejection"

Patent Application Number:	JP 2020-118498	
Date of Delivery:	September 6, 2022	
Applied Provision:	Patent Law Article(s)	36(6)(ii) (Clarity)
		36(6)(i) (Support requirement)

The present application should be rejected for the following reasons. The applicant may present an argument against the reasons within three months from the date of delivery of this notice.

Reasons

1. (Clarity) The following claims do not comply with the requirements under Patent Law Article 36(6)(ii) as being unclear.

2. (Support requirement) The following claims do not comply with the requirements under Patent Law Article 36(6)(i) as lacking the support of the detailed description.

Remarks

- Reason 1 (Clarity)
- Claims 1 to 8

Claim 1 recites "an air permeable material that seals upon contact with blood from the first portion of the sample of blood". However, it is not clear from the above recitation whether the "air permeable material" after contact with blood seals from air.

From the recitation of "seals … from the first portion of the sample of blood", it can be understood that it is sufficient if the "air permeable material" seals from the sample of blood that is liquid. Further, the recitation of "air permeable material" can be interpreted by itself as always permeable to air. Therefore, the "air permeable material" after contact with blood can be understood as not sealing from air. On the other hand, from the recitation of "seals upon contact with blood", since the "air permeable material", which is originally permeable to air, changes in its sealing, the "air permeable material" after contact with blood can be understood as sealing from air. In addition, the applicant's argument in the Argument (especially, comparison with the invention disclosed in D2) is found to presuppose that the "air permeable material" after contact with blood seals from air.

Therefore, the property of the "air permeable material" after contact with blood, referred to by the recitation of "an air permeable material that seals upon contact with blood from the first portion of the sample of blood" in claim 1, is unclear.

Further, regarding the recitation of "an air permeable material that seals upon contact with blood" in claim 6, the recitation does not include "from the first portion of the sample of blood".

However, from the recitation of "air permeable material" the "air permeable material" after contact with blood can be understood as not sealing from air. On the other hand, from the recitation of "seals upon contact with blood", the "air permeable material" after contact with blood can be understood as sealing from air. Therefore, as in claim 1, the property of the "air permeable material" after contact with blood is unclear.

The same applies to claims 2-5 and 7-8 that refer to claims 1 and 6.

Therefore, the inventions of claims 1-8 are unclear.

- Reason 2 (Support requirement)
- Claims 1 to 8

As pointed out in Reason 1, in the inventions of claims 1 and 6, as a result of it being unclear whether the "air permeable material" after contact with blood seals from the air, a configuration may be included in which the "air permeable material" after contact with blood does not seal from air.

On the other hand, the Detailed Description of the Invention (see, in particular, paragraphs [0041], [0100], etc.) exclusively describes that the "air permeable material" after contact with blood seals from air. And it is not allowed that the invention can be extended or generalized from the Detailed Description of the Invention to a configuration in which the "air permeable material" after contact with blood does not seal from air.

The same applies to claims 2-5 and 7-8 that refer to claims 1 and 6.

Therefore, the inventions of claims 1-8 are not described in the Detailed Description of the Invention.

拒絶理由通知書

特許出願の番号	特願２０２０－１１８４９８
起案日	令和　４年　９月　１日
特許庁審査官	磯野　光司　３４１１　２Ｑ００
特許出願人代理人	三好　秀和（ほか　３名）　様
適用条文	第３６条第６項第２号（明確性） 第３６条第６項第１号（サポート要件）

この出願は、次の理由によって拒絶をすべきものです。これについて意見がありましたら、この通知書の発送の日から３か月以内に意見書を提出してください。

理由

１．（明確性）この出願は、特許請求の範囲の記載が下記の点で、特許法第３６条第６項第２号に規定する要件を満たしていない。

２．（サポート要件）この出願は、特許請求の範囲の記載が下記の点で、特許法第３６条第６項第１号に規定する要件を満たしていない。

記

●理由１（明確性）について

・請求項　１－８

請求項１において「血液と接触すると前記血液サンプルの第１の部分から密封する空気透過性材料」と記載されているが、血液と接触した後の「空気透過性材料」が空気から密封するものであるのか否かが、上記記載からは明確でない。

すなわち、「血液サンプルの第１の部分から密封する」という記載からすると、「空気透過性材料」は液体である血液サンプルから密封すれば足りるようにも解せ、また、「空気透過性材料」という記載のみからは、常に空気を透過するようにも解せるため、血液と接触した後の「空気透過性材料」は空気からは密封しないようにも解せる。その一方、「血液と接触すると・・・密封する」という記載からは、元々空気を透過する「空気透過性材料」に密封に関する変化が生じる訳であるから、血液と接触した後の「空気透過性材料」は空気から密封するようにも解せる。また、意見書における出願人の主張（特に、引用文献２に記載され

た発明との対比）は、血液と接触した後の「空気透過性材料」は空気から密封するものであることを前提としていると認められる。

そのため、請求項１における「血液と接触すると前記血液サンプルの第１の部分から密封する空気透過性材料」という記載が指す、血液と接触した後の「空気透過性材料」の性質は明確でない。

また、請求項６における「血液と接触すると密封する空気透過性材料」という記載について、当該記載には「血液サンプルの第１の部分から」という記載はないものの、「空気透過性材料」という記載のみからは、血液と接触した後の「空気透過性材料」は空気からは密封しないようにも解せ、その一方、「血液と接触すると・・・密封する」という記載からは、血液と接触した後の「空気透過性材料」は空気から密封するようにも解せるため、請求項１の記載と同様に、血液と接触した後の「空気透過性材料」の性質は明確でない。

請求項１，６を引用する、請求項２－５，７－８についても同様である。

よって、請求項１－８に係る発明は明確でない。

●理由２（サポート要件）について

・請求項　１－８

理由１において指摘したように、請求項１，６に係る発明において、血液と接触した後の「空気透過性材料」が空気から密封するものであるのか否かが明確でない結果、血液と接触した後の「空気透過性材料」が空気からは密封しない構成をも含みうるものとなっている。

一方、発明の詳細な説明（特に、段落［００４１］，［０１００］等参照）には、血液と接触した後の「空気透過性材料」が空気から密封するものであることが専ら記載されている。そして、発明の詳細な説明の記載から、血液と接触した後の「空気透過性材料」が空気からは密封しない構成にまで拡張ないし一般化することができるとは認められない。

請求項１，６を引用する、請求項２－５，７－８についても同様である。

よって、請求項１－８に係る発明は、発明の詳細な説明に記載したものでない。

－－－－－－－－－－－－－－－－－－－－－－－－－－－－－－－－－－－－

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審査第一部分析診断（医学診断）（PA2J）　磯野光司（いその　こうじ）
ＴＥＬ．０３－３５８１－１１０１　内線３２９１

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Direct labeling and visualization of blood vessels with lipophilic carbocyanine dye DiI

Article in Nature Protocol · February 2008

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Direct labeling and visualization of blood vessels with lipophilic carbocyanine dye DiI

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Abstract

We describe a protocol to rapidly and reliably visualize blood vessels in experimental animals. Blood vessels are directly labeled by cardiac perfusion using a specially formulated aqueous solution containing 1,1′-dioctadecyl-3,3,3′,3′-tetramethylindocarbocyanine perchlorate (DiI), a lipophilic carbocyanine dye, which incorporates into endothelial cell membranes upon contact. By lateral diffusion, DiI also stains membrane structures, including angiogenic sprouts and pseudopodial processes that are not in direct contact. Tissues can be immediately examined by conventional and confocal fluorescence microscopy. High-quality serial optical sections using confocal microscopy are obtainable from thick tissue sections, especially at low magnification, for three-dimensional reconstruction. It takes less than 1 h to stain the vasculature in a whole animal. Compared with alternative techniques to visualize blood vessels, including space-occupying materials such as India ink or fluorescent dye-conjugated dextran, the corrosion casting technique, endothelial cell-specific markers and lectins, the present method simplifies the visualization of blood vessels and data analysis.

INTRODUCTION

We describe here a direct labeling protocol[1,2] to visualize blood vessels in small experimental animals rapidly and reliably using a lipophilic carbocyanine dye, DiI ($DiIC_{18}(3)$). Lipophilic carbocyanine dyes, including DiI, have been widely used to label cell membranes[3–8] and to trace neuronal connections in live and fixed tissues[7–14]. In the cell membrane, a DiI molecule has its two hydrocarbon chains buried in the lipid bilayer parallel to the phospholipid acyl chains, and the chromophores are on the surface of the bilayer[15].

The direct labeling technique takes advantage of the lipophilic property of DiI. A special aqueous DiI solution is formulated to have the maximum sodium chloride concentration without causing precipitation of DiI. Glucose is added to maintain the physiological osmolarity. Labeling is achieved by bringing DiI solution in direct contact with endothelial cells through cardiac perfusion. A simple perfusion device is assembled with two three-way stopcocks, a butterfly needle and three 10-ml disposable syringes for phosphate-buffered saline (PBS), DiI solution and fixative, respectively (Fig. 1).

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Note: Supplementary information is available via the HTML version of this article.

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During perfusion, DiI partitions quickly into the cell membrane (lipid) phase, the endothelial cell membrane lining the blood vessels, resulting in instantaneous labeling of blood vessels (Fig. 2). Once in the membrane, DiI molecules diffuse laterally within the lipid bilayer[3]. The lateral diffusion helps to stain membrane structures that are not in direct contact with the DiI solution, including angiogenic sprouts and psuedopodial processes of angiogenic endothelial cells (Fig. 3c,d).

As DiI is directly delivered to the endothelial cell membrane, it is possible to achieve high concentration in cell membrane and thus high signal intensities, which dramatically increases the signal-to-noise ratio. In addition, the dye itself is intensely fluorescent with slow fading when exposed to the excitation light[7,8]. The strong intensity and slow fading feature are ideal for serial optical sections using laser scanning confocal microscopy, especially at low magnification. Images can be obtained throughout the entire thickness of a tissue sample of 100 μm without noticeable deterioration of image quality. The vasculature in the inner surface of a hollow organ like the eye can be scanned as a single stack of confocal images at very low magnification (×5 objective lens). Digitized data of thick tissue sections can be used to reconstruct 3-dimemsional (3-D) images of vascular network in the samples of interest and/or to perform other analyses with suitable software. The 3-D images have the advantage of viewing the vascular network in its entirety (Fig. 3; Supplementary Movies 1–3 online). In addition, the use of thick tissue sections would save time and effort, as fewer tissue sections need to be prepared to cover the entire tissue sample. This is especially important when many samples are to be examined.

Many alternative techniques are available to visualize blood vessels. Space-occupying high-contrast materials, including India ink[16] and fluorescent dye-conjugated dextran (e.g., fluorescein isothiocyanate or FITC)[17], are used to fill blood vessels to render them visible. However, the dye molecules are not bound to blood vessels but move freely in the filling solution. When a tissue sample is compressed, especially during sample preparation, the filling solution can be squeezed out of blood vessels, resulting in interrupted or 'broken' vascular patterns. This method, however, directly stains the endothelial cell membranes.

The corrosion casting technique using low-viscosity plastics, another type of space-occupying material, to make casts of blood vessel network has been employed to study the three dimensionality of vasculature[18,19] in combination with scanning electron microscopy (SEM) [20,21]. The casts are viewed with SEM to obtain 3-D images of the vasculature. It is technically demanding to make casts and requires access to SEM[20,21]. It is also difficult to visualize angiogenic sprouts and pseudopodial processes. In comparison, the method described here is technically much simpler in sample preparation and data collection.

Blood vessels can also be visualized by endothelial cell-specific markers, including factor VIII (see ref. [22]) or CD34 (see ref. [23]). Lectins have been used as surrogate markers for endothelial cells. For example, *Ulex europaeus* I lectin recognizes human endothelial cells[24], and *Griffonia simplicifolia* isolectin B_4 specifically labels endothelial cells in mouse, rat and other laboratory animals[25,26]. Use of these markers usually requires multistep procedures. In addition, it is difficult for these techniques to achieve the high signal intensities that can be achieved by direct labeling methods described here.

The direct labeling technique with DiI provides an efficient, reliable and low-cost (the amount of DiI used per rat is less than 1 mg that costs less than USD $2) alternative to obtain high intensity, high signal-to-noise ratio labeling of blood vessels in the entire body for both low- and high-power microscopic observation. It can also be used to study angiogenic sprouts and pseudopodial processes. Although described here for use in rodents, this procedure can be adapted easily to the study of vasculature in other vertebrate animals including rabbits, either

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for the vasculature of the entire body or for *ex vivo* perfusion of a particular organ, such as rabbit kidneys.

In this method, DiI molecules are directly incorporated into the membrane of endothelial cells. As it is a lipophilic dye, the molecules in the membrane could be washed away by lipophilic solvents. It is therefore not easy to combine DiI staining with other techniques, such as immunohistochemical analysis, if the subsequent procedures involve those lipophilic solvents. This issue could be overcome by using a fixable DiI derivative, CM-DiI (C-7001, Invitrogen/Molecular Probes). CM-DiI is particularly useful in experiments that combine membrane labeling with subsequent immunohistochemical analysis, fluorescence *in situ* hybridization or electron microscopy. DiI staining is, however, compatible with the nuclear dye DAPI (4′-6-diamidino-2-phenylindole).

MATERIALS

REAGENTS

- DiI (D-282, Invitrogen/Molecular Probes; 42364, Sigma-Aldrich)
- Ethanol (100% vol/vol)
- NaCl (S7653, Sigma-Aldrich)
- KCl (P9333, Sigma-Aldrich)
- Na_2HPO_4 (S8282, Sigma-Aldrich)
- NaH_2PO_4 (S7907, Sigma-Aldrich)
- Glucose (G7568, Sigma-Aldrich)
- HCl (1 M) (13-1700, Sigma-Aldrich)
- NaOH (5 M) (S8263, Sigma-Aldrich)
- Glycerol (G6279, Sigma-Aldrich)
- Paraformaldehyde (158127, Sigma-Aldrich)
- Agarose (A5939, Sigma-Aldrich)
- Superglue (can be obtained from regular hardware stores)
- Experimental animals (rats and mice, Charles River)

▲ CRITICAL All animal experiments must comply with national laws and institutional regulations.

EQUIPMENT

- 25 gauge butterfly needles
- Microscope slides
- Standard BK7 glass coverslip (no. 1.5, 170 μm thickness)
- Three-way stopcocks
- 10-ml disposable syringes
- Aluminum boats
- Vibratome (VT1000S, Leica Microsystems)

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REAGENT SETUP

DiI stock solution—Dissolve 100 mg of DiI crystal in 16.7 ml of 100% ethanol on a rocker overnight (covered with aluminum foil when rocking) and store in the dark at room temperature (RT, 20–25 °C) for up to 1 year. ⁑ CAUTION DiI solution stains easily on skin and other surfaces. If accidental staining occurs, it can be wiped off easily by 70% ethanol.

PBS (pH 7.4)—Dissolve 8 g of NaCl, 0.2 g of KCl, 1.44 g of Na_2HPO_4 and 0.23 g of NaH_2PO_4 in 800 ml of distilled water. Adjust pH to 7.4 with HCl. Add water to 1,000 ml, filter through a 0.22-μm bottle-top filter. Store at RT for up to 1 year.

5% (wt/vol) glucose—Dissolve 50 g of glucose in 1,000 ml of distilled water. Filter through a 0.22-μm bottle-top filter. Store at RT for up to 1 year.

Diluent—Mix PBS and 5% glucose at a ratio of 1:4. Store at RT for up to 1 year.

DiI work solution—Immediately before use, add 200 μl of DiI stock solution into 10 ml of diluent, mix by quick shaking. DiI work solution should be freshly made under room lighting.

Phosphate buffer (pH 7.4)—Prepare separately a solution of 0.2 M NaH_2PO_4 and another one of 0.2 M Na_2HPO_4. Mix the two solutions at a ratio of 19:81. Check the pH with a pH meter. Adjust pH with either HCl or NaOH. Store at RT for up to 1 year.

8% (wt/vol) paraformaldehyde—Under a chemical hood, add 8 g of paraformaldehyde to 90 ml of distilled water in a beaker with a magnetic stirrer. Heat to 65 °C and adjust the pH to 7.4 (using pH paper) with 5 M NaOH. Add distilled water to adjust the final volume to 100 ml. Cool the solution and filter. Store at 4 °C for up to 1 month.

4% (wt/vol) paraformaldehyde solution—Mix 8% paraformaldehyde with 0.2 M phosphate buffer at a ratio of 1:1 before use. Store at 4 °C for up to 1 month.

80% (vol/vol) glycerol—Add 1 ml of distilled water into 4 ml of glycerol and mix well. Store at RT for up to 1 year.

5% (wt/vol) agarose—Add 20 ml of distilled water to a beaker, and add 1 g of agarose. Heat on a heat place until agarose melts. Keep 5% agarose to 60 °C. Agarose (5%) can be stored at 4 °C for up to 1 month. To use the agarose again, heat until it melts and keep it at 60 °C.

EQUIPMENT SETUP

Perfusion device—The perfusion device is assembled with two three-way stopcocks, a 25 gauge butterfly needle and three 10-ml syringes (Fig. 1). First, connect the two three-way stopcocks in series (Fig. 1, inset) and then the 25-gauge butterfly needle to the outflow port of the stopcocks (Fig. 1). Load the three syringes with 2 ml of PBS, DiI solution (5 ml for a mouse, 10 ml for a rat) and 10 ml of fixative (4% paraformaldehyde), respectively. Connect the syringe with fixative to the first inflow port and inject solution until there is no air in the line; turn the stopcock to block the port. Then, connect the DiI syringe to the second inflow port, inject solution until there is no air in the line, and turn the stopcock to block the port. Finally, connect the PBS syringe to the last inflow port and inject solution until there is no air in the line. Assembly is under room lighting. ⁂ CRITICAL Make sure that no air is trapped in the line or the syringes before proceeding to perfusion. Once in the circulation system, air will block blood vessels, resulting in poor perfusion.

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Aluminum boats—Cut a piece of Styrofoam into the shape and size of the samples of interest. Wrap the Styrofoam with a piece of aluminum foil, leaving one side open. Remove the Styrofoam and store the aluminum boats appropriately at RT.

PROCEDURE

Perfusion ● TIMING **~45 min**

▲ CRITICAL All steps are carried out under ambient lighting unless specified.

1¦ Assemble the perfusion device as described in EQUIPMENT SETUP.

? TROUBLESHOOTING

2¦ Kill a mouse or rat by CO_2 overdose in a CO_2 chamber, or by sodium phenobarbital overdose (120 mg kg^{-1}, i.p).

▲ CRITICAL STEP All animal experiments must comply with national laws and institutional regulations.

3¦ In a glass tray with an absorbing blue pat or several paper towels, position the animal on its back. Make a transverse incision to open the abdominal cavity. Expose and cut the diaphragm. Cut the chest wall on both sides up to the first or the second rib.

4¦ Take a small hemostat to hold the lower tip of the sternum and the turn the anterior chest wall toward the head of the animal to expose the chest cavity.

5¦ (Optional) If the tissues of interest are in the upper body, such as the brain or the eye, there is no need to perfuse the lower body. If this is the case, load half amount of the regular perfusion solutions in Step 1 and clamp the descending aorta to block the flow to the lower body before perfusion. This is not necessary for mice.

6¦ Insert the butterfly needle of the perfusion device into the left ventricle and then puncture the right atrium with a 16-gauge needle.

▲ CRITICAL STEP Make sure that the needle is in the left ventricle, which appears lighter than the right ventricle. Do not penetrate the opposite side of the ventricular wall. Such penetration will result in a leak in the left ventricle, making perfusion difficult.

? TROUBLESHOOTING

7¦ Inject 2 ml of PBS from the perfusion device at the rate of 1–2 ml min^{-1} (total 1–2 min). A sign of good perfusion is bleeding from the right atrium. After injection, turn the switch to block the port of PBS syringe and open the port to the DiI syringe.

? TROUBLESHOOTING

8¦ Inject 5–10 ml of the DiI solution at the rate of 1–2 ml min^{-1} (total 5–10 min). Monitor color change in the ears, nose and palms. DiI appears purple in visible light. During perfusion with DiI solution, the ears, nose and palms will turn slightly purple. After injection, turn the switch to block the port of DiI syringe and open the port to the fixative syringe.

9¦ Inject 5–10 ml of the fixative at the rate of 1–2 ml min^{-1} (total 5–10 min).

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10| Harvest tissues of interest. To make eyecup preparation, eyes are enucleated and the anterior segments are removed. The retinas are further dissected from eyecups[1]. Other tissues of interest can be harvested by directly removing them from the body.

PAUSE POINT Samples can be left in the fixative or PBS in the dark for up to 1 month at 4 °C.

CRITICAL STEP Be sure to place the used needles into a sharp container and to dispose of the animal and waste appropriately.

TROUBLESHOOTING

Tissue sectioning TIMING ~1–2 h, depending on the size of the tissue to be sectioned

11| Rinse samples in PBS 2× 15 min.

12| Embed tissue sample in 5% agarose: heat agarose in a 100-ml beaker to 60 °C and pour it (about one-third of the volume required to submerge the sample) into an aluminum boat that fits the sample. Submerge the tissue sample into the agarose and adjust the orientation. Add more agarose into the boat to keep the sample totally submerged. Samples can be kept at 4 °C in the dark up to 1 month when wrapped in plastic wrap to prevent dehydration. Remove the sample block from the aluminum boat before sectioning. Embedding is not necessary for solid tissue such as the brain and the liver.

TROUBLESHOOTING

13| Trim off excess agarose. Glue the sample to the section stage of the Vibratome using Superglue. Secure the section stage in the section chamber and adjust the sample to the appropriate orientation. Fill the sectioning chamber with PBS to submerge the sample.

TROUBLESHOOTING

14| Set the start and the end point of sectioning (for additional information regarding operating the Leica VT1000S Vibratome, please read the manufacturer's manual).

TROUBLESHOOTING

15| Set the thickness of the section to 100 μm (for additional information regarding operating the Leica VT1000S Vibratome, please read the manufacturer's manual).

TROUBLESHOOTING

16| Section the tissue and collect a section with a small (no. 6 or 8) round watercolor brush; put it on a glass slide. One slide may hold several sections.

TROUBLESHOOTING

17| Use a larger watercolor brush to remove excess PBS, add a small amount of 80% glycerol to the sections and cover with no. 1.5 cover slip. Seal it with nail polish.

PAUSE POINT Sections are better viewed as soon as possible but can be kept for several days at 4 °C in the dark.

TROUBLESHOOTING

View sections TIMING Depending largely on the number of the sections and the area of interest to be examined, ~1 h to 1 d

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18| View tissue sections under a fluorescence microscope or a confocal microscope using the filter set for rhodamine.

19| Collect a stack of confocal images. Reconstruction of 3-D images can be achieved using any image analysis software that has such a function. We used AutoVisualize 3-D (version 5.5, AutoQuant Image Inc.) and Leica Application Suite Advanced Fluorescence (LAS AF, TCS-SP5) (Leica).

● TIMING

Steps 1–10: ~45 min

Steps 11–17: ~1–2 h, depending on the size of the tissue to be sectioned

Steps 18 and 19: depending largely on the number of the sections and the area of interest to be examined, ~1 h to 1 d

? TROUBLESHOOTING

Troubleshooting advice can be found in Table 1.

ANTICIPATED RESULTS

Perfusion with DiI solution delivers dye molecules to endothelial cells lining blood vessels in the entire circulation system, thus blood vessels in the whole body are stained. DiI appears purple in color under visible light, so tissues that are well stained should appear slightly purple. Large blood vessels on the surface should be visible. Blood vessels appear intensely red under a fluorescence microscope using a rhodamine filter set (Fig. 2). Stacks of confocal images could be obtained and used to reconstruct 3-D images in hollow organs like the eye (Fig. 3a) and thick tissue samples (Fig. 3b). Because of lateral diffusion, DiI also stains membrane structures that are not in direct contact with the dye solution, including angiogenic sprouts and pseudopodial processes. Images of angiogenic sprouts with their extruding processes (3-D reconstruction) are shown in Figure 3c,d. Thick tissue sections allow efficient screening of the entire tissue of interest at low magnifications for relatively rare events, which can then be studied in detail at high magnifications and/or using an electronic zoom. For example, to study choroidal neovascularization, it is important to find the site where new blood vessels from the choriocapillaris penetrate the Bruch's membrane. In our study on choroidal neovascularization in a subretinal Matrigel model of choroidal neovascularization in the rat[1], we routinely screen the entire Matrigel-injected area (20–25 sections of 100 μm thick) to identify the penetration sites and then to carefully study them. One such site is shown in Figure 4. The combined DiI staining and DIC (differential interference contrast) image shows the site at which a new blood vessel originated in the choriocapillaris penetrated the Bruch's membrane and entered the space between the retinal pigment epithelium and the Bruch's membrane.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Acknowledgments

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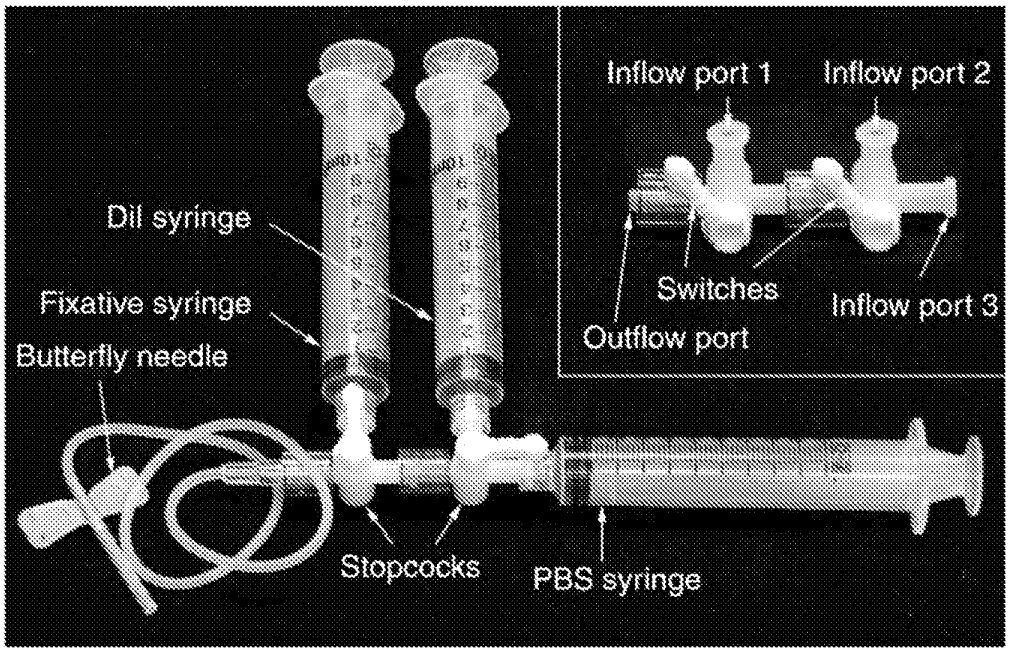


Figure 1.
Perfusion device. The main body of the perfusion device is two three-way stopcocks connected in series (inset). The output port of the stopcocks is connected to a butterfly needle. The inflow ports are connected to three 10-ml disposable syringes for PBS, DiI solution and fixative, respectively. The positions of the three syringes depend on the specific stopcock used, as stopcocks of different brands may have different configurations. It is also possible to use a single stopcock for the device. In that case, it will require change of syringes after perfusion with DiI solution. During syringe change, it is important to avoid air from entering the perfusion line.

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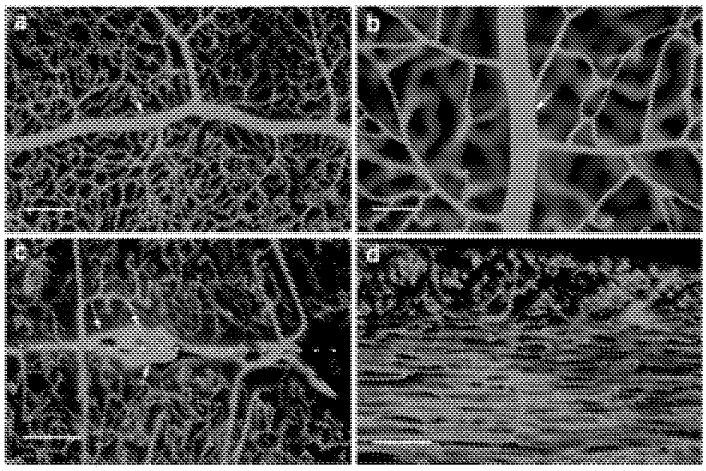


Figure 2.

Vasculature visualized by DiI labeling. (**a**) Retinal whole-mount showing an artery (arrow) on the retinal inner surface along with its branches connecting to the deep capillaries, which are also visible, although out of focus (10 objective lens). (**b**) Retinal whole-mount-showing another artery (arrow) at a higher magnification (×20 objective lens). The nuclei of endothelial cells are identifiable as oval spots in both **a** and **b**. (**c**) A brain section (100 μm thick, ×10 objective lens) showing three large blood vessels (arrows) located in the midline (dashed line) between the two hemispheres and the vascular network in the tissue. (**d**) A heart section (left ventricle, 100 μm thick, ×10 objective lens) showing capillaries in the left ventricle wall. In the outer layer (upper part), they are perpendicular to the section plane and appear as bright dots, whereas in the inner layer (lower part), they are parallel to the section plane. Tissues were viewed by fluorescence microscopy (Nikon Eclipse E800 fluorescence microscope with plan fluo ×10/0.3 numerical aperture (**NA**) or plan fluo ×20/0.5 NA objective lens and Chroma 34,000 rhodamine filter set, with the excitation wavelength of 570 nm and the emission of 590). Scale bars, 200 μm for **a**, **c** and **d**, and 100 μm for **b**.

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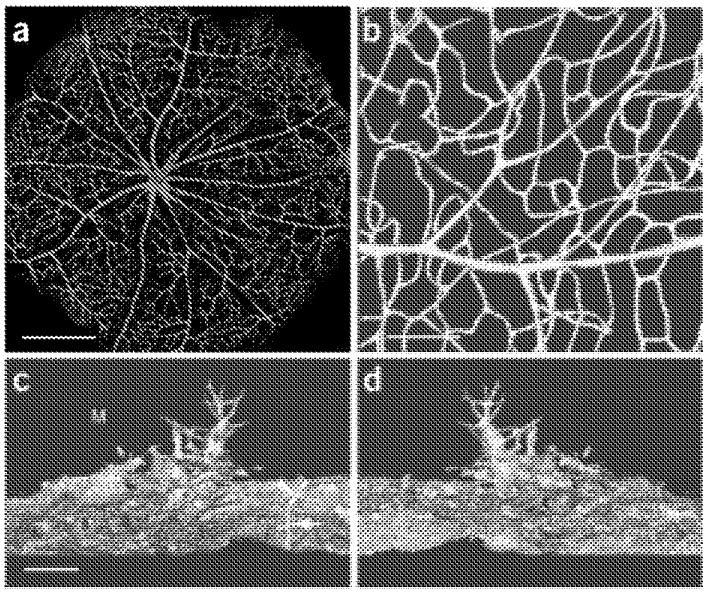


Figure 3.

Three-dimensional reconstructed images of retinal vasculature and angiogenic sprouts and pseudopodial processes. (**a**) A 3-D reconstructed image of the eyecup as a 'bird's eye' view of the vasculature of the posterior retina. The eyecup was placed in a holder and submerged in PBS for direct imaging. A ×5/0.15 NA objective lens was used to take a stack of confocal images, which were used for the reconstruction. DiI signal was detected using Leica DM6000B microscope with the ×5 objective (HC PL Fluotar/0.15) (Leica). Images were acquired by a Leica Application Suite Advanced Fluorescence (LAS AF), 1.7.0, Build 1240 software TCS-SP5 (Leica). The same software was used to create 3-D reconstruction of images and a movie clip, which shows the retinal vasculature rotated around the *x* axis (Supplementary Movie 1). (**b**) A 3-D image showing an artery on the retinal surface connected to the deep capillaries. A movie clip shows the artery and its network rotated around the *y* axis (Supplementary Movie 2). (**c**) A 3-D image of angiogenic sprouts and pseudopodial processes in a subretinal Matrigel of choroidal neovascularization[1] at a viewing angle of 0° (from the coverslip side downward). The vertical line (arrow) indicates the cross section of the choroid. Another line (arrowhead) indicates the surface of the choroicapillaris. Several sprouts from the choriocapillaris invaded the Matrigel layer (M) in the subretinal space. Their pseudopodial processes protruded into the Matrigel deposit (M) in different directions. (**d**) 3-D image of angiogenic sprouts and pseudopodial processes at a viewing angle of 180°. A movie clip shows the sprouts rotated around the *y* axis (Supplementary Movie 3). Scale bar, 400 μm for **a**, 100 μm for **b** and 20 μm for **c** and **d**.

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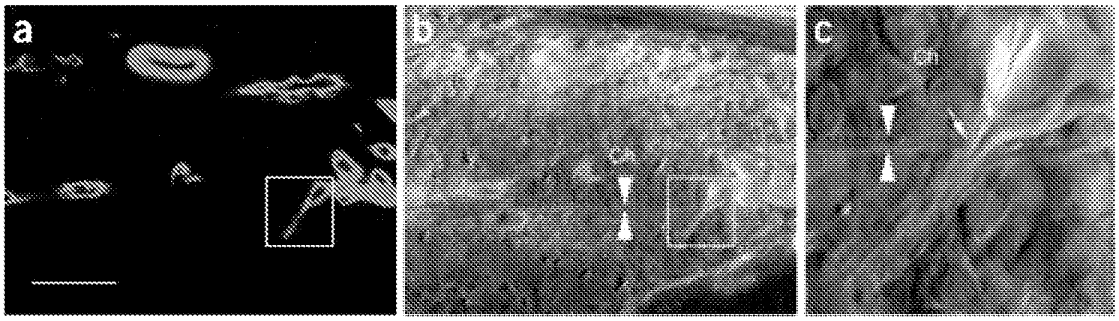


Figure 4.

Penetration of Bruch's membrane by choroidal neovascularization. Choroidal neovascularization was induced by subretinal injection of Matrigel[1]. To locate the penetration sites of choroidal neovascularization, serial tissue sections (100 μm thick each) were cut through the entire Matrigel injected area (about 2 mm in diameter). Tissue sections were screened at low power (×10 objective) under a fluorescence microscope. Potential penetration sites were further examined by confocal microscopy. (**a**) A confocal image of a new blood vessel that had penetrated the Bruch's membrane (square). (**b**) A superimposed image of DIC (differential interference contrast) and fluorescence (red) shows the penetrating blood vessel (square) relative to Bruch's membrane (between two arrowheads). (**c**) The penetration site (arrow) at higher magnification to show Bruch's membrane (between two arrowheads). Ch, choroid. Scale bar, 50 μm for **a** and **b**; 7 μm for **c** .

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TABLE 1

Troubleshooting table

Problem	Possible reason	Possible solution
Weak signal	Poor perfusion due to air trapped in the system (Steps 1 and 6)	Make sure no air is trapped in the perfusion line before perfusion. When inserting the needle into the left ventricle, slightly press the PBS syringe to allow a fluid drop to appear at the needle tip
	Poor perfusion because of a leak in the left ventricle (Step 6)	Do not penetrate the opposite side of the ventricle when inserting the butterfly needle. Using a small hemostat to clamp the leaking point sometimes works
	Poor staining because of too much PBS perfusion (Step 7)	Make sure not more than 2 ml of PBS is used before DiI perfusion
'Leak' staining	The inner lining of blood vessels are broken because of rough handling of tissue preparation and sectioning (Steps 10, 12–17)	DiI will not 'leak' to the surrounding tissues if blood vessels are intact. Be gentle during tissue harvesting. View tissue sections as soon as possible

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APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
18/898,239	**09/27/2024 04:56:23 PM Z ET**	**069366-0581370_KUR2C07US**

Title of Invention

BLOOD SAMPLE OPTIMIZATION DEVICE

Application Information

APPLICATION TYPE	Utility - Nonprovisional Application under 35 USC 111(a)	PATENT #	-
CONFIRMATION #	7801	FILED BY	Trent Tercenio
PATENT CENTER #	67356733	FILING DATE	-
CUSTOMER #	27500	FIRST NAMED INVENTOR	Bobby E. Rogers
CORRESPONDENCE ADDRESS	-	AUTHORIZED BY	Benjamin Hudson

Documents

TOTAL DOCUMENTS: 52

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This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

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NOTICE OF ALLOWANCE AND FEE(S) DUE

27500 7590 01/17/2024

PILLSBURY WINTHROP SHAW PITTMAN LLP (CV)
ATTENTION: DOCKETING DEPARTMENT
P.O BOX 10500
McLean, VA 22102

EXAMINER	
ABOUELELA, MAY A	
ART UNIT	PAPER NUMBER
3791	

DATE MAILED: 01/17/2024

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/538,990	11/30/2021	Bobby E. ROGERS	069366-0572201_KUR2C03US	3420

TITLE OF INVENTION: BLOOD SAMPLE OPTIMIZATION SYSTEM AND BLOOD CONTAMINANT SEQUESTRATION DEVICE AND METHOD

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	$480	$0.00	$0.00	$480	04/17/2024

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the ENTITY STATUS shown above. If the ENTITY STATUS is shown as SMALL or MICRO, verify whether entitlement to that entity status still applies.

If the ENTITY STATUS is the same as shown above, pay the TOTAL FEE(S) DUE shown above.

If the ENTITY STATUS is changed from that shown above, on PART B - FEE(S) TRANSMITTAL, complete section number 5 titled "Change in Entity Status (from status indicated above)".

For purposes of this notice, small entity fees are 40% the amount of undiscounted fees, and micro entity fees are 20% the amount of undiscounted fees.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Maintenance fees are due in utility patents issuing on applications filed on or after Dec. 12, 1980. It is patentee's responsibility to ensure timely payment of maintenance fees when due. More information is available at www.uspto.gov/PatentMaintenanceFees.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), by mail or fax, or via the USPTO patent electronic filing system.

By mail, send to: Mail Stop ISSUE FEE
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

By fax, send to: (571)-273-2885

INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications. **Because electronic patent issuance may occur shortly after issue fee payment, any desired continuing application should preferably be filed prior to payment of this issue fee in order not to jeopardize copendency.**

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

27500 7590 01/17/2024

PILLSBURY WINTHROP SHAW PITTMAN LLP (CV)
ATTENTION: DOCKETING DEPARTMENT
P.O BOX 10500
McLean, VA 22102

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being transmitted to the USPTO via the USPTO patent electronic filing system or by facsimile to (571) 273-2885, on the date below.

(Typed or printed name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/538,990	11/30/2021	Bobby E. ROGERS	069366-0572201_KUR2C03US	3420

TITLE OF INVENTION: BLOOD SAMPLE OPTIMIZATION SYSTEM AND BLOOD CONTAMINANT SEQUESTRATION DEVICE AND METHOD

APPLN. TYPE	ENTITY STATUS	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	SMALL	$480	$0.00	$0.00	$480	04/17/2024

EXAMINER	ART UNIT	CLASS-SUBCLASS
ABOUELELA, MAY A	3791	600-573000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

❑ Change of correspondence address (or Change of Correspondence Address form PTO/AIA/122 or PTO/SB/122) attached.

❑ "Fee Address" indication (or "Fee Address" Indication form PTO/AIA/47 or PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list
(1) The names of up to 3 registered patent attorneys or agents OR, alternatively,
(2) The name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 _____
2 _____
3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document must have been previously recorded, or filed for recordation, as set forth in 37 CFR 3.11 and 37 CFR 3.81(a). Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ❑ Individual ❑ Corporation or other private group entity ❑ Government

4a. Fees submitted: ❑ Issue Fee ❑ Publication Fee (if required)

4b. Method of Payment: *(Please first reapply any previously paid fee shown above)*

❑ Electronic Payment via the USPTO patent electronic filing system ❑ Enclosed check ❑ Non-electronic payment by credit card (Attach form PTO-2038)

❑ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment to Deposit Account No. _____

5. **Change in Entity Status** (from status indicated above)

❑ Applicant certifying micro entity status. See 37 CFR 1.29

NOTE: Absent a valid certification of Micro Entity Status (see forms PTO/SB/15A and 15B), issue fee payment in the micro entity amount will not be accepted at the risk of application abandonment.

❑ Applicant asserting small entity status. See 37 CFR 1.27

NOTE: If the application was previously under micro entity status, checking this box will be taken to be a notification of loss of entitlement to micro entity status.

❑ Applicant changing to regular undiscounted fee status.

NOTE: Checking this box will be taken to be a notification of loss of entitlement to small or micro entity status, as applicable.

NOTE: This form must be signed in accordance with 37 CFR 1.31 and 1.33. See 37 CFR 1.4 for signature requirements and certifications.

Authorized Signature _____ Date _____

Typed or printed name _____ Registration No. _____

UNITED STATES PATENT AND TRADEMARK OFFICE

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www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/538,990	11/30/2021	Bobby E. ROGERS	069366-0572201_KUR2C03US	3420

27500 7590 01/17/2024

PILLSBURY WINTHROP SHAW PITTMAN LLP (CV)
ATTENTION: DOCKETING DEPARTMENT
P.O BOX 10500
McLean, VA 22102

EXAMINER	
ABOUELELA, MAY A	
ART UNIT	PAPER NUMBER
3791	

DATE MAILED: 01/17/2024

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(Applications filed on or after May 29, 2000)

The Office has discontinued providing a Patent Term Adjustment (PTA) calculation with the Notice of Allowance.

Section 1(h)(2) of the AIA Technical Corrections Act amended 35 U.S.C. 154(b)(3)(B)(i) to eliminate the requirement that the Office provide a patent term adjustment determination with the notice of allowance. See Revisions to Patent Term Adjustment, 78 Fed. Reg. 19416, 19417 (Apr. 1, 2013). Therefore, the Office is no longer providing an initial patent term adjustment determination with the notice of allowance. The Office will continue to provide a patent term adjustment determination with the Issue Notification Letter that is mailed to applicant approximately three weeks prior to the issue date of the patent, and will include the patent term adjustment on the patent. Any request for reconsideration of the patent term adjustment determination (or reinstatement of patent term adjustment) should follow the process outlined in 37 CFR 1.705.

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

OMB Clearance and PRA Burden Statement for PTOL-85 Part B

The Paperwork Reduction Act (PRA) of 1995 requires Federal agencies to obtain Office of Management and Budget approval before requesting most types of information from the public. When OMB approves an agency request to collect information from the public, OMB (i) provides a valid OMB Control Number and expiration date for the agency to display on the instrument that will be used to collect the information and (ii) requires the agency to inform the public about the OMB Control Number's legal significance in accordance with 5 CFR 1320.5(b).

The information collected by PTOL-85 Part B is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 30 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450. Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. The United States Patent and Trademark Office (USPTO) collects the information in this record under authority of 35 U.S.C. 2. The USPTO's system of records is used to manage all applicant and owner information including name, citizenship, residence, post office address, and other information with respect to inventors and their legal representatives pertaining to the applicant's/owner's activities in connection with the invention for which a patent is sought or has been granted. The applicable Privacy Act System of Records Notice for the information collected in this form is COMMERCE/PAT-TM-7 Patent Application Files, available in the Federal Register at 78 FR 19243 (March 29, 2013).
https://www.govinfo.gov/content/pkg/FR-2013-03-29/pdf/2013-07341.pdf

Routine uses of the information in this record may include disclosure to:

1) law enforcement, in the event that the system of records indicates a violation or potential violation of law;
2) a federal, state, local, or international agency, in response to its request;
3) a contractor of the USPTO having need for the information in order to perform a contract;
4) the Department of Justice for determination of whether the Freedom of Information Act (FOIA) requires disclosure of the record;
5) a Member of Congress submitting a request involving an individual to whom the record pertains, when the individual has requested the Member's assistance with respect to the subject matter of the record;
6) a court, magistrate, or administrative tribunal, in the course of presenting evidence, including disclosures to opposing counsel in the course of settlement negotiations;
7) the Administrator, General Services Administration (GSA), or their designee, during an inspection of records conducted by GSA under authority of 44 U.S.C. 2904 and 2906, in accordance with the GSA regulations and any other relevant (i.e., GSA or Commerce) directive, where such disclosure shall not be used to make determinations about individuals;
8) another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c));
9) the Office of Personnel Management (OPM) for personnel research purposes; and
10) the Office of Management and Budget (OMB) for legislative coordination and clearance.

If you do not furnish the information requested on this form, the USPTO may not be able to process and/or examine your submission, which may result in termination of proceedings, abandonment of the application, and/or expiration of the patent.

Notice of Allowability	Application No. 17/538,990	Applicant(s) ROGERS et al.	
	Examiner MAY A ABOUELELA	Art Unit 3791	AIA (FITF) Status Yes

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☑ This communication is responsive to 12/20/2023.
   ☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2. ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

3. ☑ The allowed claim(s) is/are 1-20 . As a result of the allowed claim(s), you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see **http://www.uspto.gov/patents/init_events/pph/index.jsp** or send an inquiry to **PPHfeedback@uspto.gov.**

4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

   Certified copies:

   a) ☐ All b) ☐ Some* c) ☐ None of the:

   1. ☐ Certified copies of the priority documents have been received.
   2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
   3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____ .

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____ .

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☑ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____.
3. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material _____.
4. ☑ Interview Summary (PTO-413), Paper No./Mail Date. 10/08/2024.
5. ☑ Examiner's Amendment/Comment
6. ☑ Examiner's Statement of Reasons for Allowance
7. ☐ Other _____.

/MAY A ABOUELELA/
Primary Examiner, Art Unit 3791

Notice of Pre-AIA or AIA Status

1. The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on 12/20/2023. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Terminal Disclaimer

3. The terminal disclaimer filed on 12/20/2023 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S Patent Applications No. 9820682, 10143412 and 11185266 has been reviewed and is accepted. The terminal disclaimer has been recorded.

EXAMINER'S AMENDMENT

4. Authorization for this examiner's amendment was given in an interview with BEN HUDSON on 01/08/2024.

Claim 5 should be amended as follow:

5. (Currently Amended) The blood sample control device in accordance with claim **3** ~~2~~, wherein the housing comprises a bottom member mated with a top member, each of the

bottom member and the top member defining a part of each of the inlet, the outlet, the chamber, and the sampling channel.

Claim 10 should be amended as follow:

10. (**Currently Amended**) The bodily fluid control device in accordance with claim 6, wherein the air permeable blood barrier includes an air permeable material that at least partially seals upon contact with **the bodily fluid** ~~blood~~.

Claim 13 should be amended as follow:

13. (Currently Amended) A bodily fluid control device comprising;

an inlet;

a junction connected with the inlet;

an outlet;

a chamber connected with the inlet via the junction, the chamber having a vent that includes an air permeable bodily fluid barrier that at least partially seals upon contact with a first portion of bodily fluid;

a housing that houses and defines the inlet, the outlet, and the chamber; and

wherein the chamber and the junction **are** ~~being~~ configured to direct the first portion of the bodily fluid from the inlet into the chamber toward the air permeable bodily fluid barrier and to displace air in the chamber, whereupon at least partially sealing of the air permeable bodily fluid barrier enables at least temporary containment of the first portion of the bodily fluid in the chamber, and enables a second portion of the bodily fluid from the inlet to bypass the chamber via the junction and be directed toward the outlet.

Allowable Subject Matter

5. Claims 1-20 are allowed.

6. The following is an examiner's statement of reasons for allowance: the most pertinent prior art Eldridge et al (U.S 4,207,870) teaches a blood sample device for sampling blood conveyed from a patient, the blood device comprising; an inlet port configured to receive the blood conveyed from the patient; an outlet port; a chamber; and a sampling channel having a distal end connected with the outlet port; a junction connected between the inlet port, the chamber and the sampling channel, the junction being sized and configured such that a first portion of blood conveyed from the patient flows into the chamber to displace air therein through the air permeable blood barrier and to be sequestered in the chamber.

The prior art does not teach, disclose and/or fairly suggest the chamber having a vent that includes an air permeable blood barrier, and wherein the junction is configured to allow a second portion of blood to bypass the chamber and the first portion of blood sequestered therein to be directed into the sampling channel toward the outlet port.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MAY A ABOUELELA whose telephone number is (571)270-7917. The examiner can normally be reached 8-5.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, JACQUELINE CHENG can be reached on 5712725596. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of published or unpublished applications may be obtained from Patent Center. Unpublished application information in Patent Center is available to registered users. To file and manage patent submissions in Patent Center, visit: https://patentcenter.uspto.gov. Visit https://www.uspto.gov/patents/apply/patent-center for more information about Patent Center and https://www.uspto.gov/patents/docx for information about filing in DOCX format. For additional questions, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/MAY A ABOUELELA/
Primary Examiner, Art Unit 3791

Examiner-Initiated Interview Summary	**Application No.** 17/538,990	**Applicant(s)** ROGERS et al.		
	Examiner MAY A ABOUELELA	**Art Unit** 3791	**AIA (First Inventor to File) Status** Yes	**Page** 1 of 1

All Participants (applicant, applicants representative, PTO personnel)	**Title**	**Type**
MAY A ABOUELELA	Primary Examiner	Telephonic
BEN HUDSON	Attorney of Record	

Date of Interview: 08 January 2024

Issues Discussed:

35 U.S.C. 112

Applicant and Examiner discussed the claims set mailed on 12/20/2023. Applicant and Examiner discussed the claim language with respect to the applied prior art and the disclosure. Applicant and Examiner discussed proposed claim amendments represented by the Examiner to overcome 112 rejection for claims 5, 10 and 13. The Applicant has authorized the Examiner to amend the claims.

/MAY A ABOUELELA/ Primary Examiner, Art Unit 3791	

Applicant is reminded that a complete written statement as to the substance of the interview must be made of record in the application file. It is the applicants responsibility to provide the written statement, unless the interview was initiated by the Examiner and the Examiner has indicated that a written summary will be provided. See MPEP 713.04
Please further see:
MPEP 713.04
Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews, paragraph (b)
37 CFR § 1.2 Business to be transacted in writing

Applicant recordation instructions: It is not necessary for applicant to provide a separate record of the substance of interview.

Examiner recordation instructions: Examiners must summarize the substance of any interview of record. A complete and proper recordation of the substance of an interview should include the items listed in MPEP 713.04 for complete and proper recordation including the identification of the general thrust of each argument or issue discussed, a general indication of any other pertinent matters discussed regarding patentability and the general results or outcome of the interview, to include an indication as to whether or not agreement was reached on the issues raised.

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (02-18)
Approved for use through 11/30/2020. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT
(Not for submission under 37 CFR 1.99)

Application Number	17538990
Filing Date	2021-11-30
First Named Inventor	Bobby E. ROGERS
Art Unit	OPAP
Examiner Name	CENTRAL, DOCKET
Attorney Docket Number	069366-0572201_KUR2C03US

U.S.PATENTS Remove

Examiner Initial*	Cite No	Patent Number	Kind Code[1]	Issue Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	4416291		1983-11-22	KAUFMAN JOSEPH	
	2	10299713		2019-05-28	PATTON RICHARD G	
	3	10265007		2019-04-23	BULLINGTON GREGORY	
	4	11395612		2022-07-26	BULLINGTON GREGORY J	
	5	10881343		2021-01-05	BULLINGTON GREGORY J	
	6	10596315		2020-03-24	BULLINGTON GREGORY J	
	7	11660030		2023-05-30	BULLINGTON GREGORY J	
	8	11259727		2022-03-01	BULLINGTON GREGORY J	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.A.A/

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	17538990
	Filing Date	2021-11-30
	First Named Inventor	Bobby E. ROGERS
	Art Unit	OPAP
	Examiner Name	CENTRAL, DOCKET
	Attorney Docket Number	069366-0572201_KUR2C03US

	9	11737693		2023-08-29	BULLINGTON GREGORY J	
	10	11439332		2022-09-13	BULLINGTON GREGORY J	
	11	11589843		2023-02-28	BULLINGTON GREGORY J	
	12	11612340		2023-03-28	BULLINGTON GREGORY J	
	13	11234626		2022-02-01	BULLINGTON GREGORY J	
	14	10624977		2020-04-21	BULLINGTON GREGORY J	
	15	11653863		2023-05-23	BULLINGTON GREGORY J	
	16	11419531		2022-08-23	BULLINGTON GREGORY J	
	17	11786155		2023-10-17	BULLINGTON GREGORY J	
	18	11789017		2023-10-17	BULLINGTON GREGORY J	

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Examiner Initial*	Cite No	Publication Number	Kind Code[1]	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1	20220151525		2022-05-19	BULLINGTON GREGORY J	
	2	20220151527		2022-05-19	BULLINGTON GREGORY J	
	3	20200289039		2020-09-17	BULLINGTON GREGORY J	
	4	20210275068		2021-09-09	MIAZGA JAY M	
	5	20220304664		2022-09-29	HAMMER JEREMY	
	6	20160073937		2016-03-17	BURKHOLZ JONATHAN KARL	

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	1							☐

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	17538990
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	Art Unit	OPAP
	Examiner Name	CENTRAL, DOCKET
	Attorney Docket Number	069366-0572201_KUR2C03US

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T[5]
	1		☐

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EXAMINER SIGNATURE

Examiner Signature	/MAY A ABOUELELA/	Date Considered	01/08/2024

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. [2] Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). [3] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [4] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [5] Applicant is to place a check mark here if English language translation is attached.

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
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	Filing Date	2021-11-30
	First Named Inventor	Bobby E. ROGERS
	Art Unit	OPAP
	Examiner Name	CENTRAL, DOCKET
	Attorney Docket Number	069366-0572201_KUR2C03US

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☐ See attached certification statement.

☒ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/Benjamin F. Hudson/	Date (YYYY-MM-DD)	2023-12-20
Name/Print	Benjamin F. Hudson	Registration Number	71,474

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these record s.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.

3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.

6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).

7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.

8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.

9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.

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拒絶理由通知書

特許出願の番号	特願２０２１－２１４１７７
起案日	令和　４年１１月２９日
特許庁審査官	▲高▼木　尚哉　３６１１　２Ｑ００
特許出願人代理人	三好　秀和（ほか　３名）　様
適用条文	第３６条第６項第１号（サポート要件） 第３６条第６項第２号（明確性）

この出願は、次の理由によって拒絶をすべきものです。これについて意見がありましたら、この通知書の発送の日から３か月以内に意見書を提出してください。

理由

１．（サポート要件）この出願は、特許請求の範囲の記載が下記の点で、特許法第３６条第６項第１号に規定する要件を満たしていない。

２．（明確性）この出願は、特許請求の範囲の記載が下記の点で、特許法第３６条第６項第２号に規定する要件を満たしていない。

記

●理由１（サポート要件）について

・請求項　１－２０
・備考
本願の発明の詳細な説明には、本願発明の課題として、段落[0004]には、「血液培養を行うための血液サンプルの採取は、現代の患者ケアの重要な要素であり、正確な診断を提供することによって患者の結果に良い影響を与えることも、不必要な抗菌療法を長引かせ、入院期間を長くし、コストを増加させることによって結果に悪影響を与えることもある。」と記載され、段落[0007]には、「偽陽性の血液培養は、一般的に、不十分なサンプリング技術の結果である。それらは、必要でないときに抗生物質を使用させ、病院費及び患者の不安を増大させる。血液培養は、皮膚内への針刺しから採取され、その後で血液のサンプルを取り込むためにバキュテナー（登録商標）が取り付けられる。汚染は、穿刺部位及びその周辺の皮膚領域の不適切又は不完全な消毒によって生じ得る。それはまた、挿入

中の針による皮膚のくりぬきから、くりぬかれた皮膚細胞と関連する汚染物質とがサンプル中に引き込まれることで生じることもある。」と記載されており、血液培養のための血液サンプルの採取において、血液が汚染されることが記載されている。

そして、当該課題を解決するための手段として、段落[0014]には、「採血経路と接続される血液隔離デバイス」を備えることが記載されている。

そうすると、本願の発明の詳細な説明には、一貫して、汚染を避ける対象が「血液」であることが記載されていると言える。

しかしながら、本願の請求項１には、「流体分流デバイス」と記載されているのみであって、「流体」として「血液」を用いることが特定されていない。

よって、請求項１には、発明の詳細な説明に記載された、発明の課題を解決するための手段が反映されておらず、請求項１に係る発明は、発明の詳細な説明に記載した範囲を超えることとなる。

上記と同様の理由により、請求項８、請求項１５は、発明の詳細な説明に記載した範囲を超えることとなる。

よって、請求項１－２０に係る発明は、発明の詳細な説明に記載したものでない。

●理由２（明確性）について

・請求項　１５－２０
・備考

請求項１５には、「前記チャンバ、前記サンプリング流路及び前記分岐点は、流体の第１の部分が前記チャンバに流れ込んで前記チャンバを満たし、前記空気透過孔を通して前記チャンバ内の空気を追い出すように、及び、流体の第２の部分が前記チャンバ及び前記チャンバ内に隔離された流体の第１の部分を迂回し、前記出口ポートに向かって前記サンプリング流路に導かれるように寸法設定されかつ構成される」ことが記載されているが、「前記空気透過孔を通して前記チャンバ内の空気を追い出すように、」との記載が、「流体の第１の部分」についての記載であるのか、あるいは、「流体の第２の部分」についての記載であるのか明らかでない。（上記記載の「流体の第１の部分が前記チャンバに流れ込んで前記チャンバを満たし、前記空気透過孔を通して前記チャンバ内の空気を追い出すように、」が「流体の第１の部分が前記チャンバに流れ込んで、前記空気透過孔を通して前記チャンバ内の空気を追い出すように、前記チャンバを満たし、」を意味するのであれば、そのように記載されたい。）

したがって、請求項１５－２０に係る発明は明確でない。

－－－－－－－－－－－－－－－－－－－－－－－－－－－－－－－－－－－－

＜先行技術文献調査結果の記録＞

・調査した分野　ＩＰＣ　Ａ６１Ｂ１／００－１／３２
Ｇ０２Ｂ２３／２４－２３／２６

・先行技術文献　特開２０１３－２４０６２８号公報
特表２０１６－５０４０７５号公報
国際公開第２０１４／０５８９４５号
米国特許出願公開第２００５／０２４５８８５号明細書

この先行技術文献調査結果の記録は、拒絶理由を構成するものではありません。

この拒絶理由通知の内容に関するお問合せ又は面接のご希望がありましたら次の連絡先までご連絡ください。電子メール等で補正案等の送付を希望される場合は、その旨を電話でお知らせください。

審査第一部分析診断　医学診断(PA2J)　高木尚哉
ＴＥＬ．０３－３５８１－１１０１　内線３２９２

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18 March 2022

Examination report No. 1 for standard patent application

Griffith Hack
GPO Box 4164
Sydney NSW 2001
Australia

Your reference:	P108089.AU.1
Application number:	2021202622
Applicant name:	KURIN, INC.
Earliest priority date:	24 July 2015

Final date for acceptance:	**18 March 2023**
Date of this report:	18 March 2022
Examination request date:	6 July 2021

Dear Griffith Hack,

Your application has been examined under *section 45 of the Patents Act 1990*.

You have **12 months** from the date of this report to overcome all my objection(s) otherwise this application will lapse.

You will also need to pay any annual continuation fees that apply. Your next continuation fee is due on **22 July 2022**.

While the application is otherwise in order for acceptance, it cannot be accepted because there is a current postponement of acceptance in place.

You must respond to this report in order to gain acceptance. The Commissioner will only proceed to accept the application if you file a clear and unambiguous statement requesting the postponement be withdrawn with sufficient time for the request to be processed. If the application is not accepted by **18 March 2023**, your application will lapse.

Details of this patent application can be viewed on Auspat, our Australian patent search database.

Yours sincerely,

Kevin Sivieng
Section: MECH 4 - MEDICAL DEVICES
Phone: +61 2 6283 2609

Alternate contact: Vijay Singh
Phone: +61 2 6283 2665

Report details

Basis of the report

In examining this application I have considered:

- the specification as filed.
- allowed and/or proposed amendment/s under S104 including amendment item number 1, filed on 4 May 2021.

Summary of novelty, inventive step and patentable subject matter

	Satisfy requirements?	*Claim numbers*
Novelty/inventive step	**Yes**	1-16
	No	NONE
Patentable subject matter	**Yes**	1-16
	No	NONE

Detailed objections on issues that have been identified

Documents cited or considered relevant

D1: WO 2011162772 A1 (CLEARVIEW PATIENT SAFETY TECHNOLOGIES LLC [US], et al) 29 December 2011 [1]
Category: A

D2: WO 1996005875 A1 (BAXTER INT [US]) 29 February 1996 [2]
Category: A

D3: US 20130317391 A1 (BULLINGTON GREGORY J [US], et al) 28 November 2013 [3]
Category: A

D4: US 4207870 A (ELDRIDGE WILLIAM N [US]) 17 June 1980 [3]
Category: A

D5: US 4416291 A (KAUFMAN) 22 November 1983 [4]
& JP S 5825146 A
Category: A

D6: US 20080145933 A1 (PATTON RICHARD G [US]) 19 June 2008 [5]
Category: A

D7: JP 2001000424 A (NISSHO KK) 9 January 2001, English translation retrieved from Espacenet [5]
Category: A

[1] Cited in the search/examination report of WO 2017/019552 A1

[2] Cited in the search/examination report of EP 3622890

[3] Cited in the search/examination report of US 2017/0020427 A1

[4] Cited in the search/examination report of JP 2018525191

[5] Cited in the search/examination report of JP 2020192333

Special categories of cited documents:

A: Document defining the general state of the art which is not considered to be of particular relevance.
&: Document member of the same patent family.

END OF REPORT

פ.ק 26

תאריך : י״ג שבט תשפ״ד
23/01/2024
מספרכם : 1000-018-02

לכבוד
כץ, פרזנטי ושות׳
דרך אבא הלל 14,
רמת גן, מיקוד 52506

א. ג. נ.,

הנדון : **<u>הודעה על ליקויים בבקשת פטנט מספר 302893</u>**
סימוכין : מכתבכם מיום 08/09/2023, 10/09/2023

לתשומת לבכם : מקום בו הנכם מופנים לחוק, הכוונה היא לחוק הפטנטים, התשכ״ז – 1967. מקום בו הנכם מופנים לתקנות, הכוונה היא לתקנות הפטנטים (נוהלי הרשות, סדרי דין, מסמכים ואגרות), התשכ״ח – 1968. עליכם להשיב על הודעה זו תוך ארבעה חודשים מתאריכה, אך הנכם רשאים לבקש את הארכת התקופה, עם בקשת הארכה שתוגש יש לשלם אגרה בסך 226.00 ש״ח בעד כל חודש או חלק ממנו. **לא יינתנו יותר מארבעה חודשי ארכה בגין כל הודעה על ליקויים וסך כל תקופות הארכה במהלך הבחינה לא יעלה על 12 חודשים** בהתאם לכללים שנקבעו בחוזר הרשם 035/2017-פטנטים.

<u>הודעה זו מבוססת על המסמכים הבאים :</u>
שרטוטים מתאריך : 13/05/2023
פרטי הבקשה מתאריך : 20/08/2023
תביעות מתאריך : 20/08/2023

<u>ההפניות בהודעה זו מתייחסות לפרסומים הבאים :</u>

D1: US 3848581 A [CINQUALBRE L] - 19/11/1974
D2: US 4207870 A [BECTON DICKINSON CO] - 17/06/1980

<u>בהתאם למפורט בהמשך הודעה זו להלן סיכום עמדתי לעניין כשירות התביעות לפטנט :</u>

תביעה/ות מס׳ 2-9,12-14 הינן כשירות לפטנט בהתאם לסעיף 17(א) לחוק.
בתביעה/ות מס׳ 1,10-11,15-18 נמצאו ליקויים.
ראה הנימוקים בהמשך הודעה זו.

בהתאם להוראות **תקנה 41** הנני להודיעכם כי נמצאו בבקשה הנ״ל הליקויים המפורטים להלן :

1. <u>בחינת הבקשה מבוססת על ההודעות הבאות :</u>

1.1 הריני להודיעכם כי :

תאריך הבקשה הנוכחית, שהינה בקשת חלוקה מן הבקשה מס׳ 267684, הוקדם לתאריך 27/12/2017 , שהוא תאריך הבקשה ההורה, וזאת בהתאם ל**סעיף 24(ג) לחוק**.

2. <u>חידוש והתקדמות המצאתית</u>

2.1 תביעות 1,10-11,15-18 אינן מגדירות אמצאה שיש בה התקדמות המצאתית כהגדרתה ב**סעיף 5 לחוק**, לאור פרסומים : D1 ,D2.

תביעות 1,10-11,15-18 בבקשה שבפניי תואמות לתביעות 1,3-4,6-7,23,34 בבקשה 17/893,079 שנבחנה על ידי ה- USPTO והופק עבורה דוח בחינה בתאריך 22/08/2023. לאחר עיון בדוח הבחינה האמור ולאור תאימות התביעות, מצאתי כי הליקוי שפורט בנוגע לחוסר התקדמות המצאתית חל גם על התביעות שבפניי לפי חוק הפטנטים הישראלי.

2.2 תביעות 2-9,12-14 עונות על דרישות **סעיפים 4 ו-5 לחוק**, מאחר שהאמצאה המוגדרת בתביעות אלה לא נתפרסמה בפומבי לפני תאריך הבקשה ויש בה התקדמות המצאתית.

<u>חובת המבקש לעדכן את הרשות</u>

תשומת לבכם ל**סעיף 18א לחוק** לעניין חובת המבקשת לעדכן את הרשות על כל שינוי שחל ברשימת האסמכתאות או הפרסומים כאמור ב**סעיף 18(א) לחוק** ול**סעיף 18ג לחוק** בדבר אמצעי האכיפה.

<u>הגשת תיקונים לפירוט במהלך בחינת הבקשה</u>

באם יבוצעו תיקונים בבקשת הפטנט, תשומת לבכם מופנית **לתקנה 22(א)**. יש לשלוח לרשות עותק מלא של חלק הבקשה שבו הוכנסו התיקונים תוך סימונם באופן ברור. יש לסמן תוספות בקו תחתי (כך : <u>דוגמה</u>) והשמטות בקו חוצה (כך :~~דוגמה~~). **אין להגיש מחדש קבצים שלא תוקנו**.

לתשומת לבכם:

א) בהתאם לתקנות 22(ב) ו-42 במידה שהנכם מתקנים את הפירוט כדי להתגבר על הליקויים בהודעה זו, עליכם לפרט את הליקויים שהתיקונים באים לסלקם, לנמק כיצד תיקון הפירוט מתקן את הליקוי ולגבי תיקון בתביעות, כיצד עומד התיקון בתנאי סעיף 13 לחוק .

ב) בהתאם להוראות חוזר רשם 034/2017-פטנטים, במידה שבחינת הבקשה החלה לאחר 27.03.2017, תיקון פירוט בדרך של החלפת האמצאה שנבחנה ואשר לגביה הועלה ליקוי, באמצאה אחרת, בין אם היא הופיעה בתביעות מלכתחילה ובין אם תוארה בלבד, גם אם היא נובעת מהתיאור, אינו מהווה תיקון הליקוי ויביא לשליחת הודעה לפני סירוב.

ניתן לעיין בפרטי תיק הבקשה באתר הרשות בקישור :

https://israelpatents.justice.gov.il/#/en/patent-file/details/302893

<u>ראיון עם בוחן</u>

בהתאם לה.ע. 23.3, המפורסמת באתר הרשות, ניתן לקיים ראיון עם הבוחן באמצעות פגישה במשרדי הרשות, בשיחה טלפונית או בהיוועדות חזותית.

רשות הפטנטים מעודדת קיום של קשר ישיר בין הבוחן למבקש או בא-כוחו באמצעות שירות זה.

קיום ראיון עם בוחן מאפשר לרוב את ייעול וקיצור זמן הבחינה ואף לחיסכון בעלויות בתהליך הבחינה והאישור של בקשה לפטנט.

במסגרת הראיון ניתן לדון עם הבוחן בנושאים הקשורים לתיאור האמצאה והגדרתה, בליקויים שהועלו במהלך הבחינה ואף בתיקונים אפשריים לליקויים אלה.

תיאום הראיון יתבצע ישירות מול הבוחן (פרטי הקשר מופיעים מטה) וילווה בהודעה כתובה של יוזם הראיון שתפרט את הנושאים לדיון ואת הטיעונים העיקריים לגביהם.

לתשומת לבכם, בקשה לקיום ראיון אינה מהווה תשובה להודעת הליקויים כמשמעה בתקנה 42.

<u>השגה בפני הרשם</u>

על פי **סעיף 161 לחוק**, הנכם רשאים להשיג על החלטתי בפני רשם הפטנטים תוך ארבעה חודשים ממועד משלוח ההודעה.

בתקווה לימים שקטים ובטוחים יותר.

בכבוד רב

אלברט אקרמן
בוחן פטנטים בכיר
טלפון : 073-3927233
דואר אלקטרוני : albertak@justice.gov.il
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/893,079	08/22/2022	Bobby E. ROGERS	069366-0572192_KUR3C02US	6240

27500 7590 07/19/2023

PILLSBURY WINTHROP SHAW PITTMAN LLP (CV)
ATTENTION: DOCKETING DEPARTMENT
P.O BOX 10500
McLean, VA 22102

EXAMINER	
NGUYEN, HUONG Q	

ART UNIT	PAPER NUMBER
3791	

NOTIFICATION DATE	DELIVERY MODE
07/19/2023	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Docket_IP@pillsburylaw.com

Office Action Summary	Application No. 17/893,079	Applicant(s) ROGERS et al.	
	Examiner Huong Q NGUYEN	Art Unit 3791	AIA (FITF) Status Yes

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTHS FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☑ Responsive to communication(s) filed on 05/22/2023.

☐ A declaration(s)/affidavit(s) under **37 CFR 1.130(b)** was/were filed on _____.

2a)☑ This action is **FINAL.** 2b) ☐ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims*

5) ☑ Claim(s) 1-4,6-7 and 32-41 is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6) ☐ Claim(s) _____ is/are allowed.

7) ☑ Claim(s) 1-4,6-7 and 32-41 is/are rejected.

8) ☐ Claim(s) _____ is/are objected to.

9) ☐ Claim(s) _____ are subject to restriction and/or election requirement

* If any claims have been determined allowable, you may be eligible to benefit from the **Patent Prosecution Highway** program at a participating intellectual property office for the corresponding application. For more information, please see http://www.uspto.gov/patents/init_events/pph/index.jsp or send an inquiry to **PPHfeedback@uspto.gov.**

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☑ The drawing(s) filed on 8/22/02022 is/are: a)☐ accepted or b)☑ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

Certified copies:

a)☐ All b)☐ Some** c)☐ None of the:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

** See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☑ Notice of References Cited (PTO-892)

2) ☑ Information Disclosure Statement(s) (PTO/SB/08a and/or PTO/SB/08b) Paper No(s)/Mail Date _____.

3) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____.

4) ☐ Other: _____.

DETAILED ACTION

This office action is responsive to the amendment filed 5/22/2023. Claims 1-4, 6-7, and 32-41 remain pending and under prosecution.

Notice of Pre-AIA or AIA Status

The present application, filed on or after March 16, 2013, is being examined under the first inventor to file provisions of the AIA.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "junction" in **Claims 3-4 and 40-41** must be shown *with element numbers* or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the

filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Interpretation

The following is a quotation of 35 U.S.C. 112(f):

> (f) Element in Claim for a Combination. – An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

The following is a quotation of pre-AIA 35 U.S.C. 112, sixth paragraph:

> An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

The claims in this application are given their broadest reasonable interpretation using the plain meaning of the claim language in light of the specification as it would be understood by one of ordinary skill in the art. The broadest reasonable interpretation of a claim element (also commonly referred to as a claim limitation) is limited by the description in the specification when 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, is invoked.

As explained in MPEP § 2181, subsection I, claim limitations that meet the following three-prong test will be interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph:

(A) the claim limitation uses the term "means" or "step" or a term used as a substitute for "means" that is a generic placeholder (also called a nonce term or a non-structural term having no specific structural meaning) for performing the claimed function;

(B) the term "means" or "step" or the generic placeholder is modified by functional language, typically, but not always linked by the transition word "for" (e.g., "means for") or another linking word or phrase, such as "configured to" or "so that"; and

(C) the term "means" or "step" or the generic placeholder is not modified by sufficient structure, material, or acts for performing the claimed function.

Use of the word "means" (or "step") in a claim with functional language creates a rebuttable presumption that the claim limitation is to be treated in accordance with 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph. The presumption that the claim limitation is interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, is rebutted when the claim limitation recites sufficient structure, material, or acts to entirely perform the recited function.

Absence of the word "means" (or "step") in a claim creates a rebuttable presumption that the claim limitation is not to be treated in accordance with 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph. The presumption that the claim limitation is not interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, is rebutted when the claim limitation recites function without reciting sufficient structure, material or acts to entirely perform the recited function.

