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BLOOD SAMPLE OPTIMIZATION SYSTEM AND BLOOD CONTAMINANT SEQUESTRATION DEVICE AND METHOD

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application is a Continuation of U.S. Application No. 15/994,559, filed on May 31, 2018, entitled "BLOOD SAMPLE OPTIMIZATION SYSTEM AND BLOOD CONTAMINANT SEQUESTRATION DEVICE AND METHOD"; which is a Continuation of U.S. Application No. 15/140,448, filed on April 27, 2016, which claims the benefit of 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 – 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.

[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.

CLAIMS

1. A blood sequestration device for sequestering blood conveyed from a patient, the blood sequestration device comprising;

an inlet port for receiving the blood conveyed from the patient;

an outlet port;

a sequestration chamber having a vent that includes an air permeable blood barrier; and

a sampling channel having a distal end connected with the outlet port;

a junction connected between the inlet port, the sequestration 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 sequestration chamber to displace air therein through the air permeable blood barrier and to be sequestered in the sequestration chamber, and such that a second portion of blood is allowed to bypass the sequestration chamber and the first portion of blood sequestered therein to be directed into the sampling channel toward the outlet port.

2. The blood sequestration device in accordance with claim 1, wherein the air permeable blood barrier includes an air permeable material that at least partially seals upon contact with blood.

3. The blood sequestration device in accordance with claim 1, further comprising a housing that defines at least a part of each of the inlet port, the outlet port, the sequestration chamber, and the sampling channel.

4. The blood sequestration device in accordance with claim 3, wherein the sequestration chamber includes a sequestration channel defined in the housing.

5. The blood sequestration device in accordance with claim 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 port, the outlet port, the sequestration chamber, and the sampling channel.

6. A blood sequestration device connected with a blood sampling pathway having a patient needle or catheter and a sample collection device, the blood sequestration device comprising:

an inlet port connected with the patient needle or catheter;

an outlet port connected with the sample collection device;

a sequestration chamber having a vent that includes an air permeable blood barrier; and

and a sampling channel having a distal end connected with the outlet port;

each of the sequestration chamber and the sampling channel being connected with the inlet port via a junction that is sized and configured such that a first portion of blood flows into the sequestration chamber to displace air therein through the air permeable blood barrier and to be sequestered in the sequestration chamber, and a second portion of blood is allowed to bypass the sequestration chamber and the first portion of blood sequestered therein to be directed into the sampling channel toward the outlet port and the sample collection device.

7. The blood sequestration device in accordance with claim 6, further comprising a housing that at least partially houses and defines the inlet port, the outlet port, the sequestration chamber, and the sampling channel.

8. The blood sequestration device in accordance with claim 6, wherein the inlet port is connected with the patient needle or catheter via a first portion of the blood sampling pathway.

9. The blood sequestration device in accordance with claim 6, wherein the outlet port is connected with the sample collection device via a second portion of the blood sampling pathway.

10. The blood sequestration 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 blood.

11. The blood sequestration device in accordance with claim 7, wherein the sequestration chamber includes a sequestration channel defined in the housing.

12. The blood sequestration device in accordance with claim 11, 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.

13. A bodily fluid sequestration device comprising;

an inlet port;

an outlet port connected with the inlet port;

a sequestration chamber connected with the inlet port via a junction, the sequestration chamber having a vent that includes an air permeable bodily fluid barrier that at least partially seals upon contact with bodily fluid; and

a housing that houses and defines the inlet port, the outlet port, and the sequestration chamber, the sequestration chamber and the junction configured to direct a first portion of bodily fluid from the inlet port into the sequestration chamber toward the air permeable bodily fluid barrier and to displace air in the sequestration chamber;

whereupon at least partially sealing of the air permeable blood barrier enables sequestration of the first portion of bodily fluid in the sequestration chamber, and enables a second portion of bodily fluid from the inlet port to bypass the sequestration chamber via the junction and the first portion of bodily fluid, toward the outlet port.

14. The bodily fluid sequestration device in accordance with claim 13, wherein the air permeable bodily fluid barrier includes an air permeable material that seals upon contact with the bodily fluids.

15. The bodily fluid sequestration device in accordance with claim 13, wherein the sequestration chamber includes a sequestration channel defined in the housing.

16. The bodily fluid sequestration device in accordance with claim 13, further comprising a sampling pathway connected with the inlet port, wherein the sampling

pathway conveys the second portion of bodily fluid from the inlet port to the outlet port via the junction.

17. The bodily fluid sequestration device in accordance with claim 13, 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, and the sequestration chamber.

18. The bodily fluid sequestration device in accordance with claim 13, further comprising a sampling channel having a proximal end connected with the inlet port via the junction.

19. The blood sequestration device in accordance with claim 18, 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.

20. A blood sequestration system comprising:

a blood sampling pathway having a patient catheter and a sample collection device; and

a blood sequestration device connected on the blood sampling pathway, the blood sequestration device comprising:

an inlet port connected with the patient catheter;

an outlet port connected with the sample collection device;

a sequestration chamber having a vent that includes an air permeable blood barrier; and

and a sampling channel having a distal end connected with the outlet port;

each of the sequestration chamber and the sampling channel being connected with the inlet port via a junction that is sized and configured such that a first portion of blood flows into the sequestration chamber to displace air therein through the air permeable blood barrier and to be sequestered in the sequestration chamber, and a second

portion of blood is allowed to bypass the sequestration chamber and the first portion of blood sequestered therein to be directed into the sampling channel toward the outlet port and the sample collection device.

21. The blood sequestration system in accordance with claim 20, further comprising a housing that houses and defines the inlet port, the outlet port, the sequestration chamber, and the sampling channel.

22. The blood sequestration system in accordance with claim 20, wherein the inlet port is connected with the patient catheter via a first portion of the blood sampling pathway.

23. The blood sequestration system in accordance with claim 20, wherein the outlet port is connected with the sample collection device via a second portion of the blood sampling pathway.

24. The blood sequestration system in accordance with claim 20, wherein the air permeable blood barrier includes an air permeable material that seals at least partially upon contact with blood.

25. The blood sequestration system in accordance with claim 24, wherein the sequestration chamber includes a sequestration channel defined in the housing.

26. The blood sequestration device in accordance with claim 25, 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.

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.

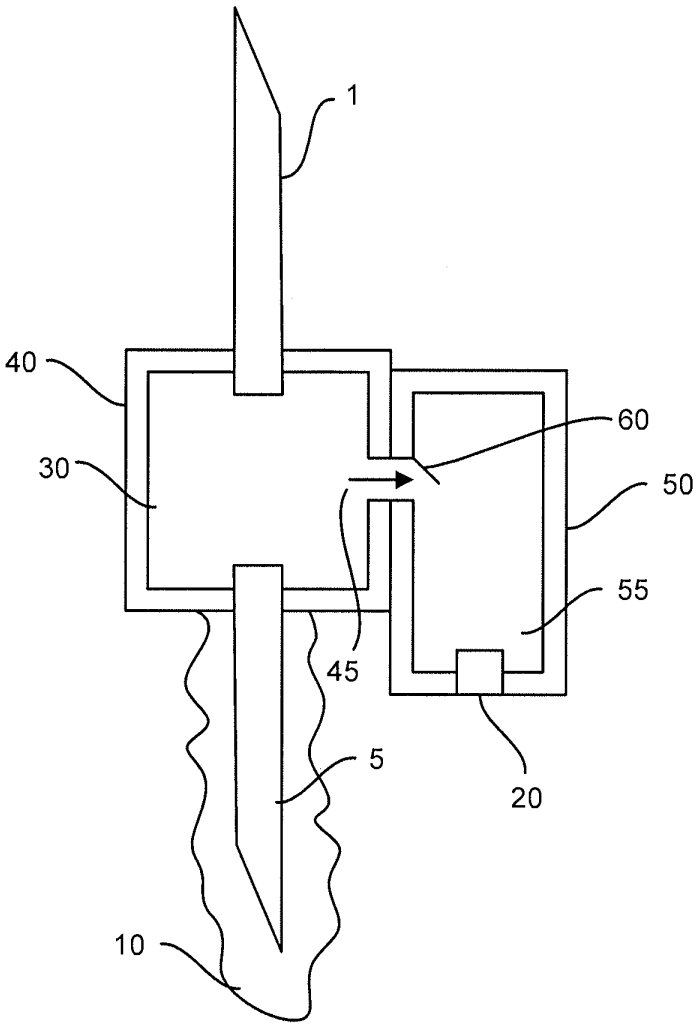


FIG. 1

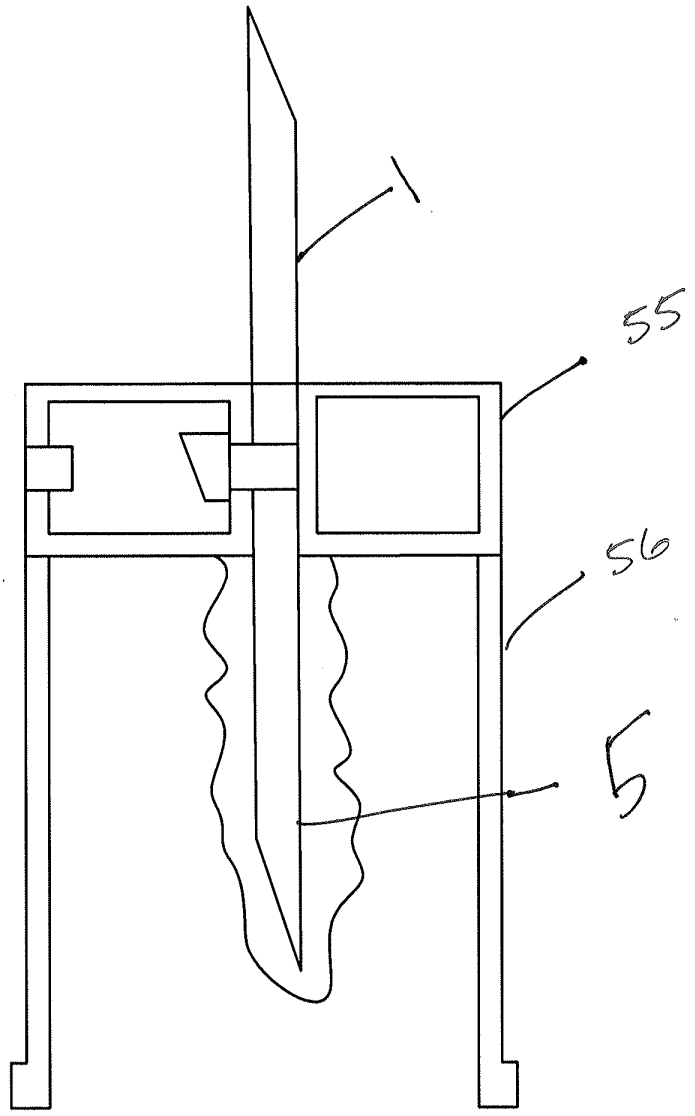


FIG. 2

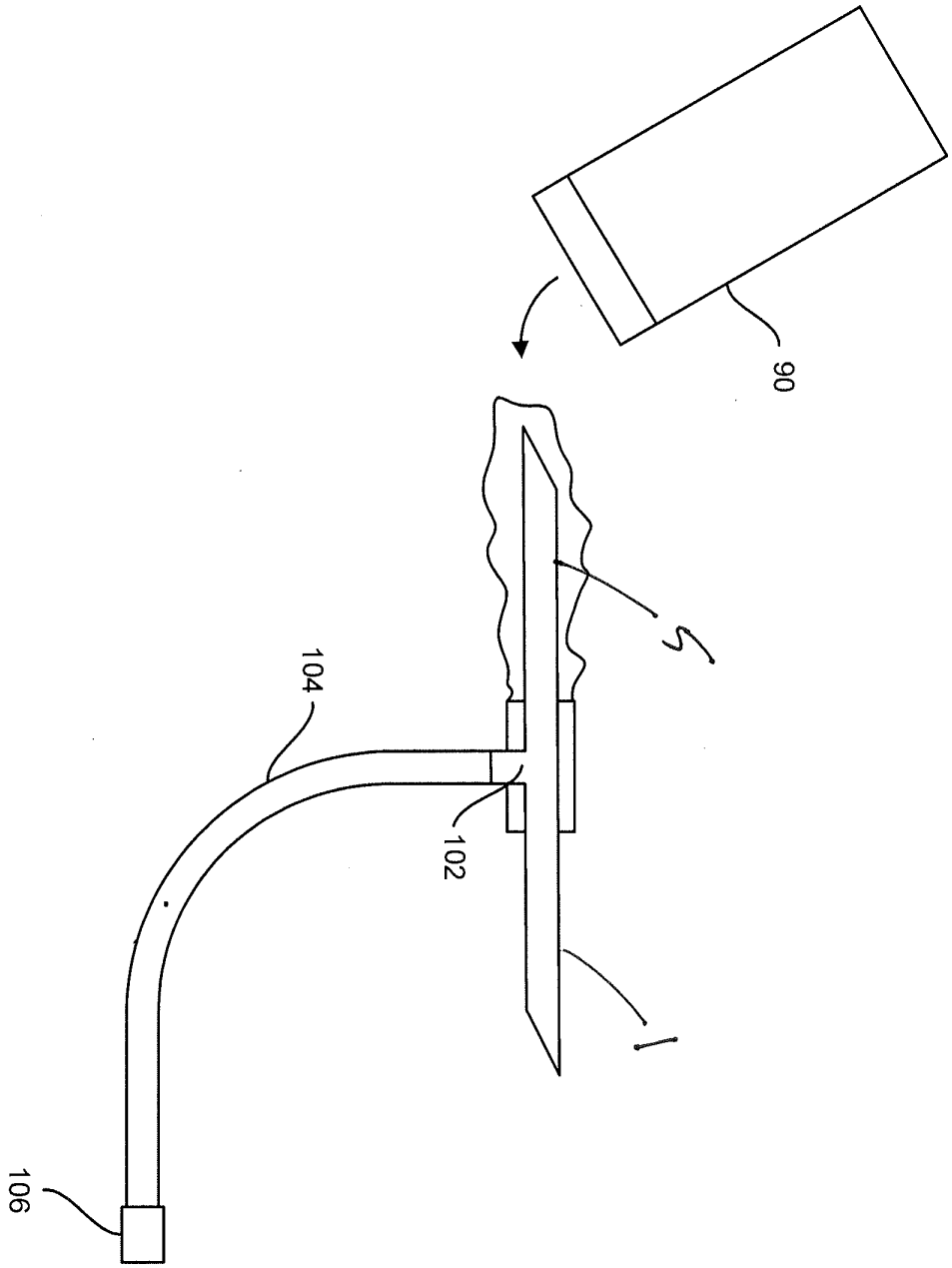


FIG. 3

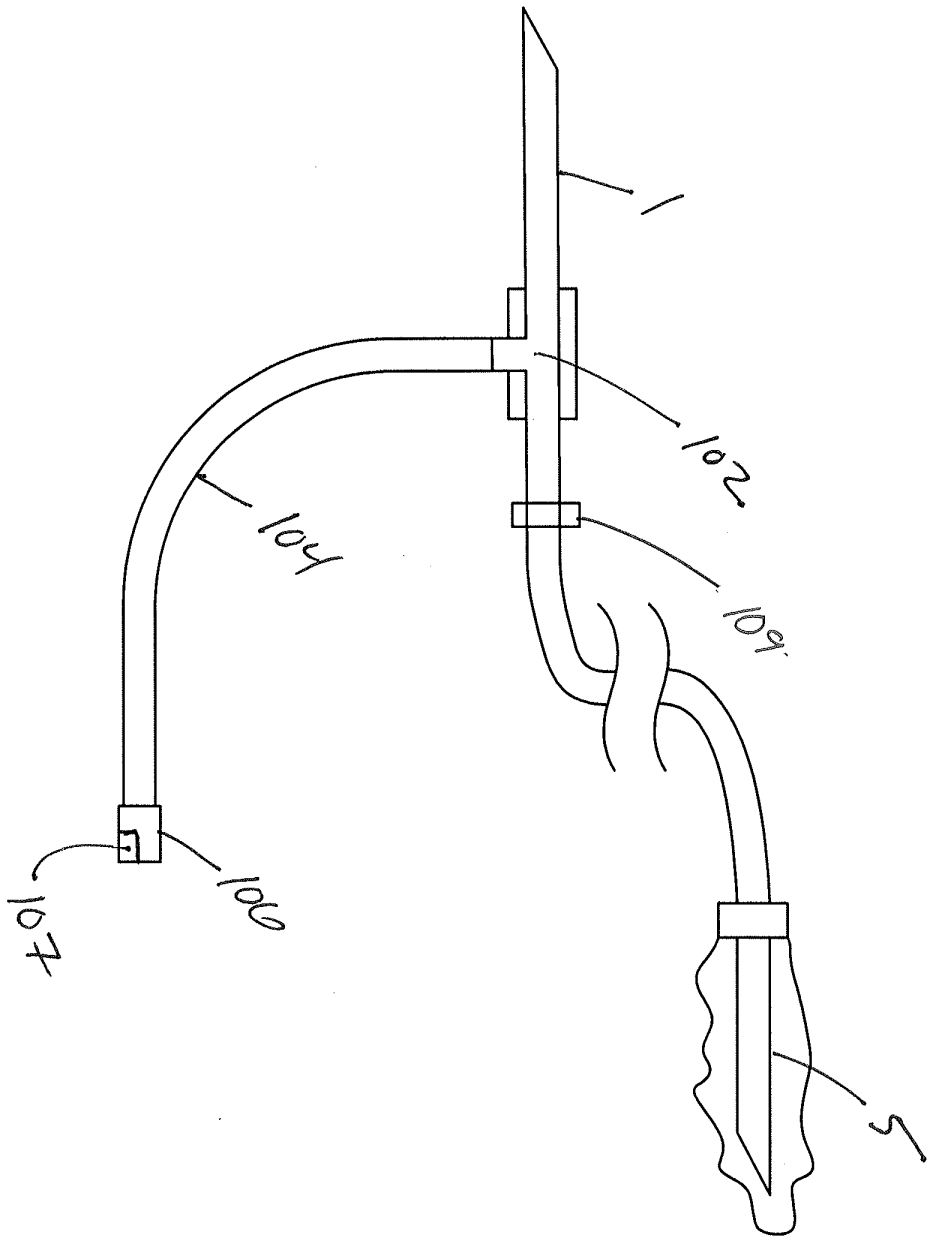


FIG. 4

FIG. 5

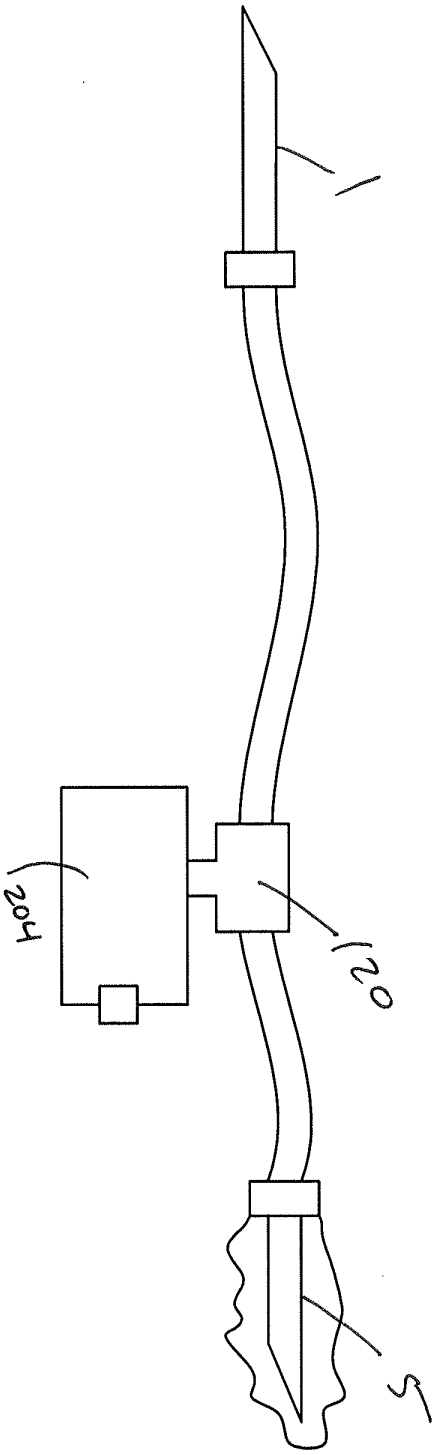
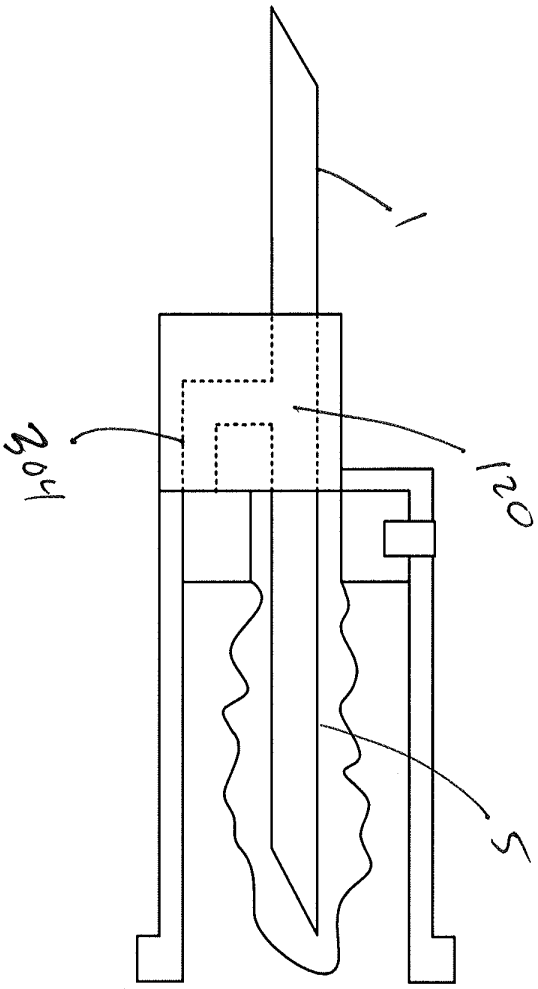


FIG. 6



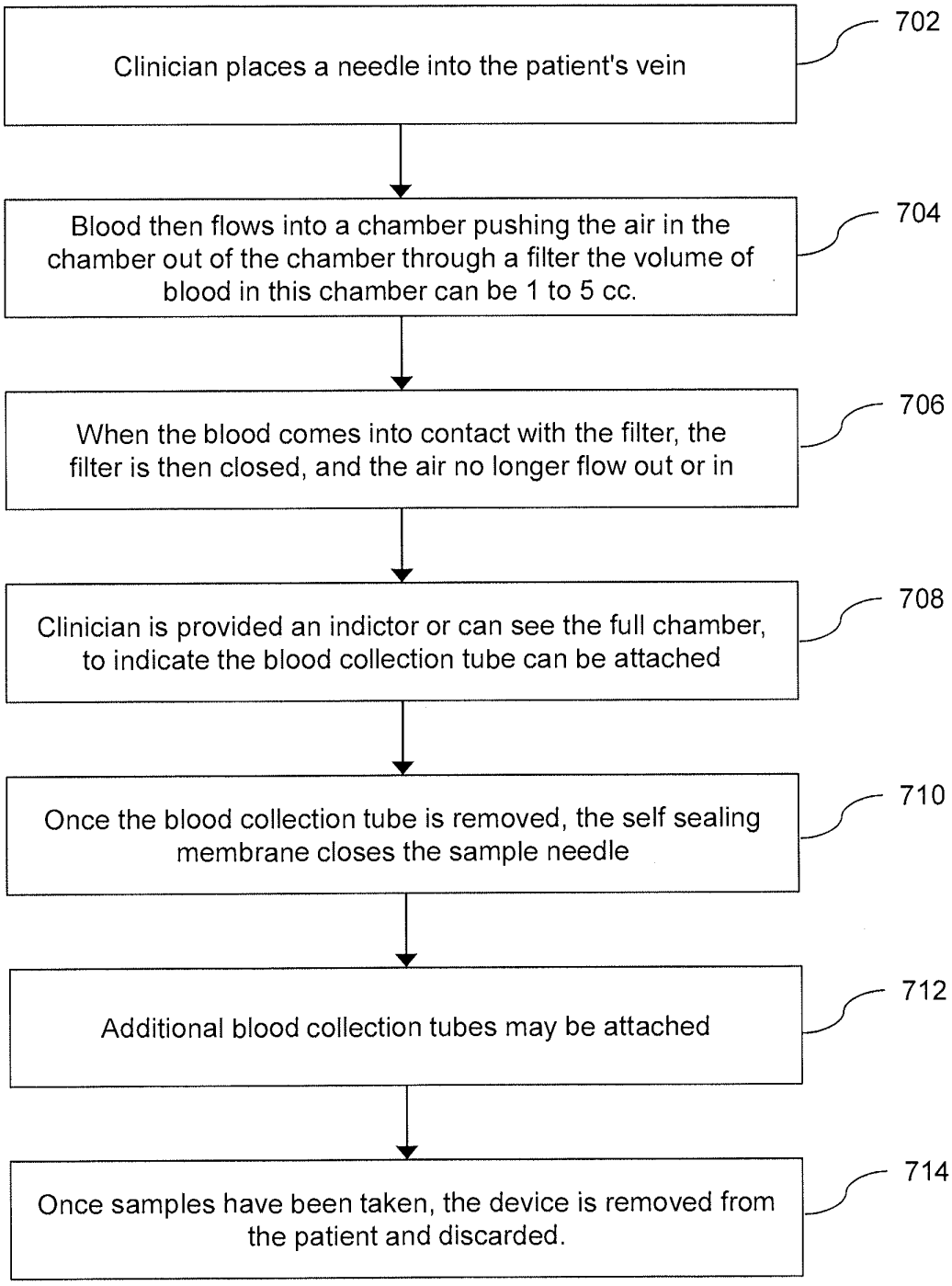
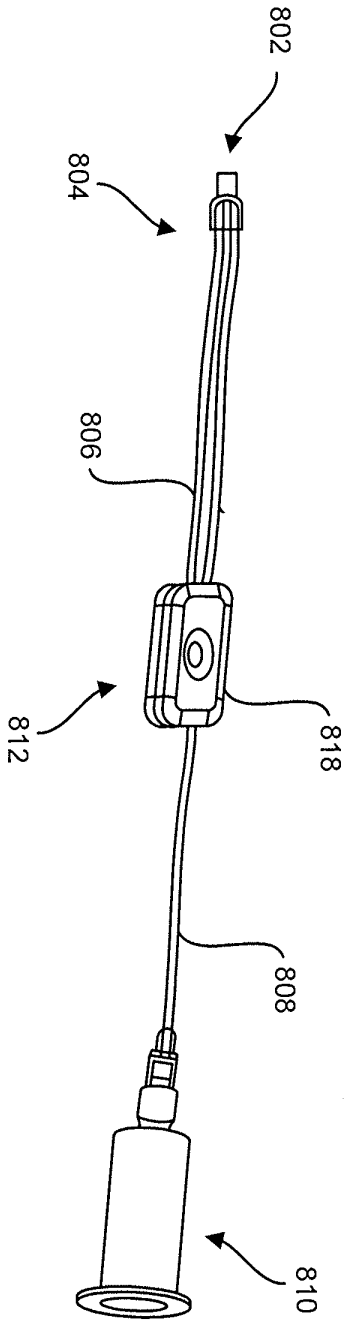

Clinician places a needle into the patient's vein
702
Blood then flows into a chamber pushing the air in the chamber out of the chamber through a filter the volume of blood in this chamber can be 1 to 5 cc.
704
When the blood comes into contact with the filter, the filter is then closed, and the air 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



800

FIG. 8A

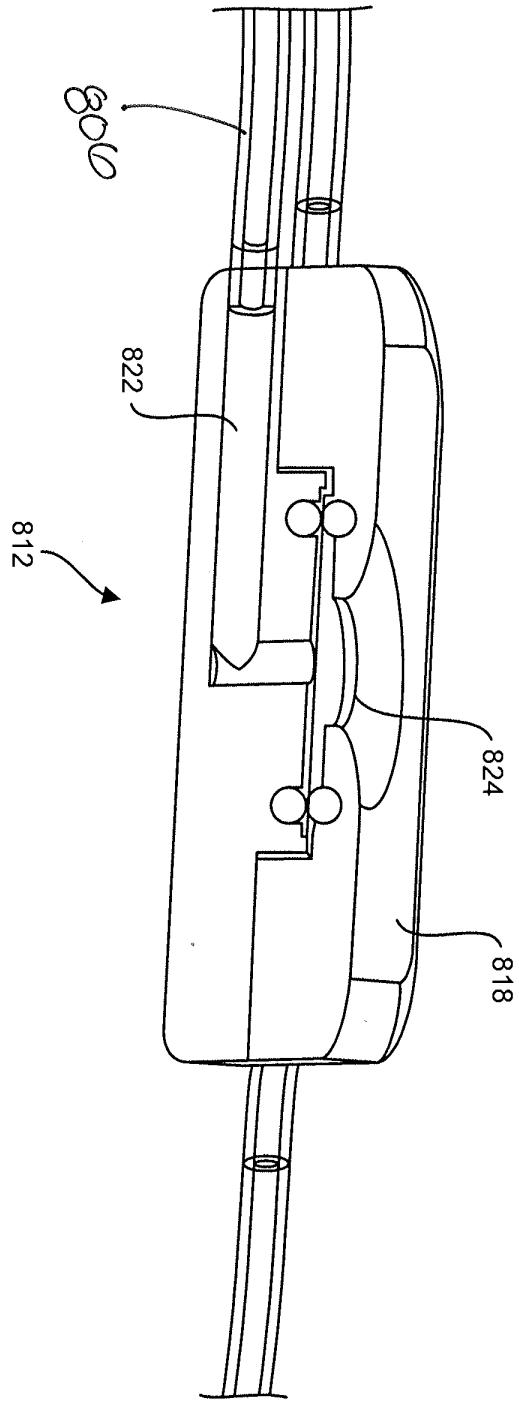


FIG. 8B

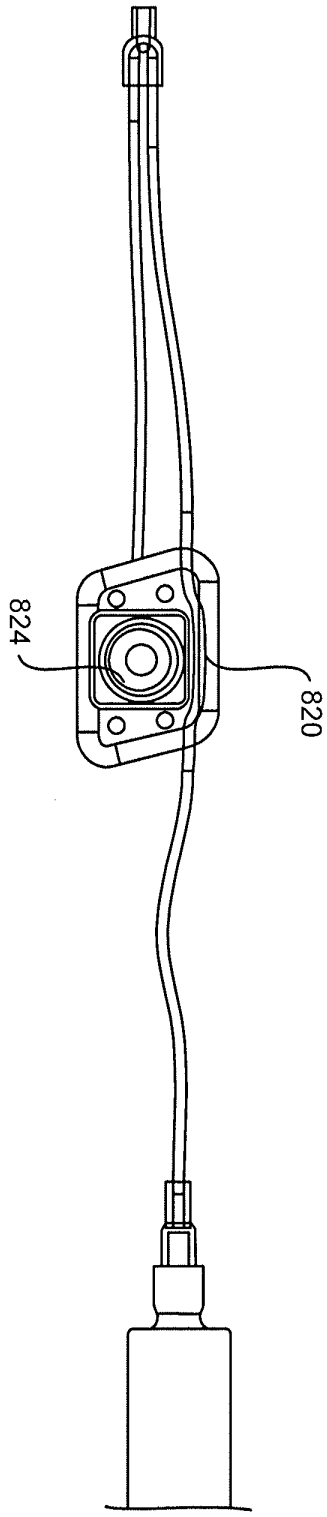
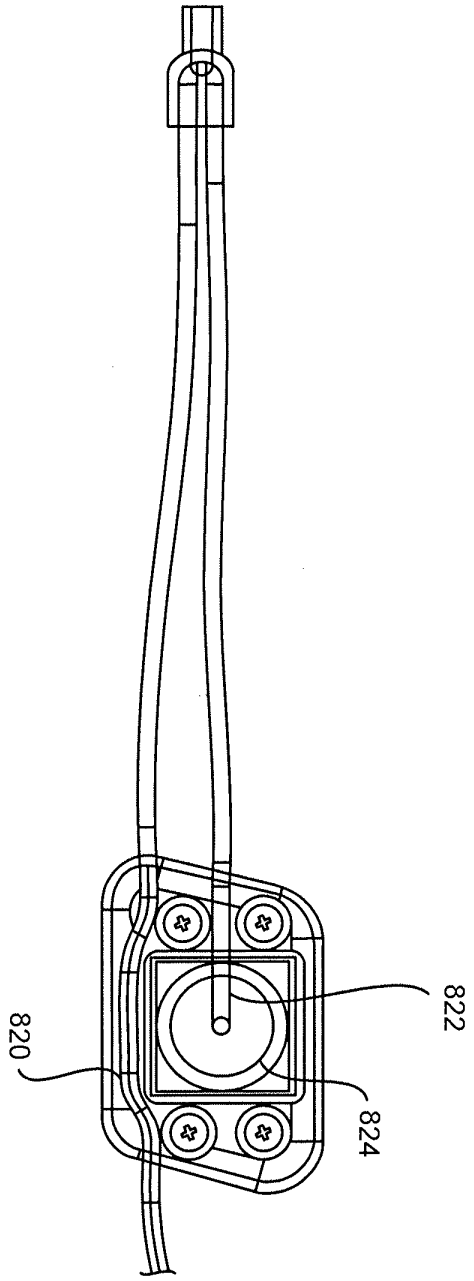


FIG. 8C

FIG. 8D



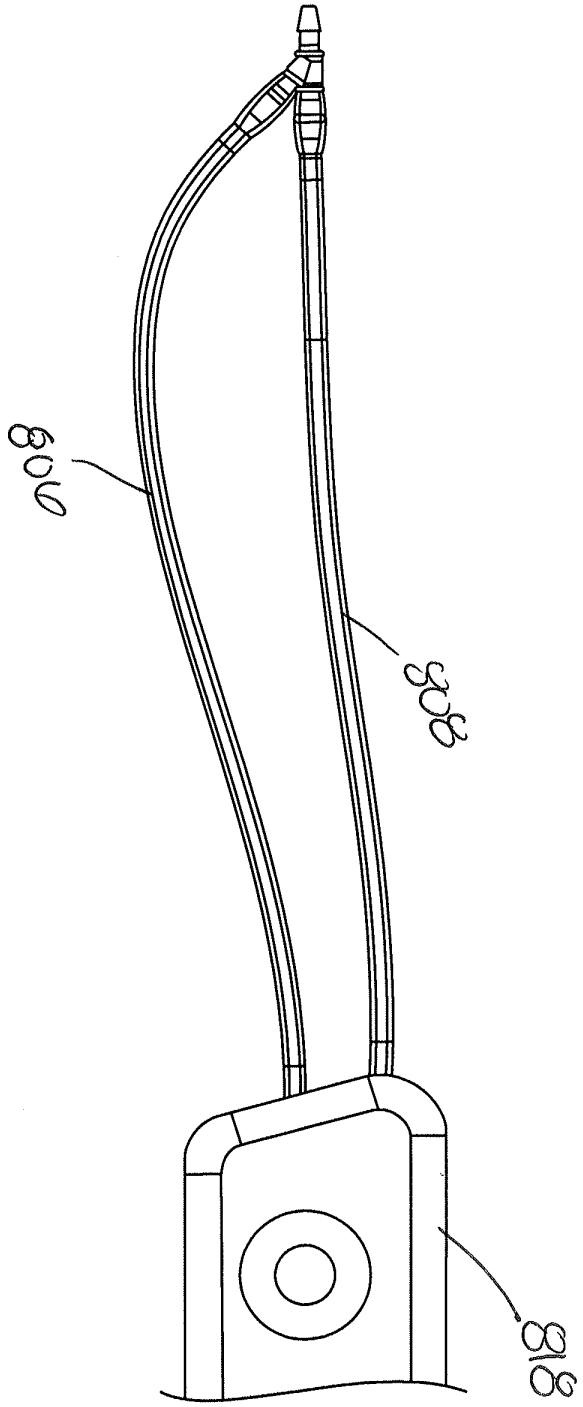
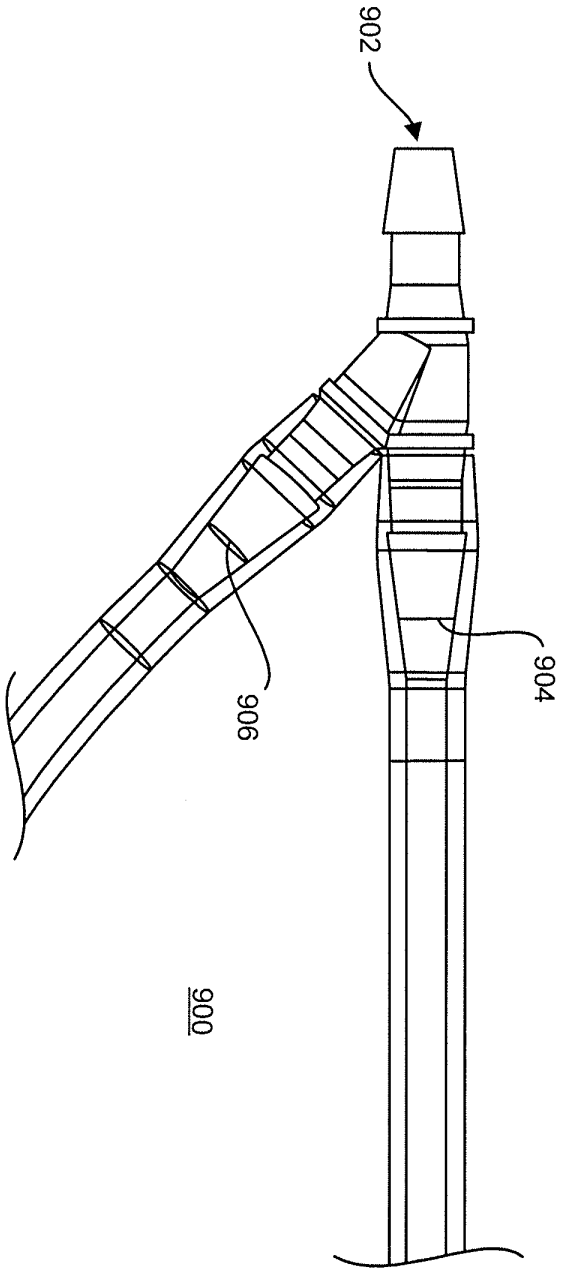


FIG. 8E

FIG. 9



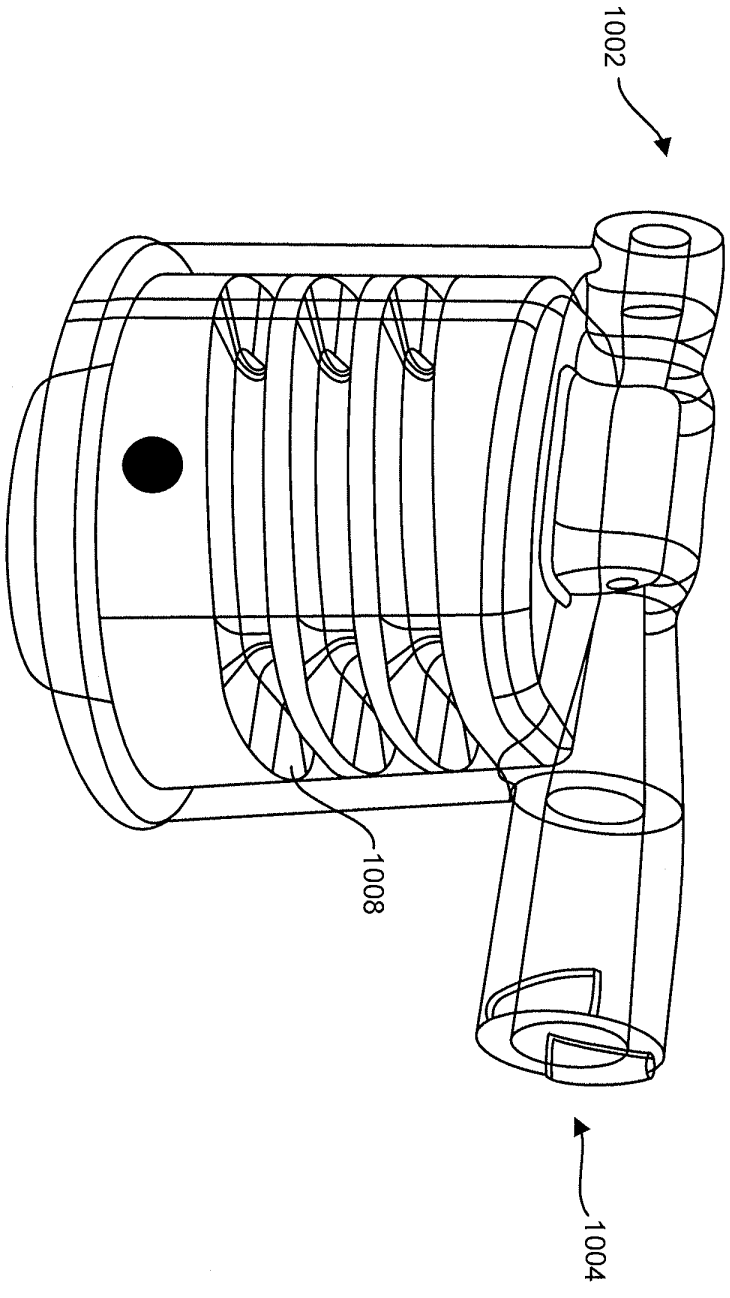


FIG. 10A

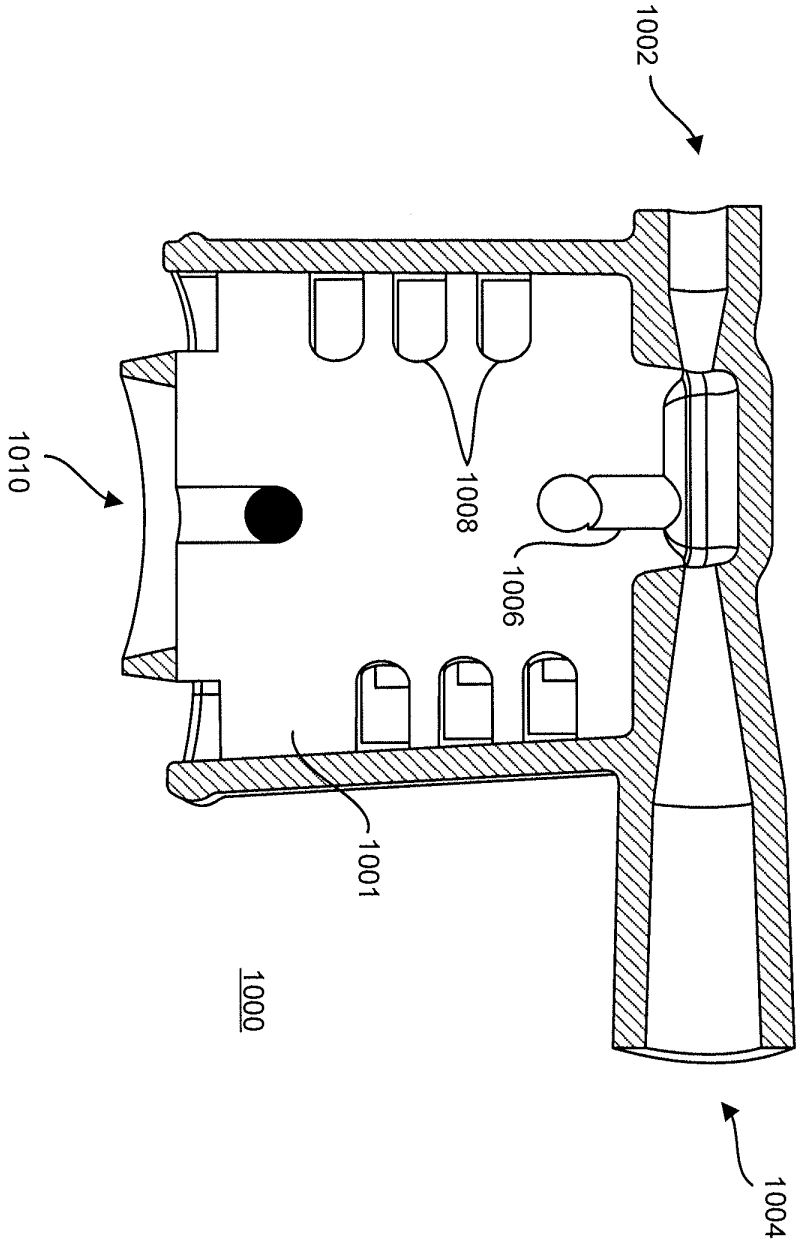


FIG. 10B

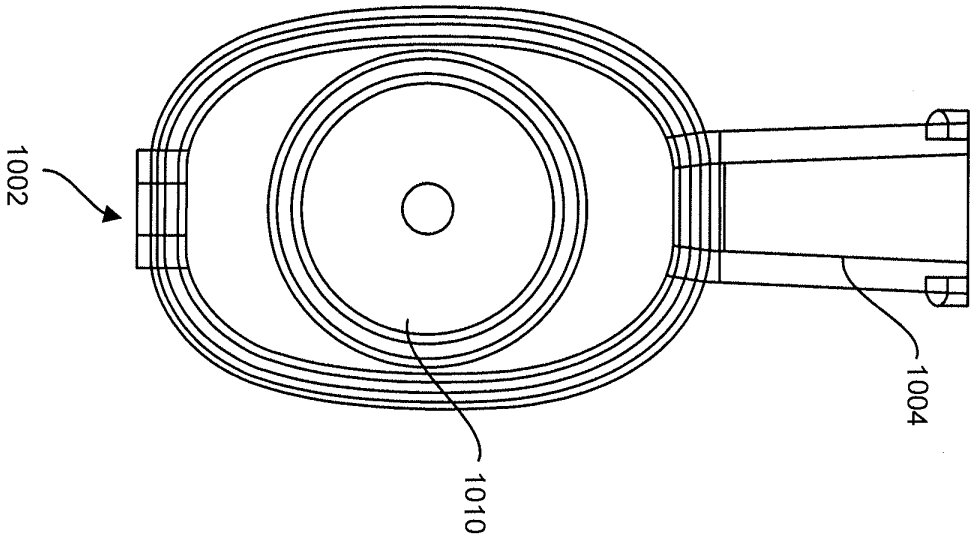


FIG. 10C

FIG. 10D

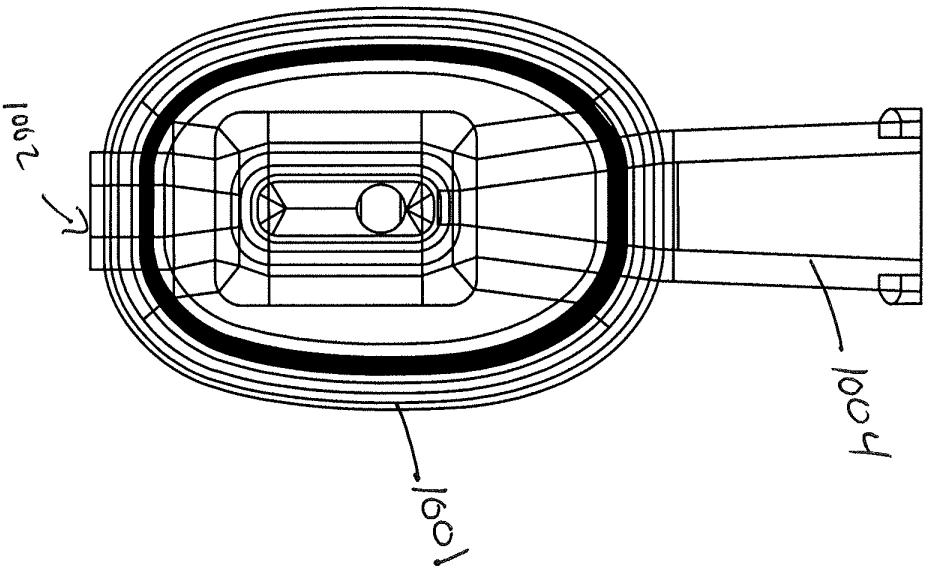
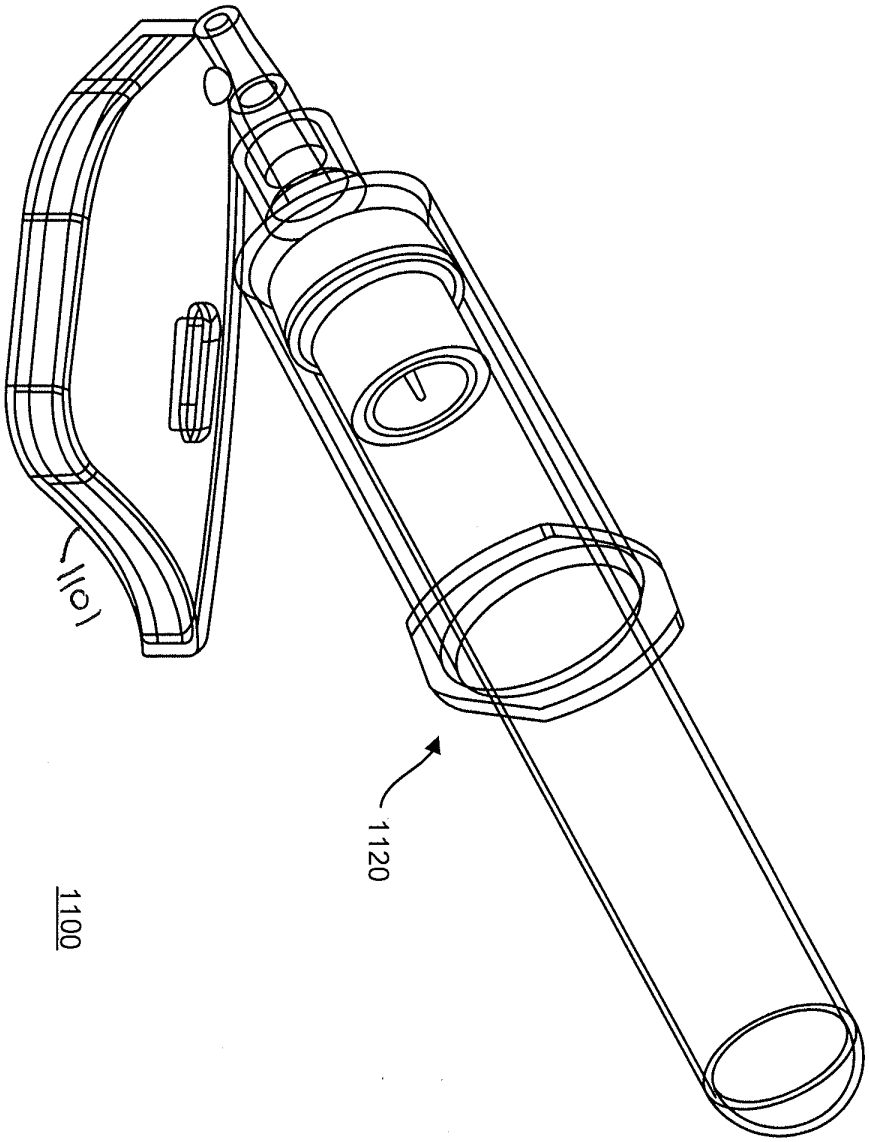


FIG. 11A



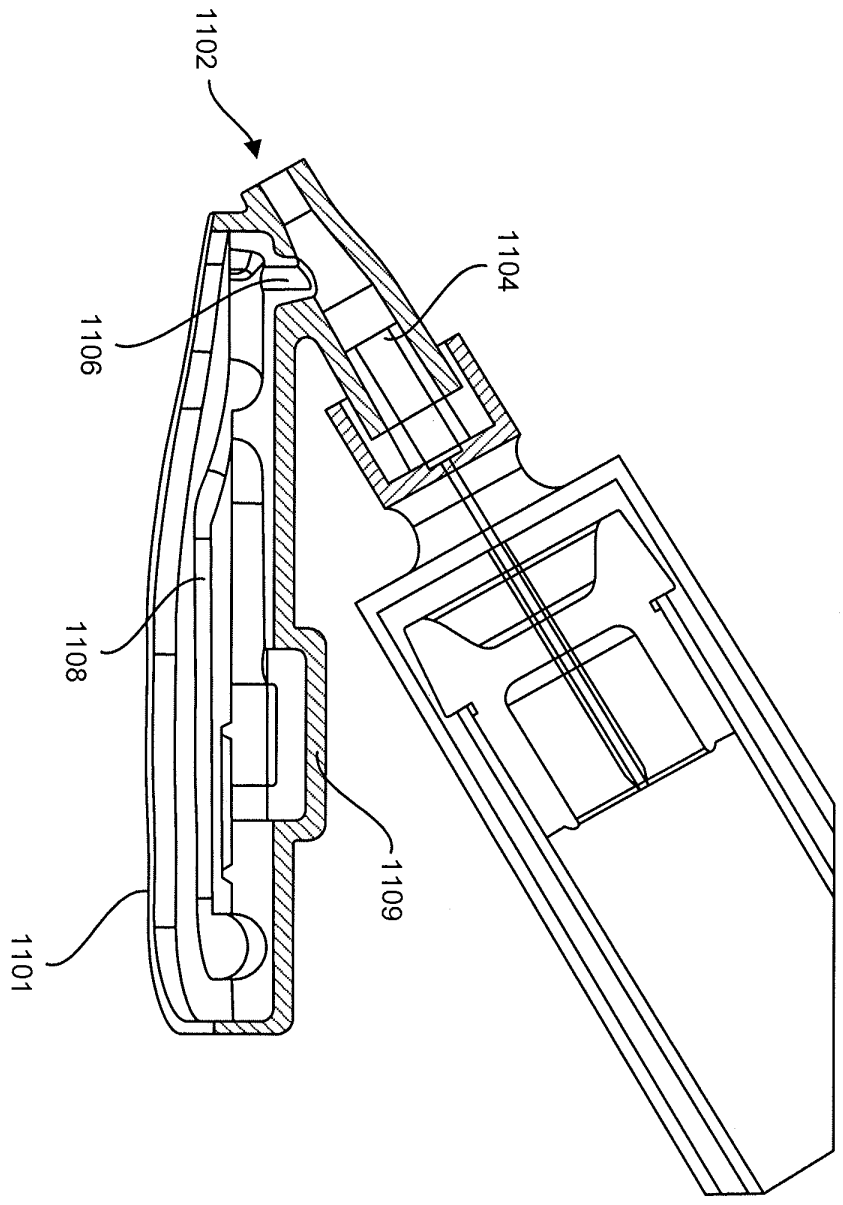


FIG. 11B

FIG. 11C

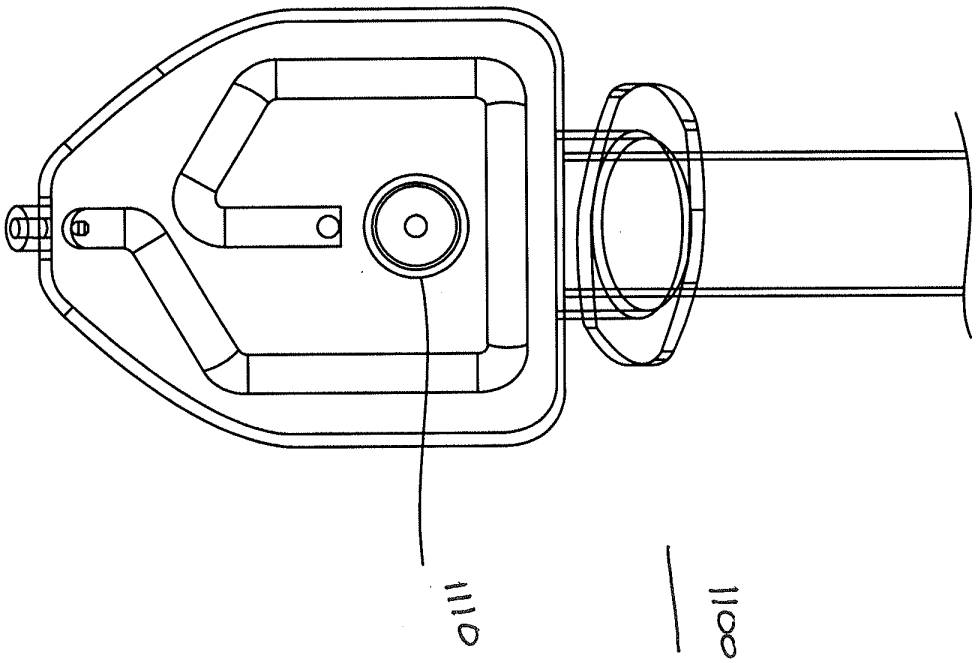


FIG. 11D

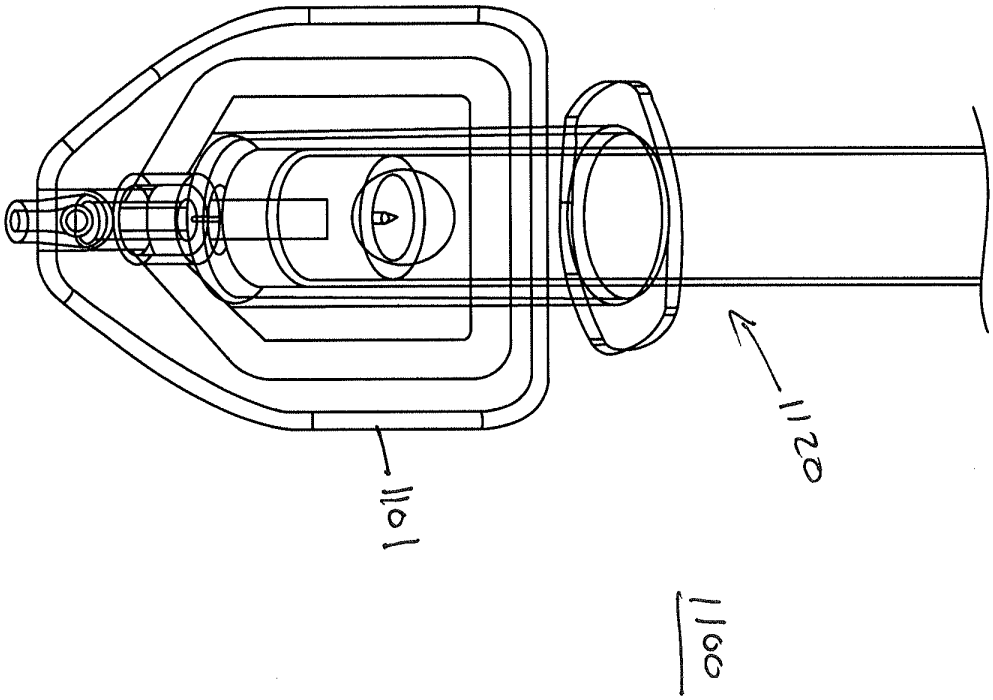
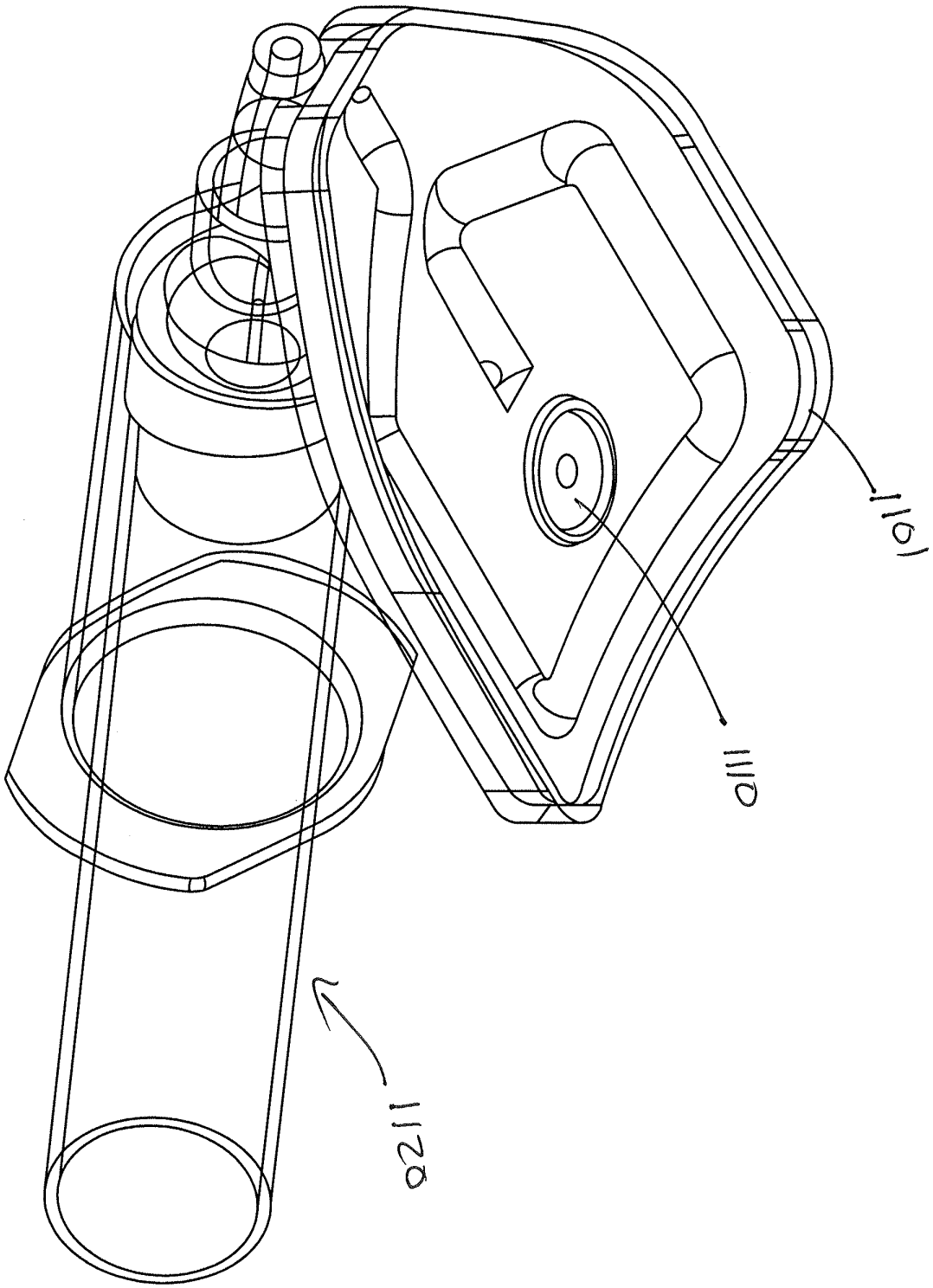


FIG. 11E



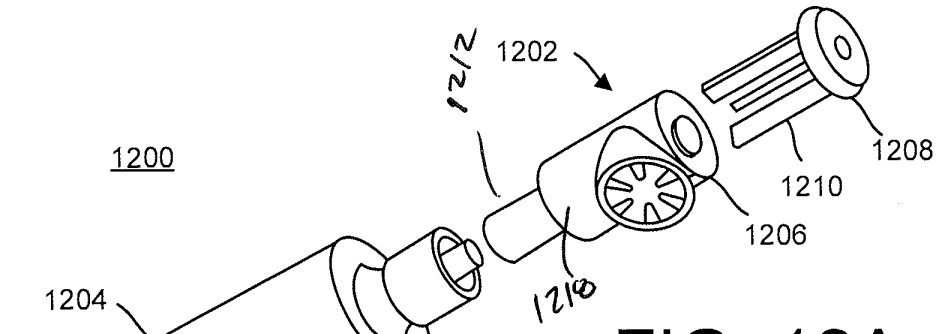


FIG. 12A

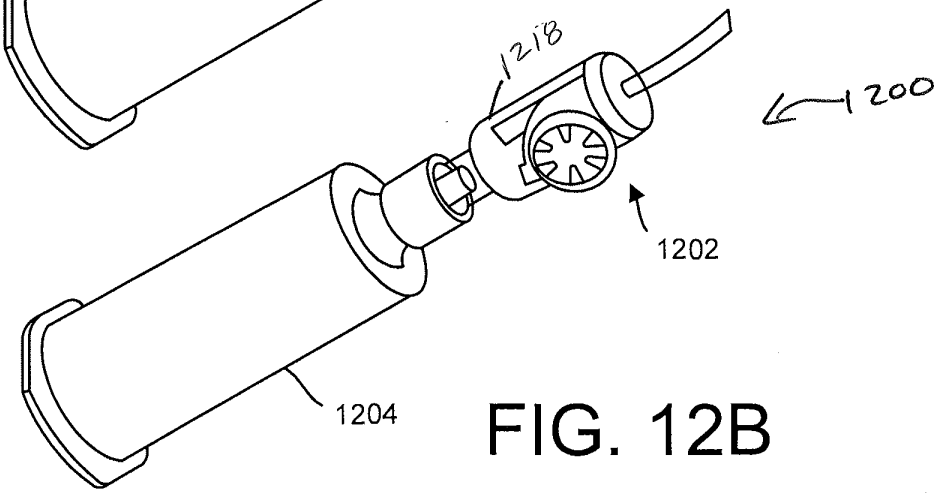


FIG. 12B

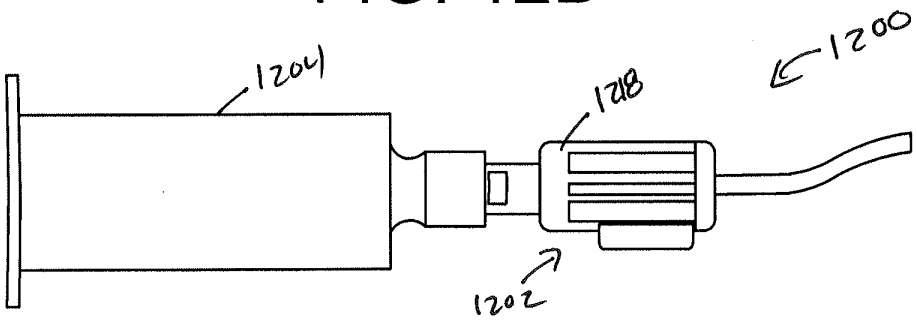


FIG. 12C

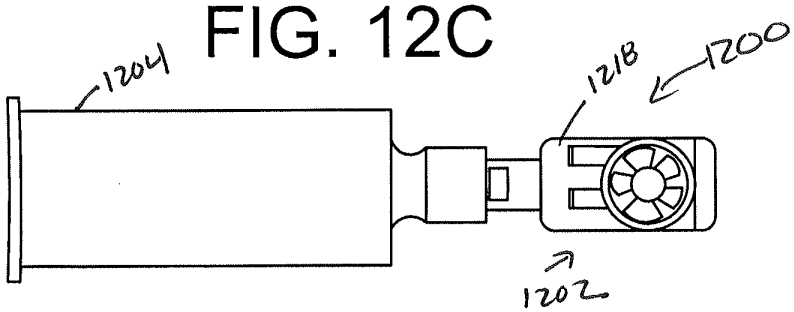


FIG. 12D

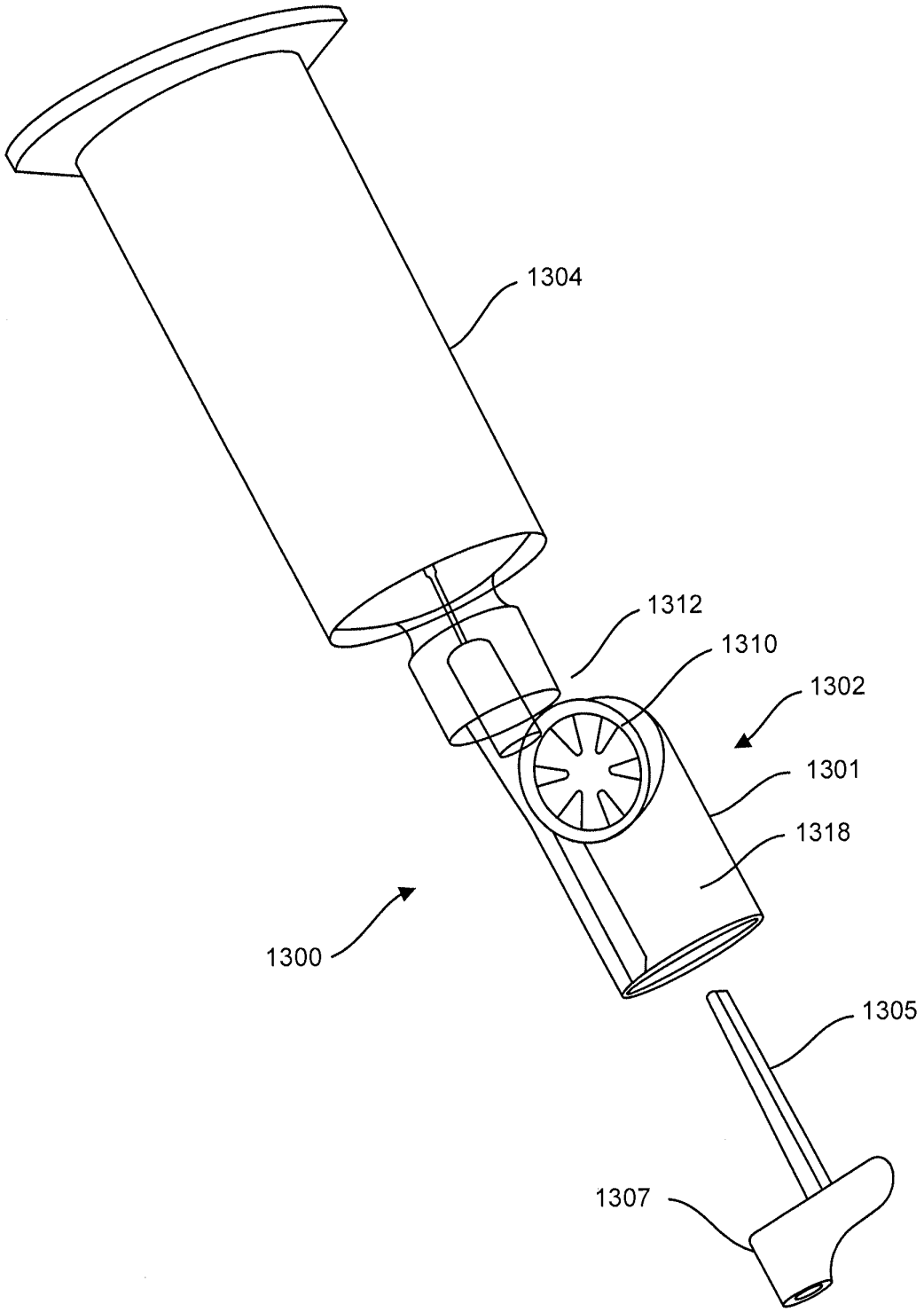


FIG. 13A

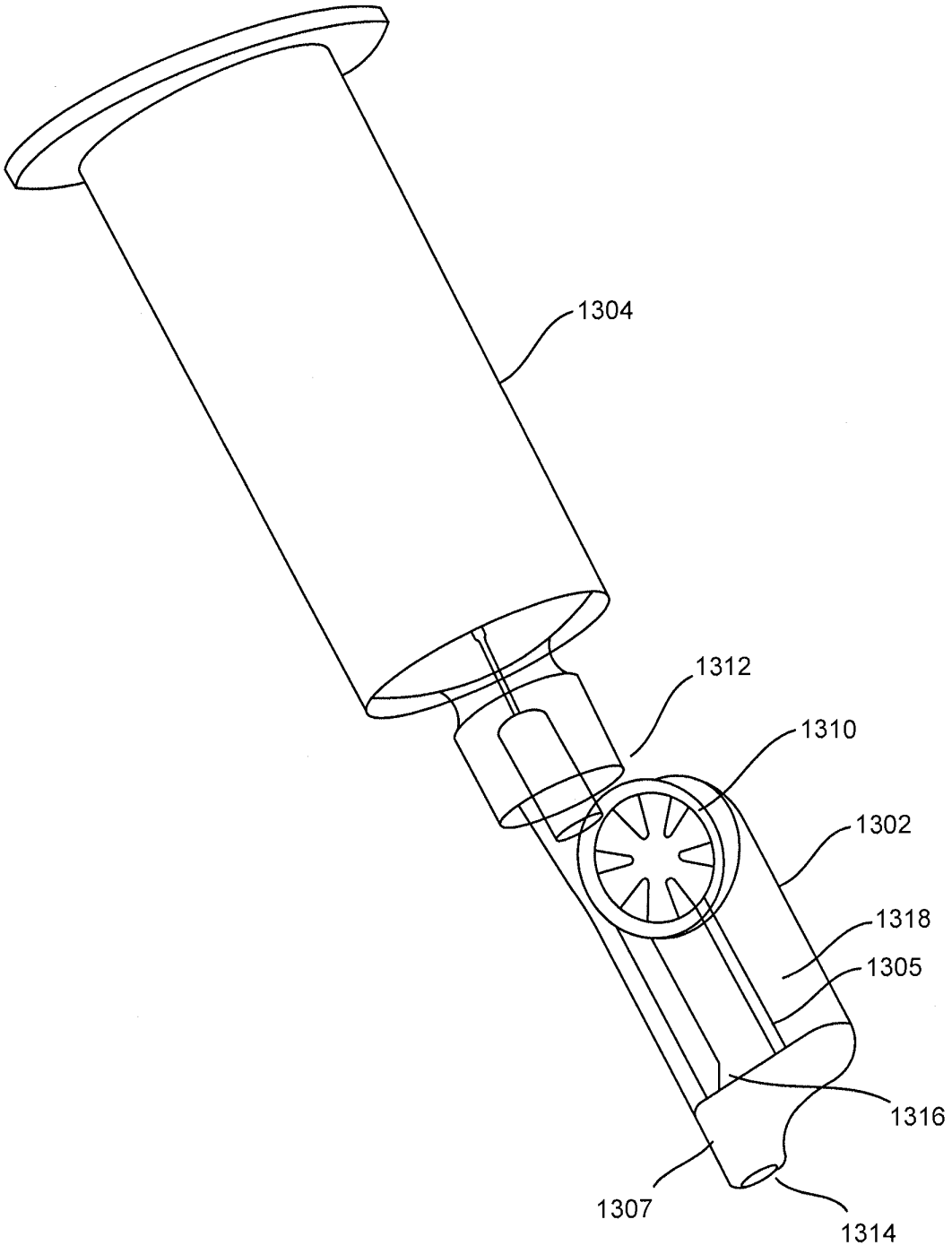


FIG. 13B

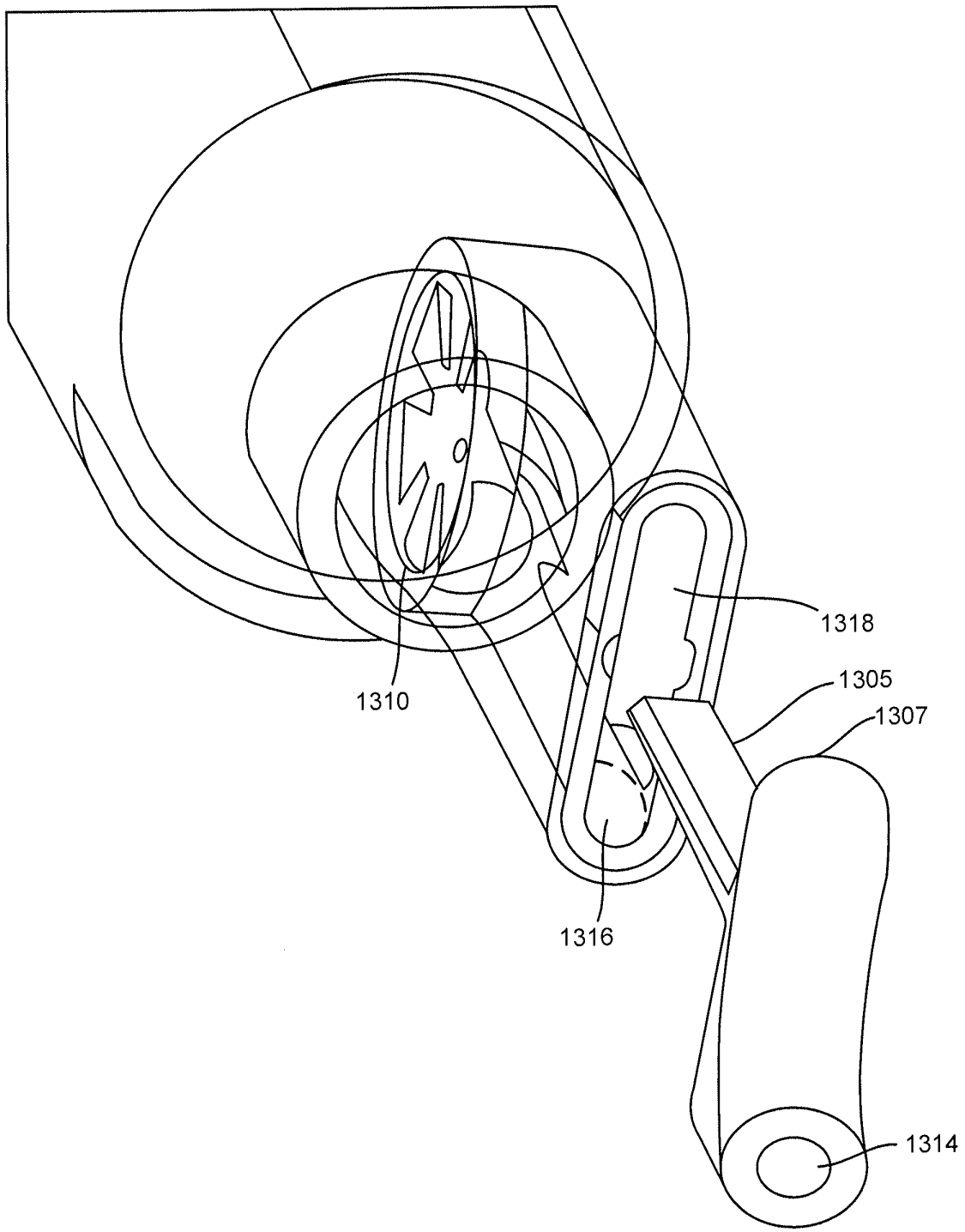


FIG. 13C

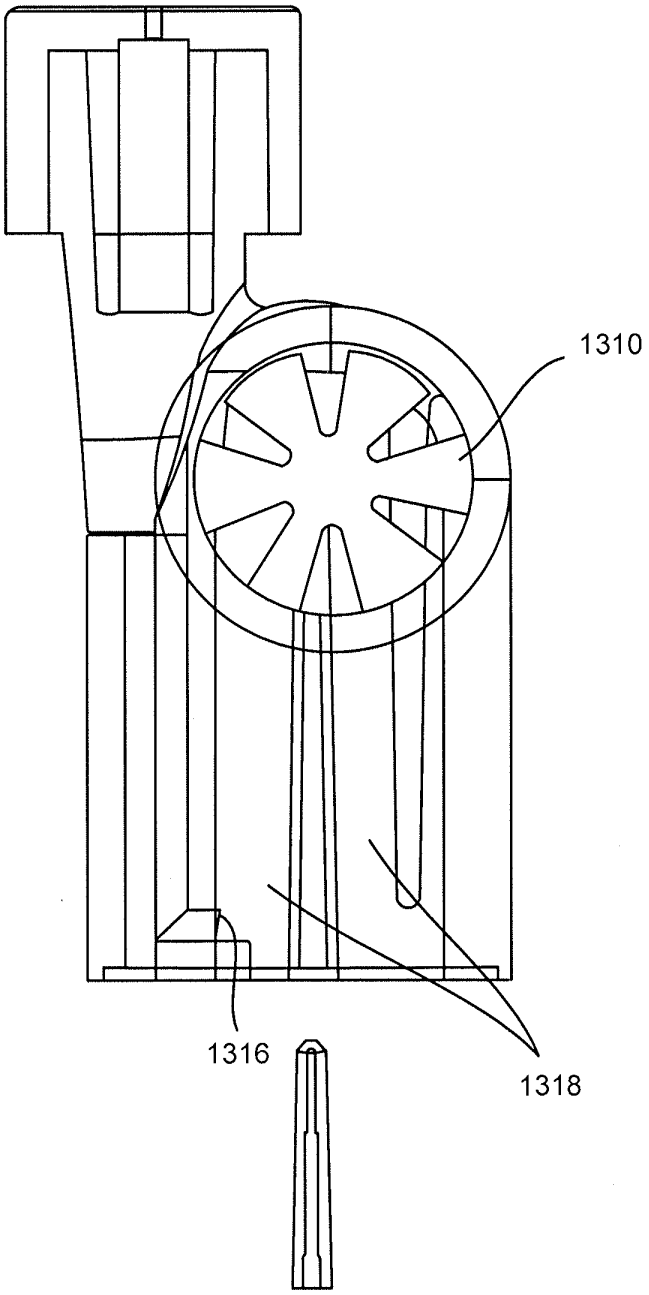


FIG. 13D

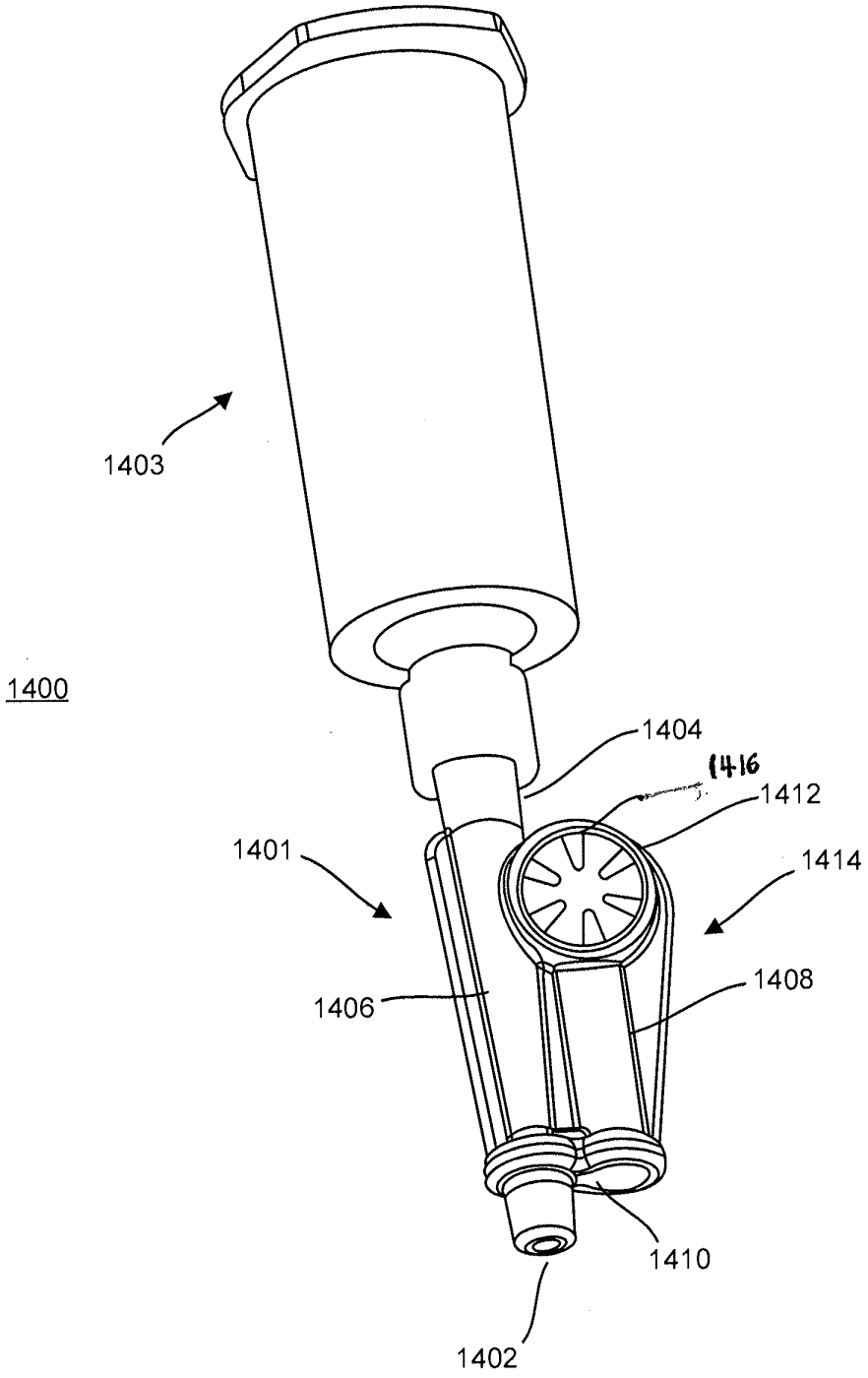


FIG. 14A

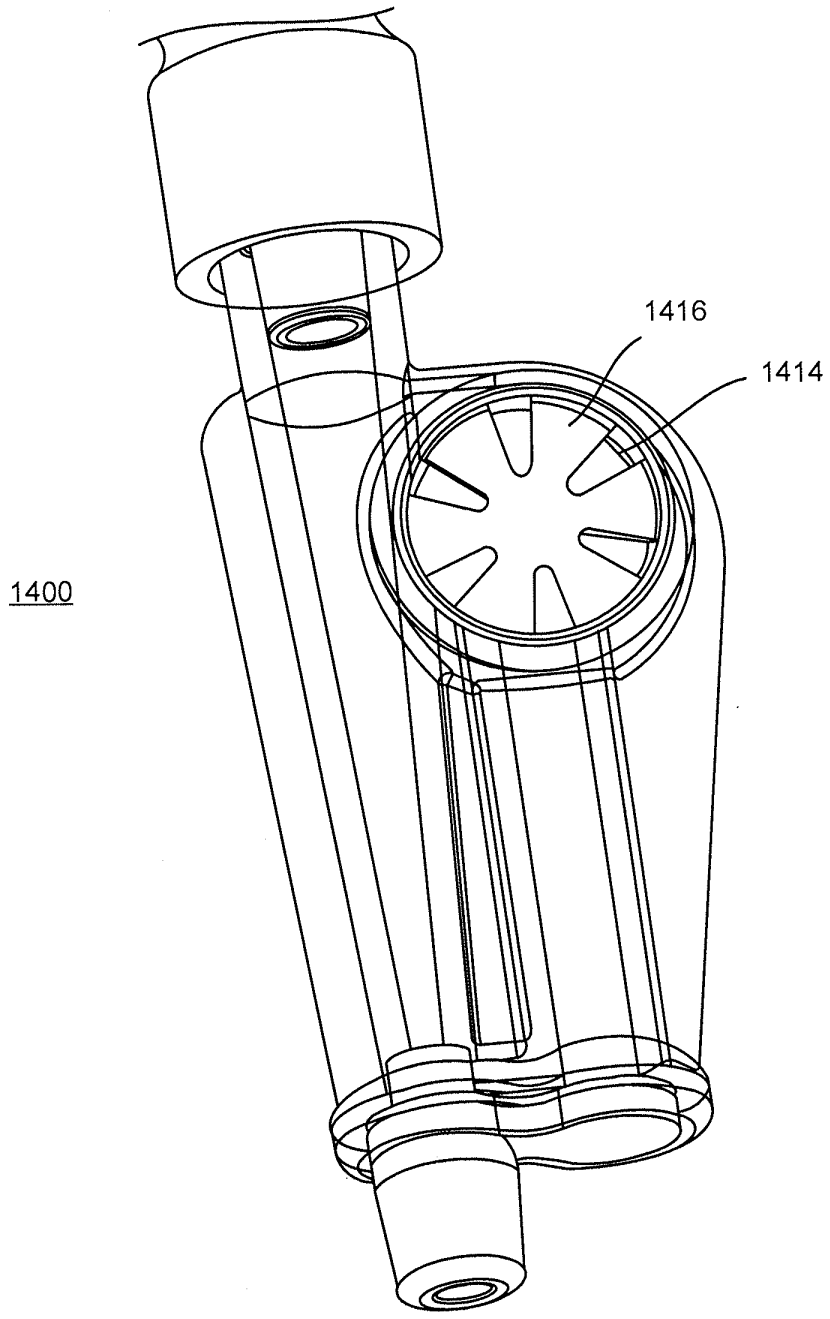


FIG. 14B

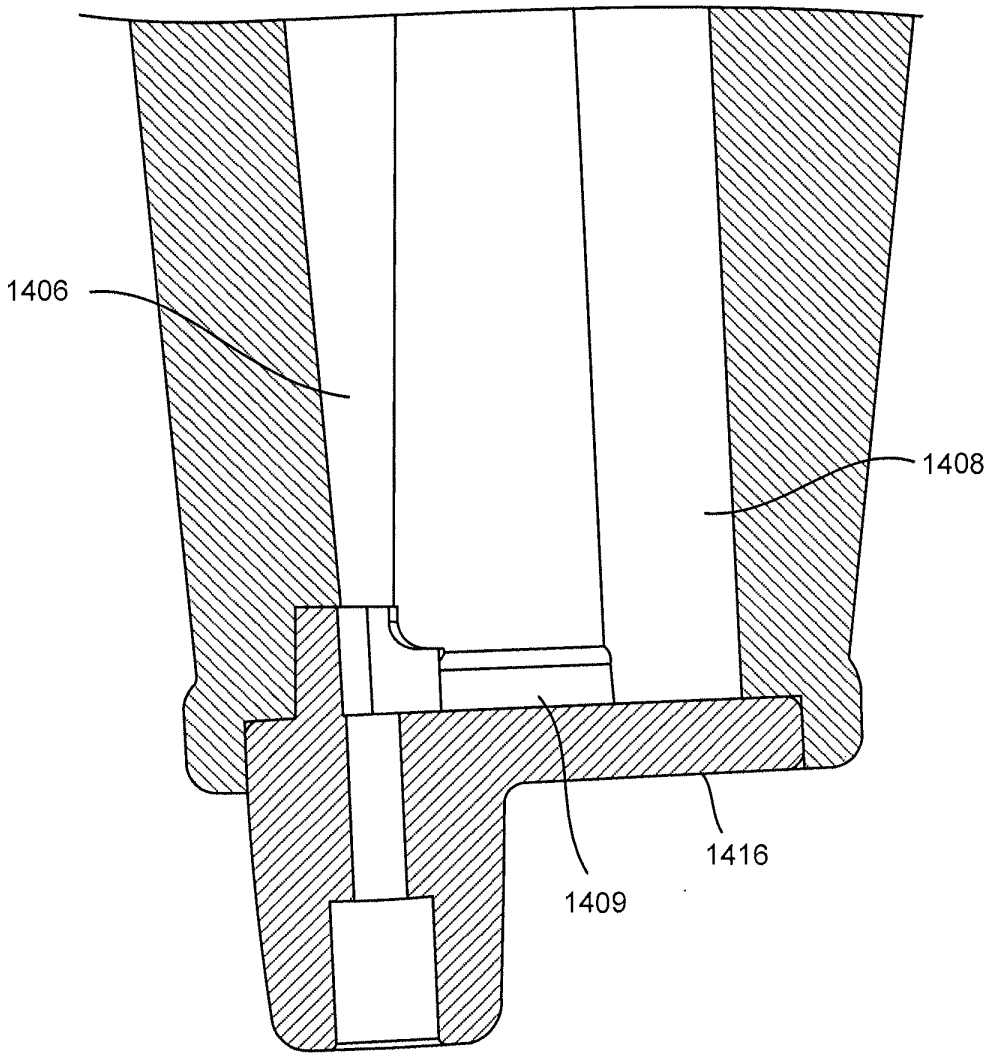


FIG. 14C

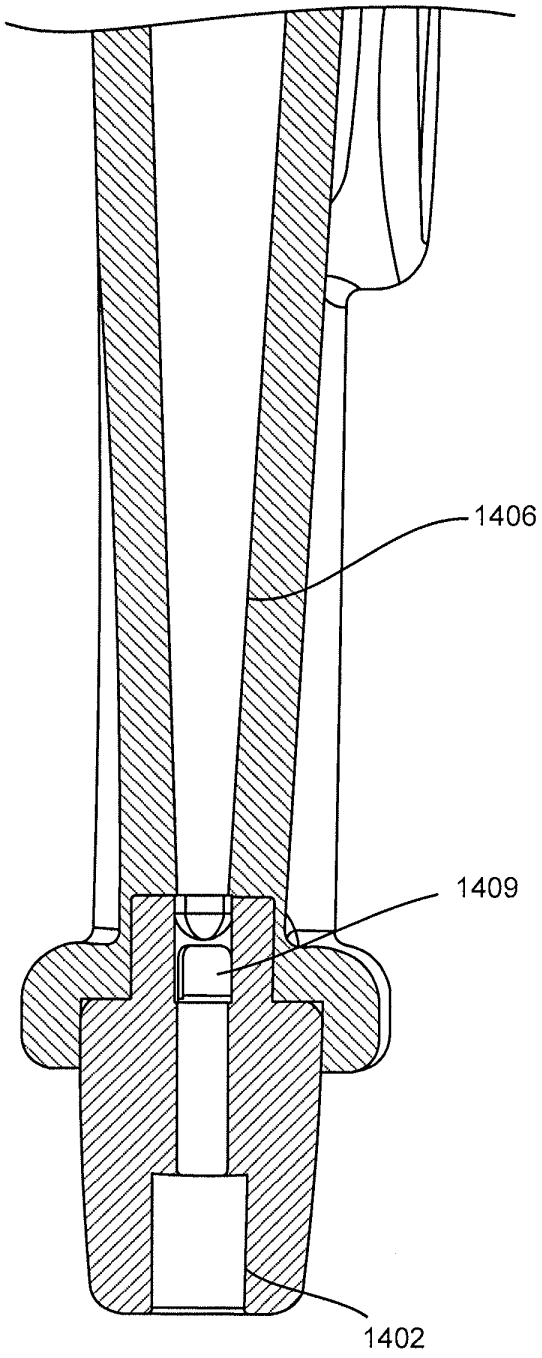


FIG. 14D

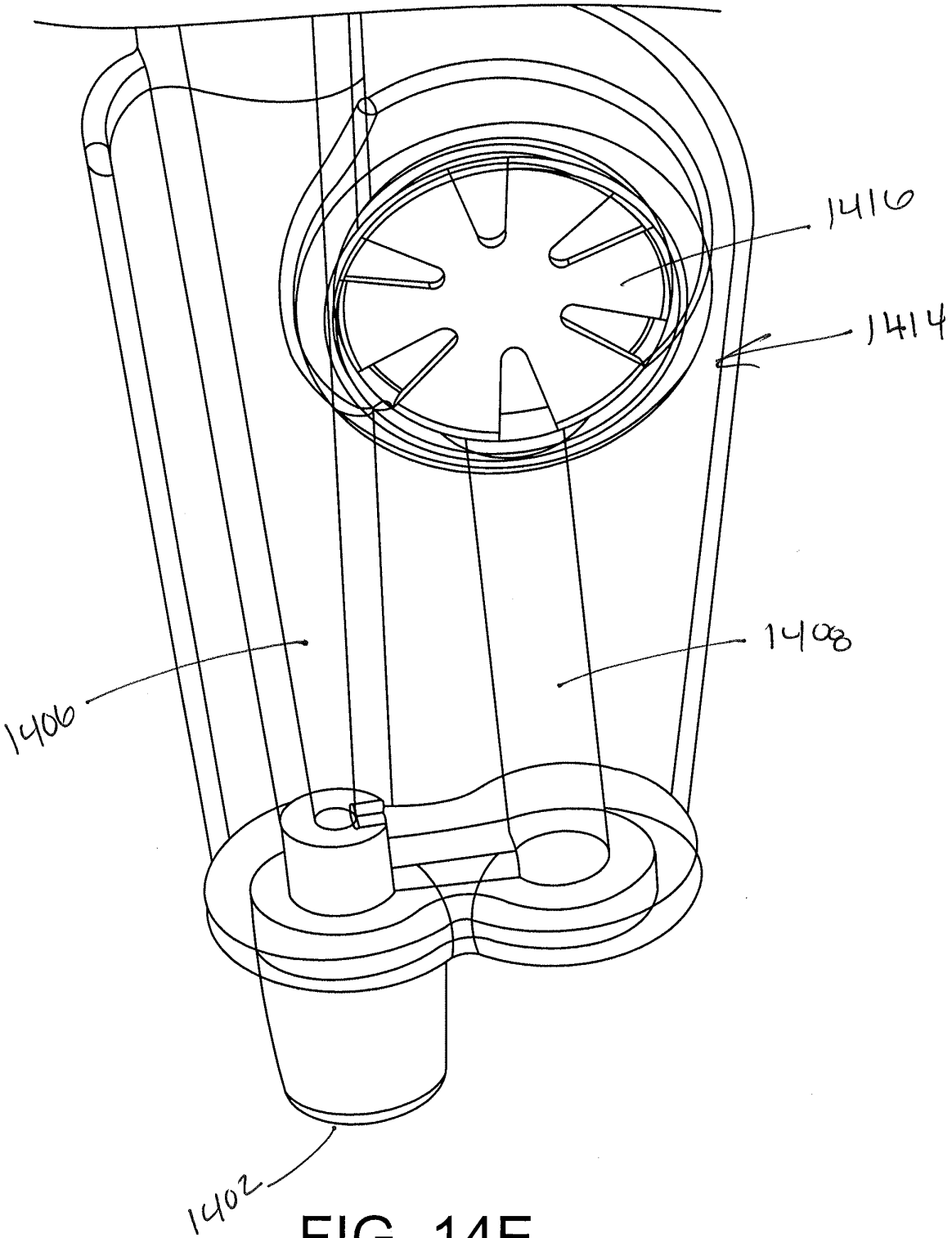


FIG. 14E

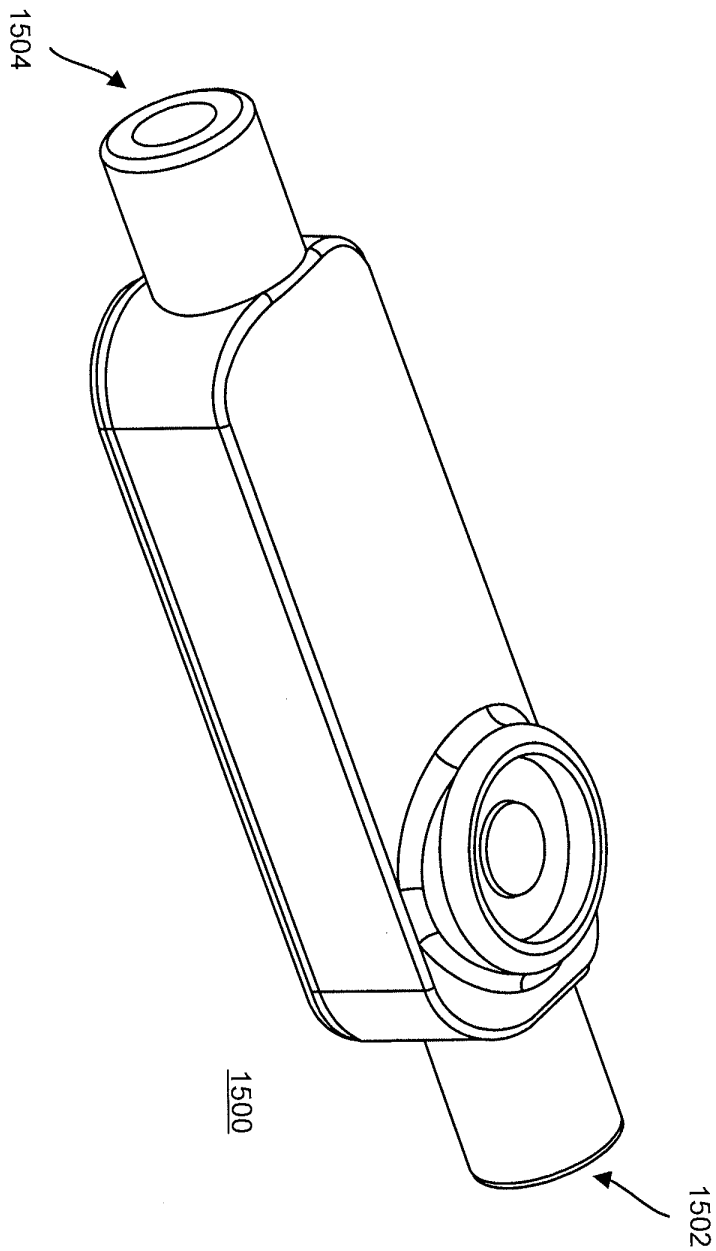


FIG. 15A

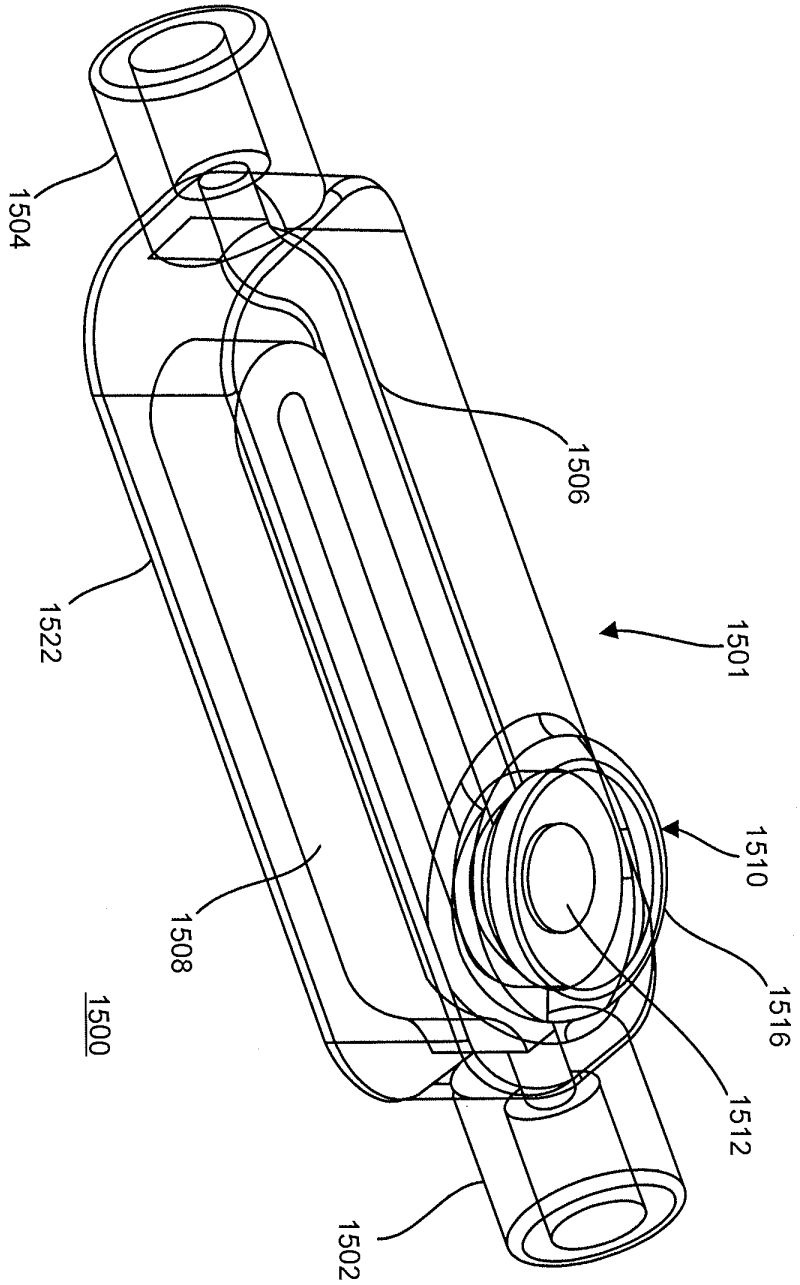


FIG. 15B

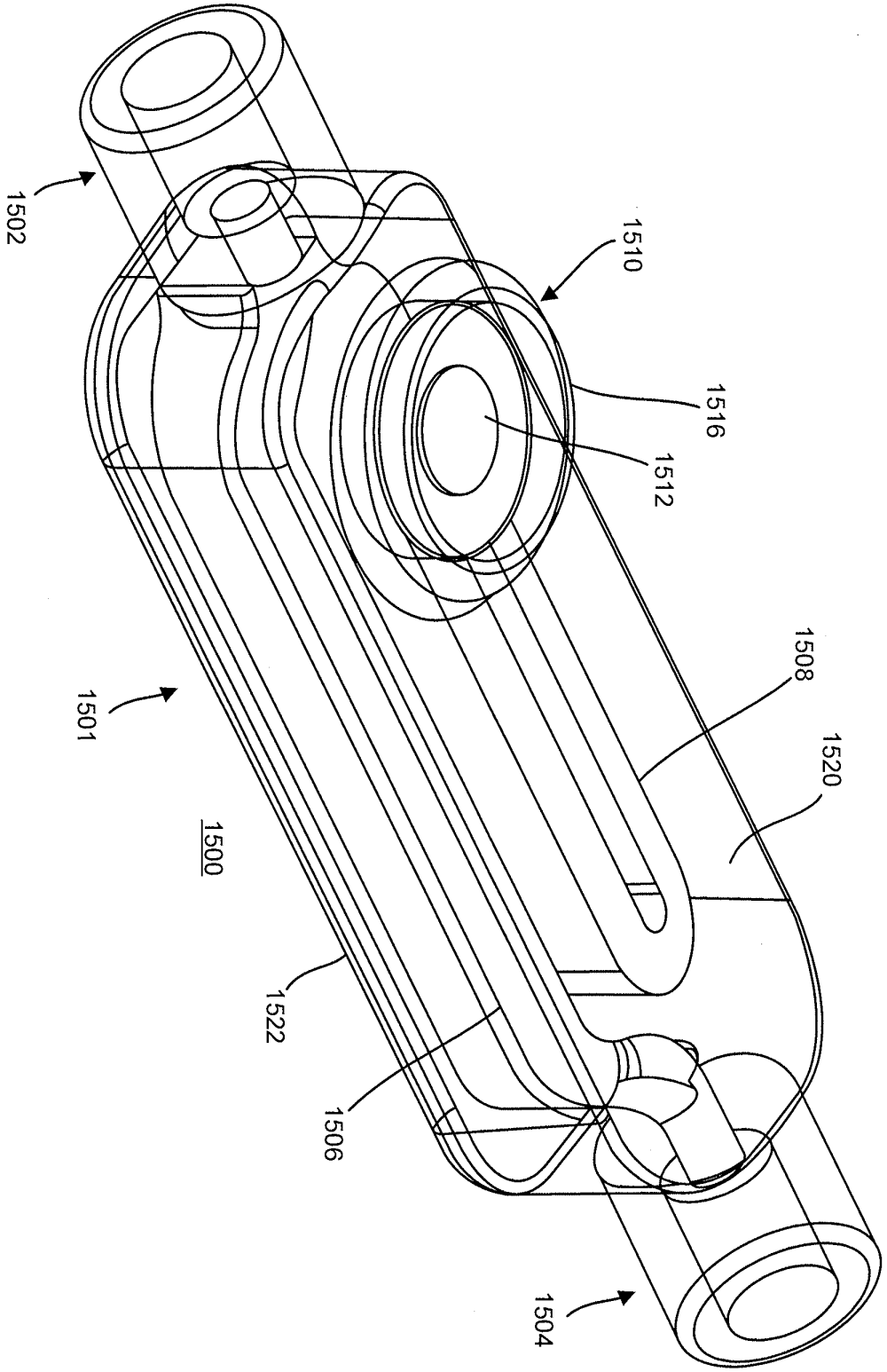


FIG. 15C

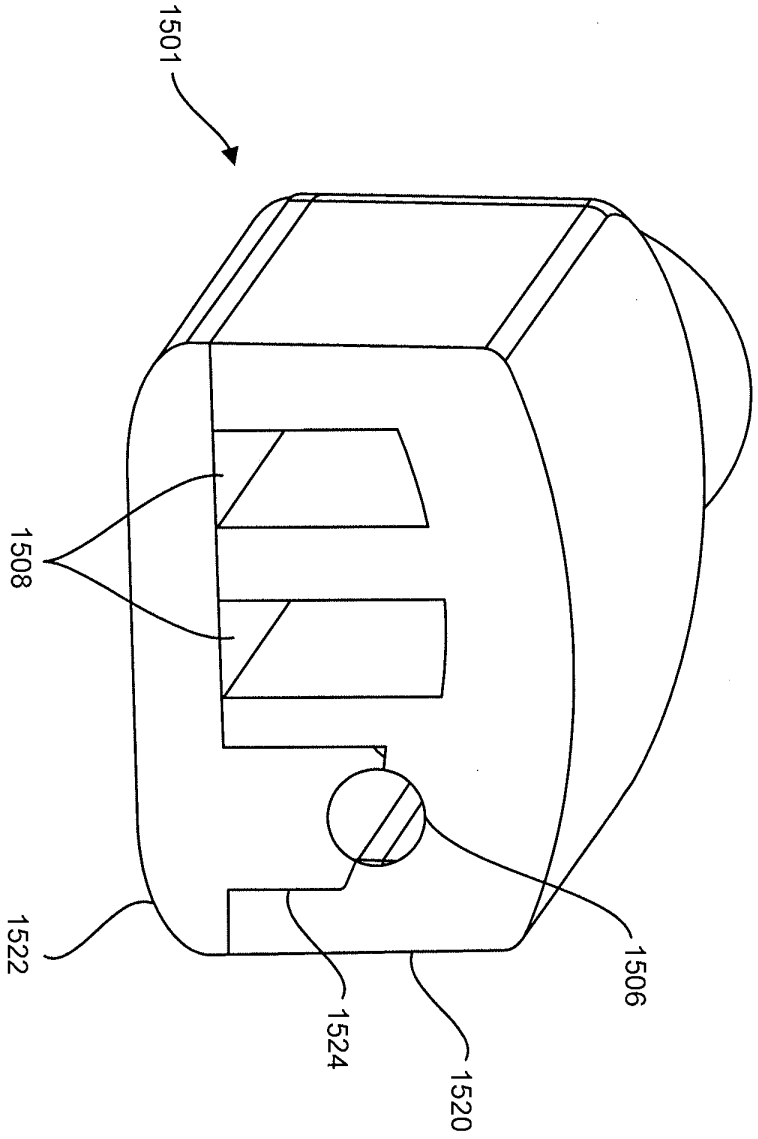


FIG. 15D

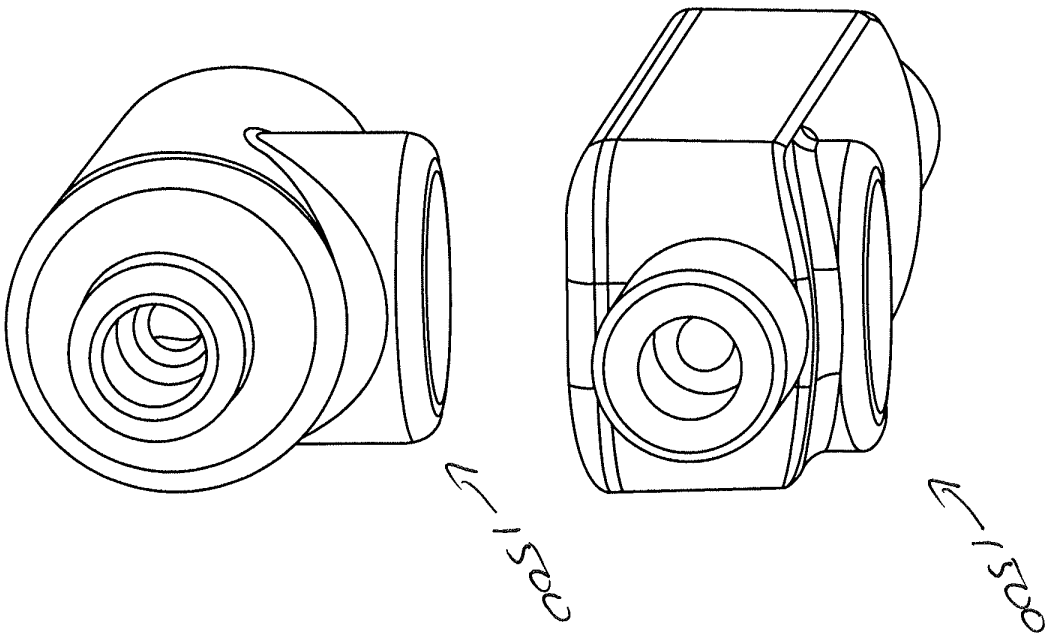


FIG. 15E

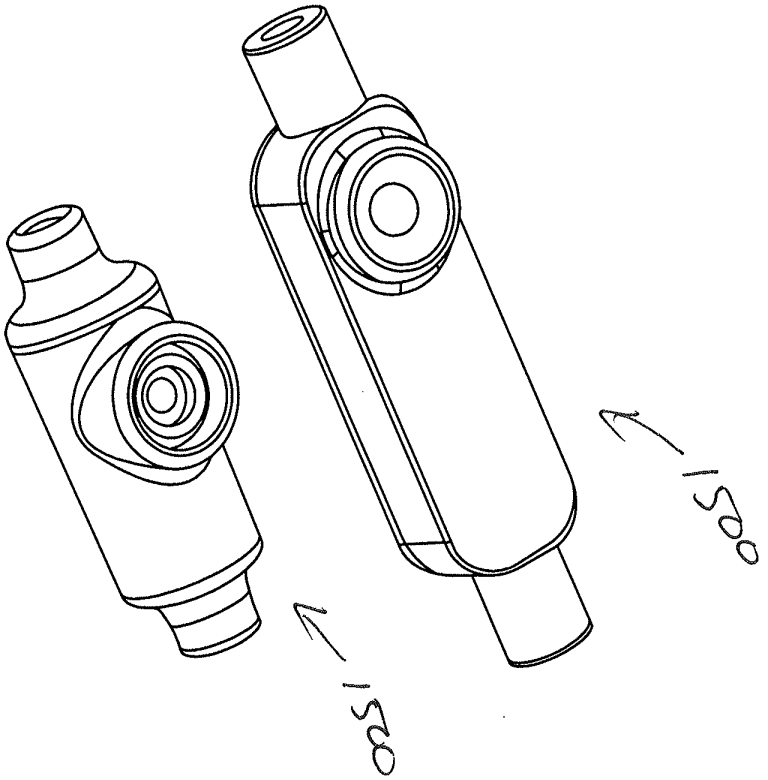


FIG. 15F

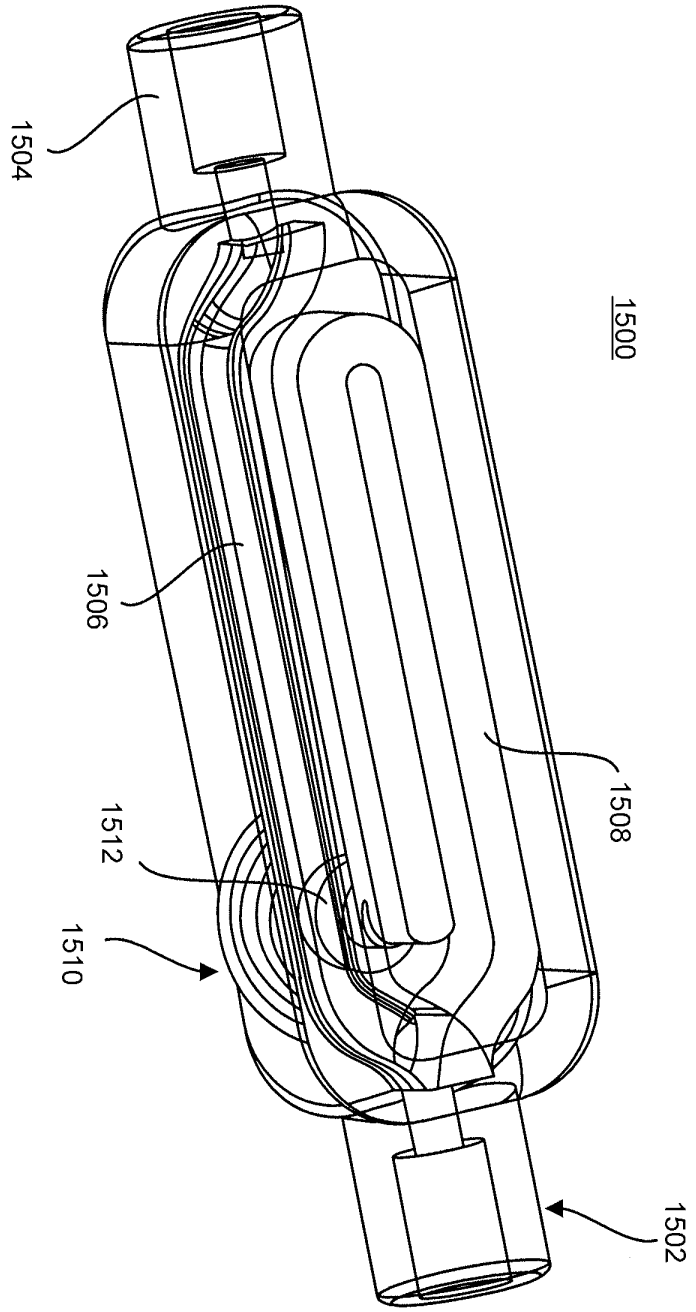


FIG. 15G

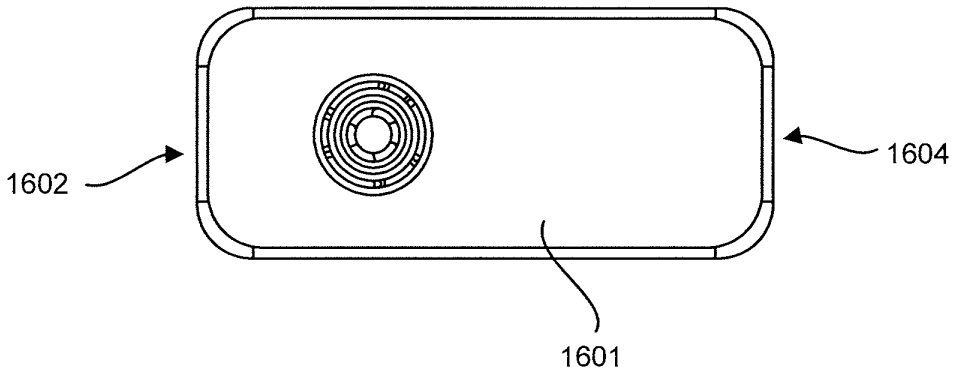


FIG. 16A

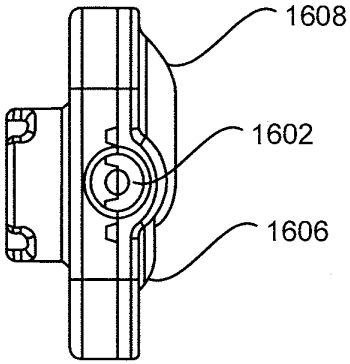


FIG. 16C

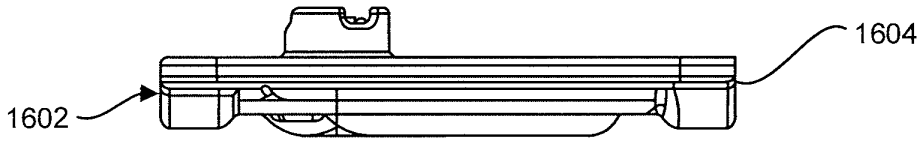


FIG. 16B

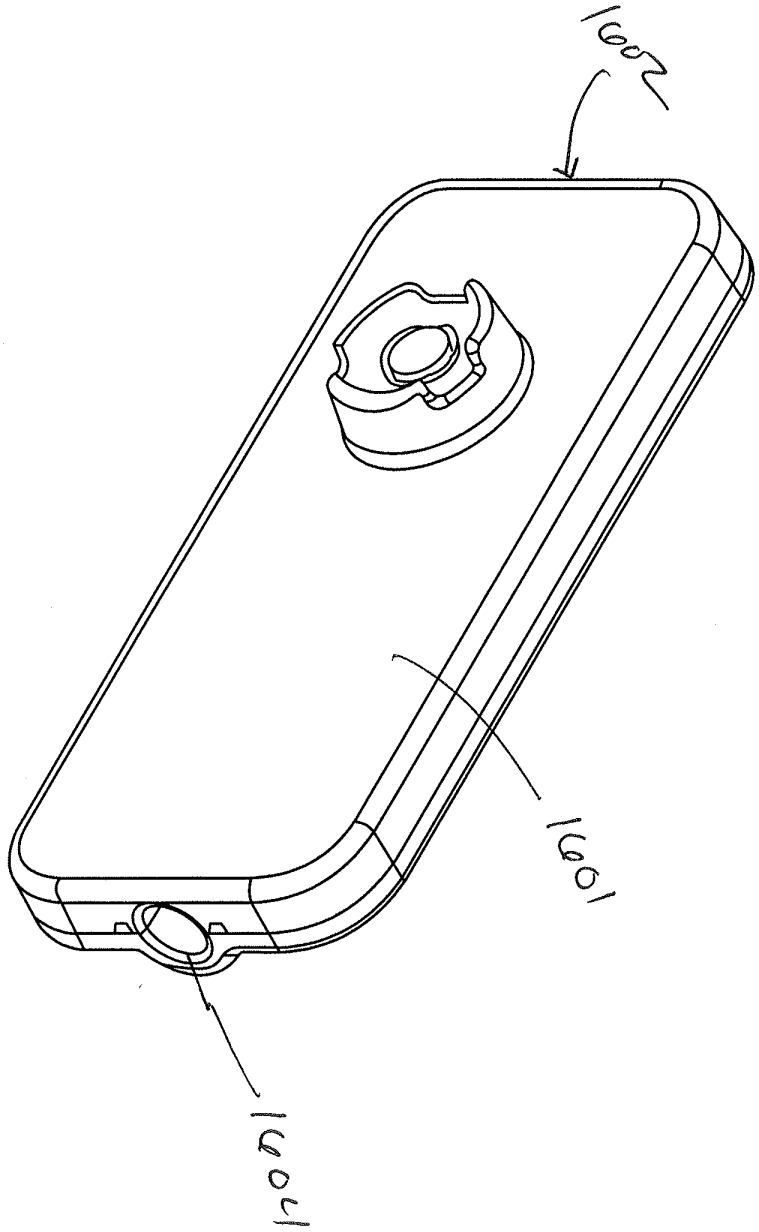


FIG. 16D

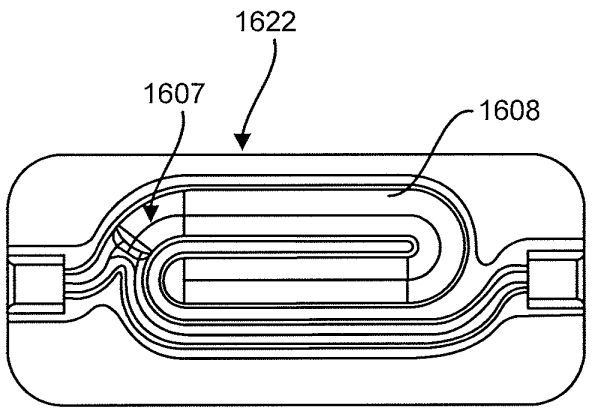


FIG. 17A

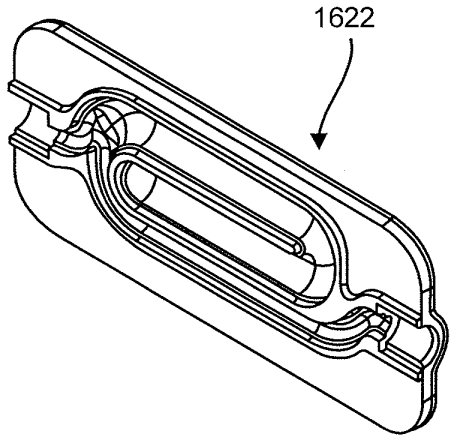


FIG. 17B

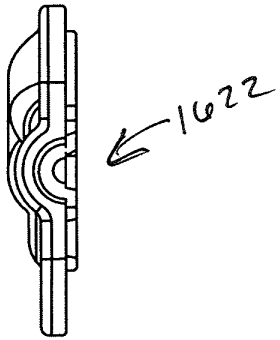


FIG. 17C

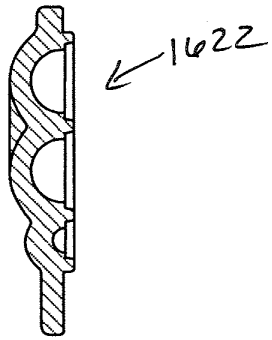


FIG. 17D

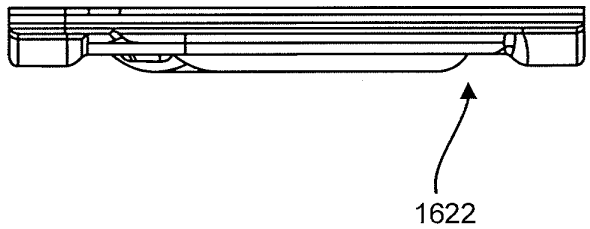


FIG. 17E

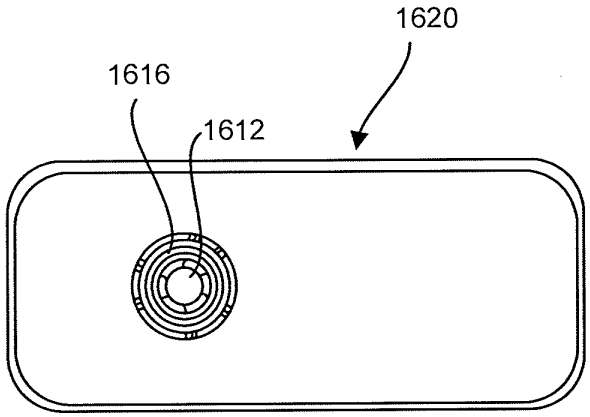


FIG. 18A

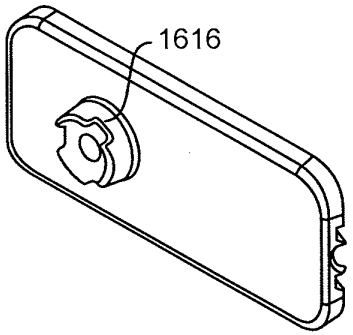


FIG. 18B

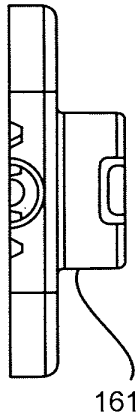


FIG. 18C

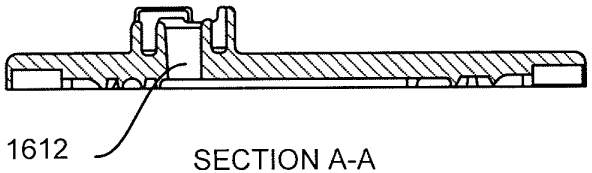


FIG. 18D

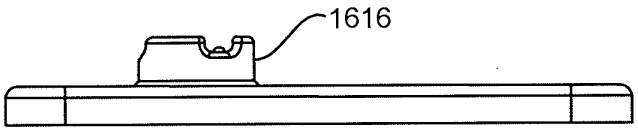


FIG. 18E

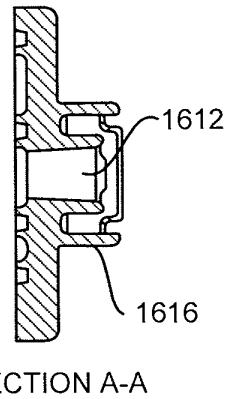


FIG. 18F

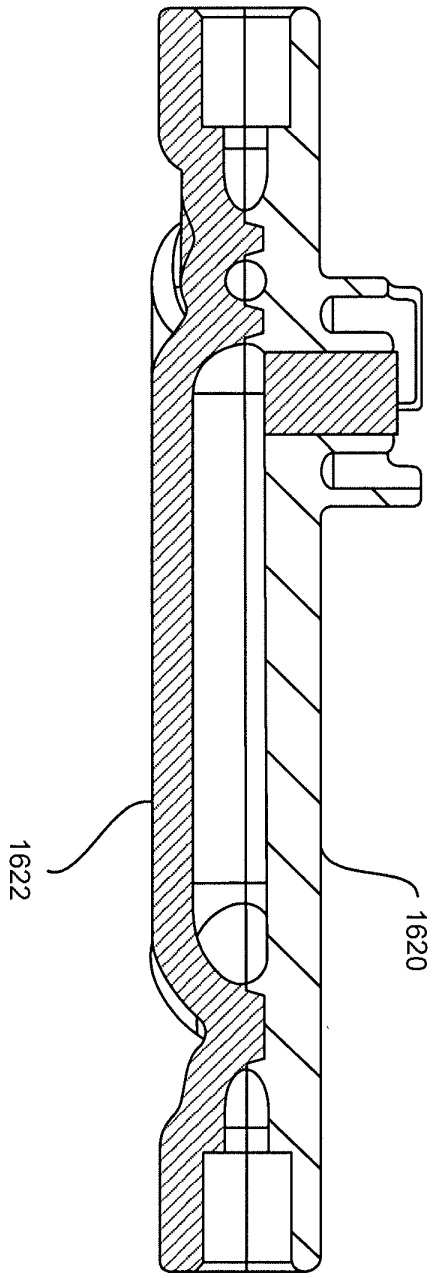


FIG. 19A

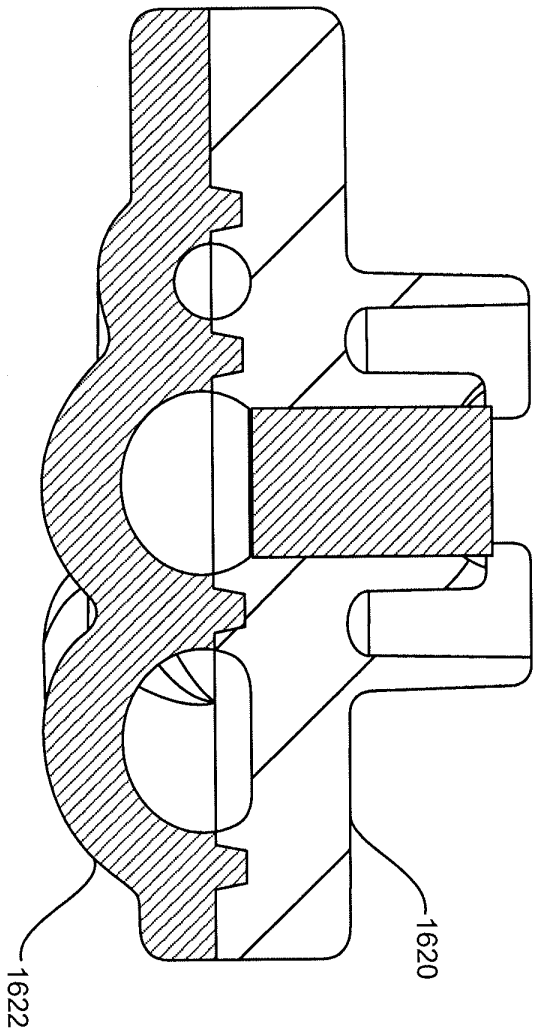


FIG. 19B

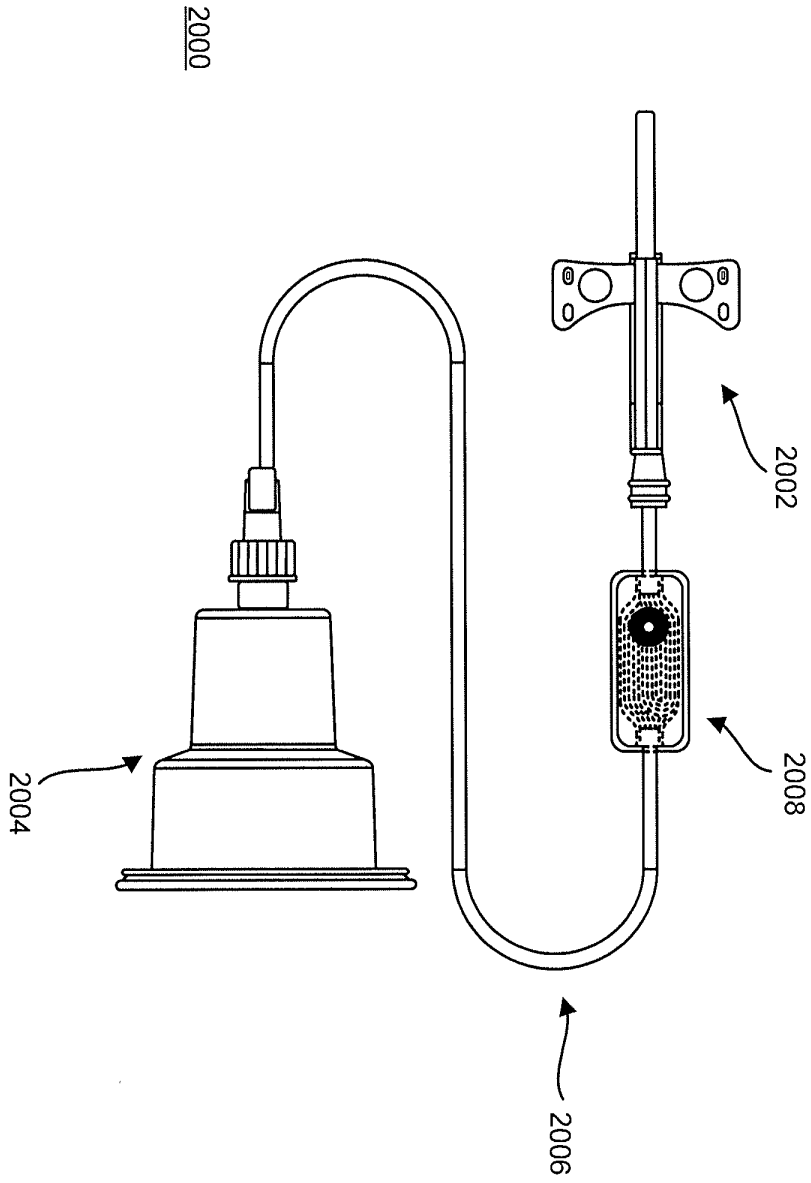


FIG. 20

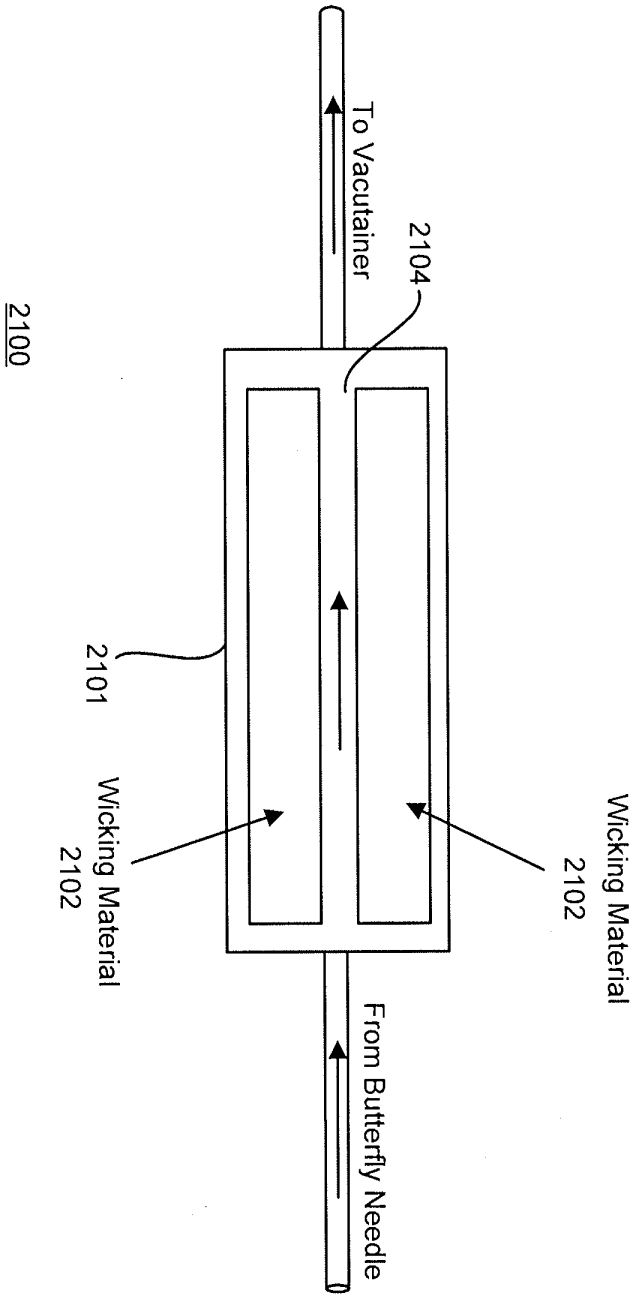

2100
To Vacutainer
2104
2101
Wicking Material
2102
Wicking Material
2102
From Butterfly Needle

FIG. 21

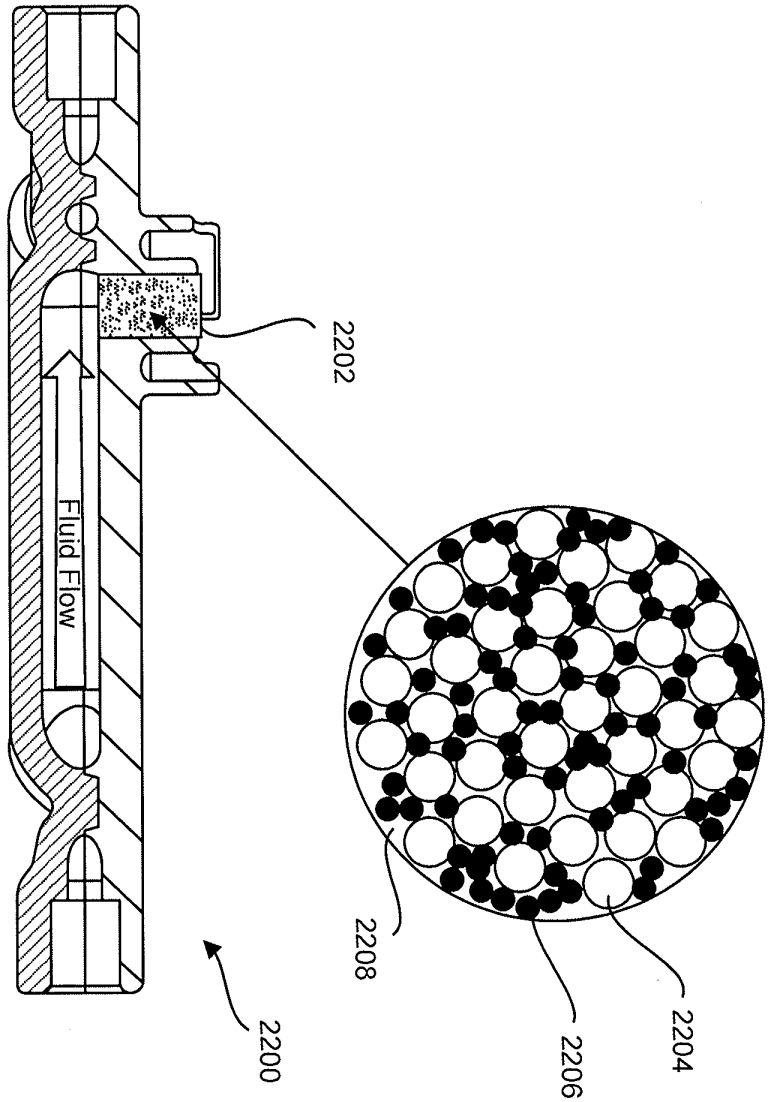


FIG. 22A

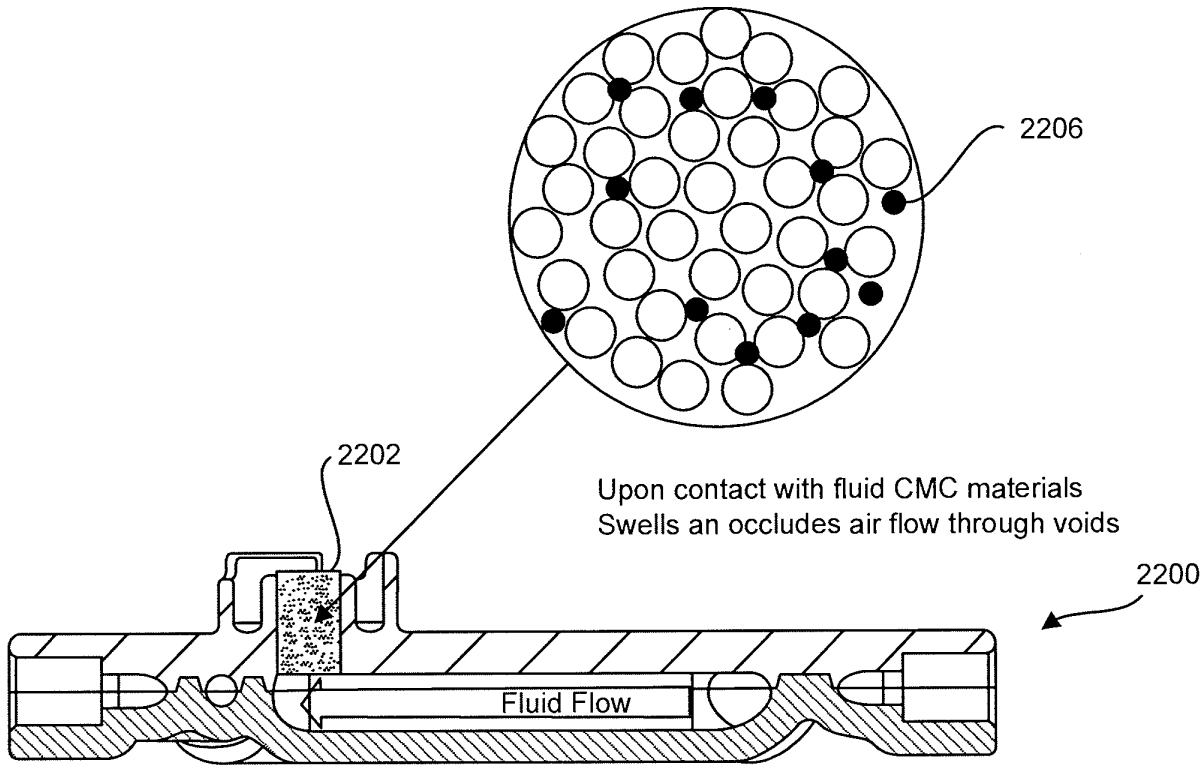

2206
2202
Upon contact with fluid CMC materials
Swells an occludes air flow through voids
2200
Fluid Flow

FIG. 22B

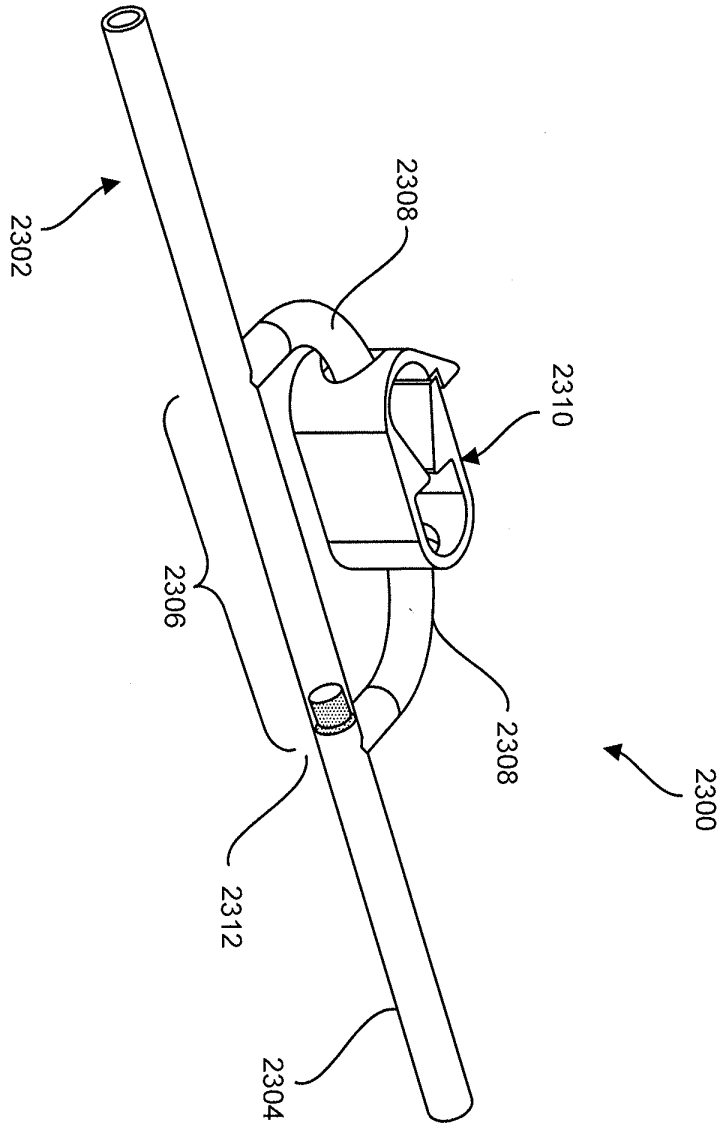


FIG. 23A

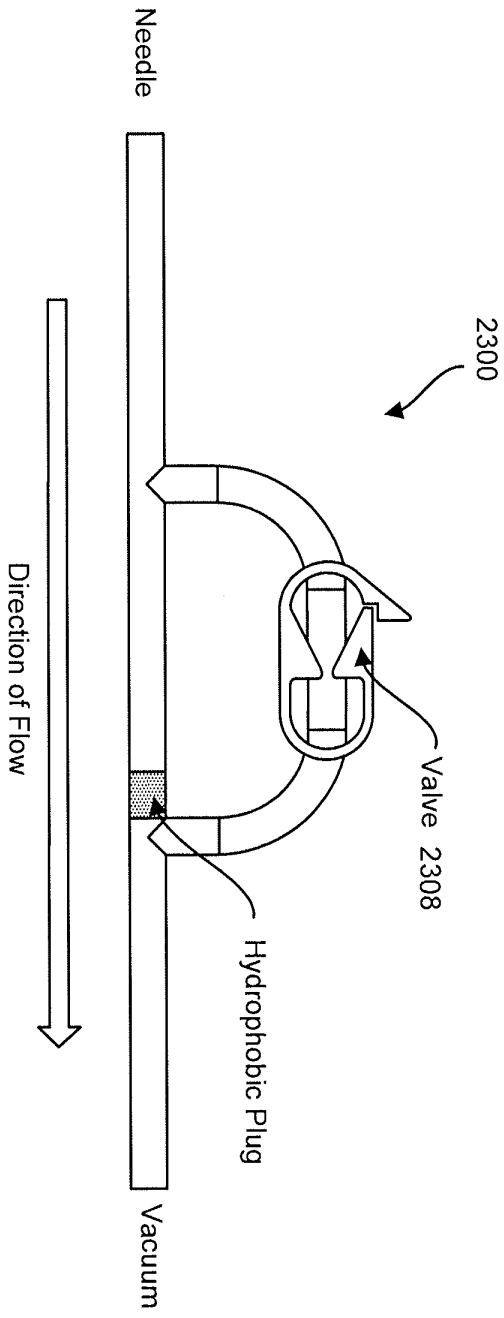

2300
Needle
Valve 2308
Hydrophobic Plug
Vacuum
Direction of Flow

FIG. 23B

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DECLARATION (37 CFR 1.63) FOR UTILITY OR DESIGN APPLICATION USING AN APPLICATION DATA SHEET (37 CFR 1.76)

Title of Invention	BLOOD SAMPLE OPTIMIZATION SYSTEM AND BLOOD CONTAMINANT SEQUESTRATION DEVICE AND METHOD

As the below named inventor, I hereby declare that:

This declaration is directed to:

- ☐ The attached application, or
- ■ United States application or PCT international application number 15/140,448 filed on April 27, 2016.

The above-identified application was made or authorized to be made by me.

I believe that I am the original inventor or an original joint inventor of a claimed invention in the application.

I hereby acknowledge that any willful false statement made in this declaration is punishable under 18 U.S.C. 1001 by fine or imprisonment of not more than five (5) years, or both.

WARNING:

Petitioner/applicant is cautioned to avoid submitting personal information in documents filed in a patent application that may contribute to identity theft. Personal information such as social security numbers, bank account numbers, or credit card numbers (other than a check or credit card authorization form PTO-2038 submitted for payment purposes) is never required by the USPTO to support a petition or an application. If this type of personal information is included in documents submitted to the USPTO, petitioners/applicants should consider redacting such personal information from the documents before submitting them to the USPTO. Petitioner/applicant is advised that the record of a patent application is available to the public after publication of the application (unless a non-publication request in compliance with 37 CFR 1.213(a) is made in the application) or issuance of a patent. Furthermore, the record from an abandoned application may also be available to the public if the application is referenced in a published application or an issued patent (see 37 CFR 1.14). Checks and credit card authorization forms PTO-2038 submitted for payment purposes are not retained in the application file and therefore are not publicly available.

LEGAL NAME OF INVENTOR

Inventor: Bobby E. Rogers Date (Optional): _____

Signature: Bobby E. Rogers

Note: An application data sheet (PTO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form or must have been previously filed. Use an additional PTO/AIA/01 form for each additional inventor.

This collection of information is required by 35 U.S.C. 115 and 37 CFR 1.63. 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 1.11 and 1.14. This collection is estimated to take 1 minute 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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LEGAL NAME OF INVENTOR

Inventor: Gino Kang Date (Optional): 1/22/2018

Signature: _____

Note: An application data sheet (PTO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form or must have been previously filed. Use an additional PTO/AIA/01 form for each additional inventor.

This collection of information is required by 35 U.S.C. 115 and 37 CFR 1.63. 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 1.11 and 1.14. This collection is estimated to take 1 minute 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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- ■ United States application or PCT international application number 15/140,448 filed on April 27, 2016.

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LEGAL NAME OF INVENTOR

Inventor: John Detloff Date (Optional): 1-23-18

Signature: John E. Detloff

Note: An application data sheet (PTO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form or must have been previously filed. Use an additional PTO/AIA/01 form for each additional inventor.

This collection of information is required by 35 U.S.C. 115 and 37 CFR 1.63. 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 1.11 and 1.14. This collection is estimated to take 1 minute 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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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	KURIN2CON3
	Application Number	
Title of Invention	BLOOD SAMPLE OPTIMIZATION SYSTEM AND BLOOD CONTAMINANT SEQUESTRATION DEVICE AND METHOD	

The application data sheet is part of the provisional or nonprovisional application for which it is being submitted. The following form contains the bibliographic data arranged in a format specified by the United States Patent and Trademark Office as outlined in 37 CFR 1.76.
This document may be completed electronically and submitted to the Office in electronic format using the Electronic Filing System (EFS) or the document may be printed and included in a paper filed application.

Secrecy Order 37 CFR 5.2:

☐ Portions or all of the application associated with this Application Data Sheet may fall under a Secrecy Order pursuant to 37 CFR 5.2 (Paper filers only. Applications that fall under Secrecy Order may not be filed electronically.)

Inventor Information:

Inventor 1 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Bobby	E.	Rogers	

Residence Information (Select One) ● US Residency Non US Residency Active US Military Service

City	State/Province	Country of Residence
San Diego	CA	US

Mailing Address of Inventor:

Address 1	10755 Scripps Poway, Parkway No. 257
Address 2	
City	San Diego
State/Province	CA
Postal Code	92131
Country	US

Inventor 2 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Gino		Kang	

Residence Information (Select One) ◉ US Residency Non US Residency Active US Military Service

City	State/Province	Country of Residence
Irvine	CA	US

Mailing Address of Inventor:

Address 1	10755 Scripps Poway, Parkway No. 257
Address 2	
City	San Diego
State/Province	CA
Postal Code	92131
Country	US

Inventor 3 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	John		Detloff	

Residence Information (Select One) ◉ US Residency Non US Residency Active US Military Service

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	KURIN2CON3
	Application Number	
Title of Invention	BLOOD SAMPLE OPTIMIZATION SYSTEM AND BLOOD CONTAMINANT SEQUESTRATION DEVICE AND METHOD	

City	San Diego	State/Province	CA	Country of Residence	US

Mailing Address of Inventor:

Address 1	10755 Scripps Poway, Parkway No. 257		
Address 2			
City	San Diego	**State/Province**	CA
Postal Code	92131	**Country**	US

All Inventors Must Be Listed - Additional Inventor Information blocks may be generated within this form by selecting the **Add** button. Add

Correspondence Information:

Enter either Customer Number or complete the Correspondence Information section below.
For further information see 37 CFR 1.33(a).

☐ **An Address is being provided for the correspondence Information of this application.**

Customer Number	158174		
Email Address		Add Email	Remove Email

Application Information:

Title of the Invention	BLOOD SAMPLE OPTIMIZATION SYSTEM AND BLOOD CONTAMINANT SEQUESTRATION DEVICE AND METHOD		
Attorney Docket Number	KURIN2CON3	**Small Entity Status Claimed**	☒
Application Type	Nonprovisional		
Subject Matter	Utility		
Total Number of Drawing Sheets (if any)		**Suggested Figure for Publication (if any)**	

Filing By Reference:

Only complete this section when filing an application by reference under 35 U.S.C. 111(c) and 37 CFR 1.57(a). Do not complete this section if application papers including a specification and any drawings are being filed. Any domestic benefit or foreign priority information must be provided in the appropriate section(s) below (i.e., "Domestic Benefit/National Stage Information" and "Foreign Priority Information").

For the purposes of a filing date under 37 CFR 1.53(b), the description and any drawings of the present application are replaced by this reference to the previously filed application, subject to conditions and requirements of 37 CFR 1.57(a).

Application number of the previously filed application	Filing date (YYYY-MM-DD)	Intellectual Property Authority or Country

Publication Information:

☐ Request Early Publication (Fee required at time of Request 37 CFR 1.219)

☐ **Request Not to Publish.** I hereby request that the attached application not be published under 35 U.S.C. 122(b) and certify that the invention disclosed in the attached application **has not and will not** be the subject of an application filed in another country, or under a multilateral international agreement, that requires publication at eighteen months after filing.

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	KURIN2CON3
	Application Number	
Title of Invention	BLOOD SAMPLE OPTIMIZATION SYSTEM AND BLOOD CONTAMINANT SEQUESTRATION DEVICE AND METHOD	

Representative Information:

Representative information should be provided for all practitioners having a power of attorney in the application. Providing this information in the Application Data Sheet does not constitute a power of attorney in the application (see 37 CFR 1.32).
Either enter Customer Number or complete the Representative Name section below. If both sections are completed the customer Number will be used for the Representative Information during processing.

Please Select One:	● Customer Number	US Patent Practitioner	◯ Limited Recognition (37 CFR 11.9)
Customer Number	158174		

Domestic Benefit/National Stage Information:

This section allows for the applicant to either claim benefit under 35 U.S.C. 119(e), 120, 121, 365(c), or 386(c) or indicate National Stage entry from a PCT application. Providing benefit claim information in the Application Data Sheet constitutes the specific reference required by 35 U.S.C. 119(e) or 120, and 37 CFR 1.78.
When referring to the current application, please leave the "Application Number" field blank.

Prior Application Status	Pending		Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
	Continuation of	15994559	2018-05-31
Prior Application Status	Patented		Remove

Application Number	Continuity Type	Prior Application Number	Filing Date (YYYY-MM-DD)	Patent Number	Issue Date (YYYY-MM-DD)
15994559	Continuation of	15140448	2016-04-27	10010282	2018-07-03

Prior Application Status	Expired		Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
15140448	Claims benefit of provisional	62318194	2016-04-04
Prior Application Status	Expired		Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
15140448	Claims benefit of provisional	62238636	2015-10-07
Prior Application Status	Expired		Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
15140448	Claims benefit of provisional	62196797	2015-07-24

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	KURIN2CON3
	Application Number	
Title of Invention	BLOOD SAMPLE OPTIMIZATION SYSTEM AND BLOOD CONTAMINANT SEQUESTRATION DEVICE AND METHOD	

Additional Domestic Benefit/National Stage Data may be generated within this form by selecting the **Add** button. Add

Foreign Priority Information:

This section allows for the applicant to claim priority to a foreign application. Providing this information in the application data sheet constitutes the claim for priority as required by 35 U.S.C. 119(b) and 37 CFR 1.55. When priority is claimed to a foreign application that is eligible for retrieval under the priority document exchange program (PDX)[i] the information will be used by the Office to automatically attempt retrieval pursuant to 37 CFR 1.55(i)(1) and (2). Under the PDX program, applicant bears the ultimate responsibility for ensuring that a copy of the foreign application is received by the Office from the participating foreign intellectual property office, or a certified copy of the foreign priority application is filed, within the time period specified in 37 CFR 1.55(g)(1).

Remove

Application Number	Country[i]	Filing Date (YYYY-MM-DD)	Access Code[i] (if applicable)

Additional Foreign Priority Data may be generated within this form by selecting the **Add** button. Add

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications

☐ This application (1) claims priority to or the benefit of an application filed before March 16, 2013 and (2) also contains, or contained at any time, a claim to a claimed invention that has an effective filing date on or after March 16, 2013.
NOTE: By providing this statement under 37 CFR 1.55 or 1.78, this application, with a filing date on or after March 16, 2013, will be examined under the first inventor to file provisions of the AIA.

PTO/AIA/14 (02-18)
Approved for use through 11/30/2020. OMB 0651-0032
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.

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	KURIN2CON3
	Application Number	
Title of Invention	BLOOD SAMPLE OPTIMIZATION SYSTEM AND BLOOD CONTAMINANT SEQUESTRATION DEVICE AND METHOD	

Authorization or Opt-Out of Authorization to Permit Access:

When this Application Data Sheet is properly signed and filed with the application, applicant has provided written authority to permit a participating foreign intellectual property (IP) office access to the instant application-as-filed (see paragraph A in subsection 1 below) and the European Patent Office (EPO) access to any search results from the instant application (see paragraph B in subsection 1 below).

Should applicant choose not to provide an authorization identified in subsection 1 below, applicant **must opt-out** of the authorization by checking the corresponding box A or B or both in subsection 2 below.

NOTE: This section of the Application Data Sheet is **ONLY** reviewed and processed with the **INITIAL** filing of an application. After the initial filing of an application, an Application Data Sheet cannot be used to provide or rescind authorization for access by a foreign IP office(s). Instead, Form PTO/SB/39 or PTO/SB/69 must be used as appropriate.

1. Authorization to Permit Access by a Foreign Intellectual Property Office(s)

A. Priority Document Exchange (PDX) - Unless box A in subsection 2 (opt-out of authorization) is checked, the undersigned hereby **grants the USPTO authority** to provide the European Patent Office (EPO), the Japan Patent Office (JPO), the Korean Intellectual Property Office (KIPO), the State Intellectual Property Office of the People's Republic of China (SIPO), the World Intellectual Property Organization (WIPO), and any other foreign intellectual property office participating with the USPTO in a bilateral or multilateral priority document exchange agreement in which a foreign application claiming priority to the instant patent application is filed, access to: (1) the instant patent application-as-filed and its related bibliographic data, (2) any foreign or domestic application to which priority or benefit is claimed by the instant application and its related bibliographic data, and (3) the date of filing of this Authorization. See 37 CFR 1.14(h)(1).

B. Search Results from U.S. Application to EPO - Unless box B in subsection 2 (opt-out of authorization) is checked, the undersigned hereby **grants the USPTO authority** to provide the EPO access to the bibliographic data and search results from the instant patent application when a European patent application claiming priority to the instant patent application is filed. See 37 CFR 1.14(h)(2).

The applicant is reminded that the EPO's Rule 141(1) EPC (European Patent Convention) requires applicants to submit a copy of search results from the instant application without delay in a European patent application that claims priority to the instant application.

2. Opt-Out of Authorizations to Permit Access by a Foreign Intellectual Property Office(s)

☐ A. Applicant **DOES NOT** authorize the USPTO to permit a participating foreign IP office access to the instant application-as-filed. If this box is checked, the USPTO will not be providing a participating foreign IP office with any documents and information identified in subsection 1A above.

☐ B. Applicant **DOES NOT** authorize the USPTO to transmit to the EPO any search results from the instant patent application. If this box is checked, the USPTO will not be providing the EPO with search results from the instant application.

NOTE: Once the application has published or is otherwise publicly available, the USPTO may provide access to the application in accordance with 37 CFR 1.14.

PTO/AIA/14 (02-18)
Approved for use through 11/30/2020. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	KURIN2CON3
	Application Number	
Title of Invention	BLOOD SAMPLE OPTIMIZATION SYSTEM AND BLOOD CONTAMINANT SEQUESTRATION DEVICE AND METHOD	

Applicant Information:

Providing assignment information in this section does not substitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.

Applicant 1 — Remove

If the applicant is the inventor (or the remaining joint inventor or inventors under 37 CFR 1.45), this section should not be completed. The information to be provided in this section is the name and address of the legal representative who is the applicant under 37 CFR 1.43; or the name and address of the assignee, person to whom the inventor is under an obligation to assign the invention, or person who otherwise shows sufficient proprietary interest in the matter who is the applicant under 37 CFR 1.46. If the applicant is an applicant under 37 CFR 1.46 (assignee, person to whom the inventor is obligated to assign, or person who otherwise shows sufficient proprietary interest) together with one or more joint inventors, then the joint inventor or inventors who are also the applicant should be identified in this section.

Clear

● Assignee	Legal Representative under 35 U.S.C. 117	Joint Inventor
Person to whom the inventor is obligated to assign.	Person who shows sufficient proprietary interest	

If applicant is the legal representative, indicate the authority to file the patent application, the inventor is:

Name of the Deceased or Legally Incapacitated Inventor:

If the Applicant is an Organization check here. ☒

Organization Name	Kurin, Inc.		
Mailing Address Information For Applicant:			
Address 1	10755 Scripps Poway Parkway, No. 257		
Address 2			
City	San Diego	**State/Province**	CA
Country	US	Postal Code	92131
Phone Number		Fax Number	
Email Address			

Additional Applicant Data may be generated within this form by selecting the Add button. Add

Assignee Information including Non-Applicant Assignee Information:

Providing assignment information in this section does not substitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.

PTO/AIA/14 (02-18)
Approved for use through 11/30/2020. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	KURIN2CON3
	Application Number	
Title of Invention	BLOOD SAMPLE OPTIMIZATION SYSTEM AND BLOOD CONTAMINANT SEQUESTRATION DEVICE AND METHOD	

Assignee 1

Complete this section if assignee information, including non-applicant assignee information, is desired to be included on the patent application publication. An assignee-applicant identified in the "Applicant Information" section will appear on the patent application publication as an applicant. For an assignee-applicant, complete this section only if identification as an assignee is also desired on the patent application publication.

Remove

If the Assignee or Non-Applicant Assignee is an Organization check here. ☐

Prefix	**Given Name**	Middle Name	**Family Name**	Suffix

Mailing Address Information For Assignee including Non-Applicant Assignee:

Address 1			
Address 2			
City		**State/Province**	
Country i		Postal Code	
Phone Number		Fax Number	
Email Address			

Additional Assignee or Non-Applicant Assignee Data may be generated within this form by selecting the Add button. Add

Signature:

Remove

NOTE: This Application Data Sheet must be signed in accordance with 37 CFR 1.33(b). **However, if this Application Data Sheet is submitted with the INITIAL filing of the application and either box A or B is not checked in subsection 2 of the "Authorization or Opt-Out of Authorization to Permit Access" section, then this form must also be signed in accordance with 37 CFR 1.14(c).**

This Application Data Sheet **must** be signed by a patent practitioner if one or more of the applicants is a **juristic entity** (e.g., corporation or association). If the applicant is two or more joint inventors, this form must be signed by a patent practitioner, **all** joint inventors who are the applicant, or one or more joint inventor-applicants who have been given power of attorney (e.g., see USPTO Form PTO/AIA/81) on behalf of **all** joint inventor-applicants.

See 37 CFR 1.4(d) for the manner of making signatures and certifications.

Signature	/JSN/			Date (YYYY-MM-DD)	2018-12-03
First Name	James	Last Name	Nolan	Registration Number	53393

Additional Signature may be generated within this form by selecting the Add button. Add

PTO/AIA/14 (02-18)
Approved for use through 11/30/2020. OMB 0651-0032
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.

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	KURIN2CON3
	Application Number	
Title of Invention	BLOOD SAMPLE OPTIMIZATION SYSTEM AND BLOOD CONTAMINANT SEQUESTRATION DEVICE AND METHOD	

This collection of information is required by 37 CFR 1.76. 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 23 minutes to complete, including gathering, preparing, and submitting the completed application data sheet 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.**

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 records.

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 CooperationTreaty.

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.

Electronic Acknowledgement Receipt

EFS ID:	34472416
Application Number:	16208559
International Application Number:	
Confirmation Number:	1020
Title of Invention:	BLOOD SAMPLE OPTIMIZATION SYSTEM AND BLOOD CONTAMINANT SEQUESTRATION DEVICE AND METHOD
First Named Inventor/Applicant Name:	Bobby E. Rogers
Customer Number:	158174
Filer:	James Scott Nolan
Filer Authorized By:	
Attorney Docket Number:	KURIN2CON3
Receipt Date:	04-DEC-2018
Filing Date:	
Time Stamp:	00:49:23
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		KURIN2CON3_Specification.pdf	241758 773e9128839586548 3b6fd965ea468b007e91022	yes	38

	Multipart Description/PDF files in .zip description		
	Document Description	**Start**	**End**
	Specification	1	32
	Claims	33	37
	Abstract	38	38

Warnings:					
Information:					
2	Drawings-only black and white line drawings	KURIN2CON3_Drawings.pdf	773162 39197fab5e3248ee7f3fc9f1fbb0b7f6e1de965f	no	50
Warnings:					
Information:					
3	Oath or Declaration filed	KURIN2CON3_Declaration_15994559.pdf	877513 9b534894ef7b35e5f0746a7ab2ce45962a90fcb9	no	3
Warnings:					
Information:					
4	Application Data Sheet	KURIN2CON3_ADS.pdf	1874312 054ab3e036ff313ef9a842ea6084276adde3c59c	no	9
Warnings:					
Information:					
		Total Files Size (in bytes):	3766745		

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 a 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.

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 NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	TOT CLAIMS	IND CLAIMS
16/208,559	12/04/2018	1629	0.00	KURIN2CON3	26	4

CONFIRMATION NO. 1020

158174
Kurin, Inc.
P.O. Box 371710
San Diego, CA 92137

FILING RECEIPT



Date Mailed: 12/28/2018

Receipt is acknowledged of this non-provisional patent application. The application will be taken up for examination in due course. Applicant will be notified as to the results of the examination. Any correspondence concerning the application must include the following identification information: the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. **If an error is noted on this Filing Receipt, please submit a written request for a Filing Receipt Correction. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections**

Inventor(s)

Bobby E. Rogers, San Diego, CA;
Gino Kang, Irvine, CA;
John Detloff, San Diego, CA;

Applicant(s)

Kurin, Inc., San Diego, CA;

Power of Attorney: None

Domestic Priority data as claimed by applicant

This application is a CON of 15/994,559 05/31/2018 PAT 10143412
which is a CON of 15/140,448 04/27/2016 PAT 10010282
which claims benefit of 62/318,194 04/04/2016
and claims benefit of 62/238,636 10/07/2015
and claims benefit of 62/196,797 07/24/2015

Foreign Applications for which priority is claimed (You may be eligible to benefit from the **Patent Prosecution Highway** program at the USPTO. Please see http://www.uspto.gov for more information.) - None.
Foreign application information must be provided in an Application Data Sheet in order to constitute a claim to foreign priority. See 37 CFR 1.55 and 1.76.

Permission to Access Application via Priority Document Exchange: Yes

Permission to Access Search Results: Yes

Applicant may provide or rescind an authorization for access using Form PTO/SB/39 or Form PTO/SB/69 as appropriate.

If Required, Foreign Filing License Granted: 12/21/2018
The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 16/208,559**
Projected Publication Date: To Be Determined - pending completion of Missing Parts
Non-Publication Request: No
Early Publication Request: No
**** SMALL ENTITY ****
Title

BLOOD SAMPLE OPTIMIZATION SYSTEM AND BLOOD CONTAMINANT SEQUESTRATION DEVICE AND METHOD

Preliminary Class

514

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications: No

PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international application under the Patent Cooperation Treaty (PCT). An international (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process **simplifies** the filing of patent applications on the same invention in member countries, but **does not result** in a grant of "an international patent" and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

Almost every country has its own patent law, and a person desiring a patent in a particular country must make an application for patent in that country in accordance with its particular laws. Since the laws of many countries differ in various respects from the patent law of the United States, applicants are advised to seek guidance from specific foreign countries to ensure that patent rights are not lost prematurely.

Applicants also are advised that in the case of inventions made in the United States, the Director of the USPTO must issue a license before applicants can apply for a patent in a foreign country. The filing of a U.S. patent application serves as a request for a foreign filing license. The application's filing receipt contains further information and guidance as to the status of applicant's license for foreign filing.

Applicants may wish to consult the USPTO booklet, "General Information Concerning Patents" (specifically, the section entitled "Treaties and Foreign Patents") for more information on timeframes and deadlines for filing foreign patent applications. The guide is available either by contacting the USPTO Contact Center at 800-786-9199, or it can be viewed on the USPTO website at http://www.uspto.gov/web/offices/pac/doc/general/index.html.

For information on preventing theft of your intellectual property (patents, trademarks and copyrights), you may wish to consult the U.S. Government website, http://www.stopfakes.gov. Part of a Department of Commerce initiative, this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific

countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4258).

LICENSE FOR FOREIGN FILING UNDER

Title 35, United States Code, Section 184

Title 37, Code of Federal Regulations, 5.11 & 5.15

GRANTED

The applicant has been granted a license under 35 U.S.C. 184, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" followed by a date appears on this form. Such licenses are issued in all applications where the conditions for issuance of a license have been met, regardless of whether or not a license may be required as set forth in 37 CFR 5.15. The scope and limitations of this license are set forth in 37 CFR 5.15(a) unless an earlier license has been issued under 37 CFR 5.15(b). The license is subject to revocation upon written notification. The date indicated is the effective date of the license, unless an earlier license of similar scope has been granted under 37 CFR 5.13 or 5.14.

This license is to be retained by the licensee and may be used at any time on or after the effective date thereof unless it is revoked. This license is automatically transferred to any related applications(s) filed under 37 CFR 1.53(d). This license is not retroactive.

The grant of a license does not in any way lessen the responsibility of a licensee for the security of the subject matter as imposed by any Government contract or the provisions of existing laws relating to espionage and the national security or the export of technical data. Licensees should apprise themselves of current regulations especially with respect to certain countries, of other agencies, particularly the Office of Defense Trade Controls, Department of State (with respect to Arms, Munitions and Implements of War (22 CFR 121-128)); the Bureau of Industry and Security, Department of Commerce (15 CFR parts 730-774); the Office of Foreign AssetsControl, Department of Treasury (31 CFR Parts 500+) and the Department of Energy.

NOT GRANTED

No license under 35 U.S.C. 184 has been granted at this time, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" DOES NOT appear on this form. Applicant may still petition for a license under 37 CFR 5.12, if a license is desired before the expiration of 6 months from the filing date of the application. If 6 months has lapsed from the filing date of this application and the licensee has not received any indication of a secrecy order under 35 U.S.C. 181, the licensee may foreign file the application pursuant to 37 CFR 5.15(b).

SelectUSA

The United States represents the largest, most dynamic marketplace in the world and is an unparalleled location for business investment, innovation, and commercialization of new technologies. The U.S. offers tremendous resources and advantages for those who invest and manufacture goods here. Through SelectUSA, our nation works to promote and facilitate business investment. SelectUSA provides information assistance to the international investor community; serves as an ombudsman for existing and potential investors; advocates on behalf of U.S. cities, states, and regions competing for global investment; and counsels U.S. economic development organizations on investment attraction best practices. To learn more about why the United States is the best country in the world to develop

technology, manufacture products, deliver services, and grow your business, visit http://www.SelectUSA.gov or call +1-202-482-6800.