Claim limitations in this application that use the word "means" (or "step") are being interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, except as

otherwise indicated in an Office action. Conversely, claim limitations in this application that do not use the word "means" (or "step") are not being interpreted under 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph, except as otherwise indicated in an Office action.

No elements are interpreted under 112(f).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112(a):

> (a) IN GENERAL.—The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention.

The following is a quotation of the first paragraph of pre-AIA 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3-4 and 40-41 are rejected under 35 U.S.C. 112(a) or 35 U.S.C. 112 (pre-AIA), first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor or a joint inventor, or for applications subject to pre-AIA 35 U.S.C. 112, the inventor(s), at the time the application was filed, had possession of the claimed invention.

The above claims recite a junction connecting the inlet port, sampling channel, and the chamber. However, as the instant invention appears to be drawn to the embodiment in Figure 24 and said junction has not been identified in Figure 24 per the drawing objection above, it is unclear that applicant has proper support for the embodiment of Figure 24 with the moving part having a first and second position along with said junction as claimed. If support exists for said junction, applicant is requested to point out portions of the disclosure showing said support.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries for establishing a background for determining obviousness under 35 U.S.C. 103 are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.

3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims the examiner presumes that the subject matter of the various claims was commonly owned as of the effective filing date of the claimed invention(s) absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and effective filing dates of each claim that was not commonly owned as of the effective filing date of the later invention in order for the examiner to consider the applicability of 35 U.S.C. 102(b)(2)(C) for any potential 35 U.S.C. 102(a)(2) prior art against the later invention.

Claim(s) 1-4, 6-7, 32, 34-38, and 40-41 is/are rejected under 35 U.S.C. 103 as being unpatentable over Cinqualbre et al (US Pat No. 3848581) in view of Eldridge (US Pat No. 4207870).

In regard to Claim 1, Cinqualbre et al disclose a device comprising:

an inlet port 2 (on end of needle 3) for receiving a blood sample, best seen in Figure 4 (Col.3: 36-Col.4: 32);

an outlet port 4 (second recess 4 from the left for second to left test tube 5), best seen in Figure 4 (Col.3: 36-Col.4: 32);

a chamber 5 (first test tube on left) connected with the inlet port and the outlet port (test tube 5 is connected to second left recess 4 by length of main canal 2), and configured to collect a first portion of the blood sample, the chamber including a material that is blood impermeable (i.e. the body 1) as well as vent 9 that is air permeable, best seen in Figure 4 (Col.3: 36-Col.4: 32);

a sampling channel 8 (second left transverse channel 8 that leads to second left recess 4 – defined as the outlet above) connected with the inlet port and configured to convey a subsequent portion of the blood sample to the outlet port while bypassing the chamber – after a first left test tube 5 (defined as the chamber above) is filled with blood, a second left test tube 5 (that is connected to the outlet defined as second left recess 4) is filled with blood, thus bypassing the first test tube/chamber as defined; and

a housing 1 that houses and defines the inlet port, the outlet port, the chamber, and the sampling channel, best seen in Figure 4 (Col.3: 36-Col.4: 32).

However, Cinqualbre et al do not expressly disclose the chamber having a material is that blood impermeable as well as air permeable. Cinqualbre et al does disclose each chamber or test tube 5 is connected to air passage 9, which enables air to escape (i.e. is air permeable) and thus vent the device to enable filling of the test tube 5 with blood.

Eldridge teach an analogous fluid sampling device comprising a plug 42 that vents using a material that is blood impermeable as well as air permeable to prevent the blood from spilling as well as prevent backflow during sampling as an analogous means of providing the desired air flow, best seen in Figure 1 and 3 (Col.2: 57-Col.3: 62).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of filing to modify the venting means of Cinqualbre et al such that it is a material that is blood impermeable as well as air permeable as taught by Eldridge above to prevent the blood from spilling as well as preventing backflow of the blood from the test tube during sampling.

2. Eldridge discloses the material is configured to seal upon contact with the first portion of the blood sample, best seen in Figure 1 and 3 (Col.2: 57-Col.3: 62).

3. Cinqualbre et al disclose a junction 12 (associated the second valve member 11 on left) connecting the inlet port 2 and the sampling channel 8 and the chamber 5 (first test tube on left), best seen in Figure 4 (Col.3: 36-Col.4: 32).

4. Cinqualbre et al disclose wherein the junction 12 as defined is configured to convey the subsequent portion of the blood sample to the outlet port 4 (defined as second recess 4 from left for second to left test tube 5) while bypassing the chamber 5 (first test tube on left), best seen in Figure 4 (Col.3: 36-Col.4: 32).

6. Cinqualbre et al disclose wherein the device is configured with a moving part 11 (associated with first left test tube 5) that is movable from a first position (valve 11 in open position) to a second position (valve 11 in closed position) to allow blood to bypass the chamber 5 (first test tube on left) and go through the sampling channel 8 (associated with second to left test tube 5) – when valve 11 of first left test tube is in the closed position (relative to the chamber 5 – defined as first left test tube), the blood flow is prevented from flowing into the chamber and thus bypasses said chamber as defined and flows into the second to left test tube, defined as the sampling channel, best seen in Figure 4 (Col.3: 36-Col.4: 32).

7. Cinqualbre et al disclose the moving part 11 as defined further configured to move from the first position to the second position after the first portion of blood flows into the chamber 5 – after the chamber (first test tube on left 5) is sufficiently filled, the user can close the valve 11 to move it into the closed position so that the next test tube in the series can be

filled, defined as the sampling channel leading to the outlet port 4 (defined relative to the second to left test tube 5), best seen in Figure 4 (Col.3: 36-Col.4: 32).

32. Cinqualbre et al disclose wherein the moving part 11 is an inner chamber housing, best seen in Figure 4 (Col.3: 36-Col.4: 32).

In regard to Claim 34, Cinqualbre et al disclose a device comprising:

an inlet port 2 (on end of needle 3) for receiving a blood sample, best seen in Figure 4 (Col.3: 36-Col.4: 32);

an outlet port 4 (second recess 4 from the left for second to left test tube 5), best seen in Figure 4 (Col.3: 36-Col.4: 32);

a chamber 5 (first test tube on left) connected with the inlet port and the outlet port (test tube 5 is connected to second left recess 4 by length of main canal 2), and configured to collect a first portion of the blood sample, the chamber including a material that is blood impermeable (i.e. the body 1) as well as vent 9 that is air permeable, best seen in Figure 4 (Col.3: 36-Col.4: 32);

a sampling channel 8 (second left transverse channel 8 that leads to second left recess 4 – defined as the outlet above) connected with the inlet port and the outlet port, the sampling channel and chamber configured to convey a subsequent portion of the blood sample through the sampling channel to the outlet port – after a first left test tube 5 (defined as the chamber above) is filled with blood, a second left test tube 5 (that is connected to the outlet defined as second left recess 4) is filled with blood; and

a housing 1 that houses and defines the inlet port, the outlet port, the chamber, and the sampling channel, best seen in Figure 4 (Col.3: 36-Col.4: 32).

However, Cinqualbre et al do not expressly disclose the chamber having a material is that blood impermeable as well as air permeable. Cinqualbre et al does disclose each chamber or test tube 5 is connected to air passage 9, which enables air to escape (i.e. is air permeable) and thus vent the device to enable filling of the test tube 5 with blood.

Eldridge teach an analogous fluid sampling device comprising a plug 42 that vents using a material that is blood impermeable as well as air permeable to prevent the blood from spilling as well as prevent backflow during sampling as an analogous means of providing the desired air flow, best seen in Figure 1 and 3 (Col.2: 57-Col.3: 62).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of filing to modify the venting means of Cinqualbre et al such that it is a material that is blood impermeable as well as air permeable as taught by Eldridge above to prevent the blood from spilling as well as preventing backflow of the blood from the test tube during sampling.

35. Eldridge discloses the device in accordance with claim 34, wherein the air permeable blood barrier is configured to seal upon contact with the first portion of the blood sample, best seen in Figure 1 and 3 (Col.2: 57-Col.3: 62).

36. Cinqualbre et al disclose the device in accordance with claim 34, wherein the device is configured with a moving part 11 (associated with first left test tube 5) that is movable from a first position (valve 11 in open position) to a second position (valve 11 in closed position) to allow blood to bypass the chamber 5 (first test tube on left) and go through the sampling

channel 8 (associated with second to left test tube 5) – when valve 11 of first left test tube is in the closed position (relative to the chamber 5 – defined as first left test tube), the blood flow is prevented from flowing into the chamber and thus bypasses said chamber as defined and flows into the second to left test tube, defined as the sampling channel, best seen in Figure 4 (Col.3: 36-Col.4: 32).

37. Cinqualbre et al disclose the device in accordance with claim 36, the moving part further configured to move from the first position to the second position after the first portion of blood flows into the chamber 5 – after the chamber (first test tube on left 5) is sufficiently filled with blood, the user can close the valve 11 to move it into closed position so that the next test tube in the series can be filled, defined as the sampling channel leading to the outlet port 4 (defined relative to the second to left test tube 5), best seen in Figure 4 (Col.3: 36-Col.4: 32).

38. Cinqualbre et al disclose the device in accordance with claim 36, wherein the moving part 11 is an inner chamber housing, best seen in Figure 4 (Col.3: 36-Col.4: 32).

40. Cinqualbre et al disclose the device in accordance with claim 34, further comprising a junction 12 (associated the second valve member 11 on left) connecting the inlet port 2 and the sampling channel 8 and the chamber 5 (first test tube on left), best seen in Figure 4 (Col.3: 36-Col.4: 32).

41. Cinqualbre et al disclose the device in accordance with claim 40, wherein the junction 12 as defined is configured to convey the subsequent portion of the blood sample to the outlet port 4 (defined as second recess 4 from left for second to left test tube 5) while bypassing the chamber 5 (first test tube on left), best seen in Figure 4 (Col.3: 36-Col.4: 32).

Claim(s) 33 and 39 is/are rejected under 35 U.S.C. 103 as being unpatentable over Cinqualbre et al in view of Eldridge, further in view of Vaillancouert (US Pat No. 6126643).

Cinqualbre et al in view of Eldridge disclose the inventio above but do not expressly disclose a locking mechanism configured to maintain the moving part in the first position until the chamber is filled, providing force to overcome the locking mechanism to enable movement of the moving part to the second position.

Vaillancouert teach that it is well-known in the art to provide an analogous blood sampling device comprising a locking mechanism 24 that enables plunger 21 to be releasably locked relative to barrel 11 so that blood is selectively introduced into the syringe, best see n in Figure 4-5 (Col.4: 63-Col.5: 53). Vaillancouert also teaches that other suitable releasable locking means may also be used to secure the plunger 21 relative to the barrel 11 (Col.5: 8-9).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of filing to modify the invention of Cinqualbre et al in view of Eldridge such that there is a locking mechanism configured to selectively maintain the moving part in the first position until the chamber is filled, as taught by Vaillancouert, to effectively prevent the moving part (valve 11 of Cinqualbre et al) from prematurely closing the window 12 before blood sufficiently fills chamber 5 (defined as first test tube on left), which when combined with the user, would thus provide force to overcome the locking mechanism to enable movement of the moving part to the second position as desired. It is noted that the disclosure does not provide any detail into how force would overcome the locking mechanism other than as broadly as has been claimed.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on nonstatutory double patenting provided the reference application or patent either is shown to be commonly owned with the examined application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. See MPEP § 717.02 for applications subject to examination under the first inventor to file provisions of the AIA as explained in MPEP § 2159. See MPEP § 2146 *et seq.* for applications not subject to examination under the first inventor to file provisions of the AIA. A terminal disclaimer must be signed in compliance with 37 CFR 1.321(b).

The USPTO Internet website contains terminal disclaimer forms which may be used. Please visit www.uspto.gov/patent/patents-forms. The filing date of the application in which the form is filed determines what form (e.g., PTO/SB/25, PTO/SB/26, PTO/AIA/25, or PTO/AIA/26) should be used. A web-based eTerminal Disclaimer may be filled out completely online using web-screens. An eTerminal Disclaimer that meets all requirements is auto-processed and approved immediately upon submission. For more information about eTerminal Disclaimers, refer to www.uspto.gov/patents/process/file/efs/guidance/eTD-info-I.jsp.

Claims 1 and 34 are rejected on the ground of nonstatutory double patenting as being unpatentable over claim 5 of U.S. Patent No. 9820682.

Although the claims at issue are not identical, they are not patentably distinct from each other because both recite a device comprising: an inlet port for receiving a blood sample; an outlet port; a chamber connected with the inlet port and the outlet port, and configured to collect a first portion of the blood sample, the chamber including a material that is an air permeable blood barrier; a sampling channel connected with the inlet port and the outlet port, the sampling channel and chamber configured to convey a subsequent portion of the blood sample through the sampling channel to the outlet port while bypassing the chamber; and a housing that houses and defines the inlet port, the outlet port, the chamber, and the sampling channel.

Claims 1 and 34 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 10010282.

Although the claims at issue are not identical, they are not patentably distinct from each other because both recite a device comprising: an inlet port for receiving a blood sample; an outlet port; a chamber connected with the inlet port and the outlet port, and configured to collect a first portion of the blood sample, the chamber including a material that is an air permeable blood barrier; a sampling channel connected with the inlet port and the outlet port, the sampling channel and chamber configured to convey a subsequent portion of the blood sample through the sampling channel to the outlet port while bypassing the chamber; and a housing that houses and defines the inlet port, the outlet port, the chamber, and the sampling channel.

Claim 1 and 34 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1 and 18 of U.S. Patent No. 10143412.

Although the claims at issue are not identical, they are not patentably distinct from each other because both recite a device comprising: an inlet port for receiving a blood sample; an outlet port; a chamber connected with the inlet port and the outlet port, and configured to collect a first portion of the blood sample, the chamber including a material that is an air permeable blood barrier; a sampling channel connected with the inlet port and the outlet port, the sampling channel and chamber configured to convey a subsequent portion of the blood sample through the sampling channel to the outlet port while bypassing the chamber; and a housing that houses and defines the inlet port, the outlet port, the chamber, and the sampling channel.

Claim 1 and 34 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1, 3, and 20-21 of U.S. Patent No. 11185266.

Although the claims at issue are not identical, they are not patentably distinct from each other because both recite a device comprising: an inlet port for receiving a blood sample; an outlet port; a chamber connected with the inlet port and the outlet port, and configured to collect a first portion of the blood sample, the chamber including a material that is an air permeable blood barrier; a sampling channel connected with the inlet port and the outlet port, the sampling channel and chamber configured to convey a subsequent portion of the blood sample through the sampling channel to the outlet port while bypassing the chamber; and a housing that houses and defines the inlet port, the outlet port, the chamber, and the sampling channel.

Claim 1 and 34 are rejected on the ground of nonstatutory double patenting as being unpatentable over claim 1 of U.S. Patent No. 10827964.

Although the claims at issue are not identical, they are not patentably distinct from each other because both recite a device comprising: an inlet port for receiving a blood sample; an outlet port; a chamber connected with the inlet port and the outlet port, and configured to collect a first portion of the blood sample, the chamber including a material that is an air permeable blood barrier; a sampling channel connected with the inlet port and the outlet port, the sampling channel and chamber configured to convey a subsequent portion of the blood sample through the sampling channel to the outlet port while bypassing the chamber; and a

housing that houses and defines the inlet port, the outlet port, the chamber, and the sampling channel.

Claim 1 and 34 are rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-2 and 8-9 of U.S. Patent No. 11311219.

Although the claims at issue are not identical, they are not patentably distinct from each other because both recite a device comprising: an inlet port for receiving a blood sample; an outlet port; a chamber connected with the inlet port and the outlet port, and configured to collect a first portion of the blood sample, the chamber including a material that is an air permeable blood barrier; a sampling channel connected with the inlet port and the outlet port, the sampling channel and chamber configured to convey a subsequent portion of the blood sample through the sampling channel to the outlet port while bypassing the chamber; and a housing that houses and defines the inlet port, the outlet port, the chamber, and the sampling channel.

Response to Arguments

Applicant's arguments with respect to claim(s) above have been considered but are moot because the new ground of rejection does not rely on any reference applied in the prior rejection of record for any teaching or matter specifically challenged in the argument.

The previous Drawing objections and 112 rejections are moot in light of applicant's amendments.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Huong Q NGUYEN whose telephone number is (571)272-8340. The examiner can normally be reached on 10 am - 6 pm.

Examiner interviews are available via telephone, in-person, and video conferencing using a USPTO supplied web-based collaboration tool. To schedule an interview, applicant is encouraged to use the USPTO Automated Interview Request (AIR) at http://www.uspto.gov/interviewpractice.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert (Tse) Chen can be reached at 5712723672. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

H.Q. NGUYEN
Examiner
Art Unit 3791

/DEVIN B HENSON/
Primary Examiner, Art Unit 3791

פ.ק 13

תאריך : כ״ג שבט תשפ״ג
14/02/2023
מספרכם : 1000-018-01

לכבוד
כץ, פרזנטי ושות׳
דרך אבא הלל 14,
רמת גן, מיקוד 52506

א. ג. נ.,

הנדון : **<u>הודעה לפני קיבול בקשת פטנט מספר 267684</u>**

סימוכין : מכתבכם מיום 23/10/2022

לתשומת לבכם: מקום בו הנכם מופנים ל״חוק״, הכוונה היא לחוק הפטנטים, התשכ״ז – 1967. מקום בו הנכם מופנים ל״תקנות״, הכוונה היא לתקנות הפטנטים (נוהלי הרשות, סדרי דין, מסמכים ואגרות), התשכ״ח – 1968. בהתאם לחוזר רשם 035/2017 – פטנטים **לא ניתן להשהות פרסום בקשות פטנט לפי סעיף 26 לחוק.**

<u>הודעה זו מבוססת על המסמכים הבאים:</u>
שרטוטים מתאריך : 26/06/2019
פרטי הבקשה מתאריך : 26/06/2019
תביעות מתאריך : 23/10/2022

<u>מענה לטיעוני המבקש</u>
מערכת התביעות המוצעת מתקבלת.

<u>הריני להודיעכם כי בחינת הבקשה הנ״ל הושלמה לפי הוראות סעיף 48ו(ג)(1) ו- (2) לחוק.</u>

<u>תשלום אגרת קיבול</u>

1. הבקשה תתקבל בהתאם לסעיף 26 לחוק לאחר תשלום אגרת הקיבול.
2. יש לשלם את האגרה תוך 3 חודשים מתאריך הודעה זו.
3. סכום האגרה נכון למועד הודעה זו הינו 764.00 ש״ח. הסכום כפוף לעדכונו על פי המדד בהתאם לתקנה 6א.

<u>הפניה בפירוט למסמך הבכורה</u>

לפי הוראות **סעיף 20 לחוזר הרשם 034/2017-פטנטים** במידה ופירוט הבקשה מכיל הפניה למסמך בכורה באמצעות הביטוי ״incorporated by reference״ ובמידה וחלפו 14 חודשים ממועד דין הקדימה (אם נדרש) לא ניתן עוד להוסיף דבר מתוך מסמך הבכורה והמבקש לא יכול להסתמך על האמור במסמך הבכורה, לצורך סעיפים 12 ו-13 לחוק.

<u>עדכון רשימות האסמכתאות והפרסומים לפי סעיף 18א לחוק</u>

לתשומת לבכם, בהתאם להוראות פרק ג' בחוזר רשם 035/2017-פטנטים חובת המבקש לעדכן את הרשות בכל שינוי שחל ברשימת הפרסומים בהתאם לסעיף 18 לחוק נמשכת עד קיבול הבקשה.

באם ברצונכם להחזיר את הבקשה לבחינה בעקבות שינוי ברשימת הפרסומים שהתרחש לאחר תשובתכם להודעת הליקויים האחרונה, עליכם להגיש בקשה לבחינה חוזרת בה עליכם לציין מהו השינוי ברשימת הפרסומים ומתי נודע על שינוי זה.

בקשה לבחינה חוזרת יש להגיש באמצעות פניה ל-"בקשה לתיקונים לאחר פ.ק. 13".

<u>הגשת בקשות חלוקה</u>

בהתאם להוראות סעיף 24(א) לחוק זכאי המבקש כל עוד לא קובלה הבקשה לדרוש את חלוקת הבקשה לבקשות אחדות. לפיכך, באם ברצונכם להגיש בקשות חלוקה מבקשה זו עליכם לעשות זאת בטרם מועד הקיבול. לא נוכל להכיר בבקשות שיוגשו לאחר מועד הקיבול של הבקשה הנוכחית כבקשות חלוקה לעניין סעיף 24(ג) לחוק.

<u>בדיקה פורמלית</u>

להודעה הנוכחית מצורף העתק פירוט הבקשה המעודכן - אם נפלו טעויות נא להודיע עליהן לרשות לפני מועד תשלום אגרת הקיבול.

לצורך אימות פרטי הפרסום בהתאם לסעיף 26 לחוק ניתן לעיין בנסח הבקשה באתר הרשות בקישור הבא:

https://israelpatents.justice.gov.il/#/en/patent-extract/267684

ניתן לעיין בפרטי תיק הבקשה באתר הרשות בקישור:

https://israelpatents.justice.gov.il/#/en/patent-file/details/267684

בכבוד רב

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20 February 2023

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To the attention of Jim Conley

P.K. 13 - Notice of Acceptance of:

IL Patent Application No.: 267684
Title: BLOOD SAMPLE OPTIMIZATION SYSTEM AND BLOOD CONTAMINANT SEQUESTRATION DEVICE AND METHOD
Filing Date: 26 June 2019
App. date: 27 December 2017
IL NP of PCT Patent Application No.: PCT/US2017/068569
Applicant(s): KURIN, INC.

Dear Jim:

1 We are pleased to report that the above identified Israel Patent Application has been accepted by the Israel Patent Office (ILPO), which issued the herein attached Notice of Acceptance dated **14 February 2023**.

The Applicant is now required to pay the Allowance Fee, by the due date of **14 May 2023**.

After the payment of the allowance fee the application shall be published for 3rd party opposition for a period of 3 months, after which if no opposition is filed the Certificate of patent will be issued.

This notice of acceptance is based on the following documents:

Drawings dated 26 June 2019
Claims dated 23 October 2022
Description dated 26 June 2019

The examiner has advised that the applicant must inform the ILPO should any opposition procedure or requests to cancel the parallel AU patent are filed before and up to the date of Grant of this application

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www.patents-il.com

Attached for your kind attention are:

- The allowed Description
- The allowed Claims
- The allowed Drawings

Please review the attached documents, namely the allowed description, claims and drawings before authorizing us to pay the allowance fee. Of course, we will review the documents as well.

We additionally remind you of the continuing responsibility of the Applicant to update the ILPO with information of cited art and/or opposition procedure and/or cancellation procedures in corresponding Applications under Section 18 of the Israel Patent Law - until the payment of the allowance fee. When the Applicant becomes aware of publications or other citations that may be relevant information/material to the examination of this application, such information/material must be forwarded to us for reporting to the ILPO. Failure to disclose such information to the ILPO may result in cancellation of an issued IL patent.

Publications filed after this notice will not be reviewed but will be on record. Should the applicant wish to receive continued examination based on new publications, a request to file for re-examination must be filed along with an update of the list of publications.

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Divisional Applications

Please be advised that pursuant to Art. 24(a) of the Act, divisional applications may be filed after the payment of the Allowance fee but before the publication. We highly recommend filng divisional applications before the payment of the allowance fee.

We look forward to receiving your instructions in due course.

Yours sincerely,

Ronen Presenti

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Submitted herewith

> The original notice in Hebrew.

> The publication documents, namely, Description, Claims, Drawings.

> Our invoice number 3083.

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BLOOD SAMPLE OPTIMIZATION SYSTEM AND BLOOD CONTAMINANT SEQUESTRATION DEVICE AND METHOD

ABSTRACT

Blood sample optimization systems and methods are described that reduce or eliminate contaminates in collected blood samples, which in turn reduces or eliminates false positive readings in blood cultures or other testing of collected blood samples. A blood sample optimization system can include a blood sequestration device located between a patient needle and a sample needle. The blood sequestration device can include a sequestration chamber for sequestering an initial, potentially contaminated aliquot of blood, and may further include a sampling channel that bypasses the sequestration chamber to convey likely uncontaminated blood between the patient needle and the sample needle after the initial aliquot of blood is sequestered in the sequestration chamber.

BACKGROUND

[0001] Bacteraemia is the presence of microorganisms in the blood. Sepsis, on the other hand, is bacteraemia in the presence of clinical symptoms and signs such as fever, tachycardia, tachypnea and hypotension. Bacteraemia and sepsis are associated with a high mortality and an increased incidence and duration of hospital stay and associated costs. Many bacteraemias, sepsis, fungaemias and other pathogens actually occur within a hospital or other healthcare settings with catheters and venipunctures being a source of contamination as potential carriers of these pathogens.

[0002] Blood cultures are the standard test used to detect microbial pathogens related to bacteraemia and sepsis in a patient's blood. The term blood culture refers to a single venipuncture, either from a peripheral site or central or arterial line, with the blood inoculated into one or more blood culture bottles or containers. One bottle is considered a blood culture where two or more are considered a set. Multiple sets may be obtained from multiple venipunctures and are associated with different sites on the patient.

[0003] These methods allow for microbial identification and susceptibility testing to be performed, which is a critical component to managing sepsis, however the lack of

rapid results and decreased sensitivity for fastidious pathogens has led to the development of improved systems and adjunctive molecular or proteomic testing.

[0004] Collection of blood samples for conducting blood cultures is a critical component of modern patient care and can either positively affect the patient outcome by providing an accurate diagnosis, or can adversely affect the outcome by prolonging unnecessary antimicrobial therapy, the length of hospital stays, and increasing costs.

[0005] One outcome of collection of blood cultures is contamination. Blood culture contamination can lead to a false positive culture result and/or significant increase in healthcare related costs. Sources of blood culture contamination include improper skin antisepsis, improper collection tube disinfection, and contamination of the initial blood draw which may then skew results.

[0006] Blood culture collection kits generally consist of a "butterfly" set, infusion set, or other type of venipuncture device as offered by companies like BD, Smiths, B. Braun and others, and aerobic and anaerobic blood culture bottles. Various different bottles are also available depending on the test requirements. These bottles are specifically designed to optimize recovery of both aerobic and anaerobic organisms. In conventional kits, a bottle used is known generally as a "Vacutainer," which is a blood collection tube formed of a sterile glass or plastic tube with a closure that is evacuated to create a vacuum inside the tube to facilitate the draw of a predetermined volume of liquid such as blood.

[0007] False positive blood cultures are typically a result of poor sampling techniques. They cause the use of antibiotics when not needed, increasing hospital costs and patient anxiety. Blood cultures are drawn from a needlestick into the skin, and then a Vacutainer is attached to capture a sample of blood. Contamination may occur from improper or incomplete disinfection of the skin area in and around the puncture site. It may also occur from the coring of the skin by the needle during insertion, with the cored skin cells and any associated contamination being pulled into the sample.

[0008] Blood flow through a hypodermic needle is laminar, and as such, a velocity gradient can be developed over the flow tube as a pressure drop is applied to the hypodermic needle. Either forceful aspiration of blood, or using a very small hypodermic

needle, can cause lysis and a release of potassium from the red blood cells, thereby rendering the blood samples abnormal.

[0009] In other instances, some patients have delicate veins that can collapse under a pressure drop or vacuum, particularly as applied by a syringe's plunger that is drawn too quickly for the patient's condition. Since such condition is impossible to know beforehand, such vein collapses are a risk and very difficult to control.

[0010] Various strategies have been implemented to decrease blood culture contamination rates, e.g. training staff with regard to aseptic collection technique, feedback with regard to contamination rates and implementation of blood culture collection kits. Although skin antisepsis can reduce the burden of contamination, 20% or more of skin organisms are located deep within the dermis and are unaffected by antisepsis. Changing needles before bottle inoculation is not advisable as it increases the risk to acquire needle stick injuries without decreasing contamination rates.

[0011] Some conventional systems and techniques for reducing blood culture contamination include discarding the initial aliquot of blood taken from central venous catheters, venipunctures, and other vascular access systems. However, these systems require the user to mechanically manipulate an intravascular device, or require a complex series of steps that are difficult to ensure being followed.

SUMMARY

[0012] This document presents systems and methods for reducing blood culture contamination, lysing of cells, and vein collapse. In some implementations, a system and method can eliminate user variability in disinfection, and also eliminate the risk of skin cells getting into the blood culture sample. The systems and methods disclosed herein do not require a change in existing clinical processes, other than to potentially indicate when a vacutainer or other blood collection device (i.e., syringe) should be attached for drawing contaminant-free blood samples.

[0013] In some implementations of the systems and methods disclosed herein the withdrawal of blood is accomplished passively by use of the patient's own blood pressure, thereby reducing the risk of vein collapse and eliminating any additional user steps over current practice. The systems and methods can be applied to accommodate

short-path direct stick or butterfly venipuncture systems. They can also be used with samples drawn through a catheter.

[0014] In one aspect, a blood sequestration device is presented. The blood sequestration device includes an inlet port and an outlet port. The blood sequestration device further includes a sequestration chamber connected with the inlet port, the sequestration chamber having a vent comprising an air permeable blood barrier. The blood sequestration device further includes a sampling channel having a proximal end connected with the inlet port and a distal end connected with the outlet port.

[0015] In another aspect, a blood sequestration device connected with a blood sampling pathway is described. The blood sampling pathway has a patient needle and a sample collection device. The blood sequestration device includes an inlet port connected with the patient needle, and a sequestration chamber connected with the inlet port, the sequestration chamber having a vent comprising an air permeable blood barrier. The blood sequestration device further includes a sampling channel having a proximal end connected with the inlet port, and an outlet port connected with a distal end of the sampling channel and with the sample collection device.

[0016] In yet another aspect, a blood sequestration device connected with a blood sampling system is described. The blood sampling system includes a patient needle for accessing a blood sample from a patient, and a sample needle that is sealed and adapted for receiving an evacuated blood collection tube. The blood sequestration device includes an inlet port connected with the patient needle to receive the blood sample from the patient. The blood sequestration device further includes a sequestration chamber connected with the inlet port and having a vent comprising an air permeable blood barrier, the sequestration chamber for receiving and sequestering a first portion of the blood sample prior to the sample needle being unsealed by the evacuated blood collection tube. The blood sequestration device further includes a sampling channel having a proximal end connected with the inlet port, the sampling channel for conveying a subsequent portion of the blood sample once the sample needle is unsealed by the evacuated blood collection tube. The blood sequestration device further includes an outlet port connected with a distal end of the sampling channel for conveying the subsequent portion of the blood sample to the sample needle.

[0017] In yet another aspect, a blood sample optimization system is disclosed and described. The blood sample optimization system includes a blood sampling system for accessing and acquiring one or more samples of a patient's blood, and a blood sequestration device for receiving and sequestering a first portion of the one or more samples of the patient's blood which might be contaminated by a venipuncture process and which could result in a false positive identification of a pathogen in the patient's blood.

[0018] The blood sampling system includes a patient needle configured for a venipuncture of a patient to access a sample of blood of a patient, a blood sampling pathway connected with the patient needle for conveying the sample of blood, and a sample needle configured for receiving an evacuated blood collection container to collect and contain a subsequent portion of the sample of blood.

[0019] In yet another aspect, a blood sequestration device is disclosed and described. In some implementations, the blood sequestration device can include an inlet port, an outlet port connected with the inlet port, and a sequestration chamber connected with the inlet port. The sequestration chamber can have a vent comprising an air permeable blood barrier.

[0020] The blood sequestration device, in one aspect can include an inlet port, an outlet port, a sequestration chamber connected with the inlet port via a junction, the sequestration chamber having a vent that includes an air permeable blood barrier, the vent being defined by an outer wall that at least partially circumscribes the air permeable blood barrier and includes one or more air vents, the vent further includes a cap that at least partially covers the wall and a one-way seal abutting the air permeable blood barrier that inhibits air from entering the sequestration chamber, and a sampling channel having a proximal end connected with the inlet port via the junction, and a distal end connected with the outlet port. In certain related aspects, the sequestration chamber, the sampling channel and the junction are sized and configured such that a first portion of blood flows into the sequestration chamber toward the air permeable blood barrier for sequestration therein, and a second portion of blood bypasses the sequestration chamber and the first portion of blood sequestered therein and is directed into the sampling channel toward the outlet port.

[0021] In another aspect, the sampling channel and the junction is sized and configured such that a first portion of blood flows into and fills the sequestration chamber to displace air therein through the vent, and such that a second portion of blood bypasses the sequestration chamber and the first portion of blood sequestered therein and is directed into the sampling channel toward the outlet port.

[0022] The blood sequestration and sampling system sequestration device, in certain aspects can include a blood sampling pathway having a patient needle on a proximal end and a sample collection device on a distal end; and a blood sequestration device attached on the blood sampling pathway between the proximal end and distal end of the blood sampling pathway. The blood sequestration device in one aspect can include an inlet port coupled with the blood sampling pathway toward the patient needle, an outlet port coupled with the blood sampling pathway toward the sample collection device, a sequestration chamber connected with the inlet port via a junction, which chamber has a vent that includes an air permeable blood barrier, the vent being defined by an outer wall that at least partially circumscribes the air permeable blood barrier and includes one or more air vents, the vent further including a cap that at least partially covers the wall and a one-way seal abutting the air permeable blood barrier that inhibits air from entering the sequestration chamber; and a sampling channel having a proximal end connected with the inlet port via the junction, and a distal end connected with the outlet port. In a certain related aspect, the sequestration chamber, the sampling channel and the junction can be sized and configured such that a first portion of blood flows into the sequestration chamber toward the air permeable blood barrier for sequestration therein, and a second portion of blood bypasses the sequestration chamber and the first portion of blood sequestered therein and is directed into the sampling channel toward the outlet port.

[0023] The blood sequestration device is connected along the blood sampling pathway between the patient needle and the sample needle, and includes an inlet port for receiving the sample of blood. The blood sequestration device further includes a sequestration chamber connected with the inlet port for receiving a first amount of the sample of blood, the sequestration chamber having a vent comprising an air permeable blood barrier for sequestering at least a first portion of the first amount of the sample of blood. The blood sequestration device may further include a sampling channel having a proximal end connected with the inlet port, the sampling channel conveying a subsequent amount of the sample of blood to the evacuated blood collection container upon the

sequestration chamber sequestering at least the first portion of the first amount of the sample of blood. The blood sequestration device further includes an outlet port connected with a distal end of the sampling channel, the outlet port for outputting the subsequent amount of the sample of blood.

[0024] The details of one or more embodiments are set forth in the accompanying drawings and the description below. Other features and advantages will be apparent from the description and drawings, and from the claims.

BRIEF DESCRIPTION OF THE DRAWINGS

[0025] These and other aspects will now be described in detail with reference to the following drawings.

[0026] FIG. 1 illustrates a blood sample optimization system.

[0027] FIG. 2 illustrates a blood sample optimization system in accordance with an alternative implementation.

[0028] FIG. 3 illustrates a blood sample optimization system in accordance with another alternative implementation.

[0029] FIG. 4 illustrates a blood sample optimization system in accordance with another alternative implementation.

[0030] FIG. 5 illustrates a blood sample optimization system in accordance with another alternative implementation.

[0031] FIG. 6 illustrates a blood sample optimization system in accordance with an alternative implementation.

[0032] FIG. 7 is a flowchart of a method for optimizing a quality of a blood culture.

[0033] FIGS. 8A – 8E illustrate a blood sequestration system for non-contaminated blood sampling, in accordance with some implementations.

[0034] FIG. 9 illustrates a pathway splitter for use in a blood sequestrations system.

[0035] FIGS. 10A – 10D illustrate a blood sequestration system for non-contaminated blood sampling, in accordance with alternative implementations.

[0036] FIGS. 11A – 11E illustrate a blood sequestration system for non-contaminated blood sampling, in accordance with other alternative implementations.

[0037] FIGS. 12A-12D illustrate a blood sample optimization system including a blood sequestration device in accordance with yet other alternative implementations.

[0038] FIGS. 13A-13D illustrate a blood sample optimization system 1300 in accordance with yet another alternative implementations.

[0039] FIGS. 14A-14E illustrate yet another implementation of a blood sampling system to sequester contaminates of an initial aliquot or sample to reduce false positives in blood cultures or tests performed on a patient's blood sample.

[0040] FIGS. 15A-15G illustrate a blood sequestration device and method of using the same, in accordance with yet another implementation.

[0041] FIGS. 16A-16D illustrate a blood sequestration device in accordance with yet another implementation.

[0042] FIGS. 17A – 17E illustrate a bottom member of a housing for a blood sequestration device.

[0043] FIGS. 18A – 18F illustrate a top member of a housing for a blood sequestration device.

[0044] FIGS. 19A and 19B illustrate a blood sequestration device having a top member mated with a bottom member.

[0045] FIG. 20 shows a blood sample optimization system including a blood sequestration device.

[0046] FIG. 21 illustrates a non-vented blood sequestration device using a wicking material chamber.

[0047] FIGS. 22A and 22B illustrate a material makeup of a filter for sequestering blood in a sequestration chamber of a blood sequestration device.

[0048] FIGS. 23A – 23E illustrate another implementation of a blood sequestration device that uses a vacuum force from a blood collection device.

[0049] FIGS. 24A – 24D illustrate another implementation of a blood optimization system and blood sequestration device.

[0050] FIGS. 25A – 25D illustrate another implementation of a blood optimization system and blood sequestration device.

[0051] FIGS. 26A – 26E illustrate another implementation of a blood optimization system and blood sequestration device.

[0052] FIGS. 27A – 27D illustrate another implementation of a blood optimization system and blood sequestration device.

[0053] FIGS. 28A – 28F illustrate another implementation of a blood optimization system and blood sequestration device.

[0054] FIGS. 29A – 29C illustrate another implementation of a blood optimization system and blood sequestration device.

[0055] FIGS. 30A – 30G illustrate another implementation of a blood optimization system and blood sequestration device.

[0056] Like reference symbols in the various drawings indicate like elements.

DETAILED DESCRIPTION

[0057] This document describes blood sample optimization systems and methods for reducing or eliminating contaminates in collected blood samples, which in turn reduces or eliminates false positive readings in blood cultures or other testing of collected blood samples. In some implementations, a blood sample optimization system includes a patient needle for vascular access to a patient's bloodstream, a sample needle for providing a blood sample to a blood collection container, such as an evacuated blood collection container or tube like a Vacutainer™ or the like, or other sampling device, and

a blood sequestration device located between the patient needle and the sample needle. The blood sequestration device includes a sequestration chamber for sequestering an initial, potentially contaminated aliquot of blood, and may further include a sampling channel that bypasses the sequestration chamber to convey likely uncontaminated blood between the patient needle and the sample needle after the initial aliquot of blood is sequestered in the sequestration chamber.

[0058] FIG. 1 illustrates a blood sample optimization system in accordance with some implementations. The system includes a patient needle 1 to puncture the skin of a patient to access the patient's vein and blood therein. The system further includes a sample needle (i.e., a resealably closed needle for use with Vacutainers™ or the like) 5, which may be contained within and initially sealed by a resealable boot 10, a Luer activated valve, or another collection interface or device. The resealable boot 10 can be pushed aside or around the sample needle 5 by application of a Vacutainer™ bottle (not shown) for drawing the patient's blood. The system can further include a low volume chamber 30 that leads to the sample needle 5, but also includes an orifice or one or more channels 45 that lead to a sequestration chamber 55 formed by a housing 50.

[0059] The sequestration chamber 55 is a chamber, channel, pathway, lock, or other structure for receiving and holding a first aliquot of the patient's blood, which may be in a predetermined or measured amount, depending on a volume of the sequestration chamber 55. The first draw of blood typically contains or is more susceptible to containing organisms that cause bacteraemia and sepsis or other pathogens than subsequent blood draws. The sequestration chamber 55 can be a vessel encased in a solid housing, formed in or defined by the housing itself, or can be implemented as tubing or a lumen. The sequestration chamber 55, regardless how formed and implemented, may have a predetermined volume. In some implementations, the predetermined volume may be based on a volume of the patient needle, i.e. ranging from less than the volume of the patient needle to any volume up to or greater than 20 times or more of the volume of the patient needle. The predetermined volume of the sequestration chamber 55 may also be established to economize or minimize an amount of blood to be sequestered and disposed of.

[0060] The sequestration chamber 55 can be formed, contained or housed in a chamber housing 50, and can be made of plastic, rubber, steel, aluminum or other suitable

material. For example, the sequestration chamber 55 could be formed of flexible tubing or other elastomeric materials. The sequestration chamber 55 further includes an air permeable blood barrier 20 that allows air to exit the sequestration chamber 55. As used herein the term "air permeable blood barrier" means an air permeable but substantially blood impermeable substance, material, or structure. Examples may include hydrophobic membranes and coatings, a hydrophilic membrane or coating combined with a hydrophobic membrane or coating, mesh, a filter, a mechanical valve, antimicrobial material, or any other means of allowing air to be displaced from the sequestration chamber 55 as it is filled with blood. In various exemplary embodiments, an air permeable blood barrier may be formed by one or more materials that allow air to pass through until contacted by a liquid, such material then becomes completely or partially sealed to prevent or inhibit the passage of air and/or liquid. In other words, prior to contact with liquid, the material forms a barrier that is air permeable. After contact with a liquid, the material substantially or completely prevents the further passage of air and/or liquid.

[0061] The orifice or channel 45 can be any desired length, cross-sectional shape or size, and/or can be formed to depart from the low volume chamber 30 at any desired angle or orientation. The orifice or channel 45 may also include a one-way flap or valve 60 that maintains an initial aliquot of blood sample within the sequestration chamber 55. In some specific implementations, the orifice or channel 45 can include a "duck bill" or flapper valve 60, or the like, for one-way flow of blood from low volume chamber 30 to the sequestration chamber 55. The air permeable blood barrier 20 can also be constructed of a material that allows air to exit but then seals upon contact with blood, thereby not allowing external air to enter sequestration chamber 55. This sealing would eliminate the need for a valve.

[0062] Valve 60 can be any type of valve or closing mechanism. Chamber 30 is designed to hold virtually no residual blood, and can be designed to be adapted to hold or allow pass-through of a particular volume or rate of blood into sequestration chamber 55. Likewise, sequestration chamber 55 may also include any type of coating, such as an anti-microbial coating, or a coating that aids identification and/or diagnosis of components of the first, sequestered blood draw.

[0063] Housing 50 and 40 can be formed of any suitable material, including plastic, such as acrylonitrile butadiene styrene (ABS) or other thermoplastic or polymeric material, rubber, steel, or aluminum. The air permeable blood barrier 20 can include a color-providing substance, or other signaling mechanism, that is activated upon contact with blood from the initial blood draw, or when air displacement is stopped, or any combination of events with blood in the sequestration chamber 55. The air permeable barrier may also include an outer layer such as a hydrophobic membrane or cover that inhibits or prevents the inadvertent or premature sealing of the filter by an external fluid source, splash etc. Sequestration chamber 55 can also be translucent or clear to enable a user to visually confirm the chamber is filled.

[0064] FIG. 2 illustrates a blood sample optimization system in accordance with some alternative implementations. In the implementation shown in FIG. 2, a sequestration chamber 55, or waste chamber, surrounds the patient needle 1, with an open-ended cuff or housing connected with the waste chamber and encircling the sample needle housing base and housing. The patient needle 1 and sample needle 5 are connected together by a boot 56, which forms a continuous blood draw channel therethrough. The boot 56 includes a single orifice or channel leading from the blood draw channel into sequestration chamber 55. The device can include more than one single orifice or channel, in other implementations. Each orifice or channel can include a one-way valve, and can be sized and adapted for predetermined amount of blood flow.

[0065] The sequestration chamber 55 includes an air permeable blood barrier. The filter can further include a sensor or indicator to sense and/or indicate, respectively, when a predetermined volume of blood has been collected in the sequestration chamber 55. That indication will alert a user to attach an evacuated blood collection tube or bottle, such as a Vacutainer™ to the sample needle 5. The housing for the sequestration chamber 55 can be any size or shape, and can include any type of material to define an interior space or volume therein. The interior space is initially filled only with air, but can also be coated with an agent or substance, such as a decontaminate, solidifying agent, or the like. Once evacuated blood collection tube is attached to the sample needle 5, blood will flow automatically into the patient needle 1, through the blood draw channel and sample needle 5, and into the bottle. The sample needle 5 is covered by a resealable boot, coating or membrane that seals the sample needle when a blood collection bottle is not attached thereon or thereto.

[0066] FIG. 3 illustrates a blood sample optimization system in accordance with some alternative implementations. In the implementation shown, a sample needle 5 is surrounded by a resealable boot or membrane, and is further connected with a patient needle 1. A blood flow channel is formed through the sample needle and the patient needle. The connection between the sample needle and patient needle includes a "T" or "Y" connector 102, which includes a channel, port or aperture leading out from the main blood flow channel to a sequestration chamber 104.

[0067] The T or Y connector 102 may include a flap or one-way valve, and have an opening that is sized and adapted for a predetermined rate of flow of blood. The sequestration chamber 104 can be formed from tubing, or be formed by a solid housing, and is initially filled with air. The sequestration chamber 104 will receive blood that flows out of a patient automatically, i.e. under pressure from the patient's own blood pressure. The sequestration chamber 104 includes an air permeable blood barrier 106, preferably at the distal end of tubing that forms the sequestration chamber 104, and which is connected at the proximal end to the T or Y connector 102. The T or Y connector 102 can branch off at any desired angle for most efficient blood flow, and can be formed so as to minimize an interface between the aperture and channel and the main blood flow channel, so as to minimize or eliminate mixing of the initial aliquot of blood with main blood draw samples.

[0068] In some alternative implementations, the sample needle may be affixed to a tubing of any length, as shown in FIG. 4, connecting at its opposite end to the T or Y connector 102. The sequestration chamber 104 can be any shape or volume so long as it will contain a predetermined amount of blood sample in the initial aliquot. The T or Y connector 102 may also include an opening or channel that is parallel to the main blood flow channel. The air permeable blood barrier may further include an indicator 107 or other mechanism to indicate when a predetermined amount of blood has been collected in the sequestration chamber, or when air being expelled reaches a certain threshold, i.e. to zero. The tubing can also include a clip 109 that can be used to pinch off and prevent fluid flow therethrough.

[0069] Once the air permeable blood barrier and primary chamber are sealed the initial aliquot of blood is trapped in the sequestration chamber 104, an evacuated blood collection tube, such as a Vacutainer™ bottle may be attached to the sample needle 5 to

obtain the sample. The blood collection tube can be removed, and the sample needle 5 will be resealed. Any number of follow-on blood collection tubes can then be attached for further blood draws or samples. Upon completion of all blood draws, the system can be discarded, with the initial aliquot of blood remaining trapped in the sequestration chamber 104.

[0070] FIG. 5 illustrates a blood sample optimization system in accordance with some alternative implementations. In the implementation shown, a sample needle 5 is connected with a patient needle by tubing. A "T" or "Y" connector 120 is added along the tubing at any desired location, and includes an aperture, port or channel leading to a sequestration chamber 204, substantially as described above.

[0071] FIG. 6 illustrates a blood sample optimization system in accordance with some alternative implementations, in which a sequestration chamber 304, formed as a primary collection channel, receives an initial aliquot of blood, and is provided adjacent to the blood sampling channel. The sequestration chamber 304 can encircle the blood sampling channel, the patient needle 1, and/or the sample needle 5. The primary collection channel can include a T or Y connector 120, or other type of aperture or channel. The sequestration chamber 304 includes an air permeable blood barrier, which can also include an indicator of being contacted by a fluid such as blood, as described above.

[0072] In some implementations, either the patient needle 1 or the sample needle 5, or both, can be replaced by a Luer lock male or female connector. However, in various implementations, the connector at a sample needle end of the blood sample optimization system is initially sealed to permit the diversion of the initial aliquot of blood to the sequestration chamber, which is pressured at ambient air pressure and includes the air outlet of the air permeable blood barrier. In this way, the system passively and automatically uses a patient's own blood pressure to overcome the ambient air pressure of the sequestration chamber to push out air through the air permeable blood barrier and displace air in the sequestration chamber with blood.

[0073] FIG. 7 is a flowchart of an exemplary method for optimizing the quality of a blood culture. At 702, a clinician places a needle into a patient's vein. At 704, blood then flows into a sequestration chamber, pushing the air in the sequestration chamber out

of the sequestration chamber through an air permeable blood barrier. In some implementations, the volume of the sequestration chamber is less than 0.1 to more than 5 cubic centimeters (cc's), or more. The sequestration chamber is sized and adapted to collect a first portion of a blood sample, which is more prone to contamination than secondary and other subsequent portion of the blood sample or subsequent draws. Since the sequestration chamber has an air-permeable blood barrier through which air can be displaced by blood pushed from the patient's vein, such blood will naturally and automatically flow into the sequestration chamber before it is drawn into or otherwise enters into a Vacutainer or other bottle for receiving and storing a blood sample.

[0074] When the sequestration chamber fills, the blood will gather at or otherwise make contact with the air permeable blood barrier, which will inhibit or prevent blood from passing therethrough. At 706, when the blood comes into contact with the entire internal surface area of the air permeable blood barrier, the air permeable blood barrier is then closed and air no longer flows out or in. At 708, the clinician may be provided an indictor or can see the full chamber, to indicate the evacuated blood collection tube, such as a Vacutainer™ can be attached. The indicator can include visibility into the primary chamber to see whether it is full, the blood barrier changing color, for example, or other indicator. The fill time of the sequestration chamber may be substantially instantaneous, so such indicator, if present, may be only that the sequestration chamber is filled.

[0075] Prior to an evacuated blood collection tube being attached, communication between the needle, sampling channel, and the sequestration chamber is restricted by the sealing of the sequestration chamber blood barrier thereby not permitting air to reenter the system through the sequestration. Sealing the communication path could also be accomplished with a mechanical twist or other movement, a small orifice or tortuous pathway, eliminating the need for a separate valve or mechanical movement or operation by the clinician. At 710, once the evacuated blood collection tube is removed, the self-sealing membrane closes the sample needle, and at 712, additional subsequent evacuated blood collection tubes may be attached. Once samples have been taken, at 714 the device is removed from the patient and discarded.

[0076] FIGS. 8A – 8E illustrate an exemplary blood sample optimization system 800 for non-contaminated blood sampling, in accordance with some implementations. The blood sample optimization system 800 includes an inlet port 802 that can be

connected to tubing, a patient needle (or both), or other vascular or venous access device, and a pathway splitter 804 having a first outlet to a sequestration chamber tubing 806 and a second outlet to sample collection tubing 808. One or both of the sequestration chamber tubing 806 and the sample collection tubing 808 can be formed of tubing. In some implementations, the sequestration chamber tubing 806 is sized so as to contain a particular volume of initial blood sample. The sample collection tubing 808 will receive a blood sample once the sequestration chamber tubing 806 is filled. The sample collection tubing 808 can be connected to a Vacutainer™ base or housing 810, or other blood sample collection device.

[0077] The blood sequestration system 800 further includes a blood sequestration device 812 which, as shown in more detail in FIGS. 8B – 8D, includes a housing 818 that includes a sampling channel 820 defining a pathway for the non-contaminated sample collection tubing 808 or connected at either end to the non-contaminated sample collection tubing 808. The sampling channel 820 can be curved through the housing 818 so as to better affix and stabilize the housing 818 at a location along the non-contaminated sample collection tubing 808.

[0078] The blood sequestration device 812 further includes a sequestration chamber 822 connected with the sequestration chamber tubing 806 or other chamber. The sequestration chamber 822 terminates at an air permeable blood barrier 824. The air permeable blood barrier 824 can also include a coloring agent that turns a different color upon full contact with blood, as an indicator that the regular collection of blood samples (i.e. the non-contaminated blood samples) can be initiated. Other indicators may be used, such as a small light, a sound generation mechanism, or the like. In some implementations, the air permeable blood barrier is positioned at a right angle from the direction of sequestration chamber 822, but can be positioned at any distance or orientation in order to conserve space and materials used for the housing 818. The housing 818 and its contents can be formed of any rigid or semi-rigid material or set of materials.

[0079] FIG. 9 illustrates a pathway splitter 900 for use in a blood sequestrations system, such as those shown in FIGS. 8A – 8E, for example. The pathway splitter 900 includes an inlet port 902, a main line outlet port 904, and a sequestration channel outlet port 906. The inlet port 902 can be connected to main tubing that is in turn connected to a

patient needle system, or directly to a patient needle. The main line outlet port 904 can be connected to main line tubing to a blood sampling system, such as a vacutainer base or housing, or directly to such blood sampling system. The sequestration channel outlet port 906 can be connected to sequestration tubing for receiving and sequestering a first sample of blood, up to a measured amount or predetermined threshold. Alternatively, the sequestration channel outlet port 906 can be connected to a sequestration chamber. The sequestration channel outlet port 906 is preferably 20-70 degrees angled from the main line outlet port 904, which in turn is preferably in-line with the inlet port 902. Once the predetermined amount of initial blood sample is sequestered in the sequestration tubing or chamber, in accordance with mechanisms and techniques described herein, follow-on blood samples will flow into the inlet port 902 and directly out the main line outlet port 904, without impedance.

[0080] FIGS. 10A – 10D illustrate a blood sequestration device 1000 in accordance with alternative implementations. The blood sequestration device 1000 includes an inlet port 1002, a main outlet port 1004, and a sequestration channel port 1006. The inlet port 1002 can be connected to a patient needle or related tubing. The main outlet port 1004 can be connected to a blood sample collection device such as a Vacutainer, associated tubing, or a Luer activated valve, or the like. The sequestration channel port 1006 splits off from the main outlet port 1004 to a sequestration chamber 1008. In some implementations, the sequestration chamber 1008 is formed as a helical channel within a housing or other container 1001.

[0081] The sequestration chamber 1008 is connected at the distal end to an air permeable blood barrier 1010, substantially as described above. Air in the sequestration chamber 1008 is displaced through the air permeable blood barrier 1010 by an initial aliquot of blood that is guided into the sequestration channel port 1006. Once the sequestration chamber 1008 is filled, further blood draws through the main outlet port 1004 can be accomplished, where these samples will be non-contaminated.

[0082] FIGS. 11A – 11E illustrate a blood sequestration device 1100 in accordance with other alternative implementations. The blood sequestration device 1100 includes an inlet port 1102, similar to the inlet ports described above, a main outlet port 1104, and a sequestration channel port 1106 that splits off from the main outlet port 1104 and inlet port 1102. The sequestration channel port is connected to a sequestration

chamber 1108. In the implementation shown in FIGS. 11A – 11E, the blood sequestration device includes a base member 1101 having a channel therein, which functions as the sequestration chamber 1108. The channel can be formed as a tortuous path through the base member 1101, which is in turn shaped and formed to rest on a limb of a patient.

[0083] A portion of the sequestration chamber 1108 can protrude from the base member or near a top surface of the base member, just before exiting to an air permeable blood barrier 1110, to serve as a blood sequestration indicator 1109. The indicator 1109 can be formed of a clear material, or a material that changes color when in contact with blood.

[0084] In some implementations, the blood sequestration device 1100 can include a blood sampling device 1120 such as a normally closed needle, Vacutainer™ shield or other collection device. The blood sampling device 1120 can be manufactured and sold with the blood sequestration device 1100 for efficiency and convenience, so that a first aliquot of blood that may be contaminated by a patient needle insertion process can be sequestered. Thereafter, the blood sampling device 1120 can draw non-contaminated blood samples to reduce the risk of false positive testing and ensure a non-contaminated sample.

[0085] FIGS. 12A-12D illustrate a blood sample optimization system 1200 in accordance with yet other alternative implementations. The system 1200 includes a blood sequestration device 1202 for attaching to a blood sampling device 1204, such as a Vacutainer™ or other collection and sampling device. The blood sequestration device 1202 is configured and arranged to receive, prior to a Vacutainer™ container or vial being attached to a collection needle of the blood sampling device 1204, a first aliquot or amount of blood, and sequester that first aliquot or amount in a sequestration channel of the blood sequestration device 1202.

[0086] In some implementations, the blood sequestration device 1202 can include an inlet port 1212, a main outlet port, and a sequestration channel port. The inlet port 1212 can be connected to a patient needle or related tubing. The main outlet port 1214 can be connected to a normally closed needle or device to enable connection with an evacuated blood collection container or other collection device such as a Vacutainer™,

associated tubing, luer connectors, syringe, a Luer activated valve, or the like. The sequestration channel port splits off from the main outlet port to a sequestration chamber 1218.

[0087] In some implementations, the sequestration chamber 1218 is formed as a channel within the body of a sequestration device 1202. The sequestration chamber 1218 can be a winding channel, such as a U-shaped channel, an S-shaped channel, a helical channel, or any other winding channel. The sequestration device 1202 can include a housing or other containing body, and one or more channels formed therein. As shown in FIGS. 12A and 12B, the sequestration device 1202 includes a main body 1206 and a cap 1208. The main body 1206 is formed with one or more cavities or channels, which are further formed with one or more arms 1210 that extend from the cap 1208, and which abut the cavities or channels in the main body 1206 to form the primary collection port and main outlet port.

[0088] FIGS. 13A-13D illustrate a blood sample optimization system 1300 in accordance with yet other alternative implementations. The system 1300 includes a blood sequestration device 1302 for attaching to a blood sampling device 1304, such as a Vacutainer or other bodily fluid collection and sampling device. The blood sequestration device 1302 is configured and arranged to receive, prior to a Vacutainer container or vial being attached to a collection needle of the blood sampling device 1304, a first aliquot or amount of blood, and to sequester that first aliquot or amount of blood or other bodily fluid in a sequestration channel of the blood sequestration device 1302.

[0089] The blood sequestration device 1302 includes a housing 1301 having an inlet port 1314, a main outlet port 1312, and a sequestration channel port 1316. The inlet port 1314 can be connected to a patient needle or associated tubing. The main outlet port 1312 can be connected to a normally closed needle or device to enable connection with an evacuated blood collection container or other collection device such as a Vacutainer™, associated tubing, luer connectors, syringe, a Luer activated valve, or the like. The sequestration channel port 1316 splits off from the main inlet port 1314 to a sequestration chamber 1318.

[0090] In the implementation shown in FIGS. 13A-D, the sequestration chamber 1318 is formed as a cavity or chamber within housing 1301 or formed by walls that define

housing 1301. The sequestration chamber 1318 can be a winding channel, such as a U-shaped channel, an S-shaped channel, a helical channel, or any other winding channel, that is defined by the cooperation and connection of housing 1301 with cap 1307 which cap 1307 can include a protrusion 1305 that provides one or more walls or directors for the winding channel in the sequestration chamber 1318. The protrusion 1305 from the cap 1307 can be straight or curved, and may have various channels, apertures or grooves embedded therein, and can extend from the cap 1307 any angle or orientation. When the cap 1307 is connected with the housing 1301 to complete the formation of the sequestration chamber 1318, the protrusion 1305 forms at least part of the winding channel to sequester a first aliquot or amount of blood or other bodily fluid in a sequestration channel formed in the sequestration chamber 1318 and by the winding channel.

[0091] The sequestration chamber 1318 includes an air permeable blood barrier 1310, substantially as described above. Air in the sequestration chamber 1318 is displaced through the air permeable blood barrier 1310 by an initial aliquot of blood that is provided into the sequestration chamber 1318 by the blood pressure of the patient. Once the sequestration chamber 1318 is filled and the air in the sequestration chamber 1318 displaced, the blood pressure of the patient will be insufficient to drive or provide further blood into the blood sequestration device 1302, and in particular the outlet port 1312, until a force such as a vacuum or other pressure, such as provided by the blood sample collection device like Vacutainer is provided to draw out a next aliquot or amount of blood or bodily fluid. Further blood draws through the main outlet port 1312 can be accomplished, where these samples will be non-contaminated since any contaminants would be sequestered in the sequestration chamber 1318 with the first aliquot of blood.

[0092] FIGS. 14A-14E illustrate yet another implementation of a blood sampling system 1400 to sequester contaminates of an initial aliquot or sample to reduce false positives in blood cultures or tests performed on a patient's blood sample. The blood sampling system 1400 includes a blood sequestration device 1401 that can be connected between a blood sample collection device 1403 and a patient needle (not shown). The blood sample collection device 1403 can be a Vacutainer or the like. The blood sequestration device 1401 includes an inlet port 1402 that can be connected with a patient needle that is inserted into a patient's vascular system for access to and withdrawing of a

blood sample. The inlet port 1402 may also be connected with tubing or other conduit that is in turn connected with the patient needle.

[0093] The inlet port 1402 defines an opening into the blood sequestration device 1401, which opening can be the same cross sectional dimensions as tubing or other conduit connected with the patient needle or the patient needle itself. For instance, the opening can be circular with a diameter of approximately 0.045 inches, but can have a diameter of between 0.01 inches or less to 0.2 inches or more. The blood sequestration device 1401 further includes an outlet port 1404, which defines an opening out of the blood sequestration device 1401 and to the blood sample collection device 1403. The outlet port 1404 may also be connected with tubing or other conduit that is in turn connected with the blood sequestration device 1403. The outlet port 1404 can further include a connector device such as a threaded cap, a Luer connector (male or female), a non threaded interference or glue joint fitting for attachment of various devices including but not limited to tubing, or the like.

[0094] The blood sequestration device 1401 further includes a sampling channel 1406 between the inlet port 1402 and the outlet port 1404, and which functions as a blood sample pathway once a first aliquot of blood has been sequestered. The sampling channel 1406 can be any sized, shaped or configured channel, or conduit. In some implementations, the sampling channel 1406 has a substantially similar cross sectional area as the opening of the inlet port 1402. In other implementations, the sampling channel 1406 can gradually widen from the inlet port 1402 to the outlet port 1404.

[0095] The blood sequestration device 1401 further includes a sequestration chamber 1408 that is connected to and split off or diverted from the sampling channel 1406 at any point between the inlet port 1402 and the outlet port 1404, but preferably from a proximal end of the sampling channel 1406 near the inlet port 1402. The sequestration chamber 1408 is at first maintained at atmospheric pressure, and includes an air outlet 1412 at or near a distal end of the sequestration chamber 1408 opposite the diversion point from the sampling channel 1406. The air outlet 1412 includes an air permeable blood barrier 1412. As shown in FIG. 14B, the air permeable blood barrier 1412 can be overlaid with a protective cover 1416. The protective cover 1416 can be sized and configured to inhibit a user from touching the air permeable blood barrier 1412 with their finger or other external implement, while still allowing air to exit the air

permeable blood barrier 1412 as the air is displaced from the sequestration chamber 1408 by blood being forced into the sequestration chamber 1408 by a patient's own blood pressure. In addition the protective cover 1416 can be constructed to inhibit or prevent accidental exposure of the air permeable blood barrier to environmental fluids or splashes. This can be accomplished in a variety of mechanical ways including but not limited to the addition of a hydrophobic membrane to the protective cover.

[0096] As shown in FIGS. 14C and 14D, the sampling channel 1406 can be cylindrical or frusto-conical in shape, going from a smaller diameter to a larger diameter, to minimize a potential to lyse red blood cells. Likewise, the sampling channel 1406 is formed with a minimal amount of or no sharp turns or edges, which can also lyse red blood cells. The sampling channel 1406 splits off to the sequestration chamber 1408 near the inlet port 1402 via a diversion pathway 1409. The diversion pathway 1409 can have any cross-sectional shape or size, but is preferably similar to the cross-sectional shape of at least part of the inlet port 1402.

[0097] In some implementations, the sampling channel 1406 and the sequestration chamber 1408 are formed by grooves, channels, locks or other pathways formed in housing 1414. The housing 1414 can be made of plastic, metal or other rigid or semi-rigid material. The housing 1414 can have a bottom member that sealably mates with a top member. One or both of the bottom member and the top member can include the sampling channel 1406 and the sequestration chamber 1408, as well as the diversion pathway 1409, the inlet port 1402, and the outlet port 1404. In some other implementations, one or more of the diversion pathway 1409, the inlet port 1402, and/or the outlet port 1404 can be at least partially formed by a cap member that is connected to either end of the housing 1414. In some implementations, the top member and the bottom member, as well as the cap member(s), can be coupled together by laser welding, heat sealing, gluing, snapping, screwing, bolting, or the like. In other implementations, some or all of the interior surface of the diversion pathway 1409 and/or sequestration chamber 1408 can be coated or loaded with an agent or substance, such as a decontaminate, solidifying agent, or the like. For instance, a solidifying agent can be provided at the diversion pathway 1409 such that when the sequestration chamber 1408 is filled and the initial aliquot of blood backs up to the diversion pathway 1409, that last amount of sequestered blood could solidify, creating a barrier between the sequestration chamber 1408 and the sampling channel 1406.

[0098] FIGS. 15A-15G illustrate a blood sequestration device 1500. The blood sequestration device 1500 can be connected to a normally closed needle or device to enable connection with an evacuated blood collection container or other collection device such as a Vacutainer™, associated tubing, luer connectors, syringe, a Luer activated valve, or the like.

[0099] The blood sequestration device 1500 includes an inlet port 1502 that can be connected with a patient needle that is inserted into a patient's vascular system for access to and withdrawing of a blood sample. The inlet port 1502 may also be connected with tubing or other conduit that is in turn connected with the patient needle. The inlet port 1502 defines an opening into the blood sequestration device 1500, which opening may be the same cross sectional dimensions as tubing or other conduit connected with the patient needle or the patient needle itself. For instance, the opening can be circular with a diameter of approximately 0.045 inches, but can have a diameter of between 0.01 inches or less to 0.2 inches or more.

[00100] The inlet port 1502 can also include a sealing or fluid-tight connector or connection, such as threading or Luer fitting, or the like. In some implementations, tubing or other conduit associated with the patient needle can be integral with the inlet port 1502, such as by co-molding, gluing, laser weld, or thermally bonding the parts together. In this manner, the blood sequestration device 1500 can be fabricated and sold with the patient needle as a single unit, eliminating the need for connecting the patient needle to the blood sequestration device 1500 at the time of blood draw or sampling.

[00101] The blood sequestration device 1500 further includes an outlet port 1504, which defines an opening out of the blood sequestration device 1500 and to the blood sample collection device. The outlet port 1504 may also be connected with tubing or other conduit that is in turn connected with the blood sequestration device, and may also include a sealing or fluid-tight connector or connection, such as threading or Luer fitting, or the like. Accordingly, as discussed above, the blood sequestration device 1500 can be fabricated and sold with the patient needle and/or tubing and the blood sample collection device as a single unit, eliminating the need for connecting the patient needle and the blood sample collection device to the blood sequestration device 1500 at the time of blood draw or sampling.

[00102] The blood sequestration device 1500 further includes a sampling channel 1506 between the inlet port 1502 and the outlet port 1504, and which functions as a blood sample pathway once a first aliquot of blood has been sequestered. The sampling channel 1506 can be any sized, shaped or configured channel or conduit. In some implementations, the sampling channel 1506 has a substantially similar cross sectional area as the opening of the inlet port 1502. In other implementations, the sampling channel 1506 can gradually widen from the inlet port 1502 to the outlet port 1504.

[00103] The blood sequestration device 1500 further includes a sequestration chamber 1508 that is connected to and split off or diverted from the sampling channel 1506 at any point between the inlet port 1502 and the outlet port 1504, but preferably from a proximal end of the sampling channel 1506 near the inlet port 1502. In some implementations, the diversion includes a Y-shaped junction. The sequestration chamber 1508 is preferably maintained at atmospheric pressure, and includes a vent 1510 at or near a distal end of the sequestration chamber 1508. The vent 1510 includes an air permeable blood barrier 1512. FIG. 15C illustrates the blood sequestration device 1500 with the sequestration chamber 1508 filled with a first aliquot or sample of blood from the patient.

[00104] The air permeable blood barrier 1512 can be covered with a protective cover 1516. The protective cover 1516 can be sized and configured to inhibit a user from touching the air permeable blood barrier 1512 with their finger or other external implement, while still allowing air to exit the air permeable blood barrier 1512 as the air is displaced from the sequestration chamber 1508 by blood being forced into the sequestration chamber 1508 by a patient's own blood pressure. The protective cover 1516 can be constructed to inhibit or prevent accidental exposure of the filter to environmental fluids or splashes. This can be accomplished in a variety of mechanical ways including but not limited to the addition of a hydrophobic membrane to the protective cover.

[00105] FIG. 15B is a perspective view of the blood sequestration device 1500 from the outlet port 1504 and top side of a housing 1501 of the blood sequestration device 1500 that includes the vent 1510, and illustrating an initial aliquot of blood filling sequestration chamber 1508 while the sampling channel 1506 is empty, before a sample collection device is activated. FIG. 15G is a perspective view of the blood sequestration

device 1500 from the outlet port 1504 and bottom side of the housing 1501 of the blood sequestration device 1500, and illustrating the initial aliquot of blood filling sequestration chamber 1508 while the sampling channel 1506 is empty, before the sample collection device is activated. FIG. 15C is another perspective view of the blood sequestration device 1500 from the inlet port 1502 and top side of a housing 1501 of the blood sequestration device 1500 that includes the vent 1510, and illustrating blood now being drawn through sampling channel 1506 while the sequestered blood remains substantially in the sequestration chamber 1508.

[00106] FIG. 15D is a cross section of the blood sequestration device 1500 in accordance with some implementations, showing the housing 1501 that defines the sampling channel 1506 and the sequestration chamber 1508. FIGS. 15E and 15F illustrate various form factors of a housing for a blood sequestration device, in accordance with one or more implementations described herein.

[00107] The sequestration chamber 1508 can have a larger cross-sectional area than the sampling channel 1506, and the cross-sectional area and length can be configured for a predetermined or specific volume of blood to be sequestered or locked. The sampling channel 1506 can be sized to be compatible with tubing for either or both of the patient needle tubing or the blood collection device tubing.

[00108] The housing 1501 can be formed of multiple parts or a single, unitary part. In some implementations, and as illustrated in FIG. 15D, the housing 1501 includes a top member 1520 and a bottom member 1522 that are mated together, one or both of which having grooves, channels, locks, conduits or other pathways pre-formed therein, such as by an injection molding process or by etching, cutting, drilling, etc. The top member 1520 can be connected with the bottom member 1522 by any mating or connection mechanism, such as by laser welding, thermal bonding, ultrasonic welding, gluing, using screws, rivets, bolts, or the like, or by other mating mechanisms such as latches, grooves, tongues, pins, flanges, or the like.

[00109] In some implementations, such as shown in FIG. 15D, the top member 1520 can include the grooves, channels, locks, conduits or other pathways, while the bottom member 1522 can include a protrusion 1524 that is sized and adapted to fit into at least one of the grooves, channels, locks or other pathways of the top member 1520. The

protrusion 1524 can provide a surface feature, such as a partial groove or channel, for instance, to complete the formation of either the sampling channel 1506 and/or the sequestration chamber 1508. In some implementations, the protrusion 1524 can be formed with one or more angled sides or surfaces for a tighter fit within the corresponding groove, channel, lock or other pathway. In yet other implementations, both the top member 1520 and the bottom member can include grooves, channels, locks or other pathways, as well as one or more protrusions 1524.

[00110] In some implementations, the sampling channel 1506 and the sequestration chamber 1508 are formed by grooves, channels, locks or other pathways formed in housing 1501. The housing 1501 can be made of any suitable material, including rubber, plastic, metal or other material. The housing 1501 can be formed of a clear or translucent material, or of an opaque or non-translucent material. In other implementations, the housing 1501 can be mostly opaque or non-translucent, while the housing surface directly adjacent to the sampling channel 1506 and/or the sequestration chamber 1508 is clear or translucent, giving a practitioner a visual cue or sign that the sequestration chamber 1508 is first filled to the extent necessary or desired, and/or then a visual cue or sign that the sequestered blood remains sequestered while a clean sample of blood is drawn through the sampling channel 1506. Other visual cues or signs of the sequestration can include, without limitation: the air permeable blood barrier 1512 turning a different color upon contact, saturation, or partial saturation with blood; a color-coded tab or indicator at any point along or adjacent to the sequestration chamber; an audible signal; a vibratory signal; or other signal.

[00111] After a venipuncture by a patient needle of a patient (not shown), which could gather a number of pathogens from the patient's skin, a first amount of the patient's blood with those pathogens will make its way into the inlet port 1502 blood sequestration device 1500 and flow into the sequestration chamber 1508 by following the path of least resistance, as the patient's own blood pressure overcomes the atmospheric pressure in the sequestration chamber 1508 to displace air therein through the air permeable blood barrier 1512. The patient's blood pressure will not be sufficient to overcome the air pressure that builds up in the sealed sampling channel 1506. Eventually, the sequestration chamber 1508, which has a predetermined volume, is filled with blood that displaces air through the air permeable blood barrier 1512. Once the blood hits the air permeable blood barrier, the blood interacts with the air permeable blood barrier 1512 material to completely or

partially seal the vent 1510. A signal or indication may be provided that the practitioner can now utilize the Vacutainer capsule or other blood sample collection device to acquire a next amount of the patient's blood for sampling. The blood in the sequestration chamber 1508 is now effectively sequestered in the sequestration chamber.

[00112] Upon filling the blood sequestration pathway 1508 but prior to use of the Vacutainer or other blood sample collection device, the patient's blood pressure may drive compression of the air in the sampling channel 1506, possibly resulting in a small amount of blood moving past the diversion point to the sequestration chamber 1508 and into the sampling channel 1506, queuing up the uncontaminated blood to be drawn through the sampling channel 1506.

[00113] In some instances, as shown in FIG. 15H, an inlet port 1532 can include a male luer connector for connecting to a removable patient needle, and an outlet port 11534 can include a female luer connector for connecting with a syringe. This implementation of the inlet port and outlet port can be used with any device described herein, for avoiding a propensity of a Vacutainer-type device collapsing a patient's vein. In this implementation, a clinician can use the syringe in a modulated fashion to obtain a blood sample. In operation, the syringe is attached to the outlet port 1004, and the needle is attached to the inlet port 1002. A venipuncture is performed with the needle, and without the clinician pulling on the syringe. An initial aliquot of blood fills a sequestration chamber, and then the syringe can be used to draw a sample of blood through the collection channel, bypassing the sequestered blood in the sequestration chamber.

[00114] FIGS. 16-19 illustrate yet another implementation of a blood sequestration device. FIGS. 16A-16D illustrate a blood sequestration device 1600 that can be connected between a blood sample collection device, such as an evacuated blood collection container like a Vacutainer™ (not shown), and a patient needle (not shown) and/or associated tubing. FIG. 17 illustrates a bottom member of the blood sequestration device, and FIG. 18 illustrates a top member of the blood sequestration device, which top member and bottom member can be mated together to form an inlet port, and outlet port, a sequestration chamber and a sampling channel, as explained more fully below. FIGS. 19A and B show the top member and bottom member mated together. It should be

understood that FIGS. 16-19 illustrate one exemplary manner of constructing a blood sequestration device as described herein, and other forms of construction are possible.

[00115] Referring to FIGS. 16A – D, the blood sequestration device 1600 includes an inlet port 1602 that can be connected with a patient needle that is inserted into a patient's vascular system for access to and withdrawing of a blood sample. The inlet port 1602 may also be connected with tubing or other conduit that is in turn connected with the patient needle. The inlet port 1602 defines an opening into the blood sequestration device 1600, which opening can be the same cross sectional dimensions as tubing or other conduit connected with the patient needle or the patient needle itself. For instance, the opening can be circular with a diameter of approximately 0.045 inches, but can have a diameter of between 0.01 inches or less to 0.2 inches or more.

[00116] The inlet port 1602 can also include a sealing or fluid-tight connector or connection, such as threading or Luer fitting, or the like. In some implementations, tubing or other conduit associated with the patient needle can be integral with the inlet port 1602, such as by co-molding, gluing, laser weld, or thermally bonding the parts together. In this manner, the blood sequestration device 1600 can be fabricated and sold with the patient needle and/or tubing as a single unit, eliminating the need for connecting the patient needle to the blood sequestration device 1600 at the time of blood draw or sampling.

[00117] The blood sequestration device 1600 further includes an outlet port 1604, which defines an opening out of the blood sequestration device 1600 and to the blood sample collection device. The outlet port 1604 may also be connected with tubing or other conduit that is in turn connected with the blood sequestration device, and may also include a sealing or fluid-tight connector or connection, such as threading or Luer fitting, or the like. Accordingly, as discussed above, the blood sequestration device 1600 can be fabricated and sold with the patient needle and/or tubing and the blood sample collection device as a single unit, eliminating the need for connecting the patient needle and the blood sample collection device to the blood sequestration device 1600 at the time of blood draw or sampling.

[00118] The blood sequestration device 1600 further includes a sampling channel 1606 between the inlet port 1602 and the outlet port 1604, and a sequestration chamber

1608 that is connected to and split off or diverted from the sampling channel 1606 at any point between the inlet port 1602 and the outlet port 1604. The sampling channel 1606 functions as a blood sampling pathway once a first aliquot of blood has been sequestered in the sequestration chamber 1608. The sampling channel 1606 can be any sized, shaped or configured channel, or conduit. In some implementations, the sampling channel 1606 has a substantially similar cross sectional area as the opening of the inlet port 1602. In other implementations, the sampling channel 1606 can gradually widen from the inlet port 1602 to the outlet port 1604. The sequestration chamber 1608 may have a larger cross section to form a big reservoir toward the sequestration channel path so that the blood will want to enter the reservoir first versus entering a smaller diameter on the sampling channel 1606, as is shown more fully in FIGS. 17 and 19.

[00119] In some exemplary implementations, the diversion between the sampling channel 1606 and the sequestration chamber 1608 is by diverter junction 1607. Diverter junction 1607 may be a substantially Y-shaped, T-shaped, or U-shaped. In some preferred exemplary implementations, and as shown in FIG. 17A – 17B, the diverter junction 1607 is configured such that the flow out of the inlet port 1602 is preferentially directed toward the sequestration chamber 1608. The sequestration chamber 1608 may also include or form a curve or ramp to direct the initial blood flow toward and into the sequestration chamber 1608.

[00120] The sequestration chamber 1608 is preferably maintained at atmospheric pressure, and includes a vent 1610 at or near a distal end of the sequestration chamber 1608. The vent 1610 may include an air permeable blood barrier 1612 as described above.

[00121] The blood sequestration device 1600 can include a housing 1601 that can be formed of multiple parts or a single, unitary part. In some implementations, and as illustrated in FIGS. 17A – 17E and FIGS. 18A – 18F, the housing 1601 includes a top member 1620 and a bottom member 1622 that are mated together. The blood sequestration device 1600 can also include a gasket or other sealing member (not shown) so that when the top member 1620 is mechanically attached with the bottom member 1622, the interface between the two is sealed by the gasket or sealing member. The FIGS. 17A – 17E illustrate a bottom member 1622 of a housing for a blood sequestration device 1600. The bottom member 1622 can include grooves, channels, locks, conduits or

other pathways pre-formed therein, such as by an injection molding process or by etching, cutting, drilling, etc., to form the sampling channel 1606, the sequestration chamber 1608, and diverter junction 1607.

[00122] The sequestration chamber 1608 may have a larger cross section than the sampling channel 1606 so that the blood will preferentially move into the sequestration chamber first versus entering a smaller diameter on the sampling channel 1606.

[00123] FIGS. 18A – 18F illustrate the top member 1620, which can be connected with the bottom member 1622 by any mating or connection mechanism, such as by laser welding, thermal bonding, gluing, using screws, rivets, bolts, or the like, or by other mating mechanisms such as latches, grooves, tongues, pins, flanges, or the like. The top member 1620 can include some or all of the grooves, channels, locks, conduits or other pathways to form the sampling channel 1606, the sequestration chamber 1608, and the diverter junction 1607. In yet other implementations, both the top member 1620 and the bottom member 1622 can include the grooves, channels, locks or other pathways.

[00124] In some implementations, the sampling channel 1606 and the sequestration chamber 1608 are formed by grooves, channels, locks or other pathways formed in housing 1601. The housing 1601 can be made of rubber, plastic, metal or any other suitable material. The housing 1601 can be formed of a clear or translucent material, or of an opaque or non-translucent material. In other implementations, the housing 1601 can be mostly opaque or non-translucent, while the housing surface directly adjacent to the sampling channel 1606 and/or the sequestration chamber 1608 may be clear or translucent, giving a practitioner a visual cue or sign that the sequestration chamber 1608 is first filled to the extent necessary or desired, and/or then a visual cue or sign that the sequestered blood remains sequestered while a clean sample of blood is drawn through the sampling channel 1606. Other visual cues or signs of the sequestration can include, without limitation: the air permeable blood barrier 1612 turning a different color upon contact, saturation, or partial saturation with blood; a color-coded tab or indicator at any point along or adjacent to the sequestration chamber; an audible signal; a vibratory signal; or other signal.

[00125] As shown in FIGS. 18A – 18F, the air permeable blood barrier 1612 can be covered with, or surrounded by, a protective member 1616. The protective member

1616 can be sized and configured to inhibit a user from touching the air permeable blood barrier 1612 with their finger or other external implement, while still allowing air to exit the air permeable blood barrier 1612 as the air is displaced from the sequestration chamber 1608. In some implementations, the protective member 1616 includes a protrusion that extends up from a top surface of the top member 1620 and around the air permeable blood barrier 1612. The protective member 1616 can be constructed to inhibit or prevent accidental exposure of the filter to environmental fluids or splashes. This can be accomplished in a variety of mechanical ways including but not limited to the addition of a hydrophobic membrane to the protective cover.

[00126] In use, the blood sequestration device 1600 includes a sampling channel 1606 and a sequestration chamber 1608. Both pathways are initially air-filled at atmospheric pressure, but the sampling channel 1606 is directed to an outlet port 1604 that will be initially sealed by a Vacutainer or other such sealed blood sampling device, and the sequestration chamber 1608 terminates at a vent 1610 to atmosphere that includes an air permeable blood barrier 1612.

[00127] After a venipuncture by a patient needle of a patient (not shown), which could gather a number of pathogens from the patient's skin, a first amount of the patient's blood with those pathogens will pass through inlet port 1602 of blood sequestration device 1600. This initial volume of potentially contaminated blood will preferentially flow into the sequestration chamber 1608 by finding the path of least resistance. The patient's own blood pressure overcomes the atmospheric pressure in the vented sequestration chamber 1608 to displace air therein through the air permeable blood barrier 1612, but is not sufficient to overcome the air pressure that builds up in the sealed sampling channel 1606. In various exemplary embodiments, the sequestration chamber 1608 and sampling channel 1606 can be configured such that the force generated by the patient's blood pressure is sufficient to overcome any effect of gravity, regardless of the blood sequestration device's orientation.

[00128] Eventually, the sequestration chamber 1608 fills with blood that displaces air through the air permeable blood barrier 1612. Once the blood contacts the air permeable blood barrier, the blood interacts with the air permeable blood barrier 1612 material to completely or partially seal the vent 1610. A signal or indication may be

provided that the practitioner can now utilize the Vacutainer or other blood sampling device.

[00129] Upon filling the blood sequestration pathway 1608 but prior to use of the Vacutainer or other blood sample collection device, the patient's blood pressure may drive compression of the air in the sampling channel 1606, possibly resulting in a small amount of blood moving past the diversion point into the sampling channel 1606, queuing up the uncontaminated blood to be drawn through the sampling channel 1606.

[00130] FIG. 19A is a side view, and FIG. 19B is a cross-sectional view, of the blood sequestration device 1600, illustrating the top member 1620 mated with the bottom member 1622.

[00131] FIG. 20 shows a blood sample optimization system 2000 that includes a patient needle 2002 for vascular access to a patient's bloodstream, a blood sample collection device 2004 to facilitate the collecting of one or more blood samples, and a conduit 2006 providing a fluid connection between the patient needle 2002 and the blood sample collection device 2004. In some implementations, the blood sample collection device 2004 includes a protective shield that includes a sealed collection needle on which a sealed vacuum-loaded container is placed, which, once pierced by the collection needle, draws in a blood sample under vacuum pressure or force through the conduit 2006 from the patient needle 2002.

[00132] The blood sample optimization system 2000 further includes a blood sequestration device 2008, located at any point on the conduit 2006 between the patient needle 2002 and the blood sample collection device 2004 as described herein.

[00133] FIG. 21 illustrates a non-vented blood sequestration device 2100 using a wicking material chamber. The blood sequestration device 2100 includes a housing 2101 that has a sampling channel 2104 that is at least partially surrounded or abutted by a sequestration chamber 2102 that is filled with a wicking material. An initial aliquot of blood is drawn in from the patient needle into the sampling channel 2104 where it is immediately wicked into the wicking material of the sequestration chamber 2102. The wicking material and/or sequestration chamber 2102 is sized and adapted to receive and hold a predetermined amount of blood, such that follow-on or later blood draws pass by the wicking material and flow straight through the sampling channel 2104 to a sampling

device such as a Vacutainer. The wicking material can include a substance such as a solidifier, a decontaminate, or other additive.

[00134] As described herein, an air permeable blood barrier may be created using a wide variety of different structures and materials. As shown in FIGS. 22A and B, an air permeable blood barrier 2202 of a blood sequestration device 2200 can include a polymer bead matrix 2204, in which at least some beads are treated to make them hydrophilic. The air permeable blood barrier 2202 further includes a self-sealing material 2206, such as carboxymethyl cellulose (CMC) or cellulose gum, or other sealing material. The air permeable blood barrier 2202 can further include voids 2208 that permit air flow before contact or during partial contact with a fluid such as blood. As shown in FIG. 22B, contact with a fluid causes the self-sealing material 2206 to swell and close off the voids 2208, occluding air flow through the voids 2208 and creating a complete or partial seal.

[00135] FIGS. 23A and B illustrate yet another implementation of a blood sequestration device 2300, having an inlet port 2302 to connect with a patient needle, an outlet port 2304 to connect with a blood sample collection device, a sequestration chamber 2306, and a sampling channel 2308 that bypasses the sequestration chamber 2306 once the sequestration chamber is filled to an initial aliquot of potentially contaminated blood to be sequestered. The sequestration chamber 2306 includes a hydrophobic plug 2312 at a distal end of the sequestration chamber 2306 that is farthest from the inlet port 2302. A vacuum or other drawing force applied from the outlet port 2304, such as from a Vacutainer or the like, draws in blood into the inlet port 2302 and directly into the sequestration chamber 2306, where the initial aliquot of blood will contact the hydrophobic plug 2312 and cause the initial aliquot of blood to back up into the sequestration chamber 2306 and be sequestered there. A small amount of blood may make its way into the sampling channel 2308, which is initially closed off by valve 2308. Upon release of the valve 2308, and under further force of the vacuum or other force, follow-on amounts of blood will flow into inlet port 2302, bypass the sequestration chamber 2306, and flow into and through sampling channel 2308 toward the outlet port 2304 and to the collection device.

[00136] The sampling channel 2308 can have any suitable geometry and can be formed of plastic tubing or any other suitable material. Valve 2308 can be a clip or other enclosing device to pinch, shunt, bend or otherwise close off the sampling channel 2308

before the initial aliquot of blood is sequestered in the sequestration chamber 2306. For instance, valve 2308 can also be formed as a flap, door or closable window or barrier within the sampling channel 2308.

[00137] FIGS. 23C – 23E illustrate an alternative implementation of the blood sequestration device 2300', in which a sequestration chamber 2320 branches off from a main collection channel 2322 between an inlet port 2316 to connect with a patient needle and an outlet port 2318 to connect with a blood sample collection device, such as a Vacutainer, a syringe, or the like. The sequestration chamber 2320 includes an air-permeable, blood impermeable blood barrier 2324, such as a hydrophobic plug of material, or a filter formed of one or more layers, for example. A valve 2324 closes off and opens the collection channel 2322, and the device 2300' can be used similarly as described above.

[00138] FIG. 24A – 24D illustrate a blood sample optimization system 2400 that includes a patient needle 2402 for vascular access to a patient's bloodstream, a blood sample collection device 2404 to facilitate the collecting of one or more blood samples for blood testing or blood cultures, and a conduit 2406 providing a fluid connection between the patient needle 2402 and the blood sample collection device 2404. In some implementations, the blood sample collection device 2404 includes a protective shield that includes a sealed collection needle on which a sealed vacuum-loaded container is placed, which, once pierced by the collection needle, draws in a blood sample under vacuum pressure or force through the conduit 2006 from the patient needle 2402.

[00139] The blood sample optimization system 2400 further includes a blood sequestration device 2408, located at any point on the conduit 2406 between the patient needle 2402 and the blood sample collection device 2404. The location of the blood sequestration device 2408 can be based on a length of the conduit between the blood sequestration device 2408 and the patient needle 2402, and the associated volume that length provides.

[00140] The blood sequestration device 2408 includes an inlet port 2412 for being connected to the conduit 2406 toward the patient needle 2402, and an outlet port 2414 for being connected to the conduit 2406 toward the blood sample collection device 2404, and a housing 2416. The housing 2416 can be any shape, although it is shown in FIGS. 24A

– D as being substantially cylindrical, and includes the inlet port 2412 and outlet port 2414, which can be located anywhere on the housing although shown as being located on opposite ends of the housing 2416.

[00141] The blood sequestration device 2408 further includes a blood sequestration chamber 2418 connected with the inlet port 2412. The blood sequestration chamber 2418 is defined by an inner chamber housing 2419 that is movable from a first position to receive and sequester a first aliquot of blood, to a second position to expose one or more apertures 2424 at a proximal end of the inner chamber housing 2419 to allow blood to bypass and/or flow around the inner chamber housing 2419 and through a blood sample channel 2422 defined by the outer surface of the inner chamber housing 2419 and the inner surface of the housing 2416. The blood sequestration chamber 2418 includes an air permeable blood barrier 2420 at a distal end of the blood sequestration chamber 2418.

[00142] In operation, the inner chamber housing 2419 is in the first position toward the inlet port 2412, such that the one or more apertures 2424 are closed, and the blood sequestration chamber 2418 is in a direct path from the patient needle. Upon venipuncture of a patient, and drawing of blood by way of a syringe or Vacutainer, or other blood collection device 2404, the initial aliquot of blood flows into the blood sequestration chamber 2418. As the initial aliquot of blood flows into the blood sequestration chamber, it displaces air therein and eventually the blood contacts the blood barrier 2420, forcing the inner chamber housing to the second position. The inner chamber housing 2419 and/or housing 2416 can include a locking mechanism of one or more small tabs, grooves, detents, bumps, ridges, or the like, to maintain the inner chamber housing 2419 in the first position until the blood sequestration chamber 2418 is filled, providing force to overcome the locking mechanism to enable movement of the inner chamber housing 2419 to the second position. Once in the second position, the initial aliquot of blood is sequestered in the blood sequestration chamber 2418 and the one or more apertures 2424 are opened to create a pathway from the inlet port 2412 to the blood sampling channel 2422, bypassing and/or flowing around the blood sequestration chamber 2418.

[00143] As described above, the housing 2416 and/or inner chamber housing 2419 can be formed as cylindrical and concentric, but can be any shape, such as squared, rectangular, elliptical, oval, or other cross-sectional shape. The outer surface of the distal

end of the inner chamber housing 2419 can have one or more outwardly projecting tangs 2421with gaps therebetween. The tangs 2421 contact the inner surface of the housing 2416 to help define the blood sampling channel 2422 therebetween, and to help stop the inner chamber housing 2419 in the second position. The gaps between the tangs 2421 enable blood to flow through the blood sampling channel 2422 and to the outlet port 2414. When the inner chamber housing 2419 is in the second position and the blood sequestration chamber 2418 is filled with the first aliquot of blood, further blood samples will automatically flow through the inlet port 2412, through the one or more apertures 2424, through the blood sampling channel 2422, through the gaps between the tangs 2421, and ultimately through the outlet port 2414 to be collected by a blood sampling device 2404.

[00144] FIGS. 25A – D show a blood optimization system 2500 and blood sequestration device 2502, formed substantially as described in FIGS. 15, 16, 17, 18 and 19, but being formed to inhibit a user or other object from touching or blocking an air venting mechanism from a blood sequestration chamber 2520. Air initially in the blood sequestration chamber 2520 is displaced by an initial aliquot of blood upon venipuncture, where a patient's blood pressure overcomes the ambient air pressure in the blood sequestration chamber 2520. The air venting mechanism includes an air permeable blood barrier 2506, such as a porous material or set of materials that allows air to escape but blocks blood from leaving the blood sequestration chamber 2520.

[00145] The air venting mechanism includes an inner wall 2516 that at least partially circumscribes or surrounds the air permeable blood barrier 2506, and an outer wall 2504 spaced apart from the inner wall 2516. The outer wall 2504 can have one or more air vents 2514 formed therein. The outer wall 2504 extends higher upward than the inner wall 2516, such that a lid 2510, such as a cap, plug, cover, etc., can be attached to the outer wall 2504 and be displaced by a small distance from the top of the inner wall 2516. A seal 2508 in the form of a silicone wafer, or other elastomeric material, fits within the outer wall 2504 to cover the air permeable blood barrier 2506 and abut the top of the inner wall 2516. The seal 2508 covers and seals the air permeable blood barrier 2506 and inhibits air from entering the blood sequestration chamber 2520 through the air permeable blood barrier 2506. A fulcrum 2512 on an underside of the lid 2510 allows the seal 2508 to flexibly disconnect from the top of the inner wall 2516 when pushed by air displaced from the blood sequestration chamber 2520, to allow air to vent from the air

permeable blood barrier 2506 and through the one or more air vents 2514 in the outer wall 2504.

[00146] FIG. 26A – E illustrate a blood sample optimization system 2600 that includes a patient needle 2602 for vascular access to a patient's bloodstream, a blood sample collection device 2604 to facilitate the collecting of one or more blood samples for blood testing or blood cultures, and a conduit 2606 providing a fluid connection between the patient needle 2602 and the blood sample collection device 2604. The conduit 2606 can include flexible tubing. In preferred implementations, the blood sample collection device 2604 includes a protective shield 2605 that includes a sealed collection needle on which a sealed vacuum-loaded container is placed, which, once pierced by the collection needle, draws in a blood sample under vacuum pressure or force through the conduit 2006 from the patient needle 2602.

[00147] The blood sample optimization system 2600 further includes a blood sequestration device 2608, located at any point on the conduit 2606 between the patient needle 2602 and the blood sample collection device 2604. The location of the blood sequestration device 2608 can be based on a length of the conduit between the blood sequestration device 2608 and the patient needle 2602, and the associated volume that length provides.

[00148] The blood sequestration device 2608 includes an inlet port 2612 for being connected to the conduit 2606 toward the patient needle 2602, and an outlet port 2614 for being connected to the conduit 2606 toward the blood sample collection device 2604. The blood sequestration device 2608 includes an outer housing 2616 and an inner housing 2617, both having a cylindrical form, and being connected concentrically. The outer housing 2616 includes an outer wall 2618 and an inner conduit 2620 that defines a blood sampling channel 2622 to convey blood through the conduit 2606 to the blood sampling device 2604. The inner housing 2617 fits snugly between the inner conduit 2620 and the outer wall 2618 of the outer housing, and is rotatable in relation to the outer housing 2616. The fit between the outer housing 2616 and the inner housing 2617 can be a friction fit that maintains the housings in a particular position. The inner housing 2617 defines a blood sequestration chamber 2624, preferably a helical or corkscrew channel around the outer surface of inner conduit 2620 of the outer housing 2616, and which

terminates at an air vent 2628 having an air permeable blood barrier, as shown in FIG. 26E.

[00149] The blood sequestration chamber 2624 is connected with the blood sampling channel 2622 via diversion junction 2624 formed in the inner conduit 2620, when the blood sequestration device in a first state, illustrated in FIG. 26C. The protective shield 2606 on the collection needle 2604 provides a block for air or blood, enabling a diversion of an initial aliquot of blood into the blood sequestration chamber 2624 as the patient's blood pressure overcomes the ambient air pressure in the blood sequestration channel 2624 to displace air therefrom through air vent 2628.

[00150] When the inner housing 2617 is rotated relative to the outer housing 2616, or vice versa, to a second state, as illustrated in FIG. 26D, the blood sequestration chamber 2624 is shut off from diversion junction 2624, enabling a direct path from the patient needle through the conduit 2606 to the collection needle 2604, via blood sampling channel 2622. The outer housing 2616 and/or inner housing 2617 can include ridges or grooves formed within a portion of their surfaces, to facilitate relative rotation from the first state to the second state.

[00151] FIGS. 27A – D illustrate a blood optimization system 2700 and blood sequestration device 2702, formed substantially as described with reference to at least FIGS. 15, 16, 17, 18, 19, and 25, but being formed to inhibit a user or other object from touching or blocking an air venting mechanism from a blood sequestration chamber 2720. Air initially in the blood sequestration chamber 2720 is displaced by an initial aliquot of blood upon venipuncture, where a patient's blood pressure overcomes the ambient air pressure in the blood sequestration chamber 2720. The air venting mechanism includes an air permeable blood barrier 2706, such as a porous material or set of materials that allows air to escape but blocks blood from leaving the blood sequestration chamber 2720.

[00152] The air venting mechanism includes an inner wall 2716 that at least partially circumscribes or surrounds the air permeable blood barrier 2706, and an outer wall 2704 spaced apart from the inner wall 2716. A cap 2722 is positioned on the air venting mechanism, preferably by having a lower cap wall 2728 that fits between the inner wall 2716 and the outer wall 2704 of the air venting mechanism, and frictionally abutting either the the inner wall 2716 or the outer wall 2704 or both. The cap 2722

further includes one or more vent holes 2724 or slits, apertures, openings, or the like, which extend through an upper surface of the cap 2722 around a downwardly extending plug 2726. The plug 2726 is sized and adapted to fit snugly within the space defined by inner wall 2716.

[00153] In a first position, as illustrated in FIG. 27C, the cap 2722 is extended from the air venting mechanism to allow air from the blood sequestration chamber 2720 to exit through the air permeable blood barrier 2706 and through the one or more vent holes 2724. Once the air from the blood sequestration chamber 2720 has been displaced, i.e., when the blood sequestration chamber 2720 is filled with the first aliquot of potentially tainted blood from the patient, then the cap 2722 can be pushed down on the air venting mechanism in a second position as shown in FIG. 27D, so that the plug 2726 fits within the inner wall 2716 over the air permeable blood barrier 2706 to seal the air venting mechanism. In either the first position or the second position, the cap 2722 protects the air permeable blood barrier 2706 from outside air or from being touched by a user.

[00154] FIGS. 28A – F illustrate a blood optimization system 2800 and blood sequestration device 2802, formed substantially as described with reference to at least FIGS. 15, 16, 17, 18, 19, 25 and 26, but utilizing a multi-layered filter, and in some implementations, a filter with trapped reactive material, for an air permeable blood barrier. As shown in FIGS. 28C and D, an air permeable blood barrier 2803 includes a first layer 2804 of an air permeable but blood impermeable material, and a second layer 2806 that includes a reactive material, such as a hydrophobic material, for repelling blood while still allowing air to pass through both layers. As shown in FIGS. 28E and F, the air permeable blood barrier 2803 can include any number of layers, such as a third layer 2808 formed of the same air permeable but blood impermeable material as first layer 2804, while a second layer 2806 includes trapped or embedded blood reactive material.

[00155] FIGS. 29A – C illustrate a blood optimization system 2900 and blood sequestration device 2902, formed substantially as described with reference to at least FIGS. 15, 16, 17, 18, 19, 25 and 26, but in which a blood sequestration chamber 2904 is at least partially filled with a blood-absorptive material 2906. The blood-absorptive material 2906 can act as a wicking material to further draw in blood to be sequestered upon venipuncture of the patient, and prior to use of a blood drawing device such as a Vacutainer™ or a syringe, or the like.

[00156] FIGS. 30A – G illustrate a blood optimization system 3000 and blood sequestration device 3002, formed substantially as described with reference to at least FIGS. 15, 16, 17, 18, 19, 25 and 26. The blood sequestration device 3000 includes an inlet port 3002 that can be connected with a patient needle that is inserted into a patient's vascular system for access to and withdrawing of a blood sample. The inlet port 3002 may also be connected with tubing or other conduit that is in turn connected with the patient needle. The inlet port 3002 defines an opening into the blood sequestration device 3000, which opening can be the same cross sectional dimensions as tubing or other conduit connected with the patient needle or the patient needle itself. For instance, the opening can be circular with a diameter of approximately 0.045 inches, but can have a diameter of between 0.01 inches or less to 0.2 inches or more.

[00157] The inlet port 3002 can also include a sealing or fluid-tight connector or connection, such as threading or Luer fitting, or the like. In some implementations, tubing or other conduit associated with the patient needle can be integral with the inlet port 3002, such as by co-molding, gluing, laser weld, or thermally bonding the parts together. In this manner, the blood sequestration device 3000 can be fabricated and sold with the patient needle and/or tubing as a single unit, eliminating the need for connecting the patient needle to the blood sequestration device 3000 at the time of blood draw or sampling.

[00158] The blood sequestration device 3000 further includes an outlet port 3004, which defines an opening out of the blood sequestration device 3000 and to the blood sample collection device. The outlet port 3004 may also be connected with tubing or other conduit that is in turn connected with the blood sequestration device, and may also include a sealing or fluid-tight connector or connection, such as threading or Luer fitting, or the like. Accordingly, as discussed above, the blood sequestration device 3000 can be fabricated and sold with the patient needle and/or tubing and the blood sample collection device as a single unit, eliminating the need for connecting the patient needle and the blood sample collection device to the blood sequestration device 3000 at the time of blood draw or sampling.

[00159] The blood sequestration device 3000 further includes a sampling channel 3006 between the inlet port 3002 and the outlet port 3004, and a sequestration chamber 3008 that is connected to and split off or diverted from the sampling channel 3006 at any

point between the inlet port 3002 and the outlet port 3004. The sampling channel 3006 functions as a blood sampling pathway once a first aliquot of blood has been sequestered in the sequestration chamber 3008. The sampling channel 3006 can be any sized, shaped or configured channel, or conduit. In some implementations, the sampling channel 3006 has a substantially similar cross sectional area as the opening of the inlet port 3002. In other implementations, the sampling channel 3006 can gradually widen from the inlet port 3002 to the outlet port 3004. The sequestration chamber 3008 may have a larger cross section to form a big reservoir toward the sequestration channel path so that the blood will want to enter the reservoir first versus entering a smaller diameter on the sampling channel 3006.

[00160] In some exemplary implementations, the diversion between the sampling channel 3006 and the sequestration chamber 3008 is by diverter junction 3007. Diverter junction 3007 may be a substantially Y-shaped, T-shaped, or U-shaped. In some preferred exemplary implementations, and as shown in FIG. 17A – 17B, the diverter junction 3007 is configured such that the flow out of the inlet port 3002 is preferentially directed toward the sequestration chamber 3008. The sequestration chamber 3008 may also include or form a curve or ramp to direct the initial blood flow toward and into the sequestration chamber 3008.

[00161] The sequestration chamber 3008 is preferably maintained at atmospheric pressure, and includes a vent 3010 at or near a distal end of the sequestration chamber 3008. The vent 3010 may include an air permeable blood barrier 3012 as described above.

[00162] The blood sequestration device 3000 can include a housing 3001 that can be formed of multiple parts or a single, unitary part. In some implementations, and as illustrated FIG. 30F, the housing 3001 includes a top member 3020 and a bottom member 3022 that are mated together. The blood sequestration device 3000 can also include a gasket or other sealing member (not shown) so that when the top member 3020 is mechanically attached with the bottom member 3022, the interface between the two is sealed by the gasket or sealing member. The bottom member 3022 can include grooves, channels, locks, conduits or other pathways pre-formed therein, such as by an injection molding process or by etching, cutting, drilling, etc., to form the sampling channel 3006, the sequestration chamber 3008, and diverter junction 3007.

[00163] The sequestration chamber 3008 may have a larger cross section than the sampling channel 3006 so that the blood will preferentially move into the sequestration chamber first versus entering a smaller diameter on the sampling channel 3006.

[00164] In some implementations, the sampling channel 3006 and the sequestration chamber 3008 are formed by grooves, channels, locks or other pathways formed in housing 3001. The housing 3001 can be made of rubber, plastic, metal or any other suitable material. The housing 3001 can be formed of a clear or translucent material, or of an opaque or non-translucent material. In other implementations, the housing 3001 can be mostly opaque or non-translucent, while the housing surface directly adjacent to the sampling channel 3006 and/or the sequestration chamber 3008 may be clear or translucent, giving a practitioner a visual cue or sign that the sequestration chamber 3008 is first filled to the extent necessary or desired, and/or then a visual cue or sign that the sequestered blood remains sequestered while a clean sample of blood is drawn through the sampling channel 3006. Other visual cues or signs of the sequestration can include, without limitation: the air permeable blood barrier 3012 turning a different color upon contact, saturation, or partial saturation with blood; a color-coded tab or indicator at any point along or adjacent to the sequestration chamber; an audible signal; a vibratory signal; or other signal.

[00165] The air permeable blood barrier 3012 can be covered with, or surrounded by, a cap 3032. The cap 3032 can be sized and configured to inhibit a user from touching the air permeable blood barrier 3012 with their finger or other external implement, while still allowing air to exit the air permeable blood barrier 3012 as the air is displaced from the sequestration chamber 3008. The cap 3032 can be constructed to inhibit or prevent accidental exposure of the filter to environmental fluids or splashes. This can be accomplished in a variety of mechanical ways including but not limited to the addition of a hydrophobic membrane to the protective cover.

[00166] The air venting mechanism includes a wall 3030 that at least partially circumscribes or surrounds the air permeable blood barrier 3012. The wall 3030 can have one or more air vents formed therein. The cap 3032 covers wall 3030 and can be snapped, glued, or otherwise attached in place. A seal 3017 in the form of a silicone wafer, or other elastomeric material, fits within the wall 3030 to cover the air permeable blood barrier 3012 and abut the top of the wall 3030. The seal 3017 covers and seals the

air permeable blood barrier 3012 and inhibits air from entering the blood sequestration chamber 3008 through the air permeable blood barrier 3012. A fulcrum 3012 on an underside of the cap 3032 allows the seal 3008 to flexibly disconnect from the top of the inner wall 3016 when pushed by air displaced from the blood sequestration chamber 3008, to allow air to vent from the air permeable blood barrier 3012 and through the one or more air vents in the wall 3030 and/or cap 3032.

[00167] In use, the blood sequestration device 3000 includes a sampling channel 3006 and a sequestration chamber 3008. Both pathways are initially air-filled at atmospheric pressure, but the sampling channel 3006 is directed to an outlet port 3004 that will be initially sealed by a Vacutainer or other such sealed blood sampling device, and the sequestration chamber 3008 terminates at a vent 3010 to atmosphere that includes an air permeable blood barrier 3012.

[00168] After a venipuncture by a patient needle of a patient (not shown), which could gather a number of pathogens from the patient's skin, a first amount of the patient's blood with those pathogens will pass through inlet port 3002 of blood sequestration device 3000. This initial volume of potentially contaminated blood will preferentially flow into the sequestration chamber 3008 by finding the path of least resistance. The patient's own blood pressure overcomes the atmospheric pressure in the vented sequestration chamber 3008 to displace air therein through the air permeable blood barrier 3012, but is not sufficient to overcome the air pressure that builds up in the sealed sampling channel 3006. In various exemplary embodiments, the sequestration chamber 3008 and sampling channel 3006 can be configured such that the force generated by the patient's blood pressure is sufficient to overcome any effect of gravity, regardless of the blood sequestration device's orientation.

[00169] Eventually, the sequestration chamber 3008 fills with blood that displaces air through the air permeable blood barrier 3012. Once the blood contacts the air permeable blood barrier, the blood interacts with the air permeable blood barrier 3012 material to completely or partially seal the vent 3010. A signal or indication may be provided that the practitioner can now utilize the Vacutainer or other blood sampling device.

[00170] Upon filling the blood sequestration pathway 3008 but prior to use of the Vacutainer or other blood sample collection device, the patient's blood pressure may drive compression of the air in the sampling channel 3006, possibly resulting in a small amount of blood moving past the diversion point into the sampling channel 3006, queuing up the uncontaminated blood to be drawn through the sampling channel 3006.

[00171] In yet another aspect, the blood sequestration chamber and/or blood sampling channel, or other component, of any of the implementations described herein, can provide a visually discernable warning or result in a component adapted for operative fluid communication with the flash chamber of an introducer for an intravenous catheter into a blood vessel of a patient. The device and method provides a visually discernable alert when blood from the patient communicates with a test component reactive to communicated blood plasma, to visually change. The reaction with the blood or the plasma occurs depending on one or a plurality of reagents positioned therein configured to test for blood contents, substances or threshold high or low levels thereof, to visually change in appearance upon a result.

[00172] In yet other aspects, the blood sequestration chamber and/or blood sampling channel can be sized and adapted to provide a particular volumetric flow of blood, either during the sequestration process and/or the sampling process.

[00173] Although a variety of embodiments have been described in detail above, other modifications are possible. Other embodiments may be within the scope of the following claims.

CLAIMS

1. A blood control device comprising; an inlet port; an outlet port;

a chamber connected with the inlet port via a junction, the chamber having a vent that includes an air permeable blood barrier, the vent being defined by an outer wall that at least partially circumscribes the air permeable blood barrier and that includes one or more air vents, the vent further including a cap that at least partially covers the outer wall and including a one-way seal abutting the air permeable blood barrier that inhibits air from entering the chamber; and

a sampling channel having a proximal end connected with the inlet port via the junction, and a distal end connected with the outlet port;

the chamber, the sampling channel and the junction being sized and configured such that a first portion of blood flows into the chamber toward the air permeable blood barrier for being held therein, and a second portion of blood bypasses the chamber and the first portion of blood held therein and is directed into the sampling channel toward the outlet port.

2. The blood control device in accordance with claim 1, further comprising a housing that houses and defines the inlet port, the outlet port, the chamber, and the sampling channel.

3. The blood control device in accordance with claim 1, wherein the vent further includes an inner wall within the outer wall and that contains the air permeable blood barrier.

4. The blood control device in accordance with claim 1, wherein the one-way seal is positioned over the inner wall and within the outer wall of the vent.

5. The blood control device in accordance with claim 4, wherein the cap includes an inner surface that faces the air permeable blood barrier, the inner surface of the cap including a fulcrum against which the seal can flexibly unseal from the air permeable blood barrier to allow air to escape the chamber.

6. The blood control device in accordance with claim 1,
wherein the air permeable blood barrier includes a sealing material that seals the vent upon contact with blood.

7. The blood control device in accordance with claim 1,
wherein the air permeable blood barrier includes a filter having a first layer and a second layer, the second layer of the filter having a hydrophobic material to repel blood.

8. A blood control and sampling system comprising;
a blood sampling pathway having a patient needle on a proximal end and a sample collection device on a distal end; and
a blood control device attached on the blood sampling pathway between the proximal end and distal end of the blood sampling pathway, the blood control device comprising:
an inlet port coupled with the blood sampling pathway toward the patient needle;
an outlet port coupled with the blood sampling pathway toward the sample collection device;
a chamber connected with the inlet port via a junction, the chamber having a vent that includes an air permeable blood barrier, the vent being defined by an outer wall that at least partially circumscribes the air permeable blood barrier and that includes one or more air vents, the vent further including a cap that at least partially covers the outer wall and including a one-way seal abutting the air permeable blood barrier that inhibits air from entering the chamber; and
a sampling channel having a proximal end connected with the inlet port via the junction, and a distal end connected with the outlet port;
the chamber, the sampling channel and the junction being sized and configured such that a first portion of blood flows into the sequestration chamber toward the air permeable blood barrier for being held therein, and a second portion of blood bypasses the chamber and the first portion of blood held therein and is directed into the sampling channel toward the outlet port.

9. The blood control system in accordance with claim 8,
wherein the blood control device further comprises a housing that houses and defines the inlet port, the outlet port, the chamber, and the sampling channel.

10. The blood control system in accordance with claim 8,
wherein the vent of the blood control device further includes an inner wall within the outer wall and that contains the air permeable blood barrier.

11. The blood control system in accordance with claim 8,
wherein the one-way seal of the vent is positioned over an inner wall and within the outer wall of the vent.

12. The blood control system in accordance with claim 11,
wherein the cap includes an inner surface that faces the air permeable blood barrier, the inner surface of the cap including a fulcrum against which the seal can flexibly unseal from the air permeable blood barrier to allow air to escape the chamber.

13. The blood control system in accordance with claim 8,
wherein the air permeable blood barrier of the blood control device includes a sealing material that seals the vent upon contact with blood.

14. The blood control system in accordance with claim 8,
wherein the air permeable blood barrier of the blood control device includes a filter having a first layer and a second layer, the second layer of the filter having a hydrophobic material to repel blood.

15. A blood control device comprising;
an inlet port;

an outlet port;

a chamber connected with the inlet port via a junction, the chamber having a vent that includes an air permeable blood barrier, the vent being defined by an outer wall

that at least partially circumscribes the air permeable blood barrier and that includes one or more air vents, the vent further including a cap that at least partially covers the outer wall and including a one-way seal abutting the air permeable blood barrier that inhibits air from entering the chamber; and

a sampling channel having a proximal end connected with the inlet port via the junction, and a distal end connected with the outlet port;

the chamber, the sampling channel and the junction being sized and configured such that a first portion of blood flows into and fills the chamber to displace air therein through the vent, and such that a second portion of blood bypasses the chamber and the first portion of blood held therein and is directed into the sampling channel toward the outlet port.

16. The blood control device in accordance with claim 15, further comprising a housing that houses and defines the inlet port, the outlet port, the chamber, and the sampling channel.

17. The blood control device in accordance with claim 15, wherein the vent further includes an inner wall within the outer wall and that contains the air permeable blood barrier.

18. The blood control device in accordance with claim 15, wherein the one-way seal is positioned over the inner wall and within the outer wall of the vent.

19. The blood control device in accordance with claim 18, wherein the cap includes an inner surface that faces the air permeable blood barrier, the inner surface of the cap including a fulcrum against which the seal can flexibly unseal from the air permeable blood barrier to allow air to escape the control chamber.

20. The blood control device in accordance with claim 15, wherein the air permeable blood barrier includes a sealing material that seals the vent upon contact with blood.

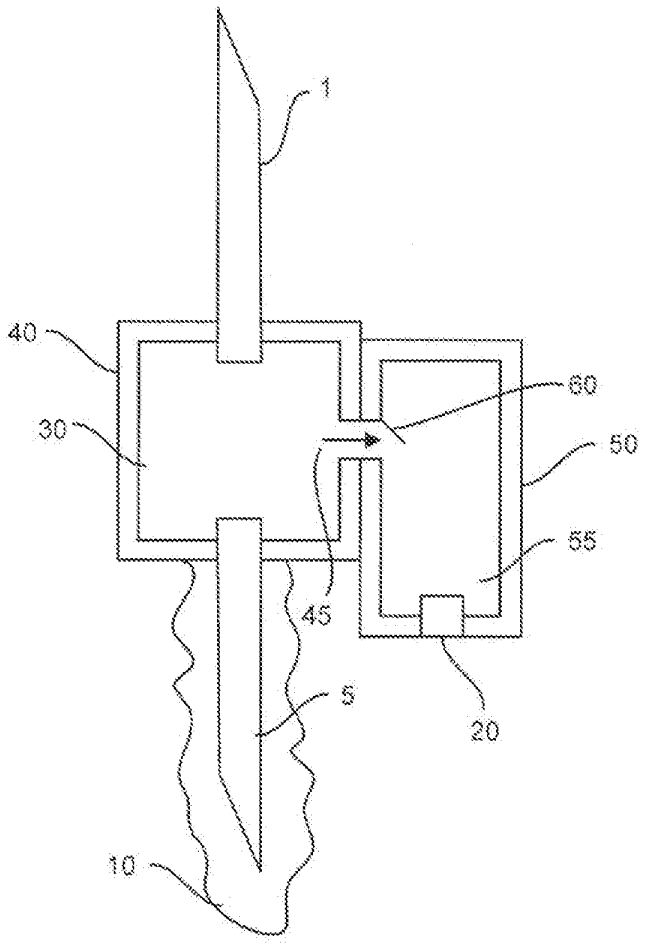


FIG. 1

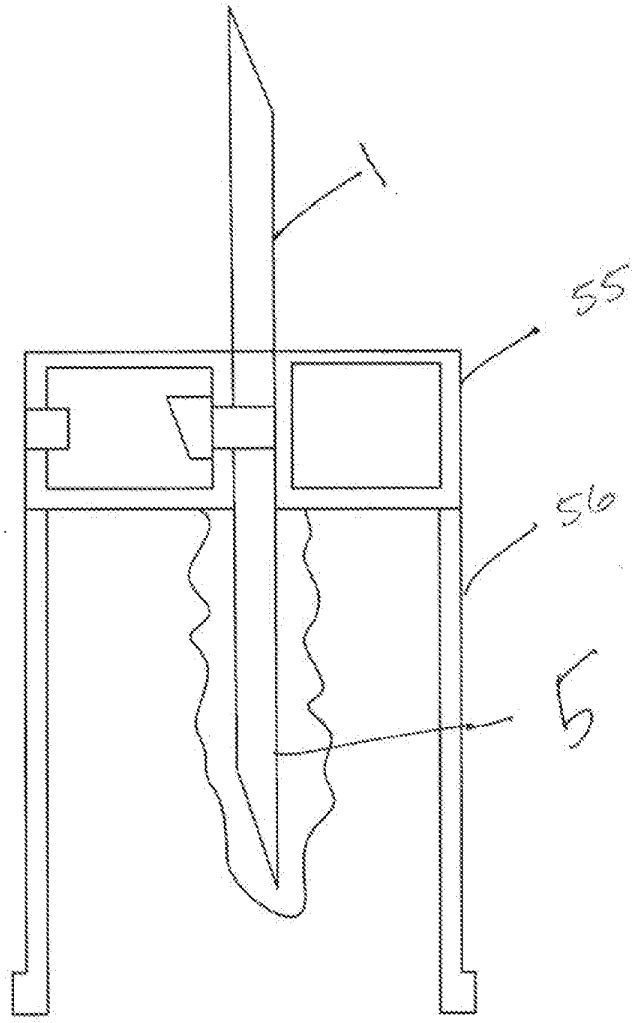


FIG. 2

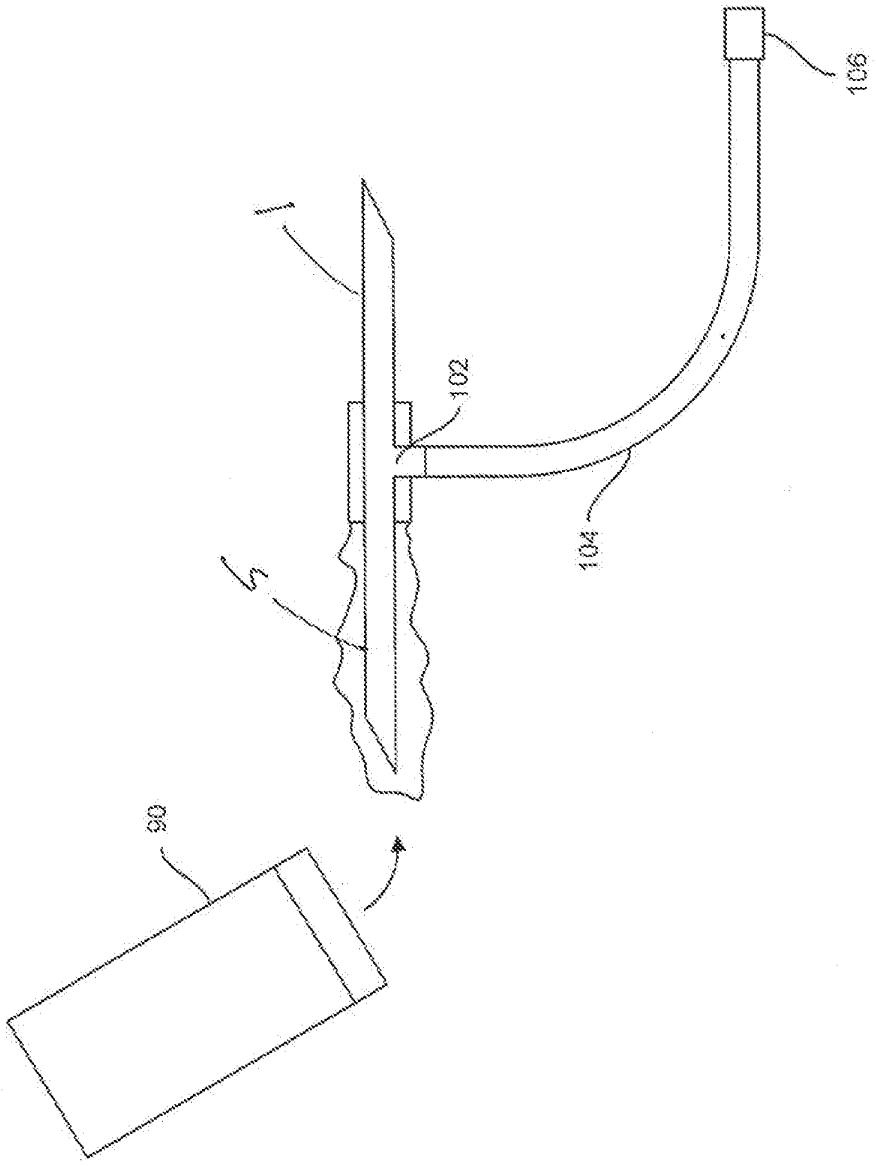


FIG. 3

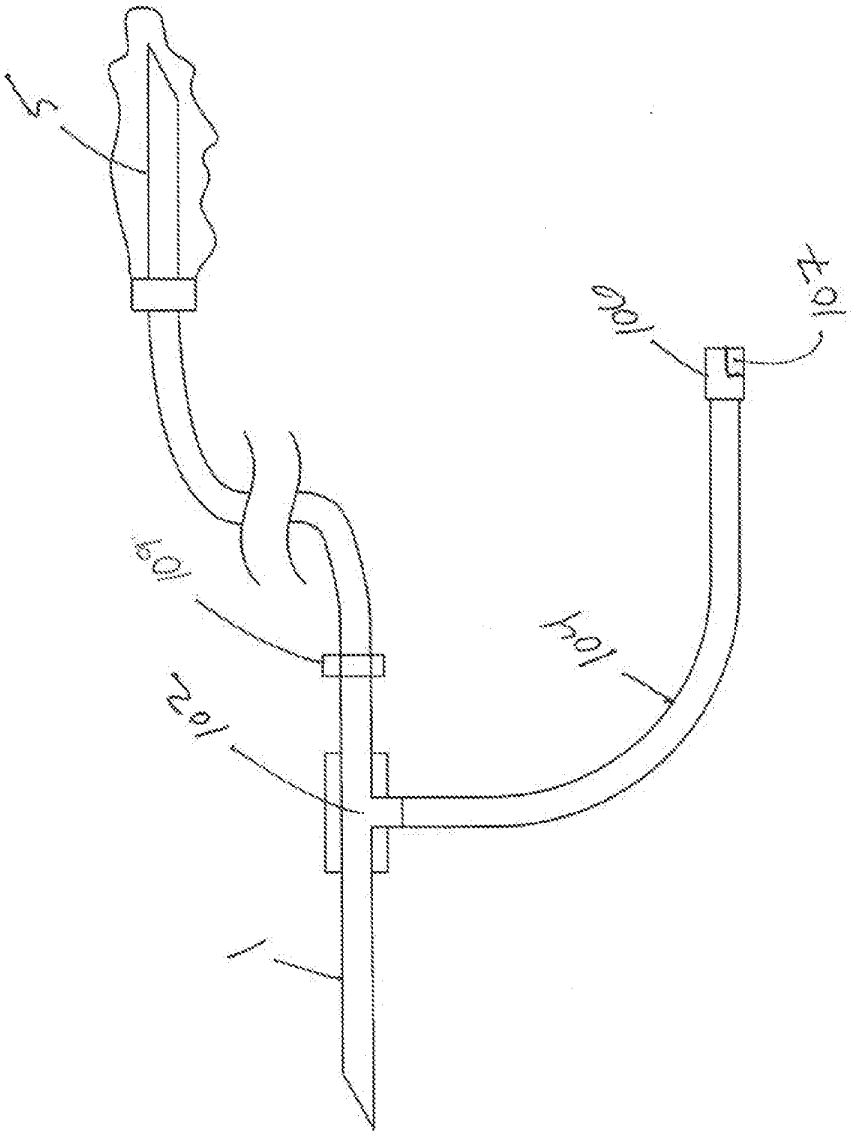


FIG. 4

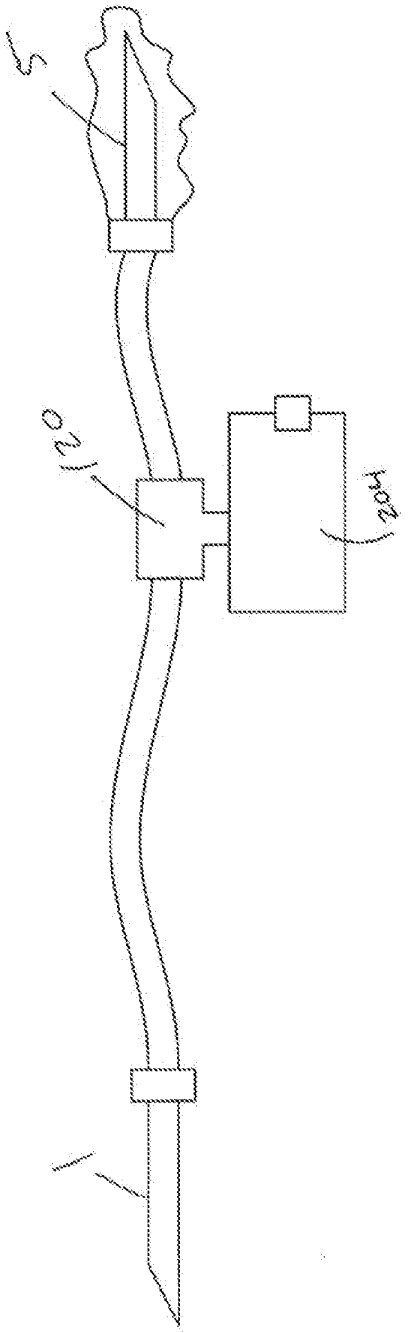


FIG. 5

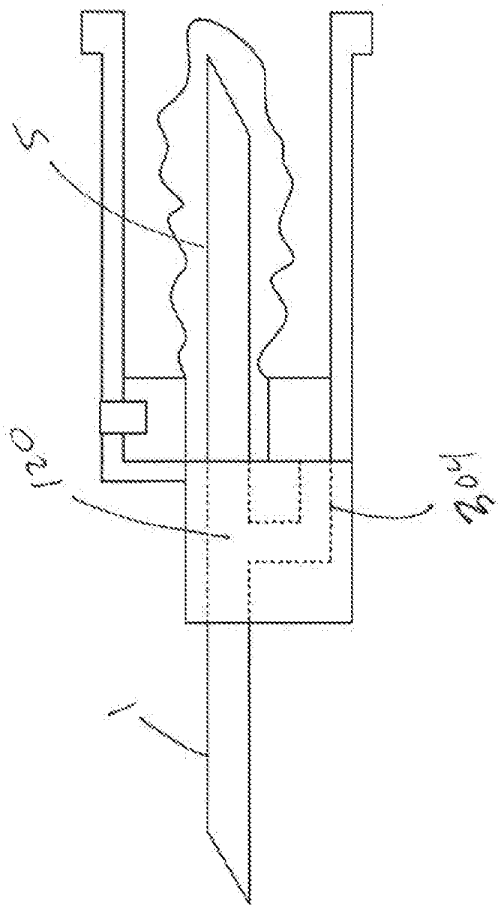


FIG. 6

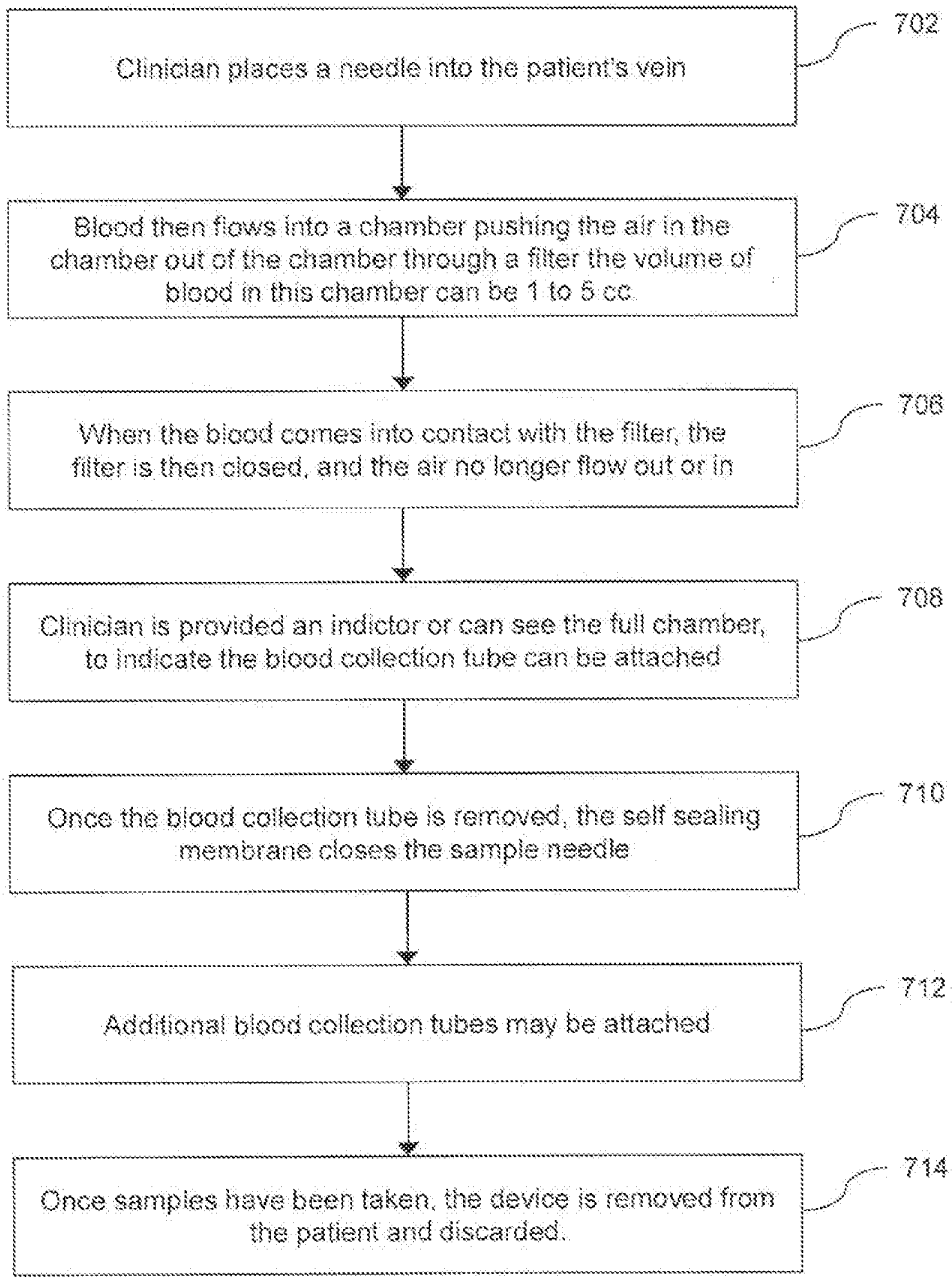

Clinician places a needle into the patient's vein
702
Blood then flows into a chamber pushing the air in the chamber out of the chamber through a filter the volume of blood in this chamber can be 1 to 5 cc
704
When the blood comes into contact with the filter, the filter is then closed, and the air no longer flow out or in
706
Clinician is provided an indictor or can see the full chamber, to indicate the blood collection tube can be attached
708
Once the blood collection tube is removed, the self sealing membrane closes the sample needle
710
Additional blood collection tubes may be attached
712
Once samples have been taken, the device is removed from the patient and discarded.
714