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 NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
16/208,559	12/04/2018	Bobby E. Rogers	KURIN2CON3

CONFIRMATION NO. 1020

158174
Kurin, Inc.
P.O. Box 371710
San Diego, CA 92137

FORMALITIES LETTER

OC000000104661477

Date Mailed: 12/28/2018

NOTICE TO FILE MISSING PARTS OF NONPROVISIONAL APPLICATION

FILED UNDER 37 CFR 1.53(b)

Filing Date Granted

Items Required To Avoid Abandonment:

An application number and filing date have been accorded to this application. The item(s) indicated below, however, are missing. Applicant is given **TWO MONTHS** from the date of this Notice within which to file all required items below to avoid abandonment. Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a).

- The statutory basic filing fee is missing.
- The application search fee must be submitted.
- The application examination fee must be submitted.
- Additional claim fees of $ **530** as a small entity, including any required multiple dependent claim fee, are required. Applicant must submit the additional claim fees or cancel the additional claims for which fees are due.
- Surcharge as set forth in 37 CFR 1.16(f) must be submitted.
  The surcharge is due for any one of:
  - late submission of the basic filing fee, search fee, or examination fee,
  - late submission of inventor's oath or declaration,
  - filing an application that does not contain at least one claim on filing, or
  - submission of an application filed by reference to a previously filed application.

SUMMARY OF FEES DUE:

The fee(s) required within **TWO MONTHS** from the date of this Notice to avoid abandonment is/are itemized below. Small entity discount is in effect. If applicant is qualified for micro entity status, an acceptable Certification of Micro Entity Status must be submitted to establish micro entity status. (See 37 CFR 1.29 and forms PTO/SB/15A and 15B.)

- $ **75** basic filing fee.
- $ **80** surcharge.
- $ **330** search fee.
- $ **380** examination fee.
- $ **230** for **1** independent claims over 3.
- $ **300** for **6** total claims over 20.

- $(**0**) previous unapplied payment amount.
- $ **1395** TOTAL FEE BALANCE DUE.

Items Required To Avoid Processing Delays:

Applicant is notified that the above-identified application contains the deficiencies noted below. No period for reply is set forth in this notice for correction of these deficiencies. However, if a deficiency relates to the inventor's oath or declaration, the applicant must file an oath or declaration in compliance with 37 CFR 1.63, or a substitute statement in compliance with 37 CFR 1.64, executed by or with respect to each actual inventor no later than the expiration of the time period set in the "Notice of Allowability" to avoid abandonment. See 37 CFR 1.53(f).

- A properly executed inventor's oath or declaration has not been received for the following inventor(s):
  Bobby E. Rogers
  Gino Kang
  John Detloff

Replies must be received in the USPTO within the set time period or must include a proper Certificate of Mailing or Transmission under 37 CFR 1.8 with a mailing or transmission date within the set time period. For more information and a suggested format, see Form PTO/SB/92 and MPEP 512.

Replies should be mailed to:

Mail Stop Missing Parts
Commissioner for Patents
P.O. Box 1450
Alexandria VA 22313-1450

Registered users of EFS-Web may alternatively submit their reply to this notice via EFS-Web, including a copy of this Notice and selecting the document description "Applicant response to Pre-Exam Formalities Notice". https://sportal.uspto.gov/authenticate/AuthenticateUserLocalEPF.html

For more information about EFS-Web please call the USPTO Electronic Business Center at 1-866-217-9197 or visit our website at http://www.uspto.gov/ebc.

If you are not using EFS-Web to submit your reply, you must include a copy of this notice.

Questions about the contents of this notice and the requirements it sets forth should be directed to the Office of Data Management, Application Assistance Unit, at **(571) 272-4000** or **(571) 272-4200** or **1-888-786-0101**.

/lphan/

PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number: 16/208,559

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY FEE($)
BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	75		N/A	
SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A	330		N/A	
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	380		N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	26 minus 20 =	* 6	x 50 =	300	OR		
INDEPENDENT CLAIMS (37 CFR 1.16(h))	4 minus 3 =	* 1	x 230 =	230			
APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).			0.00			
MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))				0.00			
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL	1315		TOTAL	

APPLICATION AS AMENDED - PART II

AMENDMENT A

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY ADDITIONAL FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE($)
Total (37 CFR 1.16(i))	*	Minus	**	=	x =		OR	x =	
Independent (37 CFR 1.16(h))	*	Minus	***	=	x =		OR	x =	
Application Size Fee (37 CFR 1.16(s))									
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
					TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

AMENDMENT B

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE($)	ADDITIONAL FEE($)		RATE($)	ADDITIONAL FEE($)
Total (37 CFR 1.16(i))	*	Minus	**	=	x =		OR	x =	
Independent (37 CFR 1.16(h))	*	Minus	***	=	x =		OR	x =	
Application Size Fee (37 CFR 1.16(s))									
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
					TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".
The "Highest Number Previously Paid For" (Total or Independent) is the highest found in the appropriate box in column 1.

To: docketing@intelligentclicks.net,jsnolan1@hotmail.com,eofficeaction@appcoll.com
From: PAIR_eOfficeAction@uspto.gov
Cc: PAIR_eOfficeAction@uspto.gov
Subject: Private PAIR Correspondence Notification for Customer Number 158174

Dec 29, 2018 06:49:01 AM

Dear PAIR Customer:

Kurin, Inc.
P.O. Box 371710
San Diego, CA 92137
UNITED STATES

The following USPTO patent application(s) associated with your Customer Number, 158174 , have new outgoing correspondence. This correspondence is now available for viewing in Private PAIR.

The official date of notification of the outgoing correspondence will be indicated on the form PTOL-90 accompanying the correspondence.

Disclaimer:
The list of documents shown below is provided as a courtesy and is not part of the official file wrapper. The content of the images shown in PAIR is the official record.

Application	Document	Mailroom Date	Attorney Docket No.
16208559	APP.FILE.REC	12/28/2018	KURIN2CON3

To view your correspondence online or update your email addresses, please visit us anytime at https://sportal.uspto.gov/secure/myportal/privatepair.

If you have any questions, please email the Electronic Business Center (EBC) at EBC@uspto.gov with 'e-Office Action' on the subject line or call 1-866-217-9197 during the following hours:

Monday - Friday 6:00 a.m. to 12:00 a.m.

Thank you for prompt attention to this notice,

UNITED STATES PATENT AND TRADEMARK OFFICE

PATENT APPLICATION INFORMATION RETRIEVAL SYSTEM

To: docketing@intelligentclicks.net,jsnolan1@hotmail.com,eofficeaction@appcoll.com
From: PAIR_eOfficeAction@uspto.gov
Cc: PAIR_eOfficeAction@uspto.gov
Subject: Private PAIR Correspondence Notification for Customer Number 158174

Dec 31, 2018 03:27:40 AM

Dear PAIR Customer:

Kurin, Inc.
P.O. Box 371710
San Diego, CA 92137
UNITED STATES

The following USPTO patent application(s) associated with your Customer Number, 158174 , have new outgoing correspondence. This correspondence is now available for viewing in Private PAIR.

The official date of notification of the outgoing correspondence will be indicated on the form PTOL-90 accompanying the correspondence.

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Application	Document	Mailroom Date	Attorney Docket No.
16208559	NTC.MISS.PRT	12/28/2018	KURIN2CON3

To view your correspondence online or update your email addresses, please visit us anytime at https://sportal.uspto.gov/secure/myportal/privatepair.

If you have any questions, please email the Electronic Business Center (EBC) at EBC@uspto.gov with 'e-Office Action' on the subject line or call 1-866-217-9197 during the following hours:

Monday - Friday 6:00 a.m. to 12:00 a.m.

Thank you for prompt attention to this notice,

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PATENT APPLICATION INFORMATION RETRIEVAL SYSTEM

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ALEXANDRIA VA 22313-1451

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Kurin, Inc.
P.O. Box 371710
San Diego, CA 92137

Courtesy Reminder for
Application Serial No: 16/208,559

Attorney Docket No: KURIN2CON3
Customer Number: 158174
Date of Electronic Notification: 12/31/2018

This is a courtesy reminder that new correspondence is available for this application. If you have not done so already, please review the correspondence. The official date of notification of the outgoing correspondence will be indicated on the form PTOL-90 accompanying the correspondence.

An email notification regarding the correspondence was sent to the following email address(es) associated with your customer number:

docketing@intelligentclicks.net
jsnolan1@hotmail.com
eofficeaction@appcoll.com

To view your correspondence online or update your email addresses, please visit us anytime at **https://sportal.uspto.gov/secure/myportal/privatepair.** If you have any questions, please email the Electronic Business Center (EBC) at EBC@uspto.gov or call 1-866-217-9197.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): **Bobby E. Rogers**	Group Art Unit: **1629**
Application Serial No.: **16/208,559**	Examiner: **Not Yet Assigned**
Filed: **June 16, 2016**	Conf. No.: **1020**
Title: **BLOOD SAMPLE OPTIMIZATION SYSTEM AND BLOOD CONTAMINANT SEQUESTRATION DEVICE AND METHOD**	

RESPONSE TO NOTICE TO FILE MISSING PARTS

Mail Stop
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Commissioner:

This Response is filed in response to the Notice to File Missing Parts dated December 28, 2018, the Notice indicates that a properly executed inventor's oath or declaration has not been received in the above-referenced patent application for the following inventors:

- Bobby E. Rogers
- Gino Kan
- John Detloff

Applicant would like to bring attention that Applicant has submitted to the USPTO the Declarations executed by all inventors referenced above from the earlier-filed patent application number 15/140,448 with filing date of April 27, 2016, now patented, patent no. 10,010,282. Applicant hereby attached the acknowledgment receipt and declarations that were submitted.

Respectfully Submitted;

Dated: February 14, 2019

/JSN/
James S. Nolan
Reg. No. 53393

James S. Nolan
P.O. Box 371710
San Diego CA 92137

PTO/AIA/01 (08-12)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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DECLARATION (37 CFR 1.63) FOR UTILITY OR DESIGN APPLICATION USING AN APPLICATION DATA SHEET (37 CFR 1.76)

Title of Invention	BLOOD SAMPLE OPTIMIZATION SYSTEM AND BLOOD CONTAMINANT SEQUESTRATION DEVICE AND METHOD

As the below named inventor, I hereby declare that:

This declaration is directed to:

- ☐ The attached application, or
- ■ United States application or PCT international application number 15/140,448 filed on April 27, 2016.

The above-identified application was made or authorized to be made by me.

I believe that I am the original inventor or an original joint inventor of a claimed invention in the application.

I hereby acknowledge that any willful false statement made in this declaration is punishable under 18 U.S.C. 1001 by fine or imprisonment of not more than five (5) years, or both.

WARNING:

Petitioner/applicant is cautioned to avoid submitting personal information in documents filed in a patent application that may contribute to identity theft. Personal information such as social security numbers, bank account numbers, or credit card numbers (other than a check or credit card authorization form PTO-2038 submitted for payment purposes) is never required by the USPTO to support a petition or an application. If this type of personal information is included in documents submitted to the USPTO, petitioners/applicants should consider redacting such personal information from the documents before submitting them to the USPTO. Petitioner/applicant is advised that the record of a patent application is available to the public after publication of the application (unless a non-publication request in compliance with 37 CFR 1.213(a) is made in the application) or issuance of a patent. Furthermore, the record from an abandoned application may also be available to the public if the application is referenced in a published application or an issued patent (see 37 CFR 1.14). Checks and credit card authorization forms PTO-2038 submitted for payment purposes are not retained in the application file and therefore are not publicly available.

LEGAL NAME OF INVENTOR

Inventor: Bobby E. Rogers Date (Optional): _____

Signature: Bobby E. Rogers

Note: An application data sheet (PTO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form or must have been previously filed. Use an additional PTO/AIA/01 form for each additional inventor.

This collection of information is required by 35 U.S.C. 115 and 37 CFR 1.63. 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 1.11 and 1.14. This collection is estimated to take 1 minute 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.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 3.

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DECLARATION (37 CFR 1.63) FOR UTILITY OR DESIGN APPLICATION USING AN APPLICATION DATA SHEET (37 CFR 1.76)

Title of invention	BLOOD SAMPLE OPTIMIZATION SYSTEM AND BLOOD CONTAMINANT SEQUESTRATION DEVICE AND METHOD

As the below named inventor, I hereby declare that:

This declaration is directed to:

- ☐ The attached application, or
- ■ United States application or PCT international application number 15/140,448 filed on April 27, 2016.

The above-identified application was made or authorized to be made by me.

I believe that I am the original inventor or an original joint inventor of a claimed invention in the application.

I hereby acknowledge that any willful false statement made in this declaration is punishable under 18 U.S.C. 1001 by fine or imprisonment of not more than five (5) years, or both.

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LEGAL NAME OF INVENTOR

Inventor: Gino Kang Date (Optional): 1/22/2018

Signature: _____

Note: An application data sheet (PTO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form or must have been previously filed. Use an additional PTO/AIA/01 form for each additional inventor.

This collection of information is required by 35 U.S.C. 115 and 37 CFR 1.63. 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 1.11 and 1.14. This collection is estimated to take 1 minute 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.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

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This declaration is directed to:

- ☐ The attached application, or
- ■ United States application or PCT international application number 15/140,448 filed on April 27, 2016.

The above-identified application was made or authorized to be made by me.

I believe that I am the original inventor or an original joint inventor of a claimed invention in the application.

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LEGAL NAME OF INVENTOR

Inventor: John Detloff Date (Optional): 1-23-18

Signature: John E. Detloff

Note: An application data sheet (PTO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form or must have been previously filed. Use an additional PTO/AIA/01 form for each additional inventor.

This collection of information is required by 35 U.S.C. 115 and 37 CFR 1.63. 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 1.11 and 1.14. This collection is estimated to take 1 minute 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.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Electronic Acknowledgement Receipt

EFS ID:	34472416
Application Number:	16208559
International Application Number:	
Confirmation Number:	1020
Title of Invention:	BLOOD SAMPLE OPTIMIZATION SYSTEM AND BLOOD CONTAMINANT SEQUESTRATION DEVICE AND METHOD
First Named Inventor/Applicant Name:	Bobby E. Rogers
Customer Number:	158174
Filer:	James Scott Nolan
Filer Authorized By:	
Attorney Docket Number:	KURIN2CON3
Receipt Date:	04-DEC-2018
Filing Date:	
Time Stamp:	00:49:23
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1		KURIN2CON3_Specification.pdf	241758 773e9128839586548 3b6fd965ea468b007e91022	yes	38

	Multipart Description/PDF files in .zip description				
	Document Description	**Start**	**End**		
	Specification	1	32		
	Claims	33	37		
	Abstract	38	38		
Warnings:					
Information:					
2	Drawings-only black and white line drawings	KURIN2CON3_Drawings.pdf	773162 39197fab5e3248ee7f3fc9f1fbb0b7f6e1de965f	no	50
Warnings:					
Information:					
3	Oath or Declaration filed	KURIN2CON3_Declaration_15994559.pdf	877513 9b534894ef7b35e5f0746a7ab2ce45962a90fcb9	no	3
Warnings:					
Information:					
4	Application Data Sheet	KURIN2CON3_ADS.pdf	1874312 054ab3e036ff313ef9a842ea6084276adde3c59c	no	9
Warnings:					
Information:					
		Total Files Size (in bytes):	3766745		

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 a 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.

PTO/AIA/80 (07-17)
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POWER OF ATTORNEY TO PROSECUTE APPLICATIONS BEFORE THE USPTO

I hereby revoke all previous powers of attorney given in the application identified in the attached statement under 37 CFR 3.73(c).

I hereby appoint:

[X] Practitioners associated with Customer Number: 158174

OR

[ ] Practitioner(s) named below (if more than ten patent practitioners are to be named, then a customer number must be used):

Name	Registration Number	Name	Registration Number

As attorney(s) or agent(s) to represent the undersigned before the United States Patent and Trademark Office (USPTO) in connection with any and all patent applications assigned only to the undersigned according to the USPTO assignment records or assignment documents attached to this form in accordance with 37 CFR 3.73(c).

Please change the correspondence address for the application identified in the attached statement under 37 CFR 3.73(c) to:

[X] The address associated with Customer Number: 158174

OR

[ ]

Firm or individual name		
Address		
City	State	Zip
Country		
Telephone	Email	

Assignee name and address: KURIN, INC.
10755 SCRIPPS POWAY PARKWAY NO. 257
SAN DIEGO, CALIFORNIA 92131

A copy of this form, together with a statement under 37 CFR 3.73(c) (Form PTO/AIA/96 or equivalent) is required to be filed in each application in which this form is used. The statement under 37 CFR 3.73(c) may be completed by one of the practitioners appointed in this form, and must identify the application in which this Power of Attorney is to be filed.

SIGNATURE of Assignee of Record

The individual whose signature and title is supplied below is authorized to act on behalf of the assignee.

Signature Bob Rogers	Date 10/15/2018
Name Bob Rogers	Telephone
Title Founder, CEO	

This collection of information is required by 37 CFR 1.31, 1.32, and 1.33. The information is required to obtain or retain a benefit by the public, which is to update (and by the USPTO to process) the file of a patent or reexamination proceeding. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 18 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, 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.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

PTO/AIA/96 (08-12)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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STATEMENT UNDER 37 CFR 3.73(c)

Applicant/Patent Owner: KURIN, INC.

Application No./Patent No.: 16208559 Filed/Issue Date: 12-04-2018

Titled: BLOOD SAMPLE OPTIMIZATION SYSTEM AND BLOOD CONTAMINANT SEQUESTRATION DEVICE AND METHOD

KURIN, INC., a Corporation

(Name of Assignee) (Type of Assignee, e.g., corporation, partnership, university, government agency, etc.)

states that, for the patent application/patent identified above, it is (choose **one** of options 1, 2, 3 or 4 below):

1. ☑ The assignee of the entire right, title, and interest.

2. ☐ An assignee of less than the entire right, title, and interest (check applicable box):

   ☐ The extent (by percentage) of its ownership interest is _____%. Additional Statement(s) by the owners holding the balance of the interest must be submitted to account for 100% of the ownership interest.

   ☐ There are unspecified percentages of ownership. The other parties, including inventors, who together own the entire right, title and interest are:

   Additional Statement(s) by the owner(s) holding the balance of the interest must be submitted to account for the entire right, title, and interest.

3. ☐ The assignee of an undivided interest in the entirety (a complete assignment from one of the joint inventors was made). The other parties, including inventors, who together own the entire right, title, and interest are:

   Additional Statement(s) by the owner(s) holding the balance of the interest must be submitted to account for the entire right, title, and interest.

4. ☐ The recipient, via a court proceeding or the like (*e.g.*, bankruptcy, probate), of an undivided interest in the entirety (a complete transfer of ownership interest was made). The certified document(s) showing the transfer is attached.

The interest identified in option 1, 2 or 3 above (not option 4) is evidenced by either (choose **one** of options A or B below):

A. ☑ An assignment from the inventor(s) of the patent application/patent identified above. The assignment was recorded in the United States Patent and Trademark Office at Reel 047978, Frame 0906, or for which a copy thereof is attached.

B. ☐ A chain of title from the inventor(s), of the patent application/patent identified above, to the current assignee as follows:

   1. From: _____ To: _____

      The document was recorded in the United States Patent and Trademark Office at

      Reel _____, Frame _____, or for which a copy thereof is attached.

   2. From: _____ To: _____

      The document was recorded in the United States Patent and Trademark Office at

      Reel _____, Frame _____, or for which a copy thereof is attached.

This collection of information is required by 37 CFR 3.73(b). 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 1.11 and 1.14. This collection is estimated to take 12 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, 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**.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

PTO/AIA/96 (08-12)
Approved for use through 01/31/2013. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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STATEMENT UNDER 37 CFR 3.73(c)

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☐ Additional documents in the chain of title are listed on a supplemental sheet(s).

☑ As required by 37 CFR 3.73(c)(1)(i), the documentary evidence of the chain of title from the original owner to the assignee was, or concurrently is being, submitted for recordation pursuant to 37 CFR 3.11.

[NOTE: A separate copy (i.e., a true copy of the original assignment document(s)) must be submitted to Assignment Division in accordance with 37 CFR Part 3, to record the assignment in the records of the USPTO. See MPEP 302.08]

The undersigned (whose title is supplied below) is authorized to act on behalf of the assignee.

/JSN/	02/14/2019
Signature	Date
James Nolan	53393
Printed or Typed Name	Title or Registration Number

[Page 2 of 2]

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.
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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)).
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.

Electronic Patent Application Fee Transmittal

Application Number:	16208559
Filing Date:	04-Dec-2018
Title of Invention:	BLOOD SAMPLE OPTIMIZATION SYSTEM AND BLOOD CONTAMINANT SEQUESTRATION DEVICE AND METHOD
First Named Inventor/Applicant Name:	Bobby E. Rogers
Filer:	James Scott Nolan/KETHYA TEUK
Attorney Docket Number:	KURIN2CON3

Filed as Small Entity

Filing Fees for Utility under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
UTILITY FILING FEE (ELECTRONIC FILING)	4011	1	75	75
UTILITY SEARCH FEE	2111	1	330	330
UTILITY EXAMINATION FEE	2311	1	380	380
Pages:				
Claims:				
CLAIMS IN EXCESS OF 20	2202	6	50	300
INDEPENDENT CLAIMS IN EXCESS OF 3	2201	1	230	230
Miscellaneous-Filing:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
LATE FILING FEE FOR OATH OR DECLARATION	2051	1	80	80
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Miscellaneous:				
		Total in USD ($)		**1395**

Electronic Acknowledgement Receipt	
EFS ID:	35155513
Application Number:	16208559
International Application Number:	
Confirmation Number:	1020
Title of Invention:	BLOOD SAMPLE OPTIMIZATION SYSTEM AND BLOOD CONTAMINANT SEQUESTRATION DEVICE AND METHOD
First Named Inventor/Applicant Name:	Bobby E. Rogers
Customer Number:	158174
Filer:	James Scott Nolan/KETHYA TEUK
Filer Authorized By:	James Scott Nolan
Attorney Docket Number:	KURIN2CON3
Receipt Date:	14-FEB-2019
Filing Date:	04-DEC-2018
Time Stamp:	16:46:48
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	$1395
RAM confirmation Number	021519INTEFSW16480501
Deposit Account	
Authorized User	
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Applicant Response to Pre-Exam Formalities Notice	KURIN2CON3_Response_NMP.pdf	54032 97f24e341406993de28b43c4c47fdbc4f906dcf3	no	2
Warnings:					
Information:					
2	Oath or Declaration filed	KURIN2CON3_Ack_Declaration1620855.pdf	928982 23d203326de7eb879834ae77a24953a0f5b8144b	no	6
Warnings:					
Information:					
3	Power of Attorney	GeneralPOAExecutedBobRogers.pdf	127696 4206860da74472c9db3b6a79e16d7c8638a0aeab	no	1
Warnings:					
Information:					
4	Assignee showing of ownership per 37 CFR 3.73	KURIN2CON_373c_Statement.pdf	117738 0243fceaaa79f2c26db43724769a6e95c97d25b9	no	3
Warnings:					
Information:					
5	Fee Worksheet (SB06)	fee-info.pdf	40444 2168829e6eca2a7d81ef11cb79edde6e896fa788	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	1268892		

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 a 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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Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NUMBER	FILING or 371(c) DATE	GRP ART UNIT	FIL FEE REC'D	ATTY.DOCKET.NO	TOT CLAIMS	IND CLAIMS
16/208,559	12/04/2018	1629	1395	KURIN2CON3	26	4

CONFIRMATION NO. 1020

UPDATED FILING RECEIPT

158174
Kurin, Inc.
P.O. Box 371710
San Diego, CA 92137

OC000000105982576

Date Mailed: 02/20/2019

Receipt is acknowledged of this non-provisional patent application. The application will be taken up for examination in due course. Applicant will be notified as to the results of the examination. Any correspondence concerning the application must include the following identification information: the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. **If an error is noted on this Filing Receipt, please submit a written request for a Filing Receipt Correction. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections**

Inventor(s)

Bobby E. Rogers, San Diego, CA;
Gino Kang, Irvine, CA;
John Detloff, San Diego, CA;

Applicant(s)

Kurin, Inc., San Diego, CA;

Power of Attorney: The patent practitioners associated with Customer Number 158174

Domestic Priority data as claimed by applicant

This application is a CON of 15/994,559 05/31/2018 PAT 10143412
which is a CON of 15/140,448 04/27/2016 PAT 10010282
which claims benefit of 62/318,194 04/04/2016
and claims benefit of 62/238,636 10/07/2015
and claims benefit of 62/196,797 07/24/2015

Foreign Applications for which priority is claimed (You may be eligible to benefit from the **Patent Prosecution Highway** program at the USPTO. Please see http://www.uspto.gov for more information.) - None.
Foreign application information must be provided in an Application Data Sheet in order to constitute a claim to foreign priority. See 37 CFR 1.55 and 1.76.

Permission to Access Application via Priority Document Exchange: Yes

Permission to Access Search Results: Yes

Applicant may provide or rescind an authorization for access using Form PTO/SB/39 or Form PTO/SB/69 as appropriate.

If Required, Foreign Filing License Granted: 12/21/2018
The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 16/208,559**
Projected Publication Date: 05/30/2019
Non-Publication Request: No
Early Publication Request: No
**** SMALL ENTITY ****
Title

BLOOD SAMPLE OPTIMIZATION SYSTEM AND BLOOD CONTAMINANT SEQUESTRATION DEVICE AND METHOD

Preliminary Class

514

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications: No

PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international application under the Patent Cooperation Treaty (PCT). An international (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process **simplifies** the filing of patent applications on the same invention in member countries, but **does not result** in a grant of "an international patent" and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

Almost every country has its own patent law, and a person desiring a patent in a particular country must make an application for patent in that country in accordance with its particular laws. Since the laws of many countries differ in various respects from the patent law of the United States, applicants are advised to seek guidance from specific foreign countries to ensure that patent rights are not lost prematurely.

Applicants also are advised that in the case of inventions made in the United States, the Director of the USPTO must issue a license before applicants can apply for a patent in a foreign country. The filing of a U.S. patent application serves as a request for a foreign filing license. The application's filing receipt contains further information and guidance as to the status of applicant's license for foreign filing.

Applicants may wish to consult the USPTO booklet, "General Information Concerning Patents" (specifically, the section entitled "Treaties and Foreign Patents") for more information on timeframes and deadlines for filing foreign patent applications. The guide is available either by contacting the USPTO Contact Center at 800-786-9199, or it can be viewed on the USPTO website at http://www.uspto.gov/web/offices/pac/doc/general/index.html.

For information on preventing theft of your intellectual property (patents, trademarks and copyrights), you may wish to consult the U.S. Government website, http://www.stopfakes.gov. Part of a Department of Commerce initiative, this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific

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Title 35, United States Code, Section 184

Title 37, Code of Federal Regulations, 5.11 & 5.15

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PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number: 16/208,559

APPLICATION AS FILED - PART I

FOR	(Column 1) NUMBER FILED	(Column 2) NUMBER EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY FEE($)
BASIC FEE (37 CFR 1.16(a), (b), or (c))	N/A	N/A	N/A	75		N/A	
SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A	330		N/A	
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A	380		N/A	
TOTAL CLAIMS (37 CFR 1.16(i))	26 minus 20 =	* 6	x 50 =	300	OR		
INDEPENDENT CLAIMS (37 CFR 1.16(h))	4 minus 3 =	* 1	x 230 =	230			
APPLICATION SIZE FEE (37 CFR 1.16(s))	If the specification and drawings exceed 100 sheets of paper, the application size fee due is $310 ($155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).			0.00			
MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))				0.00			
* If the difference in column 1 is less than zero, enter "0" in column 2.			TOTAL	1315		TOTAL	

APPLICATION AS AMENDED - PART II

AMENDMENT A

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	SMALL ENTITY RATE($)	SMALL ENTITY ADDITIONAL FEE($)	OR	OTHER THAN SMALL ENTITY RATE($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE($)
Total (37 CFR 1.16(i))	*	Minus	**	=	x =		OR	x =	
Independent (37 CFR 1.16(h))	*	Minus	***	=	x =		OR	x =	
Application Size Fee (37 CFR 1.16(s))									
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
					TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

AMENDMENT B

	(Column 1) CLAIMS REMAINING AFTER AMENDMENT		(Column 2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(Column 3) PRESENT EXTRA	RATE($)	ADDITIONAL FEE($)		RATE($)	ADDITIONAL FEE($)
Total (37 CFR 1.16(i))	*	Minus	**	=	x =		OR	x =	
Independent (37 CFR 1.16(h))	*	Minus	***	=	x =		OR	x =	
Application Size Fee (37 CFR 1.16(s))									
FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))							OR		
					TOTAL ADD'L FEE		OR	TOTAL ADD'L FEE	

* If the entry in column 1 is less than the entry in column 2, write "0" in column 3.
** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".
*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".
The "Highest Number Previously Paid For" (Total or Independent) is the highest found in the appropriate box in column 1.

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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 NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
16/208,559	12/04/2018	Bobby E. Rogers	KURIN2CON3

CONFIRMATION NO. 1020

158174
Kurin, Inc.
P.O. Box 371710
San Diego, CA 92137

POA ACCEPTANCE LETTER

OC000000105982622

Date Mailed: 02/20/2019

NOTICE OF ACCEPTANCE OF POWER OF ATTORNEY

This is in response to the Power of Attorney filed 02/14/2019.

The Power of Attorney in this application is accepted. Correspondence in this application will be mailed to the above address as provided by 37 CFR 1.33.

Questions about the contents of this notice and the requirements it sets forth should be directed to the Office of Data Management, Application Assistance Unit, at **(571) 272-4000** or **(571) 272-4200** or **1-888-786-0101**.

/yteferra/

To: docketing@intelligentclicks.net,jsnolan1@hotmail.com,eofficeaction@appcoll.com
From: PAIR_eOfficeAction@uspto.gov
Cc: PAIR_eOfficeAction@uspto.gov
Subject: Private PAIR Correspondence Notification for Customer Number 158174

Feb 20, 2019 04:22:25 AM

Dear PAIR Customer:

Kurin, Inc.
P.O. Box 371710
San Diego, CA 92137
UNITED STATES

The following USPTO patent application(s) associated with your Customer Number, 158174 , have new outgoing correspondence. This correspondence is now available for viewing in Private PAIR.

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Application	Document	Mailroom Date	Attorney Docket No.
16208559	APP.FILE.REC	02/20/2019	KURIN2CON3
	N570	02/20/2019	KURIN2CON3

To view your correspondence online or update your email addresses, please visit us anytime at https://sportal.uspto.gov/secure/myportal/privatepair.

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PATENT APPLICATION INFORMATION RETRIEVAL SYSTEM

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www.uspto.gov

APPLICATION NUMBER	FILING OR 371(C) DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO./TITLE
16/208,559	12/04/2018	Bobby E. Rogers	KURIN2CON3

CONFIRMATION NO. 1020

158174
Kurin, Inc.
P.O. Box 371710
San Diego, CA 92137

PUBLICATION NOTICE

OC000000108551196

Title:BLOOD SAMPLE OPTIMIZATION SYSTEM AND BLOOD CONTAMINANT SEQUESTRATION DEVICE AND METHOD

Publication No.US-2019-0159711-A1
Publication Date:05/30/2019

NOTICE OF PUBLICATION OF APPLICATION

The above-identified application will be electronically published as a patent application publication pursuant to 37 CFR 1.211, et seq. The patent application publication number and publication date are set forth above.

The publication may be accessed through the USPTO's publically available Searchable Databases via the Internet at www.uspto.gov. The direct link to access the publication is currently http://www.uspto.gov/patft/.

The publication process established by the Office does not provide for mailing a copy of the publication to applicant. A copy of the publication may be obtained from the Office upon payment of the appropriate fee set forth in 37 CFR 1.19(a)(1). Orders for copies of patent application publications are handled by the USPTO's Public Records Division. The Public Records Division can be reached by telephone at (571) 272-3150 or (800) 972-6382, by facsimile at (571) 273-3250, by mail addressed to the United States Patent and Trademark Office, Public Records Division, Alexandria, VA 22313-1450 or via the Internet.

In addition, information on the status of the application, including the mailing date of Office actions and the dates of receipt of correspondence filed in the Office, may also be accessed via the Internet through the Patent Electronic Business Center at www.uspto.gov using the public side of the Patent Application Information and Retrieval (PAIR) system. The direct link to access this status information is currently https://portal.uspto.gov/pair/PublicPair. Prior to publication, such status information is confidential and may only be obtained by applicant using the private side of PAIR.

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Office of Data Managment, Application Assistance Unit (571) 272-4000, or (571) 272-4200, or 1-888-786-0101

To: docketing@intelligentclicks.net,jsnolan1@hotmail.com,eofficeaction@appcoll.com
From: PAIR_eOfficeAction@uspto.gov
Cc: PAIR_eOfficeAction@uspto.gov
Subject: Private PAIR Correspondence Notification for Customer Number 158174

May 31, 2019 03:29:32 AM

Dear PAIR Customer:

Kurin, Inc.
P.O. Box 371710
San Diego, CA 92137
UNITED STATES

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Application	Document	Mailroom Date	Attorney Docket No.
16208559	NTC.PUB	05/30/2019	KURIN2CON3

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Monday - Friday 6:00 a.m. to 12:00 a.m.

Thank you for prompt attention to this notice,

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PATENT APPLICATION INFORMATION RETRIEVAL SYSTEM

PTO/SB/08a (02-18)
Approved for use through 11/30/2020. OMB 0651-0031
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT
(Not for submission under 37 CFR 1.99)

Application Number	16208559
Filing Date	2018-12-04
First Named Inventor	Bobby E. ROGERS
Art Unit	3791
Examiner Name	Tse W CHEN
Attorney Docket Number	KURIN2CON3

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	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.	
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	Art Unit	3791
	Examiner Name	Tse W CHEN
	Attorney Docket Number	KURIN2CON3

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	Examiner Name	Tse W CHEN
	Attorney Docket Number	KURIN2CON3

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	Attorney Docket Number	KURIN2CON3

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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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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.**

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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

⑤1Int. Cl.³　識別記号　庁内整理番号
A 61 B 5/14　6530—4C

⑬公開　昭和58年(1983) 4 月21日

発明の数　1
審査請求　未請求

（全 9 頁）

⑤4試料採集装置

⑳特　　願　昭57—156500
㉒出　　願　昭57(1982) 9 月 8 日
優先権主張　㉜1981年10月15日㉝米国(US)
㉛311494

⑦2発 明 者　エドワード・エル・ナジヤント
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⑦4代 理 人　弁理士　湯浅恭三　　外4名

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の開口部を開口し、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

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)

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)

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)

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携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

(7)

を設う。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閉つている。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

(9)

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

(8)

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

(10)

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ッパ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

(11)

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

(13)

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

(12)

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

(14)

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。

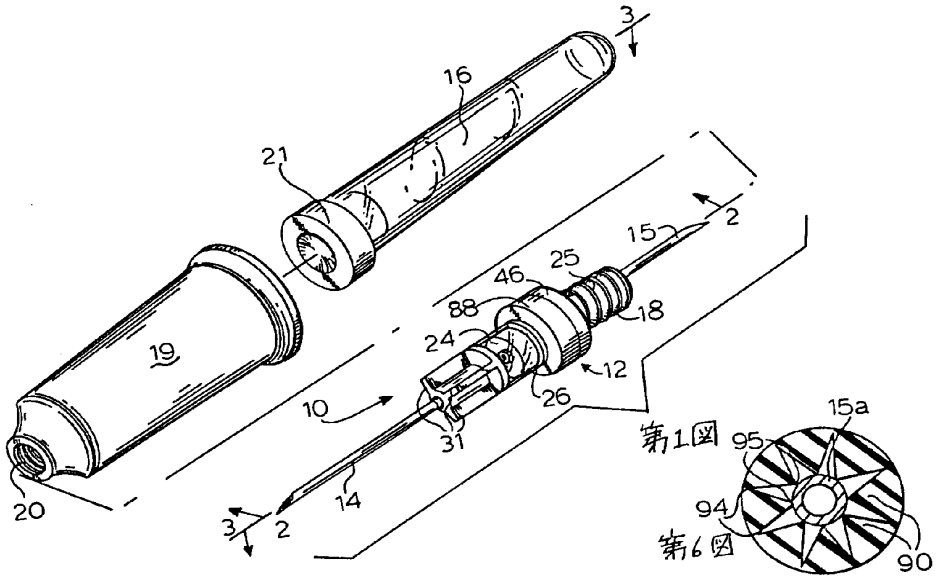
第８ａ図は本発明の他の実施態様を示す単一試料採集針組み立て体の部分拡大断面図。

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

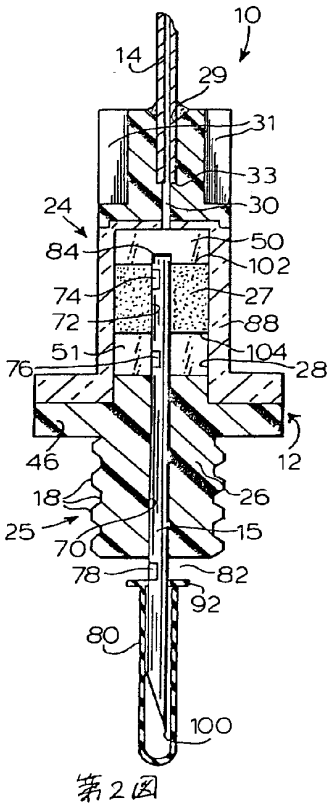
特許出願人　ベクトン・デイッキンソン・アンド・カンパニー

代理人　弁理士　湯浅恭三（外4名）

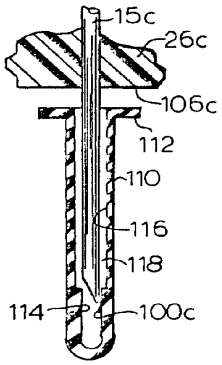


第1図

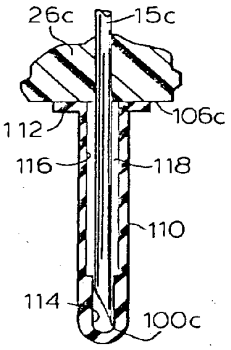
第6図



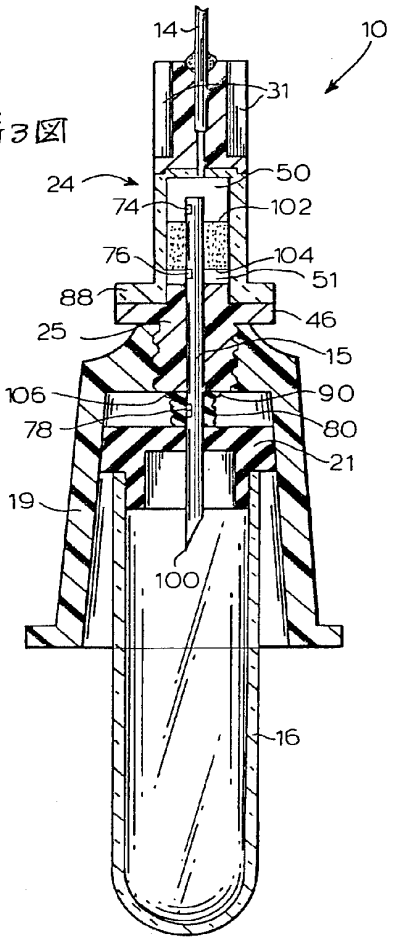
第2図



第8a図

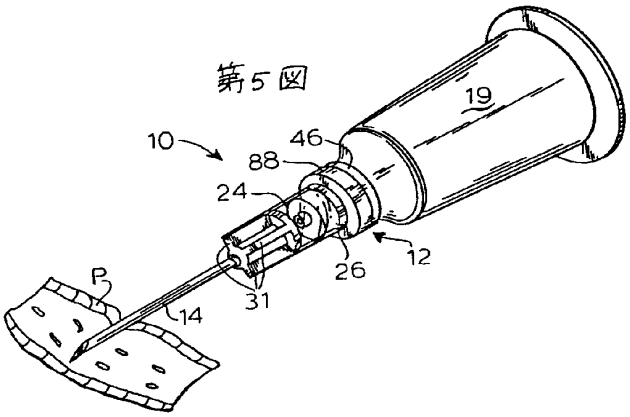


第8b図

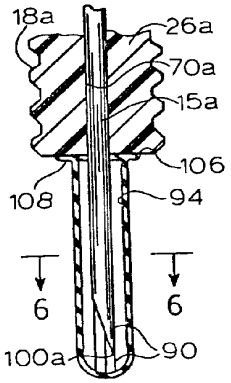


第3図

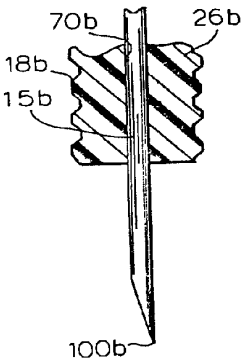
第5図


19
10
46
88
24
12
26
31
14
P

第4図


18a
26a
70a
15a
106
108
94
6
6
100a
90

第7図


70b
26b
18b
15b
100b

Espacenet

Bibliographic data: JPS5867238 (A) — 1983-04-21

SAMPLE COLLECTING APPARATUS

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Classification: - international: ***A61B5/15; A61B5/154;*** (IPC1-7): A61B5/14
- cooperative: **A61B5/15003 (EP)**; **A61B5/150213 (EP)**; **A61B5/150221 (EP)**; **A61B5/150259 (EP)**; **A61B5/150351 (EP)**; **A61B5/150404 (EP)**; **A61B5/150511 (EP)**; **A61B5/150519 (EP)**; **A61B5/150572 (EP)**; **A61B5/150702 (EP)**; **A61B5/150732 (EP)**; **A61B5/1545 (EP)**; **A61B5/155 (EP)**

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Abstract not available for JPS5867238 (A)

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DESCRIPTION JPS5867238

[0001]

The present invention relates to an apparatus for collecting a liquid sample, such as blood, from a patient. In particular, the invention relates to a needle silker for collecting one or more liquid samples from such a patient. The apparatus of the present invention employs a transparent or translucent f ¥ introduction chamber so that it is possible to observe whether the needle in question has approached the proper location. In the re-introduction chamber, the reciprocating motion is formed of a material which becomes an obstacle wall for the liquid received therein and which becomes an exhaust passage for the gas pushed out by the liquid sample received in the reject chamber. A stopper is incorporated therein. The stopper reciprocates so that when the sample liquid is first received, it completely prevents the liquid sample from being discharged, while at the same time venting the gas by the liquid sample. The stopper, when discharged into the collection container, cooperates with a vent in the discharge area of the erection stand to continuously discharge and pass the collected sample to one or more negative pressure collection containers. It reciprocates by working action. In the case where all the samples are continuously collected and discharged to a plurality of negative pressure containers, the assembly is connected to the discharge opening of the device during the replacement period of the negative pressure collecting container in preparation for discharging the next sample. Includes a cooperating flexible sleeve. As described above, it is desirable to provide a mechanism for notifying a user of such a needle assembly that the venous needle has penetrated the vein of the patient from whom the entire blood sample is to be collected. It is often difficult to place a vein in the space where blood is collected from the patient, and blood flow to the collection container may be improper for other reasons. In such a case, it would be beneficial to be able to quickly perceive the needle entering the vein and blood flowing into the needle assembly. I feel that the needle has entered this way. A negative pressure collection container is then inserted into the collection silker according to well-known blood sample collection techniques during the

single sample collection procedure. One of the problems encountered during the venipuncture stage is the air pool found in various needle assemblies for one or more blood samples. When a venous puncture is made and a negative pressure collection container has not yet been attached to the opposite end of the needle silker, under normal atmospheric conditions, blood will collect due to the pool of air remaining inside the needle assembly. It does not always flow into the needle assembly. Thus, when venipuncture is completed, blood flow is not initiated simply by obstruction of the air pocket in the needle assembly. According to this justification, by contrast, the use of a porous plug in the collection chamber—air from the collection chamber so that the collection chamber receives the blood sample from which the plug was collected.

Extrude. In addition, the stopper is operable to initially vent the extruded air during the receiving procedure, and to discharge the sample to the negative pressure collecting vessel when the negative pressure vessel is attached to the needle assembly. A needle assembly is disposed within the collection chamber to cooperate with an outlet at the negative pressure puncture needle. For example, in one embodiment of the present invention for a single-sample collection procedure, the assembly of the present invention vents all of the extruded air when a sample is introduced, and a negative pressure vessel is attached to the assembly and a negative pressure puncture for discharge is provided. When the needle penetrates into the negative pressure collecting container, the introduced sample 14—a porous plug that moves to open the passage of the assembly in response to a differential pressure to discharge into the negative pressure collecting container. Having. Another embodiment of the present invention has a flexible sleeve covering the discharge opening of the negative pressure puncture needle. The flexible sleeve is arranged to exhaust air from the third outlet at the outlet puncture needle during sample introduction. ! The retractable sleeve flexes and moves through the sixth outlet when the negative pressure blood collection container is inserted into the assembly to be recognizable by the negative pressure puncture needle. Once one sample is obtained in the negative pressure blood collection device and the negative pressure container is removed from the assembly, the flexible sleeve is then applied until the negative pressure container is attached for the second sample collection. Discharge amount of pressure puncture needle b'f! : Covered. As is well known to those skilled in the art, this procedure is repeated to collect the required number of samples U into separate negative pressure blood collection containers. Considering the use of a porous plug in a blood collection device of the type described herein, consider the earlier filed US Application No. 915.670, filed June 15, 1978, entitled "Blood collection assembly with venipuncture indication. The inventor (assignee is the same as the present application) in the body J (Blnode Sampling Assembly Having Vein Entry Indicator) William N. Erdrichsi (Wi l iam N, Eldvidge who uses the air vein to sense the vein needles). He knew he could prevent the desired blood flow to the point where he could. L. Ridge's invention includes a perforated 'J4f plug which mates with a one-way valve, which 10,000 air vents the air inside the needle silker during the first stage of the blood collection procedure. Let go outside. The vent prevents the passage of blood until the user attaches the blood collection device to the needle assembly.

Upon contact with the negative pressure of the negative pressure blood collection container, the separated one-way valve opens to carry blood from the patient's vein and to enter the blood into the collection container through a needle silker. The Eldritzzi invention recognized the use of a porous material to vent the displaced air while the whole blood reservoir was in place, but there is still room for improvement of such devices, and in particular there is room for improvement. Related to the present invention. That is, the stopper of the present invention reciprocates and does not simply act as a vent, but instead acts as a valve mechanism without having a separate and complex structure to provide valve action. That is, the stopper of the present invention cooperates with the blood introduction chamber to reciprocate and reciprocate to allow air to vent from the introduction chamber but not to discharge the blood sample and to introduce blood when the assembly is adhered to the negative pressure blood collection container. Move to discharge. Next, a description will be given with reference to the drawings. In the drawings, the same parts are denoted by the same reference numerals. FIG. 1 shows a basic needle assembly 10 that includes a housing 12, a first puncture needle 14 for insertion into a patient, and a second puncture needle 15 at the opposite end of the housing. External component cost? Is shown. The second puncture needle 15 is adapted to be inserted into a negative pressure container 16 for collecting a number of samples. The nosing 12 includes a threaded portion 25 having a screw 18 adjacent to the second puncture needle 15 into which the container support 19 is screwed by an inner silk threading screw 20 provided at its forward end. The puncture needle 15 of the negative pressure container 16 and the tea 2 is inserted into the trash container 19 so as to pass through the stopper 21 at the front end of the negative pressure container 16. Such general aspects of sample collection vessels are well known to those skilled in the art. This will be described with reference to FIG. Preferably, the housing 12 has a front end 24 and a rear end 25 which can be separated to insert a porous plug 27. The front end 241d has a cylindrical shape, and a large hole 28 is formed so that the porous stopper 27 can be reciprocally received in the groove. A small aperture 29 for receiving one puncture needle 14 is provided. In this embodiment, the small aperture 29 extends to a smaller, smaller diameter conduit 60 that connects the aperture 29 and the aperture 28 to each other. A stepped portion 6 for receiving the first puncture needle 14 in contact with the first puncture needle 14 is formed at the junction between the one hole 29 and the conduit 60. The first puncture needle 14 may be fixed in the mouth 29 by a suitable adhesive.

It will be known to those skilled in the art that the conduit 30 is not an essential element for this configuration, but merely a preferred form. Further, the diameter of conduit 0 can be varied to adjust the flow rate of fluid passing therethrough. The front end 24 of the housing also includes a number of longitudinal ribs 61 surrounding a first puncture needle extending outwardly. A garment (not shown) having a lyso in combination with the rib 31 substantially approximates the first puncture needle extending outward. The mating ribs between the piercing needle armor and

the needle assembly facilitate the user's insertion into or removal from the needle assembly of the armor. The forward end 24 also includes an annular flange 62 that serves as a mating surface when joining the two parts of the housing into an assembly. Again, an adhesive or similar suitable fixing material can be used to fix the two parts of the housing and the assembly. The rear end 25 includes a slightly projecting cylindrical portion 40 sized to fit inside the front end opening 28. On the opposite side of the rear end, the external thread 18 is provided at the portion 260 of the rear end 25 as described above by the connecting mechanism of the tube support. A hole 70, similar to the hole 29 at the front end of the housing, extends over all the rear ends of the housing. The aperture 70 is dimensioned to match the diameter of the second puncture needle 15, where again the second puncture needle is secured to the aperture 70 by a suitable material such as an adhesive. When combining the two ends R (S24 and S25) of the housing, an annular flange 46 is provided corresponding to the annular flange 32. It will be appreciated that when assembling the two parts of the housing with the stopper 27 positioned therein, the flanges 32 and 46 may be secured by a suitable securing material, such as, for example, an adhesive. Orifice 28 at front end 24 defines a tubular chamber 50 for receiving a liquid sample to be collected. To observe the contents of the tubular chamber 50 and to inform the user of the device that the puncture needle has reached the vein, the annular wall 88 at the front end forming the tubular chamber 50 is made of a translucent or transparent material. It is preferable to be formed. It will be appreciated by those skilled in the art from a manufacturing standpoint that the entire front end of the needle assembly is preferably made of a transparent material, such as a thermoplastic hard resin. However, closed windows, ports or other devices for the user of the device to view the contents of the tubular chamber 50 are also within the scope of the present invention.

The porous plug 27 is reciprocally mounted in the opening 28 and has an inner opening 72 for reciprocally fitting with the front end of the puncture needle 15 which receives a negative pressure. As is well known, the porous plug 27 is cylindrically shaped according to the aperture 28 and has a diameter that is liquid-tightly engaged with the wall of the tubular chamber 50, but is also apertured by the action of a differential pressure with the opposite surface. 28, the stopper 27 is defined so that it can reciprocate. The porous frame 27 is made of a so-called gas-permeable / liquid-impermeable material that allows the passage of a gas such as air but does not allow the passage of a liquid such as blood. Examples of materials used to form the perforated chamber frame 27 include sintered polyethylene, open cell foamed polyethylene, and other similar moldable polymeric materials such as porous polypropylene and porous polyfluorocarbon. As shown in FIG. 2, negative pressure puncture needle 15 includes a notch 74 adjacent its end 84. At this point, the notch 74 communicates with the tubular chamber 50 by the amount of the lumen of the second puncture needle 15 depending on the position of the porous stopper 27, but the end 84 of the porous frame 27 is closed by the stopper. Closed or otherwise deformed or otherwise closed. An additional notch or opening is provided for communication between the rear end 51 of the tubular chamber 50 and the second puncture

needle 15. Further, as shown in FIG. 2, a sixth notch or open lower 8 is provided for communicating between the atmosphere, that is, the outer peripheral region of the assembly of the present invention and the lumen of the second puncture needle 15. Next, a description will be given with reference to FIG. The needle assembly connected to the support 19 is shown. A first puncture needle 14 is shown inserted into a patient P undergoing venipuncture. When the puncture needle 14 of the bobbin 1 enters the vein of the patient P, blood flows from the vein into the tubular chamber 50 through the first puncture needle 14 and the small-diameter conduit 30 km. When blood flows into the tubular chamber 50, air in the tubular chamber 50 is pushed out of the tubular chamber 50 through the porous frame 27, but blood does not pass through the porous frame 27 due to the characteristics of the porous frame 27. The air which has passed through the stopper 27 from the tubular chamber 50 through the notches 74 and 76 and further through the lumen of the second puncture needle 15 and the outer notch 78 covers the outer end of the negative pressure puncture needle 15. The mirror device 0 is extruded into a region 82 (FIG. I2) between the flange 92 and the end face 106 of the housing end 25. Here, the stopper 27 remains at the position shown in FIG. 2 covering 74 orifices or notches.

Further, here, a blood sample collected from the patient P is located in the tubular chamber 50. Referring now to FIG. 6, it is shown that the silker has a support 19 attached to the hub 26 of the rear / Using 25. The negative pressure puncture needle 15 has a resilient stopper pierced by the end or point 100 and shows a negative pressure blood collection container 16 fitted in a support 19. A vacuum is created by penetrating 21, which vacuum or negative pressure removes any air remaining in tubular chamber 50 into the interior region of negative pressure vessel 16 and cutouts 74 and 76. Is drawn through the entirety of the porous frame 27 by communicating through the lumen. Since the stopper 27 is closed by the blood, a pressure difference is generated between the upper tubular chamber 50 and the lower tubular chamber 51, and the stopper 27 moves downward toward the surface of the extension 4U as shown in FIG. With this movement, the stopper 27 removes the cover of the opening or notch 74. Any residual air trapped in the lower tubular chamber 51 during this movement will pass through the notch 76 and will facilitate the movement of the plug 27. When the cutout 74 is uncovered, flow between the tubular chamber 50 and the vacuum container 16 is provided through the lumen of the vacuum puncture needle 15. On the other hand, by inserting the negative pressure container 16 into the support 19 and penetrating the puncture needle 15 through the stopper 21 by the point 100, as shown in FIG. It moves upward to a position where it engages with the bottom surface 106 of 26. Thus, the blood sample drawn from the vein of the patient P and stored in the tubular chamber 50 moves into the negative pressure collecting container 16. Once the sample has been withdrawn into the container 16, the refuse 516 is removed from the support 19, whereby the mirror device 0 closes the notch 78 and returns to a position covering the end 100 of the negative pressure puncture needle 15. In this way, the first puncture needle 14 can be continuously mounted in the container 16 and the support 19 for receiving a plurality of blood samples while remaining in the vein without leaking blood. I do. Referring now to FIG. 4, another

embodiment is shown in which the notch 78 is not cut in the negative pressure puncture needle 15a. In this device, the same parts are indicated by the same reference numerals with a suffix a. In the present embodiment, the puncture needle 15 a V (instead of the air passage or the open lower 8) has its flange 10 B closed and engaged so that the gas is not always sealed adjacent to the surface 106 a of the extension 26 a. A positioned sleeve 90 is formed.

As shown in FIG. 6, the sleeve 90 is arranged to slidably engage the puncture needle 15a. However, a point 95 inside the sleeve 90u groove has a plurality of internal grooves 94 that actually engage the outer surface of the puncture needle 15a. The groove thus provides gas communication between the puncture needle end 10Da and the upper end of the sleeve 90, where air leaks between the adjacent surface of the flange 108 of the sleeve 90 and the surface 1U6a of the extension 26a. 'Jj 94 is set to a size that allows gas to pass and liquid not to pass. It will be appreciated that the upper surface of the flange 108 can similarly envision a groove that provides ventilation between the end 100a and the atmosphere. Yet another example of the present invention that provides a complete single-blood sample collection assembly is shown in FIG. No special sleeve 80 is used as shown in this assembly and puncture needle 15b does not have a third notch or opening, such as notch 78 in the embodiment shown in FIG. . Thus, when the puncture needle 14 is inserted into a patient's vein, fluid communication is provided between the vein and the tubular chamber 50 to collect a sample in the tubular chamber 50. The device does not allow the blood sample to flow through the porous plug 27 as in the embodiment shown in FIG. In all cases, the notch 9 is cut out 74.76, and is discharged from the end 100b of the negative pressure puncture needle 15b through the lumen of the puncture needle 15. When the support is mounted on the extension 26b and the point 100b of the puncture needle 15b is inserted all the way through the stopper and into the negative pressure blood collection container 16, the tubular chamber 50 above the stopper 27 and the tubular chamber 51 below the stopper 27 are connected. A pressure difference is generated therebetween, so that the stopper 27 moves downward to open the notch 174v. This provides for fluid communication between the tubular chamber 50 and the vacuum container 16 for single sample collection into the vacuum container 16. In this embodiment, the puncture needle 14 is removed from the vein of the patient P because no further samples are collected by the assembly, and the assembly is discarded because one required sample has been collected in the negative pressure container. Another embodiment of collecting a plurality of samples similar to the embodiment shown in FIG. 4 in which air flows i between the point 100c of the negative pressure puncture needle 15c and the atmosphere is shown in FIGS. 8a and 8b. In the present embodiment, the inner diameter of the shaft portion 110 is stepped, and the inner diameter of the shaft portion 110 combined with the small inner diameter 114 of the shaft portion 110 that is in close contact with the outer surface of the puncture needle 15c is between the surface of the shaft portion 110 and the puncture needle 15. Provide a large inner diameter 116 that defines a vent passage 118 for the air flow.

Therefore, in the position shown in FIG. 8a, ventilation occurs between the end 100c of the puncture needle 15c and the atmosphere through the entire passage 118, and in the position shown in FIG. 8b, the passage 118 is closed to prevent all ventilation. . As can be appreciated from the foregoing, in the present invention, a blood collection needle assembly is provided for collecting one or more samples that incorporate the entire device for venous needle insertion to the user. . Furthermore, the device of the present invention with a porous stopper having a simple configuration having the function of a valve, passing gas but not liquid, is very simple and inexpensive to manufacture, as will be appreciated by those skilled in the art. Particularly suitable for mass production.

[0002]
BRIEF DESCRIPTION OF THE FIGURES

[0003]

FIG. 1 is a perspective view of a sample collection needle assembly, a support for a negative pressure container, and a negative pressure blood collection container used to obtain a blood sample from a patient.

FIG. 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 sectional view taken along line 3-6 in FIG. FIG. 4 is a partial sectional view similar to FIG. 2, showing another embodiment of the present invention. Show. FIG. 5 is a perspective view of the needle assembly inserted into the patient and connected to the support so that the user has full visibility into the vein. W: FIG. 6 is a sectional view taken along line 6-6 in FIG. FIG. 7 is an enlarged sectional view of the single-sample collection needle assembly, similar to FIG. 2 but showing another embodiment of the present invention. FIG. 8a is a partially enlarged cross-sectional view of a single-sample collection needle assembly showing another embodiment of the present invention. FIG. 2EBb is the embodiment of FIG. 8a in a closed, non-communicating position. 10 ... needle needle body, 12 ... housing, 14 ... first puncture needle, 15 ... second puncture needle, 16 ... · Negative pressure genitalia, # 19 ... support, 24 ... front end, # 25 ... back end, 27 ... ++ 2i porous plug, 29 ... ··· First aperture, 50 ····· Sample collection chamber, ····· Second aperture, 74 ··· W: 1: 1 opening, 76 ··· ... 6th opening, 80... Flexible sleeve, 94... Groove, # 114... Small inner diameter, 116. ..... Large inner diameter Patent applicant: Becton, Dateskinson and Canno

Patent Translate
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Notice

This translation is machine-generated. It cannot be guaranteed that it is intelligible, accurate, complete, reliable or fit for specific purposes. Critical decisions, such as commercially relevant or financial decisions, should not be based on machine-translation output.

CLAIMS JPS5867238

1.

A sample chamber having a housing and a rear end; a sample collection chamber within the housing; a first open passage at the front end in fluid communication with the sample collection chamber; and insertion into a collection source. A first puncture needle extending outwardly from said first open passageway; and a second open passageway at said rear end and in fluid communication with said sample collection chamber. A sample collection device for collecting one or more liquid samples from and draining into a negative pressure vessel for collection, wherein said first sample is located in said second open passage and into said sample collection chamber. A second puncture needle extending from the open passageway to a spaced-apart point, the second puncture needle spaced apart from the first and second apertures at a portion extending into the sample collection chamber. The first and second openings are connected to the sample collection chamber and the second puncture. Fluidly communicates between the lumens of said first opening and said second opening from a first position closing said opening to a second position opening said first opening. A gas-permeable, liquid-impermeable, annular porous stopper placed in the sample collection chamber so as to reciprocate along a second puncture needle, wherein the first puncture needle is connected to the collection source; When engaged with the liquid, the liquid pushes out all the gas therein into the sample collection chamber, flows into the second puncture needle through the first and second openings, and the second puncture needle When the vacuum container is received, the annular porous stopper moves toward the second opening passage by the action of the differential pressure on both sides thereof to open the first opening, and the annular porous stopper is closed. The gas remaining in the sample collection chamber is pushed out to the second opening located on the negative pressure side, and the liquid in the sample collection chamber is pushed out. Sample collection apparatus characterized by being adapted to be collected into the negative pressure vessel through the second puncture needle. (2. In the sample collection device according to claim

1, wherein the annular porous stopper is a sintered polyethylene, an open-cell foamed polyethylene, a porous polyethylene, a porous polyfluorocarbon y ′ , and A sample collection device that is a member made from any of the group consisting of these mixtures. (3) In the sample collection device according to claim 1, a sixth opening provided in a portion of the second puncture needle extending outward from the housing and the second puncture needle And a resilient sleeve extending over a terminal portion opposite the sample collection chamber, wherein when the negative pressure container is penetrated by the second puncture needle, the sleeve is closed at the sixth opening. A sample collection device, wherein the sample collection device is closed.

(4) The sample collecting apparatus according to claim 1, further comprising an elastic sleeve 滑 which is slidably engaged with the second puncture needle at a terminal portion 1111 opposite to the sample collecting chamber, The inner surface of the sleeve engaging the puncture needle has a plurality of longitudinally extending grooves, and the groove engaged with the puncture needle is gas-permeable and liquid-impermeable. Sample collection device. f ! 2. The sample collecting apparatus according to claim 1, wherein the housing reconnects a device for connecting a support for a negative pressure vessel. (6) The sample collecting apparatus according to claim 5, wherein a support for a negative pressure vessel is connected to the housing. (7) The sample collection device according to claim 6, wherein the housing includes a device for connecting all of the support for the negative pressure container. (8) The sample collection device according to claim 1, wherein the housing has a device for observing the entire contents of the sample collection chamber. (9) The sample collection device according to claim 8, wherein the device for viewing the contents is a transparent housing wall adjacent to the sample collection room. (10) The collection device according to claim 1, wherein a resilient sleeve slidably engaged with the F] iT @ Her puncture needle is provided at an end of the puncture needle opposite to the sample collection chamber. The inner surface of the sleeve engages with the puncture needle, the stepped inner surface is entirely formed, and a portion of the length region of the core is combined with the outer (141, 141) of the second puncture needle. The second puncture needle forming a small diameter internal aperture for sealing engagement with one surface and another portion of the lengthwise region of the stepped inner surface being silk-sealed; A large-diameter internal hole forming an air passage together with an outer surface of the sample collecting device.

UNITED STATES
PATENT AND TRADEMARK OFFICE

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ELECTRONIC ACKNOWLEDGEMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
16/208,559	06/24/2020 08:57:57 PM ET	KURIN2CON3

Title of Invention

BLOOD SAMPLE OPTIMIZATION SYSTEM AND BLOOD CONTAMINANT SEQUESTRATION DEVICE AND METHOD

Application Information

APPLICATION TYPE	Utility - Nonprovisional Application under 35 USC 111(a)	PATENT #	-
CONFIRMATION #	1020	FILED BY	KETHYA TEUK
PATENT CENTER #	60043755	FILING DATE	12/04/2018
CUSTOMER #	158174	FIRST NAMED INVENTOR	Bobby Rogers
CORRESPONDENCE ADDRESS	-	AUTHORIZED BY	James Nolan

Documents

TOTAL DOCUMENTS: 25

DOCUMENT	PAGES	DESCRIPTION	SIZE (KB)
KURIN2CON3_IDS.pdf	12	Information Disclosure Statement (IDS) Form (SB08)	1031 KB
FR_JPS5867238A_wTrans.pdf	19	Foreign Reference	1431 KB
NPL_PCTUS176589_ISR_WO.pdf	9	Foreign Reference	270 KB
EP1665986.pdf	19	Foreign Reference	781 KB
JP2012-016496_w_translation.pdf	30	Foreign Reference	798 KB

EP19200766_SearchReport.pdf	11	Foreign Reference	487 KB
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JP5867238.pdf	19	Foreign Reference	1436 KB
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WO9605875.pdf	16	Foreign Reference	634 KB
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CommunicationunderRule713.pdf	125	Foreign Reference	4474 KB
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WO2018125929A1.pdf	122	Foreign Reference	3993 KB
BULLINGTON_Exhibit_H.pdf	131	Foreign Reference	8517 KB

Digest

DOCUMENT	MESSAGE DIGEST(SHA-512)
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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.

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference	**FOR FURTHER ACTION**	see Form PCT/ISA/220 as well as, where applicable, item 5 below.
KURIN3PCT		
International application No.	International filing date *(day/month/year)*	(Earliest) Priority Date *(day/month/year)*
PCT/US2017/068569	27 December 2017 (27-12-2017)	27 December 2016 (27-12-2016)
Applicant		
KURIN, INC		

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 4 sheets.

[X] 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:
      [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))
   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,**
   [X] 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,**
   [X] 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. 30B
      [ ] as suggested by the applicant
      [ ] as selected by this Authority, because the applicant failed to suggest a figure
      [X] as selected by this Authority, because this figure better characterizes the invention
   b. [ ] none of the figures is to be published with the abstract

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

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US2017/068569	27.12.2017	27.12.2016

International Patent Classification (IPC) or both national classification and IPC
INV. A61B5/15 A61B5/153 A61B5/154 A61B5/157

Applicant
KURIN, INC

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

- ☒ 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
- ☒ 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 usually 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 notifed 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:	Date of completion of this opinion	Authorized Officer
European Patent Office Gitschiner Str. 103 D-10958 Berlin Tel. +49 30 25901 - 0 Fax: +49 30 25901 - 840	see form PCT/ISA/210	Nielsen, Michael Telephone No. +49 30 25901-0

Form PCT/ISA/237 (Cover Sheet) (January 2015)

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established 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)).

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:

   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 forming part of the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

5. Additional comments:

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

1. Statement

Novelty (N)	Yes:	Claims	1-20
	No:	Claims	
Inventive step (IS)	Yes:	Claims	1-20
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	1-20
	No:	Claims	

2. Citations and explanations

see separate sheet

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

In light of the documents cited in the international search report, it is considered that the invention as claimed in the independent claims meets the criteria mentioned in Article 33 (1) PCT, i.e. it appears to be novel, to involve an inventive step and to be industrially applicable.

Prior art: Blood drawing devices capable of isolating a pre-sample in order to minimize the risk of contamination of the main sample. Well known concept, see any of the documents cited in the search report.

Problem: As in the prior art to minimize the risk of contamination of blood drawn from a patient.

Solution: The pre-sample chamber (sequestration chamber) having **the specific vent** as defined in the independent claims 1, 8 and 15.

None of the cited documents hint to said specific solution in order to solve said problem. Contribution to the art.

Claims 2-7, 9-14 and 16 to 20 are dependent on one or more independent claims whose subject-matter is considered as being new and inventive, as discussed above, and as such said dependent claims also meet the requirements of the PCT with respect to novelty and inventive step.

Re Item VII

Certain defects in the international application

1). The independent claims are not in the two-part form in accordance with Rule 6.3(b) PCT.

2). The features of the claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).

3). Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art (see search report) is not mentioned in the description, nor are these documents identified therein.

4). Upon entering the regional phase via the European Patent Office, the requirements of Rule 43(2) EPC should be observed.

Information on Search Strategy - Pilot phase (see OJ 2015, A86)
The type of information contained in this sheet may change during the pilot for improving the usefulness of this new service.

Application Number
PCT/US2017/068569

TITLE: BLOOD SAMPLE OPTIMIZATION SYSTEM AND BLOOD CONTAMINANT SEQUESTRATION DEVICE AND METHOD

APPLICANT: KURIN, INC

IPC CLASSIFICATION: A61B5/15, A61B5/153, A61B5/154, A61B5/157

EXAMINER: Nielsen, Michael

CONSULTED DATABASES: WPI

CLASSIFICATION SYMBOLS DEFINING EXTENT OF THE SEARCH:

IPC:

CPC: A61B5/15003, A61B5/150213, A61B5/150251, A61B5/150389, A61B5/150488, A61B5/150992, A61B5/153, A61B5/150274, A61B5/1535, A61B5/1545, A61B5/157

FI/F-TERMS:

KEYWORDS OR OTHER ELEMENTS FEATURING THE INVENTION:

EPO FORM P04A42

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.

* 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
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

1

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

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
US 2014039348 A1	06-02-2014	US 2014039348 A1	06-02-2014
		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
		US 2015367069 A1	24-12-2015
		WO 2014058945 A1	17-04-2014
US 4813433 A	21-03-1989	NONE	
US 2013317391 A1	28-11-2013	US 2013317391 A1	28-11-2013
		US 2015099996 A1	09-04-2015
		US 2015351678 A1	10-12-2015
WO 2013181352 A1	05-12-2013	AU 2013267448 A1	18-12-2014
		AU 2017216493 A1	07-09-2017
		CA 2875118 A1	05-12-2013
		CN 104902817 A	09-09-2015
		CN 107736901 A	27-02-2018
		EP 2854643 A1	08-04-2015
		EP 3173021 A1	31-05-2017
		JP 6242386 B2	06-12-2017
		JP 2015519145 A	09-07-2015
		JP 2018034009 A	08-03-2018
		US 2014155781 A1	05-06-2014
		US 2015351679 A1	10-12-2015
		WO 2013181352 A1	05-12-2013

Form PCT/ISA/210 (patent family annex) (April 2005)

(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) EP 1 665 986 A1

(12) EUROPEAN PATENT APPLICATION

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A61B 5/154 *(2006.01)* ***A61B 5/155*** *(2006.01)*

(21) Application number: **05111371.0**

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(30) Priority: **29.11.2004 US 631515 P**
16.11.2005 US 280622

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Designated Contracting States:
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(54) Blood collection set with an expanded internal volume

(57) The blood collection set includes an IV needle assembly, a length of flexible plastic tubing extending from the IV needle assembly and a non-patient needle assembly. The set is formed with an internal chamber that increases the internal volume of the blood collection set. Thus, the increase in internal volume allowing for greater flash visualization on venous entry.

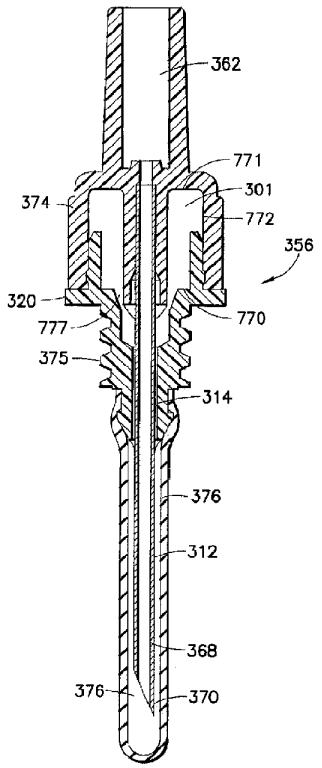


FIG.4

EP 1 665 986 A1

Printed by Jouve, 75001 PARIS (FR)

Description

BACKGROUND OF THE INVENTION

[0001] This application claims priority to U.S. Provisional Application No. 60/631,515, which was filed on November 29, 2004.

1. Field of the Invention

[0002] The subject invention relates to a blood collection set with an internal chamber, which increases the internal volume of the blood collection set thereby improving flash.

2. Description of the Related Art

[0003] Phlebotomy procedures often are carried out using a blood collection set. A typical blood collection set includes an IV needle assembly with an IV cannula that has a proximal end, a sharply pointed distal end and a lumen extending between the ends. The needle assembly also includes a plastic IV hub with a proximal end, a distal end, and a passage extending between the ends. The proximal end of the IV cannula is mounted in the passage of the IV hub so that the lumen through the IV cannula communicates with the passage through the IV hub. The needle assembly may further include a shield for shielding the IV cannula after use (a so called safety blood collection set) and a packaging cover for safely covering the IV cannula prior to use. Packaging covers typically are rigid tubes with a proximal end that can be telescoped over the IV cannula and frictionally engaged with the distal end of the IV hub. Shields for shielding the IV cannula of blood collection sets have taken many forms. Some shields are telescoped over the IV hub and can be moved from a proximal position where the cannula is exposed to a distal position where the cannula is shielded. Other shields are hinged to the IV hub and can be rotated from an open position where the IV cannula is exposed to a closed position where the IV cannula is shielded. A needle assembly for a blood collection set also may include two flexible wings that project transversely from the IV hub or from the shield. The wings can be folded into face-to-face relationship with one another to effectively define a handle that facilitates manipulation of the needle assembly. The wings then can be rotated away from one another and held against the skin of the patient.

[0004] Blood collection sets also include a length of flexible plastic tubing. The tubing has a distal end that is connected to the proximal end of the IV hub, The tubing also has a proximal end that is connected to a plastic fitting. Thus, fluid communication is provided between the lumen of the IV cannula and the plastic fitting at the proximal end of the flexible tubing. The plastic fitting may be a female luer fitting that can be connected to a male luer fitting. The fitting then can be placed in communication with a reservoir or container for collecting a sample of blood.

[0005] Phlebotomy procedures often employ evacuated tubes, such as the VACUTAINER® brand of evacuated tubes sold by Becton Dickinson and Company. Evacuated tubes often are used with a tube holder that has a proximal end, a distal end, and a tubular side wall extending between the ends. The proximal end of the holder is widely open and is configured for slidably receiving the evacuated tube. The distal end of the holder typically includes an end wall with a mounting aperture. The mounting aperture includes internal threads or other mounting structures.

[0006] The tube holder may be used with a non-patient needle assembly that has a non-patient hub with external surface configurations for mounting in the mounting aperture of the holder. The non-patient needle assembly further includes a non-patient cannula extending proximally from the hub and a multiple sample sleeve telescoped over the non-patient cannula and mounted to the proximal end of the hub. The hub of the non-patient needle assembly can be threaded or otherwise engaged in the mounting aperture of the tube holder so that the non-patient needle and the multiple sample sleeve project into the tube receiving chamber of the holder.

[0007] The blood collection set may be used by mounting the fitting at the proximal end of the flexible plastic tubing to the distal end of the hub of the non-patient needle assembly. The packaging shield that covers the non-patient cannula then may be removed, and the hub of the non-patient needle assembly may be engaged with the tube holder. The medical practitioner then grips the IV needle assembly and removes the packaging cover from the IV cannula. The gripping of the IV needle assembly may include folding the flexible wings into face-to-face engagement and gripping the folded wings between a thumb and forefinger. The pointed distal end of the IV cannula then is urged into a targeted blood vessel. The wings then may be folded into engagement with the skin of the patient and may be taped in position. An evacuated tube then is urged into the open proximal end of the blood collection tube holder so that the non-patient needle pierces the stopper of the evacuated tube. As a result, the blood vessel of the patient is placed in communication with the interior of the evacuated tube, and the pressure differential between the blood vessel and the evacuated tube will generate a flow of blood through the IV cannula, through the passage of the IV hub, through the flexible tubing, through the non-patient hub and finally through the non-patient needle and into the evacuated tube.

[0008] The translucent or opaque plastic material of blood collection sets and IV cannula shields, combined with numerous cannula shield mechanism components and the length of the typical needle hub tends to inhibit a clear indication of venous or arterial access. Blood flow into the plastic tubing does provide an indication of venous or arterial access (known as "flash") as the plastic

tubing is often formed from a highly translucent or transparent plastic material. However, because of the existence of the elements associated with the IV needle assembly the length of flash obtained from a typical venous entry may not be sufficient for blood flow to be observed in the flexible tubing at a location proximal to the IV needle assembly itself. Thus, a medical practitioner may have a delayed indication of venous or arterial access and may incorrectly assume that the blood vessel was not accessed properly. In these situations, the medical practitioner may try to access the blood vessel again even though the initial access was successful. Accordingly, the patient may be subjected to unnecessary trauma during a repeated attempt to access the targeted blood vessel. Thus, improved techniques for increasing the length of flash such that initial blood flow will be observable in the flexible tubing proximal the IV needle assembly and associated shielding elements would be desirable.

SUMMARY OF THE INVENTION

[0009] The invention relates to a blood collection set with an internal chamber provided to increase the internal volume of the blood collection set when compared to a prior art blood collection set which does not have an internal chamber. In this manner, improved flash visualization, can be provided.

[0010] "Internal chamber" as used herein means an enclosed space or compartment, which is in communication with the fluid passage of the blood collection set. The "fluid passage" is defined as any part of the blood collection set in which blood flows and can include the lumen through the IV cannula, the passage through the IV hub, the passage through the flexible tubing, the passage through the non-patient hub and lumen through the non-patient cannula. "Flash" is defined as the initial blood flow into the fluid passage on venous entry, which provides an indication of venous or arterial access before an evacuated tube is urged into the open proximal end of the blood collection tube holder. "Flash length" is the linear distance that blood flows in a proximal direction along the fluid passage on venous entry. "Flash volume" is the volume of blood that flows into the fluid passage on venous entry expressed as a percentage of the total internal volume of the blood collection set.

[0011] In one embodiment, the blood collection set includes an IV needle assembly, a length of flexible plastic tubing extending from the IV needle assembly and a non-patient needle assembly. The internal chamber is advantageously disposed on or near the non-patient needle assembly to permit an increase in the internal volume of the blood collection set without being located directly in the blood flow path.

[0012] The IV needle assembly typically comprises an IV hub having a proximal end, a distal end and a passage extending between the ends. The IV needle assembly typically further comprises an IV cannula having a proximal end mounted in the passage of the IV hub, a pointed distal end projecting distally from the IV hub and a lumen that communicates with the passage through the IV hub. The flexible tubing is typically connected to the proximal end of the IV hub. The IV needle assembly typically includes a packaging cover that protectively encloses the IV needle cannula prior to use. The packaging cover is removed immediately prior to use to permit access to the IV cannula. The IV needle assembly may further include a protective shield that is moveable relative to the IV cannula from an open position where the IV cannula is exposed to a closed position where the IV cannula is substantially shielded. The shield protects against accidental sticks with the used IV cannula. A pair of flexible wings may be mounted to the IV hub or to the shield to facilitate manipulation of the IV needle assembly.

[0013] In this embodiment, the non-patient needle assembly includes a non-patient hub having a proximal end and a distal end. The non-patient needle assembly further includes a non-patient cannula having a distal end securely mounted in the hub, a proximal end projecting proximally from the non-patient hub and a lumen that communicates with the passage through the non-patient hub. A multiple sample sleeve is typically mounted over the non-patient cannula and secured to the proximal end of the non-patient hub. External portions of the non-patient hub near the proximal end thereof may be formed with an array of external threads or other mounting structure to enable the non-patient needle assembly to be mounted to a collection tube holder or other such medical device. Or, the holder may be pre-attached with the non-patient needle assembly. The blood collection set may further include a fitting mounted to the proximal end of the flexible plastic tubing and configured for mating with the distal end of the non-patient hub. For example, the fitting may be a female luer fitting that can be engaged with the male luer taper at the distal end of the non-patient hub.

[0014] In one embodiment, the internal chamber is located in the non-patient assembly beyond the non-patient cannula proximal end, which means that the air passes through the non-patient cannula proximal end from which blood is drawn, and then into the internal chamber. Specifically, on venous entry air is compressed and flows from the fluid passage and out of the non-patient cannula proximal end where it further flows through the space between needle exterior and multiple sample sleeve. The air then flows into the internal chamber, which may be at the non-patient barb, the non-patient hub thread, the non-patient hub body, or other location or combination of locations that are beyond the non-patient cannula proximal end. The collection tube, which is applied at the non-patient cannula proximal end, draws blood from only the fluid passage and not from the internal chamber.

[0015] In another embodiment, a one-way check valve is located within the internal chamber. The valve allows air and blood to enter the internal chamber but shuts closed both when vacuum is applied. Thus, when an

evacuated collection tube is applied at the non-patient needle tip, the tube draws blood from the fluid passage but not from the internal chamber, and upon removal of the IV needle from the targeted blood vessel, the check valve closes and inhibits blood from dripping from the IV needle tip.

[0016] In a further embodiment, the internal chamber utilizes a branch in the fluid passage, e.g., a "Y" or "T". The branching may be at any location or locations along the fluid passage, but is advantageously at the proximal end such as at the non-patient hub. The branching may be in the form of a separate component added into the fluid passage such as in between the female and male luer fittings or it may be integral within the hub. The branching includes some type of internal chamber as discussed herein.

BRIEF DESCRIPTION OF THE DRAWINGS

[0017] FIG. 1A is a perspective view of a prior art blood collection set and collection tube holder.

[0018] FIG. 1B is a top plan view of the blood collection set and collection tube holder shown in FIG. 1A.

[0019] FIG. 2 is an exploded perspective view of a prior art blood collection set.

[0020] FIG. 3 is side elevation view of a prior art non-patient needle assembly, partly in section.

[0021] FIG. 4 is a cross-sectional side view of an embodiment of the non-patient needle assembly of the blood collection set.

[0022] FIG. 5 is a perspective view of the same embodiment shown in FIG. 4

[0023] FIG. 6 is a cross-sectional side view of an embodiment of the non-patient needle assembly of the blood collection set.

[0024] FIG. 7 is a perspective view of the same embodiment shown in FIG. 6

[0025] FIG. 8 is a cross-sectional side view of an embodiment of the non-patient needle assembly of the blood collection set.

[0026] FIG. 9 is an expanded view of the same embodiment shown in FIG. 8

[0027] FIG. 10 is a perspective view of one embodiment of a one way check valve.

[0028] FIG. 11 is a plan view of the same embodiment shown in FIG. 10

[0029] FIG. 12 is a cross-sectional side view of the same embodiment shown in FIG. 10

[0030] FIG. 13 is a perspective view of one embodiment of the blood collection set.

[0031] FIG. 14 is a perspective view of one embodiment of the blood collection set.

DETAILED DESCRIPTION

[0032] A prior art blood collection set that contains IV cannula shielding is identified generally by the numeral **10** in FIGS. 1A and 1B. Blood collection set **10** is employed in this embodiment with a collection tube holder **12.** Holder **12** has a proximal end **14,** a distal end **16** and a tubular sidewall **18** extending between the ends. Proximal end **14** of holder **12** is widely open and defines an entry to a tube receptacle within sidewall **18.** Thus, an evacuated collection tube can be slid in a proximal-to-distal direction through open proximal end **14** of holder **12** toward distal end **16.** Distal end **16** of holder **12** is characterized by an end wall **20.** End wall **20** is formed with an internally threaded mounting aperture **22,** as shown in FIG. 3.

[0033] Blood collection set **10** includes an IV needle assembly **24** that comprises an IV hub **26.** IV hub **26** includes a proximal end **28,** a distal end **30** and a passage (not shown) extending between the ends. IV needle assembly **24** further includes an IV cannula **32** with a proximal end **34,** a pointed distal end **36** and a lumen **38** extending between the ends. Proximal end **34** of IV cannula **32** is mounted securely in the passage of IV hub **26.** Thus, lumen **38** through IV cannula **32** communicates with the passage through IV hub **26.** Flexible wings **40** are mounted to IV hub **26** at a location near distal end **30.** Wings **40** can be folded into face-to-face relationship with one another for convenient gripping between a thumb and forefinger to enable manipulation of IV needle assembly **24.** Wings **40,** however, also can be rotated into a substantially coplanar disposition for taping to the skin of a patient.

[0034] IV needle assembly **24** further includes a tubular shield **42** that is telescoped over IV hub **26.** Shield **42** is formed with transverse slots **44** that slidably receive wings **40.** Thus, shield **42** can be slid from a proximal position, as shown in FIGS. 1A and 1B to a distal position. IV cannula **32** is exposed for use when shield **42** is in the proximal position shown in FIGS. 1A and 1B. However, IV cannula **32** is substantially surrounded by shield **42** when shield **42** is moved to the distal position. Additionally, slots **44** in shield **42** are configured to lockingly engage wings **40** when shield **42** is in the distal position to prevent or complicate a re-exposure of IV cannula **32.** In this case the presence of a shield does not inhibit flash visualization within the IV needle assembly. The shield illustrated in FIGS. 1A and 1B is one of many optional shield designs that can be incorporated into blood collection set **10.** Other designs may provide wings mounted directly to the shield. Still other designs may provide a hinged shield mounted to IV hub **26.** In still other designs, a shield may be entirely separate from IV needle assembly **24.**

[0035] Another prior art blood collection set is identified generally by the numeral **110** in FIG. 2. Fluid collection/infusion set **110** includes a length of flexible plastic tubing **112,** a proximal fitting **114,** a needle assembly **116,** a spring **118** and a barrel assembly that comprises a front barrel **120,** a rear barrel **122** and a wing **124.** Needle assembly **116** includes a needle cannula **134,** a needle hub **136** and a needle protector **138.** Needle cannula **134** has a proximal end **140,** a distal end **142** and a lumen

144 extending between the ends. Distal end 142 of needle cannula 134 is beveled to a sharp tip.

[0036] FIGS. 1 A and 1B also show that a blood collection set 10 further includes a length of flexible plastic tubing 46. Tubing 46 includes opposite proximal and distal ends 48 and 50 and a passage extending between the ends. Distal end 50 of tubing 46 is securely mounted to proximal end 28 of IV hub 26 so that the passage through IV hub 26 communicates with the passage through tubing 46. A female luer fitting 52 is securely mounted to proximal end 48 of tubing 46.

[0037] Blood collection set 10 further includes a non-patient needle assembly 54, as shown in FIG. 3. Non-patient needle assembly 54 includes a non-patient hub 56 with a proximal end 58, a distal end 60 and a fluid passage 62 extending between the ends. Exterior surface regions of non-patient hub 56 substantially adjacent proximal end 58 define an array of external threads 64 configured for threaded engagement with the internal threads formed in mounting aperture 22 of collection tube holder 12. External surface regions of non-patient hub 56 adjacent distal end define a male luer taper 66 configured for mating with female luer fitting 52. Non-patient needle assembly 54 further includes a non-patient cannula 68 having a pointed proximal end 70, a distal end 72 and a lumen 74 extending between the ends. Distal end 72 of non-patient cannula 68 is mounted securely in passage 62 through non-patient hub 56 and aligns substantially with external threads 64 on non-patient hub 56. Non-patient needle assembly 54 further includes a multiple sample sleeve 76 mounted over non-patient cannula 68 and securely engaged with proximal end 58 of non-patient hub 56. Multiple sample sleeve 76 effectively functions as a valve that prevents a flow of fluid from non-patient cannula 68. However, multiple sample sleeve 76 can be pierced by pointed proximal end 70 of non-patient cannula 68 in response to forces generated by a stopper on an evacuated collection tube.

[0038] It should be noted that flash visualization maybe acceptable in certain blood collection sets with safety features, such as the type shown in FIGS. 1A and 1B. The IV needle assembly and safety shield tend to be made from a translucent plastic material, and may only contain the IV cannula and flexible tubing, which may allow flash to be seen through the IV cannula hub walls. Therefore a minimum length of flash maybe sufficient, such that initial blood flow on venous entry maybe observed at the proximal end of the IV cannula. However in more advanced and complex IV cannula shielding mechanisms, such as the blood collection set shown in FIG. 2, the length of flash obtained from a typical venous entry may not be sufficient for blood flow to be observed in the flexible tubing at a location proximal to the IV needle assembly itself, therefore flash visualization tends to be inhibited within the IV needle assembly.

[0039] According to one embodiment of the invention, a blood collection set, for example of the type disclosed above, contains an internal chamber that increases the internal volume of the blood collection set. The increase in internal volume of the blood collection set provides a greater length of flash and therefore improved flash visualization, such that, advantageously, blood is observed in the flexible tubing proximal the IV needle assembly on the initial venous entry. While such improved or lengthened flash is particularly advantageous for such complex blood collection sets as shown in FIG 2, application in any blood collection set is contemplated.

[0040] According to this embodiment of the invention, a blood collection set includes a plurality of internal spaces that will initially be at ambient air pressure. These internal spaces include the lumen through the IV cannula, the passage through the IV hub, the passage through the flexible tubing, the passage through the non-patient hub and lumen through the non-patient cannula. The blood collection set is employed by folding wings into face-to-face engagement with one another and gripping the wings between a thumb and forefinger. Any packaging cover that may be mounted over IV cannula then is removed and discarded. The pointed distal end of the IV cannula then is urged into a targeted blood vessel. The healthcare practitioner then may release the grip on the wings, and if long term access to the blood vessel is required, the wings may be taped into face-to-face engagement with the skin of the patient. The venous or arterial access achieved with the IV cannula places the plurality of interior spaces of the blood collection set in communication with the pressure of the blood in the patient. Blood pressure exceeds the ambient air pressure. Accordingly, the pressure of air in the above-referenced internal spaces will increase, and blood will begin to flow into these internal spaces. The system will reach equilibrium as the air pressure within the blood collection set increases in response to a reduction of volume caused by the inflow of blood. Hence, a portion of the internal spaces in the system will remain filled with air at a pressure substantially equal to the venous or arterial pressure thereby preventing blood from flowing any further to or into the tubing. Stated differently, the system will include its original volume of air in the space between the proximal end of the non-patient needle and the blood that enters the blood collection set. This pressurized air will prevent any further flow of blood toward the non-patient assembly, thereby stopping flash. In prior art systems the total volume of the internal spaces maybe insufficient, such that flash maybe stopped before it can be observed. According to embodiments of the invention, however, the internal chamber which lacks direct communication to the exterior, provides more internal volume into which the air can be pushed, allowing blood to push further into the device before the pressure of the blood equals the pressure of the air. This increase in interior space thereby allows a greater length of flash to occur. Various embodiments of such internal chambers are described in detail below.

[0041] FIGS. 4 and 5 show an embodiment of the invention, where the internal chamber 301 is located be-

yond the proximal end **370** of the non-patient cannula in the non-patient hub **356** and lacks direct communication to the exterior. The internal chamber **301** is annular in cross-section and has opposite proximal **770** and distal ends **771** and a wall **772** extending therebetween; the proximal end **770** has an inlet **777** in communication with the passage. However all internal chamber geometries can be considered for the invention. The non-patient hub **356** is generally made from 2 separate parts; the male luer **374** and the non-patient thread assembly **375.** Other configurations are possible. On venous entry, air is compressed and flows from the fluid passage **362** and out of the non-patient cannula proximal end **370** where it further flows through the space **312** between needle exterior **368** and multiple sample sleeve interior **376,** then through a passage **314** through the non-patient barb and the male luer wall **320** into the internal chamber **301** through the inlet **777** in the male luer **374.**

[0042] FIGS 6 and 7 show another embodiment of the invention, with an elongated internal chamber to further increase the flash length. The internal chamber **301a** is annular in cross-section and has opposite proximal **770a** and distal ends **771a** and a wall **772a** extending therebetween, the proximal end **770a** has an inlet **777a** in communication with the passage. However all internal chamber geometries can be considered for the invention. The non-patient hub is made from 2 separate parts; the male luer **374a** and the non-patient thread assembly **375a.** The longer internal chamber **301a** is located beyond the proximal end **370a** of the non-patient cannula in the non-patient thread assembly **375a** and has no direct communication to the exterior. Other configurations are possible. On venous entry, air is compressed and flows from the fluid passage **362a** and out of the non-patient cannula proximal end **370a** where it further flows through the space **312a** between needle exterior **368a** and multiple sample sleeve interior **376a,** then through a passage **314a** through the non-patient barb into an internal chamber **301a** through an inlet **777a** in the non-patient thread assembly **375a.**

[0043] FIGS 8 to 12 show a further embodiment of the invention, in which a one-way valve **555** is located within an internal chamber similar to that shown in FIG. 6. The one way valve has a central core **550** surrounded by an annular flange **551** that has a sealing ring **552** around its outer diameter. The central core **550** is located around the non-patient needle exterior **368b** within the internal chamber **301b** and has a tapered base **553** which mates to the taper of inlet **777b.** Typically the one way valve **555** is formed from a resilient polymer such as an elastomer or thermoplastic.

[0044] As apparent to one skilled in the art, on venous entry, air flows from the fluid passage **362b** and out of the non-patient cannula proximal end **370b** where it further flows through the space **312b** between needle exterior **368b** and multiple sample sleeve interior **376b,** then through a passage **314b,** through the non-patient barb and the male luer wall **320b,** through the inlet **777b** where it moves the one-way valve **555,** flowing past the valve core base **553,** valve sealing ring **552** and into an internal chamber **301b** in the male luer **374b.** A vacuum is applied to the fluid passage, when an evacuated collection tube is applied at the non-patient needle tip. The resultant positive pressure differential between the internal chamber and the fluid passage causes the one way valve **555** to close, by the valve sealing ring **552** being pressed against the proximal end of the internal chamber **770b** and the valve core tapered base **553** being pressed into inlet 777b thereby preventing outflow of air or blood from the internal chamber,. It should be noted that the one way valve is not limited to the particular design described in this embodiment as all types of one way valves can be contemplated for this invention.

[0045] The one way valve **555** also inhibits blood from dripping from the IV needle tip upon removal of the IV needle from the targeted blood vessel after the blood collection has been completed. In prior art blood collection sets, at the instance of removal of the IV needle, the fluid passage of the blood collection set, will contain a reservoir of air and blood at venous pressure, which will be greater than the ambient atmospheric pressure. Thus a back pressure is created within the fluid passage which may cause a back-flow of blood to drip from the IV needle tip. In the embodiment of the invention shown in FIGS 8 to 12, the reservoir of air at venous pressure is within the internal chamber **301b,** therefore the back pressure causes the one way valve **555** to shut upon removal of the IV needle thereby preventing such a back-flow of blood in the fluid passage **362b.**

[0046] FIGS 13 and 14 show another embodiment of an internal chamber **401** which is branched from the fluid passage using a "Y" or "T" branched internal chamber in the fluid passage into which air is displaced. The branching may be at any location or locations along the fluid passage, but is typically near the proximal end such as at the non-patient hub. FIG 13 shows a "Y" branched internal chamber **454** in the form of a separate component added into the fluid passage **462** such as in between the female **455** and male luer **456** fittings. FIG 14 shows a "T" branched internal chamber **457,** which is an integral part of the non-patient hub, thus reducing the number of components. The use of a "Y" or "T" branched internal chamber may be accomplished with any convenient terminal shapes at the interfaces of each component. The embodiments exemplified previously are shown with luer tapered fittings but other interface designs such as direct connection to the flexible tubing may also be applied. Although typical applications use a three port "Y" or "T" branched internal chamber the use of a multiple port branched internal chamber system is also possible. The internal chamber **401,** can be a separate component which is affixed into a port **460** of the branch system as shown in FIG 13 or an integral part of the branched system as shown in FIG 14. All internal chamber geometries can also be contemplated.

Claims

1. A blood collection set comprising;
a first needle assembly comprising a first hub and a first cannula having a lumen therethrough, wherein said cannula is mounted to said first hub,
a length of flexible tubing having opposite first and second ends and a tubing passage extending between said ends, said first hub located proximate said first end for providing communication between said lumen of said first cannula and said tubing passage,
a second hub located proximate said second end and having a passage extending therethrough, said second hub passage being in fluid communication with said tubing passage,
a non-patient cannula having opposite proximal and distal ends and a lumen extending between said ends, said distal end of said non-patient cannula being mounted to said second hub such that said lumen through said non-patient cannula communicates with said second hub passage,
a multiple sample sleeve covering said non-patient cannula and mounted to said second hub, and
an internal chamber in communication with said second hub passage, wherein said internal chamber is located within said second hub or is branched from said second hub passage, and wherein said internal chamber lacks direct communication to the exterior.

2. The blood collection set of claim 1, wherein said second hub further comprises a male luer and a non-patient thread assembly, which form said internal chamber.

3. The blood collection set of claim 1, wherein said internal chamber communicates with said second hub passage beyond said proximal end of said non-patient cannula.

4. The blood collection set of claim 1, further comprising a one way valve, wherein said one way valve inhibits an outflow of air or fluid from said internal chamber.

5. The blood collection set of claim 4, wherein said one way valve is located within said internal chamber.

6. The blood collection set of claim 1, wherein upon venous access by said first needle cannula, venous pressure causes blood to flow into said tubing passage, such that the total internal volume of said internal chamber and tubing passage results in a flash length of at least approximately 0.25 inches in linear distance in a proximal direction along said tubular passage from said first end of said flexible tubing.

7. The blood collection set of claim 1, wherein upon venous access by said first needle cannula, venous pressure causes blood to flow into said tubing passage, such that the total internal volume of said internal chamber and tubing passage results in a flash length of at least approximately 0.50 inches in linear distance in a proximal direction along said tubular passage from said first end of said flexible tubing.

8. The blood collection set of claim 1, wherein said internal chamber is branched from said second hub passage.

9. The blood collection set of claim 8, wherein said internal chamber is a Y branched internal chamber or a T branched internal chamber.

10. The blood collection set of claim 1, wherein the volume of said internal chamber is at least approximately 1.0 ml.

11. The blood collection set of claim 10, wherein said volume of said internal chamber is approximately 1.0 ml to approximately 3.0 ml.

12. The blood collection set of claim 11, wherein said volume of said internal chamber is approximately 1.0 ml to approximately 2.0 ml.

13. A blood collection set comprising;
a first needle assembly comprising a first hub and a first cannula having a lumen therethrough, wherein said cannula is mounted to said first hub,
a length of flexible tubing having opposite first and second ends and a tubing passage extending between said ends, said first hub located proximate said first end for providing communication between said lumen of said first cannula and said tubing passage,
a second hub located proximate said second end and having a passage extending therethrough, said second hub passage being in fluid communication with said tubing passage,
a non-patient cannula having opposite proximal and distal ends and a lumen extending between said ends, said distal end of said non-patient cannula being mounted to said second hub such that said lumen through said non-patient cannula communicates with said second hub passage,
a multiple sample sleeve covering said non-patient cannula and mounted to said second hub, and
an internal chamber in communication with said second hub passage, wherein said internal chamber is located within said second hub or is branched from said second hub passage, and wherein said internal chamber lacks direct communication to the exterior,
wherein upon on venous access by said first needle cannula, venous pressure causes blood to flow into said tubing passage, such that the total internal volume of said internal chamber and tubing passage

results in flash being observed within said flexible tubing.

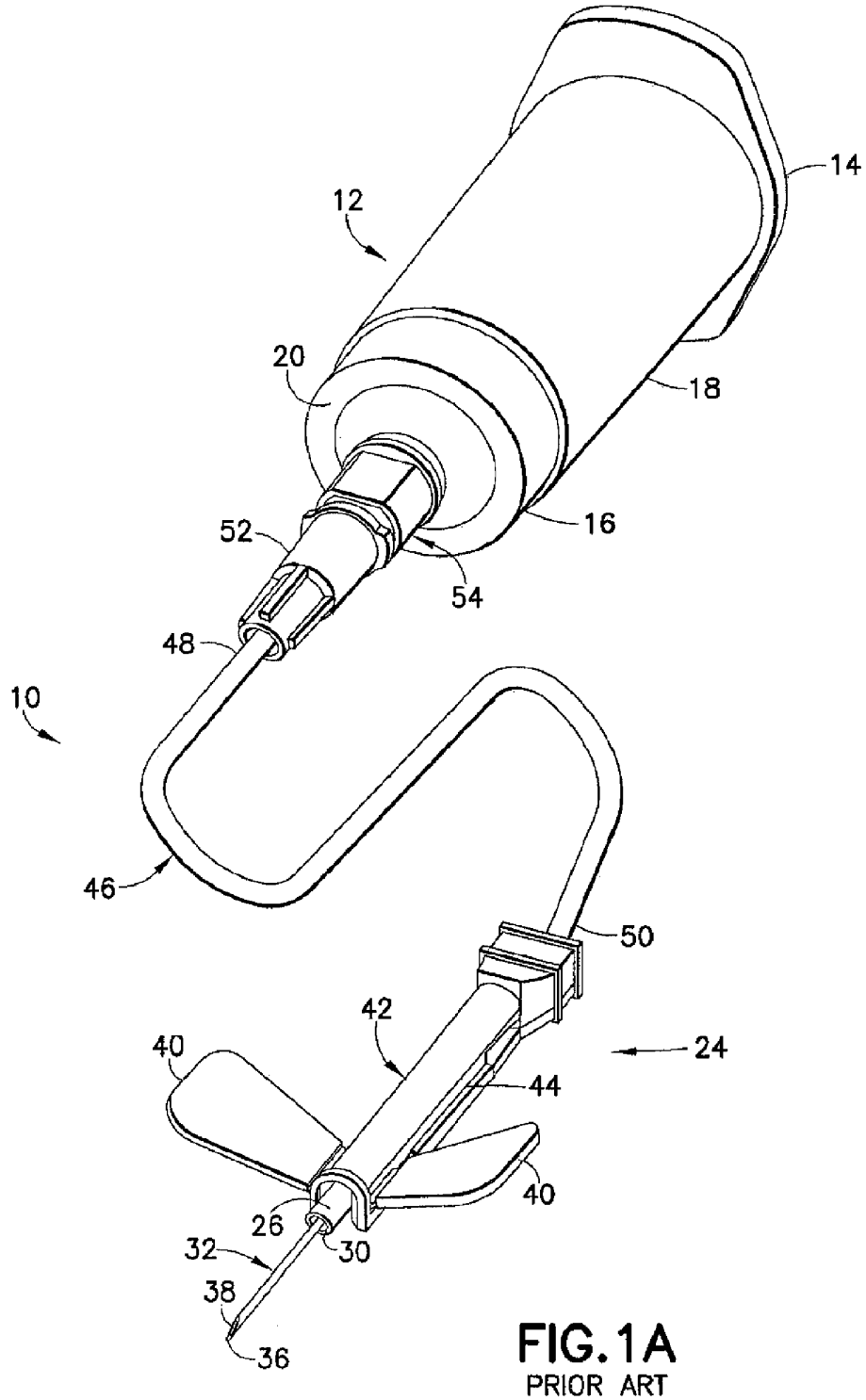


FIG. 1A
PRIOR ART

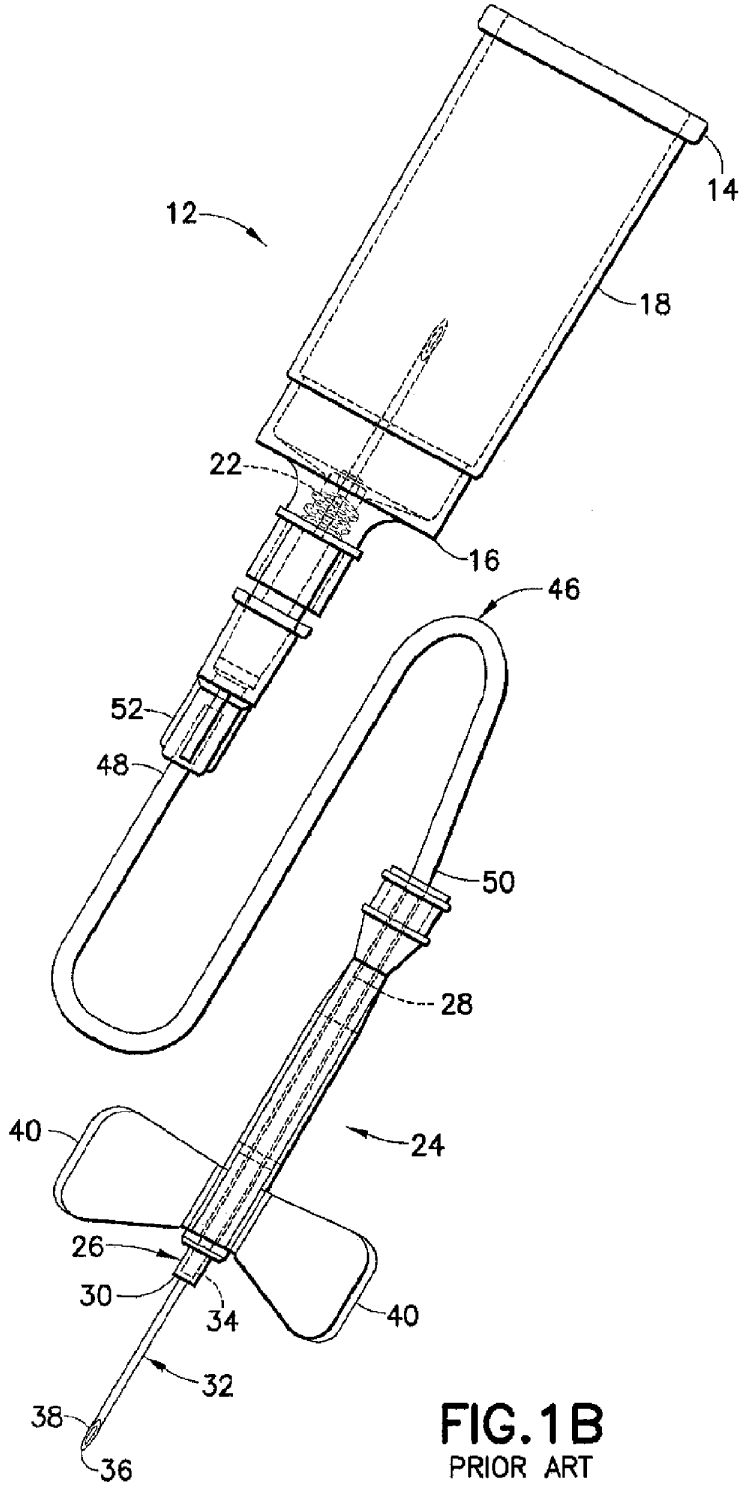


FIG. 1B
PRIOR ART

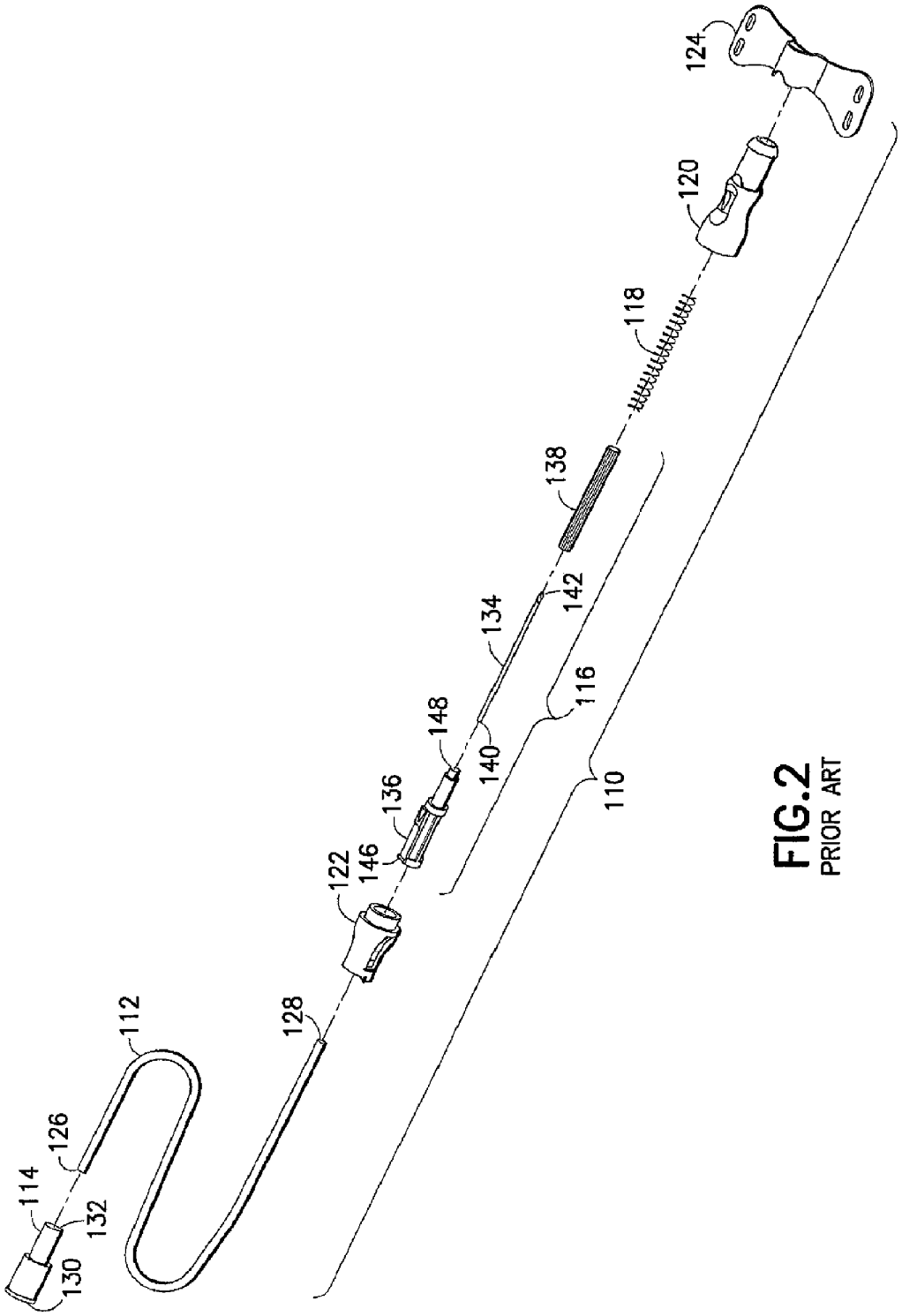


FIG.2
PRIOR ART

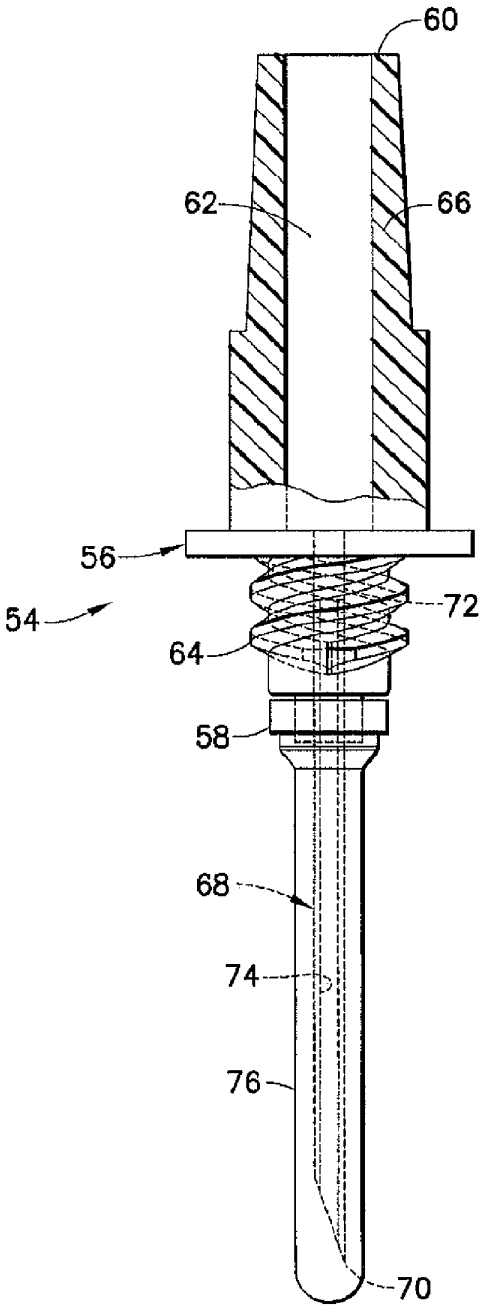


FIG.3
PRIOR ART

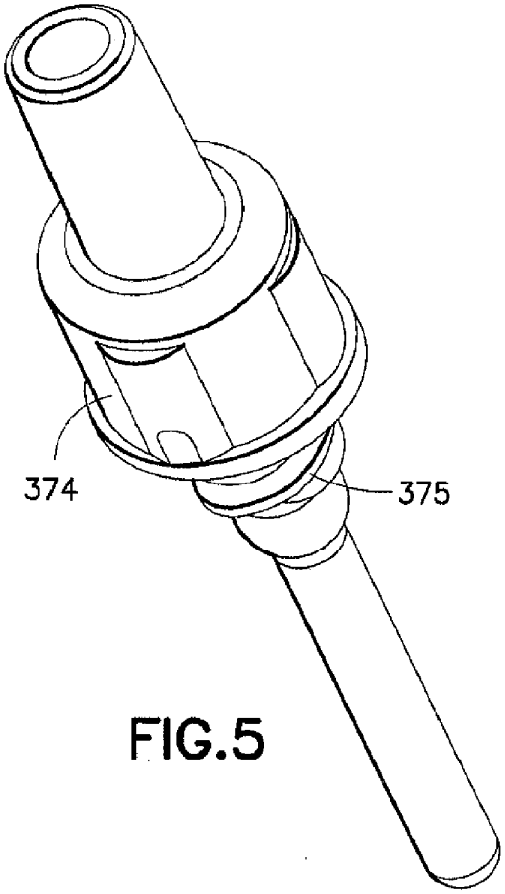

374
375

FIG.5

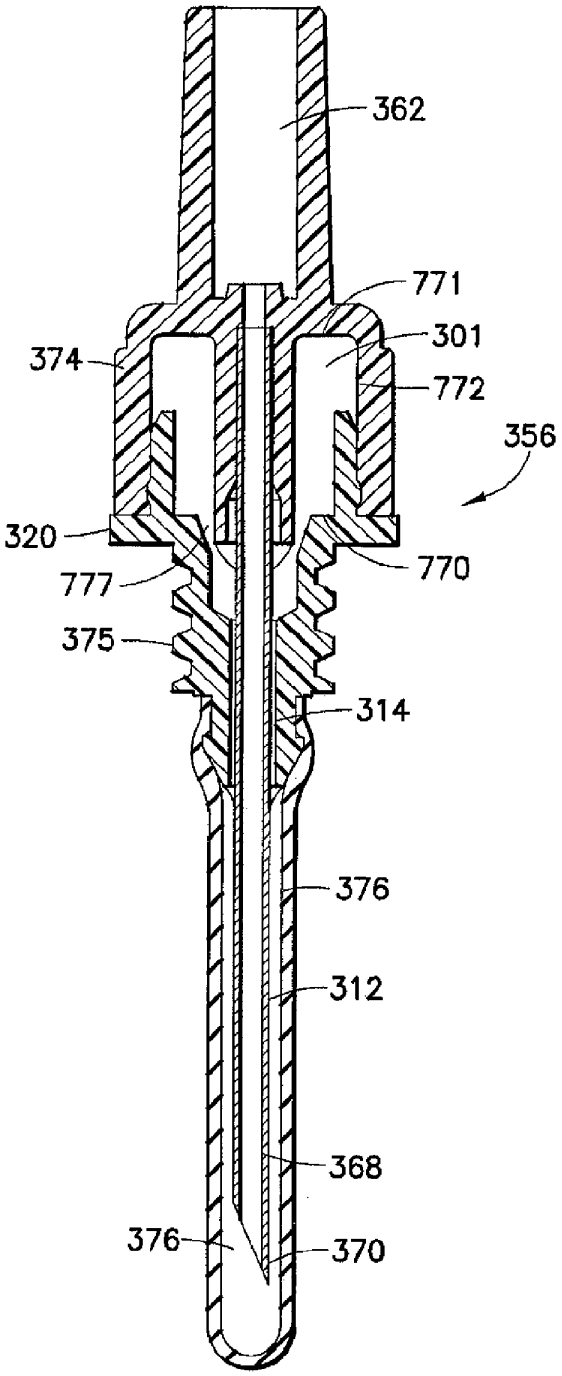

362
771
301
374
772
356
320
770
777
375
314
376
312
368
376
370

FIG.4

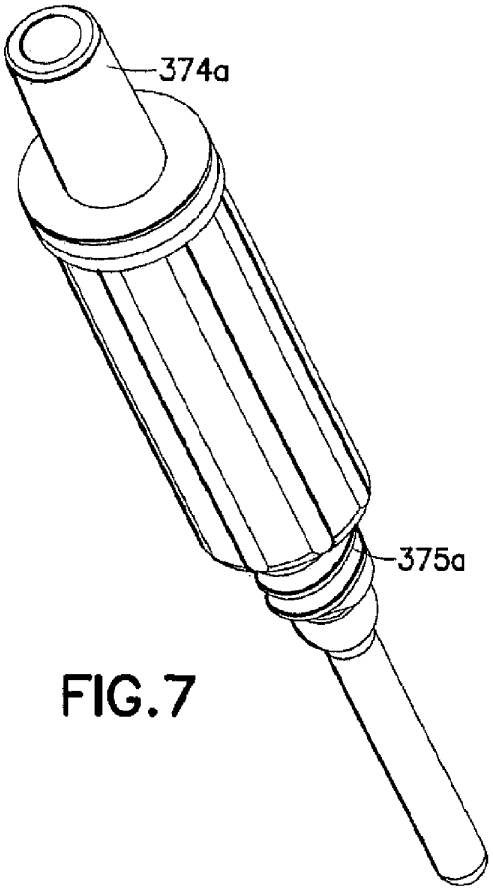

374a
375a

FIG.7

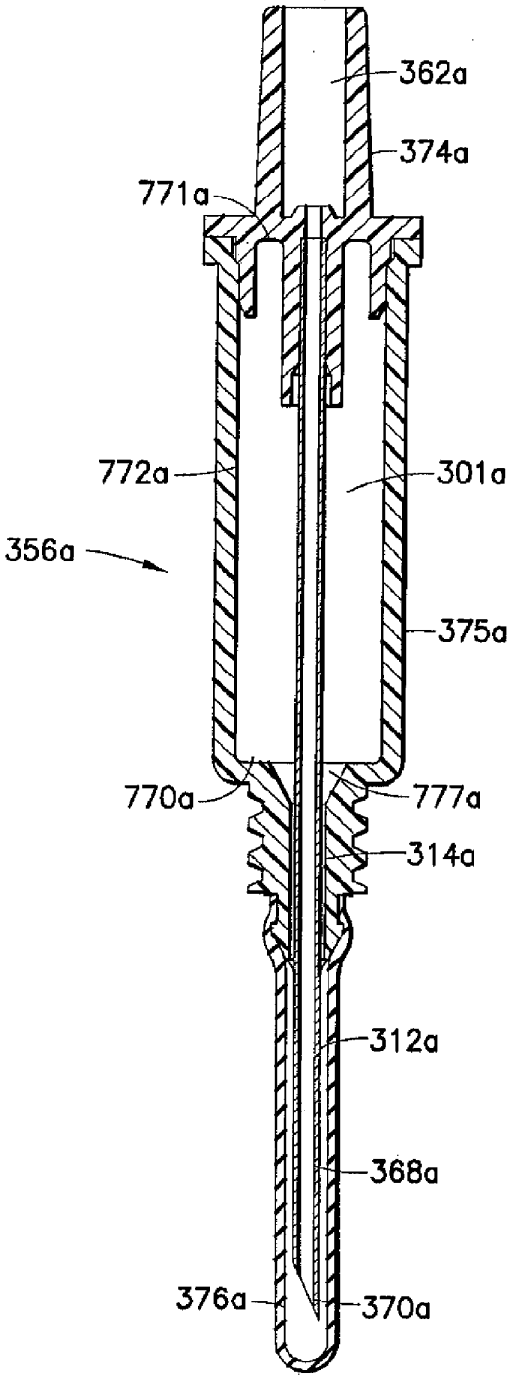

362a
374a
771a
772a
301a
356a
375a
770a
777a
314a
312a
368a
376a
370a

FIG.6

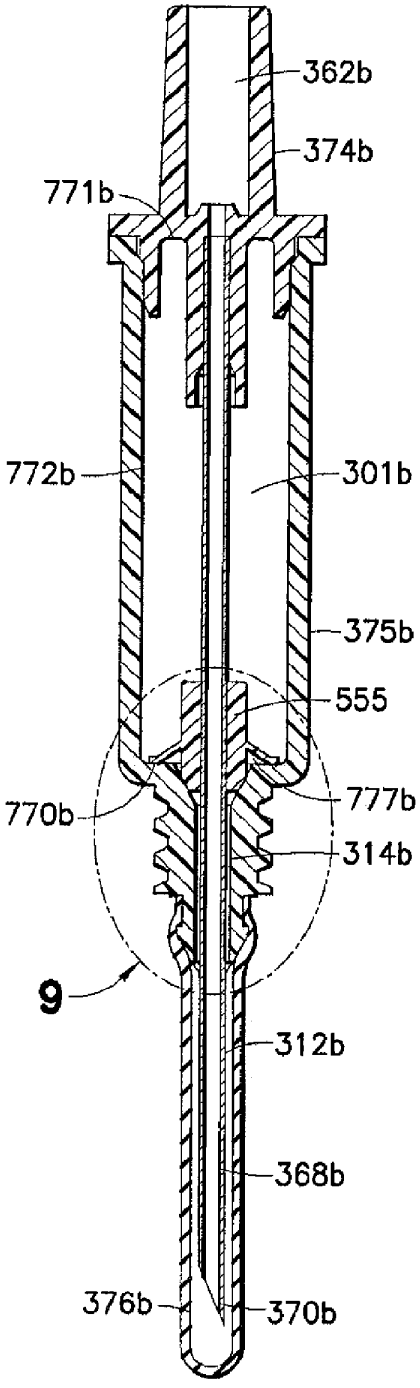

362b
374b
771b
772b
301b
375b
555
770b
777b
314b
9
312b
368b
376b
370b

FIG.8

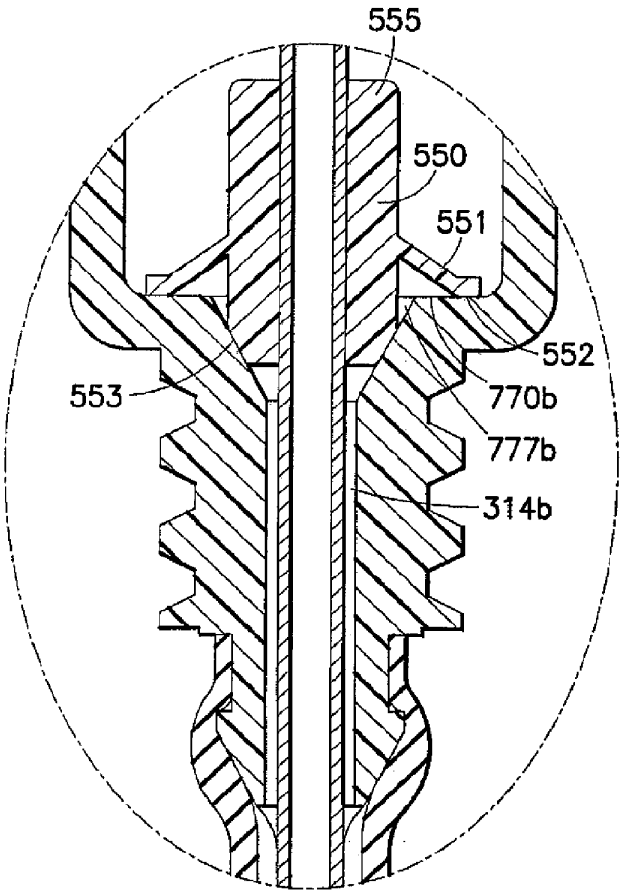

555
550
551
552
553
770b
777b
314b

FIG.9

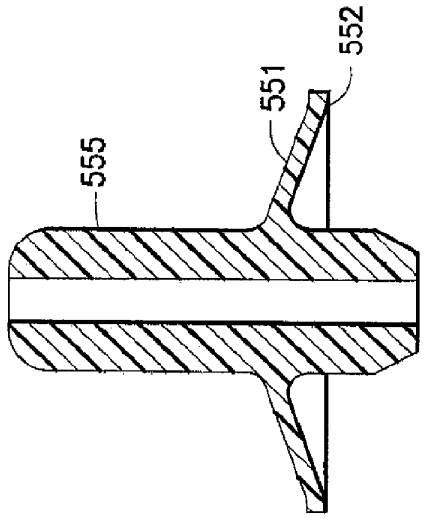


FIG.12

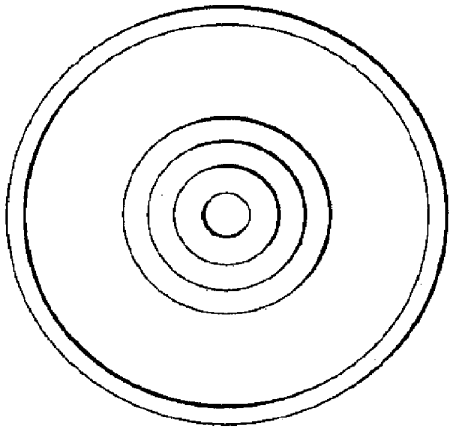


FIG.11

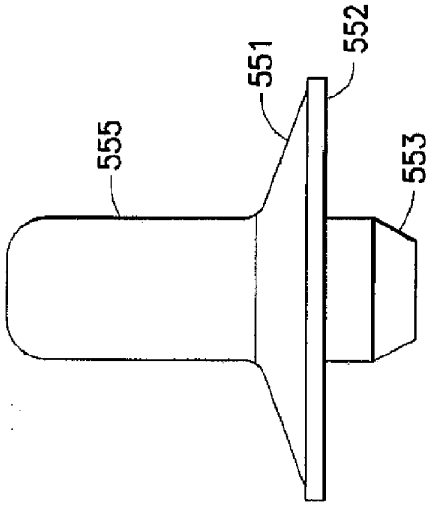


FIG.10

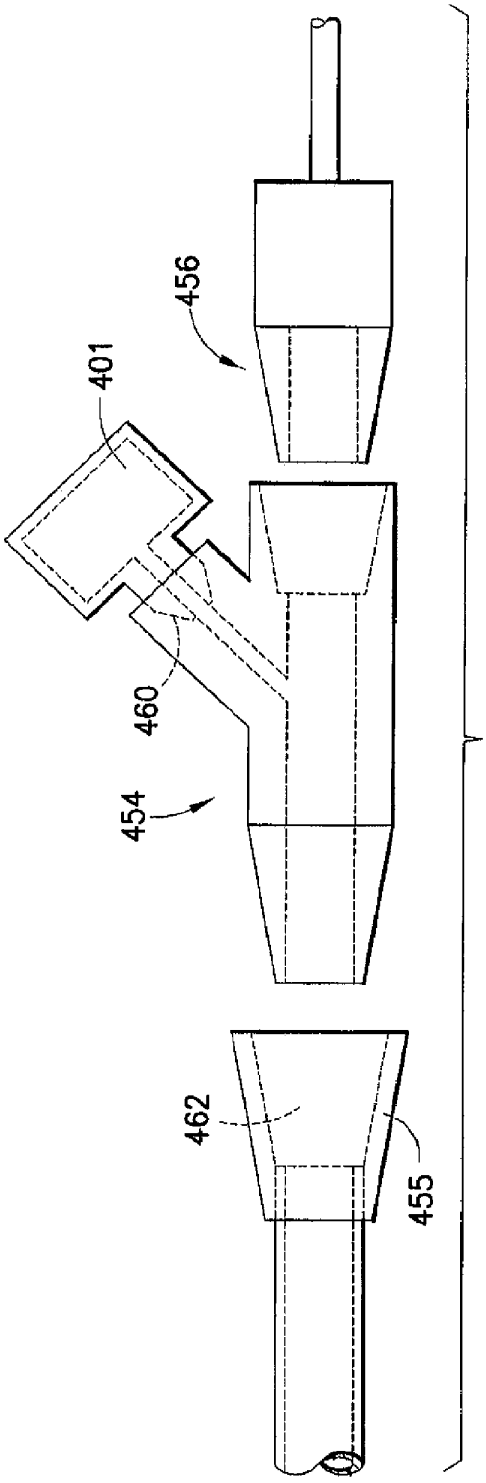


FIG.13

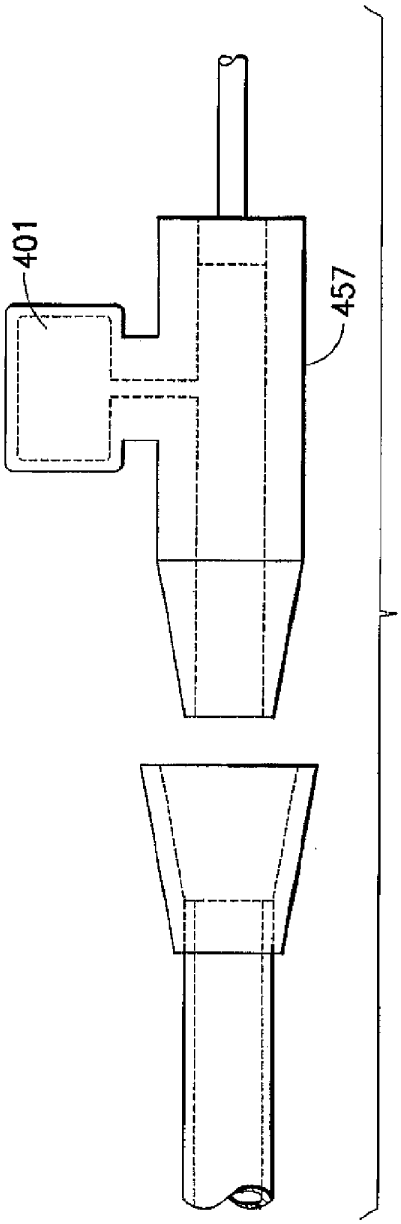


FIG.14

European Patent Office

EUROPEAN SEARCH REPORT

Application Number
EP 05 11 1371

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (IPC)
Y	EP 1 442 705 A (BECTON, DICKINSON AND COMPANY) 4 August 2004 (2004-08-04)	1-3,6-13	A61B5/154 A61B5/155
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Y	WO 2004/062499 A (BECTON DICKINSON AND COMPANY) 29 July 2004 (2004-07-29) * paragraph [0030]; figures 3,4 *	1-3,6,7, 10-12	

TECHNICAL FIELDS SEARCHED (IPC)

A61B
A61M

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
Munich	16 March 2006	Ceccarelli, D

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
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A : technological background
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E : earlier patent document, but published on, or after the filing date
D : document cited in the application
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EPO FORM 1503 03.82 (P04C01)

ANNEX TO THE EUROPEAN SEARCH REPORT ON EUROPEAN PATENT APPLICATION NO. EP 05 11 1371

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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16-03-2006

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EPO FORM P0459

For more details about this annex : see Official Journal of the European Patent Office, No. 12/82

Espacenet

Bibliographic data: JP2012016496 (A) — 2012-01-26

SAMPLING PORT

Inventor(s): MURAKOSHI MASAHIDE; AKIYAMA MASAHIRO; HAYAKAWA AYA ± (MURAKOSHI MASAHIDE, ; AKIYAMA MASAHIRO, ; HAYAKAWA AYA)

Applicant(s): TERUMO CORP ± (TERUMO CORP)

Classification: **- international:** ***A61B5/15; A61B5/154;*** *A61M39/02*
- cooperative: **A61B5/15003**; **A61B5/150389**; **A61B5/150503**; **A61B5/150572**; **A61B5/150732**; **A61B5/150992**; **A61B5/154**

Application number: JP20100156165 20100708 Global Dossier

Priority number(s): JP20100156165 20100708

Also published as: JP5599244 (B2)

Abstract of JP2012016496 (A)

PROBLEM TO BE SOLVED: To provide a sampling port that maintains a force for holding a rubber cap to a needle assembly even if creases are formed by the elastic contraction of the rubber cap when a hollow needle is inserted into a rubber plug of a blood collecting tube, thereby preventing leakage of blood.SOLUTION: The sampling port 20 includes a body part 30 with an opening 31 formed for inserting the blood collecting tube 50 comprising the rubber plug 51; the hollow needle 61 insertable through the rubber plug of the blood collecting tube; a hub 64 for supporting the proximal end of the hollow needle; the elastic rubber cap 70 covering the hollow needle; and a holding part 80 holding the rubber cap. The sampling port 20 further includes the needle assembly 60 mounted on the body part, and a plate 92 serving as a preventing member 90 having a through-hole 91 which the hollow needle covered with the rubber cap penetrates, and preventing the creases 71 formed by the elastic contraction of the rubber cap when the hollow needle is inserted into the rubber plug, from reaching the holding part.

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DESCRIPTION JP2012016496

An object of the present invention is to maintain a holding force for holding a rubber cap on a needle assembly even if the rubber cap is elastically compressed and wrinkles are generated as the hollow needle is inserted into the rubber plug of the blood collection tube. , Provide a sampling port that can sufficiently prevent blood leakage. A sampling port (20) includes a body portion (30) having an opening (31) for inserting a blood collection tube (50) provided with a rubber plug (51), a hollow needle (61) insertable into the rubber plug of the blood collection tube, and a hollow needle A needle assembly 60 attached to the main body, comprising: a hub 64 for supporting the proximal end of the needle; an elastic rubber cap 70 covered with a hollow needle; and a holding portion 80 for holding the rubber cap. It has a through hole 91 through which the hollow needle covered with the rubber cap penetrates, and prevents the weir 71 caused by the elastic contraction of the rubber cap accompanying the insertion of the hollow needle into the rubber plug from reaching the holding portion And a plate 92 as the suppressing member 90. [Selected figure] Figure 4

サンプリングポート

[0001]
The present invention relates to a sampling port for holding a blood collection tube.

[0002]

When blood is collected using a blood collection tube provided with a rubber plug, a sampling port for holding the blood collection tube is used (see Patent Document 1).

The sampling port has a main body having an opening for inserting a blood collection tube, and a needle assembly having a hollow needle insertable into a rubber plug of the blood collection tube is attached to the main body. There is. The hollow needle is covered with an elastic rubber cap to prevent blood leakage.

[0003]

As the blood collection tube is inserted into the main body of the sampling port and the hollow needle is inserted through the rubber plug, the rubber cap is elastically compressed to expose the hollow needle while causing wrinkles. The exposed hollow needle collects blood into a blood collection tube. When the blood collection tube is pulled out after blood collection, the rubber cap elastically expands so as to stretch the eyelid from the contracted state, and restores a state in which the hollow needle is covered again. This prevents the leakage of blood from the hollow needle. The rubber cap is held to the needle assembly, for example by bringing the root portion into intimate contact with the needle assembly.

[0004]
Japanese Patent Application Laid-Open No. 2002-291724

[0005]

However, wrinkles caused by elastic compression of the rubber cap as the hollow needle is inserted into the rubber plug of the blood collection tube may reach the root of the rubber cap.

In such a case, the root portion of the rubber cap swells, and the holding force for holding the rubber cap on the needle assembly is weakened. For this reason, when the tip of the rubber cap bites into the minute insertion hole of the rubber plug of the blood collection tube, the rubber cap is pulled together when pulling out the blood collection tube, and the position of the rubber cap etc. And there is a risk that the prevention of blood leakage will be inadequate.

[0006]
The present invention has been made to solve the problems associated with the prior art

described above, and even if the rubber cap is elastically shrunk as a result of insertion of the hollow needle into the rubber plug of the blood collection tube, wrinkles may occur, It is an object of the present invention to provide a sampling port which can maintain a holding force for holding a rubber cap on a needle assembly, thereby sufficiently preventing blood leakage.

[0007]

A sampling port according to the present invention for achieving the above object comprises: a main body portion having an opening for inserting a blood collection tube provided with a rubber plug; a hollow needle insertable into the rubber plug of the blood collection tube; A needle assembly attached to the main body, comprising: a hub for supporting the proximal end of the hollow needle; a rubber cap having elasticity which is placed on the hollow needle; and a holding part for holding the rubber cap A holder provided with a through hole through which the hollow needle covered with the rubber cap penetrates, and the rubber cap being elastically contracted along with the insertion of the hollow needle into the rubber plug; And the suppression member which suppresses that it reaches.

[0008]

The suppressing member prevents the wrinkles generated by the elastic contraction of the rubber cap with the insertion of the hollow needle into the rubber stopper of the blood collection tube from reaching the holding portion, so the rubber cap at the portion of the holding portion Does not expand, and the holding force for holding the rubber cap on the needle assembly is not weak.

Therefore, even if the rubber cap is pulled together when pulling out the blood collection tube after blood collection, the position of the rubber cap does not shift, and it is possible to sufficiently prevent the leakage of the blood.

In this way, even if the rubber cap is elastically contracted and wrinkles occur as the hollow needle is inserted into the rubber plug of the blood collection tube, the holding force for holding the rubber cap on the needle assembly can be maintained. Thus, it is possible to provide a sampling port that can sufficiently prevent blood leakage.

[0009]

FIG. 1 is a block diagram showing a blood bag system in which a sampling port is incorporated. FIG. 2 is a perspective view showing an initial blood flow bag shown in FIG. 1 and a sampling port. It is sectional drawing which shows the principal part of the sampling port before inserting a blood collection tube. It is sectional drawing which shows the principal part of the sampling port after inserting a blood collection tube. 5 (A) is a perspective view showing a plate as a restraining member, FIG. 5 (B) is a cross-sectional view taken along line 5B-5B of FIG. 5 (A), and FIG. 5 (C) is FIG. 5C is an enlarged sectional view of the 5C portion of FIG. 6 (A) and 6 (B) are cross-sectional views showing how the plate as the suppressing member is fixed to the main body. FIG. 7A is a conceptual diagram for explaining the operation of the present embodiment, and FIG. 7B is a conceptual diagram for explaining the operation in the case of a comparative example in which a plate is not provided. FIGS. 8A to 8D are cross-sectional views showing modified examples of the plate. FIGS. 9 (A) and 9 (B) are plan views showing further modifications of the plate.

[0010]

Hereinafter, embodiments of the present invention will be described with reference to the attached drawings. In the description of the drawings, the same elements will be denoted by the same reference symbols, without redundant description. Also, the dimensional proportions of the drawings are exaggerated for the convenience of the description, and may differ from the actual proportions.

[0011]

Referring to FIG. 1, the blood bag system 10 shown in the figure is a blood collection device that removes an initial flow (initial blood flow) of the collected blood when collecting blood and uses the initial blood flow as a blood for examination. is there. First run blood is removed because bacteria present on the skin and under the skin enter with the skin fragments at the time of puncture.

[0012]

The blood bag system 10 includes a blood collection needle 11, a blood bag 12 for storing blood collected via the blood collection needle 11, a blood collection tube 13 for communicating the

blood collection needle 11 with the blood bag 12, and a middle of the blood collection tube 13. And an initial blood flow bag 16 communicating with the blood collection tube 13 via the branch tube 15 connected to the branch connector 14, and a sampling port 20 connected to the end of the initial blood flow bag 16 doing. The branch connector 14 is provided with a sealing member 17 for sealing the communication with the blood bag 12. The sealing member 17 blocks the communication to the blood bag 12 until the blood collection of the initial blood into the initial blood bag 16 is completed. The branch tube 15 is provided with a clamp member 18 for blocking the blood flow to the initial blood flow bag 16. When blood collection of primary blood flow ends, the branch tube 15 is clamped by the clamp member 18 and the blood flow to the primary blood flow bag 16 is cut off. Thereafter, the sealing member 17 is opened and blood collection to the blood bag 12 is started.

[0013]

FIG. 2 shows a state in which the initial blood flow stored in the initial blood flow bag 16 is collected as the test blood. A sampling port 20 is connected to the blood removal tube 19 connected to the initial blood flow bag 16. A lid member 40 for opening and closing the opening 31 is rotatably connected to the sampling port 20 via a hinge 41. When the primary flow blood stored in the primary blood flow bag 16 is collected as the blood for examination, a vacuum blood collection tube 50 (corresponding to a blood collection tube) provided with a rubber plug 51 is inserted into the sampling port 20 from the opening 31.

[0014]

The reduced pressure blood collection tube 50 is a device for collecting the initial blood flow stored in the initial blood flow bag 16. The reduced pressure blood collection tube 50 has a blood collection tube main body 52 and a rubber plug 51 fitted in the opening of the blood collection tube main body 52. The inside of the reduced pressure blood collection tube 50 is in a vacuum or reduced pressure state. When the reduced pressure blood collection tube 50 is connected to the sampling port 20, the rubber plug 51 is pierced by the hollow needle 61. As a result, the inside of the reduced pressure blood collection tube 50 and the blood removal tube 19 communicate with each other, and the initial flow blood from the blood removal tube 19 is collected in the reduced pressure blood collection tube 50.

[0015]

With reference to FIGS. 3 and 4, the sampling port 20 according to the embodiment can be described as follows: a body portion 30 provided with an opening 31 for inserting a blood collection tube 50 provided with a rubber plug 51; 50, a hollow needle 61 which can be inserted through the rubber plug 51, a hub 64 which supports the proximal end of the hollow needle 61, an elastic rubber cap 70 which is put on the hollow needle 61, and a holding which holds the rubber cap 70 And a needle assembly 60 attached to the body portion 30. The sampling port 20 further suppresses the wedge 71 (see FIG. 4) generated by the elastic contraction of the rubber cap 70 due to the insertion of the hollow needle 61 into the rubber plug 51 from reaching the holding portion 80. A member 90 is provided. The suppression member 90 includes a through hole 91 through which the hollow needle 61 covered with the rubber cap 70 passes. In FIGS. 3 and 4, the upper side in the drawings is the "upper side" of each member, and the lower side in the drawings is the "lower side" of each member. Details will be described below.

[0016]

The main body 30 has a cylindrical shape, and the lower side has a tapered shape. The main body portion 30 is provided with an insertion port 32 for inserting the needle assembly 60 and a locking portion 33 for preventing the needle assembly 60 inserted from being removed.

[0017]

The main body 30 is rotatably attached to the needle assembly 60. By making it pivotable, the main body portion 30 can be pivoted with respect to the needle assembly 60, and the position of the lid member 40 with respect to the initial blood flow bag 16 can be easily finely adjusted.

[0018]

The needle assembly 60 has a hollow needle 61 having a sharp needle point at its tip, a connecting portion 62 connected to the blood removal tube 19, and a boss 63 for holding the proximal end of the hollow needle 61. ing. The hub 64 is provided to project radially outward of the boss portion 63. When the needle assembly 60 is inserted into the insertion port 32 of the main body 30, the hub 64 gets over the locking portion 33 and is attached to the main body 30. The upper end of the hub 64 in the figure is formed in an inclined surface so as to easily get over the locking portion 33 when the hub 64 is inserted.

[0019]
In order to rotatably attach the body 30 to the needle assembly 60, the clearance between the connection 62 of the needle assembly 60 and the insertion opening 32 of the body 30, and the outer periphery of the hub 64 and the body The dimension of the clearance between 30 and is adjusted.

[0020]

The rubber cap 70 causes the blood collection tube 50 to be inserted into the main body portion 30, and as the hollow needle 61 is inserted into the rubber plug 51, the rubber cap 70 is elastically compressed to expose the hollow needle 61 while producing a crease 71.

When the blood collection tube 50 is pulled out, the rubber cap 70 elastically extends from the contracted state so as to extend the fold 71 and restores to a state in which the hollow needle 61 is again covered. This prevents the blood from leaking from the hollow needle 61.

[0021]

The holding portion 80 is composed of a lock member 81 through which the hollow needle 61 is inserted and attached to the boss portion 63 of the needle assembly 60. The lock member 81 has an undercut shape in which the proximal end side of the hollow needle 61 is smaller in diameter than the distal end. The undercut shape of the lock member 81 holds the rubber cap 70.

[0022]

Referring to FIGS. 5A and 5B, the suppressing member 90 has a disk-shaped flat plate portion 93 fitted in the main body portion 30, and a convex portion 94 projecting toward the upper side at the central portion of the flat plate portion 93. And a plate 92 having A through hole 91 through which the hollow needle 61 to which the rubber cap 70 is attached passes is formed in the convex portion 94. As shown in FIG. 5C, on the outer peripheral edge of the flat plate portion 93, a ring-shaped projection 95 protruding outward in the radial direction is provided integrally with the flat plate portion 93.

[0023]

Referring again to FIGS. 3 and 4, the plate 92 is mounted in the main body 30 at a position above the locking member 81 forming the holding portion 80. As the blood collection tube 50 is inserted into the main body portion 30 and the hollow needle 61 is inserted into the rubber plug 51, the rubber cap 70 is elastically shrunk to expose the hollow needle 61 while producing a crease 71. . The clearance S between the through hole 91 of the plate 92 and the rubber cap 70 is relatively small. Therefore, the plate 92 prevents the crease 71 produced by the elastic compression of the rubber cap 70 from reaching the holding portion 80 (FIG. 4).

[0024]

As described above, the body 30 is pivotally attached to the needle assembly 60. Then, between the through hole 91 of the plate 92 fixed to the main body 30 and the rubber cap 70, a clearance S for allowing the main body 30 to pivot is set. By setting the clearance S to a dimension that does not inhibit the rotation of the main body 30, the rotational position of the main body 30 relative to the needle assembly 60, the position of the lid member 40 relative to the initial blood flow bag 16, etc. It becomes possible.

[0025]

By providing the plate 92 with the convex portion 94, the range which is not influenced by the crease 71 in the longitudinal direction of the rubber cap 70 can be enlarged. As a result, the reduction in holding force for holding the rubber cap 70 on the needle assembly 60 can be further suppressed. Even if the arrangement position of the plate 92 is shifted to the upper side from the position shown in FIG. However, in this case, since the position of the blood collection tube 50 is also shifted to the upper side, it may be necessary to slightly increase the length dimension of the main body 30 in the longitudinal direction. Therefore, by providing the plate 92 with the projection 94 projecting toward the opening 31 of the main body 30, the length of the main body 30 in the longitudinal direction is maintained, and the longitudinal direction of the rubber cap 70 is maintained. It is possible to secure a sufficient holding force for holding the rubber cap 70 on the needle assembly 60 by increasing the range not affected by the wedge 71.

[0026]
The constituent materials of the main body 30, the lid member 40, the needle assembly 60 excluding the hollow needle 61, the holding part 80, and the plate 92 are not particularly limited, but, for example, polycarbonate, polyethylene, polypropylene, ethylene-vinyl acetate co Examples thereof include polyolefins such as polymers and modified polyolefins.

[0027]
The constituent material of the hollow needle 61 is not particularly limited. For example, various metal materials such as stainless steel, aluminum or aluminum alloy, titanium or titanium alloy, super elastic alloy such as Ni-Ti alloy, various hard materials such as polyphenylene sulfide The resin material etc. are mentioned.

[0028]
The material of the rubber cap 70 is not particularly limited, but, for example, natural rubber, isoprene rubber, butadiene rubber, styrene-butadiene rubber, nitrile rubber, chloroprene rubber, butyl rubber, acrylic rubber, ethylene-propylene rubber, hydrin rubber, There are various rubber materials such as urethane rubber, silicone rubber and fluorine rubber.

[0029]

6A and 6B show how the plate 92 is fixed to the main body portion 30. FIG.

In the present embodiment, the main body 30 is formed of a resin material that shrinks more than the resin material forming the plate 92 when heat is applied.

This is because the plate 92 can be fixed to the main body 30 by applying heat for sterilization.

[0030]

More specifically, as shown in FIG. 6A, before the heat is applied, the inner diameter of the main body 30 is relatively large, and the ring-shaped projection 95 of the plate 92 bites into the main body 30 with a slight dimension.

Since the plate 92 can be inserted into the main body 30 relatively easily, the plate 92 can be easily incorporated.

[0031]

Then, as shown in FIG. 6 (B), when heat is applied in, for example, high-pressure steam sterilization (autoclave) performed for sterilization, the main body portion 30 contracts more than the plate 92. As a result, the ring-shaped projection 95 of the plate 92 further bites into the main body 30, and the plate 92 can be easily fixed to the main body 30.

[0032]
As a combination example of the above resin materials, for example, polypropylene can be applied as a molding material of the main body 30, and polycarbonate can be applied as a molding material of the plate 92.

[0033]
The operation of this embodiment will be described.

[0034]

When collecting blood, the blood collection tube 50 is inserted into the main body 30 of the sampling port 20, and the hollow needle 61 is inserted through the rubber plug 51.

As the hollow needle 61 is inserted into the rubber plug 51, the rubber cap 70 is elastically shrunk to expose the hollow needle 61 while producing a weir 71.

[0035]

Referring to FIG. 7B, in the case of the comparative example in which the plate 92 is not provided, the rubber cap 170 is elastically shrunk as the hollow needle 161 is inserted into the rubber plug 51 of the blood collection tube 50. The ridges 171 produced by the above may reach

the root of the rubber cap 170.

In such a case, the root portion of the rubber cap 170 is expanded, and the holding force for holding the rubber cap 170 on the needle assembly 160 is weakened. For this reason, when the blood collection tube 50 is pulled out, the rubber cap 170 is pulled together, the position of the rubber cap 170, and the like are shifted, and there is a possibility that the prevention of the leakage of the blood becomes insufficient.

[0036]

On the other hand, referring to FIGS. 4 and 7A, in the present embodiment, the plate 92 is located in the main body 30 at a position on the upper side of the lock member 81 forming the holding portion 80. Attached to The plate 92 prevents the hook 71 generated by the elastic contraction of the rubber cap 70 with the insertion of the hollow needle 61 into the rubber plug 51 of the blood collection tube 50 from reaching the lock member 81. Since the rubber cap 70 does not expand at the portion of the locking member 81, the holding force for holding the rubber cap 70 on the needle assembly 60 is not weakened.

[0037]

The exposed hollow needle 61 is inserted into the rubber plug 51 to collect blood into the blood collection tube 50. When the blood collection tube 50 is pulled out after blood collection, the rubber cap 70 elastically expands so as to extend the fold 71 from the contracted state, and restores the state of being re-covered with the hollow needle 61. This prevents the blood from leaking from the hollow needle 61. The rubber cap 70 is held by the needle assembly 60 at the locking member 81.

[0038]

When the blood collection tube 50 is pulled out in a state in which the tip of the rubber cap 70 bites into a minute insertion hole of the rubber plug 51 of the blood collection tube 50, the rubber cap 70 is pulled together. However, since the portion of the lock member 81 is not affected by the wedge 71, the holding force remains set at the initial stage. Therefore, the rubber cap 70 does not come off the hollow needle 61, and biting of the blood collection tube 50 into

the rubber plug 51 is released. As a result, the position of the rubber cap 70 and the like do not shift, and it is possible to sufficiently prevent the leakage of blood.

[0039]
As described above, even if the rubber cap 70 is elastically contracted as a result of insertion of the hollow needle 61 into the rubber plug 51 of the blood collection tube 50 and a crease 71 is generated, the rubber cap 70 is held on the needle assembly 60 Can maintain the holding force, thereby providing a sampling port 20 capable of sufficiently preventing blood leakage.

[0040]
The body portion 30 is rotatably attached to the needle assembly 60, and the plate 92 is fixed to the body portion 30, so that the body portion 30 is pivoted between the through hole 91 and the rubber cap 70. Since the allowable clearance S is provided, it is possible to easily finely adjust the rotational position or the like of the main body 30 with respect to the needle assembly 60.

[0041]
Further, since the plate 92 is provided with the convex portion 94 projecting toward the opening 31 side of the main body 30, the length of the rubber cap 70 in the longitudinal direction is maintained while the length of the main body 30 in the longitudinal direction is maintained. It is possible to secure a sufficient holding force for holding the rubber cap 70 on the needle assembly 60 by enlarging the range not affected by the hook 71.

[0042]
Further, since the ring-shaped projection 95 protruding radially outward is provided on the outer peripheral edge of the plate 92, the plate 92 is inserted into the main body 30 so that the ring-like projection 95 bites into the main body 30 with a slight dimension. It can be inserted, and the plate 92 can be easily incorporated.

[0043]

Further, the main body portion 30 is formed of a resin material that shrinks more than the resin material forming the plate 92 when heat is applied, and the plate 92 is formed of the main body portion 30 by applying heat for sterilization. The plate 92 can be relatively easily inserted into the main body 30 before applying heat, and the plate 92 can be easily incorporated.

On the other hand, when heat for sterilization is applied, the main body 30 contracts more than the plate 92.

Thus, the plate 92 can be easily fixed to the main body 30.

[0044]
(Modified Example of Plate) The plate has a through hole 91 through which the hollow needle 61 to which the rubber cap 70 is attached penetrates, and the rubber cap 70 is elastic with the insertion of the hollow needle 61 into the rubber plug 51 of the blood collection tube 50. The shape can be modified to an appropriate shape as long as the wrinkles 71 generated by being compressed are prevented from reaching the holding portion 80.

[0045]
For example, referring to FIG. 8, plate 92a (FIG. 8A) in which convex portion 94 smoothly protrudes from flat plate portion 93, and plates 92b and 92c having a flat upper surface with the entire thickness increased. 8 (B) (C), a plate 92 d (FIG. 8 (D)) having a cap shape that covers the holding portion 80 without covering the entire bottom surface of the main body 30 can be exemplified.

[0046]
Further, referring to FIG. 9, a plate 92e of a type in which a through portion is not formed in flat portion 93 (FIG. 9A) and a plate 92f of a type in which a through portion 96 is formed in flat portion 93 (FIG. 9B). Can also be

[0047]

(Other Modifications) Although the lock member 81 having the undercut shape is illustrated as the holding portion 80 for holding the rubber cap 70, the holding portion 80 is not limited to this case.

The holding portion 80 can be appropriately modified as long as it has a function of preventing the rubber cap 70 from coming off and holding the same in the needle assembly 60.

For example, the holding unit 80 may use a form in which the rubber cap 70 is adhered and held to the hollow needle 61 with an adhesive, a form in which the rubber cap 70 is adhered to the hollow needle 61 by ultrasonic welding, and a clip. The form etc. which hold ¦ maintain the rubber cap 70 to the hollow needle 61 can be illustrated by the insertion which was carried out.

These holding portions 80 may be used alone, or two or more types of holding portions 80 may be combined.

[0048]

Reference Signs List 20 sampling port, 30 main body, 31 opening, 50 vacuum blood collection tube (blood collection tube), 51 rubber stopper, 60 needle assembly, 61 hollow needle, 64 hub, 70 rubber cap, 71 hook, 80 holder, 81 lock Members, 90 restraint members, 91 through holes, 92 plates (suppression members), 93 flat plate parts, 94 convex parts, 95 ring-shaped projections, S clearance.

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CLAIMS JP2012016496

1.
A main body having an opening for inserting a blood collection tube provided with a rubber plug, a hollow needle insertable into the rubber plug of the blood collection tube, a hub supporting a proximal end of the hollow needle, A needle assembly attached to the main body portion, the needle assembly attached to the main body portion; and the hollow needle through which the rubber cap is passed. And a suppressing member that has a through hole for suppressing the wrinkles generated by the elastic contraction of the rubber cap with the insertion of the hollow needle into the rubber plug. Characteristic sampling port.

2.
The main body portion is rotatably attached to the needle assembly, the suppressing member is fixed to the main body portion, and the rotation of the main body portion is performed between the through hole and the rubber cap. The sampling port according to claim 1, having a clearance that allows movement.

3.
The said main-body part is cylindrical shape, The said suppression member is disk shape and is provided with the convex part which protrudes toward the said opening part side of the said main-body part. Sampling port.

4.
The sampling port according to any one of claims 1 to 3, wherein an outer peripheral edge of the

suppressing member is provided with a ring-shaped protrusion that protrudes radially outward.

5.

The main body portion is formed of a resin material that shrinks more than the resin material forming the suppression member when heat is applied, and the suppression member is reduced to the main body portion by applying heat for sterilization. The sampling port according to any one of claims 1 to 4, wherein the sampling port is fixed.

Espacenet

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SAMPLING PORT

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Abstract of JP2012016496 (A)

PROBLEM TO BE SOLVED: To provide a sampling port that maintains a force for holding a rubber cap to a needle assembly even if creases are formed by the elastic contraction of the rubber cap when a hollow needle is inserted into a rubber plug of a blood collecting tube, thereby preventing leakage of blood.SOLUTION: The sampling port 20 includes a body part 30 with an opening 31 formed for inserting the blood collecting tube 50 comprising the rubber plug 51; the hollow needle 61 insertable through the rubber plug of the blood collecting tube; a hub 64 for supporting the proximal end of the hollow needle; the elastic rubber cap 70 covering the hollow needle; and a holding part 80 holding the rubber cap. The sampling port 20 further includes the needle assembly 60 mounted on the body part, and a plate 92 serving as a preventing member 90 having a through-hole 91 which the hollow needle covered with the rubber cap penetrates, and preventing the creases 71 formed by the elastic contraction of the rubber cap when the hollow needle is inserted into the rubber plug, from reaching the holding part.

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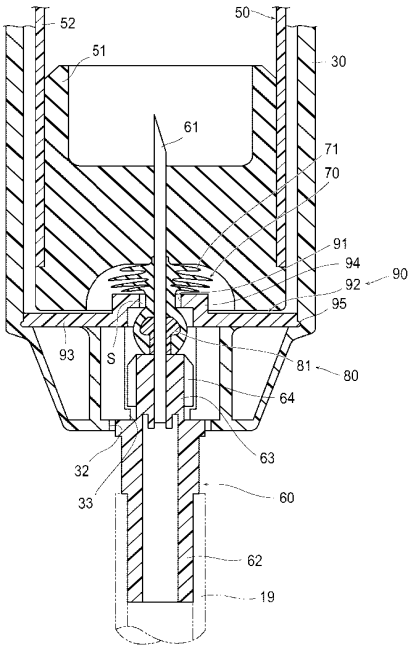
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最終頁に続く

(54)【発明の名称】サンプリングポート

(57)【要約】
【課題】採血管のゴム栓への中空針の挿通に伴ってゴムキャップが弾性的に縮められて皺が生じても、ゴムキャップを針組立体に保持するための保持力を維持でき、もって、血液の漏洩を十分に防止し得るサンプリングポートを提供する。
【解決手段】サンプリングポート２０は、ゴム栓５１を備える採血管５０を挿入するための開口部３１が形成された本体部３０と、採血管のゴム栓に挿通自在な中空針６１と、中空針の基端部を支持するハブ６４と、中空針に被せられた弾性を有するゴムキャップ７０と、ゴムキャップを保持する保持部８０と、を備え、本体部に取り付けられた針組立体６０と、ゴムキャップが被せられた中空針が貫通する貫通孔９１を備え、ゴム栓への中空針の挿通に伴ってゴムキャップが弾性的に縮められることによって生じる皺７１が保持部に達することを抑制する抑制部材９０としてのプレート９２と、を有している。
【選択図】図４



【特許請求の範囲】
【請求項１】
ゴム栓を備える採血管を挿入するための開口部が形成された本体部と、
前記採血管の前記ゴム栓に挿通自在な中空針と、前記中空針の基端部を支持するハブと、前記中空針に被せられた弾性を有するゴムキャップと、前記ゴムキャップを保持する保持部と、を備え、前記本体部に取り付けられた針組立体と、
前記ゴムキャップが被せられた前記中空針が貫通する貫通孔を備え、前記ゴム栓への前記中空針の挿通に伴って前記ゴムキャップが弾性的に縮められることによって生じる皺が前記保持部に達することを抑制する抑制部材と、を有することを特徴とするサンプリングポート。
【請求項２】
前記本体部は、前記針組立体に対して回動自在に取り付けられ、
前記抑制部材は、前記本体部に固定されており、前記貫通孔と前記ゴムキャップとの間に、前記本体部の回動を許容するクリアランスを有する、請求項１に記載のサンプリングポート。
【請求項３】
前記本体部は、円筒形状であり、
前記抑制部材は、円盤形状であり、前記本体部の前記開口部の側に向けて突出する凸部を備えている、請求項１または請求項２に記載のサンプリングポート。
【請求項４】
前記抑制部材の外周縁には、径方向外方に突出するリング状突起が設けられている、請求項１～３のいずれか１つに記載のサンプリングポート。
【請求項５】
前記本体部は、熱を印加したときに前記抑制部材を形成する樹脂材料よりも大きく収縮する樹脂材料から形成されており、滅菌のための熱を印加することによって、前記抑制部材を前記本体部に対して固定する、請求項１～４のいずれか１つに記載のサンプリングポート。
【発明の詳細な説明】
【技術分野】
【０００１】
本発明は、採血管を保持するサンプリングポートに関する。
【背景技術】
【０００２】
ゴム栓を備える採血管を用いて採血するときには、採血管を保持するサンプリングポートが使用される（特許文献１を参照）。サンプリングポートは、採血管を挿入するための開口部が形成された本体部を有し、この本体部には、採血管のゴム栓に挿通自在な中空針を備えた針組立体が取り付けられている。中空針には、血液の漏洩を防止するために、弾性を有するゴムキャップが被せられている。
【０００３】
サンプリングポートの本体部に採血管を挿入し、中空針をゴム栓に挿通させるのに伴って、ゴムキャップは、弾性的に縮められて皺を生じながら中空針を露出させる。露出した中空針は、採血管に採血する。採血後に採血管を引き抜くと、ゴムキャップは、縮んだ状態から、皺を伸ばすように弾性的に伸び、中空針に再び被せられる状態まで復元する。これによって、中空針からの血液の漏洩を防止する。ゴムキャップは、例えば根元部分を針組立体に密着させることによって、針組立体に保持されている。
【先行技術文献】
【特許文献】
【０００４】
【特許文献１】特開２００２－２９１７２４
【発明の概要】

【発明が解決しようとする課題】
【０００５】
しかしながら、採血管のゴム栓への中空針の挿通に伴ってゴムキャップが弾性的に縮められることによって生じる皺が、ゴムキャップの根元部に達することがある。このような場合には、ゴムキャップの根元部が膨らんでしまい、ゴムキャップを針組立体に保持するための保持力が弱くなる。このため、採血管のゴム栓の微小な挿通孔にゴムキャップの先端部が食い込んでいるような場合においては、採血管を引き抜くときにゴムキャップが一緒に引っ張られてしまい、ゴムキャップの位置などがずれてしまい、血液の漏洩の防止が不十分になる虞がある。
【０００６】
本発明は、上記従来技術に伴う課題を解決するためになされたものであり、採血管のゴム栓への中空針の挿通に伴ってゴムキャップが弾性的に縮められて皺が生じても、ゴムキャップを針組立体に保持するための保持力を維持でき、もって、血液の漏洩を十分に防止し得るサンプリングポートを提供することを目的とする。
【課題を解決するための手段】
【０００７】
上記目的を達成するための本発明のサンプリングポートは、ゴム栓を備える採血管を挿入するための開口部が形成された本体部と、
前記採血管の前記ゴム栓に挿通自在な中空針と、前記中空針の基端部を支持するハブと、前記中空針に被せられた弾性を有するゴムキャップと、前記ゴムキャップを保持する保持部と、を備え、前記本体部に取り付けられた針組立体と、
前記ゴムキャップが被せられた前記中空針が貫通する貫通孔を備え、前記ゴム栓への前記中空針の挿通に伴って前記ゴムキャップが弾性的に縮められることによって生じる皺が前記保持部に達することを抑制する抑制部材と、を有している。
【発明の効果】
【０００８】
抑制部材によって、採血管のゴム栓への中空針の挿通に伴ってゴムキャップが弾性的に縮められることによって生じる皺が保持部に達することが抑制されているので、保持部の部分でゴムキャップが膨らむことがなく、ゴムキャップを針組立体に保持するための保持力が弱くならない。このため、採血後に採血管を引き抜くときにゴムキャップが一緒に引っ張られてしまっても、ゴムキャップの位置などがずれることがなく、血液の漏洩を十分に防止することが可能となる。このように、採血管のゴム栓への中空針の挿通に伴ってゴムキャップが弾性的に縮められて皺が生じても、ゴムキャップを針組立体に保持するための保持力を維持でき、もって、血液の漏洩を十分に防止し得るサンプリングポートを提供できる。
【図面の簡単な説明】
【０００９】
【図１】サンプリングポートが組み込まれた血液バッグシステムを示す構成図である。
【図２】図１に示される初流血バッグと、サンプリングポートとを示す斜視図である。
【図３】採血管を挿入する前のサンプリングポートの要部を示す断面図である。
【図４】採血管を挿入した後のサンプリングポートの要部を示す断面図である。
【図５】図５（Ａ）は、抑制部材としてのプレートを示す斜視図、図５（Ｂ）は、図５（Ａ）の５Ｂ－５Ｂ線に沿う断面図、図５（Ｃ）は、図５（Ｂ）の５Ｃ部分を拡大して示す断面図である。
【図６】図６（Ａ）（Ｂ）は、抑制部材としてのプレートを本体部に対して固定する様子を示す断面図である。
【図７】図７（Ａ）は、本実施形態の作用の説明に供する概念図、図７（Ｂ）は、プレートを設けていない対比例の場合の作用の説明に供する概念図である。
【図８】図８（Ａ）～（Ｄ）は、プレートの改変例を示す断面図である。
【図９】図９（Ａ）（Ｂ）は、プレートのさらなる改変例を示す平面図である。

【発明を実施するための形態】
【００１０】
以下、添付した図面を参照しながら、本発明の実施形態を説明する。なお、図面の説明において同一の要素には同一の符号を付し、重複する説明を省略する。また、図面の寸法比率は、説明の都合上誇張されており、実際の比率とは異なる場合がある。
【００１１】
図１を参照して、図示する血液バッグシステム１０は、血液を採取する際に、採取された血液の初流（初流血）を除去し、その初流血を検査用血液として利用する採血器具である。皮膚上や皮下に存在する細菌が穿刺時の皮膚のかけらとともに侵入するため、初流血を除去している。
【００１２】
血液バッグシステム１０は、採血針１１と、採血針１１を介して採取された血液を収納する血液バッグ１２と、採血針１１と血液バッグ１２とを連通する採血チューブ１３と、採血チューブ１３の途中に配置した分岐コネクタ１４と、分岐コネクタ１４に接続した分岐チューブ１５を介して採血チューブ１３に連通する初流血バッグ１６と、初流血バッグ１６の端部に接続されたサンプリングポート２０と、を有している。分岐コネクタ１４には血液バッグ１２への連通を封止する封止部材１７が設けられている。初流血バッグ１６への初流血の採血が終わるまで、封止部材１７は血液バッグ１２への連通を封止している。分岐チューブ１５には、初流血バッグ１６への血流を遮断するクランプ部材１８が設けられている。初流血の採血が終わると、クランプ部材１８によって分岐チューブ１５をクランプし、初流血バッグ１６への血流が遮断される。その後、封止部材１７を開放し、血液バッグ１２への採血を開始する。
【００１３】
図２には、初流血バッグ１６に収納した初流血を検査用血液として回収するときの状態が示されている。初流血バッグ１６に接続された血液取出チューブ１９にサンプリングポート２０が接続されている。サンプリングポート２０には、開口部３１を開閉する蓋部材４０がヒンジ４１を介して回動自在に接続されている。初流血バッグ１６に収納した初流血を検査用血液として回収するときには、ゴム栓５１を備える減圧採血管５０（採血管に相当する）が開口部３１からサンプリングポート２０内に挿入される。
【００１４】
減圧採血管５０は、初流血バッグ１６内に貯留された初流血を採取するための器具である。この減圧採血管５０は、採血管本体５２と、この採血管本体５２の開口に嵌め込まれているゴム栓５１と、を有している。減圧採血管５０内は、真空または減圧状態になっている。減圧採血管５０は、サンプリングポート２０に接続されたとき、ゴム栓５１が中空針６１によって刺通される。これによって、減圧採血管５０内と血液取出チューブ１９とが連通し、当該血液取出チューブ１９からの初流血が減圧採血管５０に回収される。
【００１５】
図３および図４を参照して、実施形態に係るサンプリングポート２０は、概説すれば、ゴム栓５１を備える採血管５０を挿入するための開口部３１が形成された本体部３０と、採血管５０のゴム栓５１に挿通自在な中空針６１と、中空針６１の基端部を支持するハブ６４と、中空針６１に被せられた弾性を有するゴムキャップ７０と、ゴムキャップ７０を保持する保持部８０と、を備え、本体部３０に取り付けられた針組立体６０と、を有している。サンプリングポート２０はさらに、ゴム栓５１への中空針６１の挿通に伴ってゴムキャップ７０が弾性的に縮められることによって生じる皺７１（図４を参照）が保持部８０に達することを抑制する抑制部材９０を有している。抑制部材９０は、ゴムキャップ７０が被せられた中空針６１が貫通する貫通孔９１を備えている。なお、図３および図４において図中上側を各部材における「上部側」とし、図中下側を各部材における「下部側」とする。以下詳述する。
【００１６】
本体部３０は、円筒形状を有し、下部側は先細りの形状を有している。本体部３０には

、針組立体６０を差し込むための差込口３２と、差し込まれた針組立体６０の抜けを防止する係止部３３とが設けられている。

【００１７】

本体部３０は、針組立体６０に対して回動自在に取り付けられている。回動自在にすることによって、本体部３０を針組立体６０に対して回動させて、初流血バッグ１６に対する蓋部材４０の位置などを簡単に微調整することができる。

【００１８】

針組立体６０は、先端に鋭利な針先を有する中空針６１と、血液取出チューブ１９に接続される接続部６２と、中空針６１の基端部を保持するボス部６３と、を有している。ハブ６４は、ボス部６３の径方向外方へ突出するように設けている。針組立体６０は、本体部３０の差込口３２に差し込むときにハブ６４が係止部３３を乗り越えて、本体部３０に取り付けられる。ハブ６４の図中上端は、差し込むときに係止部３３を乗り越え易いように傾斜面に形成されている。

【００１９】

本体部３０を針組立体６０に対して回動自在に取り付けるために、針組立体６０の接続部６２と本体部３０の差込口３２との間のクリアランス、およびハブ６４の外周と本体部３０との間のクリアランスの寸法が調整されている。

【００２０】

ゴムキャップ７０は、本体部３０に採血管５０を挿入させ、中空針６１をゴム栓５１に挿通させるのに伴って、弾性的に縮められて皺７１を生じながら中空針６１を露出させる。採血管５０を引き抜くと、ゴムキャップ７０は、縮んだ状態から、皺７１を伸ばすように弾性的に伸び、中空針６１に再び被せられる状態まで復元する。これによって、中空針６１からの血液の漏洩を防止する。

【００２１】

保持部８０は、中空針６１が挿通されるとともに針組立体６０のボス部６３に取り付けられたロック部材８１から構成されている。ロック部材８１は、中空針６１の基端部側が先端側よりも小径部となったアンダーカット形状を有している。ロック部材８１におけるアンダーカット形状によって、ゴムキャップ７０を保持している。

【００２２】

図５（Ａ）（Ｂ）を参照して、抑制部材９０は、本体部３０内に嵌り込む円盤形状の平板部９３と、平板部９３の中央部分において上部側に向けて突出する凸部９４とを有するプレート９２から構成されている。凸部９４に、ゴムキャップ７０が取り付けられた中空針６１が貫通する貫通孔９１が形成されている。図５（Ｃ）に示すように、平板部９３の外周縁には、径方向外方に突出するリング状突起９５が、平板部９３と一体的に設けられている。

【００２３】

図３および図４を再び参照して、プレート９２は、保持部８０をなすロック部材８１よりも上部側の位置において、本体部３０内に取り付けられている。本体部３０に採血管５０を挿入し、中空針６１をゴム栓５１に挿通させるのに伴って、ゴムキャップ７０は、弾性的に縮められて皺７１を生じながら中空針６１を露出させている。プレート９２の貫通孔９１とゴムキャップ７０との間のクリアランスＳは比較的小さい。したがって、プレート９２によって、ゴムキャップ７０が弾性的に縮められることによって生じる皺７１が保持部８０に達することが抑制される（図４）。

【００２４】

前述のように本体部３０は、針組立体６０に対して回動自在に取り付けられている。そして、本体部３０に固定されたプレート９２の貫通孔９１とゴムキャップ７０との間に、本体部３０の回動を許容するクリアランスＳを設定してある。クリアランスＳを本体部３０の回動を阻害しない寸法に設定することによって、針組立体６０に対する本体部３０の回動位置や、初流血バッグ１６に対する蓋部材４０の位置などを簡単に微調整することが可能となる。

【００２５】
プレート９２に凸部９４を備えさせることによって、ゴムキャップ７０の長手方向のうち皺７１の影響を受けない範囲を大きくすることができる。その結果、ゴムキャップ７０を針組立体６０に保持するための保持力の低下をより一層抑えることができる。プレート９２の配置位置を図４に示される位置から上部側にずらしても、ゴムキャップ７０の長手方向のうち皺７１の影響を受けない範囲を大きくすることができる。但し、この場合には、採血管５０の位置も上部側にずれるため、本体部３０の長手方向の長さ寸法を若干大きくする必要が生じる場合がある。したがって、プレート９２に本体部３０の開口部３１の側に向けて突出する凸部９４を備えさせることによって、本体部３０の長手方向の長さを維持したまま、ゴムキャップ７０の長手方向のうち皺７１の影響を受けない範囲を大きくして、ゴムキャップ７０を針組立体６０に保持するための十分な保持力を確保することが可能となる。

【００２６】
本体部３０、蓋部材４０、中空針６１を除いた針組立体６０、保持部８０、およびプレート９２の構成材料としては、特に限定されないが、例えば、ポリカーボネート、ポリエチレン、ポリプロピレン、エチレン－酢酸ビニル共重合体等のポリオレフィン、変性ポリオレフィンが挙げられる。

【００２７】
中空針６１の構成材料としては、特に限定されないが、例えば、ステンレス鋼、アルミニウムまたはアルミニウム合金、チタンまたはチタン合金、Ｎｉ－Ｔｉ合金等の超弾性合金等の各種金属材料、ポリフェニレンサルファイド等の各種硬質樹脂材料等が挙げられる。

【００２８】
また、ゴムキャップ７０の構成材料としては、特に限定されないが、例えば、天然ゴム、イソプレンゴム、ブタジエンゴム、スチレン－ブタジエンゴム、ニトリルゴム、クロロプレンゴム、ブチルゴム、アクリルゴム、エチレン－プロピレンゴム、ヒドリンゴム、ウレタンゴム、シリコーンゴム、フッ素ゴムのような各種ゴム材料が挙げられる。

【００２９】
図６（Ａ）（Ｂ）に、プレート９２を本体部３０に対して固定する様子が示される。本実施形態においては、本体部３０は、熱を印加したときにプレート９２を形成する樹脂材料よりも大きく収縮する樹脂材料から形成してある。滅菌のための熱を印加することによって、プレート９２を本体部３０に対して固定することができるからである。

【００３０】
さらに詳しくは、図６（Ａ）に示すように、熱を印加する前では、本体部３０の内径が比較的大きく、プレート９２のリング状突起９５が若干寸法だけ本体部３０に食い込んでいる。プレート９２を比較的簡単に本体部３０内に挿入できることから、プレート９２の組み込み作業を行いやすい。

【００３１】
そして、図６（Ｂ）に示すように、滅菌のために行われる例えば高圧蒸気滅菌法（オートクレーブ）における熱を印加すると、本体部３０がプレート９２よりも大きく収縮する。これによって、プレート９２のリング状突起９５が本体部３０にさらに食い込み、プレート９２を本体部３０に対して簡単に固定することができる。

【００３２】
上記のような樹脂材料の組み合わせ例として、例えば、本体部３０の成形材料としてポリプロピレンを適用し、プレート９２の成形材料としてポリカーボネートを適用することができる。

【００３３】
本実施形態の作用を説明する。

【００３４】
採血するときには、サンプリングポート２０の本体部３０に採血管５０を挿入し、中空

針６１をゴム栓５１に挿通させる。ゴム栓５１に中空針６１が挿通するのに伴って、ゴムキャップ７０は、弾性的に縮められて皺７１を生じながら中空針６１を露出させる。

【００３５】

図７（Ｂ）を参照して、プレート９２を設けていない対比例の場合には、採血管５０のゴム栓５１への中空針１６１の挿通に伴ってゴムキャップ１７０が弾性的に縮められることによって生じる皺１７１が、ゴムキャップ１７０の根元部に達することがある。このような場合には、ゴムキャップ１７０の根元部が膨らんでしまい、ゴムキャップ１７０を針組立体１６０に保持するための保持力が弱くなる。このため、採血管５０を引き抜くときにゴムキャップ１７０が一緒に引っ張られてしまい、ゴムキャップ１７０の位置などがずれてしまい、血液の漏洩の防止が不十分になる虞がある。

【００３６】

これに対して、図４および図７（Ａ）を参照して、本実施形態にあっては、プレート９２を、保持部８０をなすロック部材８１よりも上部側の位置において、本体部３０内に取り付けている。このプレート９２によって、採血管５０のゴム栓５１への中空針６１の挿通に伴ってゴムキャップ７０が弾性的に縮められることによって生じる皺７１がロック部材８１に達することが抑制される。ロック部材８１の部分でゴムキャップ７０が膨らむことがないので、ゴムキャップ７０を針組立体６０に保持するための保持力が弱くならない。

【００３７】

露出した中空針６１は、ゴム栓５１に挿通されて、採血管５０に採血する。採血後に採血管５０を引き抜くと、ゴムキャップ７０は、縮んだ状態から、皺７１を伸ばすように弾性的に伸び、中空針６１に再び被せられる状態まで復元する。これによって、中空針６１からの血液の漏洩を防止する。ゴムキャップ７０は、ロック部材８１の部分で針組立体６０に保持されている。

【００３８】

採血管５０のゴム栓５１の微小な挿通孔にゴムキャップ７０の先端部が食い込んだ状態で採血管５０を引き抜くと、ゴムキャップ７０が一緒に引っ張られる。しかし、ロック部材８１の部分は皺７１の影響を受けていないので、保持力は初期に設定したままである。このため、ゴムキャップ７０は、中空針６１から抜けずに、採血管５０のゴム栓５１への食い込みが解除される。これによって、ゴムキャップ７０の位置などがずれることがなく、血液の漏洩を十分に防止することが可能となる。

【００３９】

このように、採血管５０のゴム栓５１への中空針６１の挿通に伴ってゴムキャップ７０が弾性的に縮められて皺７１が生じても、ゴムキャップ７０を針組立体６０に保持するための保持力を維持でき、もって、血液の漏洩を十分に防止し得るサンプリングポート２０を提供できる。

【００４０】

また、本体部３０は針組立体６０に対して回動自在に取り付けられ、プレート９２は本体部３０に固定されており、貫通孔９１とゴムキャップ７０との間に本体部３０の回動を許容するクリアランスＳを有するため、針組立体６０に対する本体部３０の回動位置などを簡単に微調整することが可能となる。

【００４１】

また、プレート９２は、本体部３０の開口部３１の側に向けて突出する凸部９４を備えているため、本体部３０の長手方向の長さを維持したまま、ゴムキャップ７０の長手方向のうち皺７１の影響を受けない範囲を大きくして、ゴムキャップ７０を針組立体６０に保持するための十分な保持力を確保することが可能となる。

【００４２】

また、プレート９２の外周縁に径方向外方に突出するリング状突起９５を設けているため、リング状突起９５を若干寸法だけ本体部３０に食い込ませるようにしてプレート９２を本体部３０内に挿入させることができ、簡単にプレート９２の組み込み作業を行うこと

が可能となる。

【００４３】

また、本体部３０は、熱を印加したときにプレート９２を形成する樹脂材料よりも大きく収縮する樹脂材料から形成されており、滅菌のための熱を印加することによって、プレート９２を本体部３０に対して固定するため、熱を印加する前ではプレート９２を比較的簡単に本体部３０内に挿入でき、プレート９２の組み込み作業を行いやすい。一方、滅菌のための熱を印加すると、本体部３０がプレート９２よりも大きく収縮する。これによって、プレート９２を本体部３０に対して簡単に固定することができる。

【００４４】

（プレートの改変例）

プレートは、ゴムキャップ７０が取り付けられた中空針６１が貫通する貫通孔９１を備え、採血管５０のゴム栓５１への中空針６１の挿通に伴ってゴムキャップ７０が弾性的に縮められることによって生じる皺７１が保持部８０に達することを抑制する限りにおいて適宜の形状に改変することができる。

【００４５】

例えば、図８を参照して、凸部９４を平板部９３から滑らかに突出させたプレート９２ａ（図８（Ａ））、全体の厚みを厚くし上面を平坦面としたプレート９２ｂ、９２ｃ（図８（Ｂ）（Ｃ））、本体部３０の底面全体を覆わずに保持部８０に被せるようなキャップ形状を有するプレート９２ｄ（図８（Ｄ））などを例示することができる。

【００４６】

また、図９を参照して、平板部９３に貫通部を形成しないタイプのプレート９２ｅ（図９（Ａ））、平板部９３に貫通部９６を形成したタイプのプレート９２ｆ（図９（Ｂ））とすることもできる。

【００４７】

（その他の改変例）

ゴムキャップ７０を保持する保持部８０として、アンダーカット形状を有するロック部材８１を例示したが、保持部８０はこの場合に限定されるものではない。保持部８０は、針組立体６０に設けられゴムキャップ７０の抜けを防止して保持する機能を有している限りにおいて適宜改変することができる。例えば、保持部８０は、接着剤によってゴムキャップ７０を中空針６１に接着させて保持する形態、超音波融着によってゴムキャップ７０を中空針６１に融着させて保持する形態、クリップなどを用いた嵌め込みによってゴムキャップ７０を中空針６１に保持する形態などを例示することができる。これらの保持部８０を単独で用いてもよいし、２種以上を組み合わせた保持部８０であってもよい。

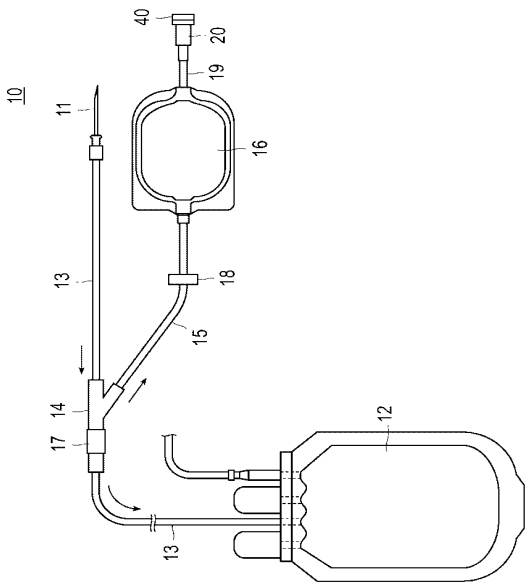
【符号の説明】

【００４８】

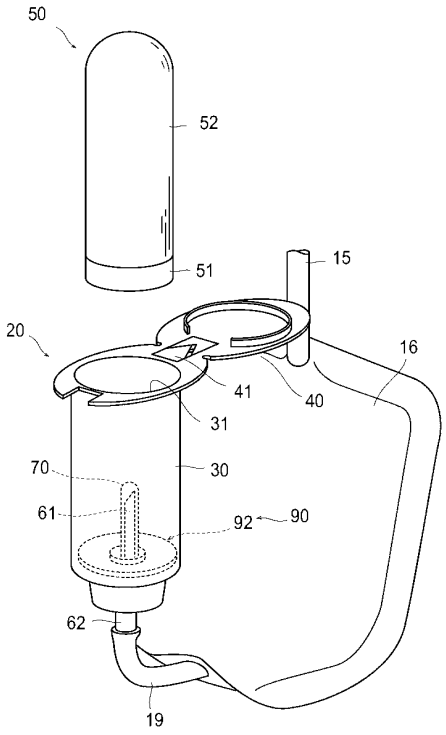
２０　サンプリングポート、
３０　本体部、
３１　開口部、
５０　減圧採血管（採血管）、
５１　ゴム栓、
６０　針組立体、
６１　中空針、
６４　ハブ、
７０　ゴムキャップ、
７１　皺、
８０　保持部、
８１　ロック部材、
９０　抑制部材、
９１　貫通孔、
９２　プレート（抑制部材）、

９３　　平板部、
９４　　凸部、
９５　　リング状突起、
Ｓ　　クリアランス。

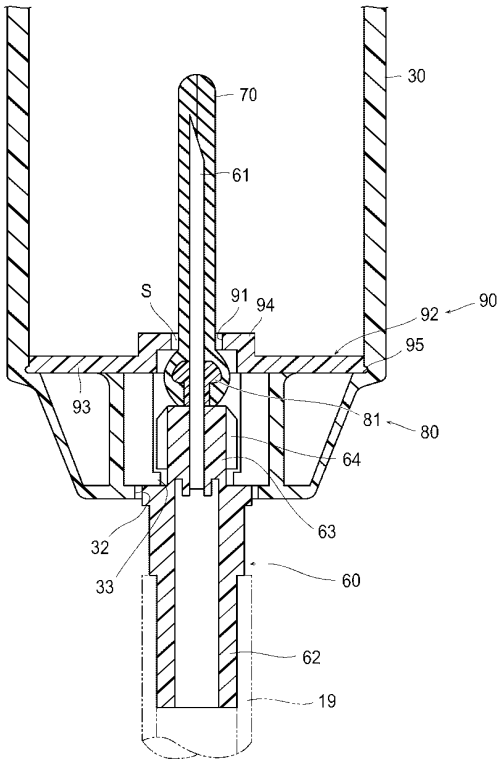
【図１】



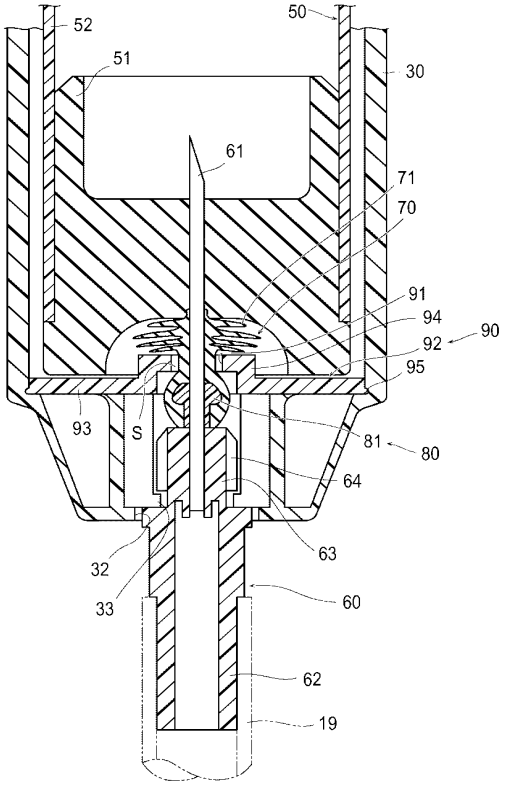
【図２】



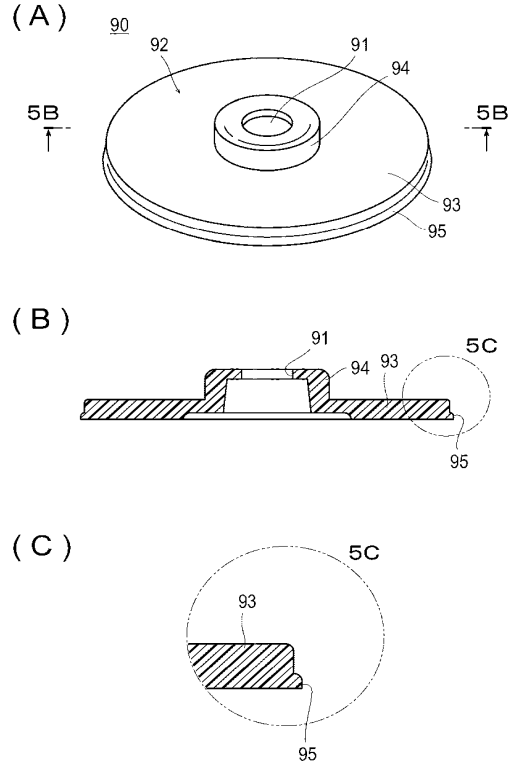
【図３】


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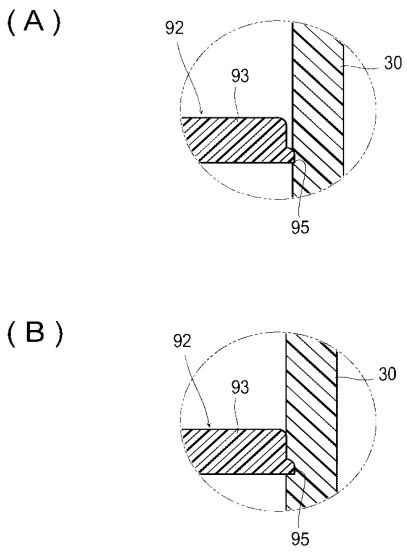
【図４】


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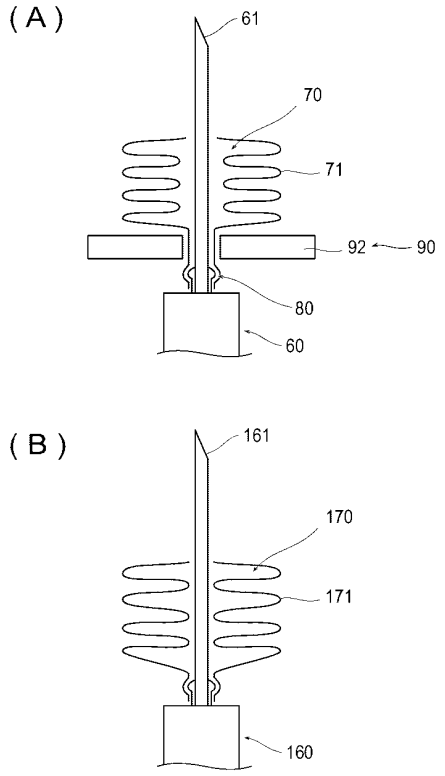
【図５】


(A)
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92
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94
5B
5B
93
95
(B)
91
5C
94
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95
(C)
5C
93
95

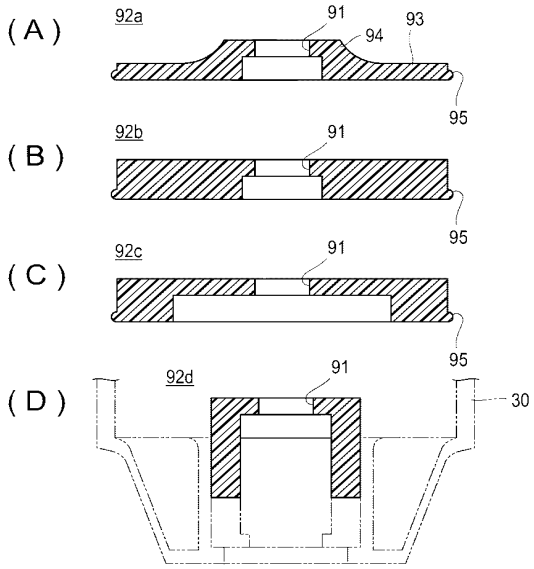
【図６】


(A)
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(B)
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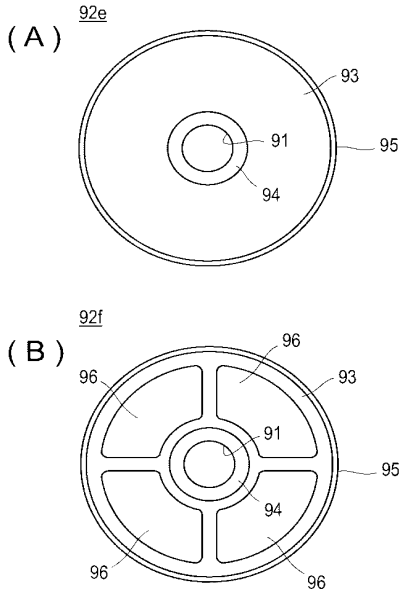
【図７】


(A)
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【図８】


(A)
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(B)
92b
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(C)
92c
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(D)
92d
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【図９】


(A)
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(B)
92f
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フロントページの続き

Ｆターム(参考) 4C038 TA01 TA10 UA10 UB07 UF03 UF11 UF14
4C066 AA07 BB10 FF05 JJ08

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Patentanwälte PartG mbB
02. Dez. 2019
EINGEGANGEN / RECEIVED

Date: 02.12.19

Reference	Application No./Patent No.
EPA-148 105	19200766.4 - 1132

Applicant/Proprietor: Kurin, Inc.

Communication

The extended European search report is enclosed.

The extended European search report includes, pursuant to Rule 62 EPC, the European search report (R. 61 EPC) or the partial European search report/ declaration of no search (R. 63 EPC) and the European search opinion.

Copies of documents cited in the European search report are attached.

☑ 0 additional set(s) of copies of such documents is (are) enclosed as well.

The following have been approved:

☐ Abstract ☑ Title

☑ The Abstract was modified and the definitive text is attached to this communication.

The following figure(s) will be published together with the abstract: 15C

Refund of search fee
If applicable under Article 9 Rules relating to fees, a separate communication from the Receiving Section on the refund of the search fee will be sent later.

Should you wish to further prosecute this application in the examination phase, your attention is drawn to the provisions of Rule 70a EPC. An invitation to respond to the extended European search report will be issued once the date of publication of the European search report has been mentioned in the European Patent Bulletin (R. 69(1), R. 70(2) EPC).

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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	
A	US 2009/227953 A1 (TAN CHEE LEONG [SG] ET AL) 10 September 2009 (2009-09-10) * the whole document *	1-14	
A	JP H08 257018 A (NISSHO KK) 8 October 1996 (1996-10-08) * abstract; figures *	1-14	
A	US 4 416 290 A (LUTKOWSKI LAWRENCE [US]) 22 November 1983 (1983-11-22) * abstract; figures *	1-14	TECHNICAL FIELDS SEARCHED (IPC) A61B
A	US 3 648 684 A (BARNWELL CLEORA W ET AL) 14 March 1972 (1972-03-14) * abstract; figures *	1-14	
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
Y : particularly relevant if combined with another document of the same category
A : technological background
O : non-written disclosure
P : intermediate document

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)

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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	

TECHNICAL FIELDS SEARCHED (IPC)

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
Y : particularly relevant if combined with another document of the same category
A : technological background
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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

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9605875 A1	29-02-1996	AT 208640 T	15-11-2001
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		US 2015351678 A1	10-12-2015
		US 2018092584 A1	05-04-2018
		US 2019209066 A1	11-07-2019

EPO FORM P0459

Information on Search Strategy - Pilot phase (see OJ 2015, A86)
The type of information contained in this sheet may change during the pilot for improving the usefulness of this new service.

Application Number
EP 19 20 0766

TITLE: BLOOD SAMPLE OPTIMIZATION SYSTEM AND BLOOD CONTAMINANT SEQUESTRATION DEVICE

APPLICANT: Kurin, Inc.

IPC CLASSIFICATION: A61B5/15, A61B5/153, A61B5/154

EXAMINER: Schultz, Ottmar

CONSULTED DATABASES: EPODOC, WPI, COMBI, TXT+

CLASSIFICATION SYMBOLS DEFINING EXTENT OF THE SEARCH:

IPC:

CPC: A61B5/15003, A61B5/150213, A61B5/150389, A61B5/150473, A61B5/150572, A61B5/153, A61B5/154

FI/F-TERMS:

KEYWORDS OR OTHER ELEMENTS FEATURING THE INVENTION:
See claims.

EPO FORM P0A/42

ABSTRACT / ZUSAMMENFASSUNG / ABRÉGÉ

19200766.4

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.

The examination is being carried out on the **following application documents**

Description, Pages

1-43 as originally filed

Claims, Numbers

1-14 as originally filed

Drawings, Sheets

1/50-50/50 as originally filed

+++++

Reference is made to the following document; the numbering will be adhered to in the rest of the procedure.

D1: WO 96/05875 A1 (BAXTER INT [US]) 29 February 1996.

1 The present application does not meet the requirements of Article 52(1) EPC, because the subject-matter of claims 1 and 6 are not new in the sense of Article 54(1) and (2) EPC.

The reasons are as follows:

1.1 Document D1 discloses (the references in parentheses applying to this document) all the features of claim 1, namely:

"A blood sequestration device (see figure 1: ref. sign 10 *"closed system blood sampling device"*) **comprising;**

an inlet port (see figure 1: ref. sign 14 *"cannula tip"*);

a junction (see fig. 1: the area where the bore 36 connects with bore 18) **connected with the inlet port;**

a sequestration chamber (see figure 1: ref. sign 22 *"blood disposal chamber"*) **having a vent** (see figure 1: ref. sign 30 *"liquid tight, air permeable hydrophobic membrane"*) **comprising an air permeable blood barrier;**

a sampling channel (see figure 1: ref. sign 36 *"bore"*) **having a proximal end connected with the inlet port via the junction and a distal end connected with an outlet port** (see fig. 1: ref. sign 42 *"luer"*); **and**

a housing (see fig. 1) **that houses and defines the inlet port, the junction, the sequestration chamber, and the sampling channel, and the outlet port,**

whereby the sequestration chamber (see figure 1: ref. sign 22 *"blood disposal chamber"*) **is connected** (see fig. 1) **with the inlet port via the junction which is configured to direct** (see page 3, lines 1 to 4: *"... It also feeds an initial fraction of withdrawn blood to a communicating blood disposal chamber which has an air permeable liquid sealed end ..."*) **the first portion of blood to the sequestration chamber** (see figure 1: ref. sign 22 *"blood disposal chamber"*), **and 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"**.

Claim 1 is thus not novel (Art. 54(1)(2) EPC).

1.2 Document D1 also discloses (the references in parentheses applying to this document) all the features of claim 1, namely:

"A system of a blood sequestration device (see figures 1, 2: ref. sign 10 *"closed system blood sampling device"*), **a blood sampling pathway** (see figures 2: ref. sign 50 *"venipuncture device"*) **having a patient needle, and a sample collection device** (see figures 2: ref. sign 70 *"syringe"*), **the blood sequestration device comprising;**

an inlet port (see figure 1: ref. sign 14 *"cannula tip"*) **connected with the patient needle;**

a junction (see fig. 1: the area where the bore 36 connects with bore 18) **connected with the inlet port opposite the blood sampling pathway;**

a sequestration chamber (see figure 1: ref. sign 22 *"blood disposal chamber"*) **having a vent** (see figure 1: ref. sign 30 *"liquid tight, air permeable hydrophobic membrane"*) **comprising an air permeable blood barrier;**

a sampling channel (see figure 1: ref. sign 36 *"bore"*) **having a proximal end connected with the inlet port; and**

an outlet port (see fig. 1: ref. sign 42 *"luer"*) **connected with a distal end of the sampling channel and with the sample collection device; and**

a housing (see fig. 1) **that houses and defines the inlet port, the outlet port, the sequestration chamber, and the sampling channel,**

whereby 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".

Claim 6 is thus not novel (Art. 54(1)(2) EPC).

2 The dependent claims 2 to 5 and 7 to 14 do not appear to contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the EPC with respect to novelty (Art. 54(1)(2), EPC) and/or inventive step (Article 56, EPC), the reasons being as follows:

Ad claims 2, 12, 13: Not novel, see D1, figure 1;

Ad claims 3, 4: Not novel, see D1, figures 1, 2;

Ad claims 5, 14: Not inventive to design the housing from two parts, see D1, figure 1;

Ad claims 7, 8, 9, 10, 11: Not novel, see D1, figures 2.

3 Further objections:

3.1 The closest prior art (see document D1) is not acknowledged in the description (Rule 42(1)(b) EPC).

3.2 Claim-like clauses appended at the end of the description (see pages 39 to 43) must also be deleted prior to grant, since they otherwise may lead to unclarity as to the actual scope of protection (Guidelines F-IV, 4.4).

3.3 "Incorporation by reference" is not an option in the European procedure since the concerned subject-matter does not fall within the scope of the claims (Article 84 EPC); the description thus requires amendment in this respect at paragraph [0001].

4 It is not at present apparent which part of the application could serve as a basis for a new, allowable claim.

5 If, however, filing an amended set of claims, **arguments in support of inventive step in the form of a problem-solution approach according to the Guidelines G-VII, 5 should be provided in an accompanying letter**.

6 Since the present description will not be consistent with the subject-matter as defined by such an amended set of claims, **to expedite the examining procedure** the applicant should then at the same time bring **all affected passages** of entire description into conformity with such an amended set of claims, i.e. the applicant should limit the application to the embodiment of the invention, namely as defined by an amended independent claim, and to the preferred embodiments, namely as defined by amended dependent claims.

In this respect, it is noted that terms like ***"... may ..."***, ***"... can ..."***, **etc.** as used throughout the description are not allowed if the related feature is part of the invention as defined by the independent claims. **Appropriate amendments are required.**

It is noted that anything denoted *"... embodiment ..."* and *"... invention ..."* must fall under the scope of protection sought, otherwise it is not an embodiment and not an invention.

Therefore, all the terms like *"... aspect of the invention ..."*, *"... embodiment ..."*, *"... invention ..."*, *"... variation of the invention ..."*, etc. related to all further inventions and further features or methods not covered by the amended set of claims should be replaced by the term *"... **example not being part of the invention** ..."*, if not then the remaining embodiments are to be excised from the amended set of claims, description and drawings or to be denoted not forming part of the present invention but represent background art that is useful for understanding the invention (see Guidelines F-IV, 4.3(iii)).

The subject-matter concerning the embodiments to be excised may be made the subject of one or more divisional applications according to Rule 36 EPC.

7 Care should then also be taken during revision of the description and the claims not to add subject-matter which extends beyond the content of the application as originally filed (Article 123(2) EPC).

Intermediate generalisations should also be avoided (Art. 123(2) EPC and Guidelines H-V, 3.2.1).

To make sure that the new set of claims meets the requirements of Art. 123(2) EPC and Guidelines H-V, 3.2.1, the applicant is requested to double check and provide basis for the amendments by references to the application as filed in the accompanying letter in his own interest.

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Espacenet

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SAMPLE COLLECTING APPARATUS

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DESCRIPTION JPS5867238

[0001]

The present invention relates to an apparatus for collecting a liquid sample, such as blood, from a patient. In particular, the invention relates to a needle silker for collecting one or more liquid samples from such a patient. The apparatus of the present invention employs a transparent or translucent f ¥ introduction chamber so that it is possible to observe whether the needle in question has approached the proper location. In the re-introduction chamber, the reciprocating motion is formed of a material which becomes an obstacle wall for the liquid received therein and which becomes an exhaust passage for the gas pushed out by the liquid sample received in the reject chamber. A stopper is incorporated therein. The stopper reciprocates so that when the sample liquid is first received, it completely prevents the liquid sample from being discharged, while at the same time venting the gas by the liquid sample. The stopper, when discharged into the collection container, cooperates with a vent in the discharge area of the erection stand to continuously discharge and pass the collected sample to one or more negative pressure collection containers. It reciprocates by working action. In the case where all the samples are continuously collected and discharged to a plurality of negative pressure containers, the assembly is connected to the discharge opening of the device during the replacement period of the negative pressure collecting container in preparation for discharging the next sample. Includes a cooperating flexible sleeve. As described above, it is desirable to provide a mechanism for notifying a user of such a needle assembly that the venous needle has penetrated the vein of the patient from whom the entire blood sample is to be collected. It is often difficult to place a vein in the space where blood is collected from the patient, and blood flow to the collection container may be improper for other reasons. In such a case, it would be beneficial to be able to quickly perceive the needle entering the vein and blood flowing into the needle assembly. I feel that the needle has entered this way. A negative pressure collection container is then inserted into the collection silker according to well-known blood sample collection techniques during the

single sample collection procedure. One of the problems encountered during the venipuncture stage is the air pool found in various needle assemblies for one or more blood samples. When a venous puncture is made and a negative pressure collection container has not yet been attached to the opposite end of the needle silker, under normal atmospheric conditions, blood will collect due to the pool of air remaining inside the needle assembly. It does not always flow into the needle assembly. Thus, when venipuncture is completed, blood flow is not initiated simply by obstruction of the air pocket in the needle assembly. According to this justification, by contrast, the use of a porous plug in the collection chamber—air from the collection chamber so that the collection chamber receives the blood sample from which the plug was collected.

Extrude. In addition, the stopper is operable to initially vent the extruded air during the receiving procedure, and to discharge the sample to the negative pressure collecting vessel when the negative pressure vessel is attached to the needle assembly. A needle assembly is disposed within the collection chamber to cooperate with an outlet at the negative pressure puncture needle. For example, in one embodiment of the present invention for a single-sample collection procedure, the assembly of the present invention vents all of the extruded air when a sample is introduced, and a negative pressure vessel is attached to the assembly and a negative pressure puncture for discharge is provided. When the needle penetrates into the negative pressure collecting container, the introduced sample 14—a porous plug that moves to open the passage of the assembly in response to a differential pressure to discharge into the negative pressure collecting container. Having. Another embodiment of the present invention has a flexible sleeve covering the discharge opening of the negative pressure puncture needle. The flexible sleeve is arranged to exhaust air from the third outlet at the outlet puncture needle during sample introduction. ! The retractable sleeve flexes and moves through the sixth outlet when the negative pressure blood collection container is inserted into the assembly to be recognizable by the negative pressure puncture needle. Once one sample is obtained in the negative pressure blood collection device and the negative pressure container is removed from the assembly, the flexible sleeve is then applied until the negative pressure container is attached for the second sample collection. Discharge amount of pressure puncture needle b'f! : Covered. As is well known to those skilled in the art, this procedure is repeated to collect the required number of samples U into separate negative pressure blood collection containers. Considering the use of a porous plug in a blood collection device of the type described herein, consider the earlier filed US Application No. 915.670, filed June 15, 1978, entitled "Blood collection assembly with venipuncture indication. The inventor (assignee is the same as the present application) in the body J (Blnode Sampling Assembly Having Vein Entry Indicator) William N. Erdrichsi (Wi l iam N, Eldvidge who uses the air vein to sense the vein needles). He knew he could prevent the desired blood flow to the point where he could. L. Ridge's invention includes a perforated 'J4f plug which mates with a one-way valve, which 10,000 air vents the air inside the needle silker during the first stage of the blood collection procedure. Let go outside. The vent prevents the passage of blood until the user attaches the blood collection device to the needle assembly.

Upon contact with the negative pressure of the negative pressure blood collection container, the separated one-way valve opens to carry blood from the patient's vein and to enter the blood into the collection container through a needle silker. The Eldritzzi invention recognized the use of a porous material to vent the displaced air while the whole blood reservoir was in place, but there is still room for improvement of such devices, and in particular there is room for improvement. Related to the present invention. That is, the stopper of the present invention reciprocates and does not simply act as a vent, but instead acts as a valve mechanism without having a separate and complex structure to provide valve action. That is, the stopper of the present invention cooperates with the blood introduction chamber to reciprocate and reciprocate to allow air to vent from the introduction chamber but not to discharge the blood sample and to introduce blood when the assembly is adhered to the negative pressure blood collection container. Move to discharge. Next, a description will be given with reference to the drawings. In the drawings, the same parts are denoted by the same reference numerals. FIG. 1 shows a basic needle assembly 10 that includes a housing 12, a first puncture needle 14 for insertion into a patient, and a second puncture needle 15 at the opposite end of the housing. External component cost? Is shown. The second puncture needle 15 is adapted to be inserted into a negative pressure container 16 for collecting a number of samples. The nosing 12 includes a threaded portion 25 having a screw 18 adjacent to the second puncture needle 15 into which the container support 19 is screwed by an inner silk threading screw 20 provided at its forward end. The puncture needle 15 of the negative pressure container 16 and the tea 2 is inserted into the trash container 19 so as to pass through the stopper 21 at the front end of the negative pressure container 16. Such general aspects of sample collection vessels are well known to those skilled in the art. This will be described with reference to FIG. Preferably, the housing 12 has a front end 24 and a rear end 25 which can be separated to insert a porous plug 27. The front end 241d has a cylindrical shape, and a large hole 28 is formed so that the porous stopper 27 can be reciprocally received in the groove. A small aperture 29 for receiving one puncture needle 14 is provided. In this embodiment, the small aperture 29 extends to a smaller, smaller diameter conduit 60 that connects the aperture 29 and the aperture 28 to each other. A stepped portion 6 for receiving the first puncture needle 14 in contact with the first puncture needle 14 is formed at the junction between the one hole 29 and the conduit 60. The first puncture needle 14 may be fixed in the mouth 29 by a suitable adhesive.

It will be known to those skilled in the art that the conduit 30 is not an essential element for this configuration, but merely a preferred form. Further, the diameter of conduit 0 can be varied to adjust the flow rate of fluid passing therethrough. The front end 24 of the housing also includes a number of longitudinal ribs 61 surrounding a first puncture needle extending outwardly. A garment (not shown) having a lyso in combination with the rib 31 substantially approximates the first puncture needle extending outward. The mating ribs between the piercing needle armor and

the needle assembly facilitate the user's insertion into or removal from the needle assembly of the armor. The forward end 24 also includes an annular flange 62 that serves as a mating surface when joining the two parts of the housing into an assembly. Again, an adhesive or similar suitable fixing material can be used to fix the two parts of the housing and the assembly. The rear end 25 includes a slightly projecting cylindrical portion 40 sized to fit inside the front end opening 28. On the opposite side of the rear end, the external thread 18 is provided at the portion 260 of the rear end 25 as described above by the connecting mechanism of the tube support. A hole 70, similar to the hole 29 at the front end of the housing, extends over all the rear ends of the housing. The aperture 70 is dimensioned to match the diameter of the second puncture needle 15, where again the second puncture needle is secured to the aperture 70 by a suitable material such as an adhesive. When combining the two ends R (S24 and S25) of the housing, an annular flange 46 is provided corresponding to the annular flange 32. It will be appreciated that when assembling the two parts of the housing with the stopper 27 positioned therein, the flanges 32 and 46 may be secured by a suitable securing material, such as, for example, an adhesive. Orifice 28 at front end 24 defines a tubular chamber 50 for receiving a liquid sample to be collected. To observe the contents of the tubular chamber 50 and to inform the user of the device that the puncture needle has reached the vein, the annular wall 88 at the front end forming the tubular chamber 50 is made of a translucent or transparent material. It is preferable to be formed. It will be appreciated by those skilled in the art from a manufacturing standpoint that the entire front end of the needle assembly is preferably made of a transparent material, such as a thermoplastic hard resin. However, closed windows, ports or other devices for the user of the device to view the contents of the tubular chamber 50 are also within the scope of the present invention.

The porous plug 27 is reciprocally mounted in the opening 28 and has an inner opening 72 for reciprocally fitting with the front end of the puncture needle 15 which receives a negative pressure. As is well known, the porous plug 27 is cylindrically shaped according to the aperture 28 and has a diameter that is liquid-tightly engaged with the wall of the tubular chamber 50, but is also apertured by the action of a differential pressure with the opposite surface. 28, the stopper 27 is defined so that it can reciprocate. The porous frame 27 is made of a so-called gas-permeable / liquid-impermeable material that allows the passage of a gas such as air but does not allow the passage of a liquid such as blood. Examples of materials used to form the perforated chamber frame 27 include sintered polyethylene, open cell foamed polyethylene, and other similar moldable polymeric materials such as porous polypropylene and porous polyfluorocarbon. As shown in FIG. 2, negative pressure puncture needle 15 includes a notch 74 adjacent its end 84. At this point, the notch 74 communicates with the tubular chamber 50 by the amount of the lumen of the second puncture needle 15 depending on the position of the porous stopper 27, but the end 84 of the porous frame 27 is closed by the stopper. Closed or otherwise deformed or otherwise closed. An additional notch or opening is provided for communication between the rear end 51 of the tubular chamber 50 and the second puncture

needle 15. Further, as shown in FIG. 2, a sixth notch or open lower 8 is provided for communicating between the atmosphere, that is, the outer peripheral region of the assembly of the present invention and the lumen of the second puncture needle 15. Next, a description will be given with reference to FIG. The needle assembly connected to the support 19 is shown. A first puncture needle 14 is shown inserted into a patient P undergoing venipuncture. When the puncture needle 14 of the bobbin 1 enters the vein of the patient P, blood flows from the vein into the tubular chamber 50 through the first puncture needle 14 and the small-diameter conduit 30 km. When blood flows into the tubular chamber 50, air in the tubular chamber 50 is pushed out of the tubular chamber 50 through the porous frame 27, but blood does not pass through the porous frame 27 due to the characteristics of the porous frame 27. The air which has passed through the stopper 27 from the tubular chamber 50 through the notches 74 and 76 and further through the lumen of the second puncture needle 15 and the outer notch 78 covers the outer end of the negative pressure puncture needle 15. The mirror device 0 is extruded into a region 82 (FIG. I2) between the flange 92 and the end face 106 of the housing end 25. Here, the stopper 27 remains at the position shown in FIG. 2 covering 74 orifices or notches.

Further, here, a blood sample collected from the patient P is located in the tubular chamber 50. Referring now to FIG. 6, it is shown that the silker has a support 19 attached to the hub 26 of the rear / Using 25. The negative pressure puncture needle 15 has a resilient stopper pierced by the end or point 100 and shows a negative pressure blood collection container 16 fitted in a support 19. A vacuum is created by penetrating 21, which vacuum or negative pressure removes any air remaining in tubular chamber 50 into the interior region of negative pressure vessel 16 and cutouts 74 and 76. Is drawn through the entirety of the porous frame 27 by communicating through the lumen. Since the stopper 27 is closed by the blood, a pressure difference is generated between the upper tubular chamber 50 and the lower tubular chamber 51, and the stopper 27 moves downward toward the surface of the extension 4U as shown in FIG. With this movement, the stopper 27 removes the cover of the opening or notch 74. Any residual air trapped in the lower tubular chamber 51 during this movement will pass through the notch 76 and will facilitate the movement of the plug 27. When the cutout 74 is uncovered, flow between the tubular chamber 50 and the vacuum container 16 is provided through the lumen of the vacuum puncture needle 15. On the other hand, by inserting the negative pressure container 16 into the support 19 and penetrating the puncture needle 15 through the stopper 21 by the point 100, as shown in FIG. It moves upward to a position where it engages with the bottom surface 106 of 26. Thus, the blood sample drawn from the vein of the patient P and stored in the tubular chamber 50 moves into the negative pressure collecting container 16. Once the sample has been withdrawn into the container 16, the refuse 516 is removed from the support 19, whereby the mirror device 0 closes the notch 78 and returns to a position covering the end 100 of the negative pressure puncture needle 15. In this way, the first puncture needle 14 can be continuously mounted in the container 16 and the support 19 for receiving a plurality of blood samples while remaining in the vein without leaking blood. I do. Referring now to FIG. 4, another

embodiment is shown in which the notch 78 is not cut in the negative pressure puncture needle 15a. In this device, the same parts are indicated by the same reference numerals with a suffix a. In the present embodiment, the puncture needle 15 a V (instead of the air passage or the open lower 8) has its flange 10 B closed and engaged so that the gas is not always sealed adjacent to the surface 106 a of the extension 26 a. A positioned sleeve 90 is formed.

As shown in FIG. 6, the sleeve 90 is arranged to slidably engage the puncture needle 15a. However, a point 95 inside the sleeve 90u groove has a plurality of internal grooves 94 that actually engage the outer surface of the puncture needle 15a. The groove thus provides gas communication between the puncture needle end 10Da and the upper end of the sleeve 90, where air leaks between the adjacent surface of the flange 108 of the sleeve 90 and the surface 1U6a of the extension 26a. 'Jj 94 is set to a size that allows gas to pass and liquid not to pass. It will be appreciated that the upper surface of the flange 108 can similarly envision a groove that provides ventilation between the end 100a and the atmosphere. Yet another example of the present invention that provides a complete single-blood sample collection assembly is shown in FIG. No special sleeve 80 is used as shown in this assembly and puncture needle 15b does not have a third notch or opening, such as notch 78 in the embodiment shown in FIG. . Thus, when the puncture needle 14 is inserted into a patient's vein, fluid communication is provided between the vein and the tubular chamber 50 to collect a sample in the tubular chamber 50. The device does not allow the blood sample to flow through the porous plug 27 as in the embodiment shown in FIG. In all cases, the notch 9 is cut out 74.76, and is discharged from the end 100b of the negative pressure puncture needle 15b through the lumen of the puncture needle 15. When the support is mounted on the extension 26b and the point 100b of the puncture needle 15b is inserted all the way through the stopper and into the negative pressure blood collection container 16, the tubular chamber 50 above the stopper 27 and the tubular chamber 51 below the stopper 27 are connected. A pressure difference is generated therebetween, so that the stopper 27 moves downward to open the notch 174v. This provides for fluid communication between the tubular chamber 50 and the vacuum container 16 for single sample collection into the vacuum container 16. In this embodiment, the puncture needle 14 is removed from the vein of the patient P because no further samples are collected by the assembly, and the assembly is discarded because one required sample has been collected in the negative pressure container. Another embodiment of collecting a plurality of samples similar to the embodiment shown in FIG. 4 in which air flows i between the point 100c of the negative pressure puncture needle 15c and the atmosphere is shown in FIGS. 8a and 8b. In the present embodiment, the inner diameter of the shaft portion 110 is stepped, and the inner diameter of the shaft portion 110 combined with the small inner diameter 114 of the shaft portion 110 that is in close contact with the outer surface of the puncture needle 15c is between the surface of the shaft portion 110 and the puncture needle 15. Provide a large inner diameter 116 that defines a vent passage 118 for the air flow.

Therefore, in the position shown in FIG. 8a, ventilation occurs between the end 100c of the puncture needle 15c and the atmosphere through the entire passage 118, and in the position shown in FIG. 8b, the passage 118 is closed to prevent all ventilation. . As can be appreciated from the foregoing, in the present invention, a blood collection needle assembly is provided for collecting one or more samples that incorporate the entire device for venous needle insertion to the user. . Furthermore, the device of the present invention with a porous stopper having a simple configuration having the function of a valve, passing gas but not liquid, is very simple and inexpensive to manufacture, as will be appreciated by those skilled in the art. Particularly suitable for mass production.

[0002]
BRIEF DESCRIPTION OF THE FIGURES

[0003]

FIG. 1 is a perspective view of a sample collection needle assembly, a support for a negative pressure container, and a negative pressure blood collection container used to obtain a blood sample from a patient.

FIG. 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 sectional view taken along line 3-6 in FIG. FIG. 4 is a partial sectional view similar to FIG. 2, showing another embodiment of the present invention. Show. FIG. 5 is a perspective view of the needle assembly inserted into the patient and connected to the support so that the user has full visibility into the vein. W: FIG. 6 is a sectional view taken along line 6-6 in FIG. FIG. 7 is an enlarged sectional view of the single-sample collection needle assembly, similar to FIG. 2 but showing another embodiment of the present invention. FIG. 8a is a partially enlarged cross-sectional view of a single-sample collection needle assembly showing another embodiment of the present invention. FIG. 2EBb is the embodiment of FIG. 8a in a closed, non-communicating position. 10 ... needle needle body, 12 ... housing, 14 ... first puncture needle, 15 ... second puncture needle, 16 ... · Negative pressure genitalia, # 19 ... support, 24 ... front end, # 25 ... back end, 27 ... ++ 2i porous plug, 29 ... ··· First aperture, 50 ····· Sample collection chamber, ····· Second aperture, 74 ··· W: 1: 1 opening, 76 ··· ... 6th opening, 80... Flexible sleeve, 94... Groove, # 114... Small inner diameter, 116. ..... Large inner diameter Patent applicant: Becton, Dateskinson and Canno

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CLAIMS JPS5867238

1.

A sample chamber having a housing and a rear end; a sample collection chamber within the housing; a first open passage at the front end in fluid communication with the sample collection chamber; and insertion into a collection source. A first puncture needle extending outwardly from said first open passageway; and a second open passageway at said rear end and in fluid communication with said sample collection chamber. A sample collection device for collecting one or more liquid samples from and draining into a negative pressure vessel for collection, wherein said first sample is located in said second open passage and into said sample collection chamber. A second puncture needle extending from the open passageway to a spaced-apart point, the second puncture needle spaced apart from the first and second apertures at a portion extending into the sample collection chamber. The first and second openings are connected to the sample collection chamber and the second puncture. Fluidly communicates between the lumens of said first opening and said second opening from a first position closing said opening to a second position opening said first opening. A gas-permeable, liquid-impermeable, annular porous stopper placed in the sample collection chamber so as to reciprocate along a second puncture needle, wherein the first puncture needle is connected to the collection source; When engaged with the liquid, the liquid pushes out all the gas therein into the sample collection chamber, flows into the second puncture needle through the first and second openings, and the second puncture needle When the vacuum container is received, the annular porous stopper moves toward the second opening passage by the action of the differential pressure on both sides thereof to open the first opening, and the annular porous stopper is closed. The gas remaining in the sample collection chamber is pushed out to the second opening located on the negative pressure side, and the liquid in the sample collection chamber is pushed out. Sample collection apparatus characterized by being adapted to be collected into the negative pressure vessel through the second puncture needle. (2. In the sample collection device according to claim

1, wherein the annular porous stopper is a sintered polyethylene, an open-cell foamed polyethylene, a porous polyethylene, a porous polyfluorocarbon y ′ , and A sample collection device that is a member made from any of the group consisting of these mixtures. (3) In the sample collection device according to claim 1, a sixth opening provided in a portion of the second puncture needle extending outward from the housing and the second puncture needle And a resilient sleeve extending over a terminal portion opposite the sample collection chamber, wherein when the negative pressure container is penetrated by the second puncture needle, the sleeve is closed at the sixth opening. A sample collection device, wherein the sample collection device is closed.

(4) The sample collecting apparatus according to claim 1, further comprising an elastic sleeve 滑 which is slidably engaged with the second puncture needle at a terminal portion 1111 opposite to the sample collecting chamber, The inner surface of the sleeve engaging the puncture needle has a plurality of longitudinally extending grooves, and the groove engaged with the puncture needle is gas-permeable and liquid-impermeable. Sample collection device. f ! 2. The sample collecting apparatus according to claim 1, wherein the housing reconnects a device for connecting a support for a negative pressure vessel. (6) The sample collecting apparatus according to claim 5, wherein a support for a negative pressure vessel is connected to the housing. (7) The sample collection device according to claim 6, wherein the housing includes a device for connecting all of the support for the negative pressure container. (8) The sample collection device according to claim 1, wherein the housing has a device for observing the entire contents of the sample collection chamber. (9) The sample collection device according to claim 8, wherein the device for viewing the contents is a transparent housing wall adjacent to the sample collection room. (10) The collection device according to claim 1, wherein a resilient sleeve slidably engaged with the F] iT @ Her puncture needle is provided at an end of the puncture needle opposite to the sample collection chamber. The inner surface of the sleeve engages with the puncture needle, the stepped inner surface is entirely formed, and a portion of the length region of the core is combined with the outer (141, 141) of the second puncture needle. The second puncture needle forming a small diameter internal aperture for sealing engagement with one surface and another portion of the lengthwise region of the stepped inner surface being silk-sealed; A large-diameter internal hole forming an air passage together with an outer surface of the sample collecting device.

⑲ 日本国特許庁（JP）　　⑪ 特許出願公開

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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の開口部を開口し、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

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)

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)

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)

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携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

(7)

を設う。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閉つている。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

(9)

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

(8)

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

(10)

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ッパ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

(11)

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

(13)

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

(12)

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

(14)

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

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

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。

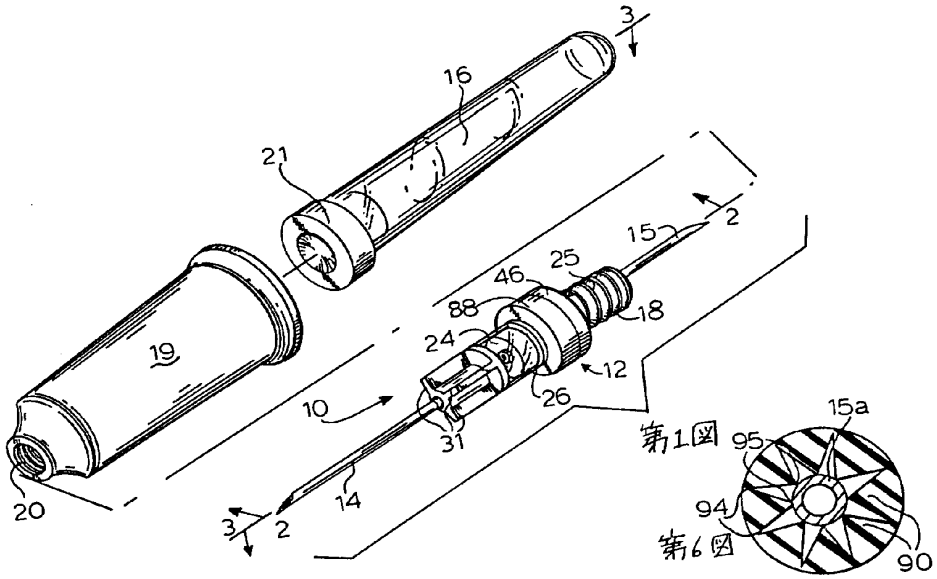
第８ａ図は本発明の他の実施態様を示す単一試料採集針組み立て体の部分拡大断面図。

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

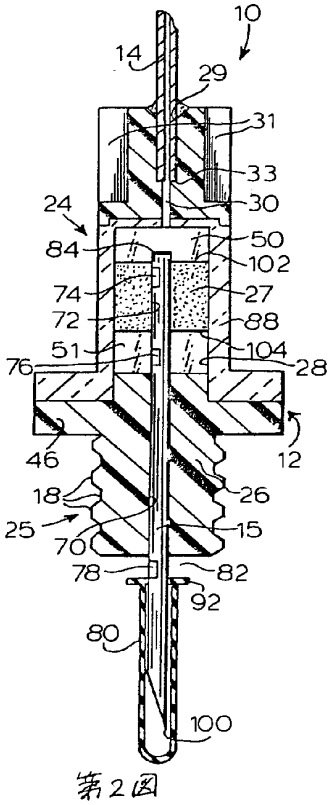
特許出願人　ベクトン・デイッキンソン・アンド・カンパニー

代理人　弁理士　湯浅恭三（外４名）

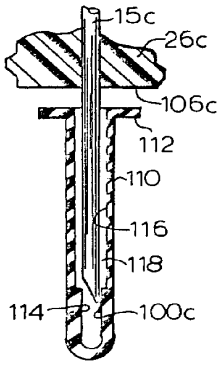


第1図

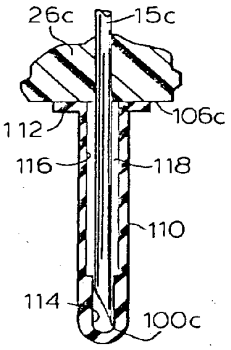
第6図



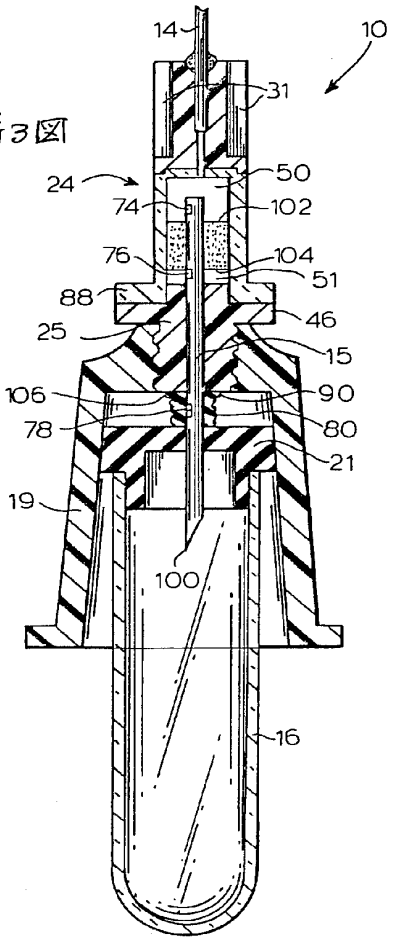
第2図



第8a図

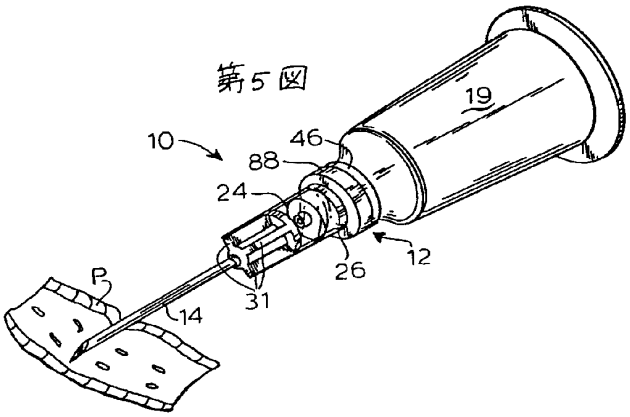


第8b図

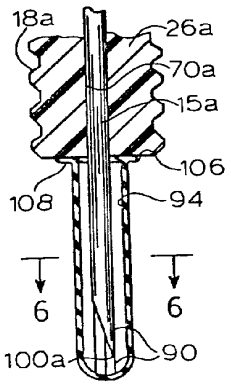


第3図

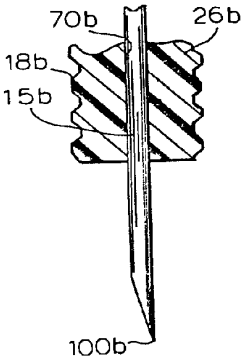
第5図


19
10
46
88
24
12
26
31
14
P

第4図


18a
26a
70a
15a
106
108
94
6
6
100a
90

第7図


70b
26b
18b
15b
100b

Espacenet

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BLOOD SAMPLE OPTIMIZATION SYSTEM AND BLOOD CONTAMINANT SEQUESTRATION DEVICE AND METHOD

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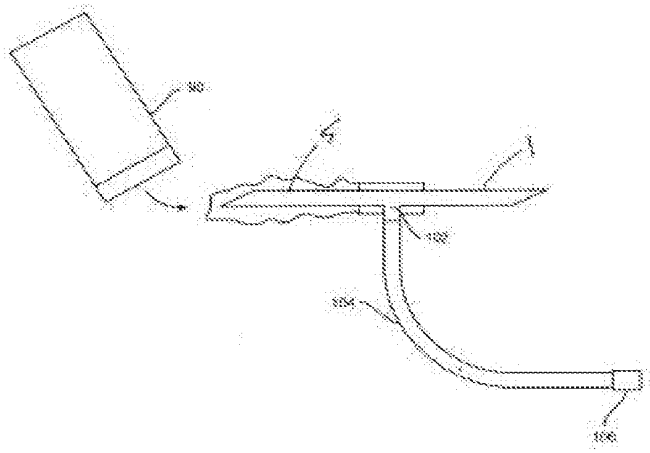
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Abstract of corresponding document: US2017020427 (A1)

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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最終頁に続く

(54)【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

(57)【特許請求の範囲】
【請求項１】
血液サンプル最適化システムであって、
採血システムであって、
患者の血液サンプルを取り出せるようにするために患者の静脈穿刺用に構成された患者針と、
前記患者針に接続され、前記血液サンプルを運ぶように構成された採血経路と、
前記血液サンプルの後続の部分を採取しかつ収容するために真空採血管を受け入れるように構成されたサンプル針と
を含む採血システムと、
前記患者針と前記サンプル針との間に前記採血経路に沿って接続された血液隔離装置であって、
前記血液サンプルを受け入れるように構成された入口ポートと、
前記入口ポートに接続されかつ空気透過性血液バリアを含む通気口を有する隔離チャンバであって、前記血液サンプルの最初の量を受け入れかつ前記血液サンプルの最初の量の少なくとも最初の部分を隔離するように構成された隔離チャンバと、
前記入口ポートに接続された近位端を有し、前記血液サンプルの後続の部分を受け入れるように構成されたサンプリング流路と
を含み、
前記隔離チャンバ、前記サンプリング流路及び前記入口ポートは、前記血液サンプル

の後続の部分が前記隔離チャンバ及び前記隔離チャンバ内に隔離された前記血液サンプルの最初の部分を迂回することを可能にしかつ前記血液サンプルの後続の部分を前記サンプリング流路の遠位端に接続された出口ポートに向かわせるように構成され、前記出口ポートは、前記血液サンプルの後続の部分を前記真空採血管に排出するように構成され、

前記入口ポート、前記出口ポート、前記隔離チャンバ及び前記サンプリング流路を収容しかつ画定するハウジングをさらに含む、血液隔離装置と

を含む、血液サンプル最適化システム。

【請求項２】

前記血液隔離装置の前記隔離チャンバは周囲空気圧であり、前記隔離チャンバは患者の血圧が前記隔離チャンバ内の周囲空気圧に打ち勝つことによって前記血液サンプルの最初の部分を受け入れる、請求項１に記載の血液サンプル最適化システム。

【請求項３】

前記サンプル針は、前記採血経路及び前記サンプリング流路を介した前記患者針へのアクセスを開くために前記真空採血管によって穿孔されるシールを含む、請求項２に記載の血液サンプル最適化システム。

【請求項４】

前記血液隔離装置の前記サンプリング流路は、前記サンプル針を開封する前記真空採血管によって真空圧力下で前記血液サンプルの後続部分を前記入口ポートに進入させる、請求項３に記載の血液サンプル最適化システム。

【請求項５】

前記血液隔離装置の前記空気透過性血液バリアは、血液と接触すると密封する空気透過性材料を含む、請求項１に記載の血液サンプル最適化システム。

【請求項６】

前記採血システムの前記採血経路はチューブを含む、請求項１に記載の血液サンプル最適化システム。

【請求項７】

患者から血液サンプルを取り出せるようにするように構成された患者針と、密封されたサンプル針であって、前記サンプル針を開封しかつ取り出せるようにされた血液サンプルを患者から採取するために真空採血管を受け入れるように適合されたサンプル針とを含む血液採取システムに接続された血液隔離装置であって、

前記患者針に接続され、患者からの血液サンプルを受け入れるように構成されたた入口ポートと、

前記入口ポートに接続された出口ポートと、

前記入口ポートに接続されかつ空気透過性血液バリアを含む通気口を有する隔離チャンバであって、前記サンプル針が前記真空採血管によって開封される前に前記血液サンプルの最初の部分を受け入れかつ隔離するように構成された隔離チャンバと、

前記入口ポートに接続された近位端を有し、前記血液サンプルの後続の部分を受け入れるように構成されたサンプリング流路と

を含み、

前記隔離チャンバ、前記サンプリング流路及び前記入口ポートは、前記血液サンプルの後続の部分が前記隔離チャンバ及び前記隔離チャンバ内に隔離された前記血液サンプルの最初の部分を迂回することを可能にしかつ前記血液サンプルの後続の部分を前記サンプリング流路の遠位端に接続された前記出口ポートに向かわせるように構成され、

前記入口ポート、前記出口ポート、前記隔離チャンバ及び前記サンプリング流路を収容しかつ画定するハウジングをさらに含む、血液隔離装置。

【請求項８】

前記隔離チャンバは周囲空気圧であり、前記隔離チャンバは患者の血圧が前記隔離チャンバ内の周囲空気圧に打ち勝つことによって前記血液サンプルの最初の部分を受け入れる、請求項７に記載の血液隔離装置。

【請求項９】

前記空気透過性血液バリアは、血液と接触すると密封する空気透過性材料を含む、請求項７に記載の血液隔離装置。
【請求項１０】
前記隔離チャンバは、前記ハウジング内に画定された隔離流路を含む、請求項７に記載の血液隔離装置。
【請求項１１】
血液サンプル最適化システムであって、
採血システムであって、
患者の血液サンプルを取り出せるようにするために患者の静脈穿刺用に構成された患者針と、
前記患者針に接続され、前記血液サンプルを運ぶように構成された採血経路と、
前記血液サンプルの後続の部分を採取しかつ収容するために真空採血管を受け入れるように構成されたサンプル針と
を含む採血システムと、
前記患者針と前記サンプル針との間に前記採血経路に沿って接続された血液隔離装置であって、
前記血液サンプルを受け入れるように構成された入口ポートと、
前記入口ポート及び前記採血システムのサンプル針に接続された出口ポートと、
前記入口ポートに接続されかつ空気透過性血液バリアを含む通気口を有する隔離チャンバであって、前記血液サンプルの最初の量を受け入れかつ前記血液サンプルの最初の量の少なくとも最初の部分を隔離するように構成された隔離チャンバと、
前記入口ポートに接続された近位端を有し、前記血液サンプルの後続の部分を受け入れるように構成されたサンプリング流路と
を含み、
前記隔離チャンバ、前記サンプリング流路及び前記入口ポートは、前記血液サンプルの後続の部分が前記隔離チャンバ及び前記隔離チャンバ内に隔離された前記血液サンプルの最初の部分を迂回することを可能にしかつ前記血液サンプルの後続の部分を前記サンプリング流路の遠位端に接続された前記出口ポートに向かわせるように構成され、
前記入口ポート、前記出口ポート、前記隔離チャンバ及び前記サンプリング流路を収容しかつ画定するハウジングをさらに含む、血液隔離装置と
を含む、血液サンプル最適化システム。
【請求項１２】
前記血液隔離装置の前記隔離チャンバは周囲空気圧であり、前記隔離チャンバは患者の血圧が前記隔離チャンバ内の周囲空気圧に打ち勝つことによって前記血液サンプルの最初の部分を受け入れる、請求項１１に記載の血液サンプル最適化システム。
【請求項１３】
前記サンプル針は、前記採血経路を介した前記患者針へのアクセスを開くために前記真空採血管によって穿孔されるシールを含む、請求項１１に記載の血液サンプル最適化システム。
【請求項１４】
前記血液隔離装置の前記空気透過性血液バリアは、血液と接触すると密封する空気透過性材料を含む、請求項１１に記載の血液サンプル最適化システム。
【請求項１５】
前記隔離チャンバは、前記ハウジング内に画定された隔離流路を含む、請求項１１に記載の血液サンプル最適化システム。
【請求項１６】
前記採血システムの前記採血経路はチューブを含む、請求項１１に記載の血液サンプル最適化システム。
【発明の詳細な説明】
【背景技術】

【０００１】
関連出願との相互参照
本出願は、２０１６年４月２７日に出願された「血液サンプル最適化システム及び血液汚染物質隔離装置及び方法」と題する米国非仮出願第１５／１４０，４４３号及び２０１６年４月２７日に出願された「血液サンプル最適化システム及び血液汚染物質隔離装置及び方法」と題する米国非仮出願第１５／１４０，４４８号の優先権の利益を主張するものであり、これらの米国非仮出願の両方が２０１５年７月２４日に出願された「血液培養改良システム及び方法」と題する米国仮特許出願第６２／１９６，７９７号、２０１５年１０月７日に出願された「非汚染採血用の血液隔離システム」と題する米国仮出願第６２／２３８，６３６号、及び２０１６年４月４日に出願された「血液サンプル最適化システム及び血液汚染物質隔離装置及び方法」と題する米国仮特許出願第６２／３１８，１９４号の優先権を主張しており、これらの開示はその全体が参照により本明細書に含まれるものとする。

【０００２】
菌血症は、血液中に微生物が存在することである。一方、敗血症は、発熱、頻脈、頻呼吸及び低血圧などの臨床症状及び臨床兆候がある場合の菌血症である。菌血症及び敗血症は、高い死亡率、入院発生率及び入院期間と関連する費用の増加とを伴う。多くの菌血症、敗血症、真菌血症及び他の病原体が実際に病院又は他の医療施設内で発生し、カテーテル及び静脈穿刺がこれらの病原体の潜在的なキャリアとしての汚染源である。

【０００３】
血液培養は、患者の血液中の菌血症及び敗血症に関連する微生物病原体を検出するのに使用される標準検査である。血液培養という用語は、血液が１つ以上の血液培養ボトル又は容器に接種される、末梢部位又は中心ライン又は動脈ラインからの１回の静脈穿刺を指す。１つのボトルが１つの血液培養と見なされ、２つ以上がセットと見なされる。複数のセットは複数の静脈穿刺から得られ、患者の異なる部位に関連する。

【０００４】
これらの方法は、敗血症を管理する上で重要な要素である微生物同定及び感受性検査を可能にするが、迅速な結果が得られないことと厄介な病原体に対する感度が低いことが、改良されたシステムの開発及び補助的な分子検査又はプロテオミクス検査につながっている。

【０００５】
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。

【０００６】
血液培養の採取の１つの結果は、汚染である。血液培養の汚染は、偽陽性の培養結果及び／又は医療関連コストの著しい増加につながる可能性がある。血液培養の汚染の原因は、不適切な皮膚消毒、不適切な採取管の消毒、最初の採血の汚染を含み、これらは結果を歪める可能性がある。

【０００７】
血液培養採取キットは、一般に、ＢＤ、スミス、ビー・ブラウンなどの会社によって提供される「バタフライ」セット、輸液セット、又は他のタイプの静脈穿刺装置と、好気性血液培養ボトル及び嫌気性血液培養ボトルとで構成される。様々な異なるボトルも検査要件に応じて利用可能である。これらのボトルは、好気性生物と嫌気性生物の両方の回収を最適化するように特別に設計されている。従来のキットでは、使用されるボトルは一般に「バキュテナー（登録商標）」として知られており、これは、所定の量の血液などの液体の採取を容易にするべく管の内部に真空を作り出すために排気される蓋を備える滅菌ガラス管又は滅菌プラスチック管から形成される採血管である。

【０００８】

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。

【０００９】

皮下注射針を通る血流は層流であり、このため、皮下注射針に圧力降下が加えられるときに流管にわたって流速勾配が発生する。血液を強く吸引するか又は非常に小さな皮下注射針を使用すると、溶解及び赤血球からのカリウムの放出が起こり、それにより血液サンプルが異常になる可能性がある。

【００１０】

他の例では、一部の患者は繊細な静脈を有し、繊細な静脈は、特に患者の状態に対してあまりにも急速に引き出される注射器のプランジャによって加えられるような圧力低下又は真空の下で崩壊し得る。このような状態は事前に知ることが不可能であるため、このような静脈崩壊は危険であり、制御することは非常に困難である。

【００１１】

血液培養の汚染率を低下させるために、例えば、無菌採取技術に関するスタッフの訓練、汚染率に関するフィードバック、及び血液培養採取キットの導入など、様々な戦略が実施されている。皮膚消毒は汚染の心配を減らすことができるが、２０％以上の皮膚の微生物は真皮の深部に位置し、消毒の影響を受けない。ボトル接種の前に針を交換することは、汚染率を低下させることなく針刺し損傷を受ける危険性を高めるので推奨されない。

【００１２】

血液培養の汚染を低減するための一部の従来のシステム及び技術は、中心静脈カテーテル、静脈穿刺及び他の血管アクセスシステムから採取された最初のアリコートの血液を捨てることを含む。しかしながら、これらのシステムは、ユーザーが血管内装置を機械的に操作することを必要とするか又は確実にすることが困難な複雑な一連のステップを踏むこと必要とする。

【発明の概要】

【発明が解決しようとする課題】

【００１３】

本明細書は、血液培養の汚染、細胞の溶解、及び静脈崩壊を低減するためのシステム及び方法を提示する。一部の実施では、システム及び方法は、ユーザーの消毒のばらつきをなくし、また皮膚細胞が血液培養サンプルに入り込む危険性をなくすこともできる。本明細書に開示されたシステム及び方法は、汚染物質のない血液サンプルを採取するためにバキュテナー（登録商標）又は他の採血装置（すなわち、注射器）をいつ取り付けるべきかを潜在的に示す以外は、既存の臨床プロセスの変更を必要としない。

【００１４】

本明細書に開示されたシステム及び方法の一部の実施では、採血は、患者自身の血圧の使用によって受動的に成し遂げられ、それによって静脈崩壊の危険性を低減し、現行の実務を超える更なるユーザーのステップを排除する。システム及び方法は、短経路の直接刺し又はバタフライ静脈穿刺システムに適合するように適用されることができる。カテーテルを通して採取されたサンプルと共に使用されることもできる。

【課題を解決するための手段】

【００１５】

一態様では、血液隔離装置が提示されている。血液隔離装置は、入口ポートと出口ポートとを含む。血液隔離装置は、入口ポートと接続される隔離チャンバであって、空気透過性血液バリアを含む通気口を有する隔離チャンバを更に含む。血液隔離装置は、入口ポートと接続される近位端と、出口ポートと接続される遠位端とを有する、サンプリング流路

を更に含む。

【００１６】

別の態様では、採血経路と接続される血液隔離装置が記載されている。採血経路は、患者針とサンプル採取装置とを有する。血液隔離装置は、患者針と接続される入口ポートと、入口ポートと接続される隔離チャンバであって、空気透過性血液バリアを含む通気口を有する隔離チャンバとを含む。血液隔離装置は、入口ポートと接続される近位端を有するサンプリング流路と、サンプリング流路の遠位端及びサンプル採取装置と接続される出口ポートとを更に含む。

【００１７】

更に別の態様では、採血システムと接続される血液隔離装置が記載されている。採血システムは、患者から血液サンプルを取り出せるようにするための患者針と、密封され且つ真空採血管を受け入れるように適合されたサンプル針とを含む。血液隔離装置は、患者からの血液サンプルを受け入れるために患者針と接続される入口ポートを含む。血液隔離装置は、入口ポートと接続され且つ空気透過性血液バリアを含む通気口を有する隔離チャンバであって、サンプル針が真空採血管によって開封されるより前に血液サンプルの最初の部分を受け入れ且つ隔離する隔離チャンバを更に含む。血液隔離装置は、入口ポートと接続される近位端を有するサンプリング流路であって、真空採血管によってサンプル針が開封されると血液サンプルの後続の部分を運ぶサンプリング流路を更に含む。血液隔離装置は、血液サンプルの後続の部分をサンプル針に運ぶためにサンプリング流路の遠位端と接続される出口ポートを更に含む。

【００１８】

更に別の態様では、血液サンプル最適化システムが開示され、記載されている。血液サンプル最適化システムは、患者の血液の１つ以上のサンプルを取り出せるようにし且つ得るための採血システムと、静脈穿刺プロセスによって汚染されている恐れがあり且つ患者の血液中の病原体の偽陽性同定をもたらす可能性がある患者の血液の１つ以上のサンプルの最初の部分を受け入れ且つ隔離するための血液隔離装置とを含む。

【００１９】

採血システムは、患者の血液のサンプルを取り出せるようにするために患者の静脈穿刺用に構成された患者針と、血液サンプルを運ぶために患者針と接続される採血経路と、血液サンプルの後続の部分を採取し且つ収容するために真空採血容器を受け入れるように構成されたサンプル針とを含む。

【００２０】

更に別の態様では、血液隔離装置が開示され、記載されている。一部の実施では、血液隔離装置は、入口ポートと、入口ポートと接続される出口ポートと、入口ポートと接続される隔離チャンバとを含むことができる。隔離チャンバは、空気透過性血液バリアを含む通気口を有することができる。

【００２１】

血液隔離装置は、患者針とサンプル針との間で採血経路に沿って接続され、血液サンプルを受け入れるための入口ポートを含む。血液隔離装置は、血液サンプルの最初の量を受け入れるために入口ポートと接続される隔離チャンバであって、血液サンプルの最初の量の少なくとも最初の部分を隔離するために空気透過性血液バリアを含む通気口を有する隔離チャンバを更に含む。血液隔離装置は、入口ポートと接続される近位端を有するサンプリング流路であって、隔離チャンバが血液サンプルの最初の量の少なくとも最初の部分を隔離すると血液サンプルの後続の量を真空採血容器に運ぶサンプリング流路を更に含む。血液隔離装置は、サンプリング流路の遠位端と接続される出口ポートであって、血液サンプルの後続の量を出力する出口ポートを更に含む。

【００２２】

１つ以上の実施形態の詳細が、添付の図面及び以下の説明に記載されている。他の特徴及び利点は、明細書及び図面並びに特許請求の範囲から明らかになるであろう。

【図面の簡単な説明】

【００２３】
以下、これら及び他の態様について、以下の図面を参照して詳細に説明する。
【図１】血液サンプル最適化システムを示す。
【図２】代替的な実施に従う血液サンプル最適化システムを示す。
【図３】別の代替的な実施に従う血液サンプル最適化システムを示す。
【図４】別の代替的な実施に従う血液サンプル最適化システムを示す。
【図５】別の代替的な実施に従う血液サンプル最適化システムを示す。
【図６】代替的な実施に従う血液サンプル最適化システムを示す。
【図７】血液培養の質を最適化するための方法のフローチャートである。
【図８Ａ】一部の実施に従う非汚染採血用の血液隔離システムを示す。
【図８Ｂ】一部の実施に従う非汚染採血用の血液隔離システムを示す。
【図８Ｃ】一部の実施に従う非汚染採血用の血液隔離システムを示す。
【図８Ｄ】一部の実施に従う非汚染採血用の血液隔離システムを示す。
【図８Ｅ】一部の実施に従う非汚染採血用の血液隔離システムを示す。
【図９】血液隔離システムに用いる経路スプリッタを示す。
【図１０Ａ】代替的な実施に従う非汚染採血用の血液隔離システムを示す。
【図１０Ｂ】代替的な実施に従う非汚染採血用の血液隔離システムを示す。
【図１０Ｃ】代替的な実施に従う非汚染採血用の血液隔離システムを示す。
【図１０Ｄ】代替的な実施に従う非汚染採血用の血液隔離システムを示す。
【図１１Ａ】他の代替的な実施に従う非汚染採血用の血液隔離システムを示す。
【図１１Ｂ】他の代替的な実施に従う非汚染採血用の血液隔離システムを示す。
【図１１Ｃ】他の代替的な実施に従う非汚染採血用の血液隔離システムを示す。
【図１１Ｄ】他の代替的な実施に従う非汚染採血用の血液隔離システムを示す。
【図１１Ｅ】他の代替的な実施に従う非汚染採血用の血液隔離システムを示す。
【図１２Ａ】更に他の代替的な実施に従う血液隔離装置を含む血液サンプル最適化システムを示す。
【図１２Ｂ】更に他の代替的な実施に従う血液隔離装置を含む血液サンプル最適化システムを示す。
【図１２Ｃ】更に他の代替的な実施に従う血液隔離装置を含む血液サンプル最適化システムを示す。
【図１２Ｄ】更に他の代替的な実施に従う血液隔離装置を含む血液サンプル最適化システムを示す。
【図１３Ａ】更に別の代替的な実施に従う血液サンプル最適化システム１３００を示す。
【図１３Ｂ】更に別の代替的な実施に従う血液サンプル最適化システム１３００を示す。
【図１３Ｃ】更に別の代替的な実施に従う血液サンプル最適化システム１３００を示す。
【図１３Ｄ】更に別の代替的な実施に従う血液サンプル最適化システム１３００を示す。
【図１４Ａ】患者の血液サンプルに対して実施される血液培養又は検査における偽陽性を低減するために最初のアリコート又はサンプルの汚染物質を隔離する採血システムの更に別の実施を示す。
【図１４Ｂ】患者の血液サンプルに対して実施される血液培養又は検査における偽陽性を低減するために最初のアリコート又はサンプルの汚染物質を隔離する採血システムの更に別の実施を示す。
【図１４Ｃ】患者の血液サンプルに対して実施される血液培養又は検査における偽陽性を低減するために最初のアリコート又はサンプルの汚染物質を隔離する採血システムの更に別の実施を示す。
【図１４Ｄ】患者の血液サンプルに対して実施される血液培養又は検査における偽陽性を低減するために最初のアリコート又はサンプルの汚染物質を隔離する採血システムの更に別の実施を示す。
【図１４Ｅ】患者の血液サンプルに対して実施される血液培養又は検査における偽陽性を低減するために最初のアリコート又はサンプルの汚染物質を隔離する採血システムの更に

別の実施を示す。
【図１５Ａ】更に別の実施に従う血液隔離装置及びそれを使用する方法を示す。
【図１５Ｂ】更に別の実施に従う血液隔離装置及びそれを使用する方法を示す。
【図１５Ｃ】更に別の実施に従う血液隔離装置及びそれを使用する方法を示す。
【図１５Ｄ】更に別の実施に従う血液隔離装置及びそれを使用する方法を示す。
【図１５Ｅ】更に別の実施に従う血液隔離装置及びそれを使用する方法を示す。
【図１５Ｆ】更に別の実施に従う血液隔離装置及びそれを使用する方法を示す。
【図１５Ｇ】更に別の実施に従う血液隔離装置及びそれを使用する方法を示す。
【図１６Ａ】更に別の実施に従う血液隔離装置を示す。
【図１６Ｂ】更に別の実施に従う血液隔離装置を示す。
【図１６Ｃ】更に別の実施に従う血液隔離装置を示す。
【図１６Ｄ】更に別の実施に従う血液隔離装置を示す。
【図１７Ａ】血液隔離装置用のハウジングの下部部材を示す。
【図１７Ｂ】血液隔離装置用のハウジングの下部部材を示す。
【図１７Ｃ】血液隔離装置用のハウジングの下部部材を示す。
【図１７Ｄ】血液隔離装置用のハウジングの下部部材を示す。
【図１７Ｅ】血液隔離装置用のハウジングの下部部材を示す。
【図１８Ａ】血液隔離装置用のハウジングの上部部材を示す。
【図１８Ｂ】血液隔離装置用のハウジングの上部部材を示す。
【図１８Ｃ】血液隔離装置用のハウジングの上部部材を示す。
【図１８Ｄ】血液隔離装置用のハウジングの上部部材を示す。
【図１８Ｅ】血液隔離装置用のハウジングの上部部材を示す。
【図１８Ｆ】血液隔離装置用のハウジングの上部部材を示す。
【図１９Ａ】下部部材と嵌合する上部部材を有する血液隔離装置を示す。
【図１９Ｂ】下部部材と嵌合する上部部材を有する血液隔離装置を示す。
【図２０】血液隔離装置を含む血液サンプル最適化システムを示す。
【図２１】ウィッキング材料チャンバを使用する通気口付きでない血液隔離装置を示す。
【図２２Ａ】血液隔離装置の隔離チャンバ内の血液を隔離するためのフィルタの材料構成を示す。
【図２２Ｂ】血液隔離装置の隔離チャンバ内の血液を隔離するためのフィルタの材料構成を示す。
【図２３Ａ】採血装置による真空力を使用する血液隔離装置の別の実施を示す。
【図２３Ｂ】採血装置による真空力を使用する血液隔離装置の別の実施を示す。　様々な図面における同様の符号は同様の要素を示す。
【発明を実施するための形態】
【００２４】
本明細書は、採取される血液サンプル中の汚染物質を低減又は排除し、その結果、採取される血液サンプルの血液培養又は他の検査における偽陽性の判断を減少又は排除する血液サンプル最適化システム及び方法を記載している。一部の実施では、血液サンプル最適化システムは、患者の血流への血管アクセスのための患者針と、バキュテナー（登録商標）のような真空採血容器又は真空採血管などの採血容器か又は他のサンプリング装置に血液サンプルを供給するためのサンプル針と、患者針とサンプル針との間に位置する血液隔離装置とを含む。血液隔離装置は、汚染されている可能性のある最初のアリコートの血液を隔離するための隔離チャンバを含み、最初のアリコートの血液が隔離チャンバ内に隔離された後に患者針とサンプル針との間の汚染されていない可能性のある血液を運ぶために隔離チャンバを迂回するサンプリング流路を更に含むことができる。
【００２５】
図１は、一部の実施に従う血液サンプル最適化システムを示す。システムは、患者の皮膚を穿刺してその中の患者の静脈及び静脈内の血液にアクセスするための患者針１を含む。システムは、再密封可能なブーツ１０、ルアー作動弁、又は別の採取インターフェース

又は装置内に収容され且つ再密封可能なブーツ１０、ルアー作動弁、又は別の採取インターフェース又は装置によって当初は密封されていることができる、サンプル針（すなわち、バキュテナー（登録商標）などと共に使用するための再密封可能に密封された針）５を更に含む。再密封可能なブーツ１０は、患者の血液を採取するためのバキュテナー（登録商標）ボトル（図示せず）を用いることによって、サンプル針５のそばに又はサンプル針５の周りに押し付けることができる。システムは、サンプル針５に通じる低容量チャンバ３０を更に含むことができるが、ハウジング５０によって形成される隔離チャンバ５５に通じる穴又は１つ以上の流路４５も含む。

【００２６】

隔離チャンバ５５は、隔離チャンバ５５の容積に応じて、所定の又は測定された量であることができる、患者の血液の最初のアリコートを受け入れ且つ保持するためのチャンバ、流路、通路、ロック、又は他の構造である。最初の採血は、一般的に、後続の採血に比べて菌血症及び敗血症を引き起こす微生物又は他の病原体を含有しているか又はより含有の影響を受けやすい。隔離チャンバ５５は、硬いハウジング内に収容されるか、ハウジング自体に形成され又はハウジング自体によって画定された容器であることができ、或いはチューブ又は内腔として実現されることができる。隔離チャンバ５５は、どのように形成され且つ実施されるかにかかわらず、所定の容積を有することができる。一部の実施では、所定の容積は、患者針の容積に基づくこと、すなわち、患者針の容積よりも少ない容積から任意の容積から患者針の容積の２０倍以上大きい容積までの範囲であることができる。隔離チャンバ５５の所定の容積は、隔離され且つ処分される血液の量を節約又は最小化するように設定されることもできる。

【００２７】

隔離チャンバ５５は、チャンバハウジング５０内に形成、包含、又は収容されることができ、プラスチック、ゴム、鋼、アルミニウム又は他の適切な材料で作られることができる。例えば、隔離チャンバ５５は、可撓性チューブ又は他のエラストマー材料から形成されることができる。隔離チャンバ５５は、空気が隔離チャンバ５５から出ることを可能にする空気透過性血液バリア２０を更に含む。本明細書で使用される「空気透過性血液バリア」という用語は、空気透過性であるが実質的に血液不透過性の物質、材料又は構造体を意味する。代表的な例は、疎水性膜及び疎水性コーティング、疎水性膜又は疎水性コーティングと組み合わせた親水性膜又は親水性コーティング、メッシュ、フィルタ、機械的弁、抗菌性材料、又は隔離チャンバ５５が血液で満たされるときに隔離チャンバ５５から空気を追い出すことができる他の任意の手段を含むことができる。様々な例示的な実施形態において、空気透過性血液バリアは、空気が液体と接触するまで通過することを可能にする１つ以上の材料によって形成されることができ、このような材料は、空気及び／又は液体の通過を防止又は阻止するために完全に又は部分的に密封される。言い換えれば、液体との接触より前に、材料は空気透過性のバリアを形成している。液体との接触後、材料は、空気及び／又は液体の更なる通過を実質的に又は完全に防止する。

【００２８】

穴又は流路４５は、任意の所望の長さ、断面形状又はサイズであることができ、且つ／又は任意の所望の角度又は向きで低容量チャンバ３０から離れるように形成されることができる。穴又は流路４５はまた、最初のアリコートの血液サンプルを隔離チャンバ５５内に保持する一方向フラップ又は一方向弁６０を含むことができる。一部の特定の実施では、穴又は流路４５は、低容量チャンバ３０から隔離チャンバ５５への一方向の血液の流れのための「ダックビル」弁又はフラッパ弁６０などを含むことができる。空気透過性血液バリア２０は、空気が出ることを可能にするが血液と接触すると密封する材料で構成することもでき、それによって外気が隔離チャンバ５５に入ることを許容しない。この密封は弁を不要にする。

【００２９】

弁６０は、任意のタイプの弁又は開閉機構であることができる。チャンバ３０は、実質的に残留血液を保持しないように設計されており、特定の容積又は割合の血液を隔離チャ

ンバ５５に保持し又は通過させるように構成することができる。同様に、隔離チャンバ５５は、抗菌コーティングのような任意のタイプのコーティング、又は隔離された最初の採血の成分の同定及び／又は診断を支援するコーティングも含むことができる。

【００３０】

ハウジング５０及び４０は、アクリロニトリルブタジエンスチレン（ＡＢＳ）又は他の熱可塑性材料又はポリマー材料などのプラスチック、ゴム、鋼、又はアルミニウムを含む任意の適切な材料から形成されることができる。空気透過性血液バリア２０は、最初の採血による血液と接触すると又は空気の追い出しが停止されたときに、又は事象と隔離チャンバ５５内の血液との任意の組み合わせの場合に活性化される、色提供物質又は他の信号伝達機構を含むことができる。空気透過性のバリアはまた、外部流体源、しぶき等によるフィルタの不注意による又は早過ぎる密封を阻止又は防止する疎水性膜又はカバーなどの外層を含むことができる。隔離チャンバ５５はまた、チャンバが充填されたことをユーザーが視覚的に確認することを可能にするために半透明又は透明であることができる。

【００３１】

図２は、一部の代替的な実施に従う血液サンプル最適化システムを示す。図２に示す実施では、隔離チャンバ５５又は廃棄チャンバが患者針１を取り囲み、端部が開放されたカフ又はハウジングが廃棄チャンバと接続され、サンプル針ハウジングベース及びハウジングを取り囲んでいる。患者針１とサンプル針５とは、ブーツ５６によって互いと接続されており、ブーツ５６は、それを貫通する連続的な採血流路を形成している。ブーツ５６は、採血流路から隔離チャンバ５５に通じる単一の穴又は流路を含む。装置は、他の実施では、複数の穴又は流路を含むことができる。各穴又は流路は、一方向弁を含むことができ、所定の量の血流のために寸法設定され且つ適合されることができる。

【００３２】

隔離チャンバ５５は、空気透過性血液バリアを含む。フィルタは、所定容積の血液が隔離チャンバ５５に集められたときに、それぞれ、感知及び／又は指示するためのセンサ又は指標を更に含むことができる。その指示は、バキュテナー（登録商標）などの真空採血管又はボトルをサンプル針５に取り付けるようにユーザーに警告する。隔離チャンバ５５用のハウジングは、任意のサイズ又は形状であることができ、ハウジング内の内部空間又は容積を画定するために任意のタイプの材料を含むことができる。内部空間は、最初は空気のみで満たされているが、汚染除去剤、凝固剤などの薬剤又は物質でコーティングされることもできる。真空採血管がサンプル針５に取り付けられると、血液は自動的に患者針１に、採血流路及びサンプル針５を通ってボトルに流入する。サンプル針５は、採血ボトルがサンプル針に取り付けられていないときにサンプル針を密封する再密封可能なブーツ、コーティング又は膜によって覆われている。

【００３３】

図３は、一部の代替的な実施に従う血液サンプル最適化システムを示す。図示の実施では、サンプル針５は、再密封可能なブーツ又は膜によって取り囲まれ、更に患者針１と接続される。サンプル針及び患者針を通って血液流路が形成される。サンプル針と患者針との間の接続は、主血液流路から隔離チャンバ１０４へと導く流路、ポート又は開口部を含む「Ｔ」又は「Ｙ」コネクタ１０２を含む。

【００３４】

Ｔ又はＹコネクタ１０２は、フラップ又は一方向弁を含み、所定の流量の血液のために寸法設定され且つ適合された穴を有する。隔離チャンバ１０４は、チューブから形成され又は硬いハウジングによって形成されることができ、最初は空気で満たされている。隔離チャンバ１０４は、自動的に、すなわち、患者自身の血圧による圧力下で患者から流出する血液を受け入れる。隔離チャンバ１０４は、好ましくは隔離チャンバ１０４を形成し且つ近位端がＴ又はＹコネクタ１０２に接続されたチューブの遠位端に、空気透過性血液バリア１０６を含む。Ｔ又はＹコネクタ１０２は、最も効率的な血流のために任意の所望の角度で分岐することができ、最初のアリコートの血液と主要な採血サンプルとの混合を最小限に抑え又は排除するために、開口部及び流路と主血液流路との間の接合部分を最小化

するように形成されることができる。

【００３５】

一部の代替的な実施では、サンプル針は、図４に示すように、その反対側の端部がＴ又はＹコネクタ１０２と接続している任意の長さのチューブに取り付けられることができる。隔離チャンバ１０４は、最初のアリコートに所定量の血液サンプルを含む限り、任意の形状又は容積であることができる。Ｔ又はＹコネクタ１０２はまた、主血液流路に対して平行な開口部又は流路を含むことができる。空気透過性血液バリアは、所定量の血液が隔離チャンバに集められたとき、又は放出される空気が特定の閾値、すなわちゼロに達したときを示す指標１０７又は他の機構を更に含むことができる。チューブはまた、挟んでチューブを通る流体の流れを防止するのに使用することができるクリップ１０９を含むことができる。

【００３６】

空気透過性血液バリア及び一次チャンバが密封されると、最初のアリコートの血液が隔離チャンバ１０４に閉じ込められ、サンプルを得るためにバキュテナー（登録商標）ボトルのような真空採血管がサンプル針５に取り付けられる。採血管は取り外すことができ、サンプル針５は再密封される。更なる採血又はサンプルのために、任意の数の後続の採血管を取り付けることができる。全ての採血が完了すると、最初のアリコートの血液が隔離チャンバ１０４に閉じ込められたまま、システムは廃棄される。

【００３７】

図５は、一部の代替的な実施に従う血液サンプル最適化システムを示す。図示の実施では、サンプル針５が患者針とチューブによって接続されている。「Ｔ」又は「Ｙ」コネクタ１２０が、チューブに沿って任意の所望の位置に追加され、実質的に上記のように、隔離チャンバ２０４に通じる開口部、ポート又は流路を含む。

【００３８】

図６は、一次採取流路として形成された隔離チャンバ３０４が最初のアリコートの血液を受け入れ、採血流路に隣接して設けられている、一部の代替的な実施に従う血液サンプル最適化システムを示す。隔離チャンバ３０４は、採血流路、患者針１及び／又はサンプル針５を取り囲むことができる。一次採取流路は、Ｔ又はＹコネクタ１２０、又は他のタイプの開口部又は流路を含むことができる。隔離チャンバ３０４は空気透過性血液バリアを含み、上記のように、血液などの流体が接触したことの指標を含むこともできる。

【００３９】

一部の実施では、患者針１又はサンプル針５のいずれか又は両方をルアーロック雄コネクタ又はルアーロック雌コネクタで置き換えることができる。しかしながら、様々な実施で、血液サンプル最適化システムのサンプル針端部にあるコネクタを最初に密封し、周囲空気圧で加圧され且つ空気透過性血液バリアの空気出口を含む隔離チャンバへ最初のアリコートの血液をそらすことを可能にする。このようにして、システムは受動的且つ自動的に患者自身の血圧を用いて隔離チャンバの周囲空気圧に打ち勝ち、空気透過性血液バリアを通して空気を押し出し、隔離チャンバ内の空気を血液に置き換える。

【００４０】

図７は、血液培養の質を最適化するための例示的な方法のフローチャートである。７０２において、臨床医が患者の静脈に針を挿入する。７０４において、血液が隔離チャンバに流れ込み、隔離チャンバ内の空気を隔離チャンバから空気透過性血液バリアを通して押し出す。一部の実施では、隔離チャンバの容積は、０．１立方センチメートル（ｃｃ）未満から５立方センチメートル（ｃｃ）以上である。隔離チャンバは、血液サンプルの第２部分及び他の後続の部分又は後続の採取よりも汚染しやすい血液サンプルの第１部分を採取するように寸法設定され且つ適合されている。隔離チャンバは空気透過性血液バリアを有し、この血液バリアを通して空気を患者の静脈から押し出された血液で追い出すことができるので、このような血液は、血液サンプルを受け入れ且つ保管するためのバキュテナー（登録商標）又は他のボトルに引き込まれるか又は他の方法で入る前に、必然的に且つ自動的に隔離チャンバに流入する。

【００４１】
隔離チャンバがいっぱいになると、血液は、血液が通過するのを阻止又は防止する空気透過性血液バリアに集まるか、さもなければ接触する。７０６において、血液が空気透過性血液バリアの全内部表面積と接触すると、空気透過性血液バリアは閉じられ、空気はもはや流出又は流入しない。７０８において、臨床医は、バキュテナー（登録商標）などの真空採血管を取り付けることができることを示す指標を提供されるか又は満杯のチャンバを見ることができる。指標は、一次チャンバがいっぱいであるか否かを確認するための一次チャンバの可視性、例えば、色を変える血液バリア、又は他の指標を含むことができる。隔離チャンバの充填時間は、実質的に瞬間的であり得るので、このような指標は、存在する場合、隔離チャンバが満たされているというだけである可能性がある。

【００４２】
真空採血管が取り付けられる前、針、サンプリング流路、及び隔離チャンバの間の連通は、隔離チャンバの血液バリアの密封によって制限され、従って隔離によって空気がシステムに再び入ることを可能にしない。連通経路の密封は、機械的にねじること又は他の動作、小さな穴又は曲がりくねった経路によって達成され、臨床医による別個の弁又は機械的な動作又は操作の必要性をなくす。７１０において、真空採血管を取り外すと、自己密封式の膜がサンプル針を密封し、７１２で、更なる後続の真空採血管を取り付けることができる。７１４において、サンプルが採取されると、装置が患者から取り外され、廃棄される。

【００４３】
図８Ａ～８Ｅは、一部の実施に従う、非汚染採血用の例示的な血液サンプル最適化システム８００を示す。血液サンプル最適化システム８００は、チューブ、患者針（又は両方）、又は他の血管又は静脈アクセス装置に接続されることができる入口ポート８０２と、隔離チャンバチューブ８０６への第１出口とサンプル採取チューブ８０８への第２出口とを有する経路スプリッタ８０４とを含む。隔離チャンバチューブ８０６及びサンプル採取チューブ８０８の一方又は両方は、チューブから形成されることができる。一部の実施では、隔離チャンバチューブ８０６は、特定の量の当初血液サンプルを収容するように寸法設定される。サンプル採取チューブ８０８は、ひとたび隔離チャンバチューブ８０６が満たされると、血液サンプルを受け入れる。サンプル採取チューブ８０８は、バキュテナー（登録商標）ベース又はハウジング８１０、又は他の血液サンプル採取装置に接続されることができる。

【００４４】
血液隔離システム８００は血液隔離装置８１２を更に含み、血液隔離装置８１２は、図８Ｂ～８Ｄにより詳細に示すようにハウジング８１８を含み、ハウジング８１８は、非汚染サンプル採取チューブ８０８用の経路を画定するか又はいずれかの端部が非汚染サンプル採取チューブ８０８と接続されるサンプリング流路８２０を含む。サンプリング流路８２０は、非汚染サンプル採取チューブ８０８に沿った位置でハウジング８１８をより良好に固定し且つ安定させるように、ハウジング８１８を通って曲線状であることができる。

【００４５】
血液隔離装置８１２は、隔離チャンバチューブ８０６と接続される隔離チャンバ８２２又は他のチャンバを更に含む。隔離チャンバ８２２は、空気透過性血液バリア８２４で終端している。空気透過性血液バリア８２４はまた、血液サンプル（すなわち、非汚染血液サンプル）の正式な採取を開始することができる指標として、血液との完全な接触時に異なる色に変わる着色剤を含むことができる。小さい光、音発生機構などの他の指標を使用することができる。一部の実施では、空気透過性血液バリアは、隔離チャンバ８２２の方向から直角に配置されているが、ハウジング８１８に使用される空間及び材料を節約するために任意の距離又は向きに配置されることができる。ハウジング８１８及びその内容物は、任意の剛性材料又は半剛性材料又は一連の材料から形成されることができる。

【００４６】
図９は、例えば、図８Ａ～８Ｅに示すような血液隔離システムに用いる経路スプリッタ

９００を示す。経路スプリッタ９００は、入口ポート９０２と、主管路出口ポート９０４と、隔離流路出口ポート９０６とを含む。入口ポート９０２は、同様に患者針システムに接続される主チューブに、又は直接患者針に接続されることができる。主管路出口ポート９０４は、バキュテナー（登録商標）ベース又はハウジングなどの採血システムへの主管路チューブに、又は直接そのような採血システムに接続されることができる。隔離流路出口ポート９０６は、測定された量又は所定の閾値まで血液の第１サンプルを受け入れ且つ隔離するための隔離チューブに接続されることができる。代わりに、隔離流路出口ポート９０６は、隔離チャンバに接続することができる。隔離流路出口ポート９０６は、好ましくは、主管路出口ポート９０４から２０～７０度の角度に曲げられ、一方、主管路出口ポート９０４は、好ましくは、入口ポート９０２と一直線である。所定の量の最初の血液サンプルが、本明細書に記載された機構及び技術に従って隔離チューブ又は隔離チャンバ内に隔離されると、後続の血液サンプルは、入口ポート９０２に流入し、障害物なしで主管路出口ポート９０４から直接流出する。

【００４７】

図１０Ａ～１０Ｄは、別の実施に従う血液隔離装置１０００を示す。血液隔離装置１０００は、入口ポート１００２と、主出口ポート１００４と、隔離流路ポート１００６とを含む。入口ポート１００２は、患者針又は関連するチューブと接続されることができる。主出口ポート１００４は、バキュテナー（登録商標）、関連するチューブ、又はルアー作動弁などの血液サンプル採取装置に接続されることができる。隔離流路ポート１００６は、主出口ポート１００４から隔離チャンバ１００８に分離する。一部の実施では、隔離チャンバ１００８は、ハウジング又は他の容器１００１内に螺旋流路として形成される。

【００４８】

隔離チャンバ１００８は、実質的に上記のように、遠位端が空気透過性血液バリア１０１０に接続される。隔離チャンバ１００８内の空気は、空気透過性血液バリア１０１０を通して、隔離流路ポート１００６内に案内される最初のアリコートの血液によって追い出される。ひとたび隔離チャンバ１００８が満たされると、主出口ポート１００４を通る更なる採血が成し遂げられ、これらのサンプルは汚染されていない。

【００４９】

図１１Ａ～１１Ｅは、他の代替的な実施に従う血液隔離装置１１００を示す。血液隔離装置１１００は、上述の入口ポートと同様の入口ポート１１０２と、主出口ポート１１０４と、主出口ポート１１０４及び入口ポート１１０２から分離する隔離流路ポート１１０６とを含む。隔離流路ポートは、隔離チャンバ１１０８に接続されている。図１１Ａ～１１Ｅに示す実施では、血液隔離装置は、隔離チャンバ１１０８として機能する流路を内部に有するベース部材１１０１を含む。流路は、ベース部材１１０１を通る曲がりくねった経路として形成されることができ、一方、ベース部材１１０１は、患者の四肢に載るように成形され且つ形成される。

【００５０】

隔離チャンバ１１０８の一部は、血液隔離指標１１０９として機能するように、空気透過性血液バリア１１１０に出る直前に、ベース部材から又はベース部材の上面付近に突出することができる。指標１１０９は、透明な材料、又は血液と接触すると変色する材料で形成されることができる。

【００５１】

一部の実施では、血液隔離装置１１００は、常時閉じている針、バキュテナー（登録商標）シールド又は他の採取装置などの採血装置１１２０を含むことができる。採血装置１１２０は、患者針の挿入プロセスによって汚染される恐れがある最初のアリコートの血液を隔離することができるように、効率及び利便性のために血液隔離装置１１００と共に製造及び販売されることができる。従って、採血装置１１２０は、偽陽性の検査のリスクを低減するように非汚染血液サンプルを採取し且つ非汚染サンプルを確実にすることができる。

【００５２】

図１２Ａ～１２Ｄは、更に他の代替的な実施に従う血液サンプル最適化システム１２００を示す。システム１２００は、バキュテナー（登録商標）又は他の採取及びサンプリング装置のような採血装置１２０４に取り付けるための血液隔離装置１２０２を含む。血液隔離装置１２０２は、バキュテナー（登録商標）容器又はバイアルが採血装置１２０４の採取針に取り付けられる前に、最初のアリコート又は量の血液を受け入れ、且つその最初のアリコート又は量を血液隔離装置１２０２の隔離流路内に隔離するように、構成され且つ配置されている。

【００５３】

一部の実施では、血液隔離装置１２０２は、入口ポート１２１２と、主出口ポートと、隔離流路ポートとを含むことができる。入口ポート１２１２は、患者針又は関連するチューブに接続されることができる。主出口ポート１２１４は、真空採血容器又はバキュテナー（登録商標）などの他の採取装置、関連するチューブ、ルアーコネクタ、注射器、ルアー作動弁との接続を可能にするために、常時閉じている針又は装置に接続されることができる。隔離流路ポートは、主出口ポートから隔離チャンバ１２１８に分離する。

【００５４】

一部の実施では、隔離チャンバ１２１８は、隔離装置１２０２の本体内の流路として形成される。隔離チャンバ１２１８は、Ｕ字形流路、Ｓ字形流路、螺旋流路、又は任意の他の曲がりくねった流路などの曲がりくねった流路であることができる。隔離装置１２０２は、ハウジング又は他の収容体、及びその中に形成された１つ以上の流路を含むことができる。図１２Ａ及び１２Ｂに示すように、隔離装置１２０２は、本体１２０６とキャップ１２０８とを含む。本体１２０６には１つ以上の空洞又は流路が形成され、空洞又は流路にはキャップ１２０８から延びる１つ以上のアーム１２１０が更に形成され、１つ以上のアーム１２１０は、本体１２０６の空洞又は流路に当接して一次採取ポート及び主出口ポートを形成している。

【００５５】

図１３Ａ～１３Ｄは、更に他の代替的な実施に従う血液サンプル最適化システム１３００を示す。システム１３００は、バキュテナー（登録商標）又は他の体液採取及びサンプリング装置などの採血装置１３０４に取り付けるための血液隔離装置１３０２を含む。血液隔離装置１３０２は、バキュテナー（登録商標）容器又はバイアルが採血装置１３０４の採取針に取り付けられる前に、最初のアリコート又は量の血液を受け入れ、且つその最初のアリコート又は量の血液又は他の体液を血液隔離装置１３０２の隔離流路内に隔離するように、構成され且つ配置されている。

【００５６】

血液隔離装置１３０２は、入口ポート１３１４と、主出口ポート１３１２と、隔離流路ポート１３１６とを有するハウジング１３０１を含む。入口ポート１３１４は、患者針又は関連するチューブに接続されることができる。主出口ポート１３１２は、真空採血容器又はバキュテナー（登録商標）などの他の採取装置、関連するチューブ、ルアーコネクタ、注射器、ルアー作動弁との接続を可能にするために、常時閉じている針又は装置に接続されることができる。隔離流路ポート１３１６は、主入口ポート１３１４から隔離チャンバ１３１８に分離する。

【００５７】

図１３Ａ～１３Ｄに示す実施例では、隔離チャンバ１３１８は、ハウジング１３０１内の空洞又はチャンバとして形成され、又はハウジング１３０１を画定する壁によって形成される。隔離チャンバ１３１８は、Ｕ字形流路、Ｓ字形流路、螺旋流路などの曲がりくねった流路、又はハウジング１３０１とキャップ１３０７との協働及び接続によって画定される任意の他の曲がりくねった流路であることができ、キャップ１３０７は、隔離チャンバ１３１８内の曲がりくねった流路のための１つ以上の壁又はディレクタを提供する突出部１３０５を含むことができる。キャップ１３０７からの突出部１３０５は、真っ直ぐであるか湾曲していることができ、様々な流路、開口部又は溝が埋め込まれていることができ、キャップ１３０７から任意の角度又は向きで延びることができる。隔離チャンバ１３

１８の形成を完了するためにキャップ１３０７がハウジング１３０１と接続されると、突出部１３０５は曲がりくねった流路の少なくとも一部を形成し、隔離チャンバ１３１８内に曲がりくねった流路によって形成される隔離流路に最初のアリコート又は量の血液又は他の体液を隔離する。

【００５８】

隔離チャンバ１３１８は、実質的に上記のように空気透過性血液バリア１３１０を含む。隔離チャンバ１３１８内の空気は、患者の血圧によって隔離チャンバ１３１８内に供給される最初のアリコートの血液によって空気透過性血液バリア１３１０を通して追い出される。隔離チャンバ１３１８が満たされ、隔離チャンバ１３１８内の空気が追い出されると、バキュテナー（登録商標）のような血液サンプル採取装置によって提供されるような真空又は他の圧力のような力が次のアリコート又は量の血液又は体液を引き抜くために提供されるまで、患者の血圧は、血液隔離装置１３０２、特に、出口ポート１３１２に更なる血液を追い込み又は提供するのには不十分である。主出口ポート１３１２を通して更なる採血を行うことができ、あらゆる汚染物質が最初のアリコートの血液と共に隔離チャンバ１３１８内に隔離されているので、これらのサンプルは汚染されない。

【００５９】

図１４Ａ～１４Ｅは、患者の血液サンプルに対して実施される血液培養又は検査における偽陽性を低減するために最初のアリコート又はサンプルの汚染物質を隔離する採血システム１４００の更に別の実施を示す。採血システム１４００は、血液サンプル採取装置１４０３と患者針（図示せず）との間に接続されることができる血液隔離装置１４０１を含む。血液サンプル採取装置１４０３は、バキュテナー（登録商標）などであることができる。血液隔離装置１４０１は、血液サンプルへのアクセス及び血液サンプルの採取のために患者の血管系に挿入される患者針と接続されることができる入口ポート１４０２を含む。入口ポート１４０２は、同様に患者針と接続されるチューブ又は他の導管と接続されることもできる。

【００６０】

入口ポート１４０２は、血液隔離装置１４０１への開口部を画定し、この開口部は、患者針と接続されるチューブ又は他の導管又は患者針自体と同じ断面寸法であることができる。例えば、開口部は、約０．０４５インチ（１．１４３ｍｍ）の直径を有する円形であることができるが、０．０１インチ（０．２５４ｍｍ）から０．２インチ（５．０８ｍｍ）又はそれ以上の直径を有することができる。血液隔離装置１４０１は、血液隔離装置１４０１から及び血液サンプル採取装置１４０３への開口部を画定する出口ポート１４０４を更に含む。出口ポート１４０４は、同様に血液隔離装置１４０３と接続されるチューブ又は他の導管と接続されることもできる。出口ポート１４０４は、ねじ付きキャップ、ルアーコネクタ（雄型又は雌型）、チューブなどを含むがそれらに限定されない様々な装置の取り付け用のねじが切られていない締め代又は接着継手などのコネクタ装置を更に含むことができる。

【００６１】

血液隔離装置１４０１は、入口ポート１４０２と出口ポート１４０４との間にサンプリング流路１４０６を更に含み、サンプリング流路１４０６は、最初のアリコートの血液が隔離されると血液サンプル経路として機能する。サンプリング流路１４０６は、任意のサイズ、形状又は構成の流路又は導管であることができる。一部の実施では、サンプリング流路１４０６は、入口ポート１４０２の開口部と実質的に同様の断面積を有する。他の実施では、サンプリング流路１４０６は、入口ポート１４０２から出口ポート１４０４まで徐々に広がることができる。

【００６２】

血液隔離装置１４０１は隔離チャンバ１４０８を更に含み、隔離チャンバ１４０８は、入口ポート１４０２と出口ポート１４０４との間の任意の位置でサンプリング流路１４０６に接続され且つサンプリング流路１４０６から分離又は方向転換されるが、好ましくは入口ポート１４０２の近くのサンプリング流路１４０６の近位端に接続され且つ近位端か

ら分離又は方向転換される。隔離チャンバ１４０８は、最初は大気圧に維持され、サンプリング流路１４０６からの方向転換点と反対側の隔離チャンバ１４０８の遠位端又はその近傍に空気出口１４１２を含む。空気出口１４１２は、空気透過性血液バリア１４１２を含む。図１４Ｂに示すように、空気透過性血液バリア１４１２は、保護カバー１４１６で覆われていることができる。保護カバー１４１６は、ユーザーが彼らの指又は他の外部器具で空気透過性血液バリア１４１２に触れるのを妨げるように寸法設定され且つ構成されることができ、一方それでも患者自身の血圧によって隔離チャンバ１４０８内に強制的に血液が供給されることによって空気が隔離チャンバから追い出されるときに空気が空気透過性血液バリア１４１２から出ることを可能にする。また、保護カバー１４１６は、空気透過性血液バリアが周囲の流体又は飛沫に偶発的に曝されるのを阻止又は防止するように構成されることができる。これは、保護カバーに疎水性膜を追加することを含むがそれに限定されない、様々な機械的方法で行うことができる。

【００６３】

図１４Ｃ及び１４Ｄに示すように、サンプリング流路１４０６は、赤血球を溶解する可能性を最小限に抑えるために、より小さい直径からより大きい直径になる円筒形又は円錐台形であることができる。同様に、サンプリング流路１４０６は、赤血球を溶解する可能性がある急カーブ又は鋭角が最小限の量で又はなしで形成される。サンプリング流路１４０６は、方向転換経路１４０９を通して入口ポート１４０２の近くで隔離チャンバ１４０８へと分離する。方向転換経路１４０９は、任意の断面形状又はサイズを有することができるが、好ましくは、入口ポート１４０２の少なくとも一部の断面形状と同様である。

【００６４】

一部の実施では、サンプリング流路１４０６及び隔離チャンバ１４０８は、ハウジング１４１４に形成された溝、流路、ロック又は他の経路によって形成される。ハウジング１４１４は、プラスチック、金属又は他の剛性又は半剛性材料で作られることができる。ハウジング１４１４は、上部部材と密封可能に嵌合する下部部材を有することができる。下部部材及び上部部材の一方又は両方は、サンプリング流路１４０６及び隔離チャンバ１４０８、並びに方向転換経路１４０９、入口ポート１４０２、及び出口ポート１４０４を含むことができる。一部の他の実施態様では、方向転換経路１４０９、入口ポート１４０２、及び／又は出口ポート１４０４のうちの１つ以上が、ハウジング１４１４のいずれかの端部に接続されるキャップ部材によって少なくとも部分的に形成されることができる。一部の実施では、上部部材及び下部部材、並びにキャップ部材は、レーザ溶接、ヒートシール、接着、スナップ止め、ねじ止め、ボルト止めなどによって互いに連結されることができる。他の実施では、方向転換経路１４０９及び／又は隔離チャンバ１４０８の内面の一部又は全部が、汚染除去剤、凝固剤などの薬剤又は物質でコーティング又は充填されることができる。例えば、隔離チャンバ１４０８が満たされて最初のアリコートの血液が方向転換経路１４０９に戻るとき、隔離された血液の最後の量が凝固し、隔離チャンバ１４０８とサンプリング流路１４０６との間に障壁を作り出すように、方向転換経路１４０９に凝固剤を設けることができる。

【００６５】

図１５Ａ～１５Ｇは、血液隔離装置１５００を示す。血液隔離装置１５００は、真空採血容器又はバキュテナー（登録商標）などの他の採取装置、関連するチューブ、ルアーコネクタ、注射器、ルアー作動弁などとの接続を可能にするために常時閉じている針又は装置に接続されることができる。

【００６６】

血液隔離装置１５００は、血液サンプルへのアクセス及び血液サンプルの採取のために患者の血管系に挿入される患者針と接続されることができる入口ポート１５０２を含む。入口ポート１５０２は、同様に患者針と接続されるチューブ又は他の導管と接続されることもできる。入口ポート１５０２は、血液隔離装置１５００への開口部を画定し、この開口部は、患者針と接続されるチューブ又は他の導管又は患者針自体と同じ断面寸法であることができる。例えば、開口部は、約０．０４５インチ（１．１４３ｍｍ）の直径を有す

る円形であることができるが、０．０１インチ（０．２５４ｍｍ）から０．２インチ（５．０８ｍｍ）又はそれ以上の直径を有することができる。

【００６７】

入口ポート１５０２はまた、ねじ切り又はルアーフィッティングなどのような密封又は流体密封のコネクタ又は接続部を含むことができる。一部の実施では、患者針に結合されているチューブ又は他の導管は、部品同士の共成形、接着、レーザ溶接、又は熱接合などによって、入口ポート１５０２と一体化されることができる。これによって、血液隔離装置１５００は、患者針と共に単一ユニットとして製造及び販売され、採血又はサンプリングの際に患者針を血液隔離装置１５００に接続する必要性をなくすことができる。

【００６８】

血液隔離装置１５００は、血液隔離装置１５００から及び血液サンプル採取装置への開口部を画定する出口ポート１５０４を更に含む。出口ポート１５０４は、同様に血液隔離装置と接続されるチューブ又は他の導管と接続されることもでき、ねじ切り又はルアーフィッティングなどの密封又は流体密封コネクタ又は接続部を含むことができる。したがって、上記のように、血液隔離装置１５００は、患者針及び／又はチューブ及び血液サンプル採取装置と共に単一ユニットとして製造及び販売され、採血又はサンプリングの際に患者針及び血液サンプル採取装置を血液隔離装置１５００に接続する必要性をなくすことができる。

【００６９】

血液隔離装置１５００は、入口ポート１５０２と出口ポート１５０４との間にサンプリング流路１５０６を更に含み、サンプリング流路１５０６は、最初のアリコートの血液が隔離されると血液サンプル経路として機能する。サンプリング流路１５０６は、任意のサイズ、形状、又は構成の流路又は導管であることができる。一部の実施では、サンプリング流路１５０６は、入口ポート１５０２の開口部と実質的に同様の断面積を有する。他の実施では、サンプリング流路１５０６は、入口ポート１５０２から出口ポート１５０４まで徐々に広がることができる。

【００７０】

血液隔離装置１５００は隔離チャンバ１５０８を更に含み、隔離チャンバ１５０８は、入口ポート１５０２と出口ポート１５０４との間の任意の位置でサンプリング流路１５０６に接続され且つサンプリング流路１５０６から分離又は方向転換されるが、好ましくは入口ポート１５０２の近くのサンプリング流路１５０６の近位端に接続され且つ近位端から分離又は方向転換される。一部の実施では、分水路はＹ字路を含む。隔離チャンバ１５０８は、好ましくは大気圧に維持され、隔離チャンバ１５０８の遠位端又はその近傍に通気口１５１０を含む。通気口１５１０は、空気透過性血液バリア１５１２を含む。図１５Ｃは、隔離チャンバ１５０８が患者からの血液の最初のアリコート又はサンプルで満たされた血液隔離装置１５００を示す。

【００７１】

空気透過性血液バリア１５１２は、保護カバー１５１６で覆されていることができる。保護カバー１５１６は、ユーザーが彼らの指又は他の外部器具で空気透過性血液バリア１５１２に触れるのを妨げるように寸法設定され且つ構成されることができ、一方それでも患者自身の血圧によって隔離チャンバ１５０８内に強制的に血液が供給されることによって空気が隔離チャンバから追い出されるときに空気が空気透過性血液バリア１５１２から出ることを可能にする。保護カバー１５１６は、フィルタが周囲の流体又は飛沫に偶発的に曝されるのを阻止又は防止するように構成されることができる。これは、保護カバーに疎水性膜を追加することを含むがそれに限定されない、様々な機械的方法で行うことができる。

【００７２】

図１５Ｂは、血液隔離装置１５００の出口ポート１５０４及び通気口１５１０を含むハウジング１５０１の上面からの血液隔離装置１５００の斜視図であり、サンプル採取装置が起動される前、サンプリング流路１５０６が空である間に最初のアリコートの血液が隔

離チャンバ１５０８を満たすことを示す。図１５Ｇは、血液隔離装置１５００の出口ポート１５０４及びハウジング１５０１の底面からの血液隔離装置１５００の斜視図であり、サンプル採取装置が起動される前、サンプリング流路１５０６が空である間に最初のアリコートの血液が隔離チャンバ１５０８を満たすことを示す。図１５Ｃは、血液隔離装置１５００の入口ポート１５０２及び通気口１５１０を含むハウジング１５０１の上面からの血液隔離装置１５００の別の斜視図であり、隔離された血液は実質的に隔離チャンバ１５０８内にとどまっている間に血液がサンプリング流路１５０６を通って採取されることを示す。

【００７３】

図１５Ｄは、一部の実施に従う血液隔離装置１５００の断面図であり、サンプリング流路１５０６及び隔離チャンバ１５０８を画定するハウジング１５０１を示す。図１５Ｅ及び１５Ｆは、本明細書に記載される１つ以上の実施に従う血液隔離装置用のハウジングの様々なフォームファクタを示す。

【００７４】

隔離チャンバ１５０８は、サンプリング流路１５０６よりも大きい断面積を有することができ、断面積又は長さは、所定の又は特定の血液量が隔離又はロックされるように構成されることができる。サンプリング流路１５０６は、患者針のチューブ又は採血装置のチューブのいずれか又は両方のためのチューブに適合するように寸法設定されることができる。

【００７５】

ハウジング１５０１は、複数の部品又は単一の一体部品から形成されることができる。一部の実施では、図１５Ｄに示すように、ハウジング１５０１は、互いに嵌合する上部部材１５２０と下部部材１５２２とを含み、それらの一方又は両方は、例えば、射出成形プロセスによって又はエッチング、切削、穿孔などによって予め形成された溝、流路、ロック、導管又は他の経路を有する。上部部材１５２０は、レーザ溶接、熱接合、超音波溶接、接着、ねじ、リベット、ボルトなどを使用することなどの任意の嵌合又は接続機構によって、又はラッチ、溝、舌状部、ピン、フランジなどの他の嵌合機構によって、下部部材１５２２と接続されることができる。

【００７６】

一部の実施では、図１５Ｄに示すように、上部部材１５２０は、溝、流路、ロック、導管又は他の経路を含むことができ、一方、下部部材１５２２は、上部部材１５２０の溝、流路、ロック又は他の経路のうちの少なくとも１つに嵌合するように寸法設定され且つ適合された突出部１５２４を含むことができる。突出部１５２４は、例えば、サンプリング流路１５０６及び／又は隔離チャンバ１５０８のいずれかの形成を完了させるために、部分的な溝又は部分的な流路などの表面特徴を提供することができる。一部の実施では、突出部１５２４は、対応する溝、流路、ロック又は他の経路内によりぴったりと嵌合するために、１つ以上の傾斜した側面又は面を形成されることができる。更に他の実施では、上部部材１５２０と下部部材の両方が、溝、流路、ロック又は他の経路、並びに１つ以上の突出部１５２４を含むことができる。

【００７７】

一部の実施では、サンプリング流路１５０６及び隔離チャンバ１５０８は、ハウジング１５０１に形成された溝、流路、ロック又は他の経路によって形成される。ハウジング１５０１は、ゴム、プラスチック、金属又は他の材料を含む任意の適切な材料で作られることができる。ハウジング１５０１は、透明又は半透明の材料から、又は不透明又は非半透明の材料から形成されることができる。他の実施では、ハウジング１５０１は、大部分が不透明又は非透明であることができるが、サンプリング流路１５０６及び／又は隔離チャンバ１５０８に直接隣接するハウジング表面は、透明又は半透明であり、最初に隔離チャンバ１５０８が必要又は所望の程度まで満たされているという視覚的な合図又はサイン、及び／又は、次に汚染されていない血液サンプルがサンプリング流路１５０６を通して採取される間、隔離された血液が隔離されたままであるという視覚的な合図又はサインを施

術者に与える。隔離の他の視覚的な合図又はサインは、以下に限定されるものではないが、血液の接触、浸透、又は部分的な浸透で空気透過性血液バリア１５１２が異なる色に変わること、隔離チャンバに沿った又は隔離チャンバに隣接する任意の位置にある色分けされたタブ又は指標、可聴信号、振動信号、又は他の信号を含むことができる。

【００７８】

患者の皮膚から多数の病原体を集める可能性がある患者針（図示せず）による静脈穿刺の後、患者自身の血圧が隔離チャンバ１５０８内の大気圧に打ち勝って空気透過性血液バリア１５１２を通して隔離チャンバ１５０８内の空気を追い出すので、これらの病原体を有する患者の血液の最初の量が、血液隔離装置１５００入口ポート１５０２に入り、最も抵抗の少ない経路をたどることによって隔離チャンバ１５０８に流入する。患者の血圧は、密封されたサンプリング流路１５０６内で高まっている空気圧に打ち勝つのに十分ではない。最終的に、所定の容積を有する隔離チャンバ１５０８は、空気透過性血液バリア１５１２を通して空気を追い出す血液で満たされる。血液が空気透過性血液バリアに衝突すると、血液は空気透過性血液バリア１５１２の材料と相互作用して、通気口１５１０を完全に又は部分的に密封する。施術者がいまやバキュテナー（登録商標）カプセル又は他の血液サンプル採取装置を利用してサンプリングのために患者の血液の次の量を得ることができるという信号又は表示を提供することができる。隔離チャンバ１５０８内の血液は、このとき隔離チャンバ内で事実上隔離されている。

【００７９】

血液隔離経路１５０８を満たすと、バキュテナー（登録商標）又は他の血液サンプル採取装置の使用より前に、患者の血圧は、サンプリング流路１５０６内の空気の圧縮を引き起こし、場合によっては少量の血液が隔離チャンバ１５０８への方向転換点を過ぎてサンプリング流路１５０６に移動し、サンプリング流路１５０６を通して採取される汚染されていない血液を待ち行列に入れる。

【００８０】

図１６～１９は、血液隔離装置の更に別の実施を示す。図１６Ａ～１６Ｄは、バキュテナー（登録商標）（図示せず）のような真空採血容器のような血液サンプル採取装置と患者針（図示せず）及び／又は関連するチューブとの間に接続されることができる血液隔離装置１６００を示す。図１７は、血液隔離装置の下部部材を示し、図１８は、血液隔離装置の上部部材を示し、上部部材及び下部部材は、以下でより詳しく説明するように、相互に嵌合して、入口ポート、出口ポート、隔離チャンバ及びサンプリング流路を形成することができる。図１９Ａ及び１９Ｂは、互いに嵌合する上部部材及び下部部材を示す。図１６～１９は本明細書に記載される血液隔離装置を構成する１つの例示的な方法を示しており、他の形態の構成も可能であることを理解されたい。

【００８１】

図１６Ａ～１６Ｄを参照すると、血液隔離装置１６００は、血液サンプルへのアクセス及び血液サンプルの採取のために患者の血管系に挿入される患者針と接続されることができる入口ポート１６０２を含む。入口ポート１６０２は、同様に患者針と接続されるチューブ又は他の導管と接続されることもできる。入口ポート１６０２は、血液隔離装置１６００への開口部を画定し、この開口部は、患者針と接続されるチューブ又は他の導管又は患者針自体と同じ断面寸法であることができる。例えば、開口部は、約０．０４５インチ（１．１４３ｍｍ）の直径を有する円形であることができるが、０．０１インチ（０．２５４ｍｍ）から０．２インチ（５．０８ｍｍ）又はそれ以上の直径を有することができる。

【００８２】

入口ポート１６０２はまた、ねじ切り又はルアーフィッティングなどのような密封又は流体密封コネクタ又は接続部を含むことができる。一部の実施では、患者針に結合されているチューブ又は他の導管は、部品同士の共成形、接着、レーザー溶接、又は熱接合などによって、入口ポート１６０２と一体化されることができる。これによって、血液隔離装置１６００は、患者針及び／又はチューブと共に単一ユニットとして製造及び販売され、

採血又はサンプリングの際に患者針を血液隔離装置１６００に接続する必要性をなくすことができる。

【００８３】

血液隔離装置１６００は、血液隔離装置１６００から及び血液サンプル採取装置への開口部を画定する出口ポート１６０４を更に含む。出口ポート１６０４は、同様に血液隔離装置と接続されるチューブ又は他の導管と接続されることもでき、ねじ切り又はルアーフィッティングなどの密封又は流体密封コネクタ又は接続部を含むことができる。したがって、上記のように、血液隔離装置１６００は、患者針及び／又はチューブ及び血液サンプル採取装置と共に単一ユニットとして製造及び販売され、採血又はサンプリングの際に患者針及び血液サンプル採取装置を血液隔離装置１６００に接続する必要性をなくすことができる。

【００８４】

血液隔離装置１６００は、入口ポート１６０２と出口ポート１６０４との間のサンプリング流路１６０６と、入口ポート１６０２と出口ポート１６０４との間の任意の位置でサンプリング流路１６０６に接続され且つサンプリング流路１６０６から分離又は方向転換される隔離チャンバ１６０８とを更に含む。サンプリング流路１６０６は、最初のアリコートの血液が隔離チャンバ１６０８内に隔離されると、採血経路として機能する。サンプリング流路１６０６は、任意のサイズ、形状又は構成の流路又は導管であることができる。一部の実施では、サンプリング流路１６０６は、入口ポート１６０２の開口部と実質的に同様の断面積を有する。他の実施では、サンプリング流路１６０６は、入口ポート１６０２から出口ポート１６０４まで徐々に広がることができる。隔離チャンバ１６０８は、図１７及び１９により詳しく示すように、血液がサンプリング流路１６０６のより小さい直径に入るのに対して、まずリザーバに入ろうとするように、隔離流路の経路に向かって大きいリザーバを形成するべくより大きい断面を有することができる。

【００８５】

一部の例示的な実施では、サンプリング流路１６０６と隔離チャンバ１６０８との間の方向転換は、方向転換分岐点１６０７によって行われる。方向転換分岐点１６０７は、実質的にＹ字形、Ｔ字形、又はＵ字形であることができる。一部の好ましい例示的な実施では、図１７Ａ～１７Ｂに示すように、方向転換分岐点１６０７は、入口ポート１６０２からの流れが優先的に隔離チャンバ１６０８に向けられるように構成される。隔離チャンバ１６０８はまた、最初の血液流を隔離チャンバ１６０８に向かって且つ隔離チャンバ１６０８内に移動させるための湾曲部又は傾斜路を含むか又は形成することができる。

【００８６】

隔離チャンバ１６０８は、好ましくは大気圧に維持され、隔離チャンバ１６０８の遠位端又はその近傍に通気口１６１０を含む。通気口１６１０は、上記のように空気透過性血液バリア１６１２を含むことができる。

【００８７】

血液隔離装置１６００は、複数の部品又は単一の一体部品から形成されることができるハウジング１６０１を含むことができる。一部の実施では、図１７Ａ～１７Ｄ及び図１８Ａ～１８Ｆに示すように、ハウジング１６０１は、互いに嵌合する上部部材１６２０と下部部材１６２２とを含む。血液隔離装置１６００は、上部部材１６２０が下部部材１６２２に機械的に取り付けられたときに、両者の間の接合部分がガスケット又は密封部材によって密封されるように、ガスケット又は他の密封部材（図示せず）を含むこともできる。図１７Ａ～１７Ｄは、血液隔離装置１６００用のハウジングの下部部材１６２２を示す。下部部材１６２２は、サンプリング流路１６０６、隔離チャンバ１６０８、及び方向転換分岐点１６０７を形成するために、射出成形プロセスによって又はエッチング、切削、穿孔などによって予め形成された溝、流路、ロック、導管又は他の経路を含むことができる。

【００８８】

隔離チャンバ１６０８は、血液がサンプリング流路１６０６のより小さい直径に入るの

に対して、まず隔離チャンバ内に優先的に移動するように、サンプリング流路１６０６よりも大きい断面を有することができる。

【００８９】

図１８Ａ～１８Ｆは、レーザ溶接、熱接合、接着、ねじ、リベット、ボルトなどを使用することなどの任意の嵌合又は接続機構によって、又はラッチ、溝、舌状部、ピン、フランジなどの他の嵌合機構によって、下部部材１６２２と接続可能な上部部材１６２０を示す。上部部材１６２０は、サンプリング流路１６０６、隔離チャンバ１６０８、及び方向転換分岐点１６０７を形成するために、溝、流路、ロック、導管又は他の経路の一部又はすべてを含むことができる。更に他の実施では、上部部材１６２０と下部部材１６２２の両方が、溝、流路、ロック又は他の経路を含むことができる。

【００９０】

一部の実施では、サンプリング流路１６０６及び隔離チャンバ１６０８は、ハウジング１６０１に形成された溝、流路、ロック又は他の経路によって形成される。ハウジング１６０１は、ゴム、プラスチック、金属又は任意の他の適切な材料で作られることができる。ハウジング１６０１は、透明又は半透明の材料から、又は不透明又は非半透明の材料から形成されることができる。他の実施では、ハウジング１６０１は、大部分が不透明又は非半透明であることができるが、サンプリング流路１６０６及び／又は隔離チャンバ１６０８に直接隣接するハウジング表面は、透明又は半透明であることができ、最初に隔離チャンバ１６０８が必要又は所望の程度まで満たされているという視覚的な合図又はサイン、及び／又は、次に汚染されていない血液サンプルがサンプリング流路１６０６を通して採取される間、隔離された血液が隔離されたままであるという視覚的な合図又はサインを施術者に与える。隔離の他の視覚的な合図又はサインは、以下に限定されるものではないが、血液の接触、浸透、又は部分的な浸透で空気透過性血液バリア１６１２が異なる色に変わること、隔離チャンバに沿った又は隔離チャンバに隣接する任意の位置にある色分けされたタブ又は指標、可聴信号、振動信号、又は他の信号を含むことができる。

【００９１】

図１８Ａ～１８Ｆに示すように、空気透過性血液バリア１６１２は、保護部材１６１６で覆われているか又は保護部材１６１６によって包囲されていることができる。保護部材１６１６は、ユーザーが彼らの指又は他の外部器具で空気透過性血液バリア１６１２に触れるのを妨げるように寸法設定され且つ構成されることができ、一方それでも空気が隔離チャンバ１６０８から追い出されるときに空気が空気透過性血液バリア１６１２から出ることを可能にする。一部の実施では、保護部材１６１６は、上部部材１６２０の上面から上に空気透過性血液バリア１６１２の周りに延びる突出部を含む。保護カバー１６１６は、フィルタが周囲の流体又は飛沫に偶発的に曝されるのを阻止又は防止するように構成されることができる。これは、保護カバーに疎水性膜を追加することを含むがそれに限定されない、様々な機械的方法で行うことができる。

【００９２】

使用時、血液隔離装置１６００は、サンプリング流路１６０６と隔離チャンバ１６０８とを含む。両方の経路が、最初は大気圧で空気を充填されているが、サンプリング流路１６０６は、最初はバキュテナー（登録商標）又は他のこのような密封された採血装置によって密封されている出口ポート１６０４に向けられ、隔離チャンバ１６０８は、空気透過性血液バリア１６１２を含む大気への通気口１６１０で終端している。

【００９３】

患者の皮膚から多数の病原体を集める可能性がある患者針（図示せず）による静脈穿刺の後、これらの病原体を有する患者の血液の最初の量が、血液隔離装置１６００の入口ポート１６０２を通過する。この汚染されている可能性のある血液の最初の量は、最も抵抗の少ない経路を見出すことによって、隔離チャンバ１６０８に優先的に流入する。患者自身の血圧は、通気口付きの隔離チャンバ１６０８内の大気圧に打ち勝ち、空気透過性血液バリア１６１２を通して隔離チャンバ１６０８内の空気を追い出すが、密封されたサンプリング流路１６０６内で高まっている空気圧に打ち勝つには不十分である。様々な例示的

な実施形態では、隔離チャンバ１６０８及びサンプリング流路１６０６は、患者の血圧によって生じた力が、血液隔離装置の向きに関わらず、重力の影響に打ち勝つのに十分であるように構成されることができる。

【００９４】

最終的に、隔離チャンバ１６０８は、空気透過性血液バリア１６１２を通して空気を追い出す血液で満たされる。血液が空気透過性血液バリアと接触すると、血液は空気透過性血液バリア１６１２の材料と相互作用して通気口１６１０を完全に又は部分的に密封する。施術者がいまやバキュテナー（登録商標）又は他の採血装置を利用することができるという信号又は表示を提供することができる。

【００９５】

血液隔離経路１６０８を満たすと、バキュテナー（登録商標）又は他の血液サンプル採取装置の使用より前に、患者の血圧は、サンプリング流路１６０６内の空気の圧縮を引き起こし、場合によっては少量の血液が方向転換点を過ぎてサンプリング流路１６０６に移動しサンプリング流路１５０６を通して採取される汚染されていない血液を待ち行列に入れる。

【００９６】

図１９Ａは、血液隔離装置１６００の側面図であり、図１９Ｂは、血液隔離装置１６００の断面図であり、下部部材１６２２と嵌合する上部部材１６２０を示す。

【００９７】

図２０は、患者の血流への血管アクセスのための患者針２００２と、１つ以上の血液サンプルの採取を容易にする血液サンプル採取装置２００４と、患者針２００２と血液サンプル採取装置２００４との間の流体接続を提供する導管２００６とを含む血液サンプル最適化システム２０００を示す。一部の実施では、血液サンプル採取装置２００４は、密封された採取針を含む保護シールドを含み、採取針に密封された真空容器が置かれ、容器は採取針によって一度穿孔されると、患者針２００２から導管２００６を通して真空圧力又は真空力で血液サンプルを吸い込む。

【００９８】

血液サンプル最適化システム２０００は、本明細書で説明するように、患者針２００２と血液サンプル採取装置２００４との間の導管２００６上の任意の点に位置する血液隔離装置２００８を更に含む。

【００９９】

図２１は、ウィッキング材料チャンバを使用する通気口付きでない血液隔離装置２１００を示す。血液隔離装置２１００は、ウィッキング材料で満たされた隔離チャンバ２１０２によって少なくとも部分的に囲まれ又は当接されるサンプリング流路２１０４を有するハウジング２１０１を含む。最初のアリコートの血液が患者針からサンプリング流路２１０４に引き込まれ、サンプリング流路２１０４において隔離チャンバ２１０２のウィッキング材料の中に直ちに逃がされる。ウィッキング材料及び／又は隔離チャンバ２１０２は、後続の又はそれ以降の採血がウィッキング材料を通り過ぎ、サンプリング流路２１０４を通って直接バキュテナー（登録商標）などのサンプリング装置に流れるように、所定量の血液を受け入れ且つ保持するように寸法設定され且つ適合されている。ウィッキング材料は、固化剤、汚染除去剤、又は他の添加剤などの物質を含むことができる。

【０１００】

本明細書に記載されるように、空気透過性血液バリアは、多種多様な異なる構造及び材料を用いて作られることができる。図２２Ａ及び２２Ｂに示すように、血液隔離装置２２００の空気透過性血液バリア２２０２は、少なくとも一部のビーズが親水性になるように処理されたポリマービーズマトリックス２２０４を含むことができる。空気透過性血液バリア２２０２は、カルボキシメチルセルロース（ＣＭＣ）又はセルロースガムなどの自己密封材料２２０６、又は他の密封材料を更に含む。空気透過性血液バリア２２０２は、血液などの流体との接触前又は部分接触中の空気の流れを可能にする空隙２２０８を更に含むことができる。図２２Ｂに示すように、流体と接触すると、自己密封材料２２０６が膨

張して空隙２２０８を閉鎖し、空隙２２０８を通る空気の流れを閉塞し、完全に又は部分的に密封する。

【０１０１】

図２３Ａ及び２３Ｂは、患者針と接続するための入口ポート２３０２と、血液サンプル採取装置と接続するための出口ポート２３０４と、隔離チャンバ２３０６と、隔離チャンバ２３０６と、隔離するべき汚染されている可能性のある血液の最初のアリコートまで隔離チャンバが満たされると隔離チャンバ２３０６を迂回するサンプリング流路２３０８とを有する、血液隔離装置２３００の更に別の実施を示している。隔離チャンバ２３０６は、入口ポート２３０２から最も遠い隔離チャンバ２３０６の遠位端に疎水性プラグ２３１２を含む。バキュテナー（登録商標）などからのような、出口ポート２３０４から加えられる真空力又は他の吸引力は、血液を入口ポート２３０２内に、そして隔離チャンバ２３０６内に直接吸い込み、そこで最初のアリコートの血液が疎水性プラグ２３１２に接触し、最初のアリコートの血液を隔離チャンバ２３０６に戻してそこで隔離させる。少量の血液が、最初は弁２３０８によって閉鎖されているサンプリング流路２３０８に入ることができる。弁２３０８が解放されると、真空の更なる力又は他の力の下で、後続の量の血液が入口ポート２３０２に流れ、隔離チャンバ２３０６を迂回し、サンプリング流路２３０８を通り抜けて出口ポート２３０４に向かって流れ、採取装置に送られる。

【０１０２】

サンプリング流路２３０８は、任意の適切な幾何学的形状を有することができ、プラスチックチューブ又は任意の他の適切な材料から形成されることができる。弁２３０８は、最初のアリコートの血液が隔離チャンバ２３０６内に隔離される前にサンプリング流路を挟み、脇へそらし、曲げ、又は他の方法で閉じるためにクリップ又は他の包囲装置であることができる。

【０１０３】

様々な実施形態を上記で詳細に説明してきたが、他の変更も可能である。他の実施形態は、添付の特許請求の範囲内に含まれ得る。

【図１】

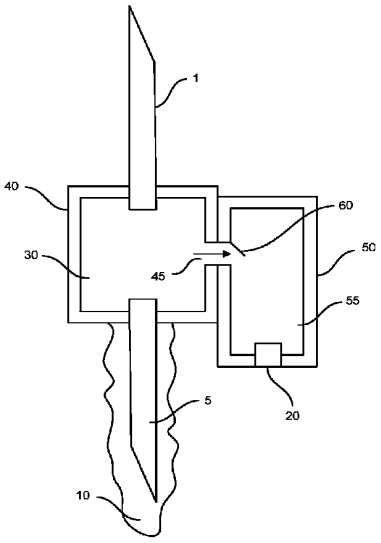


FIG. 1

【図２】

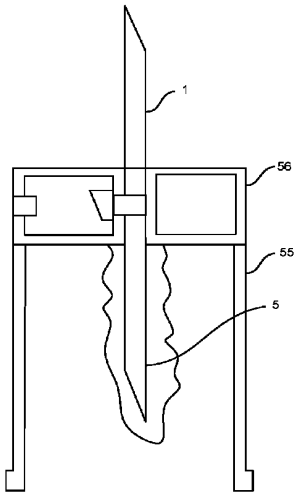


FIG. 2

【図３】

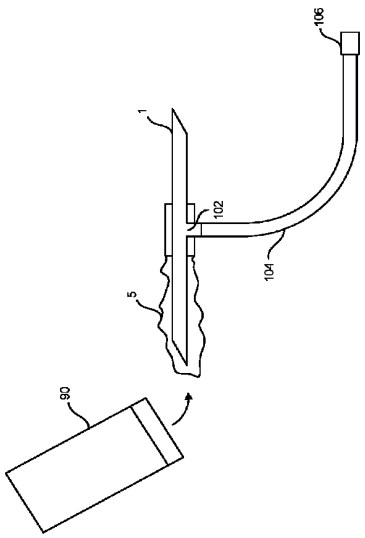


FIG. 3

【図４】

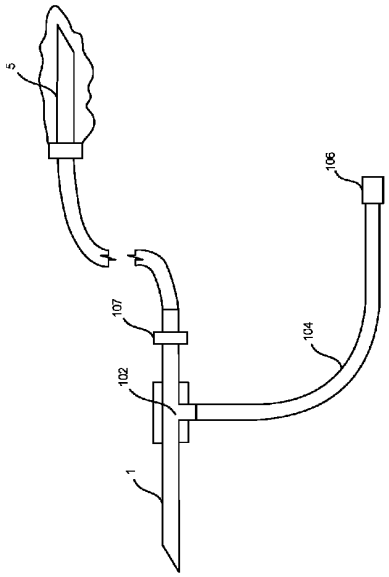


FIG. 4

【図５】

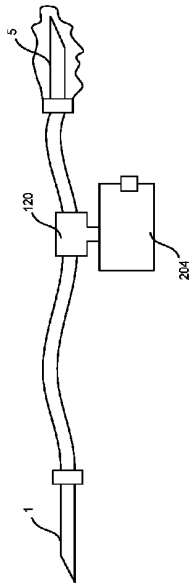


FIG. 5

【図６】

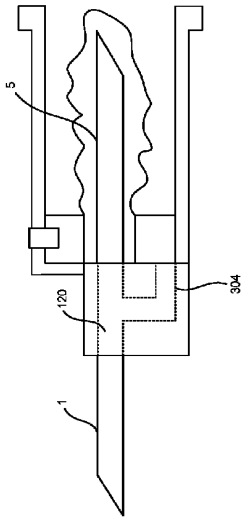


FIG. 6

【図７】

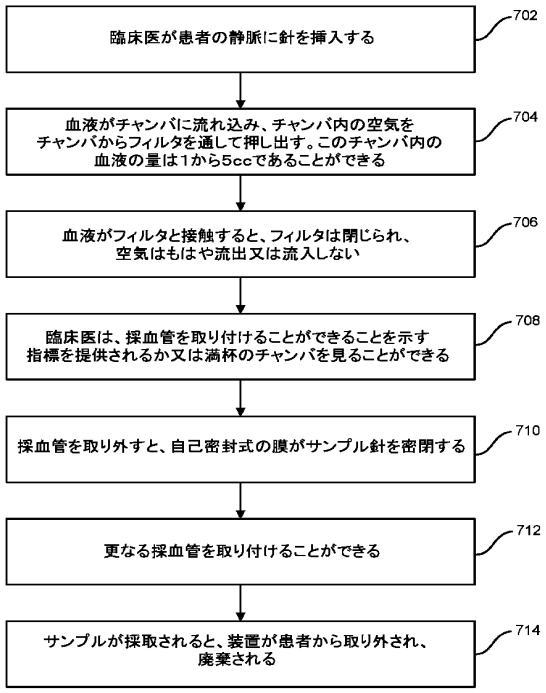


FIG. 7

【図８Ａ】

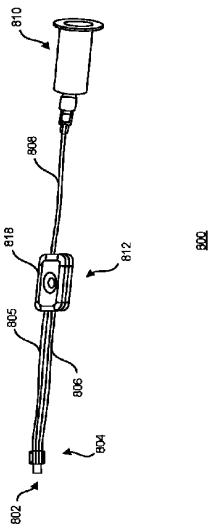


FIG. 8A

【図８Ｂ】

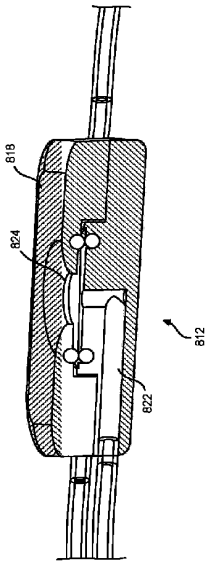


FIG. 8B

【図８Ｃ】

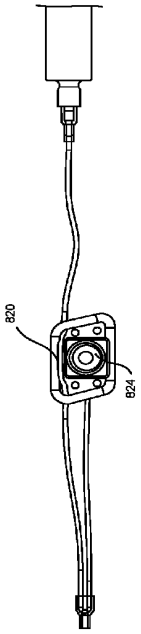


FIG. 8C

【図８Ｄ】

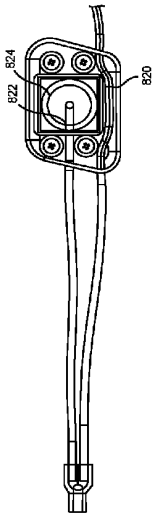


FIG. 8D

【図８Ｅ】

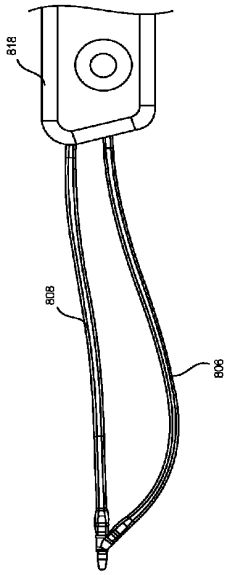


FIG. 8E

【図９】

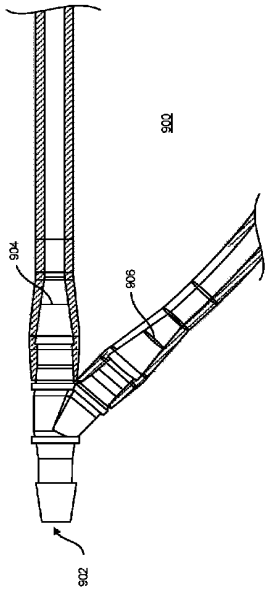


FIG. 9

【図１０Ａ】

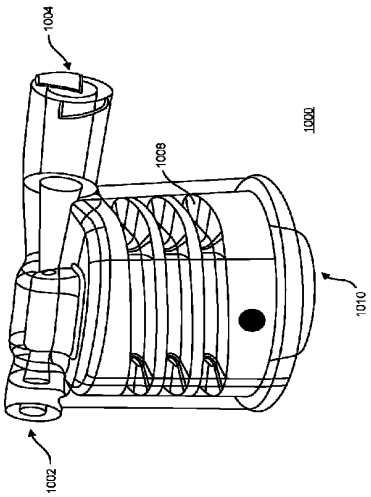


FIG. 10A

【図１０Ｂ】

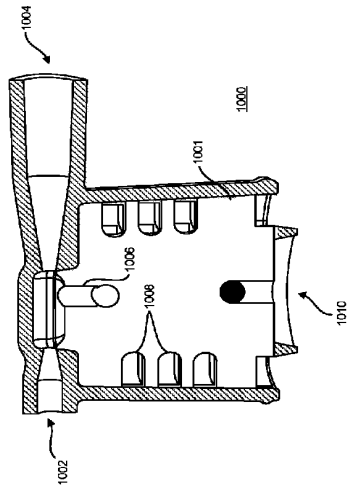


FIG. 10B

【図１０Ｃ】

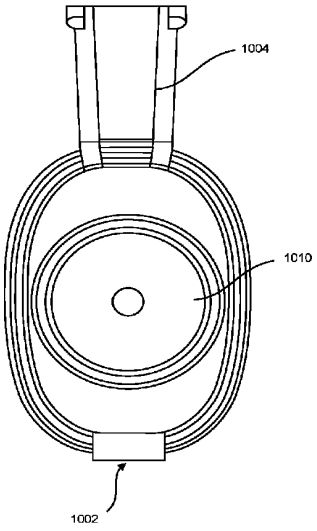


FIG. 10C

【図１０Ｄ】

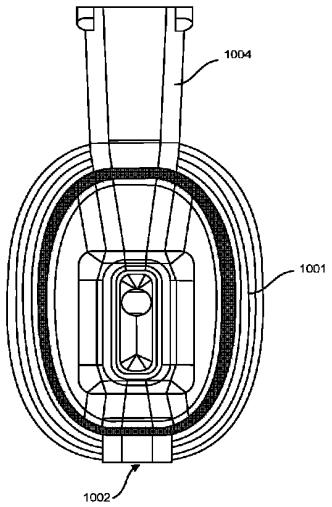


FIG. 10D

【図１１Ａ】

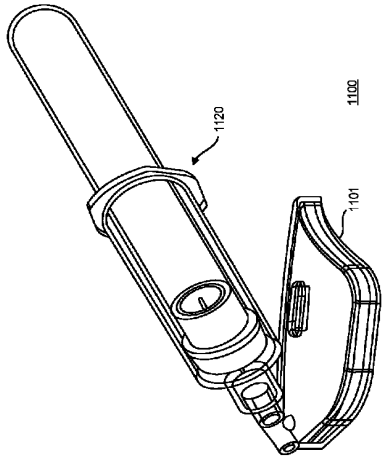


FIG. 11A

【図１１Ｂ】

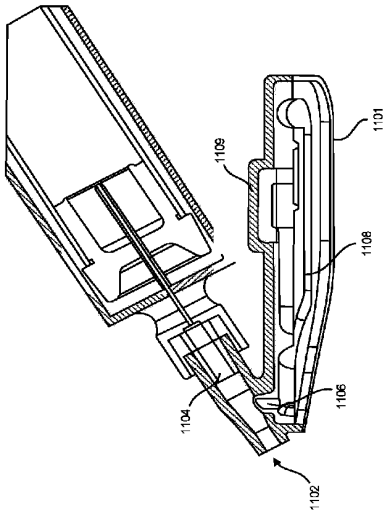


FIG. 11B

【図１１Ｃ】

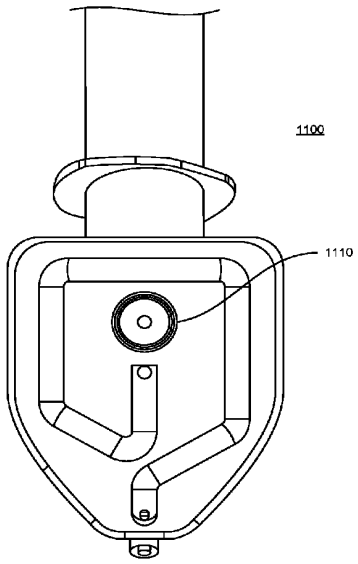


FIG. 11C

【図１１Ｄ】

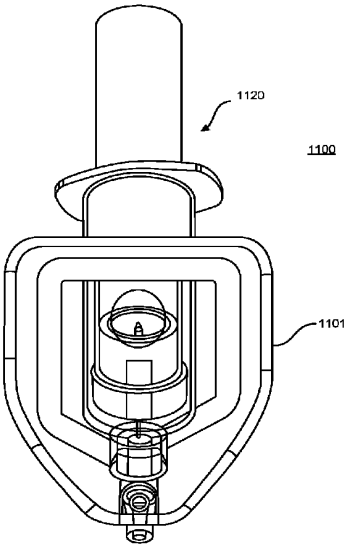


FIG. 11D

【図１１Ｅ】

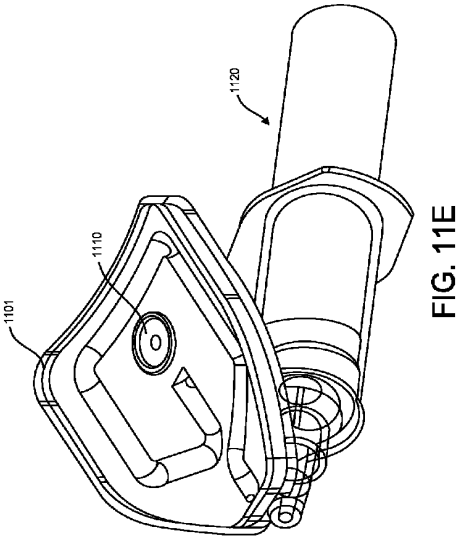


FIG. 11E

【図１２Ａ】

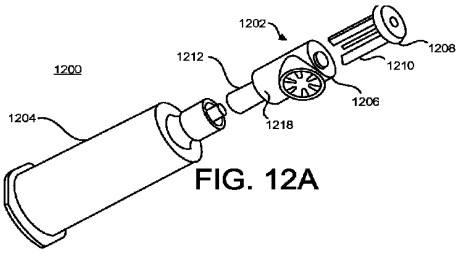


FIG. 12A

【図１２Ｂ】

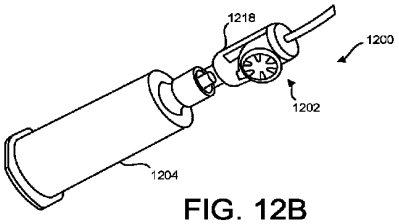


FIG. 12B

【図１２Ｃ】

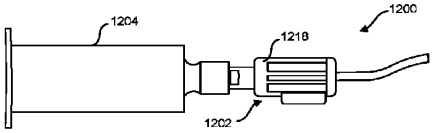


FIG. 12C

【図１２Ｄ】

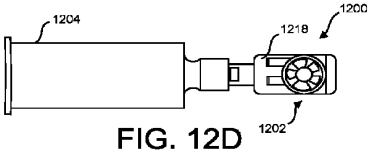


FIG. 12D

【図１３Ａ】

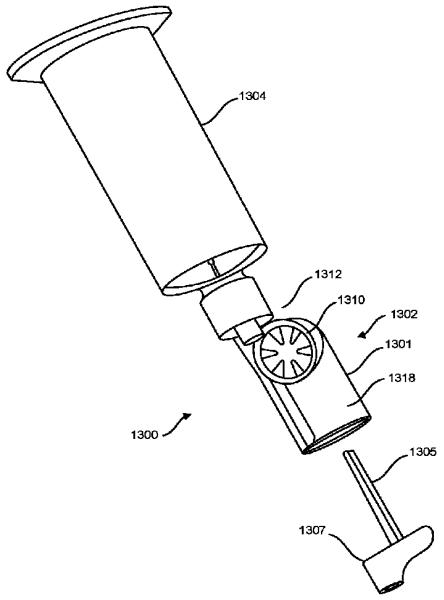


FIG. 13A

【図１３Ｂ】

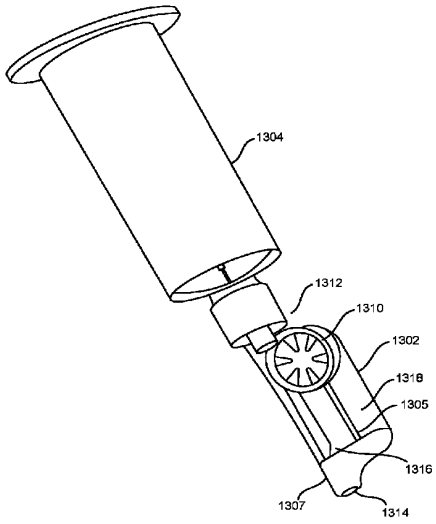


FIG. 13B

【図１３Ｃ】

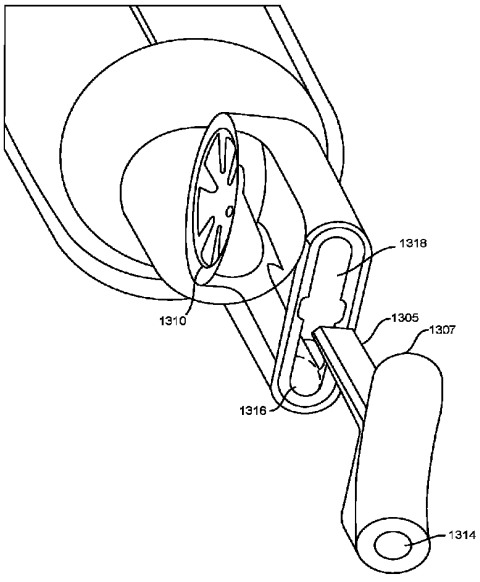


FIG. 13C

【図１３Ｄ】

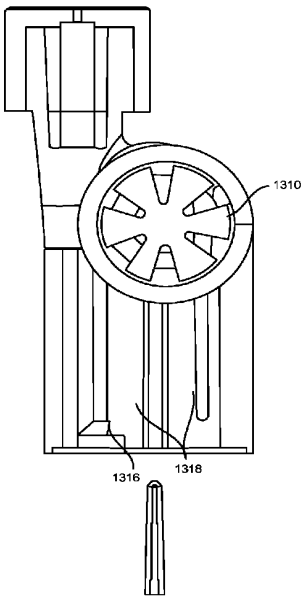


FIG. 13D

【図１４Ａ】

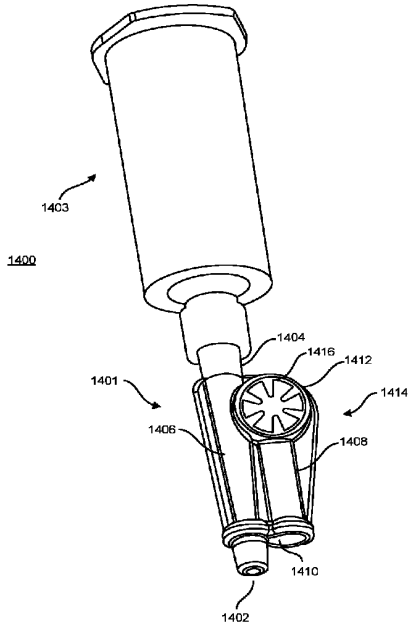


FIG. 14A

【図１４Ｂ】

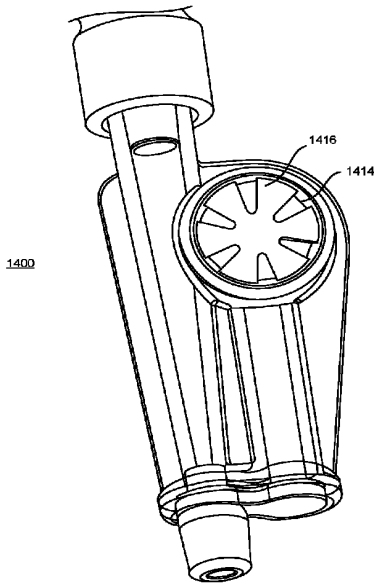


FIG. 14B

【図１４Ｃ】

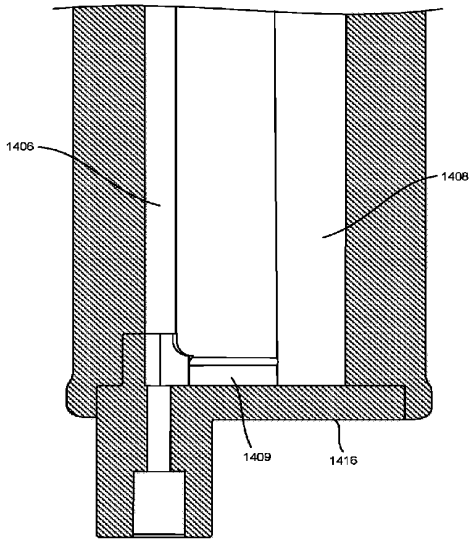


FIG. 14C

【図１４Ｄ】

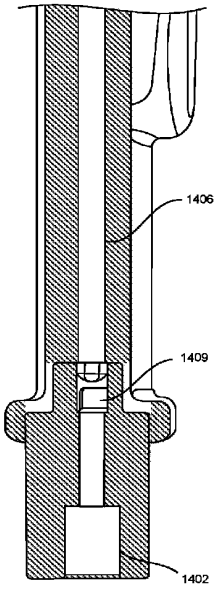


FIG. 14D

【図１４Ｅ】

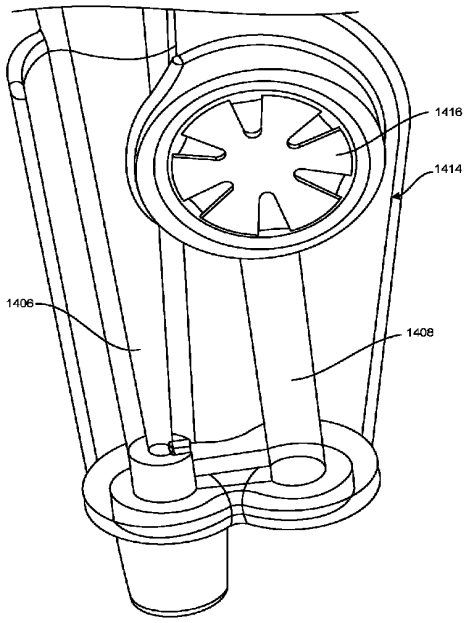


FIG. 14E

【図１５Ａ】

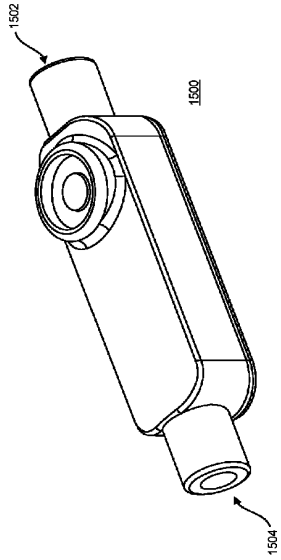


FIG. 15A

【図１５Ｂ】

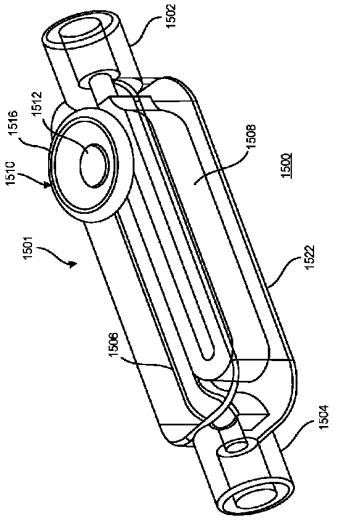


FIG. 15B

【図１５Ｃ】

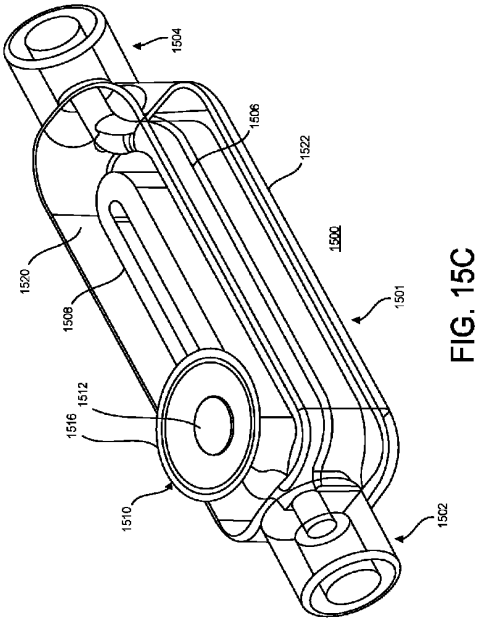


FIG. 15C

【図１５Ｄ】

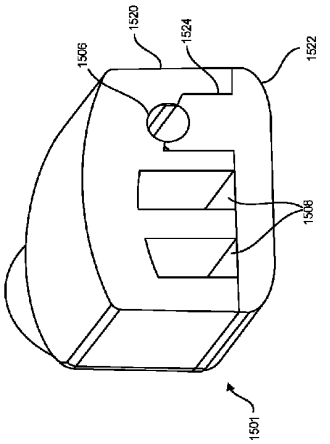


FIG. 15D

【図１５Ｅ】

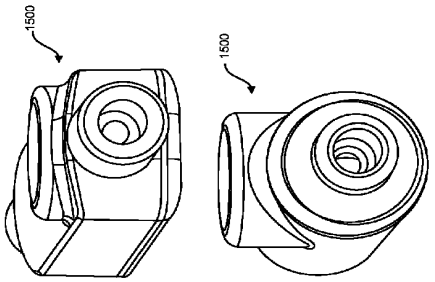


FIG. 15E

【図１５Ｆ】

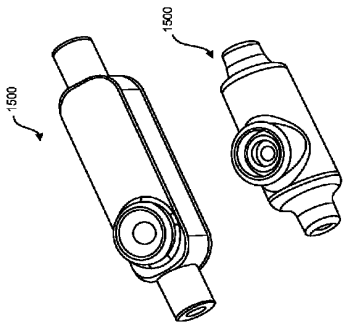


FIG. 15F

【図１５Ｇ】

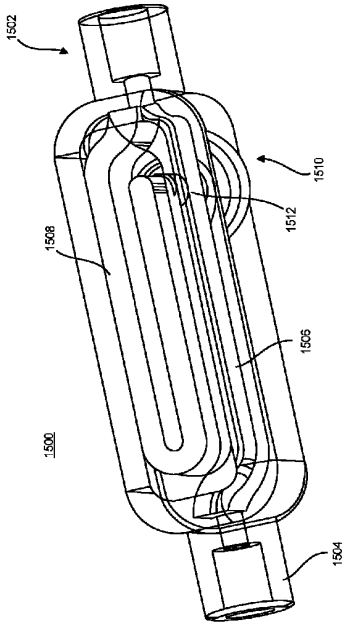


FIG. 15G

【図１６Ａ】

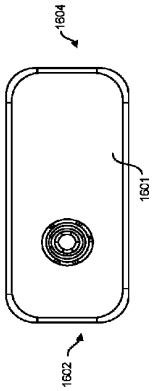


FIG. 16A

【図１６Ｂ】

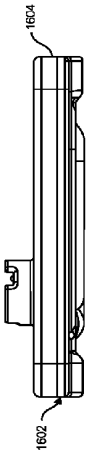


FIG. 16B

【図１６Ｃ】

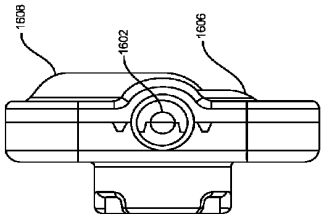


FIG. 16C

【図１６Ｄ】

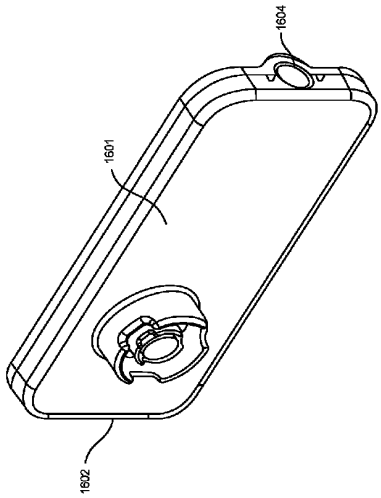


FIG. 16D

【図１７Ａ】

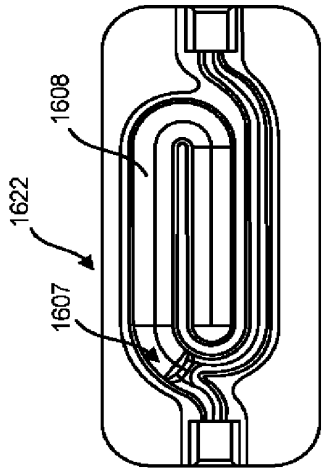


FIG. 17A

【図１７Ｂ】

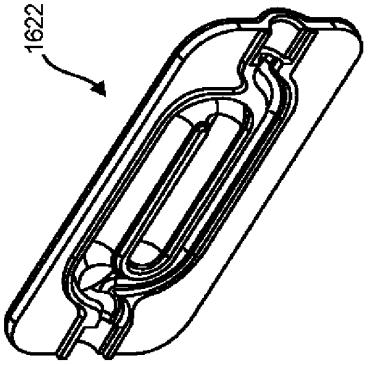


FIG. 17B

【図１７Ｃ】

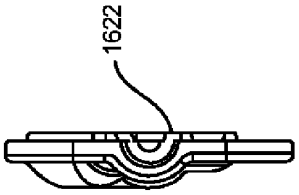


FIG. 17C

【図１７Ｄ】

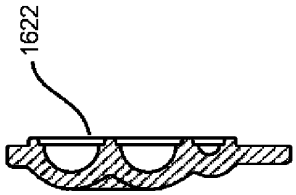


FIG. 17D

【図１７Ｅ】

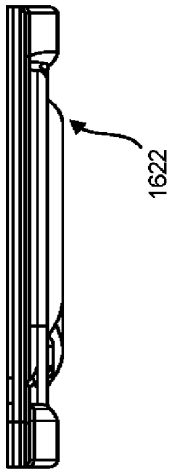


FIG. 17E

【図１８Ａ】

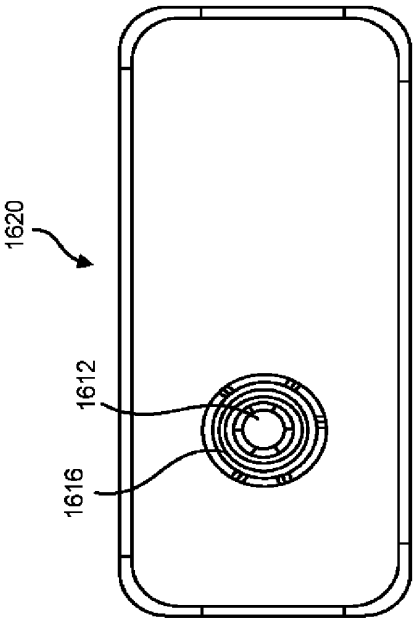


FIG. 18A

【図１８Ｂ】

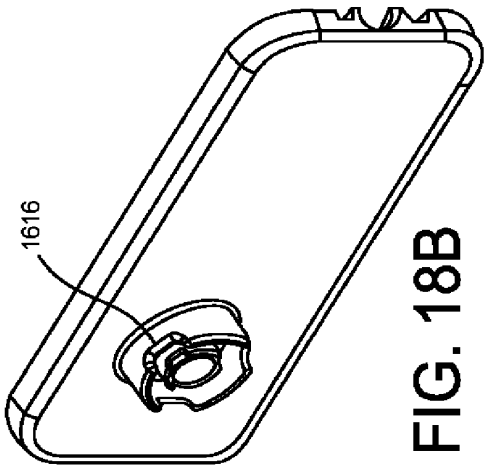


FIG. 18B

【図１８Ｃ】

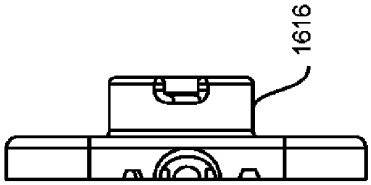


FIG. 18C

【図１８Ｄ】

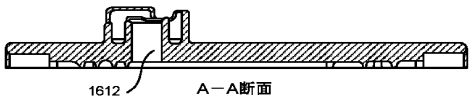


FIG. 18D

【図１８Ｅ】

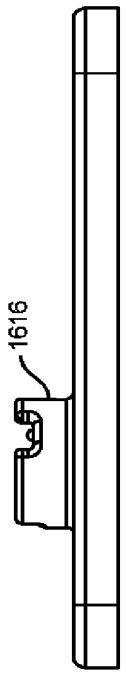


FIG. 18E

【図１８Ｆ】

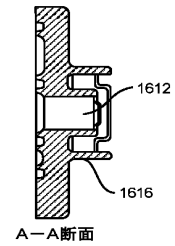


FIG. 18F

【図１９Ａ】

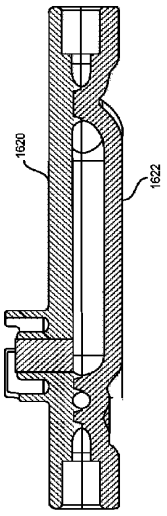


FIG. 19A

【図１９Ｂ】

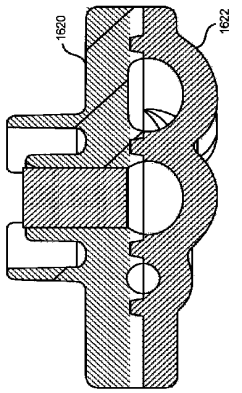


FIG. 19B

【図２０】

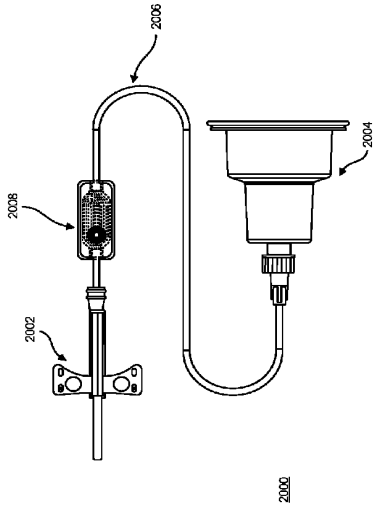


FIG. 20

【図２１】

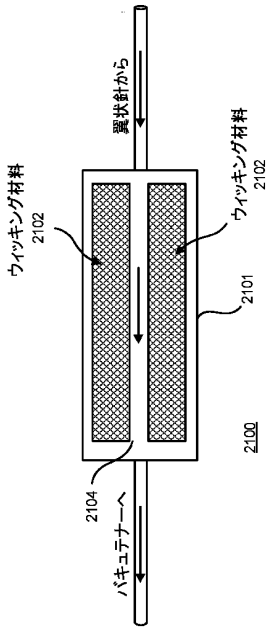


FIG. 21

【図２２Ａ】

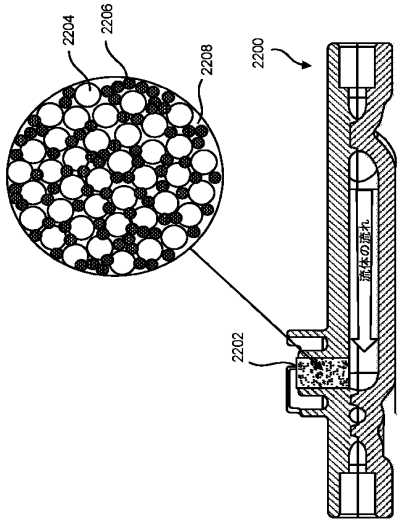


FIG. 22A

【図２２Ｂ】

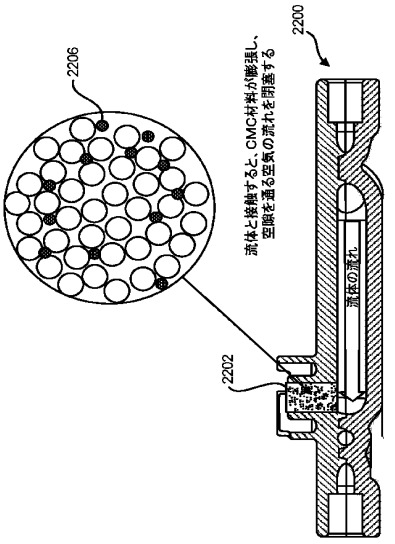


FIG. 22B

【図２３Ａ】

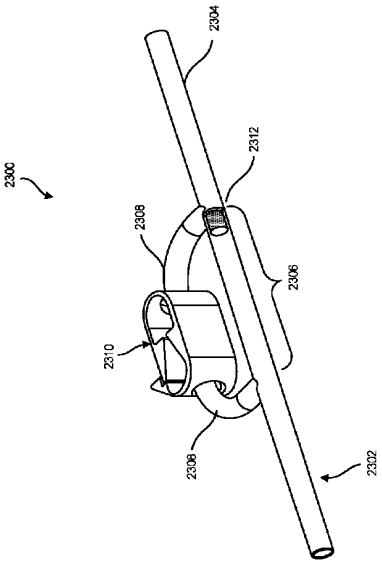


FIG. 23A

【図２３Ｂ】

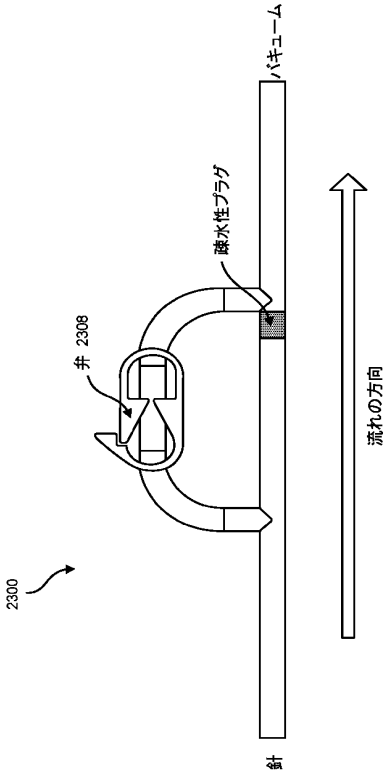


FIG. 23B

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審査官 清水 裕勝

(56)参考文献 特開昭５８－０２５１４６（ＪＰ，Ａ）
特開昭５８－０６７２３８（ＪＰ，Ａ）
特開２０１２－０１６４９６（ＪＰ，Ａ）
特開昭５７－０８９８６９（ＪＰ，Ａ）
特表平０９－５０４７２６（ＪＰ，Ａ）
特開平０２－２２４７４２（ＪＰ，Ａ）
米国特許第０４２０７８７０（ＵＳ，Ａ）

(58)調査した分野(Int.Cl.，ＤＢ名)
Ａ６１Ｂ ５／１５３－５／１５４

Espacenet

Bibliographic data: JPH09504726 (A) — 1997-05-13

CLOSED SYSTEM BLOOD SAMPLING DEVICE

Inventor(s):

Applicant(s):

Classification: **- international:** ***A61B5/15;*** (IPC1-7): A61B5/14
- cooperative: **A61B5/15003 (EP)**; **A61B5/150213 (EP)**; **A61B5/150259 (EP)**; **A61B5/150992 (EP)**; **A61B5/155 (EP)**

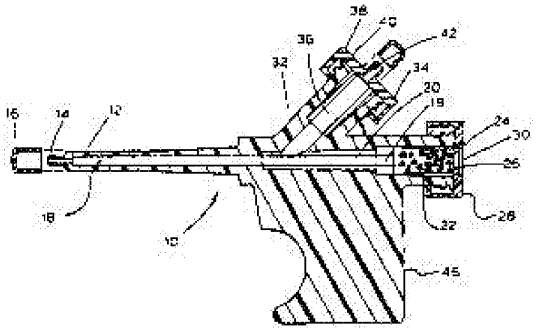
Application number: JP19950508283 19950822

Priority number(s): WO1995US10702 19950822 ; US19940296207 19940825

Also published as: AT208640 (T) AU3412795 (A) AU686450 (B2) CA2173331 (A1) DE69523887 (T2) more

Abstract not available for JPH09504726 (A)
Abstract of corresponding document: WO9605875 (A1)

The invention comprises a closed system blood sampling device comprising a bifurcated capillary tube (10) which has a first branch (12) having a cannula shaped end (14) for withdrawing and conveying blood to a communicating blood collection zone. The second branch of the bifurcated capillary tube (32) is connected to and is in fluid communication with the blood collection zone. It terminates in an opening adapted to receive a blood withdrawal device.