FIG. 7

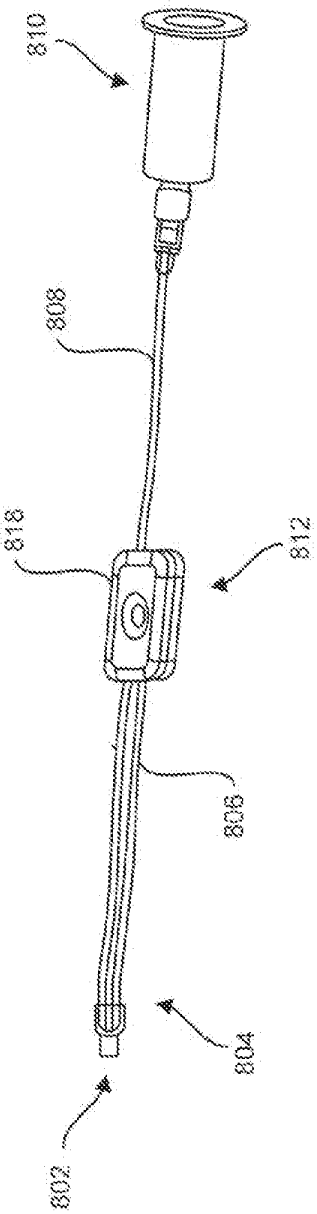


FIG. 8A

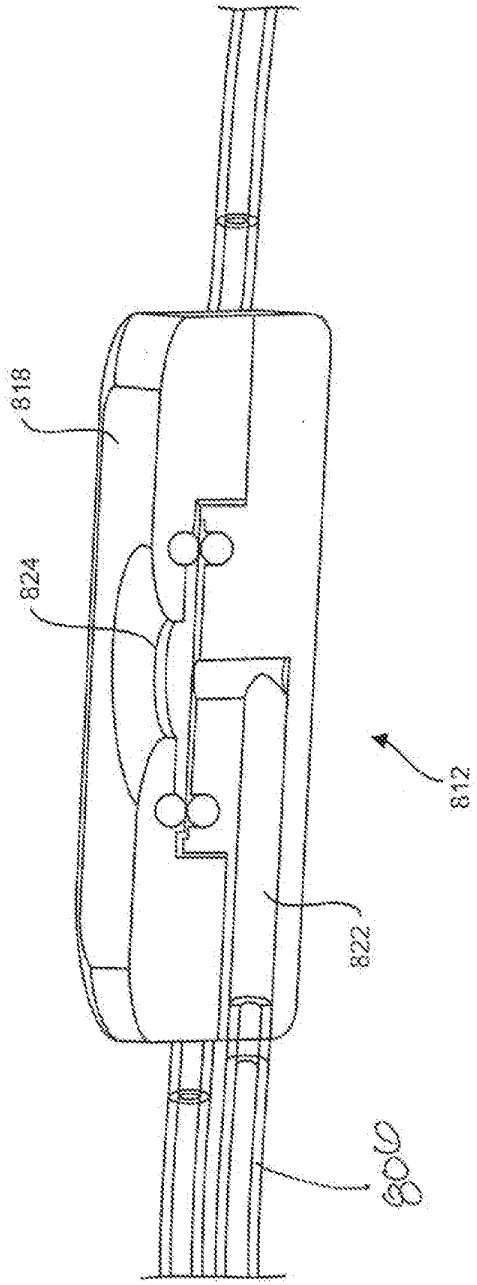


FIG. 8B

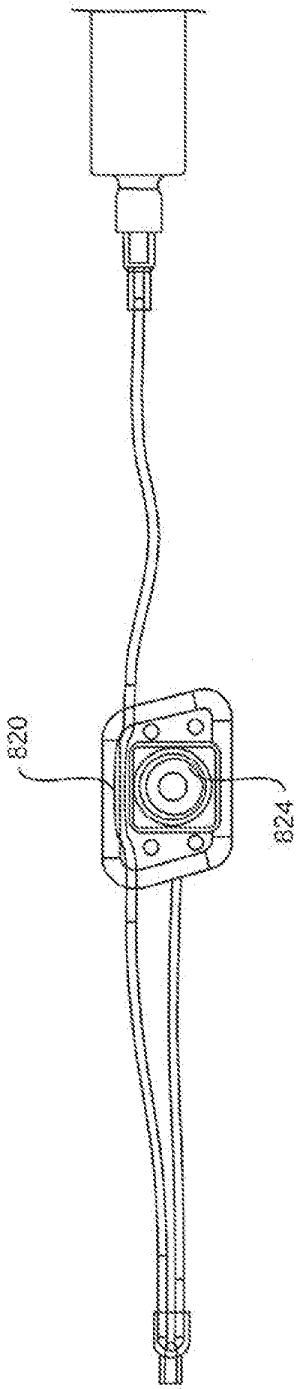


FIG. 8C

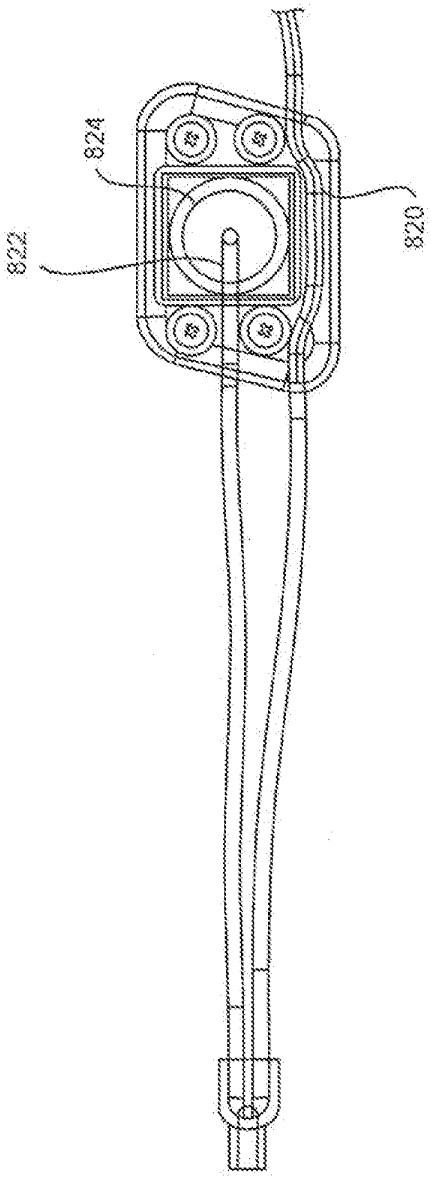


FIG. 8D

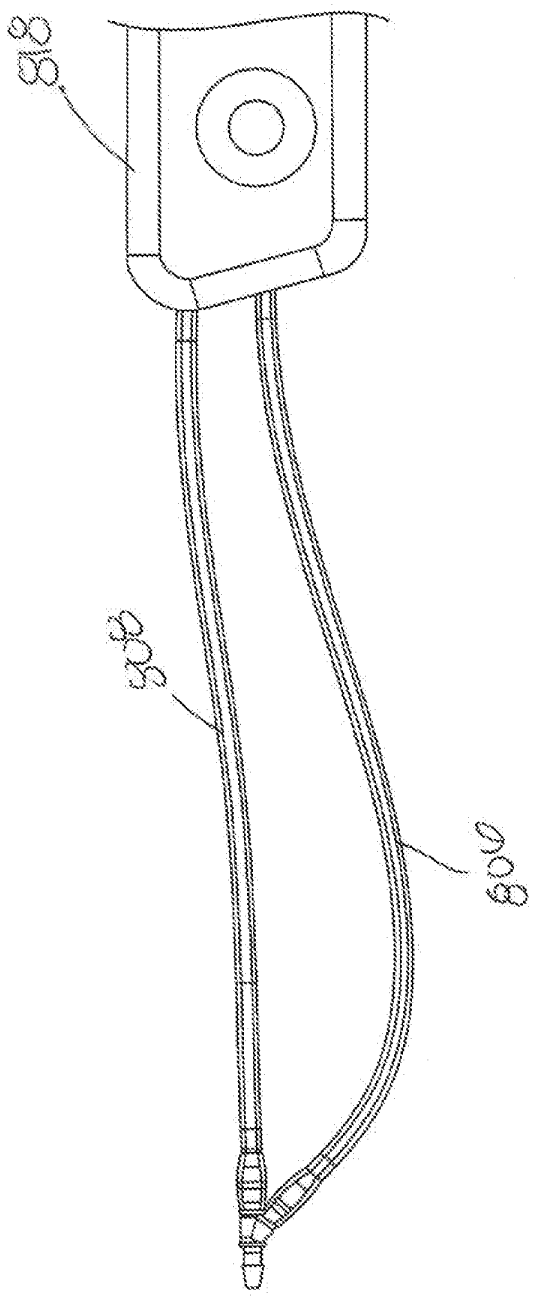


FIG. 8E

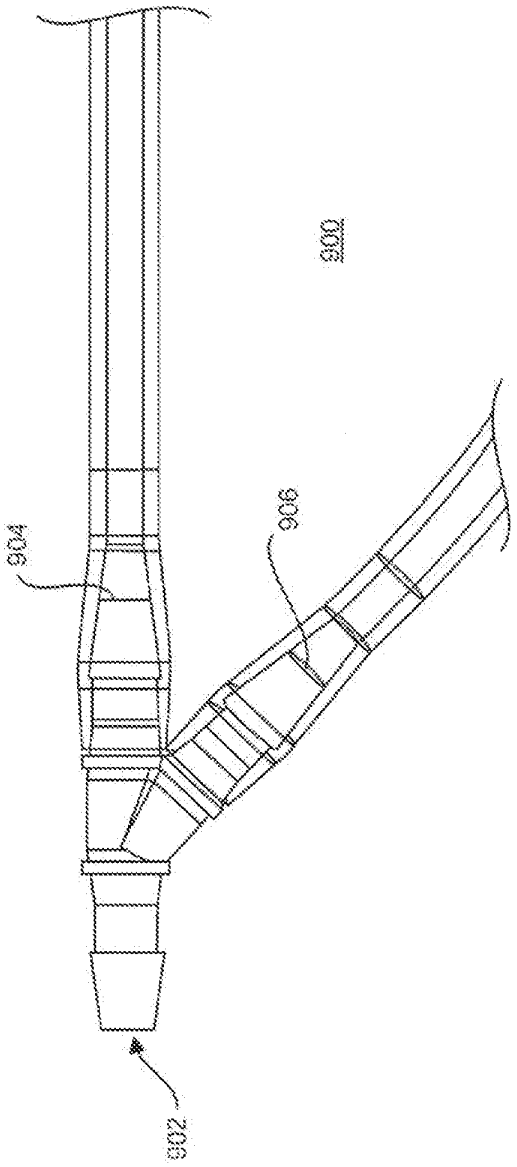


FIG. 9

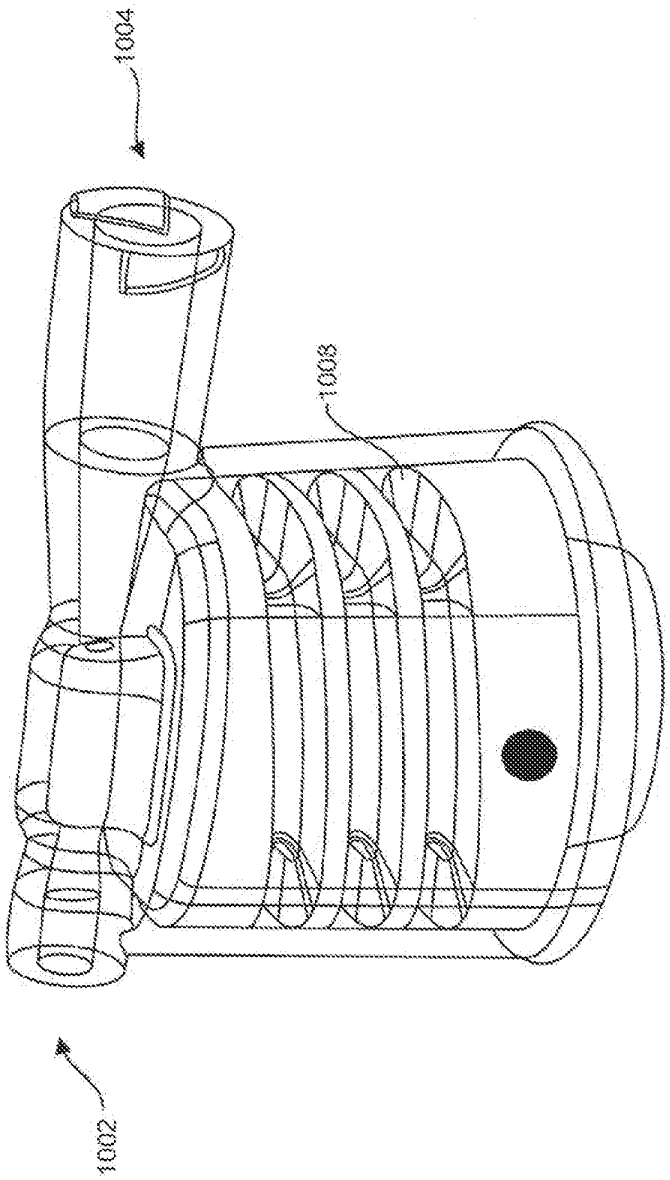


FIG. 10A

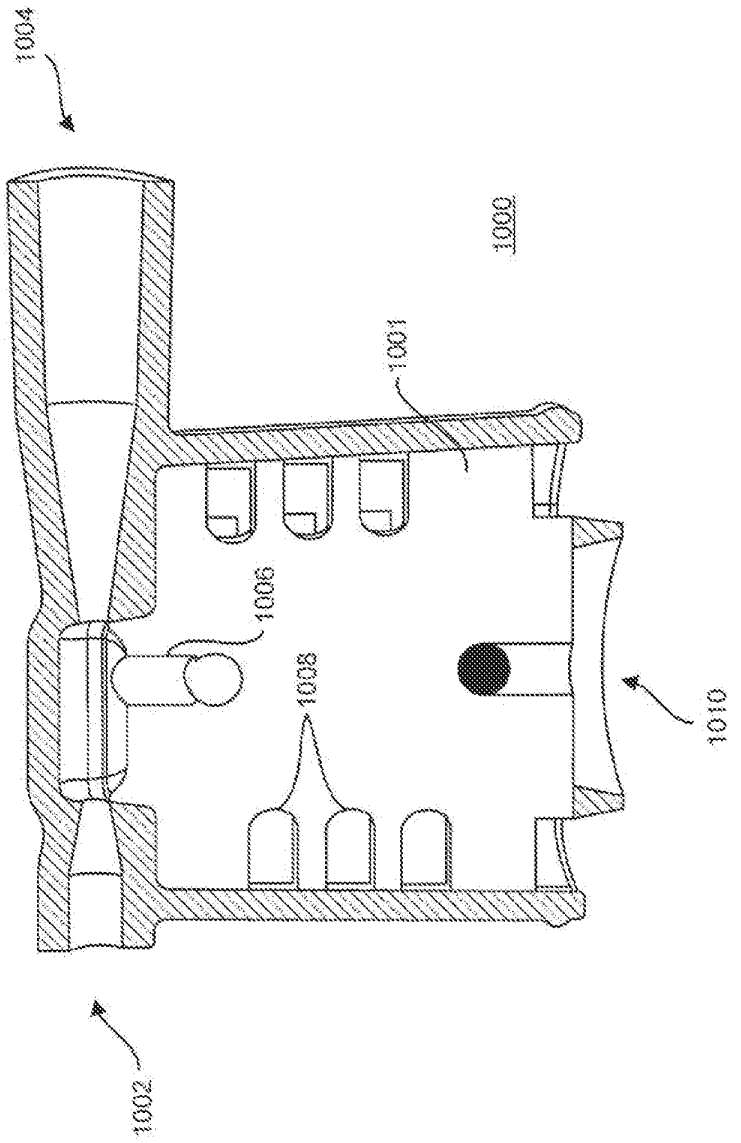


FIG. 10B

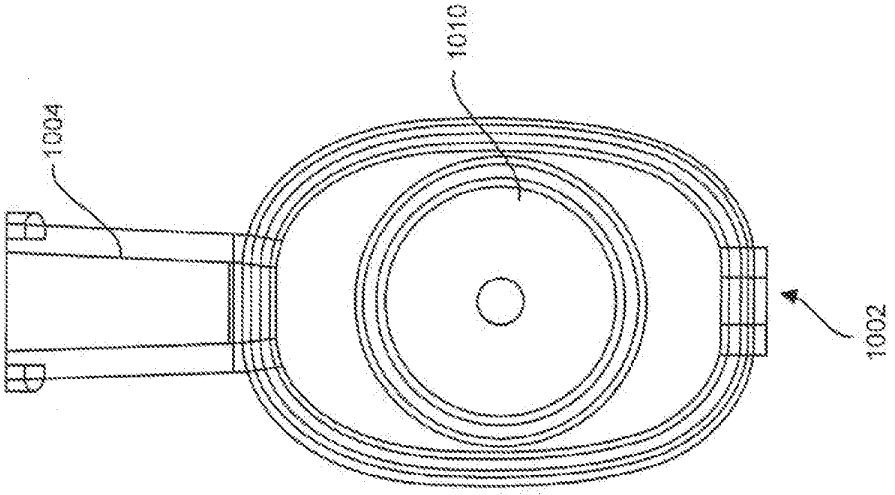


FIG. 10C

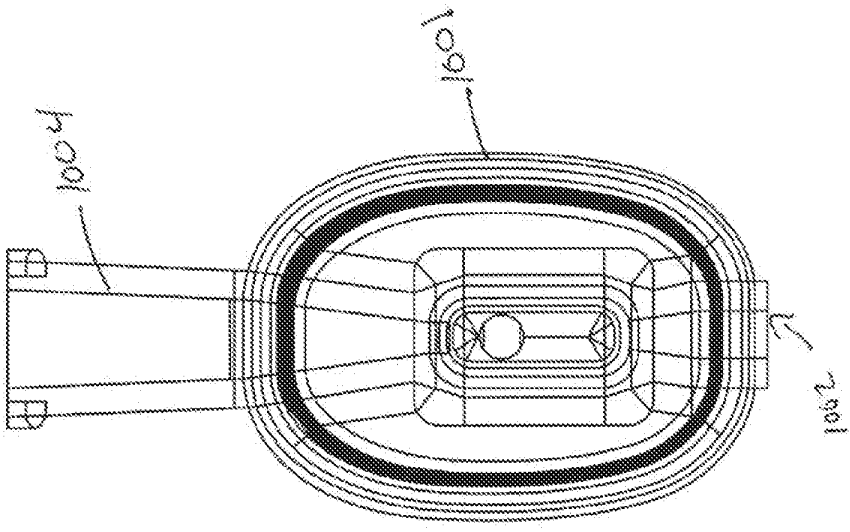


FIG. 10D

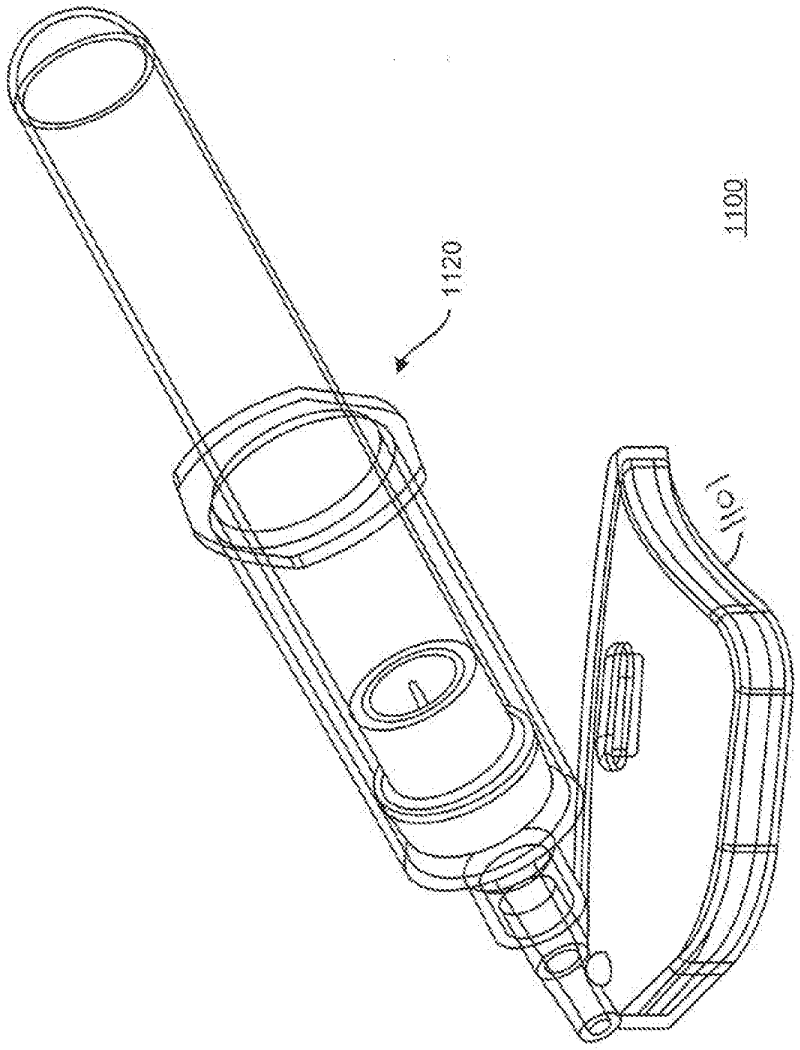


FIG. 11A

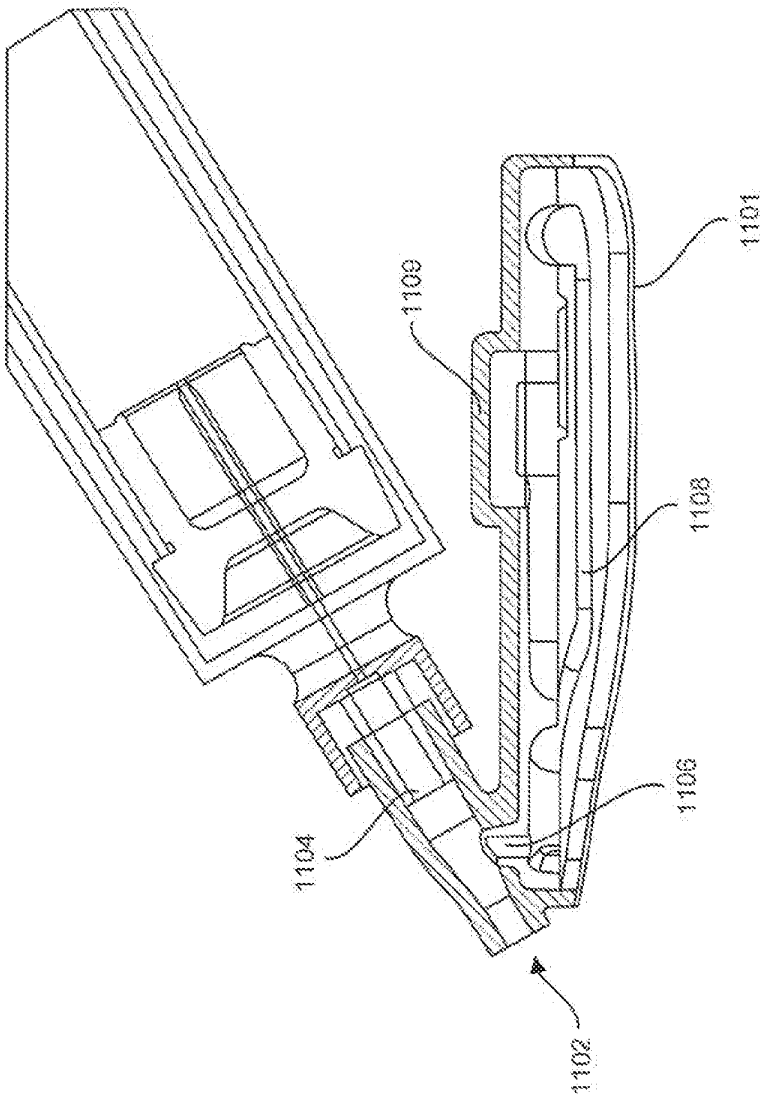


FIG. 11B

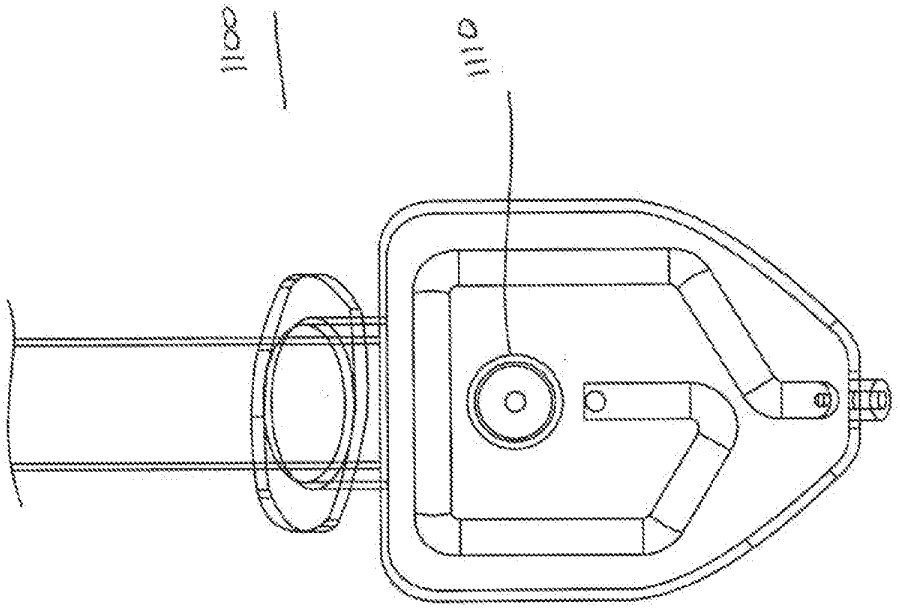


FIG. 11C

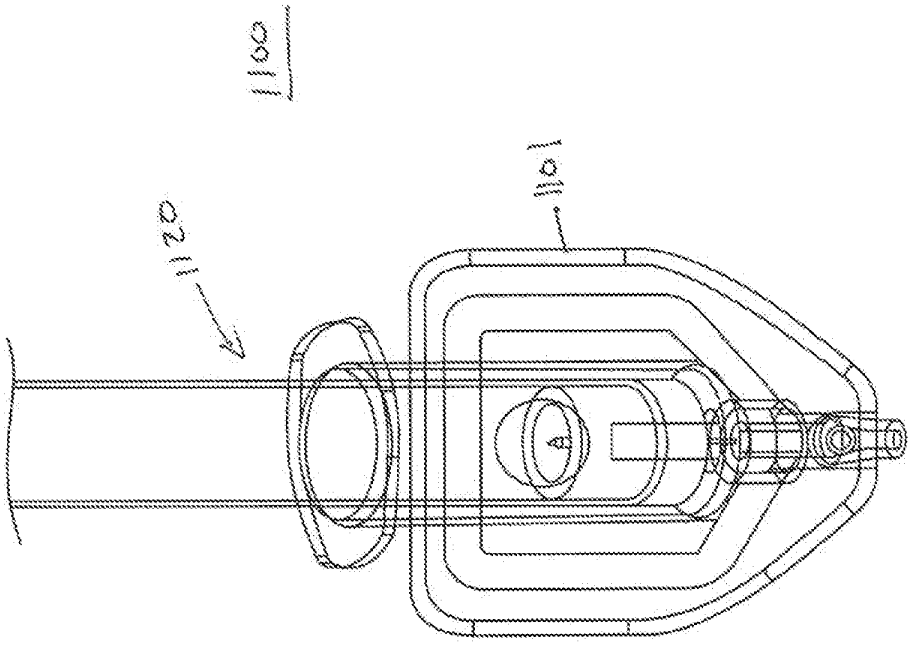


FIG. 11D

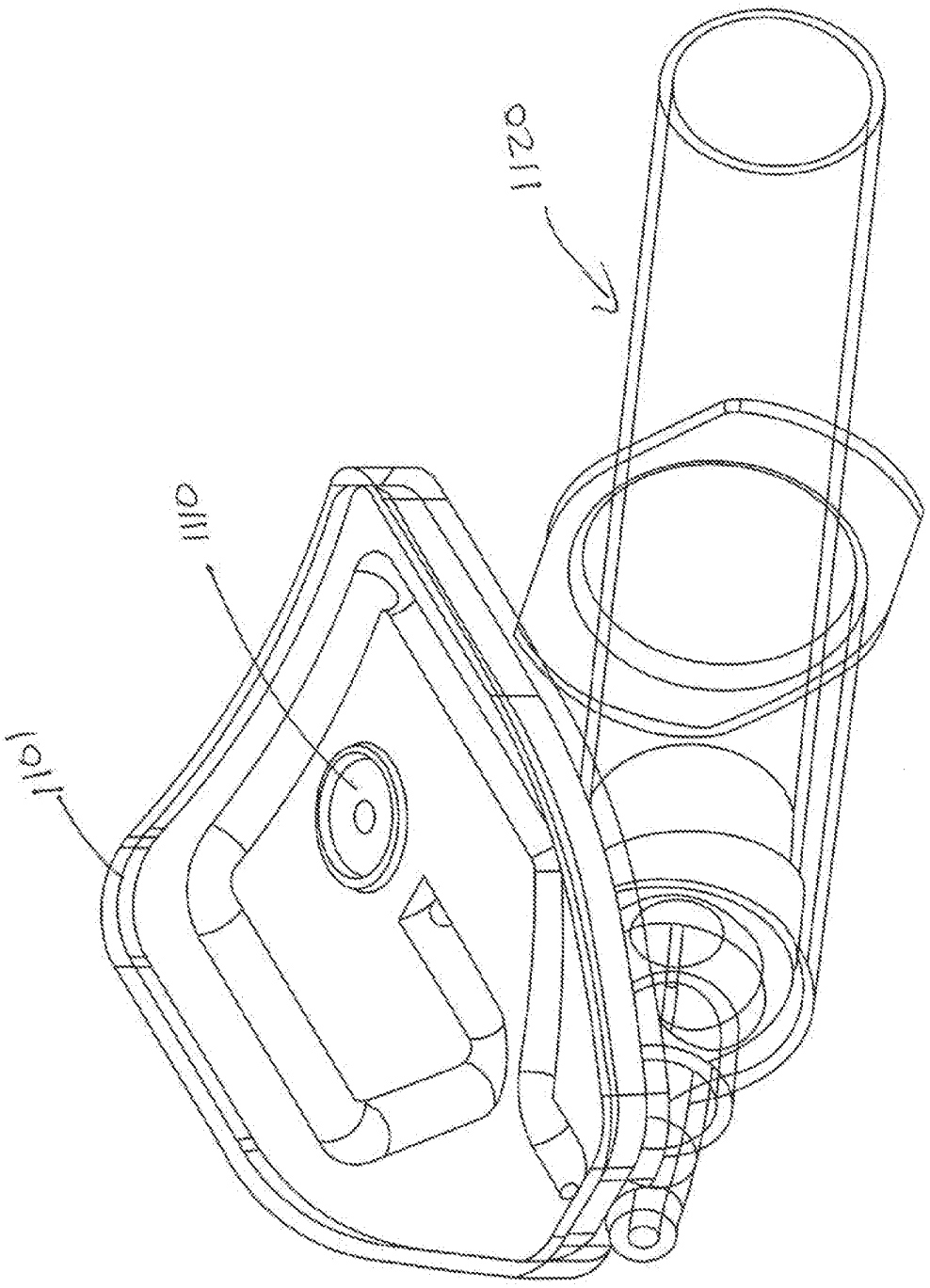


FIG. 11E

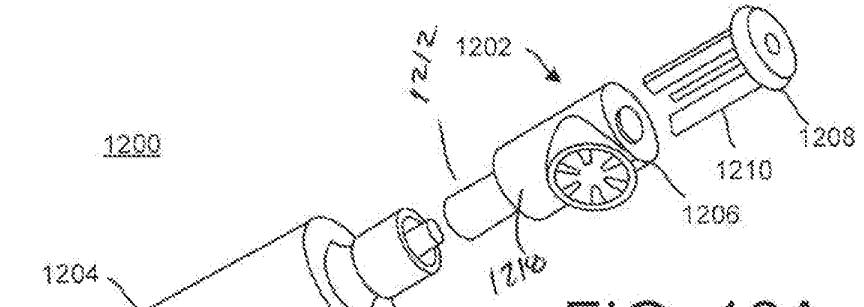


FIG. 12A

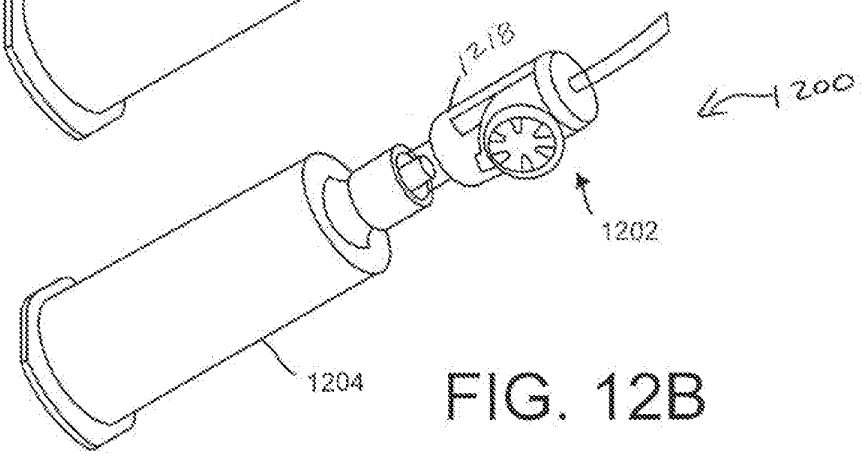


FIG. 12B

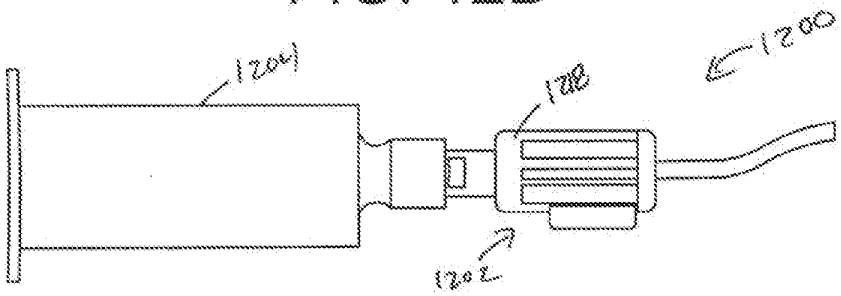


FIG. 12C

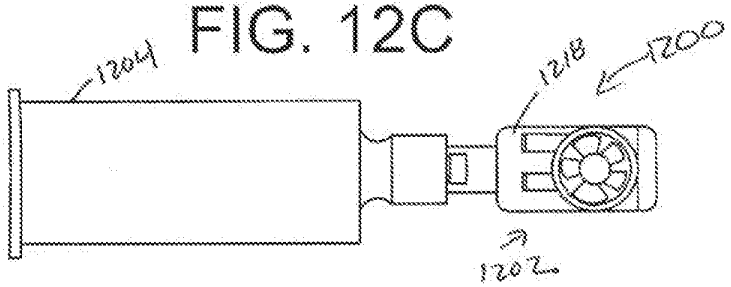


FIG. 12D

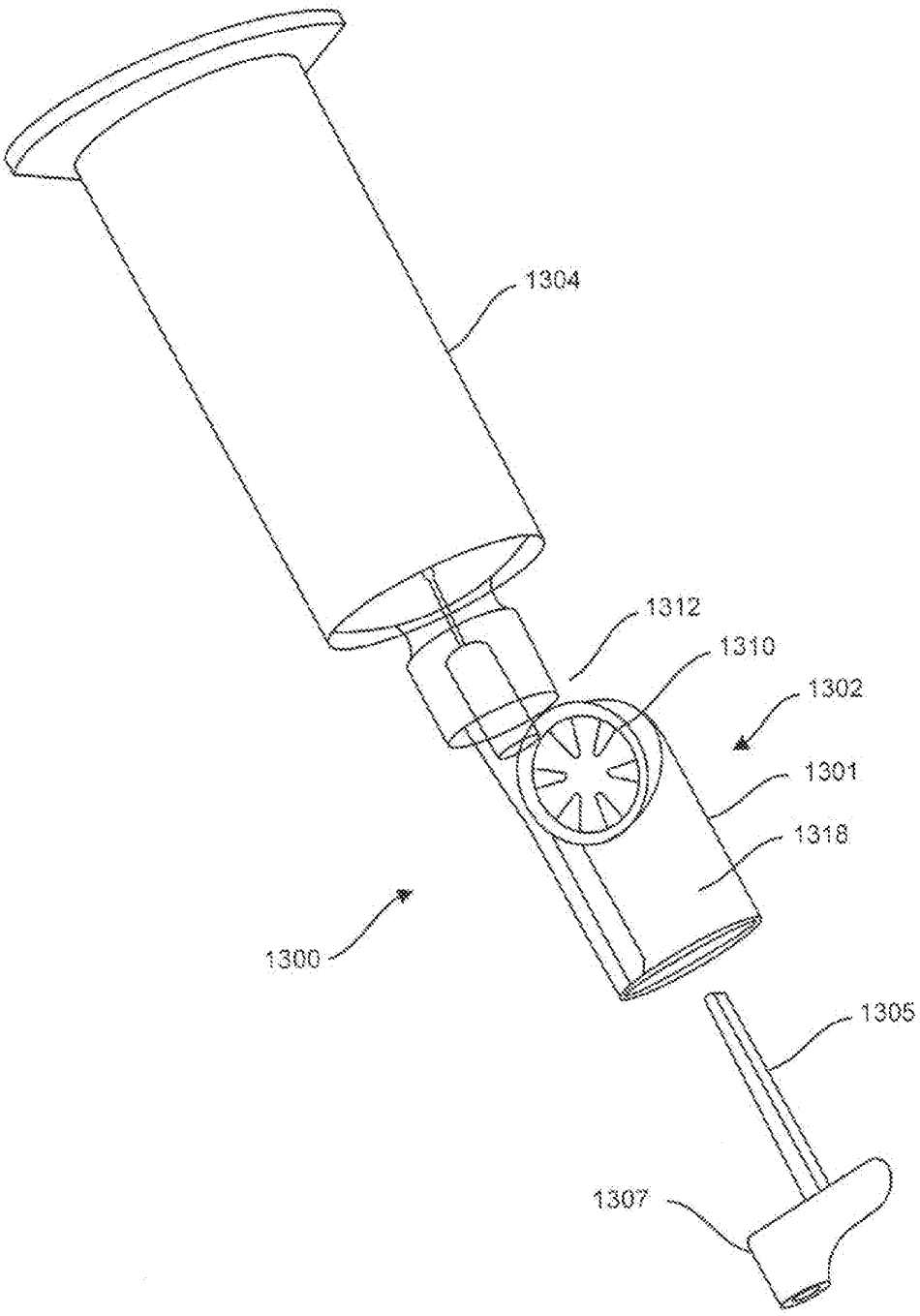


FIG. 13A

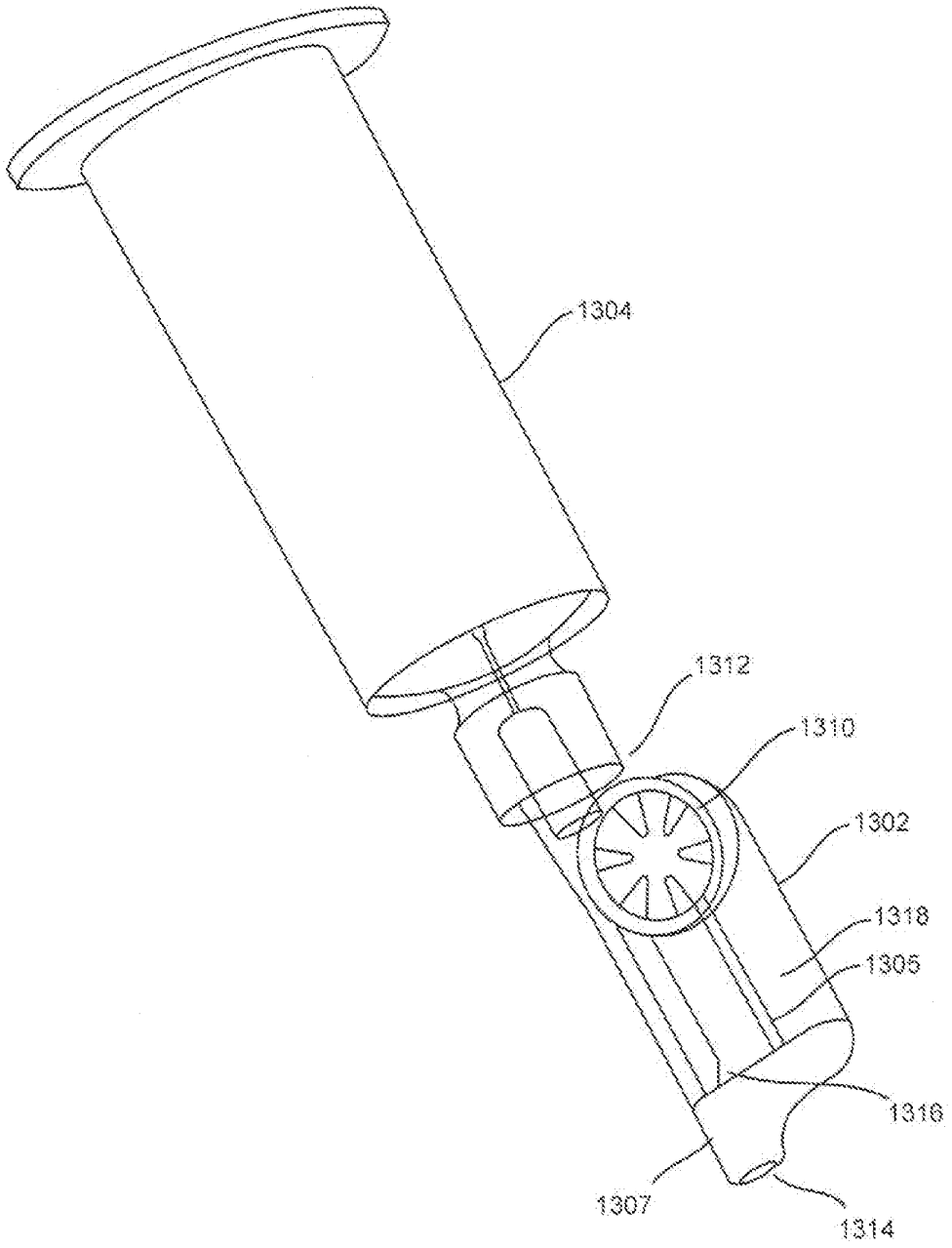


FIG. 13B

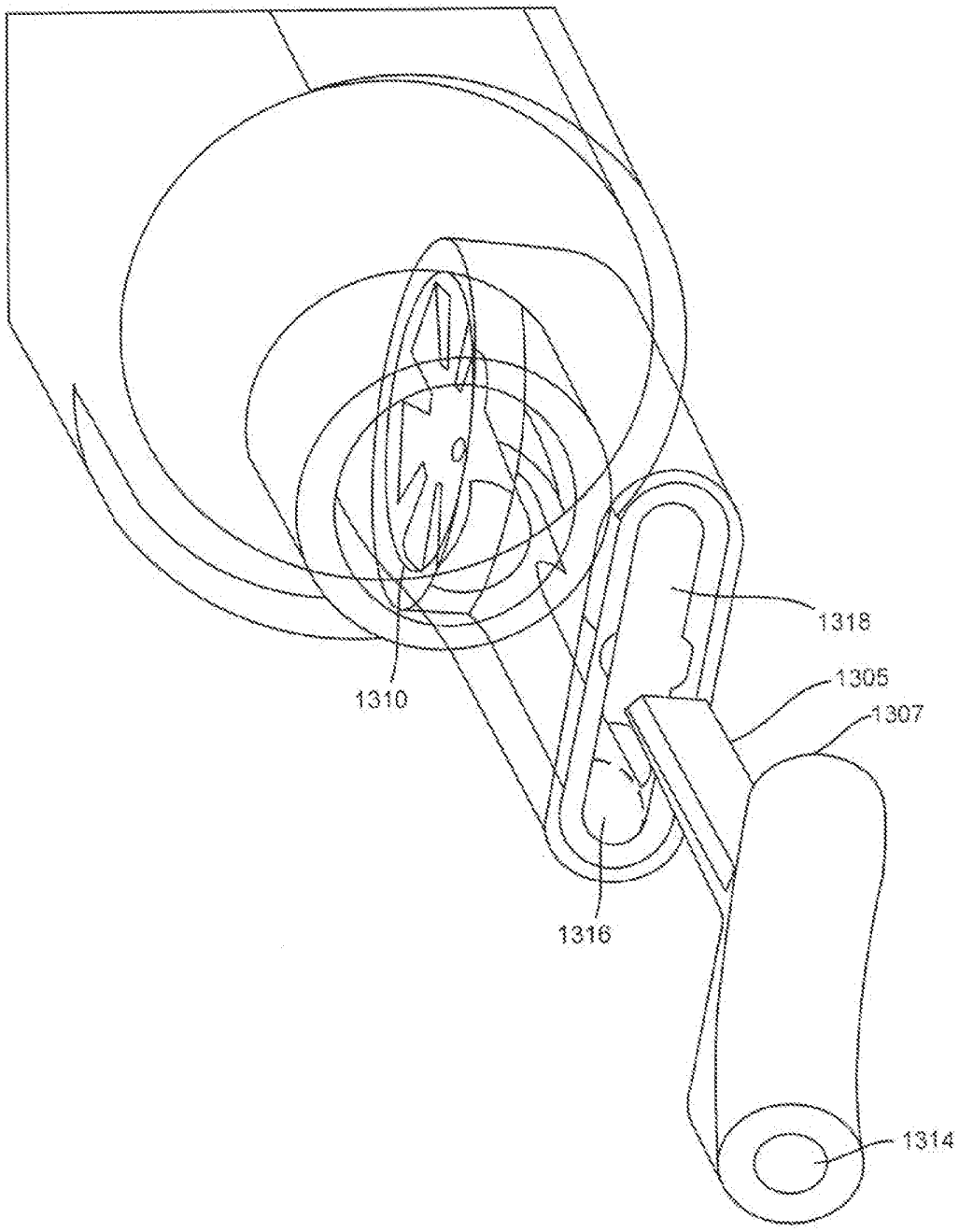


FIG. 13C

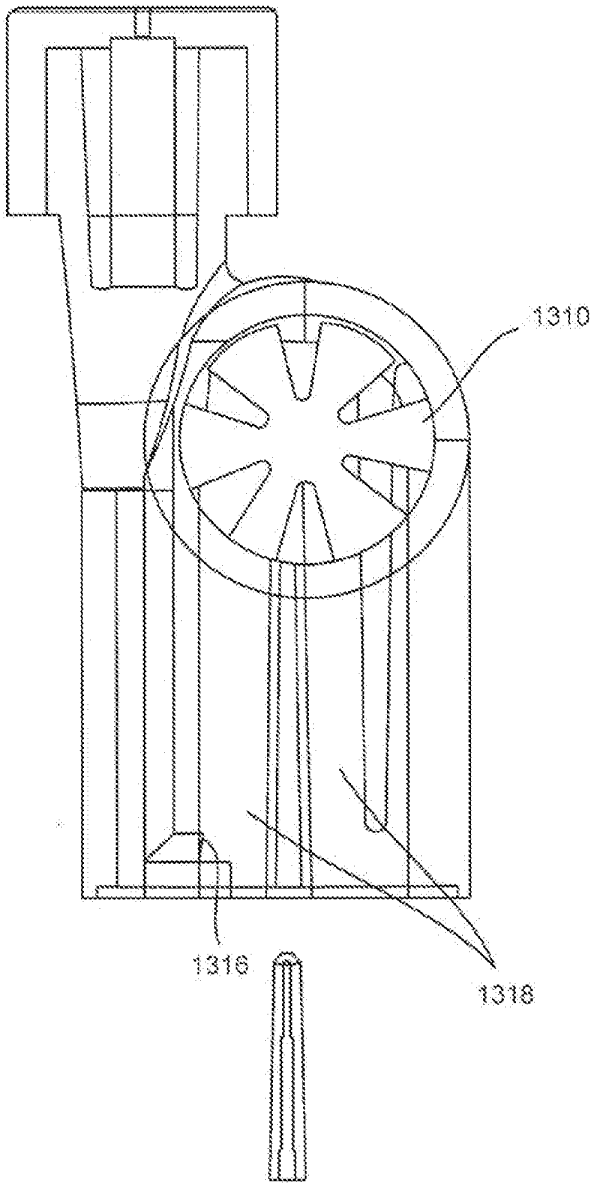


FIG. 13D

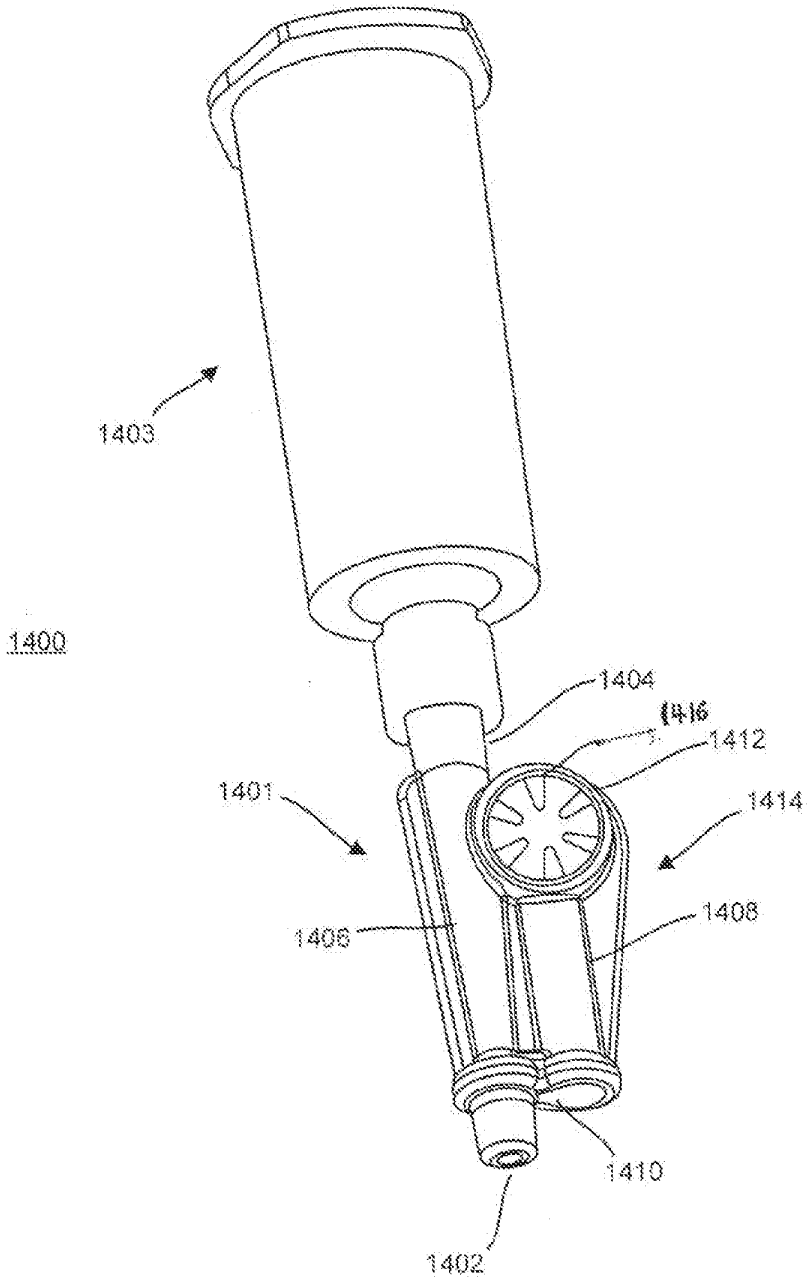


FIG. 14A

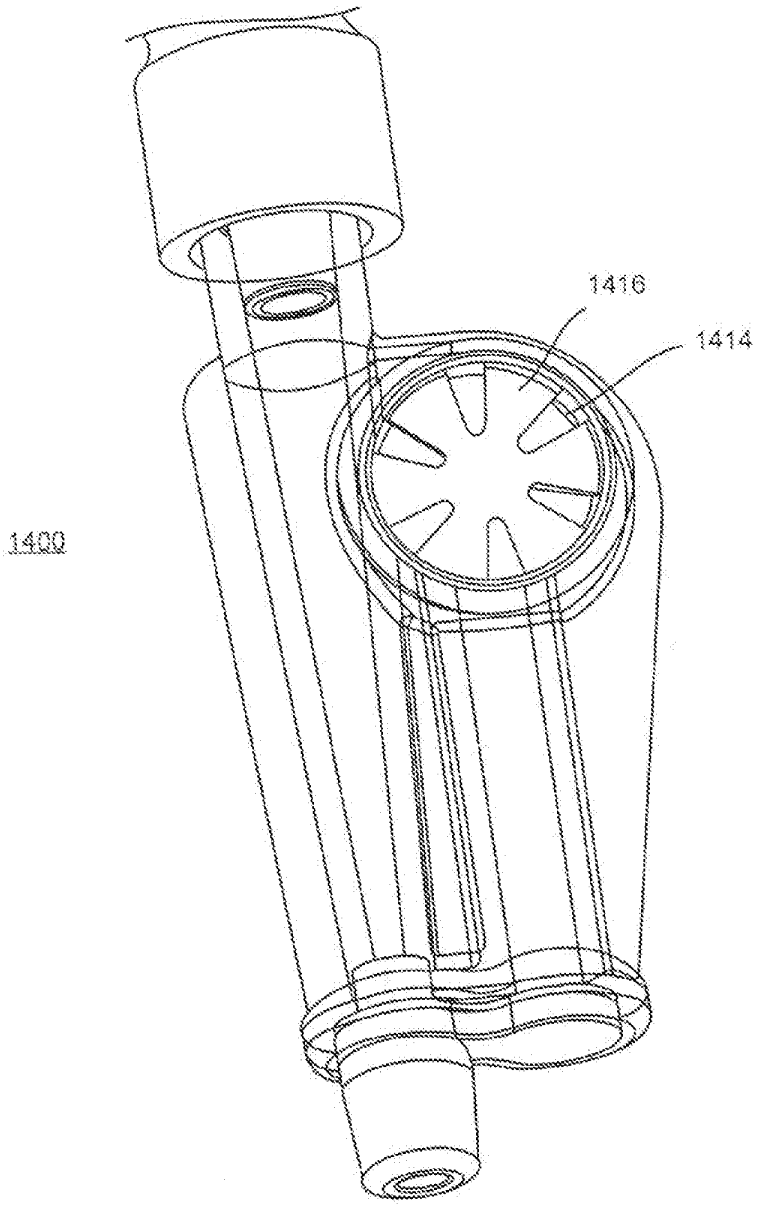


FIG. 14B

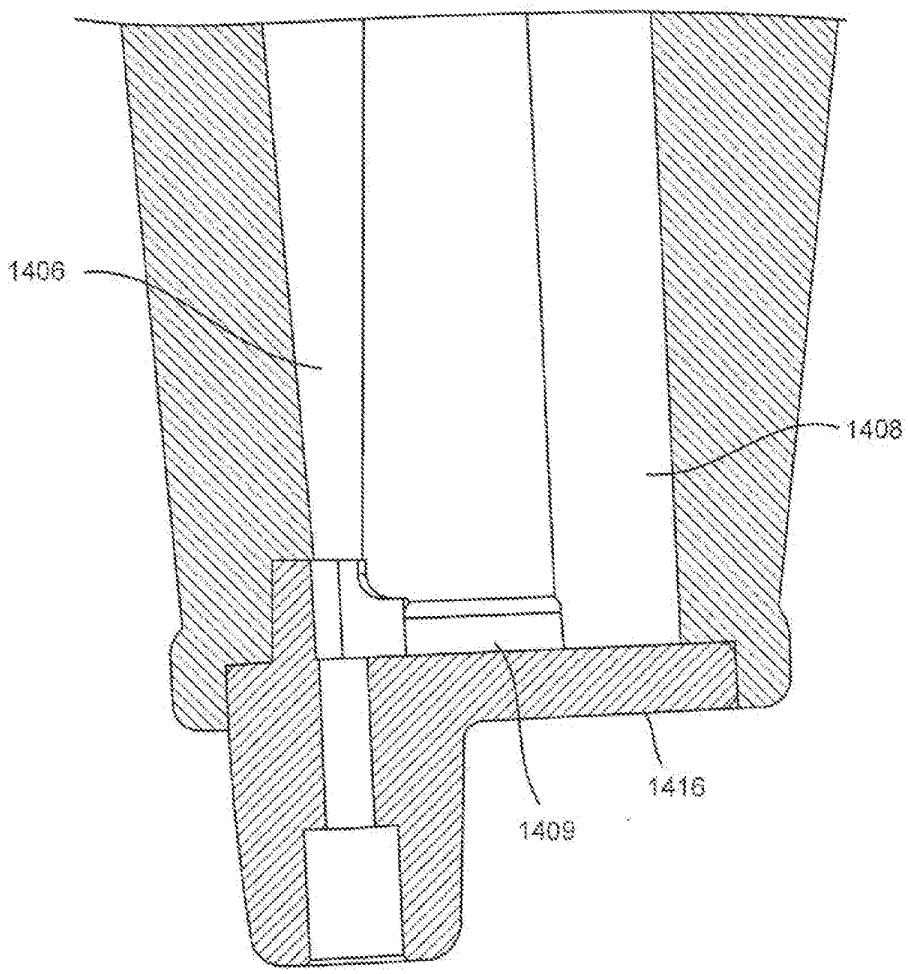


FIG. 14C

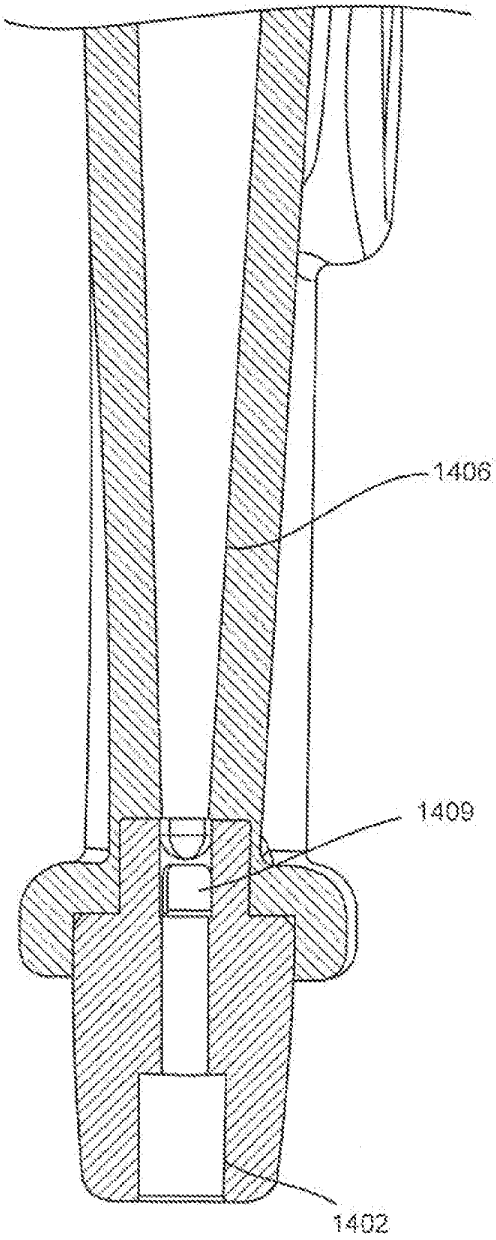


FIG. 14D

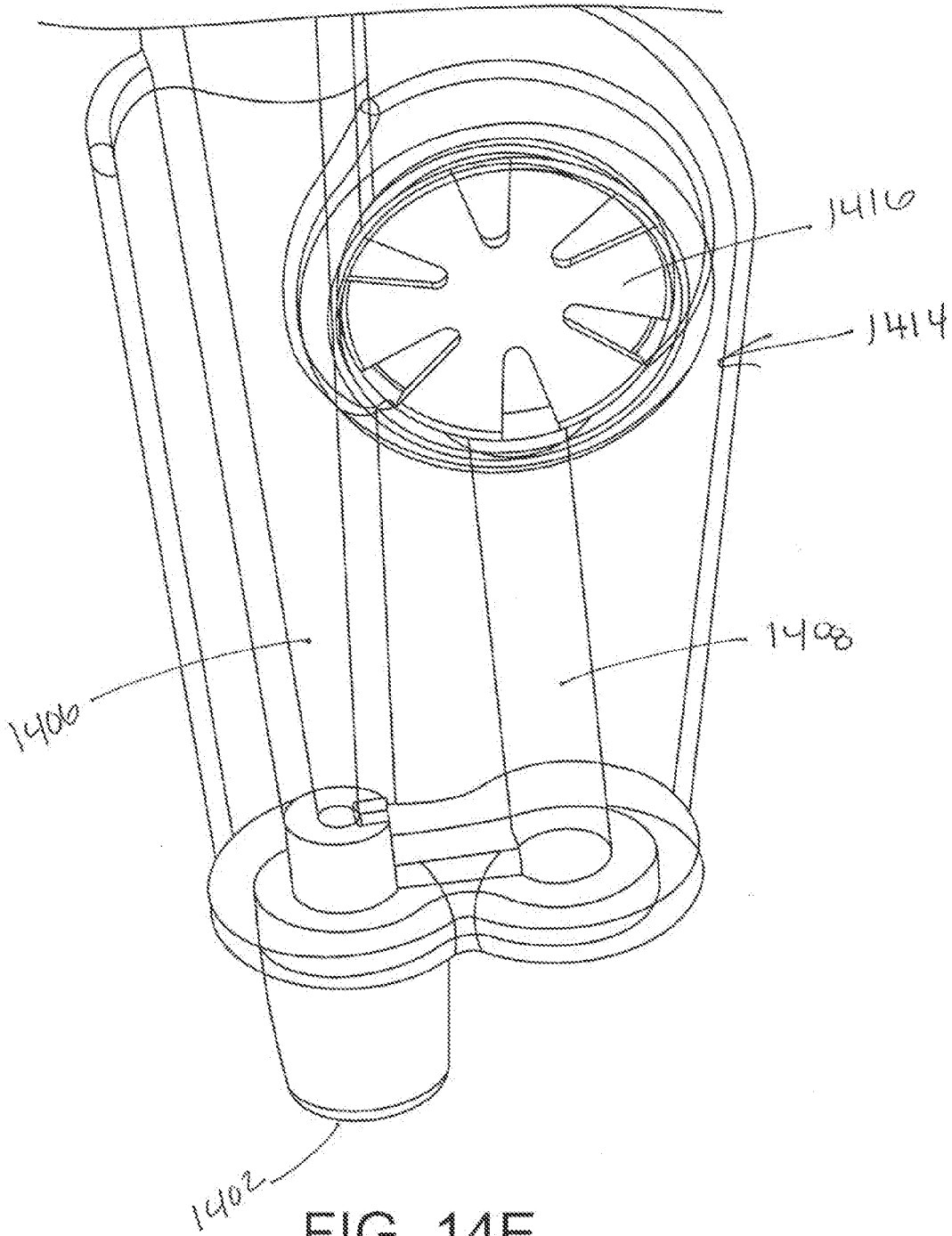


FIG. 14E

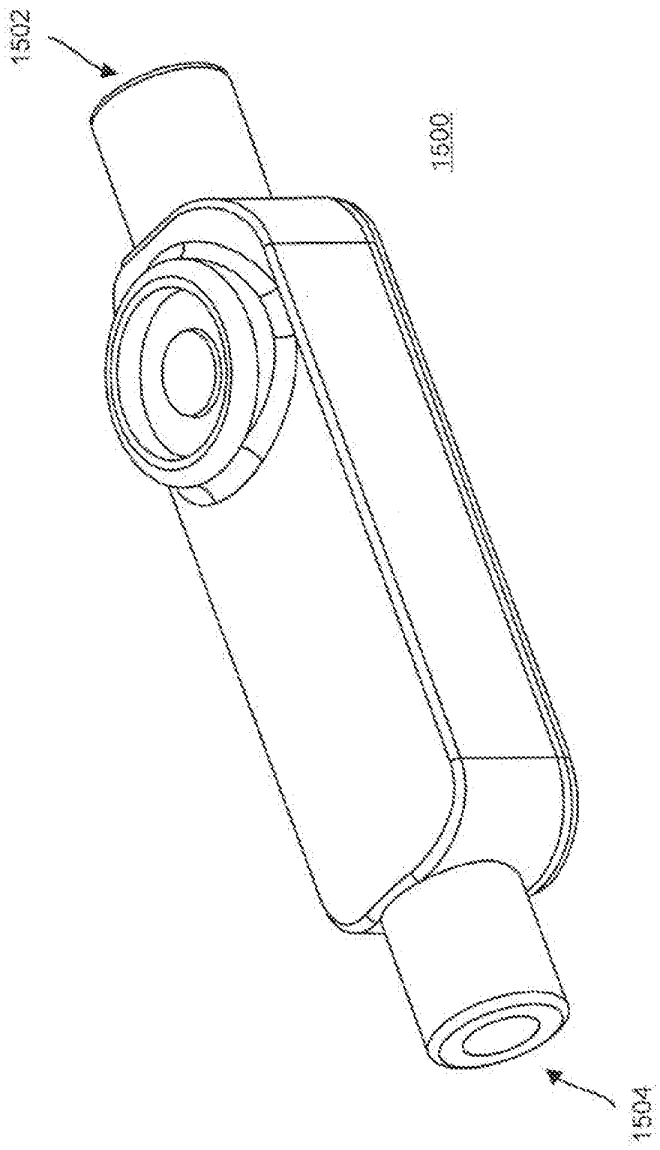


FIG. 15A

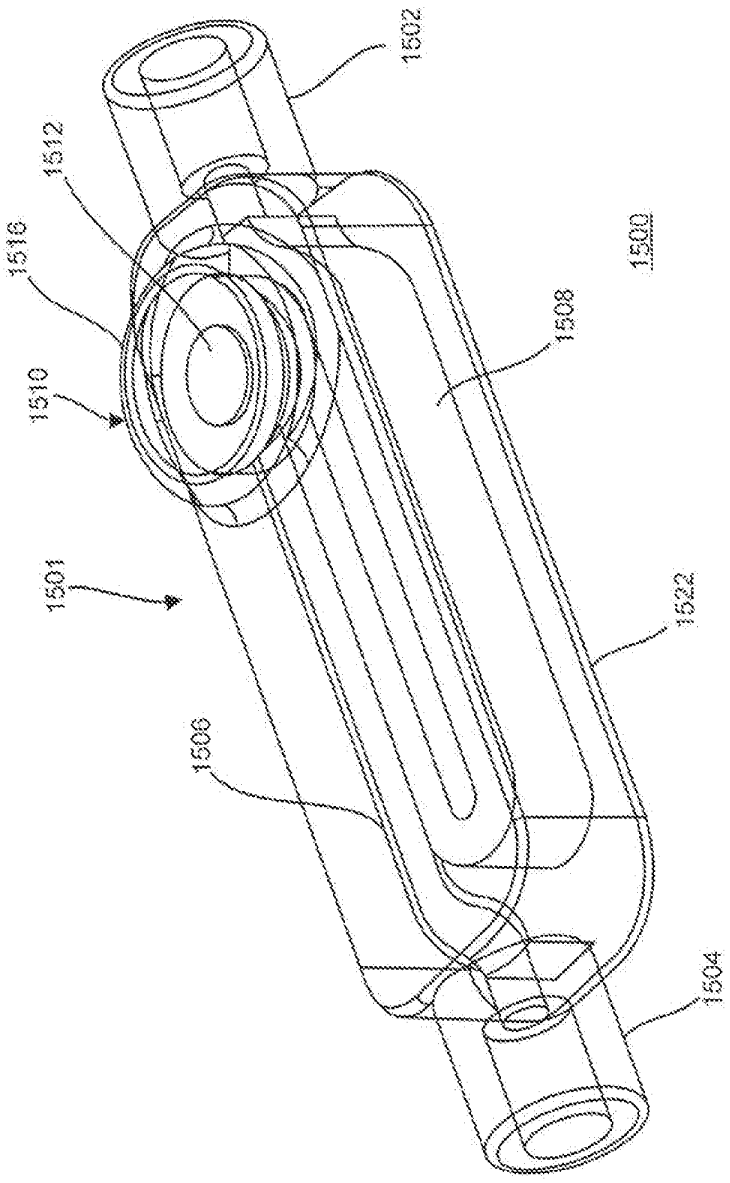


FIG. 15B

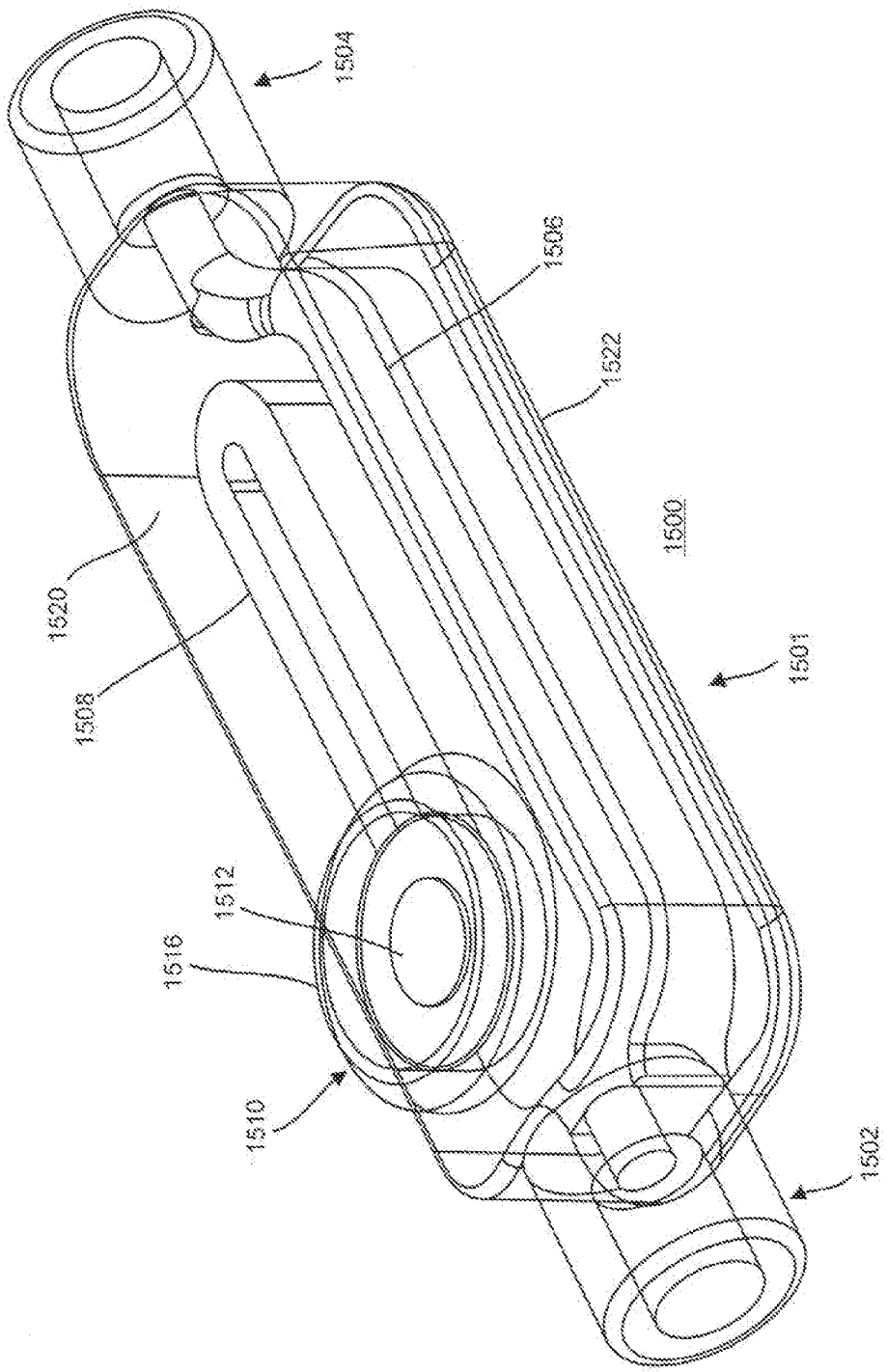


FIG. 15C

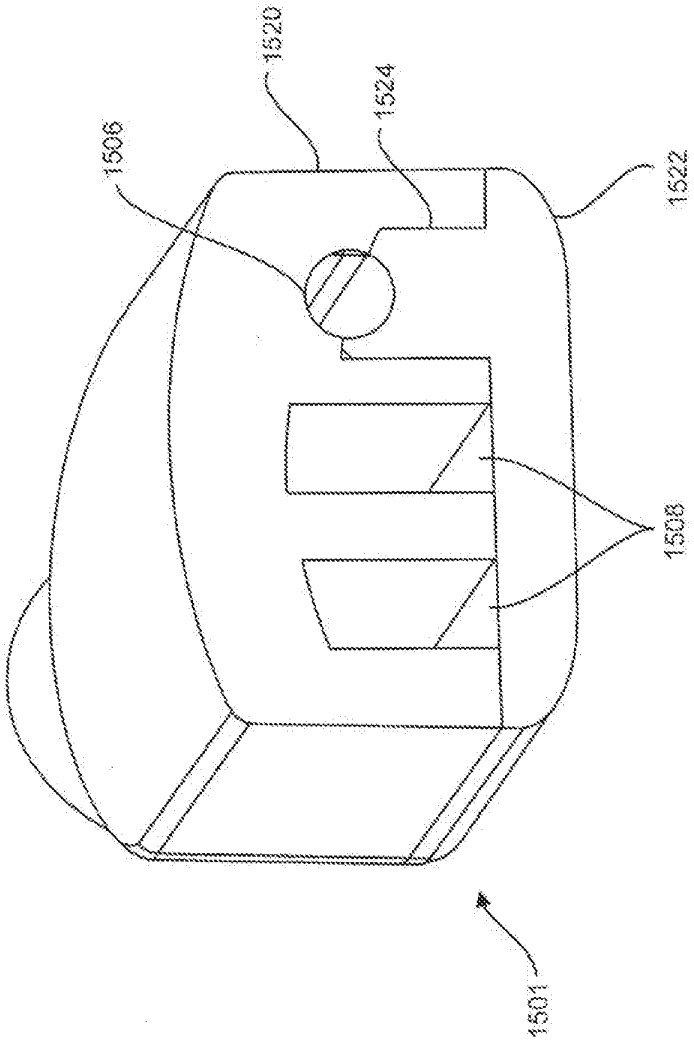


FIG. 15D

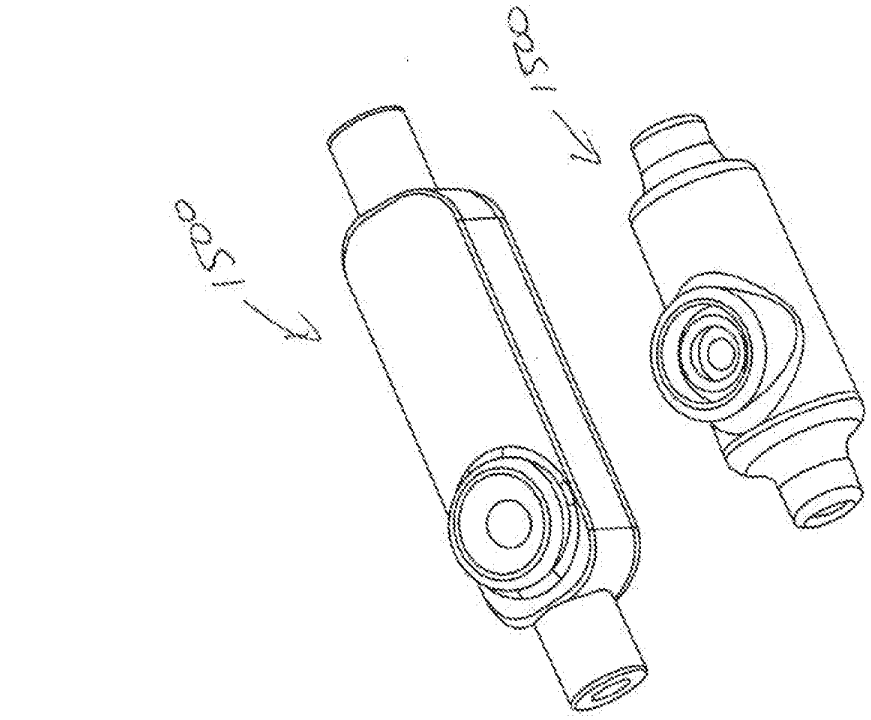


FIG. 15F

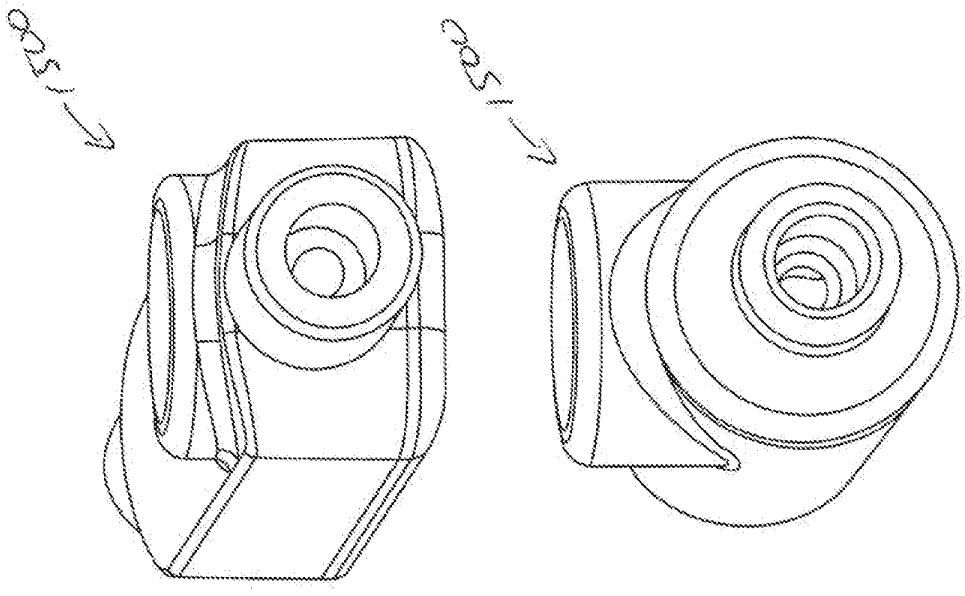


FIG. 15E

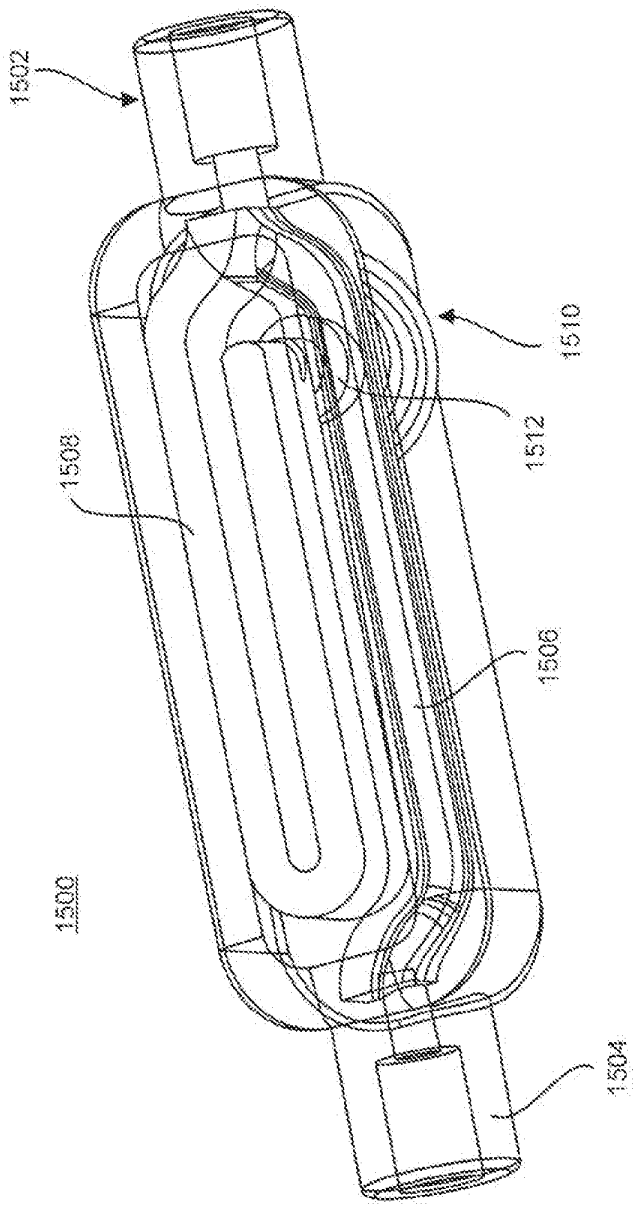


FIG. 15G

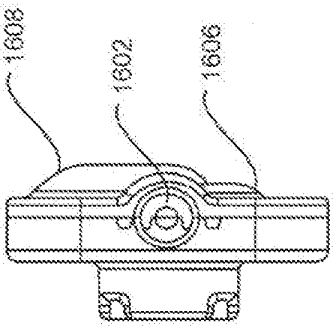


FIG. 16C

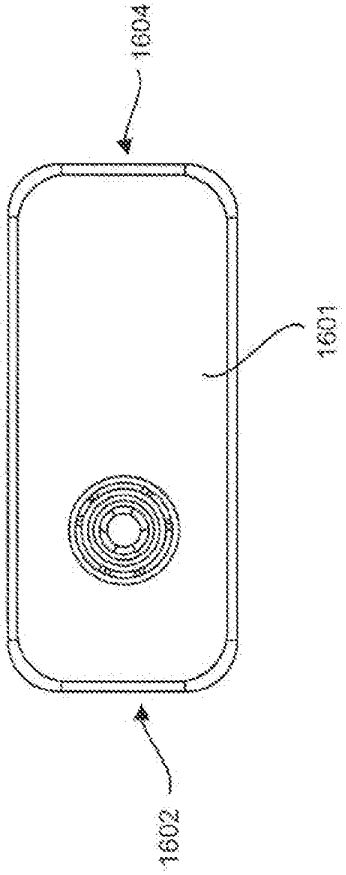


FIG. 16A

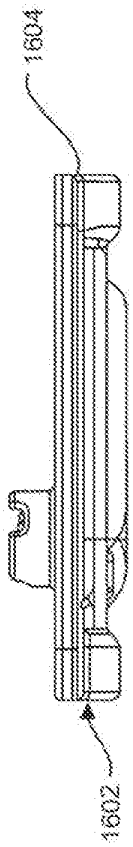


FIG. 16B

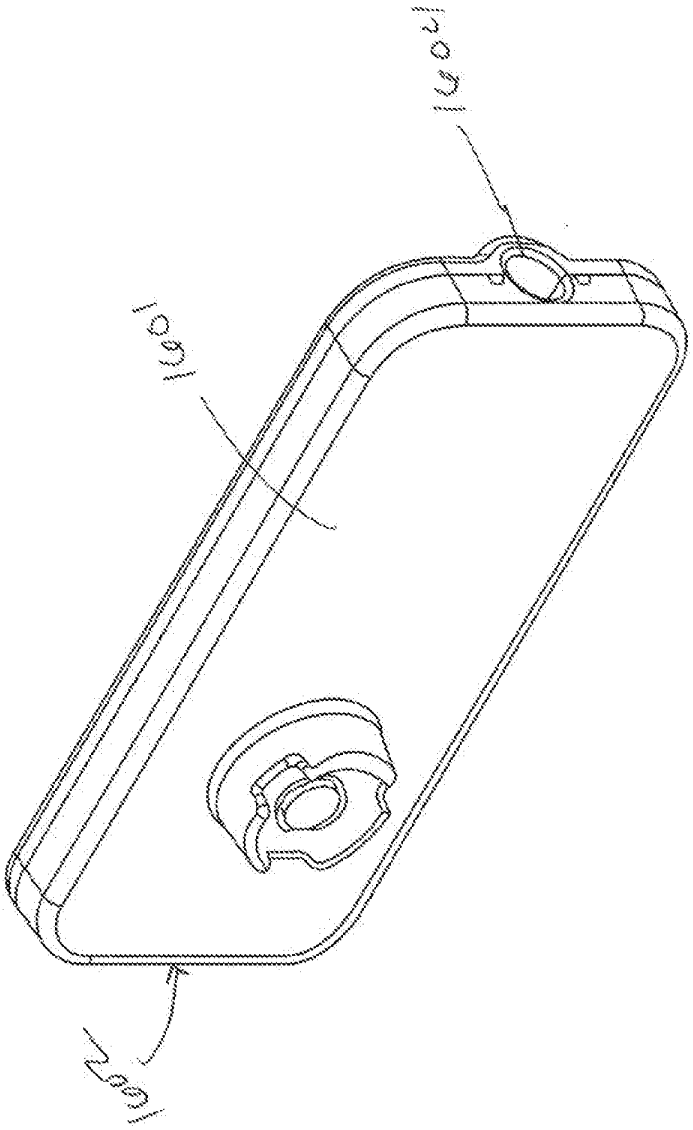


FIG. 16D

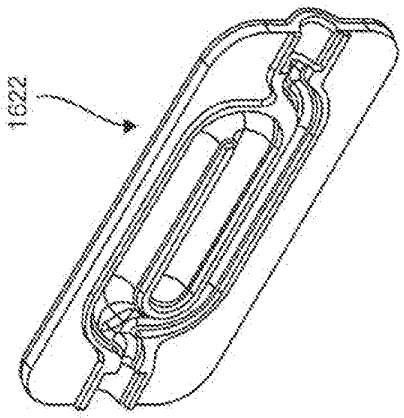


FIG. 17B

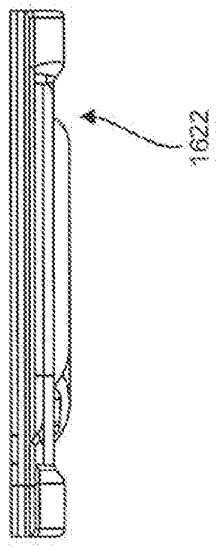


FIG. 17E

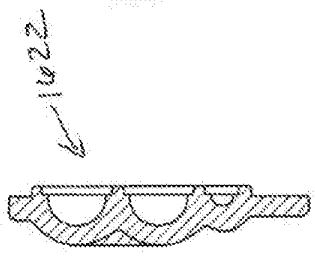


FIG. 17D

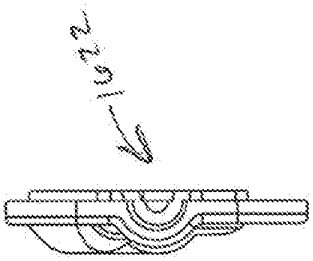


FIG. 17C

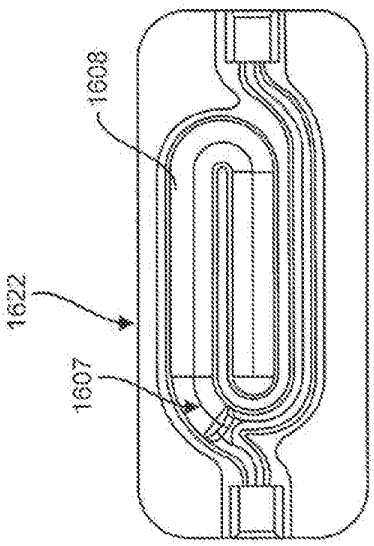


FIG. 17A

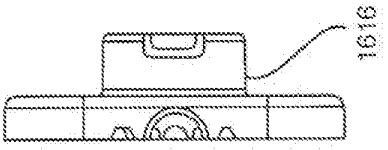


FIG. 18C

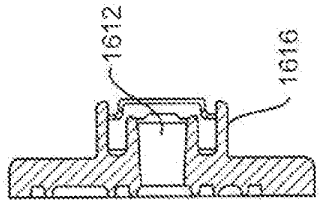


FIG. 18F

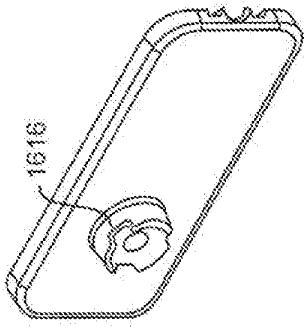


FIG. 18B

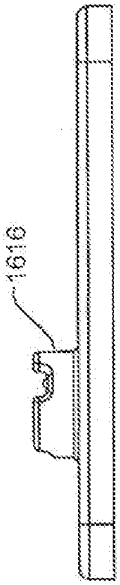


FIG. 18E

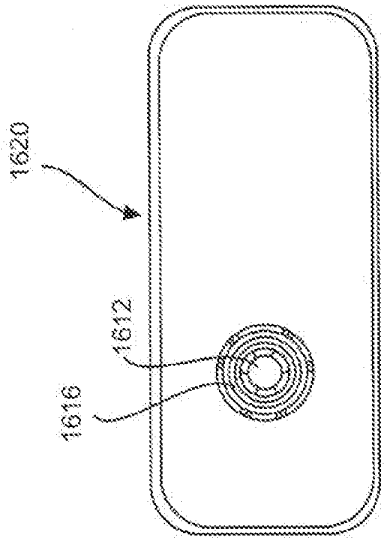


FIG. 18A

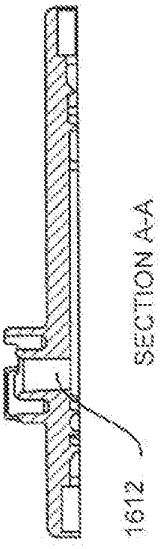


FIG. 18D

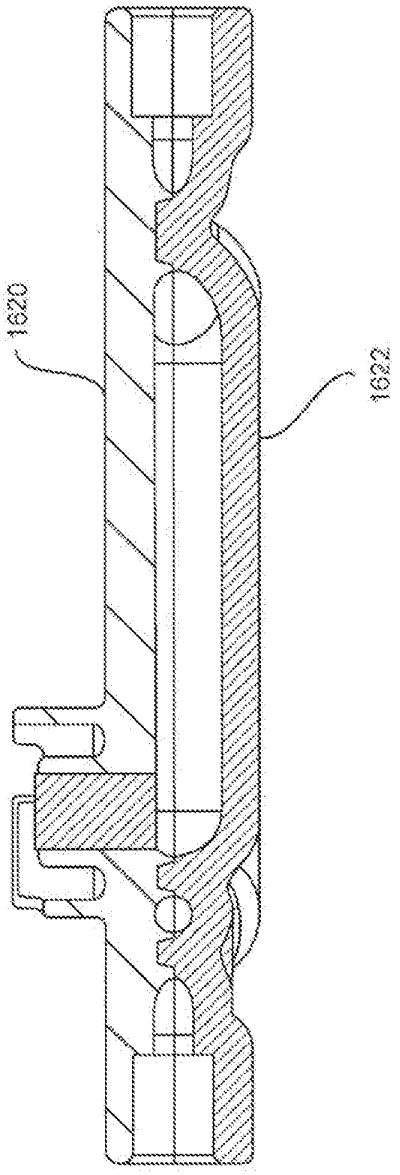


FIG. 19A

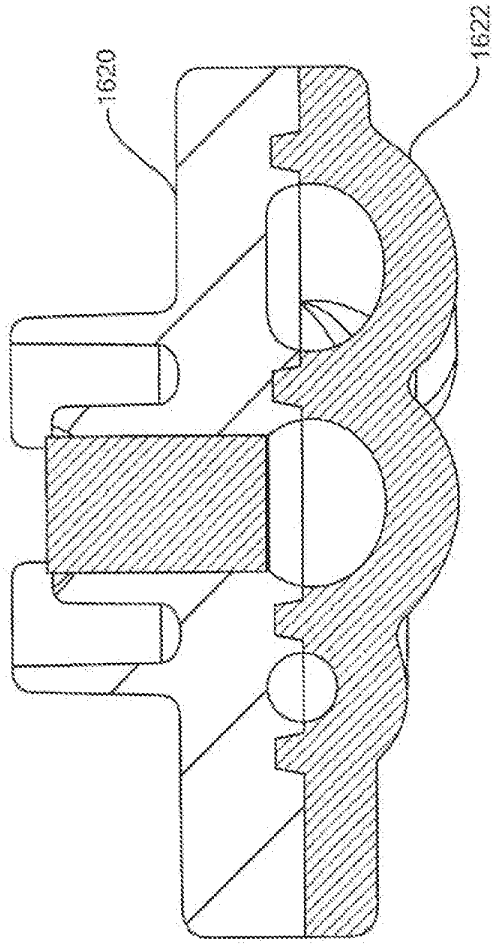


FIG. 19B

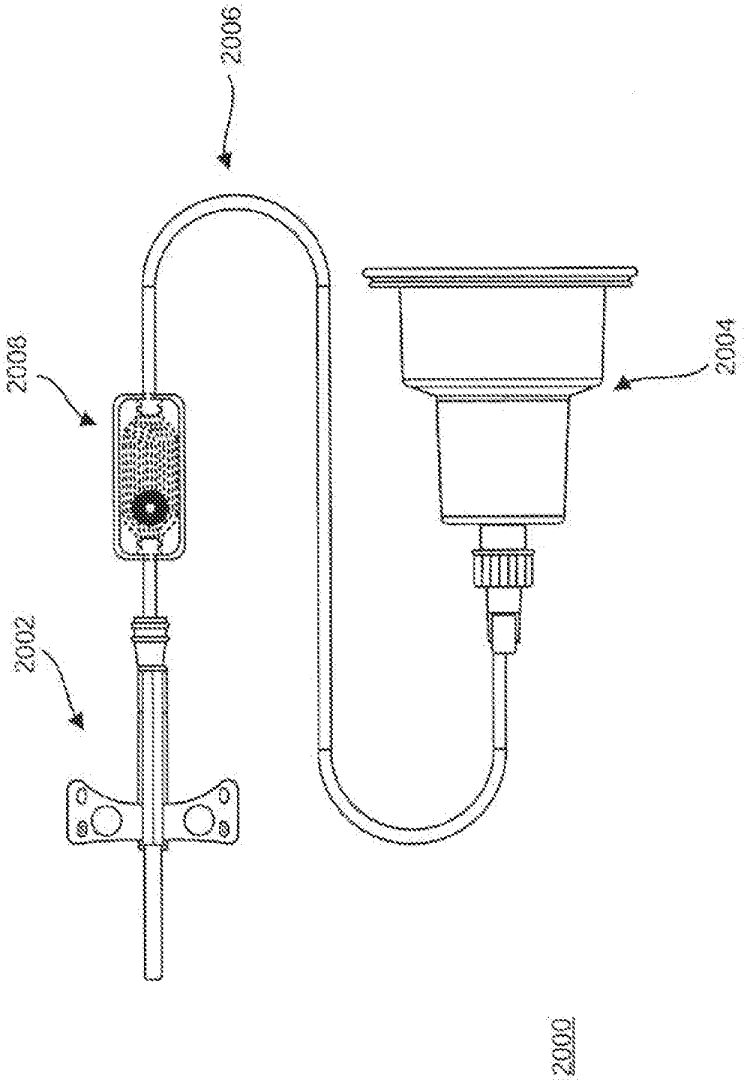


FIG. 20

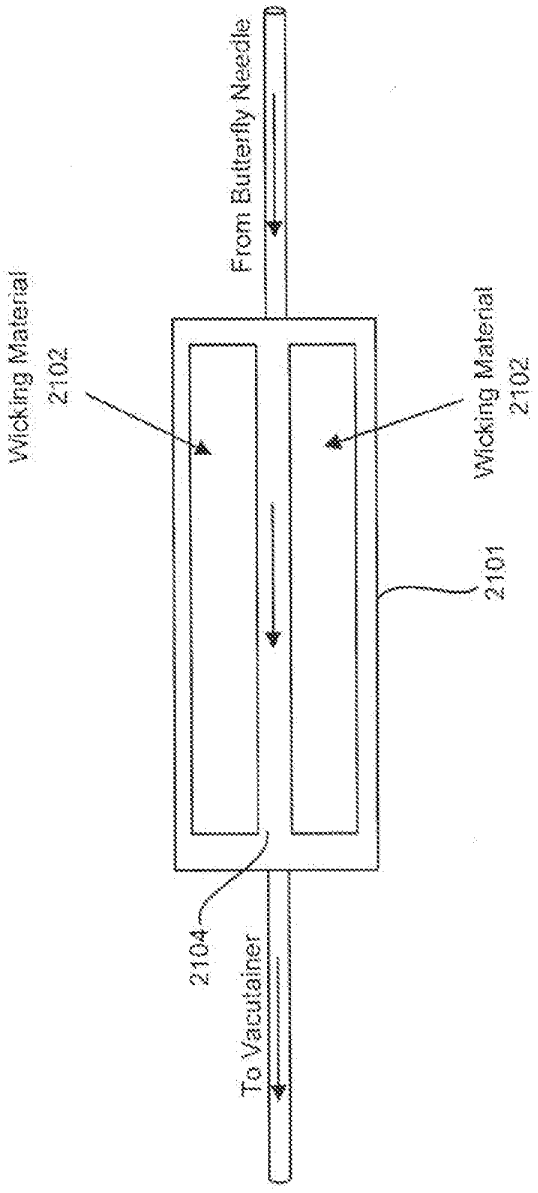

From Butterfly Needle
Wicking Material
2102
Wicking Material
2102
2101
2104
To Vacutainer
2100

FIG. 21

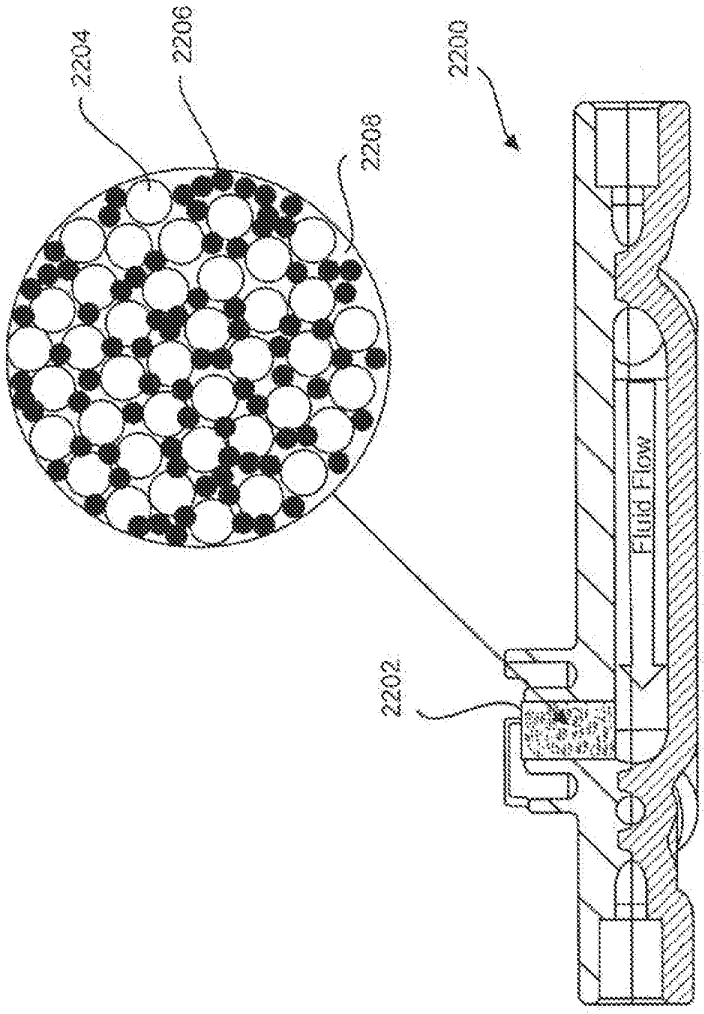


FIG. 22A

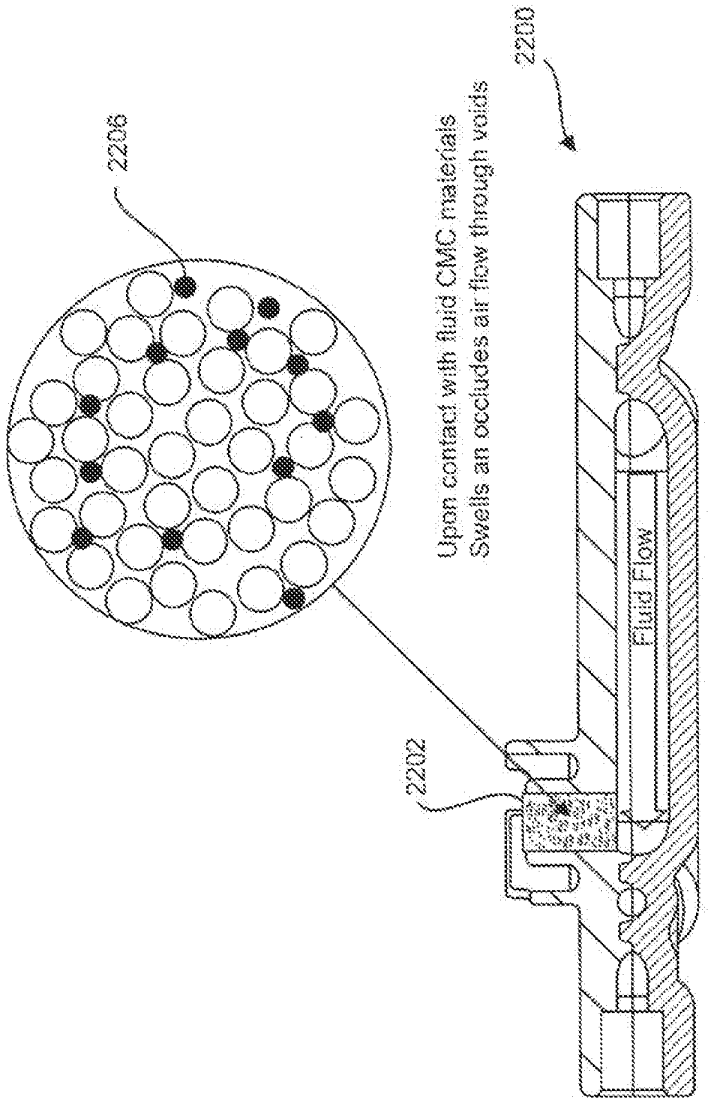

2206
2200
Upon contact with fluid CMC materials
Swells an occludes air flow through voids
Fluid Flow
2202

FIG. 22B

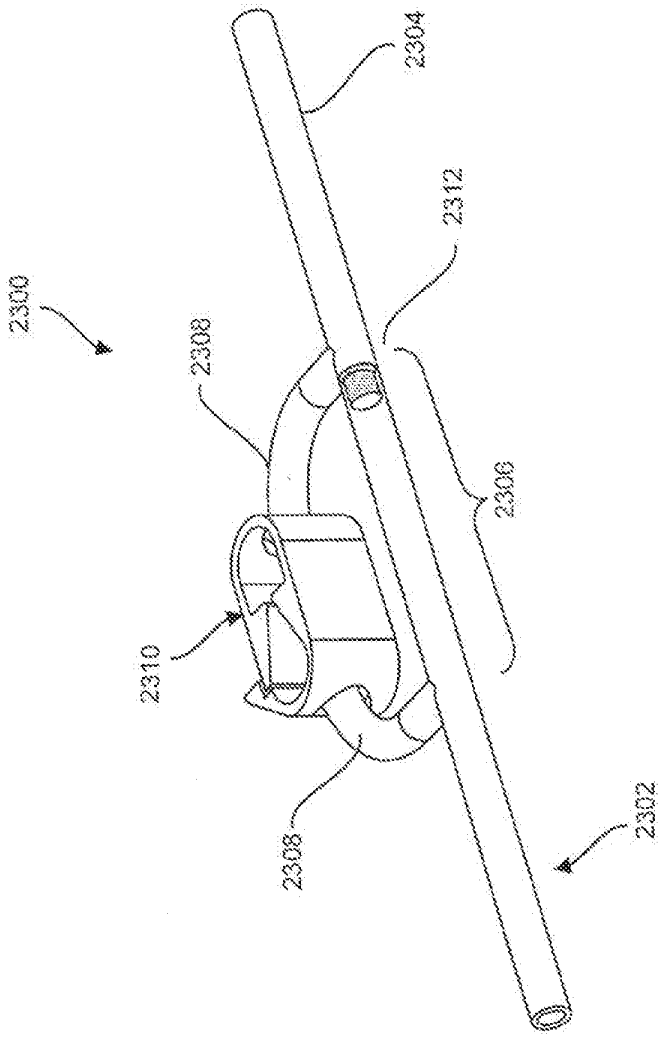


FIG. 23A

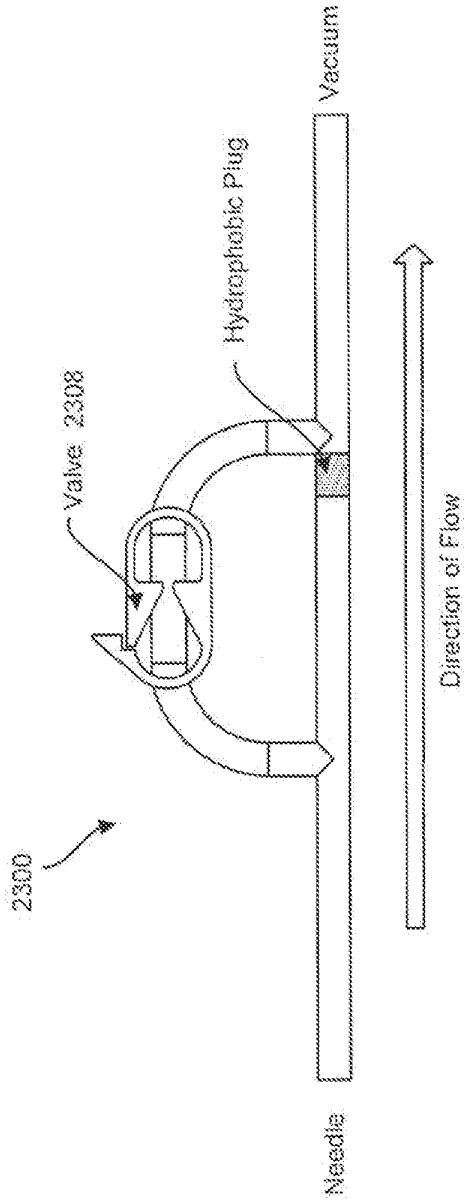

Vacuum
Hydrophobic Plug
Valve 2308
Direction of Flow
2300
Needle

FIG. 23B

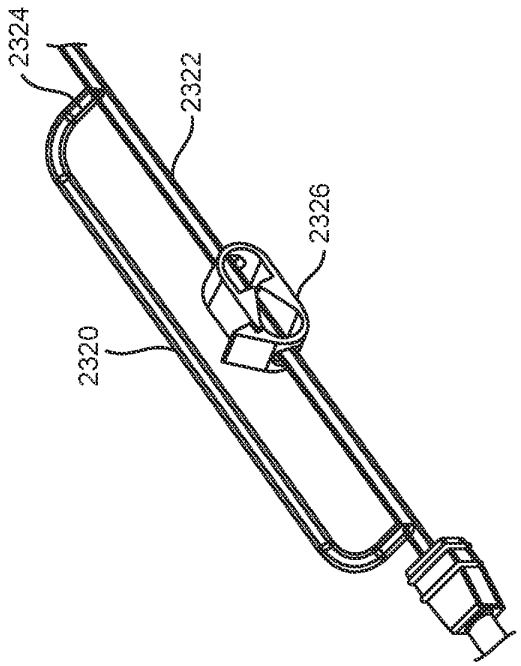


FIG. 23D

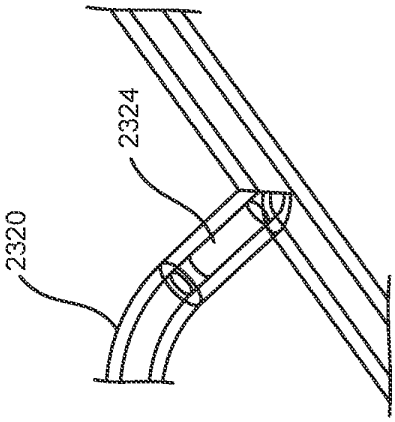


FIG. 23E

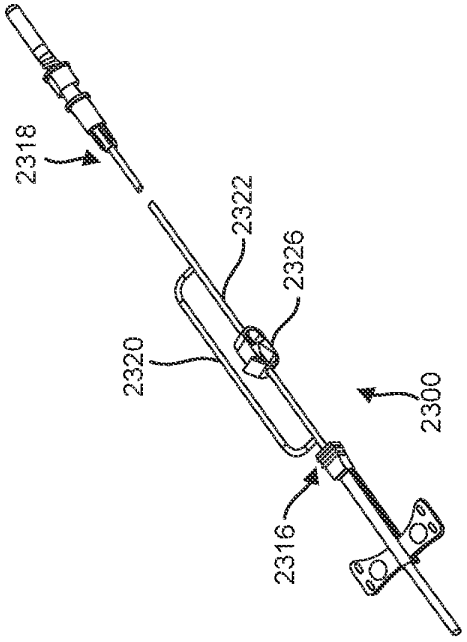


FIG. 23C

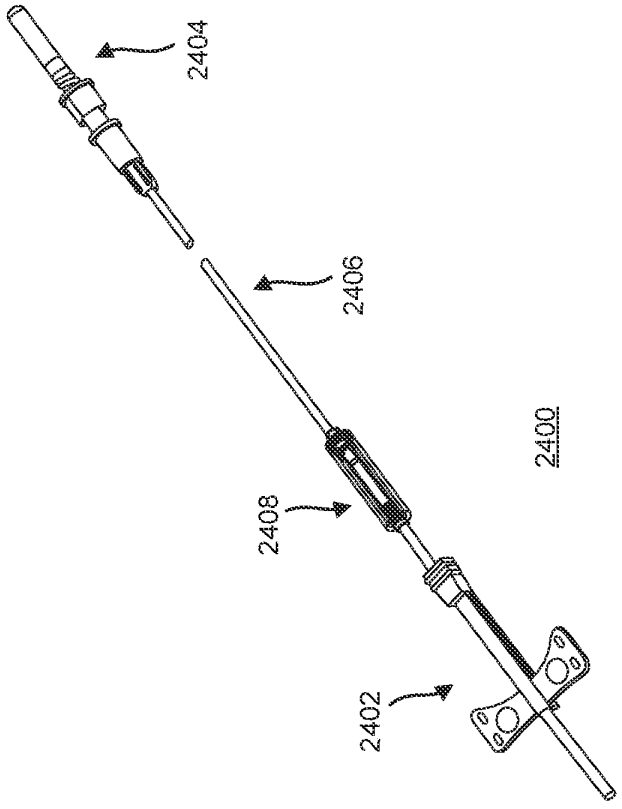


FIG. 24A

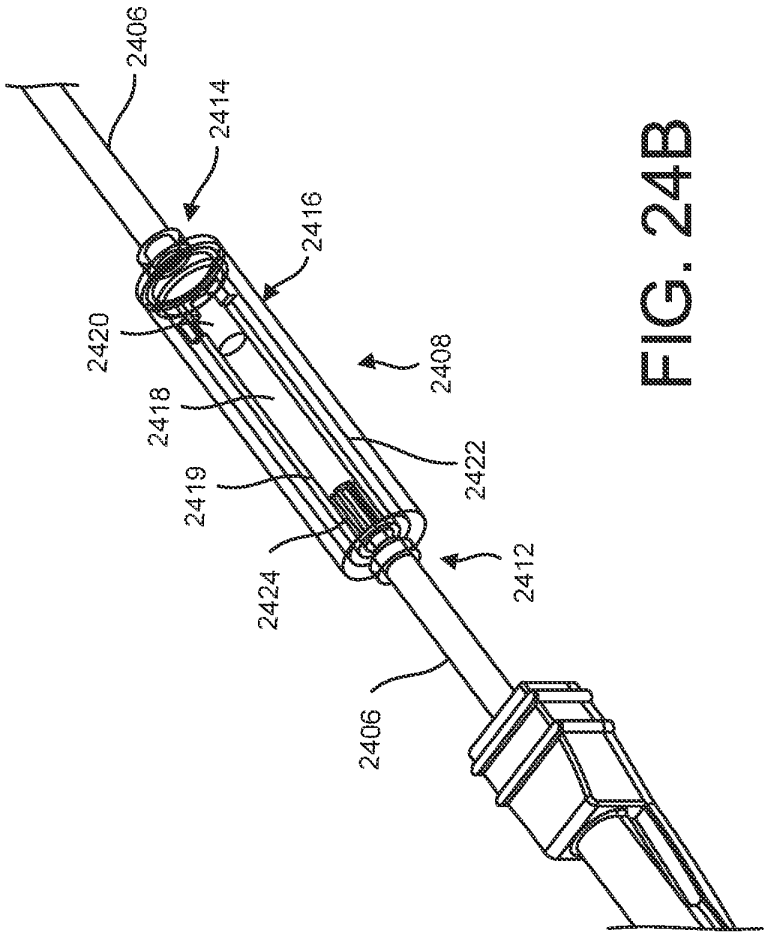


FIG. 24B

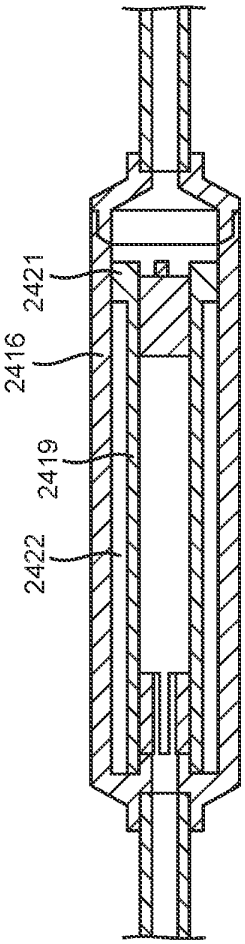


FIG. 24C

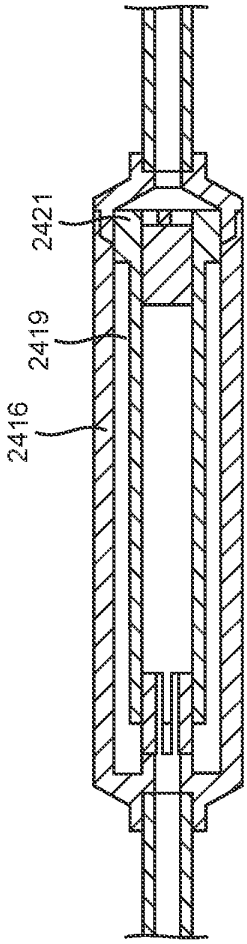


FIG. 24D

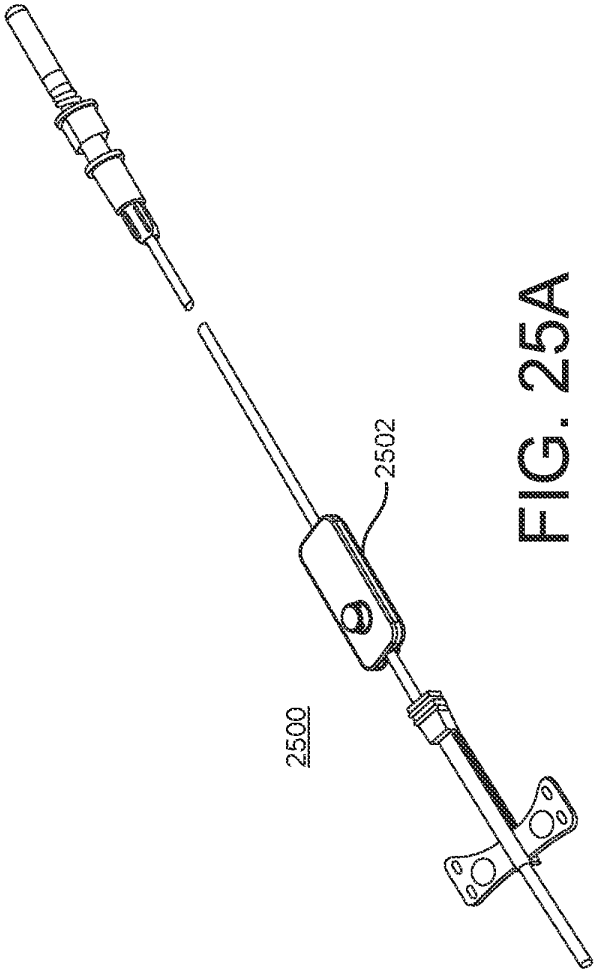


FIG. 25A

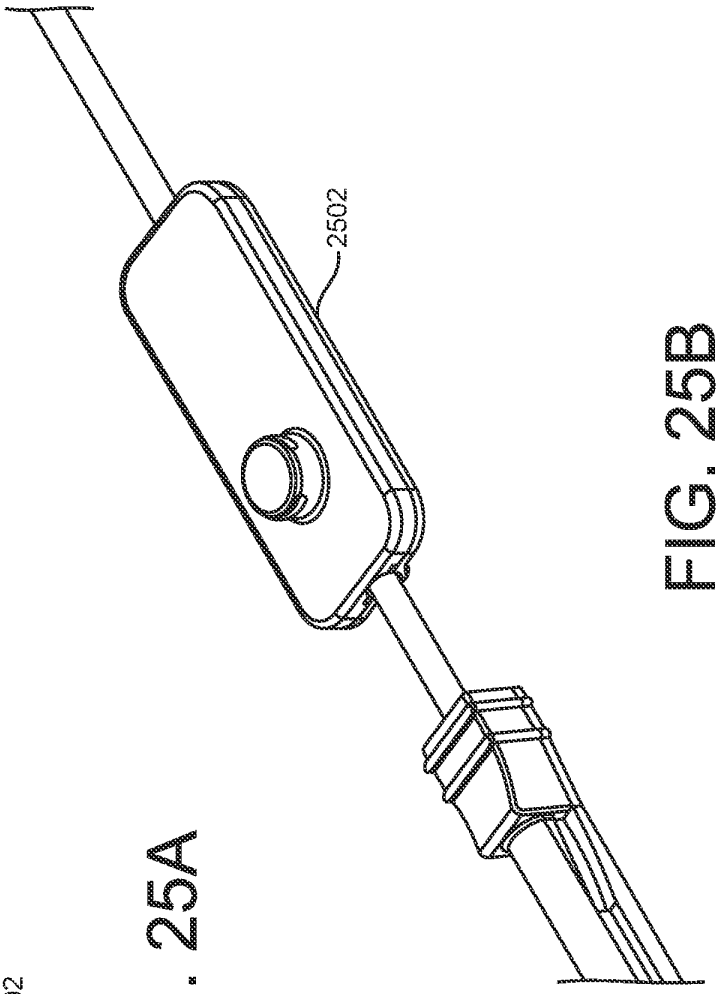


FIG. 25B

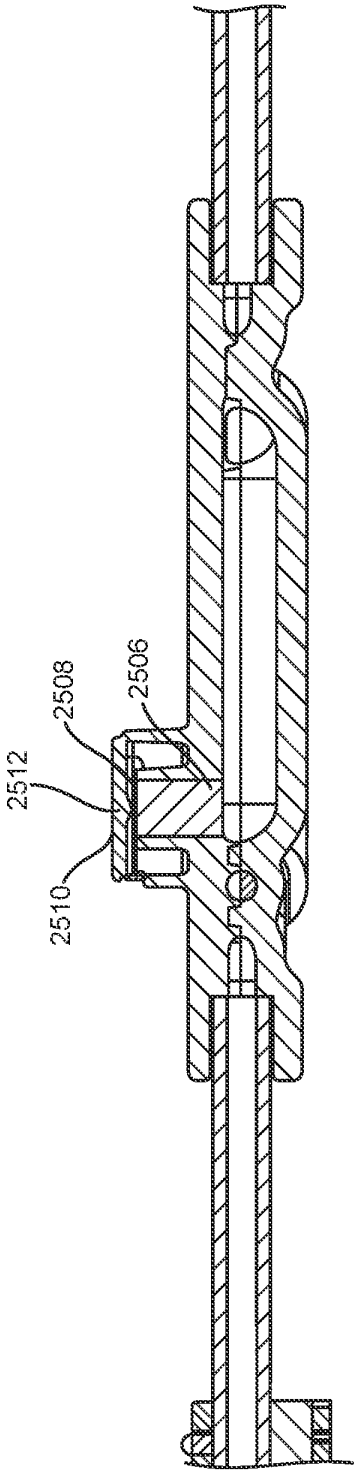


FIG. 25C

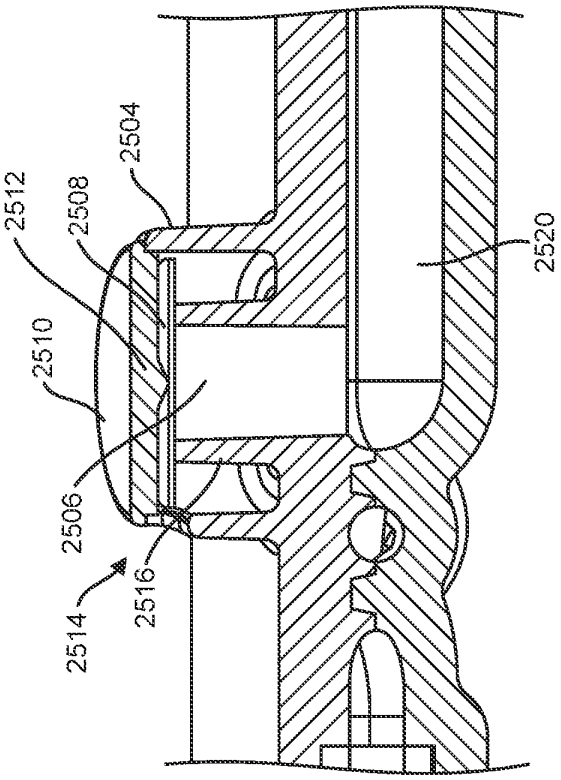


FIG. 25D

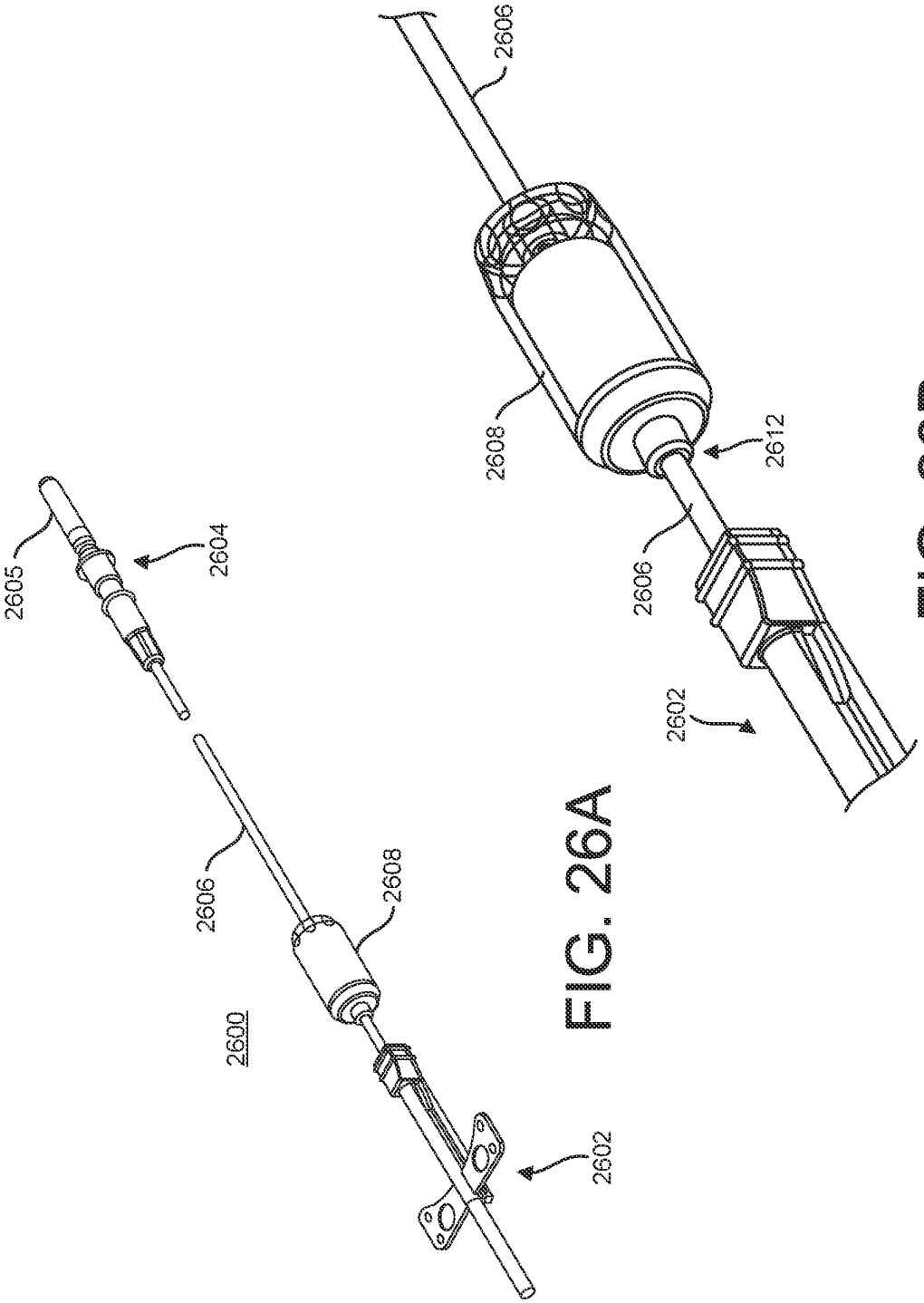


FIG. 26A

FIG. 26B

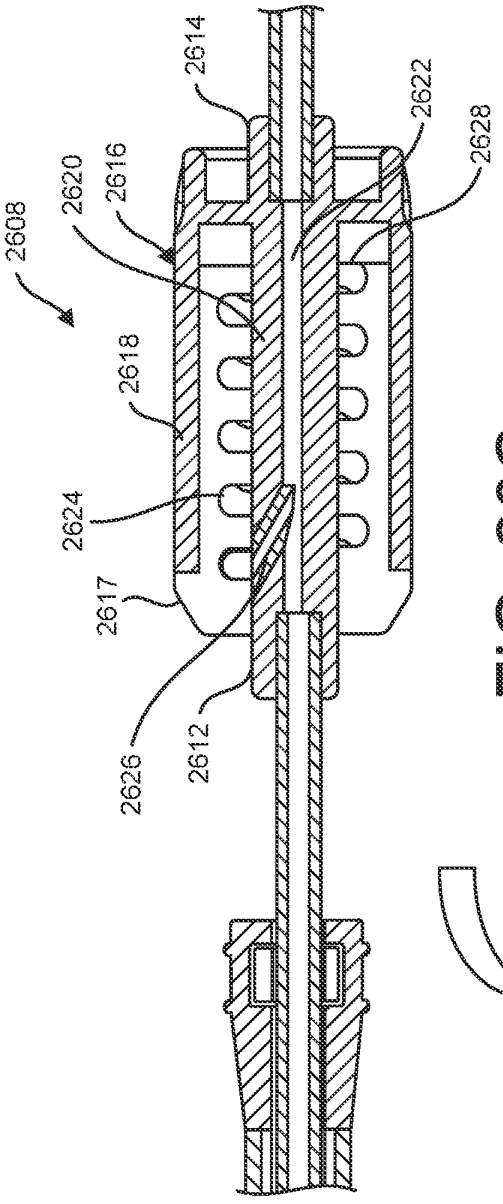


FIG. 26C

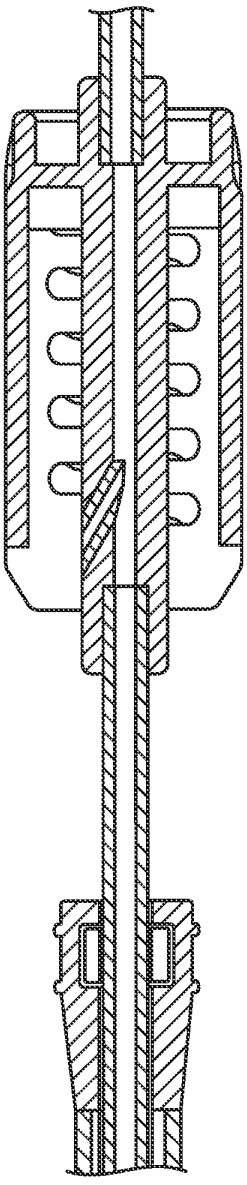


FIG. 26D

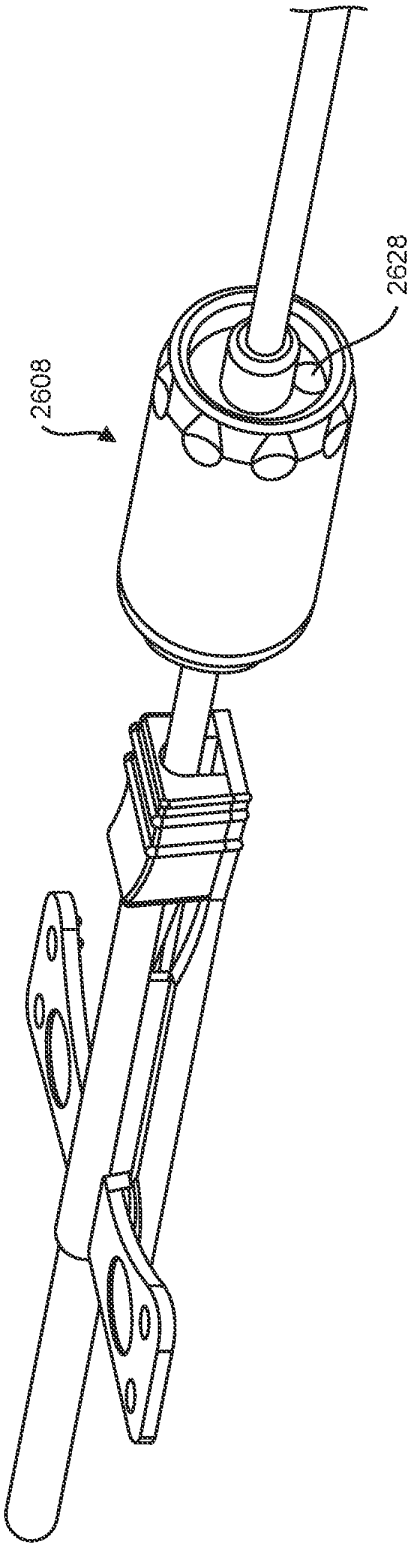


FIG. 26E

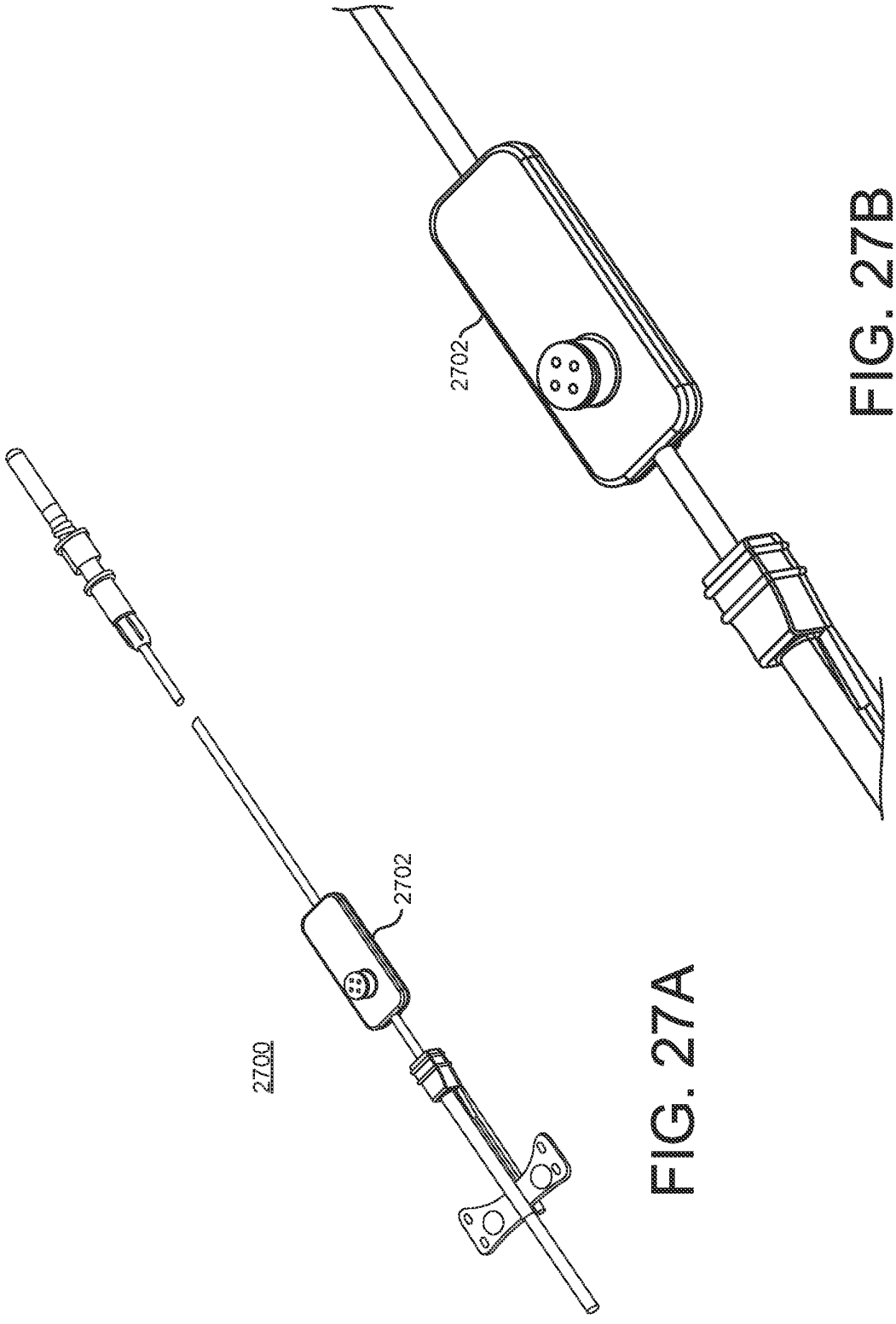


FIG. 27A

FIG. 27B

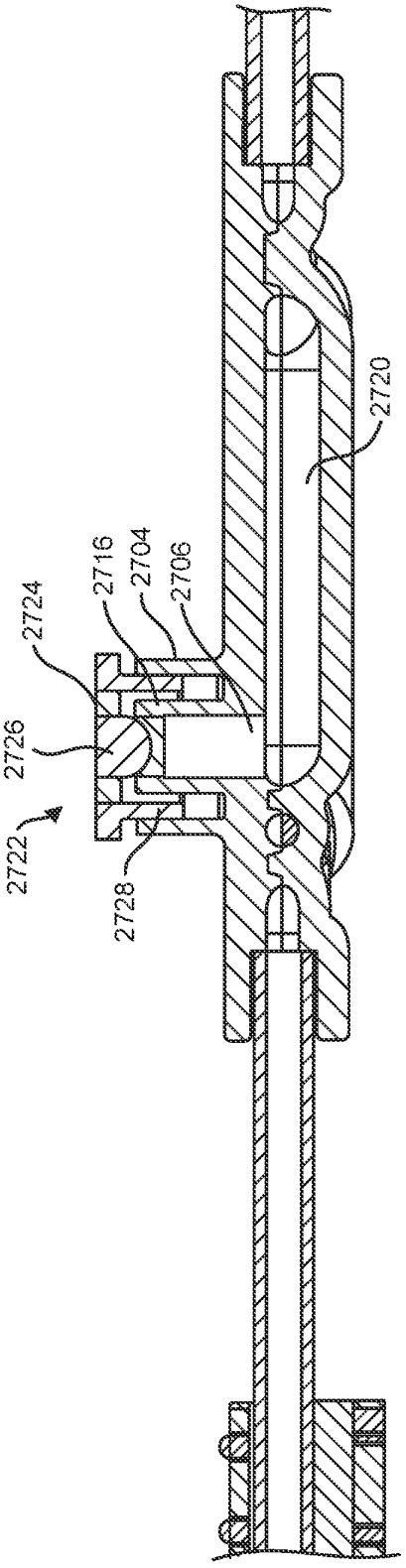


FIG. 27C

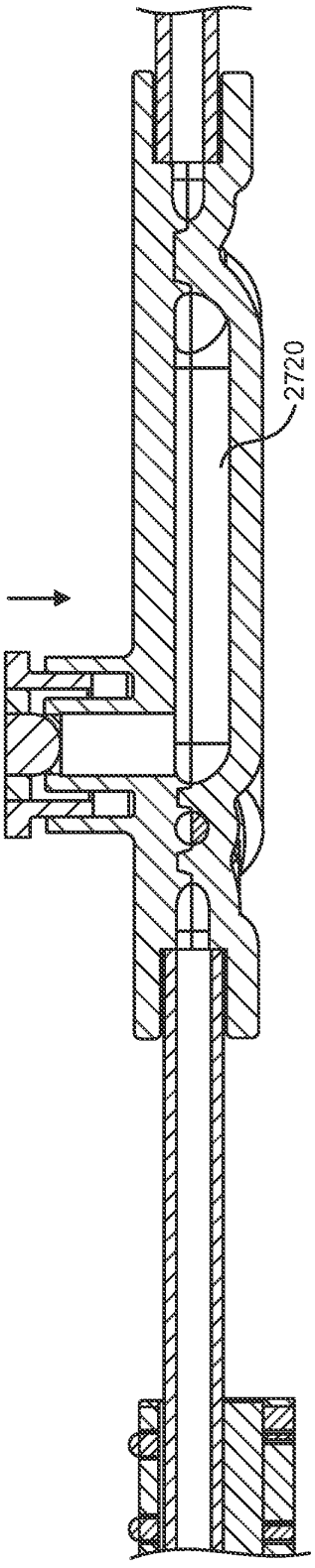


FIG. 27D

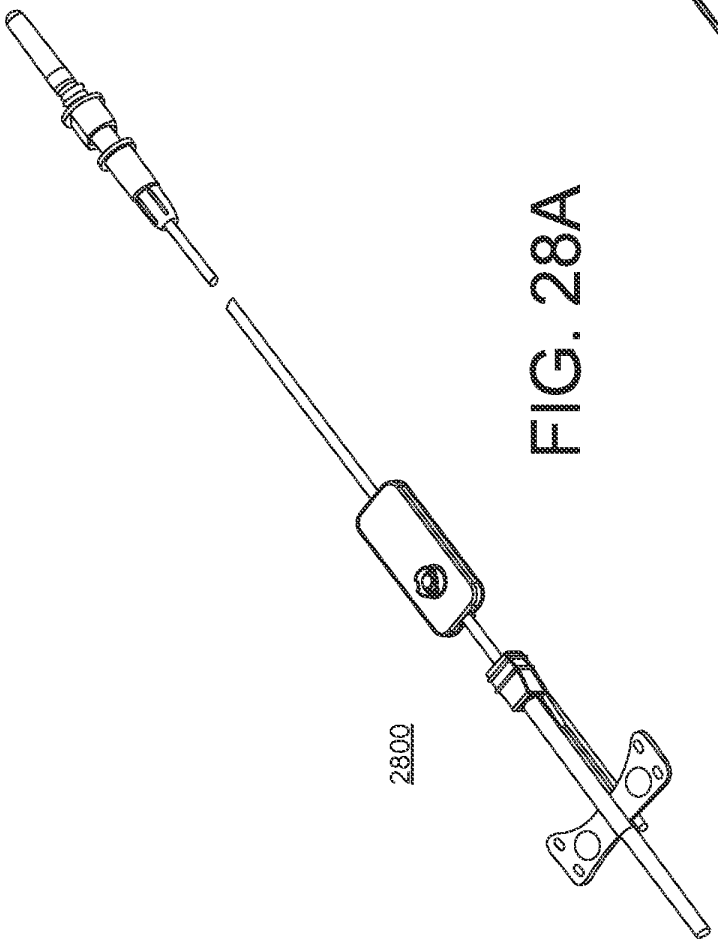


FIG. 28A

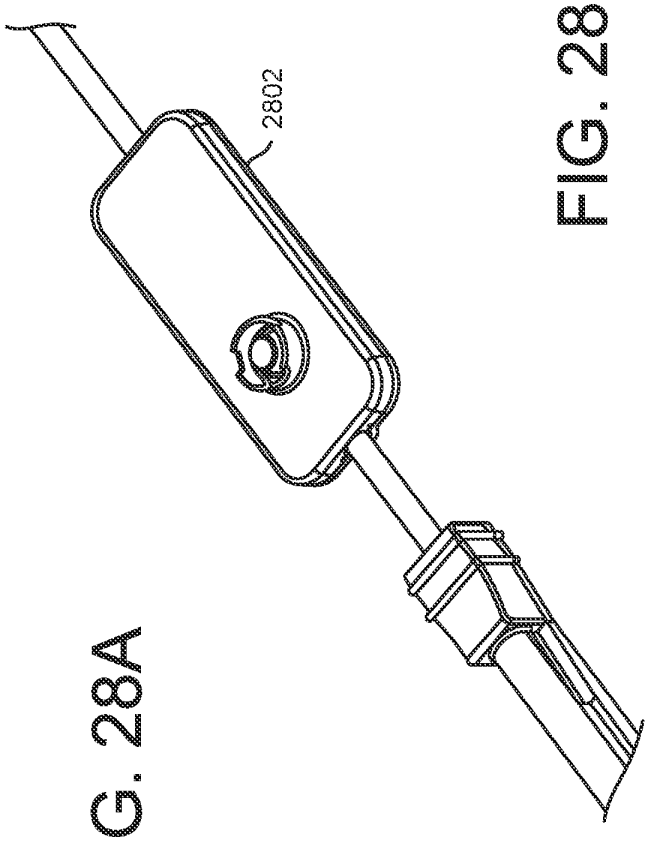


FIG. 28B

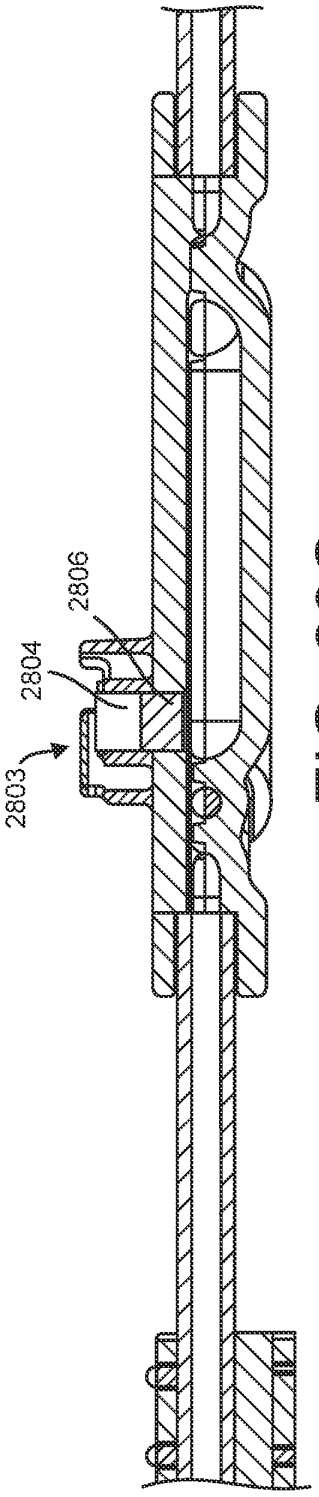


FIG. 28C

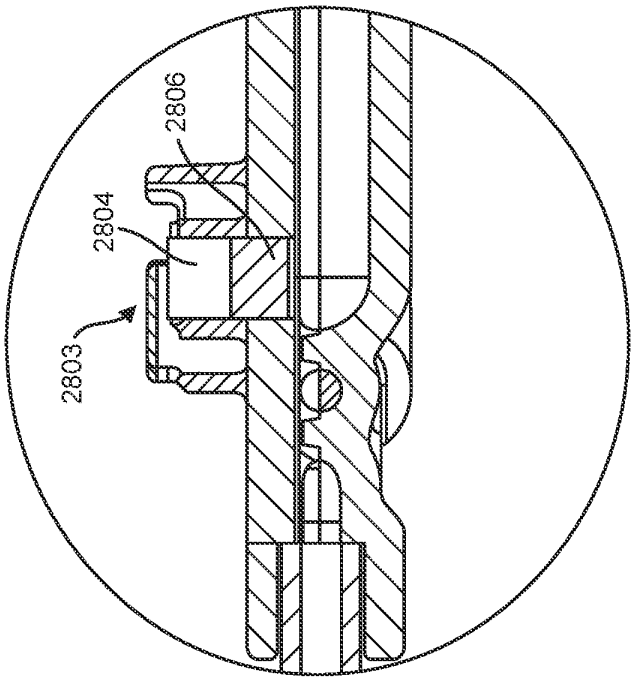


FIG. 28D

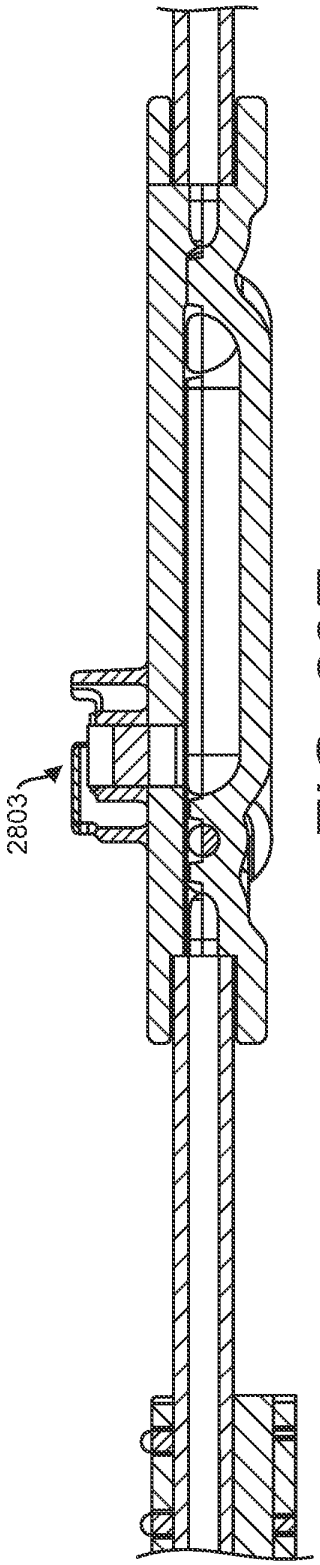


FIG. 28E

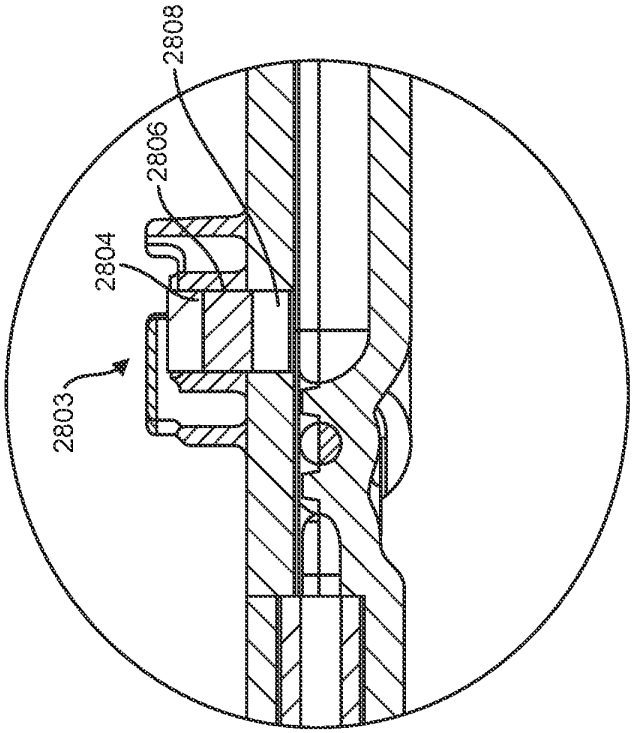


FIG. 28F

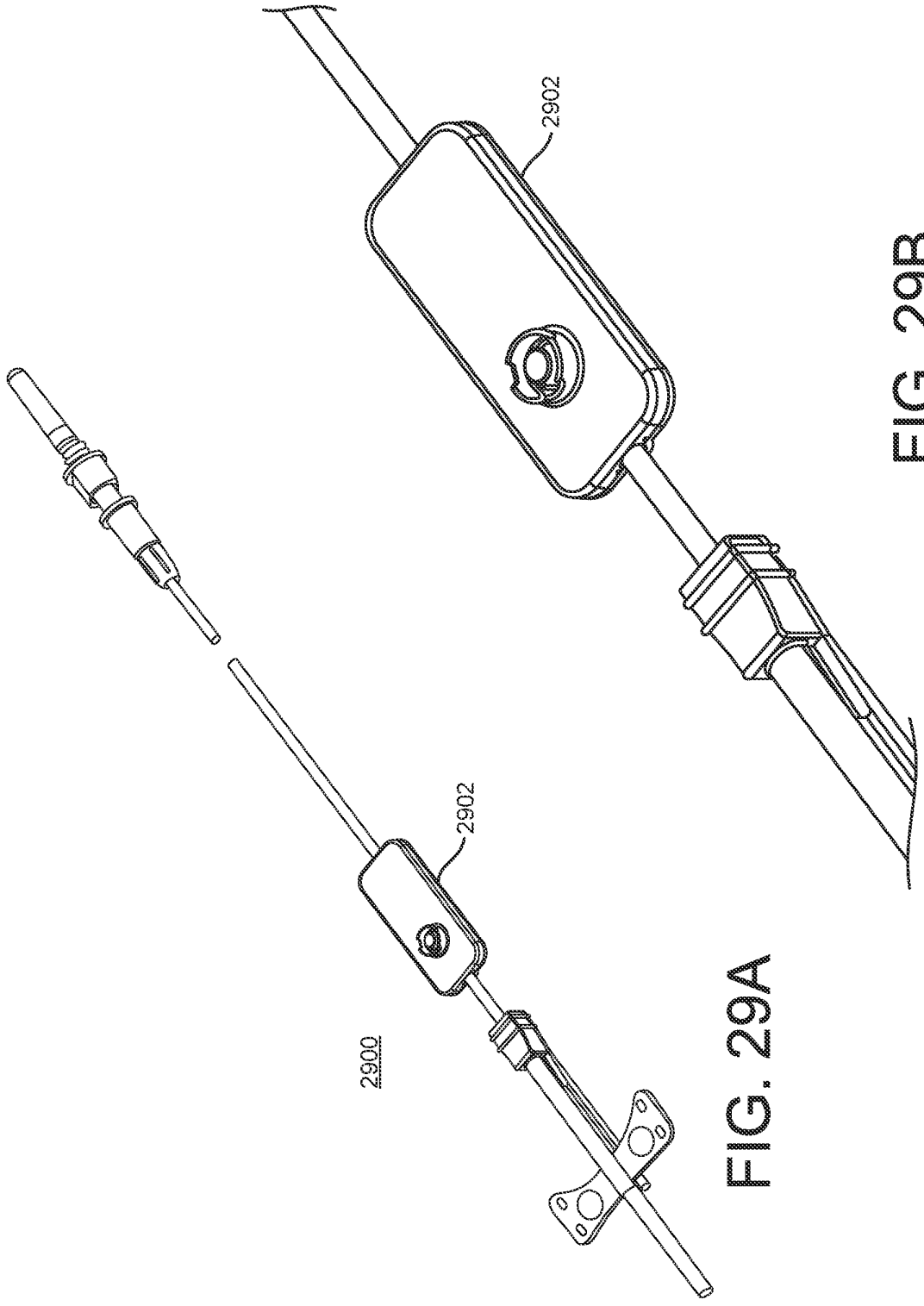


FIG. 29A

FIG. 29B

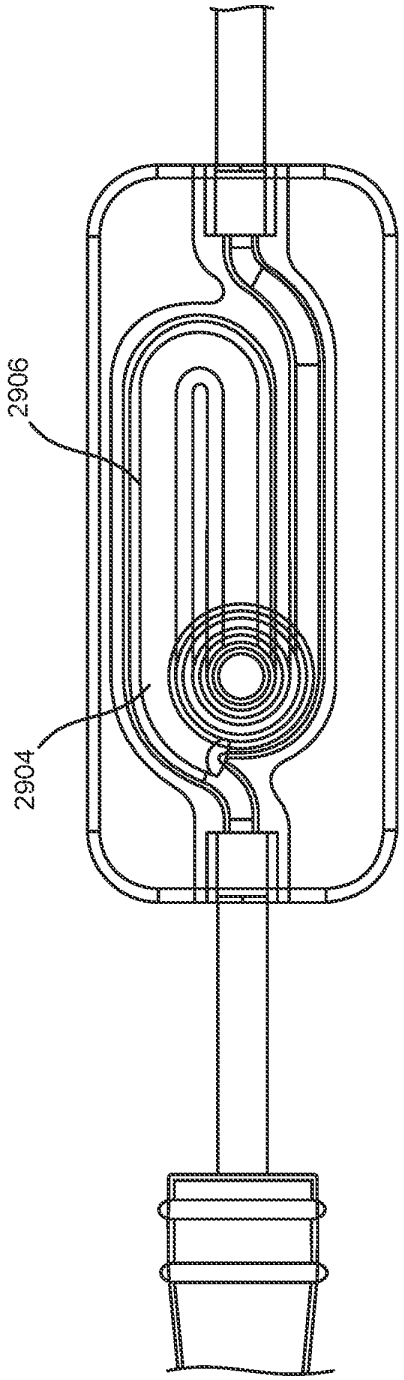


FIG. 29C

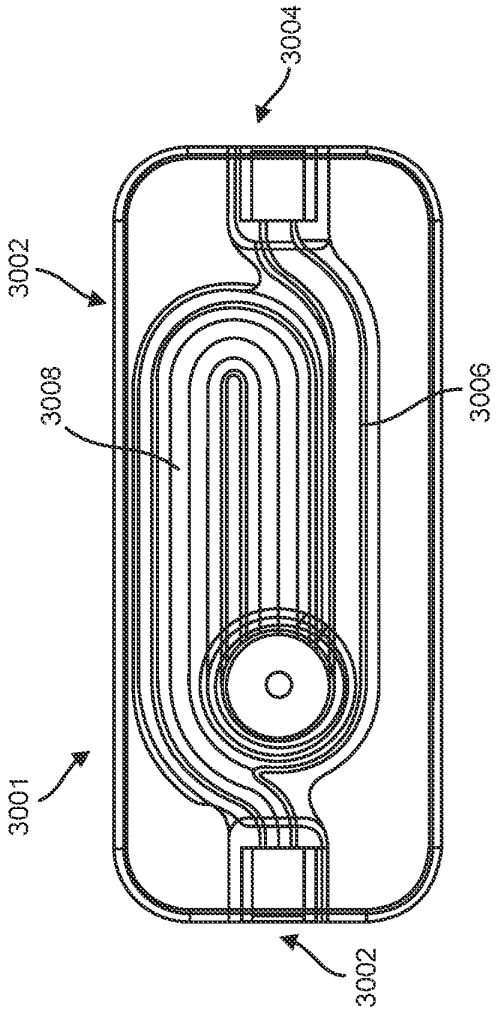


FIG. 30A

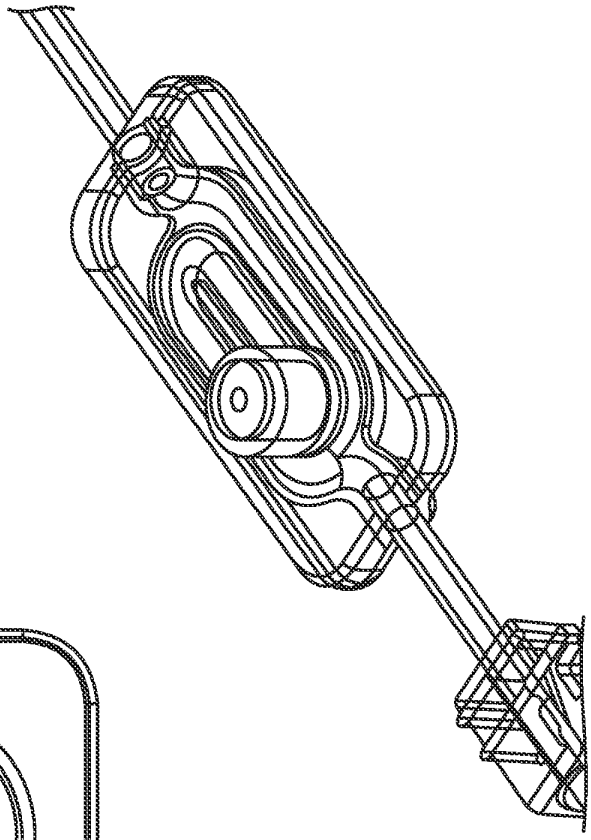


FIG. 30B

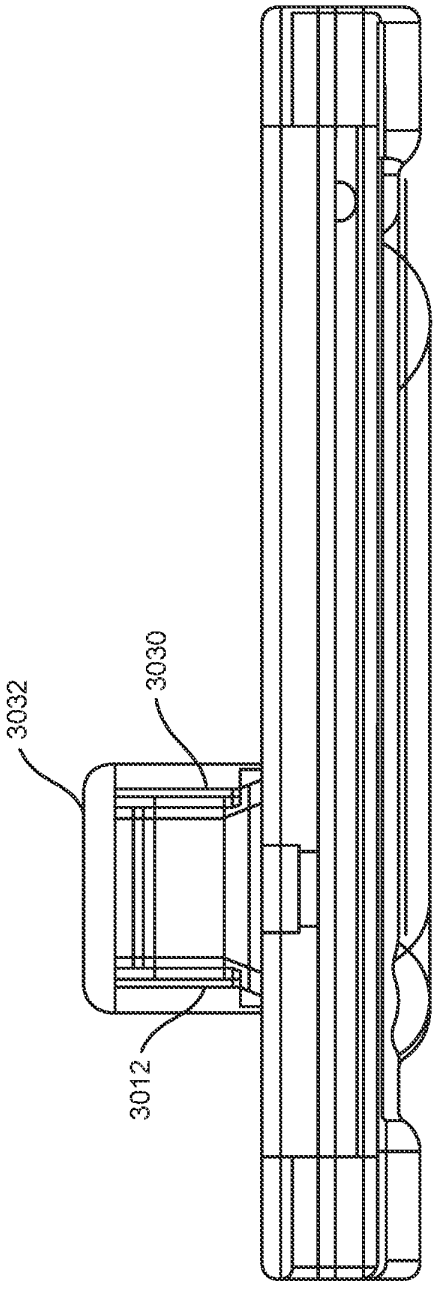


FIG. 30C

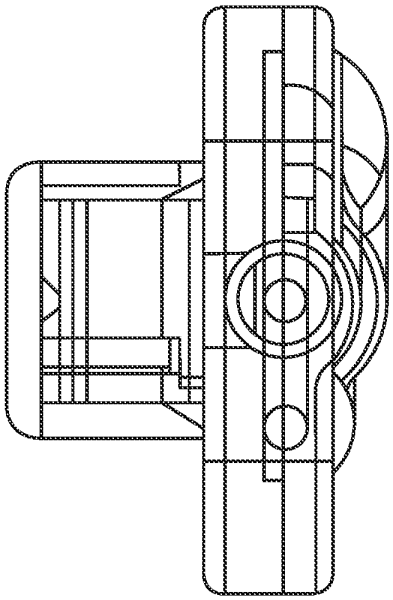


FIG. 30D

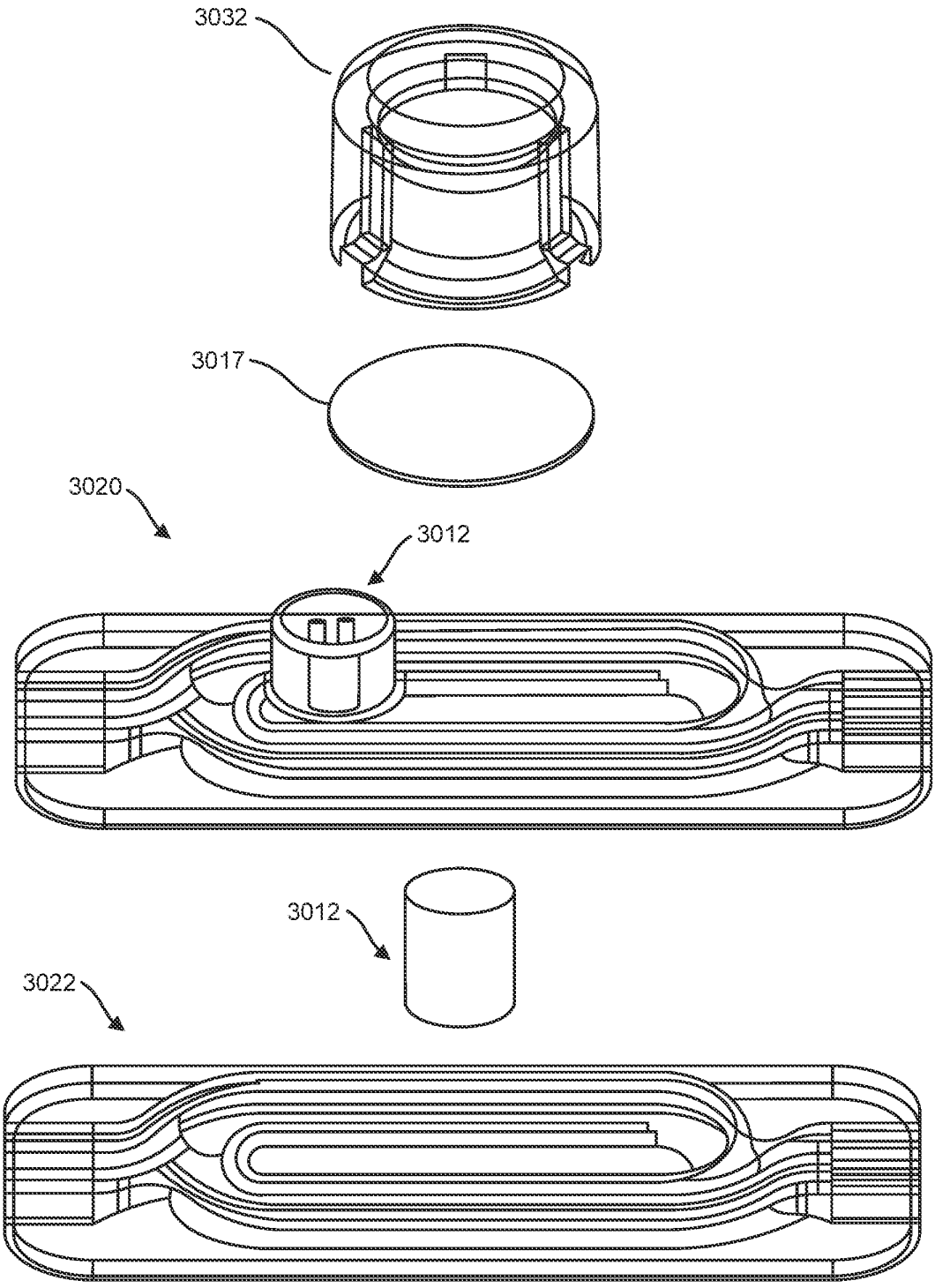


FIG. 30E

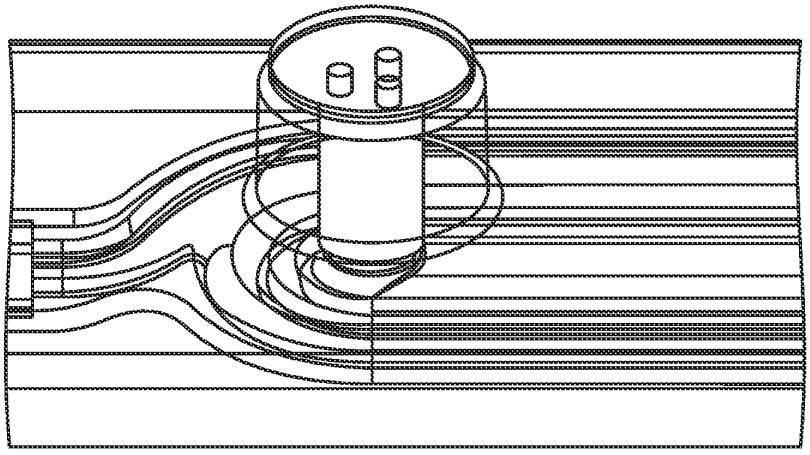


FIG. 30F

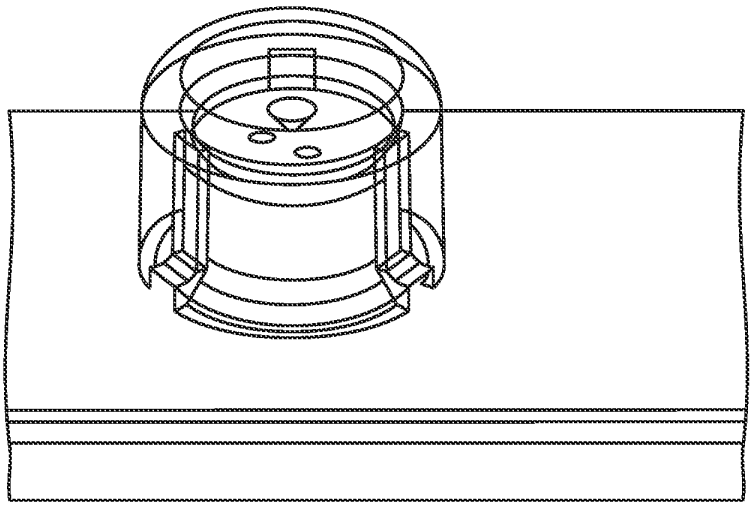


FIG. 30G

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Annex to EPO Form 2004, Communication pursuant to Rule 71(3) EPC

Bibliographical data of European patent application No. 19 200 766.4

For the intended grant of the European patent, the bibliographical data are set out below, for information:

Title of invention:

- BLUTPROBENOPTIMIERUNGSSYSTEM SOWIE VORRICHTUNG ZUR SEQUESTRIERUNG VON BLUTKONTAMINANTEN
- BLOOD SAMPLE OPTIMIZATION SYSTEM AND BLOOD CONTAMINANT SEQUESTRATION DEVICE
- SYSTÈME D'OPTIMISATION D'ÉCHANTILLON DE SANG ET DISPOSITIF DE SÉQUESTRATION DE CONTAMINANTS DU SANG

Classification: INV. A61B5/15 A61B5/153 A61B5/154

Date of filing: 22.07.2016

Priority claimed:
US / 24.07.2015 / USP201562196797
US / 07.10.2015 / USP201562238636
US / 04.04.2016 / USP201662318194
US / 27.04.2016 / USA201615140448
US / 27.04.2016 / USA201615140443

Contracting States* for which fees have been paid:
AL AT BE BG CH CY CZ DE DK EE ES FI FR GB GR HR HU IE IS IT LI LT LU LV MC MK MT NL NO PL PT RO RS SE SI SK SM TR

Extension States* for which fees have been paid:

Validation States* for which fees have been paid:

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*)	If the time limit for the payment of designation fees according to Rule 39(1) EPC has not yet expired and the applicant has not withdrawn any designation, **all Contracting States/Extension States/Validation States** are currently still deemed to be designated. See also Rule 71a(3) EPC and, if applicable, the above Note to users of the automatic debiting procedure.
**)	If two or more applicants have designated different Contracting States, this is indicated here.