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Description: JPH09504726 (A) — 1997-05-13

CLOSED SYSTEM BLOOD SAMPLING DEVICE

Description not available for JPH09504726 (A)
Description of corresponding document: WO9605875 (A1)

A high quality text as facsimile in your desired language may be available amongst the following family members:

AU686450 (B2) CA2173331 (A1) DE69523887 (T2) US5947932 (A) WO9605875 (A1)

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CLOSED SYSTEM BLOOD SAMPLING DEVICE
FIELD OF THE INVENTION
The invention relates to closed system blood sampling devices.

BACKGROUND OF THE INVENTION
Arterial blood gas sampling is a standard procedure often used to help assess respiratory function in the critically ill. In some cases, samples can be drawn as many as 20 times a day.

For the typical neonatal patient weighing 1000 grams and having approximately 85 cc of total body fluid capacity, the volume of blood samples becomes a critical factor.

A technique called the 3 drop method is gaining substantial clinical acceptance in neonatal units across the country. This method calls for inserting a blunt hypodermic needle as far as possible into a standard sleeve stoppered T
Connector. Three drops of blood estimated to be approximately .06 cc are allowed to drip onto a gauge pad, thereby clearing the cannula of heparinized or non-circulating blood while providing a fresh arterial sample to the surface. 3 more drops are then collected in a micro container followed by cannula withdrawal. Blood cannula contents within the cannula lumen and the previously collected micro container sample are then aspirated into a tuberculin type syringe for transport to the blood lab for testing. A flush of the T-Connector to eliminate residual blood then ensues.This procedure provides the ability to withdraw a controlled blood volume; .06 cc as necessary discard and .12 cc to perhaps .20 cc for actual blood gas testing.

Several opportunities for procedural improvement exist.

One challenge is the open environment method of collection which could foster blood contamination and/or the spread of infectious diseases. Secondarily, the collection process in regard to volume accuracy is difficult to control and highly sensitive to variations in clinician technique, catheter positioning and arterial pressure. If a device can be designed for closed system collection which could also insure consistency of sample volume time after time, treatment of neonatal patients where blood volume levels are critical, accuracy improvements could be a major clinical benefit.

THE DRAWINGS

Fig. 1 is a horizontal cut away side view showing the closed system blood sampling device of the invention.

Fig. 2 is a vertical, partial schematic view showing the closed system blood sampling device connected to an injection site which, in turn, is fitted into a venipuncture device used to
withdraw arterial blood.

In the drawings, like parts have like numbers.

THE INVENTION

The invention is a closed system 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 communicating blood collection zone. The blood collection zone is for storing a quantity of withdrawn blood. It also feeds an initial fraction of withdrawn blood to a communicating blood disposal chamber which has an air permeable liquid sealed end.

The second branch of the bifurcated capillary tube is connected to and is in fluid communication with the blood collection zone. It terminates in an opening adapted to receive a blood withdrawal device.

In preferred embodiments the closed system blood sampling device the cannula shaped end is blunt, the blood disposal chamber has its end fitted with a cap containing an air permeable hydrophobic membrane, and the blood disposal chamber contains a porous blood adsorbent. The second branch has an interior angle not greater than 90 degrees and preferably the interior angle is 60 degrees. It is also desirable that the cannula shaped end be tapered so that it snugly fits into the preferred injection sites more fully described hereafter.

Preferably, the closed system blood sampling device is removed from the injection site before the blood sample is withdrawn therefrom by means such as a tuberculum syringe or aspirated directly into a blood gas analyzer.

While the closed blood sampling device is particularly suited for obtaining neonatal blood samples it is readily adapted to obtain samples from a variety of patient types.

DETAILED DESCRIPTION OF THE INVENTION

In Fig. 1 the closed system blood sampling device is designated generally by the numeral 10. It is preferably constructed of a clear chemically inert non-toxic plastic such as polycarbonate. It comprises a blood withdrawal cannula shaped end 12. The cannula tip 14 is blunt and necked down to prevent injection site from blood flash back

during arterial sampling. To maintain sterility the cannula tip is fitted with a removable cap 16 which is removed just before the blood sampling device is to be used.

Fig. 1 shows the cannula shaped end 12 to be tapered.

This particular configuration was selected so that the cannula may engage and generally mate with a particular injection site, the details of which will be more fully described hereafter. The interior bore 18 of the cannula shaped end is dimensioned to allow withdrawn blood to move along the bore by means of capillary action driven by normally positive arterial blood pressure.

The interior capillary bore 18 connects with and continues into a larger outer diameter lumen 20. The continuous bore 18 of the cannula 12 and the lumen 20 comprise a blood collection zone. Bore 18 as it exits the lumen 20 empties into blood disposal chamber 22. In a preferred embodiment of the invention, blood disposal chamber 22 contains a blood retaining means such as adsorbing material 24 which may be rayon or cellulosic wadding. The open end 26 of the blood disposal chamber 22 is closed with a cap 28 that has its top fitted with a liquid tight, air permeable hydrophobic membrane 30 which allows air to be evacuated from the blood sampling device 10 of the invention. A suitable membrane material is sheet polytetrafloroethylene having a thickness of about 0.8 microns.

Fitted to the lumen 20, and in fluid communication therewith, is the second branch or port 32. It is positioned so as to have an interior angle 34 not exceeding 90 degrees. The interior angle is preferably about 60 degrees. The bore 36 connects with and corresponds in dimension with bore 18. Port 32 terminates and is sealed by adapter cap 38 whose top 40 is fitted with a capillary luer 42. The capillary luer is protected from contamination by means of protective cap 44 which is removed just prior to blood being withdrawn from the closed blood sampling device. The port 32 and its bore 36 form a part of the blood collection zone previously described. For convenience of use, the closed blood sampling device is fitted with pistol grip handle 46.

The blood collection zone has a larger liquid capacity than the liquid capacity of the blood disposal chamber. If the closed blood sampling device described were to be used in neonatal blood sampling, the liquid capacity of the blood collection zone might be 0.12 cc and the liquid capacity of the blood disposal chamber 22 would be about 0.06 cc.

The use of the closed blood sampling device of the invention to withdraw and sample blood is illustrated in Fig. 2 which shows artery 48 in communication with a venipuncture device 50 which was inserted through subcutaneous tissue 52.

The neck 54 of the venipuncture device 50 is adapted to receive an injection site 56. While conventional injection sites may be used as such or adapted to be used in the practice of the invention, it is preferred that the injection site be of the type having a resilient resealable septum which is preferably pre-slit.

An injection site of this type is available from Baxter Healthcare Corporation and is a Neonatal T-Connector Luer sold under the brand name, InterLink, a registered trademark of Baxter Healthcare Corporation.

Such pre-slit, resilient, resealable injection sites and their method of fabrication are described in U.S. 5,188,620 the disclosure of which is incorporated herein by reference. The pre-slit resilient resealable injection sites described in this patent are designed to receive blunt cannulas. Another injection site related to the injection sites detailed in U.S. 5,188,620 is described in U.S. 5,300,034. This patent also details numerous publications and references which describe the preferred injection sites used in the practice of this invention. This patent and the publications listed therein also are incorporated herein by reference.

The injection site 56 is fitted with T-connector 58 which, in turn, is fitted with microbore tubing which, through female luer 62, is connected to IV line 64. The distal end 64 of the injection site 56 is connected to the neck 54 of the venipuncture device 50. The proximal end 66 of the injection site 56 is fitted with a pre-slit resilient resealing septum 68 adapted to receive the blood withdrawal cannula 12 which is dimensioned to fit snugly into the injection site. Inserted into the second branch or port 32 is a conventional syringe 70, such as a tuberculum blood draw syringe, or an arterial blood gas loss of resistance syringe.

The device's cannula 12 would be inserted through the septum 68 of the injection site 56 and positioned so that the tip 14 of the cannula 12 was fully inserted into the injection site adjacent to the venipuncture device. In doing so, the residual volume of the actual T-Housing would be eliminated as a measurable factor in blood draw volume. Arterial pressure would cause blood flow to enter and flow up the device via capillary action. As blood moved up the hydrophobic membrane 30 of the device, air would escape via the upstream hydrophobic membrane 30. Original blood first present in the catheter would be pushed beyond the luer bifurcation for retention in the device and eventual disposal. The device would be withdrawn from the T-Connector as soon as visual confirmation of the blood filled lumen was made. The vented removal cap 44 would be removed from the bifurcated luer 42 and replaced by the syringe 70 which would be aspirated to remove the arterial blood sample. Residual blood volume upstream of the bifurcation would remain in the device for subsequent disposal.

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Claims: JPH09504726 (A) — 1997-05-13

CLOSED SYSTEM BLOOD SAMPLING DEVICE

Claims not available for JPH09504726 (A)
Claims of corresponding document: WO9605875 (A1)

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AU686450 (B2) CA2173331 (A1) DE69523887 (T2) US5947932 (A) WO9605875 (A1)

- Original claims
- Claims tree

The EPO does not accept any responsibility for the accuracy of data and information originating from other authorities than the EPO; in particular, the EPO does not guarantee that they are complete, up-to-date or fit for specific purposes.

WE CLAIM:

1. A closed system blood sampling device comprising a bifurcated capillary tube comprising:
a. a first branch having a cannula shaped end for withdrawing and conveying blood to a communicating;
b. blood collection zone for storing a quantity of withdrawn blood and feeding an initial fraction of withdrawn blood to a communicating;
c. blood disposal chamber having an air permeable liquid sealed end; and,
d. a second branch connected to and in fluid communication with the blood collection zone which terminates in an opening adapted to receive a blood withdrawal device.

2. The closed system blood sampling device of Claim 1 where the cannula shaped end is blunt, the blood disposal chamber has its end fitted with a cap containing an air permeable hydrophobic membrane, and the blood disposal chamber contains a porous blood adsorbent.

3. The closed system blood sampling device of Claim 1 where the second branch has an interior angle not greater than 90 degrees.

4. The closed system blood sampling device of Claim 3 where the second branch has an angle of about 60 degrees.

5. The closed system blood sampling device of Claim 2 where the cannula shaped end is tapered.

6. The closed system blood sampling device of Claim 2 where the blunt cannula shaped end is adapted to be received by a injection site which contains a resilient resealing means.

7. The closed system blood sampling device of Claim 6 where the injection site is a pre-slit injection site.

8. The closed system blood sampling device of Claim 2 where the blood collection zone has a volume greater than the volume of the blood disposal chamber.

9. A method of sampling blood from a patient having an artery fitted with a venipuncture device which is attached to an injection site containing the closed blood sampling device of
Claim 1 which comprises the steps of:
a. withdrawing blood through the cannula shaped end of the closed blood sampling device thereby sequentially filling the blood disposal chamber and then the blood collection zone;
b. withdrawing through the opening in the second branch the blood contained in the blood collection zone for subsequent processing; and,
then,
c. discarding the closed system blood sampling device

10. The method of Claim 9 where the cannula is blunt, the blood disposal chamber has its end fitted with a cap containing an air permeable hydrophobic membrane, and contains a porous blood adsorbent.

11. The method of Claim 9 where the second branch has an interior angle not greater than 90 degrees.

12. The method Claim 11 where the second branch has an angle of about 60 degrees.

13. The method of Claim 10 where the cannula shaped end is tapered.

14. The method of Claim 10 where the blunt cannula shaped end is adapted to be received by a injection site which contains a resilient resealing means.

15. The method of Claim 14 where the injection site is a pre-slit injection site.

16. The method of Claim 10 where the blood collection zone has a volume greater than the volume of the blood disposal chamber.

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference	**FOR FURTHER ACTION**	see Form PCT/ISA/220 as well as, where applicable, item 5 below.
50828-501001WO		
International application No.	International filing date *(day/month/year)*	(Earliest) Priority Date *(day/month/year)*
PCT/US2016/043709	22 July 2016 (22-07-2016)	24 July 2015 (24-07-2015)
Applicant		
CALLIOPE SOLUTIONS, INC.		

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 5 sheets.

[X] 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:
      [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))
   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,**
   [X] 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
   [X] 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. 15C
      [X] 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

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

Box No. IV Text of the abstract (Continuation of item 5 of the first sheet)

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.

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2016/043709

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B5/15 A61B5/153 A61B5/154
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.
X	WO 2011/162772 A1 (CLEARVIEW PATIENT SAFETY TECHNOLOGIES LLC [US]; FISCHEL LLOYD [US]; BR) 29 December 2011 (2011-12-29)	1-5, 7-13, 15-20
A	paragraph [0070] figure 15 abstract	6,14
A	US 2009/227953 A1 (TAN CHEE LEONG [SG] ET AL) 10 September 2009 (2009-09-10) the whole document	1-20
A	JP H08 257018 A (NISSHO KK) 8 October 1996 (1996-10-08) abstract; figures	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 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
11 October 2016	19/10/2016

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	Schultz, Ottmar

2

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

International application No
PCT/US2016/043709

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 4 416 290 A (LUTKOWSKI LAWRENCE [US]) 22 November 1983 (1983-11-22) abstract; figures	1-20
A	US 3 648 684 A (BARNWELL CLEORA W ET AL) 14 March 1972 (1972-03-14) abstract; figures	1-20
A	EP 1 665 986 A1 (BECTON DICKINSON CO [US]) 7 June 2006 (2006-06-07) figures 13,14	1-20
A	US 4 056 101 A (GEISSLER ULRICH C ET AL) 1 November 1977 (1977-11-01) abstract; figures	1-20
A	US 2013/317391 A1 (BULLINGTON GREGORY J [US] ET AL) 28 November 2013 (2013-11-28) paragraphs [0084] - [0094] figures 16-18	1-20

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 2011162772 A1	29-12-2011	NONE	
US 2009227953 A1	10-09-2009	US 2009227953 A1	10-09-2009
		US 2010262038 A1	14-10-2010
		US 2012330187 A1	27-12-2012
JP H08257018 A	08-10-1996	NONE	
US 4416290 A	22-11-1983	NONE	
US 3648684 A	14-03-1972	NONE	
EP 1665986 A1	07-06-2006	BR PI0505336 A	11-07-2006
		EP 1665986 A1	07-06-2006
		JP 4914601 B2	11-04-2012
		JP 2006150083 A	15-06-2006
		US 2006129064 A1	15-06-2006
US 4056101 A	01-11-1977	NONE	
US 2013317391 A1	28-11-2013	US 2013317391 A1	28-11-2013
		US 2015099996 A1	09-04-2015
		US 2015351678 A1	10-12-2015

Information on Search Strategy - Pilot phase (see OJ 2015, A86)
The type of information contained in this sheet may change during the pilot for improving the usefulness of this new service.

Application Number
PCT/US2016/043709

TITLE: BLOOD SAMPLE OPTIMIZATION SYSTEM AND BLOOD CONTAMINANT SEQUESTRATION DEVICE AND METHOD

APPLICANT: CALLIOPE SOLUTIONS, INC.

IPC CLASSIFICATION: A61B5/15, A61B5/153, A61B5/154

EXAMINER: Schultz, Ottmar

CONSULTED DATABASES: EPODOC, WPI, COMBI, TXT+

CLASSIFICATION SYMBOLS DEFINING EXTENT OF THE SEARCH:

IPC:

CPC: A61B5/15003, A61B5/150213, A61B5/150389, A61B5/150473, A61B5/150572, A61B5/153, A61B5/154

FI/F-TERMS:

KEYWORDS OR OTHER ELEMENTS FEATURING THE INVENTION:
See claims.

EPO FORM P04A42

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US2016/043709	22.07.2016	24.07.2015

International Patent Classification (IPC) or both national classification and IPC
INV. A61B5/15 A61B5/153 A61B5/154

Applicant
CALLIOPE SOLUTIONS, INC.

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

- ☒ 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
- ☒ 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 usually 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 notifed 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:	Date of completion of this opinion	Authorized Officer
European Patent Office Gitschiner Str. 103 D-10958 Berlin Tel. +49 30 25901 - 0 Fax: +49 30 25901 - 840	see form PCT/ISA/210	Schultz, Ottmar Telephone No. +49 30 25901-0

Form PCT/ISA/237 (Cover Sheet) (January 2015)

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established 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)).

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:

   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 forming part of the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

5. Additional comments:

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

1. Statement

Novelty (N)	Yes:	Claims	2, 6, 7, 11, 14
	No:	Claims	1, 3-5, 8-10, 12, 13, 15-20
Inventive step (IS)	Yes:	Claims	6, 14
	No:	Claims	1-5, 7-13, 15-20
Industrial applicability (IA)	Yes:	Claims	1-20
	No:	Claims	

2. Citations and explanations

see separate sheet

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

+++++

Reference is made to the following document:

D1: WO 2011/162772 A1 (CLEARVIEW PATIENT SAFETY TECHNOLOGIES LLC [US]; FISCHEL LLOYD [US]; BR) 29 December 2011.

+++++

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

+++++

1 INDEPENDENT CLAIMS 1, 8, 17

1.1 Claims 8 seeks to define a blood sequestration device by being connected with a blood sampling pathway having a patient needle and a sample collection device whereby said blood sampling pathway does not form part of the claimed blood sequestration device.

This would only be the case if e.g. claim 8 defined e.g. "A system of a blood sequestration device and a blood sampling pathway having a patient needle and a sample collection device, whereby the blood sequestration device is connected with the blood sampling pathway, said blood sequestration device comprising...".

The technical features and the related definitions of the blood sampling pathway can therefore not be used to render the subject-matter of claim 8 either novel or inventive.

Since the intended limitation does not belong to the subject-matter claimed, namely the blood sequestration device, this said limitation leads to uncertainty with regard to the actual protection sought, contrary to the requirements of Article 6 PCT.

The same reasoning applies, mutatis mutandis, to the subject-matter of the corresponding independent claim 17, which therefore is also considered not meeting the requirements of Article 6 PCT.

1.2 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 1 is not new in the sense of Article 33(2) PCT. The reason is the following:

Document D1 discloses (the references in parenthesis applying to this document) in figure 15 all the features of independent claim 1, namely:

"A blood sequestration device (see figure 15) comprising;

an inlet port (see ref. sign 117 "well");

an outlet port (see ref. sign 330 "sleeve connector");

a sequestration chamber (see ref. sign 117 "guide tube aperture") connected with the inlet port, the sequestration chamber having a vent (see ref. sign 117 "venting member") comprising an air permeable blood barrier;

a sampling channel (see the channel formed in the sleeve connector 330) having a proximal end connected with the inlet port and a distal end connected with the outlet port; and

a housing (see ref. sign 116 "guide tube") that houses and defines the inlet port, the outlet port, the sequestration chamber, and the sampling channel".

1.3 The same reasoning applies, mutatis mutandis, to the subject-matter of the corresponding independent claims 8 an 17, which therefore are also considered not new (Article 33(1) and (2) PCT).

2 DEPENDENT CLAIMS 2-7, 9-16, 18-20

2.1 Dependent claims 2 to 5, 7, 9 to 13, 15, 16 and 18 to 20 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty (Article 33(2) PCT) and/or inventive step (Article 33(3) PCT), the reasons being as follows:

As far as the features of these said dependent claims are not already explicitly anticipated by document D1 (for further details, see the relevant passages as cited in the International Search Report and in the above-mentioned paragraph 1), these features would be chosen by a person skilled in the art simply by routine trial and error or these said features are at least generally known by a person skilled in the art either to be one of several straightforward possibilities from which this said person would select or to be regarded by this said person as a normal design option and thus would not add any inventive merit to the subject-matter of the these said dependent claims.

2.2 The features of dependent claims 6 and 14 in combination with the features of any claim to which these said claims refer, seem neither to be known from, nor rendered obvious by, the available prior art.

+++++

Re Item VII

Certain defects in the international application

+++++

1 The independent claims are not in the two-part form in accordance with Rule 6.3(b) PCT with those features known in combination from the prior art (e.g. one of the documents cited in the International Search Report) being placed in the preamble (Rule 6.3(b)(i) PCT) and with the remaining features being included in the characterising part (Rule 6.3(b)(ii) PCT).

2 Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the documents cited in the International Search Report is not mentioned in the description, nor are at least some of these documents identified therein.

3 The features of the claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).

+++++

Re Item VIII

Certain observations on the international application

+++++

Claims 8 seeks to define a blood sequestration device by being connected with a blood sampling pathway having a patient needle and a sample collection device whereby said blood sampling pathway does not form part of the claimed blood sequestration device.

This would only be the case if e.g. claim 8 defined e.g. "A system of a blood sequestration device and a blood sampling pathway having a patient needle and a sample collection device, whereby the blood sequestration device is connected with the blood sampling pathway, said blood sequestration device comprising...".

The technical features and the related definitions of the blood sampling pathway can therefore not be used to render the subject-matter of claim 8 either novel or inventive.

Since the intended limitation does not belong to the subject-matter claimed, namely the blood sequestration device, this said limitation leads to uncertainty with regard to the actual protection sought, contrary to the requirements of Article 6 PCT.

The same reasoning applies, mutatis mutandis, to the subject-matter of the corresponding independent claim 17, which therefore is also considered not meeting the requirements of Article 6 PCT.

+++++

拒絶理由通知書

特許出願の番号	特願２０１８－５２３３８４
起案日	令和　１年　７月１６日
特許庁審査官	清水　裕勝　　５２６２　２Ｑ００
特許出願人代理人	三好　秀和（外　３名）　様
適用条文	第２９条第１項、第２９条第２項

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．（新規性）この出願の下記の請求項に係る発明は、その出願前に日本国内又は外国において、頒布された下記の刊行物に記載された発明又は電気通信回線を通じて公衆に利用可能となった発明であるから、特許法第２９条第１項第３号に該当し、特許を受けることができない。

２．（進歩性）この出願の下記の請求項に係る発明は、その出願前に日本国内又は外国において、頒布された下記の刊行物に記載された発明又は電気通信回線を通じて公衆に利用可能となった発明に基いて、その出願前にその発明の属する技術の分野における通常の知識を有する者が容易に発明をすることができたものであるから、特許法第２９条第２項の規定により特許を受けることができない。

記　　（引用文献等については引用文献等一覧参照）

●理由１（新規性）、理由２（進歩性）について

・請求項１－２、５、７－９、１１－１２、１４
・引用文献等１
・備考
引用文献１には、静脈に穿刺した針から真空採血管に血液を採取するシステムが記載されている。（特に、特許請求の範囲、第６頁左上欄第２０行－同頁左下欄第１行、第７図等参照）
そして、第７図を参酌すると、引用文献１に記載された発明は、空気透過性血液不透過性の多孔性プラグ５２（本願発明の「空気透過性血液バリア」に相当。

）と横孔４８との間に空間を有し、かつ、プラグ５２で血液をブロックしてから真空採血管を挿入して横孔４８を通じて、プラグ５２を迂回して血液を採取するものであるから、当該「空間」は、血液サンプルの最初の量を受け入れる「隔離チャンバ」としても機能すると認められる。

そうしてみると、本願請求項１－２、５、７－９、１１－１２、１４に係る発明の構成と、引用文献１に記載された発明の構成との間に差異があるとは認められない。

したがって、本願請求項１－２、５、７－９、１１－１２、１４に係る発明は、引用文献１に記載された発明であるか、引用文献１に記載された発明に基づいて、当業者が容易になし得たものといえる。

●理由２（進歩性）について

・請求項６、１６
・引用文献等１
・備考
採血経路の形状や材質は、発明を具体化する際に当業者が適宜決定する事項と認められる。

したがって、本願請求項６、１６に係る発明は、引用文献１に記載された発明に基づいて、当業者が容易に想到し得たものといえる。

・請求項３－４、１３
・引用文献等１－２
・備考
引用文献２に記載されているように、真空採血管を用いて採血する技術分野において、サンプル針に真空採血管によって穿孔されるシールを設けることは周知技術である。（特に、第２図等参照）

したがって、本願請求項３－４、１３に係る発明は、引用文献１－２に記載された発明に基づいて、当業者が容易になし得たものである。

・請求項１０、１５
・引用文献等１、３
・備考
引用文献３に記載されているように、採血時の最初の血流が通る流路を設けることは周知技術である。（特に、段落[００１１]－[００１２]等参照）

したがって、本願請求項１０、１５に係る発明は、引用文献１、３に記載された発明に基づいて、当業者が容易になし得たものである。

＜引用文献等一覧＞

１．特開昭５８－２５１４６号公報
２．特開昭５８－６７２３８号公報（周知技術を示す文献）
３．特開２０１２－１６４９６号公報（周知技術を示す文献）

－－－－－－－－－－－－－－－－－－－－－－－－－－－－－－－－－－－－

＜先行技術文献調査結果の記録＞

・調査した分野　　ＩＰＣ　Ａ６１Ｂ５／１５３－５／１５４

・先行技術文献　　特開昭５７－８９８６９号公報
特表平９－５０４７２６号公報
特開平２－２２４７４２号公報
米国特許第４２０７８７０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。

＜補正をする際の注意＞
（１）明細書、特許請求の範囲について補正をする場合は、補正により記載を変更した個所に下線を引いてください（特許法施行規則様式第１３備考６、７）。
（２）補正は、この出願の国際出願日における国際特許出願の明細書若しくは図面（図面の中の説明に限る。）の翻訳文、国際出願日における国際特許出願の請求の範囲の翻訳文（特許協力条約第１９条（１）の規定に基づく補正後の請求の範囲の翻訳文が提出された場合にあっては、当該翻訳文）又は国際出願日における国際特許出願の図面（図面の中の説明を除く。）（以下、翻訳文等という。）（誤訳訂正書を提出して明細書、特許請求の範囲又は図面について補正をした場合にあっては、翻訳文等又は当該補正後の明細書、特許請求の範囲若しくは図面）に記載した事項の範囲内で行わなければなりません。また、意見書で、各補正事項について補正が適法なものである理由を、根拠となる翻訳文等（誤訳訂正書を提出して明細書、特許請求の範囲又は図面について補正をした場合にあっては、翻訳文等又は当該補正後の明細書、特許請求の範囲若しくは図面）の記載箇所を明確に示したうえで主張してください。
（３）特許請求の範囲について補正をする際には、特許法第１７条の２第４項に違反する補正とならないよう、注意してください。

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。

審査第一部　分析診断（医学診断）　清水裕勝
ＴＥＬ．０３－３５８１－１１０１　内線３２９１
ＦＡＸ．０３－３５８５－２０５５

Japanese Patent Application No. 2018-523384
Your Ref: KURIN2JP
Our Ref: TS/KRN-C0137JP01
August 26, 2019

Translation of "Notice of Reasons for Rejection"

Patent Application Number:	JP 2018-523384
Date of Delivery:	July 23, 2019
Applied Provision:	Patent Law Articles 29(1), and 29(2)

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. The inventions of the following claims should not be granted a patent under Patent Law Article 29(1)(iii) as lacking novelty over the documents listed below.

2. The inventions of the following claims should not be granted a patent under Patent Law Article 29(2) as lacking inventive step over the documents listed below.

Remarks (See the Document List below)

- Reasons 1 and 2
- Claims 1-2, 5, 7-9, 11-12 and 14
- Document D1

D1 discloses a system for collecting blood in an evacuated blood collection tube from a needle punctured into a vein. (See especially the claims, page 6, upper left column, line 20 to lower left column, line 1, Figure 7, etc.)

Referring to FIG. 7, the invention disclosed in D1 has a space between an air-permeable blood-impermeable porous plug 52 (corresponding to the "air permeable blood barrier" of the present invention) and a side hole 48, the blood is blocked by the plug 52 before the evacuated blood collection tube is inserted, the blood is collected through the side hole 48 to bypass the plug 52, and thus the "space" functions as a "sequestration chamber" for receiving a first amount of blood sample.

As a result, it is not recognized that there is a difference between the invention of claims 1-2, 5, 7-9, 11-12 and 14 and the invention disclosed in D1.

Therefore, the inventions of claims 1-2, 5, 7-9, 11-12 and 14 are the inventions disclosed in D1 or could have been easily made by those skilled in the art based on the invention disclosed in D1.

- Reason 2

- Claims 6 and 16
- Document D1

The shape and material of the blood sampling pathway are matters that could have been appropriately determined by those skilled in the art when the invention is embodied.

Therefore, the inventions of claims 6 and 16 could have been easily conceived by those skilled in the art based on the invention disclosed in D1.

- Claims 3-4 and 13
- Documents D1 and D2

As disclosed in D2, in the technical field of collecting blood using an evacuated blood collection tube, it is a well-known art to provide a sample needle with a seal to be pierced by an evacuated blood collection tube. (See especially Figure 2 etc.)

Therefore, the invention of claims 3-4 and 13 could have been easily made by those skilled in the art based on the invention disclosed in D1 and D2.

- Claims 10 and 15
- Documents D1 and D3

As disclosed in D3, it is a well-known art to provide a channel through which an initial blood flow passes during blood collection. (See especially paragraphs [0011]-[0012] etc.)

Therefore, the invention of claims 10 and 15 could have been easily made by those skilled in the art based on the invention disclosed in D1 and D3.

Document List

D1: JP S58-25146A
D2: JP S58-67238A (Document disclosing well-known art)
D3: JP 2012-16496A (Document disclosing well-known art)

Record of the Result of Prior Art Search

Technical field(s) searched	IPC A61B 5/153-5/154
Prior art document(s)	JP S57-89869A
	JP H9-504726A
	JP H2-224742A
	US 4,207,870B

This record is not a component of the reasons for rejection.

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（出願人による申告）国等の委託研究の成果に係る特許出願（平成２２年度経済産業省「戦略的基盤技術高度化支援事業」委託研究、産業技術力強化法第１９条の適用を受ける特許出願）

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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】

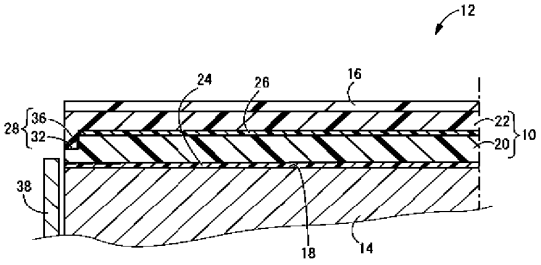
また、上述の二層構造の補助板２０，２２に加えて、更に補助板を積層状態で且つ固着手段で固着せしめて追加することも可能である。このように第三層の補助板を採用することで、弾性支持状態を実現したり、或いは中間層を使い捨てする等の態様も可能となる。

【符号の説明】

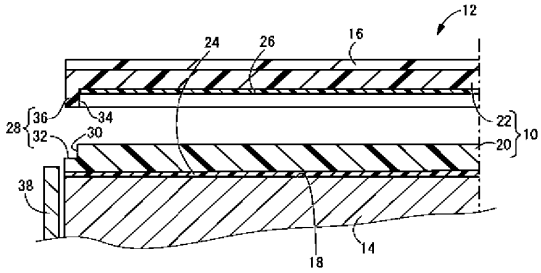
【０１０３】

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

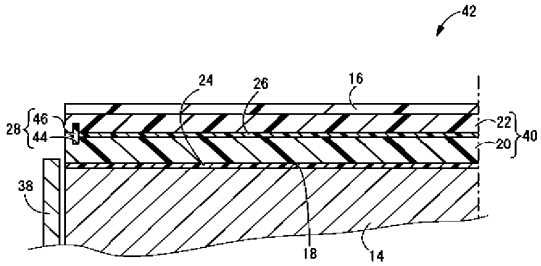
【図１】



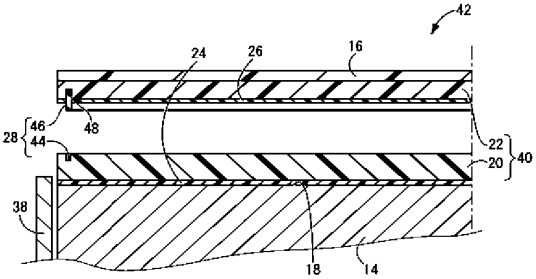
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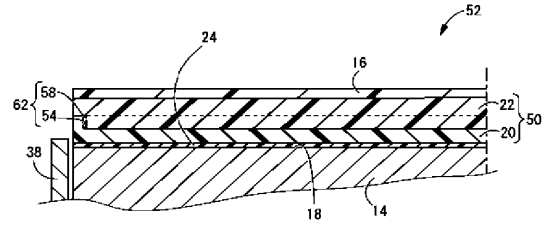
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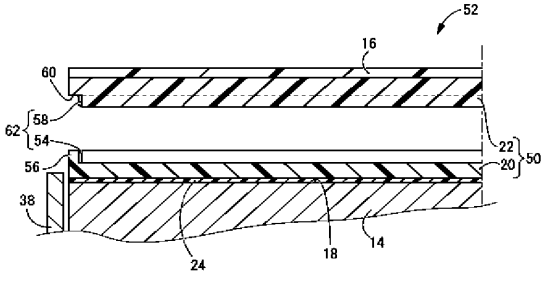
【図４】



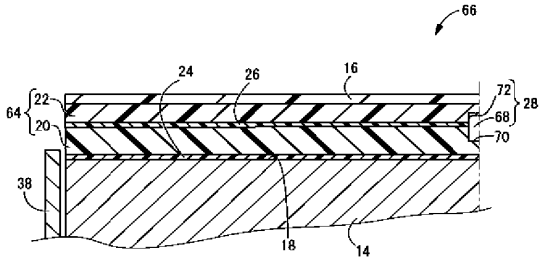
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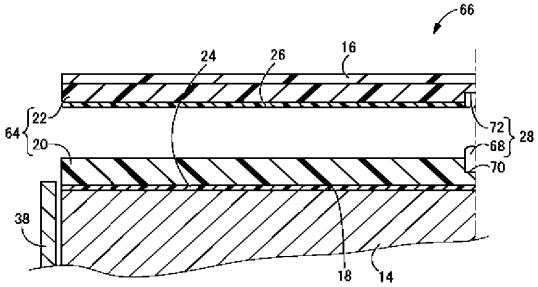
【図６】



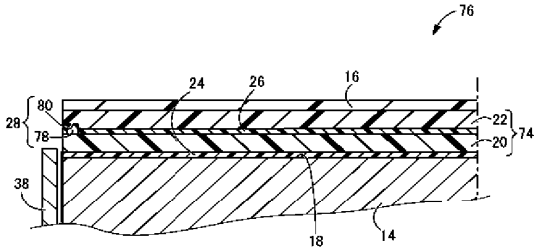
【図７】



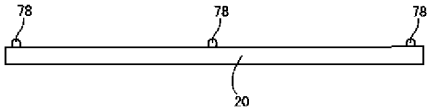
【図８】



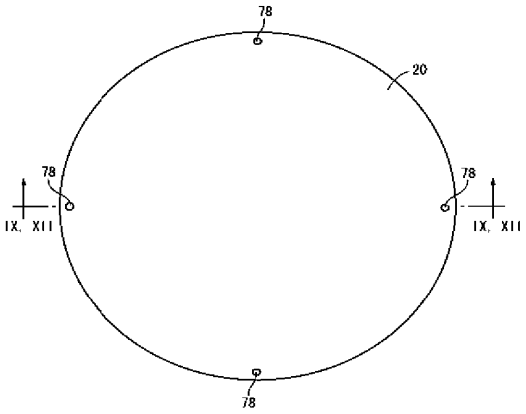
【図９】



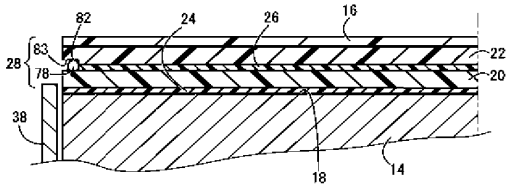
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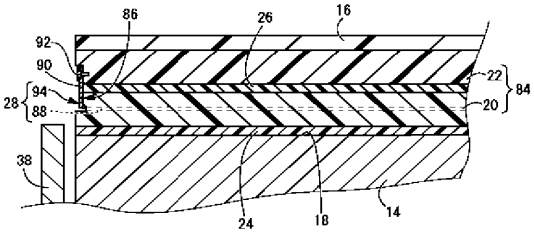
【図１１】



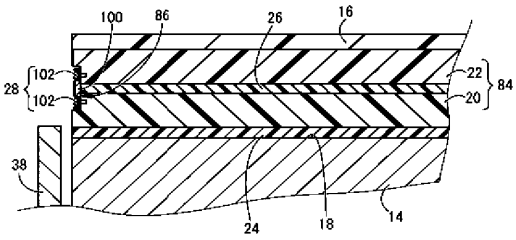
【図１２】



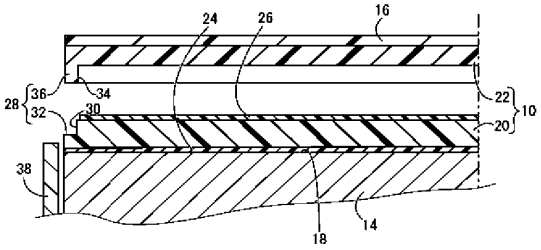
【図１３】



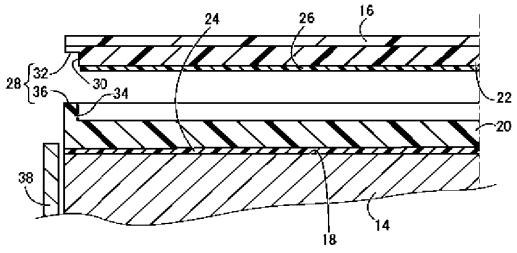
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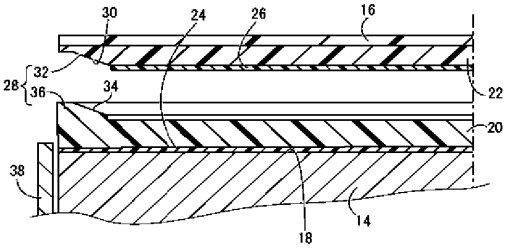
【図１５】



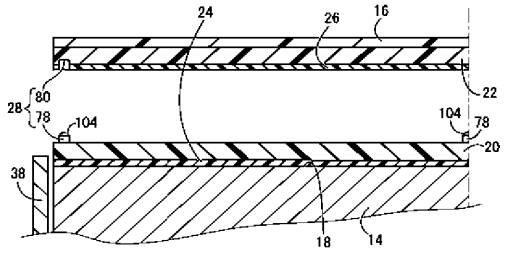
【図１６】



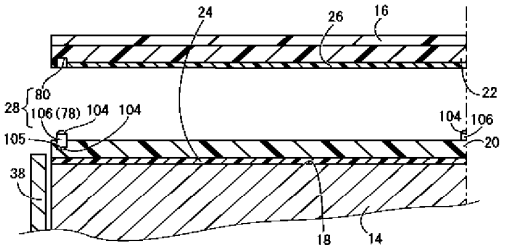
【図１７】



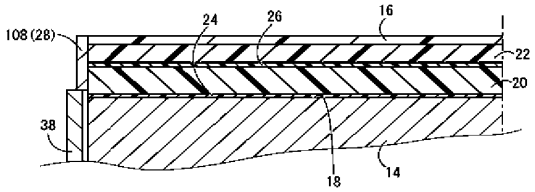
【図１８】



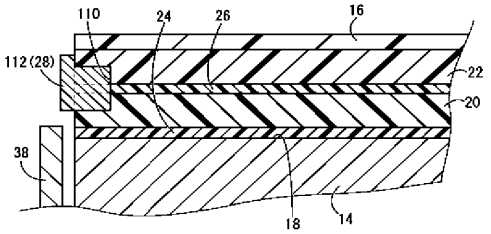
【図１９】



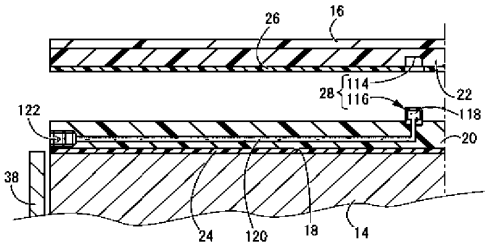
【図２０】



【図２１】



【図２２】



フロントページの続き

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特開平０７－３２８９１５（ＪＰ，Ａ）

(58)調査した分野(Int.Cl.，ＤＢ名)
Ｂ２４Ｂ　３７／１２
Ｈ０１Ｌ　２１／３０４

Espacenet

Bibliographic data: JP5789869 (B2) — 2015-10-07

POLISHING PAD AUXILIARY PLATE, AND POLISHING DEVICE EQUIPPED WITH POLISHING PAD AUXILIARY PLATE

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Applicant(s): TOHO ENGINEERING KK, ; 東邦エンジニアリング株式会社

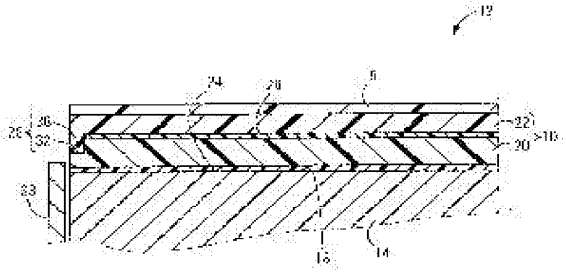
Classification: - international: *B24B37/12*
- cooperative: B24B37/22 (EP, US)

Application number: JP20110165360 20110728 Global Dossier

Priority number(s): JP20110165360 20110728

Also published as: JP2013027951 (A) TW201304904 (A) TWI594842 (B) US2013029566 (A1) US8992288 (B2)

Abstract of JP2013027951 (A)



PROBLEM TO BE SOLVED: To provide a novel polishing pad auxiliary plate which can easily achieve the repeated attachment/detachment of a polishing pad on/from a rotating surface plate with high positional accuracy and is applicable also to the rotating surface plates of various types of polishing devices without requiring large modification.SOLUTION: This polishing pad auxiliary plate 10 which is attached to the rotating surface plate 14 of the polishing device 12 includes a lower auxiliary plate 20 and an upper auxiliary plate 22. A positioning means is installed between the upper and lower auxiliary plates 22, 20. As compared with an auxiliary plate of conventional structure in which a positioning means is installed between auxiliary plates and a rotating surface plate, the polishing pad auxiliary plate 10 enables the easy and accurate positioning of the center axis of the polishing pad 16 on the rotating surface plate 14, and is widely applicable also to the rotating surface plates 14 of various types of polishing devices.

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DESCRIPTION JP5789869

Polishing pad auxiliary plate and polishing apparatus provided with polishing pad auxiliary plate

[0001]
The present invention relates to a technique related to polishing of a substrate which is a workpiece requiring high flatness processing accuracy such as a silicon wafer, a semiconductor substrate, and a glass substrate, and particularly relates to polishing the surface of the substrate. TECHNICAL FIELD The present invention relates to a technique that makes it possible to reuse a polishing pad used when performing polishing.

[0002]

As is well known, in the manufacture of semiconductors, a polishing process for planarizing the surface of a substrate such as a silicon wafer, a semiconductor substrate, or a glass substrate as a constituent material is performed.

Such polishing treatment is generally performed by directly fixing a disk-shaped polishing pad made of a resin material or the like directly on a rotating platen of a polishing apparatus with a double-sided tape, and supplying a polishing liquid containing abrasive grains, Polishing is performed by relatively rotating the substrate.

[0003]

As a polishing pad for performing such a polishing treatment, a resin pad made of foamed or non-foamed urethane or the like, as described in JP-A-2002-11630 (Patent Document 1) and the like, is used. Has been adopted. Also, in many cases, the polishing surface of such a polishing pad is provided with a groove processing such as concentric, lattice, radial, or the like, or bubbles of a foamed resin are opened.

[0004]

By the way, when performing polishing using a polishing pad, when changing the type of substrate to be polished, the polishing pad used for polishing must be peeled off from the rotary platen and replaced with another polishing pad. May not be. In addition, for example, when the polishing pad that has been degraded due to the polishing process is to be reused for the purpose of re-use or the like, the polishing pad is moved from the rotary platen to another processing device such as surface grooving. It needs to be peeled off.

[0005]

However, since the thin disk-shaped polishing pad is firmly fixed to the rotating platen of the polishing apparatus with an adhesive tape, when the polishing pad is peeled off from the rotating platen, Damage such as bending, bending, wrinkling, and tearing is likely to occur. Therefore, due to such damage, there is a problem in that the polishing pad cannot be reused and has to be discarded in many cases even though the life of the polishing pad has not been reached.

[0006]

In addition, the work of peeling the polishing pad from the rotary platen with great care so as not to damage it has a problem that it requires a skill and attention, and thus places a heavy burden on the operator. In addition, since a considerable amount of time is required to separate the polishing pad from the rotary platen, the polishing apparatus, which is an expensive and valuable equipment, must be stopped for a long time, and the operation time of the equipment must be reduced. There was also a problem that was restricted.

[0007]

In view of this, the present inventor has previously disclosed in Japanese Unexamined Patent Application Publication No. 2010-214579 (Patent Document 2) a method in which an auxiliary plate is attached to the back surface of a polishing pad, and the polishing pad is attached to a rotating platen of a polishing apparatus via the auxiliary plate. On the other hand, a polishing pad with an auxiliary plate that is fixed with a double-sided tape was proposed. In such a polishing pad with an auxiliary plate, since the polishing pad is attached to and detached from the rotary platen while being supported by the auxiliary plate, damage to the polishing pad during attachment and detachment is reinforced by the auxiliary plate. Therefore, the polishing pad can be attached to and detached from the rotary platen with good workability while preventing the polishing pad from being damaged.

[0008]
However, as a result of further research and study by the present inventors, it has been found that it is difficult to say that the polishing pad with the auxiliary plate proposed in Patent Literature 2 is easily compatible with all polishing apparatuses.

[0009]

That is, when the polishing pad is overlaid and fixed on the rotating surface plate, it is necessary to align the center of the polishing pad with the rotation center of the rotating surface plate, especially in a polishing pad having a groove or the like on the polishing surface. Accuracy is required for center alignment.

When the number of attachment / detachment of the polishing pad to the rotary platen increases by adopting the auxiliary plate as described above, the work of center alignment when mounting the polishing pad on the rotary platen becomes more difficult, and the labor burden is increased. Being big is a big problem.

[0010]

Further, in the polishing pad with an auxiliary plate proposed in Patent Document 2, the auxiliary plate is detachably mounted while being center-aligned with respect to the rotary platen. A fixing means such as an outer ring may be provided on the outer peripheral surface of the board. On

the other hand, in some polishing apparatuses, 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. Therefore, if such a peripheral ring is to be employed, when a polishing apparatus happens to be used in which the space on the outer peripheral side of the rotary platen is narrow, the polishing apparatus may need to be modified. It is.

[0011]
JP, 2002-11630, A JP, 2010-214579, A

[0012]
The present invention has been made in view of the above-described circumstances, and it has been made possible to easily attach / detach a polishing pad to / from a rotating surface plate while sufficiently securing a fixing force of the polishing pad to the rotating surface plate. In addition, a polishing pad auxiliary plate having a novel structure that can prevent the polishing pad from being damaged particularly when the polishing pad is removed from the rotary platen and can be advantageous in realizing reuse of the polishing pad, for example, is provided. To provide.

[0013]
In addition, the present invention can easily and accurately perform the centering operation when mounting the polishing pad on the rotating surface plate, can reduce the labor burden, and can provide a conventional polishing apparatus of various specifications. It is another object of the present invention to provide an auxiliary pad for a polishing pad having an improved structure, which can be easily and advantageously applied to the rotary platen in the above without requiring any special modification.

[0014]
Further, another object of the present invention is to provide a polishing apparatus provided with a polishing pad auxiliary plate having such a novel structure.

[0015]
In order to solve such a problem, a first aspect of the present invention relating to a polishing pad auxiliary plate includes (A) a polishing pad attached to a rotating plate of a polishing apparatus so that the polishing pad can be detachably attached to the rotating plate. A polishing pad auxiliary plate to be attached, wherein (B) a lower auxiliary plate which is arranged to be superimposed on the upper surface of the rotary platen, and (C) a first fixing device which fixes

the lower auxiliary plate to the rotary platen. Means; (D) an upper auxiliary plate provided with a pad supporting surface on which the polishing pad is superimposed and fixed, and arranged on the upper surface of the lower auxiliary plate; and (E) the upper auxiliary plate. (F) positioning means for positioning the lower auxiliary plate and the upper auxiliary plate with respect to each other and aligning the center axes thereof, and The lower auxiliary plate is provided with the first fixing hand with respect to the rotary platen of the polishing device. The upper auxiliary plate is removed from the lower auxiliary plate fixed to the rotary platen while being fixed to the rotating platen, so that the polishing is performed while being fixed to the pad supporting surface of the upper auxiliary plate. The pad can be removed from the rotary platen, and the removed upper auxiliary plate can be fixed to the lower auxiliary plate again by being fixed to the lower auxiliary plate in a state of being aligned by the positioning means. The fixing force between the lower auxiliary plate and the upper auxiliary plate by the second fixing means is larger than the fixing force between the rotary platen and the lower auxiliary plate by the first fixing means. It is characterized by a polishing pad auxiliary plate that is also small.

[0016]

In the polishing pad auxiliary plate having the structure according to the present invention, the polishing pad is fixedly mounted on the rotary platen via the upper auxiliary plate and the lower auxiliary plate.

This allows the upper auxiliary plate to be removed from the lower auxiliary plate while the lower auxiliary plate is fixed to the rotary platen, and the polishing pad to be removed from the rotary platen while being fixed to the upper auxiliary plate. Becomes possible.

[0017]

Therefore, while the polishing pad is reinforced and protected by the upper auxiliary plate, the polishing pad can be removed from the rotary platen while preventing damage to the polishing pad, and handling of the thin polishing pad becomes easy.

For example, when the polishing pad is repeatedly attached / detached when the polishing target or the polishing conditions are changed, or when the worn polishing pad is removed and re-mounted after the regenerating process, the attaching / detaching of the polishing pad to / from the rotating platen or polishing. It is also possible to easily perform operations such as

reproduction processing on the pads.

[0018]

In addition, since the lower auxiliary plate fixed to the rotating platen and the upper auxiliary plate removed together with the polishing pad are mutually centered by the positioning means, it is necessary to align the lower auxiliary plate with the rotating platen. The polishing pad can be more easily attached and detached.

In particular, since the positioning means is provided between the lower auxiliary plate and the upper auxiliary plate, it is not necessary to perform special processing or the like on the rotary platen.

In addition, such positioning means can be prevented from protruding more to the outer peripheral side than the rotary platen.For example, a special modification is required for a polishing apparatus or the like in which a protective cover or the like is provided on the outer peripheral side of the rotary platen. Applicable without application.

[0019]
In the polishing pad auxiliary plate according to the first aspect of the present invention, in the polishing pad auxiliary plate, the fixing force between the lower auxiliary plate and the upper auxiliary plate by the second fixing unit is adjusted by the rotation by the first fixing unit. An aspect is adopted in which the force is smaller than the fixing force between the surface plate and the lower auxiliary plate.

[0020]

According to such a first aspect, by setting the fixing force in the first and second fixing means by mutually adjusting, the upper auxiliary plate with the polishing pad fixed is fixed to the rotating platen. The work of removing the lower auxiliary plate from the fixed state is further facilitated.

In short, there is no need to perform any special operation to keep the lower auxiliary plate fixed

to the rotary platen, and the upper side of the polishing pad is supported while the lower auxiliary plate remains fixed to the rotary platen. It can be easily removed from the rotary platen while being fixed to the plate.

[0021]
A second aspect of the present invention is the polishing pad auxiliary plate according to the first aspect, wherein the positioning means is located on an inner peripheral side of outer peripheral surfaces of the lower auxiliary plate and the upper auxiliary plate. It is provided.

[0022]

In the polishing pad auxiliary plate of this aspect, the protrusion of the upper and lower auxiliary plates to the outer peripheral side in the positioning means is completely avoided.

Therefore, for example, even when the outer diameter of the upper and lower auxiliary plates is set to be equal to or slightly smaller than the outer diameter of the rotary platen, the polishing pad is secured from the rotary platen while ensuring a sufficiently large supporting surface. It is possible to prevent the positioning means from protruding on the outer peripheral side, and even if a protective cover or the like is installed on the outer peripheral side of the rotary platen, it may be an obstacle when applying the polishing pad auxiliary plate according to the present invention. Be avoided.

[0023]
A third aspect of the present invention is the polishing pad auxiliary plate according to the second aspect, wherein the positioning means is provided on one of the lower auxiliary plate and the upper auxiliary plate and projects toward the other. And an engaging concave portion provided on the other of the lower auxiliary plate and the upper auxiliary plate and engaged with the engaging convex portion.

[0024]

In the polishing pad auxiliary plate 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.

In addition, by adjusting the shape, size, number, and the like of the engaging protrusions and the engaging recesses, the direction and the acting force of the positioning operation can be easily set with a large degree of freedom.

[0025]
According to a fourth aspect of the present invention, in the auxiliary pad for a polishing pad according to the third aspect, the engaging protrusion and the engaging recess are located on outer peripheral portions of the lower auxiliary plate and the upper auxiliary plate. It is formed with an engaging portion that engages.

[0026]

In the polishing pad auxiliary plate of this aspect, the engaging outer peripheral surface of the engaging convex portion and the engagement of the engaging concave portion are located at the outer peripheral portion distant from the center of the polishing pad auxiliary plate and are fitted into the concave and convex portions. By forming the inner peripheral surface, the relative positioning accuracy of the upper and lower auxiliary plates, in particular, the positioning accuracy in the radial direction can be improved.

As shown in the sixth and seventh embodiments described later, the engaging outer peripheral surface of the engaging convex portion and the engaging inner peripheral surface of the engaging concave portion are formed around the center of the polishing pad auxiliary plate. It may be in the form of extending in the circumferential direction along the outer peripheral edge of the auxiliary pad for polishing pad, or may be formed on the periphery like an engaging convex portion and an engaging concave portion formed on the outer peripheral portion of the auxiliary plate for polishing pad. It may be a partially located form.

[0027]
According to a fifth aspect of the present invention, in the auxiliary pad for a polishing pad according to the fourth aspect, the engaging portion in the engaging convex portion and the engaging concave portion includes the lower auxiliary plate and the upper auxiliary plate. Are formed by an annular engaging outer peripheral surface and an engaging inner peripheral surface which extend continuously in the circumferential direction and are fitted to each other.

[0028]
In the auxiliary plate for a polishing pad of this aspect, more preferably, the engagement concave portion and the engagement convex portion are formed with an annular engagement inner and outer peripheral surface extending around the central axis of the auxiliary pad for the polishing pad. Accordingly, when the upper auxiliary plate is attached to the lower auxiliary plate, mutual alignment in the circumferential direction is not required, and work can be performed easily and quickly.

[0029]
A sixth aspect of the present invention is the auxiliary pad for a polishing pad according to the fourth aspect, wherein the lower auxiliary plate is provided at a plurality of locations on the outer peripheral portion of the lower auxiliary plate and the upper auxiliary plate. The engagement recess opening toward the other at one of the overlapping surfaces of the plate and the upper auxiliary plate, and one at the other of the mutual overlapping surfaces of the lower auxiliary plate and the upper auxiliary plate. The engaging protrusions protruding toward each other are formed at positions corresponding to each other, and the engaging portions are configured by fitting of the engaging protrusions into the engaging recesses.

[0030]
In the polishing pad auxiliary plate of this aspect, the mutual positioning of the upper and lower auxiliary plates can be easily realized not only in the direction perpendicular to the axis but also in the circumferential direction around the central axis.

[0031]
According to a seventh aspect of the present invention, in the polishing pad auxiliary plate according to the fourth aspect, a plurality of locations on an outer peripheral portion of one of the lower auxiliary plate and the upper auxiliary plate are arranged from a plurality of locations on the periphery toward the other. The protruding engagement convex portion is formed of an elastic material, and the engagement convex portion is formed on an outer peripheral surface of the other of the lower auxiliary plate and the upper auxiliary plate so as to be opened. The engaging portion is configured by engaging a tip of the portion.

[0032]

In the auxiliary plate for a polishing pad of this aspect, the engagement portion can be formed by

exposing the engagement portion on the outer peripheral surface of the upper and lower auxiliary plate, whereby the engagement state of the engagement portion can be easily confirmed visually or the like. It becomes possible.

Further, in this aspect, the engagement state of the engagement portion can be stably maintained by utilizing the elasticity of the engagement projection.

[0033]
According to an eighth aspect of the present invention, in the auxiliary pad for a polishing pad according to the third aspect, the engaging convex portion and the engaging concave portion are arranged on a central axis of the lower auxiliary plate and the upper auxiliary plate. It is provided.

[0034]

In the auxiliary pad for a polishing pad of this aspect, by providing the engaging convex portion and the engaging concave portion on the central axis of the upper and lower auxiliary plates, the central axis of the upper and lower auxiliary plates can be aligned by one engaging portion. become.

Further, when the mutual positioning of the engaging convex portion and the engaging concave portion provided on the center axis is not required, the mutual positioning of the upper and lower auxiliary plates in the circumferential direction is not necessary, and the engaging convex portion and the engaging concave portion are not required. Can easily be engaged.

[0035]
A ninth aspect of the present invention is the polishing pad auxiliary plate according to the eighth aspect, wherein the outer peripheral surface of the engagement convex portion and the inner peripheral surface of the engagement concave portion are formed with screw grooves that are screwed together. The second fixing means is formed by screwing the engaging projection and the engaging recess forming the positioning means.

[0036]

In the polishing pad auxiliary plate of the present aspect, the fixing force between the upper auxiliary plate and the lower auxiliary plate can be obtained by the positioning means.

Therefore, it is possible to constitute the second fixing means only by such positioning means, or to supplement the fixing force between the upper and lower auxiliary plates by the second fixing means by the positioning means.

[0037]
A tenth aspect of the present invention is the polishing pad auxiliary plate according to any one of the third, fourth, fifth, sixth, eighth, and ninth aspects, wherein one of the lower auxiliary plate and the upper auxiliary plate is provided. The provided engaging projection is made of the same material as one of the lower auxiliary plate and the upper auxiliary plate.

[0038]

In the polishing pad auxiliary plate of the present aspect, it is possible to prevent the support characteristics of the polishing pad in the auxiliary plate superimposed on the upper and lower portions from being largely different locally at the portion where the engaging projection is formed.

Therefore, when a pressing force acts on the surface of the polishing pad during pad polishing, the pressing reaction force and the elasticity of the polishing pad are reduced at the portions where the engaging projections and engaging recesses are formed on the upper and lower auxiliary plates supporting the polishing pad. It is possible to reduce or avoid inconveniences such as polishing accuracy caused by local differences in characteristics such as the polishing accuracy.

[0039]
Further, according to the present invention, the polishing pad auxiliary plate according to the present invention according to any one of the first to tenth aspects is mounted on an upper surface of a rotary platen, and a gap is formed on an outer peripheral side of the rotary platen. A polishing apparatus in which a protective member is disposed at a distance, and which is located on the inner peripheral side with respect to the outer peripheral end surfaces of the rotary platen and the auxiliary plate for the polishing pad and provided with the positioning means, is also

characterized in that the polishing apparatus is characterized in that. .

[0040]
By employing a polishing pad auxiliary plate structured according to the present invention or using a polishing apparatus structured according to the present invention, the polishing pad is easily removed from the rotary platen while preventing damage to the polishing pad. This makes it possible to easily and accurately adjust the position of the polishing pad to the rotating platen when mounting the polishing pad.

[0041]

FIG. 1 is a longitudinal sectional view showing a main part of a polishing apparatus equipped with a polishing pad auxiliary plate as a first embodiment of the present invention.

FIG. 2 is an explanatory view of a vertical section showing a state where a polishing pad is removed in the polishing apparatus shown in FIG. 1.

The longitudinal section showing the important section of the polisher equipped with the auxiliary board for polishing pads as a second embodiment of the present invention.

FIG. 4 is an explanatory longitudinal sectional view showing a state in which a polishing pad is removed in the polishing apparatus shown in FIG. 3.

The longitudinal section showing the important section of the polish device in which the auxiliary board for polish pads as a 3rd embodiment of the present invention was attached.

FIG. 6 is an explanatory longitudinal sectional view showing a state where a polishing pad is removed in the polishing apparatus shown in FIG. 5.

The longitudinal section showing the important section of the polish device in which the auxiliary board for polish pads as a 4th embodiment of the present invention was attached.

FIG. 8 is an explanatory view of a vertical section showing a state where a polishing pad is removed in the polishing apparatus shown in FIG. 7. The longitudinal section showing the important section of the polish device in which the auxiliary board for polish pads as a 5th embodiment of the present invention was attached. FIG. 10 is a side view of a lower auxiliary plate constituting the polishing pad auxiliary plate shown in FIG. 9. FIG. 11 is a plan view of the lower auxiliary plate shown in FIG. 10. The longitudinal section showing the important section of the polisher equipped with the auxiliary board for polishing pads as a 6th embodiment of the present invention. The longitudinal section showing the important section of the polisher equipped with the auxiliary board for polishing pads as a 7th embodiment of the present invention. The longitudinal section showing the important section of the polisher equipped with the auxiliary board for polishing pads as an 8th embodiment of the present invention. FIG. 19 is an explanatory view of a vertical section showing a state in which a polishing pad auxiliary plate is removed as a ninth embodiment of the present invention. The explanatory view of the longitudinal section showing the state where the auxiliary board for polishing pads as a 10th embodiment of the present invention was removed. The explanatory view of the longitudinal section showing the state where the auxiliary board for polishing pads as an eleventh embodiment of the present invention was removed. The explanatory view of the longitudinal section showing the state where the auxiliary board for polishing pads as a 12th embodiment of the present invention was removed. The longitudinal section explanatory drawing showing the state where the auxiliary board for polishing pads as a 13th embodiment of the present invention was removed. Explanatory drawing of the longitudinal section which shows the state which positioned the auxiliary plate for polishing pads as 14th embodiment of this invention. Explanatory drawing of the longitudinal section which shows the state which positioned the auxiliary plate for polishing pads as 15th embodiment of this invention. The explanatory view of the longitudinal section showing the state where the auxiliary board for polishing pads as a 16th embodiment of the present invention was removed.

[0042]

Hereinafter, embodiments of the present invention will be described with reference to the drawings. First, FIGS. 1 and 2 show a polishing pad auxiliary plate 10 as a first embodiment of the present invention. The polishing pad auxiliary plate 10 is used by being attached to a rotary platen 14 of a polishing apparatus 12, and a polishing pad 16 is detachably attached to the rotary platen 14.

[0043]

The polishing apparatus is used, for example, as a CMP apparatus as described in, for example, Japanese Patent Application Laid-Open No. 2010-141155, and has a well-known basic structure. A rotating shaft extending in the vertical direction is rotatably supported by the installed apparatus main body, and a disk-shaped rotating surface plate 14 is fixed to an upper end of the rotating shaft. The rotary platen 14 has a flat upper surface 18 extending in the horizontal direction, and the upper surface 18 is a support surface of the polishing pad 16. Further, a rotation output shaft of an electric motor is connected to the rotation shaft, and the driving force of the electric motor is transmitted, so that the rotation shaft and, consequently, the rotation platen 14 are driven to rotate around the center axis. I have. A nozzle for supplying a polishing slurry is arranged above the upper surface 18 supporting the polishing pad 16, and a nozzle or the like to be polished is held on the polishing pad 16 while being rotated while being held. A polishing head for performing polishing by pressing is provided.

[0044]

In such a polishing apparatus, the polishing pad auxiliary plate 10 mounted on the rotary platen 14 includes a lower auxiliary plate 20 and an upper auxiliary plate 22. The lower auxiliary plate 20 is fixed to the upper surface 18 of the rotary platen 14 by first fixing means 24, and the upper auxiliary plate 22 is further fixed to the upper surface of the lower auxiliary plate 20. It is fixed by two fixing means 26. That is, the lower auxiliary plate 20 and the upper auxiliary plate 22 are overlapped and fixed to each other via the second fixing means 26 to form the polishing pad auxiliary plate 10 having a two-layer structure as a whole. It is attached to the upper surface 18 of the turntable 14 by first fixing means 24.

[0045]

Each of the lower auxiliary plate 20 and the upper auxiliary plate 22 is formed in a thin and substantially circular flat plate shape, and has a flat surface (upper surface) and a back surface (lower surface). It is desirable that the upper and lower auxiliary plates 22 and 20 are made of a harder material than the polishing pad 16 to be mounted, or have a higher 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 rotating platen 14, while the upper auxiliary plate 22 can be attached and detached after being attached to the rotating platen 14. Therefore, it is desirable that at least the upper auxiliary plate 22 should have a higher member rigidity than the polishing pad 16.

[0046]

However, the upper auxiliary plate 22 supports the polishing pad 16 and, in addition to the polishing process by the polishing device 12, the strength and rigidity required for various processes such as dressing, cleaning, and re-grooving on the polishing pad surface. Any material 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 do not bear the supporting strength or rigidity of the polishing pad 16 by itself. For example, during polishing, the upper auxiliary plate 22 is placed on the rotating platen 14 of the polishing apparatus 12. Since the lower surface is supported by the rotating platen 14 by being used in a superposed state, the strength and rigidity of a single body are not required to that extent. Therefore, in addition to metals such as stainless steel, synthetic resins, fiber-reinforced resins, and the like can be used as the material for forming the lower auxiliary plate 20 and the upper auxiliary plate 22. In particular, synthetic resin materials are lighter in weight and easier to process and handle than metal materials. For example, polycarbonate and the like have the advantage of being stable in thickness dimensional accuracy and excellent in low distortion characteristics against temperature changes. .

[0047]

In order to obtain a stable supporting force over the entire polishing pad 16, it is preferable that the outer diameter of the upper auxiliary plate 22 be set to be equal to or larger than the outer diameter of the polishing pad 16, and that the lower auxiliary It is desirable that the outer diameter of the plate 20 is set to be equal to or greater than the outer diameter of the upper auxiliary plate 22, and the outer diameter of the lower auxiliary plate 20 is set to be equal to or less than the outer diameter of the rotary platen 12. It is desirable. 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 diameters of the mounted rotating platen 14 are also almost the same. By doing so, it is possible to ensure a sufficiently large supporting area for the polishing pad 16. This makes it possible to mount the polishing pad 16 having substantially the same size as the rotary platen 14 on the rotary platen 14 with substantially the same support force over the entirety thereof.

[0048]

Furthermore, as the first fixing means 24 and the second fixing means 26, the lower auxiliary plate 20 and the upper auxiliary plate 22 are fixed to the upper surface 18 of the rotary platen 14 against external force exerted during polishing. What is necessary is just to be able to hold ¦ maintain, and it does not specifically limit. Specifically, an adhesive or a pressure-sensitive adhesive, or a double-sided tape in which an adhesive or a pressure-sensitive adhesive is adhered to both surfaces of a substrate sheet or the like can be adopted as the first and second fixing means 24 and 26. In addition, negative pressure attraction using negative pressure air or the like, magnetic attraction using a permanent magnet or an electromagnet, and the like can also be adopted. In addition, it is desirable that the fixing means made of an adhesive or the like exerts a substantially uniform fixing force over substantially the entire flat superimposed surface of the lower auxiliary plate 20 and the upper auxiliary plate 22. The fixing force can be obtained, and the problem that the support characteristics of the polishing pad 16 locally differ on the surface of the polishing pad auxiliary plate 10 can be avoided.

[0049]

For example, the fixing force can be turned ON / OFF by negative pressure suction or an electromagnet, but when a fixed fixing force is exerted such as an adhesive, the lower auxiliary plate 20 with respect to the rotary platen 14 by the first fixing means 24. It is preferable that the second fixing means 26 be set so that the fixing force of the upper auxiliary plate 22 to the lower auxiliary plate 20 is smaller than the fixing force of the upper auxiliary plate 22. Accordingly, when the upper auxiliary plate 22 is peeled off from the lower auxiliary plate 20 and removed, it is possible to easily realize that the lower auxiliary plate 20 is left fixed on the rotary platen 14. The concrete realization of such a difference in the fixing force is to make the fixing means itself different from each other such as the material of the adhesive or the pressure-sensitive adhesive, and to fix the fixing area and the state of the fixing surface (surface roughness, the presence or absence of plasma treatment, etc.). Can also be realized by making them different from each other.

[0050]

Further, the surface (upper surface) of the upper auxiliary plate 22 serves as a polishing pad support surface, and the polishing pad 16 is attached in an overlapping manner. As the polishing pad 16, various types of conventionally known polishing pads can be employed. The back surface of the polishing pad 16 is fixed to the surface of the upper auxiliary plate 22 using a conventionally known adhesive tape or a suitable adhesive for attaching the polishing pad.

[0051]

It is desirable that the fixing means of the polishing pad 16 to the upper auxiliary plate 22 be set to a larger fixing force than the second fixing means 26 described above. Thus, when the upper auxiliary plate 22 is detached from the lower auxiliary plate 20 with the polishing pad 16 fixed, the polishing pad 16 can be expected from the upper auxiliary plate 22 even if the upper auxiliary plate 22 is curved. Can be effectively prevented.

[0052]
The outer diameter of the polishing pad 16 is generally set to a standard value, but is often set to be equal to or smaller than the outer diameter of the upper surface 18 of the rotary platen 14 to be mounted.

[0053]

Further, for example, at least one between the upper surface 18 of the rotary platen 14 and the lower auxiliary plate 20, between the lower auxiliary plate 20 and the upper auxiliary plate 22, and between the upper auxiliary plate 22 and the polishing pad 16. An appropriate cushion layer may be provided.

By providing such a cushion layer, it is possible to achieve uniform polishing efficiency over the entire surface of the workpiece during polishing using the polishing pad 16.

[0054]

As such a cushion layer, for example, a resin sheet to which a certain degree of compressibility has been imparted by foaming, an elastomer sheet, a rubber sheet, or the like can be suitably used. In addition, the cushion layer can be formed by the first fixing means 24, the second fixing means 26, and the fixing means for fixing the polishing pad 16 to the upper auxiliary plate 22. Note that the cushion layer is formed so as to exist at a constant thickness over substantially the entire support region of the polishing pad 16 in order to prevent local distortion on the support surface of the polishing pad 16. Is desirable.

[0055]

Positioning means 28 is provided between the lower auxiliary plate 20 and the upper auxiliary plate 22 constituting the polishing pad auxiliary plate 10 so as to position each other and align the central axis. In the present embodiment, a circular step surface 30 is formed on the outer peripheral portion of the lower auxiliary plate 20 and extends around the entire circumference around the central axis of the lower auxiliary plate 20. By reducing the thickness of the lower auxiliary plate 20 on the outer peripheral side of the stepped surface 30, the lower auxiliary plate 20 has a notched cross-sectional shape that opens to the outer peripheral surface of the lower auxiliary plate 20 and is continuous over the entire circumference in the circumferential direction. An extended engagement recess 32 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 step surface 34 extending over the entire circumference around the central axis of the upper auxiliary plate 22 is formed on the outer peripheral portion of the upper auxiliary plate 22. By increasing the thickness of the upper auxiliary plate 22 on the outer peripheral side of the step surface 34, an annular engagement member extending continuously along the outer peripheral edge of the upper auxiliary plate 22 over the entire circumference in the circumferential direction is provided. A mating projection 36 is formed integrally with the upper auxiliary plate 22 so as to protrude therefrom. The engaging projection 36 and the engaging recess 32 may be formed on either of the upper and lower auxiliary plates 22 and 20.

[0057]

The step surface 30 and the engaging concave portion 32 of the lower auxiliary plate 20 are aligned with the step surface 34 and the engaging convex portion 36 of the upper auxiliary plate 22, respectively. And the inner peripheral surface of the engagement. When the upper auxiliary plate 22 is superimposed on the lower auxiliary plate 20, the engagement convex portion 36 is fitted into the engagement concave portion 32, and the step surface 34 is superimposed on the step surface 30 in the radial direction, and Is formed. Thus, the positioning means 28 is constituted by the engaging concave portion 32 and the engaging convex portion 36, and the lower auxiliary plate 20 and the upper auxiliary plate 20 are aligned with the central axes

aligned with each other in the radial direction. The auxiliary plate 22 is superposed. Note that the positioning means 28 is provided on the inner peripheral side of the outer peripheral surfaces of the upper and lower auxiliary plates 22 and 20, so that the upper and lower auxiliary plates 22 and 20, and further, the polishing device 12 are not enlarged. .

[0058]

In the polishing apparatus 12 provided with the polishing pad auxiliary plate 10 having such a structure, as shown in FIG. 1, the upper and lower auxiliary plates 22 and 20 are disposed on the upper surface 18 of the rotating platen 14. The polishing plate auxiliary plate 10 is fixed and attached, and the polishing table 16 is fixedly supported on the upper surface of the upper auxiliary plate 22. Then, the rotary platen 14 is driven to rotate, and the workpiece such as a substrate is processed. To perform CMP (chemical mechanical polishing). The polishing apparatus 12 includes the polishing pad auxiliary plate 10 having a specific structure, so that the following special technical effects can be exhibited.

[0059]

First, as shown in FIG. 2, while the polishing pad 16 is fixed to the upper surface of the upper auxiliary plate 22, the upper auxiliary plate 22 is fixed to the rotating platen 14 by the first fixing means 24. By removing the polishing pad 16 from the side auxiliary plate 20, the polishing pad 16 can be removed from the rotary platen 14. Then, even when the polishing pad 16 is removed from the rotating platen 14 and the surface (polishing surface) of the polishing pad 16 is cleaned or reworked, the polishing pad 16 can be fixed to the upper surface of the upper auxiliary plate 22. Accordingly, the upper auxiliary plate 22 reinforces not only when the polishing pad 16 is attached to and detached from the rotary platen 14, when the polishing pad 16 is cleaned or reworked, but also when the polishing pad 16 is transferred or stored. The function can prevent the polishing pad 16 from being bent or damaged, and can keep the polishing pad 16 in a good state.

[0060]

Also, when the polishing pad 16 is removed from the rotary platen 14 together with the upper auxiliary plate 22, the lower auxiliary plate 20 is left on the upper surface 18 of the rotary platen 14. When the polishing pad 16 is mounted on the rotating platen 14 again, the positioning

means 28 provided between the upper auxiliary plate 22 and the lower auxiliary plate 20 causes the upper auxiliary plate 22 and thus the polishing pad 16 to move downward. The center axis can be aligned with high precision and easily with respect to the plate 20 and thus the rotary platen 14.

[0061]

Here, the engaging concave portion 32 and the engaging convex portion 36 constituting the positioning means 28 are overlapped with almost no gap in a state where they are fitted to each other. Adverse effects on the vehicle can be prevented. In the present embodiment, an engaging portion, in other words, a positioning means 28 is formed at an outer peripheral edge of the outer peripheral portions of the upper and lower auxiliary plates 22 and 20, and a diameter which is a main region for polishing in the polishing pad 16. Since it is separated from the middle part in the direction, even if there is a small gap between the fitting portions of the engaging concave portions 32 and the engaging convex portions 36, the polishing characteristics of the polishing pad 16 are so large that a great problem occurs in the polishing characteristics. Adverse effects can be avoided.

[0062]

In addition, the engaging concave portion 32 and the engaging convex portion 36 that constitute the positioning means 28 are located on the overlapping surface of the upper and lower auxiliary plates 22 and 20, in other words, the outer peripheral end surfaces of the rotary platen 14 and the polishing pad auxiliary plate 10. Since it is formed on the inner peripheral side, the protrusion of the upper and lower auxiliary plates 22 and 20 on the outer peripheral surface can be avoided. Therefore, for example, as shown in FIGS. 1 and 2, even when the protective member 38 is installed near the outer peripheral side of the rotary platen 14 in the polishing apparatus 12, The polishing apparatus 12 provided with the upper and lower auxiliary plates 22 and 20 provided with the positioning means 28 can be realized while avoiding interference.

[0063]

Further, as described above, the polishing pad 16 can be quickly attached to and detached from the rotary platen 14 with accurate positioning accuracy while preventing the polishing pad 16 from being damaged. Therefore, the operation time of the expensive polishing equipment is not unnecessarily limited, and the improvement of the operation efficiency of the polishing equipment and the improvement of the production efficiency (polishing work efficiency) of

substrates and the like can be achieved.

[0064]

Further, since the attachment and detachment of the polishing pad 16 to and from the rotary platen 14 are easily realized, the polishing pad 16 can be reused at a practical level without special skill or knowledge.

That is, for example, the polishing pad 16 once removed from the rotary platen 14 is reused when the type of the object to be polished such as a substrate is switched, or the surface is grooved by another processing device as a measure against deterioration. The reuse of the polishing pad 16 once removed from the rotary platen 14 after reworking, etc., can be considered at a practical level.

[0065]

As described above, the first embodiment of the present invention has been described, but the specific structure of the present invention is not limited to the first embodiment. A plurality of other embodiments of the present invention provided with positioning means having a different structure between the upper and lower auxiliary plates 22 and 20 will be exemplified below, but these embodiments do not limit the configuration of the present invention. In the following embodiments, members and portions having the same structure as in the first embodiment are denoted by the same reference numerals as those in the first embodiment in corresponding portions in the drawings. , And detailed description thereof will be omitted.

[0066]
FIGS. 3 and 4 show a polishing apparatus 42 having a polishing pad auxiliary plate 40 according to a second embodiment of the present invention.

[0067]

In the polishing pad auxiliary plate 40, an engagement recess 44 is formed by an annular groove extending continuously in the circumferential direction on the outer peripheral portion of the

upper surface of the lower auxiliary plate 20.

On the other hand, an engagement projection 46 is formed on the outer peripheral portion of the lower surface of the upper auxiliary plate 22 by an annular projection extending continuously in the circumferential direction. The engaging projection 46 may be formed integrally with the upper auxiliary plate 22, but may be formed separately as shown in the figure. That is, in the present embodiment, an annular peripheral groove 48 which is opened on the lower surface of the upper auxiliary plate 22 and extends in the circumferential direction is formed, and the annular groove 48 formed separately from the peripheral groove 48 is formed. Is fitted and fixed at one end in the axial direction to form an engagement projection 46.

[0068]

The engaging concave portion 44 of the lower auxiliary plate 20 and the engaging convex portion 46 of the upper auxiliary plate 22 are both formed at corresponding radial positions around the center axis, and the upper and lower auxiliary plates 22 and 20 are overlapped. At this time, the upper and lower auxiliary plates 22, 20 are radially aligned with each other by fitting the engagement convex portion 46 into the engagement concave portion 44. In the present embodiment, the respective radially overlapping surfaces of the both side wall surfaces in the engagement concave portion 44 of the lower auxiliary plate 20 and the inner and outer peripheral surfaces of the engagement convex portion 46 of the upper auxiliary plate form two An engagement inner peripheral surface and an engagement outer peripheral surface of the set are configured.

[0069]
FIGS. 5 and 6 show a polishing apparatus 52 having a polishing pad auxiliary plate 50 according to a third embodiment of the present invention.

[0070]

In this polishing pad auxiliary plate 50, a step surface 54 as a circular engagement inner peripheral surface extending over the entire circumference around the central axis is formed on the outer peripheral portion of the lower auxiliary plate 20.

On the outer peripheral side of the step surface 54, the thickness of the lower auxiliary plate 20 is increased, so that the annular shape extends continuously along the outer peripheral edge of the lower auxiliary plate 20 in the entire circumferential direction. Are formed integrally with the lower auxiliary plate 20.

[0071]

On the other hand, a step surface 58 is formed on the outer peripheral portion of the upper auxiliary plate 22 as a circular engaging outer peripheral surface extending all around the central axis. By reducing the thickness of the upper auxiliary plate 22 on the outer peripheral side of the stepped surface 58, the upper auxiliary plate 22 extends continuously over the entire circumference in a circumferential direction with a cutout cross-sectional shape opened to the outer peripheral surface of the upper auxiliary plate 22. An annular engagement recess 60 is formed integrally with the upper auxiliary plate 22.

[0072]

Further, a female screw is formed on the step surface 54 of the lower auxiliary plate 20, while a male screw is formed on the step surface 58 of the upper auxiliary plate 22. Then, the male screw of the step surface 58 of the upper auxiliary plate 22 is screwed with the female screw of the step surface 54 of the lower auxiliary plate 20, and the step surface 54 of the lower auxiliary plate 20 and the step surface 58 of the upper auxiliary plate 22 are screwed. The upper auxiliary plate 22 is superimposed on the upper surface of the lower auxiliary plate 20 by superposing the upper auxiliary plate 22 in the radial direction. Further, in such a superimposed state, the second fixing means 62 for detachably fixing the upper and lower auxiliary plates 22 and 20 is formed by the screw structure of the step surfaces 58 and 54 of the upper and lower auxiliary plates 22 and 20. .

[0073]
The screw direction of the female and male screws in such a screwed structure is set so that the screws are not loosened in consideration of the rotational reaction force exerted on the rotary platen 14 of the polishing device 12 during polishing. Is desirable.

[0074]
FIGS. 7 and 8 show a polishing apparatus 66 having a polishing pad auxiliary plate 64 according

to a fourth embodiment of the present invention.

[0075]

In the polishing pad auxiliary plate 64, a columnar engaging projection 68 protruding upward is formed at the center of the upper surface of the lower auxiliary plate 20.

The engaging projection 68 may be formed integrally with the lower auxiliary plate 20, but may be formed separately as shown in the figure.

That is, in the present embodiment, a circular fitting recess 70 is formed on the central axis of the lower auxiliary plate 20, and a columnar block formed separately from the fitting recess 70 is formed in the fitting recess 70. The engagement protrusion 68 is formed by being fitted and fixed at one end in the axial direction. On the other hand, at the center of the lower surface of the upper auxiliary plate 22, a bottomed circular engaging concave portion 72 that opens to the lower surface on the central axis is formed. The engaging projection 68 and the engaging recess 72 may be formed on either of the upper and lower auxiliary plates 22 and 20.

[0076]

Then, when the upper and lower auxiliary plates 22 and 20 are overlapped, the engagement convex portion 68 is fitted into the engagement concave portion 72 so that the upper and lower auxiliary plates 22 and 20 are aligned with each other in the radial direction. It has become. In this embodiment, the outer peripheral surface of the engaging projection 68 of the lower auxiliary plate 20 and the inner peripheral surface of the engaging concave portion 72 of the upper auxiliary plate 22 allow the outer peripheral surface of the engagement and the inner peripheral surface of the engagement to be engaged. It is configured.

[0077]
FIG. 9 shows a polishing apparatus 76 having a polishing pad auxiliary plate 74 as a fifth embodiment of the present invention.

[0078]

In the polishing pad auxiliary plate 74, a columnar engaging projection 78 protruding upward is formed at the outer peripheral portion of the upper surface of the lower auxiliary plate 20.

The engaging projection 78 may be formed integrally with the lower auxiliary plate 20, or may be formed with a fitting recess in the lower auxiliary plate 20 like the engaging projection in the fourth embodiment. Alternatively, a separate pin or the like may be fixed by press fitting or the like. Further, as shown in FIGS. 10 to 11, a plurality of such engaging projections 78 are formed independently from each other at a predetermined distance in the circumferential direction on the outer peripheral portion of the lower auxiliary plate 20. Particularly preferably, the plurality of engaging projections 78 are formed at equal intervals in the circumferential direction and on the same circle on the central axis.

[0079]

On the other hand, on the outer peripheral portion of the lower surface of the upper auxiliary plate 22, a bottomed circular engaging concave portion 80 is provided at a position corresponding to each of the formation positions of the plurality of engaging convex portions 78 on the lower auxiliary plate 20. It is formed to open downward. The engaging projection 78 and the engaging recess 80 may be formed on either of the upper and lower auxiliary plates 22 and 20.

[0080]

When the upper and lower auxiliary plates 22 and 20 are overlapped, the engagement convex portions 78 are fitted into the engagement concave portions 80, respectively, so that the upper and lower auxiliary plates 22 and 20 are radially aligned with each other. It has become. In this embodiment, the outer peripheral surface of the engaging projection 78 of the lower auxiliary plate 20 and the inner peripheral surface of the engaging concave portion 80 of the upper auxiliary plate 22 define the outer peripheral surfaces of the lower auxiliary plate 20 and the upper auxiliary plate 22. An engaging outer peripheral surface and an engaging inner peripheral surface located at the portion are configured.

[0081]

In particular, as in the present embodiment, by employing positioning means including a plurality of engaging projections 78 and engaging recesses 80 that are independent in the circumferential direction, the superimposed upper and lower auxiliary plates 22 and 20 can be moved only in the radial direction. It is possible to position each other even in the circumferential direction.

[0082]
In place of the plurality of independent engaging recesses 80 formed in the upper auxiliary plate 22, a circumferential groove extending continuously in the circumferential direction around the central axis of the upper auxiliary plate 22 may be employed, or FIG. As shown in the sixth embodiment of the present invention, a circular step surface 82 is formed extending around the outer periphery of the upper auxiliary plate 22 over the entire circumference around the central axis, and is formed to be smaller than the step surface 82. By reducing the thickness on the outer peripheral side, it is also possible to form an annular engaging recess 83 extending continuously over the entire circumference in a circumferential direction with a notched cross-sectional shape opened to the outer peripheral surface of the upper auxiliary plate 22. .

[0083]
As described above, in the upper auxiliary plate 22, by forming the engaging surface of the engaging convex portion 78 of the lower auxiliary plate 20 continuously over the entire circumference, when the upper and lower auxiliary plates 20 and 22 are overlapped, There is no need to position the auxiliary plates 20 and 22 in the circumferential direction, and the mounting operation can be easily performed.

[0084]
FIG. 13 shows a polishing pad auxiliary plate 84 as a seventh embodiment of the present invention.

[0085]

In the polishing pad auxiliary plate 84, small diameter portions are provided in the upper part of the outer peripheral surface of the lower auxiliary plate 20 and the lower part of the outer peripheral surface of the upper auxiliary plate 22, respectively.

Then, the upper and lower auxiliary plates 22 and 20 are overlapped with each other, so that

each small diameter portion extends between the upper and lower auxiliary plates 22 and 20 with a predetermined width and extends over the entire circumference in the circumferential direction. A receiving recess 86 having a shape is formed.

[0086]

At the lower end of the small-diameter portion of the lower auxiliary plate 20, a groove-shaped engaging concave portion 88 is formed.

The engagement recess 88 is opened at the bottom surface of the accommodation recess 86 on the outer peripheral surface of the lower auxiliary plate 20.

Here, the bottom surface of the housing recess 86 refers to an annular surface of the surface forming the housing recess 86 that straddles the upper and lower auxiliary plates 22 and 20 and extends in the vertical direction in FIG.

On the other hand, a plate-shaped engaging convex portion 90 made of an elastic material is fixed to a small-diameter portion of the upper auxiliary plate 22 constituting the accommodation recess 86 at a base end thereof with a fixing pin 92 and attached. The engaging projection 90 is accommodated in an accommodation recess 86 formed on the outer peripheral surface of the upper and lower auxiliary plates 22, 20, and extends from the upper auxiliary plate 22 onto the outer peripheral surface of the lower auxiliary plate 20. I have. Then, the engaging claw portion 94 formed at the tip portion of the engaging convex portion 90 is engaged with the engaging concave portion 88 formed on the small diameter portion of the lower auxiliary plate 20, and It is configured to be held in a locked state based on elasticity.

[0087]

Furthermore, a plurality of such engaging projections 90 are provided on the outer peripheral surfaces of the upper and lower auxiliary plates 22 and 20 at a predetermined distance in the circumferential direction. Each of the engaging projections 90 attached to the outer peripheral surface of the upper auxiliary plate 22 is elastically pressed against the outer peripheral surface of the lower auxiliary plate 20, so that the upper and lower auxiliary plates 22, 20 are aligned on the central axis. And positioning means for positioning each other. Further, by engaging the

engaging claw portion 94 of the engaging convex portion 90 with the engaging concave portion 88, the upper and lower auxiliary plates 22, 20 are held in an overlapping state, and a fixing means for applying a fixing force is also configured. I have.

[0088]

It should be noted that, instead of the engagement projection 90 having the engagement claw portion 94 that engages with the engagement recess 88 as described above, for example, as in the eighth embodiment of the present invention shown in FIG. A connecting plate 100 which extends over the auxiliary plates 22 and 20 and is superimposed on the bottom surface of the accommodation recess 86 is adopted, and both end portions of the connecting plate 100 are attached to the outer peripheral surface of each of the upper and lower auxiliary plates 22 and 20. It is also possible to fix them with connecting pins 102, 102. Note that 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 auxiliary plates 22, 20 by the connecting plate 100 can be released. The attachment / detachment of the upper auxiliary plate 22 to which the polishing pad 16 is fixed is allowed.

[0089]

Further, the first fixing means 24 and the second fixing means 26 made of a double-sided tape or the like shown in the first to eighth embodiments are used when the upper and lower auxiliary plates 22 and 20 and the rotary platen 14 are removed. Is desirably held on the fixing surface on the member side. This facilitates handling of the upper and lower auxiliary plates 22, 20 and the first and second fixing means 24, 26 in the detached state. It should be noted that which fixing surface the first and second fixing means 24 and 26 remain on is determined by making the fixing forces on both surfaces of the first fixing means and the second fixing means 24 and 26 themselves different from each other. It can be set by making the surface roughness, material, etc. of the upper and lower auxiliary plates 22, 20 and the rotary platen 14 to be fixed different from each other.

[0090]

In particular, the first fixing means 24 is desirably held on the fixing surface on the lower auxiliary plate 20 side when the lower auxiliary plate 20 is detached, so that the maintenance of

the upper surface 18 of the rotary platen 14 is facilitated. Become. On the other hand, as shown in FIG. 2 in the first embodiment, the second fixing means 26 is held on the fixing surface on the upper auxiliary plate 22 side when the upper auxiliary plate 22 is removed. Alternatively, for example, as in a ninth embodiment of the present invention shown in FIG. By holding the second fixing means 26 on the fixing surface on the upper auxiliary plate 22 side, the detached upper auxiliary plate 22 can be removed from the rotating platen of a device for reworking such as grooving of the polishing pad 16. At the time of mounting, it is also possible to use the second fixing means 26 held by the upper auxiliary plate 22 for mounting. On the other hand, by holding the second fixing means 26 on the fixing surface on the lower auxiliary plate 20 side, when mounting another upper auxiliary plate 22 with another polishing pad 16 mounted on the lower auxiliary plate 20, It is also possible to attach using the second fixing means 26 held on the lower auxiliary plate 20.

[0091]

Further, the engaging concave portions 32, 44, 60, 72, 80, (83), 88 and the engaging convex portions 36, 46, 56, 70, 78, 90 shown in the first to seventh embodiments are lower. The side auxiliary plate 20 and the upper auxiliary plate 22 may be provided on mutually opposite sides. For example, as shown in FIG. 16 of the tenth embodiment of the present invention, the engaging outer peripheral surface of the polishing pad auxiliary plate 10 shown in FIGS. It is also possible to form the step surface 30 and the engaging concave portion 32 that constitute the upper auxiliary plate 22, and to form the step surface 34 and the engaging convex portion 36 that form the inner peripheral peripheral surface on the lower auxiliary plate 20. It is possible.

[0092]

Furthermore, the engaging concave portions 32, 44, 60, 72, 80, (83) and the engaging convex portions 36, 46, 56, 70, 78 shown in the first to sixth embodiments are overlapped with each other. It is also possible to give an inclination angle with respect to the outer peripheral surface of the engaging projection for positioning the upper and lower auxiliary plates 22 and 20 and the inner peripheral surface of the engaging recess. For example, as shown in FIG. 17, an eleventh embodiment of the present invention includes a step surface 34 as an engagement inner peripheral surface of an engagement convex portion 36 formed on the outer peripheral portion of the lower auxiliary plate 20 so as to protrude. On the other hand, the engaging convex portion 36 has a taper in an inclined direction that gradually tapers in the projecting direction, while the engaging convex portion 36 has a stepped surface 30 as an engaging outer peripheral surface of the engaging concave portion 32 formed in the outer peripheral portion of the upper auxiliary

plate 22. Thus, a taper of the inclination direction and the inclination angle corresponding to the step surface 34 can be provided. Thereby, the work of fitting the engaging projections 36 into the engaging recesses 32 and superimposing the upper and lower auxiliary plates 22 and 20 can be further performed by using the taper provided on the two stepped surfaces 34 and 30 as a guide surface. This can be easily performed.

[0093]

Incidentally, as shown in the twelfth embodiment of the present invention shown in FIG. 18 and the thirteenth embodiment of the present invention shown in FIG. 19, the lower auxiliary plate 20 is independent in the circumferential direction. Even when adopting a plurality of projection-shaped engaging projections 78 formed in a plurality of positions and a plurality of hole-shaped engaging recesses 80 formed at corresponding positions of the upper auxiliary plate 22, the engagement projections 78 can be used. The tapered portion 104 having a tapered shape can be formed by giving a slant angle to the outer peripheral surface of the protruding tip portion of the projection. In FIG. 19, a separately formed locking pin 106 is fixed to a fitting hole 105 formed in the lower auxiliary plate 20 by press-fitting or the like, thereby forming an engaging projection 78. The lower end of the locking pin 106 is also provided with a tapered portion 104 similar to the upper end. Thereby, the direction of the locking pin 106 is lost and the handling is easy, and the press-fitting work into the fitting hole 105 is also easy.

[0094]

Further, in the fourteenth embodiment of the present invention shown in FIG. 20, as a kind of positioning means for aligning the center axis in the state where the upper and lower auxiliary plates 22 and 20 are superimposed, a straddle between the upper and lower auxiliary plates 22 and 20 is provided. A positioning sleeve 108 is shown which is extrapolated. The positioning sleeve 108 has an inner diameter that is the same as or slightly larger than the outer diameter of the upper and lower auxiliary plates 22 and 20 each having a disk shape having substantially the same outer diameter. Is formed. The positioning sleeve 108 is used when the upper and lower auxiliary plates 22 and 20 are overlapped, and the upper and lower auxiliary plates 22 and 20 are overlapped in the positioning sleeve 108, so that the upper and lower auxiliary plates 22 and 20 are aligned with the center axis. They can be overlapped in the axial direction and fixed to each other by the second fixing means 26. Therefore, after the upper and lower auxiliary plates 22 and 20 are overlapped and fixed to each other, the positioning sleeve 108 can be removed, thereby positioning the upper and lower auxiliary plates 22 and 20 on the outer peripheral surface. It is possible to fix them to each other without any means and in an accurate alignment

state.

[0095]

Furthermore, in the fifteenth embodiment of the present invention shown in FIG. 21, a slit-like engagement groove 110 extending over the overlapping direction in the overlapping state of the upper and lower auxiliary plates 22 and 20 is formed. ing. The engagement grooves 110 are opened in the outer peripheral surfaces of the upper and lower auxiliary plates 22 and 20 and have a predetermined depth inward in the radial direction, and a plurality of the engagement grooves 110 are provided independently of each other in the circumferential direction of the upper and lower auxiliary plates 22 and 20. Have been. When the plate-shaped engagement plate 112 is fitted into the engagement groove 110 from the opening on the outer peripheral surface, the upper and lower auxiliary plates 22 and 20 are positioned relative to each other by the engagement plate 112. Is connected. Although the engagement plate 112 is formed separately from the upper and lower auxiliary plates 22 and 20, for example, one of the upper and lower auxiliary plates 22 and 20 may be integrally formed with a shape protruding toward the other. . In that case, the engagement groove 110 is formed only on the other auxiliary plate.

[0096]

Further, in the sixteenth embodiment of the present invention shown in FIG. 22, a fitting concave portion 114 is formed on the lower surface of the upper auxiliary plate 22 as an engaging concave portion. Particularly, in the present embodiment, the fitting concave portion 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 is formed with a fitting convex portion 116 as an engaging convex portion projecting upward on the upper surface superimposed on the upper auxiliary plate 22. In the present embodiment, the fitting protrusion 116 is formed as an annular protrusion corresponding to the fitting recess 114. Then, in a state where the upper and lower auxiliary plates 22 and 20 are overlapped, the fitting convex portion 116 enters the fitting concave portion 114 and is positioned.

[0097]

Further, the fitting protrusion 116 has a hollow structure, and a fluid reservoir 118 is formed inside the fitting protrusion 116 so as to be sealed with respect to an external space.

Furthermore, 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 swellable and deformable in the radial direction. Specifically, for example, by forming the fitting convex portion 116 with a rubber elastic body or the like, an inner peripheral wall that can swell inward in the radial direction and an outer peripheral wall that can swell outward in the radial direction can be realized. is there.

[0098]

Further, the lower auxiliary plate 22 is formed with a fluid passage 120 communicating with the fluid reservoir 118 and extending radially outward and opening on the outer peripheral surface. , A pressure screw 122 is screwed. In addition, a sealed area including the fluid passage 120 and the fluid reservoir 118 sealed by the pressure screw 122 is filled with an incompressible fluid such as oil.

[0099]

Thereby, 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 peripheral wall and the outer peripheral wall of the fluid reservoir 118 can bulge outward. As a result, the fitting convex portion 116 is expanded and pressed against the inner surface of the fitting concave portion 114, so that the upper and lower auxiliary plates 22, 20 can be positioned relative to each other by mutual frictional force, and can also exert a fixing force. I have.

[0100]

When removing the upper auxiliary plate 22 from the lower auxiliary plate 20, the pressure of the fluid reservoir 118 is reduced by rotating the pressing screw 122 in a direction to loosen the outer auxiliary plate 20 to move the outer peripheral side of the lower auxiliary plate 20. By lowering, the pressing force of the fitting projection 116 against the fitting recess 114 can be released.

[0101]

In addition, although not enumerated one by one, the present invention can be implemented with various changes, modifications, improvements, etc. based on the knowledge of those skilled in the art. By attaching an O-ring or a sealing material to the portion, it is also possible to prevent

foreign matter from entering the overlapping surface of the upper and lower auxiliary plates and the like.

[0102]

Further, in addition to the above-described auxiliary plates 20 and 22 having the two-layer structure, it is also possible to add additional auxiliary plates in a stacked state and fixed by fixing means.

By employing the auxiliary plate of the third layer as described above, it is possible to realize an elastic supporting state or to dispose the intermediate layer in a disposable manner.

[0103]

10, 40, 50, 64, 74, 84: auxiliary plate for polishing pad, 12, 42, 52, 66, 76: polishing device, 14: rotary platen, 16: polishing pad, 18: upper surface, 20: lower side Auxiliary plate, 22: upper auxiliary plate, 24: first fixing means, 26, 62: second fixing means, 28: positioning means, 30, 58: step surface (engaging outer peripheral 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

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DESCRIPTION JP5789869

Polishing pad auxiliary plate and polishing apparatus provided with polishing pad auxiliary plate

[0001]
The present invention relates to a technique related to polishing of a substrate which is a workpiece requiring high flatness processing accuracy such as a silicon wafer, a semiconductor substrate, and a glass substrate, and particularly relates to polishing the surface of the substrate. TECHNICAL FIELD The present invention relates to a technique that makes it possible to reuse a polishing pad used when performing polishing.

[0002]

As is well known, in the manufacture of semiconductors, a polishing process for planarizing the surface of a substrate such as a silicon wafer, a semiconductor substrate, or a glass substrate as a constituent material is performed.

Such polishing treatment is generally performed by directly fixing a disk-shaped polishing pad made of a resin material or the like directly on a rotating platen of a polishing apparatus with a double-sided tape, and supplying a polishing liquid containing abrasive grains, Polishing is performed by relatively rotating the substrate.

[0003]

As a polishing pad for performing such a polishing treatment, a resin pad made of foamed or non-foamed urethane or the like, as described in JP-A-2002-11630 (Patent Document 1) and the like, is used. Has been adopted. Also, in many cases, the polishing surface of such a polishing pad is provided with a groove processing such as concentric, lattice, radial, or the like, or bubbles of a foamed resin are opened.

[0004]

By the way, when performing polishing using a polishing pad, when changing the type of substrate to be polished, the polishing pad used for polishing must be peeled off from the rotary platen and replaced with another polishing pad. May not be. In addition, for example, when the polishing pad that has been degraded due to the polishing process is to be reused for the purpose of re-use or the like, the polishing pad is moved from the rotary platen to another processing device such as surface grooving. It needs to be peeled off.

[0005]

However, since the thin disk-shaped polishing pad is firmly fixed to the rotating platen of the polishing apparatus with an adhesive tape, when the polishing pad is peeled off from the rotating platen, Damage such as bending, bending, wrinkling, and tearing is likely to occur. Therefore, due to such damage, there is a problem in that the polishing pad cannot be reused and has to be discarded in many cases even though the life of the polishing pad has not been reached.

[0006]

In addition, the work of peeling the polishing pad from the rotary platen with great care so as not to damage it has a problem that it requires a skill and attention, and thus places a heavy burden on the operator. In addition, since a considerable amount of time is required to separate the polishing pad from the rotary platen, the polishing apparatus, which is an expensive and valuable equipment, must be stopped for a long time, and the operation time of the equipment must be reduced. There was also a problem that was restricted.

[0007]

In view of this, the present inventor has previously disclosed in Japanese Unexamined Patent Application Publication No. 2010-214579 (Patent Document 2) a method in which an auxiliary plate is attached to the back surface of a polishing pad, and the polishing pad is attached to a rotating platen of a polishing apparatus via the auxiliary plate. On the other hand, a polishing pad with an auxiliary plate that is fixed with a double-sided tape was proposed. In such a polishing pad with an auxiliary plate, since the polishing pad is attached to and detached from the rotary platen while being supported by the auxiliary plate, damage to the polishing pad during attachment and detachment is reinforced by the auxiliary plate. Therefore, the polishing pad can be attached to and detached from the rotary platen with good workability while preventing the polishing pad from being damaged.

[0008]
However, as a result of further research and study by the present inventors, it has been found that it is difficult to say that the polishing pad with the auxiliary plate proposed in Patent Literature 2 is easily compatible with all polishing apparatuses.

[0009]

That is, when the polishing pad is overlaid and fixed on the rotating surface plate, it is necessary to align the center of the polishing pad with the rotation center of the rotating surface plate, especially in a polishing pad having a groove or the like on the polishing surface. Accuracy is required for center alignment.

When the number of attachment / detachment of the polishing pad to the rotary platen increases by adopting the auxiliary plate as described above, the work of center alignment when mounting the polishing pad on the rotary platen becomes more difficult, and the labor burden is increased. Being big is a big problem.

[0010]

Further, in the polishing pad with an auxiliary plate proposed in Patent Document 2, the auxiliary plate is detachably mounted while being center-aligned with respect to the rotary platen. A fixing means such as an outer ring may be provided on the outer peripheral surface of the board. On

the other hand, in some polishing apparatuses, 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. Therefore, if such a peripheral ring is to be employed, when a polishing apparatus happens to be used in which the space on the outer peripheral side of the rotary platen is narrow, the polishing apparatus may need to be modified. It is.

[0011]
JP, 2002-11630, A JP, 2010-214579, A

[0012]
The present invention has been made in view of the above-described circumstances, and it has been made possible to easily attach / detach a polishing pad to / from a rotating surface plate while sufficiently securing a fixing force of the polishing pad to the rotating surface plate. In addition, a polishing pad auxiliary plate having a novel structure that can prevent the polishing pad from being damaged particularly when the polishing pad is removed from the rotary platen and can be advantageous in realizing reuse of the polishing pad, for example, is provided. To provide.

[0013]
In addition, the present invention can easily and accurately perform the centering operation when mounting the polishing pad on the rotating surface plate, can reduce the labor burden, and can provide a conventional polishing apparatus of various specifications. It is another object of the present invention to provide an auxiliary pad for a polishing pad having an improved structure, which can be easily and advantageously applied to the rotary platen in the above without requiring any special modification.

[0014]
Further, another object of the present invention is to provide a polishing apparatus provided with a polishing pad auxiliary plate having such a novel structure.

[0015]
In order to solve such a problem, a first aspect of the present invention relating to a polishing pad auxiliary plate includes (A) a polishing pad attached to a rotating plate of a polishing apparatus so that the polishing pad can be detachably attached to the rotating plate. A polishing pad auxiliary plate to be attached, wherein (B) a lower auxiliary plate which is arranged to be superimposed on the upper surface of the rotary platen, and (C) a first fixing device which fixes

the lower auxiliary plate to the rotary platen. Means; (D) an upper auxiliary plate provided with a pad supporting surface on which the polishing pad is superimposed and fixed, and arranged on the upper surface of the lower auxiliary plate; and (E) the upper auxiliary plate. (F) positioning means for positioning the lower auxiliary plate and the upper auxiliary plate with respect to each other and aligning the center axes thereof, and The lower auxiliary plate is provided with the first fixing hand with respect to the rotary platen of the polishing device. The upper auxiliary plate is removed from the lower auxiliary plate fixed to the rotary platen while being fixed to the rotating platen, so that the polishing is performed while being fixed to the pad supporting surface of the upper auxiliary plate. The pad can be removed from the rotary platen, and the removed upper auxiliary plate can be fixed to the lower auxiliary plate again by being fixed to the lower auxiliary plate in a state of being aligned by the positioning means. The fixing force between the lower auxiliary plate and the upper auxiliary plate by the second fixing means is larger than the fixing force between the rotary platen and the lower auxiliary plate by the first fixing means. It is characterized by a polishing pad auxiliary plate that is also small.

[0016]

In the polishing pad auxiliary plate having the structure according to the present invention, the polishing pad is fixedly mounted on the rotary platen via the upper auxiliary plate and the lower auxiliary plate.

This allows the upper auxiliary plate to be removed from the lower auxiliary plate while the lower auxiliary plate is fixed to the rotary platen, and the polishing pad to be removed from the rotary platen while being fixed to the upper auxiliary plate. Becomes possible.

[0017]

Therefore, while the polishing pad is reinforced and protected by the upper auxiliary plate, the polishing pad can be removed from the rotary platen while preventing damage to the polishing pad, and handling of the thin polishing pad becomes easy.

For example, when the polishing pad is repeatedly attached / detached when the polishing target or the polishing conditions are changed, or when the worn polishing pad is removed and re-mounted after the regenerating process, the attaching / detaching of the polishing pad to / from the rotating platen or polishing. It is also possible to easily perform operations such as

reproduction processing on the pads.

[0018]

In addition, since the lower auxiliary plate fixed to the rotating platen and the upper auxiliary plate removed together with the polishing pad are mutually centered by the positioning means, it is necessary to align the lower auxiliary plate with the rotating platen. The polishing pad can be more easily attached and detached.

In particular, since the positioning means is provided between the lower auxiliary plate and the upper auxiliary plate, it is not necessary to perform special processing or the like on the rotary platen.

In addition, such positioning means can be prevented from protruding more to the outer peripheral side than the rotary platen.For example, a special modification is required for a polishing apparatus or the like in which a protective cover or the like is provided on the outer peripheral side of the rotary platen. Applicable without application.

[0019]
In the polishing pad auxiliary plate according to the first aspect of the present invention, in the polishing pad auxiliary plate, the fixing force between the lower auxiliary plate and the upper auxiliary plate by the second fixing unit is adjusted by the rotation by the first fixing unit. An aspect is adopted in which the force is smaller than the fixing force between the surface plate and the lower auxiliary plate.

[0020]

According to such a first aspect, by setting the fixing force in the first and second fixing means by mutually adjusting, the upper auxiliary plate with the polishing pad fixed is fixed to the rotating platen. The work of removing the lower auxiliary plate from the fixed state is further facilitated.

In short, there is no need to perform any special operation to keep the lower auxiliary plate fixed

to the rotary platen, and the upper side of the polishing pad is supported while the lower auxiliary plate remains fixed to the rotary platen. It can be easily removed from the rotary platen while being fixed to the plate.

[0021]
A second aspect of the present invention is the polishing pad auxiliary plate according to the first aspect, wherein the positioning means is located on an inner peripheral side of outer peripheral surfaces of the lower auxiliary plate and the upper auxiliary plate. It is provided.

[0022]

In the polishing pad auxiliary plate of this aspect, the protrusion of the upper and lower auxiliary plates to the outer peripheral side in the positioning means is completely avoided.

Therefore, for example, even when the outer diameter of the upper and lower auxiliary plates is set to be equal to or slightly smaller than the outer diameter of the rotary platen, the polishing pad is secured from the rotary platen while ensuring a sufficiently large supporting surface. It is possible to prevent the positioning means from protruding on the outer peripheral side, and even if a protective cover or the like is installed on the outer peripheral side of the rotary platen, it may be an obstacle when applying the polishing pad auxiliary plate according to the present invention. Be avoided.

[0023]
A third aspect of the present invention is the polishing pad auxiliary plate according to the second aspect, wherein the positioning means is provided on one of the lower auxiliary plate and the upper auxiliary plate and projects toward the other. And an engaging concave portion provided on the other of the lower auxiliary plate and the upper auxiliary plate and engaged with the engaging convex portion.

[0024]

In the polishing pad auxiliary plate 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.

In addition, by adjusting the shape, size, number, and the like of the engaging protrusions and the engaging recesses, the direction and the acting force of the positioning operation can be easily set with a large degree of freedom.

[0025]
According to a fourth aspect of the present invention, in the auxiliary pad for a polishing pad according to the third aspect, the engaging protrusion and the engaging recess are located on outer peripheral portions of the lower auxiliary plate and the upper auxiliary plate. It is formed with an engaging portion that engages.

[0026]

In the polishing pad auxiliary plate of this aspect, the engaging outer peripheral surface of the engaging convex portion and the engagement of the engaging concave portion are located at the outer peripheral portion distant from the center of the polishing pad auxiliary plate and are fitted into the concave and convex portions. By forming the inner peripheral surface, the relative positioning accuracy of the upper and lower auxiliary plates, in particular, the positioning accuracy in the radial direction can be improved.

As shown in the sixth and seventh embodiments described later, the engaging outer peripheral surface of the engaging convex portion and the engaging inner peripheral surface of the engaging concave portion are formed around the center of the polishing pad auxiliary plate. It may be in the form of extending in the circumferential direction along the outer peripheral edge of the auxiliary pad for polishing pad, or may be formed on the periphery like an engaging convex portion and an engaging concave portion formed on the outer peripheral portion of the auxiliary plate for polishing pad. It may be a partially located form.

[0027]
According to a fifth aspect of the present invention, in the auxiliary pad for a polishing pad according to the fourth aspect, the engaging portion in the engaging convex portion and the engaging concave portion includes the lower auxiliary plate and the upper auxiliary plate. Are formed by an annular engaging outer peripheral surface and an engaging inner peripheral surface which extend continuously in the circumferential direction and are fitted to each other.

[0028]
In the auxiliary plate for a polishing pad of this aspect, more preferably, the engagement concave portion and the engagement convex portion are formed with an annular engagement inner and outer peripheral surface extending around the central axis of the auxiliary pad for the polishing pad. Accordingly, when the upper auxiliary plate is attached to the lower auxiliary plate, mutual alignment in the circumferential direction is not required, and work can be performed easily and quickly.

[0029]
A sixth aspect of the present invention is the auxiliary pad for a polishing pad according to the fourth aspect, wherein the lower auxiliary plate is provided at a plurality of locations on the outer peripheral portion of the lower auxiliary plate and the upper auxiliary plate. The engagement recess opening toward the other at one of the overlapping surfaces of the plate and the upper auxiliary plate, and one at the other of the mutual overlapping surfaces of the lower auxiliary plate and the upper auxiliary plate. The engaging protrusions protruding toward each other are formed at positions corresponding to each other, and the engaging portions are configured by fitting of the engaging protrusions into the engaging recesses.

[0030]
In the polishing pad auxiliary plate of this aspect, the mutual positioning of the upper and lower auxiliary plates can be easily realized not only in the direction perpendicular to the axis but also in the circumferential direction around the central axis.

[0031]
According to a seventh aspect of the present invention, in the polishing pad auxiliary plate according to the fourth aspect, a plurality of locations on an outer peripheral portion of one of the lower auxiliary plate and the upper auxiliary plate are arranged from a plurality of locations on the periphery toward the other. The protruding engagement convex portion is formed of an elastic material, and the engagement convex portion is formed on an outer peripheral surface of the other of the lower auxiliary plate and the upper auxiliary plate so as to be opened. The engaging portion is configured by engaging a tip of the portion.

[0032]

In the auxiliary plate for a polishing pad of this aspect, the engagement portion can be formed by

exposing the engagement portion on the outer peripheral surface of the upper and lower auxiliary plate, whereby the engagement state of the engagement portion can be easily confirmed visually or the like. It becomes possible.

Further, in this aspect, the engagement state of the engagement portion can be stably maintained by utilizing the elasticity of the engagement projection.

[0033]
According to an eighth aspect of the present invention, in the auxiliary pad for a polishing pad according to the third aspect, the engaging convex portion and the engaging concave portion are arranged on a central axis of the lower auxiliary plate and the upper auxiliary plate. It is provided.

[0034]

In the auxiliary pad for a polishing pad of this aspect, by providing the engaging convex portion and the engaging concave portion on the central axis of the upper and lower auxiliary plates, the central axis of the upper and lower auxiliary plates can be aligned by one engaging portion. become.

Further, when the mutual positioning of the engaging convex portion and the engaging concave portion provided on the center axis is not required, the mutual positioning of the upper and lower auxiliary plates in the circumferential direction is not necessary, and the engaging convex portion and the engaging concave portion are not required. Can easily be engaged.

[0035]
A ninth aspect of the present invention is the polishing pad auxiliary plate according to the eighth aspect, wherein the outer peripheral surface of the engagement convex portion and the inner peripheral surface of the engagement concave portion are formed with screw grooves that are screwed together. The second fixing means is formed by screwing the engaging projection and the engaging recess forming the positioning means.

[0036]

In the polishing pad auxiliary plate of the present aspect, the fixing force between the upper auxiliary plate and the lower auxiliary plate can be obtained by the positioning means.

Therefore, it is possible to constitute the second fixing means only by such positioning means, or to supplement the fixing force between the upper and lower auxiliary plates by the second fixing means by the positioning means.

[0037]
A tenth aspect of the present invention is the polishing pad auxiliary plate according to any one of the third, fourth, fifth, sixth, eighth, and ninth aspects, wherein one of the lower auxiliary plate and the upper auxiliary plate is provided. The provided engaging projection is made of the same material as one of the lower auxiliary plate and the upper auxiliary plate.

[0038]

In the polishing pad auxiliary plate of the present aspect, it is possible to prevent the support characteristics of the polishing pad in the auxiliary plate superimposed on the upper and lower portions from being largely different locally at the portion where the engaging projection is formed.

Therefore, when a pressing force acts on the surface of the polishing pad during pad polishing, the pressing reaction force and the elasticity of the polishing pad are reduced at the portions where the engaging projections and engaging recesses are formed on the upper and lower auxiliary plates supporting the polishing pad. It is possible to reduce or avoid inconveniences such as polishing accuracy caused by local differences in characteristics such as the polishing accuracy.

[0039]
Further, according to the present invention, the polishing pad auxiliary plate according to the present invention according to any one of the first to tenth aspects is mounted on an upper surface of a rotary platen, and a gap is formed on an outer peripheral side of the rotary platen. A polishing apparatus in which a protective member is disposed at a distance, and which is located on the inner peripheral side with respect to the outer peripheral end surfaces of the rotary platen and the auxiliary plate for the polishing pad and provided with the positioning means, is also

characterized in that the polishing apparatus is characterized in that. .

[0040]
By employing a polishing pad auxiliary plate structured according to the present invention or using a polishing apparatus structured according to the present invention, the polishing pad is easily removed from the rotary platen while preventing damage to the polishing pad. This makes it possible to easily and accurately adjust the position of the polishing pad to the rotating platen when mounting the polishing pad.

[0041]

FIG. 1 is a longitudinal sectional view showing a main part of a polishing apparatus equipped with a polishing pad auxiliary plate as a first embodiment of the present invention.

FIG. 2 is an explanatory view of a vertical section showing a state where a polishing pad is removed in the polishing apparatus shown in FIG. 1.

The longitudinal section showing the important section of the polisher equipped with the auxiliary board for polishing pads as a second embodiment of the present invention.

FIG. 4 is an explanatory longitudinal sectional view showing a state in which a polishing pad is removed in the polishing apparatus shown in FIG. 3.

The longitudinal section showing the important section of the polish device in which the auxiliary board for polish pads as a 3rd embodiment of the present invention was attached.

FIG. 6 is an explanatory longitudinal sectional view showing a state where a polishing pad is removed in the polishing apparatus shown in FIG. 5.

The longitudinal section showing the important section of the polish device in which the auxiliary board for polish pads as a 4th embodiment of the present invention was attached.

FIG. 8 is an explanatory view of a vertical section showing a state where a polishing pad is removed in the polishing apparatus shown in FIG. 7. The longitudinal section showing the important section of the polish device in which the auxiliary board for polish pads as a 5th embodiment of the present invention was attached. FIG. 10 is a side view of a lower auxiliary plate constituting the polishing pad auxiliary plate shown in FIG. 9. FIG. 11 is a plan view of the lower auxiliary plate shown in FIG. 10. The longitudinal section showing the important section of the polisher equipped with the auxiliary board for polishing pads as a 6th embodiment of the present invention. The longitudinal section showing the important section of the polisher equipped with the auxiliary board for polishing pads as a 7th embodiment of the present invention. The longitudinal section showing the important section of the polisher equipped with the auxiliary board for polishing pads as an 8th embodiment of the present invention. FIG. 19 is an explanatory view of a vertical section showing a state in which a polishing pad auxiliary plate is removed as a ninth embodiment of the present invention. The explanatory view of the longitudinal section showing the state where the auxiliary board for polishing pads as a 10th embodiment of the present invention was removed. The explanatory view of the longitudinal section showing the state where the auxiliary board for polishing pads as an eleventh embodiment of the present invention was removed. The explanatory view of the longitudinal section showing the state where the auxiliary board for polishing pads as a 12th embodiment of the present invention was removed. The longitudinal section explanatory drawing showing the state where the auxiliary board for polishing pads as a 13th embodiment of the present invention was removed. Explanatory drawing of the longitudinal section which shows the state which positioned the auxiliary plate for polishing pads as 14th embodiment of this invention. Explanatory drawing of the longitudinal section which shows the state which positioned the auxiliary plate for polishing pads as 15th embodiment of this invention. The explanatory view of the longitudinal section showing the state where the auxiliary board for polishing pads as a 16th embodiment of the present invention was removed.

[0042]

Hereinafter, embodiments of the present invention will be described with reference to the drawings. First, FIGS. 1 and 2 show a polishing pad auxiliary plate 10 as a first embodiment of the present invention. The polishing pad auxiliary plate 10 is used by being attached to a rotary platen 14 of a polishing apparatus 12, and a polishing pad 16 is detachably attached to the rotary platen 14.

[0043]

The polishing apparatus is used, for example, as a CMP apparatus as described in, for example, Japanese Patent Application Laid-Open No. 2010-141155, and has a well-known basic structure. A rotating shaft extending in the vertical direction is rotatably supported by the installed apparatus main body, and a disk-shaped rotating surface plate 14 is fixed to an upper end of the rotating shaft. The rotary platen 14 has a flat upper surface 18 extending in the horizontal direction, and the upper surface 18 is a support surface of the polishing pad 16. Further, a rotation output shaft of an electric motor is connected to the rotation shaft, and the driving force of the electric motor is transmitted, so that the rotation shaft and, consequently, the rotation platen 14 are driven to rotate around the center axis. I have. A nozzle for supplying a polishing slurry is arranged above the upper surface 18 supporting the polishing pad 16, and a nozzle or the like to be polished is held on the polishing pad 16 while being rotated while being held. A polishing head for performing polishing by pressing is provided.

[0044]

In such a polishing apparatus, the polishing pad auxiliary plate 10 mounted on the rotary platen 14 includes a lower auxiliary plate 20 and an upper auxiliary plate 22. The lower auxiliary plate 20 is fixed to the upper surface 18 of the rotary platen 14 by first fixing means 24, and the upper auxiliary plate 22 is further fixed to the upper surface of the lower auxiliary plate 20. It is fixed by two fixing means 26. That is, the lower auxiliary plate 20 and the upper auxiliary plate 22 are overlapped and fixed to each other via the second fixing means 26 to form the polishing pad auxiliary plate 10 having a two-layer structure as a whole. It is attached to the upper surface 18 of the turntable 14 by first fixing means 24.

[0045]

Each of the lower auxiliary plate 20 and the upper auxiliary plate 22 is formed in a thin and substantially circular flat plate shape, and has a flat surface (upper surface) and a back surface (lower surface). It is desirable that the upper and lower auxiliary plates 22 and 20 are made of a harder material than the polishing pad 16 to be mounted, or have a higher 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 rotating platen 14, while the upper auxiliary plate 22 can be attached and detached after being attached to the rotating platen 14. Therefore, it is desirable that at least the upper auxiliary plate 22 should have a higher member rigidity than the polishing pad 16.

[0046]

However, the upper auxiliary plate 22 supports the polishing pad 16 and, in addition to the polishing process by the polishing device 12, the strength and rigidity required for various processes such as dressing, cleaning, and re-grooving on the polishing pad surface. Any material 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 do not bear the supporting strength or rigidity of the polishing pad 16 by itself. For example, during polishing, the upper auxiliary plate 22 is placed on the rotating platen 14 of the polishing apparatus 12. Since the lower surface is supported by the rotating platen 14 by being used in a superposed state, the strength and rigidity of a single body are not required to that extent. Therefore, in addition to metals such as stainless steel, synthetic resins, fiber-reinforced resins, and the like can be used as the material for forming the lower auxiliary plate 20 and the upper auxiliary plate 22. In particular, synthetic resin materials are lighter in weight and easier to process and handle than metal materials. For example, polycarbonate and the like have the advantage of being stable in thickness dimensional accuracy and excellent in low distortion characteristics against temperature changes. .

[0047]

In order to obtain a stable supporting force over the entire polishing pad 16, it is preferable that the outer diameter of the upper auxiliary plate 22 be set to be equal to or larger than the outer diameter of the polishing pad 16, and that the lower auxiliary It is desirable that the outer diameter of the plate 20 is set to be equal to or greater than the outer diameter of the upper auxiliary plate 22, and the outer diameter of the lower auxiliary plate 20 is set to be equal to or less than the outer diameter of the rotary platen 12. It is desirable. 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 diameters of the mounted rotating platen 14 are also almost the same. By doing so, it is possible to ensure a sufficiently large supporting area for the polishing pad 16. This makes it possible to mount the polishing pad 16 having substantially the same size as the rotary platen 14 on the rotary platen 14 with substantially the same support force over the entirety thereof.

[0048]

Furthermore, as the first fixing means 24 and the second fixing means 26, the lower auxiliary plate 20 and the upper auxiliary plate 22 are fixed to the upper surface 18 of the rotary platen 14 against external force exerted during polishing. What is necessary is just to be able to hold ¦ maintain, and it does not specifically limit. Specifically, an adhesive or a pressure-sensitive adhesive, or a double-sided tape in which an adhesive or a pressure-sensitive adhesive is adhered to both surfaces of a substrate sheet or the like can be adopted as the first and second fixing means 24 and 26. In addition, negative pressure attraction using negative pressure air or the like, magnetic attraction using a permanent magnet or an electromagnet, and the like can also be adopted. In addition, it is desirable that the fixing means made of an adhesive or the like exerts a substantially uniform fixing force over substantially the entire flat superimposed surface of the lower auxiliary plate 20 and the upper auxiliary plate 22. The fixing force can be obtained, and the problem that the support characteristics of the polishing pad 16 locally differ on the surface of the polishing pad auxiliary plate 10 can be avoided.

[0049]

For example, the fixing force can be turned ON / OFF by negative pressure suction or an electromagnet, but when a fixed fixing force is exerted such as an adhesive, the lower auxiliary plate 20 with respect to the rotary platen 14 by the first fixing means 24. It is preferable that the second fixing means 26 be set so that the fixing force of the upper auxiliary plate 22 to the lower auxiliary plate 20 is smaller than the fixing force of the upper auxiliary plate 22. Accordingly, when the upper auxiliary plate 22 is peeled off from the lower auxiliary plate 20 and removed, it is possible to easily realize that the lower auxiliary plate 20 is left fixed on the rotary platen 14. The concrete realization of such a difference in the fixing force is to make the fixing means itself different from each other such as the material of the adhesive or the pressure-sensitive adhesive, and to fix the fixing area and the state of the fixing surface (surface roughness, the presence or absence of plasma treatment, etc.). Can also be realized by making them different from each other.

[0050]

Further, the surface (upper surface) of the upper auxiliary plate 22 serves as a polishing pad support surface, and the polishing pad 16 is attached in an overlapping manner. As the polishing pad 16, various types of conventionally known polishing pads can be employed. The back surface of the polishing pad 16 is fixed to the surface of the upper auxiliary plate 22 using a conventionally known adhesive tape or a suitable adhesive for attaching the polishing pad.

[0051]

It is desirable that the fixing means of the polishing pad 16 to the upper auxiliary plate 22 be set to a larger fixing force than the second fixing means 26 described above. Thus, when the upper auxiliary plate 22 is detached from the lower auxiliary plate 20 with the polishing pad 16 fixed, the polishing pad 16 can be expected from the upper auxiliary plate 22 even if the upper auxiliary plate 22 is curved. Can be effectively prevented.

[0052]
The outer diameter of the polishing pad 16 is generally set to a standard value, but is often set to be equal to or smaller than the outer diameter of the upper surface 18 of the rotary platen 14 to be mounted.

[0053]

Further, for example, at least one between the upper surface 18 of the rotary platen 14 and the lower auxiliary plate 20, between the lower auxiliary plate 20 and the upper auxiliary plate 22, and between the upper auxiliary plate 22 and the polishing pad 16. An appropriate cushion layer may be provided.

By providing such a cushion layer, it is possible to achieve uniform polishing efficiency over the entire surface of the workpiece during polishing using the polishing pad 16.

[0054]

As such a cushion layer, for example, a resin sheet to which a certain degree of compressibility has been imparted by foaming, an elastomer sheet, a rubber sheet, or the like can be suitably used. In addition, the cushion layer can be formed by the first fixing means 24, the second fixing means 26, and the fixing means for fixing the polishing pad 16 to the upper auxiliary plate 22. Note that the cushion layer is formed so as to exist at a constant thickness over substantially the entire support region of the polishing pad 16 in order to prevent local distortion on the support surface of the polishing pad 16. Is desirable.

[0055]

Positioning means 28 is provided between the lower auxiliary plate 20 and the upper auxiliary plate 22 constituting the polishing pad auxiliary plate 10 so as to position each other and align the central axis. In the present embodiment, a circular step surface 30 is formed on the outer peripheral portion of the lower auxiliary plate 20 and extends around the entire circumference around the central axis of the lower auxiliary plate 20. By reducing the thickness of the lower auxiliary plate 20 on the outer peripheral side of the stepped surface 30, the lower auxiliary plate 20 has a notched cross-sectional shape that opens to the outer peripheral surface of the lower auxiliary plate 20 and is continuous over the entire circumference in the circumferential direction. An extended engagement recess 32 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 step surface 34 extending over the entire circumference around the central axis of the upper auxiliary plate 22 is formed on the outer peripheral portion of the upper auxiliary plate 22. By increasing the thickness of the upper auxiliary plate 22 on the outer peripheral side of the step surface 34, an annular engagement member extending continuously along the outer peripheral edge of the upper auxiliary plate 22 over the entire circumference in the circumferential direction is provided. A mating projection 36 is formed integrally with the upper auxiliary plate 22 so as to protrude therefrom. The engaging projection 36 and the engaging recess 32 may be formed on either of the upper and lower auxiliary plates 22 and 20.

[0057]

The step surface 30 and the engaging concave portion 32 of the lower auxiliary plate 20 are aligned with the step surface 34 and the engaging convex portion 36 of the upper auxiliary plate 22, respectively. And the inner peripheral surface of the engagement. When the upper auxiliary plate 22 is superimposed on the lower auxiliary plate 20, the engagement convex portion 36 is fitted into the engagement concave portion 32, and the step surface 34 is superimposed on the step surface 30 in the radial direction, and Is formed. Thus, the positioning means 28 is constituted by the engaging concave portion 32 and the engaging convex portion 36, and the lower auxiliary plate 20 and the upper auxiliary plate 20 are aligned with the central axes

aligned with each other in the radial direction. The auxiliary plate 22 is superposed. Note that the positioning means 28 is provided on the inner peripheral side of the outer peripheral surfaces of the upper and lower auxiliary plates 22 and 20, so that the upper and lower auxiliary plates 22 and 20, and further, the polishing device 12 are not enlarged. .

[0058]

In the polishing apparatus 12 provided with the polishing pad auxiliary plate 10 having such a structure, as shown in FIG. 1, the upper and lower auxiliary plates 22 and 20 are disposed on the upper surface 18 of the rotating platen 14. The polishing plate auxiliary plate 10 is fixed and attached, and the polishing table 16 is fixedly supported on the upper surface of the upper auxiliary plate 22. Then, the rotary platen 14 is driven to rotate, and the workpiece such as a substrate is processed. To perform CMP (chemical mechanical polishing). The polishing apparatus 12 includes the polishing pad auxiliary plate 10 having a specific structure, so that the following special technical effects can be exhibited.

[0059]

First, as shown in FIG. 2, while the polishing pad 16 is fixed to the upper surface of the upper auxiliary plate 22, the upper auxiliary plate 22 is fixed to the rotating platen 14 by the first fixing means 24. By removing the polishing pad 16 from the side auxiliary plate 20, the polishing pad 16 can be removed from the rotary platen 14. Then, even when the polishing pad 16 is removed from the rotating platen 14 and the surface (polishing surface) of the polishing pad 16 is cleaned or reworked, the polishing pad 16 can be fixed to the upper surface of the upper auxiliary plate 22. Accordingly, the upper auxiliary plate 22 reinforces not only when the polishing pad 16 is attached to and detached from the rotary platen 14, when the polishing pad 16 is cleaned or reworked, but also when the polishing pad 16 is transferred or stored. The function can prevent the polishing pad 16 from being bent or damaged, and can keep the polishing pad 16 in a good state.

[0060]

Also, when the polishing pad 16 is removed from the rotary platen 14 together with the upper auxiliary plate 22, the lower auxiliary plate 20 is left on the upper surface 18 of the rotary platen 14. When the polishing pad 16 is mounted on the rotating platen 14 again, the positioning

means 28 provided between the upper auxiliary plate 22 and the lower auxiliary plate 20 causes the upper auxiliary plate 22 and thus the polishing pad 16 to move downward. The center axis can be aligned with high precision and easily with respect to the plate 20 and thus the rotary platen 14.

[0061]

Here, the engaging concave portion 32 and the engaging convex portion 36 constituting the positioning means 28 are overlapped with almost no gap in a state where they are fitted to each other. Adverse effects on the vehicle can be prevented. In the present embodiment, an engaging portion, in other words, a positioning means 28 is formed at an outer peripheral edge of the outer peripheral portions of the upper and lower auxiliary plates 22 and 20, and a diameter which is a main region for polishing in the polishing pad 16. Since it is separated from the middle part in the direction, even if there is a small gap between the fitting portions of the engaging concave portions 32 and the engaging convex portions 36, the polishing characteristics of the polishing pad 16 are so large that a great problem occurs in the polishing characteristics. Adverse effects can be avoided.

[0062]

In addition, the engaging concave portion 32 and the engaging convex portion 36 that constitute the positioning means 28 are located on the overlapping surface of the upper and lower auxiliary plates 22 and 20, in other words, the outer peripheral end surfaces of the rotary platen 14 and the polishing pad auxiliary plate 10. Since it is formed on the inner peripheral side, the protrusion of the upper and lower auxiliary plates 22 and 20 on the outer peripheral surface can be avoided. Therefore, for example, as shown in FIGS. 1 and 2, even when the protective member 38 is installed near the outer peripheral side of the rotary platen 14 in the polishing apparatus 12, The polishing apparatus 12 provided with the upper and lower auxiliary plates 22 and 20 provided with the positioning means 28 can be realized while avoiding interference.

[0063]

Further, as described above, the polishing pad 16 can be quickly attached to and detached from the rotary platen 14 with accurate positioning accuracy while preventing the polishing pad 16 from being damaged. Therefore, the operation time of the expensive polishing equipment is not unnecessarily limited, and the improvement of the operation efficiency of the polishing equipment and the improvement of the production efficiency (polishing work efficiency) of

substrates and the like can be achieved.

[0064]

Further, since the attachment and detachment of the polishing pad 16 to and from the rotary platen 14 are easily realized, the polishing pad 16 can be reused at a practical level without special skill or knowledge.

That is, for example, the polishing pad 16 once removed from the rotary platen 14 is reused when the type of the object to be polished such as a substrate is switched, or the surface is grooved by another processing device as a measure against deterioration. The reuse of the polishing pad 16 once removed from the rotary platen 14 after reworking, etc., can be considered at a practical level.

[0065]

As described above, the first embodiment of the present invention has been described, but the specific structure of the present invention is not limited to the first embodiment. A plurality of other embodiments of the present invention provided with positioning means having a different structure between the upper and lower auxiliary plates 22 and 20 will be exemplified below, but these embodiments do not limit the configuration of the present invention. In the following embodiments, members and portions having the same structure as in the first embodiment are denoted by the same reference numerals as those in the first embodiment in corresponding portions in the drawings. , And detailed description thereof will be omitted.

[0066]

FIGS. 3 and 4 show a polishing apparatus 42 having a polishing pad auxiliary plate 40 according to a second embodiment of the present invention.

[0067]

In the polishing pad auxiliary plate 40, an engagement recess 44 is formed by an annular groove extending continuously in the circumferential direction on the outer peripheral portion of the

upper surface of the lower auxiliary plate 20.

On the other hand, an engagement projection 46 is formed on the outer peripheral portion of the lower surface of the upper auxiliary plate 22 by an annular projection extending continuously in the circumferential direction. The engaging projection 46 may be formed integrally with the upper auxiliary plate 22, but may be formed separately as shown in the figure. That is, in the present embodiment, an annular peripheral groove 48 which is opened on the lower surface of the upper auxiliary plate 22 and extends in the circumferential direction is formed, and the annular groove 48 formed separately from the peripheral groove 48 is formed. Is fitted and fixed at one end in the axial direction to form an engagement projection 46.

[0068]

The engaging concave portion 44 of the lower auxiliary plate 20 and the engaging convex portion 46 of the upper auxiliary plate 22 are both formed at corresponding radial positions around the center axis, and the upper and lower auxiliary plates 22 and 20 are overlapped. At this time, the upper and lower auxiliary plates 22, 20 are radially aligned with each other by fitting the engagement convex portion 46 into the engagement concave portion 44. In the present embodiment, the respective radially overlapping surfaces of the both side wall surfaces in the engagement concave portion 44 of the lower auxiliary plate 20 and the inner and outer peripheral surfaces of the engagement convex portion 46 of the upper auxiliary plate form two An engagement inner peripheral surface and an engagement outer peripheral surface of the set are configured.

[0069]
FIGS. 5 and 6 show a polishing apparatus 52 having a polishing pad auxiliary plate 50 according to a third embodiment of the present invention.

[0070]

In this polishing pad auxiliary plate 50, a step surface 54 as a circular engagement inner peripheral surface extending over the entire circumference around the central axis is formed on the outer peripheral portion of the lower auxiliary plate 20.

On the outer peripheral side of the step surface 54, the thickness of the lower auxiliary plate 20 is increased, so that the annular shape extends continuously along the outer peripheral edge of the lower auxiliary plate 20 in the entire circumferential direction. Are formed integrally with the lower auxiliary plate 20.

[0071]

On the other hand, a step surface 58 is formed on the outer peripheral portion of the upper auxiliary plate 22 as a circular engaging outer peripheral surface extending all around the central axis. By reducing the thickness of the upper auxiliary plate 22 on the outer peripheral side of the stepped surface 58, the upper auxiliary plate 22 extends continuously over the entire circumference in a circumferential direction with a cutout cross-sectional shape opened to the outer peripheral surface of the upper auxiliary plate 22. An annular engagement recess 60 is formed integrally with the upper auxiliary plate 22.

[0072]

Further, a female screw is formed on the step surface 54 of the lower auxiliary plate 20, while a male screw is formed on the step surface 58 of the upper auxiliary plate 22. Then, the male screw of the step surface 58 of the upper auxiliary plate 22 is screwed with the female screw of the step surface 54 of the lower auxiliary plate 20, and the step surface 54 of the lower auxiliary plate 20 and the step surface 58 of the upper auxiliary plate 22 are screwed. The upper auxiliary plate 22 is superimposed on the upper surface of the lower auxiliary plate 20 by superposing the upper auxiliary plate 22 in the radial direction. Further, in such a superimposed state, the second fixing means 62 for detachably fixing the upper and lower auxiliary plates 22 and 20 is formed by the screw structure of the step surfaces 58 and 54 of the upper and lower auxiliary plates 22 and 20. .

[0073]
The screw direction of the female and male screws in such a screwed structure is set so that the screws are not loosened in consideration of the rotational reaction force exerted on the rotary platen 14 of the polishing device 12 during polishing. Is desirable.

[0074]
FIGS. 7 and 8 show a polishing apparatus 66 having a polishing pad auxiliary plate 64 according

to a fourth embodiment of the present invention.

[0075]

In the polishing pad auxiliary plate 64, a columnar engaging projection 68 protruding upward is formed at the center of the upper surface of the lower auxiliary plate 20.

The engaging projection 68 may be formed integrally with the lower auxiliary plate 20, but may be formed separately as shown in the figure.

That is, in the present embodiment, a circular fitting recess 70 is formed on the central axis of the lower auxiliary plate 20, and a columnar block formed separately from the fitting recess 70 is formed in the fitting recess 70. The engagement protrusion 68 is formed by being fitted and fixed at one end in the axial direction. On the other hand, at the center of the lower surface of the upper auxiliary plate 22, a bottomed circular engaging concave portion 72 that opens to the lower surface on the central axis is formed. The engaging projection 68 and the engaging recess 72 may be formed on either of the upper and lower auxiliary plates 22 and 20.

[0076]

Then, when the upper and lower auxiliary plates 22 and 20 are overlapped, the engagement convex portion 68 is fitted into the engagement concave portion 72 so that the upper and lower auxiliary plates 22 and 20 are aligned with each other in the radial direction. It has become. In this embodiment, the outer peripheral surface of the engaging projection 68 of the lower auxiliary plate 20 and the inner peripheral surface of the engaging concave portion 72 of the upper auxiliary plate 22 allow the outer peripheral surface of the engagement and the inner peripheral surface of the engagement to be engaged. It is configured.

[0077]
FIG. 9 shows a polishing apparatus 76 having a polishing pad auxiliary plate 74 as a fifth embodiment of the present invention.

[0078]

In the polishing pad auxiliary plate 74, a columnar engaging projection 78 protruding upward is formed at the outer peripheral portion of the upper surface of the lower auxiliary plate 20.

The engaging projection 78 may be formed integrally with the lower auxiliary plate 20, or may be formed with a fitting recess in the lower auxiliary plate 20 like the engaging projection in the fourth embodiment. Alternatively, a separate pin or the like may be fixed by press fitting or the like. Further, as shown in FIGS. 10 to 11, a plurality of such engaging projections 78 are formed independently from each other at a predetermined distance in the circumferential direction on the outer peripheral portion of the lower auxiliary plate 20. Particularly preferably, the plurality of engaging projections 78 are formed at equal intervals in the circumferential direction and on the same circle on the central axis.

[0079]

On the other hand, on the outer peripheral portion of the lower surface of the upper auxiliary plate 22, a bottomed circular engaging concave portion 80 is provided at a position corresponding to each of the formation positions of the plurality of engaging convex portions 78 on the lower auxiliary plate 20. It is formed to open downward. The engaging projection 78 and the engaging recess 80 may be formed on either of the upper and lower auxiliary plates 22 and 20.

[0080]

When the upper and lower auxiliary plates 22 and 20 are overlapped, the engagement convex portions 78 are fitted into the engagement concave portions 80, respectively, so that the upper and lower auxiliary plates 22 and 20 are radially aligned with each other. It has become. In this embodiment, the outer peripheral surface of the engaging projection 78 of the lower auxiliary plate 20 and the inner peripheral surface of the engaging concave portion 80 of the upper auxiliary plate 22 define the outer peripheral surfaces of the lower auxiliary plate 20 and the upper auxiliary plate 22. An engaging outer peripheral surface and an engaging inner peripheral surface located at the portion are configured.

[0081]

In particular, as in the present embodiment, by employing positioning means including a plurality of engaging projections 78 and engaging recesses 80 that are independent in the circumferential direction, the superimposed upper and lower auxiliary plates 22 and 20 can be moved only in the radial direction. It is possible to position each other even in the circumferential direction.

[0082]
In place of the plurality of independent engaging recesses 80 formed in the upper auxiliary plate 22, a circumferential groove extending continuously in the circumferential direction around the central axis of the upper auxiliary plate 22 may be employed, or FIG. As shown in the sixth embodiment of the present invention, a circular step surface 82 is formed extending around the outer periphery of the upper auxiliary plate 22 over the entire circumference around the central axis, and is formed to be smaller than the step surface 82. By reducing the thickness on the outer peripheral side, it is also possible to form an annular engaging recess 83 extending continuously over the entire circumference in a circumferential direction with a notched cross-sectional shape opened to the outer peripheral surface of the upper auxiliary plate 22. .

[0083]
As described above, in the upper auxiliary plate 22, by forming the engaging surface of the engaging convex portion 78 of the lower auxiliary plate 20 continuously over the entire circumference, when the upper and lower auxiliary plates 20 and 22 are overlapped, There is no need to position the auxiliary plates 20 and 22 in the circumferential direction, and the mounting operation can be easily performed.

[0084]
FIG. 13 shows a polishing pad auxiliary plate 84 as a seventh embodiment of the present invention.

[0085]

In the polishing pad auxiliary plate 84, small diameter portions are provided in the upper part of the outer peripheral surface of the lower auxiliary plate 20 and the lower part of the outer peripheral surface of the upper auxiliary plate 22, respectively.

Then, the upper and lower auxiliary plates 22 and 20 are overlapped with each other, so that

each small diameter portion extends between the upper and lower auxiliary plates 22 and 20 with a predetermined width and extends over the entire circumference in the circumferential direction. A receiving recess 86 having a shape is formed.

[0086]

At the lower end of the small-diameter portion of the lower auxiliary plate 20, a groove-shaped engaging concave portion 88 is formed.

The engagement recess 88 is opened at the bottom surface of the accommodation recess 86 on the outer peripheral surface of the lower auxiliary plate 20.

Here, the bottom surface of the housing recess 86 refers to an annular surface of the surface forming the housing recess 86 that straddles the upper and lower auxiliary plates 22 and 20 and extends in the vertical direction in FIG.

On the other hand, a plate-shaped engaging convex portion 90 made of an elastic material is fixed to a small-diameter portion of the upper auxiliary plate 22 constituting the accommodation recess 86 at a base end thereof with a fixing pin 92 and attached. The engaging projection 90 is accommodated in an accommodation recess 86 formed on the outer peripheral surface of the upper and lower auxiliary plates 22, 20, and extends from the upper auxiliary plate 22 onto the outer peripheral surface of the lower auxiliary plate 20. I have. Then, the engaging claw portion 94 formed at the tip portion of the engaging convex portion 90 is engaged with the engaging concave portion 88 formed on the small diameter portion of the lower auxiliary plate 20, and It is configured to be held in a locked state based on elasticity.

[0087]

Furthermore, a plurality of such engaging projections 90 are provided on the outer peripheral surfaces of the upper and lower auxiliary plates 22 and 20 at a predetermined distance in the circumferential direction. Each of the engaging projections 90 attached to the outer peripheral surface of the upper auxiliary plate 22 is elastically pressed against the outer peripheral surface of the lower auxiliary plate 20, so that the upper and lower auxiliary plates 22, 20 are aligned on the central axis. And positioning means for positioning each other. Further, by engaging the

engaging claw portion 94 of the engaging convex portion 90 with the engaging concave portion 88, the upper and lower auxiliary plates 22, 20 are held in an overlapping state, and a fixing means for applying a fixing force is also configured. I have.

[0088]

It should be noted that, instead of the engagement projection 90 having the engagement claw portion 94 that engages with the engagement recess 88 as described above, for example, as in the eighth embodiment of the present invention shown in FIG. A connecting plate 100 which extends over the auxiliary plates 22 and 20 and is superimposed on the bottom surface of the accommodation recess 86 is adopted, and both end portions of the connecting plate 100 are attached to the outer peripheral surface of each of the upper and lower auxiliary plates 22 and 20. It is also possible to fix them with connecting pins 102, 102. Note that 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 auxiliary plates 22, 20 by the connecting plate 100 can be released. The attachment / detachment of the upper auxiliary plate 22 to which the polishing pad 16 is fixed is allowed.

[0089]

Further, the first fixing means 24 and the second fixing means 26 made of a double-sided tape or the like shown in the first to eighth embodiments are used when the upper and lower auxiliary plates 22 and 20 and the rotary platen 14 are removed. Is desirably held on the fixing surface on the member side. This facilitates handling of the upper and lower auxiliary plates 22, 20 and the first and second fixing means 24, 26 in the detached state. It should be noted that which fixing surface the first and second fixing means 24 and 26 remain on is determined by making the fixing forces on both surfaces of the first fixing means and the second fixing means 24 and 26 themselves different from each other. It can be set by making the surface roughness, material, etc. of the upper and lower auxiliary plates 22, 20 and the rotary platen 14 to be fixed different from each other.

[0090]

In particular, the first fixing means 24 is desirably held on the fixing surface on the lower auxiliary plate 20 side when the lower auxiliary plate 20 is detached, so that the maintenance of

the upper surface 18 of the rotary platen 14 is facilitated. Become. On the other hand, as shown in FIG. 2 in the first embodiment, the second fixing means 26 is held on the fixing surface on the upper auxiliary plate 22 side when the upper auxiliary plate 22 is removed. Alternatively, for example, as in a ninth embodiment of the present invention shown in FIG. By holding the second fixing means 26 on the fixing surface on the upper auxiliary plate 22 side, the detached upper auxiliary plate 22 can be removed from the rotating platen of a device for reworking such as grooving of the polishing pad 16. At the time of mounting, it is also possible to use the second fixing means 26 held by the upper auxiliary plate 22 for mounting. On the other hand, by holding the second fixing means 26 on the fixing surface on the lower auxiliary plate 20 side, when mounting another upper auxiliary plate 22 with another polishing pad 16 mounted on the lower auxiliary plate 20, It is also possible to attach using the second fixing means 26 held on the lower auxiliary plate 20.

[0091]

Further, the engaging concave portions 32, 44, 60, 72, 80, (83), 88 and the engaging convex portions 36, 46, 56, 70, 78, 90 shown in the first to seventh embodiments are lower. The side auxiliary plate 20 and the upper auxiliary plate 22 may be provided on mutually opposite sides. For example, as shown in FIG. 16 of the tenth embodiment of the present invention, the engaging outer peripheral surface of the polishing pad auxiliary plate 10 shown in FIGS. It is also possible to form the step surface 30 and the engaging concave portion 32 that constitute the upper auxiliary plate 22, and to form the step surface 34 and the engaging convex portion 36 that form the inner peripheral peripheral surface on the lower auxiliary plate 20. It is possible.

[0092]

Furthermore, the engaging concave portions 32, 44, 60, 72, 80, (83) and the engaging convex portions 36, 46, 56, 70, 78 shown in the first to sixth embodiments are overlapped with each other. It is also possible to give an inclination angle with respect to the outer peripheral surface of the engaging projection for positioning the upper and lower auxiliary plates 22 and 20 and the inner peripheral surface of the engaging recess. For example, as shown in FIG. 17, an eleventh embodiment of the present invention includes a step surface 34 as an engagement inner peripheral surface of an engagement convex portion 36 formed on the outer peripheral portion of the lower auxiliary plate 20 so as to protrude. On the other hand, the engaging convex portion 36 has a taper in an inclined direction that gradually tapers in the projecting direction, while the engaging convex portion 36 has a stepped surface 30 as an engaging outer peripheral surface of the engaging concave portion 32 formed in the outer peripheral portion of the upper auxiliary

plate 22. Thus, a taper of the inclination direction and the inclination angle corresponding to the step surface 34 can be provided. Thereby, the work of fitting the engaging projections 36 into the engaging recesses 32 and superimposing the upper and lower auxiliary plates 22 and 20 can be further performed by using the taper provided on the two stepped surfaces 34 and 30 as a guide surface. This can be easily performed.

[0093]

Incidentally, as shown in the twelfth embodiment of the present invention shown in FIG. 18 and the thirteenth embodiment of the present invention shown in FIG. 19, the lower auxiliary plate 20 is independent in the circumferential direction. Even when adopting a plurality of projection-shaped engaging projections 78 formed in a plurality of positions and a plurality of hole-shaped engaging recesses 80 formed at corresponding positions of the upper auxiliary plate 22, the engagement projections 78 can be used. The tapered portion 104 having a tapered shape can be formed by giving a slant angle to the outer peripheral surface of the protruding tip portion of the projection. In FIG. 19, a separately formed locking pin 106 is fixed to a fitting hole 105 formed in the lower auxiliary plate 20 by press-fitting or the like, thereby forming an engaging projection 78. The lower end of the locking pin 106 is also provided with a tapered portion 104 similar to the upper end. Thereby, the direction of the locking pin 106 is lost and the handling is easy, and the press-fitting work into the fitting hole 105 is also easy.

[0094]

Further, in the fourteenth embodiment of the present invention shown in FIG. 20, as a kind of positioning means for aligning the center axis in the state where the upper and lower auxiliary plates 22 and 20 are superimposed, a straddle between the upper and lower auxiliary plates 22 and 20 is provided. A positioning sleeve 108 is shown which is extrapolated. The positioning sleeve 108 has an inner diameter that is the same as or slightly larger than the outer diameter of the upper and lower auxiliary plates 22 and 20 each having a disk shape having substantially the same outer diameter. Is formed. The positioning sleeve 108 is used when the upper and lower auxiliary plates 22 and 20 are overlapped, and the upper and lower auxiliary plates 22 and 20 are overlapped in the positioning sleeve 108, so that the upper and lower auxiliary plates 22 and 20 are aligned with the center axis. They can be overlapped in the axial direction and fixed to each other by the second fixing means 26. Therefore, after the upper and lower auxiliary plates 22 and 20 are overlapped and fixed to each other, the positioning sleeve 108 can be removed, thereby positioning the upper and lower auxiliary plates 22 and 20 on the outer peripheral surface. It is possible to fix them to each other without any means and in an accurate alignment

state.

[0095]

Furthermore, in the fifteenth embodiment of the present invention shown in FIG. 21, a slit-like engagement groove 110 extending over the overlapping direction in the overlapping state of the upper and lower auxiliary plates 22 and 20 is formed. ing. The engagement grooves 110 are opened in the outer peripheral surfaces of the upper and lower auxiliary plates 22 and 20 and have a predetermined depth inward in the radial direction, and a plurality of the engagement grooves 110 are provided independently of each other in the circumferential direction of the upper and lower auxiliary plates 22 and 20. Have been. When the plate-shaped engagement plate 112 is fitted into the engagement groove 110 from the opening on the outer peripheral surface, the upper and lower auxiliary plates 22 and 20 are positioned relative to each other by the engagement plate 112. Is connected. Although the engagement plate 112 is formed separately from the upper and lower auxiliary plates 22 and 20, for example, one of the upper and lower auxiliary plates 22 and 20 may be integrally formed with a shape protruding toward the other. . In that case, the engagement groove 110 is formed only on the other auxiliary plate.

[0096]

Further, in the sixteenth embodiment of the present invention shown in FIG. 22, a fitting concave portion 114 is formed on the lower surface of the upper auxiliary plate 22 as an engaging concave portion. Particularly, in the present embodiment, the fitting concave portion 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 is formed with a fitting convex portion 116 as an engaging convex portion projecting upward on the upper surface superimposed on the upper auxiliary plate 22. In the present embodiment, the fitting protrusion 116 is formed as an annular protrusion corresponding to the fitting recess 114. Then, in a state where the upper and lower auxiliary plates 22 and 20 are overlapped, the fitting convex portion 116 enters the fitting concave portion 114 and is positioned.

[0097]

Further, the fitting protrusion 116 has a hollow structure, and a fluid reservoir 118 is formed inside the fitting protrusion 116 so as to be sealed with respect to an external space.

Furthermore, 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 swellable and deformable in the radial direction. Specifically, for example, by forming the fitting convex portion 116 with a rubber elastic body or the like, an inner peripheral wall that can swell inward in the radial direction and an outer peripheral wall that can swell outward in the radial direction can be realized. is there.

[0098]

Further, the lower auxiliary plate 22 is formed with a fluid passage 120 communicating with the fluid reservoir 118 and extending radially outward and opening on the outer peripheral surface. , A pressure screw 122 is screwed. In addition, a sealed area including the fluid passage 120 and the fluid reservoir 118 sealed by the pressure screw 122 is filled with an incompressible fluid such as oil.

[0099]

Thereby, 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 peripheral wall and the outer peripheral wall of the fluid reservoir 118 can bulge outward. As a result, the fitting convex portion 116 is expanded and pressed against the inner surface of the fitting concave portion 114, so that the upper and lower auxiliary plates 22, 20 can be positioned relative to each other by mutual frictional force, and can also exert a fixing force. I have.

[0100]

When removing the upper auxiliary plate 22 from the lower auxiliary plate 20, the pressure of the fluid reservoir 118 is reduced by rotating the pressing screw 122 in a direction to loosen the outer auxiliary plate 20 to move the outer peripheral side of the lower auxiliary plate 20. By lowering, the pressing force of the fitting projection 116 against the fitting recess 114 can be released.

[0101]

In addition, although not enumerated one by one, the present invention can be implemented with various changes, modifications, improvements, etc. based on the knowledge of those skilled in the art. By attaching an O-ring or a sealing material to the portion, it is also possible to prevent

foreign matter from entering the overlapping surface of the upper and lower auxiliary plates and the like.

[0102]

Further, in addition to the above-described auxiliary plates 20 and 22 having the two-layer structure, it is also possible to add additional auxiliary plates in a stacked state and fixed by fixing means.

By employing the auxiliary plate of the third layer as described above, it is possible to realize an elastic supporting state or to dispose the intermediate layer in a disposable manner.

[0103]

10, 40, 50, 64, 74, 84: auxiliary plate for polishing pad, 12, 42, 52, 66, 76: polishing device, 14: rotary platen, 16: polishing pad, 18: upper surface, 20: lower side Auxiliary plate, 22: upper auxiliary plate, 24: first fixing means, 26, 62: second fixing means, 28: positioning means, 30, 58: step surface (engaging outer peripheral 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

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(54)【発明の名称】車両における操作対象装置の制御装置及び制御方法

(57)【特許請求の範囲】
【請求項１】
複数の検出領域を有し、車両のステアリングホイールにおける運転者が握る握持部の所定の範囲に、前記握持部を覆うように装着されたタッチセンサから得られる接触検出信号に基づいて、どの検出領域が触られているかを示す位置データを含むセンサデータを生成するセンサデータ生成部と、
前記センサデータに基づいて、運転者が前記握持部を握っているか否か、及び、前記タッチセンサに対する入力操作を検出する検出部と、
前記検出部によって運転者が前記握持部を握っていることが検出され、かつ、前記タッチセンサに対して特定の入力操作が行われたことが検出された場合に、前記特定の入力操作に応じて、前記タッチセンサによって操作する対象の操作対象装置を制御する制御部と、
を備え、
前記制御部は、方向指示器が操作されたとき車両が特定の状態にあるとして、前記操作対象装置の制御を無効とすることを特徴とする車両における操作対象装置の制御装置。
【請求項２】
複数の検出領域を有し、車両のステアリングホイールにおける運転者が握る握持部の所定の範囲に、前記握持部を覆うように装着されたタッチセンサから得られる接触検出信号に基づいて、どの検出領域が触られているかを示す位置データを含むセンサデータを生成するセンサデータ生成部と、

前記センサデータに基づいて、運転者が前記握持部を握っているか否か、及び、前記タッチセンサに対する入力操作を検出する検出部と、
前記検出部によって運転者が前記握持部を握っていることが検出され、かつ、前記タッチセンサに対して特定の入力操作が行われたことが検出された場合に、前記特定の入力操作に応じて、前記タッチセンサによって操作する対象の操作対象装置を制御する制御部と、
を備え、
前記制御部は、シフトレバーのシフト位置がリバースとなったとき車両が特定の状態にあるとして、前記操作対象装置の制御を無効とすることを特徴とする車両における操作対象装置の制御装置。

【請求項３】
前記タッチセンサには、前記複数の検出領域の一部を含み、運転者の手のひらの接触を検出するグリップ検出エリアと、前記複数の検出領域の他の一部を含み、指の接触による前記特定の入力操作を検出する操作検出エリアとが設定されており、
前記検出部は、前記グリップ検出エリアから得られる接触検出信号に基づくセンサデータによって運転者が前記握持部を握っているか否かを検出し、前記操作検出エリアから得られる接触検出信号に基づくセンサデータによって前記特定の入力操作を検出する
ことを特徴とする請求項１または２に記載の車両における操作対象装置の制御装置。

【請求項４】
複数の検出領域を有し、車両のステアリングホイールにおける運転者が握る握持部の所定の範囲に、前記握持部を覆うように装着されたタッチセンサから得られる接触検出信号に基づいて、どの検出領域が触られているかを示す位置データを含むセンサデータを生成するセンサデータ生成部と、
前記センサデータに基づいて、運転者が前記握持部を握っているか否か、及び、前記タッチセンサに対する入力操作を検出する検出部と、
前記検出部によって運転者が前記握持部を握っていることが検出され、かつ、前記タッチセンサに対して特定の入力操作が行われたことが検出された場合に、前記特定の入力操作に応じて、前記タッチセンサによって操作する対象の操作対象装置を制御する制御部と、
を備え、
前記タッチセンサには、前記複数の検出領域の一部を含み、運転者の手のひらの接触を検出するグリップ検出エリアと、前記複数の検出領域の他の一部を含み、指の接触による前記特定の入力操作を検出する操作検出エリアとが設定されており、
前記検出部は、前記グリップ検出エリアから得られる接触検出信号に基づくセンサデータによって運転者が前記握持部を握っているか否かを検出し、前記操作検出エリアから得られる接触検出信号に基づくセンサデータによって前記特定の入力操作を検出し、
前記制御部は、車両が特定の状態にあるときに、前記操作対象装置の制御を無効とすることを特徴とする車両における操作対象装置の制御装置。

【請求項５】
前記制御部は、前記特定の入力操作として、前記操作検出エリアに対して、前記握持部を前記ステアリングホイールの径方向に切断したときの断面における周方向に離間した２箇所を２つの指によって操作したパターンに応じて、前記操作対象装置を制御することを特徴とする請求項３または４に記載の車両における操作対象装置の制御装置。

【請求項６】
前記制御部は、さらに、前記ステアリングホイールの回転角度が所定の角度を超えたとき車両が特定の状態にあるとして、前記操作対象装置の制御を無効とすることを特徴とする請求項１～４のいずれか１項に記載の車両における操作対象装置の制御装置。

【請求項７】
前記タッチセンサは、運転者が左手で握る握持部の所定の範囲に装着された第１のタッチセンサと右手で握る握持部の所定の範囲に装着された第２のタッチセンサとを含み、

前記制御部は、前記特定の入力操作として、前記第１のタッチセンサに対する第１の入力操作と前記第２のタッチセンサに対する第２の入力操作との組み合わせによるパターンに応じて、前記操作対象装置を制御する

ことを特徴とする請求項１～６のいずれか１項に記載の車両における操作対象装置の制御装置。

【請求項８】

複数の検出領域を有し、車両のステアリングホイールにおける運転者が握る握持部の所定の範囲に、前記握持部を覆うように装着されたタッチセンサを運転者が握っているか否かを検出し、

前記タッチセンサに対して特定の入力操作が行われたか否かを検出し、

方向指示器が操作されたか否かを検出し、

車両が、方向指示器が操作された特定の状態にはないことが検出され、運転者が前記タッチセンサを握っていることが検出され、かつ、前記特定の入力操作が行われたことが検出された場合に、前記タッチセンサによって操作する対象の操作対象装置を制御し、車両が、方向指示器が操作された特定の状態にあることが検出された場合には、前記操作対象装置を制御を無効とする

ことを特徴とする車両における操作対象装置の制御方法。

【請求項９】

複数の検出領域を有し、車両のステアリングホイールにおける運転者が握る握持部の所定の範囲に、前記握持部を覆うように装着されたタッチセンサを運転者が握っているか否かを検出し、

前記タッチセンサに対して特定の入力操作が行われたか否かを検出し、

シフトレバーのシフト位置がリバースとなったか否かを検出し、

車両が、シフトレバーのシフト位置がリバースとなった特定の状態にはないことが検出され、運転者が前記タッチセンサを握っていることが検出され、かつ、前記特定の入力操作が行われたことが検出された場合に、前記タッチセンサによって操作する対象の操作対象装置を制御し、車両が、シフトレバーのシフト位置がリバースとなった特定の状態にあることが検出された場合には、前記操作対象装置を制御を無効とする

ことを特徴とする車両における操作対象装置の制御方法。

【請求項１０】

前記タッチセンサには、前記複数の検出領域の一部を含み、運転者の手のひらの接触を検出するグリップ検出エリアと、前記複数の検出領域の他の一部を含み、指の接触による前記特定の操作を検出する操作検出エリアとが設定されており、

前記グリップ検出エリアに対する手のひらの接触によって、運転者が前記タッチセンサを握っていることを検出し、

前記操作検出エリアに対する指の接触によって、前記特定の入力操作が行われたことを検出する

ことを特徴とする請求項８または９に記載の車両における操作対象装置の制御方法。

【請求項１１】

複数の検出領域を有し、車両のステアリングホイールにおける運転者が握る握持部の所定の範囲に、前記握持部を覆うように装着されたタッチセンサを運転者が握っているか否かを検出し、

前記タッチセンサに対して特定の入力操作が行われたか否かを検出し、

車両が特定の状態にあるか否かを検出し、

車両が特定の状態にはないことが検出され、運転者が前記タッチセンサを握っていることが検出され、かつ、前記特定の入力操作が行われたことが検出された場合に、前記タッチセンサによって操作する対象の操作対象装置を制御し、

前記タッチセンサには、前記複数の検出領域の一部を含み、運転者の手のひらの接触を検出するグリップ検出エリアと、前記複数の検出領域の他の一部を含み、指の接触による前記特定の操作を検出する操作検出エリアとが設定されており、

前記グリップ検出エリアに対する手のひらの接触によって、運転者が前記タッチセンサを握っていることを検出し、
前記操作検出エリアに対する指の接触によって、前記特定の入力操作が行われたことを検出する
ことを特徴とする車両における操作対象装置の制御方法。
【請求項１２】
前記特定の入力操作として、前記操作検出エリアに対して、前記握持部を前記ステアリングホイールの径方向に切断したときの断面における周方向に離間した２箇所を２つの指によって操作したパターンに応じて、前記操作対象装置を制御することを特徴とする請求項１０または１１に記載の車両における操作対象装置の制御方法。
【請求項１３】
前記ステアリングホイールの回転角度が所定の角度を超えたとき車両が特定の状態にあるにあるとして、前記操作対象装置の制御を無効とすることを特徴とする請求項８～１１のいずれか１項に記載の車両における操作対象装置の制御方法。
【請求項１４】
前記タッチセンサは、運転者が左手で握る握持部の所定の範囲に装着された第１のタッチセンサと右手で握る握持部の所定の範囲に装着された第２のタッチセンサとを含み、
前記特定の入力操作として、前記第１のタッチセンサに対する第１の入力操作と前記第２のタッチセンサに対する第２の入力操作との組み合わせによるパターンに応じて、前記操作対象装置を制御する
ことを特徴とする請求項８～１３のいずれか１項に記載の車両における操作対象装置の制御方法。
【発明の詳細な説明】
【技術分野】
【０００１】
本発明は、車両に搭載されているナビゲーション装置等の車載機器、または、変速機や方向指示器等の車両の動作を制御する車両動作制御装置を操作対象装置とし、操作対象装置を制御する制御装置及び制御方法に関する。
【背景技術】
【０００２】
車両に搭載されているナビゲーション装置等の車載機器を操作するための操作スイッチをステアリングホイールに配置した車両が普及している（特許文献１参照）。操作スイッチをステアリングホイールに配置すれば、運転者は車載機器を操作する際に車載機器まで手を伸ばす必要がないので、操作性が向上する。特許文献１に記載されているように、操作スイッチは、実際には、運転者が手で握る握持部であるステアリングホイールの円環状部ではなく、エアバッグが収納されているセンター部と円環状部との間を連結する連結部に配置されるのが通常である。従って、運転者は、操作スイッチを操作するために、握っている円環状部から手を離したり、手を大きくずらしたりする必要がある。特許文献２には、円環状部の背面や内側側面に操作スイッチを配置することが記載されている。
【先行技術文献】
【特許文献】
【０００３】
【特許文献１】特開２００７－１０６３５３号公報
【特許文献２】特開２００５－３４８１２３号公報
【特許文献３】特開２００８－１９５２２０号公報
【発明の概要】
【発明が解決しようとする課題】
【０００４】
特許文献２に記載の発明によれば、円環状部に操作スイッチを配置しているので、円環状部から手を離したり、手を大きくずらしたりすることなく、操作スイッチを操作するこ

とができる。しかしながら、特許文献２に記載されている操作スイッチは押しボタンによるキーや凹凸を設けたキーであり、この種のキーは運転者がステアリングホイールを操作する際の支障となる可能性がある。運転者が握る円環状部に大きな凹凸を設けることは好ましくない。また、円環状部に操作スイッチのような操作部を配置した場合、運転者が通常の運転のために円環状部を握っている場合のように、操作対象装置を操作しようとする意思がない場合に、不用意に操作対象装置が操作されないようにすることが求められる。さらに、車両の状態によっては誤操作を招く場合があり、誤操作を極力少なくすることが求められる。

【０００５】

本発明はこのような要望に対応するため、握持部から手を離したり、手を大きくずらしたりすることなく操作対象装置を操作することができ、運転者がステアリングホイールを操作する際に支障となる可能性を大幅に低減させることができる車両における操作対象装置の制御装置及び制御方法を提供することを目的とする。また、誤操作を大幅に低減させることができる車両における操作対象装置の制御装置及び制御方法を提供することを目的とする。

【課題を解決するための手段】

【０００６】

本発明は、上述した従来の技術の課題を解決するため、複数の検出領域を有し、車両のステアリングホイールにおける運転者が握る握持部の所定の範囲に、前記握持部を覆うように装着されたタッチセンサから得られる接触検出信号に基づいて、どの検出領域が触られているかを示す位置データを含むセンサデータを生成するセンサデータ生成部と、前記センサデータに基づいて、運転者が前記握持部を握っているか否か、及び、前記タッチセンサに対する入力操作を検出する検出部と、前記検出部によって運転者が前記握持部を握っていることが検出され、かつ、前記タッチセンサに対して特定の入力操作が行われたことが検出された場合に、前記特定の入力操作に応じて、前記タッチセンサによって操作する対象の操作対象装置を制御する制御部とを備え、前記制御部は、方向指示器が操作されたとき車両が特定の状態にあるとして、前記操作対象装置の制御を無効とすることを特徴とする車両における操作対象装置の制御装置を提供する。

【０００７】

本発明は、上述した従来の技術の課題を解決するため、複数の検出領域を有し、車両のステアリングホイールにおける運転者が握る握持部の所定の範囲に、前記握持部を覆うように装着されたタッチセンサから得られる接触検出信号に基づいて、どの検出領域が触られているかを示す位置データを含むセンサデータを生成するセンサデータ生成部と、前記センサデータに基づいて、運転者が前記握持部を握っているか否か、及び、前記タッチセンサに対する入力操作を検出する検出部と、前記検出部によって運転者が前記握持部を握っていることが検出され、かつ、前記タッチセンサに対して特定の入力操作が行われたことが検出された場合に、前記特定の入力操作に応じて、前記タッチセンサによって操作する対象の操作対象装置を制御する制御部とを備え、前記制御部は、シフトレバーのシフト位置がリバースとなったとき車両が特定の状態にあるとして、前記操作対象装置の制御を無効とすることを特徴とする車両における操作対象装置の制御装置を提供する。

【０００８】

上記の車両における操作対象装置の制御装置において、前記タッチセンサには、前記複数の検出領域の一部を含み、運転者の手のひらの接触を検出するグリップ検出エリアと、前記複数の検出領域の他の一部を含み、指の接触による前記特定の入力操作を検出する操作検出エリアとが設定されており、前記検出部は、前記グリップ検出エリアから得られる接触検出信号に基づくセンサデータによって運転者が前記握持部を握っているか否かを検出し、前記操作検出エリアから得られる接触検出信号に基づくセンサデータによって前記特定の入力操作を検出することが好ましい。

【０００９】

本発明は、上述した従来の技術の課題を解決するため、複数の検出領域を有し、車両の

ステアリングホイールにおける運転者が握る握持部の所定の範囲に、前記握持部を覆うように装着されたタッチセンサから得られる接触検出信号に基づいて、どの検出領域が触られているかを示す位置データを含むセンサデータを生成するセンサデータ生成部と、前記センサデータに基づいて、運転者が前記握持部を握っているか否か、及び、前記タッチセンサに対する入力操作を検出する検出部と、前記検出部によって運転者が前記握持部を握っていることが検出され、かつ、前記タッチセンサに対して特定の入力操作が行われたことが検出された場合に、前記特定の入力操作に応じて、前記タッチセンサによって操作する対象の操作対象装置を制御する制御部とを備え、前記タッチセンサには、前記複数の検出領域の一部を含み、運転者の手のひらの接触を検出するグリップ検出エリアと、前記複数の検出領域の他の一部を含み、指の接触による前記特定の入力操作を検出する操作検出エリアとが設定されており、前記検出部は、前記グリップ検出エリアから得られる接触検出信号に基づくセンサデータによって運転者が前記握持部を握っているか否かを検出し、前記操作検出エリアから得られる接触検出信号に基づくセンサデータによって前記特定の入力操作を検出し、前記制御部は、車両が特定の状態にあるときに、前記操作対象装置の制御を無効とすることを特徴とする車両における操作対象装置の制御装置を提供する。

【００１０】

上記の車両における操作対象装置の制御装置において、前記制御部は、前記特定の入力操作として、前記操作検出エリアに対して、前記握持部を前記ステアリングホイールの径方向に切断したときの断面における周方向に離間した２箇所を２つの指によって操作したパターンに応じて、前記操作対象装置を制御することが好ましい。

上記の車両における操作対象装置の制御装置において、前記制御部は、さらに、前記ステアリングホイールの回転角度が所定の角度を超えたとき車両が特定の状態にあるとして、前記操作対象装置の制御を無効とすることが好ましい。

上記の車両における操作対象装置の制御装置において、前記タッチセンサは、運転者が左手で握る握持部の所定の範囲に装着された第１のタッチセンサと右手で握る握持部の所定の範囲に装着された第２のタッチセンサとを含み、前記制御部は、前記特定の入力操作として、前記第１のタッチセンサに対する第１の入力操作と前記第２のタッチセンサに対する第２の入力操作との組み合わせによるパターンに応じて、前記操作対象装置を制御することが好ましい。

【００１１】

本発明は、上述した従来の技術の課題を解決するため、複数の検出領域を有し、車両のステアリングホイールにおける運転者が握る握持部の所定の範囲に、前記握持部を覆うように装着されたタッチセンサを運転者が握っているか否かを検出し、前記タッチセンサに対して特定の入力操作が行われたか否かを検出し、方向指示器が操作されたか否かを検出し、車両が、方向指示器が操作された特定の状態にはないことが検出され、運転者が前記タッチセンサを握っていることが検出され、かつ、前記特定の入力操作が行われたことが検出された場合に、前記タッチセンサによって操作する対象の操作対象装置を制御し、車両が、方向指示器が操作された特定の状態にあることが検出された場合には、前記操作対象装置を制御を無効とすることを特徴とする車両における操作対象装置の制御方法を提供する。

【００１２】

本発明は、上述した従来の技術の課題を解決するため、複数の検出領域を有し、車両のステアリングホイールにおける運転者が握る握持部の所定の範囲に、前記握持部を覆うように装着されたタッチセンサを運転者が握っているか否かを検出し、前記タッチセンサに対して特定の入力操作が行われたか否かを検出し、シフトレバーのシフト位置がリバースとなったか否かを検出し、車両が、シフトレバーのシフト位置がリバースとなった特定の状態にはないことが検出され、運転者が前記タッチセンサを握っていることが検出され、かつ、前記特定の入力操作が行われたことが検出された場合に、前記タッチセンサによって操作する対象の操作対象装置を制御し、車両が、シフトレバーのシフト位置がリバースとなった特定の状態にあることが検出された場合には、前記操作対象装置を制御を無効と

することを特徴とする車両における操作対象装置の制御方法を提供する。

【００１３】

上記の車両における操作対象装置の制御方法において、前記タッチセンサには、前記複数の検出領域の一部を含み、運転者の手のひらの接触を検出するグリップ検出エリアと、前記複数の検出領域の他の一部を含み、指の接触による前記特定の操作を検出する操作検出エリアとが設定されており、前記グリップ検出エリアに対する手のひらの接触によって、運転者が前記タッチセンサを握っていることを検出し、前記操作検出エリアに対する指の接触によって、前記特定の入力操作が行われたことを検出することが好ましい。

【００１４】

本発明は、上述した従来の技術の課題を解決するため、複数の検出領域を有し、車両のステアリングホイールにおける運転者が握る握持部の所定の範囲に、前記握持部を覆うように装着されたタッチセンサを運転者が握っているか否かを検出し、前記タッチセンサに対して特定の入力操作が行われたか否かを検出し、車両が特定の状態にあるか否かを検出し、車両が特定の状態にはないことが検出され、運転者が前記タッチセンサを握っていることが検出され、かつ、前記特定の入力操作が行われたことが検出された場合に、前記タッチセンサによって操作する対象の操作対象装置を制御し、前記タッチセンサには、前記複数の検出領域の一部を含み、運転者の手のひらの接触を検出するグリップ検出エリアと、前記複数の検出領域の他の一部を含み、指の接触による前記特定の操作を検出する操作検出エリアとが設定されており、前記グリップ検出エリアに対する手のひらの接触によって、運転者が前記タッチセンサを握っていることを検出し、前記操作検出エリアに対する指の接触によって、前記特定の入力操作が行われたことを検出することを特徴とする車両における操作対象装置の制御方法を提供する。

【００１５】

上記の車両における操作対象装置の制御方法において、前記特定の入力操作として、前記操作検出エリアに対して、前記握持部を前記ステアリングホイールの径方向に切断したときの断面における周方向に離間した２箇所を２つの指によって操作したパターンに応じて、前記操作対象装置を制御することが好ましい。

上記の車両における操作対象装置の制御方法において、前記ステアリングホイールの回転角度が所定の角度を超えたとき車両が特定の状態にあるにあるとして、前記操作対象装置の制御を無効とすることが好ましい。

上記の車両における操作対象装置の制御方法において、前記タッチセンサは、運転者が左手で握る握持部の所定の範囲に装着された第１のタッチセンサと右手で握る握持部の所定の範囲に装着された第２のタッチセンサとを含み、前記特定の入力操作として、前記第１のタッチセンサに対する第１の入力操作と前記第２のタッチセンサに対する第２の入力操作との組み合わせによるパターンに応じて、前記操作対象装置を制御することが好ましい。

【発明の効果】

【００１６】

本発明の車両における操作対象装置の制御装置及び制御方法によれば、握持部から手を離したり、手を大きくずらしたりすることなく操作対象装置を操作することができ、運転者がステアリングホイールを操作する際に支障となる可能性を大幅に低減させることができる。また、誤操作を大幅に低減させることができる。

【図面の簡単な説明】

【００１７】

【図１】本発明の車両における操作対象装置の制御装置の一実施形態を示すブロック図である。

【図２】一実施形態の操作対象装置の制御装置を備える車両の例を示す部分平面図である。

【図３】一実施形態におけるタッチセンサをステアリングホイールに装着する位置及び範囲の例を示す図である。

【図４】一実施形態におけるタッチセンサをステアリングホイールに装着する位置及び範囲の他の例を示す図である。
【図５】タッチセンサを変形ステアリングホイールに装着する例を示す図である。
【図６】ステアリングホイールにおけるタッチセンサの部分を握っている状態でセンサデータが得られる部分の例を示す部分斜視図である。
【図７】タッチセンサにおける断面周方向の座標を示す断面図である。
【図８】図６に示すタッチセンサを展開した状態を示す平面図である。
【図９】図８に示す各領域を均等の大きさに変換した状態を示す模式図である。
【図１０】ステアリングホイールにおけるタッチセンサの部分を握っていると判定するための要件の例を示す図である。
【図１１】タッチセンサに対する特定の入力操作の例を示す模式図である。
【図１２】タッチセンサに対する特定の入力操作の他の例を示す模式図である。
【図１３】タッチセンサに対する特定の入力操作のさらに他の例を示す模式図である。
【図１４】一実施形態の動作を説明するためのフローチャートである。
【図１５】ステアリングホイールの回転角度を説明するための図である。
【図１６】図１４のステップＳ４の具体的な処理の例を示すフローチャートである。
【図１７】タッチセンサを操作した際に色を変化させるための構成例を示す模式的な斜視図である。
【図１８】タッチセンサを操作した際に触覚を変化させるための構成例を示す模式的な斜視図である。
【図１９】ステアリングホイールの構成例を示す平面図である。
【発明を実施するための形態】
【００１８】
以下、本発明の車両における操作対象装置の制御装置及び制御方法の一実施形態について、添付図面を参照して説明する。図１，図２において、車載機器１００は、車両のダッシュボード内に装着されている。図１に示す例では、車載機器１００は、制御部１０，ナビゲーション処理部１１，オーディオ再生部１２，テレビジョン（ＴＶ）チューナ１３，映像信号処理部１４，映像表示部１５，音声信号処理部１６，表示素子１７，記憶部１８を備えている。制御部１０は検出部１０ａを含む。
【００１９】
ナビゲーション処理部１１は地図データを保持する記憶部とＧＰＳアンテナ等を有しており、制御部１０とナビゲーション処理部１１とが協同して経路案内を行う。オーディオ再生部１２は、制御部１０による制御に従って、例えばコンパクトディスク等の光ディスクや半導体メモリに記録されているオーディオ信号を再生する。ＴＶチューナ１３は、制御部１０による制御に従って、所定の放送局のＴＶ放送波信号を受信する。ナビゲーション処理部１１またはＴＶチューナ１３より出力された映像信号は、制御部１０を介して映像信号処理部１４に入力されて処理され、液晶パネル等の映像表示部１５に表示される。
【００２０】
ナビゲーション処理部１１，オーディオ再生部１２，ＴＶチューナ１３より出力された音声信号は、制御部１０を介して音声信号処理部１６に入力されて処理され、外部のスピーカ２０にて発音される。音声信号処理部１６は増幅部を含む。スピーカ２０は、車両のドアの内部等に設置されている。表示素子１７は例えば発光ダイオード（ＬＥＤ）であり、制御部１０による制御に従って、後述するタッチセンサ２１の接触状態に応じて点灯または消灯する。表示素子１７は、運転者から視認できるように、例えば車載機器１００の筐体に配置する。表示素子１７を車載機器１００から離して、車両のステアリングホイール２００の近傍に配置してもよい。記憶部１８は不揮発性のメモリである。
【００２１】
図２に示すように、操作部であるタッチセンサ２１は、ステアリングホイール２００の円環状部２００ｒに装着されている。円環状部２００ｒは、運転者が運転の際に握る部分である握持部である。図２に示す例では、タッチセンサ２１は、円環状部２００ｒにおけ

る左右それぞれの所定の角度範囲に装着されている。タッチセンサ２１は、複数箇所の接触を検出することができる、いわゆる多点検出（マルチタッチ）のタッチセンサである。タッチセンサ２１は、円環状部２００ｒの径方向の断面の周上に、３６０°の範囲で装着することが好ましい。３６０°未満の範囲であっても、実質的に円環状部２００ｒの断面の周のほぼ全体を覆っていればよい。

【００２２】

運転者は、円環状部２００ｒのタッチセンサ２１が装着された部分を握っている。図１において、タッチセンサ２１の出力はセンサデータ生成部２２に入力される。タッチセンサ２１を手で触ると、接触検出信号がセンサデータ生成部２２へと入力される。センサデータ生成部２２は、入力された接触検出信号に基づいて、タッチセンサ２１のどの位置から接触検出信号が得られたかを示す位置データを含むセンサデータを生成して制御部１０に供給する。タッチセンサ２１とセンサデータ生成部２２とを一体化してもよいし、センサデータ生成部２２を制御部１０内に設けてもよい。

【００２３】

タッチセンサ２１としては、例えば投影式静電容量（相互キャパシタンス）方式のタッチセンサを用いることができる。円環状部２００ｒに装着するタッチセンサ２１としては、一例として、ミクロ技術研究所が開発した可撓性を有するタッチパネルを採用することができる。この可撓性を有するタッチパネルは、センサ部を０．０２～０．０５ｍｍの板厚を有する超薄板ガラスとし、超薄板ガラスとＰＥＴ（ポリエチレンテレフタレート）フィルムとを貼り合わせた構造になっている。円環状部２００ｒにタッチセンサ２１を装着しても、タッチセンサ２１は手や指で知覚できるほどの凹凸を有さないので、運転者がステアリングホイール２００を操作する際に支障となることはほとんどない。

【００２４】

図２に破線にて示すように、タッチセンサ２１と車載機器１００とを結ぶ電線を、ステアリングホイール２００及びダッシュボードの内部を通して配線することが好ましい。

【００２５】

図１，図２において、ステアリング角センサ３１は、ステアリングホイール２００の回転角度を検出する。方向指示器センサ３２は、方向指示器３２０の操作を検出する。シフトレバーセンサ３３は、シフトレバー３３０によるシフト位置がどこにあるかを検出する。ステアリング角センサ３１，方向指示器センサ３２，シフトレバーセンサ３３の各検出信号は、車内通信部３４を介して制御部１０へと供給される。

【００２６】

図３を用いて、タッチセンサ２１をステアリングホイール２００の円環状部２００ｒに装着する位置及び範囲の例について説明する。なお、上、下、右、左とは、ステアリングホイール２００を回転させていない状態（車両が直進する状態）において、運転者の位置からステアリングホイール２００を見たときの上、下、右、左であるとする。図３（Ａ）は、円環状部２００ｒの全周にタッチセンサ２１を装着した例である。図３（Ｂ）は、図２と同様であり、円環状部２００ｒにおける上方で左右それぞれの所定の角度範囲にタッチセンサ２１を互いに離間させて装着した例である。図３（Ｃ）は、円環状部２００ｒにおける上方で右側のみの所定の角度範囲にタッチセンサ２１を装着した例である。

【００２７】

図３（Ｄ）は、円環状部２００ｒにおける下方で左右それぞれの所定の角度範囲にタッチセンサ２１を互いに離間させて装着した例である。図３（Ｅ）は、円環状部２００ｒにおける頂部を含む上方の比較的広い角度範囲にタッチセンサ２１を装着した例である。図３（Ｅ）は図３（Ｂ）における左右のタッチセンサ２１を連結したものに相当する。

【００２８】

図４は、図３（Ｂ）における左右のタッチセンサ２１を、上側のタッチセンサ２１ａと下側のタッチセンサ２１ｂとに分割した例である。図４の例では、上側のタッチセンサ２１ａは手の人差し指と親指による接触を検出し、下側のタッチセンサ２１ｂは主として手のひら，中指，薬指による接触を検出する。図５は、円形ではない変形ステアリングホイ

ール２０１にタッチセンサ２１を装着した例である。タッチセンサ２１は、変形ステアリングホイール２０１の左右の直線部２０１ｓに装着されている。運転者は握持部である直線部２０１ｓを握って運転し、タッチセンサ２１が手のひらや指による接触を検出する。

【００２９】

ここで、図２に示すように、タッチセンサ２１が円環状部２００ｒにおける上方で左右に装着されており、運転者がタッチセンサ２１の部分を握っている場合に、タッチセンサ２１によって手のひらや指の接触がどのように検出されるかについて説明する。図６は、図２の右側のタッチセンサ２１を運転者が握った場合に、手のひらと指が接触している範囲の例を示している。運転者が円環状部２００ｒを手で握る握り方、手の大きさは一様ではなく、図６は単なる例である。

【００３０】

図６に示す例では、ハッチングを付したＴｐで示す複数の検出領域Ｒが手のひらの接触を検出している部分であり、ハッチングを付したＴｔで示す複数の検出領域Ｒが親指の接触を検出している部分である。以下、手のひら接触検出部Ｔｐ、親指接触検出部Ｔｔと称することとする。図６では見えていない車両の進行方向側であるタッチセンサ２１の裏面側には、人差し指が接触する。

【００３１】

図６に示すように、タッチセンサ２１は手のひらや指の接触を検出する検出部分として複数の検出領域Ｒを有している。タッチセンサ２１の各検出領域Ｒには座標が設定されている。図６に示すように、円環状部２００ｒの周方向において、タッチセンサ２１の下端部に位置している検出領域Ｒを座標０とし、上端部に位置している検出領域Ｒまで１，２，…，３０，３１と周方向の座標を設定している。タッチセンサ２１における円環状部２００ｒの周方向の座標をＹ座標とする。

【００３２】

図７は、タッチセンサ２１を装着している部分で円環状部２００ｒの径方向に円環状部２００ｒを切断した断面図である。図７に示すように、円環状部２００ｒの断面において、例えば円環状部２００ｒの内径側に位置している検出領域Ｒを座標０とする。断面における周方向のそれぞれの検出領域Ｒに、円環状部２００ｒの内径側から正面側、正面側から外径側、外径側から裏面側、裏面側から内径側へと図７の反時計方向に１，２，…，２１，２２と座標を設定している。タッチセンサ２１における断面の周方向の座標をＸ座標とする。センサデータ生成部２２は、接触検出信号が得られた検出領域ＲのＸ座標，Ｙ座標によって運転者がタッチセンサ２１のどこを触っているかを示す位置データを得ることができる。

【００３３】

図６に示すタッチセンサ２１を展開すると、図８のようになる。図８に示すタッチセンサ２１の各領域を均等の大きさに変換した状態を模式的に示すと、図９のようになる。図８，図９においては、手のひら接触検出部Ｔｐと親指接触検出部Ｔｔに加えて、人差し指が接触している複数の検出領域Ｒである人差し指接触検出部Ｔｉも示している。なお、タッチセンサ２１に中指や薬指または小指が接触すれば、タッチセンサ２１はそれらの指の接触も検出する。本実施形態においては、運転者が、タッチセンサ２１上で特定の入力操作を行うのに好適な親指または人差し指を操作のための指として用いることとする。

【００３４】

親指または人差し指による入力操作の詳細については後に詳述することとする。制御部１０の検出部１０ａは、センサデータ生成部２２から出力されるセンサデータに基づいて、親指または人差し指によってタッチセンサ２１上で入力操作が行われたことを検出する。検出部１０ａは、センサデータ生成部２２から出力されるセンサデータに基づいて、円環状部２００ｒ（タッチセンサ２１）を握っていることも検出する。制御部１０は、タッチセンサ２１に対して行った特定の入力操作に応じて操作対象装置を制御する。

【００３５】

操作対象装置は一例として車載機器１００である。具体的には、制御部１０は、特定の

入力操作に応じて、ナビゲーション処理部１１における経路案内に関する制御を実行させたり、オーディオ再生部１２におけるオーディオ信号を再生または停止させたり、再生するトラック（楽曲）を進めたり戻したりすることができる。また、制御部１０は、特定の入力操作に応じて、ＴＶチューナ１３における受信チャンネルを切り換えたり、音声信号処理部１６の増幅部を制御して音量を減少または増加させたりすることができる。

【００３６】

操作対象装置の他の例は、車両の動作を制御する車両動作制御装置である。具体的には、制御部１０は、車内通信部３４を介して、変速機、方向指示器、エアーコンディショナのオン・オフ、エアーコンディショナの設定温度等を制御してもよい。なお、操作対象装置を車両動作制御装置とする場合には、センサデータ生成部２２から出力されるセンサデータを車両が有する制御部に入力して、車両動作制御装置を制御することが好ましい。操作対象装置を制御する制御部は、車載機器１００内の制御部１０であってもよいし、車両に備えられている車載機器１００外部の制御部であってもよい。

【００３７】

本実施形態によれば、運転者が握る円環状部２００ｒに極めて薄いタッチセンサ２１を装着して、タッチセンサ２１を操作することによって操作対象装置を操作するので、円環状部２００ｒから手を離したり、手を大きくずらしたりすることなく操作対象装置を操作することができる。また、タッチセンサ２１は円環状部２００ｒの表面上で凹凸がないため、運転者がステアリングホイール２００を操作する際に支障となる可能性はほとんどない。

【００３８】

ところで、運転者が通常の運転のために円環状部２００ｒを握っている場合のように、操作対象装置を操作しようとする意思がない場合に、不用意に操作対象装置が操作されないようにすることが必要となる。そこで、本実施形態においては、運転者が意図しない誤操作を回避するために、次のようにしている。

【００３９】

図８，図９に示すように、タッチセンサ２１上の複数の検出領域Ｒに、手のひらの接触を検出するためのグリップ検出エリアＡｒｇと、親指または人差し指による操作入力を有効として、操作入力を検出するための操作検出エリアＡｒｖと、グリップ検出エリアＡｒｇと操作検出エリアＡｒｖとの間の中間領域であり、操作入力を無効とする操作無効エリアＡｒivとを設定している。手のひら接触検出部Ｔｐはグリップ検出エリアＡｒｇ内に位置し、親指接触検出部Ｔｔ及び人差し指接触検出部Ｔｉは操作検出エリアＡｒｖ内に位置する。

【００４０】

操作無効エリアＡｒivは、グリップ検出エリアＡｒｇと操作検出エリアＡｒｖと同様に、手のひらまたは指の接触を検出する検出領域Ｒを有するものの、制御部１０（検出部１０ａ）またはセンサデータ生成部２２が操作無効エリアＡｒivからの入力操作を無効とするように処理することによって、操作無効エリアとすることができる。また、操作無効エリアＡｒivの範囲に検出領域Ｒを設けないようにタッチセンサ２１を構成することにより、操作無効エリアとしてもよい。この場合、図４に示す例と実質的に等価である。

【００４１】

運転者が通常の運転のために円環状部２００ｒを握っている場合には、手のひら接触検出部Ｔｐと親指接触検出部Ｔｔ及び人差し指接触検出部Ｔｉとは比較的近い位置となる。そこで、運転者が単に円環状部２００ｒを握っている場合と、操作対象装置を操作しようとしてタッチセンサ２１を触った場合とを的確に区別するために、本実施形態においては、操作無効エリアＡｒivを設けている。運転者は、操作対象装置を操作しようとする場合には、親指や人差し指を意図的に伸ばしてタッチセンサ２１を触って、後述する特定の入力操作を行うようにする。制御部１０は、操作検出エリアＡｒｖ内で後述する特定の入力操作が行われた場合に、入力操作に応じて操作対象装置を制御する。

【００４２】

運転者が運転のために円環状部２００ｒを握っていない状態で、操作検出エリアＡｒｖに不用意に触った場合に、操作対象装置が誤操作されることを回避することも必要である。そこで、本実施形態においては、検出部１０ａは、グリップ検出エリアＡｒｇで所定の面積以上の手のひら接触検出部Ｔｐが得られた場合に、円環状部２００ｒを握っていると判断する。制御部１０は、円環状部２００ｒを握っており、かつ、操作検出エリアＡｒｖ内で特定の操作が行われた場合に操作対象装置を制御するように構成している。円環状部２００ｒを握っていると判断する手のひら接触検出部Ｔｐの面積は、複数の運転者がステアリングホイール２００を通常の握り方で握った場合の面積を統計的に調べて、適宜に設定すればよい。

【００４３】

グリップ検出エリアＡｒｇにおける手のひら接触検出部Ｔｐの面積は、運転者が円環状部２００ｒを握っていると判定するための要件の一例であり、判定するための要件これに限定されるものではない。図１０は、タッチセンサ２１のグリップ検出エリアＡｒｇの部分で円環状部２００ｒを切断した断面を示している。検出部１０ａは、手のひら接触検出部Ｔｐの断面周方向の角度θが所定の角度以上のときに円環状部２００ｒを握っていると判断することができる。所定の角度は例えば１８０°である。

【００４４】

以上のように、本実施形態においては、運転者が円環状部２００ｒ（タッチセンサ２１）を握っているか否かを判定して、円環状部２００ｒを握っている場合のみタッチセンサ２１に対する操作入力を受け付けるようにしているので、操作検出エリアＡｒｖに不用意に触った場合の誤操作を回避することができる。本実施形態においては、好ましい構成として、操作検出エリアＡｒｖをグリップ検出エリアＡｒｇから所定の距離離間させた位置に設けているので、運転者が意図的にタッチセンサ２１に対して特定の入力操作を行っていることを的確に検出することができる。従って、誤操作を大幅に低減させることができる。

【００４５】

また、本実施形態においては、グリップ検出エリアＡｒｇにおける手のひら接触検出部Ｔｐの面積や断面周方向の角度θを、運転者が円環状部２００ｒを握っているか否かを判定する要件としているので、円環状部２００ｒを握っているか否かを的確に判定することができる。従って、運転者が円環状部２００ｒを握っていない状態で、操作検出エリアＡｒｖに不用意に触った場合の誤操作も回避することができる。

【００４６】

制御部１０は、検出部１０ａが、グリップ検出エリアＡｒｇからの接触検出信号に基づくセンサデータによって運転者が円環状部２００ｒ（タッチセンサ２１）を握っていることを検出した場合に、運転者に、操作検出エリアＡｒｖによる操作入力が可能であることを知らせるために、表示素子１７を点灯させる。運転者は、表示素子１７の点灯・消灯によって、タッチセンサ２１によって操作対象装置を操作することができるか否かを判断することができる。表示素子１７をステアリングホイール２００の近傍に配置する方が好ましい。

【００４７】

ところで、図３（Ａ）のように円環状部２００ｒの全周にタッチセンサ２１を装着したり、図３（Ｅ）のように比較的広い範囲にタッチセンサ２１を装着したりした場合には、運転者がタッチセンサ２１を握る位置は固定されない。そこで、図８及び図９で説明したグリップ検出エリアＡｒｇと操作検出エリアＡｒｖや、必要に応じて設ける操作無効エリアＡｒivの位置は、運転者がタッチセンサ２１を握った位置に応じて動的に設定する必要がある。

【００４８】

そこで、制御部１０は、グリップ検出エリアＡｒｇ等が未設定の状態でタッチセンサ２１が握られた場合には、手のひら接触検出部Ｔｐを含む領域をグリップ検出エリアＡｒｇに設定する。手のひら接触検出部Ｔｐを含むＹ座標の所定の範囲をグリップ検出エリアＡ

ｒｇとすればよい。前述のように、手のひら接触検出部Ｔｐは所定の面積以上となるので、タッチセンサ２１上の複数の検出領域Ｒにおいて所定の面積以上触られていることが検出された部分が手のひら接触検出部Ｔｐとなる。または、図１０で説明したように、タッチセンサ２１の部分で円環状部２００ｒを切断した断面周方向で、所定の角度以上触られていることが検出された部分が手のひら接触検出部Ｔｐとなる。

【００４９】

制御部１０は、グリップ検出エリアＡｒｇを設定したら、グリップ検出エリアＡｒｇよりも上側のＹ座標の所定の範囲を操作検出エリアＡｒｖと設定する。この場合、必要に応じて、グリップ検出エリアＡｒｇと隣接するＹ座標の所定の範囲を操作無効エリアＡｒｉｖとして設定し、グリップ検出エリアＡｒｇをグリップ検出エリアＡｒｇから離間させた位置とする。

【００５０】

次に、図１１～図１３を用いて、運転者が親指または人差し指を用いてタッチセンサ２１に対して行う特定の入力操作の例を説明する。図１１（Ａ）～（Ｅ）は、タッチセンサ２１の運転者と対向する正面側または裏面側である半分を模式的な平面で示している。図１１（Ａ）～（Ｅ）に示す操作は、正面側であれ親指で、裏面側であれば人差し指で行われることになる。図１１（Ａ）において、D_Rは、親指または人差し指をタッチセンサ２１（操作検出エリアＡｒｖ）上で右方向に滑らせる右方向ドラッグであり、D_Lは親指または人差し指を右方向に滑らせる左方向ドラッグである。D_Uは親指または人差し指を上方向に滑らせる上方向ドラッグであり、D_Dは親指または人差し指をした方向に滑らせる下方向ドラッグである。

【００５１】

図１１（Ａ）において、右方向ドラッグD_R，左方向ドラッグD_L，上方向ドラッグD_U，下方向ドラッグD_Dの代わりに、親指または人差し指でそれぞれの方向にタッチセンサ２１をはじくフリックとしてもよい。

【００５２】

図１１（Ｂ）は、親指または人差し指でタッチセンサ２１をたたくタップＴを示している。図１１（Ｃ）は、親指または人差し指でタッチセンサ２１上に円弧を描くようにドラッグする円弧ドラッグD_Cを示している。図１１（Ｄ）は、親指または人差し指でタッチセンサ２１上にジグザグ状にドラッグするジグザグドラッグD_Zを示している。図１１（Ｅ）は、親指または人差し指で記号を書くようにドラッグする記号入力ドラッグD_Sを示している。図１１（Ｅ）は記号として数字の３を描いた状態を示している。記号としては、認識が比較的容易な数字やアルファベットを用いることが好ましい。

【００５３】

図１２（Ａ）～（Ｄ）は、タッチセンサ２１を開いてタッチセンサ２１の正面側の半分である正面部２１ｆと裏面側の半分である裏面部２１ｒとを模式的な平面で示している。正面部２１ｆは、図８，図９に示すＸ座標の０～１１の部分であり、裏面部２１ｒは、Ｘ座標の１２～２２の部分である。図８，図９に示す例では、厳密には正面部２１ｆと裏面部２１ｒとは均等の面積にはならないが、図１２（Ａ）～（Ｄ）では正面部２１ｆと裏面部２１ｒとを同じ面積で示している。図１２（Ａ）～（Ｄ）は理解を容易にするため、裏面部２１ｒは、裏面部２１ｒを円環状部２００ｒの裏面側から見た状態ではなく、正面部２１ｆから裏面部２１ｒを透視した状態を示している。

【００５４】

図１２（Ａ）～（Ｄ）に示すように、正面部２１ｆに対する親指による入力操作と裏面部２１ｒに対する人差し指による入力操作とを組み合わせたパターンをタッチセンサ２１に対する特定の入力操作としてもよい。図１２（Ａ）は、正面部２１ｆで親指を右方向に滑らせる右方向ドラッグD_{TR}と、裏面部２１ｒで人差し指を右方向に滑らせる右方向ドラッグD_{IR}との双方を行う例である。親指及び人差し指の双方を円環状部２００ｒの内周側から外周側へとドラッグすることにより、図１２（Ａ）が実現される。親指と人差し指の双方を、図１２（Ａ）とは逆方向にドラッグするパターンとしてもよい。

【００５５】
図１２（Ｂ）は、正面部２１ｆで親指を左方向に滑らせる左方向ドラッグ$Ｄ_{ＴＬ}$と、裏面部２１ｒで人差し指を右方向に滑らせる右方向ドラッグ$Ｄ_{ＩＲ}$との双方を行う例である。親指を円環状部２００ｒの外周側から内周側へとドラッグし、人差し指を円環状部２００ｒの内周側から外周側へとドラッグすることにより、図１２（Ｂ）が実現される。図１２（Ｃ）は、正面部２１ｆで親指を右方向に滑らせる右方向ドラッグ$Ｄ_{ＴＲ}$と、裏面部２１ｒで人差し指を左方向に滑らせる左方向ドラッグ$Ｄ_{ＩＬ}$との双方を行う例である。親指を円環状部２００ｒの内周側から外周側へとドラッグし、人差し指を円環状部２００ｒの外周側から内周側へとドラッグすることにより、図１２（Ｃ）が実現される。
【００５６】
図１２（Ｄ）は、正面部２１ｆで親指を上方向に滑らせる上方向ドラッグ$Ｄ_{ＴＵ}$と、裏面部２１ｒで人差し指を下方向に滑らせる下方向ドラッグ$Ｄ_{ＩＤ}$との双方を行う例である。親指を下方向、人差し指を上方向にドラッグとするパターンとしてもよく、親指と人差し指の双方を上方向または下方向にドラッグするパターンとしてもよい。ここでは、正面部２１ｆに対する親指による入力操作と裏面部２１ｒに対する人差し指による入力操作とを組み合わせた種々のパターンを示したが、入力操作のしやすさを考慮して適宜選択すればよい。
【００５７】
図１２（Ａ）～（Ｄ）に示すように、親指による入力操作と人差し指による入力操作とを組み合わせたパターンを、操作対象装置を制御するための特定の入力操作とすれば、さらに大幅に誤操作を低減させることが可能となる。
【００５８】
さらには、図３（Ａ），（Ｂ），（Ｄ），（Ｅ）や図４，図５のように、左右の手でタッチセンサ２１（２１ａ，２１ｂ）を操作できる場合に、左右の手による操作を組み合わせたパターンを、操作対象装置を制御するための特定の入力操作とすることも可能である。図１３（Ａ）～（Ｄ）は、図３（Ｂ）における左側のタッチセンサ２１を左側タッチセンサ２１Ｌとし、右側のタッチセンサ２１を右側タッチセンサ２１Ｒとした場合の、左右の手による操作を組み合わせたパターンの例を示している。ここでは、親指によって操作する図１２の正面部２１ｆに相当する面を模式的な平面で示している。
【００５９】
図１３（Ａ）は、左側タッチセンサ２１Ｌに対して親指を左方向に滑らせる左方向ドラッグ$Ｄ_{ＴＬ}$と、右側タッチセンサ２１Ｒに対して親指を右方向に滑らせる右方向ドラッグ$Ｄ_{ＴＲ}$とを組み合わせたパターンである。図１３（Ｂ）は、左側タッチセンサ２１Ｌに対して親指を右方向に滑らせる右方向ドラッグ$Ｄ_{ＴＲ}$と、右側タッチセンサ２１Ｒに対して親指を左方向に滑らせる左方向ドラッグ$Ｄ_{ＴＬ}$とを組み合わせたパターンである。
【００６０】
図１３（Ｃ）は、左側タッチセンサ２１Ｌと右側タッチセンサ２１Ｒの双方に対して、親指を上方向に滑らせる上方向ドラッグ$Ｄ_{ＴＵ}$を組み合わせたパターンである。図１３（Ｄ）は、左側タッチセンサ２１Ｌと右側タッチセンサ２１Ｒの双方に対して、親指を下方向に滑らせる下方向ドラッグ$Ｄ_{ＴＤ}$を組み合わせたパターンである。
【００６１】
左右の手による入力操作を組み合わせたパターンを、操作対象装置を制御するための特定の入力操作とすれば、運転者は円環状部２００ｒを両手で握ることになるので、安全運転に寄与することが可能である。特に、図３（Ｂ）の例は、円環状部２００ｒを両手で握る最も適切な位置にタッチセンサ２１を装着しているので、安全運転に寄与する点で最も好ましい。両手で左右のタッチセンサ２１を握っている場合に入力操作を受け付けるようにしてもよい。片手がタッチセンサ２１から離れた場合に入力操作を受け付けない状態としてもよい。片手がタッチセンサ２１から離れた場合には入力操作を受け付ける状態を継続してもよい。片手のみの特定の入力操作を用いる場合であっても、両手で左右のタッチセンサ２１を握っている場合に入力操作を受け付けるようにすれば、安全運転に寄与する

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【００６２】

運転者が通常の運転のために円環状部２００ｒを握っていて、操作対象装置を操作しようとする意思がない場合に、偶然に、親指による入力操作と人差し指による入力操作とを組み合わせた特定のパターンや、左右の手による入力操作を組み合わせた特定のパターンになってしまう可能性は比較的低いと考えられる。そこで、親指による入力操作と人差し指による入力操作とを組み合わせた特定のパターンや、左右の手による入力操作を組み合わせた特定のパターンのみを用いる場合には、上述した誤操作を回避するための工夫の一部または全てを省略してもよい。勿論、左右の手による入力操作を組み合わせた特定のパターンのみを用いる場合であっても、上述した誤操作を回避するための工夫を併せて採用することが好ましい。

【００６３】

記憶部１８は、以上説明した特定の入力操作または特定の入力操作を組み合わせたパターンと、操作対象装置に対する制御の種別とを対応させたテーブルを記憶している。制御部１０は、記憶部１８に記憶されたテーブルに従って、タッチセンサ２１に入力された操作に応じて操作対象装置を制御する。記憶部１８を制御部１０内に設けてもよい。

【００６４】

図１４のフローチャートを用いて、本実施形態において制御部１０で実行される処理について改めて説明する。図１３において、制御部１０は、ステップＳ１にて、センサデータ生成部２２から出力されるセンサデータを取得する。制御部１０は、ステップＳ２にて、検出部１０ａによる検出出力に基づいて、円環状部２００ｒが握られているか否かを判定する。円環状部２００ｒが握られていると判定されれば（YES）、制御部１０は、ステップＳ３に処理を移し、円環状部２００ｒが握られていると判定されなければ（NO）、制御部１０は、ステップＳ１に処理を戻す。

【００６５】

制御部１０は、ステップＳ３にて、検出部１０ａによる検出出力に基づいて、入力操作があったか否かを判定する。入力操作があったと判定されれば（YES）、制御部１０は、ステップＳ４に処理を移し、操作入力があったと判定されなければ（NO）、制御部１０は、ステップＳ１に処理を戻す。制御部１０は、ステップＳ４にて、ステップＳ３における入力操作によって操作対象装置に対する操作を許可するか否かを判定する。操作を許可すると判定されれば（YES）、制御部１０は、ステップＳ５に処理を移し、操作を許可すると判定されなければ（NO）、制御部１０は、ステップＳ１に処理を戻す。

【００６６】

上述のように、制御部１０は、操作検出エリアＡｒｖ内で特定の入力操作がなされた場合に操作対象装置に対する操作を許可し、操作無効エリアＡｒiv内で特定の入力操作がなされたとしても操作対象装置に対する操作を許可しない。また、制御部１０は、操作検出エリアＡｒｖ内で何らかの入力操作がなされたとしても、上述した特定の入力操作でない場合は操作対象装置に対する操作を許可せず、特定の入力操作がなされた場合のみ操作対象装置に対する操作を許可する。

【００６７】

制御部１０は、ステップＳ５にて、入力操作に基づいた操作を確定し、ステップＳ６にて、操作対象装置に対して、確定した操作に応じた制御を実行して、ステップＳ１に処理を戻す。

【００６８】

また、ステップＳ４では、車両が特定の状態にあるときに、操作対象装置に対する制御を許可しないようにする（即ち、無効にする）ことが好ましい。制御部１０には、操作対象装置に対する制御を許可するか否かを判断するためのステアリングホイール２００の回転角度が設定されている。図１５に示すように、ステアリングホイール２００を回転させていない状態を回転角度０°とし、例えば右方向に回転させたときをプラス、左方向に回転させたときをマイナスとして、一例として回転角度±３０°の範囲でタッチセンサ２１

に対する入力操作を有効として許可し、回転角度が±３０°を超えたらタッチセンサ２１に対する入力操作を無効として不許可とする。

【００６９】

回転角度が±３０°を超えた場合には、車両は右折または左折をしていたり、コーナリング走行していたりする特定の状態である。このような特定の状態で操作対象装置を制御しようとすれば誤操作が発生する可能性が高い。言い換えれば、このような特定の状態における操作入力は、ユーザの意図していない操作入力である可能性が高い。また安全性の上でも好ましくない。そこで、本実施形態では、車両が特定の状態にあるときには、操作対象装置に対する制御を無効とする。

【００７０】

前述のように、制御部１０にはステアリング角センサ３１によって検出されたステアリングホイール２００の回転角度が入力される。制御部１０は、ステアリング角センサ３１によって検出されたステアリングホイール２００の回転角度に応じて、タッチセンサ２１に対する入力操作を有効とする状態と無効とする状態とを切り換える。制御部１０には方向指示器センサ３２からの検出信号も入力される。そこで、制御部１０は、方向指示器センサ３２からの検出信号によって方向指示器３２０が操作された場合に、タッチセンサ２１に対する入力操作を無効としてもよい。方向指示器３２０が操作された場合は、ステアリングホイール２００が所定の回転角度を超えて回転される特定の状態になるとみなすことができる。なお、方向指示器３２０が右折または左折の合図以外の操作を兼用している場合があるが、ここでの方向指示器３２０の操作とは右折または左折の合図を行う操作である。

【００７１】

さらに、車両を後退させている最中にタッチセンサ２１に対して特定の入力操作を行って操作対象装置を制御することは好ましくない。誤操作が発生する可能性が高く、安全性の上でも好ましくない。そこで、制御部１０は、シフトレバーセンサ３３からの検出信号によって、シフトレバー３３０のシフト位置がリバースとなった場合にも、タッチセンサ２１に対する入力操作を無効とすることが好ましい。ステアリングホイール２００の回転角度が例えば±３０°の所定角度を超えた場合、または、方向指示器３２０が操作された場合に加えて、シフトレバー３３０のシフト位置がリバースとなった場合に操作対象装置に対する制御を無効とすることが好ましいが、一方のみとしてもよい。

【００７２】

なお、操作対象装置に対する制御を無効にするとは、仮に上述した特定の入力操作がなされたとしても特定の入力操作を無効として操作対象装置に対する制御を不許可とすることであってもよく、制御部１０に対してセンサデータ生成部２２から何らかのセンサデータが入力されても、制御部１０がセンサデータを無効することであってもよい。結果として、操作対象装置に対する制御を無効とすればよい。

【００７３】

図１６のフローチャートを用いて、図１４のステップＳ４の具体的な処理の例を説明する。図１６において、制御部１０は、ステップＳ４１にて、シフトレバー３３０のシフト位置がリバースであるか否かを判定する。シフト位置がリバースであれば（YES）、制御部１０は、ステップＳ４５にて、ステップＳ３での入力操作を不許可として、図１４のステップＳ１に移行させる。シフト位置がリバースでなければ（NO）、制御部１０は、ステップＳ４２にて、方向指示器３２０が操作されたか否かを判定する。方向指示器３２０が操作されたら（YES）、制御部１０は、ステップＳ４５にて、ステップＳ３での入力操作を不許可として、図１４のステップＳ１に移行させる。

【００７４】

方向指示器３２０が操作されなかったら（NO）、制御部１０は、ステップＳ４３にて、ステアリングホイール２００の回転角度が所定角度を超えたか否かを判定する。ステアリングホイール２００の回転角度が所定角度を超えたら（YES）、制御部１０は、ステップＳ４５にて、ステップＳ３での入力操作を不許可として、図１４のステップＳ１に移行さ

せる。ステアリングホイール２００の回転角度が所定角度を超えていなかったら（NO）、制御部１０は、ステップＳ４４にて、操作検出エリアＡｒｖ内で特定の入力操作がなされたか否かを判定する。特定の入力操作がなされなかったら（NO）、制御部１０は、ステップＳ４５にて、ステップＳ３での入力操作を不許可として、図１４のステップＳ１に移行させる。ステップＳ４５にて、入力操作を不許可とすれば、操作対象装置に対する制御が無効となる。特定の入力操作がなされたら（YES）、制御部１０は、ステップＳ４６にて、ステップＳ３での入力操作を許可して、図１４のステップＳ５に移行させる。

【００７５】

図１６に示す例では、ステップＳ４１，Ｓ４２，Ｓ４３の全てを設けたが、これらのステップの内の１つまたは２つのみとしてもよい。また、ステップＳ４１，Ｓ４２，Ｓ４３の全てまたはこれらのステップの内の２つを設ける場合、順番は任意である。なお、ここではシフトレバー３３０と称したが、車両の直進と後退の切り換え、変速機の変速比を変える操作部の形状は任意であり、フロアシフト，コラムシフト，パドルシフト等のいずれでもよい。これらは全てシフトレバーに含まれる。

【００７６】

以上のように、車両が右折，左折，コーナリング走行，後退等の特定の状態にあるときに、操作対象装置に対する制御を無効とすれば、運転者はこれらの特定の状態のときにタッチセンサ２１に対する入力操作を行わない。従って、安全性の向上に寄与する。

【００７７】

本実施形態による動作をまとめると、次の通りである。検出部１０ａ（第１の検出部）は、ステアリングホイール２００，２０１における運転者が握る握持部（円環状部２００ｒまたは直線部２０１ｓ）に装着されたタッチセンサ２１における第１のエリアが触られている状態であることを検出する。第１のエリアの例は、グリップ検出エリアＡｒｇである。検出部１０ａ（第２の検出部）は、第１のエリアが触られている状態で、タッチセンサ２１における第１のエリアよりも上側に位置する第２のエリアに対して特定の入力操作がなされたことを検出する。第２のエリアの例は、操作検出エリアＡｒｖである。運転時、親指または人差し指は手のひらよりも上方に位置するので、第１のエリアよりも上側を第２のエリアとすればよい。そして、第１のエリアが触られている状態であり、特定の入力操作がなされたら、タッチセンサ２１によって操作する対象の操作対象装置を特定の入力操作に応じて制御する。

【００７８】

上側に位置するエリアとは、ステアリングホイール２００を回転させていない状態で運転者が握持部を握った状態で、第１のエリアよりも上側に位置するエリアである。第１のエリアが所定の面積以上触られていることを検出した場合に、第１のエリアが触られている状態であるとすることが好ましい。

【００７９】

また、別の観点では、次の通りである。検出部１０ａ（第１の検出部）は、ステアリングホイール２００，２０１における運転者が握る握持部（円環状部２００ｒまたは直線部２０１ｓ）の所定の範囲に、握持部を覆うように装着されたタッチセンサ２１が、タッチセンサ２１上の第１のエリアにおいて、握持部をステアリングホイール２００，２０１の径方向に切断したときの断面における周方向の所定角度以上触られている状態であることを検出する。検出部１０ａ（第２の検出部）は、第１のエリアが所定角度以上触られている状態で、タッチセンサ２１における第１のエリアとは異なる第２のエリアに対して特定の入力操作がなされたことを検出する。第１のエリアが前記所定角度以上触られている状態であり、特定の入力操作がなされたら、タッチセンサ２１によって操作する対象の操作対象装置を特定の入力操作に応じて制御する。

【００８０】

第２のエリアは、第１のエリアよりも上側に位置するエリアであることが好ましい。上側に位置するエリアとは、ステアリングホイール２００を回転させていない状態で運転者が握持部を握った状態で、第１のエリアよりも上側に位置するエリアである。

【００８１】
図１７及び図１８は、タッチセンサ２１を操作したことを運転者に効果的に知らせるための構成例を示している。図１７及び図１８は、図９と同様、タッチセンサ２１を展開して矩形状に変換した模式図である。図１７は、タッチセンサ２１の下面側に発色物質を含む色変化シート４１を設けた例である。タッチセンサ２１に透明導電膜を用いることにより、運転者は、タッチセンサ２１を介して、タッチセンサ２１の下面に配置されている色変化シート４１の色を見ることができる。制御部１０による制御によって、タッチセンサ２１を触った部分の色変化シート４１の色を変化させることにより、運転者はタッチセンサ２１を操作したことを認識することができる。
【００８２】
図１８は、タッチセンサ２１の上面側に触覚（手触り）を変化させる触覚フィードバックシート４２を設けた例である。触覚フィードバックシート４２としては、例えば、フィンランドのSenseg社が開発した“E-Sense”と称されるシートを採用することができる。このシートは、フィルムを帯電させることで触覚のフィードバックを実現するものである。タッチセンサ２１の上面側に触覚フィードバックシート４２を設けても、タッチセンサ２１は指等の接触を検出することが可能である。触覚フィードバックシート４２を介してタッチセンサ２１を操作した場合に、制御部１０による制御によって、触覚フィードバックシート４２の触覚を変化させることにより、運転者はタッチセンサ２１を操作したことを認識することができる。
【００８３】
次に、図１９を用いてステアリングホイールの構成例について説明する。図１９に示すステアリングホイール２１０は、操作対象装置に対する制御信号をステアリングホイール２１０から出力させるように構成したものである。図１９において、図１，図２と同一部分には同一符号を付し、その説明を適宜省略する。図１９に示すように、ステアリングホイール２１０は、例えば円環状部２００ｒ以外の部分に、図１のセンサデータ生成部２２と同様のセンダデータ生成部２３と、制御部１０と同様の制御部２４を備えている。制御部２４は、検出部１０ａと同様の検出部２４ａと、制御信号発生部２４ｂを有する。
【００８４】
ステアリングホイール２１０を車両に装着した場合、制御信号発生部２４ｂは、タッチセンサ２１に対する特定の入力操作に応じて、操作対象装置を制御するための制御信号を発生する。制御信号発生部２４ｂより出力された制御信号はケーブル２５を介して出力端子２６へと出力される。出力端子２６を操作対象装置に接続すれば、制御信号によって操作対象装置を制御することが可能となる。特定の入力操作の例は図１１～図１３と同様である。制御信号発生部２４ｂが制御信号を発生する要件も上述と同様である。
【００８５】
本発明は以上説明した本実施形態に限定されるものではなく、本発明の要旨を逸脱しない範囲において種々変更可能である。タッチセンサ２１を、面ファスナを用いて円環状部２００ｒに着脱自在に装着するようにしてもよい。円環状部２００ｒを握持部としたが、握持部は必ずしも円環状でなくてもよい。
【００８６】
タッチセンサ２１は１枚のシートによって構成する必要はなく、複数のタッチセンサの片によってタッチセンサ２１を構成してもよい。複数のタッチセンサの片によってタッチセンサ２１を構成すれば、一つ一つのタッチセンサの片の形状を簡単な形にすることができるため、タッチセンサを生産する際に有利である。なお、複数のタッチセンサの片によってタッチセンサ２１を構成する場合、必ずしもタッチセンサの片を隙間なく配置しなくてもよい。本実施形態のタッチパネル２１は、握持部を覆うように装着されているが、本実施形態における、握持部を覆うように装着されているということは、複数のタッチセンサの片からなるタッチセンサ２１が、タッチセンサの片と片との間に隙間がある状態で、握持部を覆うように装着されていることも含むものとする。
【００８７】

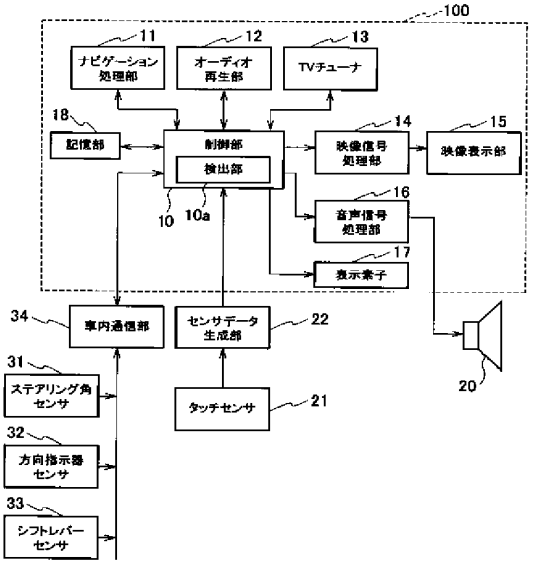
さらには、タッチセンサ２１を設ける範囲を、運転者が運転時に握る握持部（円環状部２００ｒまたは直線部２０１ｓ）に限定せず、例えばエアバッグ等が収納されるセンター部と円環状部２００ｒとの間を連結する連結部の表面まで広げてもよい。連結部は、図２においては、図2に示す状態で左右の手の間に位置する部分であり、図１９においては、センサデータ生成部２３及び制御部２４が設けられている部分である。このようにタッチセンサ２１を連結部の表面まで広げて、連結部における握持部に近い位置に操作検出エリアＡｒｖを設定してもよい。握持部に近い位置であれば、運転者が運転時に握持部から手を離したり、手を大きくずらしたりすることなく操作対象装置を操作することができる。よって、タッチセンサ２１を連結部の表面まで広げた構成としても、運転者がステアリングホイール２００，２０１，２１０を操作する際に支障となる可能性はほとんどない。

【符号の説明】

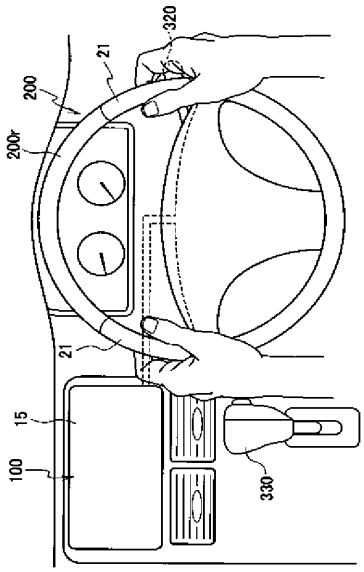
【００８８】

１０，２４　制御部
１０ａ，２４ａ　検出部
１１　ナビゲーション処理部
１２　オーディオ再生部
１３　テレビジョンチューナ
１４　映像信号処理部
１５　映像表示部
１６　音声信号処理部
１７　表示素子
１８　記憶部
２０　スピーカ
２１　タッチセンサ
２２，２３　センサデータ生成部
２４ｂ　制御信号発生部
２５　ケーブル
２６　出力端子
３１　ステアリング角センサ
３２　方向指示器センサ
３３　シフトレバーセンサ
３４　車内通信部
２００，２０１，２１０　ステアリングホイール
２００ｒ　円環状部（握持部）
２０１ｓ　直線部（握持部）

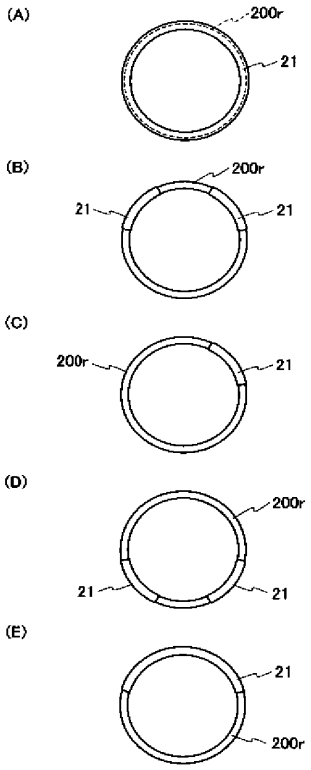
【図１】


100
11
ナビゲーション処理部
12
オーディオ再生部
13
TVチューナ
18
記憶部
制御部
検出部
14
映像信号処理部
15
映像表示部
10
10a
16
音声信号処理部
17
表示素子
34
車内通信部
センサデータ生成部
22
20
31
ステアリング角センサ
タッチセンサ
21
32
方向指示器センサ
33
シフトレバーセンサ

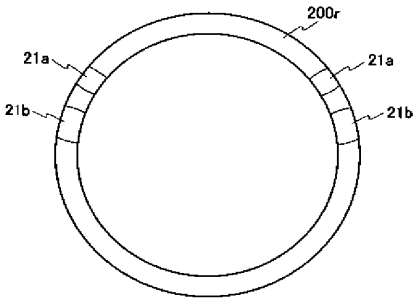
【図２】


320
21
200
200r
21
15
100
330

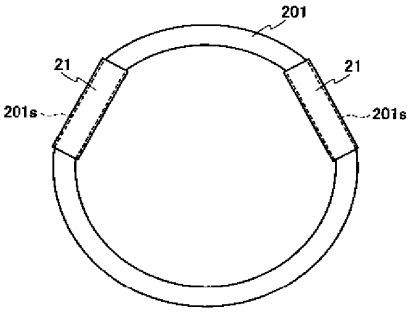
【図３】


(A)
200r
21
(B)
200r
21
21
(C)
200r
21
(D)
200r
21
21
(E)
21
200r

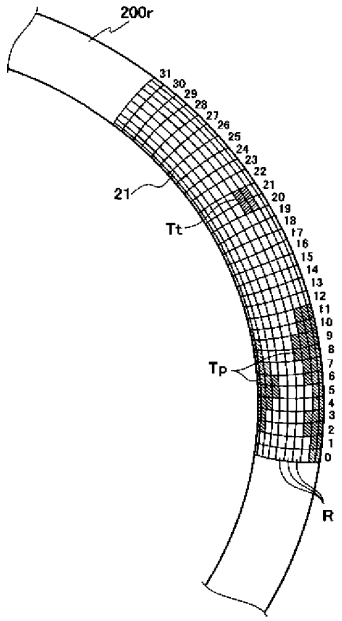
【図４】


200r
21a
21a
21b
21b

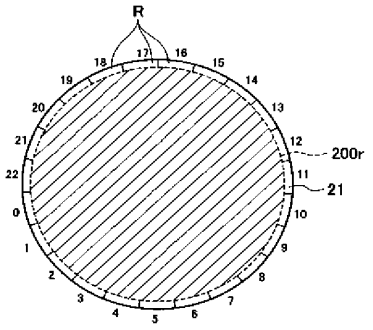
【図５】


201
21
21
201s
201s

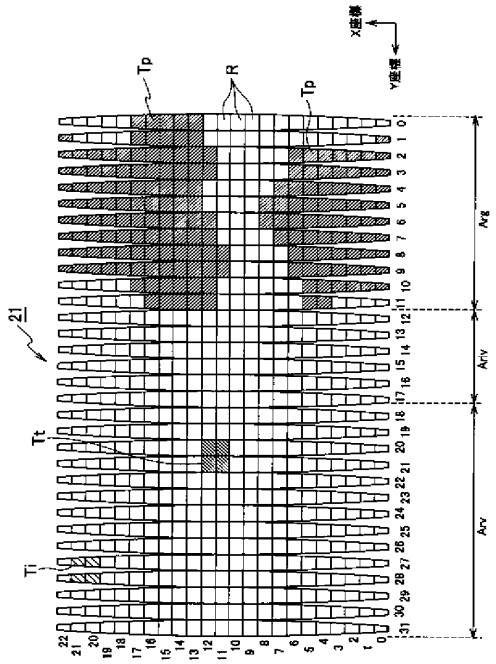
【図６】


200r
21
Tt
Tp
R

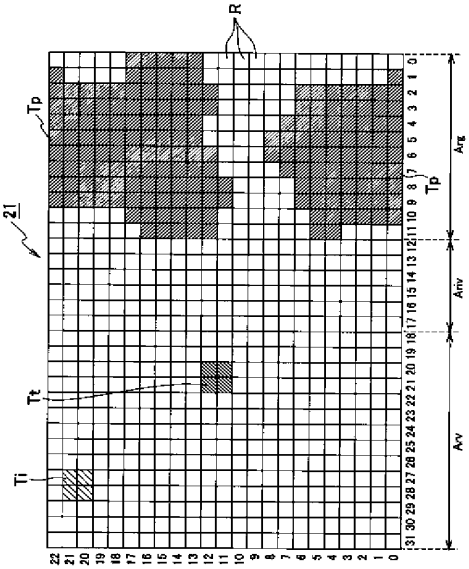
【図７】


R
200r
21

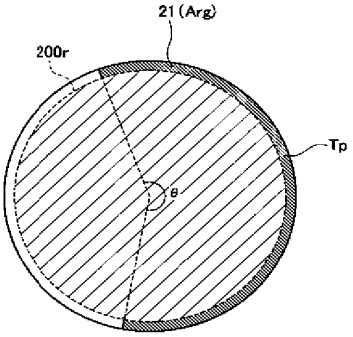
【図８】


X座標
Y座標
Tp
R
Tp
21
Tt
Ti
Arg
Arv
Arv

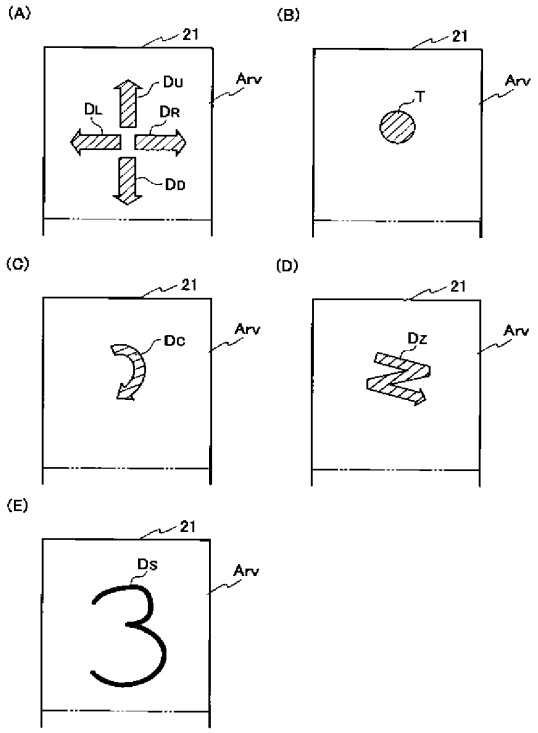
【図９】


R
Tp
21
Tt
Ti
Tp
Arg
Arv
Arv

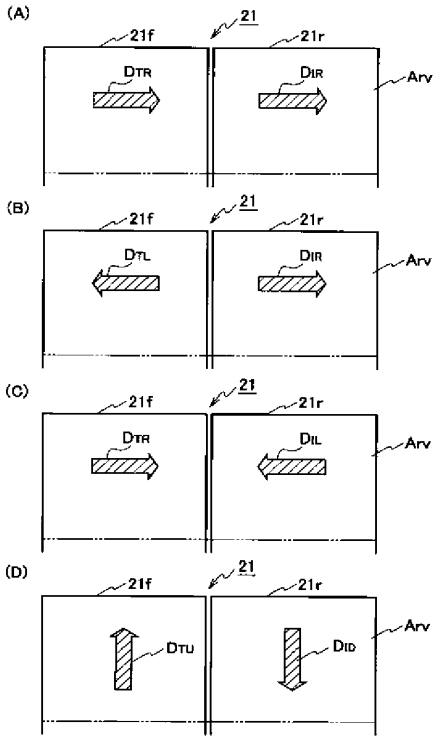
【図１０】



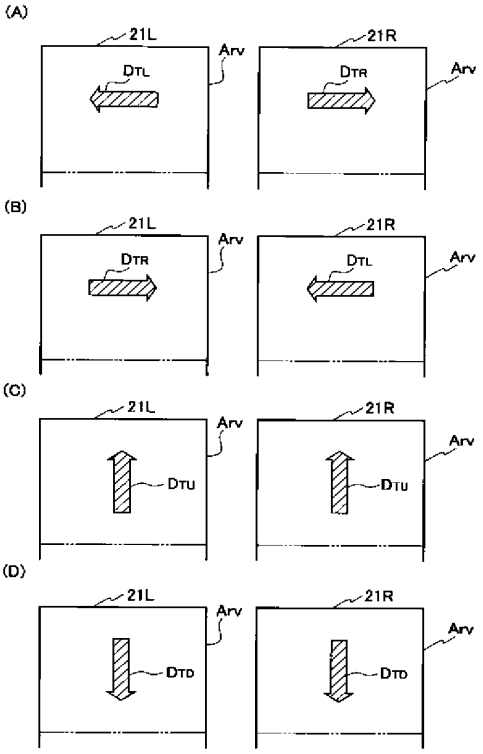
【図１１】



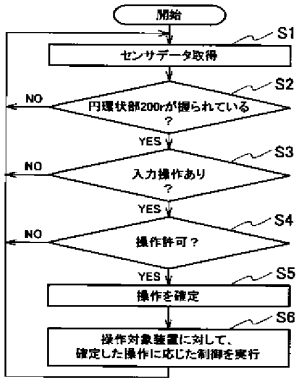
【図１２】



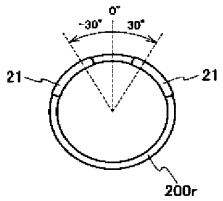
【図１３】



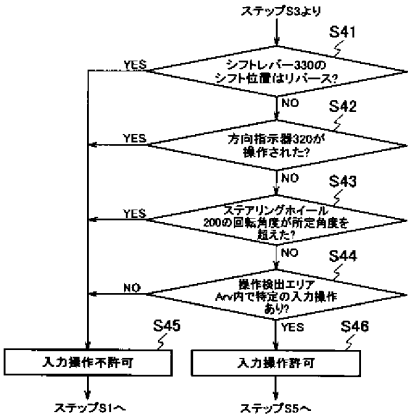
【図１４】



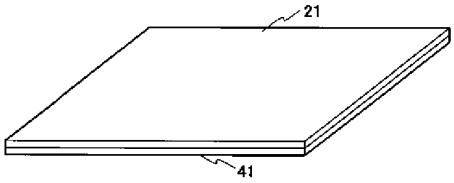
【図１５】



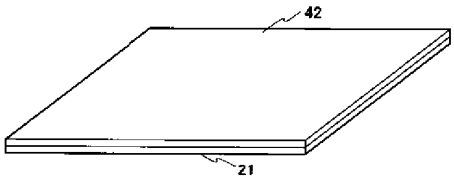
【図１６】



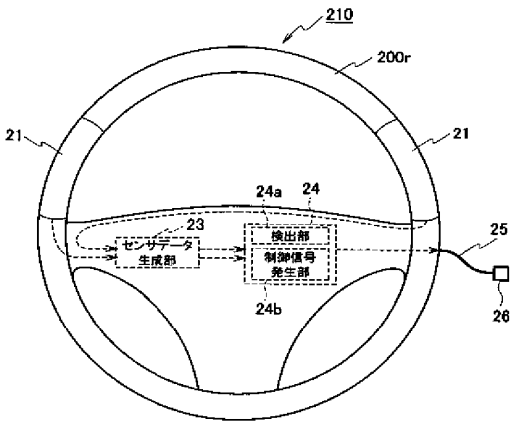
【図１７】



【図１８】



【図１９】



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特開２００７－０７６４９１（ＪＰ，Ａ）
実開昭６１－１６１８５２（ＪＰ，Ｕ）
特開平０６－１５６１１４（ＪＰ，Ａ）

(58)調査した分野(Int.Cl.，ＤＢ名)
Ｂ６０Ｒ １６／０２
Ｂ６０Ｒ １６／０２７

EUROPEAN PATENT OFFICE

Patent Abstracts of Japan

PUBLICATION NUMBER : 08257018
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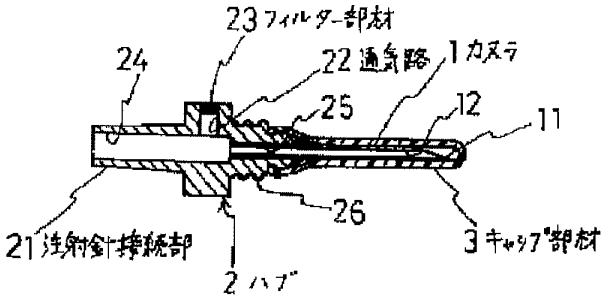
APPLICATION DATE : 22-03-95
APPLICATION NUMBER : 07062943

APPLICANT : NISSHO CORP;

INVENTOR : IKEGAMI TAKASHI;

INT.CL. : A61B 5/14 A61M 5/32

TITLE : BLOOD-GATHERING ADAPTER



ABSTRACT : PURPOSE: To provide a blood-gathering adapter by which the fact that the edge tip is stuck into a blood vessel can be confirmed since blood flows in an intermediate part of its transparent hub when the edge tip of an injection needle connected to this is stuck into a blood vessel.

CONSTITUTION: A blood gathering adapter is composed of a hollow cannula 1 having the edge tip 11 on the tip, a transparent hollow hub 2 to support and fix a rear end part of this cannula 1 by its tip part and a cap member 3 which is put on the cannula 1 and is made of a rubber elastic body. An injection needle connecting part 21 is arranged in a rear end part of the hub 2, and a ventilating passage 22 is arranged in an intermediate part of the hub 2, and an outlet of this ventilating passage 22 is blocked up by a gas permeable and liquid impermeable filter member 23.

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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

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(51)Int.Cl.[6]		識別記号	庁内整理番号	ＦＩ		技術表示箇所
Ａ６１Ｂ	5/14	３００	7638－2Ｊ	Ａ６１Ｂ	5/14	３００Ｅ
Ａ６１Ｍ	5/32			Ａ６１Ｍ	5/32	

審査請求　未請求　請求項の数４　ＯＬ　（全　４　頁）

(21)出願番号　特願平7－62943

(22)出願日　平成７年(1995)３月22日

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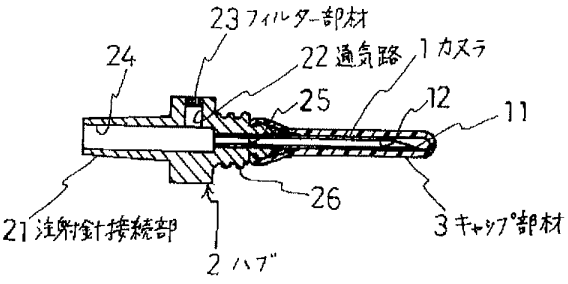
(72)発明者　池上　孝
大阪市北区豊崎３丁目３番13号　株式会社ニプロ内

(54)【発明の名称】　採血用アダプタ

(57)【要約】

【目的】　これに接続される注射針の刃先が血管に刺入されたときに、その透明なハブの中間部分に血液が流れ込み、これによって刃先が血管内に刺入されたことを確認できる採血用アダプタを提供する。

【構成】　採血用アダプタは、先端に刃先１１を有する中空のカヌラ１と、その先端部でこのカヌラ１の後端部を支持し固定する透明な中空のハブ２と、カヌラ１に被冠されたゴム弾性体製のキャップ部材３からなっている。そして、ハブ２の後端部には注射針接続部２１が設けられており、ハブ２の中間部には通気路２２が設けられ、この通気路２２の出口はガス透過性かつ液体不透過性のフィルター部材２３で塞がれている。



【特許請求の範囲】
【請求項１】　先端に刃先を有する中空のカヌラと、その先端部で該カヌラの後端部を支持し固定するとともに、その後端部に注射針のハブを液密に挿着可能な注射針接続部を備えた透明な中空のハブと、前記カヌラに被冠されたゴム弾性体製のキャップ部材とからなり、前記ハブの先端部と注射針接続部の間の中空部分に、該中空部分を外気と連通する通気路が設けられ、該通気路の出口がガス透過性かつ液体不透過性のフィルター部材で塞がれてなる採血用アダプタ。
【請求項２】　注射針接続部が注射針のハブと嵌合可能なルアーチップに形成されている請求項１に記載の採血用アダプタ。
【請求項３】　ルアーチップと同心状かつその外側に注射針のハブと結合可能な雌型結合手段を設けた請求項２に記載の採血用アダプタ。
【請求項４】　請求項１の採血用アダプタに注射針を接続してなる採血針。
【発明の詳細な説明】
【０００１】
【産業上の利用分野】本発明は採血用アダプタに関する。より詳しくは、血管より血液を採取するための真空採血管に用いる採血用アダプタであって、これに通常の注射針を接続することにより採血針として使用できるとともに、刃先が血管に刺入されたことを確認することができる採血用アダプタに関する。
【０００２】
【従来の技術】従来より、採血管による採血に際して、図４に示すような採血針を用いて採血しており、勘と経験によって刃先が血管内に入ったことを確認していた。しかしながら、このような勘と経験に頼る採血では、勘や経験の乏しい初心者や、血管が細くて見にくいまたは見えない患者の場合、血管内への刃先の刺入を確認できないため、何回も刺し直したりすることがあり、そのため、採血者にとっても被採血者にとっても大きな負担を強いられることになり、また、場合によっては、新たに真空採血管、採血針、その他の採血器具を用意して採血のし直しをしなければならず、不経済であった。そこで、刃先が血管に刺入されたことを確認することができる採血針が提案されている（特開平４－１３２５４１号公報など）。
【０００３】上記特開平４－１３２５４１号公報の採血針は、ハブに弾性チップの内腔部と外部雰囲気とを連通させる通気孔を設け、この通気孔の外部口部に通気性フィルタを取り付けたことを特徴とするもので、採血針に流入する血液（いわゆるフラッシュバック）を確認することにより、刃先が血管に刺入されたことを確認するようにしたものである。しかしながら、上記の採血針は弾性チップ内に流入した血液を透明なハブの通気孔に導こうとするものなので、フラッシュバックの確認に要する時間が長く、また、弾性チップの内部に溜まった血液が漏れる虞があり問題である。
【０００４】
【発明が解決しようとする課題】本発明は、上記の事情に鑑みてなされたもので、これに接続される注射針の刃先が血管に刺入されたときに、その透明なハブの中間部分に血液が流れ込み、これによって刃先が血管内に刺入されたことを確認できる採血用アダプタを提供することを目的とする。また、この採血用アダプタと注射針の組合せからな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】本発明は、上記の課題を解決するために、先端に刃先を有する中空のカヌラと、その先端部で該カヌラの後端部を支持し固定するとともに、その後端部に注射針のハブを液密に挿着可能な注射針接続部を備えた透明な中空のハブと、前記カヌラに被冠されたゴム弾性体製のキャップ部材とからなり、前記ハブの先端部と注射針接続部の間の中空部分に、該中空部分を外気と連通する通気路が設けられ、該通気路の出口がガス透過性かつ液体不透過性のフィルター部材で塞がれてなる採血用アダプタを採用している。また、この採血用アダプタに注射針を接続した構成を採用している。ここで、注射針接続部はこれに接続される注射針のハブと嵌合可能なルアーチップに形成してもよく、また、ルアーチップの外側にはこれと同心状に注射針のハブと螺合あるいはルアー結合可能な雌型結合手段を設けてもよい。
【０００６】
【作用】上記構成によれば、採血用アダプタを採血針ホルダーに取り付け、その注射針接続部に注射針を接続して、この注射針を血管に刺入すると、注射針の中空部分および採血用アダプタの中空部分に存在する空気が、流入する血液により採血用アダプタの通気路を通りガス透過性のフィルター部材を透過して外部に追い出されるので、血液は注射針の中空部分を通って採血用アダプタの中空部分に流入し、さらに通気路を通ってフィルター部材に達する。従って、透明なハブに形成された通気路を観察すれば、容易に注射針の血管内への刺入を確認することができる。また、この時、フィルター部材が液体不透過性なので、血液がフィルター部材を透過して外部に漏れることはない。
【０００７】
【実施例】次に本発明の実施例について図面に基づいて説明する。図１は本発明の一実施例に係る採血用アダプタの縦断面図であり、図２は他の実施例を示す図、図３は図１に示す採血用アダプタに注射針を取り付けた状態を示す図である。図１に示すように、本発明の採血用アダプタは、先端に刃先１１を有する中空のカヌラ１と、その先端部でこのカヌラ１の後端部を支持し固定する透明な中空のハブ２と、カヌラ１に被冠されたゴム弾性体

製のキャップ部材３からなっている。そして、ハブ２の後端部には注射針接続部２１が設けられており、ハブ２の中間部には通気路２２が設けられ、この通気路２２の出口はガス透過性かつ液体不透過性のフィルター部材２３で塞がれている。

【０００８】ハブ２は例えばポリエチレンやポリプロピレン、ポリエステル、ポリスチレンなどの透明な合成樹脂で中空に形成された部材であり、先端部と中間部および後端部からなる。ハブ２の先端部の中空部分２５には一般にステンレス鋼で形成されたカヌラ１の後端部が挿入され、接着剤で固定されており、このカヌラ１にはゴム弾性体の例えば天然ゴムや、イソプレンゴム、ブタジエンゴム、ニトリルゴムなどで形成されたキャップ部材３が被せられている。また、ハブ２の先端部の外壁には雄型結合手段の例えば雄ネジ２６が形成されており、採血針ホルダー（図示していない）に螺合できるようになっている。

【０００９】ハブ２の後端部はハブ２の先端部の中空部分２５と連通する中空部分２４を有する注射針接続部２１になっており、注射針４のハブ４１を嵌合できるよう一般に外径がテーパ状に縮径された所謂ルアーチップに形成されている。ルアーチップに形成された注射針接続部２１の外側には、採血操作の途中で注射針４のハブ４１が注射針接続部２１から脱落することがないように、例えば図２に示すように、ハブ２の中間部から注射針接続部２１方向にこれと同心状に延びるフード状の雌型結合手段２７を設け、注射針４のハブ４１の端部外壁に設けた雄型結合手段（図示していない）と螺合またはルアー結合するようにしてもよい。尚、注射針接続部２１としては通常、注射針４のハブ４１に挿着される雄型の結合部材が採用されるが、注射針のハブを雄型の結合端に形成することにより雌型の結合部材を採用することもできる。

【００１０】ハブ２の中間部は幅広の鍔状に突出した部分であり、中空部分２４を外気と連通する通気路２２が設けられており、通気路２２の出口はフィルター部材２３で塞がれている。このフィルター部材２３はガス透過性かつ液体不透過性のフィルター（疎水性フィルター）であり、このようなフィルターとしては、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採用されるが、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構わない。

【００１１】次に、本発明の採血用アダプタの使用について図３を用いて説明する。先ず、採血用アダプタＡを採血針ホルダー（図示していない）に取り付け、採血用アダプタＡの注射針接続部２１に注射針４を接続する。次に注射針４の刃先４３を血管に刺入すると、注射針４の中空部分４４および採血用アダプタＡの中空部分２４、２５に存在する空気が、流入する血液により採血用アダプタＡの通気路２２を通りガス透過性のフィルター部材２３を透過して外部に追い出される。すると、血液は注射針４の中空部分４４を通って採血用アダプタＡの中空部分２４に流入し、さらに通気路２２を通ってフィルター部材２３に達する。従って、透明なハブ２に設けられた注射針接続部２１や通気路２２を観察すれば、容易に注射針４の刃先４３の血管内への刺入を確認することができる。また、この時、フィルター部材２３が液体不透過性なので、血液がフィルター部材２３を透過して外部に漏れることはない。

【００１２】

【発明の効果】以上説明してきたことから明らかなように、本発明の採血用アダプタを採用することにより、次のような効果を奏することができる。

通常の注射針を接続することにより採血針として使用することができるので、経済的である。

これに接続された注射針の刃先が血管に刺入されたことを容易に確認できるので、注射針の刺し直しによる被採血者の負担を無くすることができる。

採血のし直しをしなくて済む。

【図面の簡単な説明】

【図１】本発明の一実施例に係る採血用アダプタの縦断面図である。

【図２】本発明の他の実施例を示す図である。

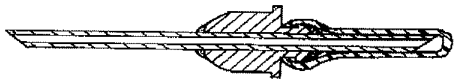
【図３】図１に示す採血用アダプタに注射針を取り付けた状態を示す図である。

【図４】従来の採血針を示す図である。

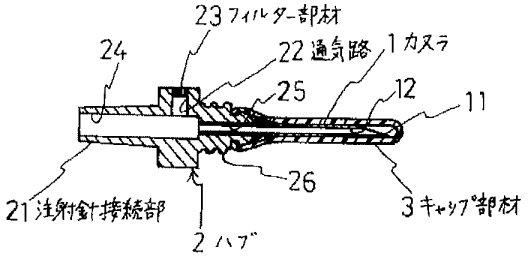
【符号の説明】

１　カヌラ
２　ハブ
２１　注射針接続部
２２　通気路
２３　フィルター部材
２７　雌型結合手段
３　キャップ部材
４　注射針
Ａ　採血用アダプタ

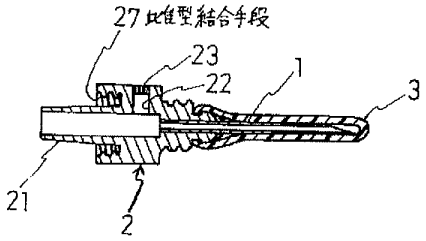
【図４】



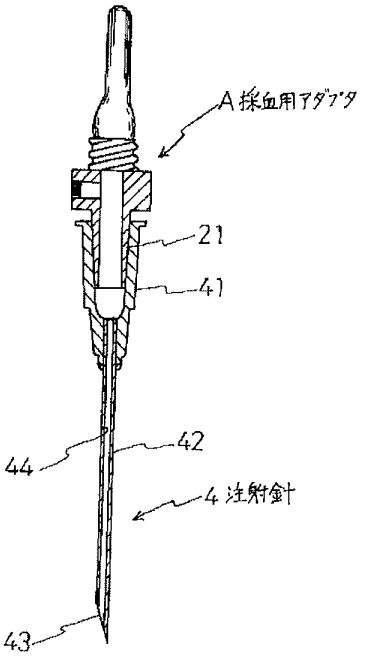
【図1】


23 フィルター部材
24
22 通気路
1 カヌラ
25
12
11
26
21 注射針接続部
2 ハブ
3 キャップ部材

【図2】


27 比重型結合手段
23
22
1
3
21
2

【図3】


A 採血用アダプタ
21
41
42
44
4 注射針
43

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DESCRIPTION JPH08257018

[0001]

BACKGROUND OF THE INVENTION 1. Field of the Invention The present invention relates to a blood collecting adapter. More specifically, it is a blood collection adapter used for a vacuum blood collection tube for collecting blood from a blood vessel, which can be used as a blood collection needle by connecting a normal injection needle thereto, and the cutting edge is inserted into the blood vessel. The present invention relates to a blood collection adapter capable of confirming the fact.

[0002]

2. Description of the Related Art Conventionally, at the time of blood collection using a blood collection tube, blood has been collected using a blood collection needle as shown in FIG. 4, and it has been confirmed from intuition and experience that the cutting edge has entered the blood vessel. However, in blood collection that relies on such intuition and experience, beginners with poor intuition and experience, or patients with thin or difficult to see blood vessels cannot see the insertion of the cutting edge into blood vessels, so many times This can be a burden on both the blood donor and the blood recipient, and in some cases, a new vacuum blood collection tube, blood collection needle, or other blood collection device may be needed. Blood sampling had to be done again, which was uneconomical. Therefore, a blood collection needle has been proposed that can confirm that the blade tip has been inserted into a blood vessel (Japanese Patent Laid-Open No. 4-132541).

[0003]

The blood collection needle disclosed in Japanese Patent Application Laid-Open No. HEI 4-132541 is characterized in that a hub is provided with a ventilation hole for communicating the inner cavity of the elastic tip with the external atmosphere, and a gas permeable filter is attached to the outside opening of the ventilation hole. By checking the blood (so-called flashback) flowing into the blood collection needle, it is confirmed that the cutting edge has been inserted into a blood vessel. However, since the above blood collection needle attempts to guide the blood flowing into the elastic tip to the ventilation hole of the transparent hub, it takes a long time to check the flashback, and the blood collected inside the elastic tip may be reduced. There is a risk of leakage, which is a problem.

[0004]

SUMMARY OF THE INVENTION The present invention has been made in view of the above circumstances, and has an intermediate portion of a transparent hub when a blade of a syringe needle connected thereto is inserted into a blood vessel. It is an object of the present invention to provide a blood collection adapter capable of confirming that blood flows into a blood vessel and that the blade tip is inserted into a blood vessel. It is another object of the present invention to provide a blood collection needle comprising a combination of the blood collection adapter and a syringe needle.

[0005]

SUMMARY OF THE INVENTION In order to solve the above-mentioned problems, the present invention provides a hollow cannula having a cutting edge at a front end, and supports and fixes a rear end of the cannula at the front end. A transparent hollow hub provided with an injection needle connection portion into which an hub of the injection needle can be inserted in a liquid-tight manner, and a cap member made of a rubber elastic material covered with the cannula. An air passage communicating the outside air with the hollow portion is provided in a hollow portion between the distal end portion and the injection needle connection portion, and an outlet of the air passage is closed with a gas-permeable and liquid-impermeable filter member. The adapter for blood collection is adopted. Further, a configuration in which an injection needle is connected to the blood collection adapter is employed. Here, the injection needle connecting portion may be formed in a luer tip that can be fitted to the hub of the injection needle connected thereto, and the hub of the injection needle and the screw are concentrically provided on the

outside of the luer tip. A female coupling means capable of joint or luer coupling may be provided.

[0006]

According to the above arrangement, the blood collection adapter is attached to the blood collection needle holder, the injection needle is connected to the injection needle connection portion, and the injection needle is inserted into a blood vessel. Since the air present in the hollow part of the adapter passes through the gas-permeable filter member through the ventilation path of the blood collecting adapter and is expelled to the outside by the inflowing blood, the blood passes through the hollow part of the injection needle for blood collection. It flows into the hollow part of the adapter and further through the ventilation path to the filter element. Therefore, by observing the air passage formed in the transparent hub, it is possible to easily confirm the insertion of the injection needle into the blood vessel. Further, at this time, since the filter member is impermeable to liquid, blood does not pass through the filter member and leak to the outside.

[0007]

Next, an embodiment of the present invention will be described with reference to the drawings. FIG. 1 is a longitudinal sectional view of a blood collection adapter according to one embodiment of the present invention, FIG. 2 is a view showing another embodiment, and FIG. 3 is a state in which a syringe needle is attached to the blood collection adapter shown in FIG. FIG. As shown in FIG. 1, the blood collection adapter of the present invention includes a hollow cannula 1 having a cutting edge 11 at a front end, and a transparent hollow hub 2 for supporting and fixing the rear end of the cannula 1 at the front end. , And a cap member 3 made of a rubber elastic material and covered with the cannula 1. An injection needle connecting portion 21 is provided at the rear end of the hub 2, and an air passage 22 is provided at an intermediate portion of the hub 2, and an outlet of the air passage 22 is gas-permeable and liquid-impermeable. The filter member 23 is closed.

[0008]

The hub 2 is a hollow member made of a transparent synthetic resin such as polyethylene, polypropylene, polyester, or polystyrene, and has a front end, an intermediate portion, and a rear

end. A rear end portion of a cannula 1 generally made of stainless steel is inserted into a hollow portion 25 at a front end portion of the hub 2 and fixed with an adhesive. The cannula 1 has a rubber elastic body such as natural rubber, A cap member 3 made of isoprene rubber, butadiene rubber, nitrile rubber, or the like is covered. The outer wall of the distal end of the hub 2 is provided with a male screw 26, for example, as a male coupling means so that it can be screwed into a blood collection needle holder (not shown).

[0009]

The rear end of the hub 2 is an injection needle connecting portion 21 having a hollow portion 24 communicating with a hollow portion 25 at the distal end of the hub 2, and the outer diameter is generally tapered so that the hub 41 of the injection needle 4 can be fitted. It is formed in a so-called luer tip having a reduced diameter. As shown in FIG. 2, for example, as shown in FIG. 2, the hub 41 of the injection needle 4 does not fall off the injection needle connection portion 21 during the blood collection operation outside the injection needle connection portion 21 formed on the luer tip. A hood-shaped female coupling means 27 extending concentrically from the intermediate portion of the hub 2 toward the injection needle connecting portion 21 is provided, and a male coupling means provided on the outer wall of the end of the hub 41 of the injection needle 4 (shown in the drawing). May be screwed or luer-coupled. Incidentally, a male coupling member inserted into the hub 41 of the injection needle 4 is usually used as the injection needle connecting portion 21. However, by forming the hub of the injection needle at the male coupling end, the female coupling member is formed. May be employed.

[0010]

An intermediate portion of the hub 2 is a portion protruding in a wide flange shape, and a ventilation path 22 that communicates the hollow portion 24 with the outside air is provided. An outlet of the ventilation path 22 is closed by a filter member 23. The filter member 23 is a gas-permeable and liquid-impermeable filter (hydrophobic filter). As such a filter, a layered filter made of a polymer sintered body such as polypropylene or polyethylene is preferably used. However, a membrane-like so-called membrane filter made of a hydrophobic resin such as polypropylene or polyethylene may be used.

[0011]

Next, the use of the blood collection adapter of the present invention will be described with reference to FIG. First, the blood collection adapter A is attached to a blood collection needle holder (not shown), and the injection needle 4 is connected to the injection needle connection portion 21 of the blood collection adapter A. Next, when the cutting edge 43 of the injection needle 4 is inserted into the blood vessel, the air existing in the hollow portion 44 of the injection needle 4 and the hollow portions 24 and 25 of the blood collection adapter A is caused to flow by the flowing blood. The gas passes through the gas permeable filter member 23 and is expelled to the outside. Then, the blood flows into the hollow portion 24 of the blood collection adapter A through the hollow portion 44 of the injection needle 4 and further reaches the filter member 23 through the air passage 22. Therefore, by observing the injection needle connecting portion 21 and the ventilation path 22 provided on the transparent hub 2, it is possible to easily confirm the insertion of the cutting edge 43 of the injection needle 4 into the blood vessel. At this time, since the filter member 23 is impermeable to liquid, blood does not pass through the filter member 23 and leak to the outside.

[0012]

As apparent from the above description, the following effects can be obtained by employing the blood collection adapter of the present invention. It is economical because it can be used as a blood collection needle by connecting a normal injection needle. Since it is possible to easily confirm that the cutting edge of the injection needle connected to this is inserted into the blood vessel, it is possible to eliminate the burden on the blood sampling subject due to the reinsertion of the injection needle. There is no need to recollect blood.

[0013]
BRIEF DESCRIPTION OF THE FIGURES

[0014]
1 is a longitudinal sectional view of a blood collection adapter according to an embodiment of the present invention.

[0015]
2 is a diagram showing another embodiment of the present invention.

[0016]
3 is a diagram showing a state where the injection needle is attached to the adapter for blood collection shown in FIG.

[0017]
4 is a diagram showing a conventional blood collection needle.

[0018]
Explanation of reference numerals

[0019]
DESCRIPTION OF SYMBOLS 1 Canula 2 Hub 21 Injection needle connection part 22 Air passage 23 Filter member 27 Female coupling means 3 Cap member 4 Injection needle A Blood collection adapter

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CLAIMS JPH08257018

1.
A hollow cannula having a cutting edge at its distal end, and a rear end of the cannula supported and fixed at the distal end, and a syringe needle connection portion at the rear end of the cannula which can insert a hub of a syringe needle in a liquid-tight manner. It is composed of a transparent hollow hub and a cap member made of a rubber elastic material covered by the cannula, and communicates the hollow portion with the outside air at a hollow portion between the distal end portion of the hub and the injection needle connection portion. A blood collection adapter provided with an air passage, wherein an outlet of the air passage is closed by a gas-permeable and liquid-impermeable filter member.

2.
The blood sampling adapter according to claim 1, wherein the injection needle connection portion is formed on a luer tip that can be fitted to a hub of the injection needle.

3.
3. The blood collection adapter according to claim 2, further comprising female coupling means concentric with the luer tip and outside the luer tip and capable of coupling to the hub of the injection needle.

4.
A blood collection needle formed by connecting an injection needle to the blood collection adapter according to claim 1.

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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.

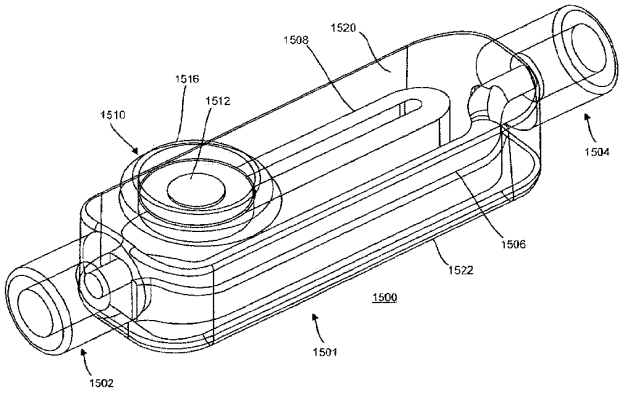


FIG. 15C

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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).

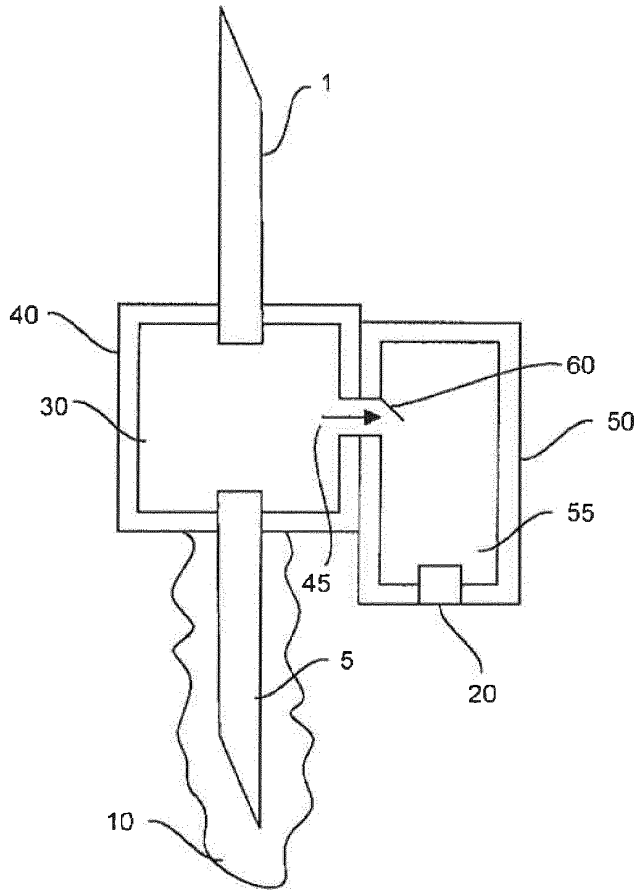


FIG. 1

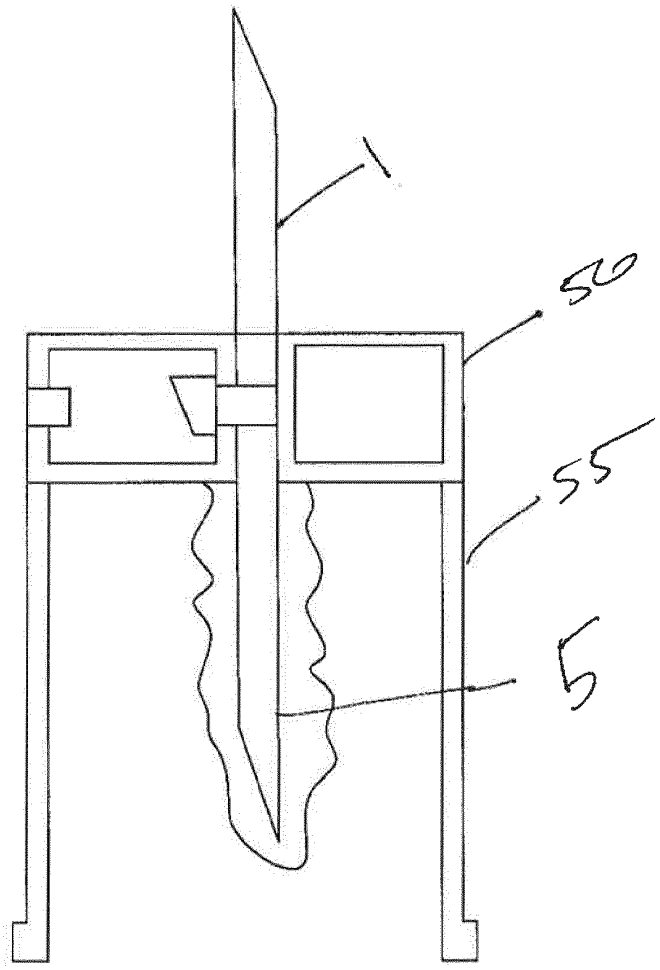


FIG. 2

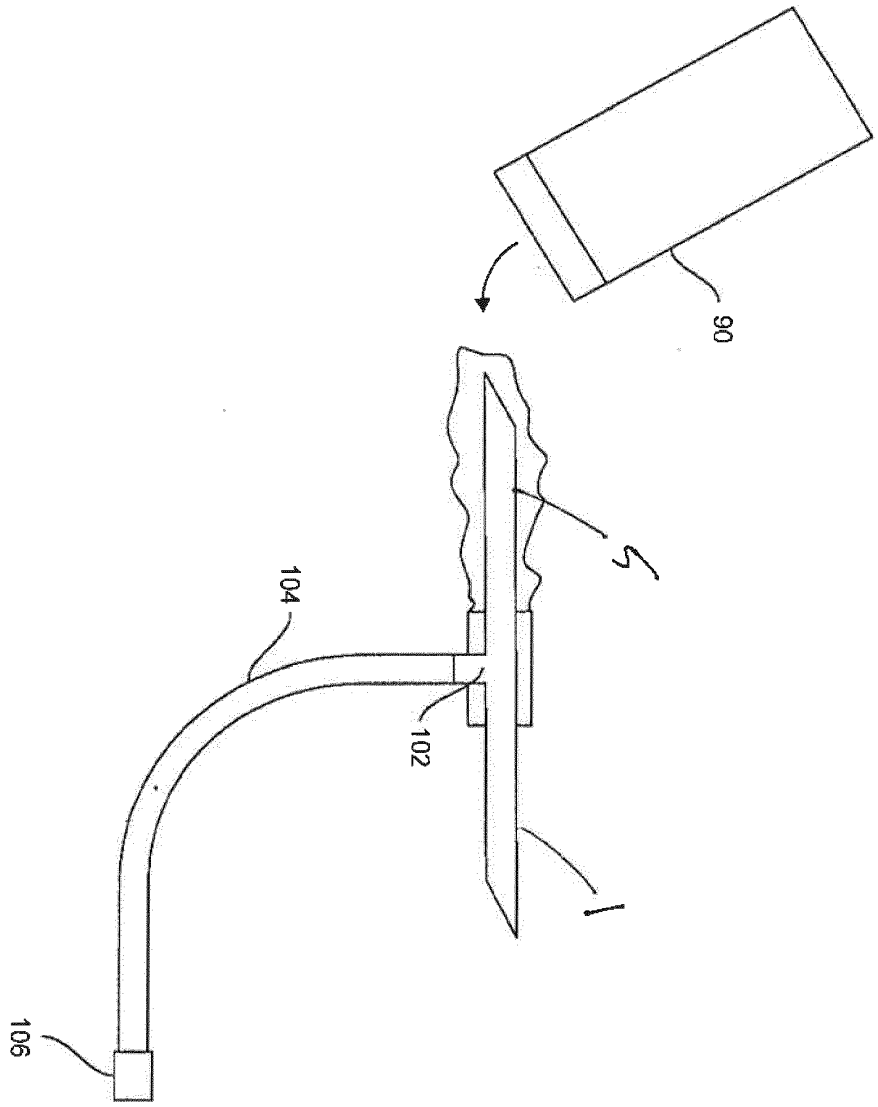


FIG. 3

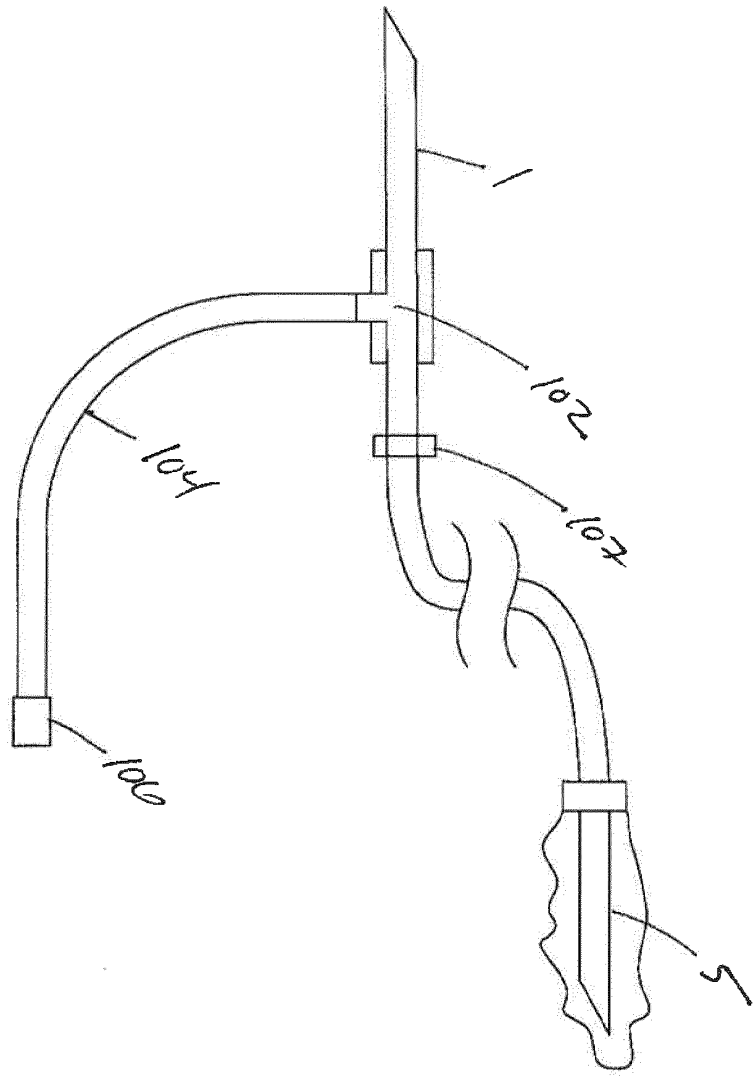


FIG. 4

FIG. 5

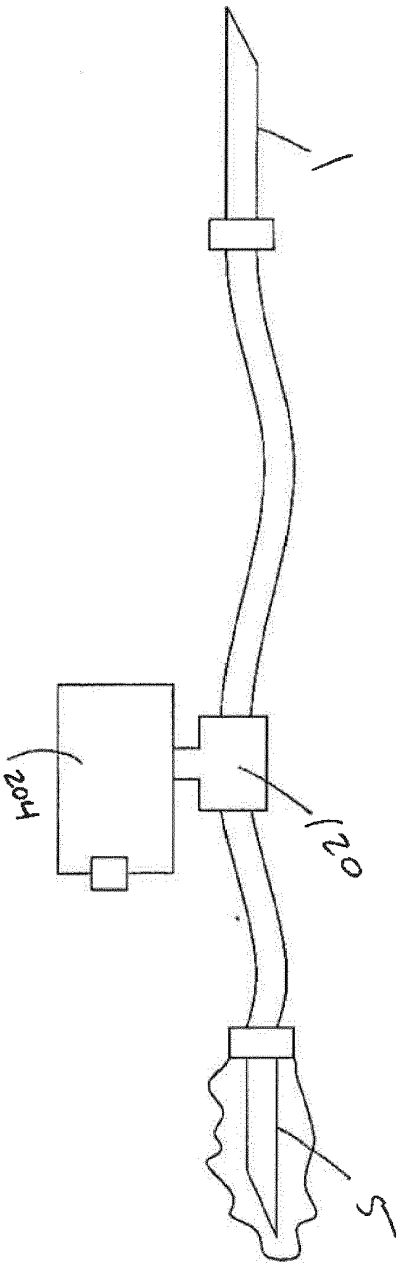
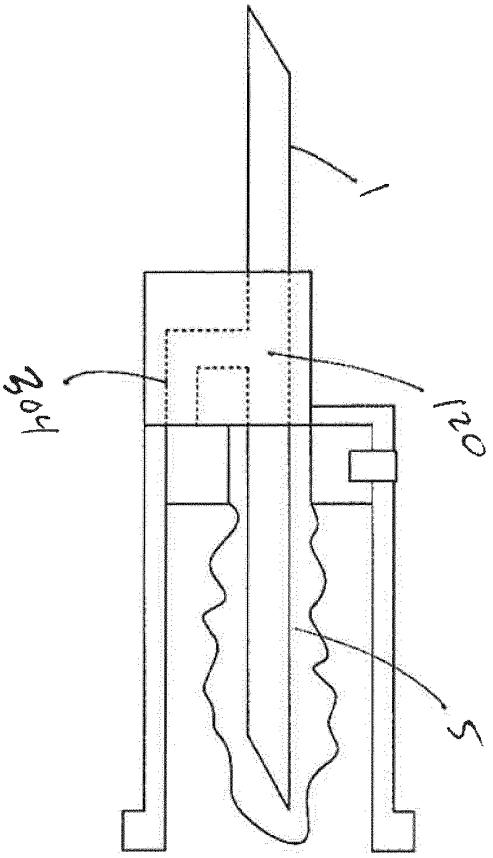


FIG. 6



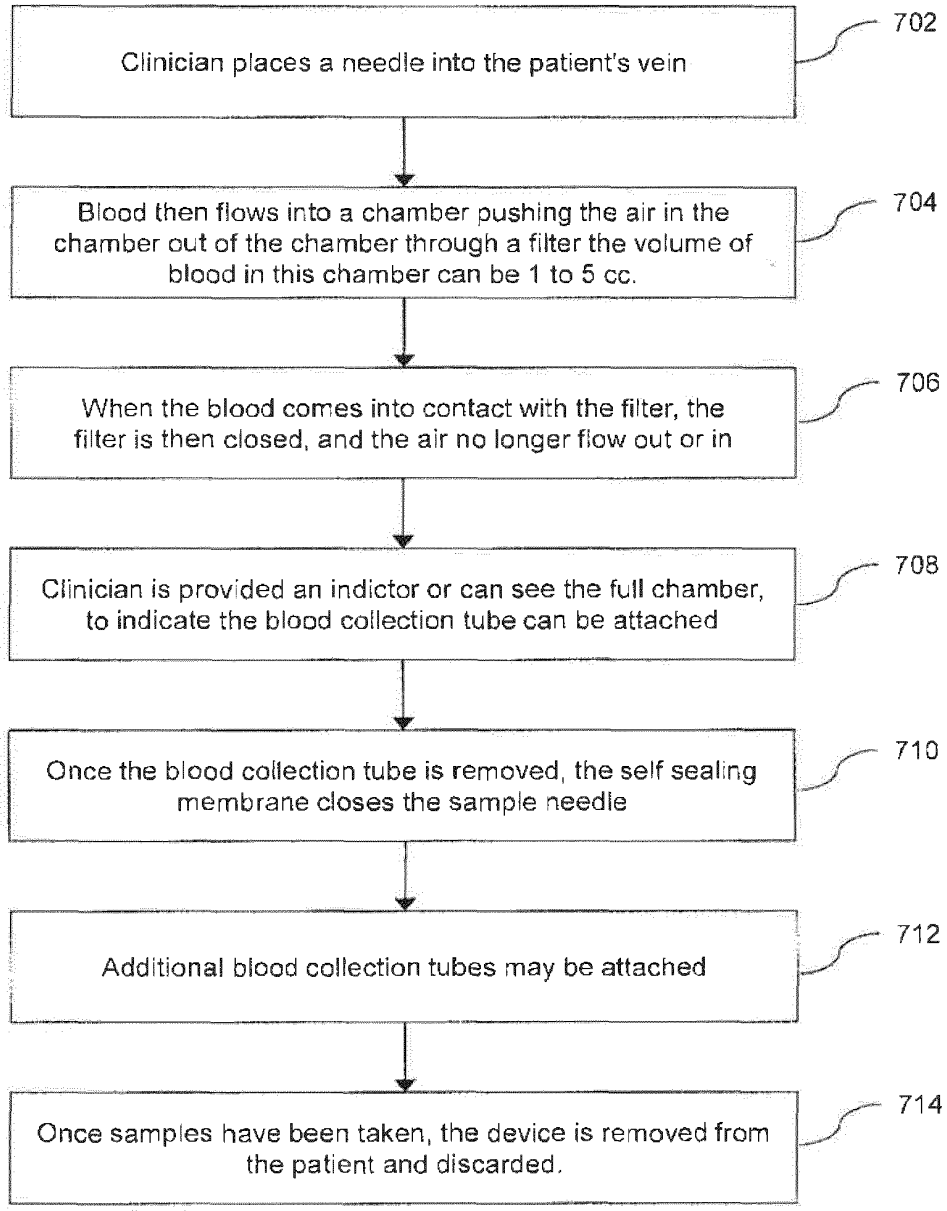

Clinician places a needle into the patient's vein
702
Blood then flows into a chamber pushing the air in the chamber out of the chamber through a filter the volume of blood in this chamber can be 1 to 5 cc.
704
When the blood comes into contact with the filter, the filter is then closed, and the air 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

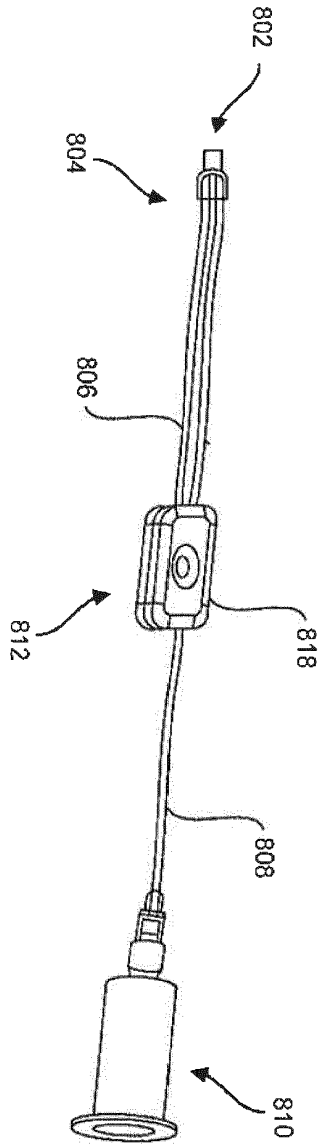


FIG. 8A

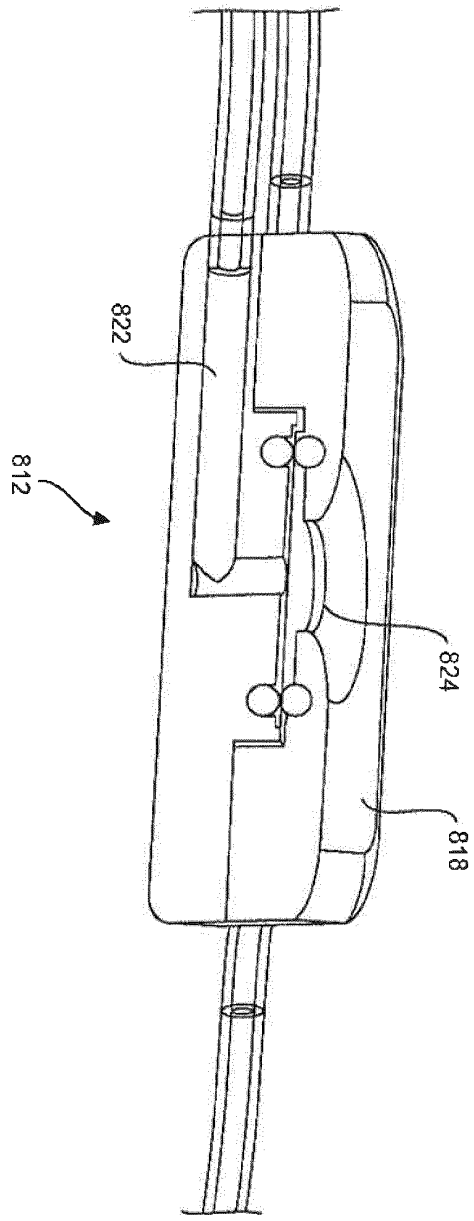


FIG. 8B

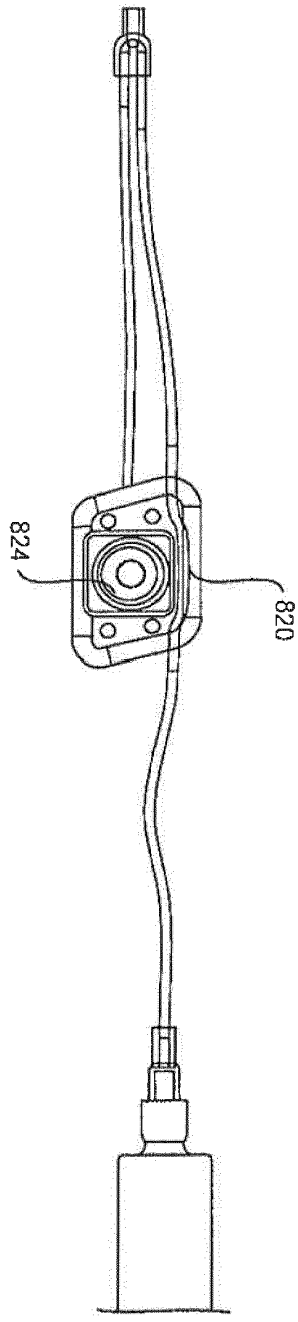


FIG. 8C

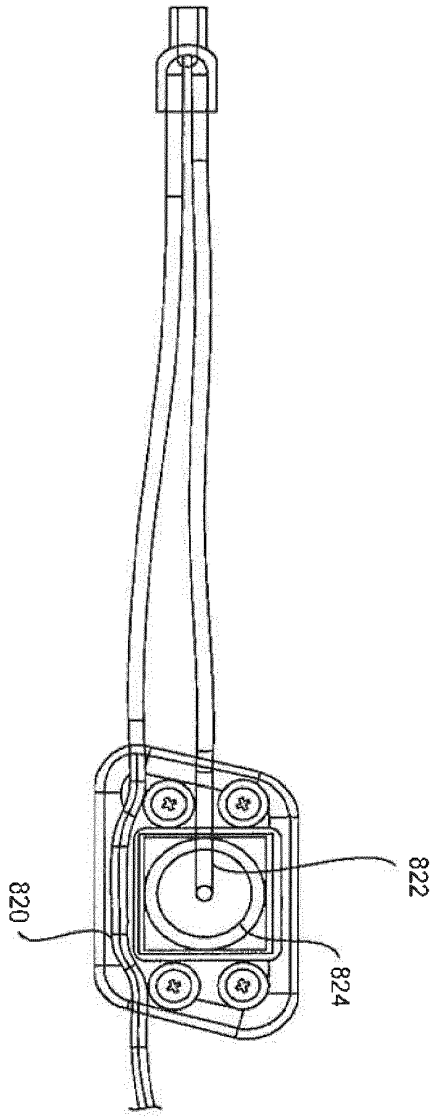


FIG. 8D

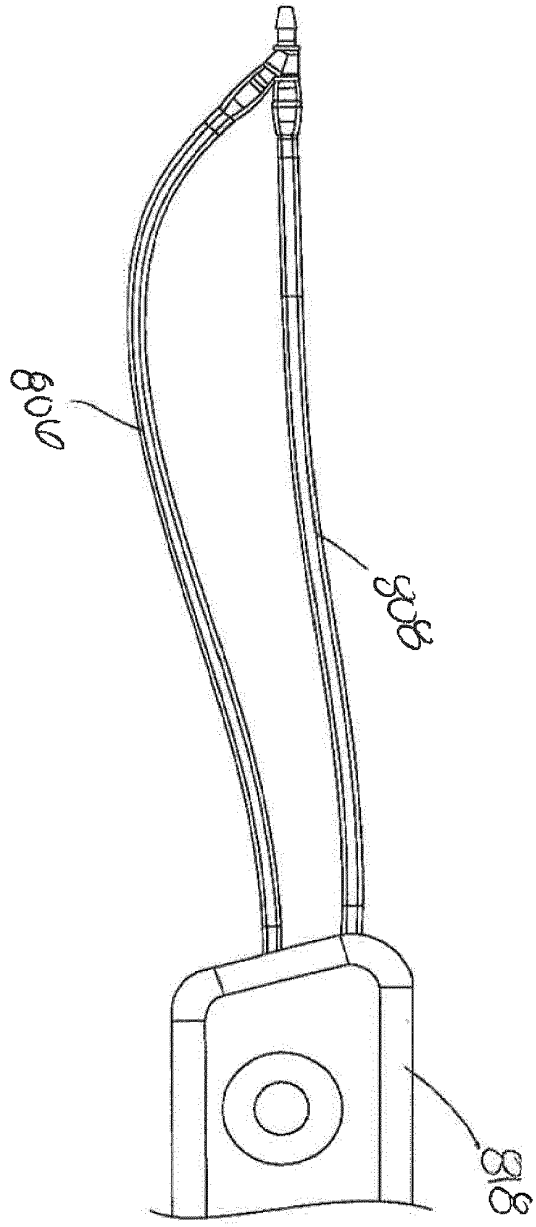


FIG. 8E

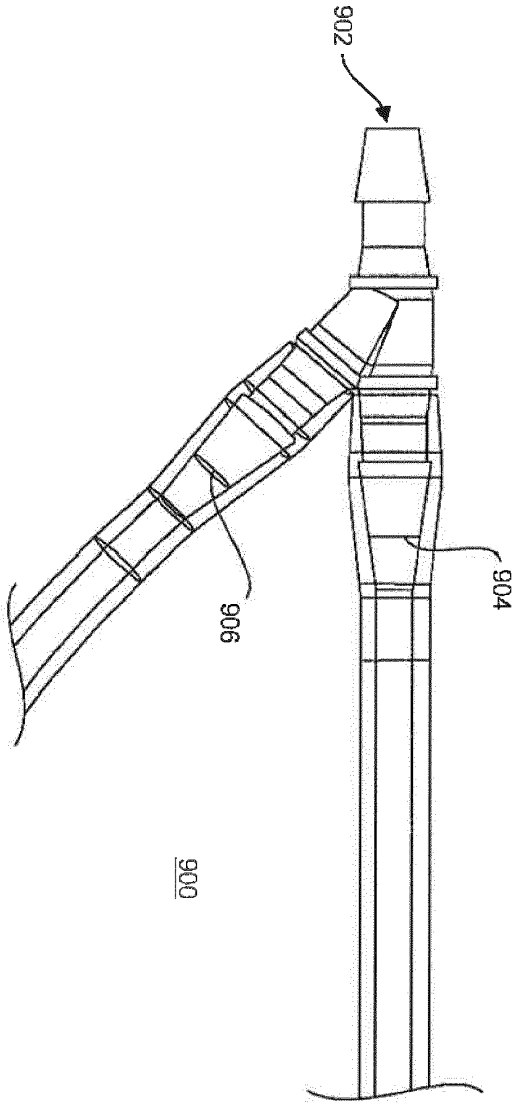


FIG. 9

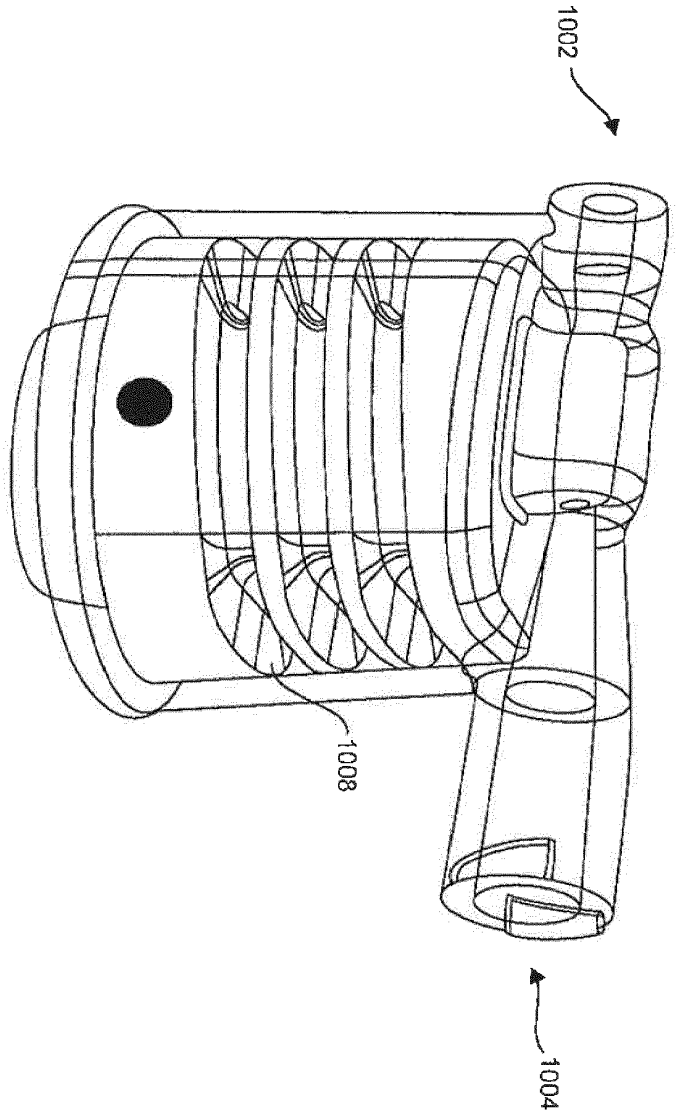


FIG. 10A

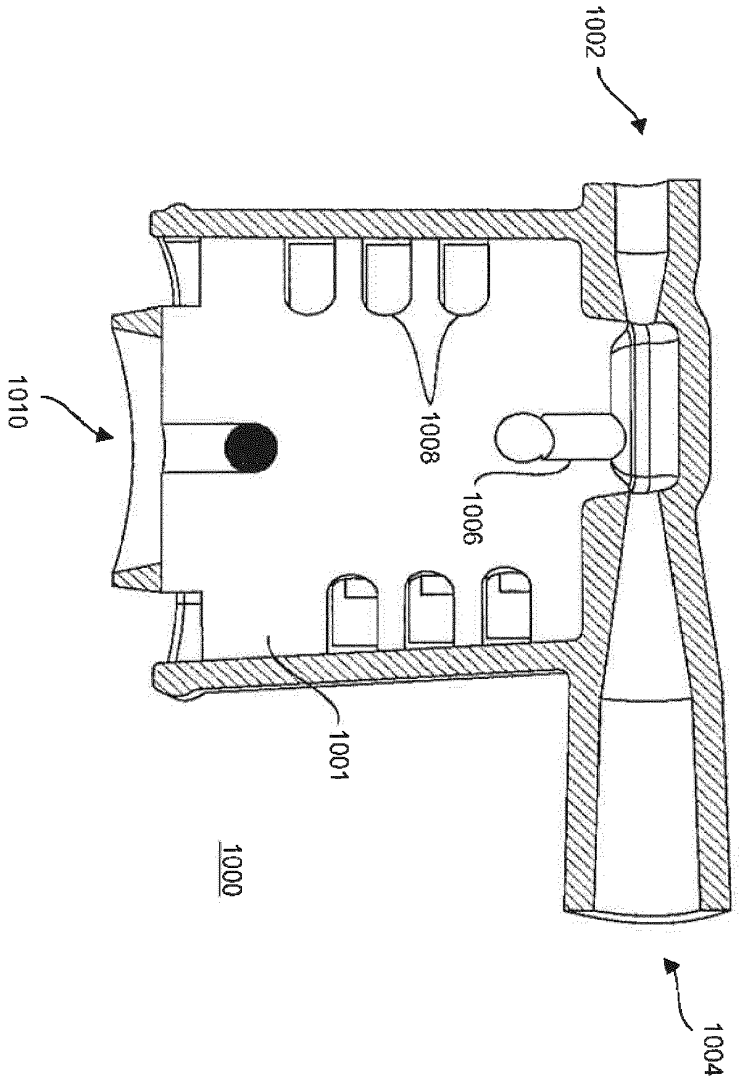


FIG. 10B

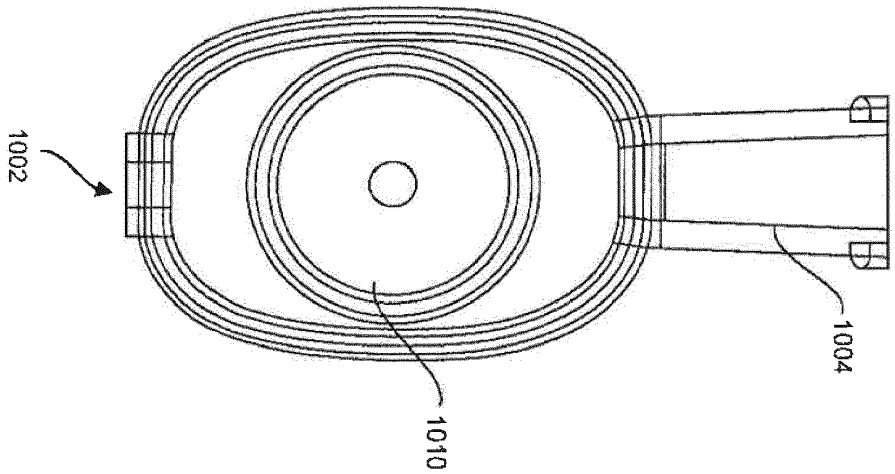


FIG. 10C

FIG. 10D

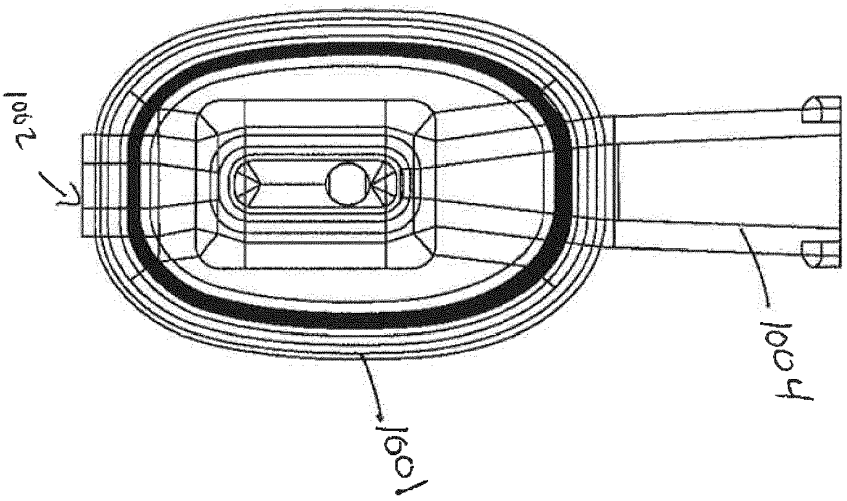
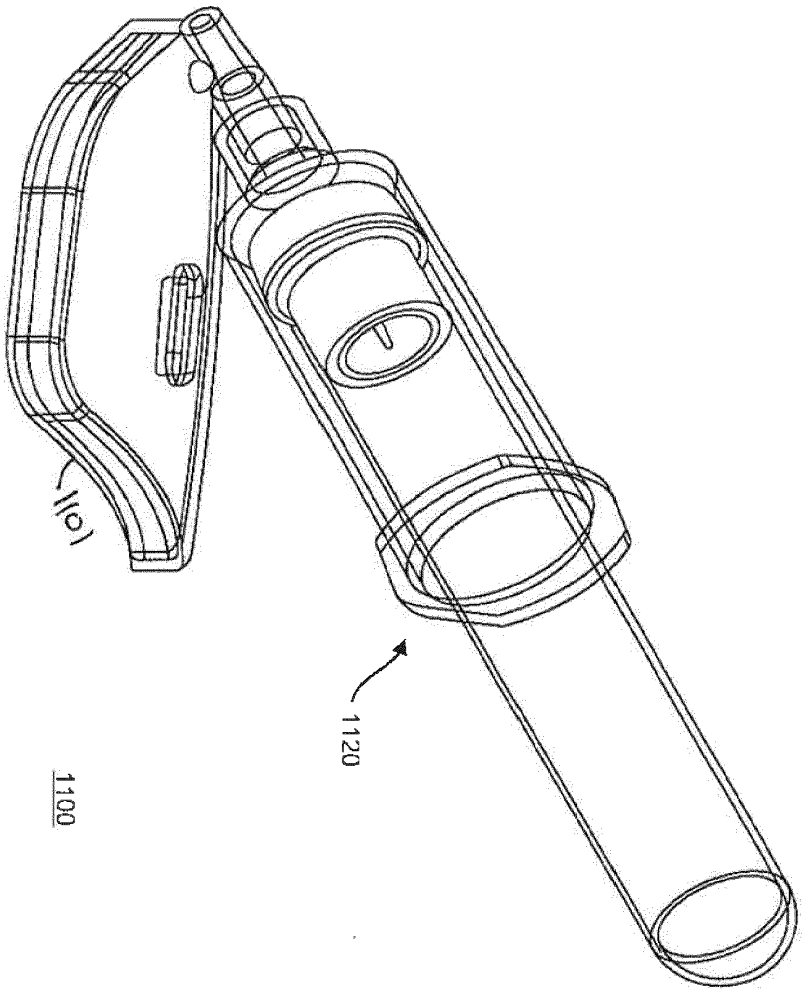


FIG. 11A



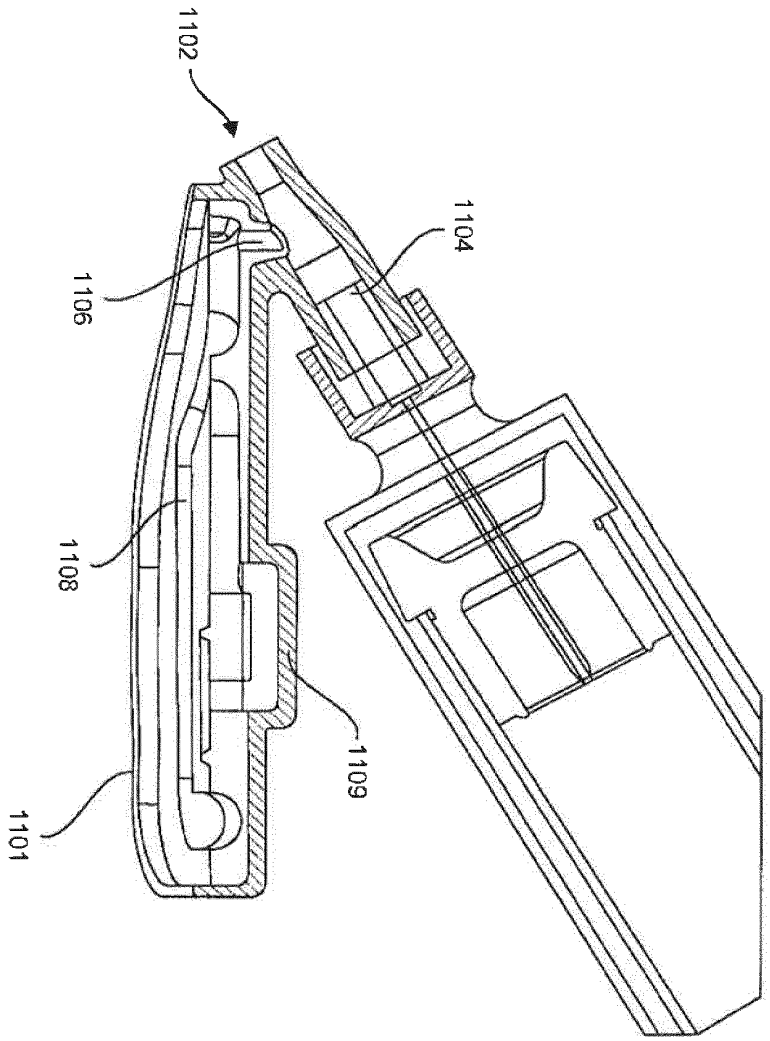


FIG. 11B

FIG. 11C

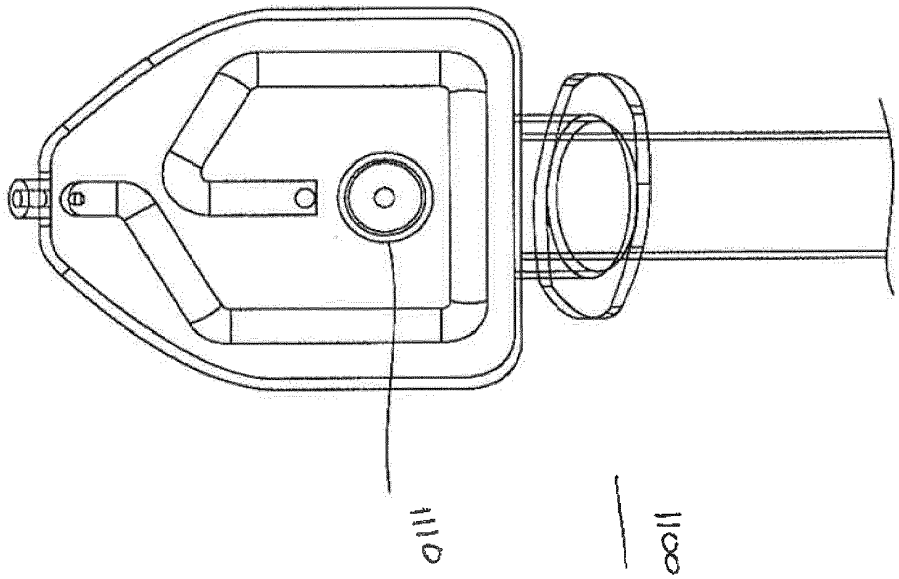
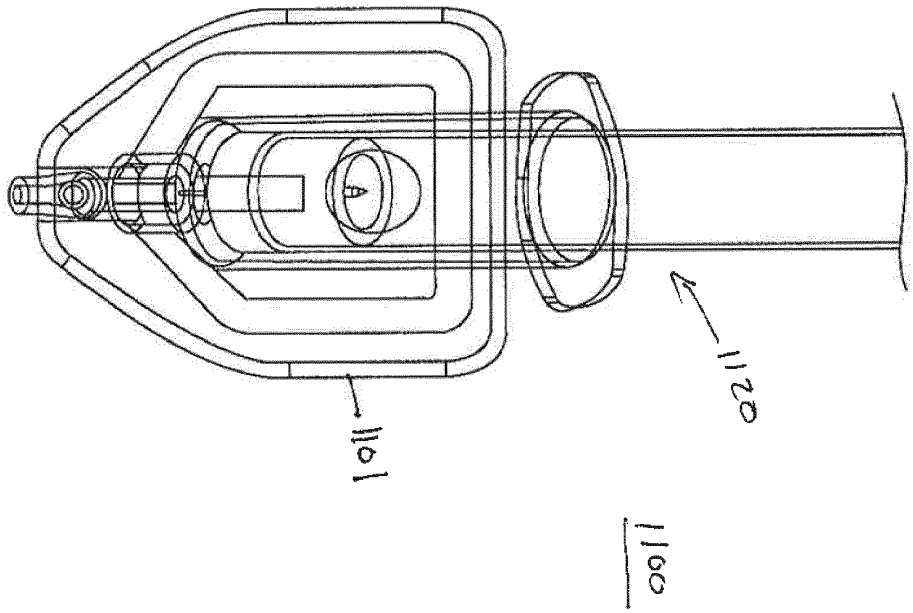