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Application No.	Ref.	Date
19 200 766.4 - 1122	KUR-19054-P-EP	31.08.2022
Applicant Kurin, Inc.		

Communication under Rule 71(3) EPC

1. Intention to grant

You are informed that the examining division intends to grant a European patent on the basis of the above application, with the text and drawings and the related bibliographic data as indicated below.

A copy of the relevant documents is enclosed.

1.1 In the text for the Contracting States:
AL AT BE BG CH CY CZ DE DK EE ES FI FR GB GR HR HU IE IS IT LI LT LU LV MC MK MT NL NO PL PT RO RS SE SI SK SM TR

Description, Pages

2, 3, 5, 7-37	as originally filed	
1, 4, 4a	filed in electronic form on	18-09-2020

Claims, Numbers

1-14	filed in electronic form on	18-09-2020

Drawings, Sheets

1/50-50/50	as originally filed

With the following amendments to the above-mentioned documents proposed by the division

Description, Pages	1, 4, 4a, 5, 7, 9, 23, 25, 29, 31, 34
	Delete Previous: 6

Registered letter
EPO Form 2004C 07.20CXP

Comments

DESCRIPTION
Page 1: Deletion of irrelevant and/or superfluous information (Rule 48(1)(c) EPC, Guidelines F-II, 7.4)
Pages 4, 5, 7, 9, 29, 34: Description adapted to the claims (Art. 84 EPC)
Pages 4(a), 5, 7: Description adapted to amended claims (Art. 84 EPC)
Page 6: (PAGE DELETED) - Description adapted to amended claims (Art. 84 EPC)
Pages 23, 25, 31: Insertion of SI/metric units (Rule 49(10) EPC)
Pages 38-43: (PAGE DELETED) -

1.2 Bibliographic data

The title of the invention in the three official languages of the European Patent Office, the international patent classification, the designated contracting states, the registered name(s) of the applicant(s) and the other bibliographic data are shown on **EPO Form 2056** (enclosed).

2. Invitation

You are invited, **within a non-extendable period of four months** of notification of this communication,

2.1 to EITHER approve the text communicated above and verify the bibliographic data (Rule 71(5) EPC)

(1) by filing a translation of the claim(s) in the other two official languages of the EPO

	Fee code	EUR
(2a) by paying the fee for grant including the fee for publication:	**007**	990.00
minus any amount already paid (Rule 71a(5) EPC):		0.00
Total amount:		990.00
(3) by paying additional claims fees under Rule 71(4) EPC; number of claims fees payable: 0	**016**	0.00
minus any amount already paid (Rule 71a(5) EPC):		0.00
Total amount:		0.00

Important: If the translations of the claims and fees have already been filed and paid respectively in reply to a previous communication under Rule 71(3) EPC, e.g. in the case of resumption of examination after approval (see Guidelines C-V, 6), **agreement as to the text to be granted** (Rule 71a(1) EPC) must be expressed within the same time limit (e.g. by approving the text and verifying the bibliographic data, by confirming that grant proceedings can go ahead with the documents on file and/or by stating which translations of the claims already on file are to be used).

Note 1: See "Notes concerning fee payments" below.
Note 2: Any overpaid "minus" amounts will be refunded when the decision to grant (EPO Form 2006A) has been issued.
Note 3: For the calculation of the grant fee under Article 2(2), No. 7, RFees (old fee structure), the number of pages is determined on the basis of a clean copy of the application documents, in which text deleted as a result of any amendments by the examining division is not shown.

Such clean copy is made available via on-line file inspection only.

2.2 OR, in the case of disapproval, to request reasoned amendments or corrections to the text communicated above or keep to the latest text submitted by you (Rule 71(6) EPC).

In this case the translations of the claims and fee payments mentioned under point 2.1 above are NOT due.

The terms "amendment(s)" and "correction(s)" refer only to amendments or corrections of the application documents and not of other documents (e.g. bibliographic data, the designation of the inventor, etc.).

If filing amendments, you must identify them and indicate the basis for them in the application as filed. Failure to meet either requirement may lead to a communication from the examining division requesting that you correct this deficiency (Rule 137(4) EPC).

2.3 Bibliographic data

Where you request a change or correction of bibliographic data in response to the Rule 71(3) communication, this will **not** cause the sending of a further communication under Rule 71(3) EPC. You will still have to pay the fees and file translations in reply to the Rule 71(3) communication in the case of 2.1 above, unless you also file a reasoned request for amendments or corrections in response to the Rule 71(3) communication (see case 2.2 above).

3. Loss of rights

If neither of the two possible actions above (see points 2.1 or 2.2) is performed in due time, the European patent application will be deemed to be withdrawn (Rule 71(7) EPC).

4. Further procedure

4.1 In the case of point 2.1 above

4.1.1 The decision to grant the European patent will be issued, and the **mention of the grant** of the patent will be published in the European Patent Bulletin, if the requirements concerning the translation of the claims and the payment of all fees are fulfilled and there is agreement as to the text to be granted (Rule 71a(1) EPC).

Note on payment of the renewal fee:
If a renewal fee becomes due before the next possible date for publication of the mention of the grant of the European patent, publication will be effected only after the renewal fee and any additional fee have been paid (Rule 71a(4) EPC).

Under Article 86(2) EPC, the obligation to pay renewal fees to the European Patent Office terminates with the payment of the renewal fee due in respect of the year in which the mention of the grant of the European patent is published.

Note on payment of the designation fee(s):
If the designation fee(s) become(s) due after the communication under Rule 71(3) EPC, the mention of the grant of the European patent will not be published until these fees have been paid (Rule 71a(3) EPC).

4.1.2 After publication, the **European patent specification** can be downloaded free of charge from the EPO publication server https://data.epo.org/publication-server.

4.1.3 Filing of translations in the contracting states

As regards translation requirements prescribed by the contracting states under Article 65(1) EPC, please consult the website of the European Patent Office
www.epo.org →Law & practice →Legal texts, National law relating to the EPC
www.epo.org →Law & practice →All Legal texts →London Agreement

In the case of a valid extension or validation

As regards translation requirements prescribed by the extension or validation states, please consult the website of the European Patent Office
www.epo.org ➞Law & practice ➞Legal texts, National law relating to the EPC

Failure to supply a prescribed translation in a contracting state, or in an extension or validation state may result in the patent being deemed to be void *ab initio* in the state concerned (Art. 65(3) EPC).

4.2 In the case of 2.2 above

If the present communication under Rule 71(3) EPC is based on an auxiliary request and, within the time limit, you maintain the main request or a higher ranking request which is not allowable, the application will be refused (Art. 97(2) EPC).

If the examining division gives its consent to the requested amendments or corrections, it will issue a new communication under Rule 71(3) EPC; otherwise, it shall resume the examination proceedings (Rule 71(6) EPC).

5. Filing of a divisional application

Any divisional application relating to this European patent application must be filed directly with the European Patent Office in Munich, The Hague or Berlin and will be in the language of the proceedings for the present application, or if the latter was not in an official language of the EPO, the divisional application may be filed in the language of the present application as filed (see Article 76(1) and Rule 36(2) EPC). Any such divisional application must be filed while the present application is still pending (Rule 36(1) EPC; Guidelines A-IV, 1.1.1).

6. Notes concerning fee payments

6.1 Making payments

For payments made via deposit account, please note that as from 1 December 2017 debit orders will only be carried out if filed in an electronically processable format (xml), using an accepted means of filing as laid down in the Arrangements for deposit accounts (ADA), published in the Supplementary publication in the Official Journal.

All relevant information related to the modes of payment of fees to the EPO can be retrieved from the EPO website at "**Making Payments**".

6.2 Information concerning fee amounts

Procedural fees are usually adjusted every two years, on even years, with effect from 1 April. Therefore, before making a payment, parties should verify the amounts actually due on the date of payment using the applicable version of the Schedule of fees and expenses, published as a Supplement to the Official Journal of the EPO, available on the EPO website (**www.epo.org**) at **www.epo.org/schedule-of-fees**. The "Schedule of fees" table allows the viewing, downloading and searching of individual fee amounts, both current and previous.

6.3 Note to users of the automatic debiting procedure

The fee for grant, including the fee for publication, and any additional claims fees due under Rule 71(4) EPC will be debited automatically on the date of filing of the translations of the claims, or on the last day of the period of this communication. However, if the designation fee(s) become(s) due as set out in Rule 71a(3) EPC and/or a renewal fee becomes due as set out in Rule 71a(4) EPC, these should be paid separately by another permitted way of payment in order not to delay the publication of the mention of the grant. The same applies in these circumstances to the payment of extension and validation fees. The same applies in these circumstances to the payment of extension and validation fees.

Examining Division:

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2nd Examiner:	Przykutta, Andreas
1st Examiner:	Nielsen, Michael

Acquaviva, Laure
For the Examining Division
Tel. No.: +49 89 2399 - 5656

Enclosures: Text intended for grant

EPO Form 2056

Registered letter
EPO Form 2004C 07.20CXP

Europäisches Patentamt
European Patent Office
Office européen des brevets

Application No.: EP19200766

Intention to grant a European patent

Electronically authenticated

31.08.2022

Date

Marios Kakoullis	Michael Nielsen	Andreas Przykutta
Chairperson	1st examiner	2nd examiner

~~BLOOD SAMPLE OPTIMIZATION SYSTEM AND BLOOD CONTAMINANT SEQUESTRATION DEVICE AND METHOD~~

~~CROSS-REFERENCE TO~~ RELATED APPLICATIONS

[0001] This application claims the benefit of priority of U.S. Non-Provisional Application Serial No. 15/140,443, filed on April 27, 2016 and titled "BLOOD SAMPLE OPTIMIZATION SYSTEM AND BLOOD CONTAMINANT SEQUESTRATION DEVICE AND METHOD" and U.S. Non-Provisional Application Serial No. 15/140,448, filed on April 27, 2016 and titled "BLOOD SAMPLE OPTIMIZATION SYSTEM AND BLOOD CONTAMINANT SEQUESTRATION DEVICE AND METHOD", both of which claim priority to U.S. Provisional Application Serial No. 62/196,797, filed on July 24, 2015 and titled "BLOOD CULTURE IMPROVEMENT SYSTEM AND METHOD"; U.S. Provisional Application Serial No. 62/238,636, filed on October 7, 2015 and titled "BLOOD SEQUESTRATION SYSTEM FOR NON-CONTAMINATED BLOOD SAMPLING"; and U.S. Provisional Application Serial No. 62/318,194, filed on April 4, 2016 and titled "BLOOD SAMPLE OPTIMIZATION SYSTEM AND BLOOD CONTAMINANT SEQUESTRATION DEVICE AND METHOD".

BACKGROUND

[0002] Bacteraemia is the presence of microorganisms in the blood. Sepsis, on the other hand, is bacteraemia in the presence of clinical symptoms and signs such as fever, tachycardia, tachypnea and hypotension. Bacteraemia and sepsis are associated with a high mortality and an increased incidence and duration of hospital stay and associated costs. Many bacteraemias, sepsis, fungaemias and other pathogens actually occur within a hospital or other healthcare settings with

catheters and venipunctures being a source of contamination as potential carriers of these pathogens.

[0003] Blood cultures are the standard test used to detect microbial pathogens related to bacteraemia and sepsis in a patient's blood. The term blood culture refers to a single venipuncture, either from a peripheral site or central or arterial line, with the blood inoculated into one or more blood culture bottles or containers. One bottle is considered a blood culture where two or more are considered a set. Multiple sets may be obtained from multiple venipunctures and are associated with different sites on the patient.

[0004] These methods allow for microbial identification and susceptibility testing to be performed, which is a critical component to managing sepsis, however the lack of rapid results and decreased sensitivity for fastidious pathogens has led to the development of improved systems and adjunctive molecular or proteomic testing.

[0005] Collection of blood samples for conducting blood cultures is a critical component of modern patient care and can either positively affect the patient outcome by providing an accurate diagnosis, or can adversely affect the outcome by prolonging unnecessary antimicrobial therapy, the length of hospital stays, and increasing costs.

[0006] One outcome of collection of blood cultures is contamination. Blood culture contamination can lead to a false positive culture result and/or significant increase in healthcare related costs. Sources of blood culture contamination include improper skin antisepsis, improper collection tube disinfection, and contamination of the initial blood draw which may then skew results.

[0007] Blood culture collection kits generally consist of a "butterfly" set, infusion set, or other type of venipuncture device as offered by companies like BD, Smiths, B. Braun and others, and aerobic and anaerobic blood culture bottles.

Various different bottles are also available depending on the test requirements. These bottles are specifically designed to optimize recovery of both aerobic and anaerobic organisms. In conventional kits, a bottle used is known generally as a "Vacutainer," which is a blood collection tube formed of a sterile glass or plastic tube with a closure that is evacuated to create a vacuum inside the tube to facilitate the draw of a predetermined volume of liquid such as blood.

[0008] False positive blood cultures are typically a result of poor sampling techniques. They cause the use of antibiotics when not needed, increasing hospital costs and patient anxiety. Blood cultures are drawn from a needlestick into the skin, and then a Vacutainer is attached to capture a sample of blood. Contamination may occur from improper or incomplete disinfection of the skin area in and around the puncture site. It may also occur from the coring of the skin by the needle during insertion, with the cored skin cells and any associated contamination being pulled into the sample.

[0009] Blood flow through a hypodermic needle is laminar, and as such, a velocity gradient can be developed over the flow tube as a pressure drop is applied to the hypodermic needle. Either forceful aspiration of blood, or using a very small hypodermic needle, can cause lysis and a release of potassium from the red blood cells, thereby rendering the blood samples abnormal.

[0010] In other instances, some patients have delicate veins that can collapse under a pressure drop or vacuum, particularly as applied by a syringe's plunger that is drawn too quickly for the patient's condition. Since such condition is impossible to know beforehand, such vein collapses are a risk and very difficult to control.

[0011] Various strategies have been implemented to decrease blood culture contamination rates, e.g. training staff with regard to aseptic collection technique, feedback with regard to contamination rates and implementation of blood culture collection kits. Although skin antisepsis can reduce the burden of contamination,

20% or more of skin organisms are located deep within the dermis and are unaffected by antisepsis. Changing needles before bottle inoculation is not advisable as it increases the risk to acquire needle stick injuries without decreasing contamination rates.

[0012] Some conventional systems and techniques for reducing blood culture contamination include discarding the initial aliquot of blood taken from central venous catheters, venipunctures, and other vascular access systems. However, these systems require the user to mechanically manipulate an intravascular device, or require a complex series of steps that are difficult to ensure being followed.

[0012a] WO 96/05875 A1 discloses a blood sampling device comprising a bifurcated capillary tube which has a first branch having a cannula shaped end for withdrawing and conveying blood to a blood collection zone for storing a quantity of withdrawn blood and feeding an initial fraction of withdrawn blood to a blood disposal chamber having an air permeable liquid sealed end; and a second branch connected to the blood collection zone which terminates in an opening adapted to receive a blood withdrawal device.

SUMMARY

[0013] This document presents systems and methods ∂ ▛ (a method is not claimed) ▟ ∂ for reducing blood culture contamination, lysing of cells, and vein collapse. In some implementations, a system and method can eliminate user variability in disinfection, and also eliminate the risk of skin cells getting into the blood culture sample. The systems and methods disclosed herein do not require a change in existing clinical processes, other than to potentially indicate when a vacutainer or other blood collection device (i.e., syringe) should be attached for drawing contaminant-free blood samples.

[0014] In some implementations of the systems and methods disclosed herein the withdrawal of blood is accomplished passively by use of the patient's own blood pressure, thereby reducing the risk of vein collapse and eliminating any additional user steps over current practice. The systems and methods can be applied to

accommodate short-path direct stick or butterfly venipuncture systems. They can also be used with samples drawn through a catheter.

[0015] In one aspect, a blood sequestration device is 2 ▛ provided, comprising; an inlet port; a junction connected with the inlet port; a sequestration chamber having a vent comprising an air permeable blood barrier; a sampling channel having a proximal end connected with the inlet port via the junction, and a distal end connected with an outlet port; and a housing that houses and defines the inlet port, the junction, the sequestration chamber, the sampling channel, and the outlet port, wherein the sequestration chamber is connected with the inlet port via the junction which is configured to direct a first portion of blood to the sequestration chamber, wherein the air permeable blood barrier includes an air permeable material that seals at least partially upon contact with a portion of the first portion of blood. ▟ 2 ~~presented. The blood sequestration device includes an inlet port and an outlet port. The blood sequestration device further includes a sequestration chamber connected with the inlet port, the sequestration chamber having a vent comprising an air permeable~~

~~blood barrier. The blood sequestration device further includes a sampling channel having a proximal end connected with the inlet port and a distal end connected with the outlet port.~~

[0016] In another aspect, a 2 ▮ system of a blood sequestration device, a blood sampling pathway having a patient needle, and a sample collection device is provided, the blood sequestration device comprising; an inlet port connected with the patient needle; a junction connected with the inlet port opposite the blood sampling pathway; a sequestration chamber having a vent comprising an air permeable blood barrier; a sampling channel having a proximal end connected with the inlet port; and an outlet port connected with a distal end of the sampling channel and with the sample collection device; and a housing that houses and defines the inlet port, the outlet port, the sequestration chamber, and the sampling channel, wherein the sequestration chamber is connected with the inlet port and the air permeable blood barrier includes an air permeable material that seals at least partially upon contact with blood. ▮ 2 ~~blood sequestration device connected with a blood sampling pathway is described. The blood sampling pathway has a patient needle and a sample collection device. The blood sequestration device includes an inlet port connected with the patient needle, and a sequestration chamber connected with the inlet port, the sequestration chamber having a vent comprising an air permeable blood barrier. The blood sequestration device further includes a sampling channel having a proximal end connected with the inlet port, and an outlet port connected with a distal end of the sampling channel and with the sample collection device.~~

~~**[0017]** In yet another aspect, a blood sequestration device connected with a blood sampling system is described. The blood sampling system includes a patient needle for accessing a blood sample from a patient, and a sample needle that is sealed and adapted for receiving an evacuated blood collection tube. The blood sequestration device includes an inlet port connected with the patient needle to receive the blood sample from the patient. The blood sequestration device further includes a sequestration chamber connected with the inlet port and having a vent comprising an air permeable blood barrier, the sequestration chamber for receiving and sequestering a first portion of the blood sample prior to the sample needle being unsealed by the evacuated blood collection tube. The blood sequestration~~

device further includes a sampling channel having a proximal end connected with the inlet port, the sampling channel for conveying a subsequent portion of the blood sample once the sample needle is unsealed by the evacuated blood collection tube. The blood sequestration device further includes an outlet port connected with a distal end of the sampling channel for conveying the subsequent portion of the blood sample to the sample needle.

~~sequestration device further includes an outlet port connected with a distal end of the sampling channel, the outlet port for outputting the subsequent amount of the sample of blood.~~

[0022] The details of one or more embodiments are set forth in the accompanying drawings and the description below. Other features and advantages will be apparent from the description and drawings, and from the claims. The invention is best illustrated by figures 16A to 19B.

BRIEF DESCRIPTION OF THE DRAWINGS

[0023] These and other aspects will now be described in detail with reference to the following drawings.

[0024] FIG. 1 illustrates a blood sample optimization system.

[0025] FIG. 2 illustrates a blood sample optimization system in accordance with an alternative implementation.

[0026] FIG. 3 illustrates a blood sample optimization system in accordance with another alternative implementation.

[0027] FIG. 4 illustrates a blood sample optimization system in accordance with another alternative implementation.

[0028] FIG. 5 illustrates a blood sample optimization system in accordance with another alternative implementation.

[0029] FIG. 6 illustrates a blood sample optimization system in accordance with an alternative implementation.

[0030] FIG. 7 is a flowchart of a method for optimizing a quality of a blood culture.

[0031] FIGS. 8A – 8E illustrate a blood sequestration system for non-contaminated blood sampling, in accordance with some implementations.

[0032] FIG. 9 illustrates a pathway splitter for use in a blood sequestrations system.

[0033] FIGS. 10A – 10D illustrate a blood sequestration system for non-contaminated blood sampling, in accordance with alternative implementations.

[0034] FIGS. 11A – 11E illustrate a blood sequestration system for non-contaminated blood sampling, in accordance with other alternative implementations.

[0035] FIGS. 12A-12D illustrate a blood sample optimization system including a blood sequestration device in accordance with yet other alternative implementations.

[0036] FIGS. 13A-13D illustrate a blood sample optimization system 1300 in accordance with yet another alternative implementations.

[0037] FIGS. 14A-14E illustrate yet another implementation of a blood sampling system to sequester contaminates of an initial aliquot or sample to reduce false positives in blood cultures or tests performed on a patient's blood sample.

[0038] FIGS. 15A-15G illustrate a blood sequestration device and method of using the same, in accordance with yet another implementation.

[0039] FIGS. 16A-16D illustrate a blood sequestration device in accordance with yet another implementation.

[0040] FIGS. 17A – 17E illustrate a bottom member of a housing for a blood sequestration device.

[0041] FIGS. 18A – 18F illustrate a top member of a housing for a blood sequestration device.

01.10.2019

[0042] FIGS. 19A and 19B illustrate a blood sequestration device having a top member mated with a bottom member.

[0043] FIG. 20 shows a blood sample optimization system including a blood sequestration device.

[0044] FIG. 21 illustrates a non-vented blood sequestration device using a wicking material chamber.

[0045] FIGS. 22A and 22B illustrate a material makeup of a filter for sequestering blood in a sequestration chamber of a blood sequestration device.

[0046] FIGS. 23A and 23B illustrate another implementation of a blood sequestration device that uses a vacuum force from a blood collection device.

[0047] Like reference symbols in the various drawings indicate like elements.

DETAILED DESCRIPTION

[0048] This document describes blood sample optimization systems and methods (a method is not claimed) for reducing or eliminating contaminates in collected blood samples, which in turn reduces or eliminates false positive readings in blood cultures or other testing of collected blood samples. In some implementations, a blood sample optimization system includes a patient needle for vascular access to a patient's bloodstream, a sample needle for providing a blood sample to a blood collection container, such as an evacuated blood collection container or tube like a Vacutainer™ or the like, or other sampling device, and a blood sequestration device located between the patient needle and the sample needle. The blood sequestration device includes a sequestration chamber for sequestering an initial, potentially contaminated aliquot of blood, and may further include a sampling channel that bypasses the sequestration chamber to convey likely uncontaminated blood between the patient

needle and the sample needle after the initial aliquot of blood is sequestered in the sequestration chamber.

[0049] FIG. 1 illustrates a blood sample optimization system in accordance with some implementations. The system includes a patient needle 1 to puncture the skin of a patient to access the patient's vein and blood therein. The system further includes a sample needle (i.e., a resealably closed needle for use with Vacutainers™ or the like) 5, which may be contained within and initially sealed by a resealable boot 10, a Luer activated valve, or another collection interface or device. The resealable boot 10 can be pushed aside or around the sample needle 5 by application of a Vacutainer™ bottle (not shown) for drawing the patient's blood. The system can further include a low volume chamber 30 that leads to the sample needle 5, but also includes an orifice or one or more channels 45 that lead to a sequestration chamber 55 formed by a housing 50.

[0050] The sequestration chamber 55 is a chamber, channel, pathway, lock, or other structure for receiving and holding a first aliquot of the patient's blood, which may be in a predetermined or measured amount, depending on a volume of the sequestration chamber 55. The first draw of blood typically contains or is more susceptible to containing organisms that cause bacteraemia and sepsis or other pathogens than subsequent blood draws. The sequestration chamber 55 can be a vessel encased in a solid housing, formed in or defined by the housing itself, or can be implemented as tubing or a lumen. The sequestration chamber 55, regardless how formed and implemented, may have a predetermined volume. In some implementations, the predetermined volume may be based on a volume of the patient needle, i.e. ranging from less than the volume of the patient needle to any volume up to or greater than 20 times or more of the volume of the patient needle. The predetermined volume of the sequestration chamber 55 may also be established to economize or minimize an amount of blood to be sequestered and disposed of.

[0051] The sequestration chamber 55 can be formed, contained or housed in a chamber housing 50, and can be made of plastic, rubber, steel, aluminum or other suitable material. For example, the sequestration chamber 55 could be formed of flexible tubing or other elastomeric materials. The sequestration chamber 55 further includes an air permeable blood barrier 20 that allows air to exit the sequestration chamber 55. As used herein the term "air permeable blood barrier" means an air permeable but substantially blood impermeable substance, material, or structure. Examples may include hydrophobic membranes and coatings, a hydrophilic membrane or coating combined with a hydrophobic membrane or coating, mesh, a filter, a mechanical valve, antimicrobial material, or any other means of allowing air to be displaced from the sequestration chamber 55 as it is filled with blood. In various exemplary embodiments, an air permeable blood barrier may be formed by one or more materials that allow air to pass through until contacted by a liquid, such material then becomes completely or partially sealed to prevent or inhibit the passage of air and/or liquid. In other words, prior to contact with liquid, the material forms a barrier that is air permeable. After contact with a liquid, the material substantially or completely prevents the further passage of air and/or liquid.

[0052] The orifice or channel 45 can be any desired length, cross-sectional shape or size, and/or can be formed to depart from the low volume chamber 30 at any desired angle or orientation. The orifice or channel 45 may also include a one-way flap or valve 60 that maintains an initial aliquot of blood sample within the sequestration chamber 55. In some specific implementations, the orifice or channel 45 can include a "duck bill" or flapper valve 60, or the like, for one-way flow of blood from low volume chamber 30 to the sequestration chamber 55. The air permeable blood barrier 20 can also be constructed of a material that allows air to exit but then seals upon contact with blood, thereby not allowing external air to enter sequestration chamber 55. This sealing would eliminate the need for a valve.

[0053] Valve 60 can be any type of valve or closing mechanism. Chamber 30 is designed to hold virtually no residual blood, and can be designed to be adapted to hold or allow pass-through of a particular volume or rate of blood into sequestration chamber 55. Likewise, sequestration chamber 55 may also include any type of coating, such as an anti-microbial coating, or a coating that aids identification and/or diagnosis of components of the first, sequestered blood draw.

[0054] Housing 50 and 40 can be formed of any suitable material, including plastic, such as acrylonitrile butadiene styrene (ABS) or other thermoplastic or polymeric material, rubber, steel, or aluminum. The air permeable blood barrier 20 can include a color-providing substance, or other signaling mechanism, that is activated upon contact with blood from the initial blood draw, or when air displacement is stopped, or any combination of events with blood in the sequestration chamber 55. The air permeable barrier may also include an outer layer such as a hydrophobic membrane or cover that inhibits or prevents the inadvertent or premature sealing of the filter by an external fluid source, splash etc. Sequestration chamber 55 can also be translucent or clear to enable a user to visually confirm the chamber is filled.

[0055] FIG. 2 illustrates a blood sample optimization system in accordance with some alternative implementations. In the implementation shown in FIG. 2, a sequestration chamber 55, or waste chamber, surrounds the patient needle 1, with an open-ended cuff or housing connected with the waste chamber and encircling the sample needle housing base and housing. The patient needle 1 and sample needle 5 are connected together by a boot 56, which forms a continuous blood draw channel therethrough. The boot 56 includes a single orifice or channel leading from the blood draw channel into sequestration chamber 55. The device can include more than one single orifice or channel, in other implementations. Each orifice or channel can include a one-way valve, and can be sized and adapted for predetermined amount of blood flow.

[0056] The sequestration chamber 55 includes an air permeable blood barrier. The filter can further include a sensor or indicator to sense and/or indicate, respectively, when a predetermined volume of blood has been collected in the sequestration chamber 55. That indication will alert a user to attach an evacuated blood collection tube or bottle, such as a Vacutainer™ to the sample needle 5. The housing for the sequestration chamber 55 can be any size or shape, and can include any type of material to define an interior space or volume therein. The interior space is initially filled only with air, but can also be coated with an agent or substance, such as a decontaminate, solidifying agent, or the like. Once evacuated blood collection tube is attached to the sample needle 5, blood will flow automatically into the patient needle 1, through the blood draw channel and sample needle 5, and into the bottle. The sample needle 5 is covered by a resealable boot, coating or membrane that seals the sample needle when a blood collection bottle is not attached thereon or thereto.

[0057] FIG. 3 illustrates a blood sample optimization system in accordance with some alternative implementations. In the implementation shown, a sample needle 5 is surrounded by a resealable boot or membrane, and is further connected with a patient needle 1. A blood flow channel is formed through the sample needle and the patient needle. The connection between the sample needle and patient needle includes a "T" or "Y" connector 102, which includes a channel, port or aperture leading out from the main blood flow channel to a sequestration chamber 104.

[0058] The T or Y connector 102 may include a flap or one-way valve, and have an opening that is sized and adapted for a predetermined rate of flow of blood. The sequestration chamber 104 can be formed from tubing, or be formed by a solid housing, and is initially filled with air. The sequestration chamber 104 will receive blood that flows out of a patient automatically, i.e. under pressure from the patient's own blood pressure. The sequestration chamber 104 includes an air permeable

blood barrier 106, preferably at the distal end of tubing that forms the sequestration chamber 104, and which is connected at the proximal end to the T or Y connector 102. The T or Y connector 102 can branch off at any desired angle for most efficient blood flow, and can be formed so as to minimize an interface between the aperture and channel and the main blood flow channel, so as to minimize or eliminate mixing of the initial aliquot of blood with main blood draw samples.

[0059] In some alternative implementations, the sample needle may be affixed to a tubing of any length, as shown in FIG. 4, connecting at its opposite end to the T or Y connector 102. The sequestration chamber 104 can be any shape or volume so long as it will contain a predetermined amount of blood sample in the initial aliquot. The T or Y connector 102 may also include an opening or channel that is parallel to the main blood flow channel. The air permeable blood barrier may further include an indicator 107 or other mechanism to indicate when a predetermined amount of blood has been collected in the sequestration chamber, or when air being expelled reaches a certain threshold, i.e. to zero. The tubing can also include a clip 109 that can be used to pinch off and prevent fluid flow therethrough.

[0060] Once the air permeable blood barrier and primary chamber are sealed the initial aliquot of blood is trapped in the sequestration chamber 104, an evacuated blood collection tube, such as a Vacutainer™ bottle may be attached to the sample needle 5 to obtain the sample. The blood collection tube can be removed, and the sample needle 5 will be resealed. Any number of follow-on blood collection tubes can then be attached for further blood draws or samples. Upon completion of all blood draws, the system can be discarded, with the initial aliquot of blood remaining trapped in the sequestration chamber 104.

[0061] FIG. 5 illustrates a blood sample optimization system in accordance with some alternative implementations. In the implementation shown, a sample needle 5 is connected with a patient needle by tubing. A "T" or "Y" connector 120 is

added along the tubing at any desired location, and includes an aperture, port or channel leading to a sequestration chamber 204, substantially as described above.

[0062] FIG. 6 illustrates a blood sample optimization system in accordance with some alternative implementations, in which a sequestration chamber 304, formed as a primary collection channel, receives an initial aliquot of blood, and is provided adjacent to the blood sampling channel. The sequestration chamber 304 can encircle the blood sampling channel, the patient needle 1, and/or the sample needle 5. The primary collection channel can include a T or Y connector 120, or other type of aperture or channel. The sequestration chamber 304 includes an air permeable blood barrier, which can also include an indicator of being contacted by a fluid such as blood, as described above.

[0063] In some implementations, either the patient needle 1 or the sample needle 5, or both, can be replaced by a Luer lock male or female connector. However, in various implementations, the connector at a sample needle end of the blood sample optimization system is initially sealed to permit the diversion of the initial aliquot of blood to the sequestration chamber, which is pressured at ambient air pressure and includes the air outlet of the air permeable blood barrier. In this way, the system passively and automatically uses a patient's own blood pressure to overcome the ambient air pressure of the sequestration chamber to push out air through the air permeable blood barrier and displace air in the sequestration chamber with blood.

[0064] FIG. 7 is a flowchart of an exemplary method for optimizing the quality of a blood culture. At 702, a clinician places a needle into a patient's vein. At 704, blood then flows into a sequestration chamber, pushing the air in the sequestration chamber out of the sequestration chamber through an air permeable blood barrier. In some implementations, the volume of the sequestration chamber is less than 0.1 to more than 5 cubic centimeters (cc's), or more. The sequestration chamber is sized and adapted to collect a first portion of a blood sample, which is more prone

to contamination than secondary and other subsequent portion of the blood sample or subsequent draws. Since the sequestration chamber has an air-permeable blood barrier through which air can be displaced by blood pushed from the patient's vein, such blood will naturally and automatically flow into the sequestration chamber before it is drawn into or otherwise enters into a Vacutainer or other bottle for receiving and storing a blood sample.

[0065] When the sequestration chamber fills, the blood will gather at or otherwise make contact with the air permeable blood barrier, which will inhibit or prevent blood from passing therethrough. At 706, when the blood comes into contact with the entire internal surface area of the air permeable blood barrier, the air permeable blood barrier is then closed and air no longer flows out or in. At 708, the clinician may be provided an indictor or can see the full chamber, to indicate the evacuated blood collection tube, such as a Vacutainer™ can be attached. The indicator can include visibility into the primary chamber to see whether it is full, the blood barrier changing color, for example, or other indicator. The fill time of the sequestration chamber may be substantially instantaneous, so such indicator, if present, may be only that the sequestration chamber is filled.

[0066] Prior to an evacuated blood collection tube being attached, communication between the needle, sampling channel, and the sequestration chamber is restricted by the sealing of the sequestration chamber blood barrier thereby not permitting air to reenter the system through the sequestration. Sealing the communication path could also be accomplished with a mechanical twist or other movement, a small orifice or tortuous pathway, eliminating the need for a separate valve or mechanical movement or operation by the clinician. At 710, once the evacuated blood collection tube is removed, the self-sealing membrane closes the sample needle, and at 712, additional subsequent evacuated blood collection tubes may be attached. Once samples have been taken, at 714 the device is removed from the patient and discarded.

[0067] FIGS. 8A – 8E illustrate an exemplary blood sample optimization system 800 for non-contaminated blood sampling, in accordance with some implementations. The blood sample optimization system 800 includes an inlet port 802 that can be connected to tubing, a patient needle (or both), or other vascular or venous access device, and a pathway splitter 804 having a first outlet to a sequestration chamber tubing 806 and a second outlet to sample collection tubing 808. One or both of the sequestration chamber tubing 806 and the sample collection tubing 808 can be formed of tubing. In some implementations, the sequestration chamber tubing 806 is sized so as to contain a particular volume of initial blood sample. The sample collection tubing 808 will receive a blood sample once the sequestration chamber tubing 806 is filled. The sample collection tubing 808 can be connected to a Vacutainer™ base or housing 810, or other blood sample collection device.

[0068] The blood sequestration system 800 further includes a blood sequestration device 812 which, as shown in more detail in FIGS. 8B – 8D, includes a housing 818 that includes a sampling channel 820 defining a pathway for the non-contaminated sample collection tubing 808 or connected at either end to the non-contaminated sample collection tubing 808. The sampling channel 820 can be curved through the housing 818 so as to better affix and stabilize the housing 818 at a location along the non-contaminated sample collection tubing 808.

[0069] The blood sequestration device 812 further includes a sequestration chamber 822 connected with the sequestration chamber tubing 806 or other chamber. The sequestration chamber 822 terminates at an air permeable blood barrier 824. The air permeable blood barrier 824 can also include a coloring agent that turns a different color upon full contact with blood, as an indicator that the regular collection of blood samples (i.e. the non-contaminated blood samples) can be initiated. Other indicators may be used, such as a small light, a sound generation mechanism, or the like. In some implementations, the air permeable

blood barrier is positioned at a right angle from the direction of sequestration chamber 822, but can be positioned at any distance or orientation in order to conserve space and materials used for the housing 818. The housing 818 and its contents can be formed of any rigid or semi-rigid material or set of materials.

[0070] FIG. 9 illustrates a pathway splitter 900 for use in a blood sequestrations system, such as those shown in FIGS. 8A – 8E, for example. The pathway splitter 900 includes an inlet port 902, a main line outlet port 904, and a sequestration channel outlet port 906. The inlet port 902 can be connected to main tubing that is in turn connected to a patient needle system, or directly to a patient needle. The main line outlet port 904 can be connected to main line tubing to a blood sampling system, such as a vacutainer base or housing, or directly to such blood sampling system. The sequestration channel outlet port 906 can be connected to sequestration tubing for receiving and sequestering a first sample of blood, up to a measured amount or predetermined threshold. Alternatively, the sequestration channel outlet port 906 can be connected to a sequestration chamber. The sequestration channel outlet port 906 is preferably 20-70 degrees angled from the main line outlet port 904, which in turn is preferably in-line with the inlet port 902. Once the predetermined amount of initial blood sample is sequestered in the sequestration tubing or chamber, in accordance with mechanisms and techniques described herein, follow-on blood samples will flow into the inlet port 902 and directly out the main line outlet port 904, without impedance.

[0071] FIGS. 10A – 10D illustrate a blood sequestration device 1000 in accordance with alternative implementations. The blood sequestration device 1000 includes an inlet port 1002, a main outlet port 1004, and a sequestration channel port 1006. The inlet port 1002 can be connected to a patient needle or related tubing. The main outlet port 1004 can be connected to a blood sample collection device such as a Vacutainer, associated tubing, or a Luer activated valve, or the like. The sequestration channel port 1006 splits off from the main outlet port 1004 to a

sequestration chamber 1008. In some implementations, the sequestration chamber 1008 is formed as a helical channel within a housing or other container 1001.

[0072] The sequestration chamber 1008 is connected at the distal end to an air permeable blood barrier 1010, substantially as described above. Air in the sequestration chamber 1008 is displaced through the air permeable blood barrier 1010 by an initial aliquot of blood that is guided into the sequestration channel port 1006. Once the sequestration chamber 1008 is filled, further blood draws through the main outlet port 1004 can be accomplished, where these samples will be non-contaminated.

[0073] FIGS. 11A – 11E illustrate a blood sequestration device 1100 in accordance with other alternative implementations. The blood sequestration device 1100 includes an inlet port 1102, similar to the inlet ports described above, a main outlet port 1104, and a sequestration channel port 1106 that splits off from the main outlet port 1104 and inlet port 1102. The sequestration channel port is connected to a sequestration chamber 1108. In the implementation shown in FIGS. 11A – 11E, the blood sequestration device includes a base member 1101 having a channel therein, which functions as the sequestration chamber 1108. The channel can be formed as a tortuous path through the base member 1101, which is in turn shaped and formed to rest on a limb of a patient.

[0074] A portion of the sequestration chamber 1108 can protrude from the base member or near a top surface of the base member, just before exiting to an air permeable blood barrier 1110, to serve as a blood sequestration indicator 1109. The indicator 1109 can be formed of a clear material, or a material that changes color when in contact with blood.

[0075] In some implementations, the blood sequestration device 1100 can include a blood sampling device 1120 such as a normally closed needle, Vacutainer™ shield or other collection device. The blood sampling device 1120 can

be manufactured and sold with the blood sequestration device 1100 for efficiency and convenience, so that a first aliquot of blood that may be contaminated by a patient needle insertion process can be sequestered. Thereafter, the blood sampling device 1120 can draw non-contaminated blood samples to reduce the risk of false positive testing and ensure a non-contaminated sample.

[0076] FIGS. 12A-12D illustrate a blood sample optimization system 1200 in accordance with yet other alternative implementations. The system 1200 includes a blood sequestration device 1202 for attaching to a blood sampling device 1204, such as a Vacutainer™ or other collection and sampling device. The blood sequestration device 1202 is configured and arranged to receive, prior to a Vacutainer™ container or vial being attached to a collection needle of the blood sampling device 1204, a first aliquot or amount of blood, and sequester that first aliquot or amount in a sequestration channel of the blood sequestration device 1202.

[0077] In some implementations, the blood sequestration device 1202 can include an inlet port 1212, a main outlet port, and a sequestration channel port. The inlet port 1212 can be connected to a patient needle or related tubing. The main outlet port 1214 can be connected to a normally closed needle or device to enable connection with an evacuated blood collection container or other collection device such as a Vacutainer™, associated tubing, luer connectors, syringe, a Luer activated valve, or the like. The sequestration channel port splits off from the main outlet port to a sequestration chamber 1218.

[0078] In some implementations, the sequestration chamber 1218 is formed as a channel within the body of a sequestration device 1202. The sequestration chamber 1218 can be a winding channel, such as a U-shaped channel, an S-shaped channel, a helical channel, or any other winding channel. The sequestration device 1202 can include a housing or other containing body, and one or more channels formed therein. As shown in FIGS. 12A and 12B, the sequestration device 1202 includes a main body 1206 and a cap 1208. The main body 1206 is formed with

one or more cavities or channels, which are further formed with one or more arms 1210 that extend from the cap 1208, and which abut the cavities or channels in the main body 1206 to form the primary collection port and main outlet port.

[0079] FIGS. 13A-13D illustrate a blood sample optimization system 1300 in accordance with yet other alternative implementations. The system 1300 includes a blood sequestration device 1302 for attaching to a blood sampling device 1304, such as a Vacutainer or other bodily fluid collection and sampling device. The blood sequestration device 1302 is configured and arranged to receive, prior to a Vacutainer container or vial being attached to a collection needle of the blood sampling device 1304, a first aliquot or amount of blood, and to sequester that first aliquot or amount of blood or other bodily fluid in a sequestration channel of the blood sequestration device 1302.

[0080] The blood sequestration device 1302 includes a housing 1301 having an inlet port 1314, a main outlet port 1312, and a sequestration channel port 1316. The inlet port 1314 can be connected to a patient needle or associated tubing. The main outlet port 1312 can be connected to a normally closed needle or device to enable connection with an evacuated blood collection container or other collection device such as a Vacutainer™, associated tubing, luer connectors, syringe, a Luer activated valve, or the like. The sequestration channel port 1316 splits off from the main inlet port 1314 to a sequestration chamber 1318.

[0081] In the implementation shown in FIGS. 13A-D, the sequestration chamber 1318 is formed as a cavity or chamber within housing 1301 or formed by walls that define housing 1301. The sequestration chamber 1318 can be a winding channel, such as a U-shaped channel, an S-shaped channel, a helical channel, or any other winding channel, that is defined by the cooperation and connection of housing 1301 with cap 1307 which cap 1307 can include a protrusion 1305 that provides one or more walls or directors for the winding channel in the sequestration chamber 1318. The protrusion 1305 from the cap 1307 can be straight or curved,

and may have various channels, apertures or grooves embedded therein, and can extend from the cap 1307 any angle or orientation. When the cap 1307 is connected with the housing 1301 to complete the formation of the sequestration chamber 1318, the protrusion 1305 forms at least part of the winding channel to sequester a first aliquot or amount of blood or other bodily fluid in a sequestration channel formed in the sequestration chamber 1318 and by the winding channel.

[0082] The sequestration chamber 1318 includes an air permeable blood barrier 1310, substantially as described above. Air in the sequestration chamber 1318 is displaced through the air permeable blood barrier 1310 by an initial aliquot of blood that is provided into the sequestration chamber 1318 by the blood pressure of the patient. Once the sequestration chamber 1318 is filled and the air in the sequestration chamber 1318 displaced, the blood pressure of the patient will be insufficient to drive or provide further blood into the blood sequestration device 1302, and in particular the outlet port 1312, until a force such as a vacuum or other pressure, such as provided by the blood sample collection device like Vacutainer is provided to draw out a next aliquot or amount of blood or bodily fluid. Further blood draws through the main outlet port 1312 can be accomplished, where these samples will be non-contaminated since any contaminants would be sequestered in the sequestration chamber 1318 with the first aliquot of blood.

[0083] FIGS. 14A-14E illustrate yet another implementation of a blood sampling system 1400 to sequester contaminates of an initial aliquot or sample to reduce false positives in blood cultures or tests performed on a patient's blood sample. The blood sampling system 1400 includes a blood sequestration device 1401 that can be connected between a blood sample collection device 1403 and a patient needle (not shown). The blood sample collection device 1403 can be a Vacutainer or the like. The blood sequestration device 1401 includes an inlet port 1402 that can be connected with a patient needle that is inserted into a patient's vascular system for access to and withdrawing of a blood sample. The inlet port

1402 may also be connected with tubing or other conduit that is in turn connected with the patient needle.

[0084] The inlet port 1402 defines an opening into the blood sequestration device 1401, which opening can be the same cross sectional dimensions as tubing or other conduit connected with the patient needle or the patient needle itself. For instance, the opening can be circular with a diameter of approximately ≥ 0.114 cm (0.045 inches), ≥ ~~0.045 inches,~~ but can have a diameter of between ≥ 0.0254 cm (0.01 inches) ≥ ~~0.01 inches~~ or less to ≥ 0.508 cm (0.2 inches) ≥ ~~0.2 inches~~ or more. The blood sequestration device 1401 further includes an outlet port 1404, which defines an opening out of the blood sequestration device 1401 and to the blood sample collection device 1403. The outlet port 1404 may also be connected with tubing or other conduit that is in turn connected with the blood sequestration device 1403. The outlet port 1404 can further include a connector device such as a threaded cap, a Luer connector (male or female), a non threaded interference or glue joint fitting for attachment of various devices including but not limited to tubing, or the like.

[0085] The blood sequestration device 1401 further includes a sampling channel 1406 between the inlet port 1402 and the outlet port 1404, and which functions as a blood sample pathway once a first aliquot of blood has been sequestered. The sampling channel 1406 can be any sized, shaped or configured channel, or conduit. In some implementations, the sampling channel 1406 has a substantially similar cross sectional area as the opening of the inlet port 1402. In other implementations, the sampling channel 1406 can gradually widen from the inlet port 1402 to the outlet port 1404.

[0086] The blood sequestration device 1401 further includes a sequestration chamber 1408 that is connected to and split off or diverted from the sampling channel 1406 at any point between the inlet port 1402 and the outlet port 1404, but preferably from a proximal end of the sampling channel 1406 near the inlet port 1402. The sequestration chamber 1408 is at first maintained at atmospheric pressure, and includes an air outlet 1412 at or near a distal end of the sequestration

chamber 1408 opposite the diversion point from the sampling channel 1406. The air outlet 1412 includes an air permeable blood barrier 1412. As shown in FIG. 14B, the air permeable blood barrier 1412 can be overlaid with a protective cover 1416. The protective cover 1416 can be sized and configured to inhibit a user from touching the air permeable blood barrier 1412 with their finger or other external implement, while still allowing air to exit the air permeable blood barrier 1412 as the air is displaced from the sequestration chamber 1408 by blood being forced into the sequestration chamber 1408 by a patient's own blood pressure. In addition the protective cover 1416 can be constructed to inhibit or prevent accidental exposure of the air permeable blood barrier to environmental fluids or splashes. This can be accomplished in a variety of mechanical ways including but not limited to the addition of a hydrophobic membrane to the protective cover.

[0087] As shown in FIGS. 14C and 14D, the sampling channel 1406 can be cylindrical or frusto-conical in shape, going from a smaller diameter to a larger diameter, to minimize a potential to lyse red blood cells. Likewise, the sampling channel 1406 is formed with a minimal amount of or no sharp turns or edges, which can also lyse red blood cells. The sampling channel 1406 splits off to the sequestration chamber 1408 near the inlet port 1402 via a diversion pathway 1409. The diversion pathway 1409 can have any cross-sectional shape or size, but is preferably similar to the cross-sectional shape of at least part of the inlet port 1402.

[0088] In some implementations, the sampling channel 1406 and the sequestration chamber 1408 are formed by grooves, channels, locks or other pathways formed in housing 1414. The housing 1414 can be made of plastic, metal or other rigid or semi-rigid material. The housing 1414 can have a bottom member that sealably mates with a top member. One or both of the bottom member and the top member can include the sampling channel 1406 and the sequestration chamber 1408, as well as the diversion pathway 1409, the inlet port 1402, and the outlet port 1404. In some other implementations, one or more of the diversion

pathway 1409, the inlet port 1402, and/or the outlet port 1404 can be at least partially formed by a cap member that is connected to either end of the housing 1414. In some implementations, the top member and the bottom member, as well as the cap member(s), can be coupled together by laser welding, heat sealing, gluing, snapping, screwing, bolting, or the like. In other implementations, some or all of the interior surface of the diversion pathway 1409 and/or sequestration chamber 1408 can be coated or loaded with an agent or substance, such as a decontaminate, solidifying agent, or the like. For instance, a solidifying agent can be provided at the diversion pathway 1409 such that when the sequestration chamber 1408 is filled and the initial aliquot of blood backs up to the diversion pathway 1409, that last amount of sequestered blood could solidify, creating a barrier between the sequestration chamber 1408 and the sampling channel 1406.

[0089] FIGS. 15A-15G illustrate a blood sequestration device 1500. The blood sequestration device 1500 can be connected to a normally closed needle or device to enable connection with an evacuated blood collection container or other collection device such as a Vacutainer™, associated tubing, luer connectors, syringe, a Luer activated valve, or the like.

[0090] The blood sequestration device 1500 includes an inlet port 1502 that can be connected with a patient needle that is inserted into a patient's vascular system for access to and withdrawing of a blood sample. The inlet port 1502 may also be connected with tubing or other conduit that is in turn connected with the patient needle. The inlet port 1502 defines an opening into the blood sequestration device 1500, which opening may be the same cross sectional dimensions as tubing or other conduit connected with the patient needle or the patient needle itself. For instance, the opening can be circular with a diameter of approximately ≥ 0.114 cm (0.045 inches), ≥ ~~0.045 inches,~~ but can have a diameter of between ≥ 0.0254 cm (0.01 inches) ≥ ~~0.01 inches~~ or less to ≥ 0.508 cm (0.2 inches) ≥ ~~0.2 inches~~ or more.

[0091] The inlet port 1502 can also include a sealing or fluid-tight connector or connection, such as threading or Luer fitting, or the like. In some

implementations, tubing or other conduit associated with the patient needle can be integral with the inlet port 1502, such as by co-molding, gluing, laser weld, or thermally bonding the parts together. In this manner, the blood sequestration device 1500 can be fabricated and sold with the patient needle as a single unit, eliminating the need for connecting the patient needle to the blood sequestration device 1500 at the time of blood draw or sampling.

[0092] The blood sequestration device 1500 further includes an outlet port 1504, which defines an opening out of the blood sequestration device 1500 and to the blood sample collection device. The outlet port 1504 may also be connected with tubing or other conduit that is in turn connected with the blood sequestration device, and may also include a sealing or fluid-tight connector or connection, such as threading or Luer fitting, or the like. Accordingly, as discussed above, the blood sequestration device 1500 can be fabricated and sold with the patient needle and/or tubing and the blood sample collection device as a single unit, eliminating the need for connecting the patient needle and the blood sample collection device to the blood sequestration device 1500 at the time of blood draw or sampling.

[0093] The blood sequestration device 1500 further includes a sampling channel 1506 between the inlet port 1502 and the outlet port 1504, and which functions as a blood sample pathway once a first aliquot of blood has been sequestered. The sampling channel 1506 can be any sized, shaped or configured channel or conduit. In some implementations, the sampling channel 1506 has a substantially similar cross sectional area as the opening of the inlet port 1502. In other implementations, the sampling channel 1506 can gradually widen from the inlet port 1502 to the outlet port 1504.

[0094] The blood sequestration device 1500 further includes a sequestration chamber 1508 that is connected to and split off or diverted from the sampling channel 1506 at any point between the inlet port 1502 and the outlet port 1504, but preferably from a proximal end of the sampling channel 1506 near the inlet port

1502. In some implementations, the diversion includes a Y-shaped junction. The sequestration chamber 1508 is preferably maintained at atmospheric pressure, and includes a vent 1510 at or near a distal end of the sequestration chamber 1508. The vent 1510 includes an air permeable blood barrier 1512. FIG. 15C illustrates the blood sequestration device 1500 with the sequestration chamber 1508 filled with a first aliquot or sample of blood from the patient.

[0095] The air permeable blood barrier 1512 can be covered with a protective cover 1516. The protective cover 1516 can be sized and configured to inhibit a user from touching the air permeable blood barrier 1512 with their finger or other external implement, while still allowing air to exit the air permeable blood barrier 1512 as the air is displaced from the sequestration chamber 1508 by blood being forced into the sequestration chamber 1508 by a patient's own blood pressure. The protective cover 1516 can be constructed to inhibit or prevent accidental exposure of the filter to environmental fluids or splashes. This can be accomplished in a variety of mechanical ways including but not limited to the addition of a hydrophobic membrane to the protective cover.

[0096] FIG. 15B is a perspective view of the blood sequestration device 1500 from the outlet port 1504 and top side of a housing 1501 of the blood sequestration device 1500 that includes the vent 1510, and illustrating an initial aliquot of blood filling sequestration chamber 1508 while the sampling channel 1506 is empty, before a sample collection device is activated. FIG. 15G is a perspective view of the blood sequestration device 1500 from the outlet port 1504 and bottom side of the housing 1501 of the blood sequestration device 1500, and illustrating the initial aliquot of blood filling sequestration chamber 1508 while the sampling channel 1506 is empty, before the sample collection device is activated. FIG. 15C is another perspective view of the blood sequestration device 1500 from the inlet port 1502 and top side of a housing 1501 of the blood sequestration device 1500 that includes the vent 1510, and illustrating blood now being drawn through sampling channel

1506 while the sequestered blood remains substantially in the sequestration chamber 1508.

[0097] FIG. 15D is a cross section of the blood sequestration device 1500 in accordance with some implementations, showing the housing 1501 that defines the sampling channel 1506 and the sequestration chamber 1508. FIGS. 15E and 15F illustrate various form factors of a housing for a blood sequestration device, in accordance with one or more implementations described herein.

[0098] The sequestration chamber 1508 can have a larger cross-sectional area than the sampling channel 1506, and the cross-sectional area and length can be configured for a predetermined or specific volume of blood to be sequestered or locked. The sampling channel 1506 can be sized to be compatible with tubing for either or both of the patient needle tubing or the blood collection device tubing.

[0099] The housing 1501 can be formed of multiple parts or a single, unitary part. In some implementations, and as illustrated in FIG. 15D, the housing 1501 includes a top member 1520 and a bottom member 1522 that are mated together, one or both of which having grooves, channels, locks, conduits or other pathways pre-formed therein, such as by an injection molding process or by etching, cutting, drilling, etc. The top member 1520 can be connected with the bottom member 1522 by any mating or connection mechanism, such as by laser welding, thermal bonding, ultrasonic welding, gluing, using screws, rivets, bolts, or the like, or by other mating mechanisms such as latches, grooves, tongues, pins, flanges, or the like.

[00100] In some implementations, such as shown in FIG. 15D, the top member 1520 can include the grooves, channels, locks, conduits or other pathways, while the bottom member 1522 can include a protrusion 1524 that is sized and adapted to fit into at least one of the grooves, channels, locks or other pathways of the top member 1520. The protrusion 1524 can provide a surface feature, such as a partial

groove or channel, for instance, to complete the formation of either the sampling channel 1506 and/or the sequestration chamber 1508. In some implementations, the protrusion 1524 can be formed with one or more angled sides or surfaces for a tighter fit within the corresponding groove, channel, lock or other pathway. In yet other implementations, both the top member 1520 and the bottom member can include grooves, channels, locks or other pathways, as well as one or more protrusions 1524.

[00101] In some implementations, the sampling channel 1506 and the sequestration chamber 1508 are formed by grooves, channels, locks or other pathways formed in housing 1501. The housing 1501 can be made of any suitable material, including rubber, plastic, metal or other material. The housing 1501 can be formed of a clear or translucent material, or of an opaque or non-translucent material. In other implementations, the housing 1501 can be mostly opaque or non-translucent, while the housing surface directly adjacent to the sampling channel 1506 and/or the sequestration chamber 1508 is clear or translucent, giving a practitioner a visual cue or sign that the sequestration chamber 1508 is first filled to the extent necessary or desired, and/or then a visual cue or sign that the sequestered blood remains sequestered while a clean sample of blood is drawn through the sampling channel 1506. Other visual cues or signs of the sequestration can include, without limitation: the air permeable blood barrier 1512 turning a different color upon contact, saturation, or partial saturation with blood; a color-coded tab or indicator at any point along or adjacent to the sequestration chamber; an audible signal; a vibratory signal; or other signal.

[00102] After a venipuncture by a patient needle of a patient (not 2 [redacted] shown, not claimed), [redacted] 2 ~~shown),~~

which could gather a number of pathogens from the patient's skin, a first amount of the patient's blood with those pathogens will make its way into the input port 1502 blood sequestration device 1500 and flow into the sequestration chamber 1508 by following the path of least resistance, as the patient's own blood pressure

overcomes the atmospheric pressure in the sequestration chamber 1508 to displace air therein through the air permeable blood barrier 1512. The patient's blood pressure will not be sufficient to overcome the air pressure that builds up in the sealed sampling channel 1506. Eventually, the sequestration chamber 1508, which has a predetermined volume, is filled with blood that displaces air through the air permeable blood barrier 1512. Once the blood hits the air permeable blood barrier, the blood interacts with the air permeable blood barrier 1512 material to completely or partially seal the vent 1510. A signal or indication may be provided that the practitioner can now utilize the Vacutainer capsule or other blood sample collection device to acquire a next amount of the patient's blood for sampling. The blood in the sequestration chamber 1508 is now effectively sequestered in the sequestration chamber.

[00103] Upon filling the blood sequestration pathway 1508 but prior to use of the Vacutainer or other blood sample collection device, the patient's blood pressure may drive compression of the air in the sampling channel 1506, possibly resulting in a small amount of blood moving past the diversion point to the sequestration chamber 1508 and into the sampling channel 1506, queuing up the uncontaminated blood to be drawn through the sampling channel 1506.

[00104] FIGS. 16-19 illustrate yet another implementation of a blood sequestration device. FIGS. 16A-16D illustrate a blood sequestration device 1600 that can be connected between a blood sample collection device, such as an evacuated blood collection container like a Vacutainer™ (not shown), and a patient needle (not shown) and/or associated tubing. FIG. 17 illustrates a bottom member of the blood sequestration device, and FIG. 18 illustrates a top member of the blood sequestration device, which top member and bottom member can be mated together to form an input port, and output port, a sequestration chamber and a sampling channel, as explained more fully below. FIGS. 19A and B show the top member and bottom member mated together. It should be understood that FIGS.

16-19 illustrate one exemplary manner of constructing a blood sequestration device as described herein, and other forms of construction are possible.

[00105] Referring to FIGS. 16A – D, the blood sequestration device 1600 includes an inlet port 1602 that can be connected with a patient needle that is inserted into a patient's vascular system for access to and withdrawing of a blood sample. The inlet port 1602 may also be connected with tubing or other conduit that is in turn connected with the patient needle. The inlet port 1602 defines an opening into the blood sequestration device 1600, which opening can be the same cross sectional dimensions as tubing or other conduit connected with the patient needle or the patient needle itself. For instance, the opening can be circular with a diameter of approximately 2 ▛ 0.114 cm (0.045 inches), ▟ 2 ~~0.045 inches,~~ but can have a diameter of between 2 ▛ 0.0254 cm (0.01 inches) ▟ 2 ~~0.01 inches~~ or less to 2 ▛ 0.508 cm (0.2 inches) ▟ 2 ~~0.2 inches~~ or more.

[00106] The inlet port 1602 can also include a sealing or fluid-tight connector or connection, such as threading or Luer fitting, or the like. In some implementations, tubing or other conduit associated with the patient needle can be integral with the inlet port 1602, such as by co-molding, gluing, laser weld, or thermally bonding the parts together. In this manner, the blood sequestration device 1600 can be fabricated and sold with the patient needle and/or tubing as a single unit, eliminating the need for connecting the patient needle to the blood sequestration device 1600 at the time of blood draw or sampling.

[00107] The blood sequestration device 1600 further includes an outlet port 1604, which defines an opening out of the blood sequestration device 1600 and to the blood sample collection device. The outlet port 1604 may also be connected with tubing or other conduit that is in turn connected with the blood sequestration device, and may also include a sealing or fluid-tight connector or connection, such as threading or Luer fitting, or the like. Accordingly, as discussed above, the blood sequestration device 1600 can be fabricated and sold with the patient needle and/or tubing and the blood sample collection device as a single unit, eliminating the need

for connecting the patient needle and the blood sample collection device to the blood sequestration device 1600 at the time of blood draw or sampling.

[00108] The blood sequestration device 1600 further includes a sampling channel 1606 between the inlet port 1602 and the outlet port 1604, and a sequestration chamber 1608 that is connected to and split off or diverted from the sampling channel 1606 at any point between the inlet port 1602 and the outlet port 1604. The sampling channel 1606 functions as a blood sampling pathway once a first aliquot of blood has been sequestered in the sequestration chamber 1608. The sampling channel 1606 can be any sized, shaped or configured channel, or conduit. In some implementations, the sampling channel 1606 has a substantially similar cross sectional area as the opening of the inlet port 1602. In other implementations, the sampling channel 1606 can gradually widen from the inlet port 1602 to the outlet port 1604. The sequestration chamber 1608 may have a larger cross section to form a big reservoir toward the sequestration channel path so that the blood will want to enter the reservoir first versus entering a smaller diameter on the sampling channel 1606, as is shown more fully in FIGS. 17 and 19.

[00109] In some exemplary implementations, the diversion between the sampling channel 1606 and the sequestration chamber 1608 is by diverter junction 1607. Diverter junction 1607 may be a substantially Y-shaped, T-shaped, or U-shaped. In some preferred exemplary implementations, and as shown in FIG. 17A – 17B, the diverter junction 1607 is configured such that the flow out of the inlet port 1602 is preferentially directed toward the sequestration chamber 1608. The sequestration chamber 1608 may also include or form a curve or ramp to direct the initial blood flow toward and into the sequestration chamber 1608.

[00110] The sequestration chamber 1608 is preferably maintained at atmospheric pressure, and includes a vent 1610 at or near a distal end of the sequestration chamber 1608. The vent 1610 may include an air permeable blood barrier 1612 as described above.

[00111] The blood sequestration device 1600 can include a housing 1601 that can be formed of multiple parts or a single, unitary part. In some implementations, and as illustrated in FIGS. 17A – 17D and FIGS. 18A – 18F, the housing 1601 includes a top member 1620 and a bottom member 1622 that are mated together. The blood sequestration device 1600 can also include a gasket or other sealing member (not shown) so that when the top member 1620 is mechanically attached with the bottom member 1622, the interface between the two is sealed by the gasket or sealing member. The FIGS. 17A – 17D illustrate a bottom member 1622 of a housing for a blood sequestration device 1600. The bottom member 1622 can include grooves, channels, locks, conduits or other pathways pre-formed therein, such as by an injection molding process or by etching, cutting, drilling, etc., to form the sampling channel 1606, the sequestration chamber 1608, and diverter junction 1607.

[00112] The sequestration chamber 1608 may have a larger cross section than the sampling channel 1606 so that the blood will preferentially move into the sequestration chamber first versus entering a smaller diameter on the sampling channel 1606.

[00113] FIGS. 18A – 18F illustrate the top member 1620, which can be connected with the bottom member 1622 by any mating or connection mechanism, such as by laser welding, thermal bonding, gluing, using screws, rivets, bolts, or the like, or by other mating mechanisms such as latches, grooves, tongues, pins, flanges, or the like. The top member 1620 can include some or all of the grooves, channels, locks, conduits or other pathways to form the sampling channel 1606, the sequestration chamber 1608, and the diverter junction 1607. In yet other implementations, both the top member 1620 and the bottom member 1622 can include the grooves, channels, locks or other pathways.