FIG. 11D



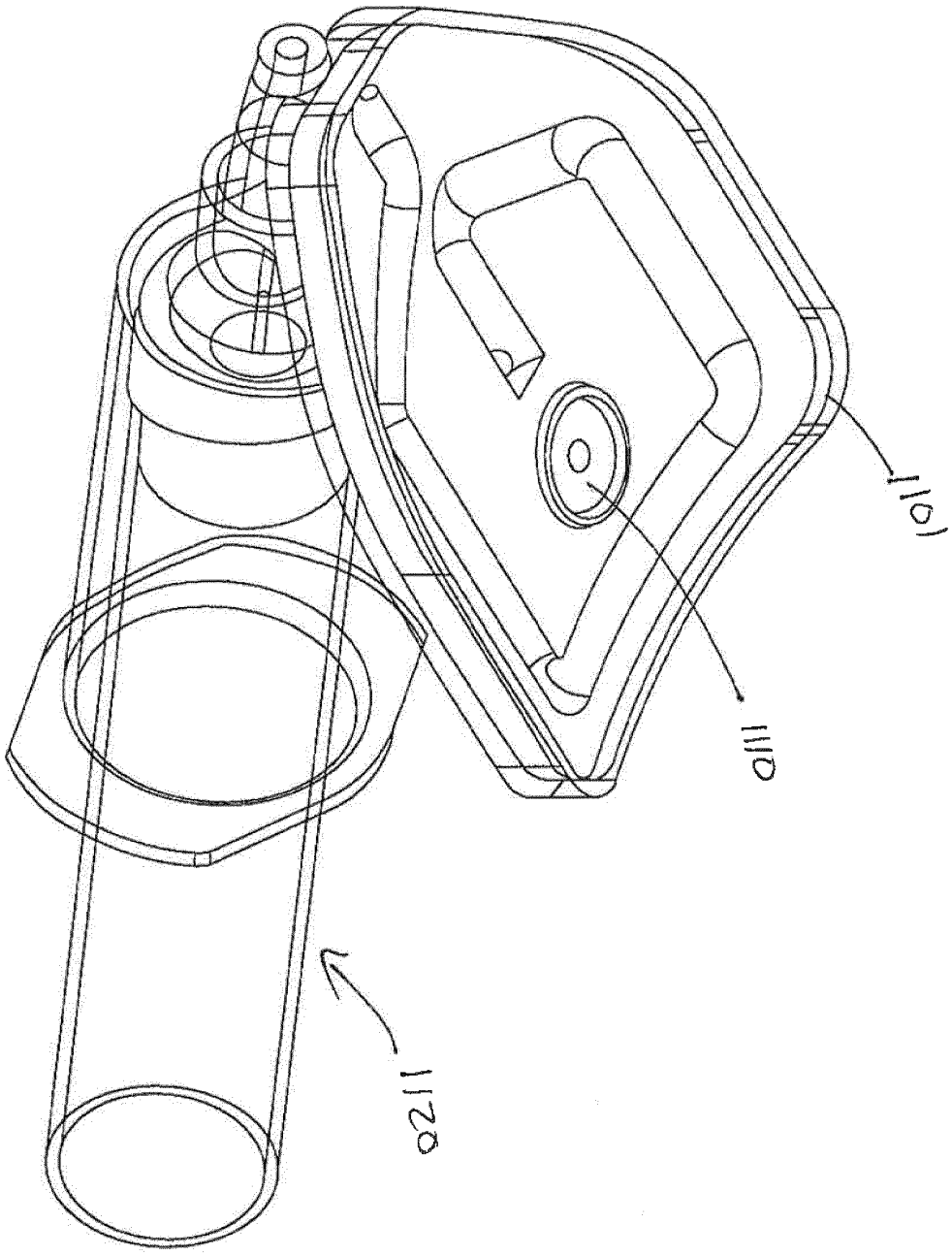


FIG. 11E

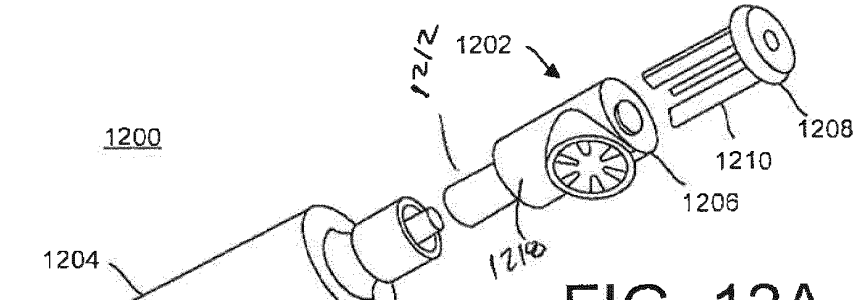


FIG. 12A

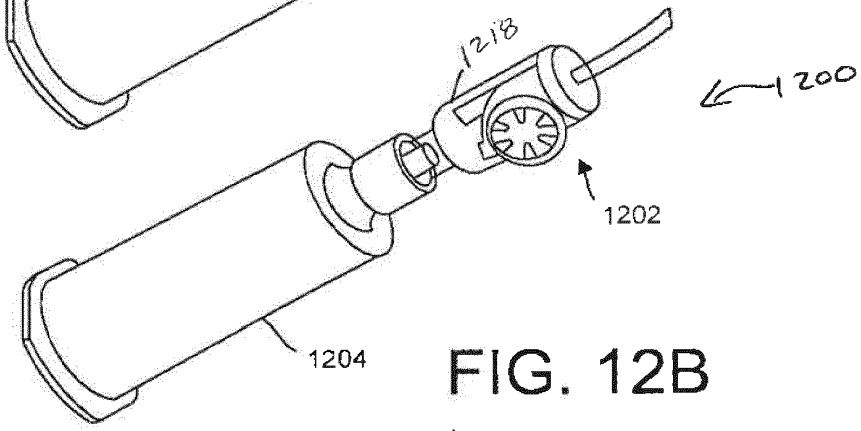


FIG. 12B

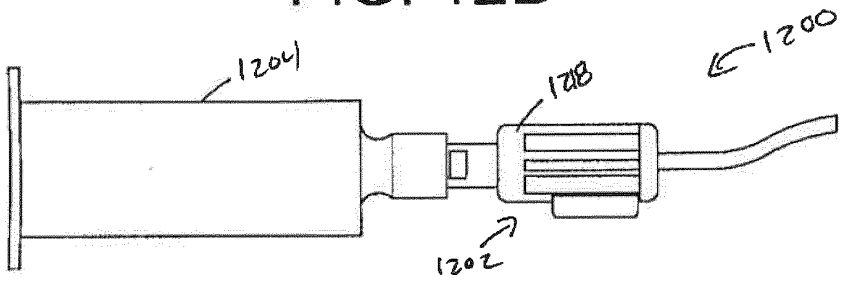


FIG. 12C

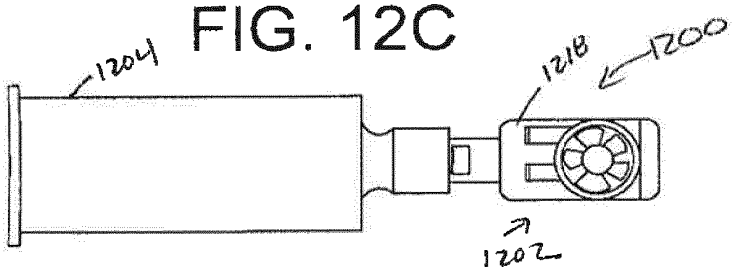


FIG. 12D

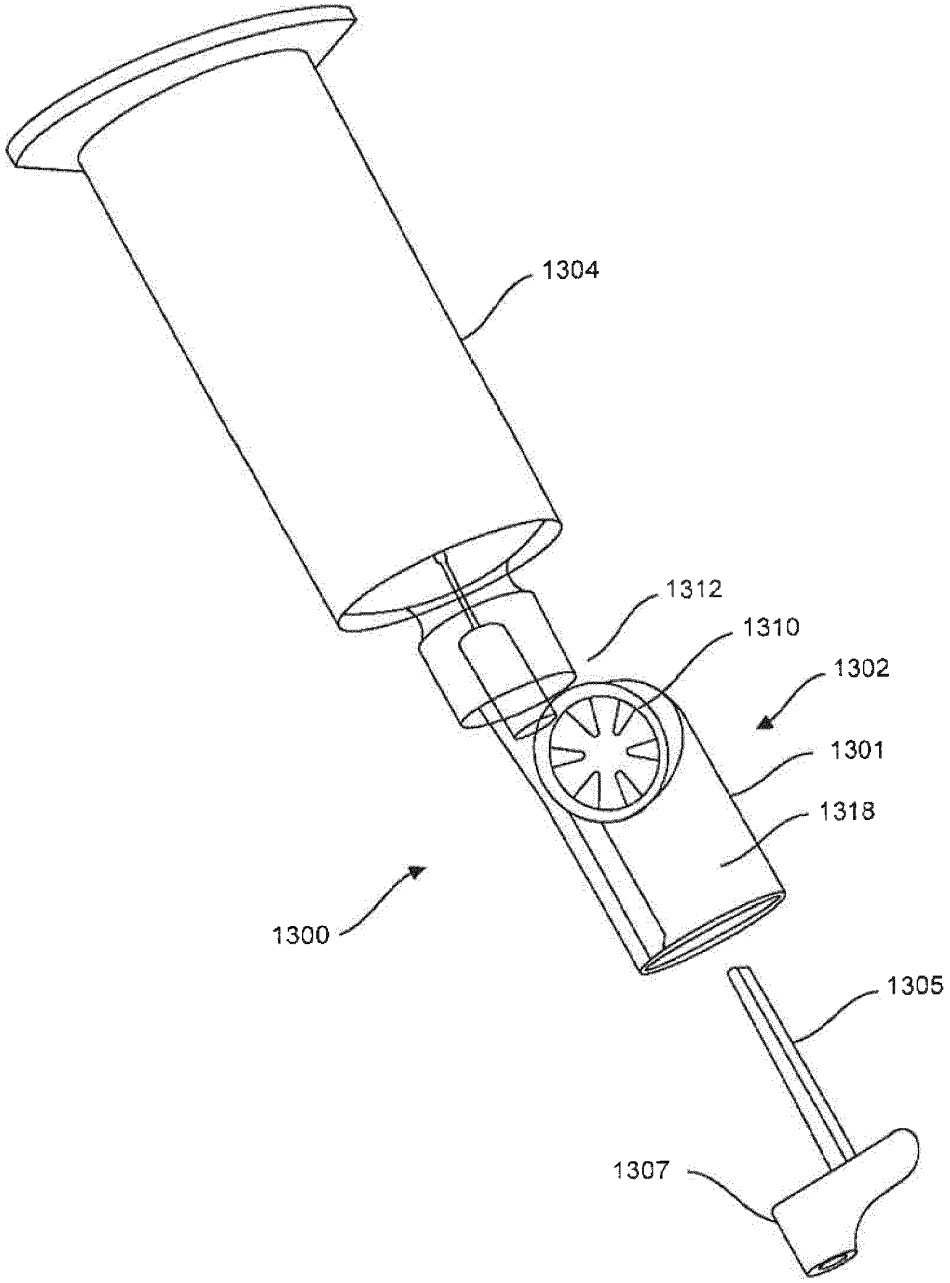


FIG. 13A

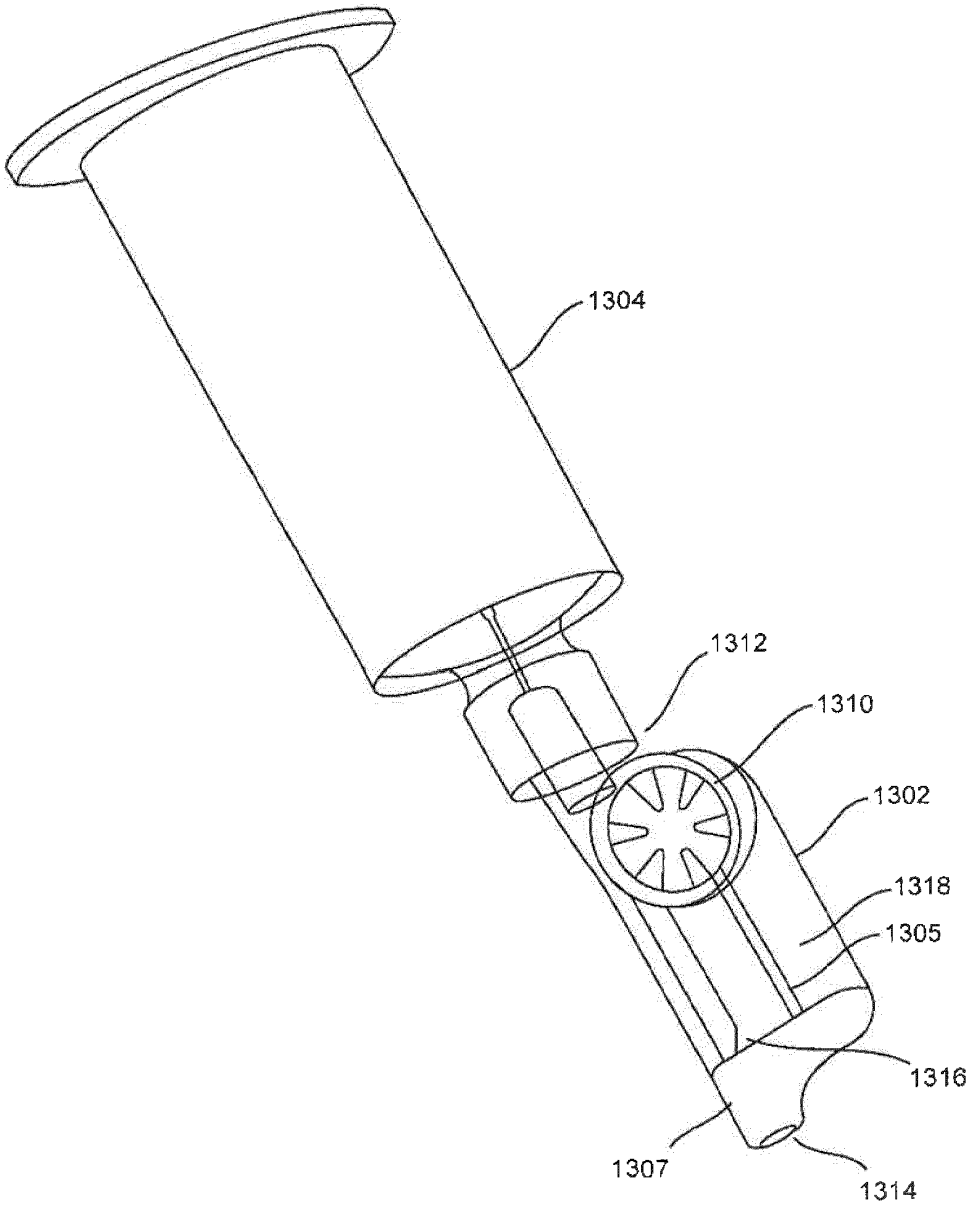


FIG. 13B

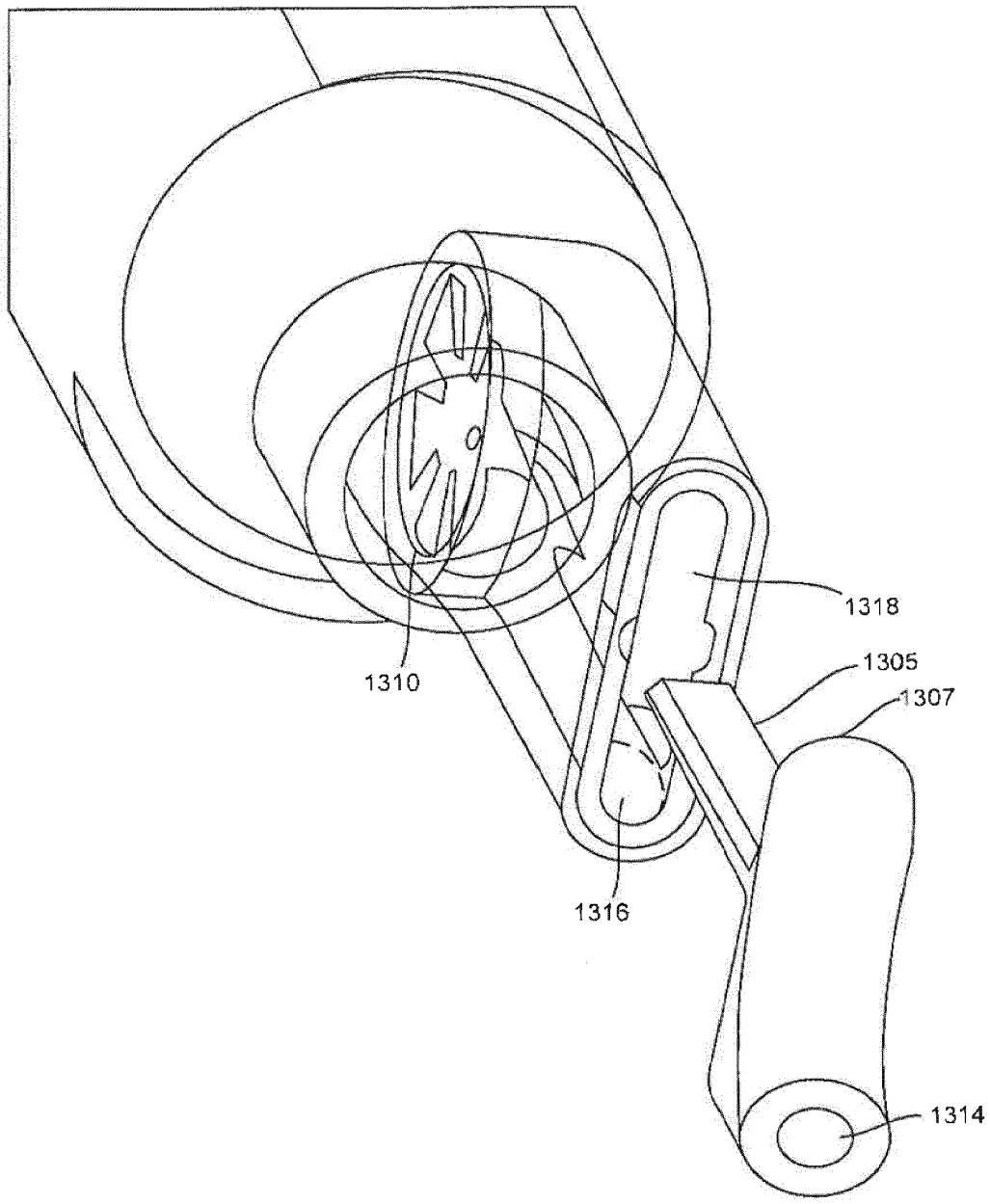


FIG. 13C

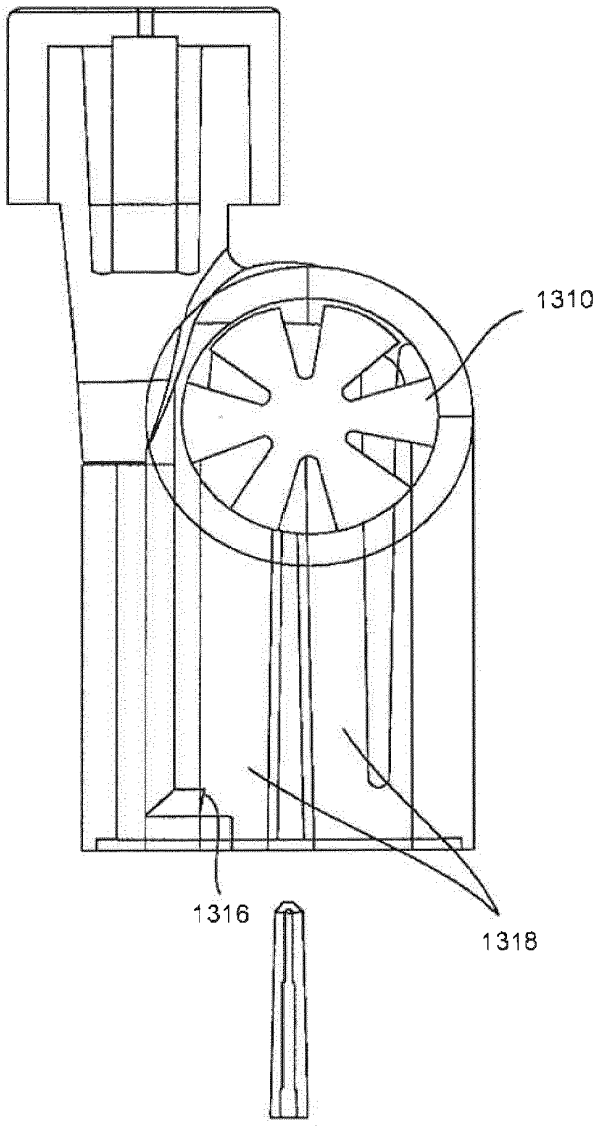


FIG. 13D

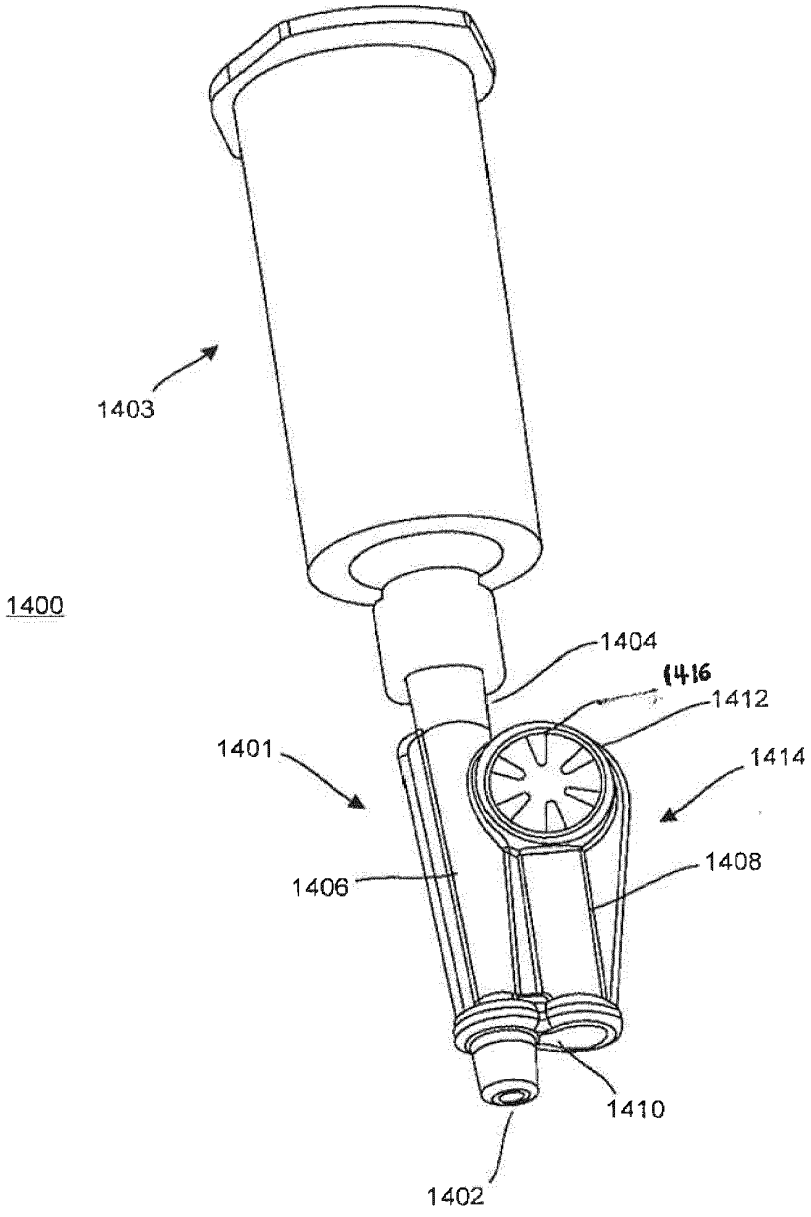


FIG. 14A

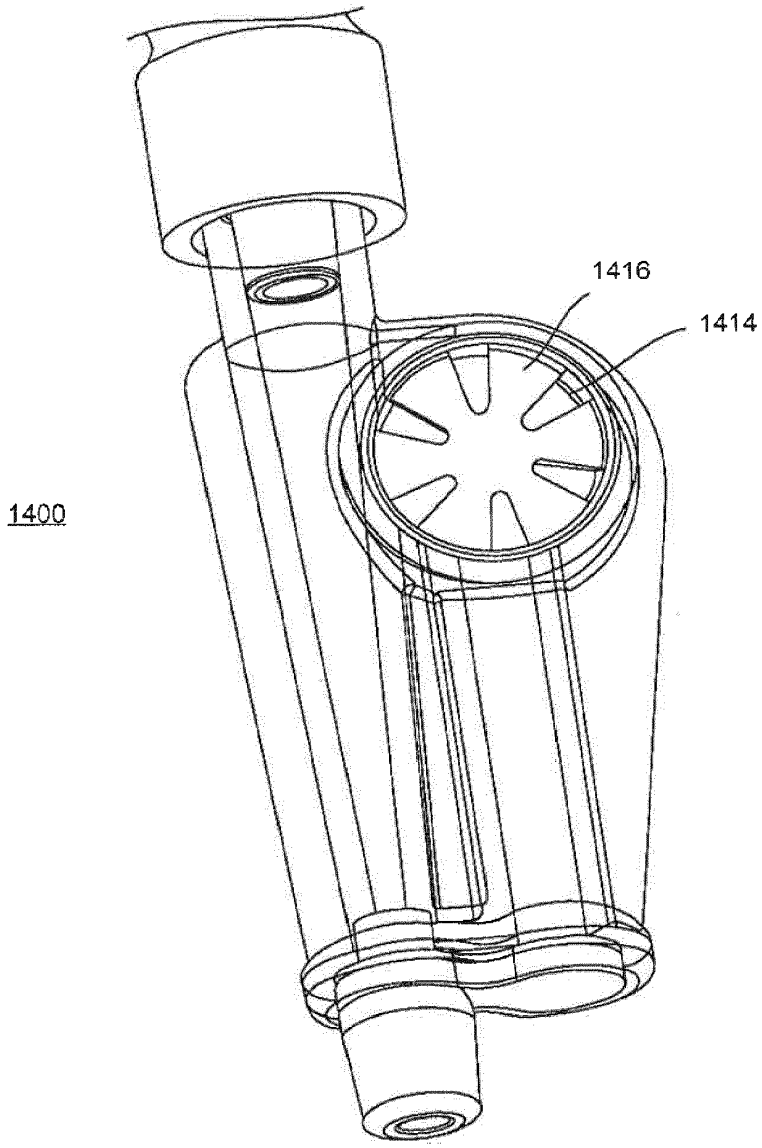


FIG. 14B

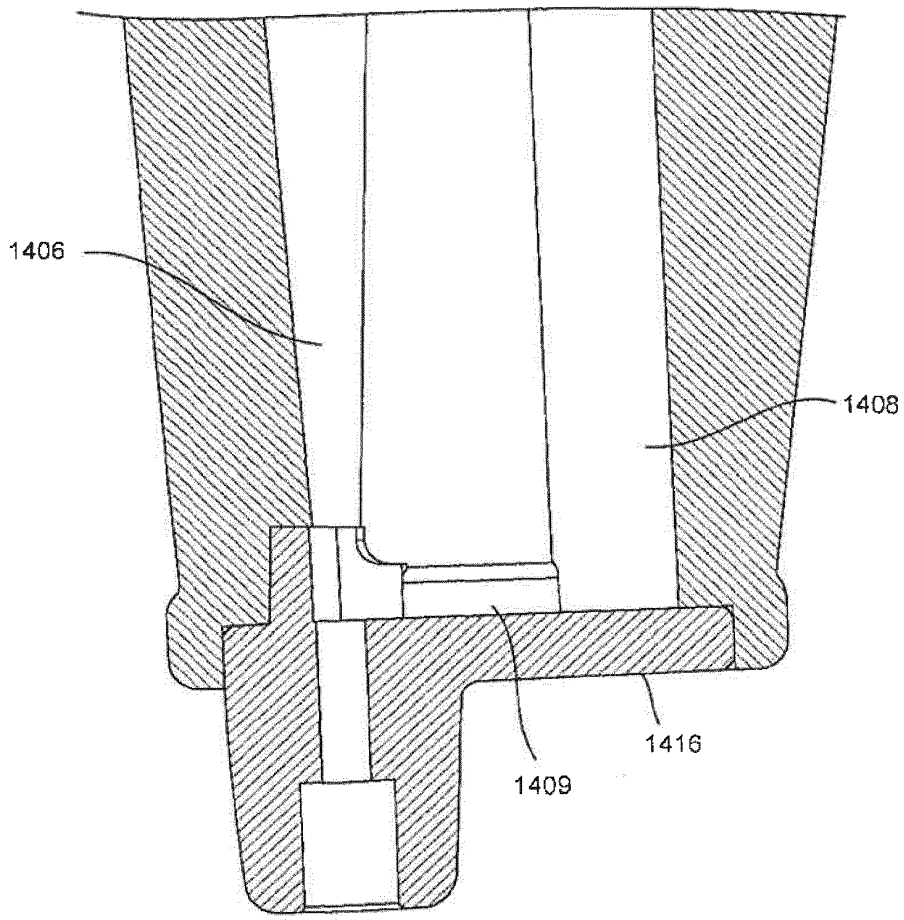


FIG. 14C

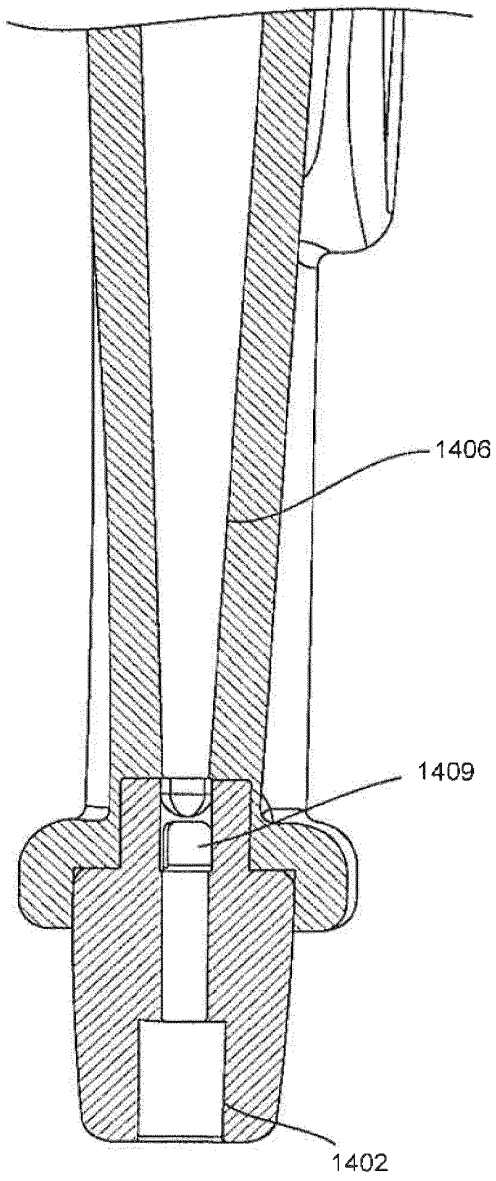


FIG. 14D

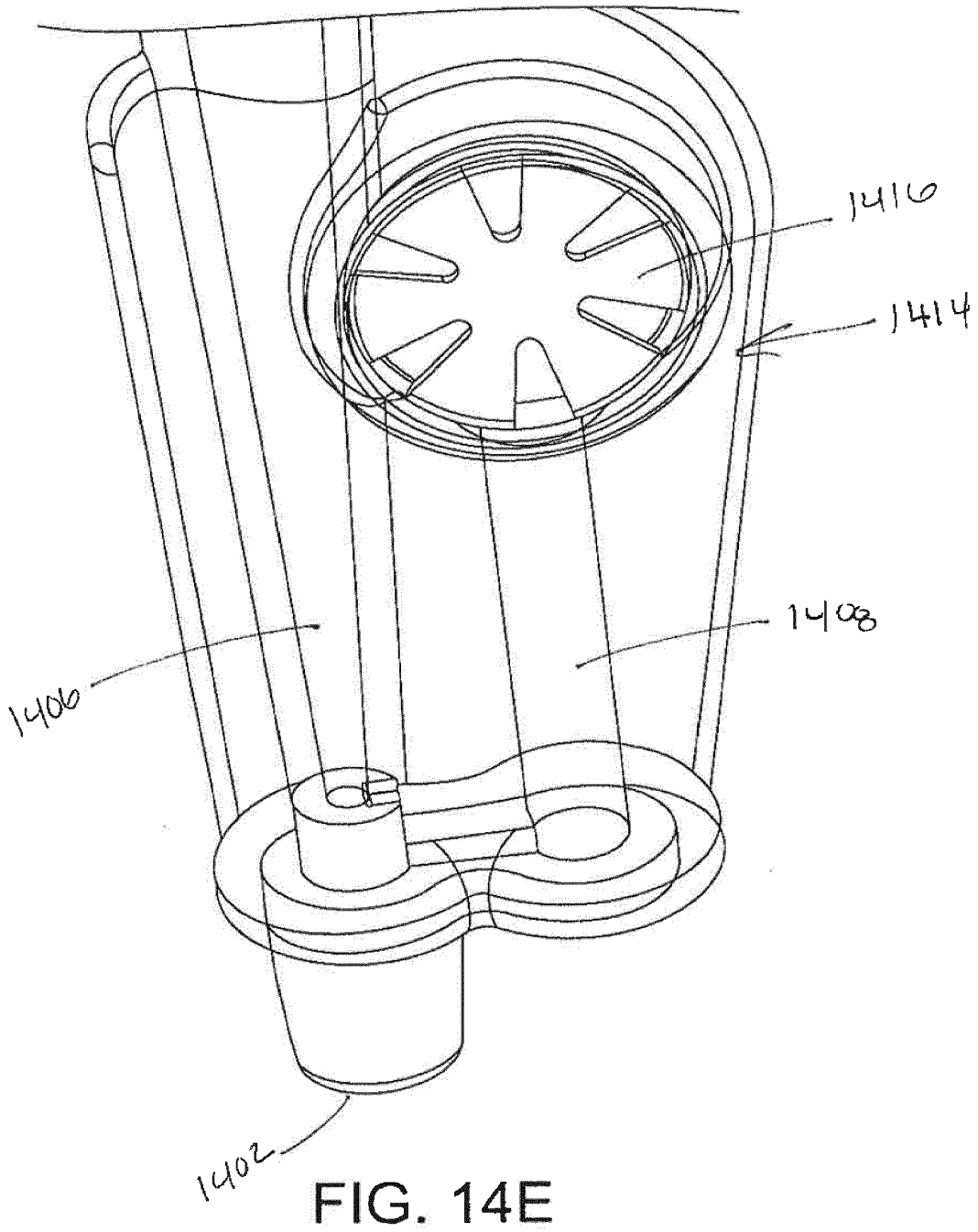


FIG. 14E

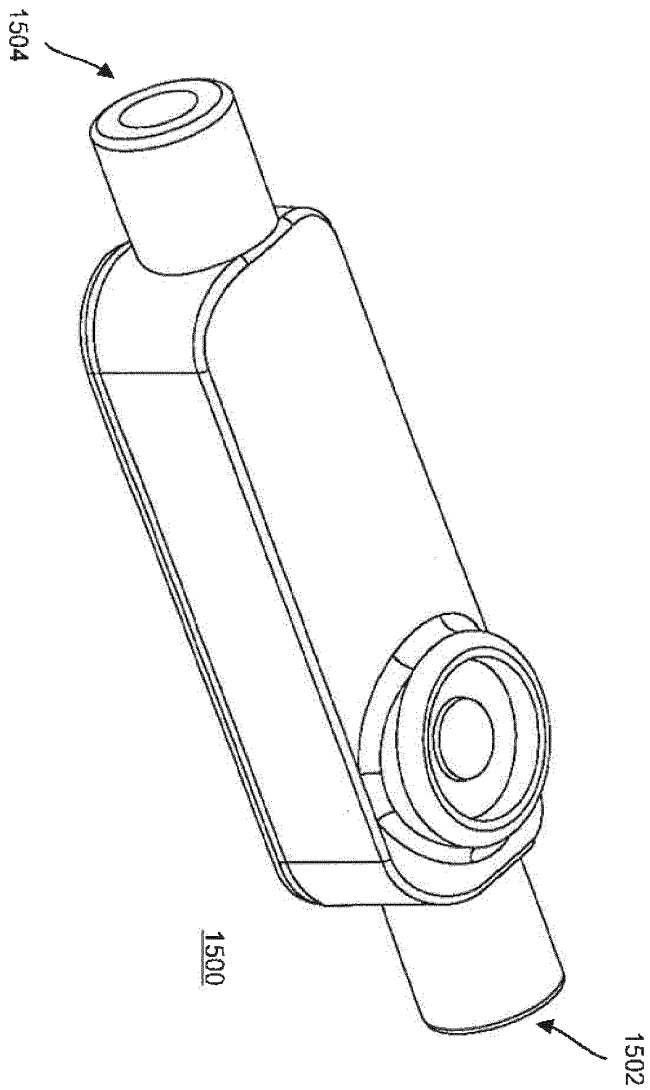


FIG. 15A

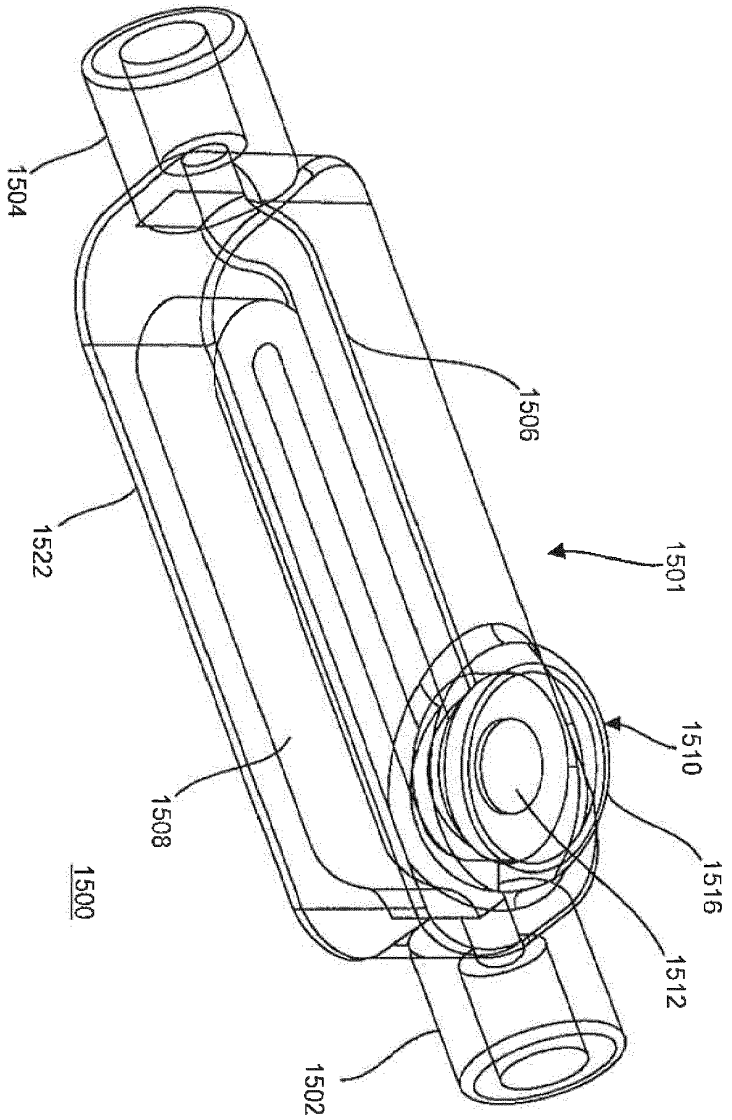


FIG. 15B

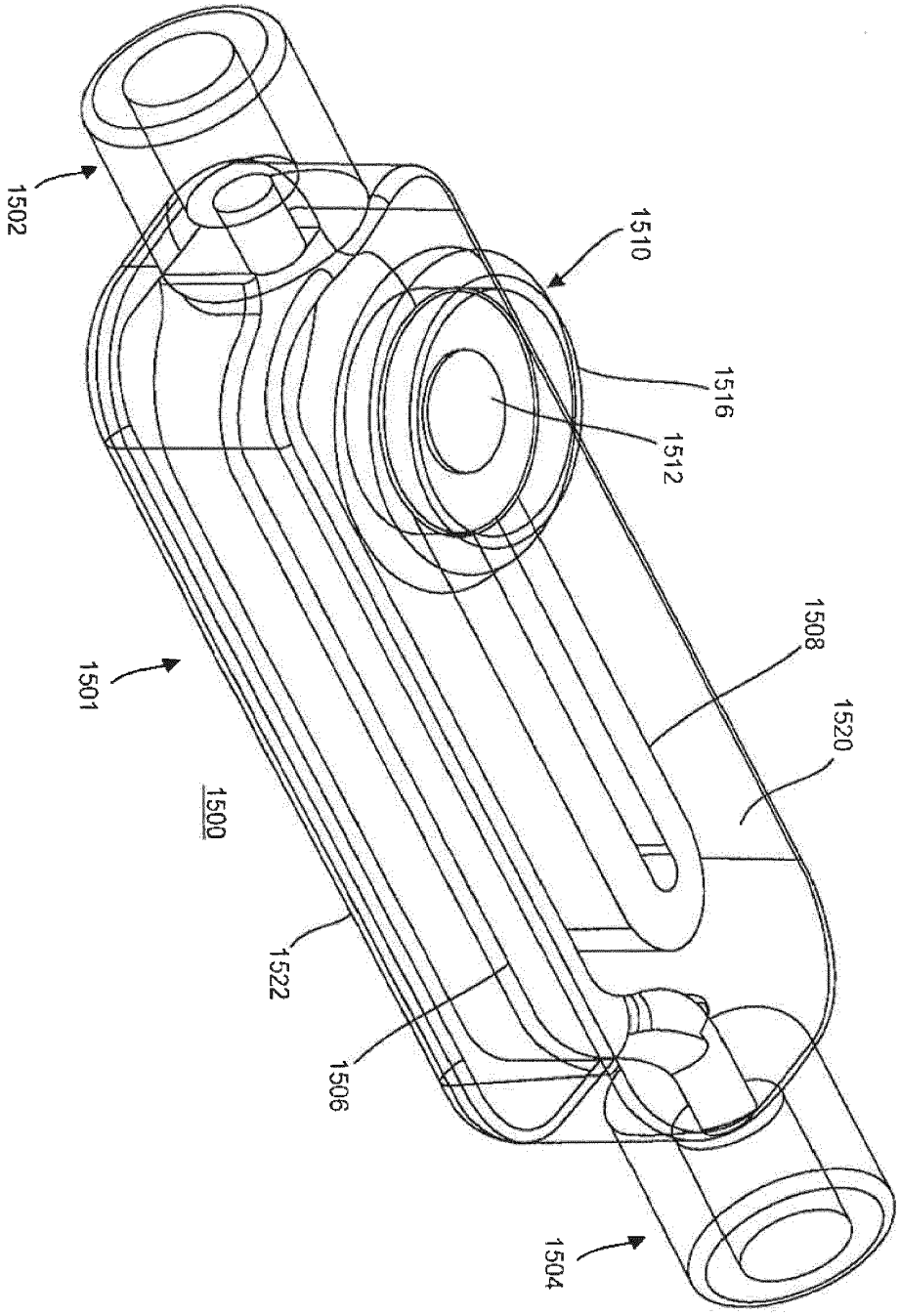


FIG. 15C

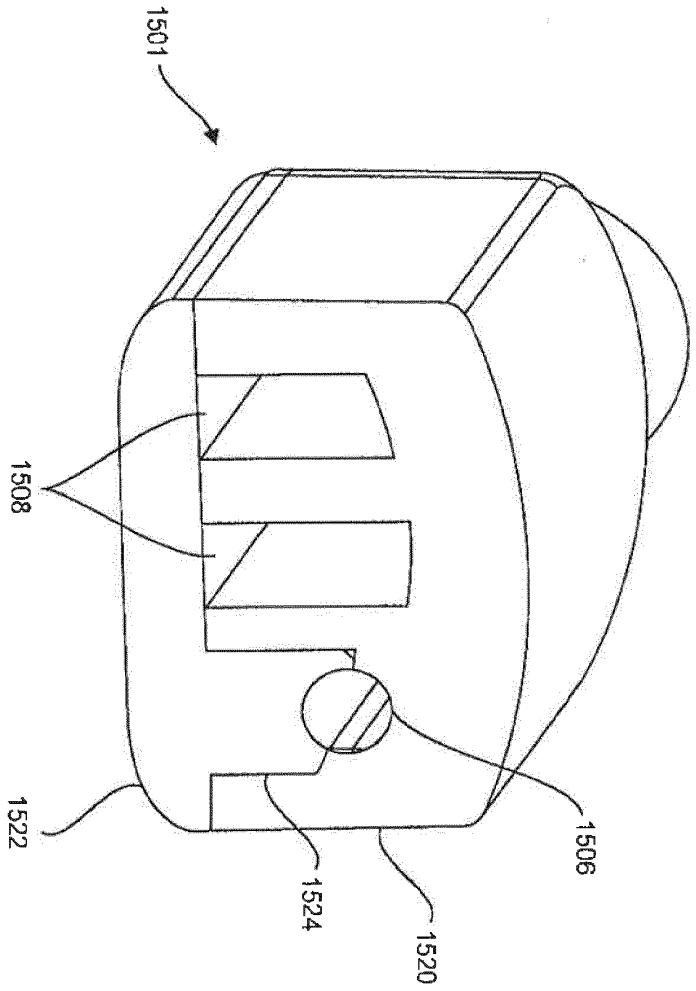


FIG. 15D

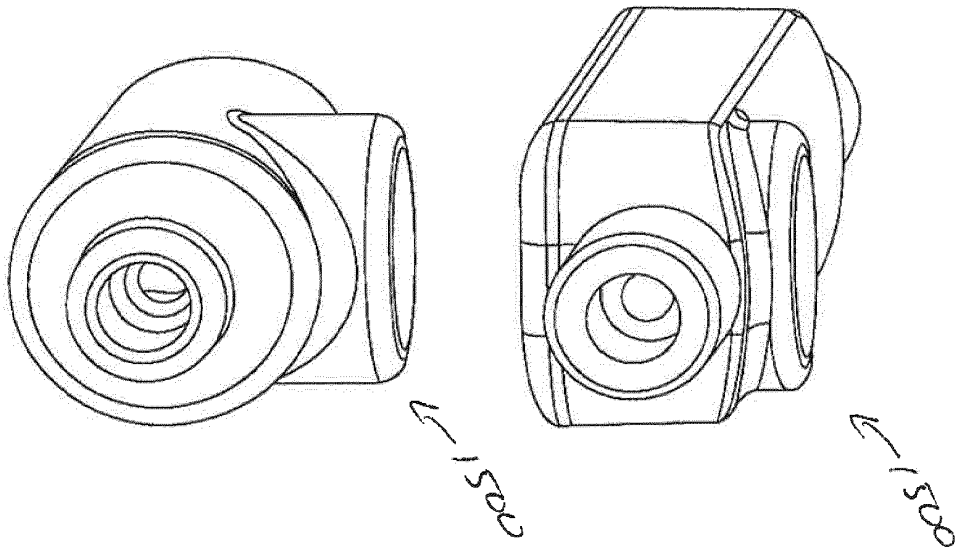


FIG. 15E

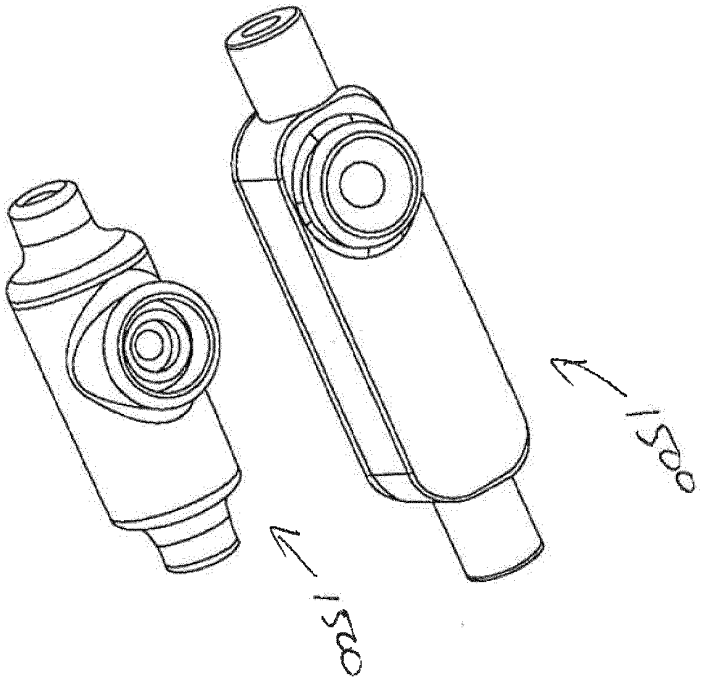


FIG. 15F

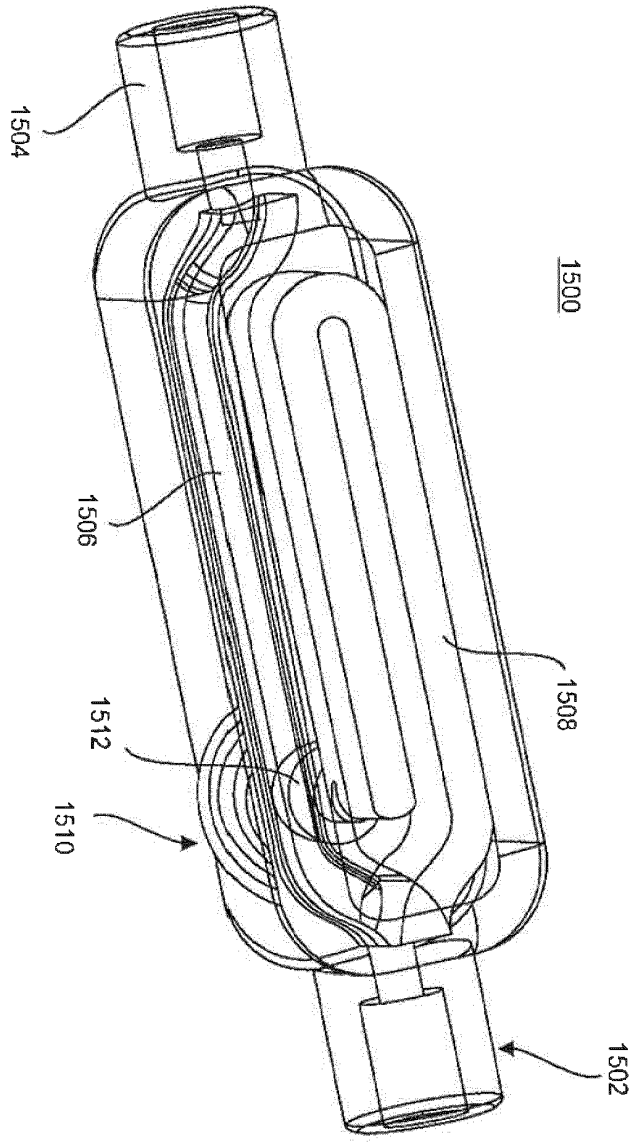


FIG. 15G

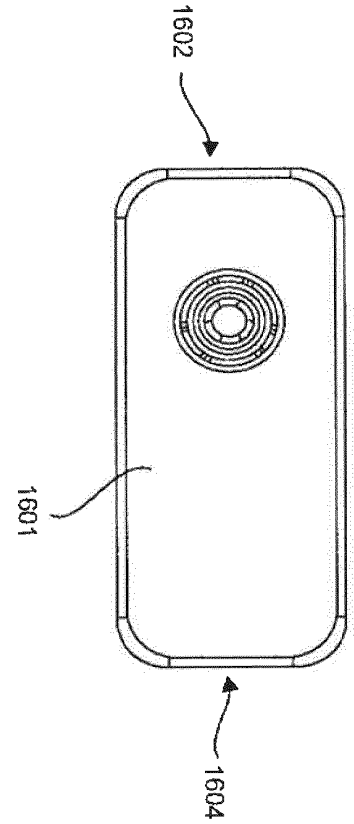


FIG. 16A

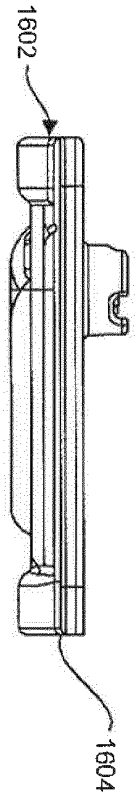


FIG. 16B

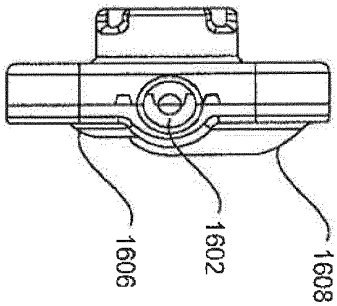


FIG. 16C

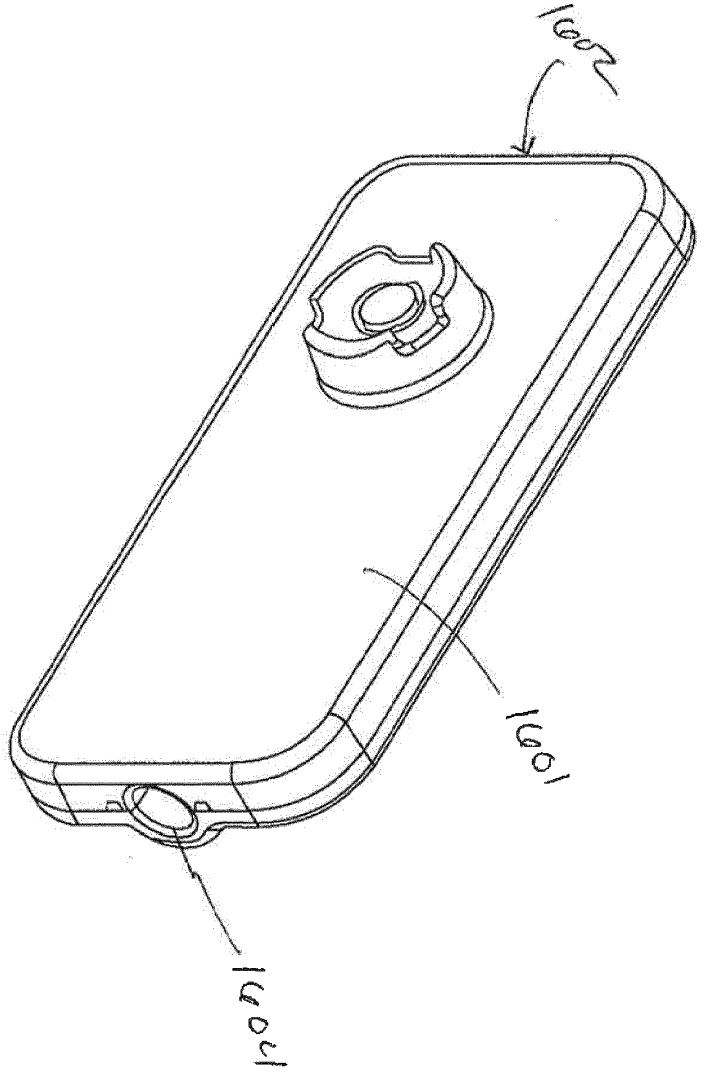


FIG. 16D

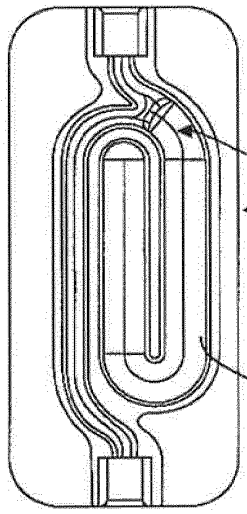


FIG. 17A

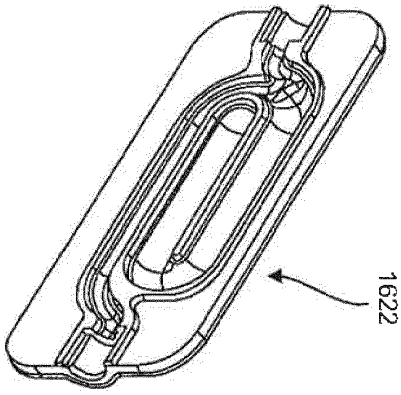


FIG. 17B

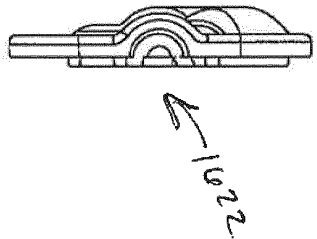


FIG. 17C

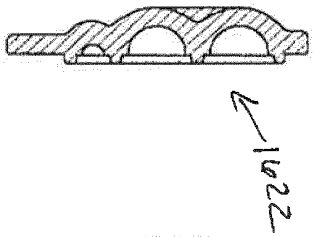


FIG. 17D

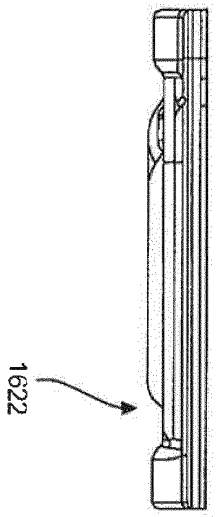


FIG. 17E

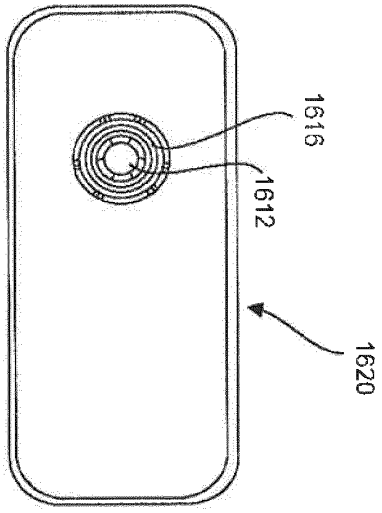


FIG. 18A

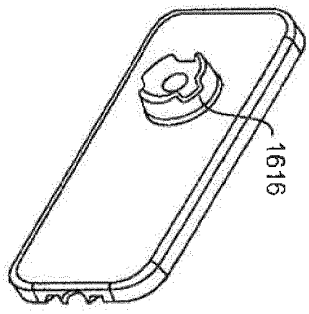


FIG. 18B

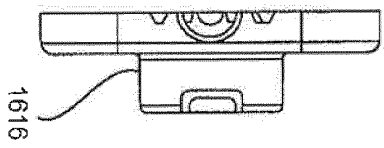


FIG. 18C

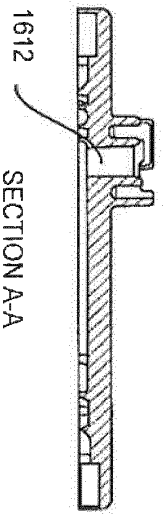


FIG. 18D

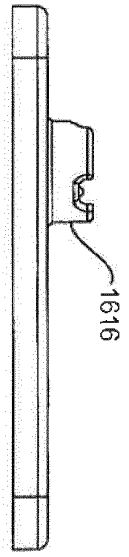


FIG. 18E

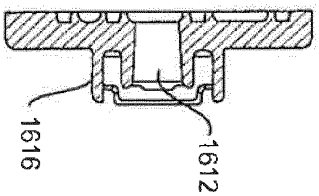


FIG. 18F

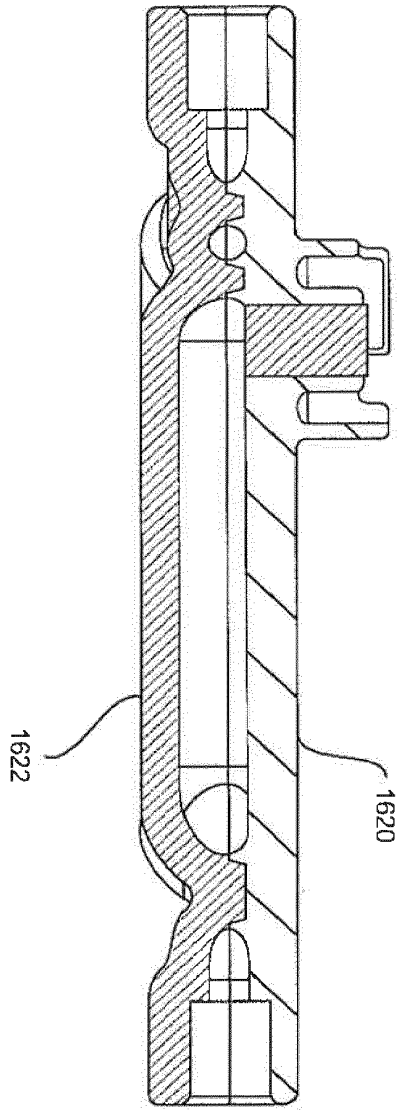


FIG. 19A

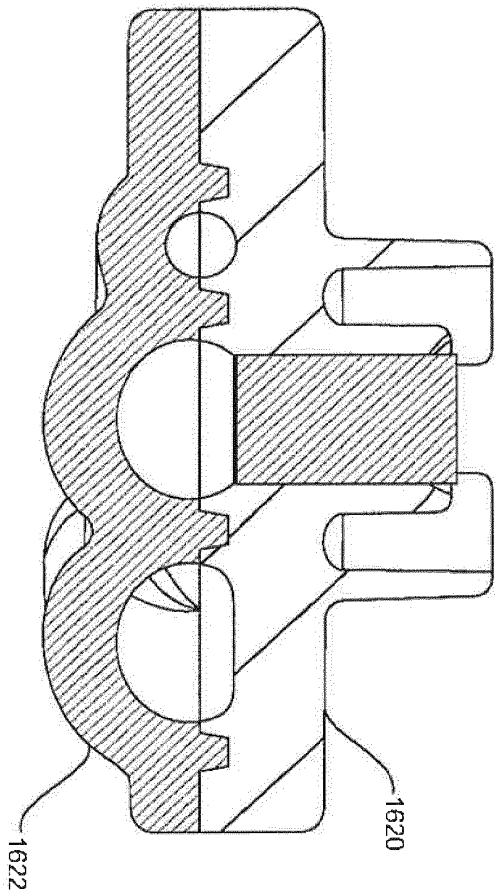


FIG. 19B

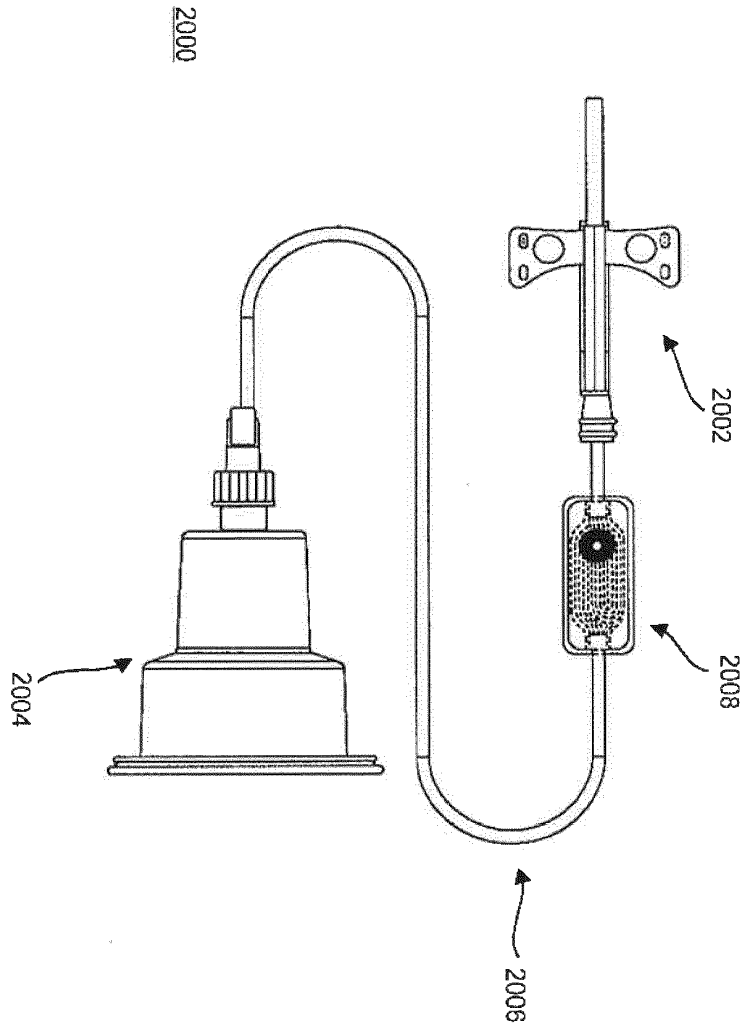


FIG. 20

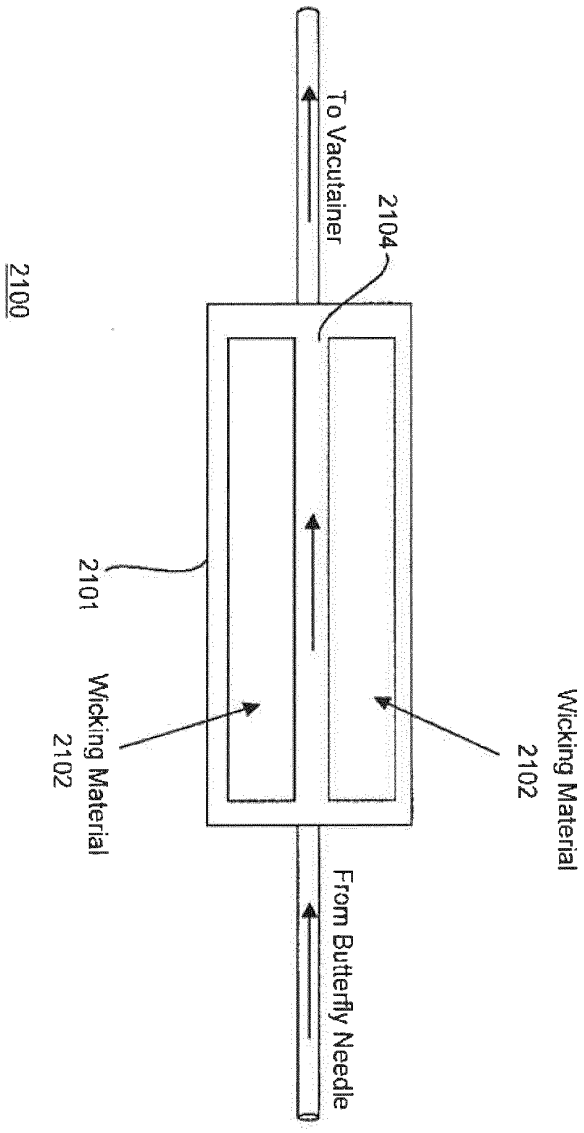

2100
To Vacutainer
2104
2101
Wicking Material
2102
Wicking Material
2102
From Butterfly Needle

FIG. 21

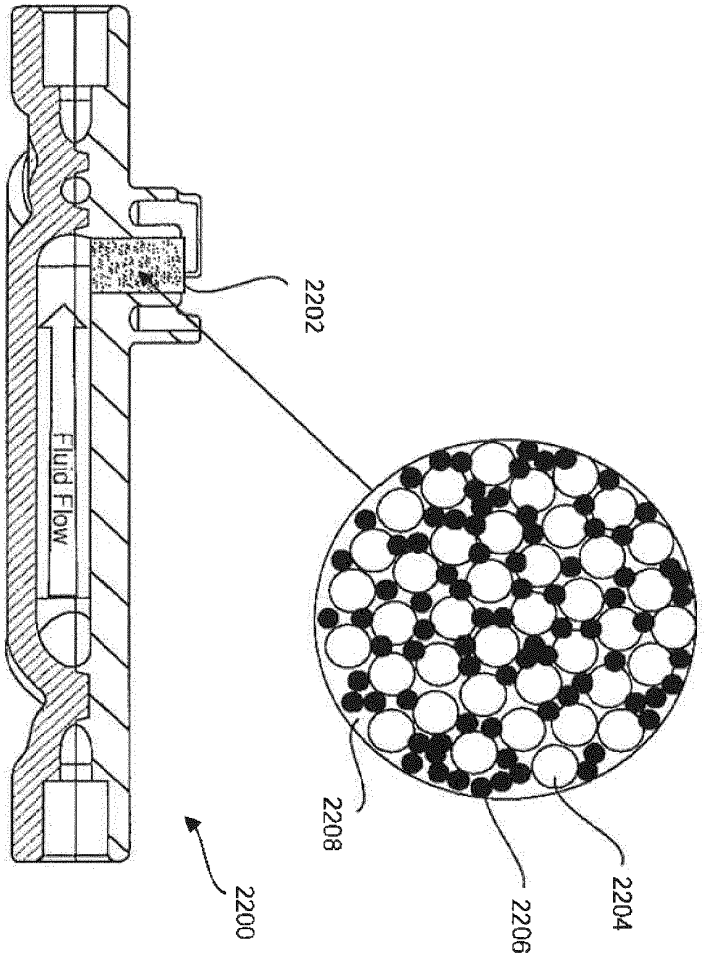


FIG. 22A

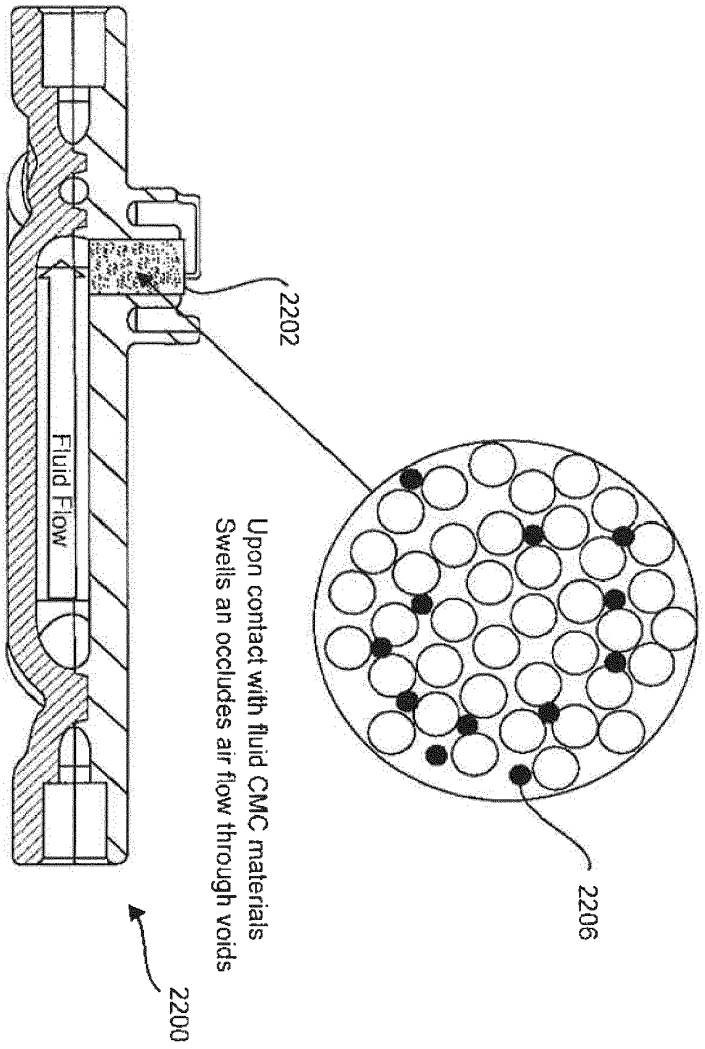

2202
Fluid Flow
Upon contact with fluid CMC materials
Swells an occludes air flow through voids
2206
2200

FIG. 22B

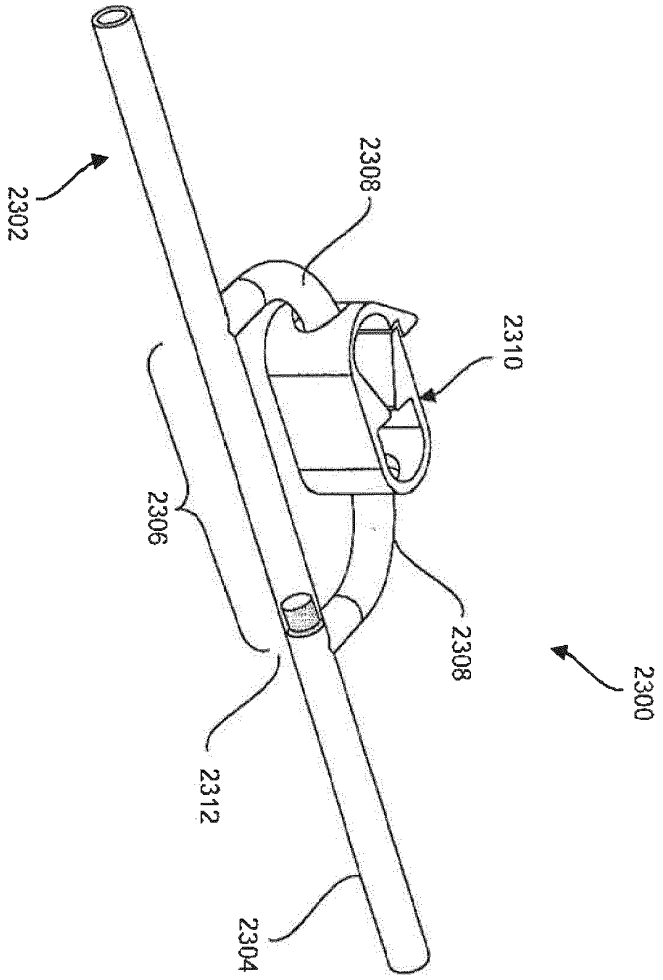


FIG. 23A

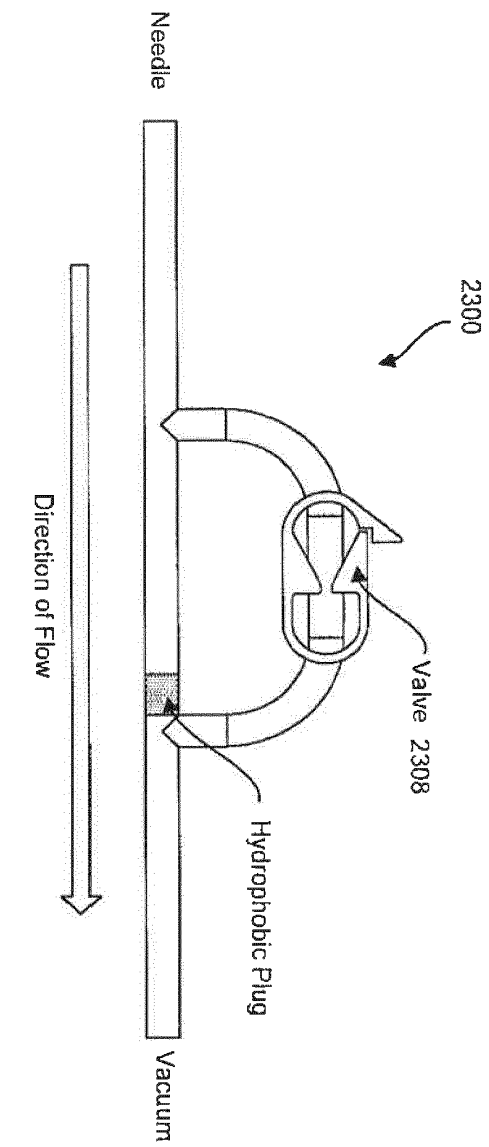

Needle
2300
Direction of Flow
Valve 2308
Hydrophobic Plug
Vacuum

FIG. 23B

Europäisches Patentamt
European Patent Office
Office européen des brevets

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	
A	US 2009/227953 A1 (TAN CHEE LEONG [SG] ET AL) 10 September 2009 (2009-09-10) * the whole document *	1-14	
A	JP H08 257018 A (NISSHO KK) 8 October 1996 (1996-10-08) * abstract; figures *	1-14	
A	US 4 416 290 A (LUTKOWSKI LAWRENCE [US]) 22 November 1983 (1983-11-22) * abstract; figures *	1-14	TECHNICAL FIELDS SEARCHED (IPC) A61B
A	US 3 648 684 A (BARNWELL CLEORA W ET AL) 14 March 1972 (1972-03-14) * abstract; figures *	1-14	
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
Y : particularly relevant if combined with another document of the same category
A : technological background
O : non-written disclosure
P : intermediate document

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)

Europäisches Patentamt
European Patent Office
Office européen des brevets

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	

TECHNICAL FIELDS SEARCHED (IPC)

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
Y : particularly relevant if combined with another document of the same category
A : technological background
O : non-written disclosure
P : intermediate document

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
The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

18-11-2019

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9605875 A1	29-02-1996	AT 208640 T	15-11-2001
		AU 686450 B2	05-02-1998
		CA 2173331 A1	29-02-1996
		DE 69523887 D1	20-12-2001
		DE 69523887 T2	29-08-2002
		EP 0725658 A1	14-08-1996
		JP H09504726 A	13-05-1997
		US 5947932 A	07-09-1999
		WO 9605875 A1	29-02-1996
WO 2011162772 A1	29-12-2011	NONE	
US 2009227953 A1	10-09-2009	US 2009227953 A1	10-09-2009
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		US 2012330187 A1	27-12-2012
JP H08257018 A	08-10-1996	NONE	
US 4416290 A	22-11-1983	NONE	
US 3648684 A	14-03-1972	NONE	
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		EP 1665986 A1	07-06-2006
		JP 4914601 B2	11-04-2012
		JP 2006150083 A	15-06-2006
		US 2006129064 A1	15-06-2006
US 4056101 A	01-11-1977	NONE	
US 2013317391 A1	28-11-2013	US 2013317391 A1	28-11-2013
		US 2015099996 A1	09-04-2015
		US 2015351678 A1	10-12-2015
		US 2018092584 A1	05-04-2018
		US 2019209066 A1	11-07-2019

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

This list of references cited by the applicant is for the reader's convenience only. It does not form part of the European patent document. Even though great care has been taken in compiling the references, errors or omissions cannot be excluded and the EPO disclaims all liability in this regard.

Patent documents cited in the description

- US 14044316 **[0001]**
- US 14044816 **[0001]**
- US 62196797 **[0001]**
- US 62238636 **[0001]**
- US 62318194 **[0001]**

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29 April 2020

Examination report No. 1 for standard patent application

Griffith Hack
GPO Box 4164
Sydney NSW 2001
Australia

Your reference	P108089.AU
Application number	2016297849
Applicant name	Kurin, Inc.
Earliest priority date	24 July 2015

Final date for acceptance:	**29 April 2021**
Date of this report:	29 April 2020
Examination request date:	11 December 2019

Dear Griffith Hack,

Your application has been examined under *section 45 of the Patents Act 1990*. I consider that this application does not meet the requirements of the Act because there are issues with the application that are explained in the report details.

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 2020**.

NOTE: There is a current postponement of acceptance in place. If you overcome all other objections before the expiration of that postponement, the Commissioner will only accept the application at that time if you have filed a clear and unambiguous statement requesting the withdrawal of that postponement. Otherwise, a further adverse report will be issued.

Details of this patent application can be viewed on AusPat, our Australian patent search database.

Yours sincerely,

Morris Ark
Section: MXT - MIXED TECHNOLOGY
Phone: (612) 6210 8487

Report details

Basis of the report

In examining this application I have considered:

- the PCT pamphlet as originally filed

Summary of novelty, inventive step and patentable subject matter

	Satisfy requirements?	*Claim numbers*
Novelty/inventive step	**Yes**	NONE
	No	1-20
Patentable subject matter	**Yes**	1-20
	No	NONE

Detailed objections on issues that have been identified

Documents cited or considered relevant

D1 : WO 2011162772 A1 (CLEARVIEW PATIENT SAFETY TECHNOLOGIES, LLC et al.) 29 December 2011 [1]
Category: **X** Claims: 1-20

[1] Cited in WO 2017019552

Special categories of cited documents:

X: The claimed invention cannot be considered novel under *subsection 7(1)* in light of the document and/or cannot be considered to involve an inventive step under *subsection 7(2)* of the Act in light of the common general knowledge considered together with the document.

Novelty and inventive step

1 The invention defined in **claims 1, 8 and 17** are not novel (and do not involve an inventive step) when compared with the following prior art document **D1**.

Regarding **claim 1**, **D1** discloses a blood sequestration device (Fig. 15; item 10) comprising;

> an inlet port (100); an outlet port (330); a sequestration chamber connected with the inlet port (117), the sequestration chamber having a vent (160) comprising an air permeable blood barrier (Para [0042]); a sampling channel (130) having a proximal end connected with the inlet port and a distal end connected with the outlet port; and a housing (116) that houses and defines the inlet port, the outlet port, the sequestration chamber, and the sampling channel.

Claims **8 and 17** define a blood sequestration device with a similar scope to claim 1, only differing by the additional features of a blood sampling pathway or blood sampling system

connected to said device. **D1** also discloses a blood sampling pathway or system connected to the blood sequestration device (Fig. 23; patient needle 184, connected to inlet 100).

Furthermore, appended **claims 2-7, 9-16, 18-20** are not considered to make any patentable contribution over the teachings of the cited document **D1** or are common general knowledge in the art or workshop improvements and which therefore cannot contribute to providing novelty or an inventive step. For example, **D1** discloses features of **claims 2, 11, 20** of the air permeable blood barrier sealing upon contact with blood (Para [0081], [0085]). Features of dependent **claim 3** are considered matters of workshop improvement over **D1**. It would be obvious to the person skilled in the art that a sequestration channel be implemented to improve transport of blood to the sequestration chamber.

END OF REPORT

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WUESTHOFF & WUESTHOFF
Patentanwälte PartG mbB
06. Nov. 2018
RECEIVED

Application No.	Ref.	Date
16 747 682.9 - 1132	EPA-142 451	31.10.2018
Applicant: KURIN, INC.		

Base 28.02./gedr.
WL 06.12.18 ✓
WV 28.01.19 ✓ vor 4/03

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 insofar 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
EPO Form 2001 11.16TRI

Schultz, Ottmar
Primary Examiner
For the Examining Division

Enclosure(s): 1 page/s reasons (Form 2906)

Registered letter
EPO Form 2001 11.16 TRI

The examination is being carried out on the **following application documents**

Description, Pages

1-33 as published

Claims, Numbers

1-20 as published

Drawings, Sheets

1/50-50/50 as published

+++++

An International Preliminary Report on Patentability has already been drawn up for the present application in accordance with the PCT. The deficiencies mentioned in that report give rise to objections under the corresponding provisions of the EPC.

+++++

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44*bis*)

Applicant's or agent's file reference 50828-501001WO	**FOR FURTHER ACTION**	See item 4 below
International application No. PCT/US2016/043709	International filing date *(day/month/year)* 22 July 2016 (22.07.2016)	Priority date *(day/month/year)* 24 July 2015 (24.07.2015)
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237		
Applicant KURIN, INC.		

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 *bis*.1(a).

2. This REPORT consists of a total of 8 sheets, including this cover sheet.

   In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:

☒	Box No. I	Basis of the report
☐	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
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or 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

4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44*bis*.3(c) and 93*bis*.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44*bis* .2).

	Date of issuance of this report 30 January 2018 (30.01.2018)
The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No. +41 22 338 82 70	Authorized officer Lingfei Bai e-mail: pct.team2@wipo.int

Form PCT/IB/373 (January 2004)

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US2016/043709	22.07.2016	24.07.2015

International Patent Classification (IPC) or both national classification and IPC
INV. A61B5/15 A61B5/153 A61B5/154

Applicant
CALLIOPE SOLUTIONS, INC.

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

- ☒ 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
- ☒ 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 usually 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 notifed 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:	Date of completion of this opinion	Authorized Officer
European Patent Office Gitschiner Str. 103 D-10958 Berlin Tel. +49 30 25901 - 0 Fax: +49 30 25901 - 840	see form PCT/ISA/210	Schultz, Ottmar Telephone No. +49 30 25901-0

Form PCT/ISA/237 (Cover Sheet) (January 2015)

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established 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)).

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:

   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 forming part of the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

5. Additional comments:

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

1. Statement

Novelty (N)	Yes:	Claims	2, 6, 7, 11, 14
	No:	Claims	1, 3-5, 8-10, 12, 13, 15-20
Inventive step (IS)	Yes:	Claims	6, 14
	No:	Claims	1-5, 7-13, 15-20
Industrial applicability (IA)	Yes:	Claims	1-20
	No:	Claims	

2. Citations and explanations

see separate sheet

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

+++++

Reference is made to the following document:

D1: WO 2011/162772 A1 (CLEARVIEW PATIENT SAFETY TECHNOLOGIES LLC [US]; FISCHEL LLOYD [US]; BR) 29 December 2011.

+++++

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

+++++

1 INDEPENDENT CLAIMS 1, 8, 17

1.1 Claims 8 seeks to define a blood sequestration device by being connected with a blood sampling pathway having a patient needle and a sample collection device whereby said blood sampling pathway does not form part of the claimed blood sequestration device.

This would only be the case if e.g. claim 8 defined e.g. "A system of a blood sequestration device and a blood sampling pathway having a patient needle and a sample collection device, whereby the blood sequestration device is connected with the blood sampling pathway, said blood sequestration device comprising...".

The technical features and the related definitions of the blood sampling pathway can therefore not be used to render the subject-matter of claim 8 either novel or inventive.

Since the intended limitation does not belong to the subject-matter claimed, namely the blood sequestration device, this said limitation leads to uncertainty with regard to the actual protection sought, contrary to the requirements of Article 6 PCT.

The same reasoning applies, mutatis mutandis, to the subject-matter of the corresponding independent claim 17, which therefore is also considered not meeting the requirements of Article 6 PCT.

1.2 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 1 is not new in the sense of Article 33(2) PCT. The reason is the following:

Document D1 discloses (the references in parenthesis applying to this document) in figure 15 all the features of independent claim 1, namely:

"A blood sequestration device (see figure 15) comprising;

an inlet port (see ref. sign 117 "well");

an outlet port (see ref. sign 330 "sleeve connector");

a sequestration chamber (see ref. sign 117 "guide tube aperture") connected with the inlet port, the sequestration chamber having a vent (see ref. sign 117 "venting member") comprising an air permeable blood barrier;

a sampling channel (see the channel formed in the sleeve connector 330) having a proximal end connected with the inlet port and a distal end connected with the outlet port; and

a housing (see ref. sign 116 "guide tube") that houses and defines the inlet port, the outlet port, the sequestration chamber, and the sampling channel".

1.3 The same reasoning applies, mutatis mutandis, to the subject-matter of the corresponding independent claims 8 an 17, which therefore are also considered not new (Article 33(1) and (2) PCT).

2 DEPENDENT CLAIMS 2-7, 9-16, 18-20

2.1 Dependent claims 2 to 5, 7, 9 to 13, 15, 16 and 18 to 20 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty (Article 33(2) PCT) and/or inventive step (Article 33(3) PCT), the reasons being as follows:

As far as the features of these said dependent claims are not already explicitly anticipated by document D1 (for further details, see the relevant passages as cited in the International Search Report and in the above-mentioned paragraph 1), these features would be chosen by a person skilled in the art simply by routine trial and error or these said features are at least generally known by a person skilled in the art either to be one of several straightforward possibilities from which this said person would select or to be regarded by this said person as a normal design option and thus would not add any inventive merit to the subject-matter of the these said dependent claims.

2.2 The features of dependent claims 6 and 14 in combination with the features of any claim to which these said claims refer, seem neither to be known from, nor rendered obvious by, the available prior art.

+++++

Re Item VII

Certain defects in the international application

+++++

1 The independent claims are not in the two-part form in accordance with Rule 6.3(b) PCT with those features known in combination from the prior art (e.g. one of the documents cited in the International Search Report) being placed in the preamble (Rule 6.3(b)(i) PCT) and with the remaining features being included in the characterising part (Rule 6.3(b)(ii) PCT).

2 Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the documents cited in the International Search Report is not mentioned in the description, nor are at least some of these documents identified therein.

3 The features of the claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).

+++++

Re Item VIII

Certain observations on the international application

+++++

Claims 8 seeks to define a blood sequestration device by being connected with a blood sampling pathway having a patient needle and a sample collection device whereby said blood sampling pathway does not form part of the claimed blood sequestration device.

This would only be the case if e.g. claim 8 defined e.g. "A system of a blood sequestration device and a blood sampling pathway having a patient needle and a sample collection device, whereby the blood sequestration device is connected with the blood sampling pathway, said blood sequestration device comprising...".

The technical features and the related definitions of the blood sampling pathway can therefore not be used to render the subject-matter of claim 8 either novel or inventive.

Since the intended limitation does not belong to the subject-matter claimed, namely the blood sequestration device, this said limitation leads to uncertainty with regard to the actual protection sought, contrary to the requirements of Article 6 PCT.

The same reasoning applies, mutatis mutandis, to the subject-matter of the corresponding independent claim 17, which therefore is also considered not meeting the requirements of Article 6 PCT.

+++++

(19)日本国特許庁(JP)　(12)公表特許公報(A)　(11)特許出願公表番号
特表2019-534792
(P2019-534792A)
(43)公表日　令和1年12月5日(2019.12.5)

(51)Int.Cl.		F I			テーマコード（参考）
B21B 27/10	(2006.01)	B21B	27/10	A	
		B21B	27/10	C	
		B21B	27/10	D	

審査請求 有　予備審査請求 未請求　（全 21 頁）

(21)出願番号　特願2019-520550 (P2019-520550)
(86)(22)出願日　平成29年10月12日 (2017.10.12)
(85)翻訳文提出日　令和1年6月13日 (2019.6.13)
(86)国際出願番号　PCT/EP2017/076000
(87)国際公開番号　WO2018/073086
(87)国際公開日　平成30年4月26日 (2018.4.26)
(31)優先権主張番号　16194099.4
(32)優先日　平成28年10月17日 (2016.10.17)
(33)優先権主張国・地域又は機関
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最終頁に続く

(54)【発明の名称】圧延スタンドのロールの冷却

【要約】
本発明は、圧延スタンド　のロール　を冷却するための冷却装置　に関する。冷却装置　は、冷却剤を受け入れて吐出するための冷却ビーム　を備える。冷却ビーム　は、前記冷却ビーム　の吐出側面　に配置された複数のフルジェットノズル　を有し、前記側面は、ロール　に面してロール　のロール軸　に平行に延在する。ほぼ一定のジェット径を有する冷却剤のジェットを、フルジェットノズルのそれぞれを通して、冷却ビーム　からロール　に向けて吐出方向　に噴霧することができる。

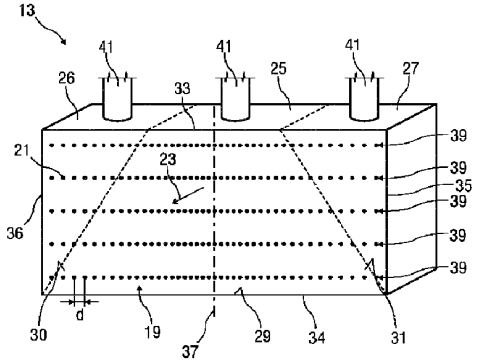


FIG 2

【特許請求の範囲】
【請求項１】
冷却剤を受け入れて吐出するための冷却棒（１３）を備えた、圧延スタンド（１）のロール（５）を冷却するための冷却装置（７）であって、
前記冷却棒（１３）が、前記冷却棒（１３）の吐出側面（１９）に配置された複数のフルジェットノズル（２１）を有し、前記吐出側面が、ロール（５）に面して前記ロール（５）のロール軸（１７）に平行に延在し、ほぼ一定のジェット径の冷却剤の冷却剤ジェットを、フルジェットノズルのそれぞれを通して、前記冷却棒（１３）から前記ロール（５）に向けて吐出方向（２３）に吐出することができる、冷却装置（７）。
【請求項２】
前記冷却棒（１３）が、冷却剤を受け入れるための、相互に分離した少なくとも２つの冷却剤室（２５～２７）に分割され、各冷却剤室（２５～２７）が、複数のフルジェットノズル（２１）が配置された前記冷却棒（１３）の前記吐出側面（１９）の部分領域（２９～３１）に対応し、前記フルジェットノズル（２１）のそれぞれを通して、冷却剤ジェットを前記冷却剤室（２５～２７）から前記ロール（５）に向けて吐出することができることを特徴とする、請求項１に記載の冷却装置（７）。
【請求項３】
第１の冷却剤室（２５）が、前記冷却棒（１３）の前記吐出側面（１９）の第１の部分領域（２９）に対応し、前記第１の部分領域（２９）が、前記冷却棒（１３）の前記吐出側面（１９）の中心線（３７）に対して鏡面対称であり、軸が前記ロール軸（１７）に垂直であることを特徴とする、請求項２に記載の冷却装置（７）。
【請求項４】
中心線（３７）に並行する第１の部分領域（２９）の範囲が、前記ロール軸（１７）の方向に沿って変化し、前記中心線（３７）に沿って最大であることを特徴とする、請求項２または３に記載の冷却装置（７）。
【請求項５】
第１の部分領域（２９）が多角形であることを特徴とする、請求項２から４のいずれか一項に記載の冷却装置（７）。
【請求項６】
各冷却剤室（２５～２７）が、前記冷却剤室（２５～２７）内に冷却剤を供給するための冷却剤供給ライン（４１）に接続され、前記冷却剤供給ライン（４１）が、前記冷却剤室（２５～２７）内に、前記冷却剤の前記吐出方向（２３）に実質的に垂直に開口していることを特徴とする、請求項２から５のいずれか一項に記載の冷却装置（７）。
【請求項７】
前記冷却剤室（２５～２７）内に供給される前記冷却剤の量を、それぞれの制御弁（４３）、および／または、それぞれのポンプ（４５）によって互いに独立して制御することができることを特徴とする、請求項２から６のいずれか一項に記載の冷却装置（７）。
【請求項８】
前記冷却剤室（２５～２７）内に供給される前記冷却剤の量を制御するための自動化システムによって特徴付けられた、請求項２から７のいずれか一項に記載の冷却装置（７）。
【請求項９】
前記ロール軸（１７）に平行な方向に沿って相互に隣り合うフルジェットノズル（２１）のノズル間隔（ｄ）が、前記方向に沿って変化していることを特徴とする、請求項１から８のいずれか一項に記載の冷却装置（７）。
【請求項１０】
前記ノズル間隔（ｄ）が、前記冷却棒（１３）の前記吐出側面（１９）の中央領域において最も狭いことを特徴とする、請求項９に記載の冷却装置（７）。
【請求項１１】
前記ノズル間隔（ｄ）が、約２５ｍｍから約５０ｍｍの間であることを特徴とする、請

求項９または１０に記載の冷却装置（７）。
【請求項１２】
前記フルジェットノズル（２１）が、相互に平行な複数のノズル列（３９）になるように配置されていることを特徴とする、請求項１から１１のいずれか一項に記載の冷却装置（７）。
【請求項１３】
前記冷却棒（１３）が、前記フルジェットノズル（２１）が取り外し可能に固定された、各フルジェットノズル（２１）のためのノズル開口を有していることを特徴とする、請求項１から１２のいずれか一項に記載の冷却装置（７）。
【請求項１４】
前記ロール（５）から冷却剤をぬぐい取るためのワイパ（１５）であって、前記冷却棒（１３）と一緒に枢動させることができるワイパ（１５）によって特徴付けられた、請求項１から１３のいずれか一項に記載の冷却装置（７）。
【請求項１５】
ロール（５）と、請求項１から１３のいずれか一項に記載されたようにそれぞれ設計された２つの冷却装置（７）と、を備えた圧延スタンド（１）であって、前記２つの冷却装置（７）が、前記ロール（５）の両側に配置されている、圧延スタンド（１）。
【発明の詳細な説明】
【技術分野】
【０００１】
本発明は、圧延スタンドのロールを冷却するための冷却装置に関する。
【背景技術】
【０００２】
圧延素材を圧延するための圧延スタンドは、冷却液体、一般的には冷却水を用いて冷却されるロールを有する。
【０００３】
特許文献１には、低圧の冷却液体を圧延スタンドのロールにかけることができる、剛性の高い凹状のシェルが開示されている。
【０００４】
特許文献２には、移動可能な関節式冷却シェルによる圧延スタンドのワークロールの流動冷却が開示されている。この場合、冷却液体は、冷却シェルを用いて主として低圧でかけられるが、さらに、冷却液体は、高圧でかけられて十分な冷却効果を生じる。
【０００５】
特許文献３には、圧延スタンドのワークロールを冷却するための冷却装置が開示されており、この装置は、関係する圧延スタンドを用いて生産される最も狭い片よりもやや狭い固定スプレー棒を有し、そのときに圧延されている片の幅に対応するワークロールのこれらの部分のみを冷却するための、軸方向に移動可能なスプレー棒を有する。
【０００６】
特許文献４には、圧延スタンドのワークロールを冷却するための方法が開示されており、この方法では、冷却水が、高圧ではなく低圧でワークロールに噴霧されるが、同時に、かけられる範囲が広くされている。
【０００７】
特許文献５には、圧延材を冷却するためのスプレー棒が開示されており、このスプレー棒は、圧延材の移動方向に横断して延在し、中央領域および つの縁領域を有して、冷却媒体をそれらのそれぞれに別々に供給することができる。
【先行技術文献】
【特許文献】
【０００８】
【特許文献１】米国特許出願公開第　　号
【特許文献２】独国特許出願公開第　　号

【特許文献３】特開平　　号
【特許文献４】特開昭　　号
【特許文献５】国際公開第　　号
【発明の概要】
【発明が解決しようとする課題】
【０００９】
圧延スタンドのロールを冷却するための改善された冷却装置を特定することが本発明の基本的な目的である。
【課題を解決するための手段】
【００１０】
本発明によれば、この目的は、請求項 の特徴によって達成される。
【００１１】
本発明の有利な実施形態は、従属請求項の主題を形成する。
【００１２】
圧延スタンドのロールを冷却するための本発明による冷却装置は、冷却剤を受け入れて吐出するための冷却棒を備える。冷却棒は、冷却棒の吐出側面に配置された複数のフルジェットノズルを有し、前記側面は、ロールに面してロールのロール軸に平行に延在する。ほぼ一定のジェット径の冷却剤の冷却剤ジェットを、各フルジェットノズルを通して、冷却棒からロールに向けて吐出方向に吐出することができる。
【００１３】
フルジェットノズルとは、ほぼ一定のジェット径で実質的に直線状の冷却剤ジェットを吐出することができるノズルを意味するものとする。冷却剤を集中させて吐出するおかげで、フルジェットノズルは、従来使用されてきたファンジェットノズルよりも、冷却棒での同じ冷却剤圧力でより高いロールへの衝撃圧を生じる。全体にかけられた大量の冷却剤の量により、典型的には、数ミリメートルから数センチメートルの厚さの特定の冷却剤膜が常にあり、良好な放熱のために冷却剤ジェットを衝突させることによって、この膜はできるだけ完全に貫通されるべきであるので、より高い衝撃圧は、ロール表面での冷却作用に直接良い効果を生じる。フルジェットノズルによって生じた、ロールへの冷却剤ジェットの高い衝撃圧のおかげで、冷却棒の冷却剤圧力は、ファンジェットノズルを使用した場合に比べて大きく下げることができ、それによって、冷却装置のエネルギー消費および運用コストを大きく下げることができることは有利である。
【００１４】
冷却剤はフルジェットノズルを通って吐出されるので、ロールからスプレー棒までの間隔はさらに、広い範囲にわたってそれほど重要ではなくなり、したがって、ロール直径に適合させる必要はない。したがって、例えば、実質的に直進する冷却剤ジェットによって、冷却剤ジェットの冷却効果に何ら大きな変化もなしに、　　から　　の間の距離で、冷却されるべきロール表面を冷却することができる。
【００１５】
冷却剤圧力の低下はまた、負荷の低減、その結果としてノズルの摩耗の低減に関係するので、これもまた、冷却棒の冷却剤圧力の低下の結果、保守費用が低減され、これがフルジェットノズルの使用の別の利点である。
【００１６】
本発明の一実施形態では、冷却棒が、冷却剤を受け入れるための、相互に分離した少なくとも つの冷却剤室に分割されることが想定されている。各冷却剤室は、複数のフルジェットノズルが配置された冷却棒の吐出側面の部分領域に対応し、フルジェットノズルのそれぞれを通して、冷却剤ジェットを冷却剤室からロールに向けて吐出することができる。冷却棒の吐出側面の異なる部分領域に対応する、相互に分離した複数の冷却剤室に、冷却棒を分割すると、互いに独立して、部分領域の冷却剤圧力を制御し、その結果、部分領域によって吐出される冷却剤流量を制御することによって、部分領域の冷却効果を互いに独立して制御することができることは有利である。それによって、位置に応じてロールの

冷却に影響を与えることが可能となり、ロール表面のより強く加熱された領域、例えば、ロール表面の中央領域を、それほど強く加熱されていない領域よりも確実に強く冷却することができることは有利である。

【００１７】

本発明の上記の実施形態の展開としては、第 の冷却剤室が、冷却棒の吐出側面の第 の部分領域に対応し、第 の部分領域が、冷却棒の吐出側面の中心線に対して鏡面対称であり、その軸がロール軸に垂直であることが想定されている。例えば、中心線に並行する第 の部分領域の範囲は、ロール軸の方向に沿って変化し、中心線に沿って最大である。例えば、第 の部分領域は多角形である。第 の部分領域が中心線に対して鏡面対称の実施形態は、ロールが概ね同様に、中心線に対して対称的に加熱されるという事実を考慮している。中心線に並行する第 の部分領域の範囲がロール軸の方向に沿って変化し、中心線に沿って最大範囲を有することは、ロールが、一般に、中心において最も強く加熱され、ロールの加熱が縁領域に向けて減少するという事実を考慮している。したがって、これに対応した第 の部分領域の構成は、第 の部分領域によって、位置に依存したロールの熱負荷にロールの冷却を適合させることを可能にする。

【００１８】

本発明の別の実施形態では、各冷却剤室が、冷却剤室内に冷却剤を供給するための冷却剤供給ラインに接続され、冷却剤供給ラインが、冷却剤室内に、冷却剤の吐出方向に実質的に垂直に開口していることが想定されている。冷却剤供給ラインが、冷却棒内に、吐出方向に実質的に垂直に開口していることによって、各冷却剤室内の冷却剤の圧力分布をほとんど均一にすることができる。それによって、開口近くのフルジェットノズルと開口から離れたフルジェットノズルとの間の圧力勾配がなくなることは有利である。

【００１９】

本発明の別の実施形態では、冷却剤室内に供給される冷却剤の量を、それぞれの制御弁、および／または、それぞれのポンプによって互いに独立して制御することができることが想定されている。これによって、上記のように、個々の冷却剤室から吐出される冷却剤ジェットの冷却効果を互いに独立して制御することができる。例えば、通常、 の圧力で冷却水を送出する水供給システムなどの、例えば、いかなるときにも存在する従来の冷却剤供給システムを、関連する圧延システムにおいて使用することができる場合には、制御弁によって冷却剤の量を制御することが特に有利である。この場合、ロール冷却をするために複雑で高価な昇圧システム無しで済ますことができる。適当であれば、制御弁と共に、ポンプによって冷却剤の量を制御することによって、圧延間の休止時、または、低い冷却能力しか必要でない圧延作業の場合に、個々のポンプを止める、またはポンプの動力を下げることができ、それによって、エネルギー消費を低減することができる。

【００２０】

本発明の別の実施形態では、冷却剤室内に供給される冷却剤の量を制御するための自動化システムが想定されている。それによって、体積流量をロール表面の温度分布に適合させるために、冷却剤室からロールに吐出される冷却剤の体積流量を自動的に制御することができることは有利である。この場合、冷却剤室内に供給される冷却剤の量は、上記の制御弁および／またはポンプを制御することを通じて、自動化システムによって制御されることが好ましい。

【００２１】

本発明の別の実施形態では、ロール軸に平行な方向に沿って相互に隣り合うフルジェットノズルのノズル間隔が前記方向に沿って変化していることが想定されている。この場合、ノズル間隔は、冷却棒の吐出側面の中央領域において最も狭いことが好ましい。例えば、ロール軸に平行な方向に沿うノズル間隔は、約 から約 の間である。本発明のこれらの実施形態によって、また、ロール軸に平行な方向に沿うノズル間隔が位置に依存したロール表面の熱負荷に従って変えられるので、フルジェットノズルの配置をこの熱負荷に適合させることもできる。最小のノズル間隔が冷却棒の吐出側面の中央領域にあるのは、ロール表面の中央領域が一般に、最大の熱負荷を受けるという事実を考慮している。

【００２２】
本発明の別の実施形態では、フルジェットノズルが、相互に平行な複数のノズル列になるように配置されていることが想定されている。これによって、冷却剤をより広い範囲にわたって、かつ、ロールが回転することと併せて、均一にロールにかけることができることは有利である。
【００２３】
本発明の別の実施形態では、冷却棒が、フルジェットノズルが取り外し可能に固定された、各フルジェットノズルのためのノズル開口を有していることが想定されている。本発明のこの実施形態によって、不良なジェットノズルを容易に交換することができることは有利である。
【００２４】
本発明の別の実施形態では、ロールから冷却剤をぬぐい取るためのワイパが提供され、ワイパと冷却棒を一緒に枢動させることができる。例えば、ワイパによって、過剰な冷却剤が、圧延材に、および／または、圧延材が つのロール間を案内されるロール間隙に導かれて、圧延材とロールとの間の摩擦を低減するための潤滑剤を洗い流すことを防ぐことができることは有利である。ワイパと冷却棒が一緒に枢動することができることによって、冷却棒を動かすための追加の装置の必要が除かれることは有利である。この場合、上記ですでに言及したフルジェットノズルを使用する利点は、この場合にもまた効果がある。すなわち、フルジェットノズルを使用することによって、スプレー棒とロールとの間の距離は、広い範囲にわたってそれほど重要ではなくなり、したがって、ロール直径に適合させる必要がなくなる。さらに、本発明はまた、ワイパを有する既存の圧延システムに対しては改造策として特に適しており、例えば、従来の高圧スプレー棒のみを本発明による冷却棒に交換するだけでよい。
【００２５】
本発明による圧延スタンドは、ロール、および本発明による つの冷却装置を備え、 つの冷却装置は、ロールの反対側に配置される。本発明による圧延スタンドの利点は、上記ですでに言及した、本発明による冷却装置の利点から生じる。
【００２６】
この発明の上記の特性、特徴、および利点、ならびにこれらを達成する態様は、図面と併せてより詳細に説明される例示的な実施形態の以下の説明と関連して、より明確かつ明瞭に理解されるであろう。
【図面の簡単な説明】
【００２７】
【図１】冷却装置を有する圧延スタンドの概略図である。
【図２】冷却棒の第 の例示的な実施形態の概略斜視図である。
【図３】図 に示した冷却棒によって吐出される冷却剤の体積流量を位置の関数として示した図である。
【図４】冷却棒の第 の例示的な実施形態の吐出側面の図である。
【図５】冷却棒の第 の例示的な実施形態の吐出側面の図である。
【図６】冷却棒の第 の例示的な実施形態の吐出側面の図である。
【図７】冷却棒の第 の例示的な実施形態の吐出側面の図である。
【図８】冷却棒の第 の例示的な実施形態の吐出側面の図である。
【図９】冷却棒の第 の例示的な実施形態の吐出側面の図である。
【図１０】冷却棒の第 の例示的な実施形態の吐出側面の図である。
【図１１】冷却棒の第 の例示的な実施形態の吐出側面の図である。
【図１２】冷却棒の第 の例示的な実施形態の吐出側面の図である。
【発明を実施するための形態】
【００２８】
すべての図面で、同じ部品には同じ参照符号が付けられている。
【００２９】

図 は、圧延素材 を圧延するための圧延スタンド の概略図である。圧延スタンド は、ワークロールとして設計された つのロール 、および各ロール に対して つの冷却装置 を備え、前記装置は、ロール の両側に配置されている。ロール は、ロール間隙 だけ間隔を置いて配置され、圧延材 を形成するために、圧延素材 をロール間隙 に圧延方向 に通す。各冷却装置 は、冷却棒 およびワイパ を備える。

【００３０】

各冷却棒 は、冷却剤を受け入れて吐出するように設計されている。冷却剤を吐出するために、冷却棒 は、冷却棒 の吐出側面 に配置された複数のフルジェットノズル を有し、前記側面は、それぞれのロール に面してロール のロール軸 に平行に延在し、ほぼ一定のジェット径の冷却剤ジェットを、フルジェットノズルのそれぞれを通して、冷却棒 からロール に向けて吐出方向 に吐出することができる。冷却剤は、冷却剤供給ライン を経て冷却棒 内に供給することができ、冷却棒 内に供給される冷却剤の量は、制御弁 、および／または、例えば周波数制御のポンプ によって制御することができる。冷却剤は、例えば、水である。

【００３１】

各ワイパ は、それぞれのロール から冷却剤をぬぐい取るように設計され、ロール に向かうように、またこれから離れるように枢動させることができる。各冷却装置 の冷却棒 およびワイパ は、冷却装置 の枢動装置に固定され、したがって、冷却棒 およびワイパ をロール に向かうように、またロール から離れるように一緒に枢動させることができることが好ましい。

【００３２】

図 は、ロール に冷却剤を吐出するための冷却棒 の第 の例示的な実施形態の概略斜視図である。冷却棒 は、相互に分離した つの冷却剤室 ～ に分割されて、冷却剤を受け入れる。各冷却剤室 ～ は、複数のフルジェットノズル が配置された吐出側面 の部分領域 ～ に対応し、冷却剤ジェットを冷却剤室 ～ からフルジェットノズルのそれぞれを通してロール に向けて吐出方向 に吐出することができる。吐出側面 は、ロール軸 に平行な つの長手方向辺 、 、およびロール軸 に垂直な つの短手方向辺 、 を有する長方形である。

【００３３】

第 の冷却剤室 は、吐出側面 の中央領域を形成する、冷却棒 の吐出側面 の第 の部分領域 に対応する。第 の部分領域 は、冷却棒 の吐出側面 の中心線 に対して鏡面対称であり、前記軸はロール軸 に垂直であり、第 の長手方向辺 に配置された つの頂点と、第 の長手方向辺 の端点にそれぞれ配置された つの頂点とを有する台形である。

【００３４】

フルジェットノズル は、それぞれがロール軸 に平行に延在する複数のノズル列 になって、吐出側面 に配置されている。この場合、各ノズル列 の相互に隣り合うフルジェットノズル のノズル間隔ｄは、中心線 に対して対称的に変化しており、その結果、ノズル間隔ｄは、吐出側面 の中央領域において最も狭く、吐出側面 の縁領域に向かって、例えば、放物線状に広くなっている。図 に示した例示的な実施形態では、ノズル間隔ｄは、各ノズル列 の端部ではノズル列 の中心での間隔の 倍大きくなっている。ノズル間隔ｄは、例えば、 から の間を変化する。ノズル列 は、吐出側面 の全範囲にわたって実質的に等間隔に延在し、したがって、ロール のロール表面に比較的均一な冷却効果を生じる。

【００３５】

図 に示した例示的な実施形態のさらなる展開としては、ノズル列 を互いに対してずらして配置することが想定され、したがって、様々なノズル列 のフルジェットノズル が、ロール軸 に垂直な方向に沿って配置されてはいない。「冷却チャネル」は、ノズル列 に垂直に延在して、そこでは、ロール に冷却剤が吐出されず、その結果、冷却効果が低下するが、この「冷却チャネル」を避けることができるので、ノズル列 の特に均一

な冷却効果が達成されることは有利である。
【００３６】
さらに、図 の隣り合う つの部分領域 ～ 間の境界線に非常に近い、または境界線上にあるフルジェットノズル は、完全に省かれるか、または、図 に示した配置に対してずらされて、隣接した部分領域 ～ の つに入るように配置され、それは分離板による冷却筒 の内部の冷却剤室 ～ への細分がこのような境界線に沿って延在するからである。
【００３７】
各フルジェットノズル は、冷却棒 のノズル開口に、例えば、ねじ込み継手によって取り外し可能に取り付けられる。フルジェットノズル はそれぞれ、例えば、約 の最小直径のノズル断面を有する。
【００３８】
各冷却剤室 ～ は、冷却剤室 ～ 内に冷却剤を供給するための冷却剤供給ライン に接続され、冷却剤供給ライン は、冷却剤室 ～ 内に、冷却剤の吐出方向 に実質的に垂直に開口している。冷却剤供給ライン の断面はそれぞれ、例えば、 からの間の直径を有する。
【００３９】
冷却剤供給ライン を経て冷却剤室 ～ 内に供給される冷却剤の量を、それぞれの制御弁 図 には示されていない 、および／または、それぞれのポンプ 図 には示されていない によって互いに独立して制御することができる。これによって、冷却剤室 ～ から吐出される冷却剤の量を、ロール表面の様々な領域の異なる熱負荷に対して適合させることができることは有利である。
【００４０】
図 は、一例として、図 に示した冷却棒 から吐出される つの冷却剤の体積流量 、 、 を、ロール軸 に平行な方向に沿う位置ｙの関数として示す。ここで、体積流量 、 、 は定格流量に対する比率で示されている。
【００４１】
定格流量は、中央位置ｙにおける第 の体積流量 である。第 の体積流量 は、冷却剤が、すべての冷却剤室 ～ に対して同じ特定の定格圧力で、すべての つの冷却剤室 ～ 内に供給された場合に生じる。第 の体積流量 は、中央位置ｙで最大となる放物線の形状を有し、中央位置ｙから つの端部領域に向かって減少して、中央位置ｙの値の半分になる。第 の体積流量 がこのような形状になる理由は、ノズル列 の中心から２ つの端部へ、ノズル列 に沿うフルジェットノズル のノズル間隔ｄが 倍になるからであり、ノズル間隔ｄの放物線状の増大が仮定される。
【００４２】
第 の体積流量 は、定格圧力のほぼ 倍の冷却剤圧力で冷却剤を第 の冷却剤室 内に供給し、定格圧力のほぼ半分の冷却剤圧力で冷却剤を他の つの冷却剤室 、 内のそれぞれに供給した場合に生じる。
【００４３】
第 の体積流量 は、定格圧力のほぼ半分の冷却剤圧力で冷却剤を第 の冷却剤室 内に供給し、定格圧力のほぼ 倍の冷却剤圧力で冷却剤を他の つの冷却剤室 、 内のそれぞれに供給した場合に生じる。
【００４４】
図 は、ロール軸 に平行な方向に沿う位置ｙへの依存性が異なるパターンを有する体積流量 、 、 を、冷却剤室 ～ の異なる冷却剤圧力によって生じさせることができ、その結果、冷却棒 から吐出される体積流量 、 、 を、ロール表面の温度分布に適合させることができることを示している。各冷却剤室 ～ の冷却剤圧力は、それぞれの制御弁 および／またはそれぞれのポンプ によって設定される。
【００４５】
図 ～図 はそれぞれ、冷却棒 の別の例示的な実施形態の吐出側面 を示す。これら

の例示的な実施形態は、図 に示した例示的な実施形態とは、冷却剤室 ～ 、およびそれに対応する吐出側面 の部分領域 ～ の形状および数だけが異なる。図 に示した例示的な実施形態のように、フルジェットノズル はそれぞれ、複数のノズル列 になるように配置され、それぞれの場合のノズル間隔dは、それに沿って中央から つの端部に向かって増大する。したがって、図 ～図 のフルジェットノズル はここでまた説明することはしない。吐出側面 のフルジェットノズル の、図 に示した例示的な実施形態と同様な分布によって、図 ～図 に示される例示的な実施形態のそれぞれで、図 と同様な体積流量 、 、 を生じさせることができる。

【００４６】

図 に示した例示的な実施形態のように、図 ～図 に示した例示的な実施形態はそれぞれ、 つの冷却剤室 ～ 、および吐出側面 にそれに対応する部分領域 ～ を有する。図 に示した例示的な実施形態と同様に、第 の部分領域 は、冷却棒 の吐出側面 の、ロール軸 に垂直な中心線 に対して鏡面対称であり、他の つの部分領域 、 は、第 の部分領域 と中心線 の異なる側で隣接する。

【００４７】

図 は、第 の部分領域 が、第 の長手方向辺 に配置された つの頂点と、第 の長手方向辺 に配置された つの頂点とを有する台形である例示的な実施形態を示す。

【００４８】

図 は、第 の部分領域 が、中心線 と第 の長手方向辺 との交点に配置された つの頂点と、第 の長手方向辺 の端部に配置された つの頂点とを有する三角形である例示な実施形態を示す。

【００４９】

図 は、第 の部分領域 が、中心線 と第 の長手方向辺 との交点に配置された つの頂点と、第 の長手方向辺 に配置された つの頂点とを有する三角形である例示的な実形態を示す。

【００５０】

図 は、第 の部分領域 が、頂点が長手方向辺 、 に配置された長方形である例示的な実施形態を示す。この例示的な実施形態では、 つの外側の部分領域 、 を経て冷却剤を吐出しないので、冷却剤の吐出を吐出側面 の中央領域からのみ生じさせることができる。したがって、この例示的な実施形態は、異なる幅の圧延素材 を圧延するのに特に適している。

【００５１】

図 は、第 の部分領域 および第 の部分領域 がそれぞれ、第 の長手方向辺 上の頂点と、第 の長手方向辺 の一端に配置された頂点と、短手方向辺 、 に配置された頂点とを有する長方形である例示的な実施形態を示す。

【００５２】

図 は、第 の部分領域 が、第 の長手方向辺 上の つの頂点と、第 の長手方向辺 の端部にそれぞれ配置された つの頂点と、それぞれの短手方向辺 、 上の頂点とを有する六角形である例示的な実施形態を示す。

【００５３】

図 は、第 の部分領域 が、中心線 と第 の長手方向辺 との交点に配置された つの頂点と、第 の長手方向辺 の端部にそれぞれ配置された つの頂点と、それぞれの短手方向辺 、 上の つの頂点とを有する五角形である例示的な実施形態を示す。

【００５４】

図 および図 に示した例示的な実施形態はそれぞれ、 つの冷却剤室 、 、およびそれに対応する、吐出側面 の部分領域 、 を有する。両方の部分領域 は、冷却棒 の吐出側面 の、ロール軸 に垂直な中心線 に対して鏡面対称である。

【００５５】

図 は、第 の部分領域 が、中心線 に配置された つの頂点と、第 の長手方向辺 の端部にそれぞれ配置された つの頂点とを有する三角形である例示的な実施形態を示す

。
【００５６】
図　は、第　の部分領域　が、中心線　に配置された　つの頂点と、第　の長手方向辺　の端部にそれぞれ配置された　つの頂点と、それぞれの短手方向辺　、　上の頂点とを有する五角形である例示的な実施形態を示す。
【００５７】
本発明を、好ましい例示的な実施形態によって、より詳細に例示および説明したが、本発明は、開示した例に限定されるものではなく、当業者は、本発明の保護の範囲を超えずにこれらから他の変形を得ることができる。
【符号の説明】
【００５８】
圧延スタンド
圧延素材、圧延材
ロール
冷却装置
ロール間隙
圧延方向
冷却棒
ワイパ
ロール軸
吐出側面
フルジェットノズル
吐出方向
～　冷却剤室
～　部分領域
、　長手方向辺
、　短手方向辺
中心線
ノズル列
冷却剤供給ライン
制御弁
ポンプ
ノズル間隔

【図１】

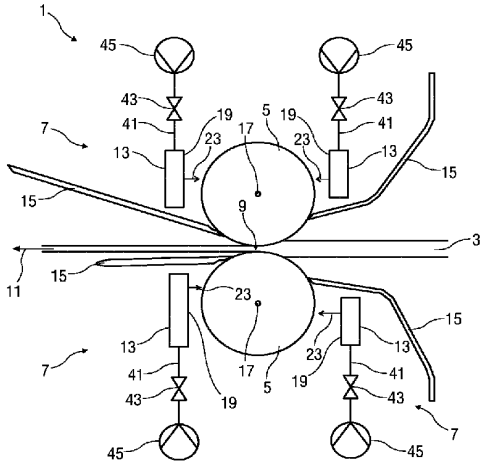


FIG 1

【図２】

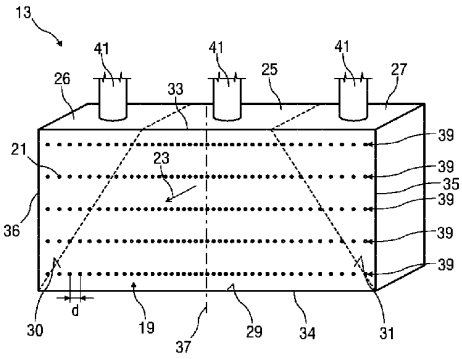


FIG 2

【図３】

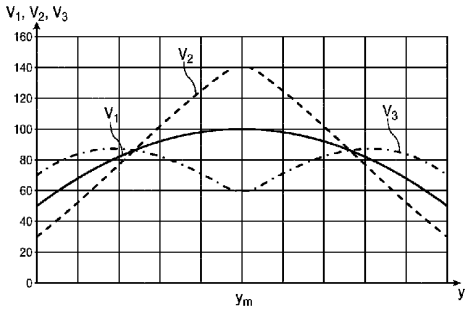


FIG 3

【図４】

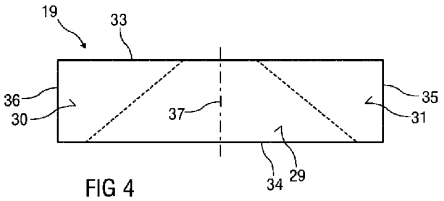


FIG 4

【図５】

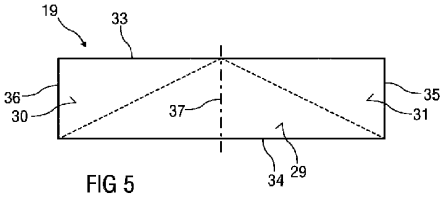


FIG 5

【図６】

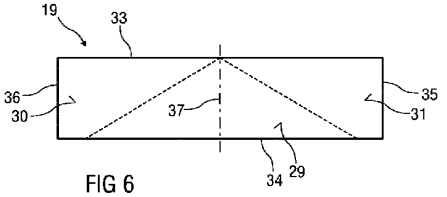


FIG 6

【図７】

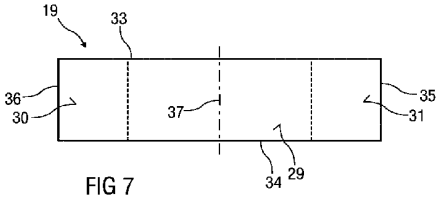


FIG 7

【図８】

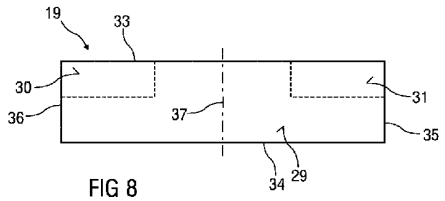


FIG 8

【図９】

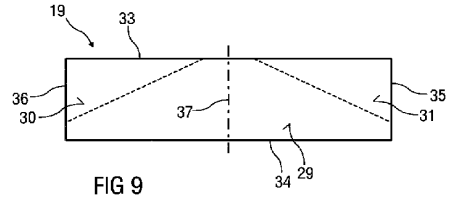


FIG 9

【図１０】

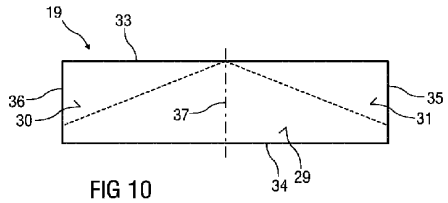


FIG 10

【図１１】

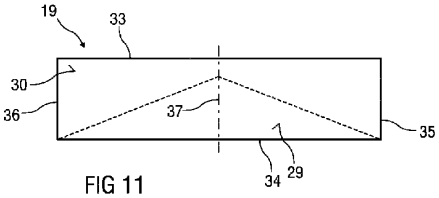


FIG 11

【図１２】

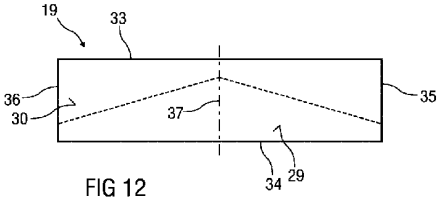


FIG 12

【国際調査報告】

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2017/076000

A. CLASSIFICATION OF SUBJECT MATTER
INV. B21B27/10
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)
B21B

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.
X	DE 200 06 508 U1 (ACHENBACH BUSCHHUETTEN GMBH [DE]) 31 August 2000 (2000-08-31)	1,15
Y	page 5, paragraph 3 - page 7, paragraph 3	2-5
X	WO 2008/149195 A1 (ARCELORMITTAL FRANCE [FR]; VANDERSCHUEREN DIRK [BE]; VAN POECKE PATRIC) 11 December 2008 (2008-12-11)	1,15
Y	page 3, line 20 - page 4, line 12; figures 1,2	2-5
Y	EP 2 792 428 A1 (SIEMENS VAI METALS TECH GMBH [AT]) 22 October 2014 (2014-10-22) paragraph [0017] - paragraph [0027]; figures 1-3	2-5
A	WO 2015/113832 A1 (LOI THERMPROCESS GMBH [DE]) 6 August 2015 (2015-08-06) page 4, line 8 - line 17	1

☐ 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 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
11 January 2018	06/03/2018

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	Frisch, Ulrich

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

INTERNATIONAL SEARCH REPORT

International application No.
PCT/EP2017/076000

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 additional sheet

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, 15

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)) (January 2015)

The International Searching Authority has found that the international application contains multiple (groups of) inventions, as follows:

1. Claims 1-5, 15

Cooling device for cooling a roller, wherein two coolant chambers are provided which are separated from each other.

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2. Claims 1, 6-8

Cooling device for cooling a roller, wherein the feed/control of the coolant is further defined.

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3. Claims 1, 9-13

Cooling device for cooling a roller, wherein the distance of the nozzles is defined.

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4. Claims 1, 14

Cooling device for cooling a roller, wherein an additional stripper is defined.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/EP2017/076000

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
DE 20006508 U1	31-08-2000	DE 20006508 U1	31-08-2000
		EP 1142652 A2	10-10-2001
		JP 2001347307 A	18-12-2001
		US 2001027672 A1	11-10-2001
WO 2008149195 A1	11-12-2008	AU 2008259470 A1	11-12-2008
		BR PI0812201 A2	25-11-2014
		CA 2690098 A1	11-12-2008
		CN 101702888 A	05-05-2010
		EP 2014379 A1	14-01-2009
		EP 2164651 A1	24-03-2010
		JP 5380438 B2	08-01-2014
		JP 2010528870 A	26-08-2010
		KR 20100020462 A	22-02-2010
		RU 2009149178 A	20-07-2011
		SI 2164651 T1	30-08-2013
		UA 99295 C2	10-08-2012
		US 2010180657 A1	22-07-2010
		WO 2008149195 A1	11-12-2008
		ZA 200908405 B	28-07-2010
EP 2792428 A1	22-10-2014	CN 105188975 A	23-12-2015
		EP 2792428 A1	22-10-2014
		EP 2986400 A1	24-02-2016
		JP 6110015 B2	05-04-2017
		JP 2016515474 A	30-05-2016
		KR 20150143746 A	23-12-2015
		RU 2015141167 A	17-05-2017
		US 2016052033 A1	25-02-2016
		WO 2014170139 A1	23-10-2014
WO 2015113832 A1	06-08-2015	DE 102014001146 A1	06-08-2015
		EP 3099829 A1	07-12-2016
		WO 2015113832 A1	06-08-2015

Form PCT/ISA/210 (patent family annex) (April 2005)

INTERNATIONALER RECHERCHENBERICHT

Internationales Aktenzeichen
PCT/EP2017/076000

A. KLASSIFIZIERUNG DES ANMELDUNGSGEGENSTANDES
INV. B21B27/10
ADD.

Nach der Internationalen Patentklassifikation (IPC) oder nach der nationalen Klassifikation und der IPC

B. RECHERCHIERTE GEBIETE

Recherchierter Mindestprüfstoff (Klassifikationssystem und Klassifikationssymbole)
B21B

Recherchierte, aber nicht zum Mindestprüfstoff gehörende Veröffentlichungen, soweit diese unter die recherchierten Gebiete fallen

Während der internationalen Recherche konsultierte elektronische Datenbank (Name der Datenbank und evtl. verwendete Suchbegriffe)
EPO-Internal, WPI Data

C. ALS WESENTLICH ANGESEHENE UNTERLAGEN

Kategorie*	Bezeichnung der Veröffentlichung, soweit erforderlich unter Angabe der in Betracht kommenden Teile	Betr. Anspruch Nr.
X	DE 200 06 508 U1 (ACHENBACH BUSCHHUETTEN GMBH [DE]) 31. August 2000 (2000-08-31)	1,15
Y	Seite 5, Absatz 3 - Seite 7, Absatz 3	2-5
X	WO 2008/149195 A1 (ARCELORMITTAL FRANCE [FR]; VANDERSCHUEREN DIRK [BE]; VAN POECKE PATRIC) 11. Dezember 2008 (2008-12-11)	1,15
Y	Seite 3, Zeile 20 - Seite 4, Zeile 12; Abbildungen 1,2	2-5
Y	EP 2 792 428 A1 (SIEMENS VAI METALS TECH GMBH [AT]) 22. Oktober 2014 (2014-10-22) Absatz [0017] - Absatz [0027]; Abbildungen 1-3	2-5
A	WO 2015/113832 A1 (LOI THERMPROCESS GMBH [DE]) 6. August 2015 (2015-08-06) Seite 4, Zeile 8 - Zeile 17	1

☐ Weitere Veröffentlichungen sind der Fortsetzung von Feld C zu entnehmen ☒ Siehe Anhang Patentfamilie

* Besondere Kategorien von angegebenen Veröffentlichungen :
"A" Veröffentlichung, die den allgemeinen Stand der Technik definiert, aber nicht als besonders bedeutsam anzusehen ist
"E" frühere Anmeldung oder Patent, die bzw. das jedoch erst am oder nach dem internationalen Anmeldedatum veröffentlicht worden ist
"L" Veröffentlichung, die geeignet ist, einen Prioritätsanspruch zweifelhaft erscheinen zu lassen, oder durch die das Veröffentlichungsdatum einer anderen im Recherchenbericht genannten Veröffentlichung belegt werden soll oder die aus einem anderen besonderen Grund angegeben ist (wie ausgeführt)
"O" Veröffentlichung, die sich auf eine mündliche Offenbarung, eine Benutzung, eine Ausstellung oder andere Maßnahmen bezieht
"P" Veröffentlichung, die vor dem internationalen Anmeldedatum, aber nach dem beanspruchten Prioritätsdatum veröffentlicht worden ist
"T" Spätere Veröffentlichung, die nach dem internationalen Anmeldedatum oder dem Prioritätsdatum veröffentlicht worden ist und mit der Anmeldung nicht kollidiert, sondern nur zum Verständnis des der Erfindung zugrundeliegenden Prinzips oder der ihr zugrundeliegenden Theorie angegeben ist
"X" Veröffentlichung von besonderer Bedeutung; die beanspruchte Erfindung kann allein aufgrund dieser Veröffentlichung nicht als neu oder auf erfinderischer Tätigkeit beruhend betrachtet werden
"Y" Veröffentlichung von besonderer Bedeutung; die beanspruchte Erfindung kann nicht als auf erfinderischer Tätigkeit beruhend betrachtet werden, wenn die Veröffentlichung mit einer oder mehreren Veröffentlichungen dieser Kategorie in Verbindung gebracht wird und diese Verbindung für einen Fachmann naheliegend ist
"&" Veröffentlichung, die Mitglied derselben Patentfamilie ist

Datum des Abschlusses der internationalen Recherche	Absendedatum des internationalen Recherchenberichts
11. Januar 2018	06/03/2018

Name und Postanschrift der Internationalen Recherchenbehörde	Bevollmächtigter Bediensteter
Europäisches Patentamt, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Frisch, Ulrich

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Formblatt PCT/ISA/210 (Blatt 2) (April 2005)

INTERNATIONALER RECHERCHENBERICHT

Internationales Aktenzeichen
PCT/EP2017/076000

Feld Nr. II Bemerkungen zu den Ansprüchen, die sich als nicht recherchierbar erwiesen haben (Fortsetzung von Punkt 2 auf Blatt 1)

Gemäß Artikel 17(2)a) wurde aus folgenden Gründen für bestimmte Ansprüche kein internationaler Recherchenbericht erstellt:

1. ☐ Ansprüche Nr.
weil sie sich auf Gegenstände beziehen, zu deren Recherche diese Behörde nicht verpflichtet ist, nämlich

2. ☐ Ansprüche Nr.
weil sie sich auf Teile der internationalen Anmeldung beziehen, die den vorgeschriebenen Anforderungen so wenig entsprechen, dass eine sinnvolle internationale Recherche nicht durchgeführt werden kann, nämlich

3. ☐ Ansprüche Nr.
weil es sich dabei um abhängige Ansprüche handelt, die nicht entsprechend Satz 2 und 3 der Regel 6.4 a) abgefasst sind.

Feld Nr. III Bemerkungen bei mangelnder Einheitlichkeit der Erfindung (Fortsetzung von Punkt 3 auf Blatt 1)

Diese Internationale Recherchenbehörde hat festgestellt, dass diese internationale Anmeldung mehrere Erfindungen enthält:

siehe Zusatzblatt

1. ☐ Da der Anmelder alle erforderlichen zusätzlichen Recherchengebühren rechtzeitig entrichtet hat, erstreckt sich dieser internationale Recherchenbericht auf alle recherchierbaren Ansprüche.

2. ☐ Da für alle recherchierbaren Ansprüche die Recherche ohne einen Arbeitsaufwand durchgeführt werden konnte, der zusätzliche Recherchengebühr gerechtfertigt hätte, hat die Behörde nicht zur Zahlung solcher Gebühren aufgefordert.

3. ☐ Da der Anmelder nur einige der erforderlichen zusätzlichen Recherchengebühren rechtzeitig entrichtet hat, erstreckt sich dieser internationale Recherchenbericht nur auf die Ansprüche, für die Gebühren entrichtet worden sind, nämlich auf die Ansprüche Nr.

4. ☒ Der Anmelder hat die erforderlichen zusätzlichen Recherchengebühren nicht rechtzeitig entrichtet. Dieser internationale Recherchenbericht beschränkt sich daher auf die in den Ansprüchen zuerst erwähnte Erfindung; diese ist in folgenden Ansprüchen erfasst:
1-5, 15

Bemerkungen hinsichtlich eines Widerspruchs

☐ Der Anmelder hat die zusätzlichen Recherchengebühren unter Widerspruch entrichtet und die gegebenenfalls erforderliche Widerspruchsgebühr gezahlt.

☐ Die zusätzlichen Recherchengebühren wurden vom Anmelder unter Widerspruch gezahlt, jedoch wurde die entsprechende Widerspruchsgebühr nicht innerhalb der in der Aufforderung angegebenen Frist entrichtet.

☐ Die Zahlung der zusätzlichen Recherchengebühren erfolgte ohne Widerspruch.

Formblatt PCT/ISA/210 (Fortsetzung von Blatt 1 (2)) (April 2005)

WEITERE ANGABEN **PCT/ISA/** 210

Die internationale Recherchenbehörde hat festgestellt, dass diese internationale Anmeldung mehrere (Gruppen von) Erfindungen enthält, nämlich:

1. Ansprüche: 1-5, 15

   Kühlvorrichtung zur Kühlung einer Walze, wobei zwei voneinander getrennte Kühlmittelkammern vorgesehen sind.

   ---

2. Ansprüche: 1, 6-8

   Kühlvorrichtung zur Kühlung einer Walze, wobei die Zuleitung / Steuerung des Kühlmittels weiter definiert wird.

   ---

3. Ansprüche: 1, 9-13

   Kühlvorrichtung zur Kühlung einer Walze, wobei der Abstand der Düsen definiert wird.

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4. Ansprüche: 1, 14

   Kühlvorrichtung zur Kühlung einer Walze, wobei ein zusätzlicher Abstreifer definiert wird

   ---

INTERNATIONALER RECHERCHENBERICHT

Angaben zu Veröffentlichungen, die zur selben Patentfamilie gehören

Internationales Aktenzeichen
PCT/EP2017/076000

Im Recherchenbericht angeführtes Patentdokument	Datum der Veröffentlichung	Mitglied(er) der Patentfamilie	Datum der Veröffentlichung
DE 20006508 U1	31-08-2000	DE 20006508 U1	31-08-2000
		EP 1142652 A2	10-10-2001
		JP 2001347307 A	18-12-2001
		US 2001027672 A1	11-10-2001
WO 2008149195 A1	11-12-2008	AU 2008259470 A1	11-12-2008
		BR PI0812201 A2	25-11-2014
		CA 2690098 A1	11-12-2008
		CN 101702888 A	05-05-2010
		EP 2014379 A1	14-01-2009
		EP 2164651 A1	24-03-2010
		JP 5380438 B2	08-01-2014
		JP 2010528870 A	26-08-2010
		KR 20100020462 A	22-02-2010
		RU 2009149178 A	20-07-2011
		SI 2164651 T1	30-08-2013
		UA 99295 C2	10-08-2012
		US 2010180657 A1	22-07-2010
		WO 2008149195 A1	11-12-2008
		ZA 200908405 B	28-07-2010
EP 2792428 A1	22-10-2014	CN 105188975 A	23-12-2015
		EP 2792428 A1	22-10-2014
		EP 2986400 A1	24-02-2016
		JP 6110015 B2	05-04-2017
		JP 2016515474 A	30-05-2016
		KR 20150143746 A	23-12-2015
		RU 2015141167 A	17-05-2017
		US 2016052033 A1	25-02-2016
		WO 2014170139 A1	23-10-2014
WO 2015113832 A1	06-08-2015	DE 102014001146 A1	06-08-2015
		EP 3099829 A1	07-12-2016
		WO 2015113832 A1	06-08-2015

Formblatt PCT/ISA/210 (Anhang Patentfamilie) (April 2005)

フロントページの続き

指定国・地域

発明者　ルーカス・ピヒラー
オーストリア・４０４０・リンツ・シュトライムリングヴェーク・７

(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2020-340
(P2020-340A)
(43)公開日　令和2年1月9日(2020.1.9)

(51)Int.Cl.			F I			テーマコード（参考）
A61J	3/00	(2006.01)	A61J	3/00	310E	3C060
B65B	61/00	(2006.01)	B65B	61/00		3E056
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）

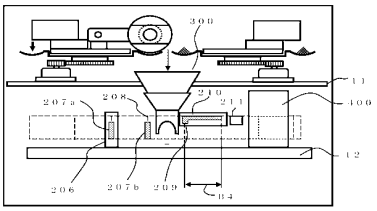
(21)出願番号　特願2018-120789 (P2018-120789)
(22)出願日　平成30年6月26日 (2018.6.26)

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(72)発明者　深津　邦夫
東京都大田区東糀谷三丁目８番８号

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凹部（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、３０５ｂと楔状の形状が、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、図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）に示すようにカムフォロワ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。

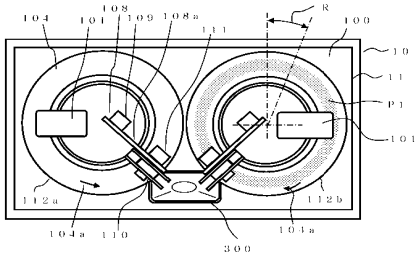
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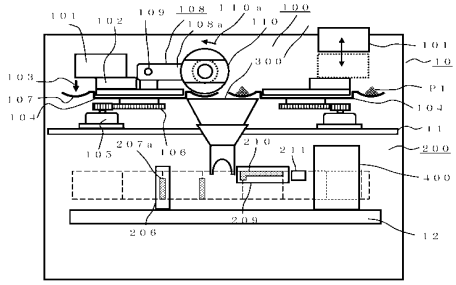
１００・・・円盤配分部（薬剤供給部）
２００・・・印刷包装機
２０１・・・分包用紙ロール（分包用紙収納部）
２０６・・・縦シール機構
２０９・・・横シール機構
２１１・・・駆動ローラ
３００・・・落下ホッパ（薬剤供給部）
４００・・・ミシン目作成装置
４０２・・・刃収納部
４０４・・・刃受け部
４１６，４１８・・・カム板
４２０・・・カム板

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）

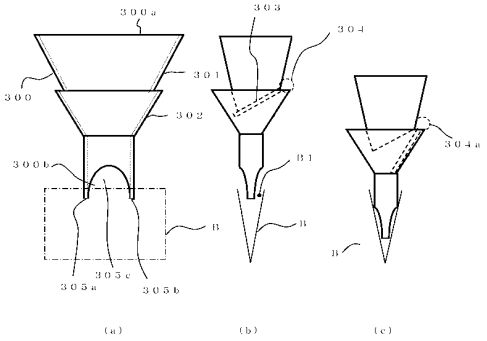
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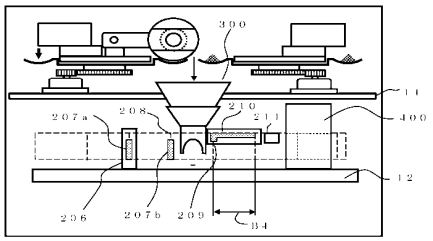
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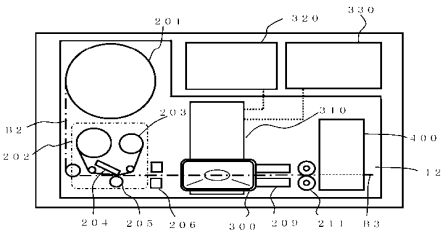
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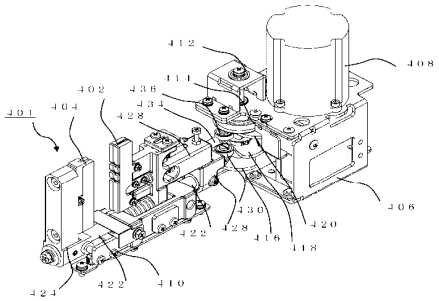
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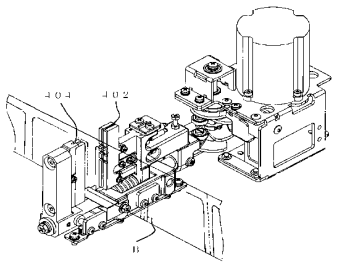
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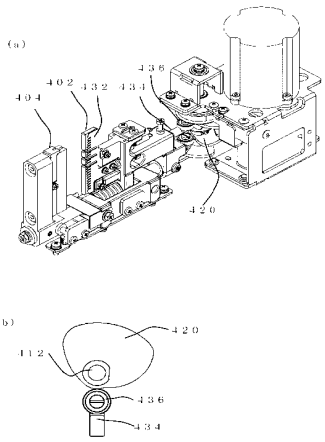
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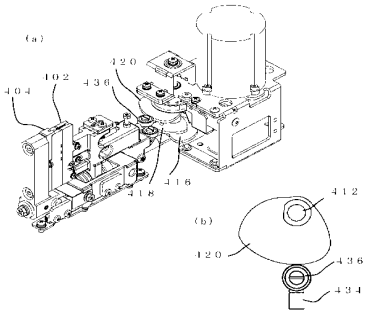
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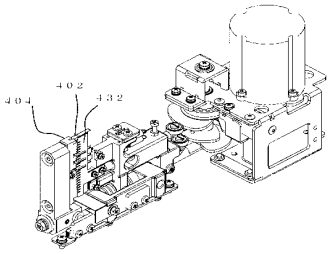
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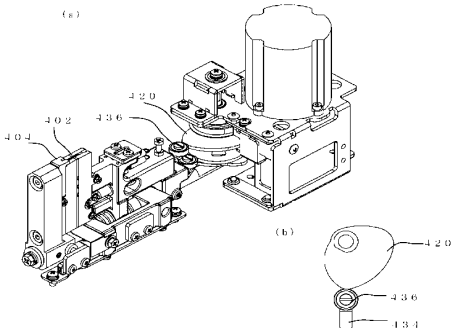
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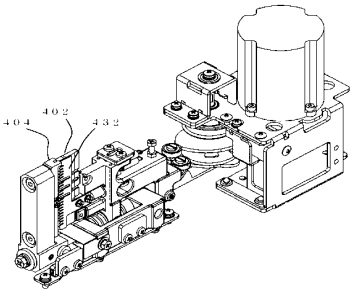
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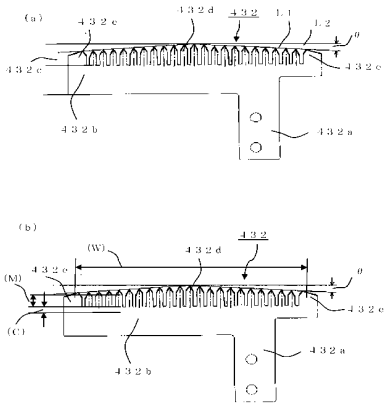
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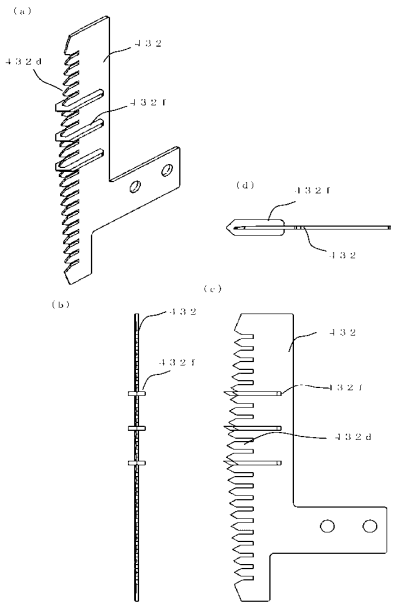
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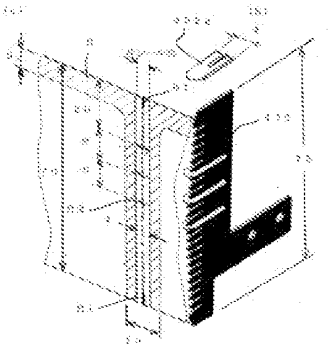
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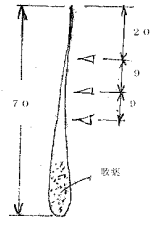
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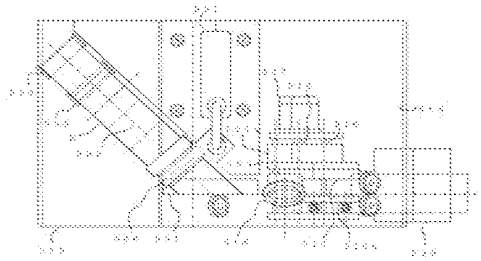
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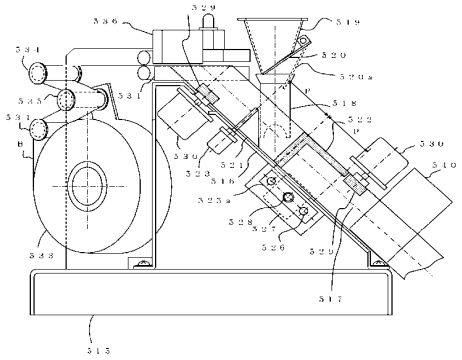
【図１６】



【図１７】



【図１８】



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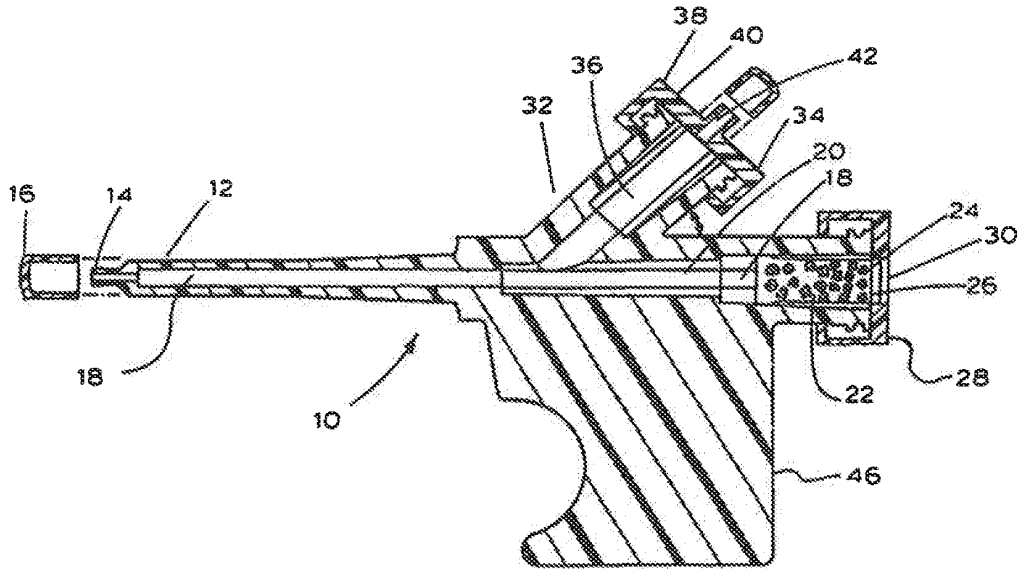
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(57) Abstract

The invention comprises a closed system blood sampling device comprising a bifurcated capillary tube (10) which has a first branch (12) having a cannula shaped end (14) for withdrawing and conveying blood to a communicating blood collection zone. The second branch of the bifurcated capillary tube (32) is connected to and is in fluid communication with the blood collection zone. It terminates in an opening adapted to receive a blood withdrawal device.

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CLOSED SYSTEM BLOOD SAMPLING DEVICE

FIELD OF THE INVENTION

The invention relates to closed system blood sampling devices.

BACKGROUND OF THE INVENTION

Arterial blood gas sampling is a standard procedure often used to help assess respiratory function in the critically ill. In some cases, samples can be drawn as many as 20 times a day. For the typical neonatal patient weighing 1000 grams and having approximately 85 cc of total body fluid capacity, the volume of blood samples becomes a critical factor.

A technique called the 3 drop method is gaining substantial clinical acceptance in neonatal units across the country. This method calls for inserting a blunt hypodermic needle as far as possible into a standard sleeve stoppered T-Connector. Three drops of blood estimated to be approximately .06 cc are allowed to drip onto a gauge pad, thereby clearing the cannula of heparinized or non-circulating blood while providing a fresh arterial sample to the surface. 3 more drops are then collected in a micro container followed by cannula withdrawal. Blood cannula contents within the cannula lumen and the previously collected micro container sample are then aspirated into a tuberculin type syringe for transport to the blood lab for testing. A flush of the T-Connector to eliminate residual blood then ensues. This procedure provides the ability to withdraw a controlled blood volume; .06 cc as necessary

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discard and .12 cc to perhaps .20 cc for actual blood gas testing.

Several opportunities for procedural improvement exist. One challenge is the open environment method of collection which could foster blood contamination and/or the spread of infectious diseases. Secondarily, the collection process in regard to volume accuracy is difficult to control and highly sensitive to variations in clinician technique, catheter positioning and arterial pressure. If a device can be designed for closed system collection which could also insure consistency of sample volume time after time, treatment of neonatal patients where blood volume levels are critical, accuracy improvements could be a major clinical benefit.

THE DRAWINGS

Fig. 1 is a horizontal cut away side view showing the closed system blood sampling device of the invention.

Fig. 2 is a vertical, partial schematic view showing the closed system blood sampling device connected to an injection site which, in turn, is fitted into a venipuncture device used to withdraw arterial blood.

In the drawings, like parts have like numbers.

THE INVENTION

The invention is a closed system 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 communicating blood collection zone. The blood

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collection zone is for storing a quantity of withdrawn blood. It also feeds an initial fraction of withdrawn blood to a communicating blood disposal chamber which has an air permeable liquid sealed end.

The second branch of the bifurcated capillary tube is connected to and is in fluid communication with the blood collection zone. It terminates in an opening adapted to receive a blood withdrawal device.

In preferred embodiments the closed system blood sampling device the cannula shaped end is blunt, the blood disposal chamber has its end fitted with a cap containing an air permeable hydrophobic membrane, and the blood disposal chamber contains a porous blood adsorbent. The second branch has an interior angle not greater than 90 degrees and preferably the interior angle is 60 degrees. It is also desirable that the cannula shaped end be tapered so that it snugly fits into the preferred injection sites more fully described hereafter.

Preferably, the closed system blood sampling device is removed from the injection site before the blood sample is withdrawn therefrom by means such as a tuberculum syringe or aspirated directly into a blood gas analyzer.

While the closed blood sampling device is particularly suited for obtaining neonatal blood samples it is readily adapted to obtain samples from a variety of patient types.

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DETAILED DESCRIPTION OF THE INVENTION

In Fig. 1 the closed system blood sampling device is designated generally by the numeral 10. It is preferably constructed of a clear chemically inert non-toxic plastic such as polycarbonate. It comprises a blood withdrawal cannula shaped end 12. The cannula tip 14 is blunt and necked down to prevent injection site from blood flash back during arterial sampling. To maintain sterility the cannula tip is fitted with a removable cap 16 which is removed just before the blood sampling device is to be used.

Fig. 1 shows the cannula shaped end 12 to be tapered. This particular configuration was selected so that the cannula may engage and generally mate with a particular injection site, the details of which will be more fully described hereafter. The interior bore 18 of the cannula shaped end is dimensioned to allow withdrawn blood to move along the bore by means of capillary action driven by normally positive arterial blood pressure.

The interior capillary bore 18 connects with and continues into a larger outer diameter lumen 20. The continuous bore 18 of the cannula 12 and the lumen 20 comprise a blood collection zone. Bore 18 as it exits the lumen 20 empties into blood disposal chamber 22. In a preferred embodiment of the invention, blood disposal chamber 22 contains a blood retaining means such as adsorbing material 24 which may be rayon or cellulosic wadding. The open end 26 of the blood disposal

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chamber 22 is closed with a cap 28 that has its top fitted with a liquid tight, air permeable hydrophobic membrane 30 which allows air to be evacuated from the blood sampling device 10 of the invention. A suitable membrane material is sheet polytetrafloroethylene having a thickness of about 0.8 microns.

Fitted to the lumen 20, and in fluid communication therewith, is the second branch or port 32. It is positioned so as to have an interior angle 34 not exceeding 90 degrees. The interior angle is preferably about 60 degrees. The bore 36 connects with and corresponds in dimension with bore 18. Port 32 terminates and is sealed by adapter cap 38 whose top 40 is fitted with a capillary luer 42. The capillary luer is protected from contamination by means of protective cap 44 which is removed just prior to blood being withdrawn from the closed blood sampling device. The port 32 and its bore 36 form a part of the blood collection zone previously described. For convenience of use, the closed blood sampling device is fitted with pistol grip handle 46.

The blood collection zone has a larger liquid capacity than the liquid capacity of the blood disposal chamber. If the closed blood sampling device described were to be used in neonatal blood sampling, the liquid capacity of the blood collection zone might be 0.12 cc and the liquid capacity of the blood disposal chamber 22 would be about 0.06 cc.

The use of the closed blood sampling device of the invention to withdraw and sample blood is illustrated in Fig. 2 which shows artery 48 in communication with a venipuncture

device 50 which was inserted through subcutaneous tissue 52. The neck 54 of the venipuncture device 50 is adapted to receive an injection site 56. While conventional injection sites may be used as such or adapted to be used in the practice of the invention, it is preferred that the injection site be of the type having a resilient resealable septum which is preferably pre-slit. An injection site of this type is available from Baxter Healthcare Corporation and is a Neonatal T-Connector Luer sold under the brand name, InterLink, a registered trademark of Baxter Healthcare Corporation.

Such pre-slit, resilient, resealable injection sites and their method of fabrication are described in U.S. 5,188,620 the disclosure of which is incorporated herein by reference. The pre-slit resilient resealable injection sites described in this patent are designed to receive blunt cannulas. Another injection site related to the injection sites detailed in U.S. 5,188,620 is described in U.S. 5,300,034. This patent also details numerous publications and references which describe the preferred injection sites used in the practice of this invention. This patent and the publications listed therein also are incorporated herein by reference.

The injection site 56 is fitted with T-connector 58 which, in turn, is fitted with microbore tubing which, through female luer 62, is connected to IV line 64. The distal end 64 of the injection site 56 is connected to the neck 54 of the venipuncture device 50. The proximal end 66 of the injection site 56 is fitted with a pre-slit resilient resealing septum 68 adapted to receive

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the blood withdrawal cannula 12 which is dimensioned to fit snugly into the injection site. Inserted into the second branch or port 32 is a conventional syringe 70, such as a tuberculum blood draw syringe, or an arterial blood gas loss of resistance syringe.

The device's cannula 12 would be inserted through the septum 68 of the injection site 56 and positioned so that the tip 14 of the cannula 12 was fully inserted into the injection site adjacent to the venipuncture device. In doing so, the residual volume of the actual T-Housing would be eliminated as a measurable factor in blood draw volume. Arterial pressure would cause blood flow to enter and flow up the device via capillary action. As blood moved up the hydrophobic membrane 30 of the device, air would escape via the upstream hydrophobic membrane 30. Original blood first present in the catheter would be pushed beyond the luer bifurcation for retention in the device and eventual disposal. The device would be withdrawn from the T-Connector as soon as visual confirmation of the blood filled lumen was made. The vented removal cap 44 would be removed from the bifurcated luer 42 and replaced by the syringe 70 which would be aspirated to remove the arterial blood sample. Residual blood volume upstream of the bifurcation would remain in the device for subsequent disposal.

WE CLAIM:

1. A closed system blood sampling device comprising a bifurcated capillary tube comprising:

a. a first branch having a cannula shaped end for withdrawing and conveying blood to a communicating;

b. blood collection zone for storing a quantity of withdrawn blood and feeding an initial fraction of withdrawn blood to a communicating;

c. blood disposal chamber having an air permeable liquid sealed end; and,

d. a second branch connected to and in fluid communication with the blood collection zone which terminates in an opening adapted to receive a blood withdrawal device.

2. The closed system blood sampling device of Claim 1 where the cannula shaped end is blunt, the blood disposal chamber has its end fitted with a cap containing an air permeable hydrophobic membrane, and the blood disposal chamber contains a porous blood adsorbent.

3. The closed system blood sampling device of Claim 1 where the second branch has an interior angle not greater than 90 degrees.

4. The closed system blood sampling device of Claim 3 where the second branch has an angle of about 60 degrees.

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5. The closed system blood sampling device of Claim 2 where the cannula shaped end is tapered.

6. The closed system blood sampling device of Claim 2 where the blunt cannula shaped end is adapted to be received by a injection site which contains a resilient resealing means.

7. The closed system blood sampling device of Claim 6 where the injection site is a pre-slit injection site.

8. The closed system blood sampling device of Claim 2 where the blood collection zone has a volume greater than the volume of the blood disposal chamber.

9. A method of sampling blood from a patient having an artery fitted with a venipuncture device which is attached to an injection site containing the closed blood sampling device of Claim 1 which comprises the steps of:

a. withdrawing blood through the cannula shaped end of the closed blood sampling device thereby sequentially filling the blood disposal chamber and then the blood collection zone;

b. withdrawing through the opening in the second branch the blood contained in the blood collection zone for subsequent processing; and, then,

c. discarding the closed system blood sampling device

10. The method of Claim 9 where the cannula is blunt, the blood disposal chamber has its end fitted with a cap containing an air permeable hydrophobic membrane, and contains a porous blood adsorbent.

11. The method of Claim 9 where the second branch has an interior angle not greater than 90 degrees.

12. The method Claim 11 where the second branch has an angle of about 60 degrees.

13. The method of Claim 10 where the cannula shaped end is tapered.

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14. The method of Claim 10 where the blunt cannula shaped end is adapted to be received by a injection site which contains a resilient resealing means.

15. The method of Claim 14 where the injection site is a pre-slit injection site.

16. The method of Claim 10 where the blood collection zone has a volume greater than the volume of the blood disposal chamber.

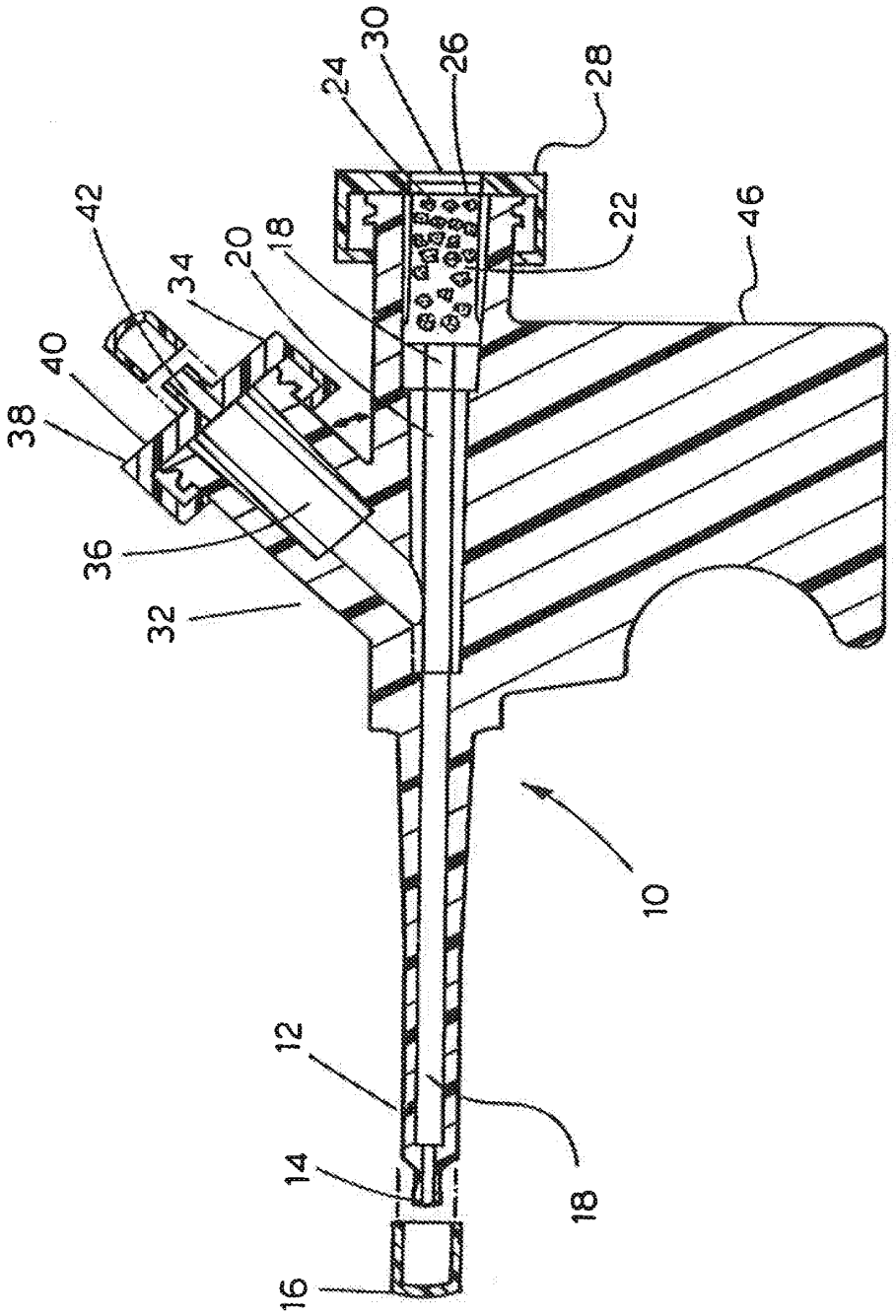


FIG. 1

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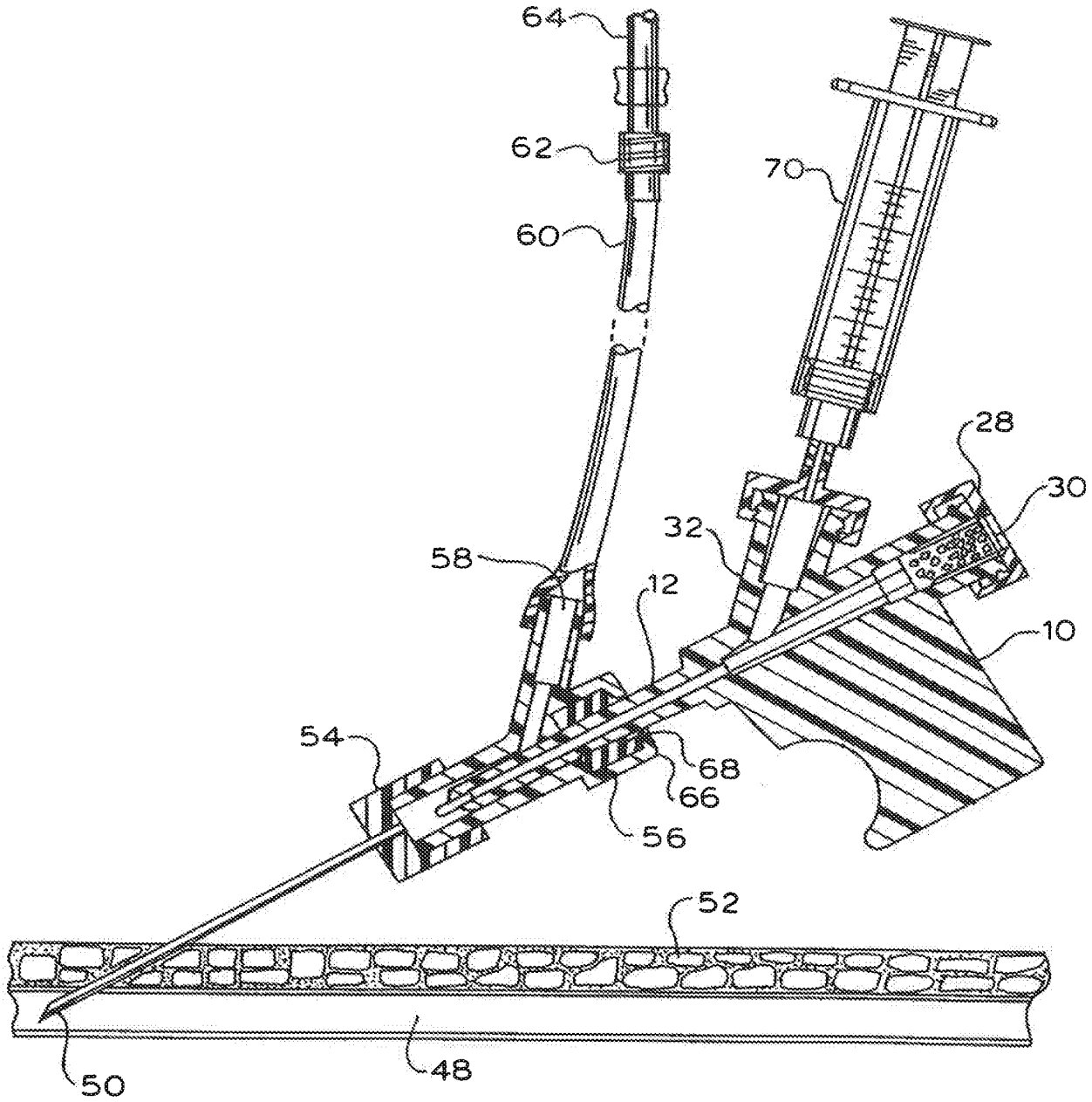


FIG. 2

SUBSTITUTE SHEET (RULE 26)

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US95/10702

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A 61M 5/00
US CL : 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)

U.S. : 604/122, 35, 125, 126, 128, 256, 258, 283, 284
128/ 760, 762, 767, 768

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)

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, A, 4,531,937 (Yates) 30 July 1985, See Entire Reference	1-7,9-15 --- 8,16

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

*	Special categories of cited documents:	"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
"A"	document defining the general state of the art which is not considered to be part of particular relevance	"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
"E"	earlier document published on or after the international filing date	"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
"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)	"&"	document member of the same patent family
"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		

Date of the actual completion of the international search 08 DECEMBER 1995	Date of mailing of the international search report 04 JAN 1996
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No.	Authorized officer SAM RIMELL Telephone No. (703) 308-0858

Form PCT/ISA/210 (second sheet)(July 1992)*

BNSDOCID: <WO_____9605875A1_I_>

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Application No.	Ref.	Date
17 840 467.9 - 1132	EPA-147 134	22.04.2020
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

1, 2, 4-44	as published	
3, 3a	filed in electronic form on	16-12-2019

Claims, Numbers

1-14	filed in electronic form on	16-12-2019

Drawings, Sheets

1/69-69/69	as published

With the following amendments to the above-mentioned documents proposed by the division

Description, Pages 1, 20, 23, 27, 40

Comments

Registered letter
EPO Form 2004C 12.17CXP

DESCRIPTION
Page 1: Deletion of irrelevant and/or superfluous information (Rule 48(1)(c) EPC, Guidelines F-II, 7.4)
Pages 20, 23, 27, 40: Insertion of SI/metric units (Rule 49(10) EPC)
CLAIMS
Page 1: Deletion of irrelevant and/or superfluous information (Rule 48(1)(c) EPC, Guidelines F-II, 7.4)

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**	960.00
	minus any amount already paid (Rule 71a(5) EPC):		0.00
		Total amount:	960.00
(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.

Note: If a waiver is expressed in response to a Rule 71(3) communication (see OJ EPO 2015, A52), the fee for grant, including the fee for publication/printing, and any additional claims fees will not be debited automatically. These fees must be paid separately by another means of payment allowed under the Rules relating to Fees.

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Enclosures: Text intended for grant

EPO Form 2056

Registered letter
EPO Form 2004C 12.17CXP

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Annex to EPO Form 2004, Communication pursuant to Rule 71(3) EPC

Bibliographical data of European patent application No. 17 840 467.9

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 CONTAMINANT DU SANG

Classification: INV. A61B5/15 A61B5/153 A61B5/154 A61B5/157

Date of filing: 27.12.2017

Priority claimed: US / 27.12.2016 / USP201662439426

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.

~~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.

US 2014/039348 A1 discloses a device including a pre-sample reservoir, an actuator mechanism and a diverter. The pre-sample reservoir can be fluidically coupled to a delivery member to receive and isolate a predetermined volume of bodily-fluid withdrawn from a patient. US 2014/107564 A1 discloses an apparatus including a cannula assembly, a housing, a fluid reservoir, a flow control mechanism and an actuator. US 4 813 433 A discloses a syringe for withdrawing fluids which consists of one-handed operated syringe. The syringe comprises a double compartmented housing, a piston disposed in one of said compartments, a piston rod connected to said piston controlling the movement of said piston in a barrel, and vent means. US 2013/317391 A1 discloses an apparatus including a housing, a flow control mechanism and an actuator. At least a portion of the flow control mechanism is movably disposed within the housing.

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 ≥ 0,1143 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.

[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 0,1143 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.

[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 ≥ 0,1143 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.

[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 ≥ 0,1143 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.

[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.

~~Amended~~ claims

1. A blood sequestration device (812, 1000, 1100, 1202, 1302, 1401, 1500, 1600, 2008, 2100, 2200, 2300, 2408, 2502, 2608, 2702, 2802, 2902, 3000) comprising;

an inlet port (802, 902, 1002, 1102, 1212, 1314, 1402, 1502, 1532, 1602, 2302, 2316, 2412, 2612, 3002);

an outlet port (904, 1004, 1104, 1214, 1312, 1404, 1504, 1534, 1604, 2304, 2318, 2414, 2614, 3004) ;

a sequestration chamber (55, 104, 204, 304, 822, 1008, 1108, 1218, 1318, 1408, 1508, 1608, 2102, 2306, 2320, 2418, 2520, 2624, 2720, 2904, 3008) connected with the inlet port via a junction, the sequestration chamber having a vent (1510, 1610, 2628, 3010) that includes an air permeable blood barrier (20, 106, 824, 1010, 1110, 1310, 1412, 1512, 1612, 2202, 2420, 2506, 2706, 2803, 3012), the vent being defined by an outer wall (2504, 2618, 2704) that at least partially circumscribes the air permeable blood barrier and includes one or more air vents (2514), the vent further including a cap (1208, 1307, 2722, 3032), 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 (820, 1406, 1508, 1606, 2104, 2308, 2422, 2622, 3006) 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 (40, 50, 818, 1301, 1414, 1501, 1601, 2101, 2416, 2616, 3001) 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 (2516, 2716, 3016) 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 (2512, 3012) 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 (800, 1200, 1300, 1400, 2000, 2400, 2500, 2600, 2700, 2800, 2900, 3000) 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 in accordance with any of claims 1 to 7 attached on the blood sampling pathway between the proximal end and distal end of the blood sampling pathway, wherein the inlet port is coupled with the blood sampling pathway toward the patient needle;

the outlet port is coupled with the blood sampling pathway toward the sample collection device.

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.

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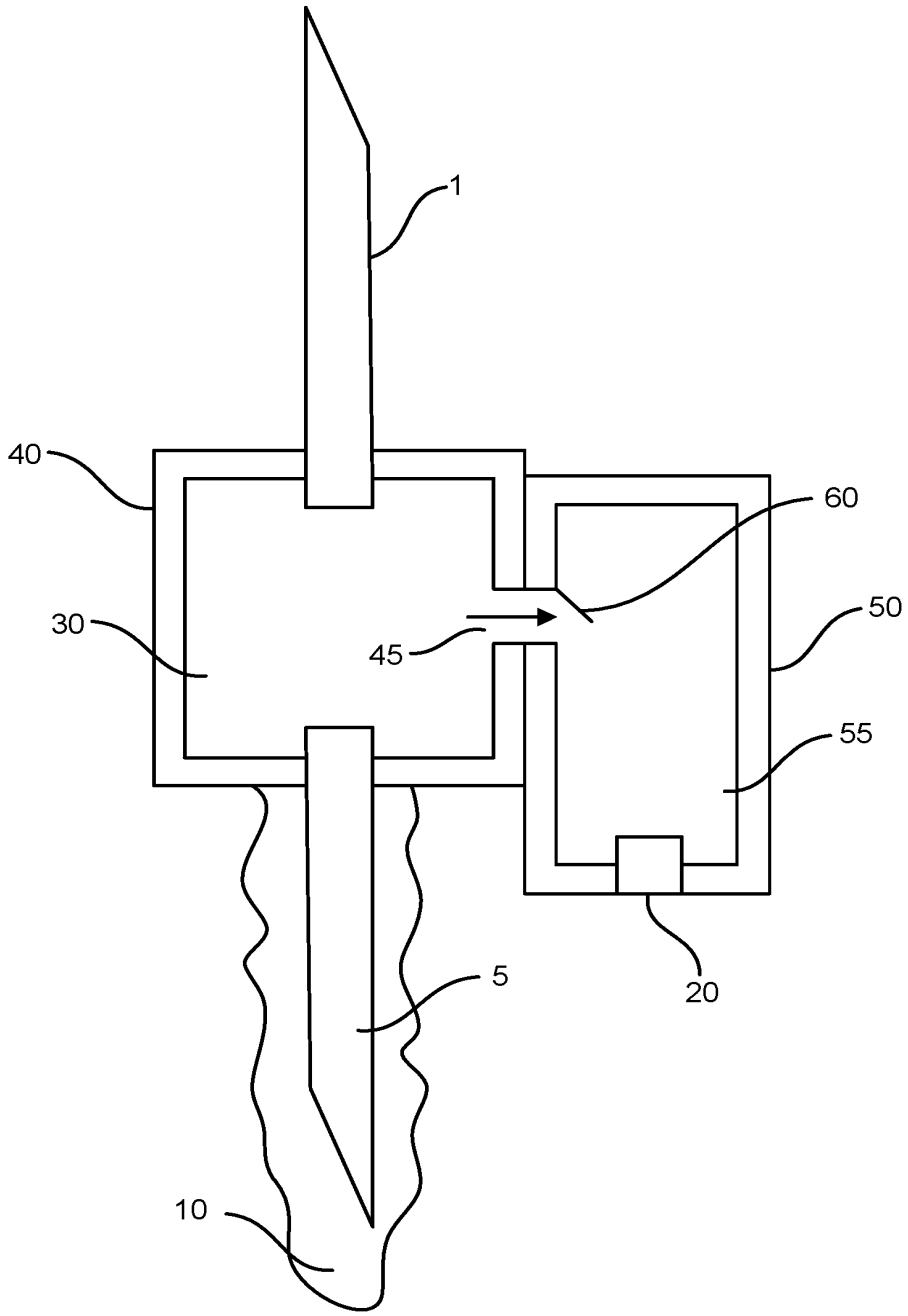


FIG. 1

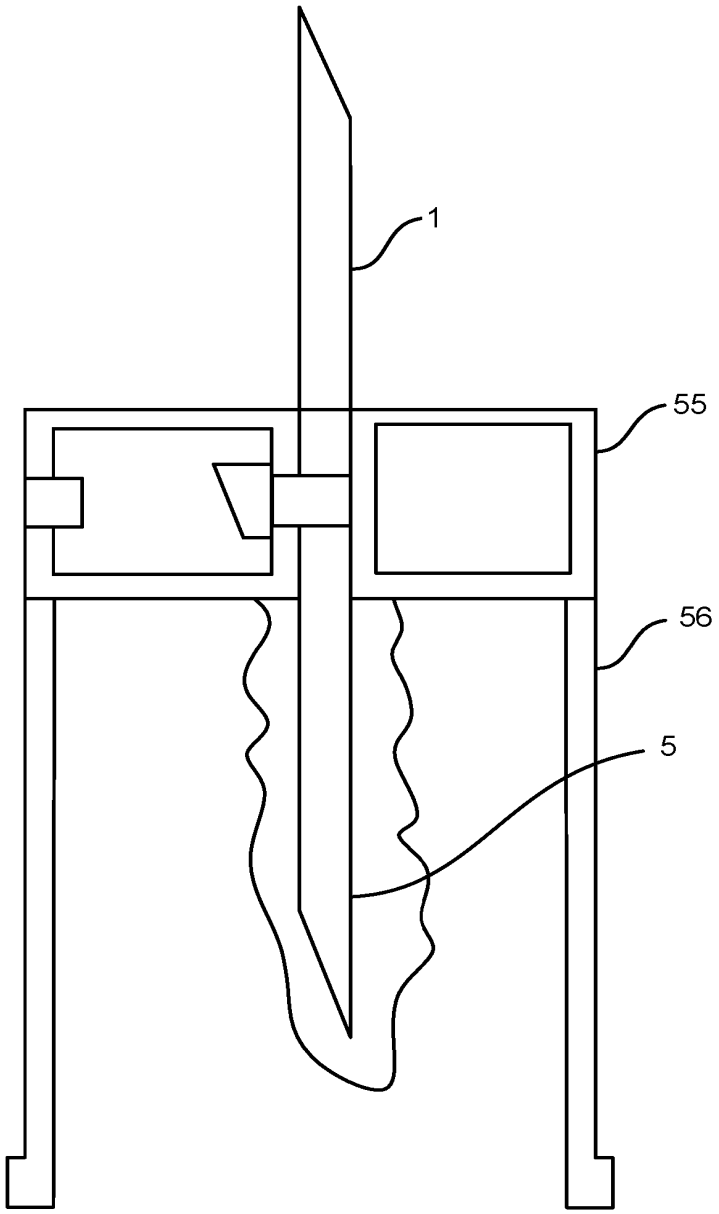


FIG. 2

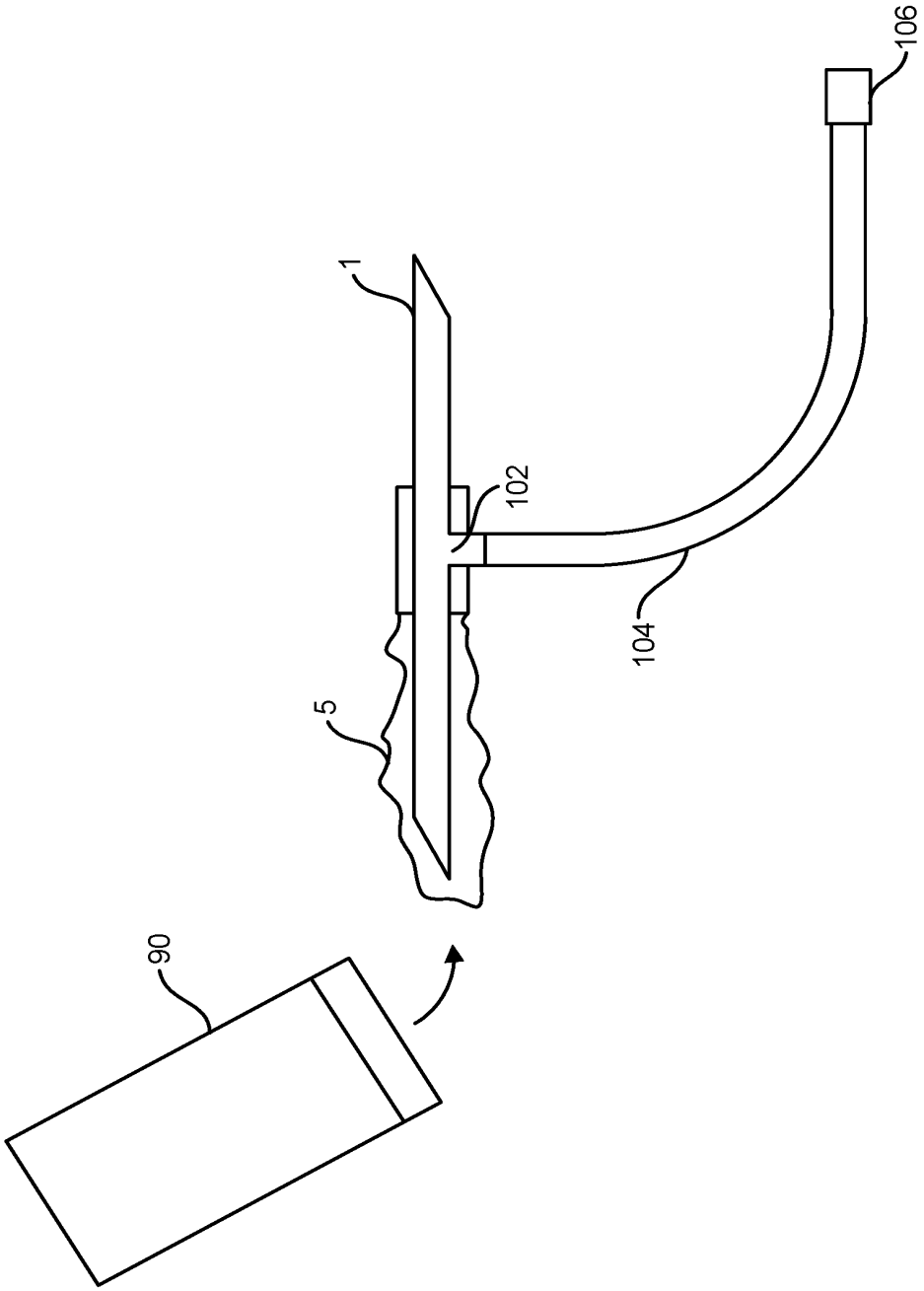


FIG. 3

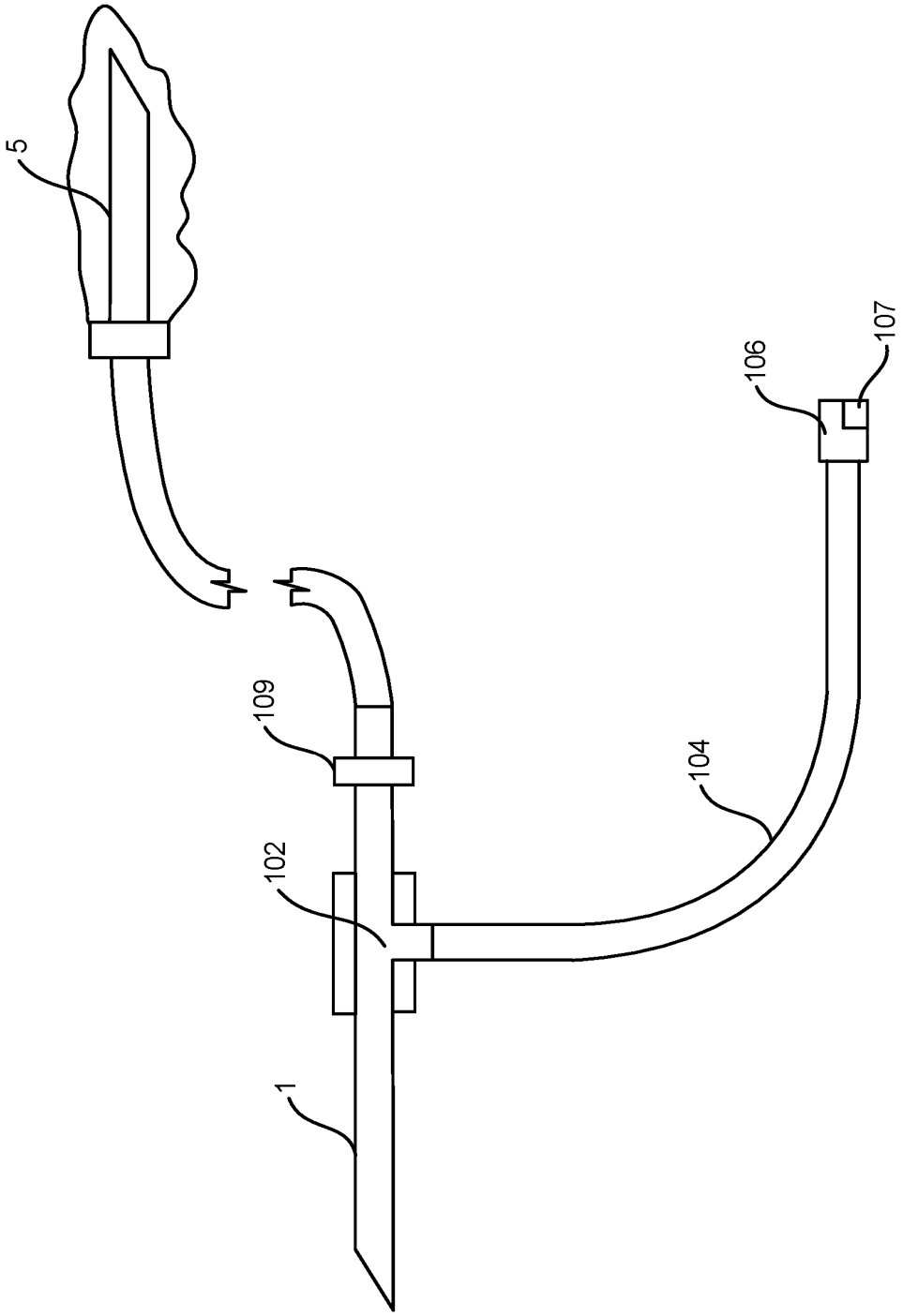


FIG. 4

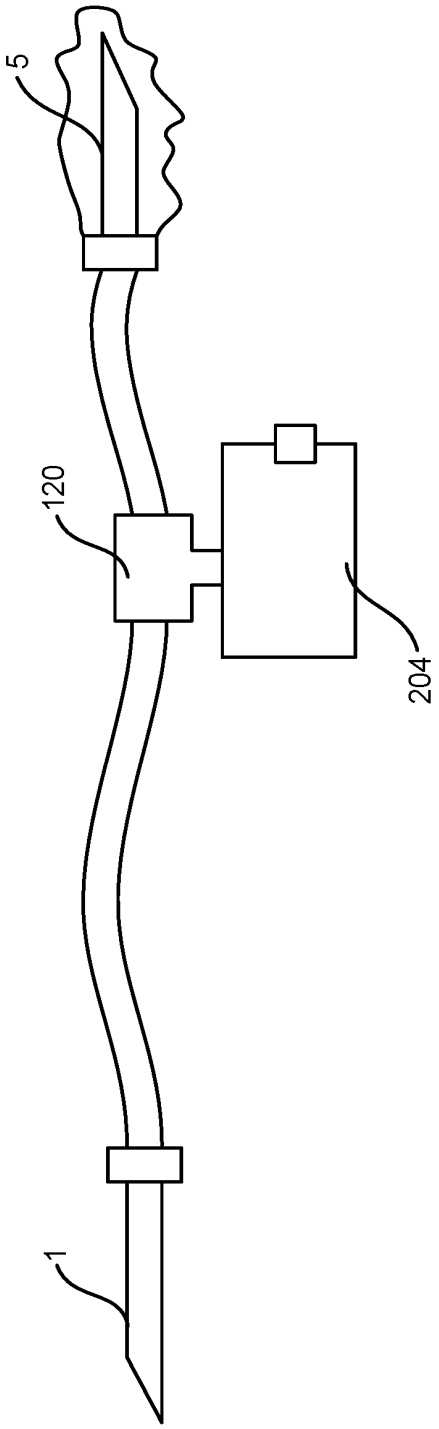


FIG. 5

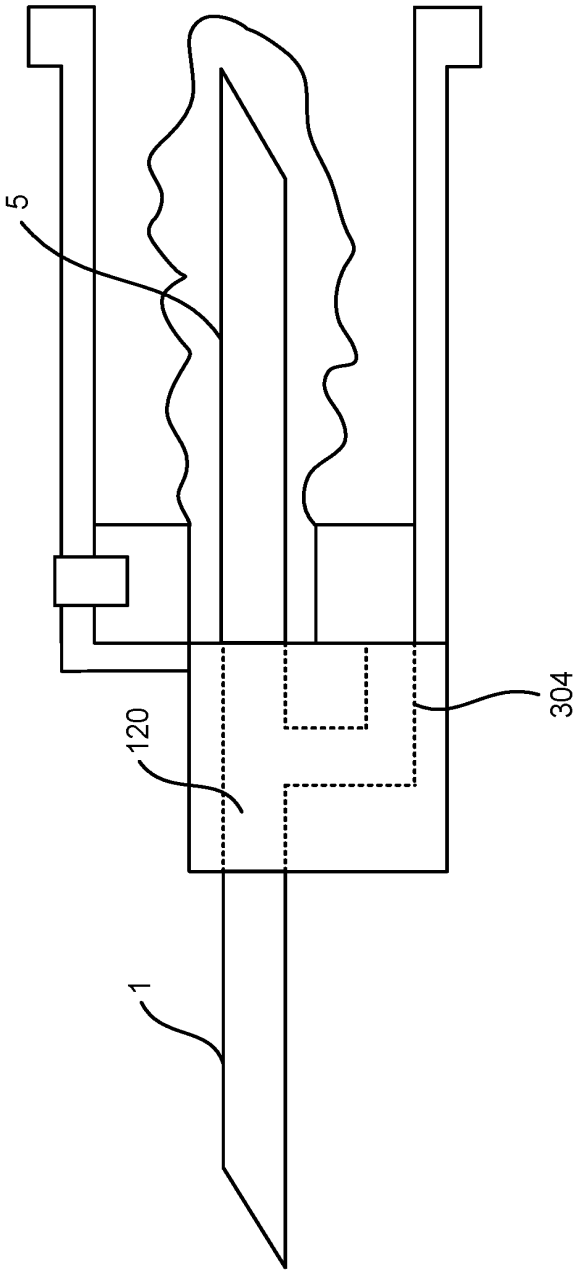


FIG. 6

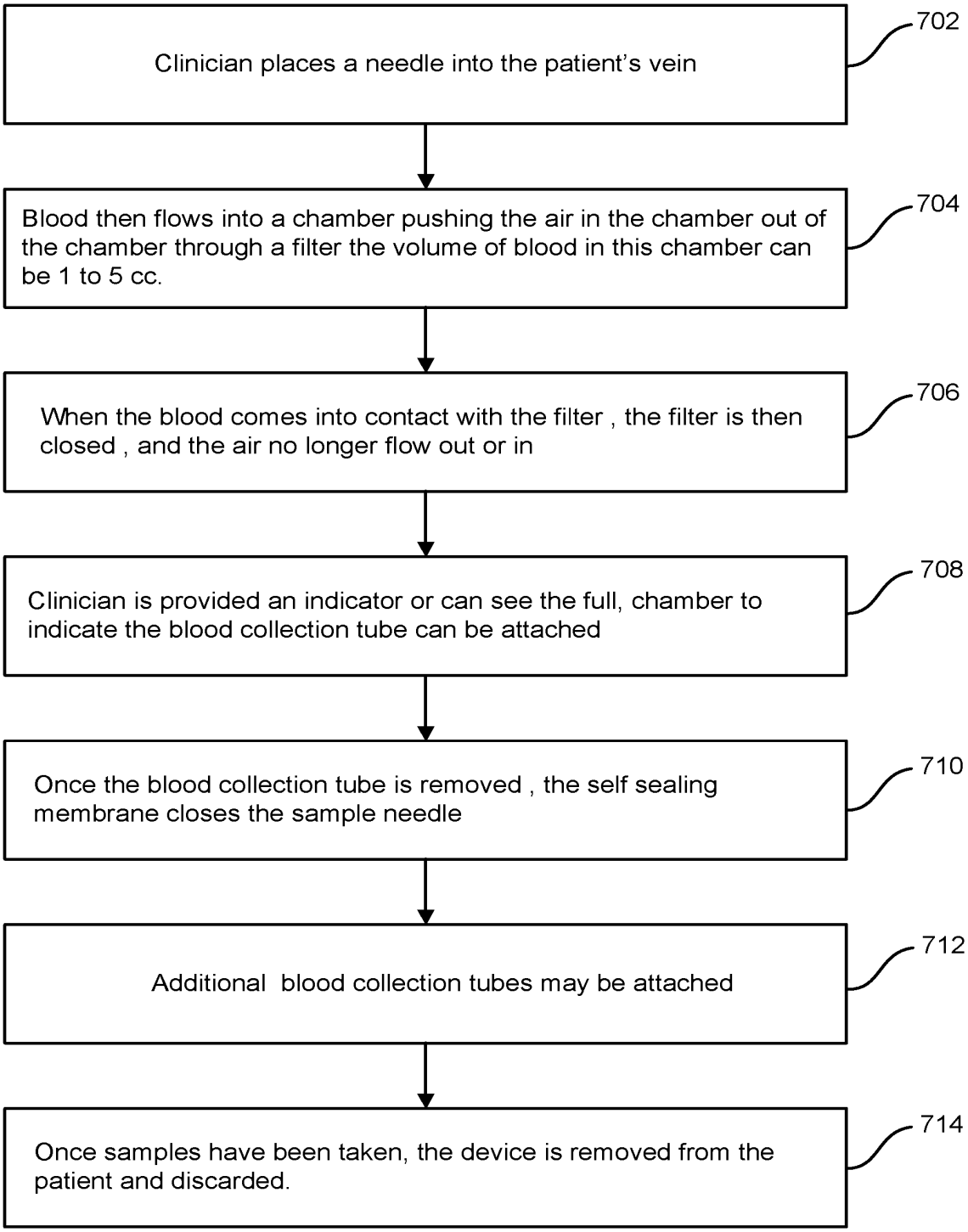
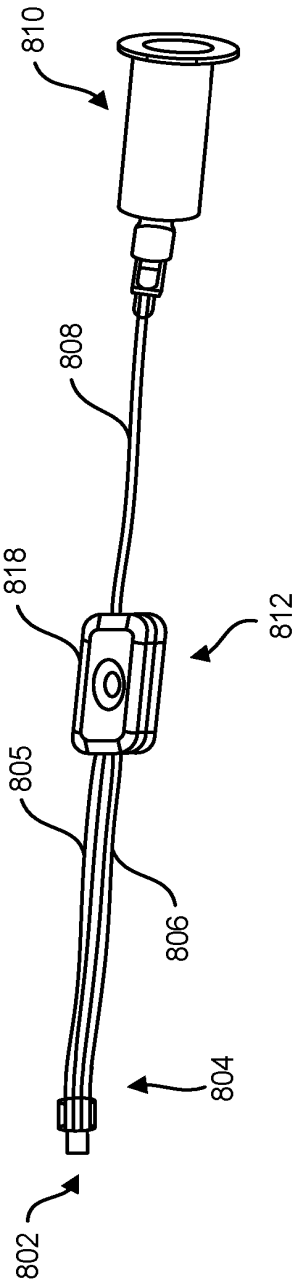

Clinician places a needle into the patient's vein
702
Blood then flows into a chamber pushing the air in the chamber out of the chamber through a filter the volume of blood in this chamber can be 1 to 5 cc.
704
When the blood comes into contact with the filter , the filter is then closed , and the air 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



800

FIG. 8A

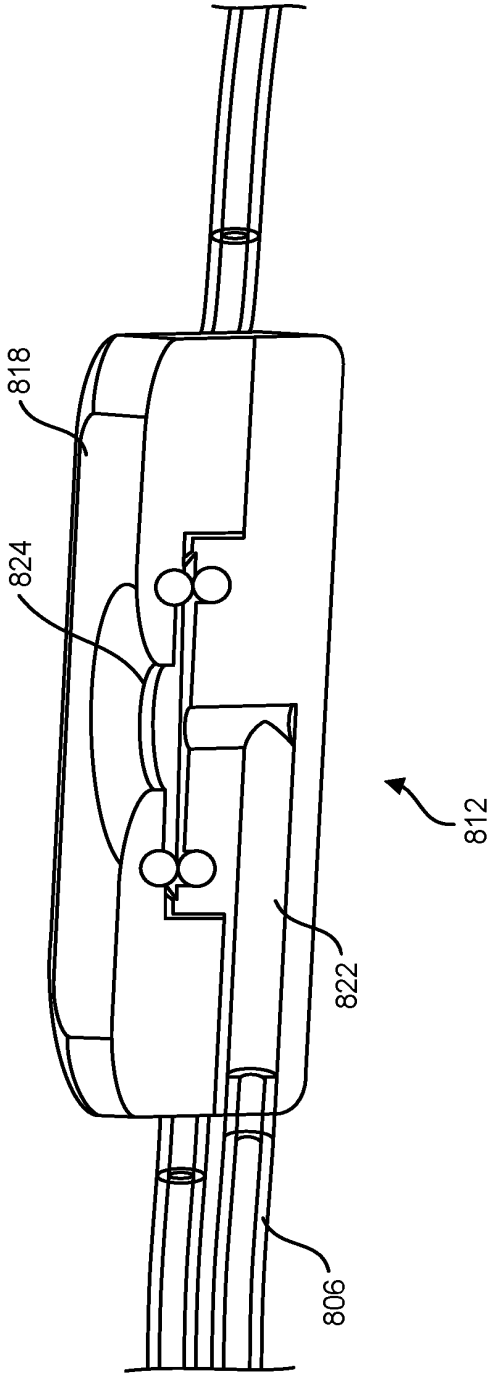


FIG. 8B

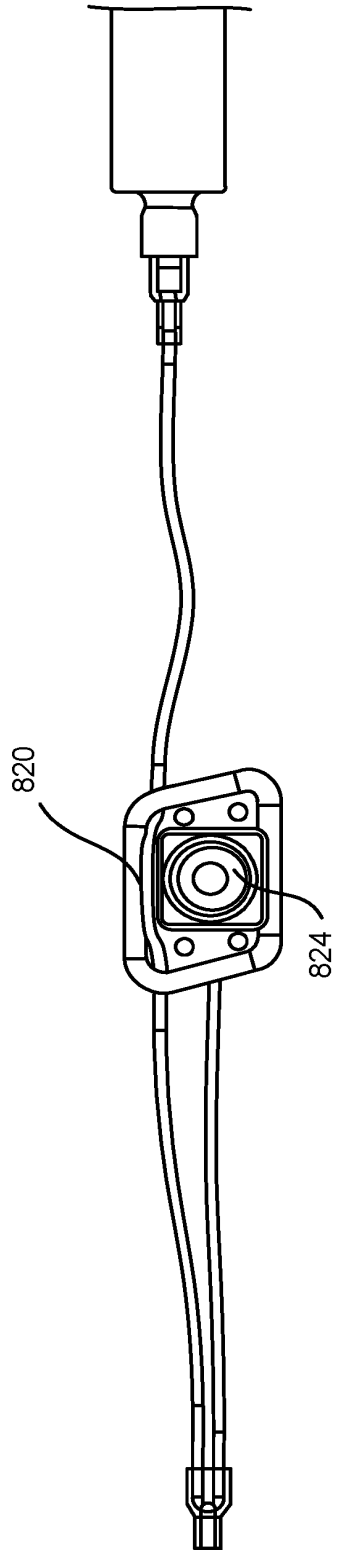


FIG. 8C

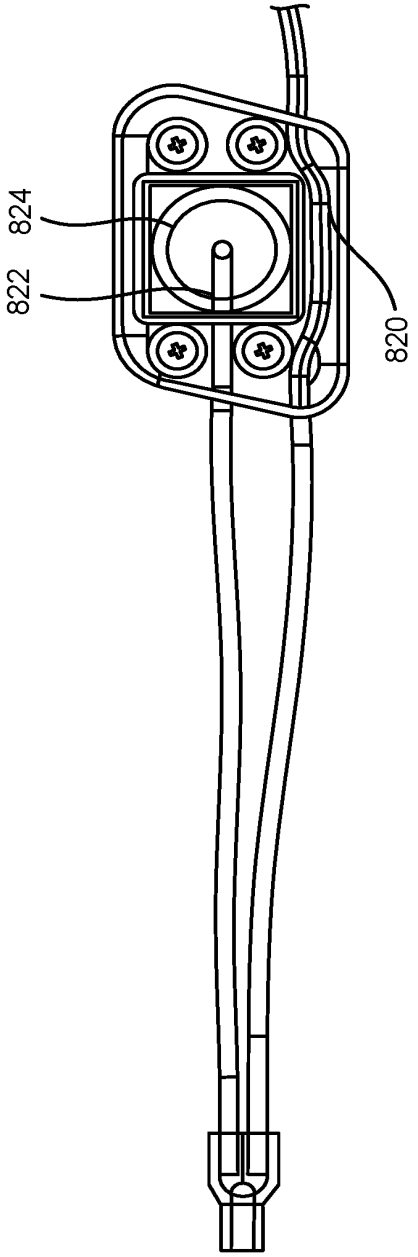


FIG. 8D

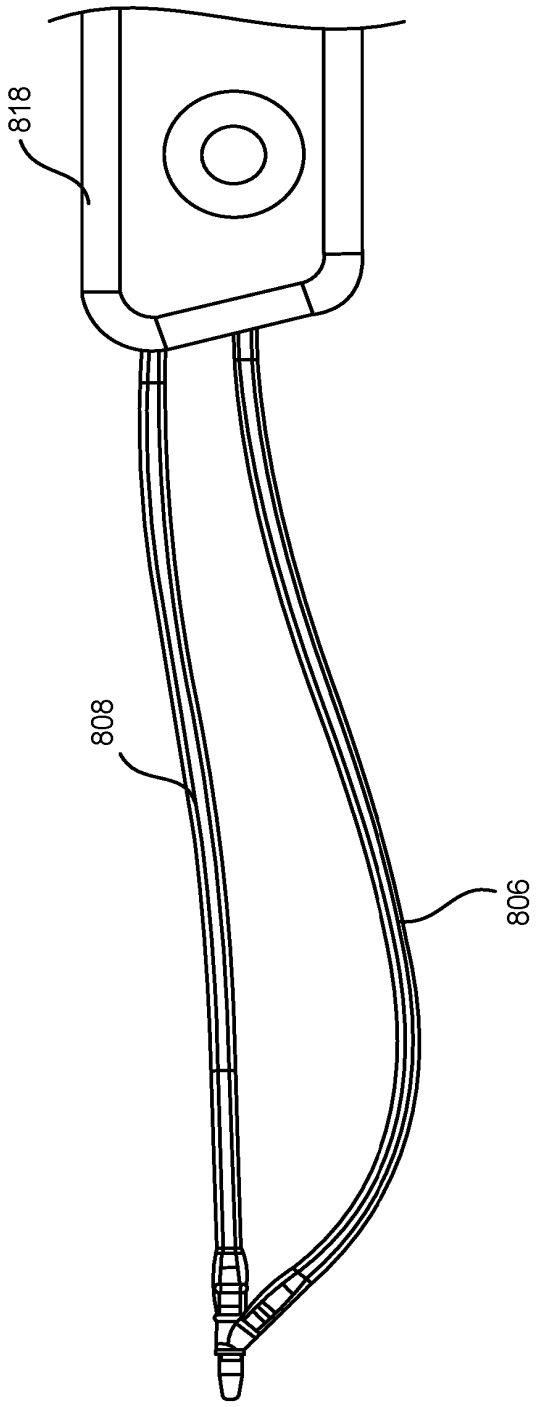


FIG. 8E

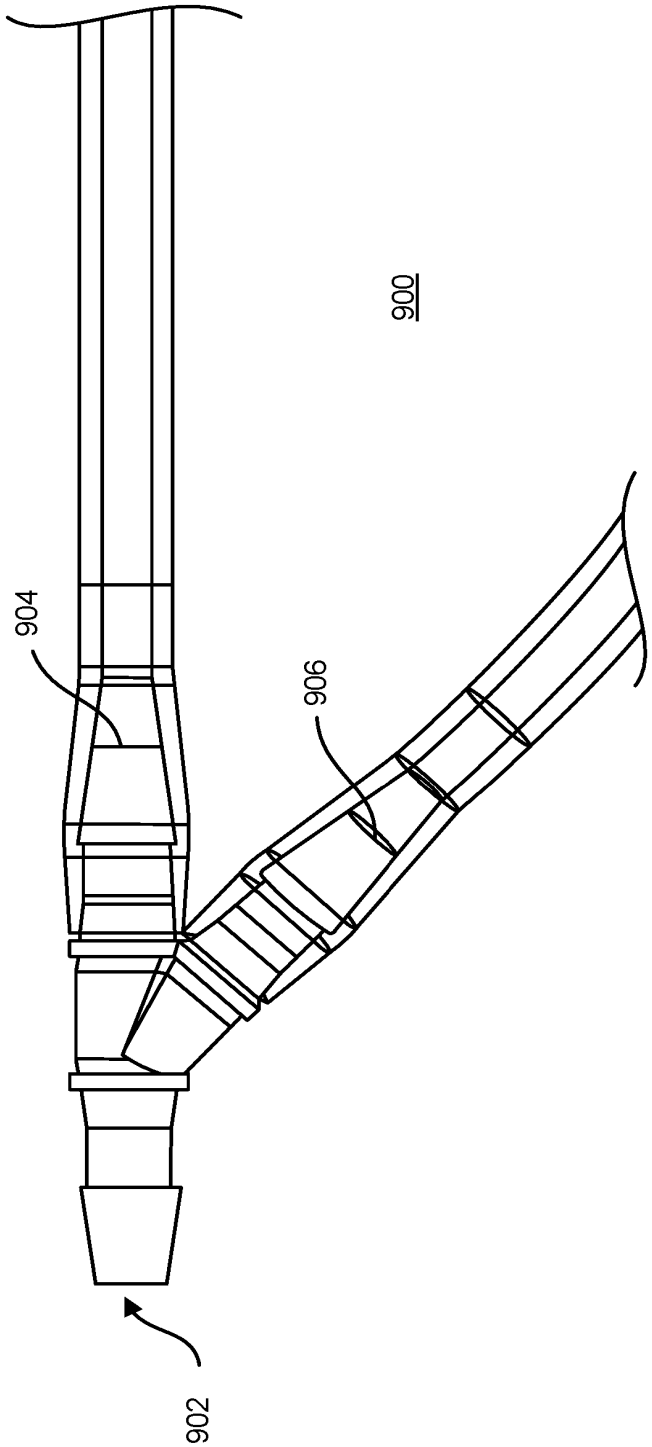


FIG. 9

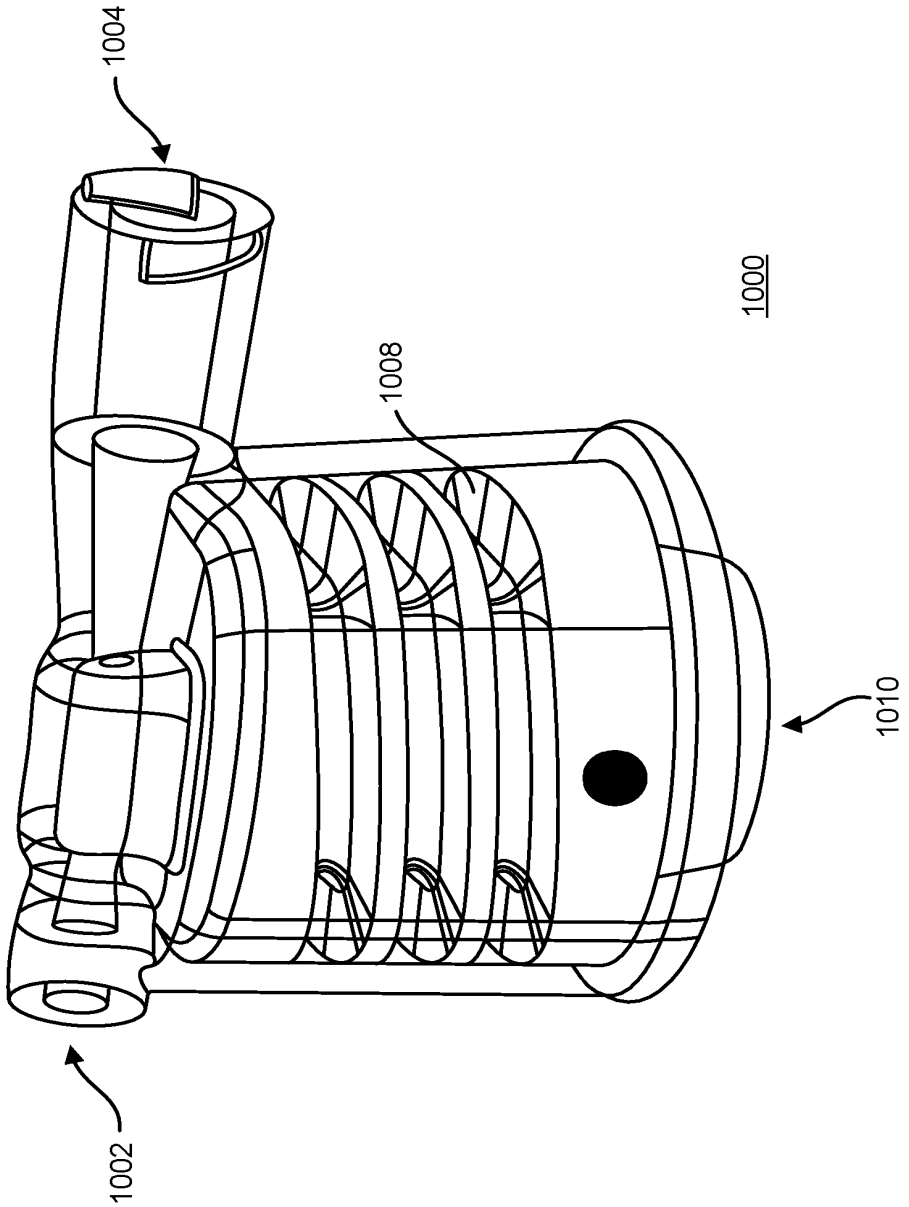


FIG. 10A

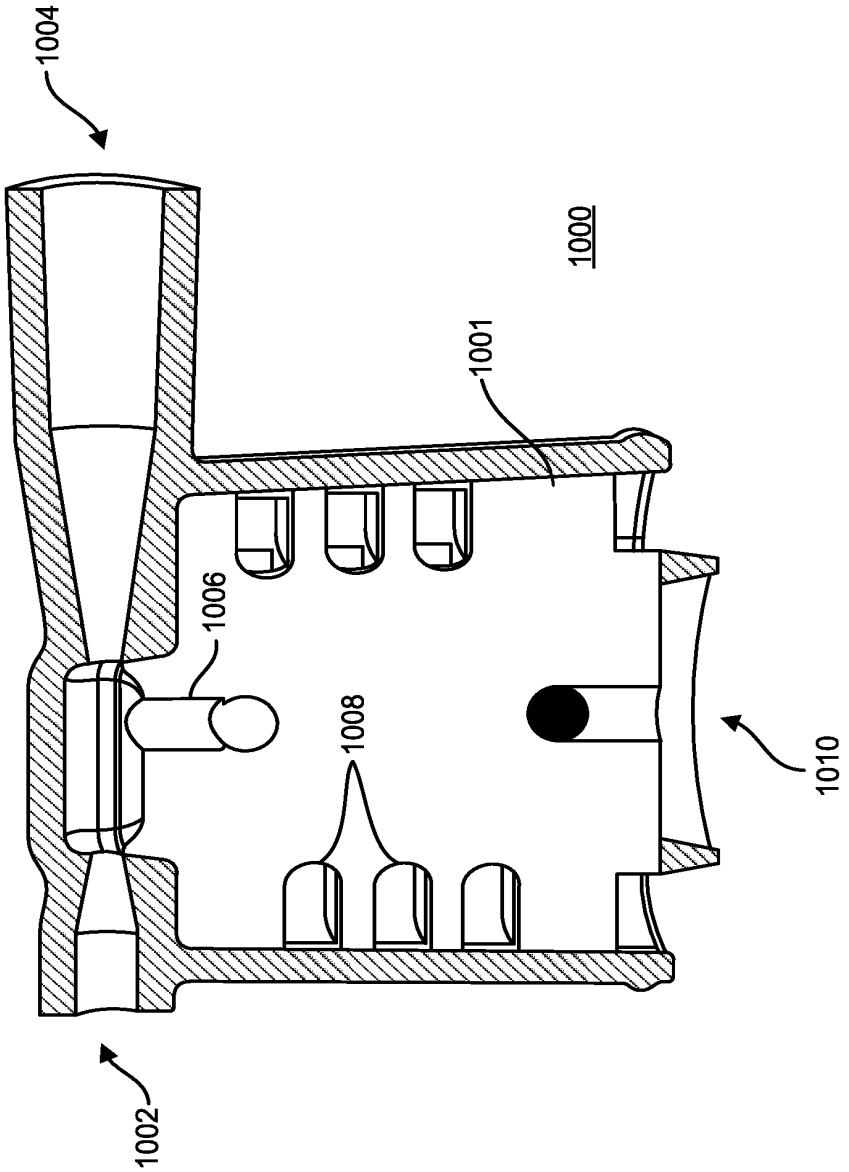


FIG. 10B

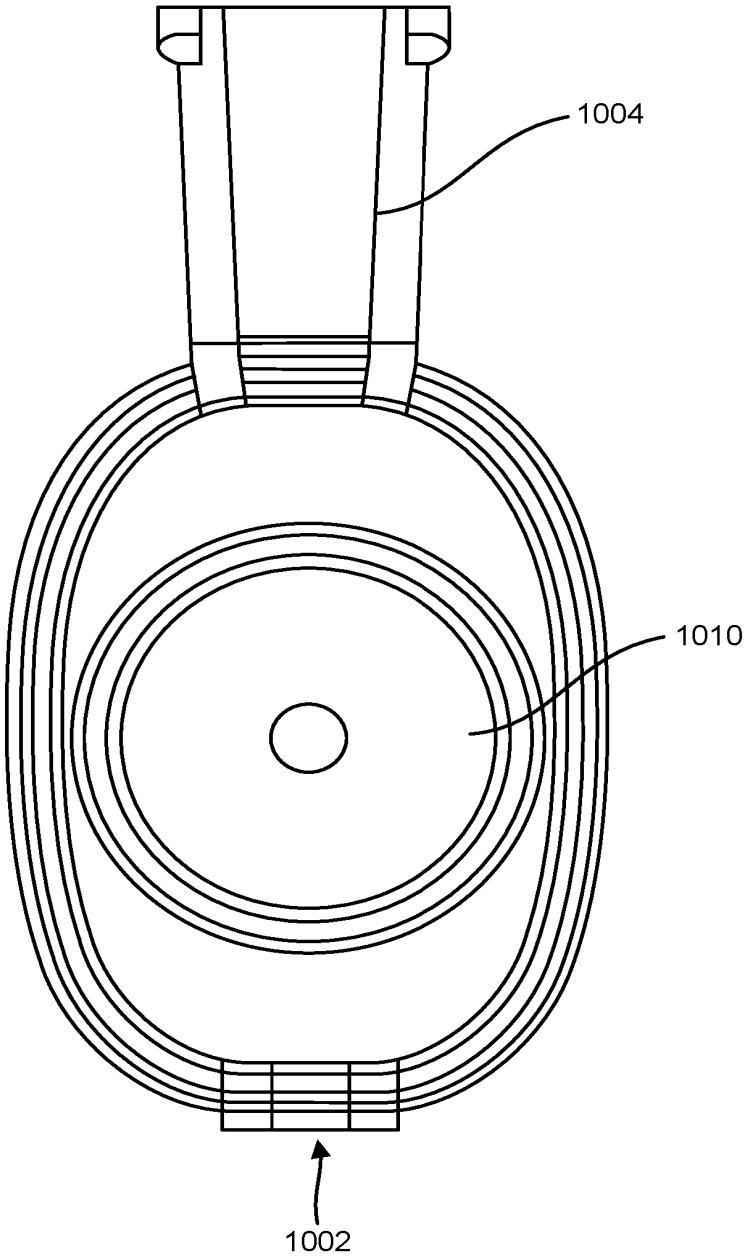


FIG. 10C

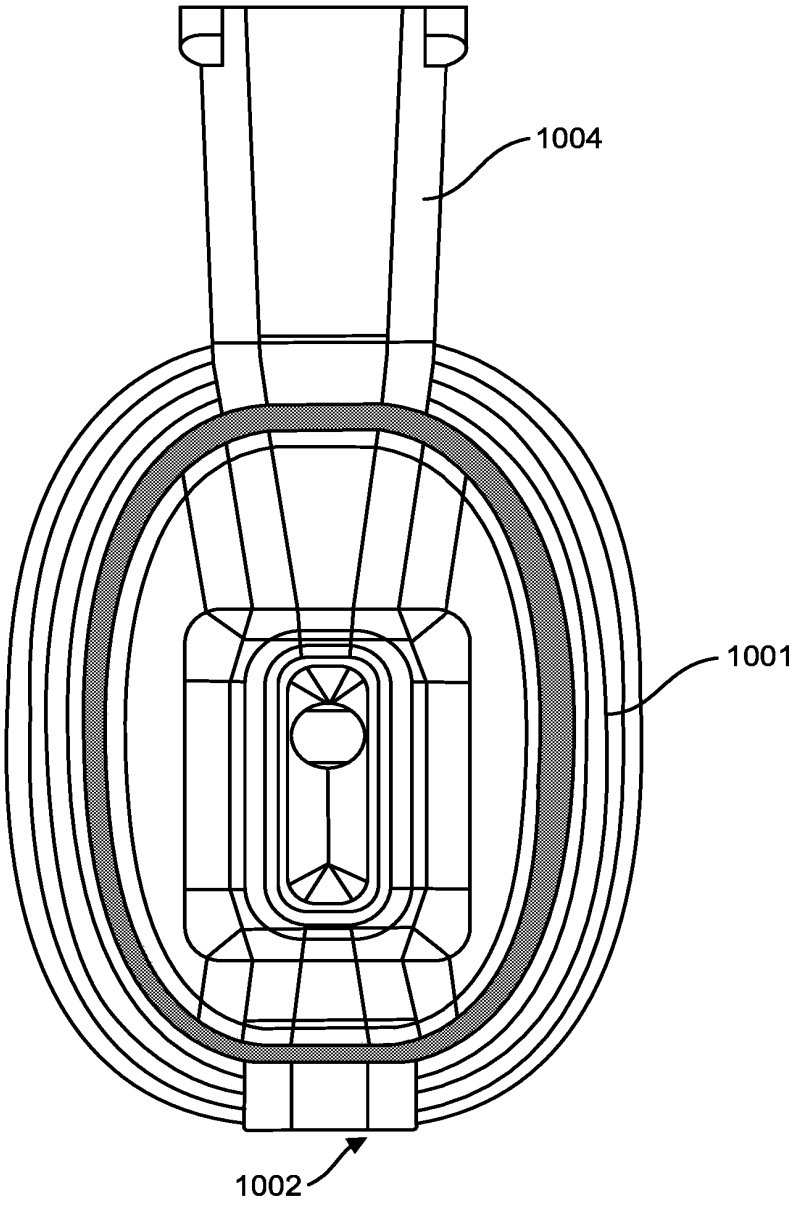


FIG. 10D

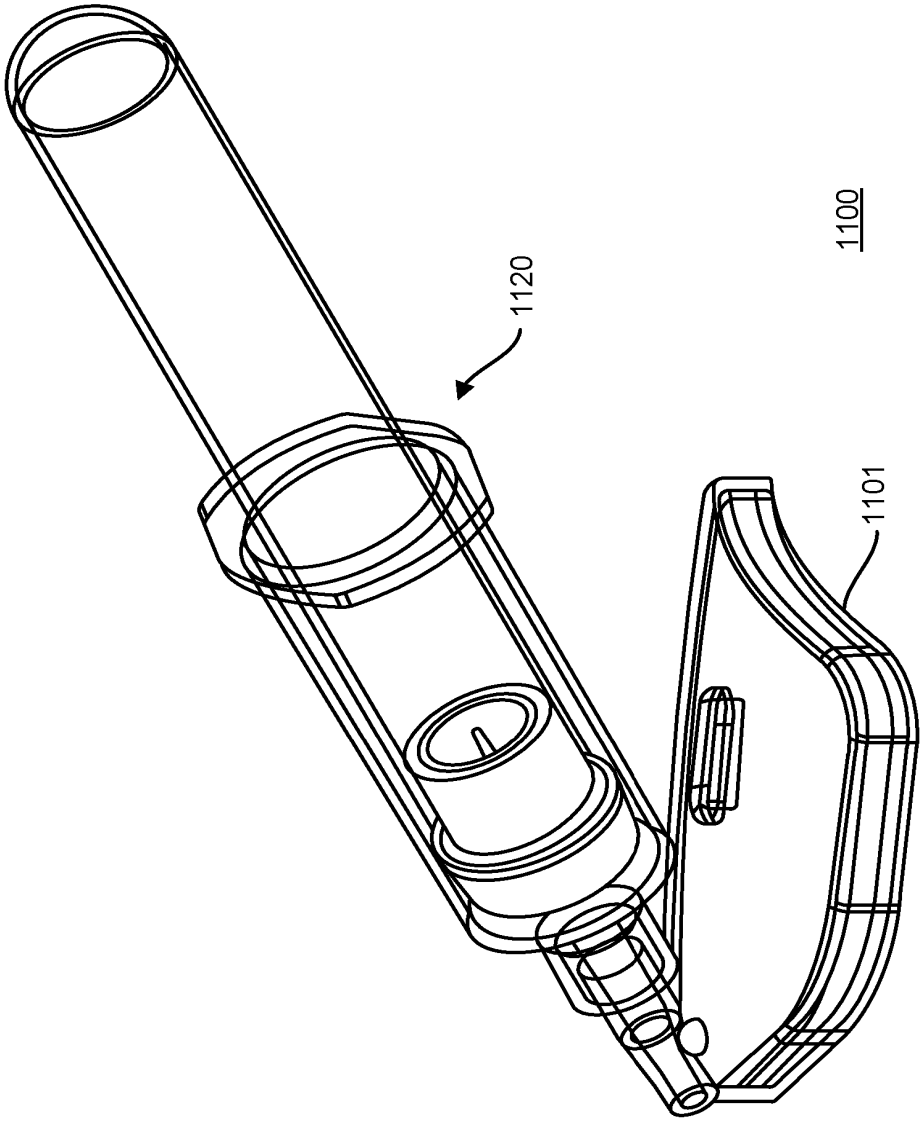


FIG. 11A

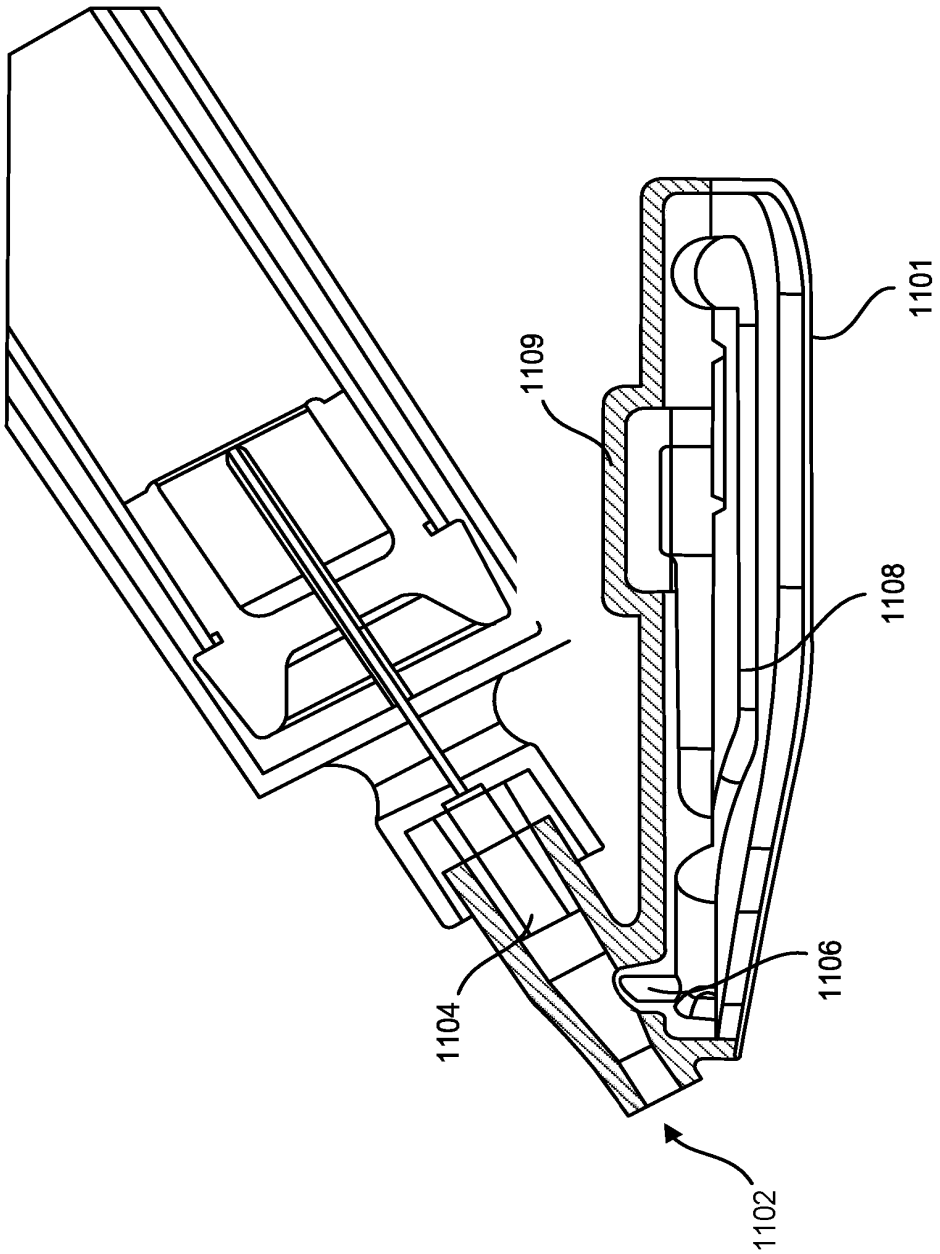


FIG. 11B

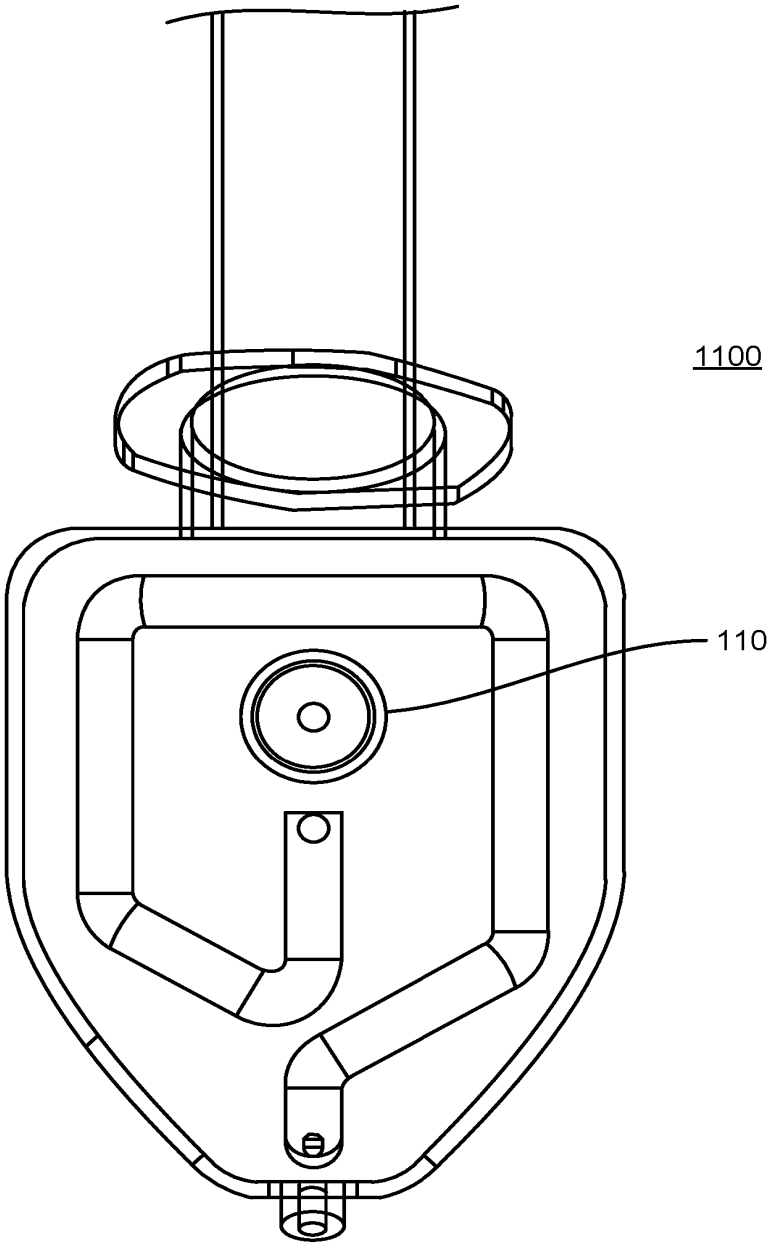


FIG. 11C

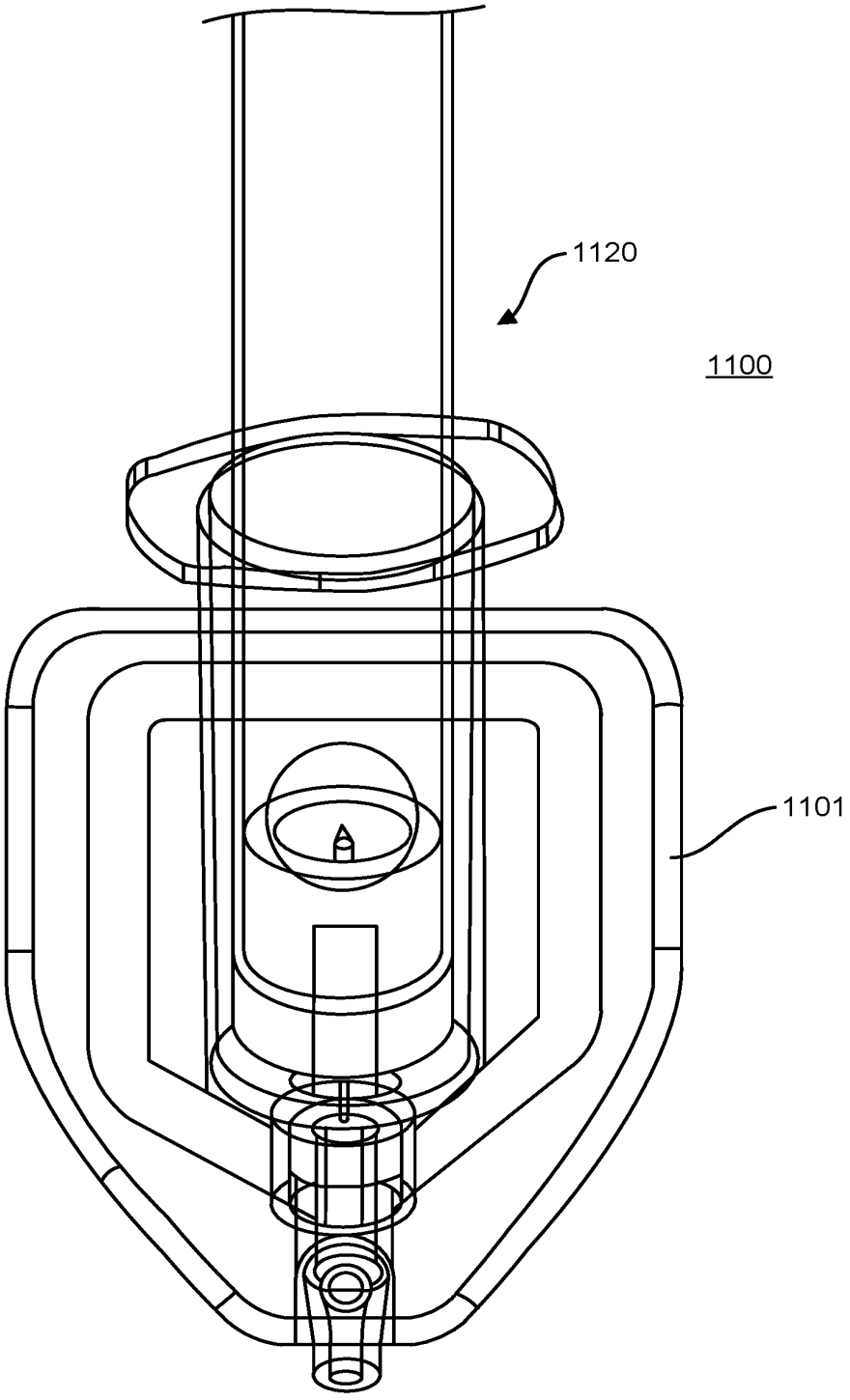


FIG. 11D

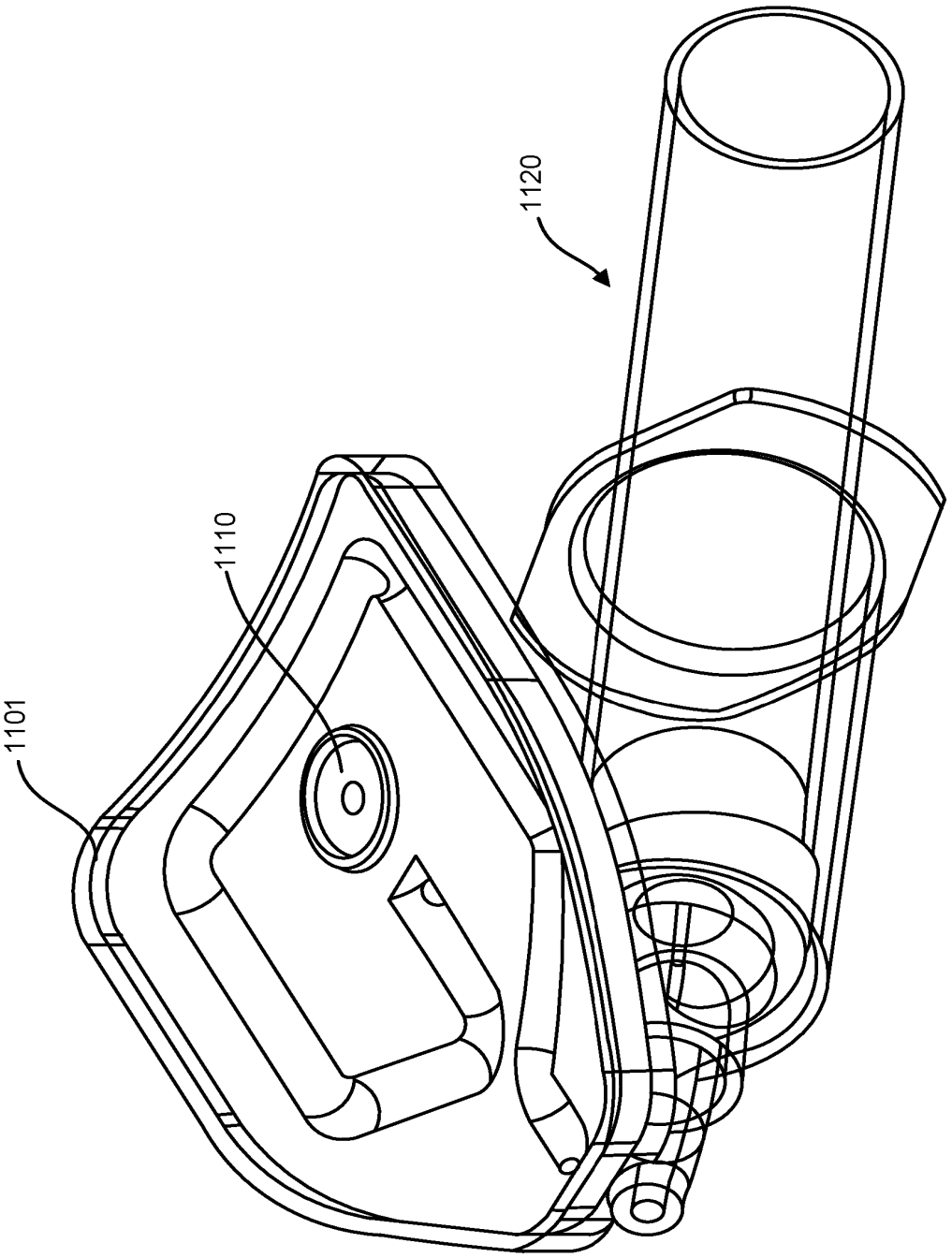


FIG. 11E

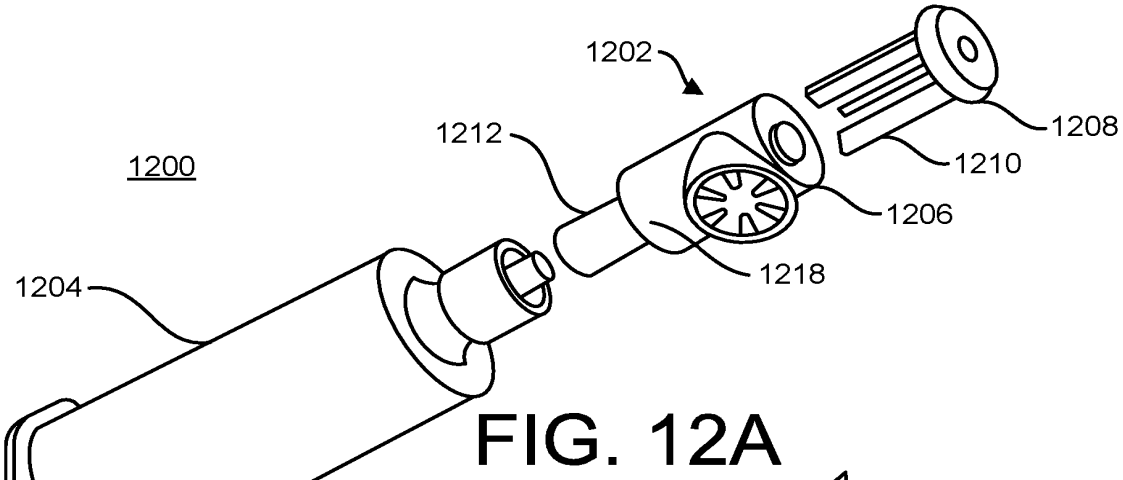


FIG. 12A

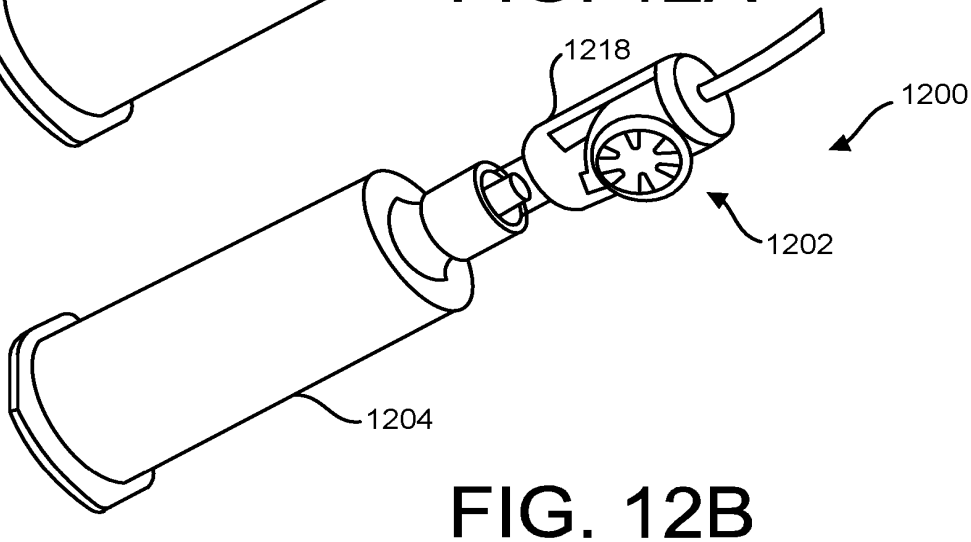


FIG. 12B

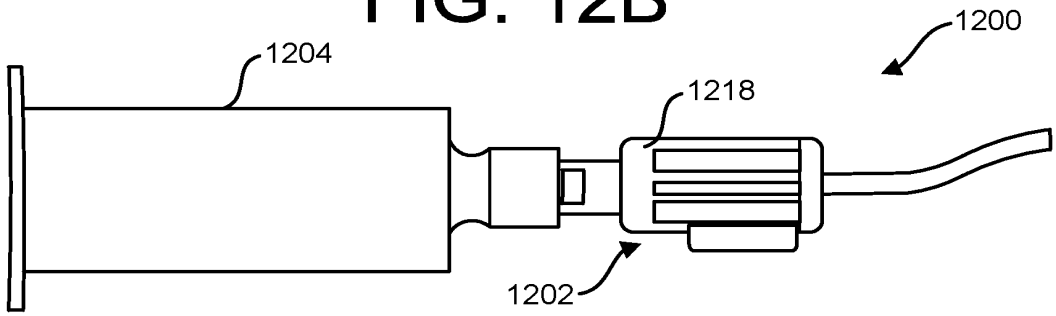


FIG. 12C

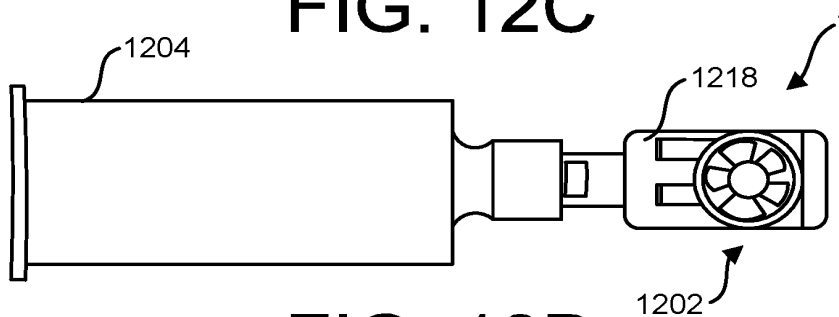


FIG. 12D

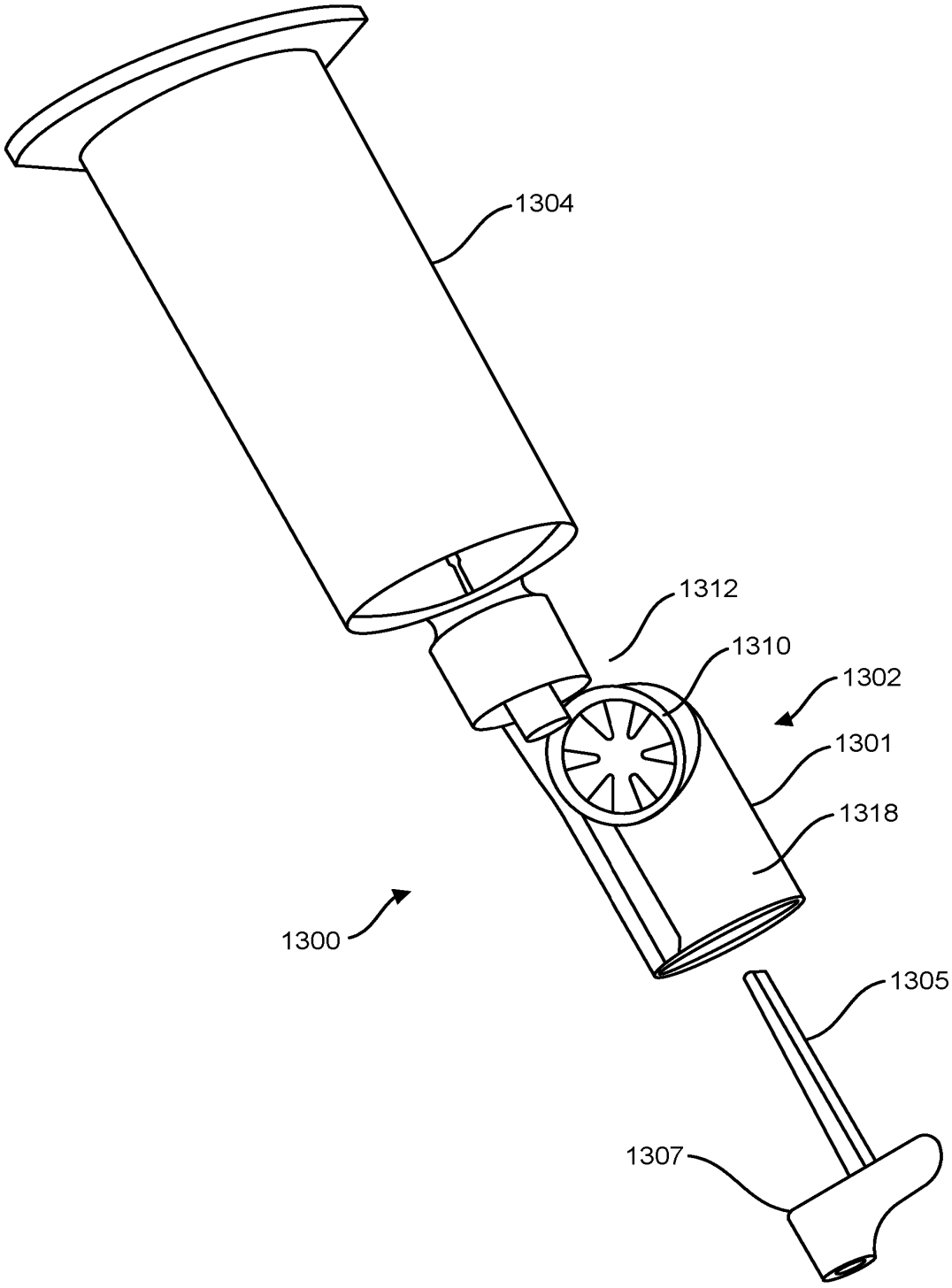


FIG. 13A

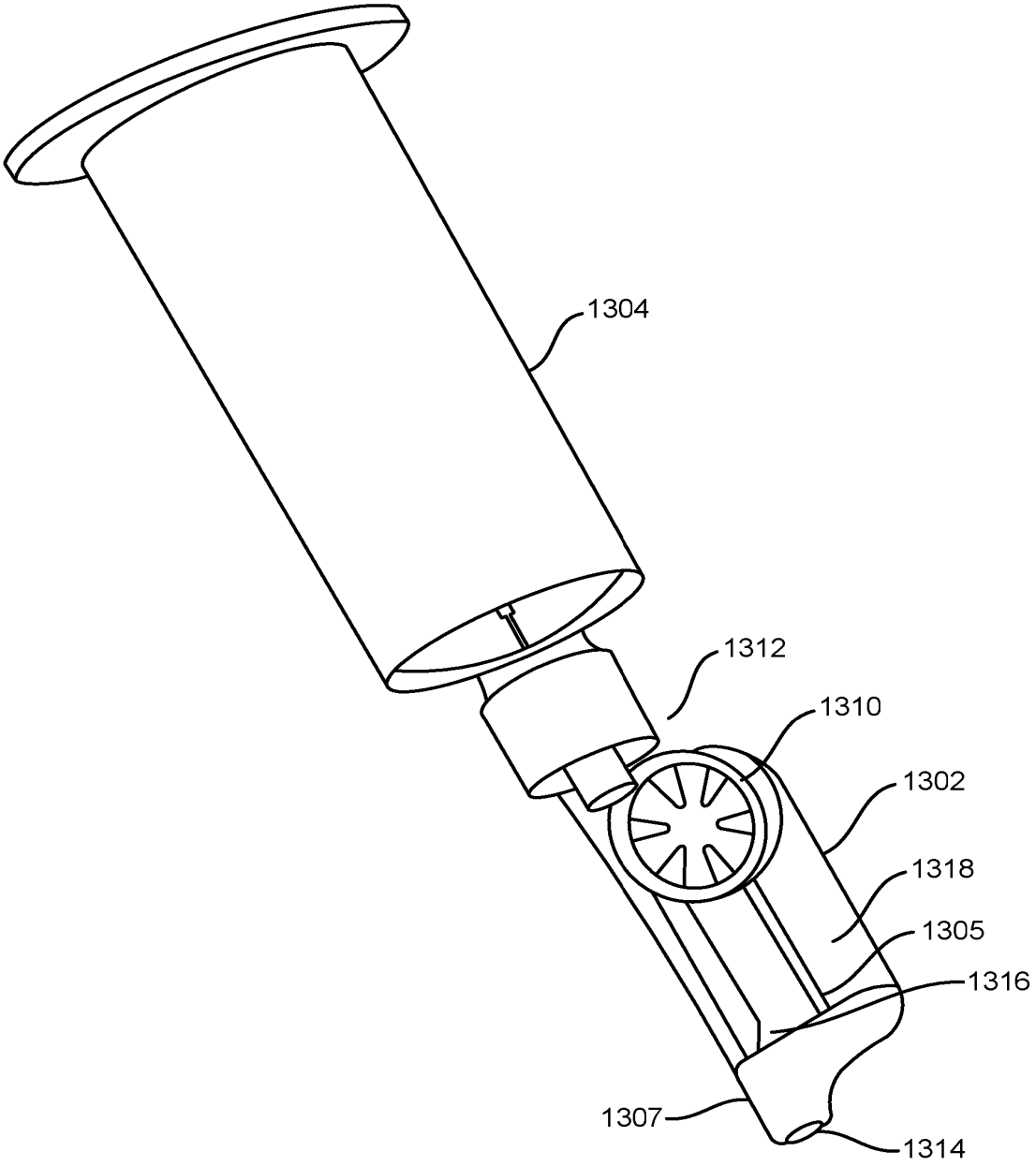


FIG. 13B

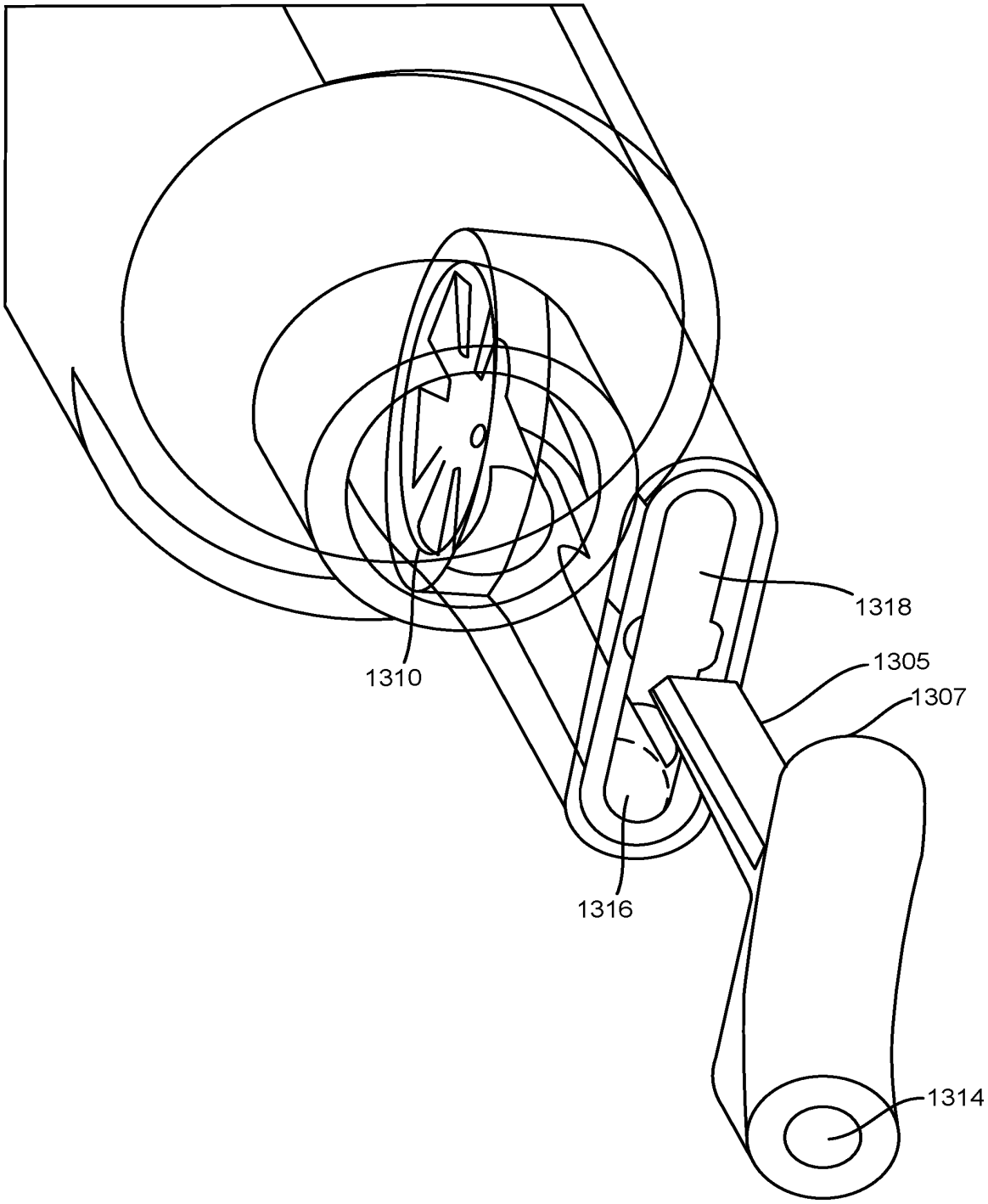


FIG. 13C

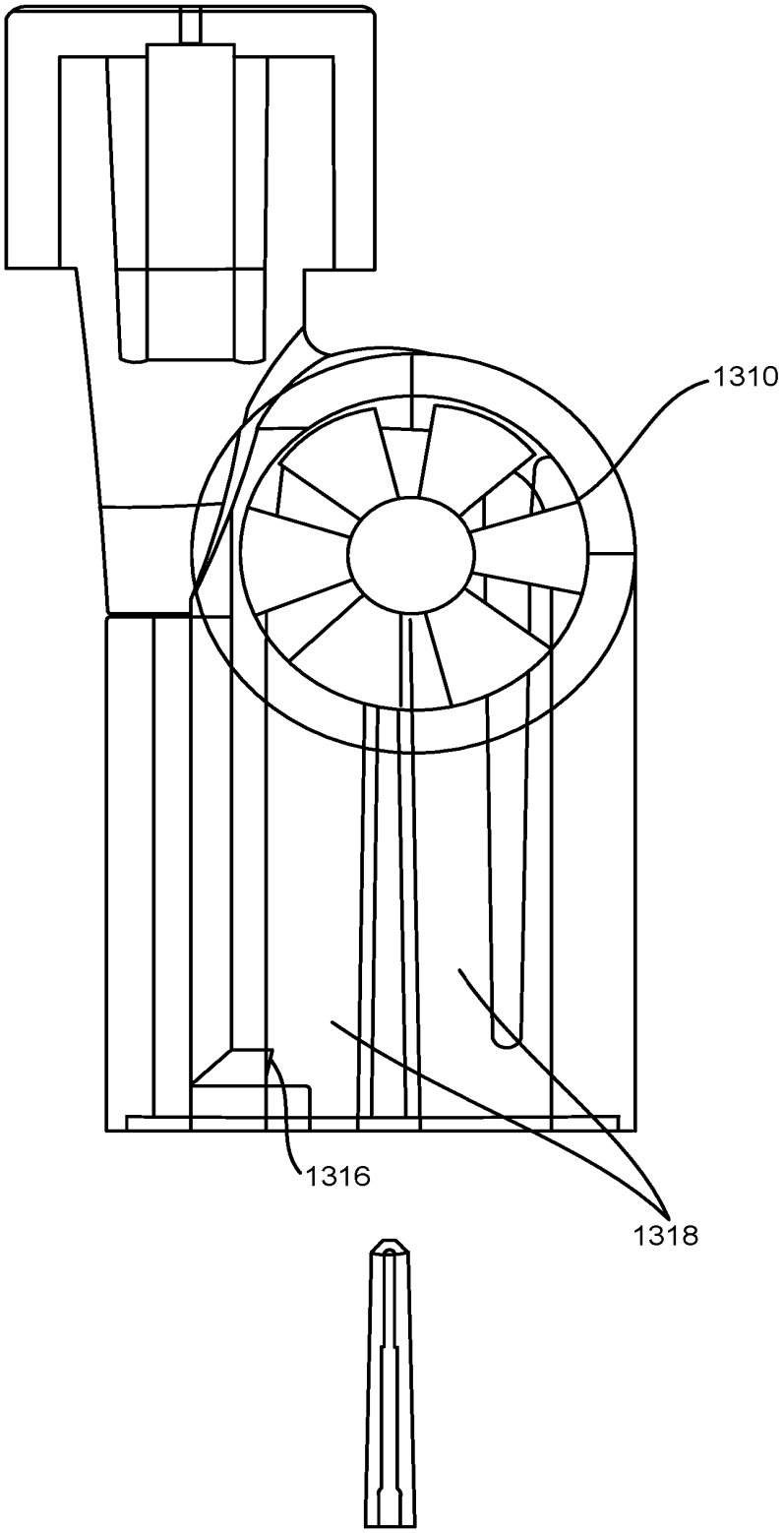


FIG. 13D

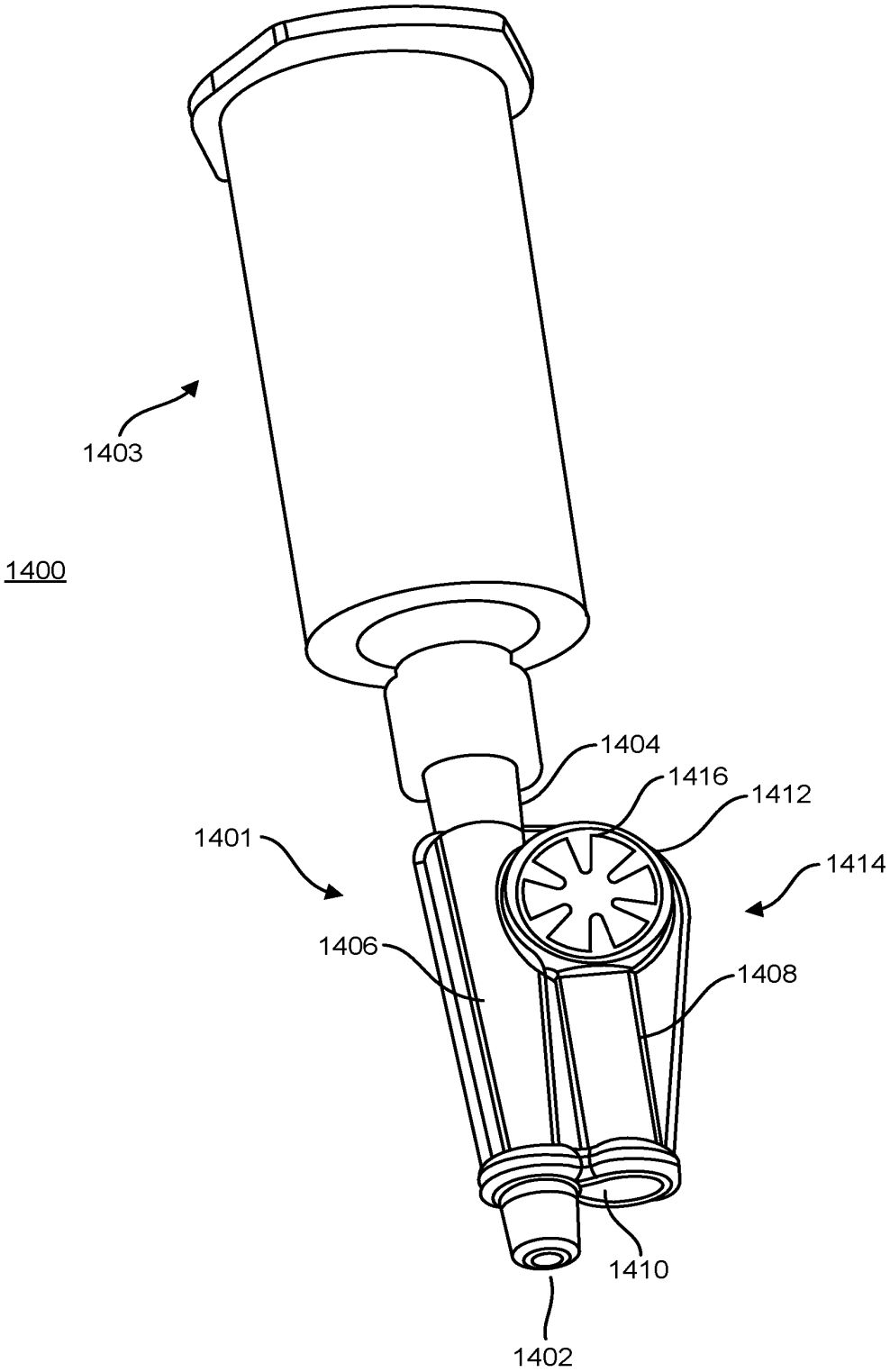


FIG. 14A

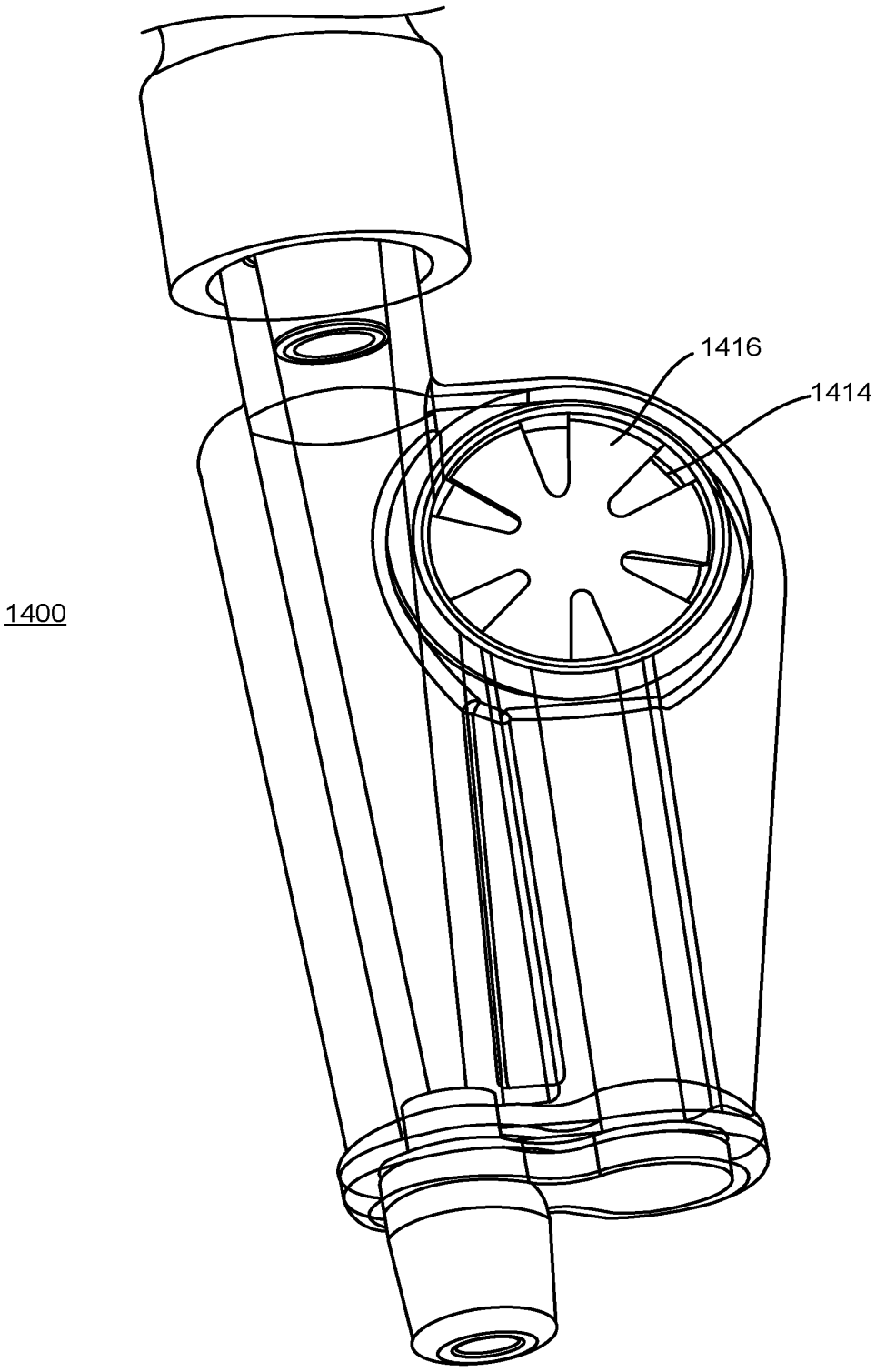


FIG. 14B

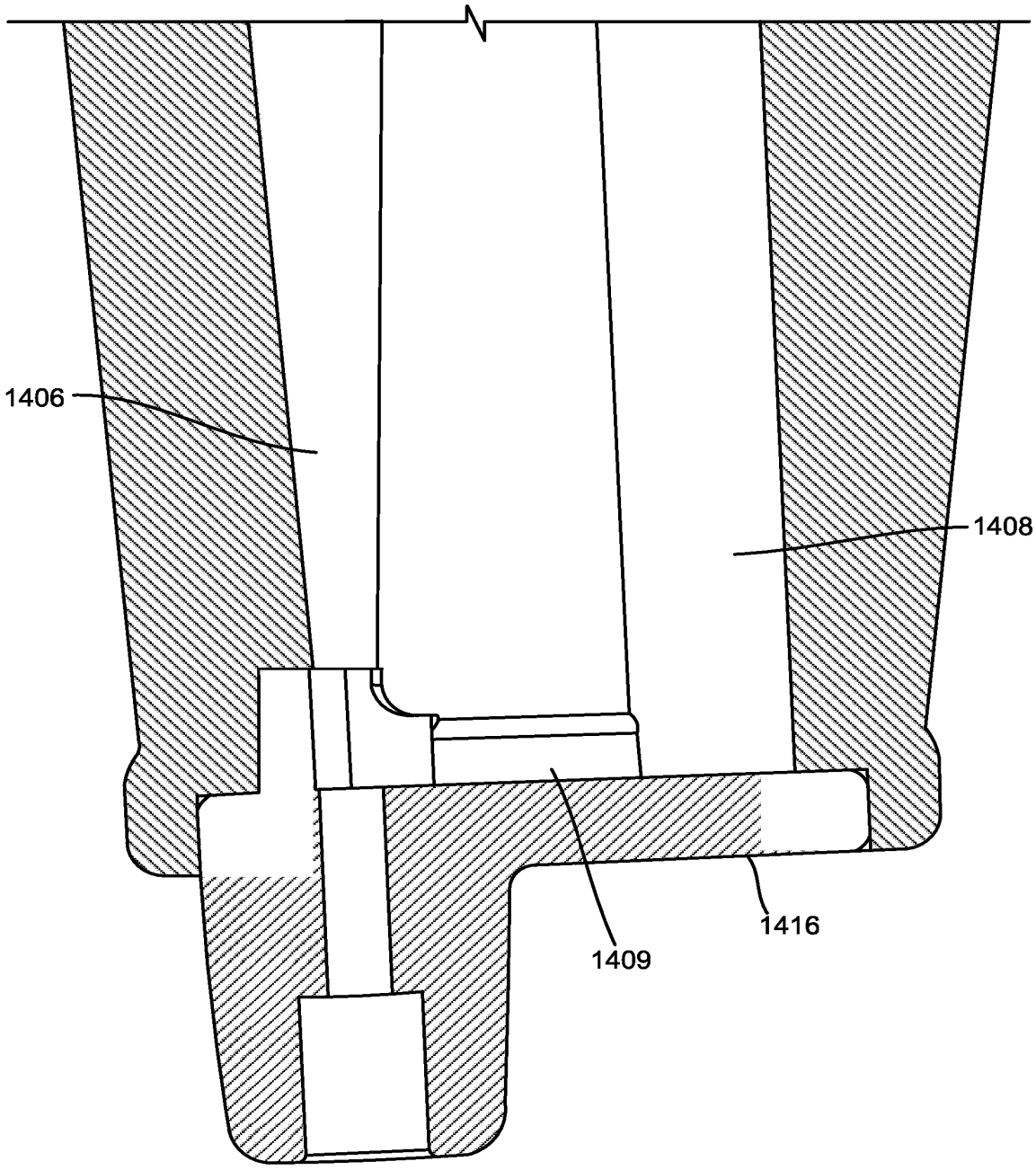


FIG. 14C

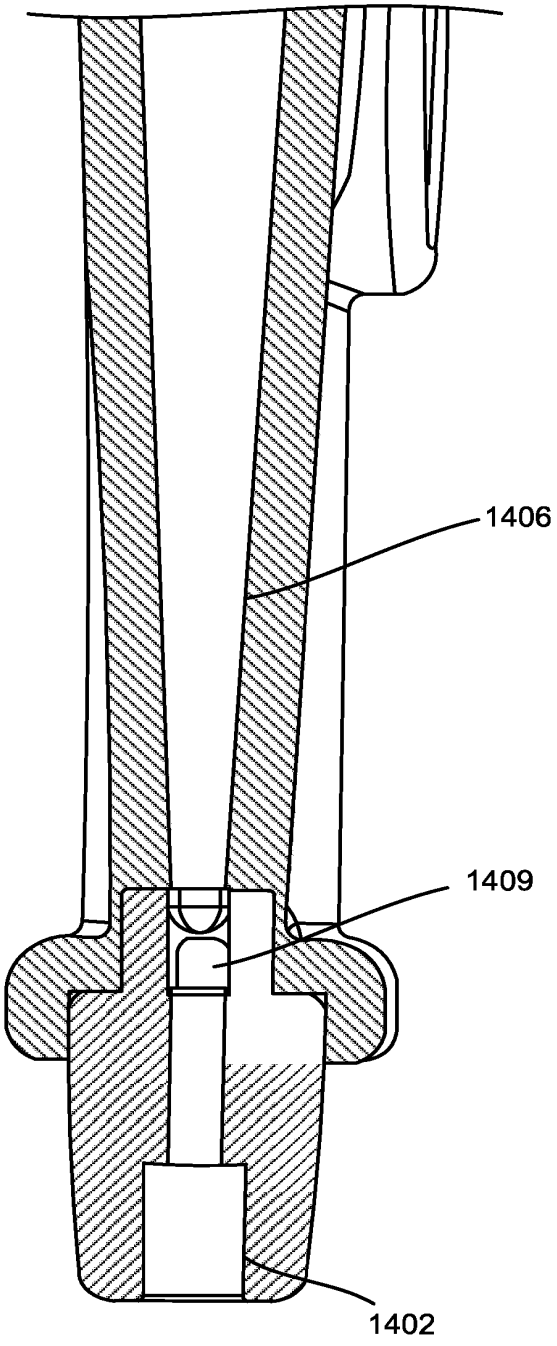


FIG. 14D

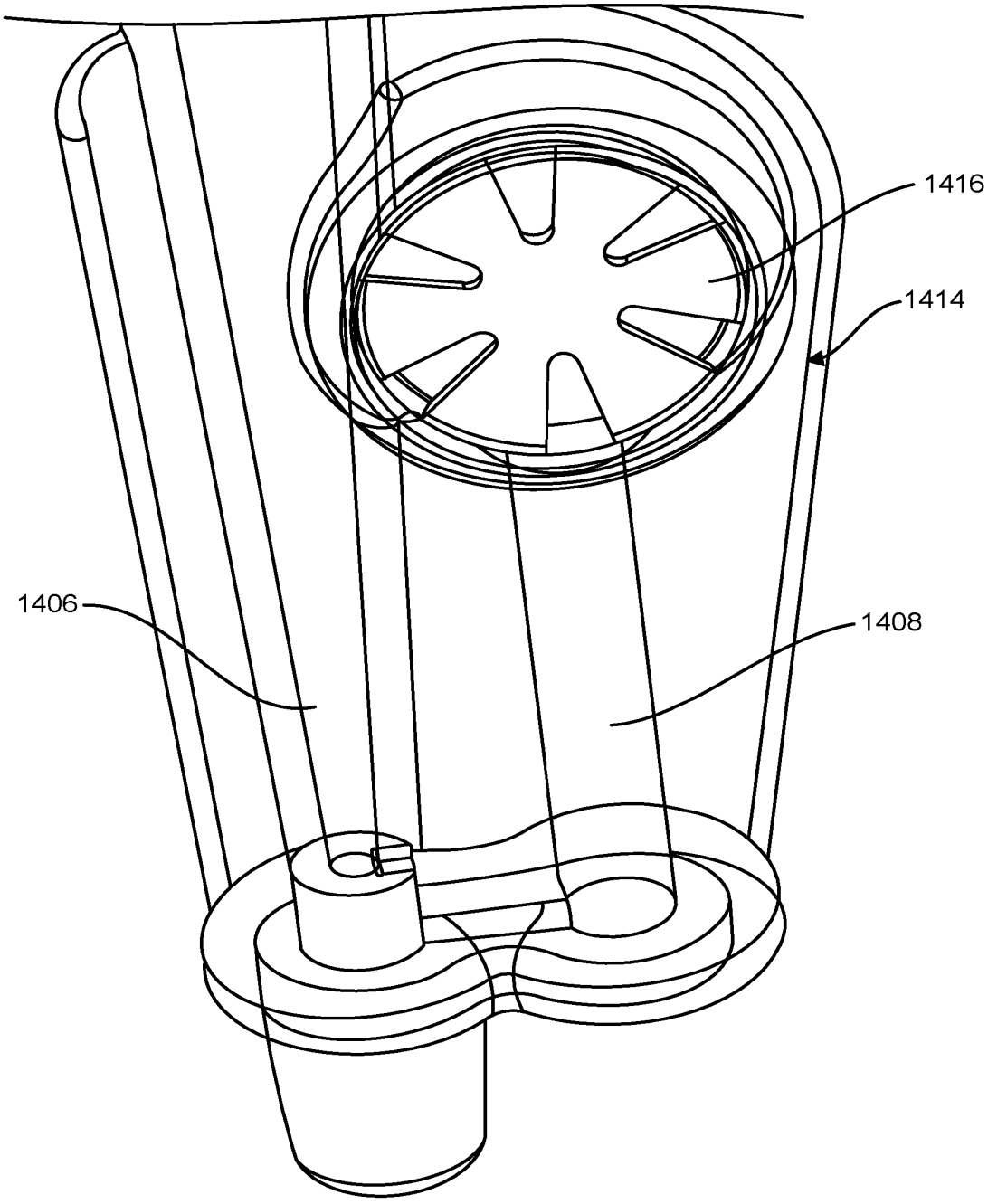


FIG. 14E

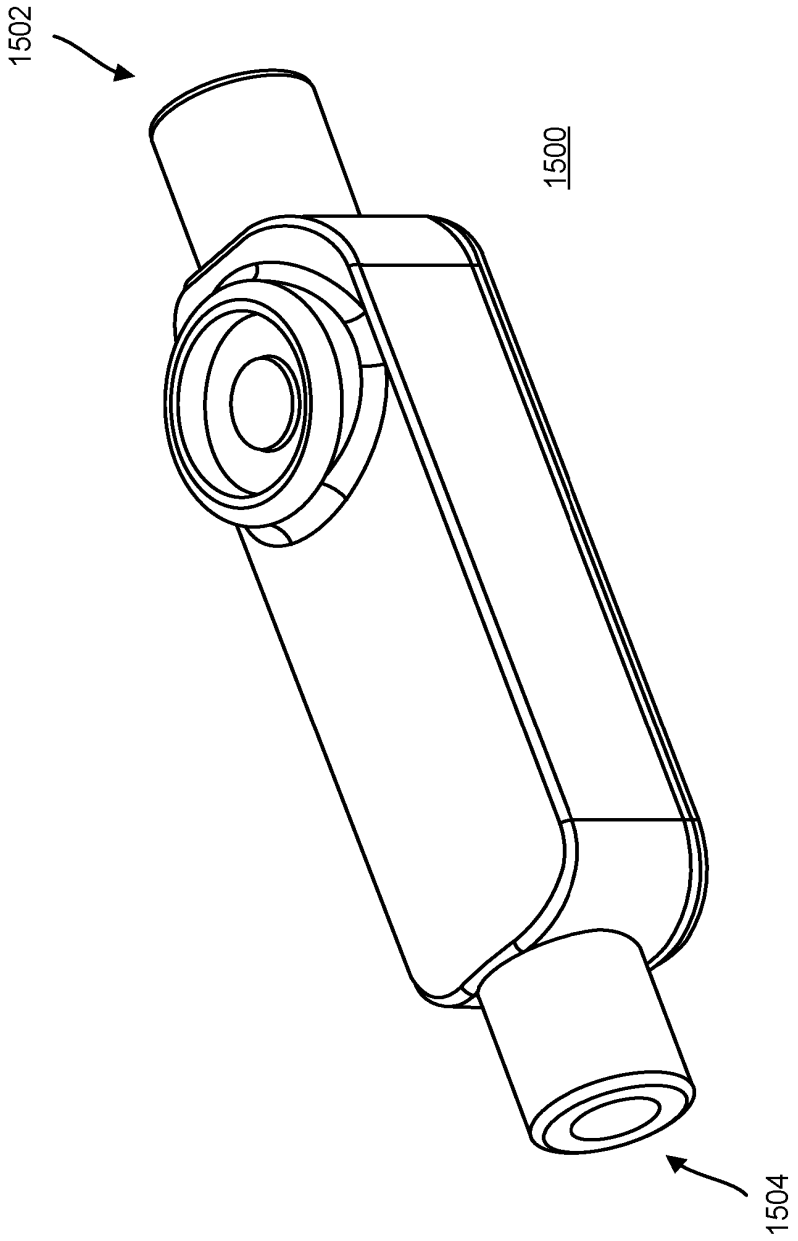


FIG. 15A

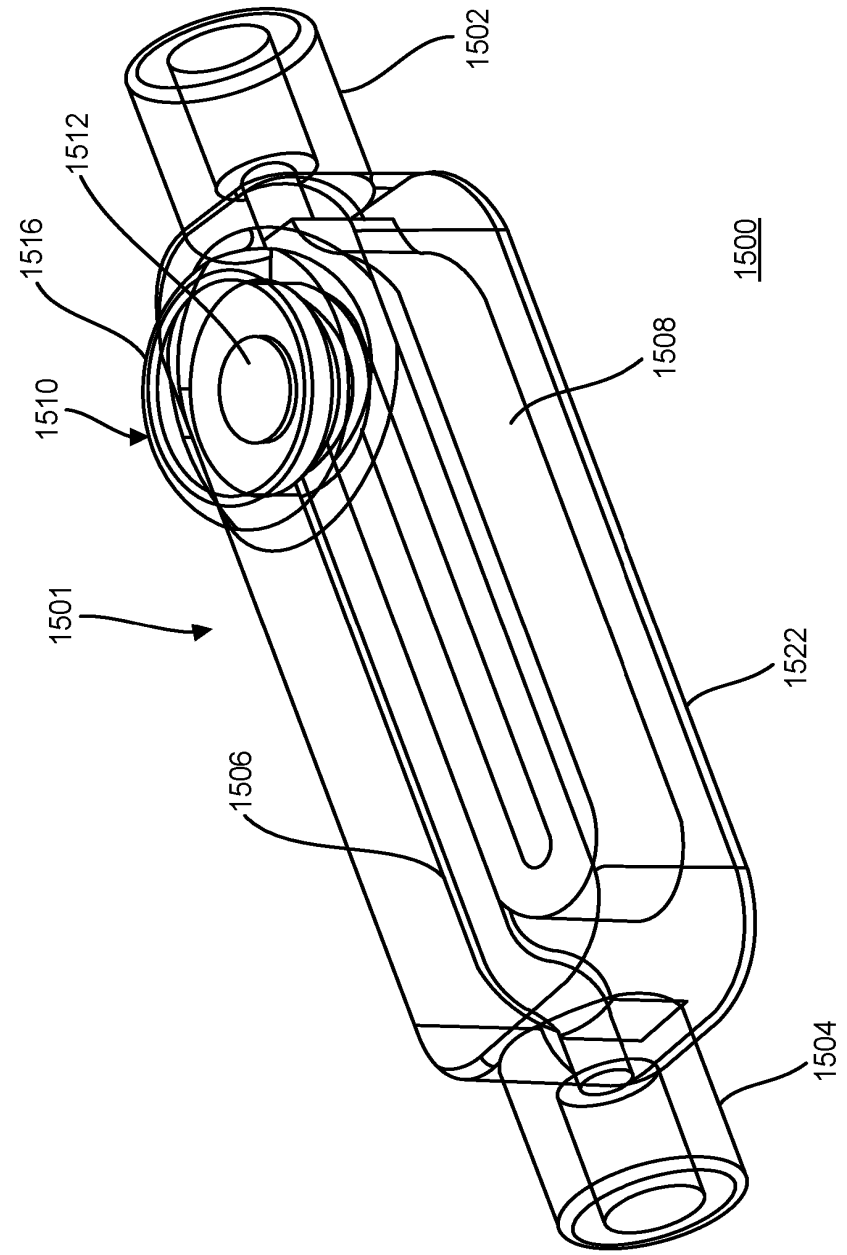


FIG. 15B

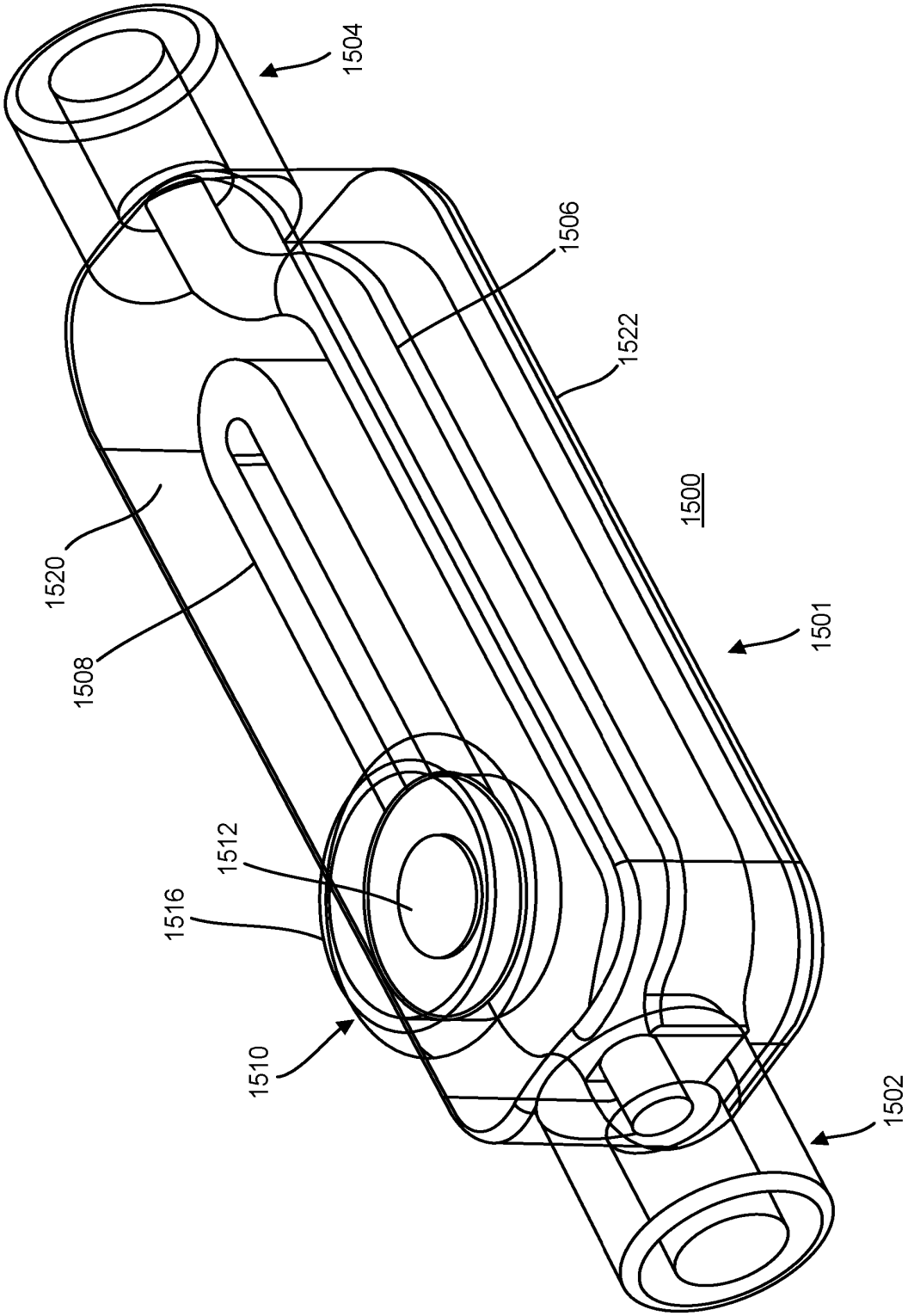


FIG. 15C

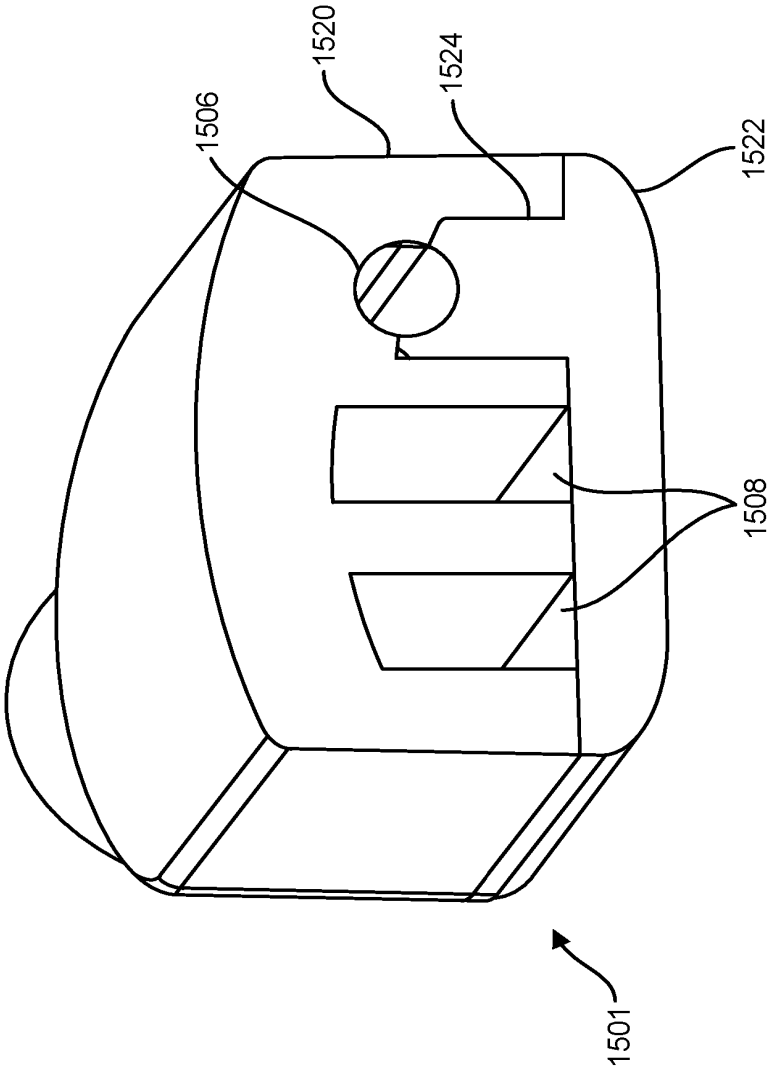


FIG. 15D

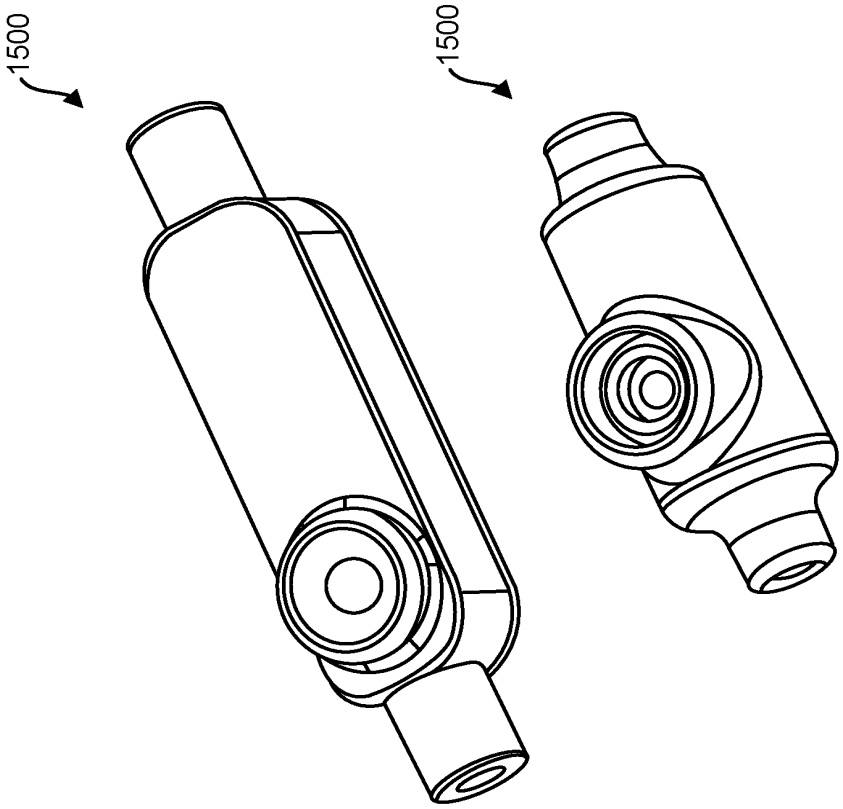


FIG. 15F

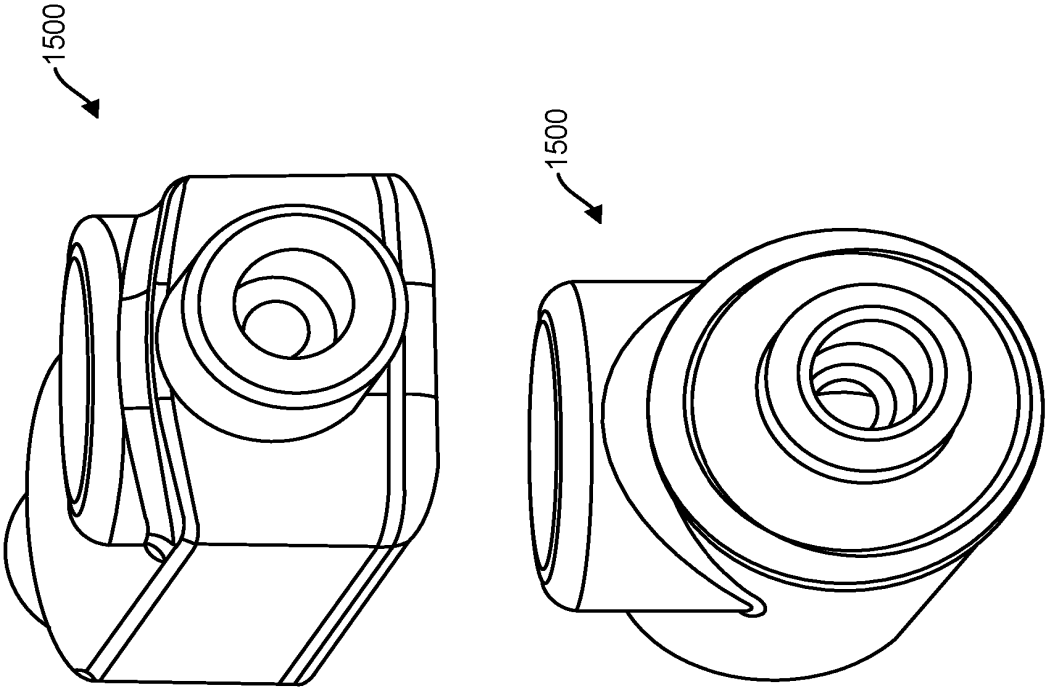


FIG. 15E

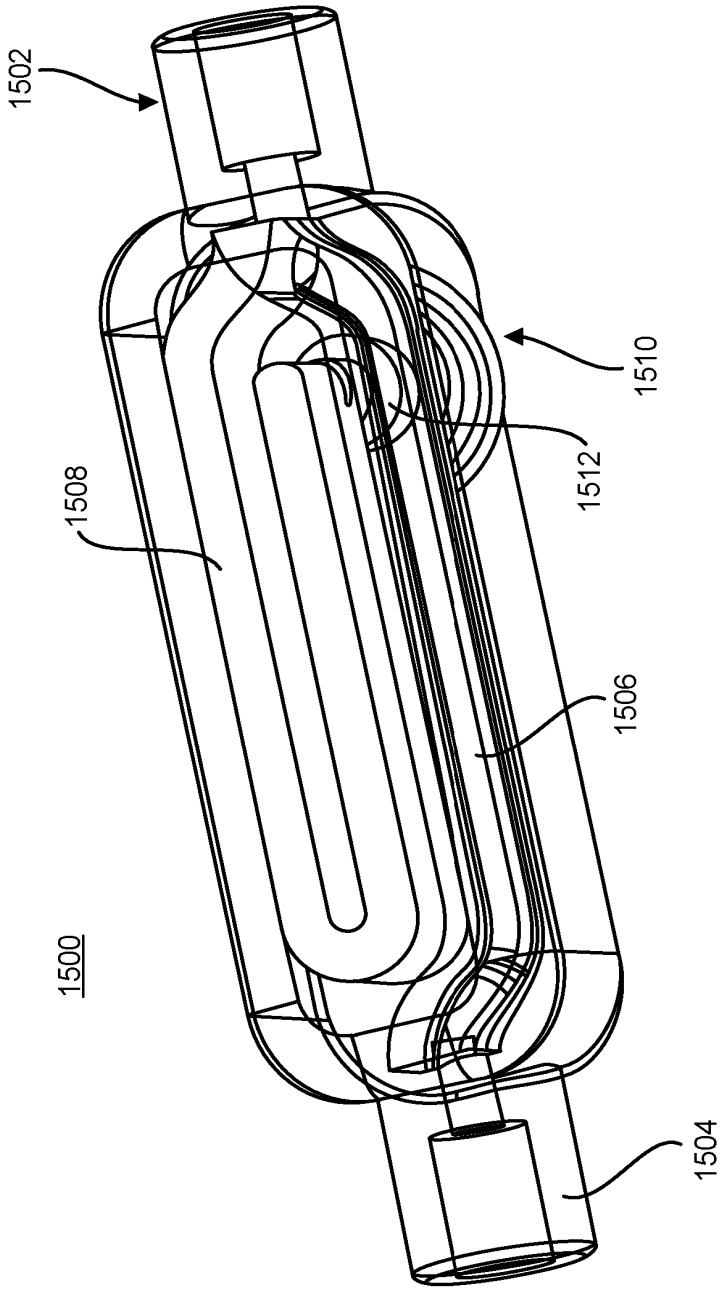


FIG. 15G

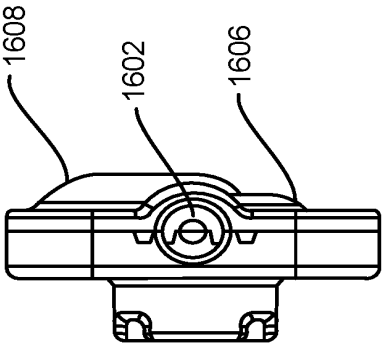


FIG. 16C

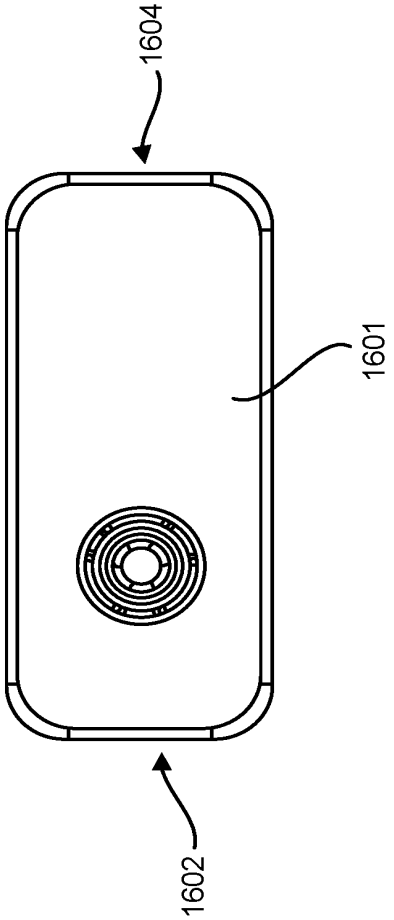


FIG. 16A

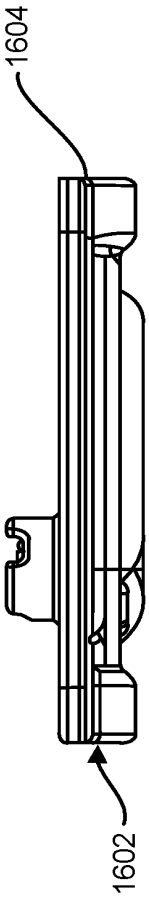


FIG. 16B

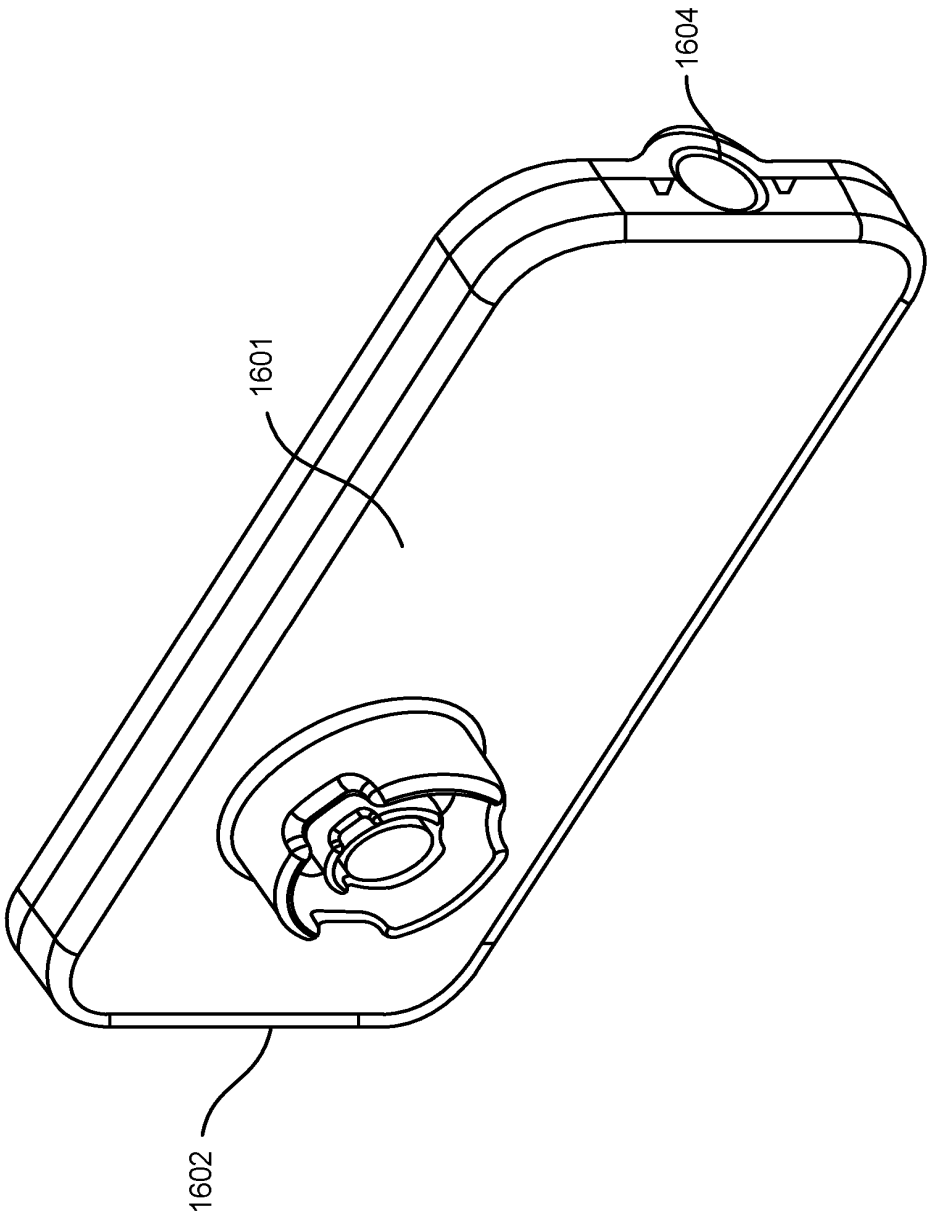


FIG. 16D

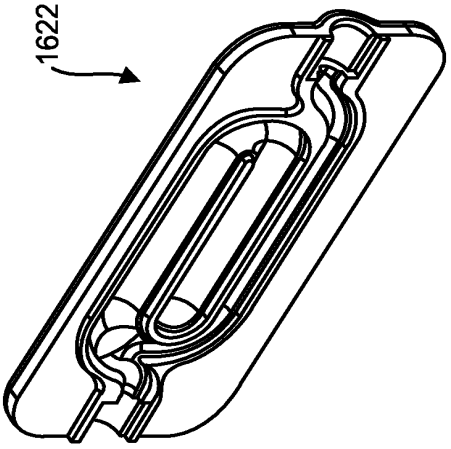


FIG. 17B



FIG. 17E

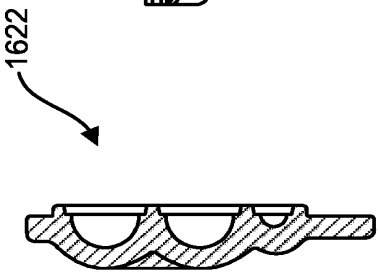


FIG. 17D

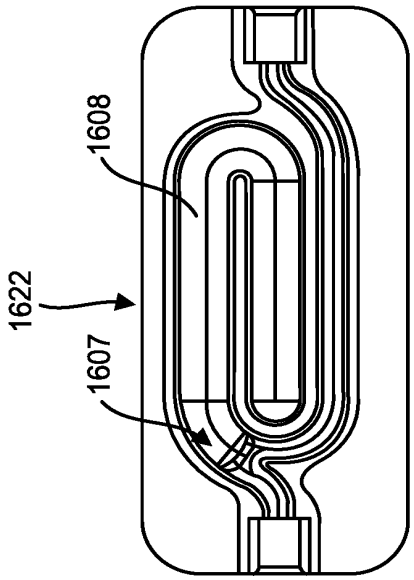


FIG. 17A

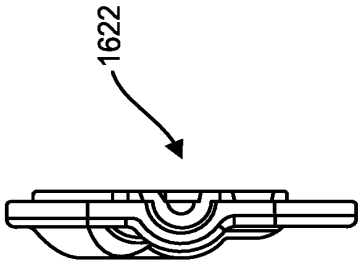


FIG. 17C

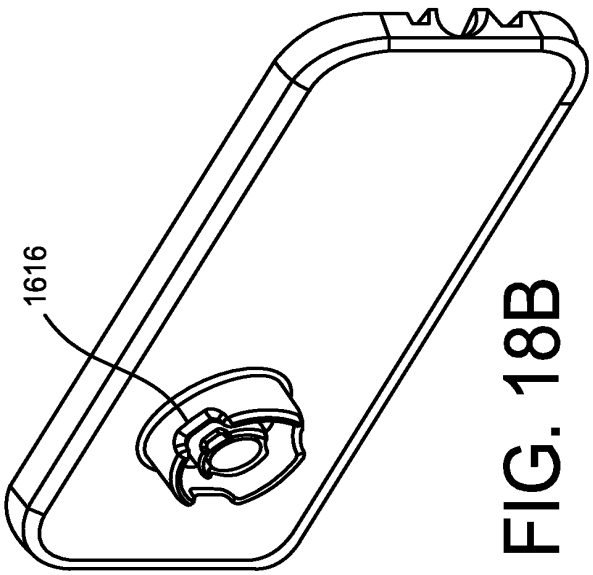


FIG. 18B

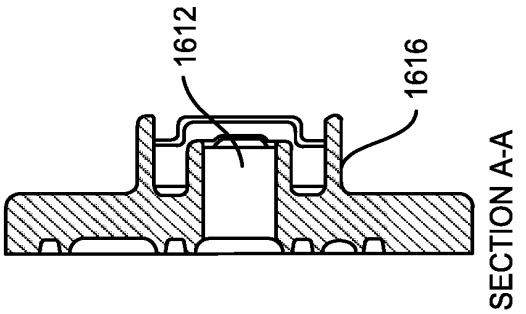


FIG. 18F

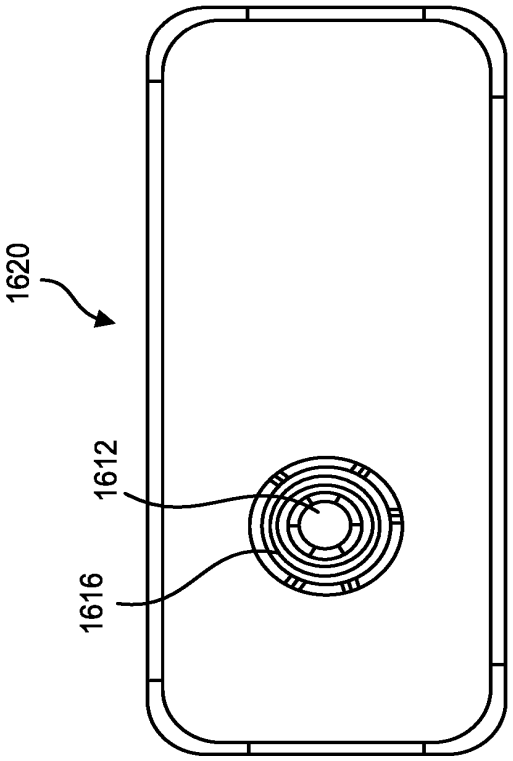


FIG. 18A

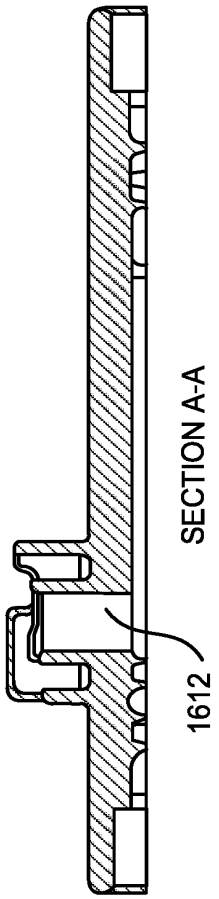


FIG. 18D

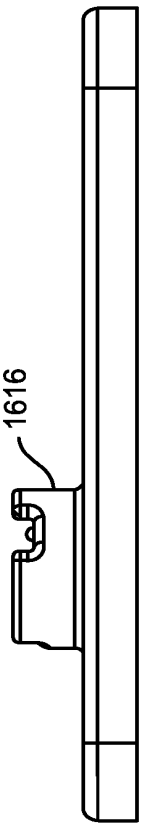


FIG. 18E

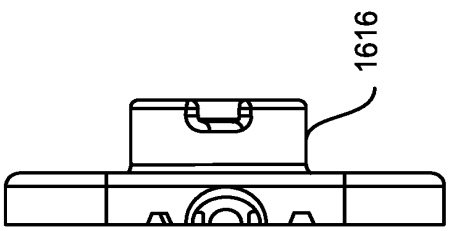


FIG. 18C

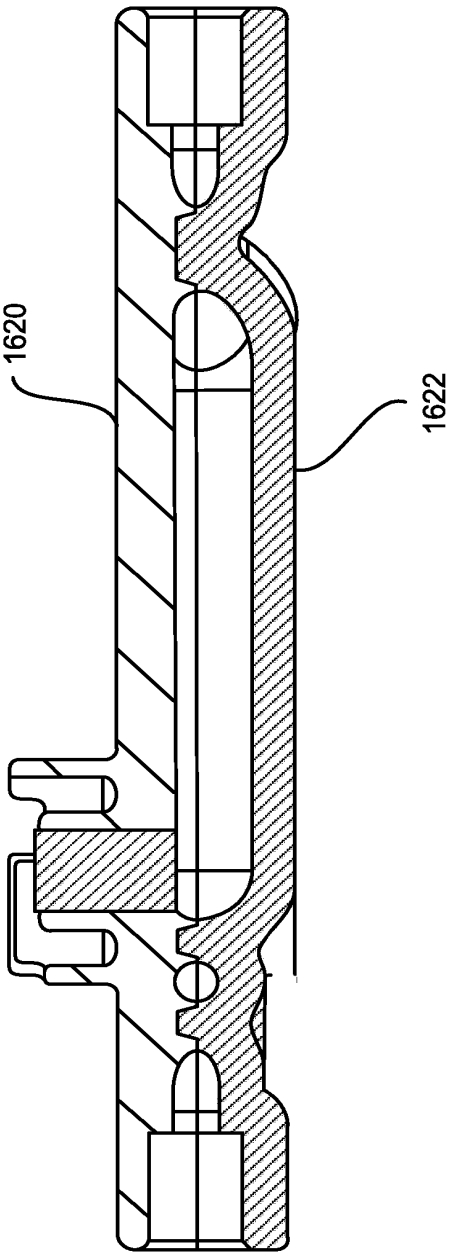


FIG. 19A

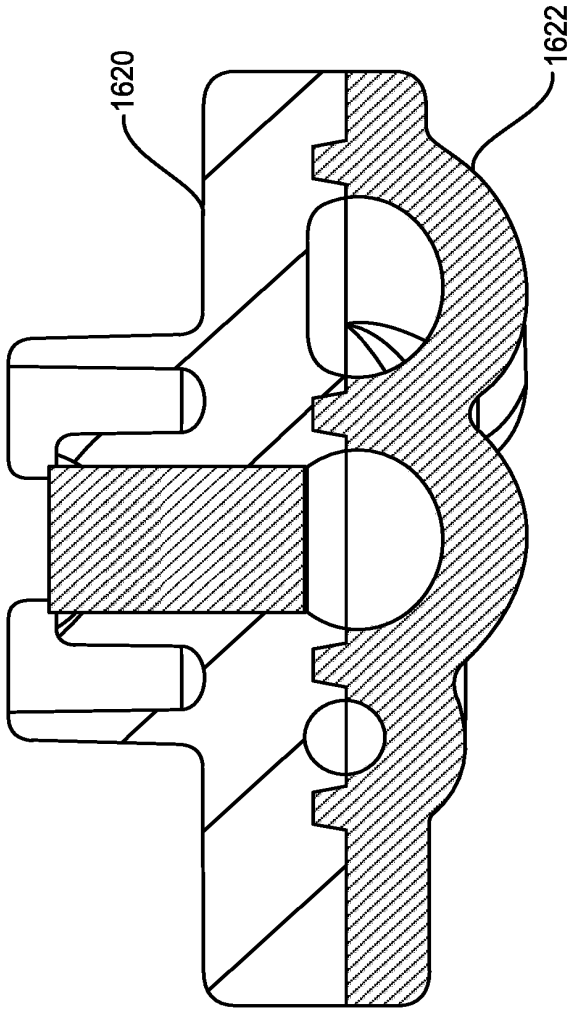


FIG. 19B

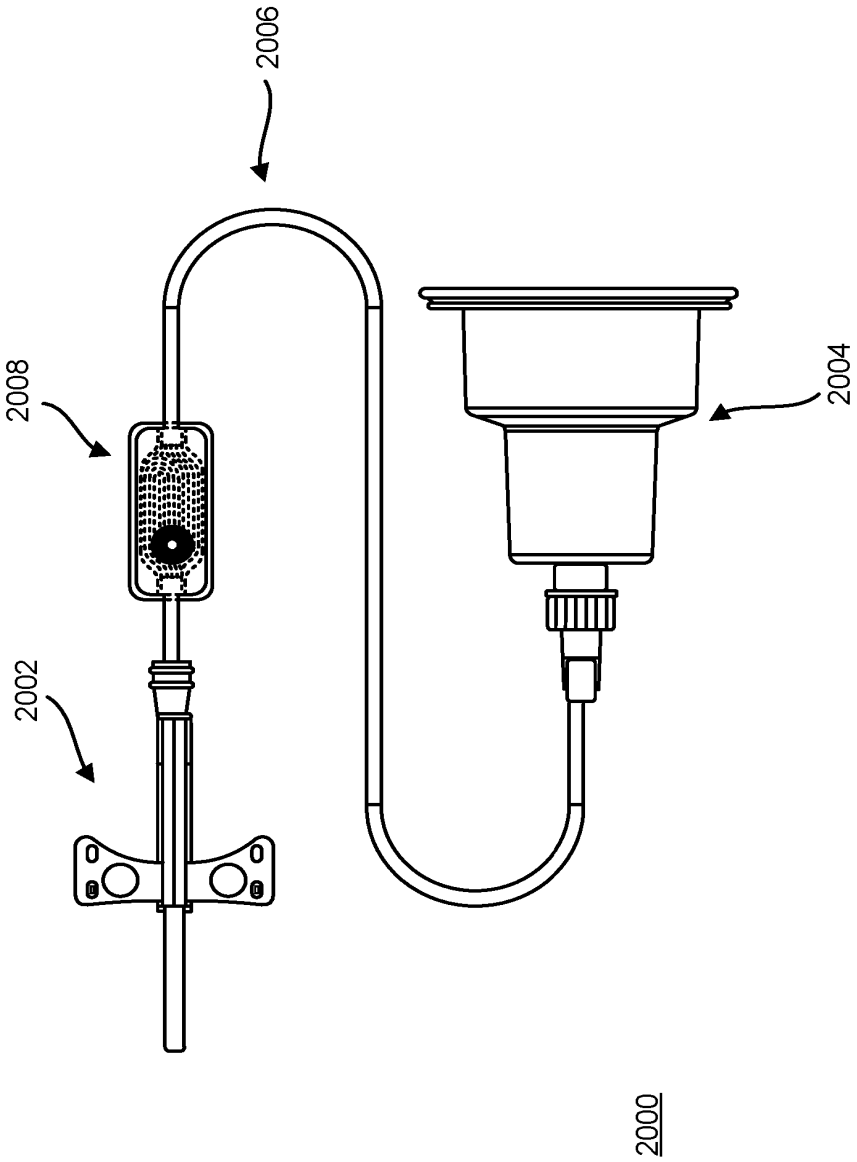


FIG. 20

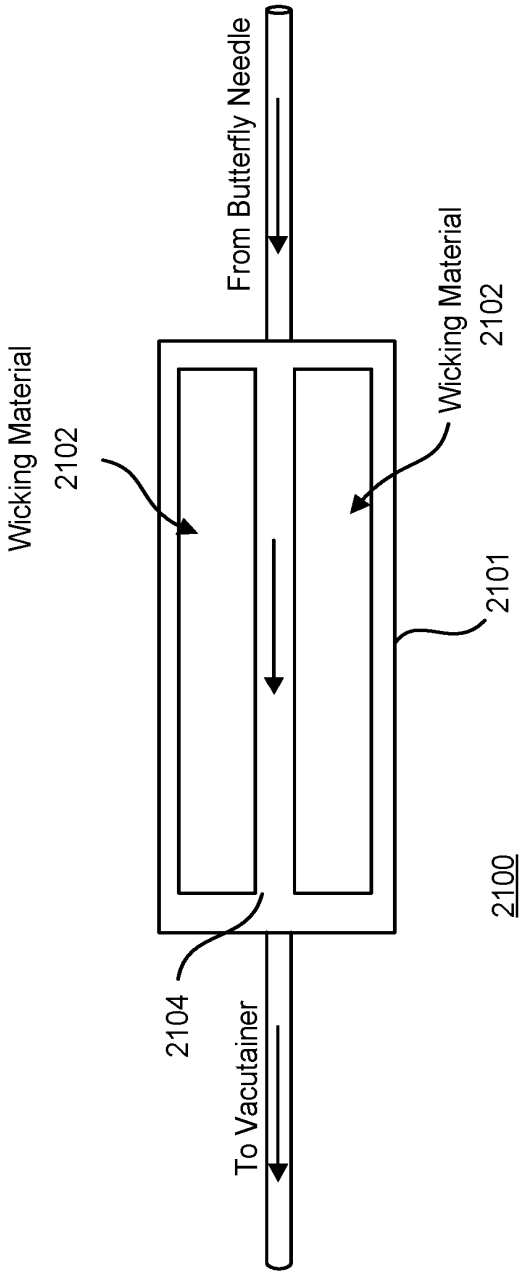

From Butterfly Needle
Wicking Material
2102
Wicking Material
2102
2101
2100
2104
To Vacutainer

FIG. 21

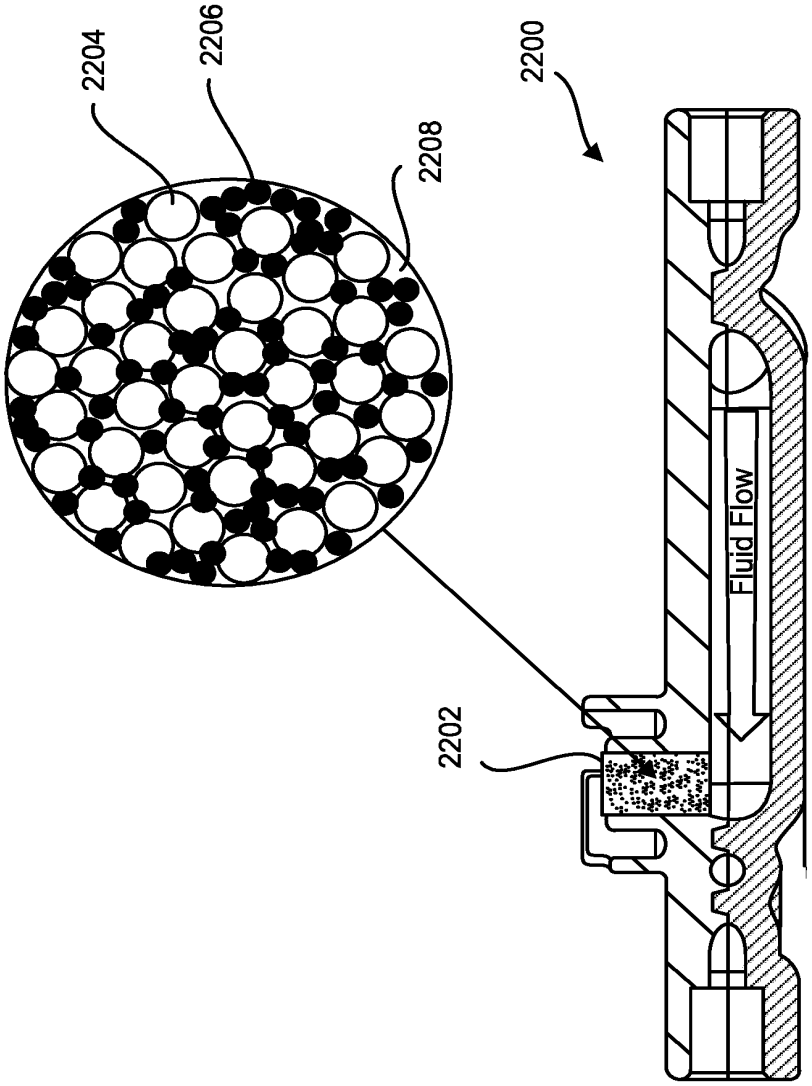


FIG. 22A

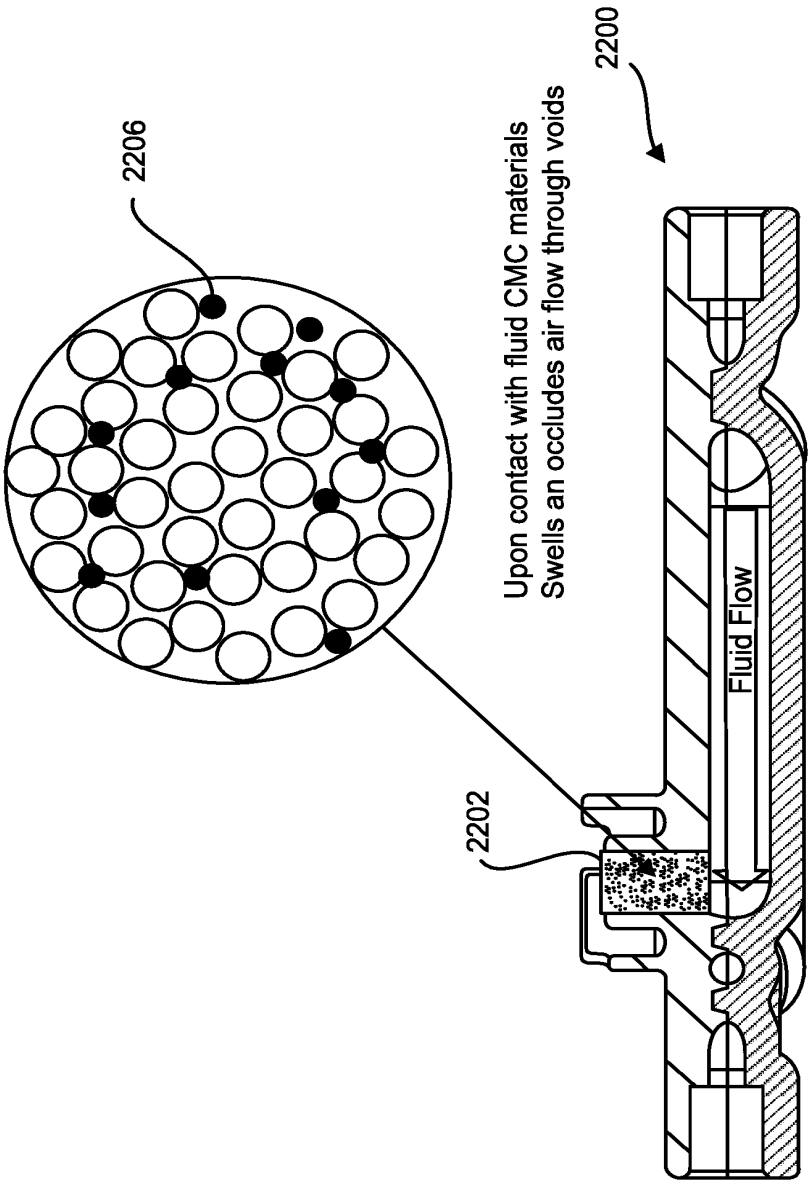

2200
2206
Upon contact with fluid CMC materials
Swells an occludes air flow through voids
Fluid Flow
2202

FIG. 22B

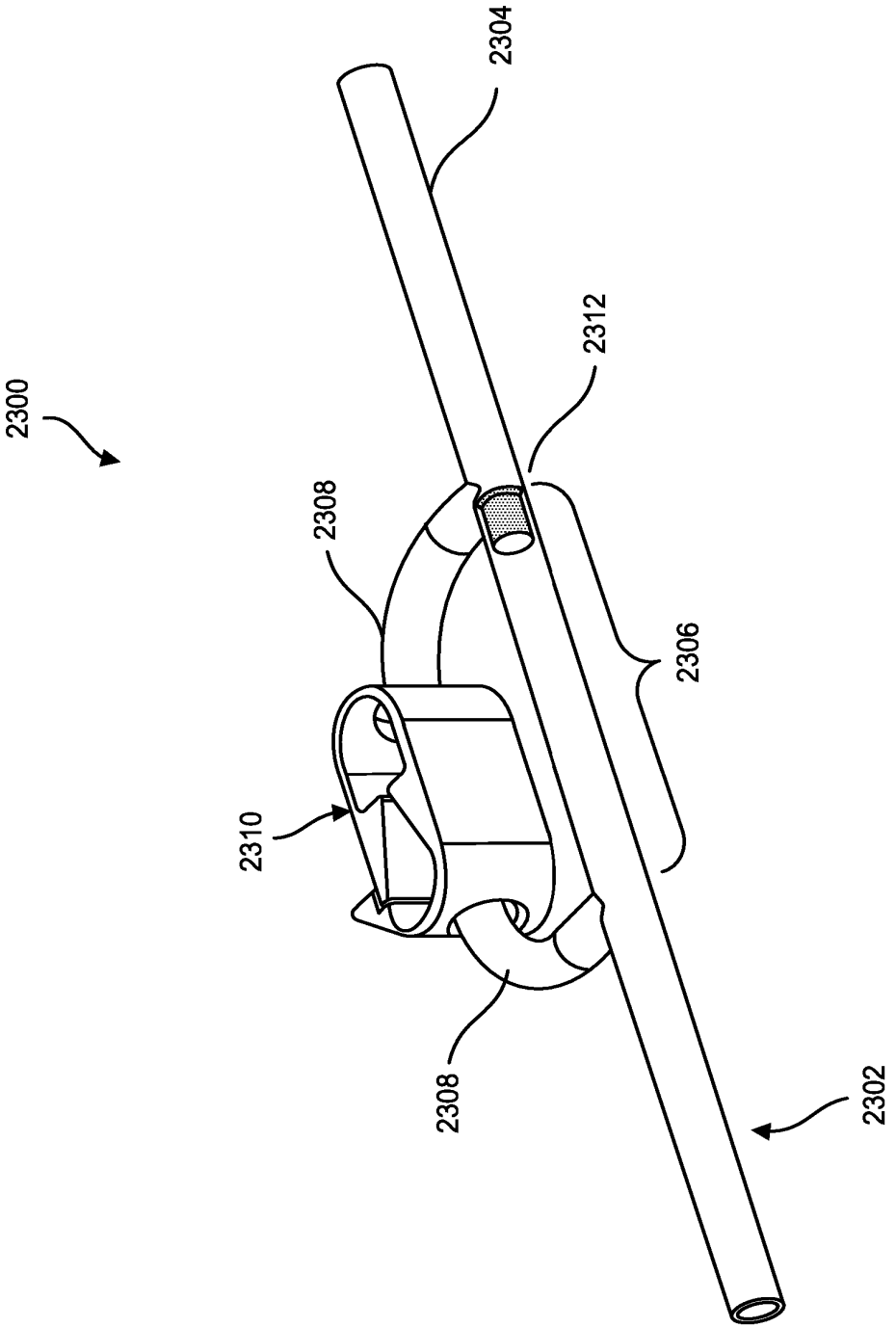


FIG. 23A

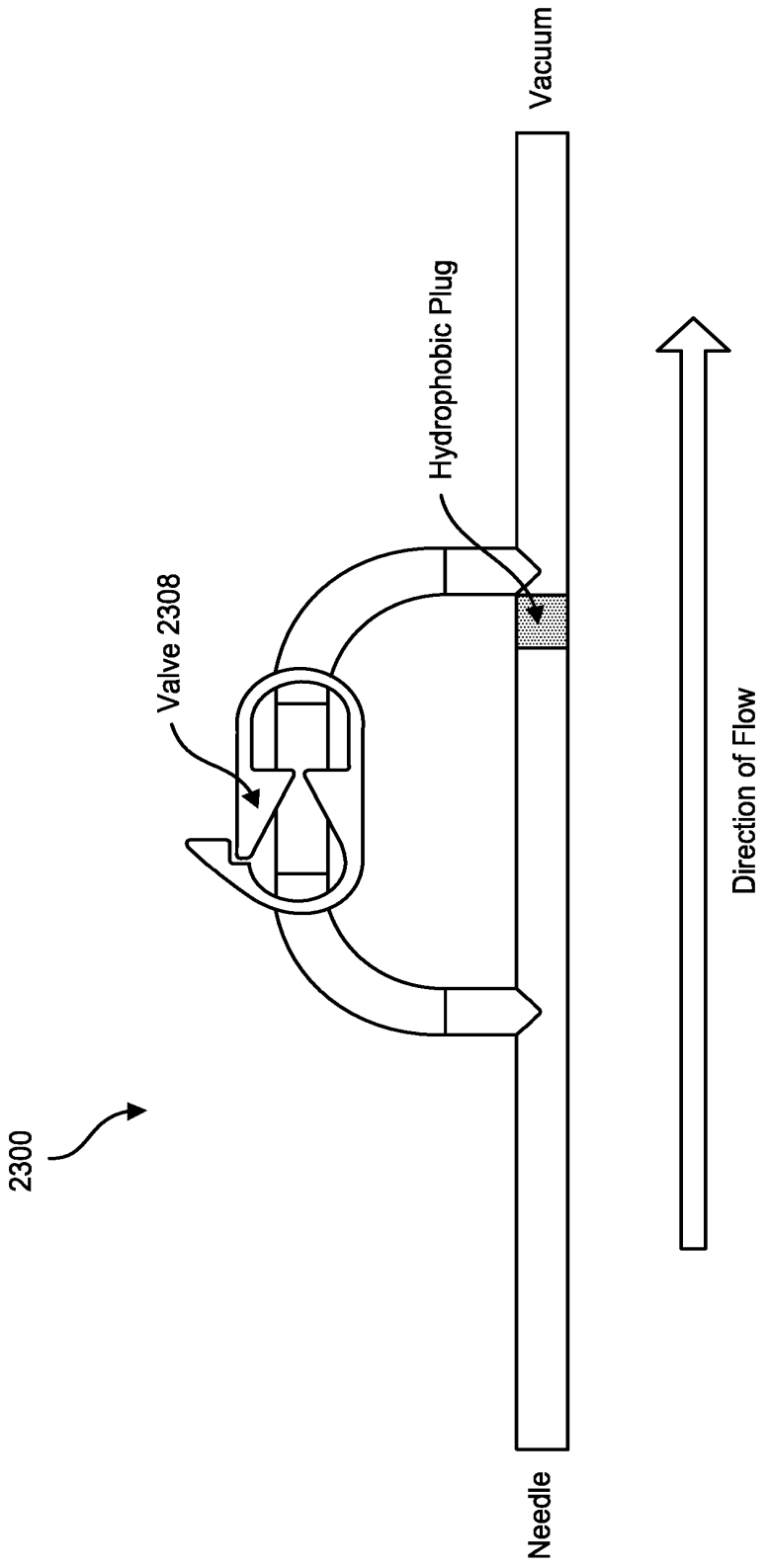

Vacuum
Hydrophobic Plug
Valve 2308
Direction of Flow
2300
Needle

FIG. 23B

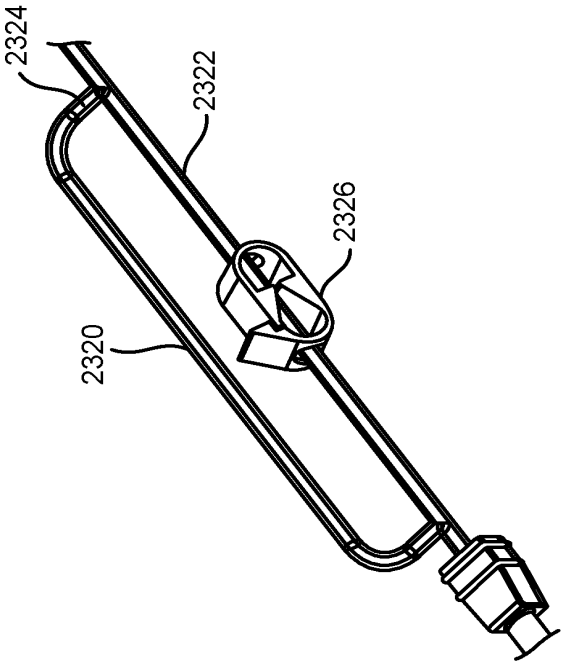


FIG. 23D

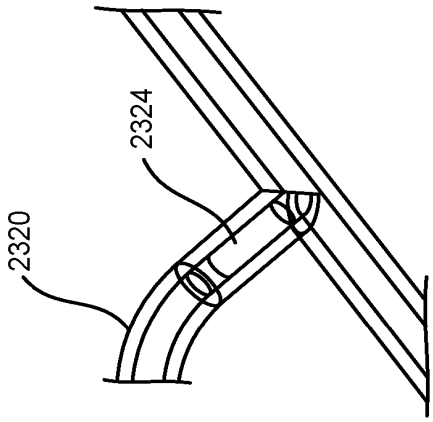


FIG. 23E

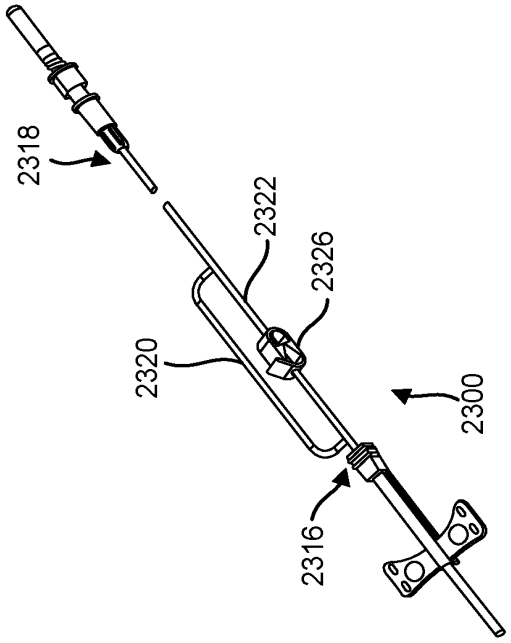


FIG. 23C

Replacement Sheet
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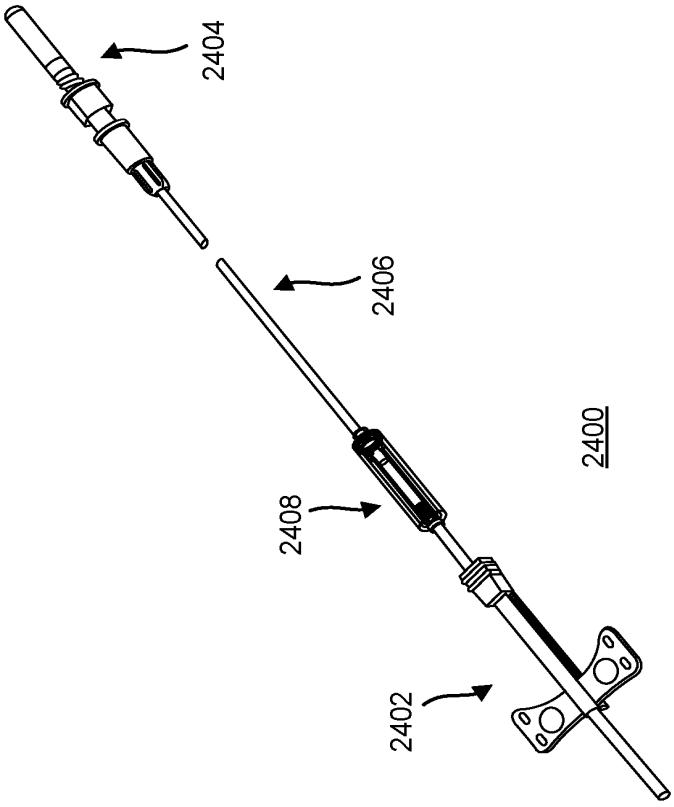


FIG. 24A

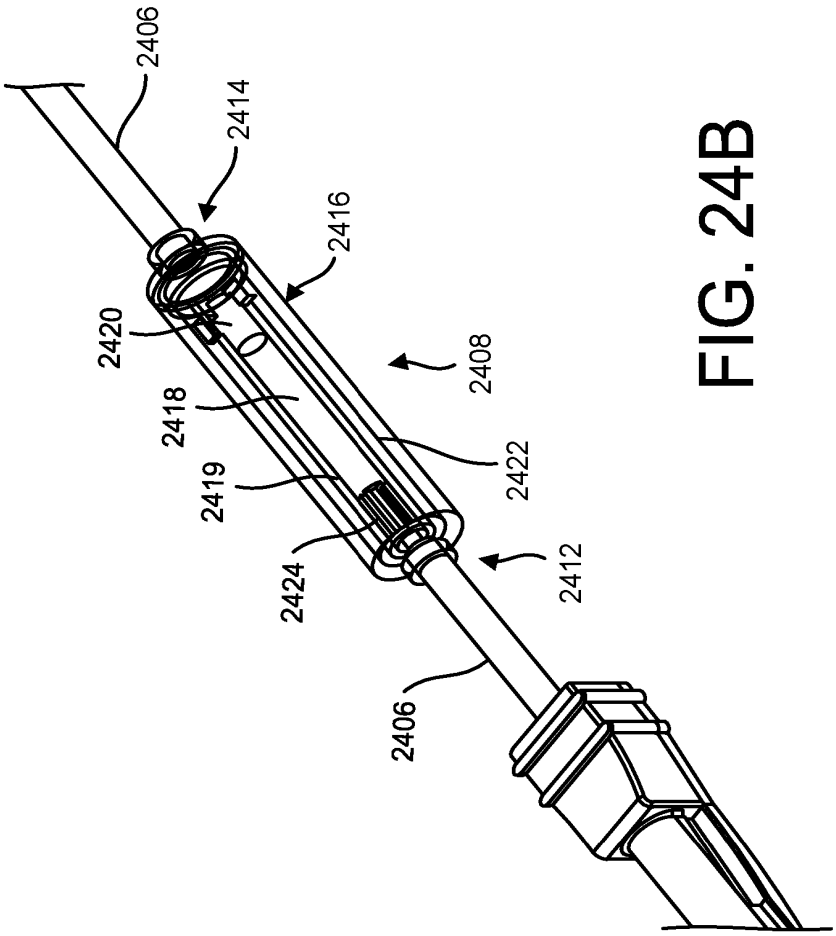


FIG. 24B

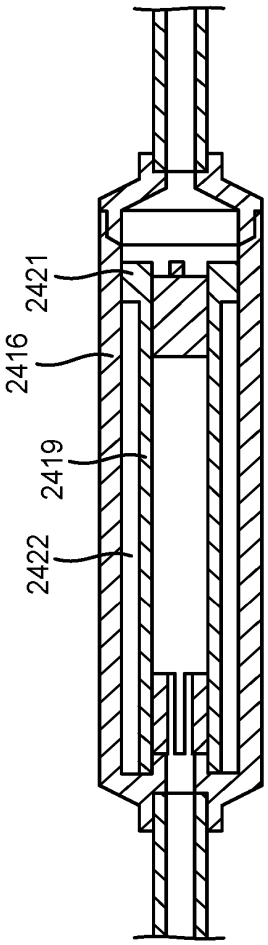


FIG. 24C

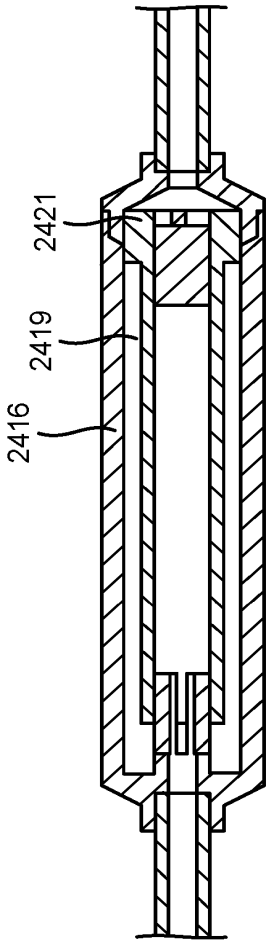


FIG. 24D

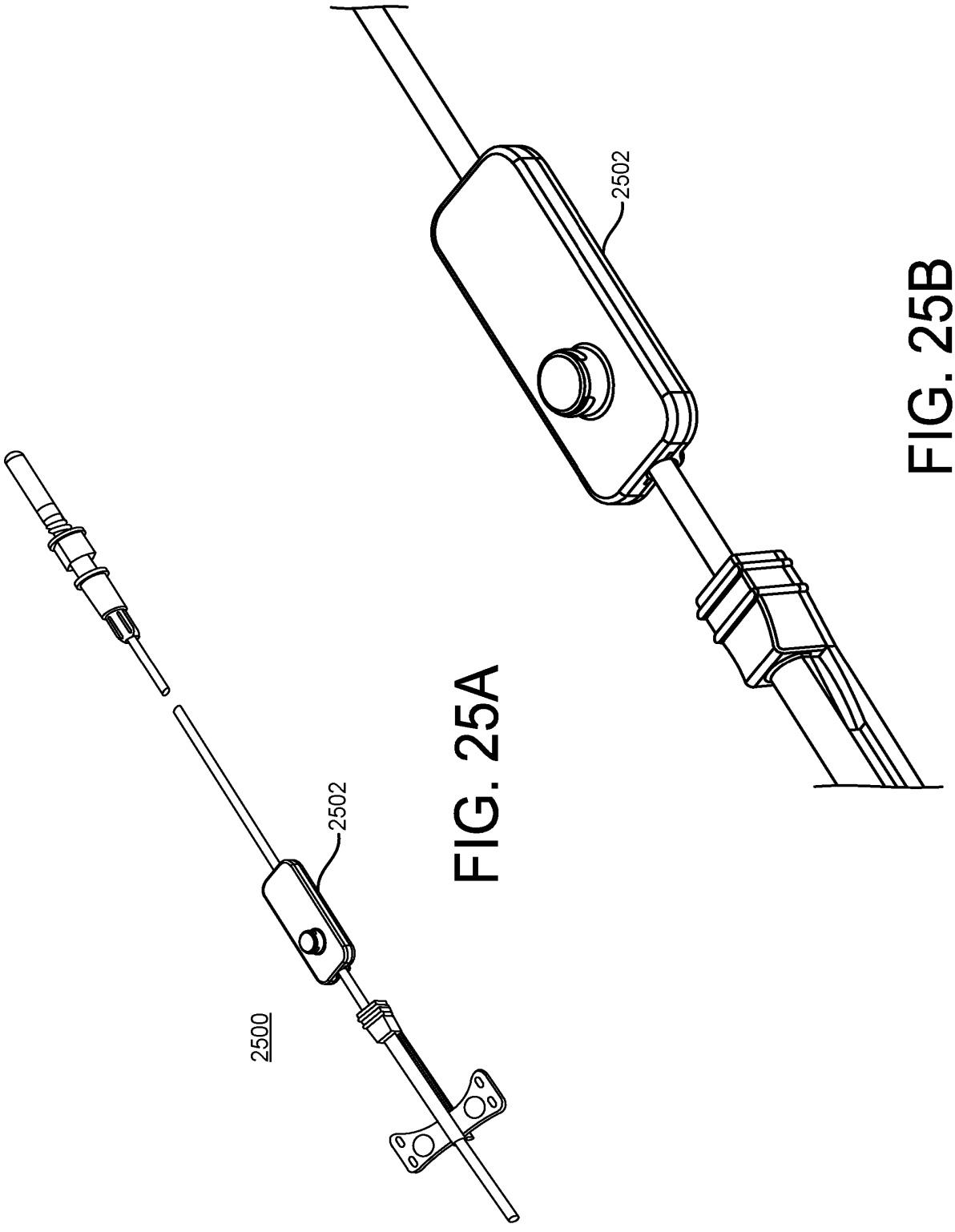


FIG. 25A

FIG. 25B

Replacement Sheet
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Docket No. KURIN3PCT
PCT/US2017/068569

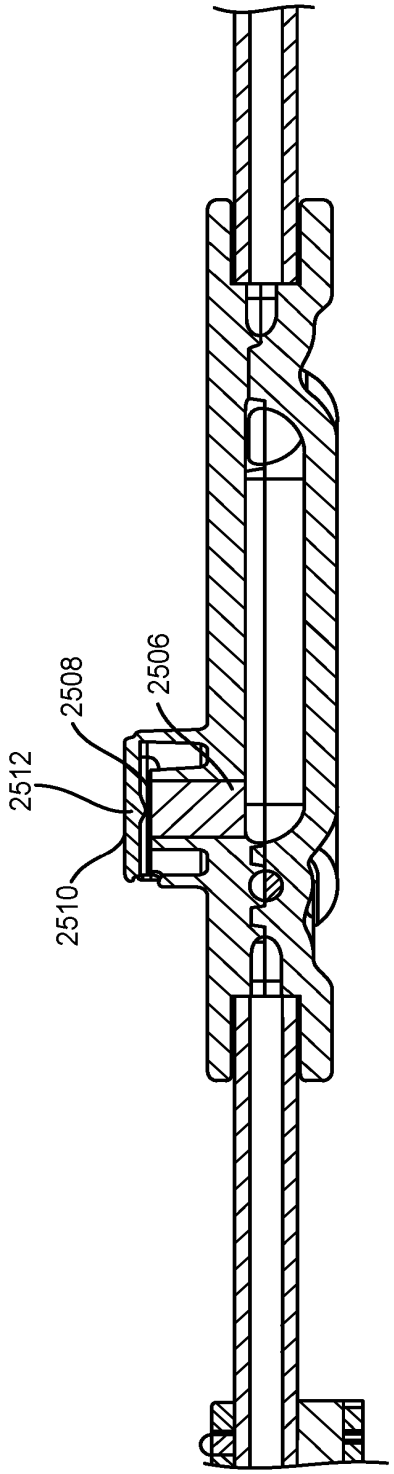


FIG. 25C

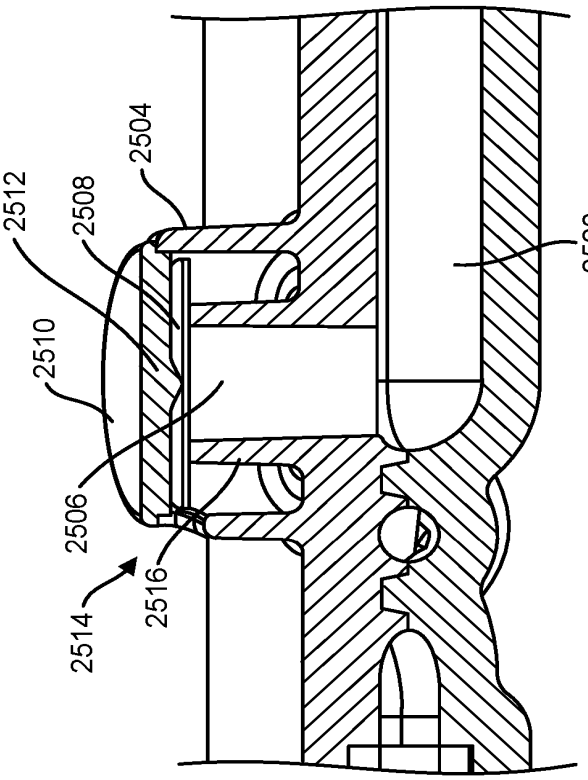


FIG. 25D

Replacement Sheet
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Docket No. KURIN3PCT
PCT/US2017/068569

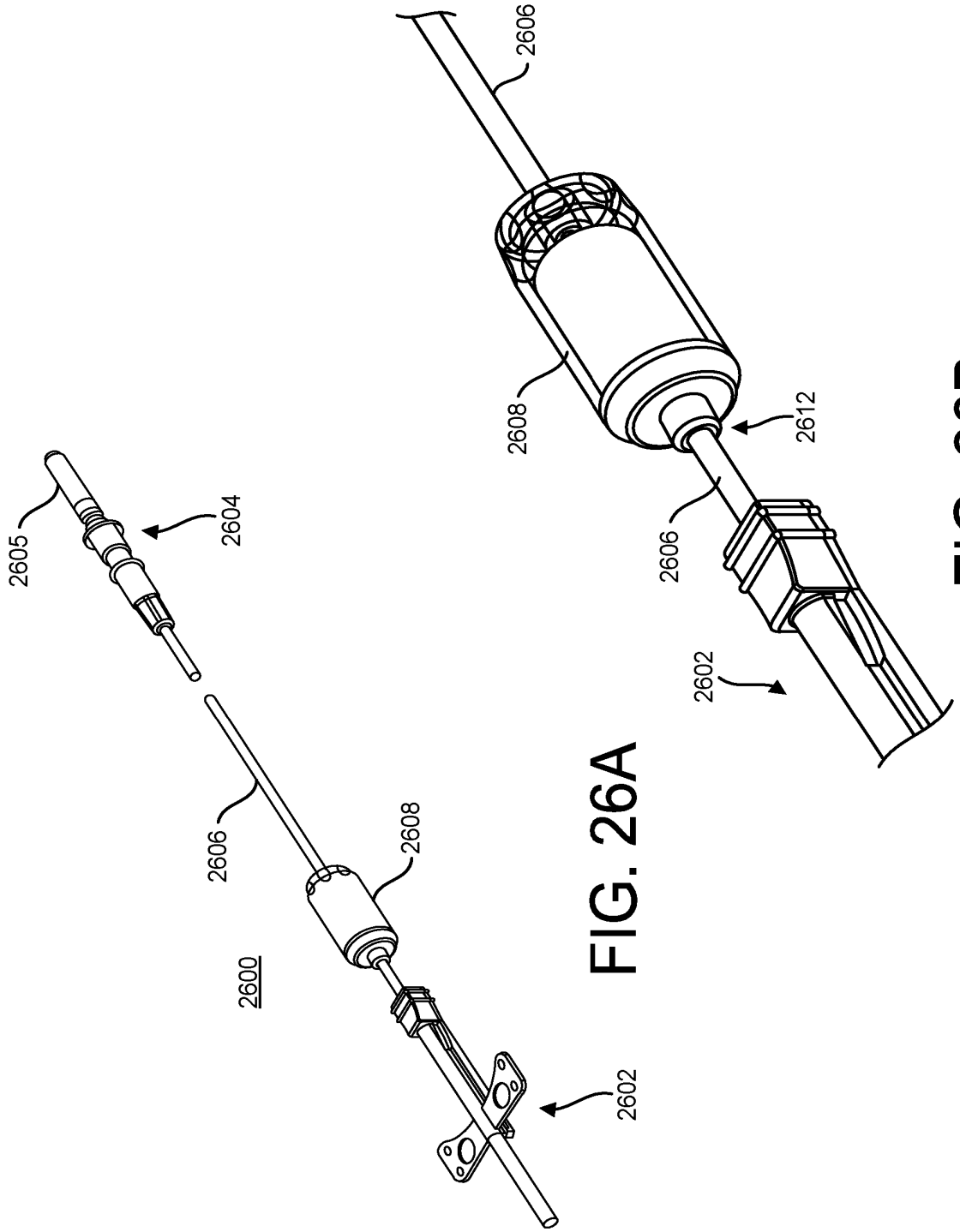


FIG. 26B

FIG. 26A

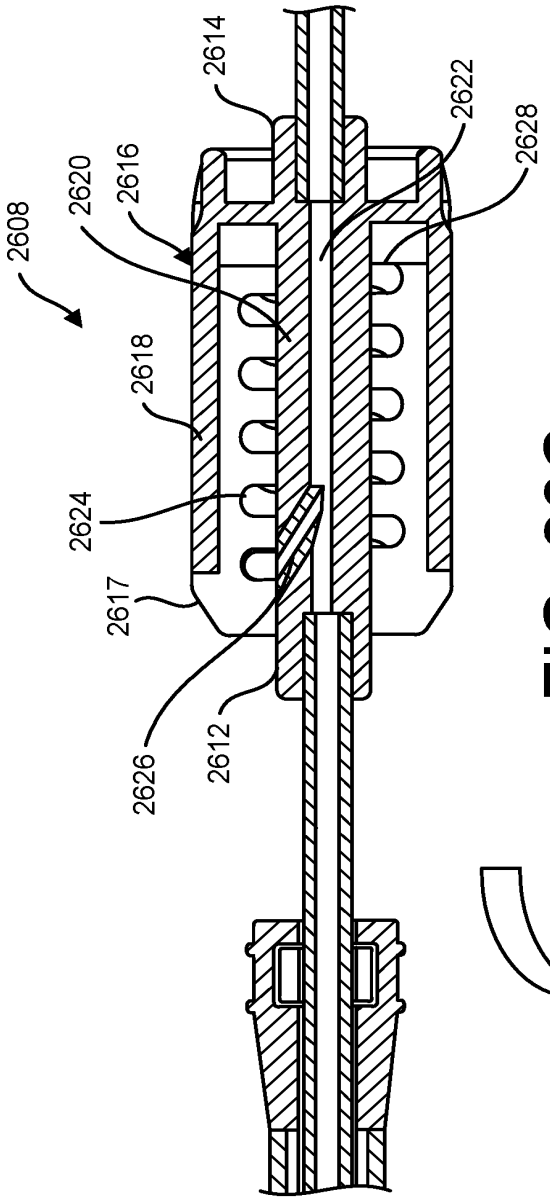


FIG. 26C

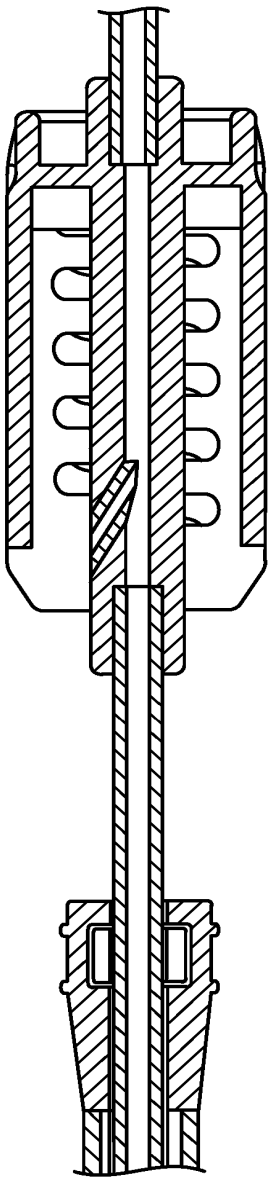


FIG. 26D

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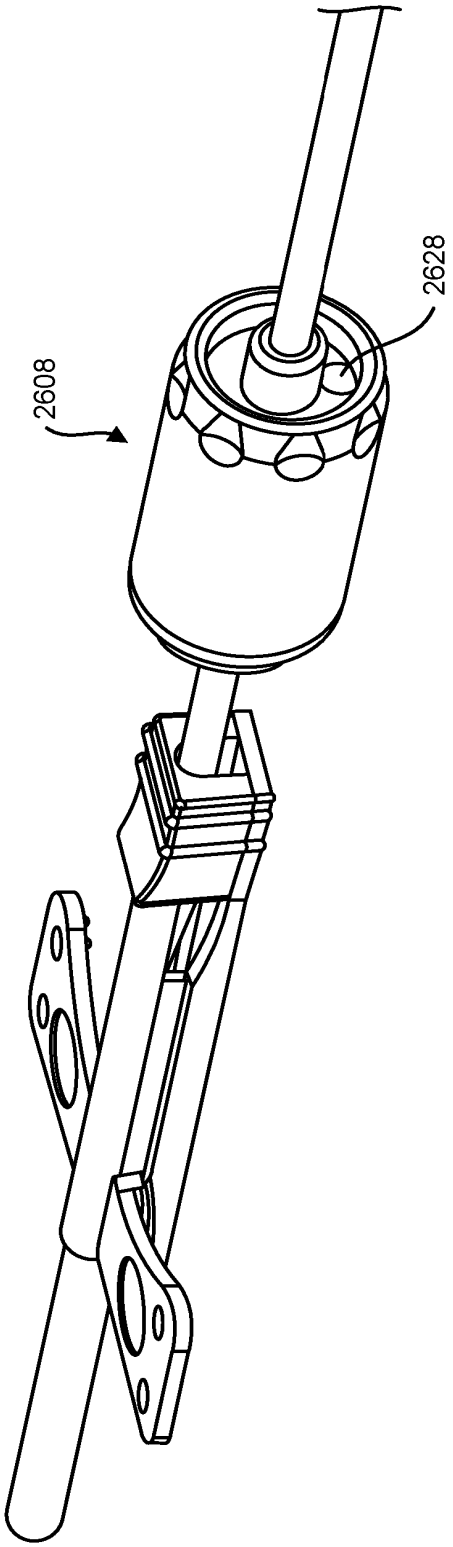


FIG. 26E

Replacement Sheet
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Docket No. KURIN3PCT
PCT/US2017/068569

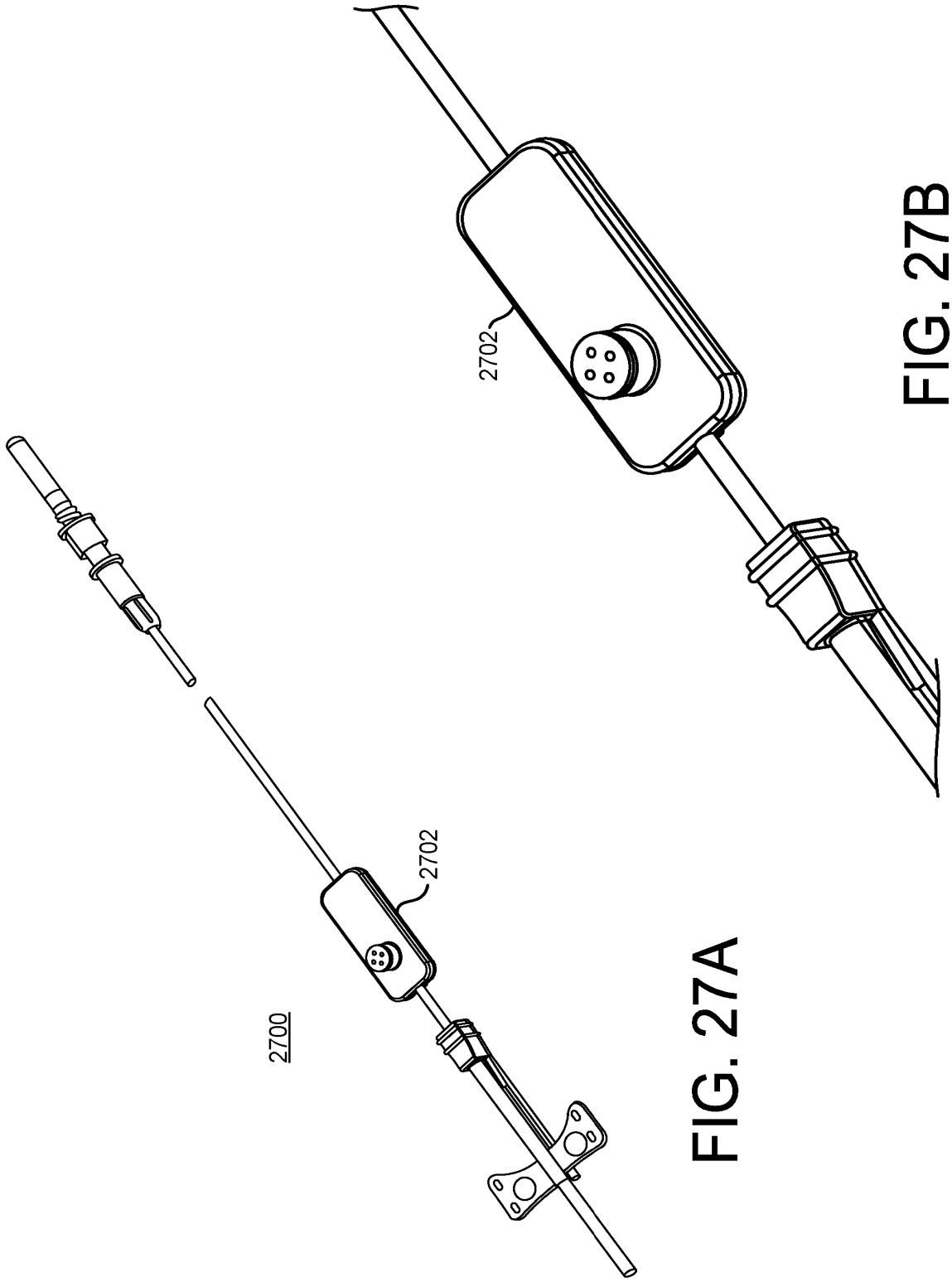


FIG. 27B

FIG. 27A

Replacement Sheet
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Docket No. KURIN3PCT
PCT/US2017/068569

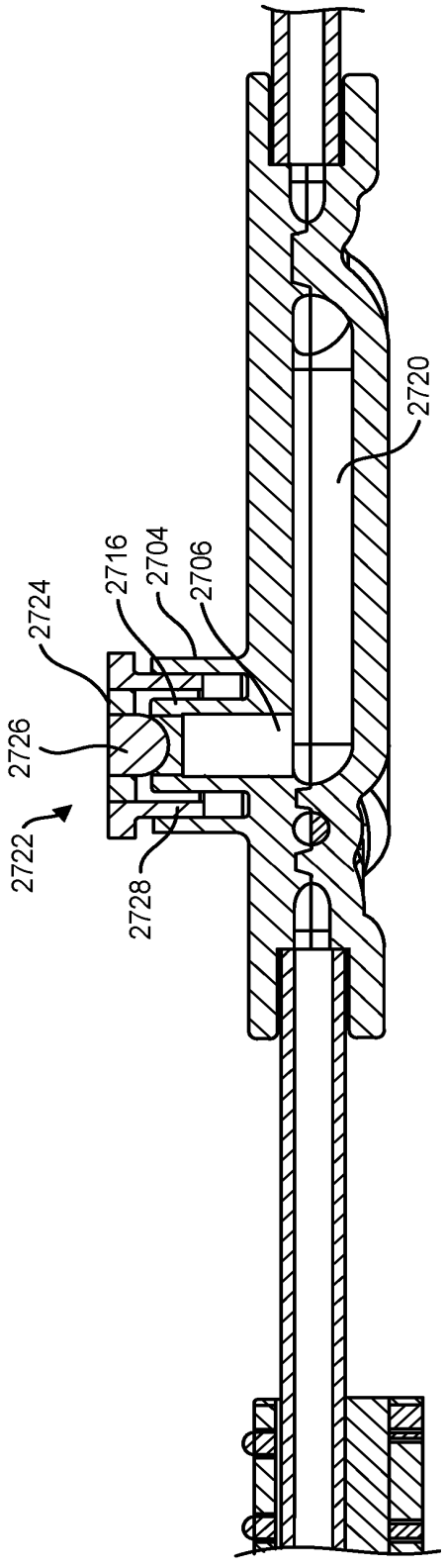


FIG. 27C

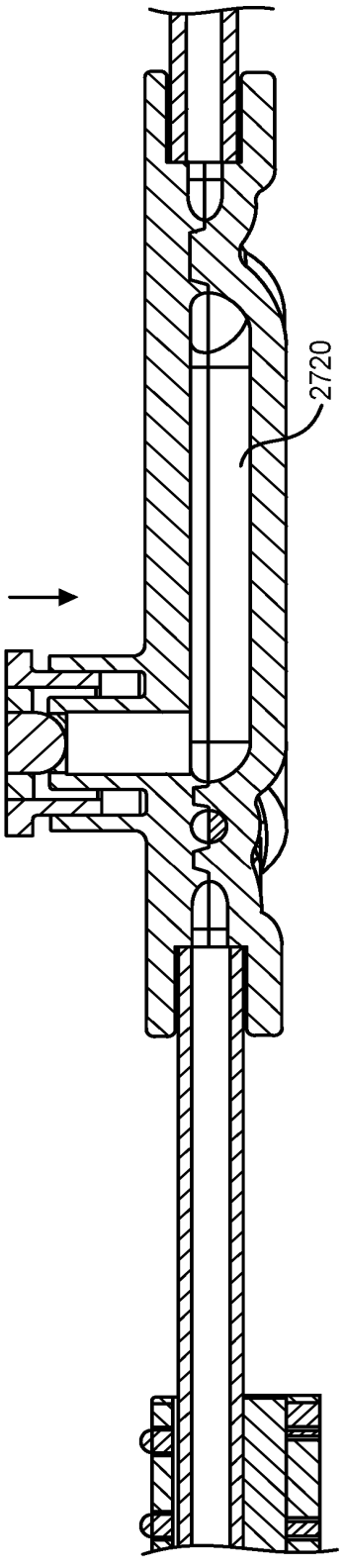


FIG. 27D

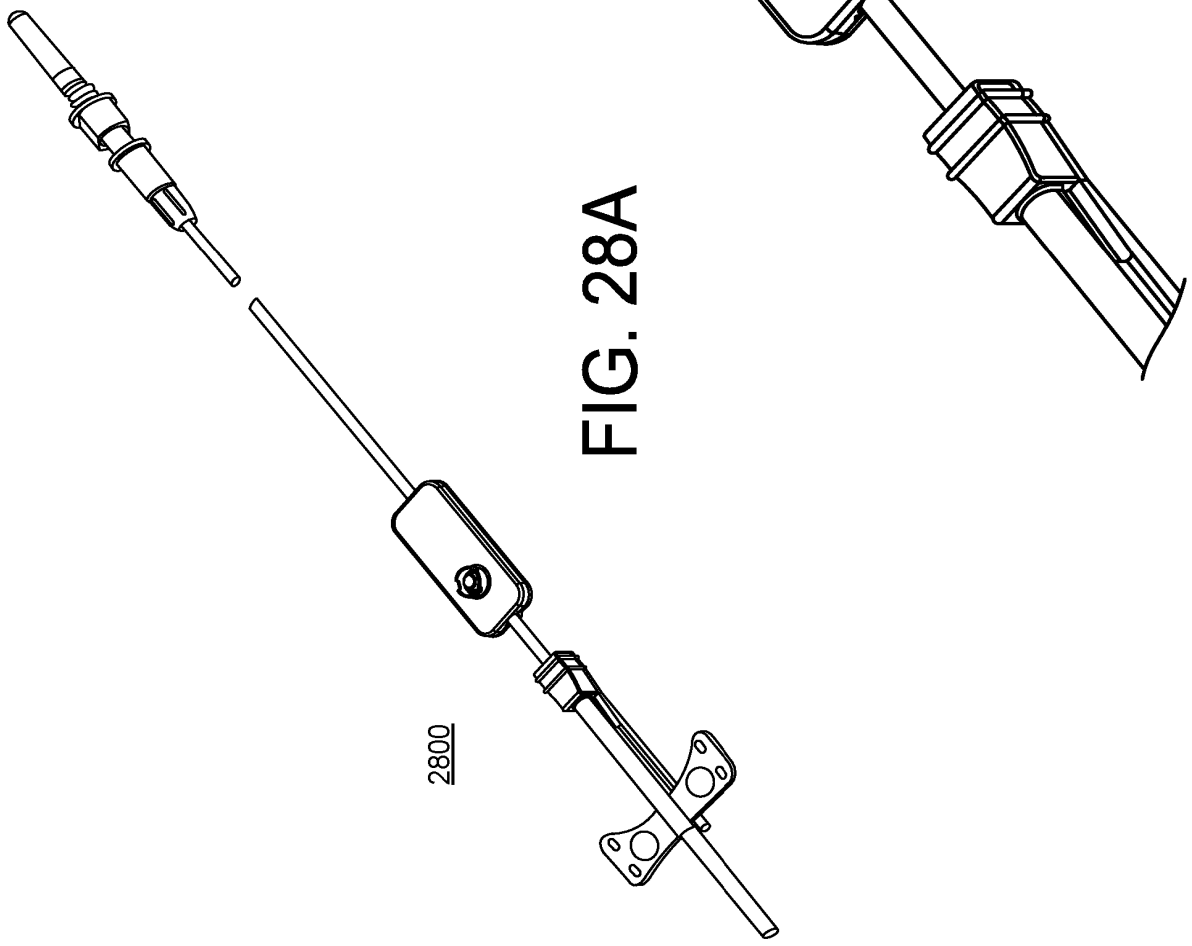


FIG. 28A

FIG. 28B

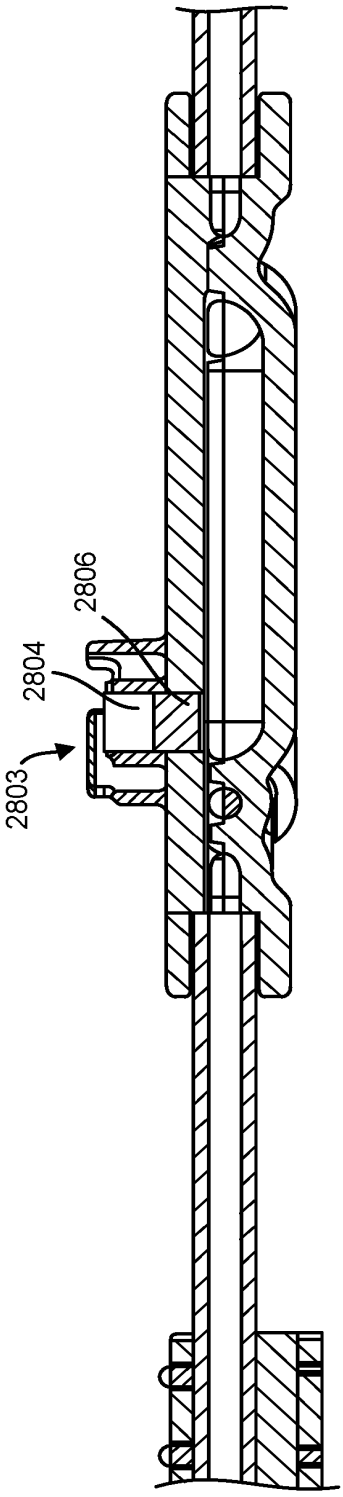


FIG. 28C

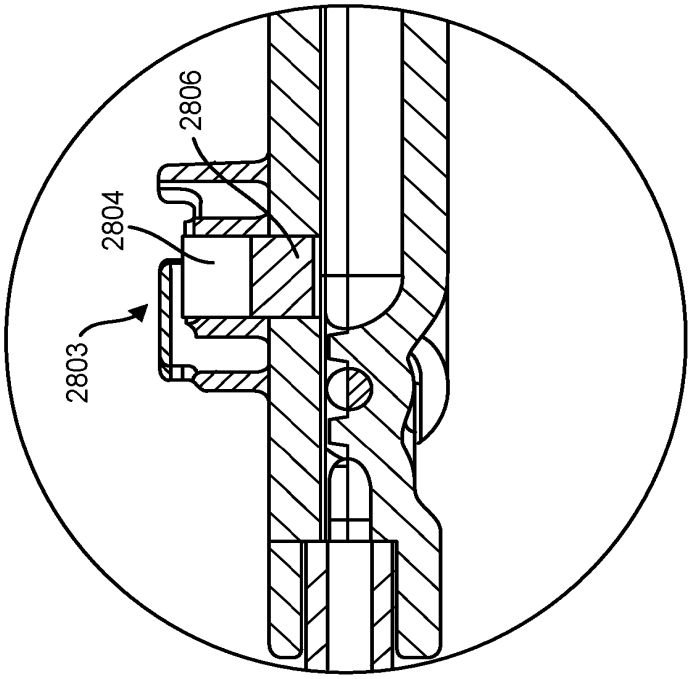


FIG. 28D

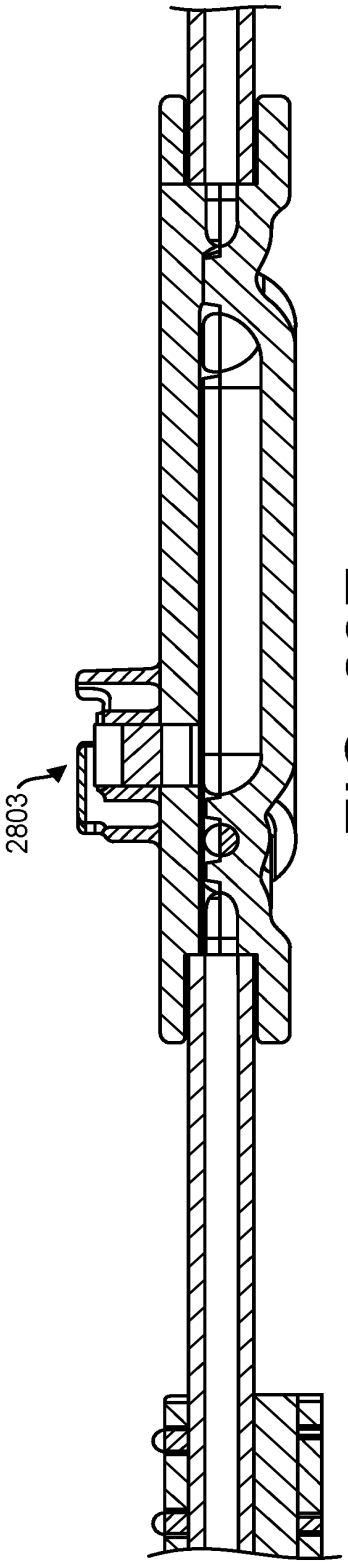


FIG. 28E

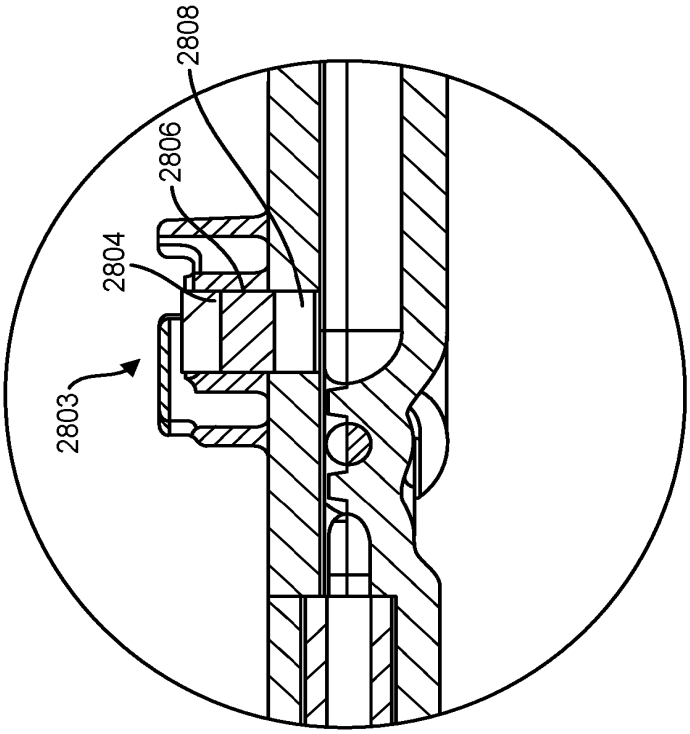


FIG. 28F

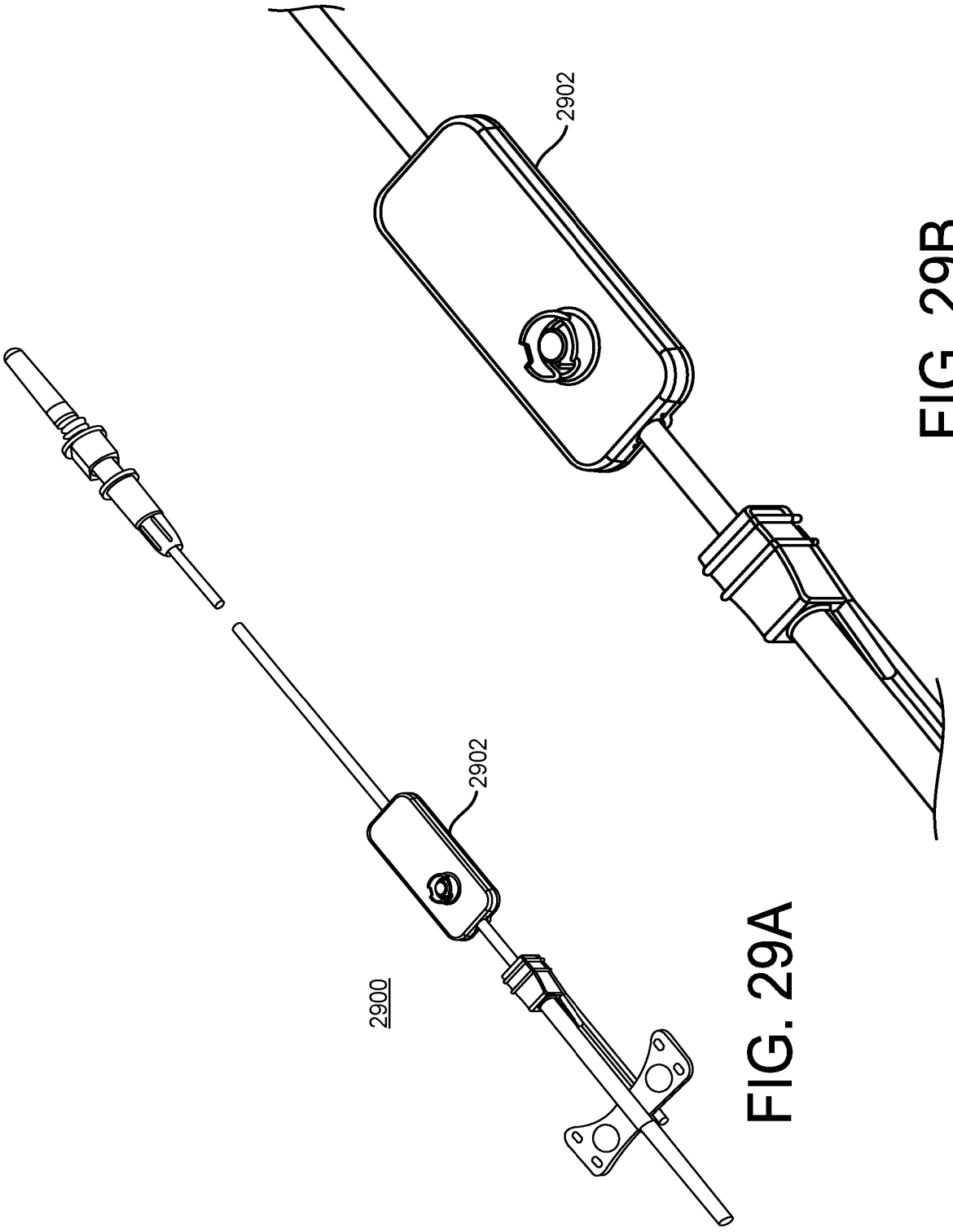


FIG. 29B

FIG. 29A

Replacement Sheet
65/69

Docket No. KURIN3PCT
PCT/US2017/068569

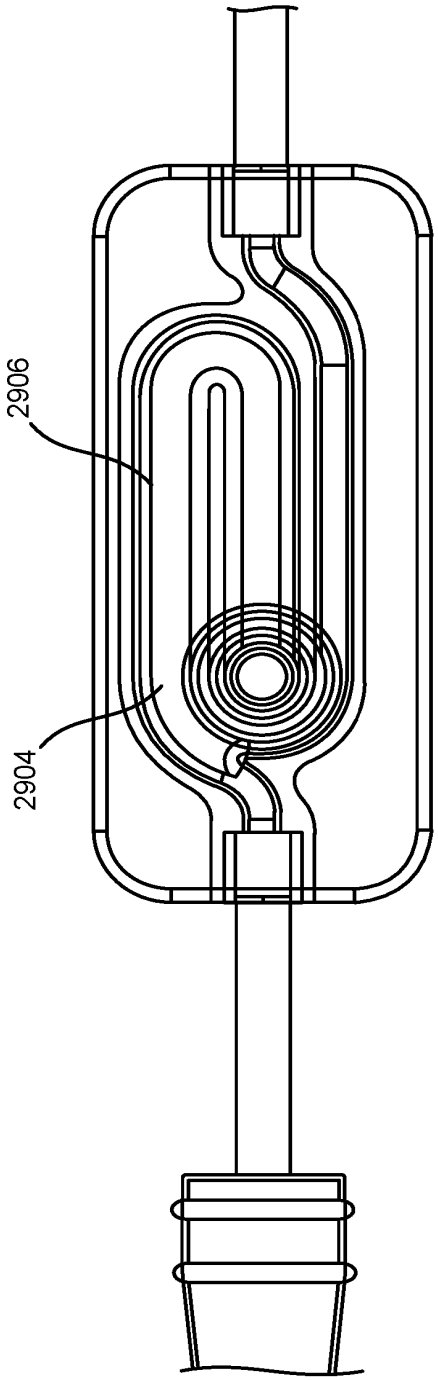


FIG. 29C

Replacement Sheet
66/69

Docket No. KURIN3PCT
PCT/US2017/068569

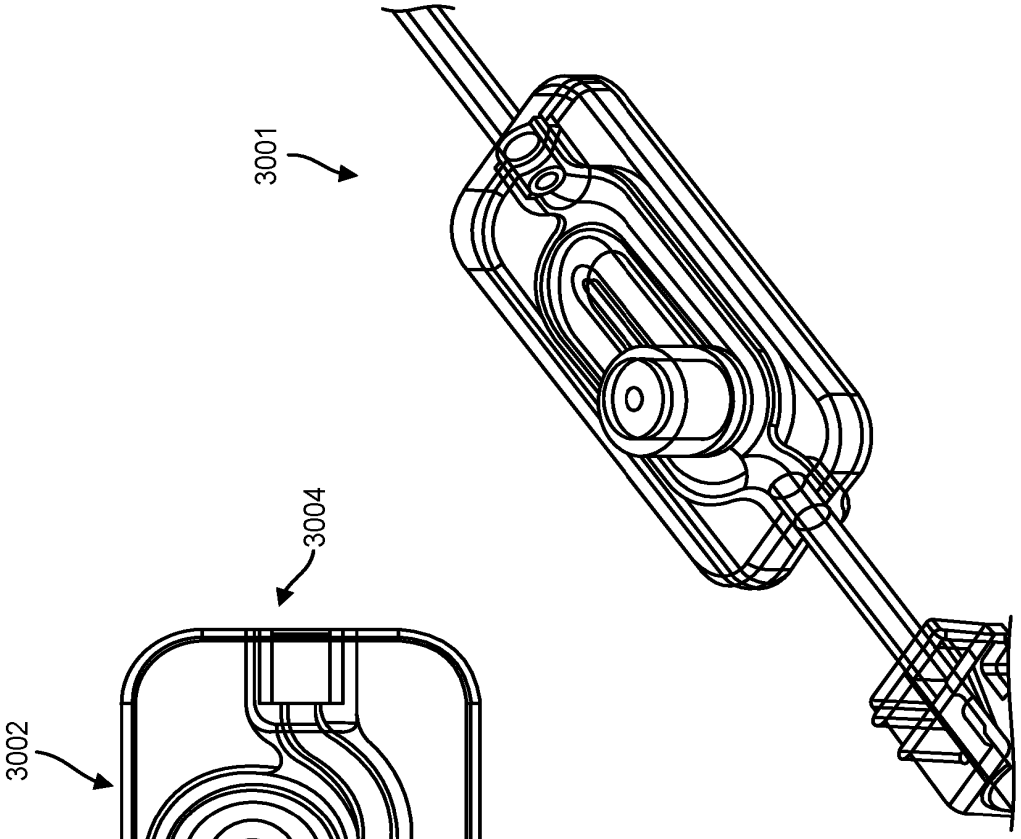


FIG. 30B

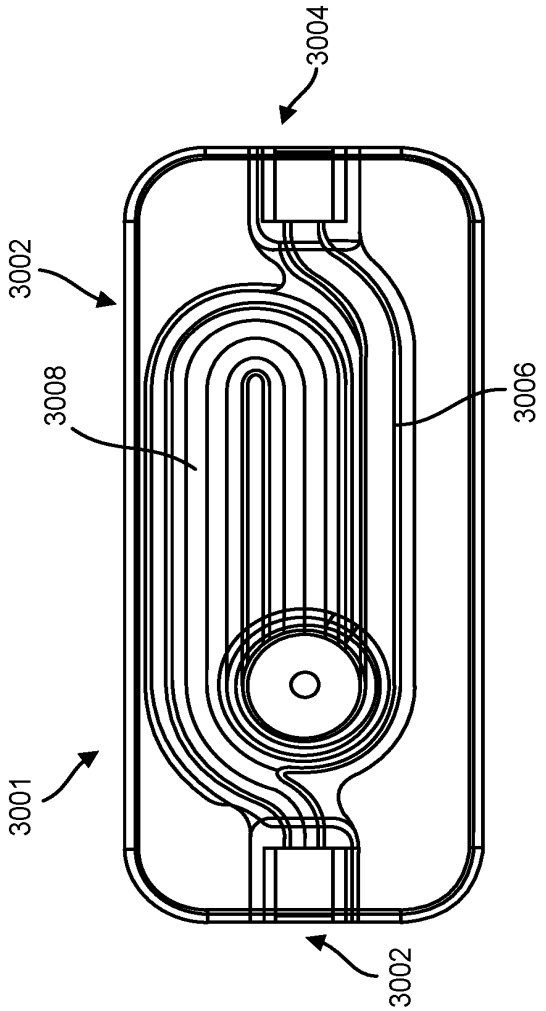


FIG. 30A

Replacement Sheet
67/69

Docket No. KURIN3PCT
PCT/US2017/068569

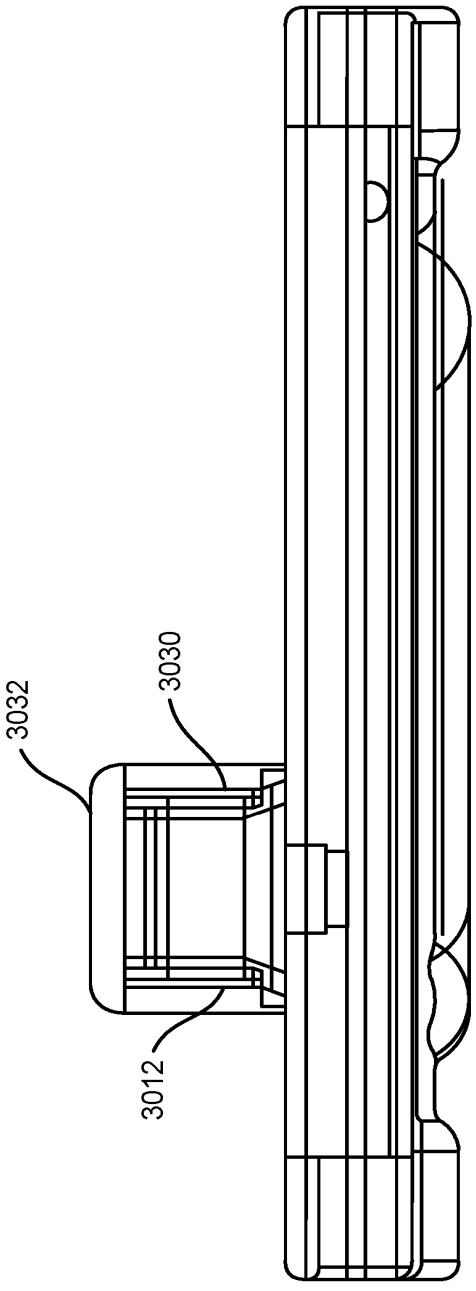


FIG. 30C

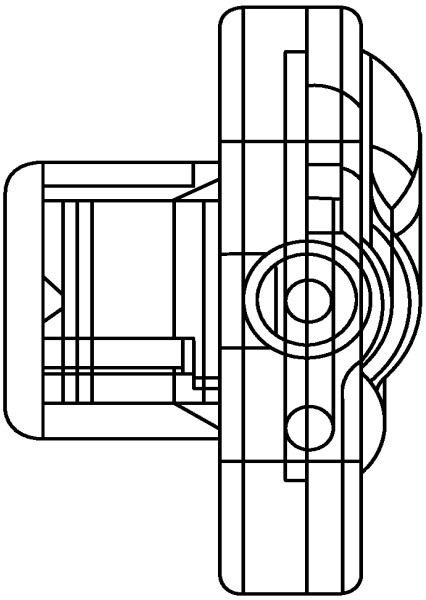


FIG. 30D

Replacement Sheet
68/69

Docket No. KURIN3PCT
PCT/US2017/068569

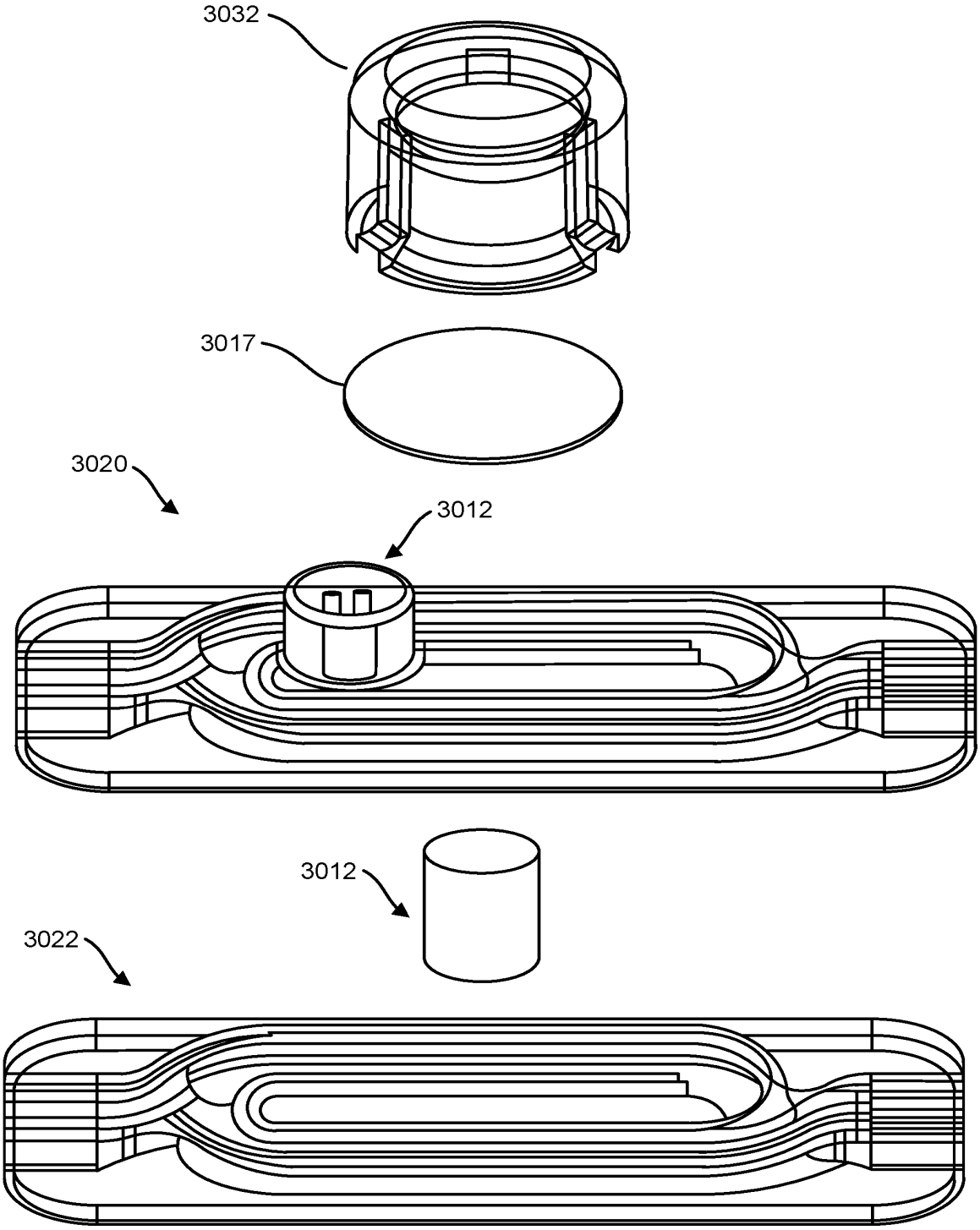


FIG. 30E

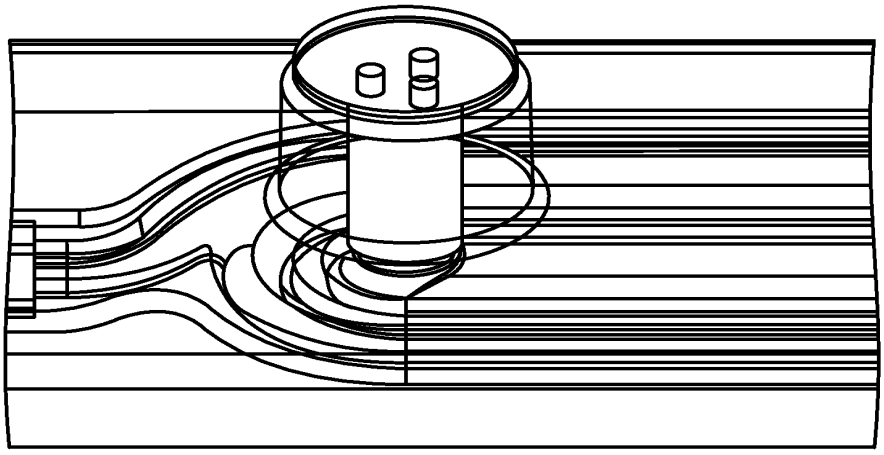


FIG. 30F

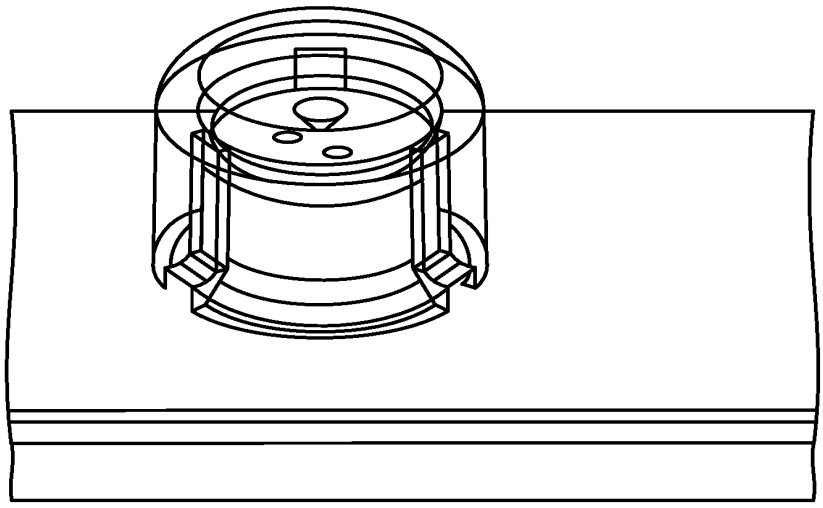


FIG. 30G

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[Continued on next page]

(54) Title: BLOOD DRAWING DEVICE WITH FLASH DETECTION

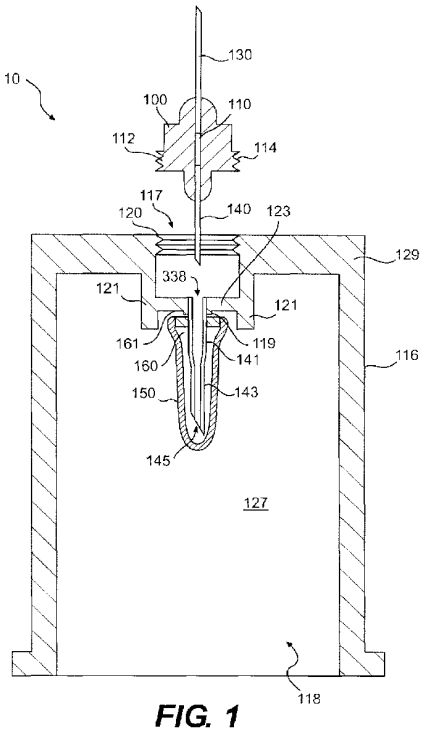


FIG. 1

(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).