[00114] In some implementations, the sampling channel 1606 and the sequestration chamber 1608 are formed by grooves, channels, locks or other

pathways formed in housing 1601. The housing 1601 can be made of rubber, plastic, metal or any other suitable material. The housing 1601 can be formed of a clear or translucent material, or of an opaque or non-translucent material. In other implementations, the housing 1601 can be mostly opaque or non-translucent, while the housing surface directly adjacent to the sampling channel 1606 and/or the sequestration chamber 1608 may be clear or translucent, giving a practitioner a visual cue or sign that the sequestration chamber 1608 is first filled to the extent necessary or desired, and/or then a visual cue or sign that the sequestered blood remains sequestered while a clean sample of blood is drawn through the sampling channel 1606. Other visual cues or signs of the sequestration can include, without limitation: the air permeable blood barrier 1612 turning a different color upon contact, saturation, or partial saturation with blood; a color-coded tab or indicator at any point along or adjacent to the sequestration chamber; an audible signal; a vibratory signal; or other signal.

[00115] As shown in FIGS. 18A – 18F, the air permeable blood barrier 1612 can be covered with, or surrounded by, a protective member 1616. The protective member 1616 can be sized and configured to inhibit a user from touching the air permeable blood barrier 1612 with their finger or other external implement, while still allowing air to exit the air permeable blood barrier 1612 as the air is displaced from the sequestration chamber 1608. In some implementations, the protective member 1616 includes a protrusion that extends up from a top surface of the top member 1620 and around the air permeable blood barrier 1612. The protective cover 1616 can be constructed to inhibit or prevent accidental exposure of the filter to environmental fluids or splashes. This can be accomplished in a variety of mechanical ways including but not limited to the addition of a hydrophobic membrane to the protective cover.

[00116] In 2 [redacted] use (neither use nor method is claimed), [redacted] 2 ~~use,~~ the blood sequestration device 1600 includes a sampling channel 1606 and a sequestration chamber 1608. Both pathways are initially air-

filled at atmospheric pressure, but the sampling channel 1606 is directed to an output port 1604 that will be initially sealed by a Vacutainer or other such sealed blood sampling device, and the sequestration chamber 1608 terminates at a vent 1610 to atmosphere that includes an air permeable blood barrier 1612.

[00117] After a venipuncture by a patient needle of a patient (not shown), which could gather a number of pathogens from the patient's skin, a first amount of the patient's blood with those pathogens will pass through input port 1602 of blood sequestration device 1600. This initial volume of potentially contaminated blood will preferentially flow into the sequestration chamber 1608 by finding the path of least resistance. The patient's own blood pressure overcomes the atmospheric pressure in the vented sequestration chamber 1608 to displace air therein through the air permeable blood barrier 1612, but is not sufficient to overcome the air pressure that builds up in the sealed sampling channel 1606. In various exemplary embodiments, the sequestration chamber 1608 and sampling channel 1606 can be configured such that the force generated by the patient's blood pressure is sufficient to overcome any effect of gravity, regardless of the blood sequestration device's orientation.

[00118] Eventually, the sequestration chamber 1608 fills with blood that displaces air through the air permeable blood barrier 1612. Once the blood contacts the air permeable blood barrier, the blood interacts with the air permeable blood barrier 1612 material to completely or partially seal the vent 1610. A signal or indication may be provided that the practitioner can now utilize the Vacutainer or other blood sampling device.

[00119] Upon filling the blood sequestration pathway 1608 but prior to use of the Vacutainer or other blood sample collection device, the patient's blood pressure may drive compression of the air in the sampling channel 1606, possibly resulting in a small amount of blood moving past the diversion point into the sampling channel 1606, queuing up the uncontaminated blood to be drawn through the sampling channel 1606.

[00120] FIG. 19A is a side view, and FIG. 19B is a cross-sectional view, of the blood sequestration device 1600, illustrating the top member 1620 mated with the bottom member 1622.

[00121] FIG. 20 shows a blood sample optimization system 2000 that includes a patient needle 2002 for vascular access to a patient's bloodstream, a blood sample collection device 2004 to facilitate the collecting of one or more blood samples, and a conduit 2006 providing a fluid connection between the patient needle 2002 and the blood sample collection device 2004. In some implementations, the blood sample collection device 2004 includes a protective shield that includes a sealed collection needle on which a sealed vacuum-loaded container is placed, which, once pierced by the collection needle, draws in a blood sample under vacuum pressure or force through the conduit 2006 from the patient needle 2002.

[00122] The blood sample optimization system 2000 further includes a blood sequestration device 2008, located at any point on the conduit 2006 between the patient needle 2002 and the blood sample collection device 2004 as described herein.

[00123] FIG. 21 illustrates a non-vented blood sequestration device 2100 using a wicking material chamber. The blood sequestration device 2100 includes a housing 2101 that has a sampling channel 2104 that is at least partially surrounded or abutted by a sequestration chamber 2102 that is filled with a wicking material. An initial aliquot of blood is drawn in from the patient needle into the sampling channel 2104 where it is immediately wicked into the wicking material of the sequestration chamber 2102. The wicking material and/or sequestration chamber 2102 is sized and adapted to receive and hold a predetermined amount of blood, such that follow-on or later blood draws pass by the wicking material and flow straight through the sampling channel 2104 to a sampling device such as a Vacutainer. The wicking material can include a substance such as a solidifier, a decontaminate, or other additive.

[00124] As described herein, an air permeable blood barrier may be created using a wide variety of different structures and materials. As shown in FIGS. 22A and B, an air permeable blood barrier 2202 of a blood sequestration device 2200 can include a polymer bead matrix 2204, in which at least some beads are treated to make them hydrophilic. The air permeable blood barrier 2202 further includes a self-sealing material 2206, such as carboxymethyl cellulose (CMC) or cellulose gum, or other sealing material. The air permeable blood barrier 2202 can further include voids 2208 that permit air flow before contact or during partial contact with a fluid such as blood. As shown in FIG. 22B, contact with a fluid causes the self-sealing material 2206 to swell and close off the voids 2208, occluding air flow through the voids 2208 and creating a complete or partial seal.

[00125] FIGS. 23A and B illustrate yet another implementation of a blood sequestration device 2300, having an inlet port 2302 to connect with a patient needle, an outlet port 2304 to connect with a blood sample collection device, a sequestration chamber 2306, and a sampling channel 2308 that bypasses the sequestration chamber 2306 once the sequestration chamber is filled to an initial aliquot of potentially contaminated blood to be sequestered. The sequestration chamber 2306 includes a hydrophobic plug 2312 at a distal end of the sequestration chamber 2306 that is farthest from the inlet port 2302. A vacuum or other drawing force applied from the outlet port 2304, such as from a Vacutainer or the like, draws in blood into the inlet port 2302 and directly into the sequestration chamber 2306, where the initial aliquot of blood will contact the hydrophobic plug 2312 and cause the initial aliquot of blood to back up into the sequestration chamber 2306 and be sequestered there. A small amount of blood may make its way into the sampling channel 2308, which is initially closed off by valve 2308. Upon release of the valve 2308, and under further force of the vacuum or other force, follow-on amounts of blood will flow into inlet port 2302, bypass the sequestration chamber 2306, and flow into and through sampling channel 2308 toward the outlet port 2304 and to the collection device.

Amended claims

1. A blood sequestration device (1500) comprising;

an inlet port (1502);

a junction (1607) connected with the inlet port (1502);

a sequestration chamber (1508) having a vent (1510) comprising an air permeable blood barrier (1512);

a sampling channel (1506) having a proximal end connected with the inlet port (1502) via the junction (1607), and a distal end connected with an outlet port (1504); and

a housing (1501) that houses and defines the inlet port (1502), the junction (1607), the sequestration chamber (1508), the sampling channel (1506), and the outlet port (1504),

wherein the sequestration chamber (1508) is connected with the inlet port (1502) via the junction (1607) which is configured to direct a first portion of blood to the sequestration chamber (1508),

characterized in that the air permeable blood barrier (1512) includes an air permeable material that seals at least partially upon contact with a portion of the first portion of blood.

2. The blood sequestration device (1500) in accordance with claim 1, wherein the sequestration chamber (1508) includes a sequestration channel defined in the housing (1501).

3. The blood sequestration device (1500) in accordance with claim 1 or 2, further comprising a blood sampling pathway connected with the inlet port (1502) opposite the junction (1607), and

wherein the inlet port (1502) defined by the housing (1501) has a cross-sectional geometry consistent with the blood sampling pathway.

4. The blood sequestration device (1500) in accordance with one of the preceding claims, wherein the sampling channel (1506) defined by the housing (1501) has a cross-sectional geometry consistent with the inlet port (1502).

5. The blood sequestration device (1500) in accordance with one of claims 2 to 4, wherein the housing (1501) comprises a bottom member (1522) mated with a top member (1520), each of the bottom member (1522) and the top member (1520)

defining a part of each of the inlet port (1502), the outlet port (1504), the sequestration chamber (1508), and the sampling channel (1506).

6. A system of a blood sequestration device (1500), a blood sampling pathway having a patient needle, and a sample collection device, the blood sequestration device (1500) comprising;

an inlet port (1502) connected with the patient needle;

a junction (1607) connected with the inlet port (1502) opposite the blood sampling pathway;

a sequestration chamber (1508) having a vent (1510) comprising an air permeable blood barrier (1512);

a sampling channel (1506) having a proximal end connected with the inlet port (1502); and

an outlet port (1504) connected with a distal end of the sampling channel (1506) and with the sample collection device; and a housing (1501) that houses and defines the inlet port (1502), the outlet port (1504), the sequestration chamber (1508), and the sampling channel (1506),

characterized in that the sequestration chamber (1508) is connected with the inlet port (1502) and the air permeable blood barrier (1512) includes an air permeable material that seals at least partially upon contact with blood.

7. The system in accordance with claim 6, wherein the inlet port (1502) is connected with the patient needle via a first portion of the blood sampling pathway.

8. The system in accordance with claim 6 or 7, wherein the outlet port (1504) is connected with the sample collection device via a second portion of the blood sampling pathway.

9. The system in accordance with one of claims 6 to 8, wherein the sequestration chamber (1508) includes a sequestration channel defined in the housing (1501).

10. The system in accordance with claim 9, wherein the sequestration channel has a proximal end connected with the inlet port (1502), and a distal end having the vent (1510) comprising an air permeable blood barrier (1512).

11. The system in accordance with one of claims 6 to 10, wherein the sequestration chamber (1508) and the sampling channel (1506) are connected with

the inlet port (1502) by the junction (1607) that is configured to direct a first portion of blood to the sequestration chamber (1508).

12. The system in accordance with one of claims 6 to 11, wherein the sampling channel (1506) has a substantially uniform cross-sectional geometry that is consistent with the blood sampling pathway.

13. The system in accordance with claim 12, wherein the sequestration chamber (1506) includes a sequestration chamber that has a cross-sectional area that is larger than the cross-sectional geometry of the sampling channel (1506).

14. The system in accordance with claim 7, member (1520), wherein the housing (1501) comprises a bottom member (1522) mated with a top member (1520), each of the bottom member (1522) and the top member (1520) defining a part of each of the inlet port (1502), the outlet port (1504), the sequestration chamber (1508), and the sampling channel (1506).

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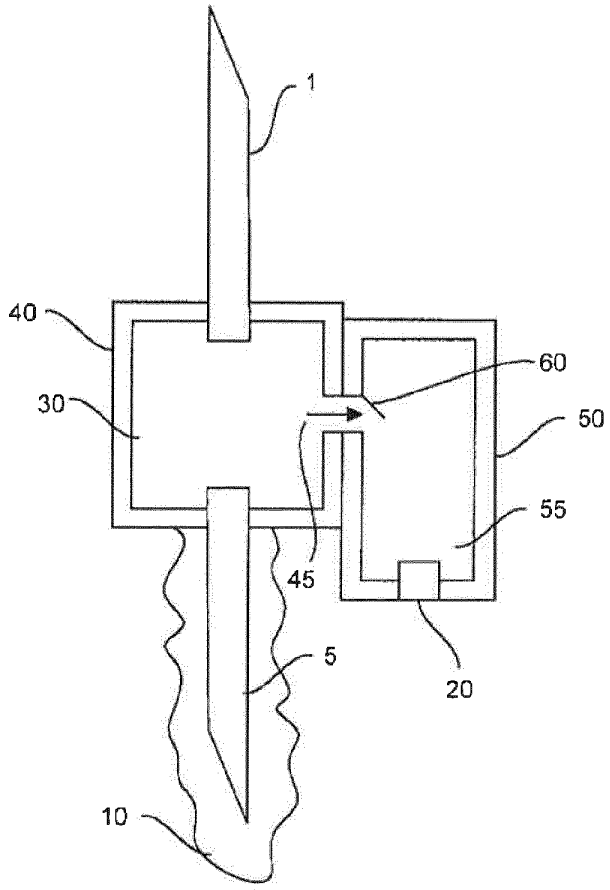


FIG. 1

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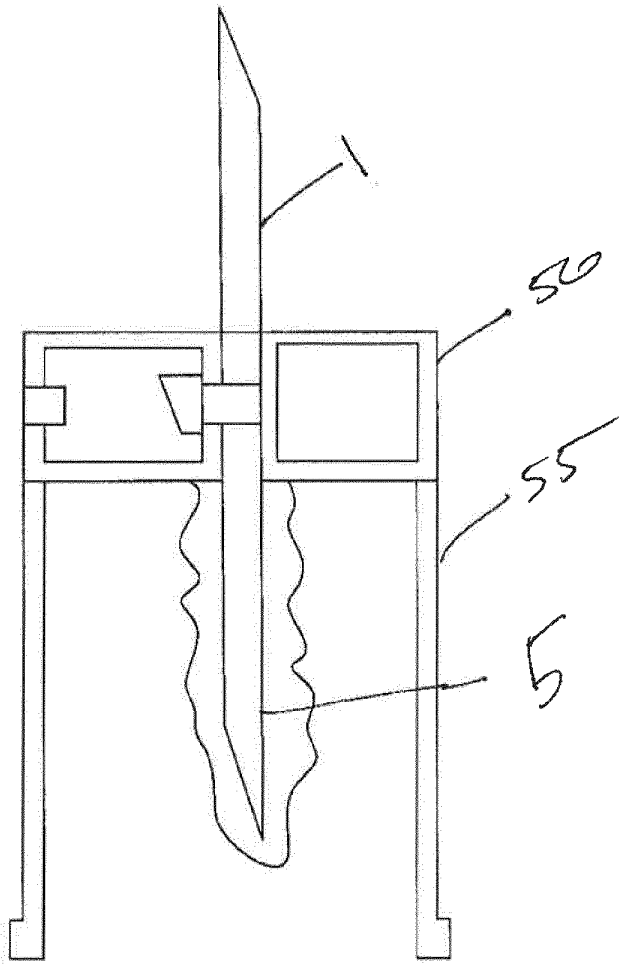


FIG. 2

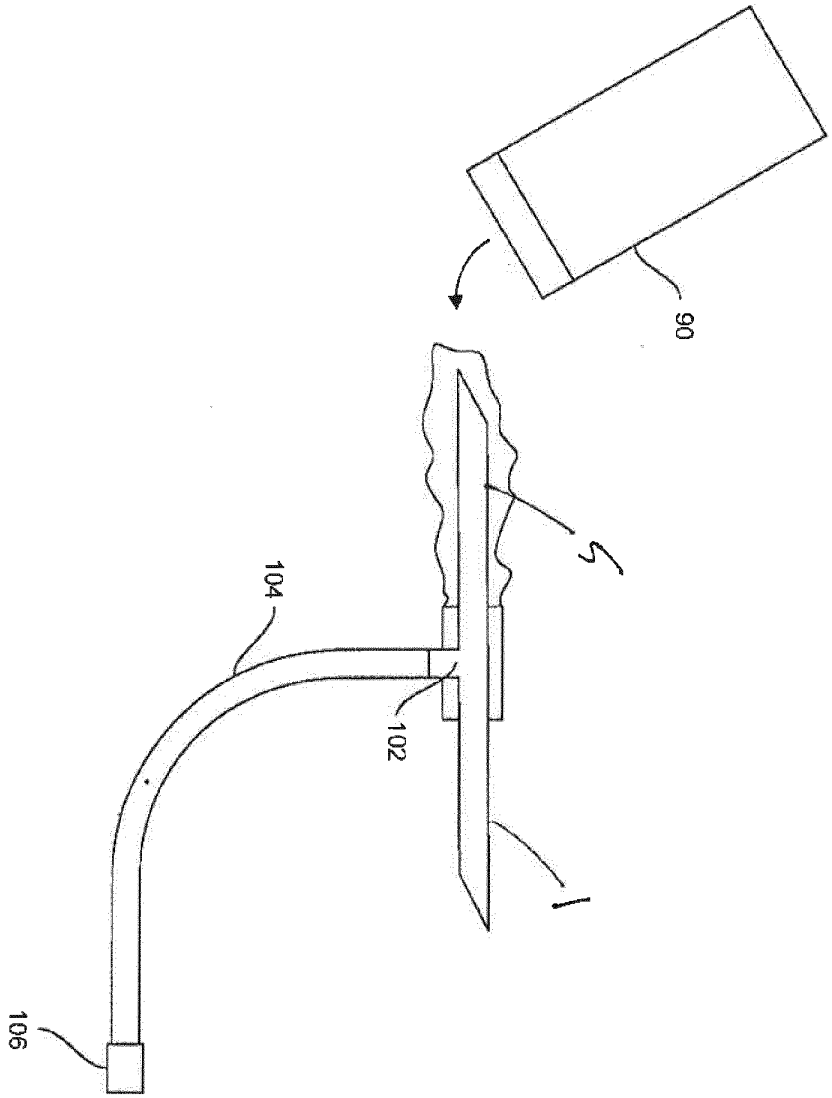


FIG. 3

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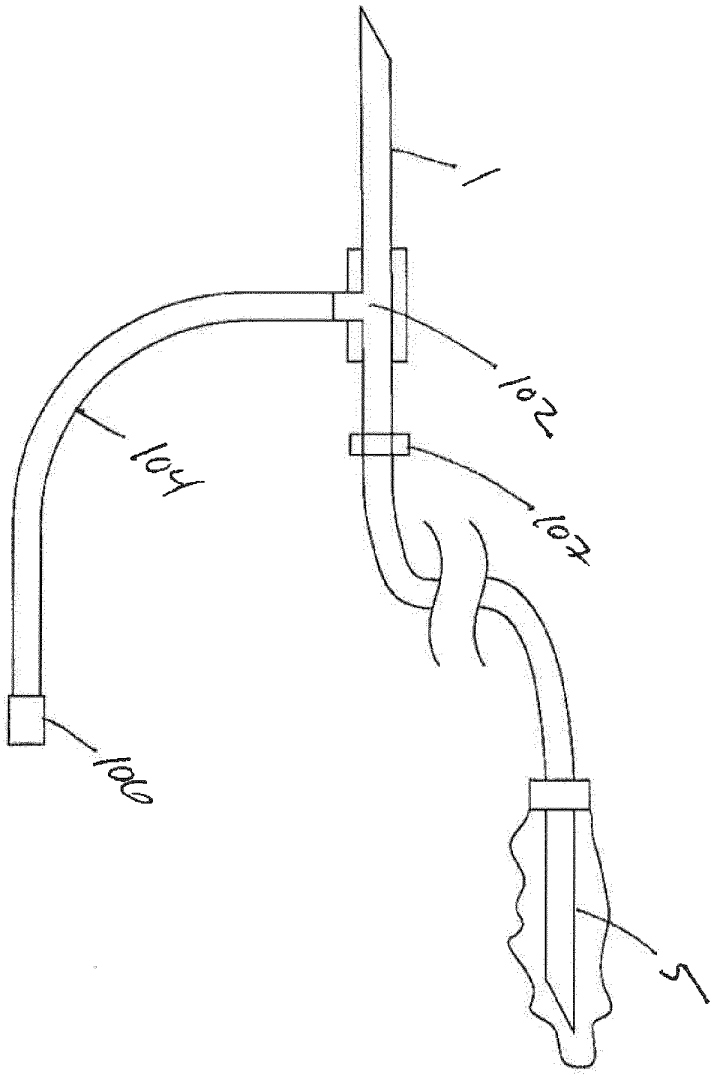


FIG. 4

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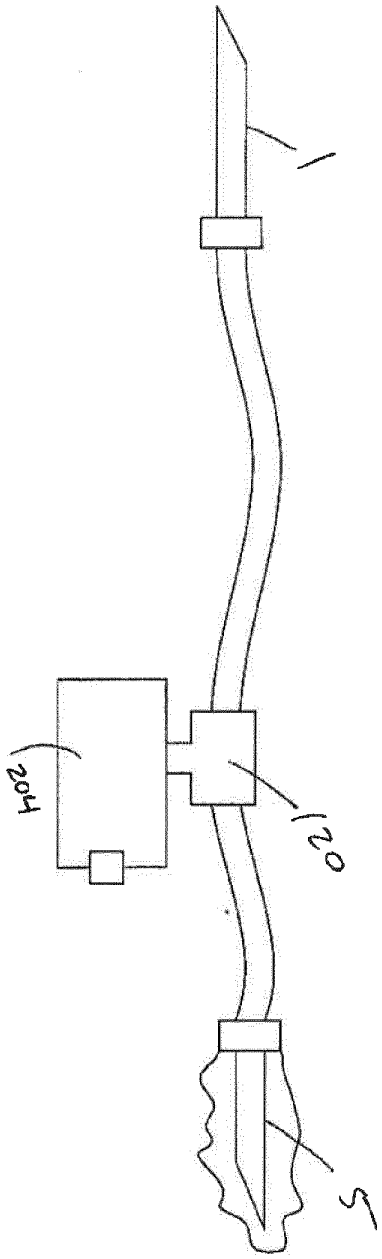


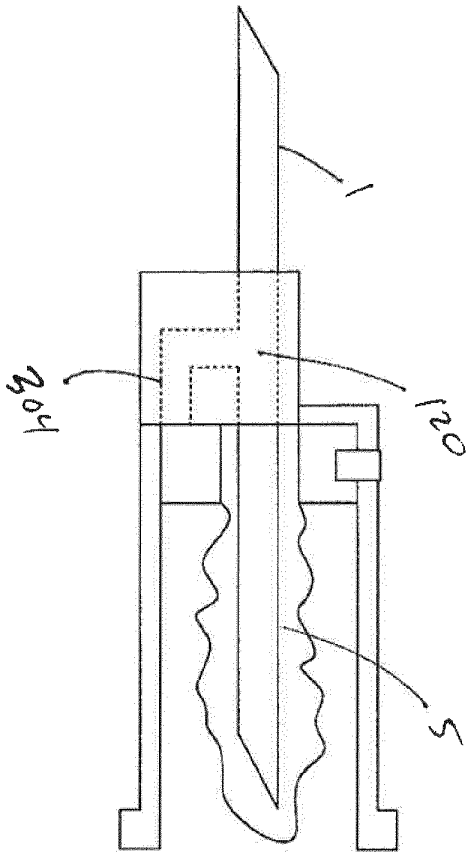
FIG. 5

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FIG. 6



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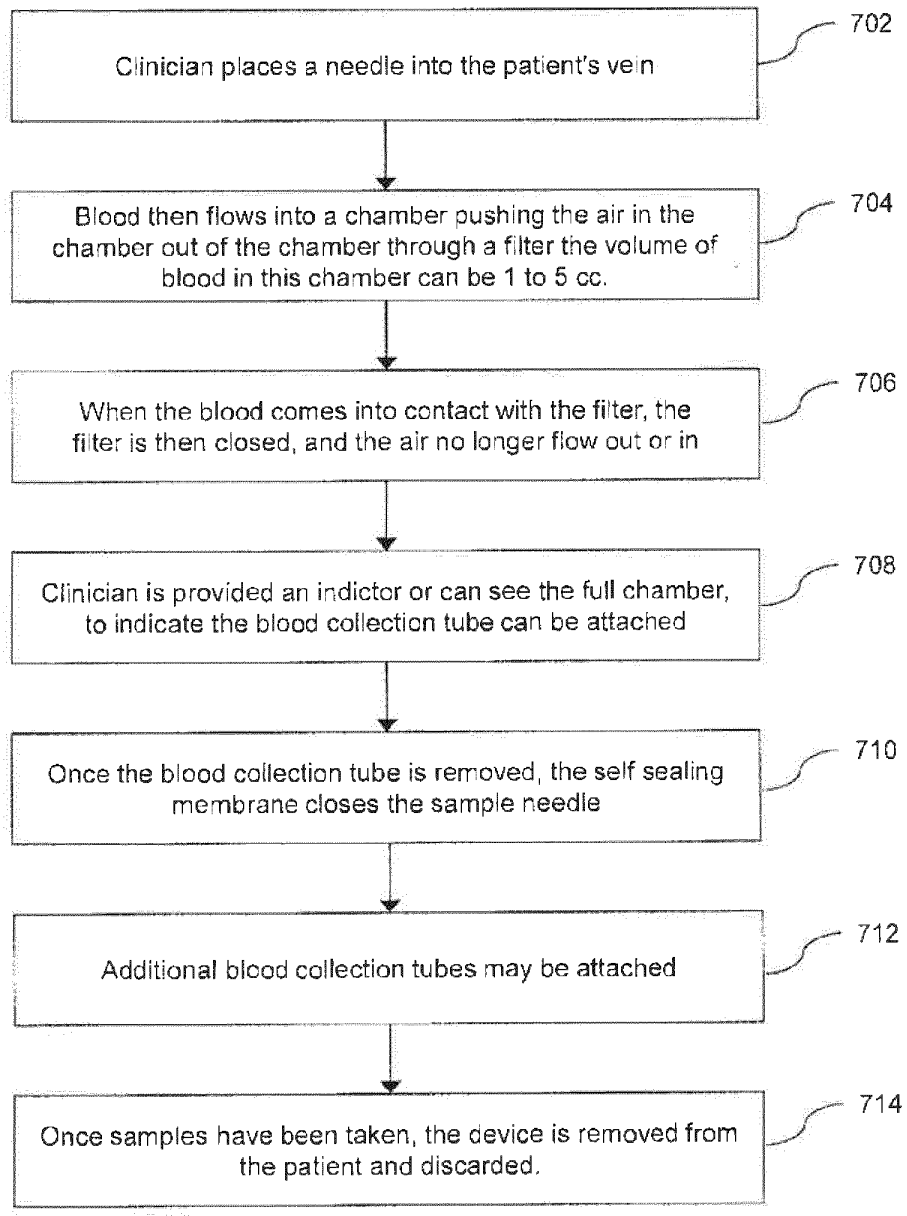
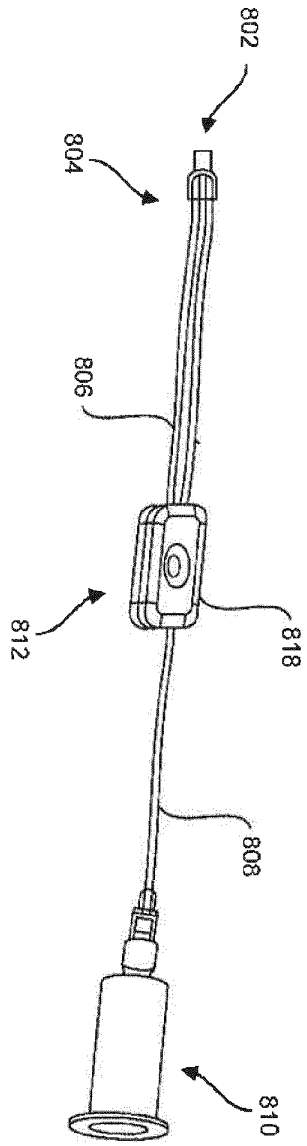

Clinician places a needle into the patient's vein
702
Blood then flows into a chamber pushing the air in the chamber out of the chamber through a filter the volume of blood in this chamber can be 1 to 5 cc.
704
When the blood comes into contact with the filter, the filter is then closed, and the air no longer flow out or in
706
Clinician is provided an indictor or can see the full chamber, to indicate the blood collection tube can be attached
708
Once the blood collection tube is removed, the self sealing membrane closes the sample needle
710
Additional blood collection tubes may be attached
712
Once samples have been taken, the device is removed from the patient and discarded.
714

FIG. 7

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FIG. 8A

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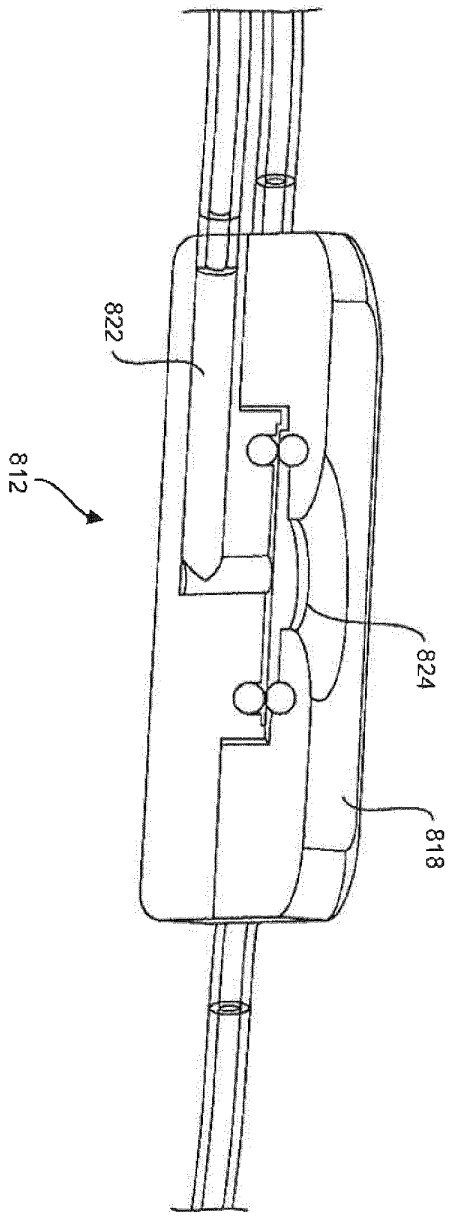


FIG. 8B

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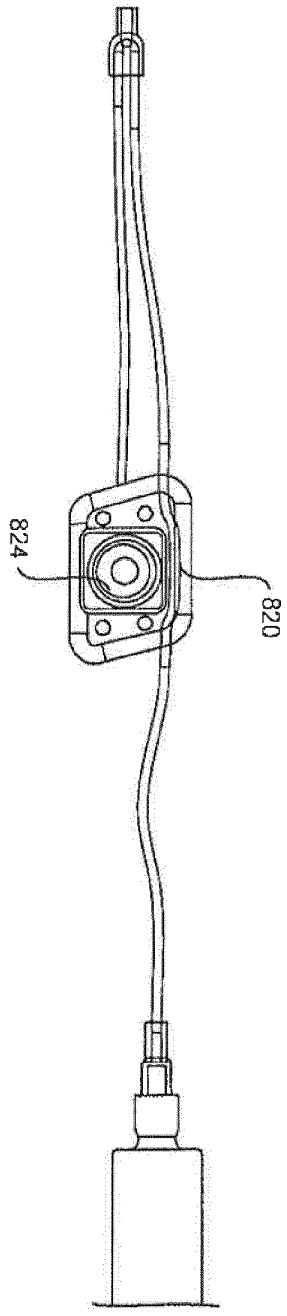
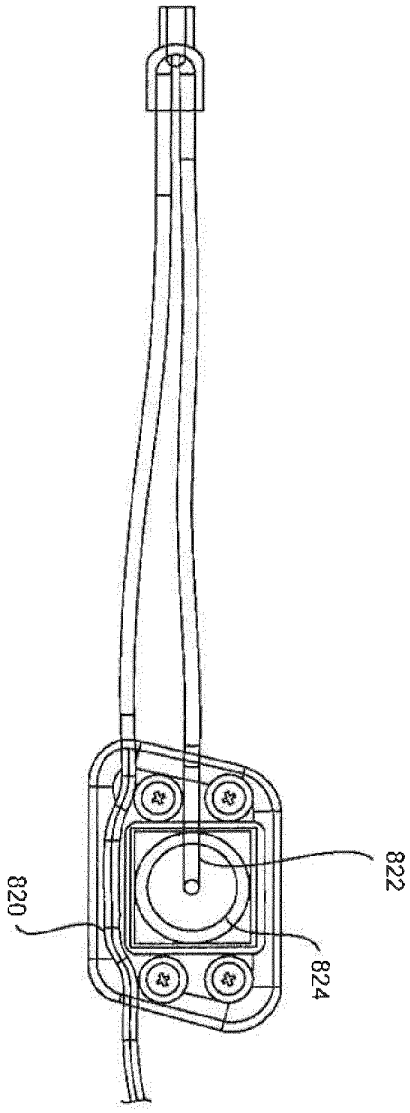


FIG. 8C

FIG. 8D



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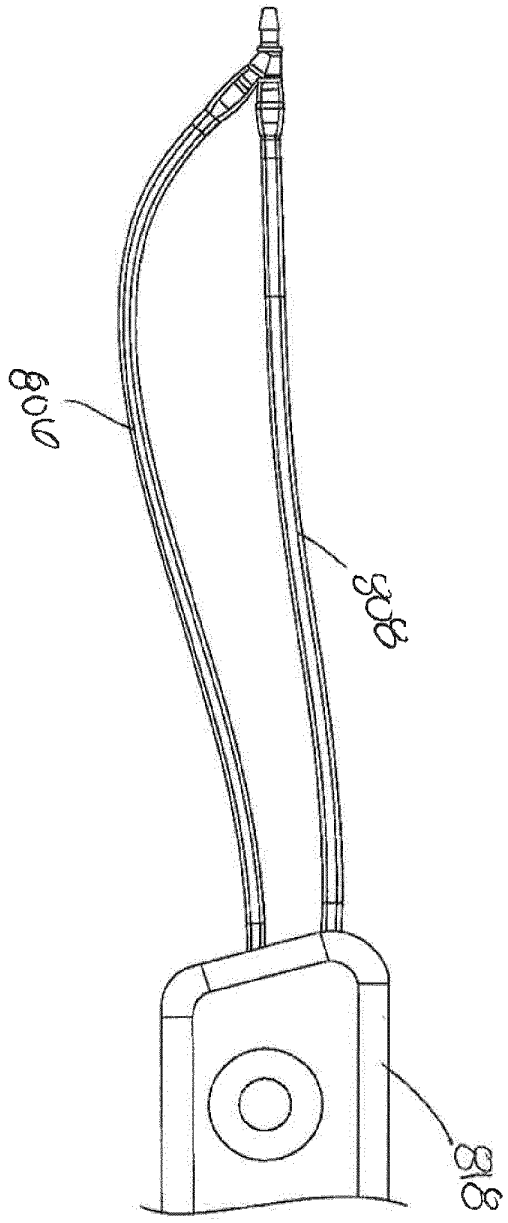


FIG. 8E

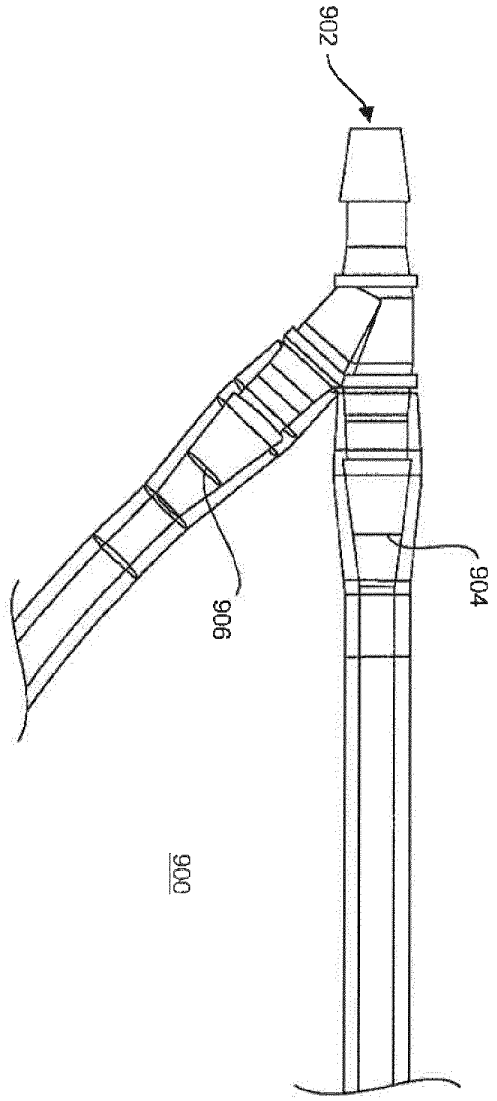


FIG. 9

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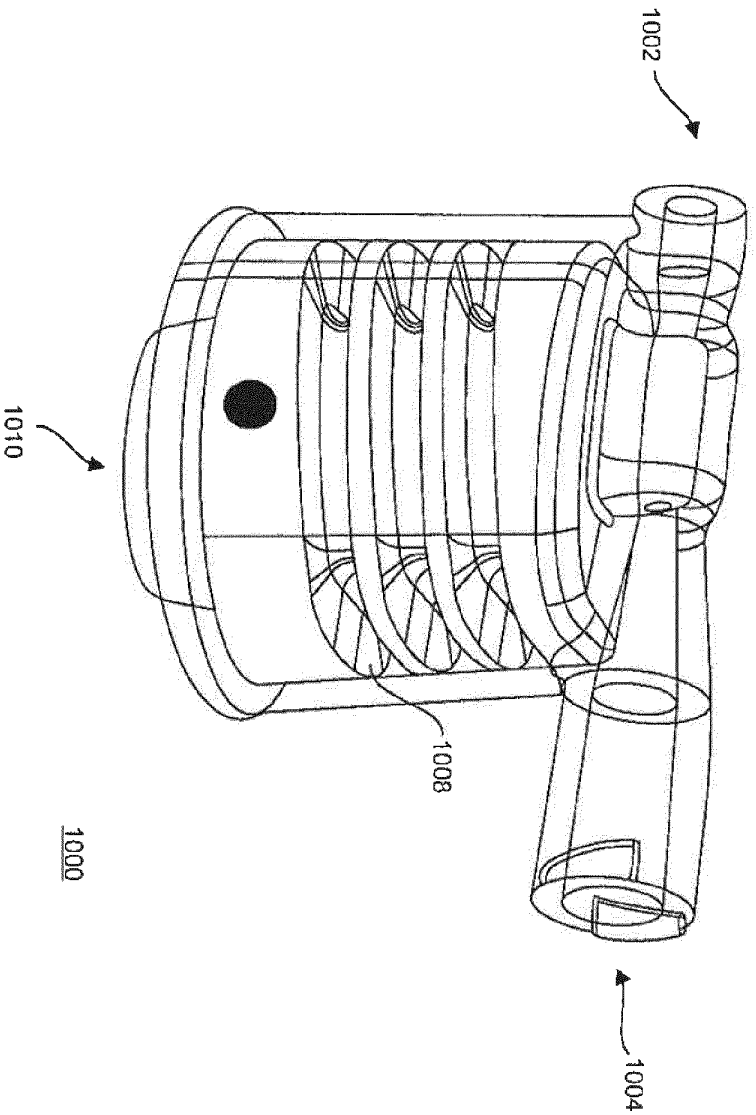


FIG. 10A

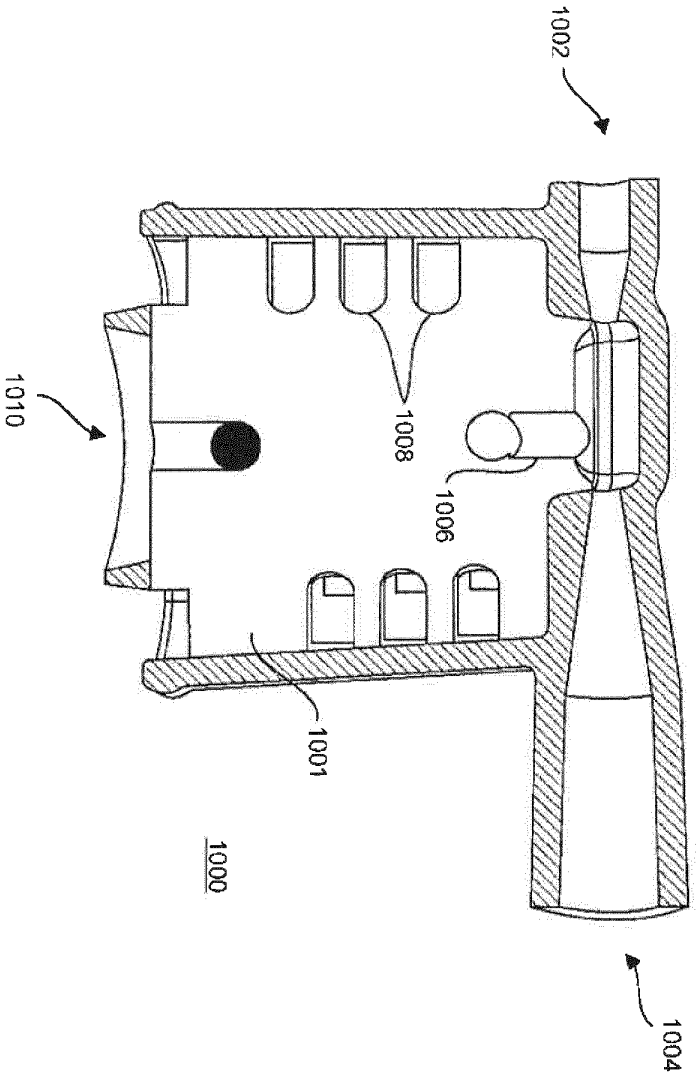


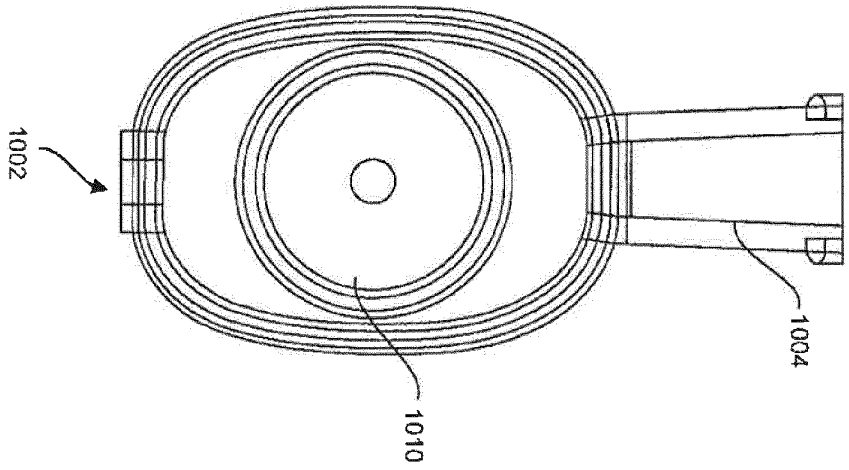
FIG. 10B

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FIG. 10C



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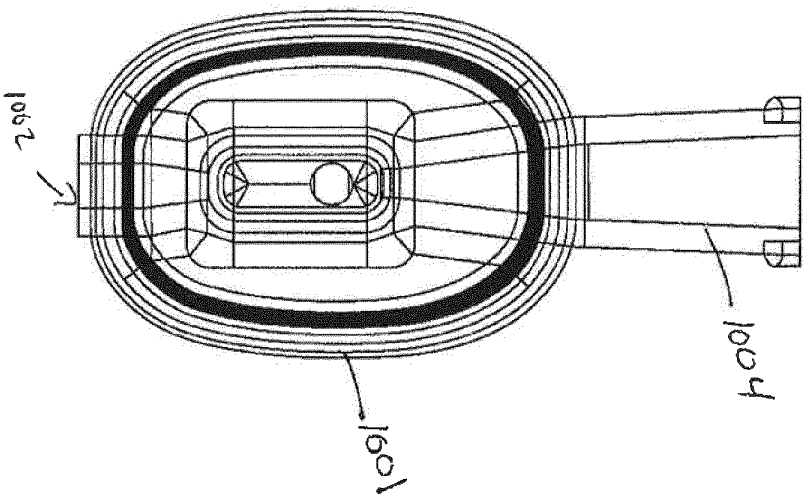


FIG. 10D

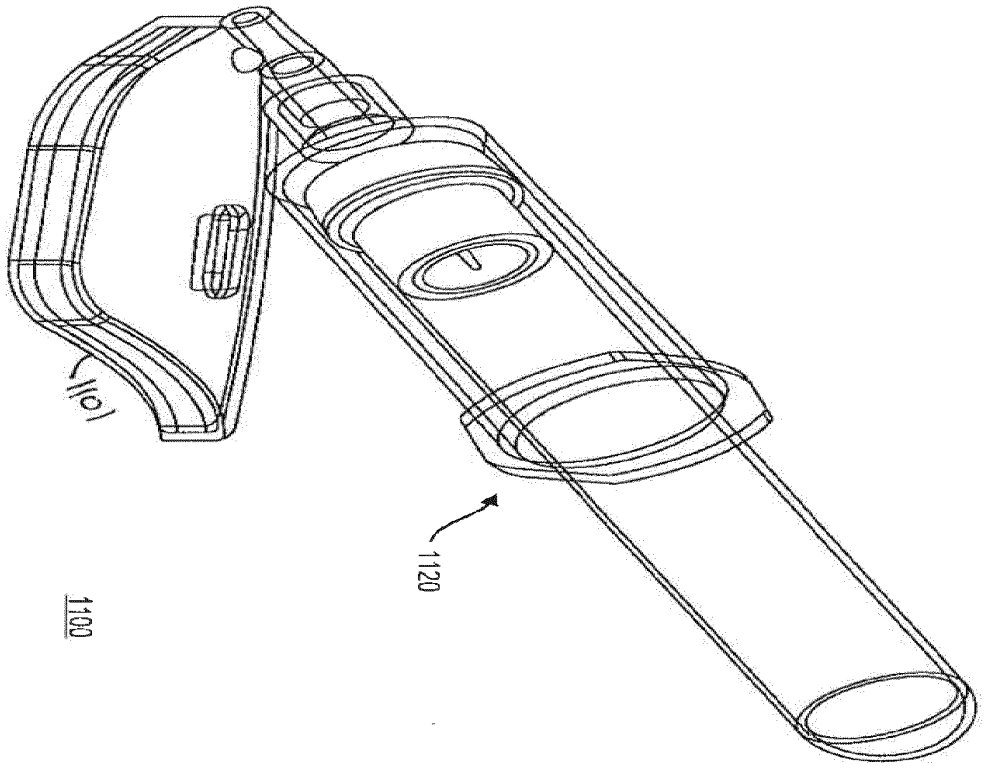


FIG. 11A

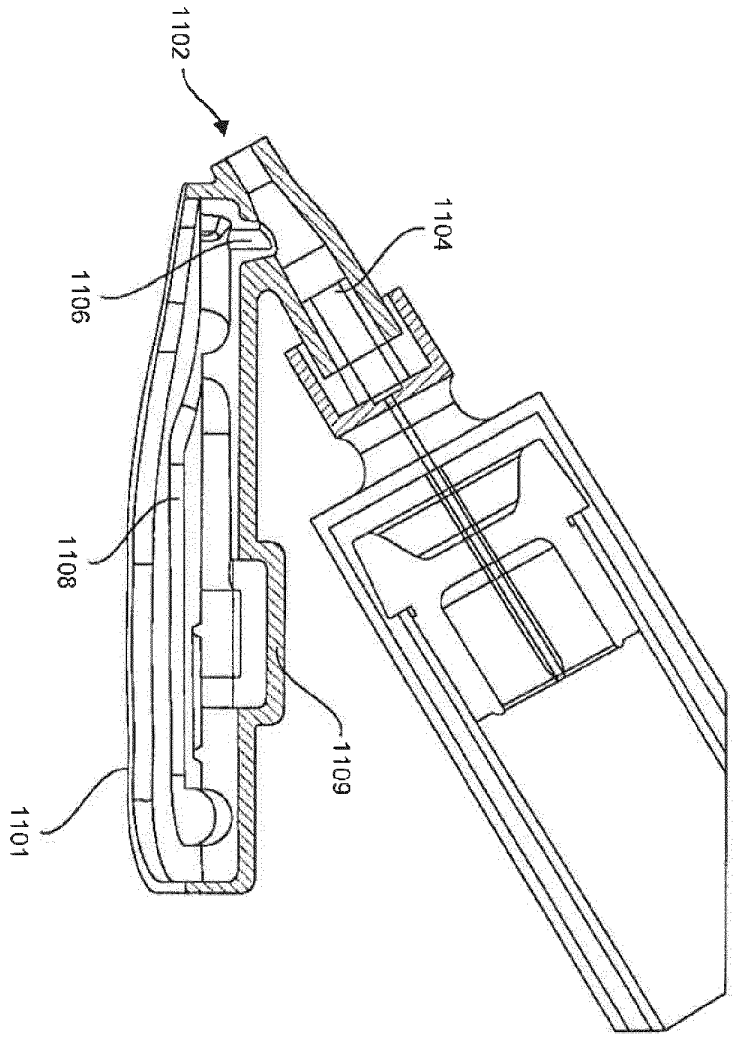


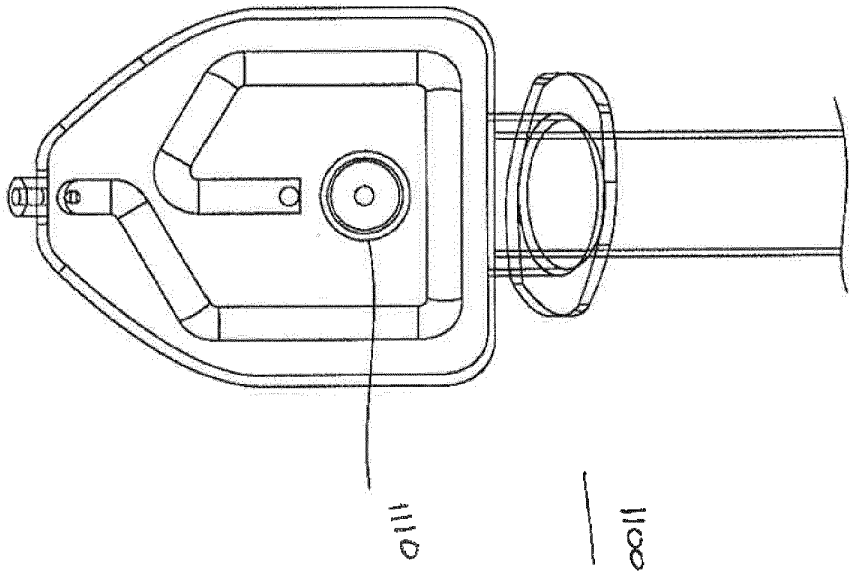
FIG. 11B

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FIG. 11C

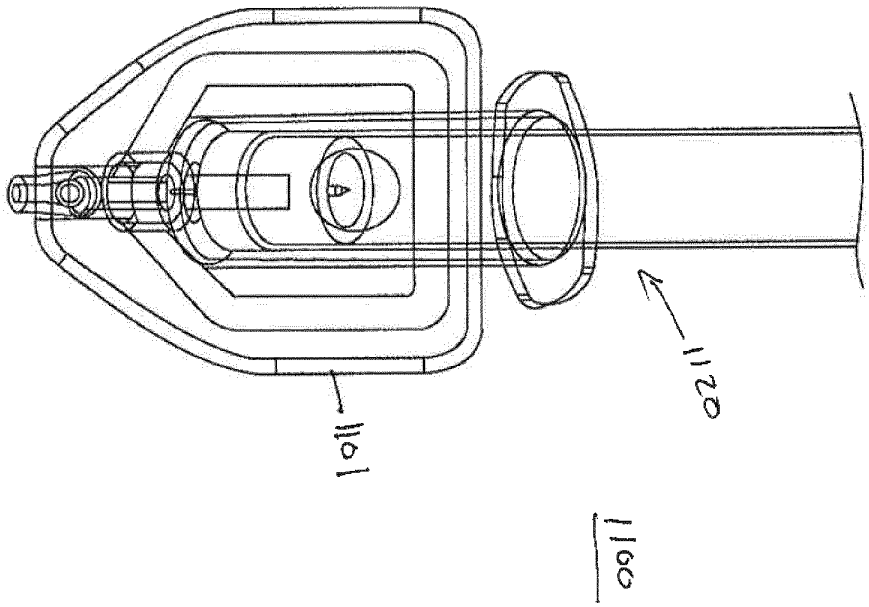


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FIG. 11D



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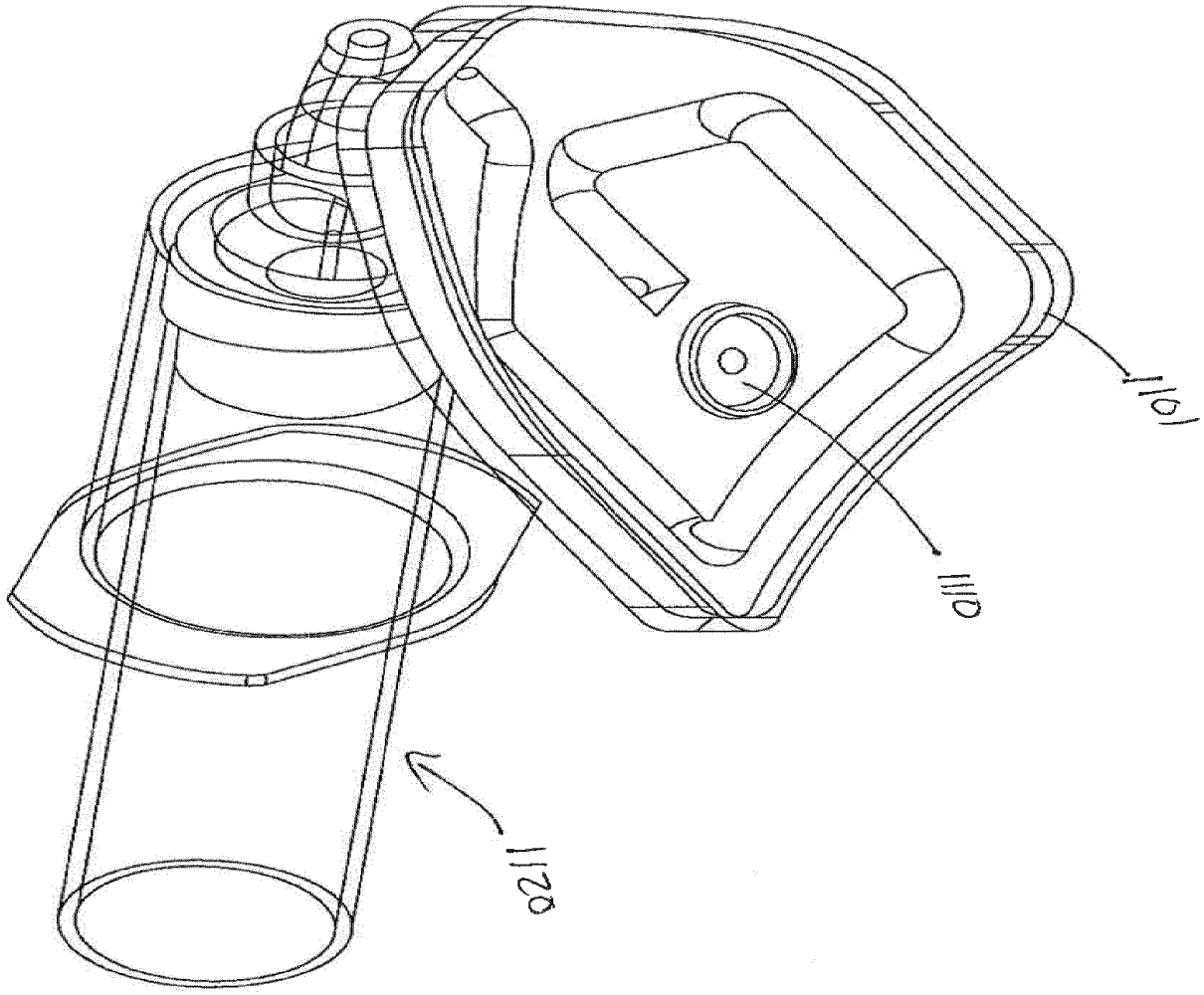


FIG. 11E

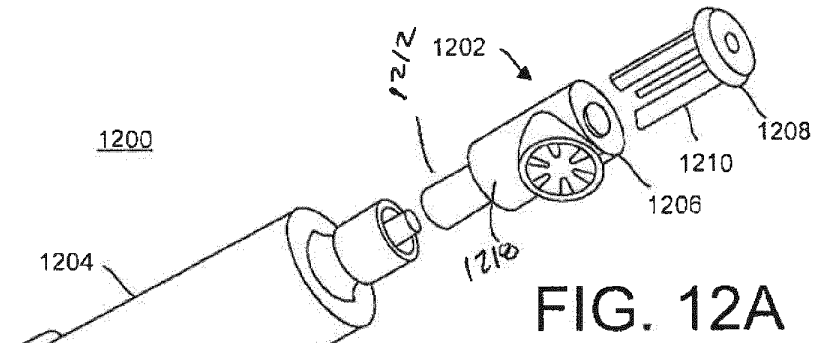


FIG. 12A

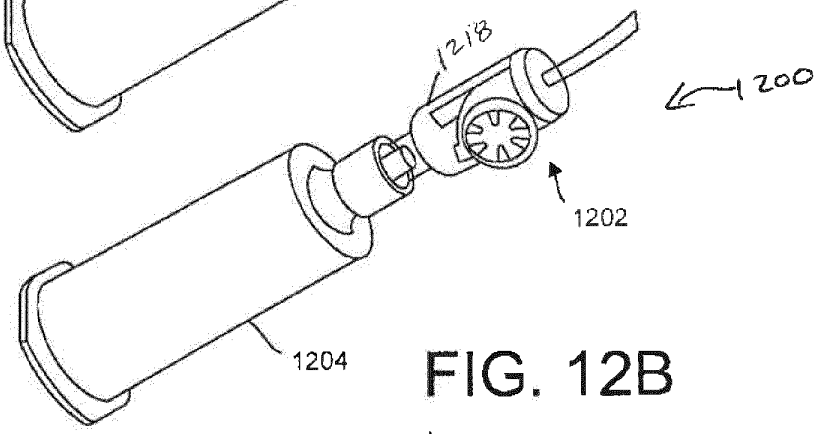


FIG. 12B

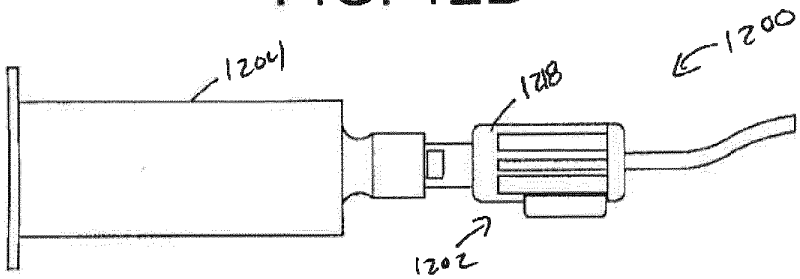


FIG. 12C

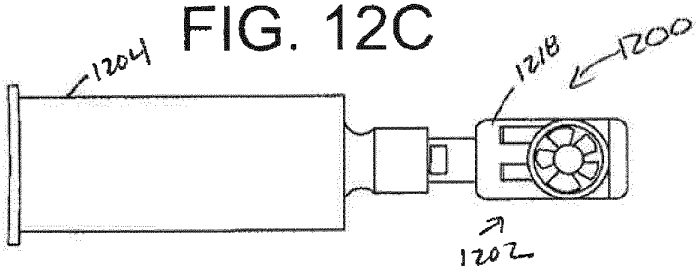


FIG. 12D

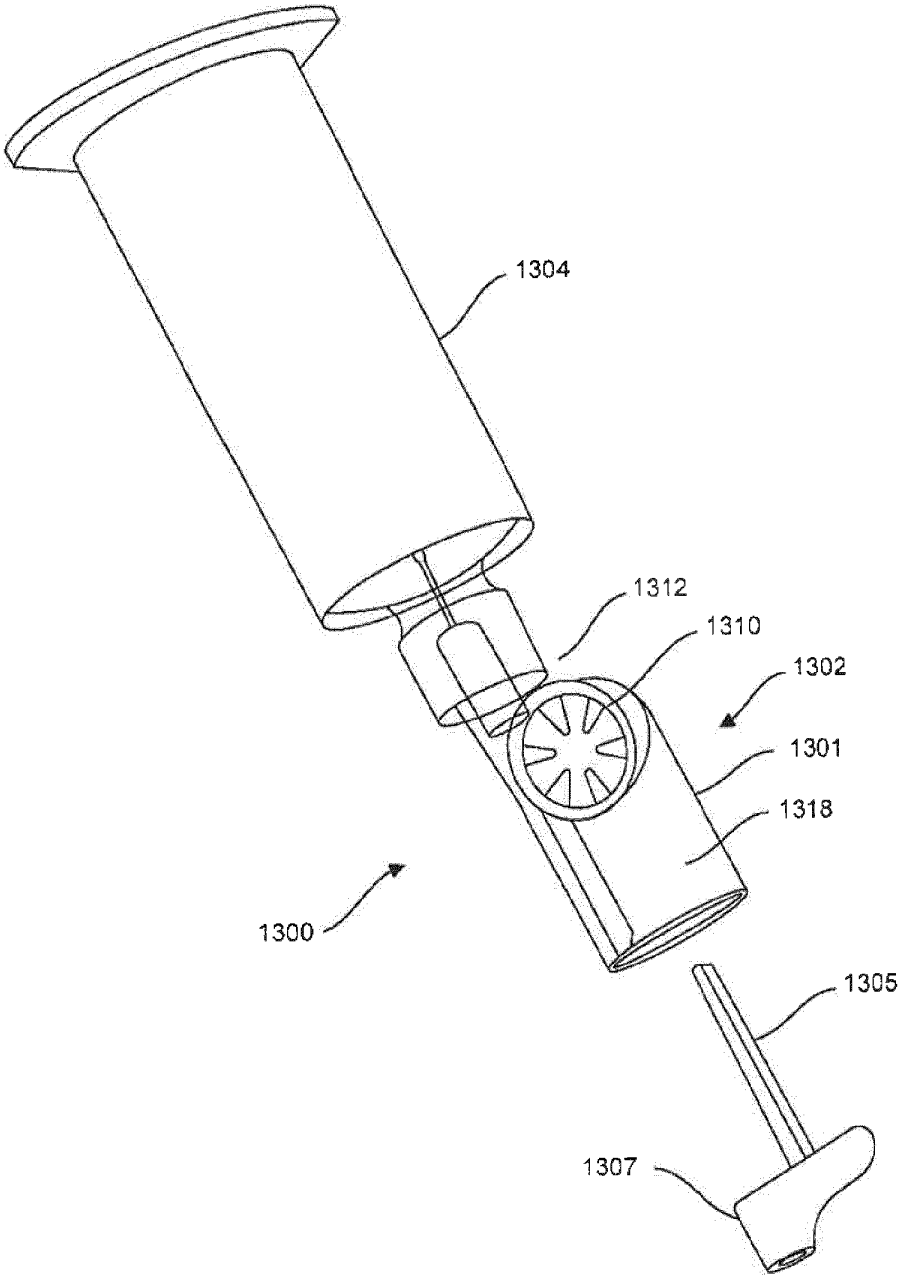


FIG. 13A

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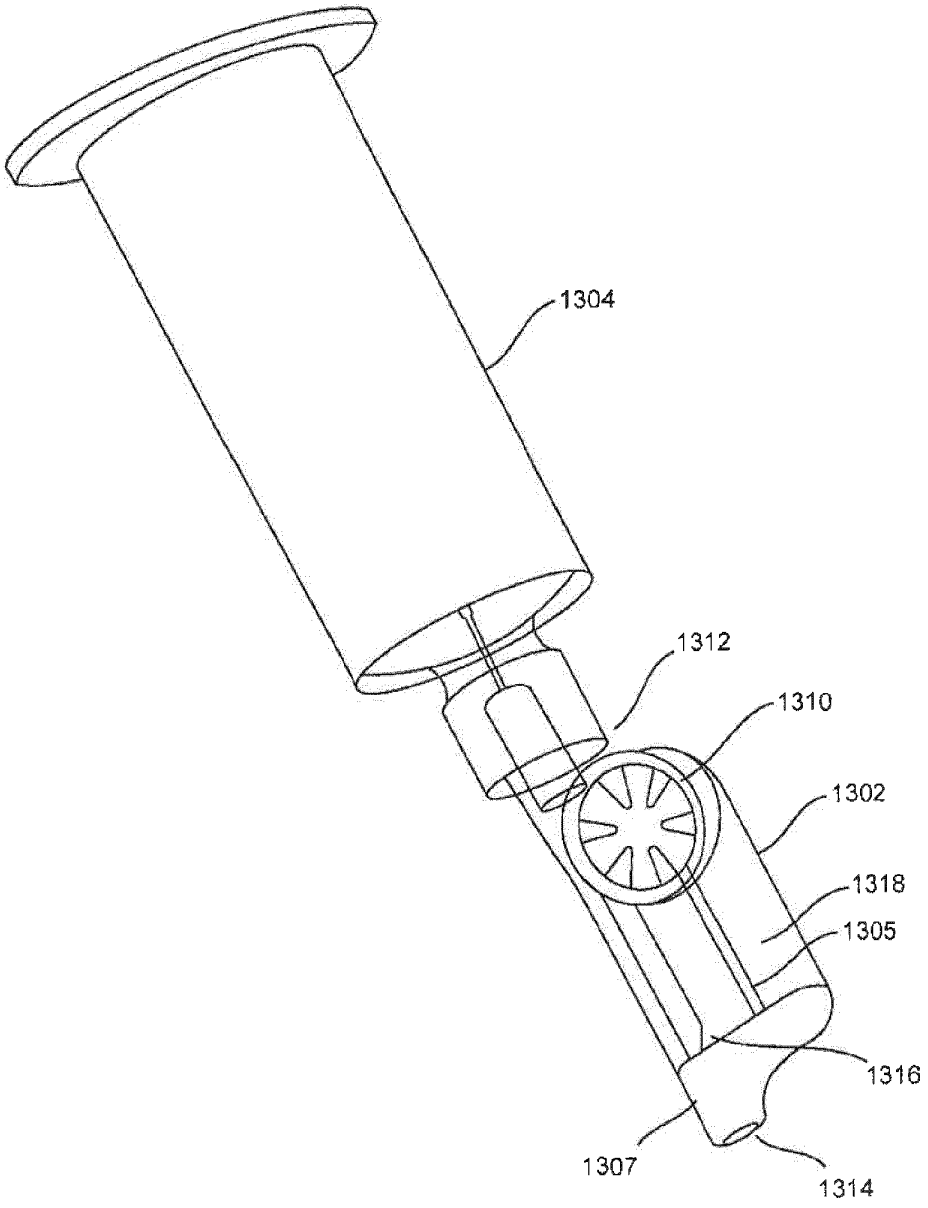


FIG. 13B

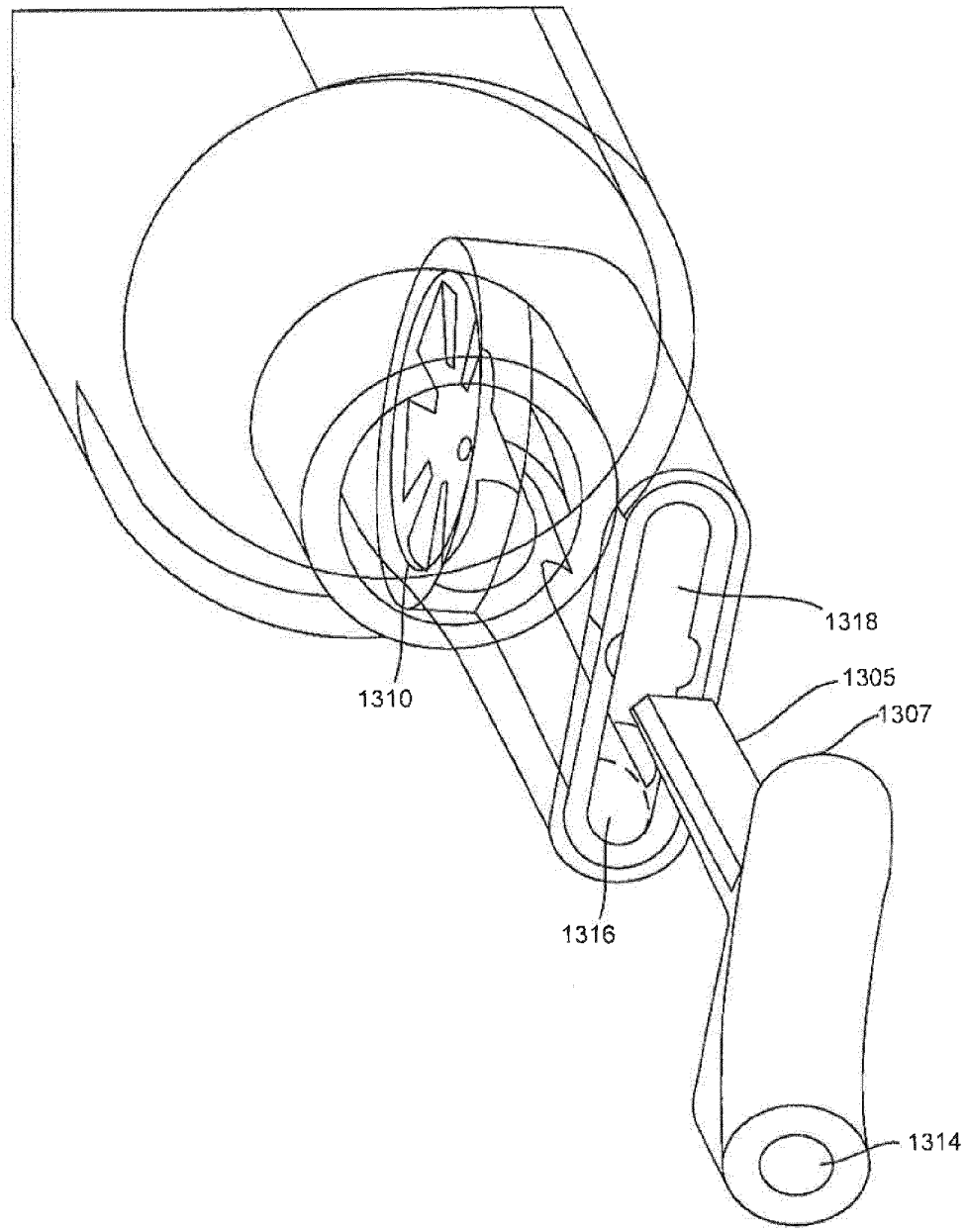


FIG. 13C

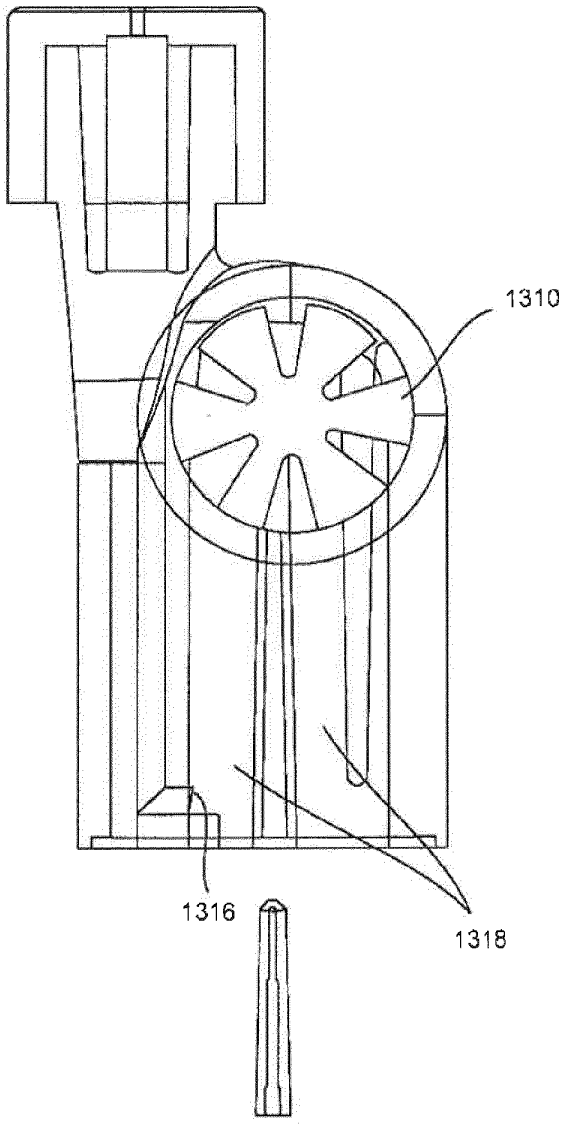


FIG. 13D

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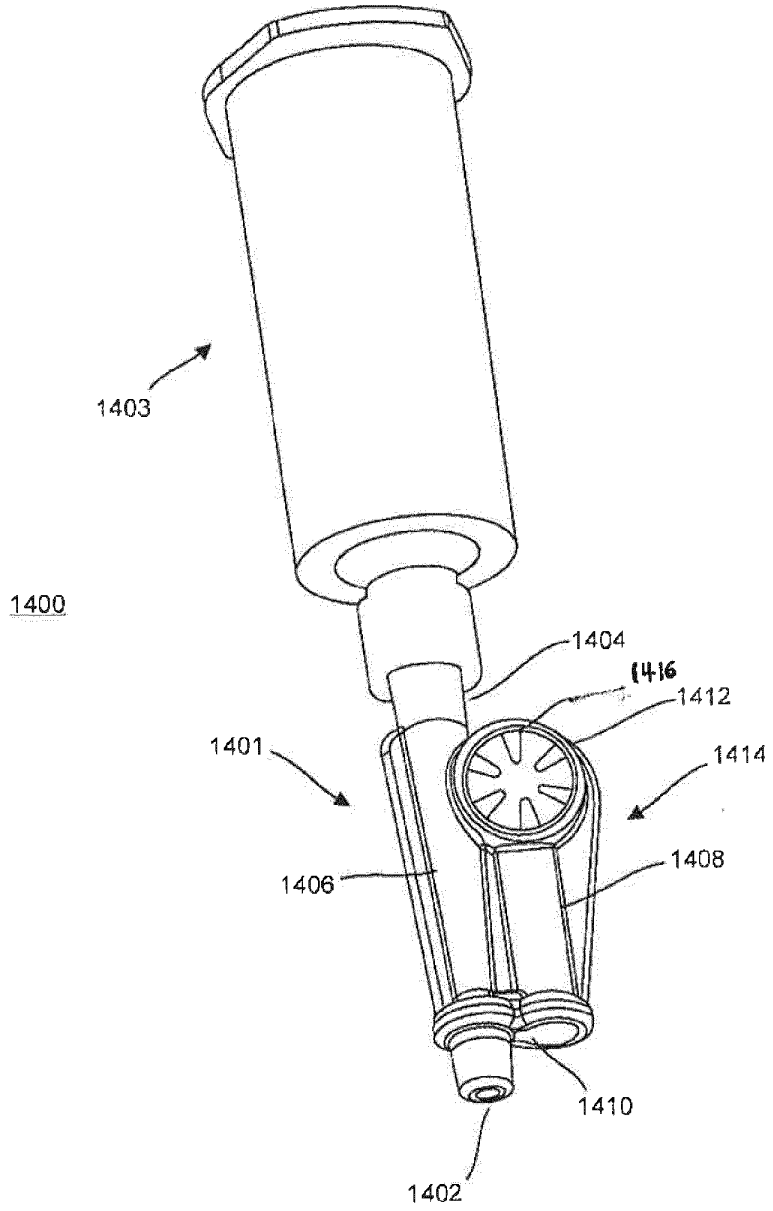


FIG. 14A

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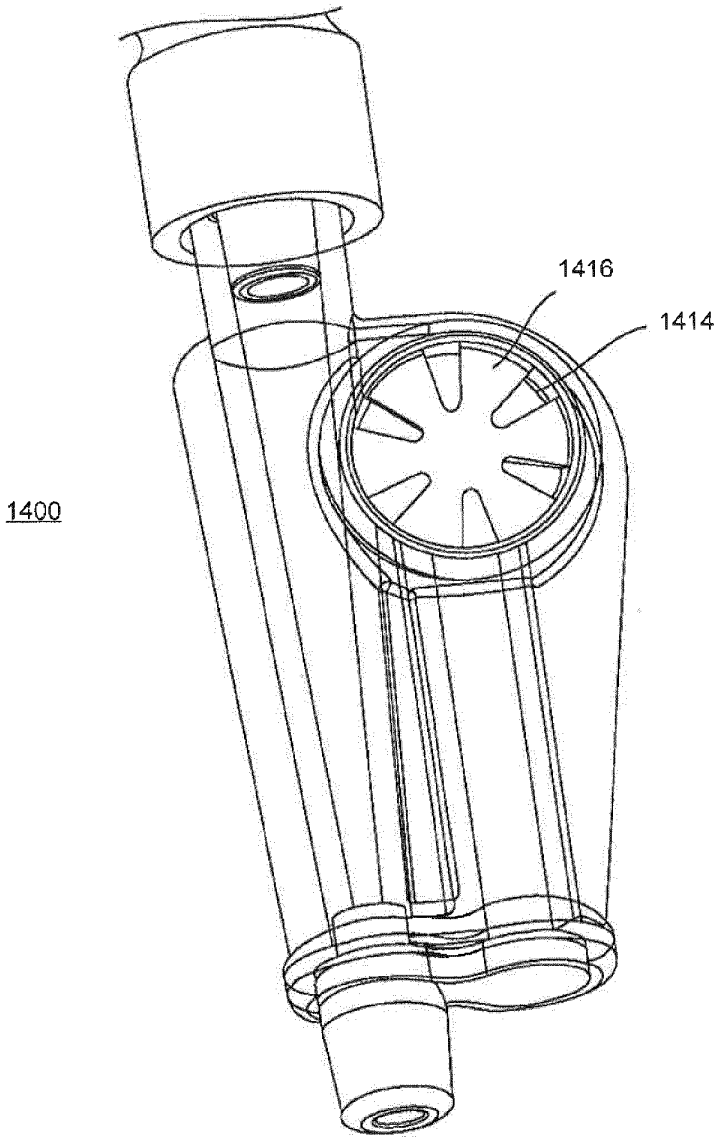


FIG. 14B

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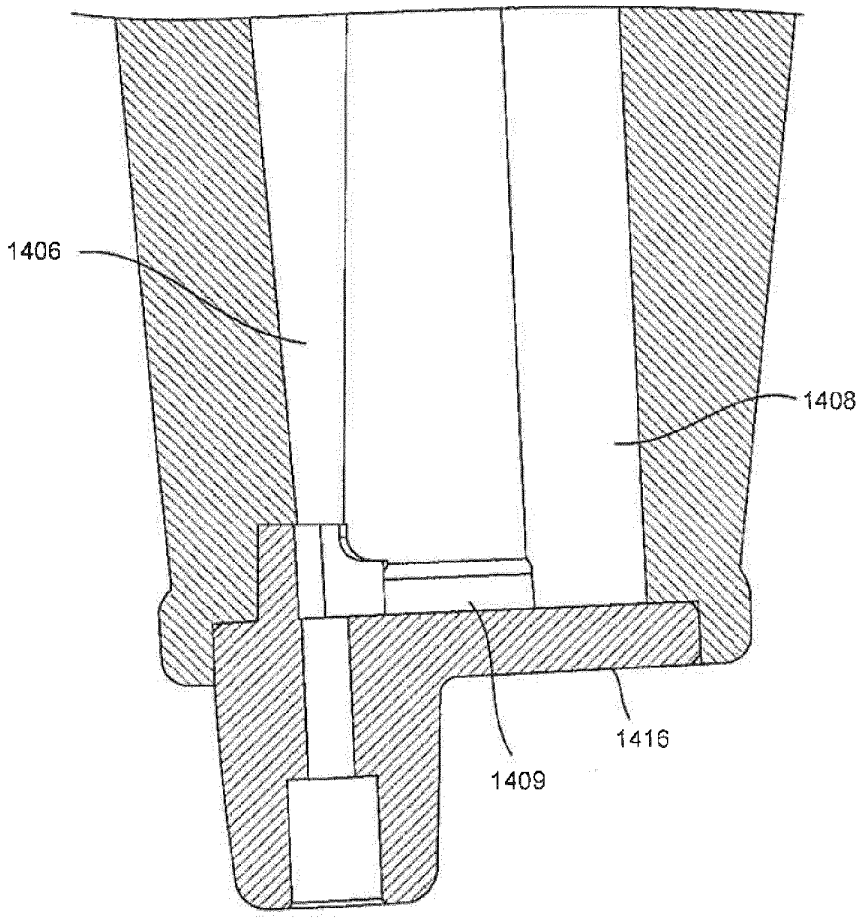


FIG. 14C

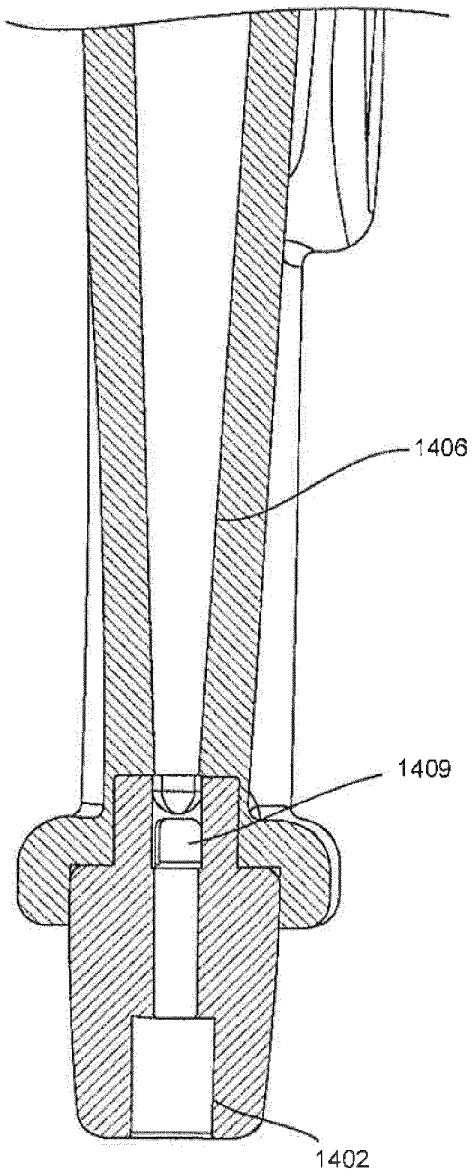


FIG. 14D

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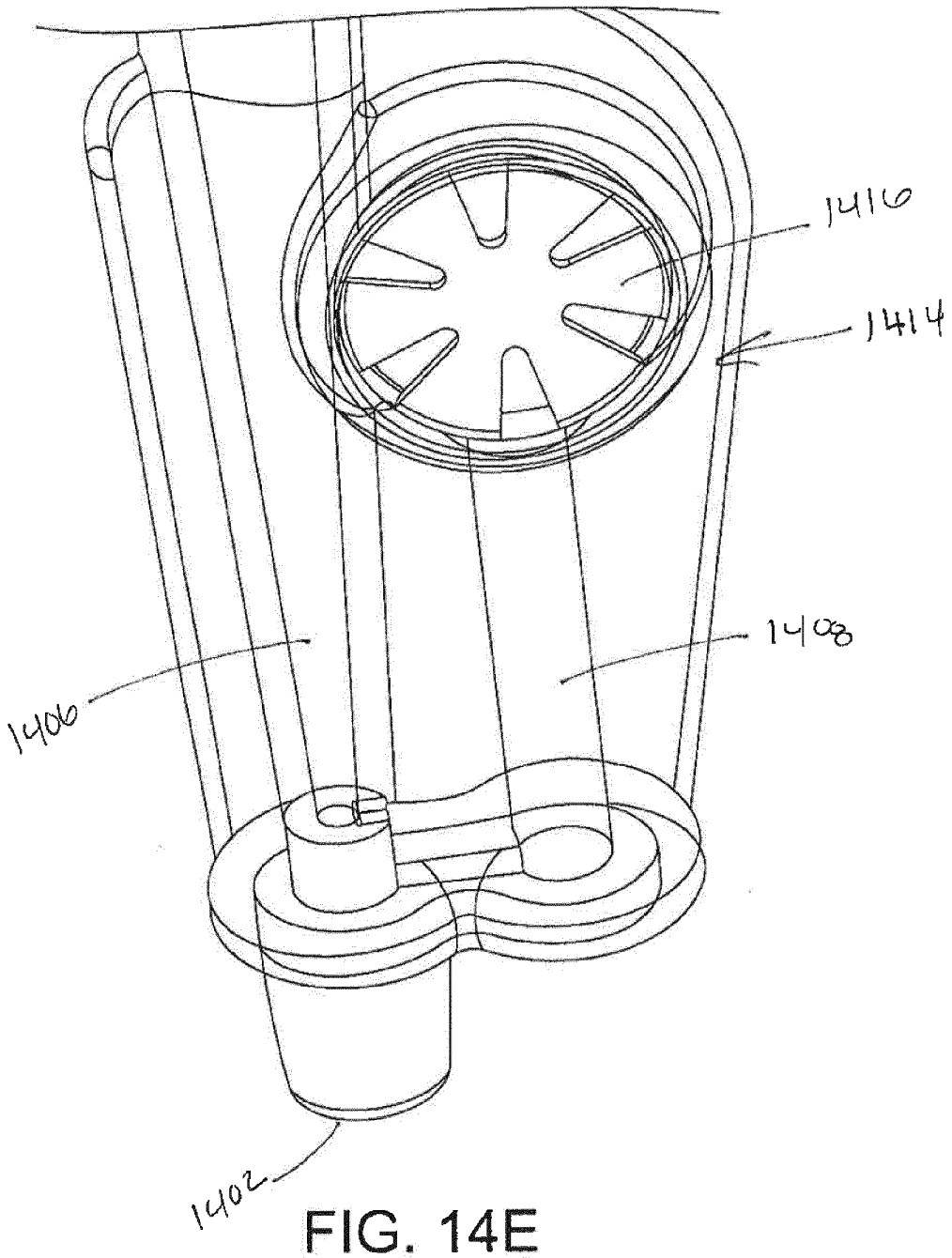


FIG. 14E

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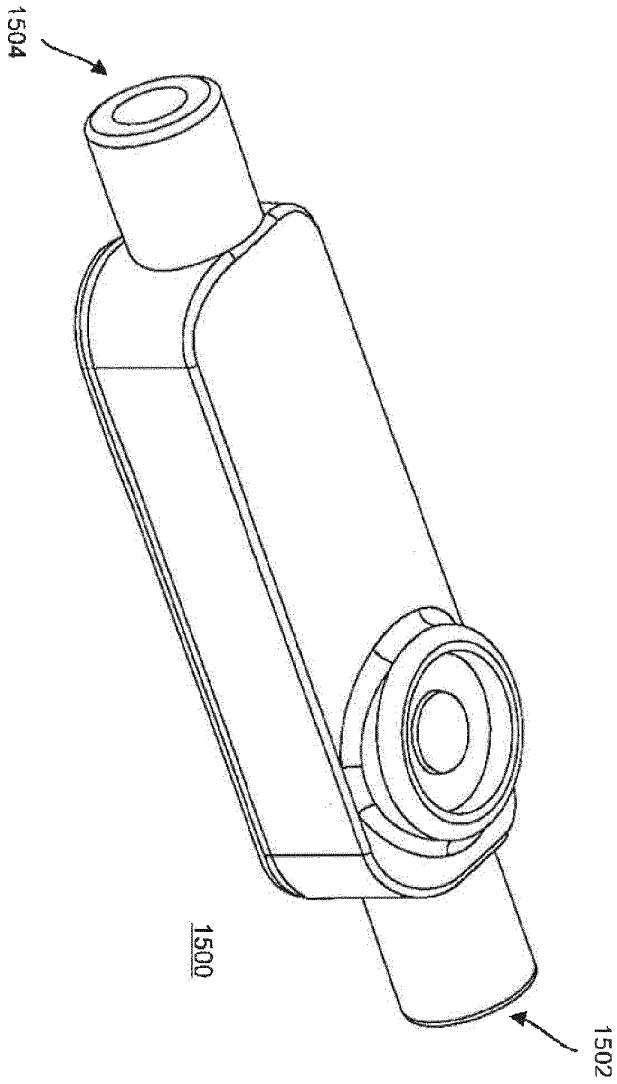


FIG. 15A

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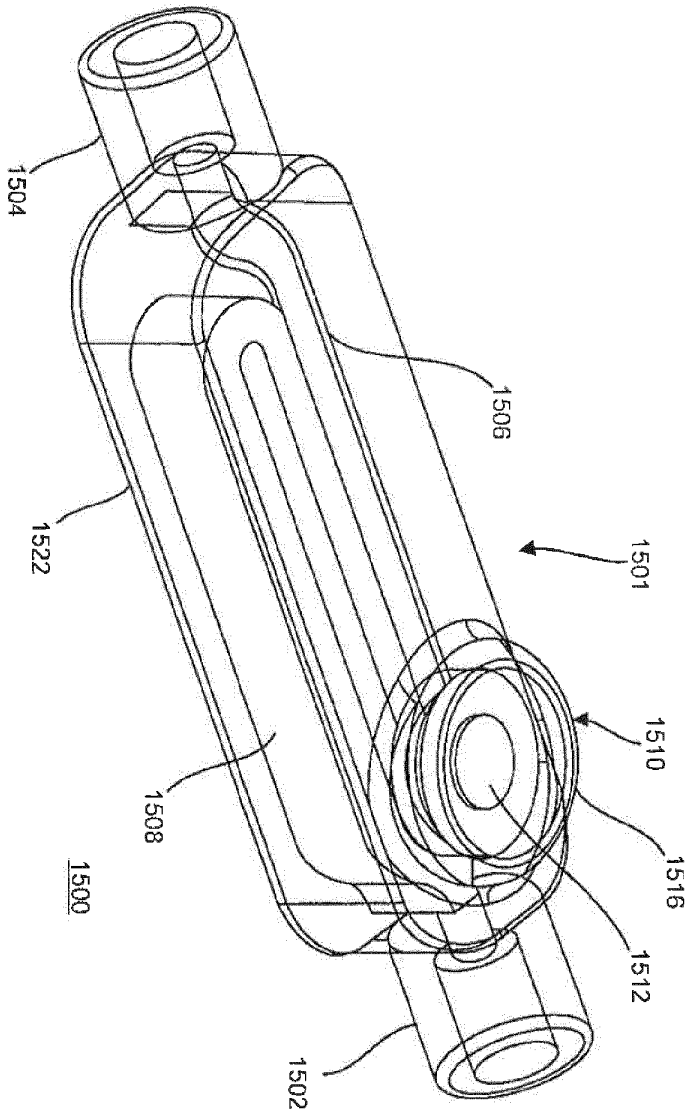


FIG. 15B

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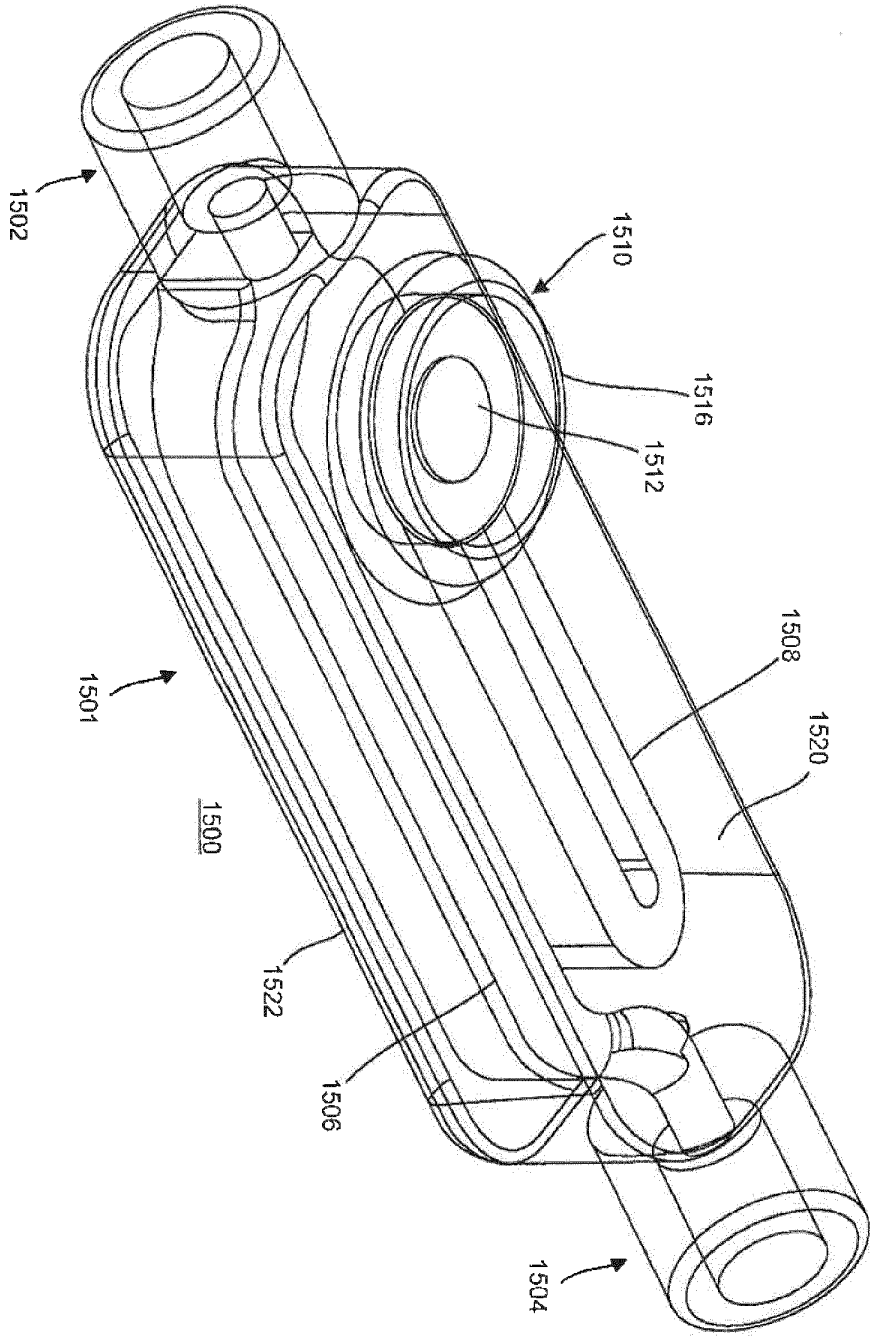


FIG. 15C

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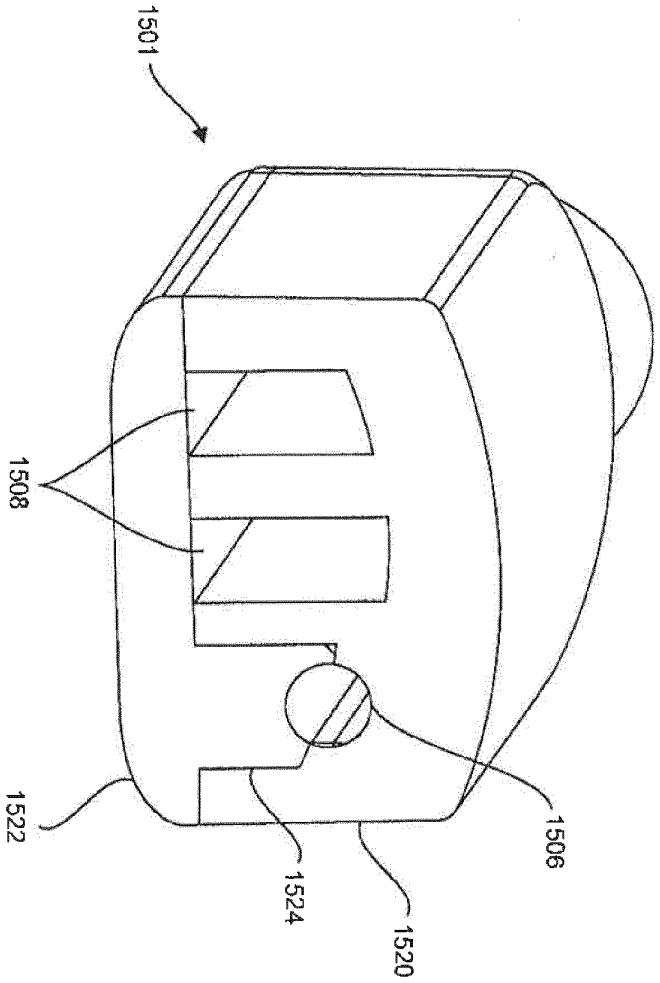


FIG. 15D

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FIG. 15E

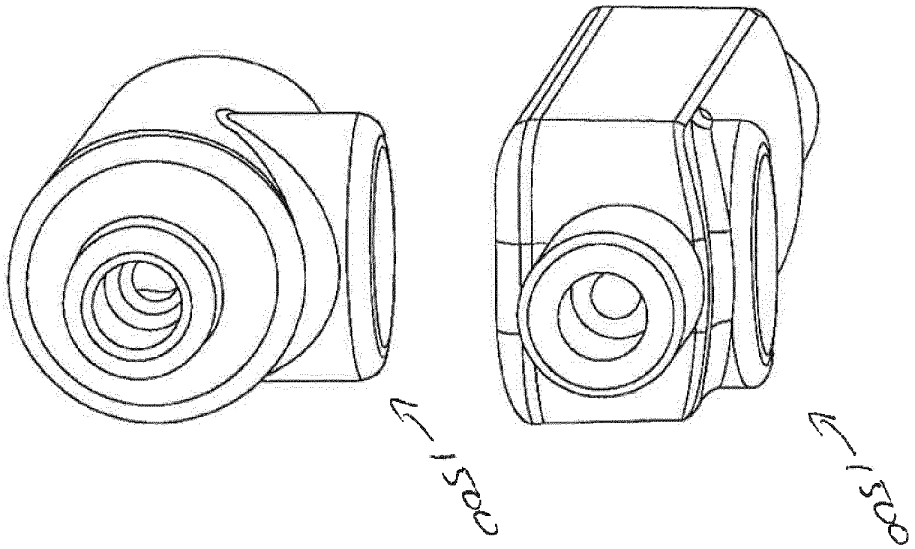
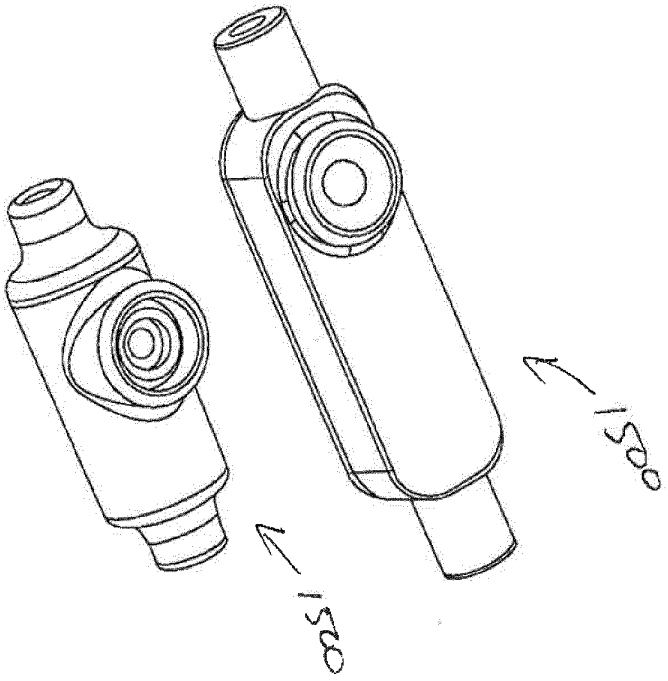


FIG. 15F



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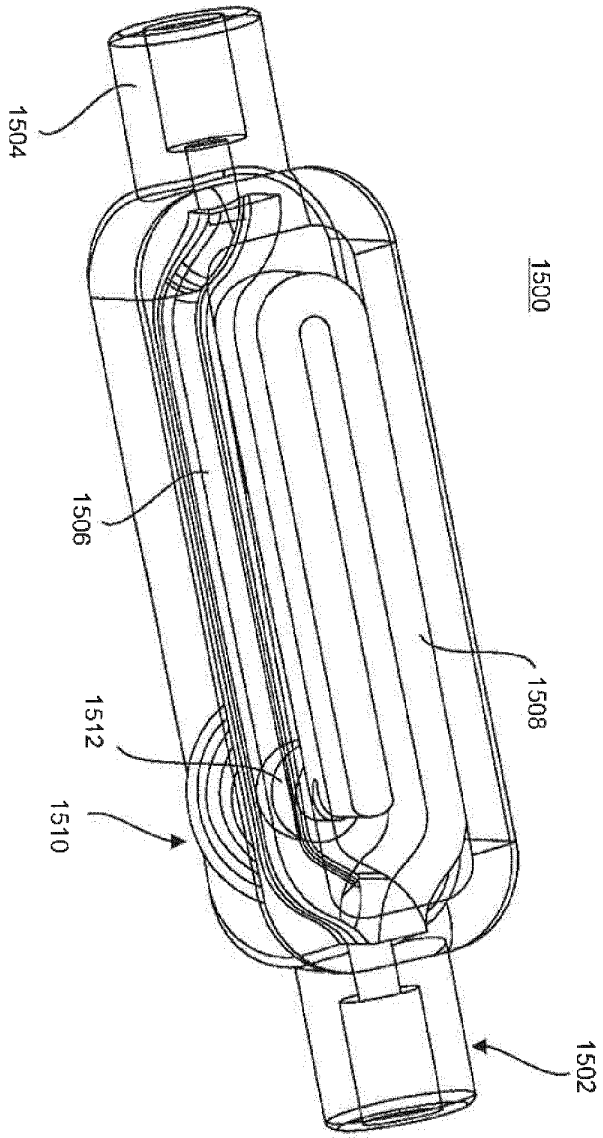


FIG. 15G

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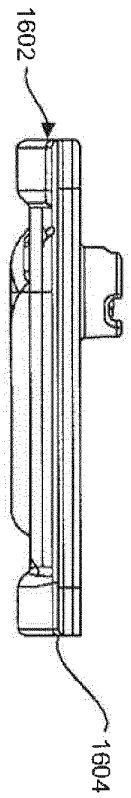


FIG. 16B

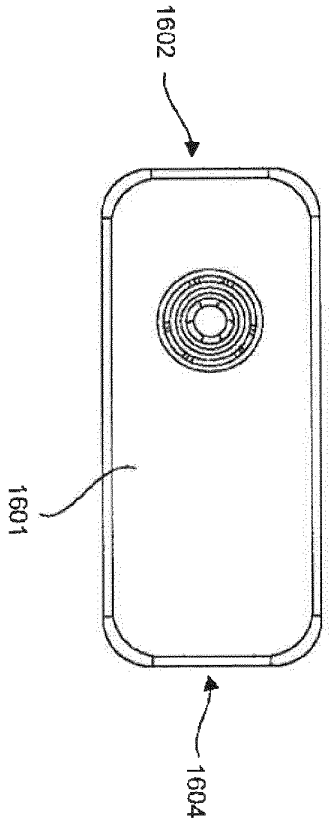


FIG. 16A

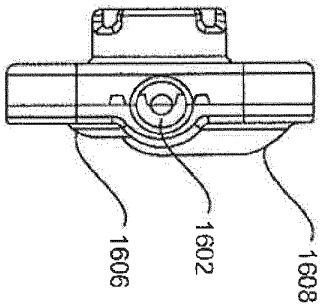


FIG. 16C

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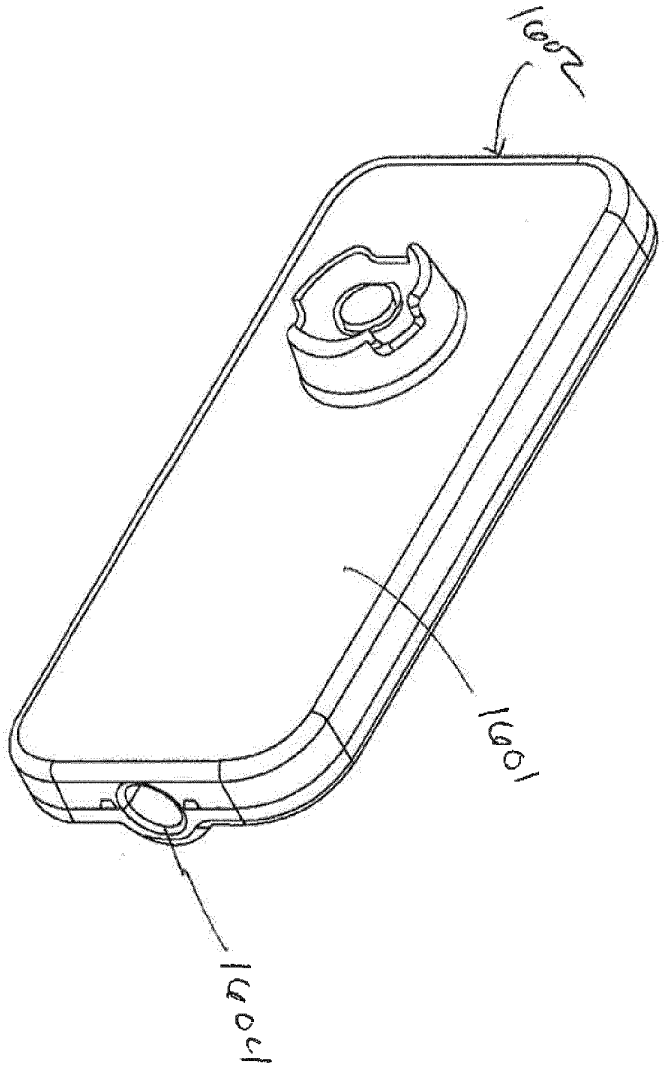


FIG. 16D

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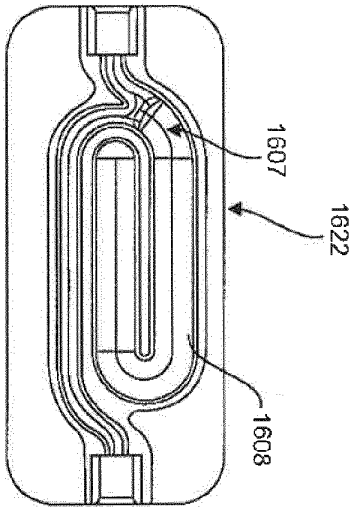


FIG. 17A

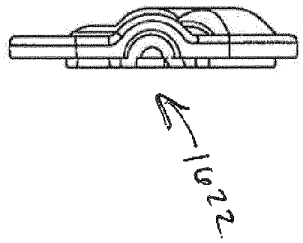


FIG. 17C

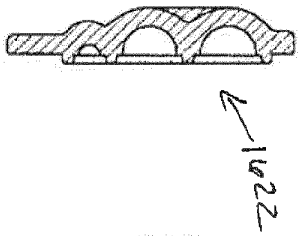


FIG. 17D

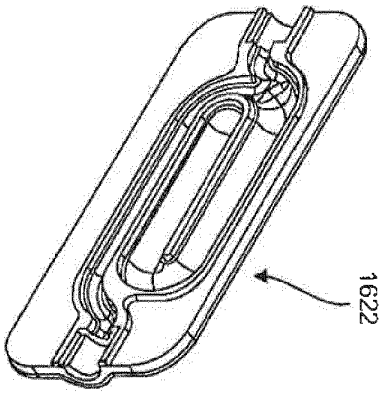


FIG. 17B

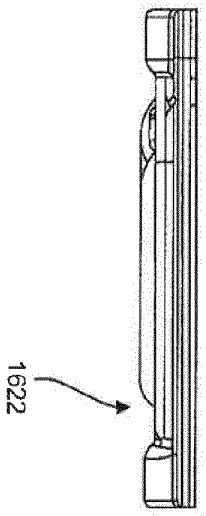


FIG. 17E

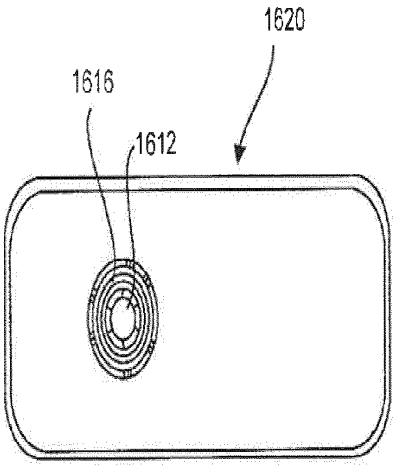


FIG. 18A

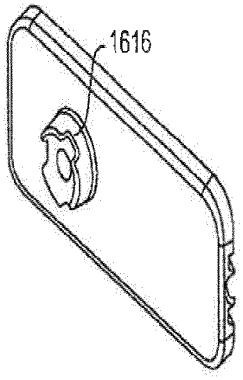


FIG. 18B

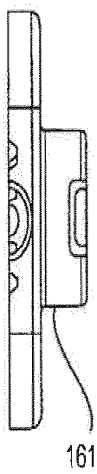


FIG. 18C

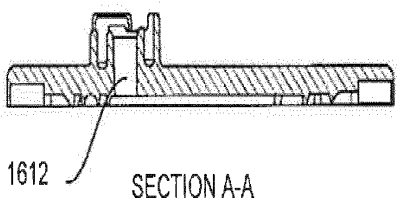


FIG. 18D

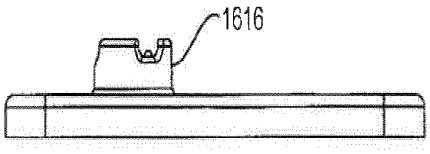


FIG. 18E

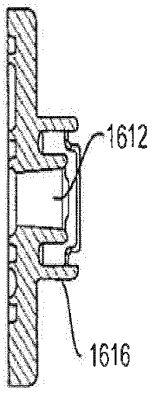


FIG. 18F

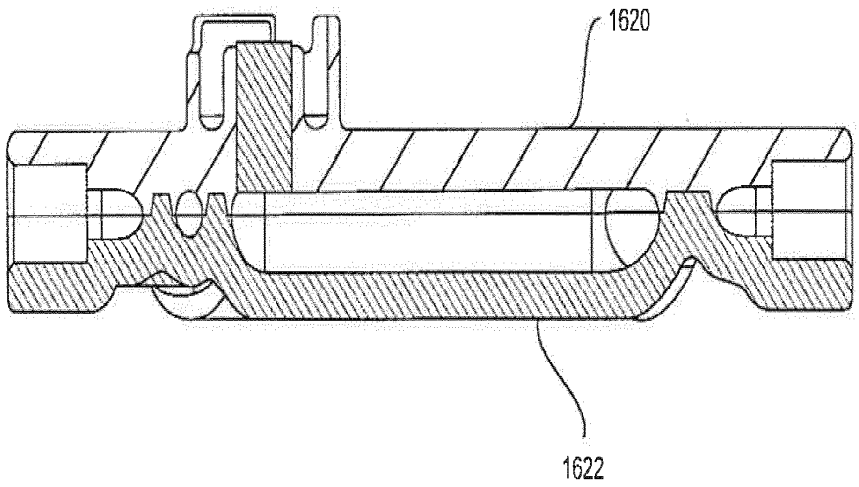


FIG. 19A

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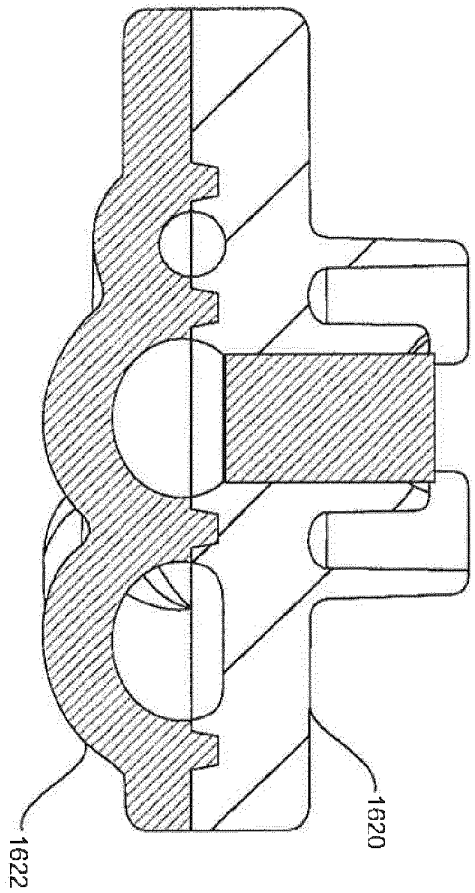


FIG. 19B

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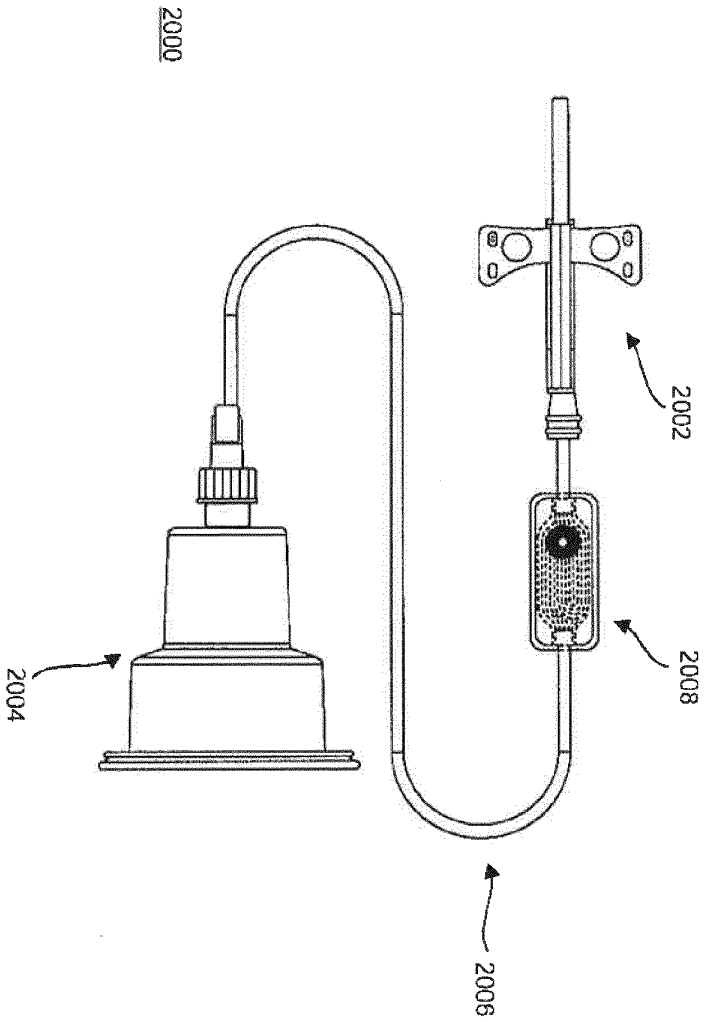


FIG. 20

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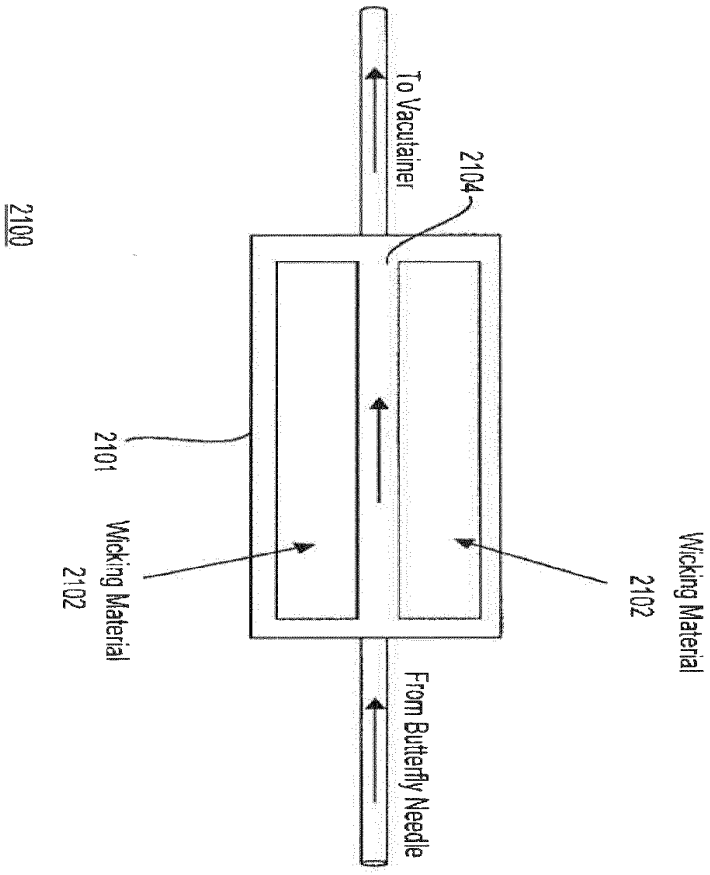


FIG. 21

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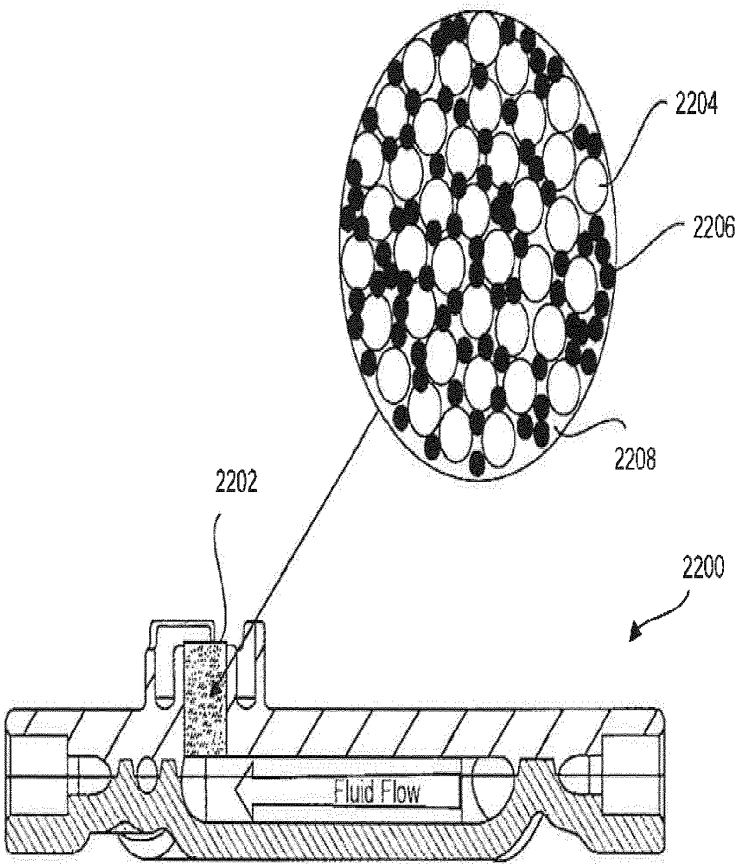


FIG. 22A

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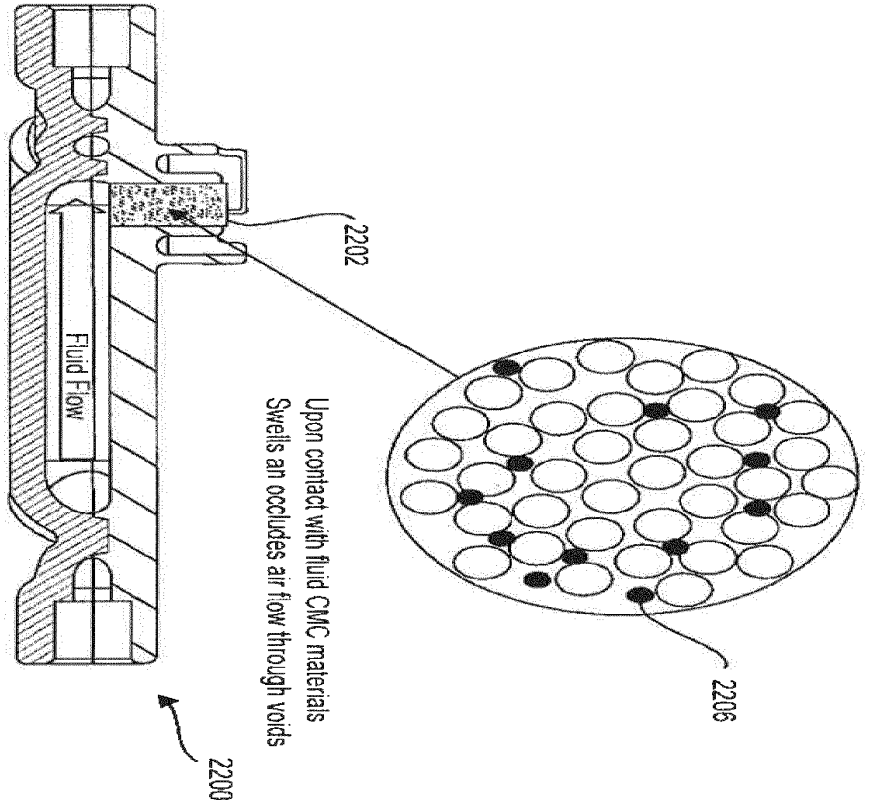


FIG. 22B

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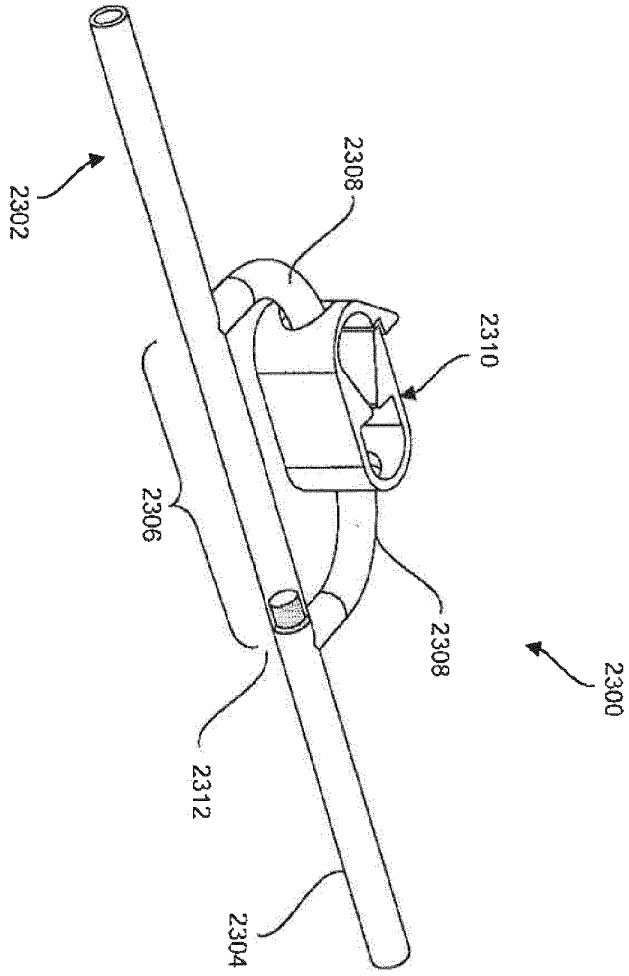


FIG. 23A

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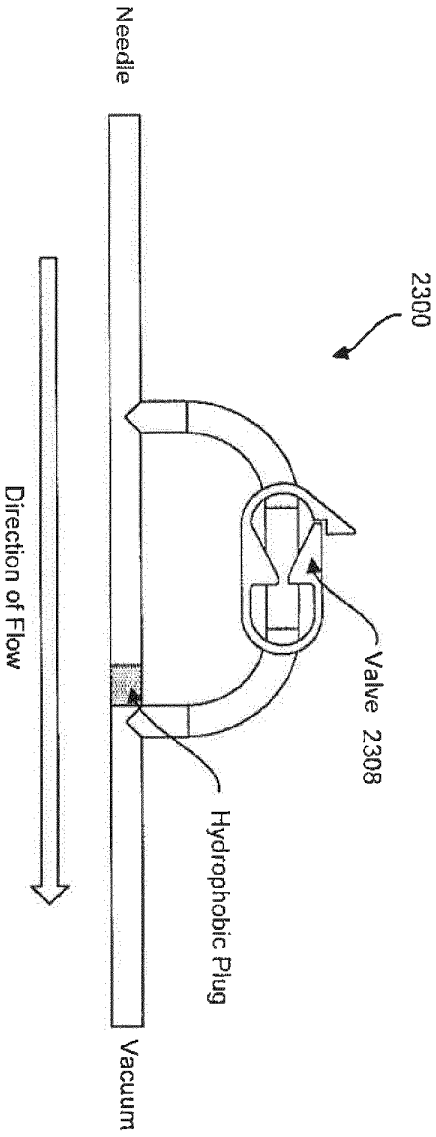


FIG. 23B

RELATED APPLICATIONS

[0001] This application claims the benefit of priority of U.S. Non-Provisional Application Serial No. 15/140,443, filed on April 27, 2016 and titled "BLOOD SAMPLE OPTIMIZATION SYSTEM AND BLOOD CONTAMINANT SEQUESTRATION DEVICE AND METHOD" and U.S. Non-Provisional Application Serial No. 15/140,448, filed on April 27, 2016 and titled "BLOOD SAMPLE OPTIMIZATION SYSTEM AND BLOOD CONTAMINANT SEQUESTRATION DEVICE AND METHOD", both of which claim priority to U.S. Provisional Application Serial No. 62/196,797, filed on July 24, 2015 and titled "BLOOD CULTURE IMPROVEMENT SYSTEM AND METHOD"; U.S. Provisional Application Serial No. 62/238,636, filed on October 7, 2015 and titled "BLOOD SEQUESTRATION SYSTEM FOR NON-CONTAMINATED BLOOD SAMPLING"; and U.S. Provisional Application Serial No. 62/318,194, filed on April 4, 2016 and titled "BLOOD SAMPLE OPTIMIZATION SYSTEM AND BLOOD CONTAMINANT SEQUESTRATION DEVICE AND METHOD".

BACKGROUND

[0002] Bacteraemia is the presence of microorganisms in the blood. Sepsis, on the other hand, is bacteraemia in the presence of clinical symptoms and signs such as fever, tachycardia, tachypnea and hypotension. Bacteraemia and sepsis are associated with a high mortality and an increased incidence and duration of hospital stay and associated costs. Many bacteraemias, sepsis, fungaemias and other pathogens actually occur within a hospital or other healthcare settings with

catheters and venipunctures being a source of contamination as potential carriers of these pathogens.

[0003] Blood cultures are the standard test used to detect microbial pathogens related to bacteraemia and sepsis in a patient's blood. The term blood culture refers to a single venipuncture, either from a peripheral site or central or arterial line, with the blood inoculated into one or more blood culture bottles or containers. One bottle is considered a blood culture where two or more are considered a set. Multiple sets may be obtained from multiple venipunctures and are associated with different sites on the patient.

[0004] These methods allow for microbial identification and susceptibility testing to be performed, which is a critical component to managing sepsis, however the lack of rapid results and decreased sensitivity for fastidious pathogens has led to the development of improved systems and adjunctive molecular or proteomic testing.

[0005] Collection of blood samples for conducting blood cultures is a critical component of modern patient care and can either positively affect the patient outcome by providing an accurate diagnosis, or can adversely affect the outcome by prolonging unnecessary antimicrobial therapy, the length of hospital stays, and increasing costs.

[0006] One outcome of collection of blood cultures is contamination. Blood culture contamination can lead to a false positive culture result and/or significant increase in healthcare related costs. Sources of blood culture contamination include improper skin antisepsis, improper collection tube disinfection, and contamination of the initial blood draw which may then skew results.

[0007] Blood culture collection kits generally consist of a "butterfly" set, infusion set, or other type of venipuncture device as offered by companies like BD, Smiths, B. Braun and others, and aerobic and anaerobic blood culture bottles.

Various different bottles are also available depending on the test requirements. These bottles are specifically designed to optimize recovery of both aerobic and anaerobic organisms. In conventional kits, a bottle used is known generally as a "Vacutainer," which is a blood collection tube formed of a sterile glass or plastic tube with a closure that is evacuated to create a vacuum inside the tube to facilitate the draw of a predetermined volume of liquid such as blood.

[0008] False positive blood cultures are typically a result of poor sampling techniques. They cause the use of antibiotics when not needed, increasing hospital costs and patient anxiety. Blood cultures are drawn from a needlestick into the skin, and then a Vacutainer is attached to capture a sample of blood. Contamination may occur from improper or incomplete disinfection of the skin area in and around the puncture site. It may also occur from the coring of the skin by the needle during insertion, with the cored skin cells and any associated contamination being pulled into the sample.

[0009] Blood flow through a hypodermic needle is laminar, and as such, a velocity gradient can be developed over the flow tube as a pressure drop is applied to the hypodermic needle. Either forceful aspiration of blood, or using a very small hypodermic needle, can cause lysis and a release of potassium from the red blood cells, thereby rendering the blood samples abnormal.

[0010] In other instances, some patients have delicate veins that can collapse under a pressure drop or vacuum, particularly as applied by a syringe's plunger that is drawn too quickly for the patient's condition. Since such condition is impossible to know beforehand, such vein collapses are a risk and very difficult to control.

[0011] Various strategies have been implemented to decrease blood culture contamination rates, e.g. training staff with regard to aseptic collection technique, feedback with regard to contamination rates and implementation of blood culture collection kits. Although skin antisepsis can reduce the burden of contamination,

20% or more of skin organisms are located deep within the dermis and are unaffected by antisepsis. Changing needles before bottle inoculation is not advisable as it increases the risk to acquire needle stick injuries without decreasing contamination rates.

[0012] Some conventional systems and techniques for reducing blood culture contamination include discarding the initial aliquot of blood taken from central venous catheters, venipunctures, and other vascular access systems. However, these systems require the user to mechanically manipulate an intravascular device, or require a complex series of steps that are difficult to ensure being followed.

[0012a] WO 96/05875 A1 discloses a blood sampling device comprising a bifurcated capillary tube which has a first branch having a cannula shaped end for withdrawing and conveying blood to a blood collection zone for storing a quantity of withdrawn blood and feeding an initial fraction of withdrawn blood to a blood disposal chamber having an air permeable liquid sealed end; and a second branch connected to the blood collection zone which terminates in an opening adapted to receive a blood withdrawal device.

SUMMARY

[0013] This document presents systems and methods (a method is not claimed) for reducing blood culture contamination, lysing of cells, and vein collapse. In some implementations, a system and method can eliminate user variability in disinfection, and also eliminate the risk of skin cells getting into the blood culture sample. The systems and methods disclosed herein do not require a change in existing clinical processes, other than to potentially indicate when a vacutainer or other blood collection device (i.e., syringe) should be attached for drawing contaminant-free blood samples.

[0014] In some implementations of the systems and methods disclosed herein the withdrawal of blood is accomplished passively by use of the patient's own blood pressure, thereby reducing the risk of vein collapse and eliminating any additional user steps over current practice. The systems and methods can be applied to

accommodate short-path direct stick or butterfly venipuncture systems. They can also be used with samples drawn through a catheter.

[0015] In one aspect, a blood sequestration device is provided, comprising; an inlet port; a junction connected with the inlet port; a sequestration chamber having a vent comprising an air permeable blood barrier; a sampling channel having a proximal end connected with the inlet port via the junction, and a distal end connected with an outlet port; and a housing that houses and defines the inlet port, the junction, the sequestration chamber, the sampling channel, and the outlet port, wherein the sequestration chamber is connected with the inlet port via the junction which is configured to direct a first portion of blood to the sequestration chamber, wherein the air permeable blood barrier includes an air permeable material that seals at least partially upon contact with a portion of the first portion of blood.

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[0016] In another aspect, a system of a blood sequestration device, a blood sampling pathway having a patient needle, and a sample collection device is provided, the blood sequestration device comprising; an inlet port connected with the patient needle; a junction connected with the inlet port opposite the blood sampling pathway; a sequestration chamber having a vent comprising an air permeable blood barrier; a sampling channel having a proximal end connected with the inlet port; and an outlet port connected with a distal end of the sampling channel and with the sample collection device; and a housing that houses and defines the inlet port, the outlet port, the sequestration chamber, and the sampling channel, wherein the sequestration chamber is connected with the inlet port and the air permeable blood barrier includes an air permeable material that seals at least partially upon contact with blood.

[0022] The details of one or more embodiments are set forth in the accompanying drawings and the description below. Other features and advantages will be apparent from the description and drawings, and from the claims. The invention is best illustrated by figures 16A to 19B.

BRIEF DESCRIPTION OF THE DRAWINGS

[0023] These and other aspects will now be described in detail with reference to the following drawings.

[0024] FIG. 1 illustrates a blood sample optimization system.

[0025] FIG. 2 illustrates a blood sample optimization system in accordance with an alternative implementation.

[0026] FIG. 3 illustrates a blood sample optimization system in accordance with another alternative implementation.

[0027] FIG. 4 illustrates a blood sample optimization system in accordance with another alternative implementation.

[0028] FIG. 5 illustrates a blood sample optimization system in accordance with another alternative implementation.

[0029] FIG. 6 illustrates a blood sample optimization system in accordance with an alternative implementation.

[0030] FIG. 7 is a flowchart of a method for optimizing a quality of a blood culture.

[0031] FIGS. 8A – 8E illustrate a blood sequestration system for non-contaminated blood sampling, in accordance with some implementations.

[0032] FIG. 9 illustrates a pathway splitter for use in a blood sequestrations system.

[0033] FIGS. 10A – 10D illustrate a blood sequestration system for non-contaminated blood sampling, in accordance with alternative implementations.

[0034] FIGS. 11A – 11E illustrate a blood sequestration system for non-contaminated blood sampling, in accordance with other alternative implementations.

[0035] FIGS. 12A-12D illustrate a blood sample optimization system including a blood sequestration device in accordance with yet other alternative implementations.

[0036] FIGS. 13A-13D illustrate a blood sample optimization system 1300 in accordance with yet another alternative implementations.

[0037] FIGS. 14A-14E illustrate yet another implementation of a blood sampling system to sequester contaminates of an initial aliquot or sample to reduce false positives in blood cultures or tests performed on a patient's blood sample.

[0038] FIGS. 15A-15G illustrate a blood sequestration device and method of using the same, in accordance with yet another implementation.

[0039] FIGS. 16A-16D illustrate a blood sequestration device in accordance with yet another implementation.

[0040] FIGS. 17A – 17E illustrate a bottom member of a housing for a blood sequestration device.

[0041] FIGS. 18A – 18F illustrate a top member of a housing for a blood sequestration device.

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[0042] FIGS. 19A and 19B illustrate a blood sequestration device having a top member mated with a bottom member.

[0043] FIG. 20 shows a blood sample optimization system including a blood sequestration device.

[0044] FIG. 21 illustrates a non-vented blood sequestration device using a wicking material chamber.

[0045] FIGS. 22A and 22B illustrate a material makeup of a filter for sequestering blood in a sequestration chamber of a blood sequestration device.

[0046] FIGS. 23A and 23B illustrate another implementation of a blood sequestration device that uses a vacuum force from a blood collection device.

[0047] Like reference symbols in the various drawings indicate like elements.

DETAILED DESCRIPTION

[0048] This document describes blood sample optimization systems and methods (a method is not claimed)

for reducing or eliminating contaminates in collected blood samples, which in turn reduces or eliminates false positive readings in blood cultures or other testing of collected blood samples. In some implementations, a blood sample optimization system includes a patient needle for vascular access to a patient's bloodstream, a sample needle for providing a blood sample to a blood collection container, such as an evacuated blood collection container or tube like a Vacutainer™ or the like, or other sampling device, and a blood sequestration device located between the patient needle and the sample needle. The blood sequestration device includes a sequestration chamber for sequestering an initial, potentially contaminated aliquot of blood, and may further include a sampling channel that bypasses the sequestration chamber to convey likely uncontaminated blood between the patient

needle and the sample needle after the initial aliquot of blood is sequestered in the sequestration chamber.

[0049] FIG. 1 illustrates a blood sample optimization system in accordance with some implementations. The system includes a patient needle 1 to puncture the skin of a patient to access the patient's vein and blood therein. The system further includes a sample needle (i.e., a resealably closed needle for use with Vacutainers™ or the like) 5, which may be contained within and initially sealed by a resealable boot 10, a Luer activated valve, or another collection interface or device. The resealable boot 10 can be pushed aside or around the sample needle 5 by application of a Vacutainer™ bottle (not shown) for drawing the patient's blood. The system can further include a low volume chamber 30 that leads to the sample needle 5, but also includes an orifice or one or more channels 45 that lead to a sequestration chamber 55 formed by a housing 50.

[0050] The sequestration chamber 55 is a chamber, channel, pathway, lock, or other structure for receiving and holding a first aliquot of the patient's blood, which may be in a predetermined or measured amount, depending on a volume of the sequestration chamber 55. The first draw of blood typically contains or is more susceptible to containing organisms that cause bacteraemia and sepsis or other pathogens than subsequent blood draws. The sequestration chamber 55 can be a vessel encased in a solid housing, formed in or defined by the housing itself, or can be implemented as tubing or a lumen. The sequestration chamber 55, regardless how formed and implemented, may have a predetermined volume. In some implementations, the predetermined volume may be based on a volume of the patient needle, i.e. ranging from less than the volume of the patient needle to any volume up to or greater than 20 times or more of the volume of the patient needle. The predetermined volume of the sequestration chamber 55 may also be established to economize or minimize an amount of blood to be sequestered and disposed of.

[0051] The sequestration chamber 55 can be formed, contained or housed in a chamber housing 50, and can be made of plastic, rubber, steel, aluminum or other suitable material. For example, the sequestration chamber 55 could be formed of flexible tubing or other elastomeric materials. The sequestration chamber 55 further includes an air permeable blood barrier 20 that allows air to exit the sequestration chamber 55. As used herein the term "air permeable blood barrier" means an air permeable but substantially blood impermeable substance, material, or structure. Examples may include hydrophobic membranes and coatings, a hydrophilic membrane or coating combined with a hydrophobic membrane or coating, mesh, a filter, a mechanical valve, antimicrobial material, or any other means of allowing air to be displaced from the sequestration chamber 55 as it is filled with blood. In various exemplary embodiments, an air permeable blood barrier may be formed by one or more materials that allow air to pass through until contacted by a liquid, such material then becomes completely or partially sealed to prevent or inhibit the passage of air and/or liquid. In other words, prior to contact with liquid, the material forms a barrier that is air permeable. After contact with a liquid, the material substantially or completely prevents the further passage of air and/or liquid.

[0052] The orifice or channel 45 can be any desired length, cross-sectional shape or size, and/or can be formed to depart from the low volume chamber 30 at any desired angle or orientation. The orifice or channel 45 may also include a one-way flap or valve 60 that maintains an initial aliquot of blood sample within the sequestration chamber 55. In some specific implementations, the orifice or channel 45 can include a "duck bill" or flapper valve 60, or the like, for one-way flow of blood from low volume chamber 30 to the sequestration chamber 55. The air permeable blood barrier 20 can also be constructed of a material that allows air to exit but then seals upon contact with blood, thereby not allowing external air to enter sequestration chamber 55. This sealing would eliminate the need for a valve.

[0053] Valve 60 can be any type of valve or closing mechanism. Chamber 30 is designed to hold virtually no residual blood, and can be designed to be adapted to hold or allow pass-through of a particular volume or rate of blood into sequestration chamber 55. Likewise, sequestration chamber 55 may also include any type of coating, such as an anti-microbial coating, or a coating that aids identification and/or diagnosis of components of the first, sequestered blood draw.

[0054] Housing 50 and 40 can be formed of any suitable material, including plastic, such as acrylonitrile butadiene styrene (ABS) or other thermoplastic or polymeric material, rubber, steel, or aluminum. The air permeable blood barrier 20 can include a color-providing substance, or other signaling mechanism, that is activated upon contact with blood from the initial blood draw, or when air displacement is stopped, or any combination of events with blood in the sequestration chamber 55. The air permeable barrier may also include an outer layer such as a hydrophobic membrane or cover that inhibits or prevents the inadvertent or premature sealing of the filter by an external fluid source, splash etc. Sequestration chamber 55 can also be translucent or clear to enable a user to visually confirm the chamber is filled.

[0055] FIG. 2 illustrates a blood sample optimization system in accordance with some alternative implementations. In the implementation shown in FIG. 2, a sequestration chamber 55, or waste chamber, surrounds the patient needle 1, with an open-ended cuff or housing connected with the waste chamber and encircling the sample needle housing base and housing. The patient needle 1 and sample needle 5 are connected together by a boot 56, which forms a continuous blood draw channel therethrough. The boot 56 includes a single orifice or channel leading from the blood draw channel into sequestration chamber 55. The device can include more than one single orifice or channel, in other implementations. Each orifice or channel can include a one-way valve, and can be sized and adapted for predetermined amount of blood flow.

[0056] The sequestration chamber 55 includes an air permeable blood barrier. The filter can further include a sensor or indicator to sense and/or indicate, respectively, when a predetermined volume of blood has been collected in the sequestration chamber 55. That indication will alert a user to attach an evacuated blood collection tube or bottle, such as a Vacutainer™ to the sample needle 5. The housing for the sequestration chamber 55 can be any size or shape, and can include any type of material to define an interior space or volume therein. The interior space is initially filled only with air, but can also be coated with an agent or substance, such as a decontaminate, solidifying agent, or the like. Once evacuated blood collection tube is attached to the sample needle 5, blood will flow automatically into the patient needle 1, through the blood draw channel and sample needle 5, and into the bottle. The sample needle 5 is covered by a resealable boot, coating or membrane that seals the sample needle when a blood collection bottle is not attached thereon or thereto.

[0057] FIG. 3 illustrates a blood sample optimization system in accordance with some alternative implementations. In the implementation shown, a sample needle 5 is surrounded by a resealable boot or membrane, and is further connected with a patient needle 1. A blood flow channel is formed through the sample needle and the patient needle. The connection between the sample needle and patient needle includes a "T" or "Y" connector 102, which includes a channel, port or aperture leading out from the main blood flow channel to a sequestration chamber 104.

[0058] The T or Y connector 102 may include a flap or one-way valve, and have an opening that is sized and adapted for a predetermined rate of flow of blood. The sequestration chamber 104 can be formed from tubing, or be formed by a solid housing, and is initially filled with air. The sequestration chamber 104 will receive blood that flows out of a patient automatically, i.e. under pressure from the patient's own blood pressure. The sequestration chamber 104 includes an air permeable

blood barrier 106, preferably at the distal end of tubing that forms the sequestration chamber 104, and which is connected at the proximal end to the T or Y connector 102. The T or Y connector 102 can branch off at any desired angle for most efficient blood flow, and can be formed so as to minimize an interface between the aperture and channel and the main blood flow channel, so as to minimize or eliminate mixing of the initial aliquot of blood with main blood draw samples.

[0059] In some alternative implementations, the sample needle may be affixed to a tubing of any length, as shown in FIG. 4, connecting at its opposite end to the T or Y connector 102. The sequestration chamber 104 can be any shape or volume so long as it will contain a predetermined amount of blood sample in the initial aliquot. The T or Y connector 102 may also include an opening or channel that is parallel to the main blood flow channel. The air permeable blood barrier may further include an indicator 107 or other mechanism to indicate when a predetermined amount of blood has been collected in the sequestration chamber, or when air being expelled reaches a certain threshold, i.e. to zero. The tubing can also include a clip 109 that can be used to pinch off and prevent fluid flow therethrough.

[0060] Once the air permeable blood barrier and primary chamber are sealed the initial aliquot of blood is trapped in the sequestration chamber 104, an evacuated blood collection tube, such as a Vacutainer™ bottle may be attached to the sample needle 5 to obtain the sample. The blood collection tube can be removed, and the sample needle 5 will be resealed. Any number of follow-on blood collection tubes can then be attached for further blood draws or samples. Upon completion of all blood draws, the system can be discarded, with the initial aliquot of blood remaining trapped in the sequestration chamber 104.

[0061] FIG. 5 illustrates a blood sample optimization system in accordance with some alternative implementations. In the implementation shown, a sample needle 5 is connected with a patient needle by tubing. A "T" or "Y" connector 120 is

added along the tubing at any desired location, and includes an aperture, port or channel leading to a sequestration chamber 204, substantially as described above.

[0062] FIG. 6 illustrates a blood sample optimization system in accordance with some alternative implementations, in which a sequestration chamber 304, formed as a primary collection channel, receives an initial aliquot of blood, and is provided adjacent to the blood sampling channel. The sequestration chamber 304 can encircle the blood sampling channel, the patient needle 1, and/or the sample needle 5. The primary collection channel can include a T or Y connector 120, or other type of aperture or channel. The sequestration chamber 304 includes an air permeable blood barrier, which can also include an indicator of being contacted by a fluid such as blood, as described above.

[0063] In some implementations, either the patient needle 1 or the sample needle 5, or both, can be replaced by a Luer lock male or female connector. However, in various implementations, the connector at a sample needle end of the blood sample optimization system is initially sealed to permit the diversion of the initial aliquot of blood to the sequestration chamber, which is pressured at ambient air pressure and includes the air outlet of the air permeable blood barrier. In this way, the system passively and automatically uses a patient's own blood pressure to overcome the ambient air pressure of the sequestration chamber to push out air through the air permeable blood barrier and displace air in the sequestration chamber with blood.

[0064] FIG. 7 is a flowchart of an exemplary method for optimizing the quality of a blood culture. At 702, a clinician places a needle into a patient's vein. At 704, blood then flows into a sequestration chamber, pushing the air in the sequestration chamber out of the sequestration chamber through an air permeable blood barrier. In some implementations, the volume of the sequestration chamber is less than 0.1 to more than 5 cubic centimeters (cc's), or more. The sequestration chamber is sized and adapted to collect a first portion of a blood sample, which is more prone