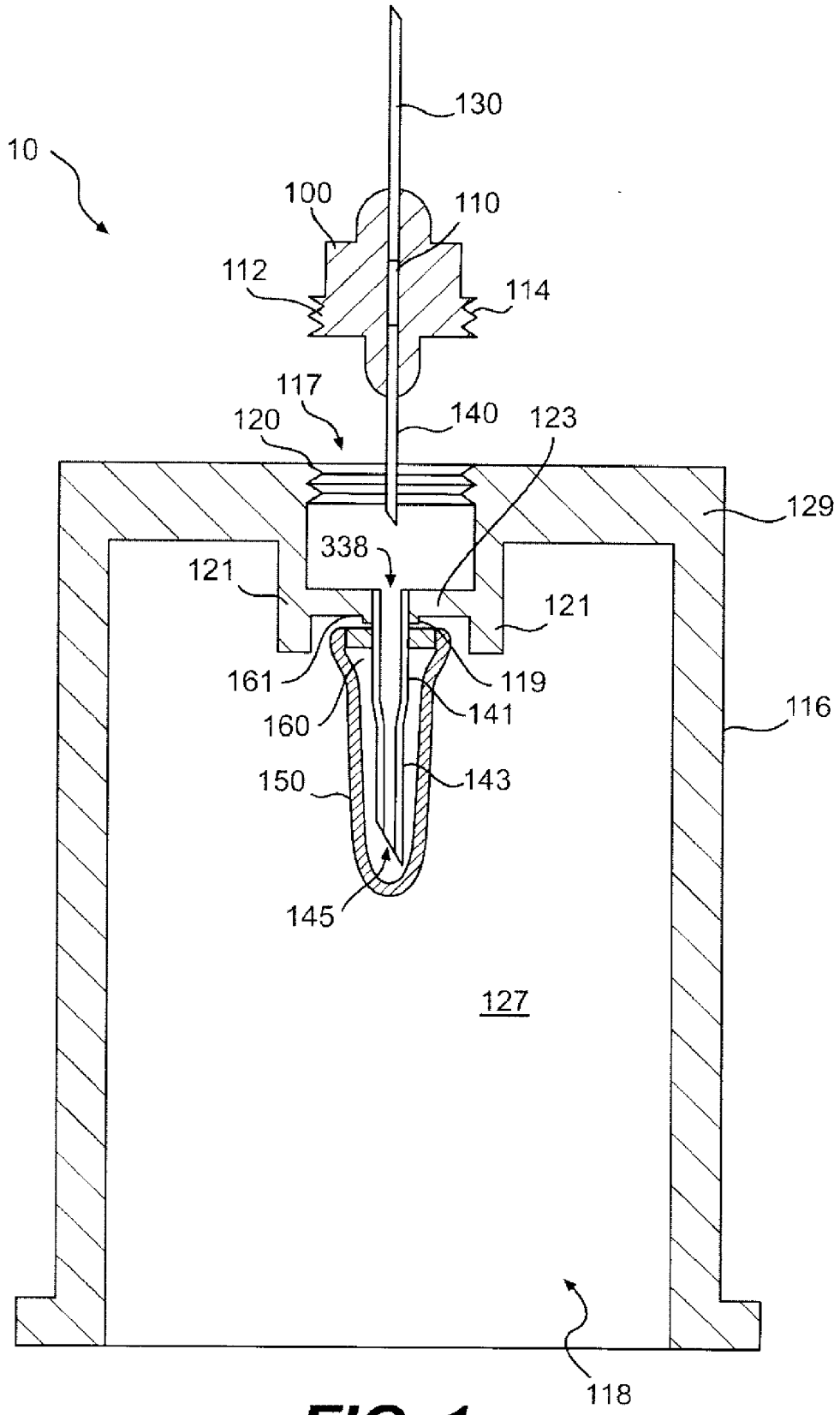

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FIG. 1

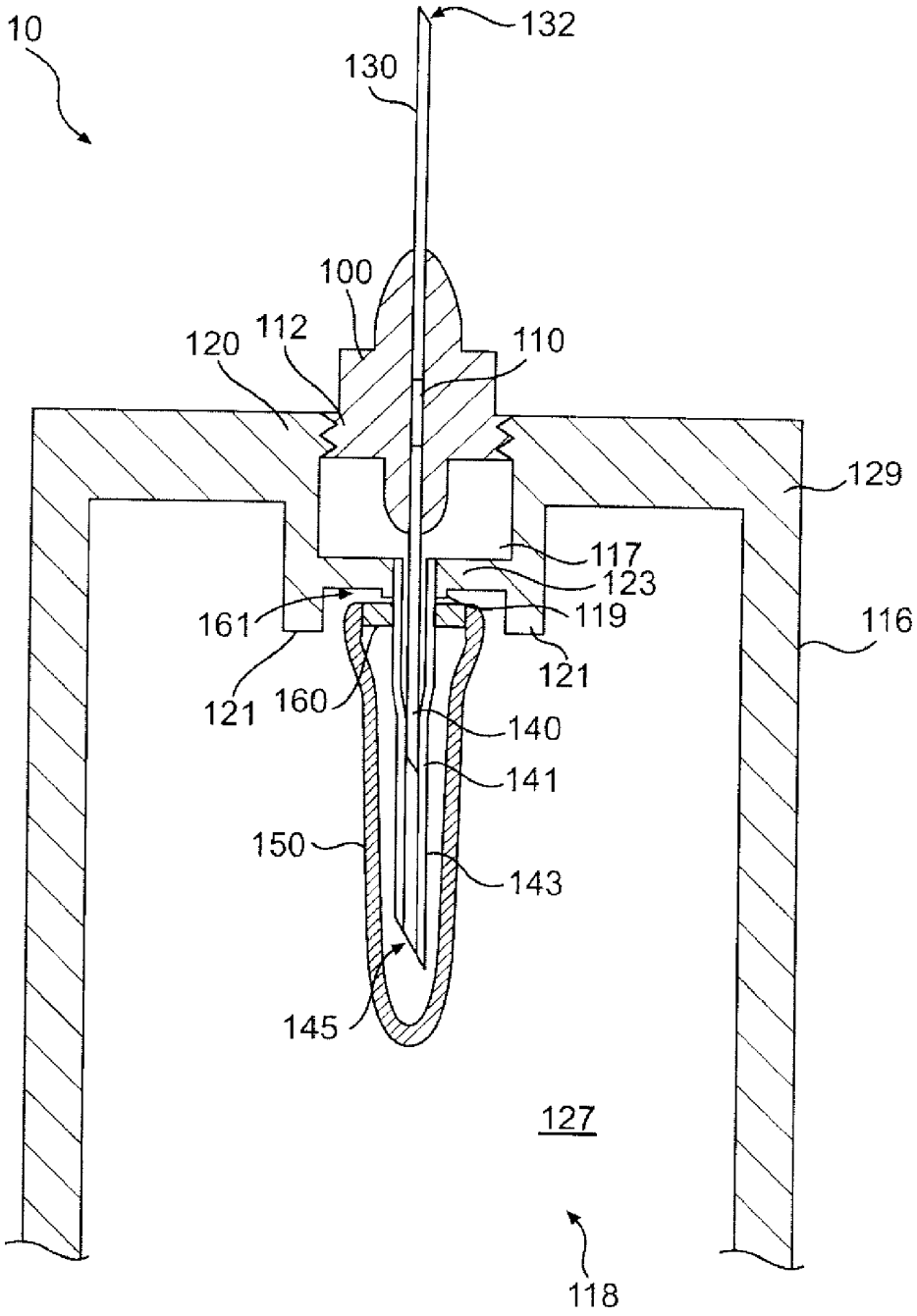

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FIG. 2

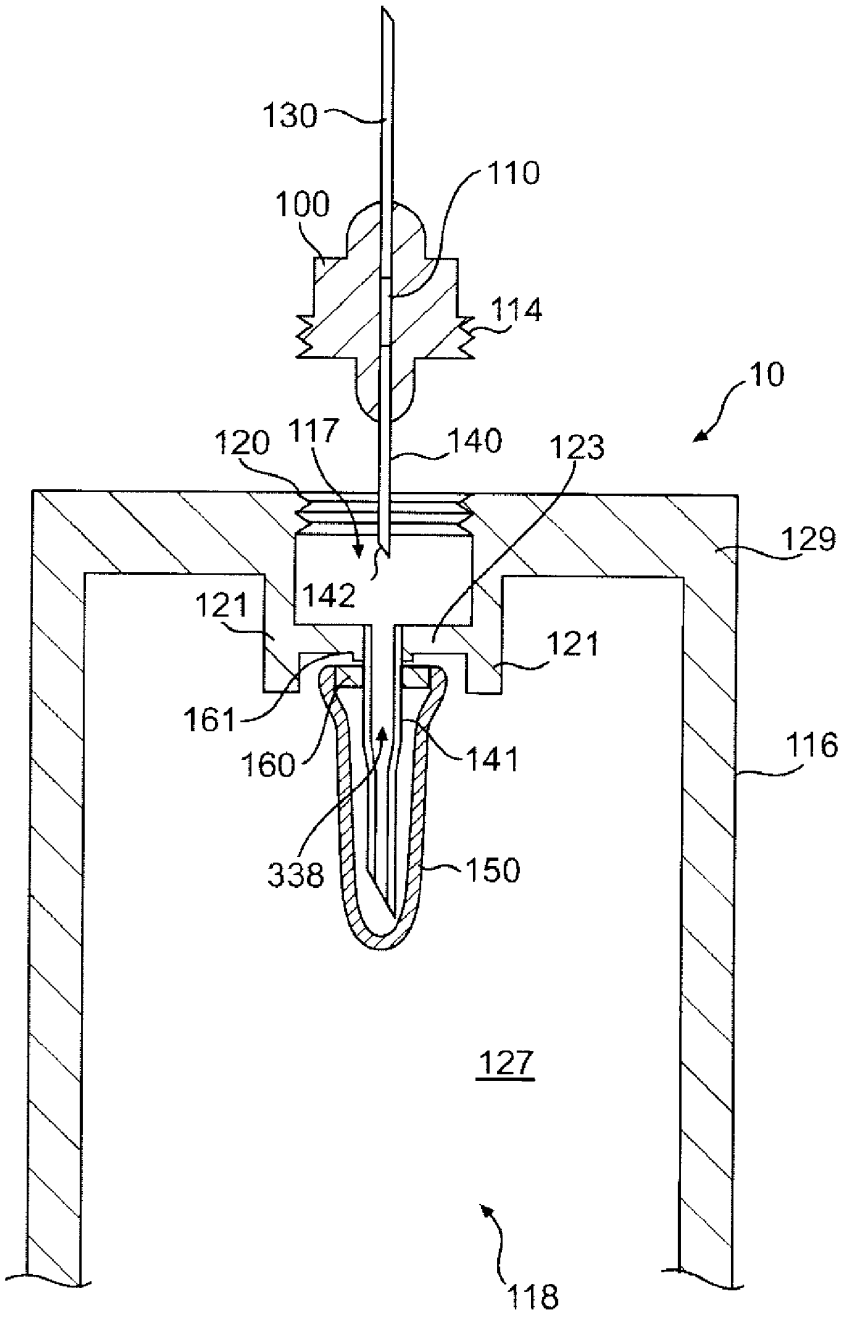


FIG. 3

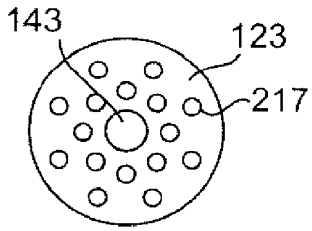


FIG. 4

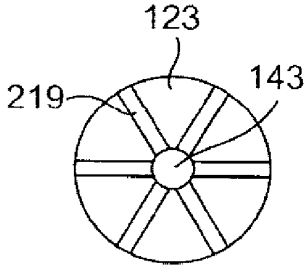


FIG. 5

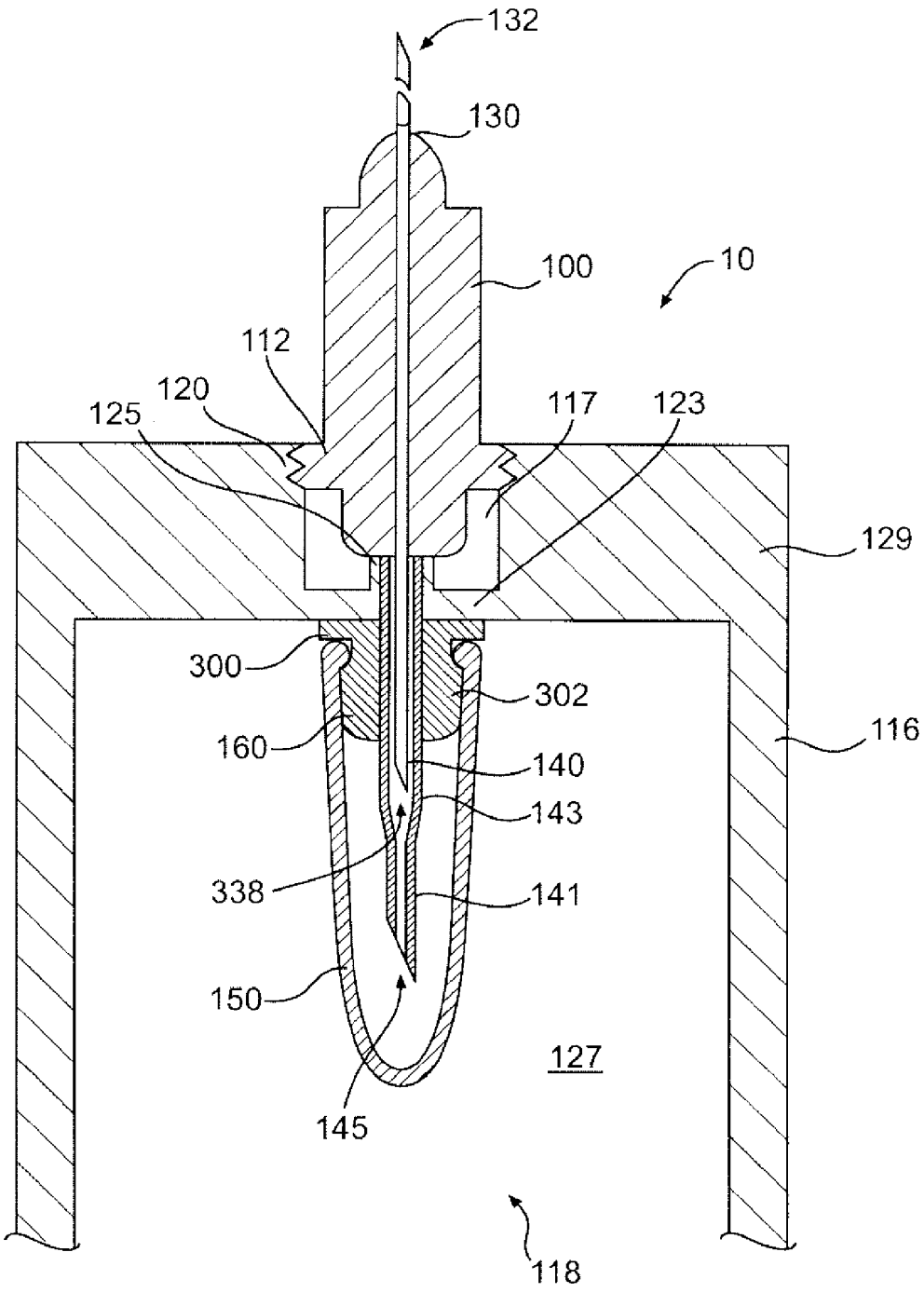

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FIG. 6

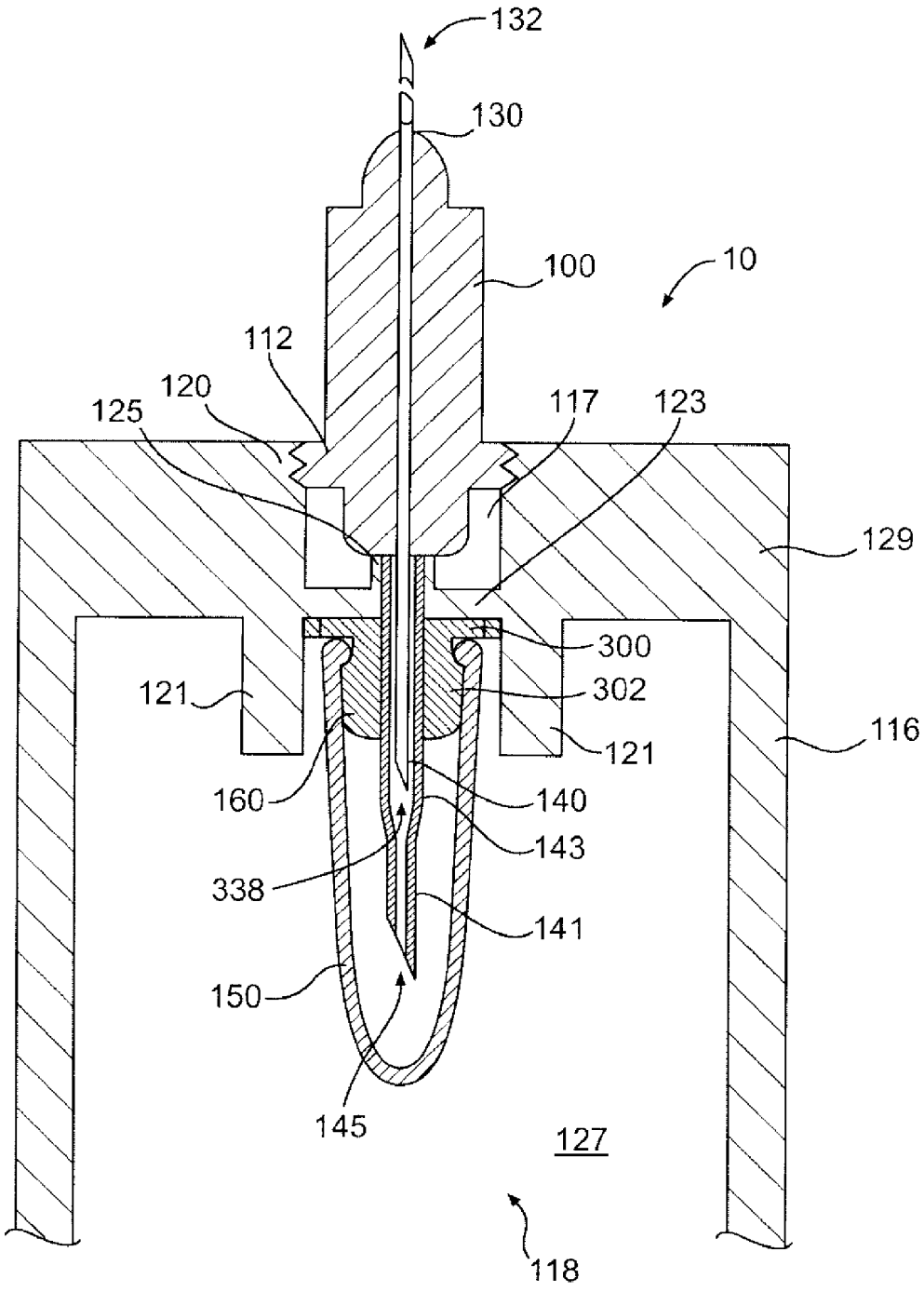

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FIG. 7

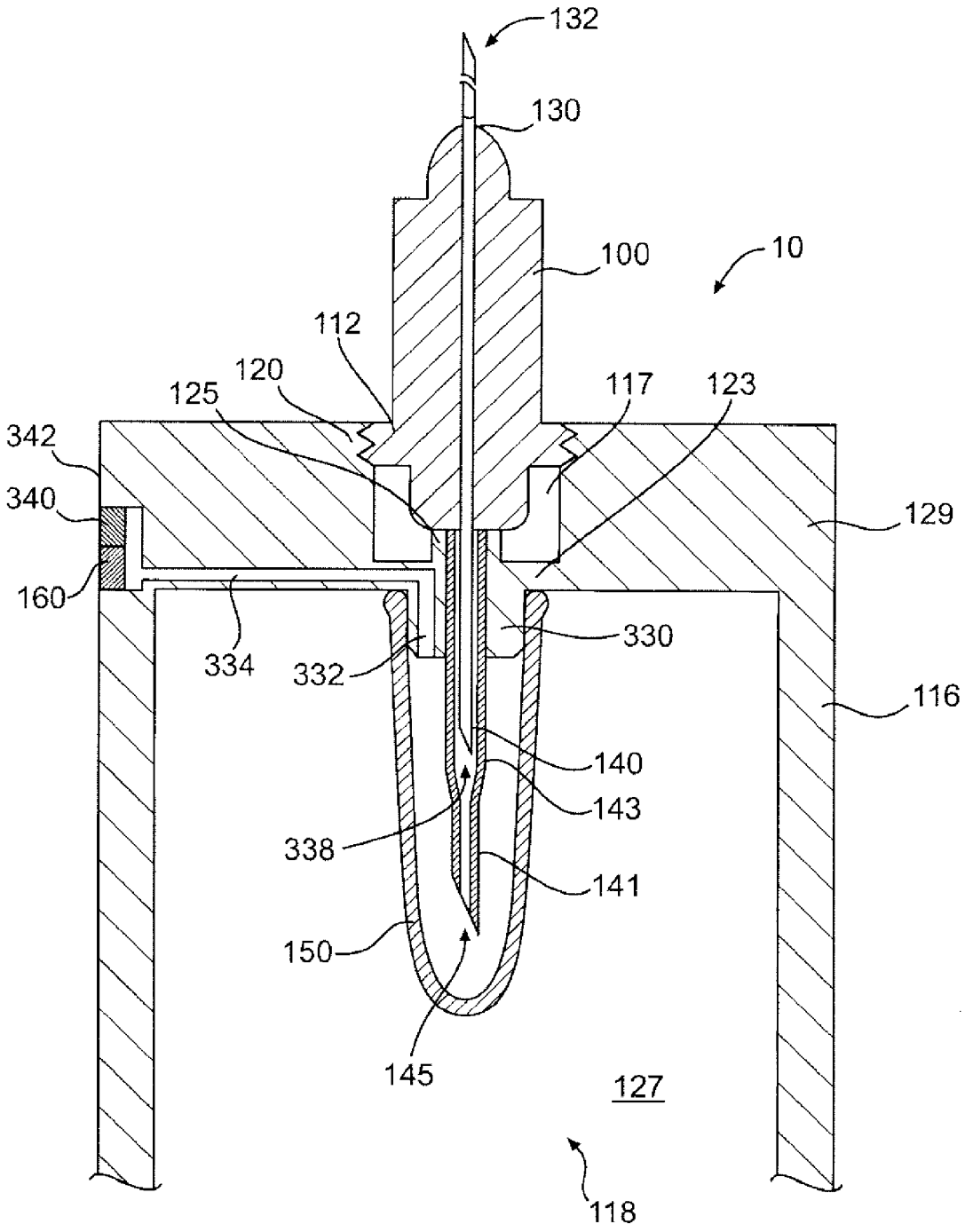

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FIG. 8

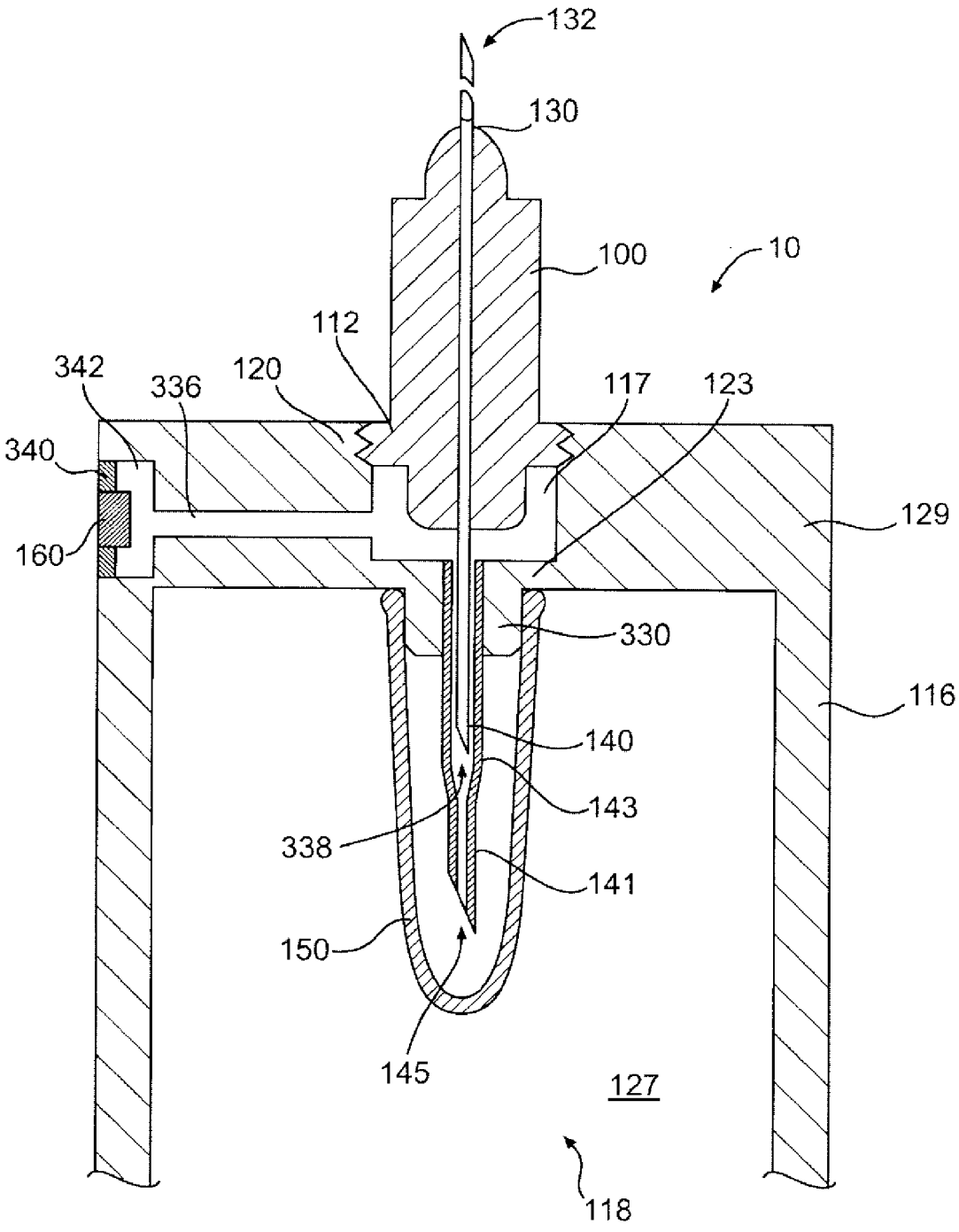

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FIG. 9

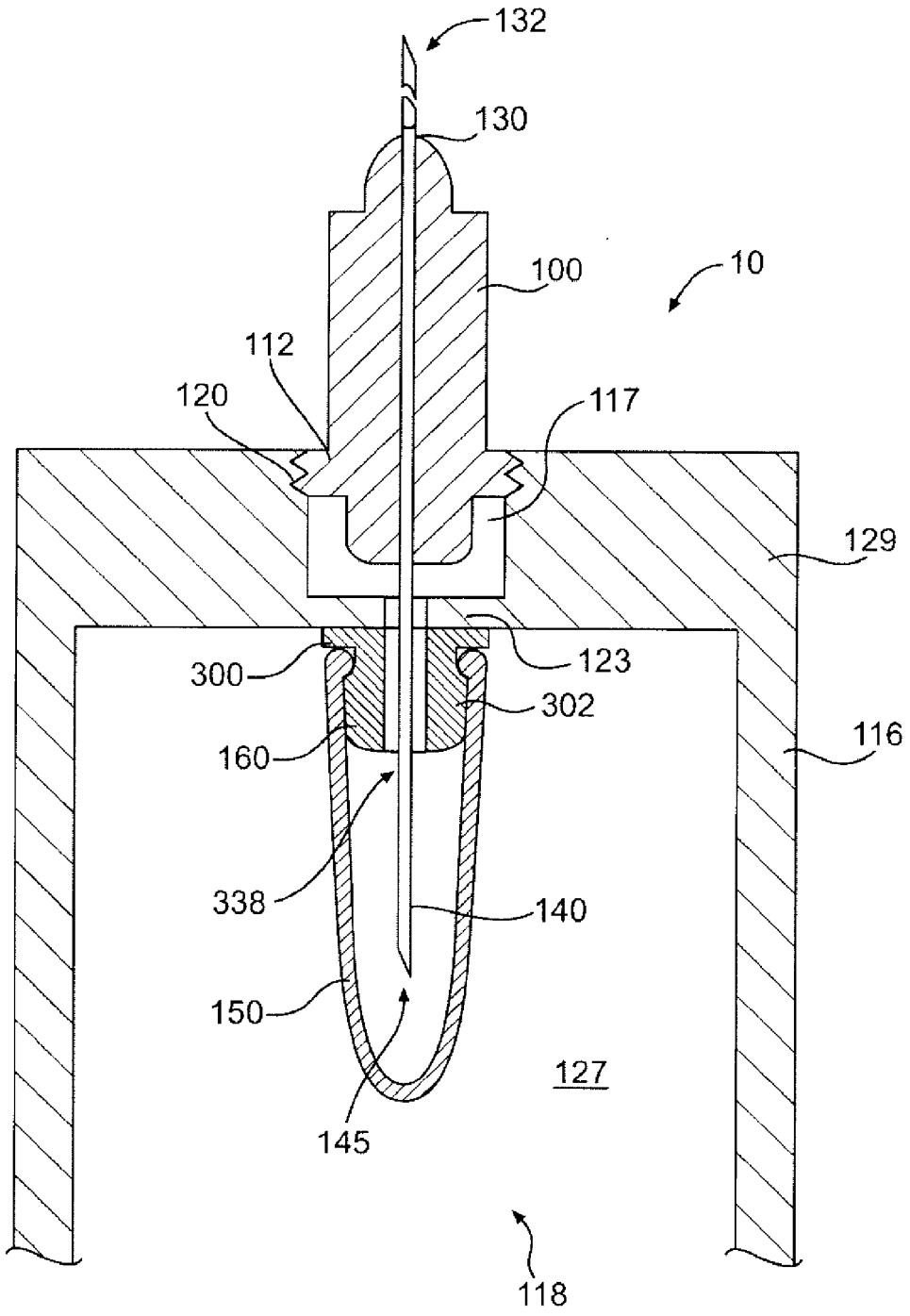

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FIG. 10

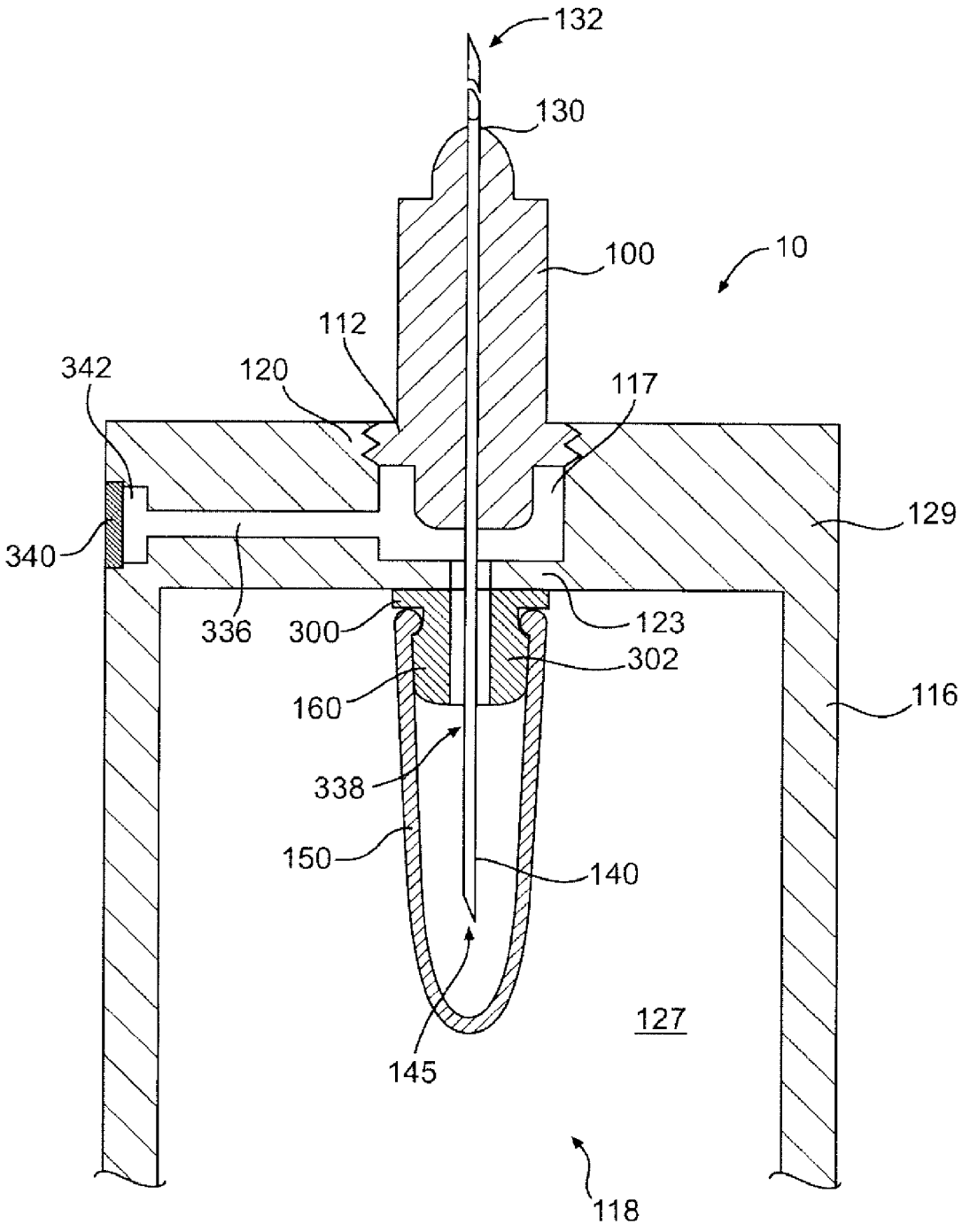

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FIG. 11

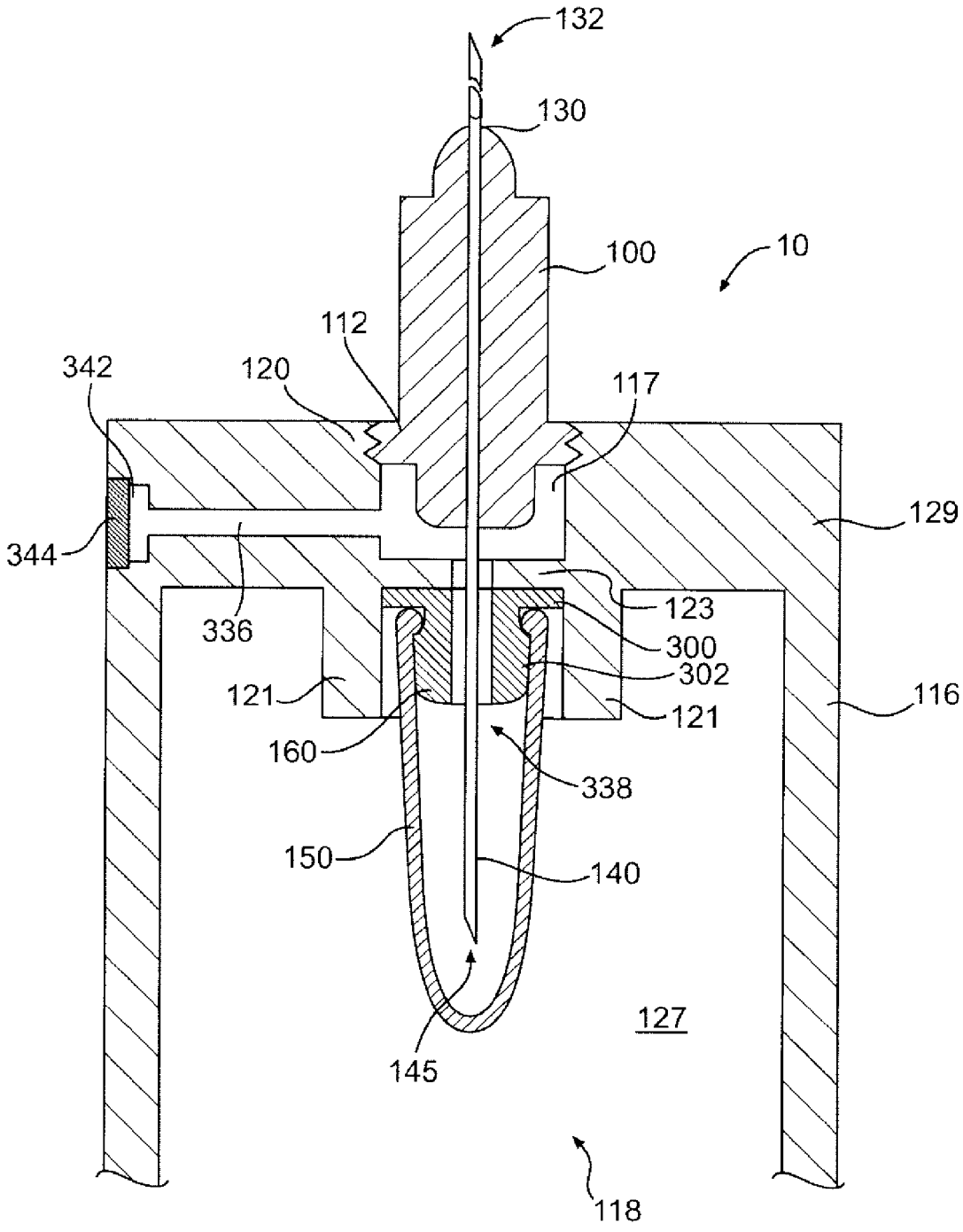

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FIG. 12

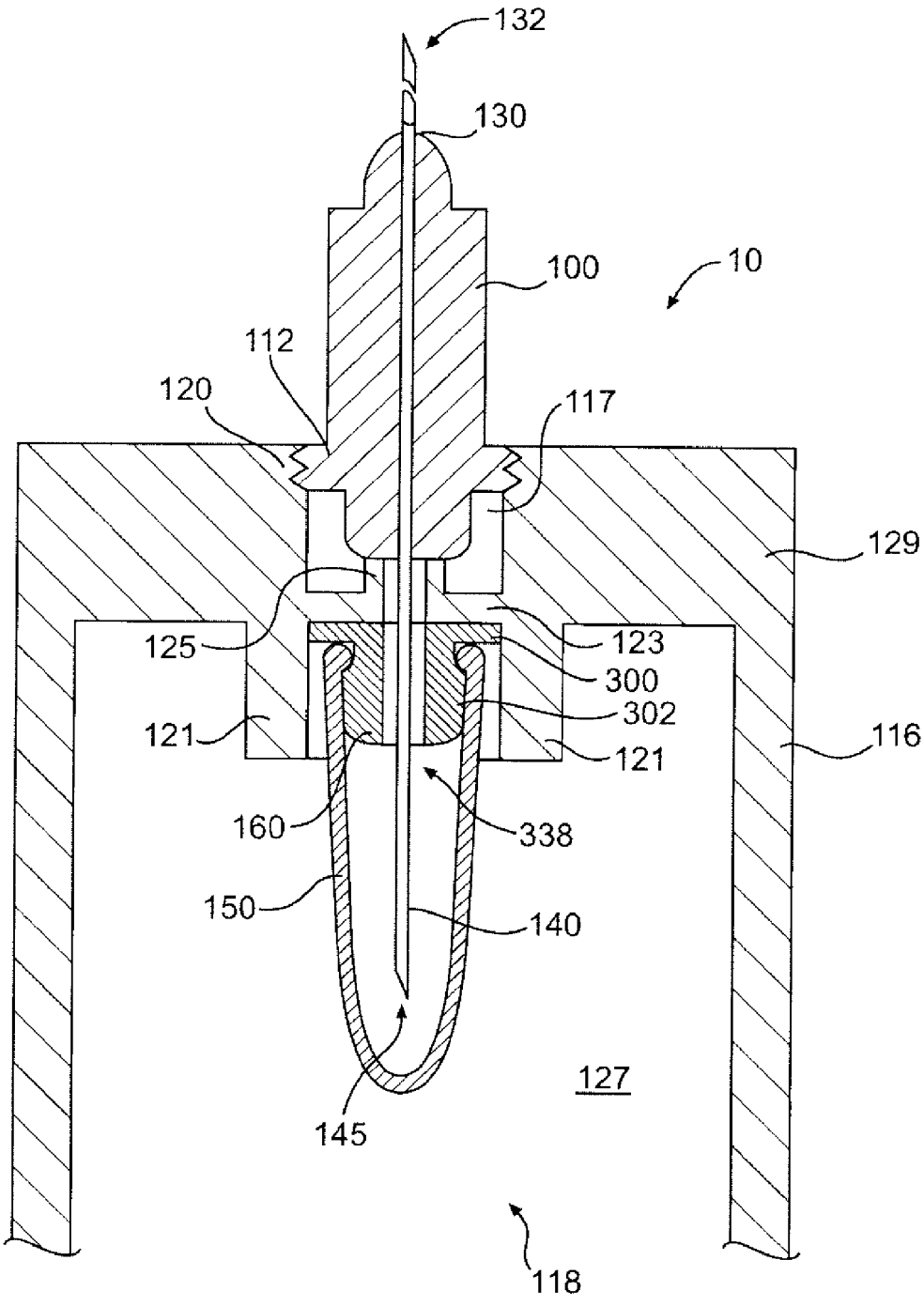

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FIG. 13

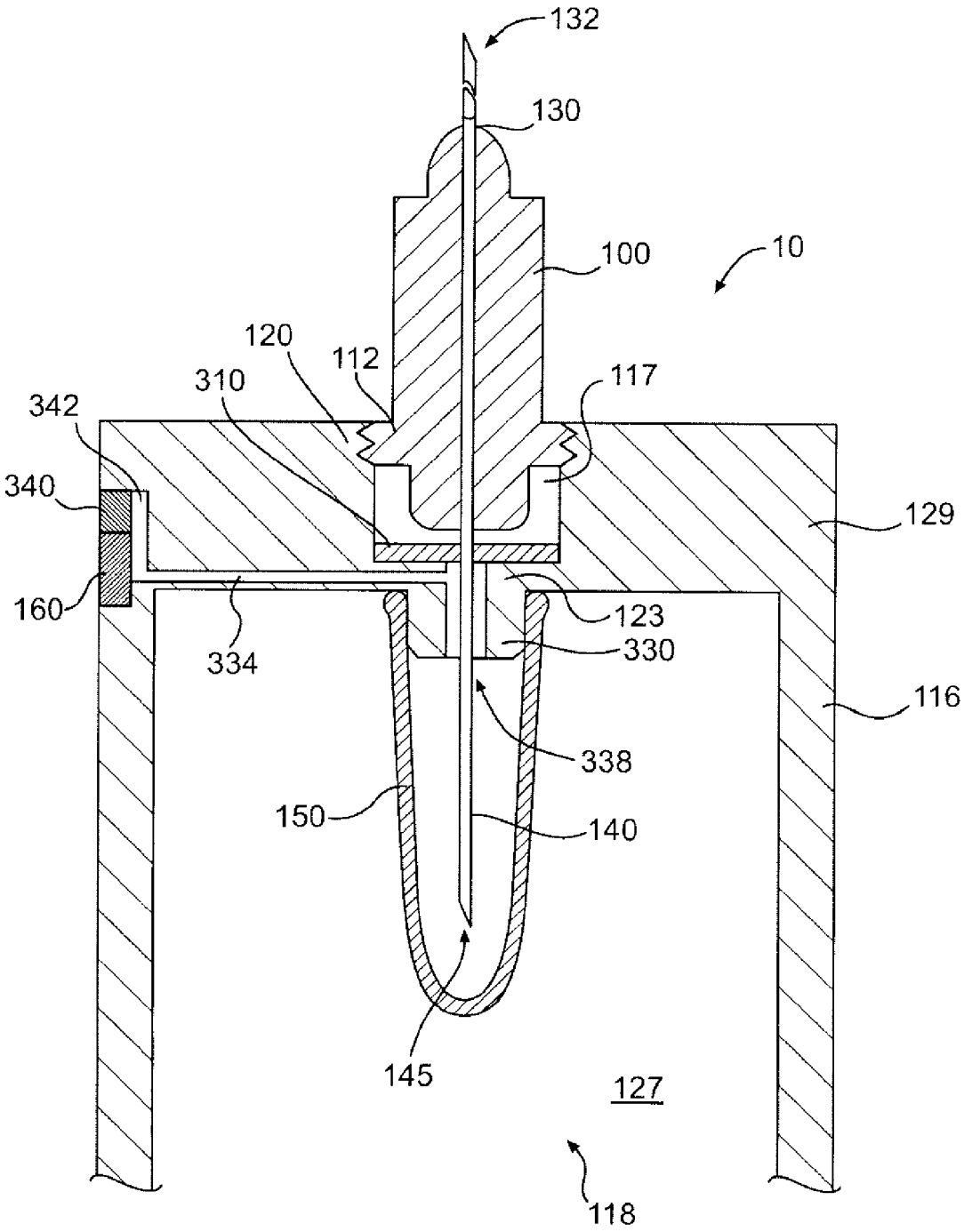

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FIG. 14

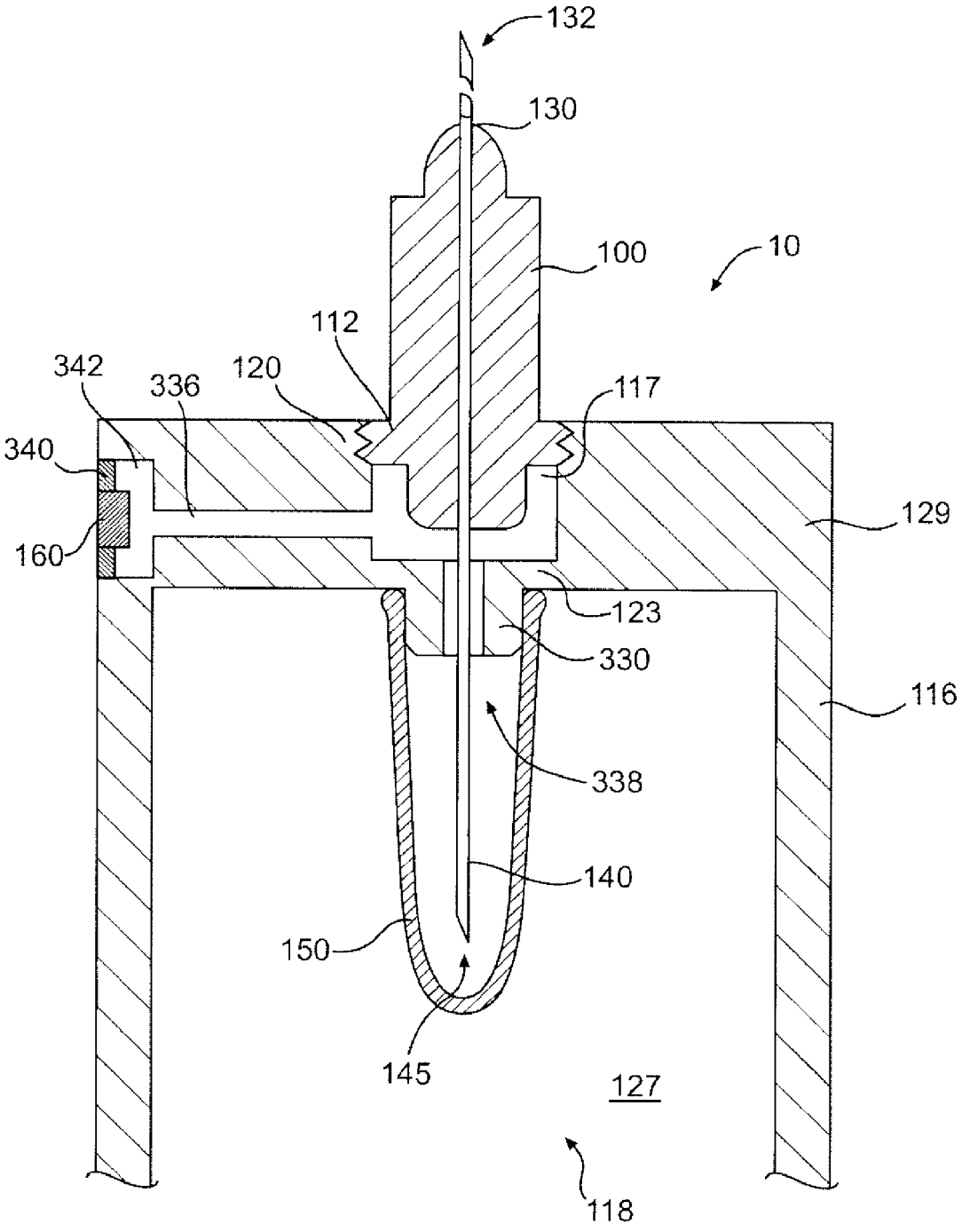

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FIG. 15

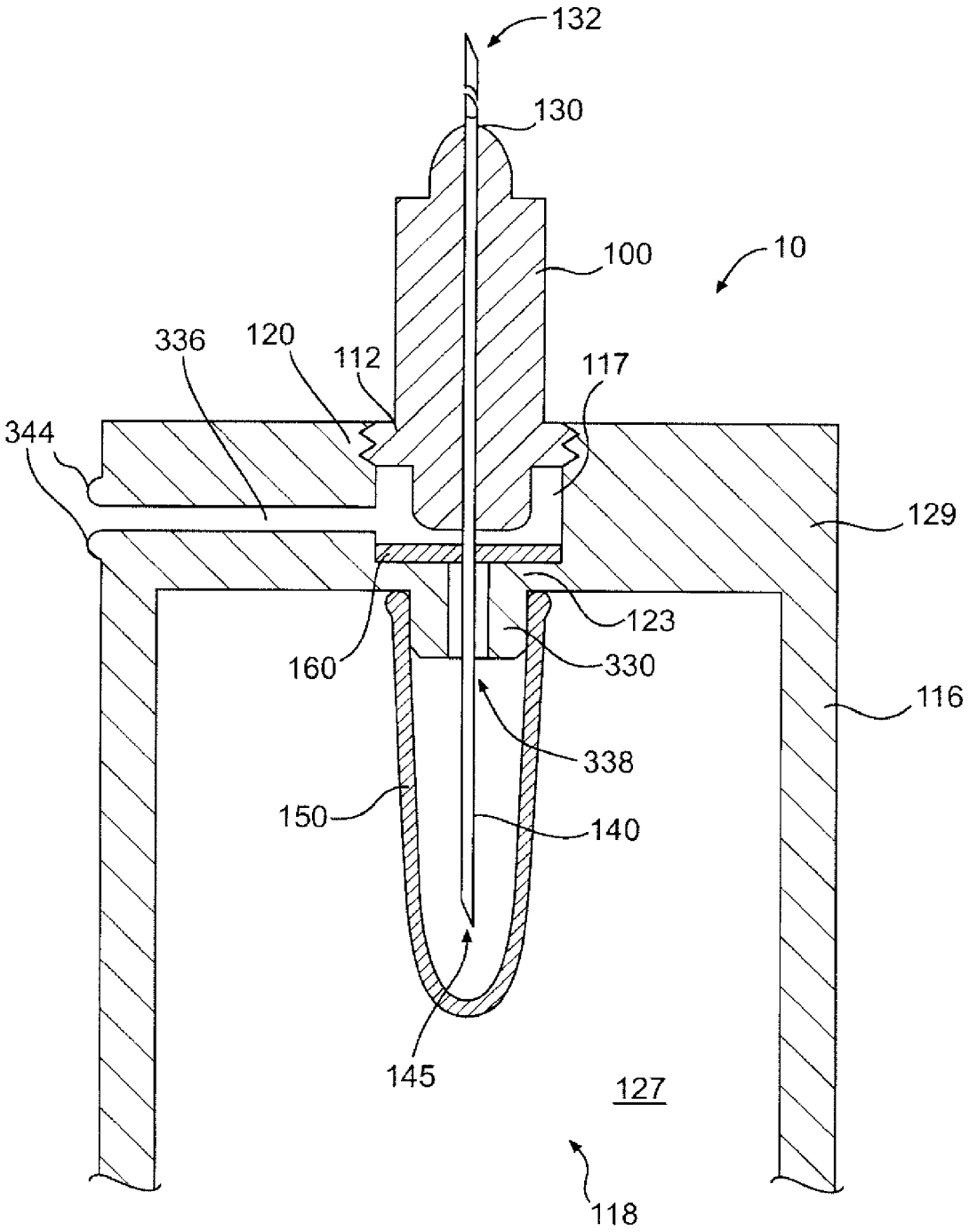

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FIG. 16

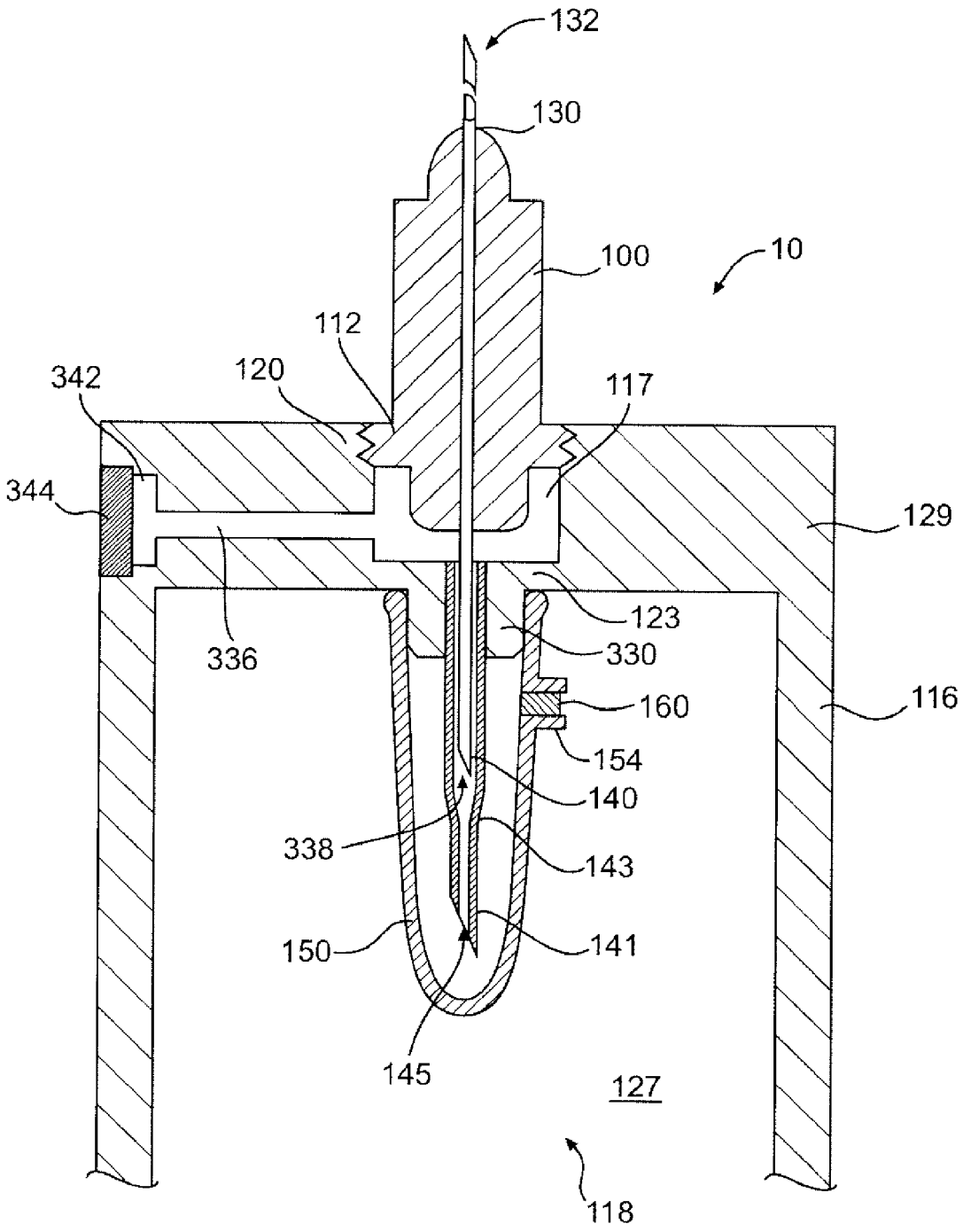

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FIG. 17

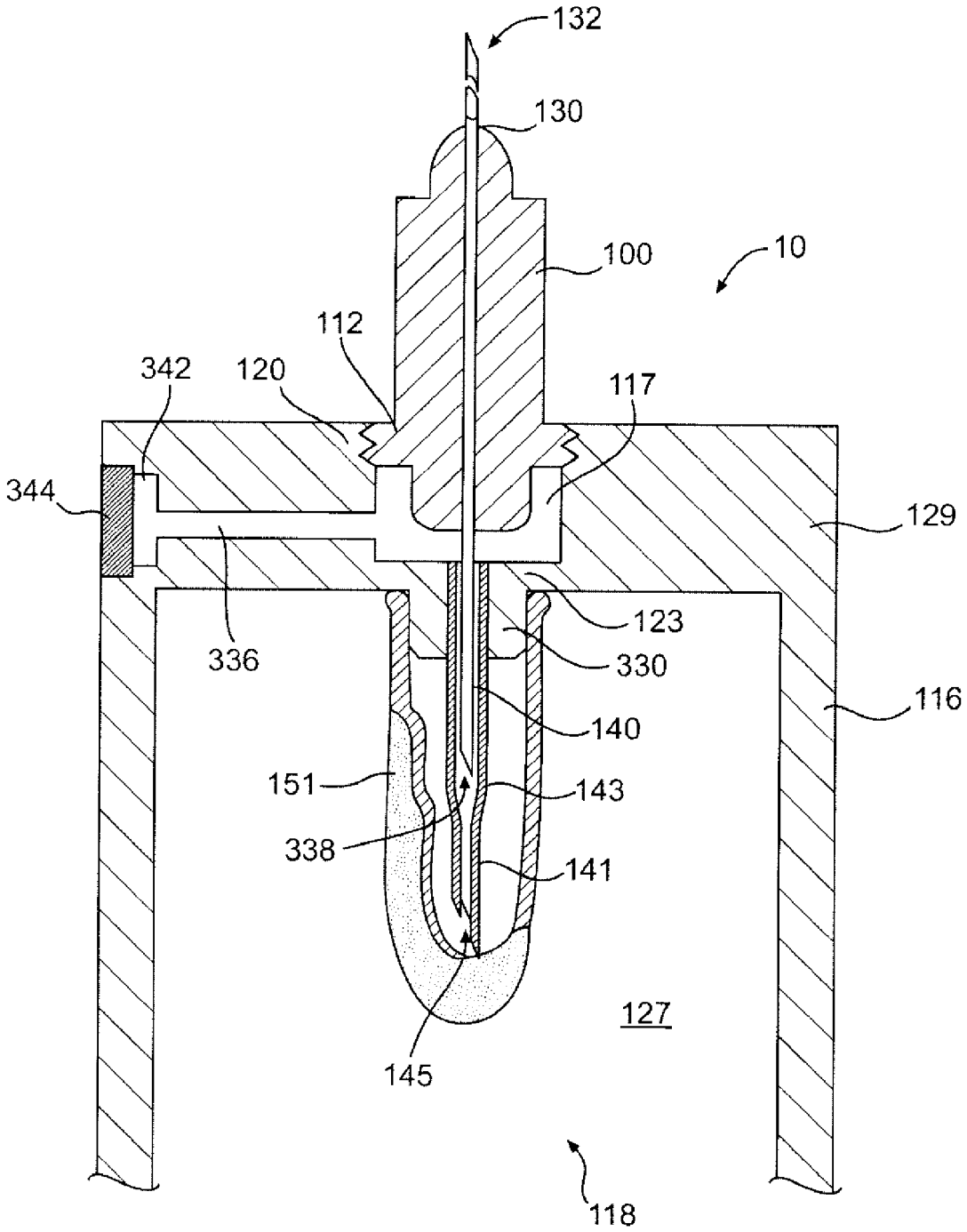

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FIG. 18

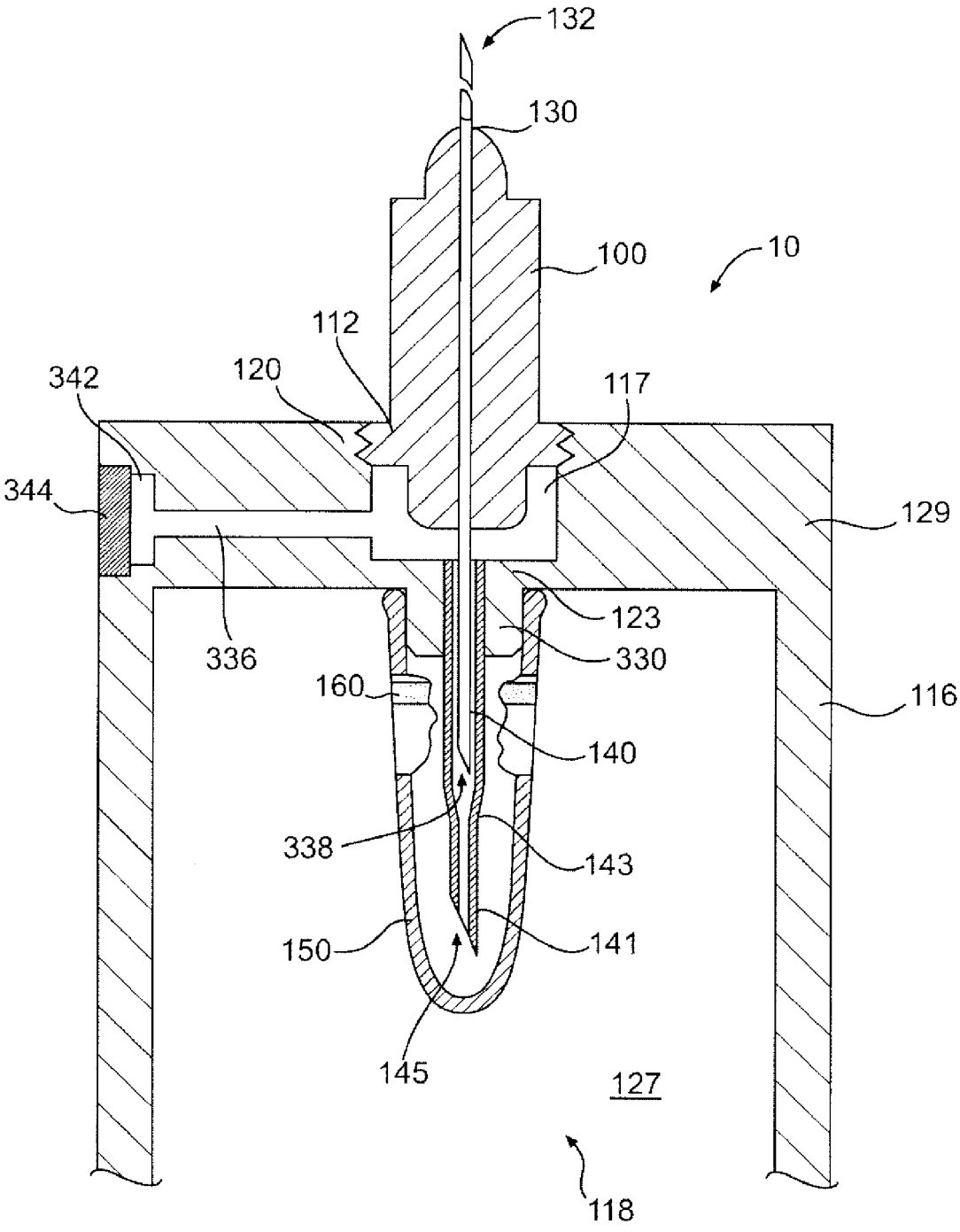

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FIG. 19

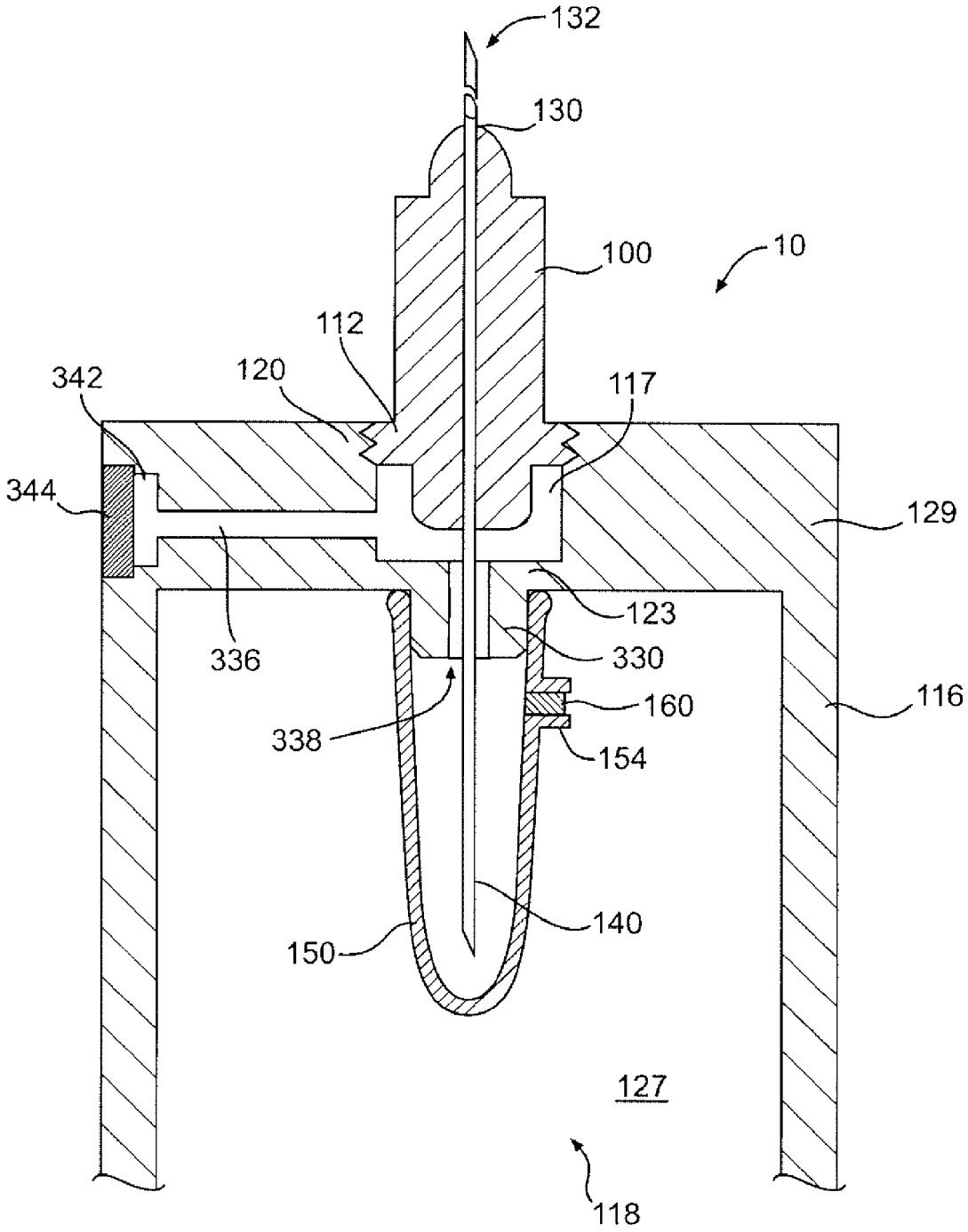

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FIG. 20

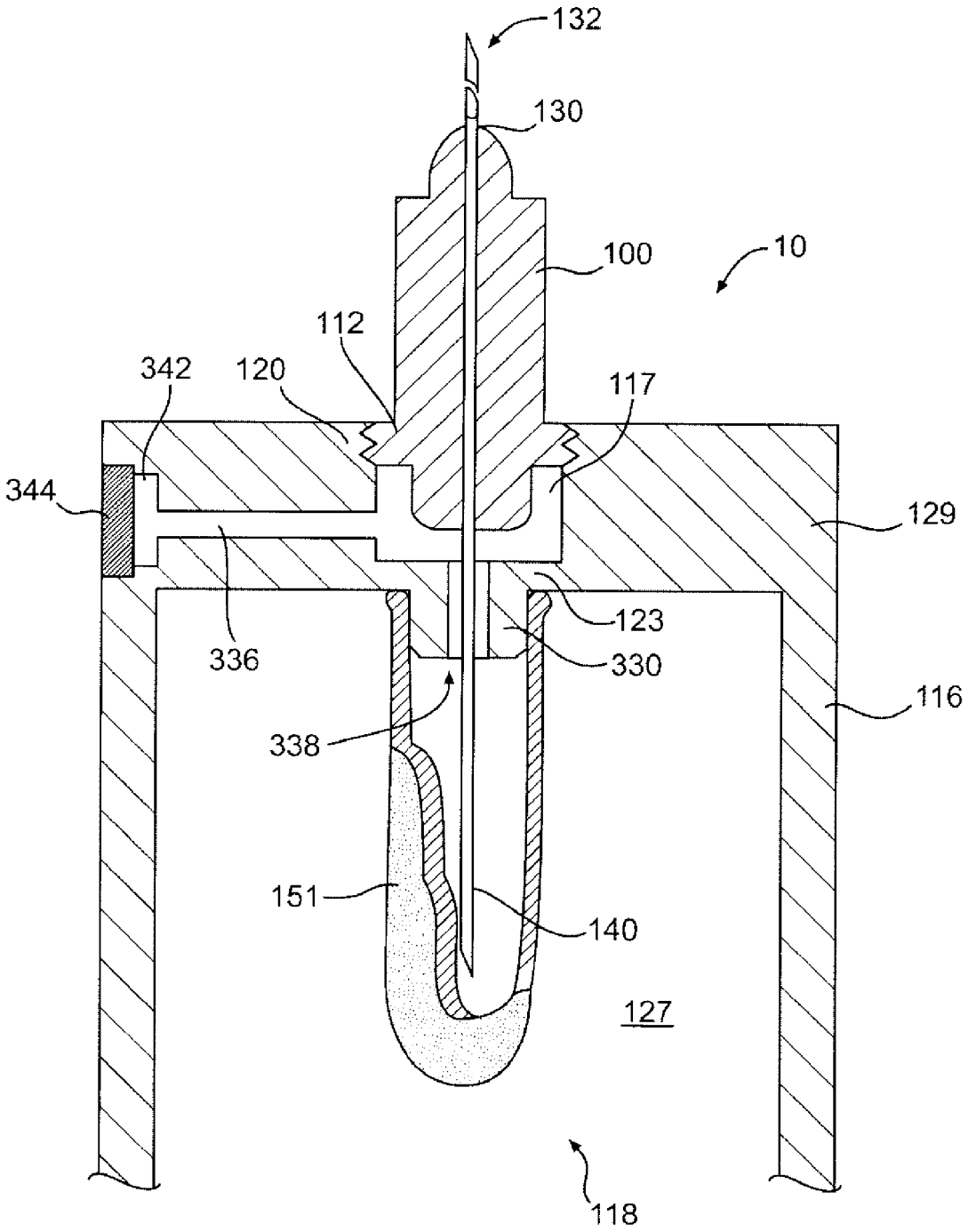

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FIG. 21

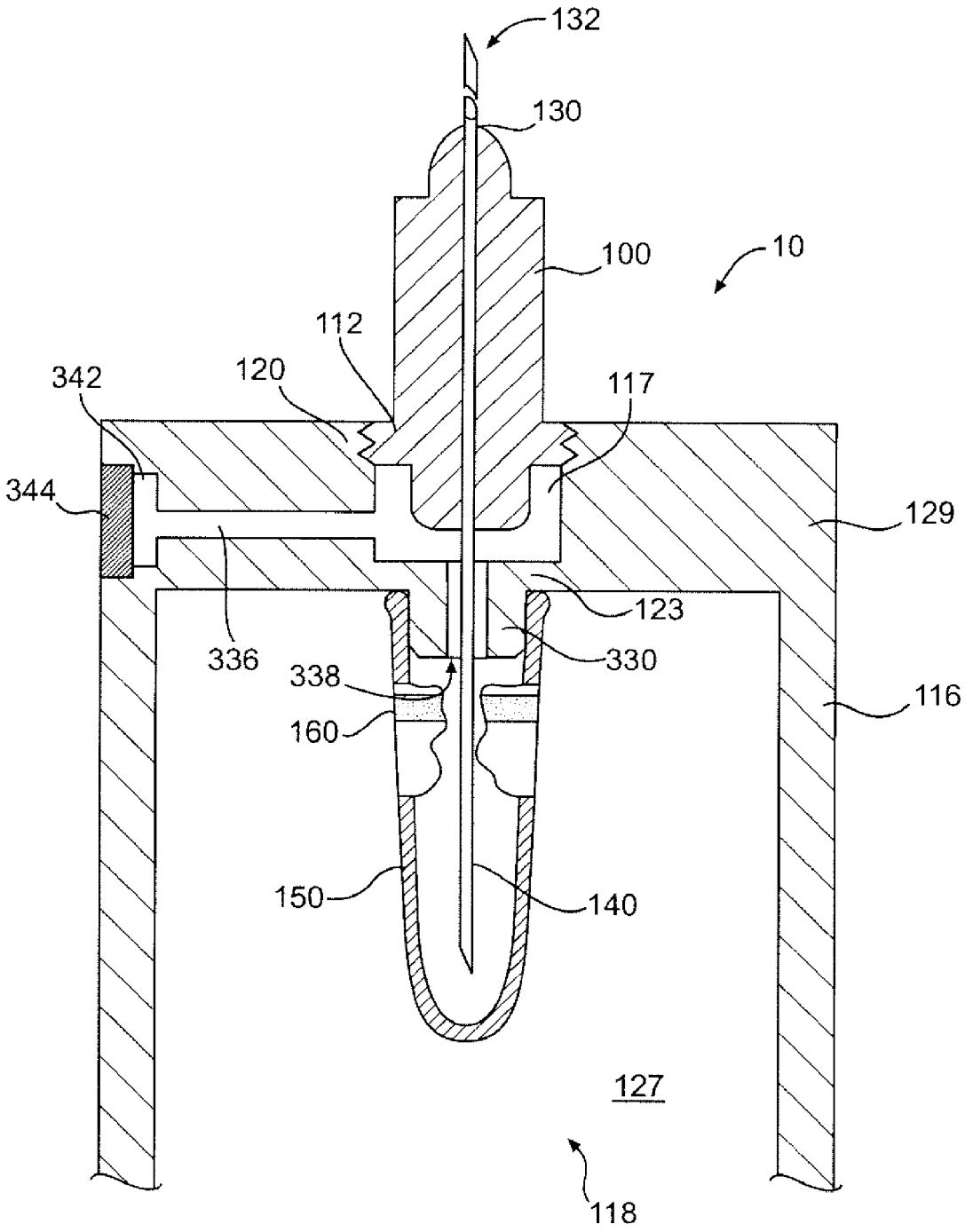

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FIG. 22

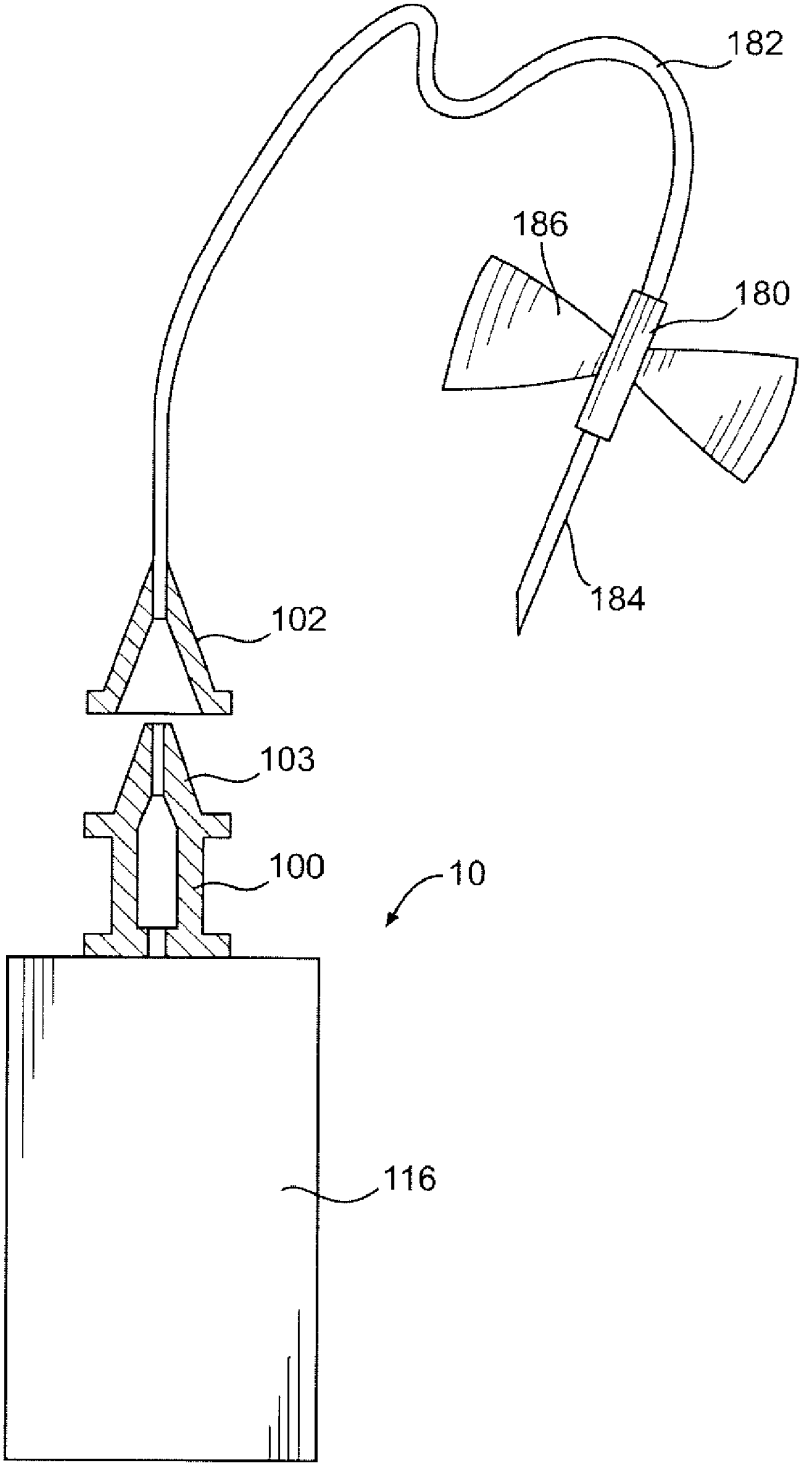


FIG. 23

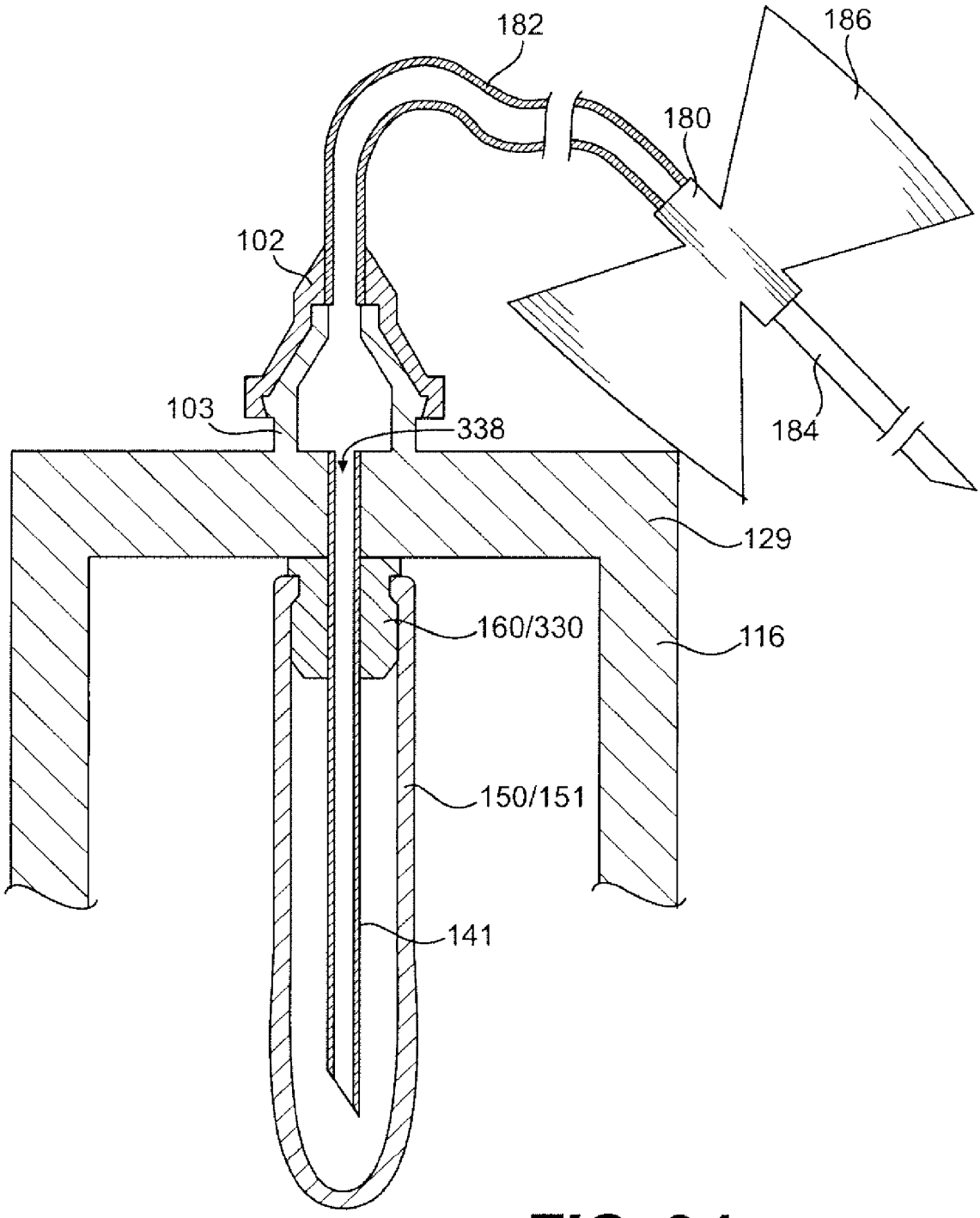


FIG. 24

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:
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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
"&" 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

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62/318,194	4 April 2016 (04.04.2016)	US
15/140,448	27 April 2016 (27.04.2016)	US
15/140,443	27 April 2016 (27.04.2016)	US

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(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

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— *with international search report (Art. 21(3))*

(54) Title: BLOOD SAMPLE OPTIMIZATION SYSTEM AND BLOOD CONTAMINANT SEQUESTRATION DEVICE AND METHOD

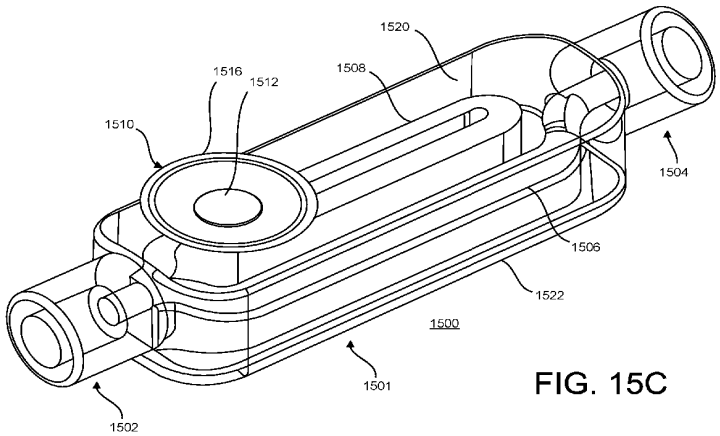


FIG. 15C

(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 (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.

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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," 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.

CLAIMS

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 claim 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 claim 1, wherein the sequestration chamber includes a sequestration channel defined in the housing.

4. The blood sequestration device in accordance with claim 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 claim 3, 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 claim 1, 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 claim 3, 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 claim 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 claim 8, 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 claim 8, 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 claim 8, wherein the sequestration chamber includes a sequestration channel defined in the housing.

13. The blood sequestration device in accordance with claim 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 claim 8, 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 claim 8, 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 claim 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 claim 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 claim 17, 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 claim 17, wherein the air permeable blood barrier includes an air permeable material that seals upon contact with blood.

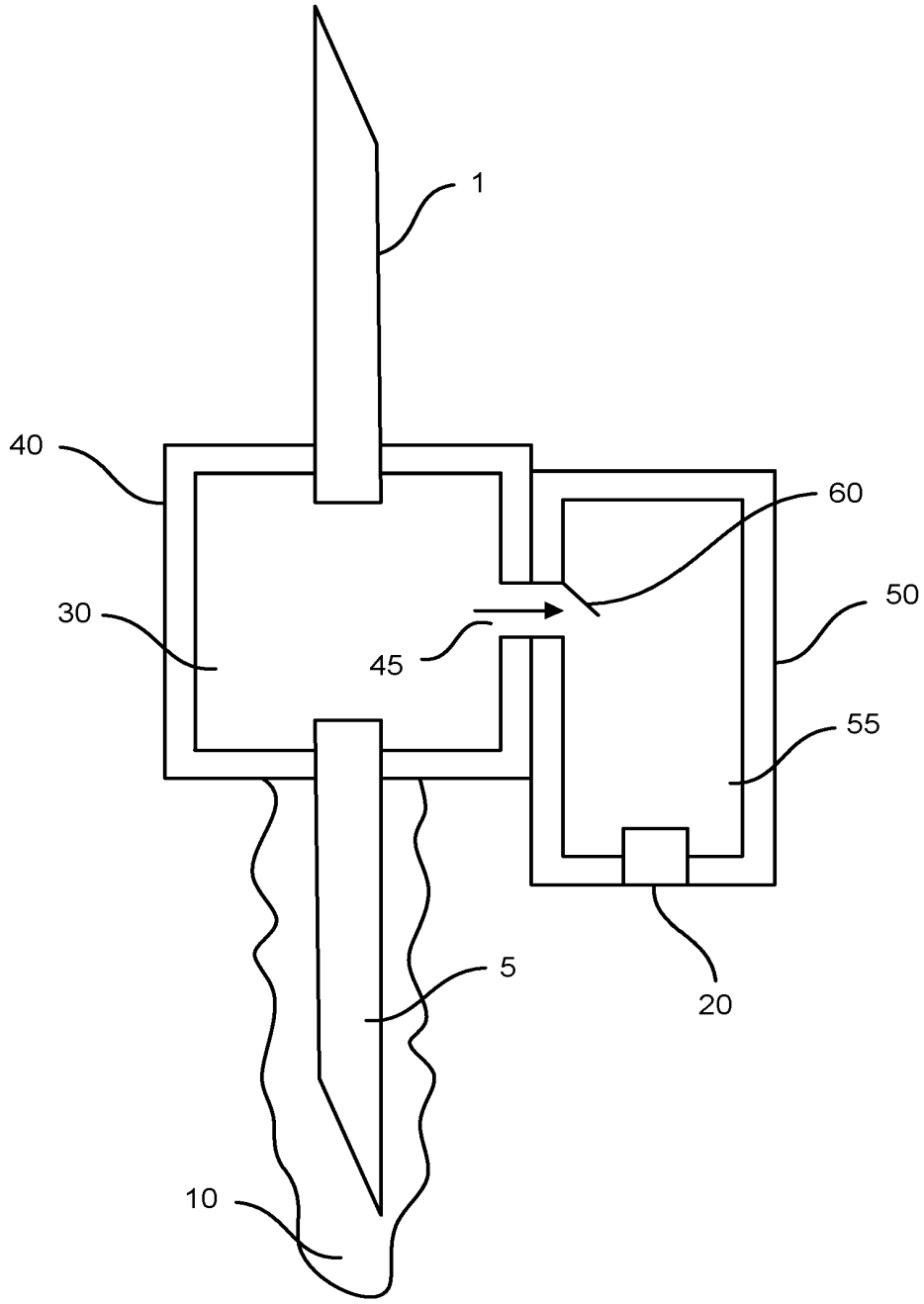


FIG. 1

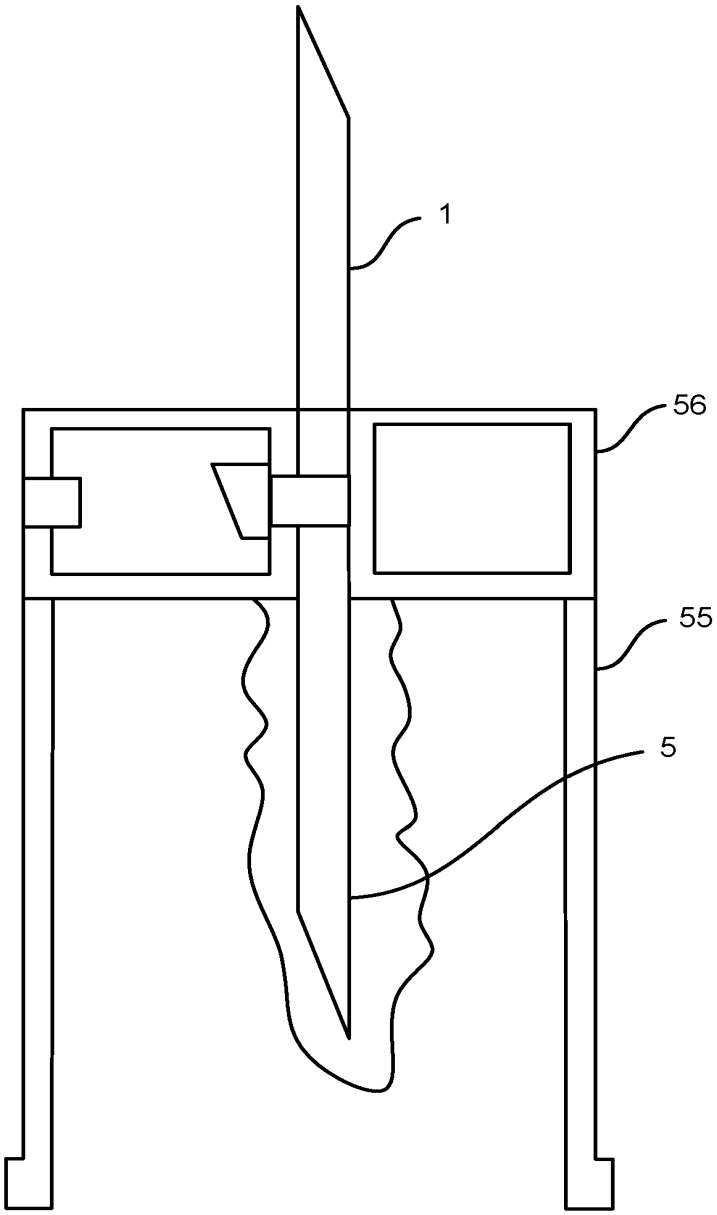


FIG. 2

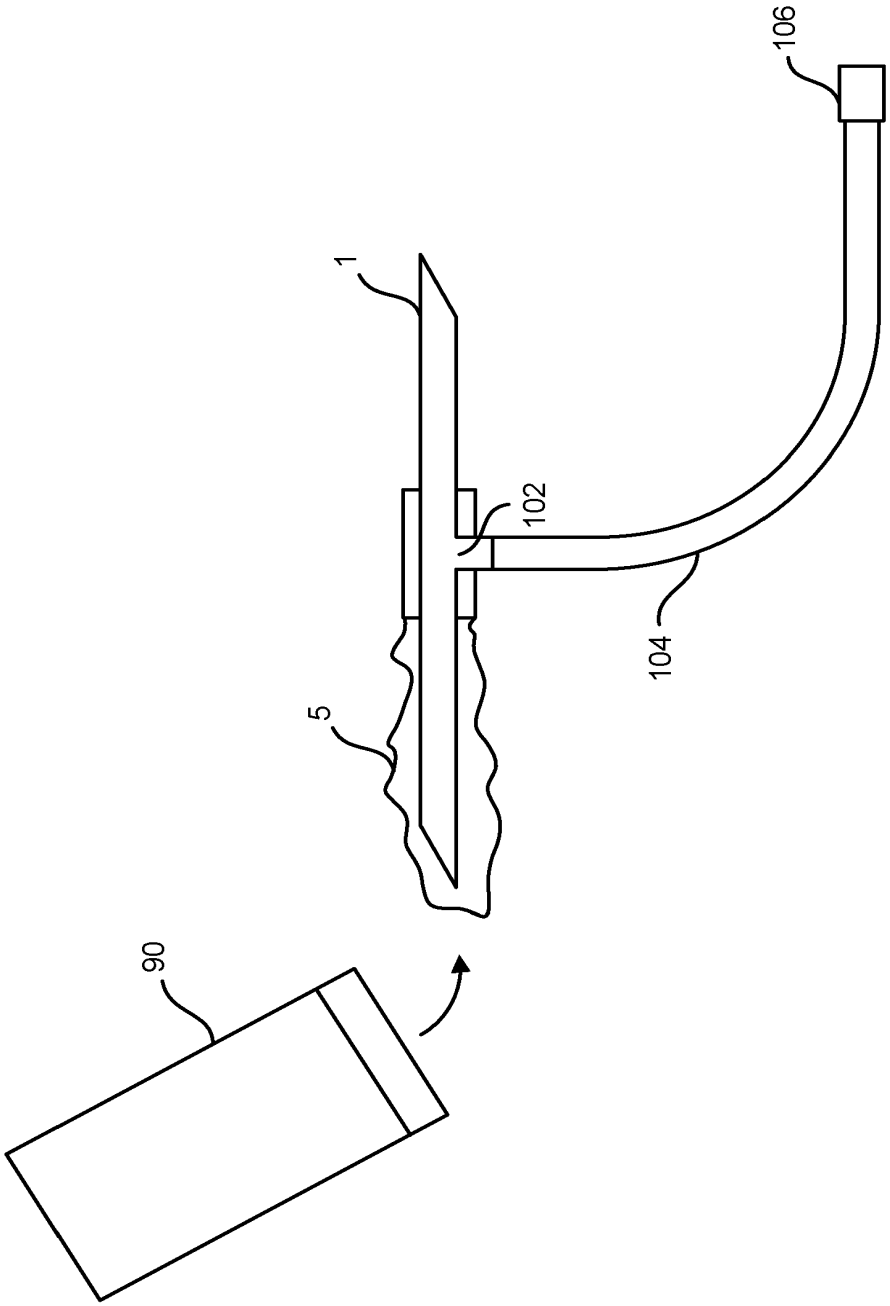


FIG. 3

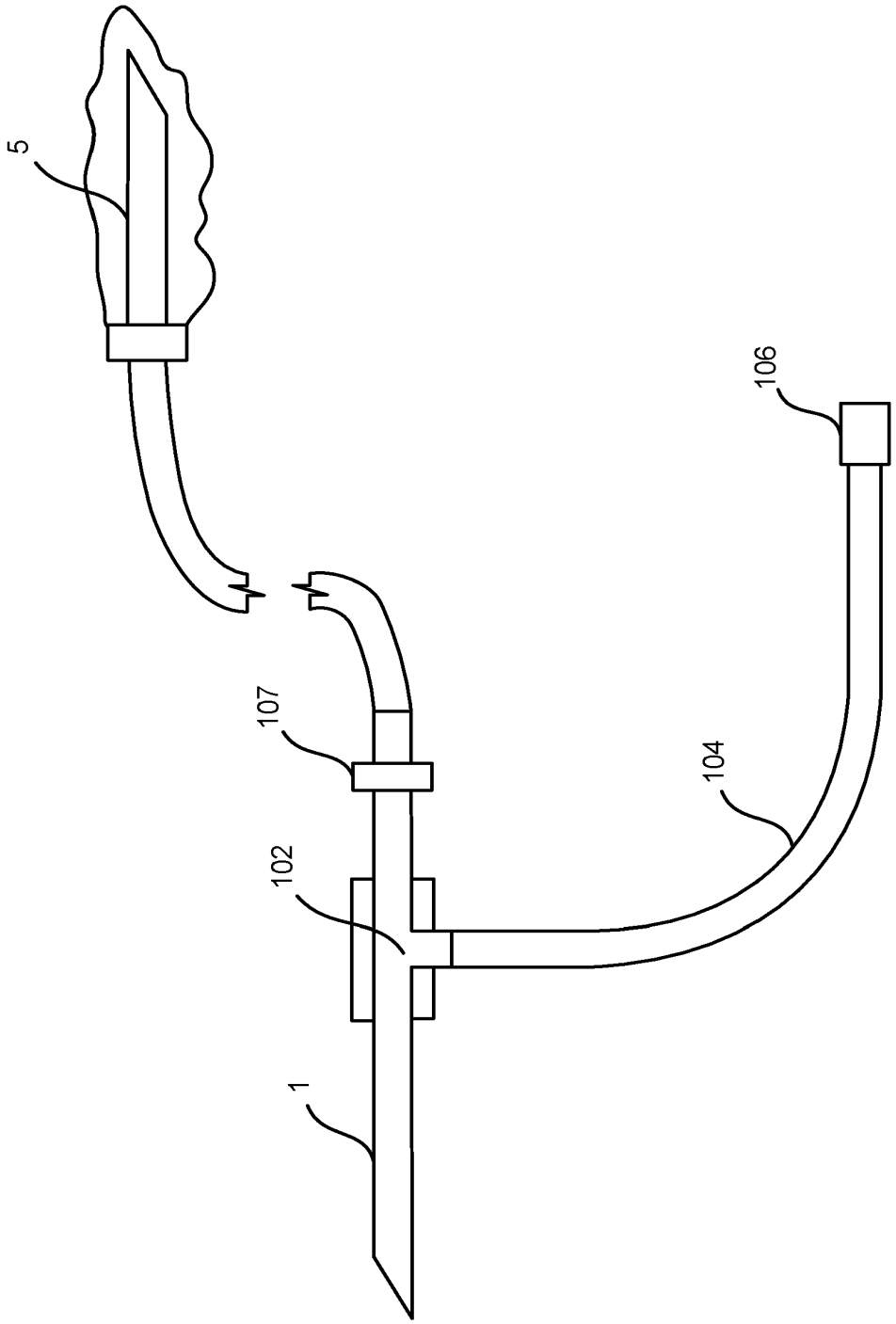


FIG. 4

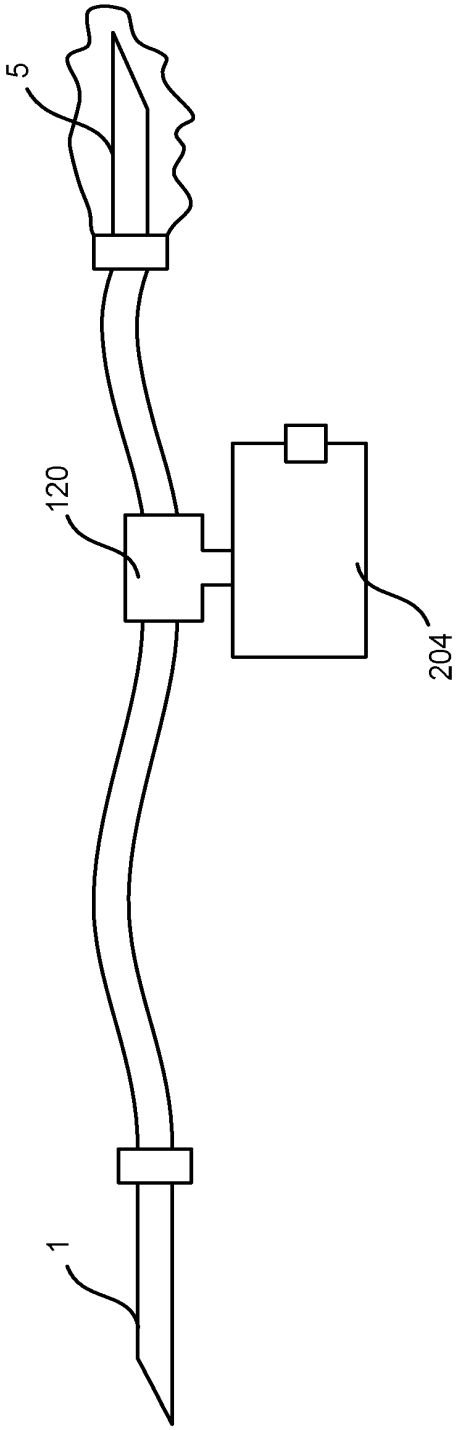


FIG. 5

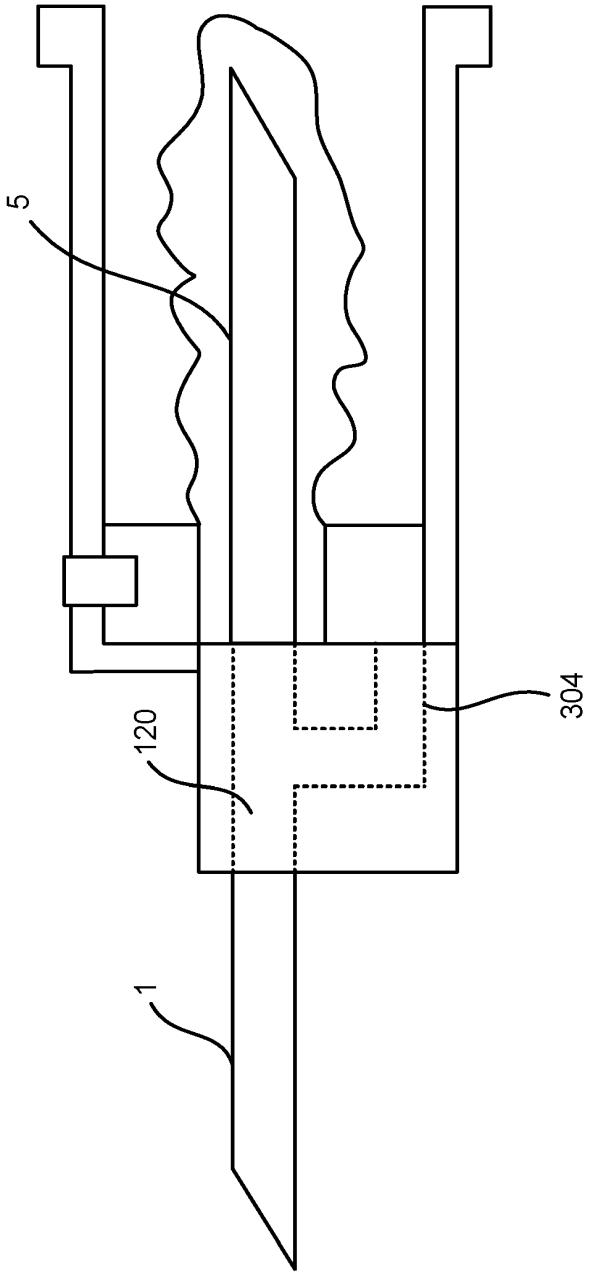


FIG. 6

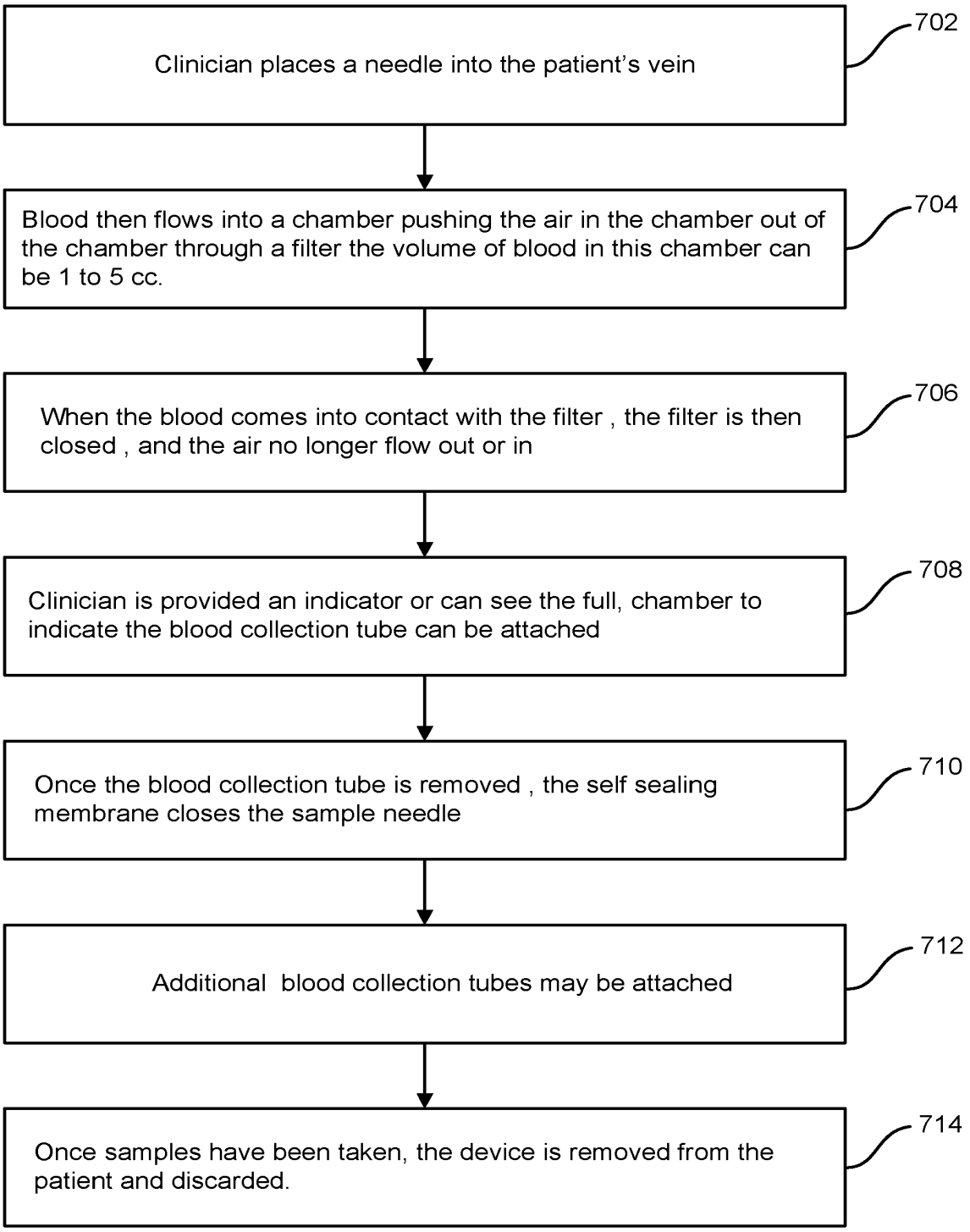
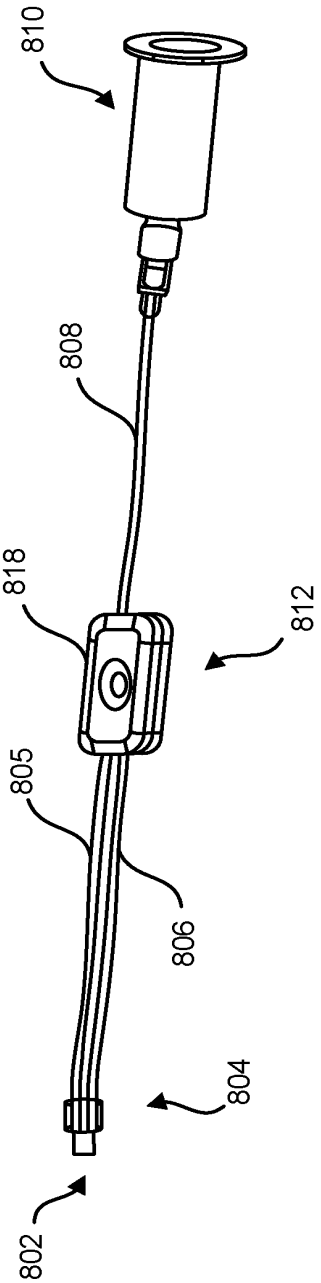

Clinician places a needle into the patient's vein
702
Blood then flows into a chamber pushing the air in the chamber out of the chamber through a filter the volume of blood in this chamber can be 1 to 5 cc.
704
When the blood comes into contact with the filter , the filter is then closed , and the air 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



800

FIG. 8A

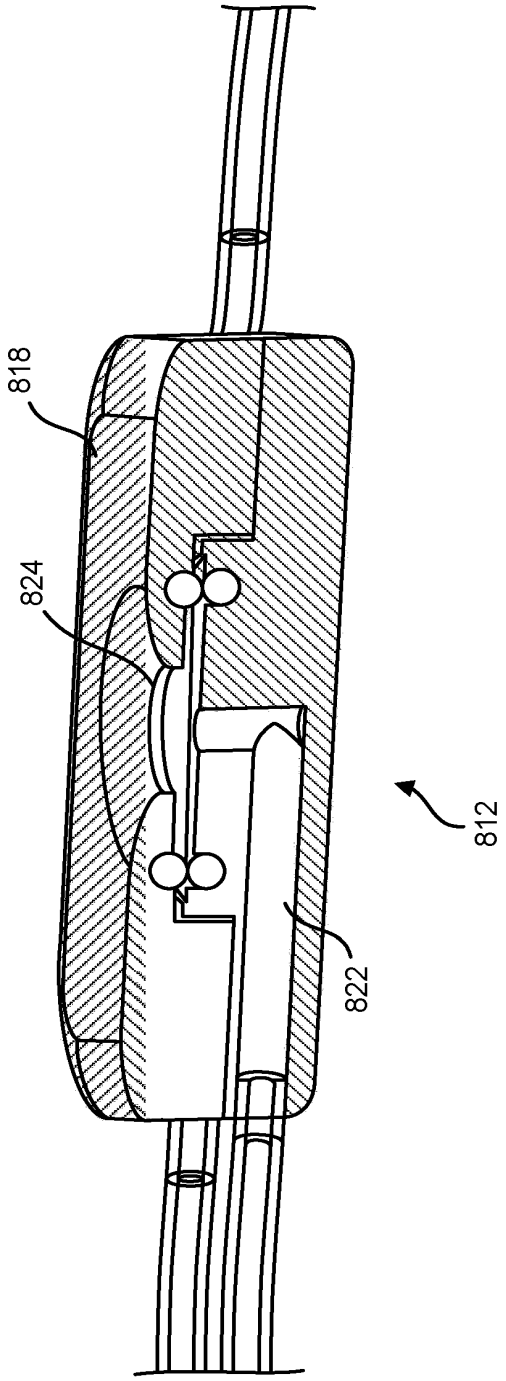


FIG. 8B

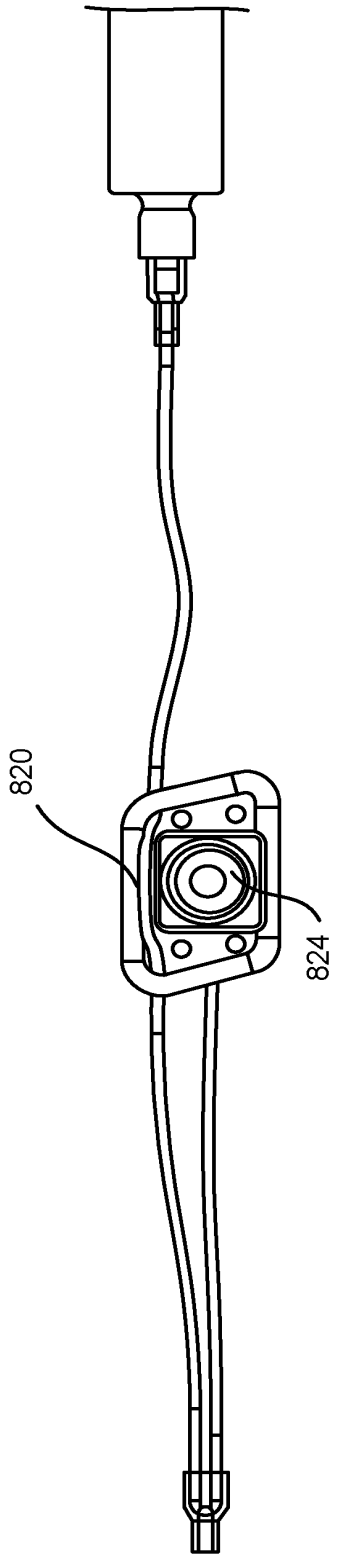


FIG. 8C

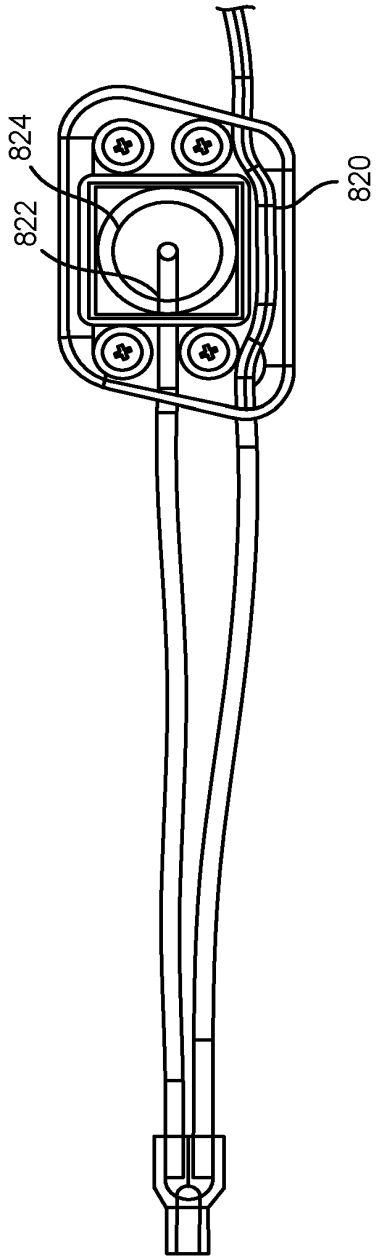


FIG. 8D

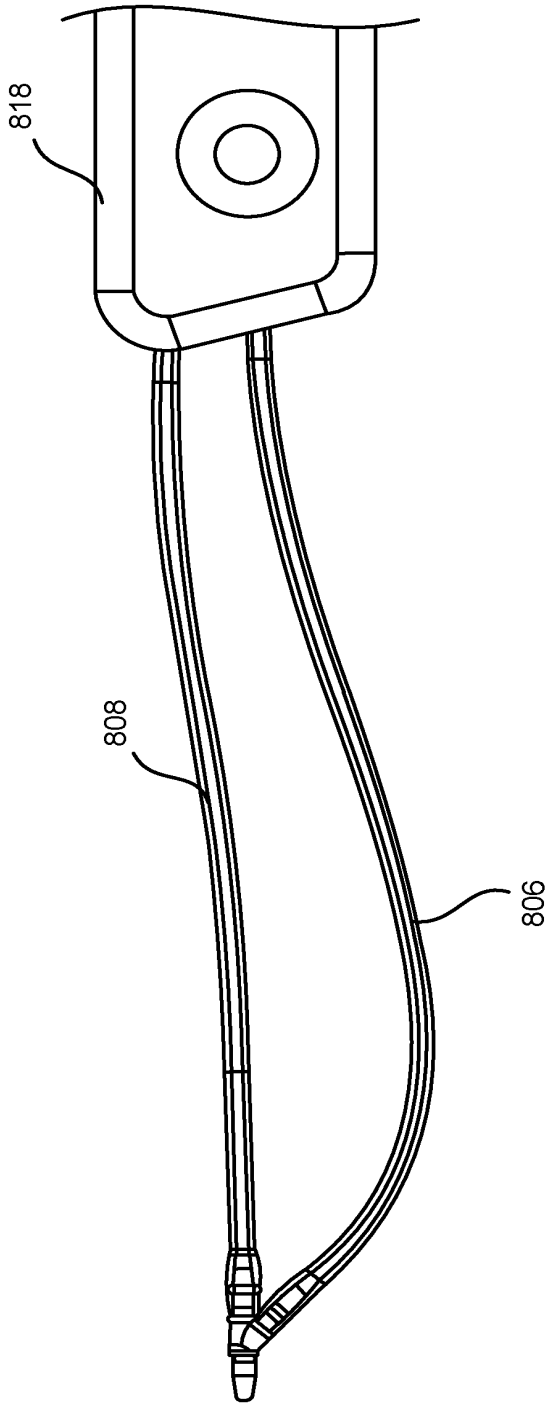


FIG. 8E

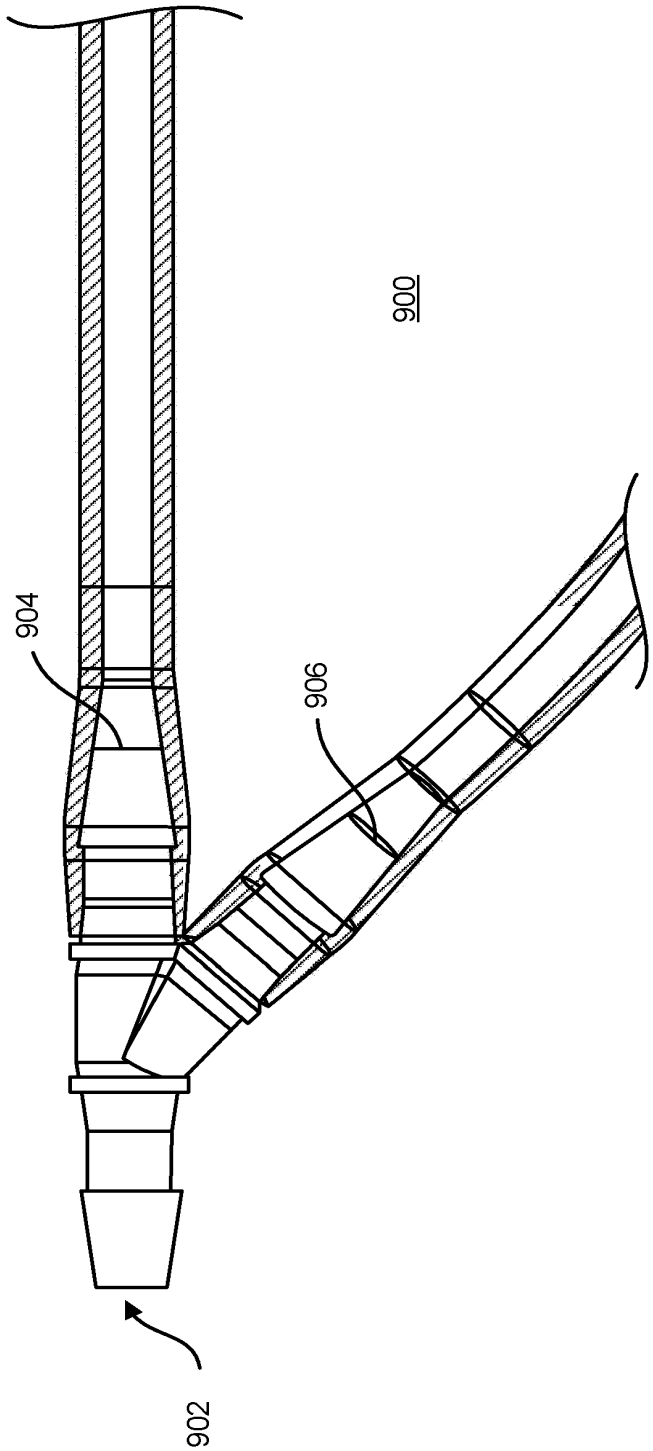


FIG. 9

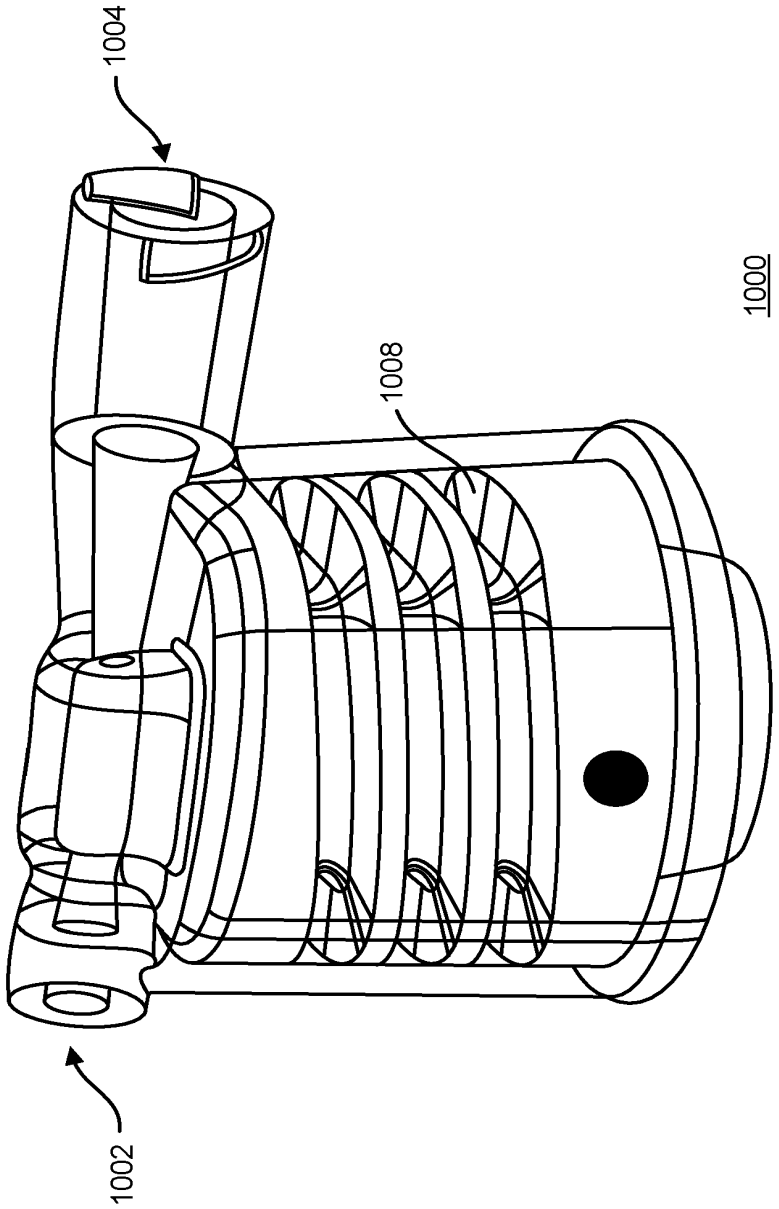


FIG. 10A

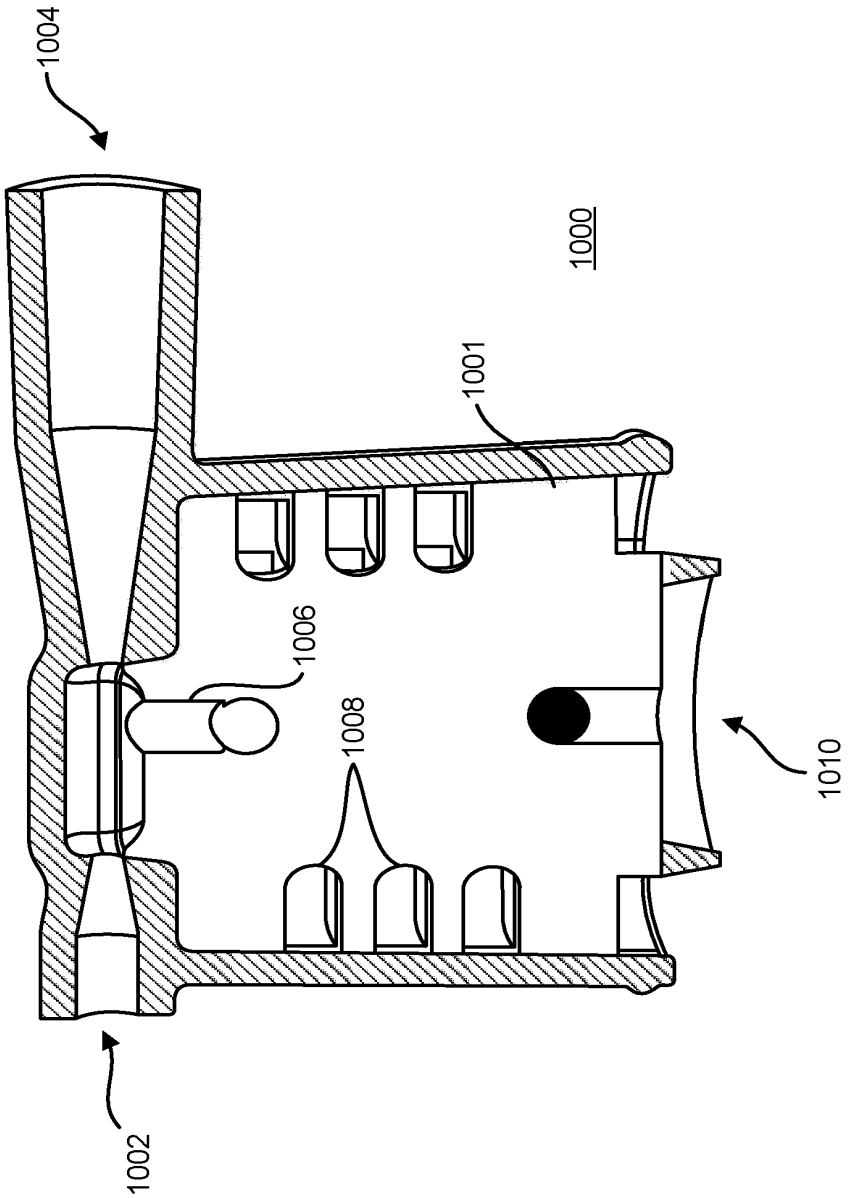


FIG. 10B

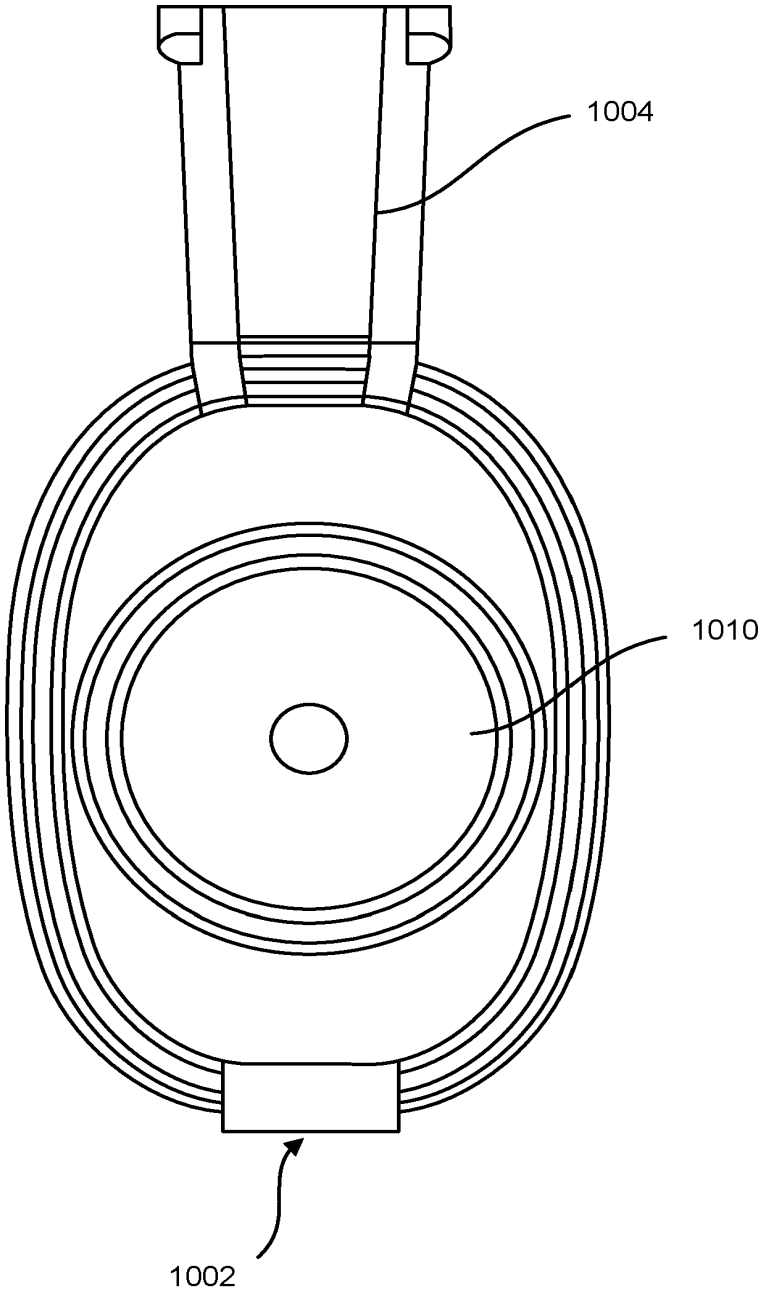


FIG. 10C

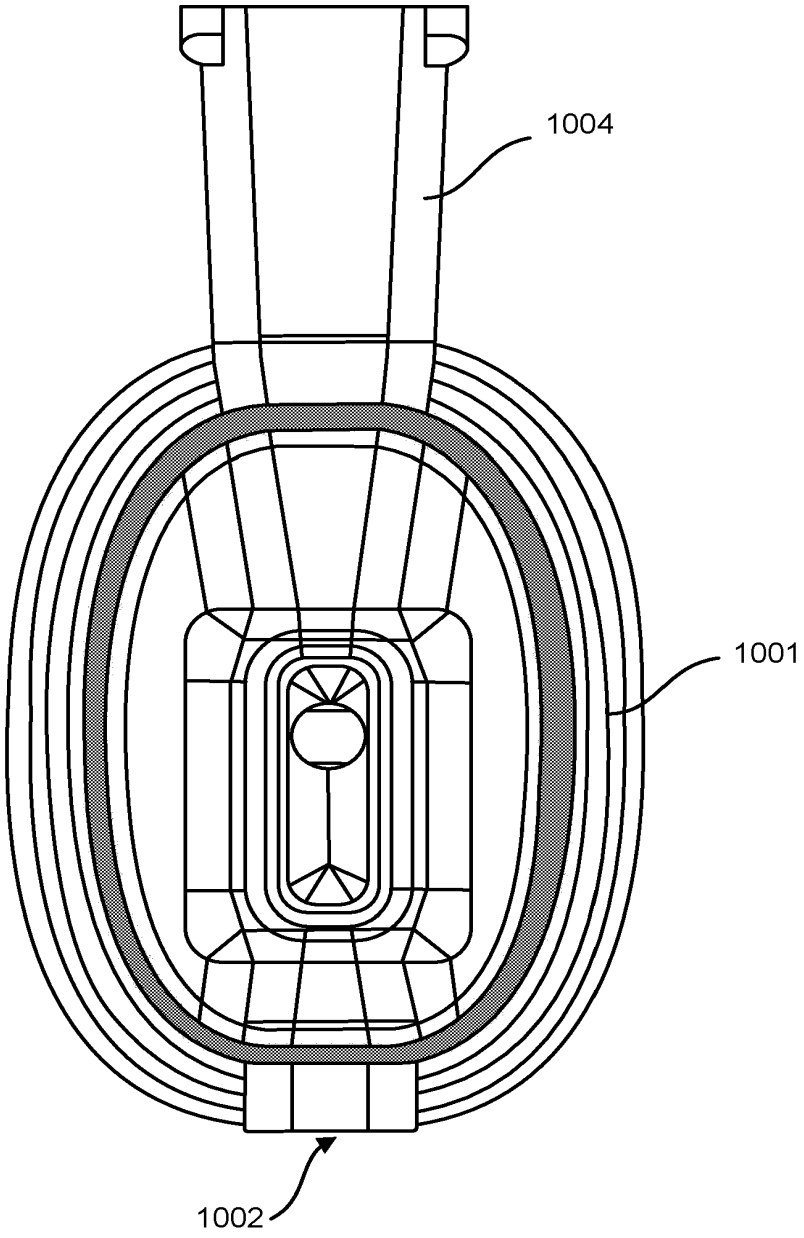


FIG. 10D

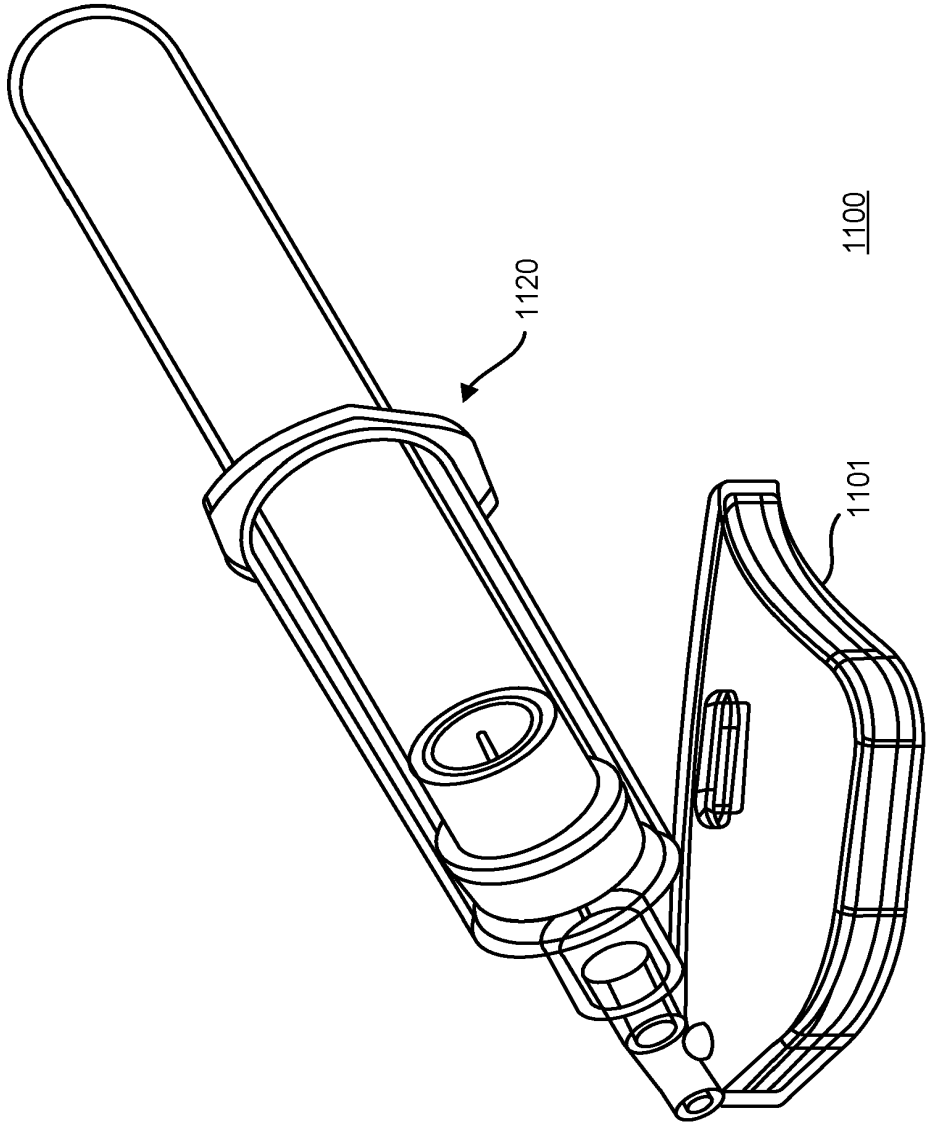


FIG. 11A

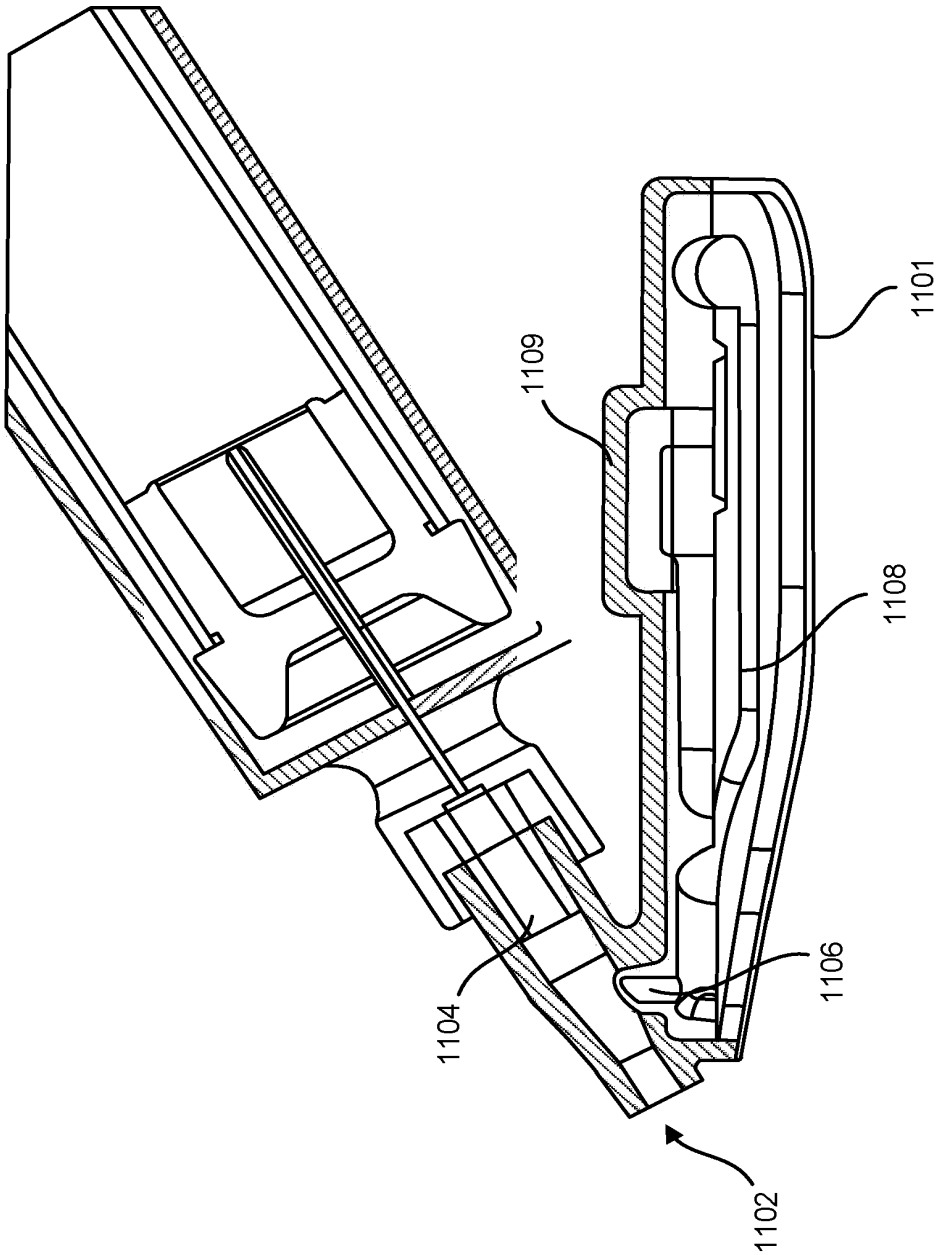


FIG. 11B

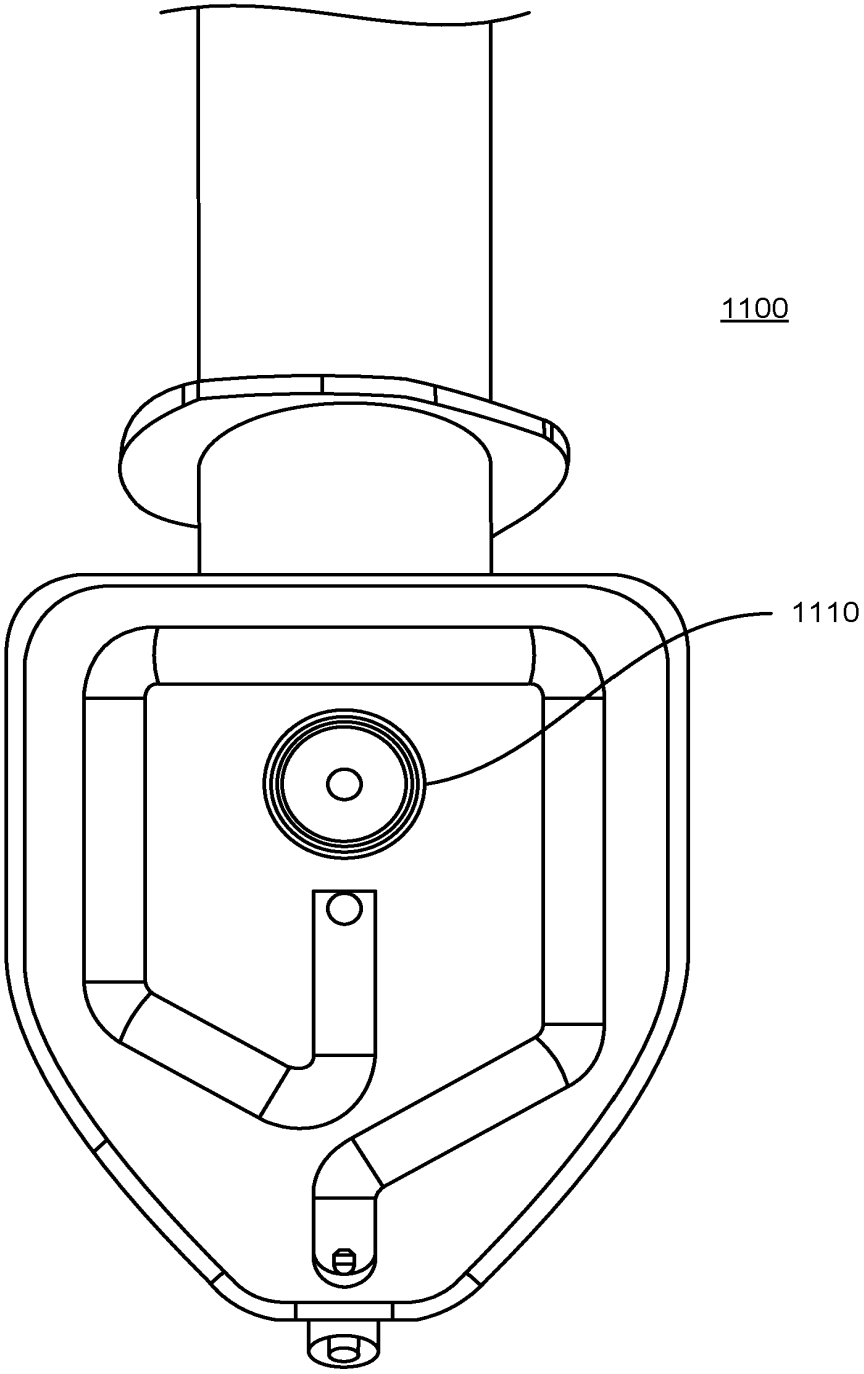


FIG. 11C

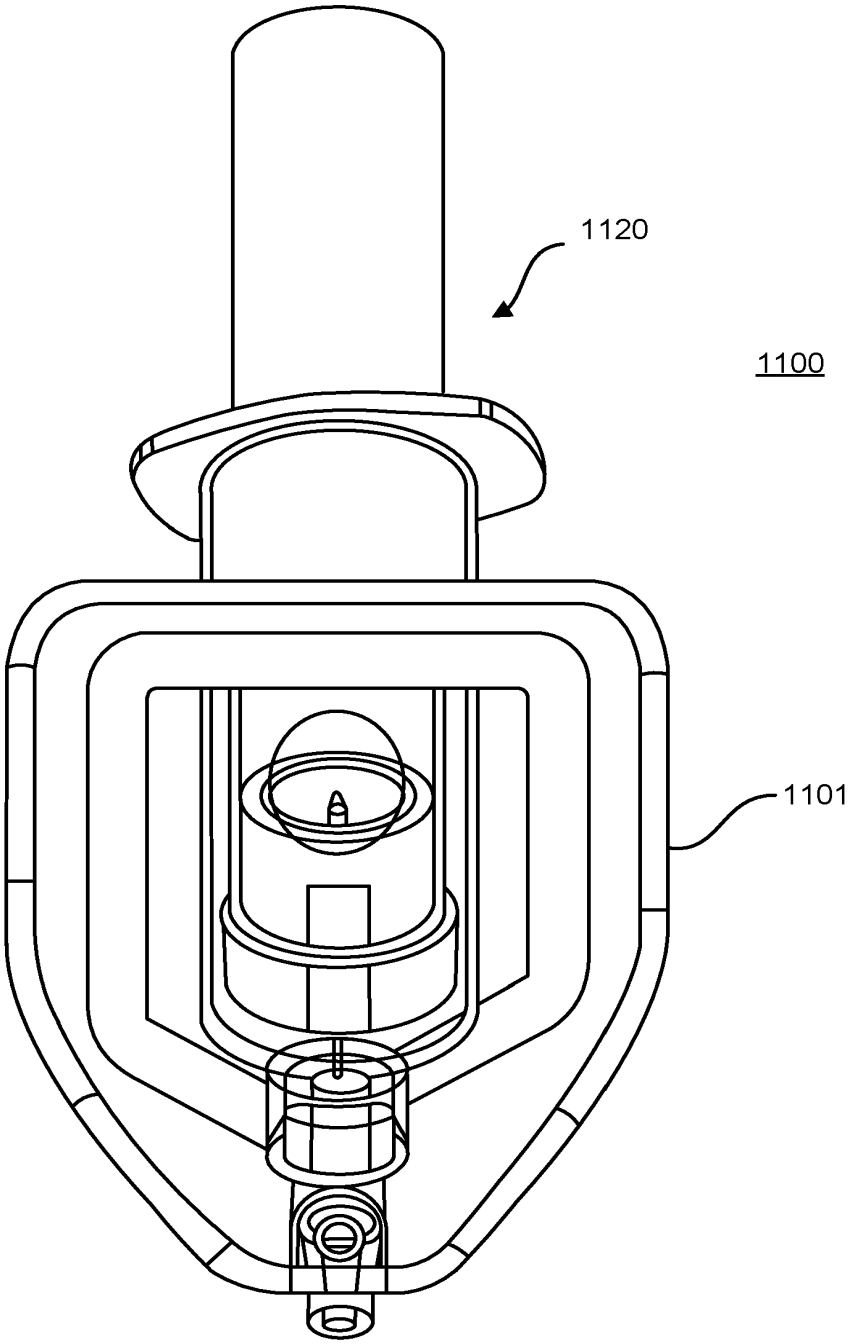


FIG. 11D

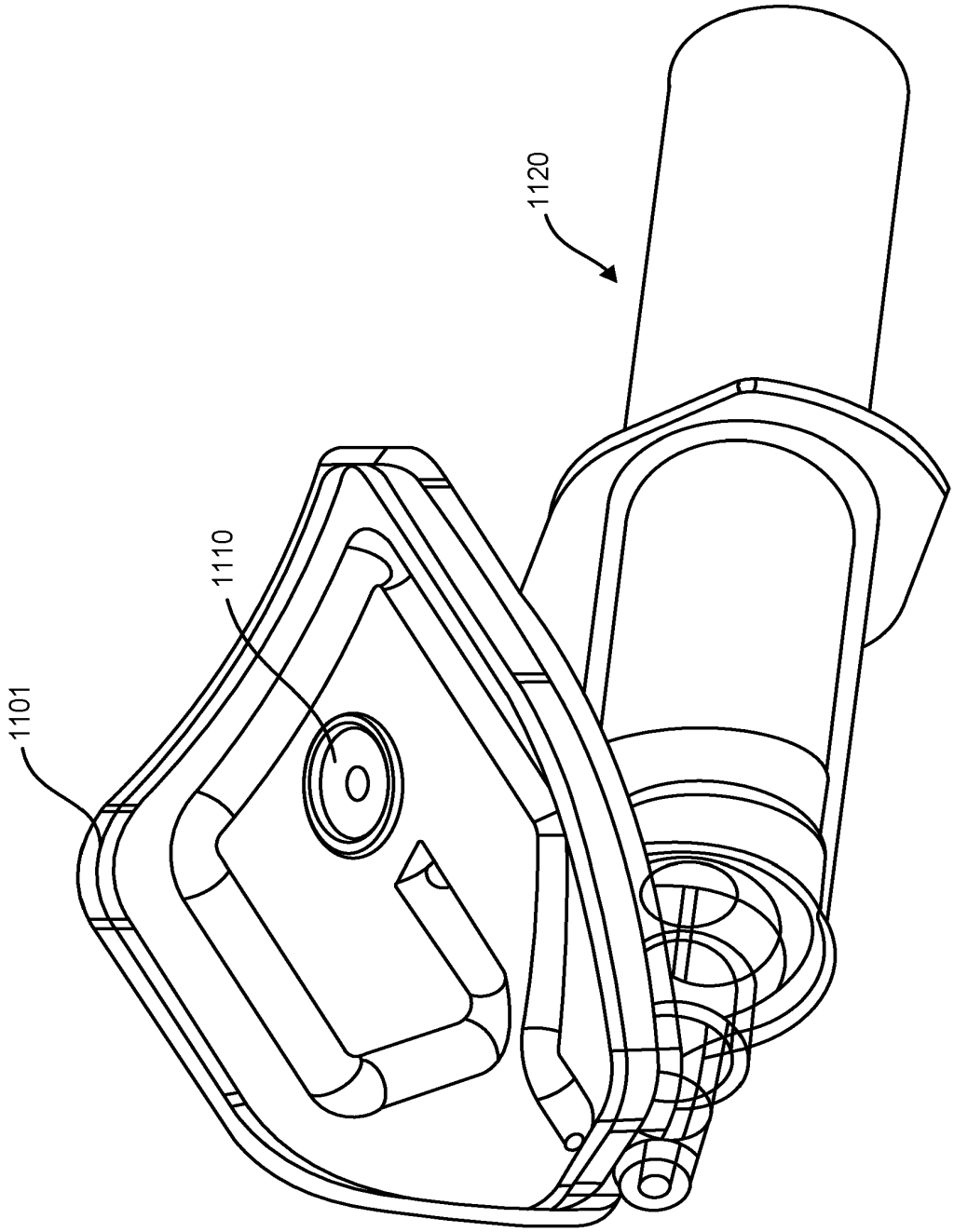


FIG. 11E

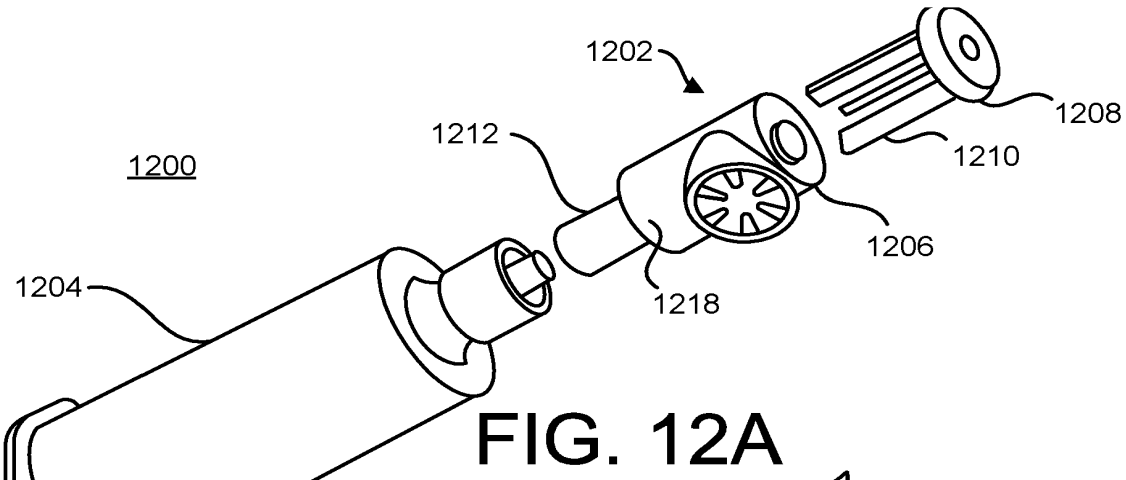


FIG. 12A

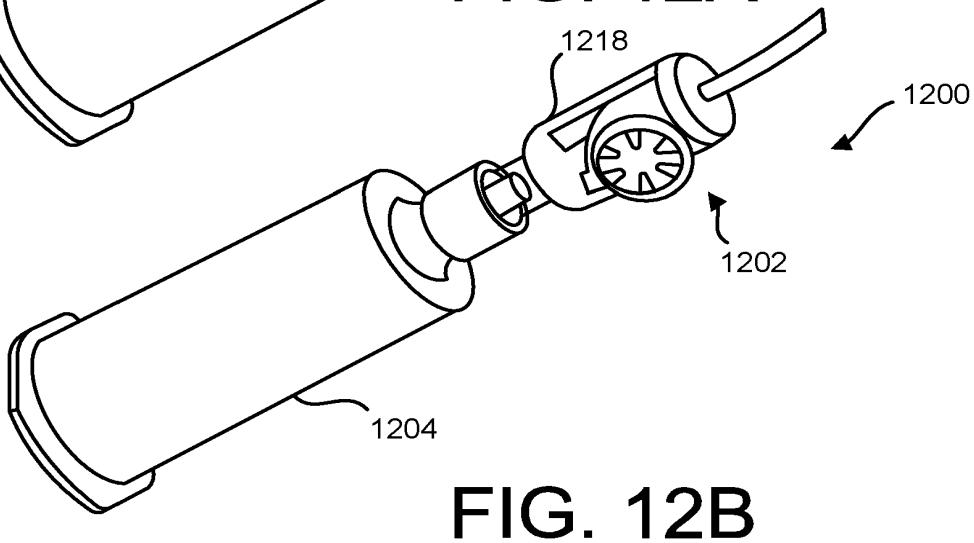


FIG. 12B

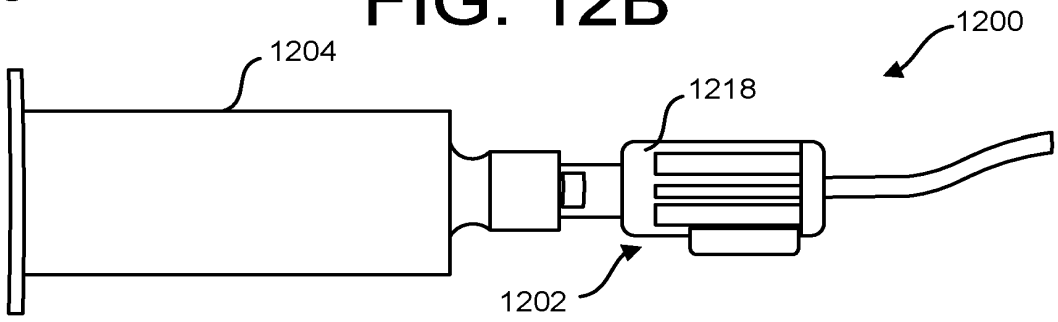


FIG. 12C

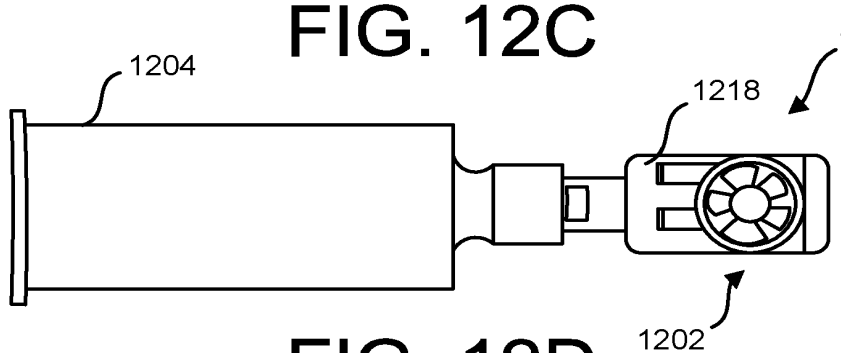


FIG. 12D

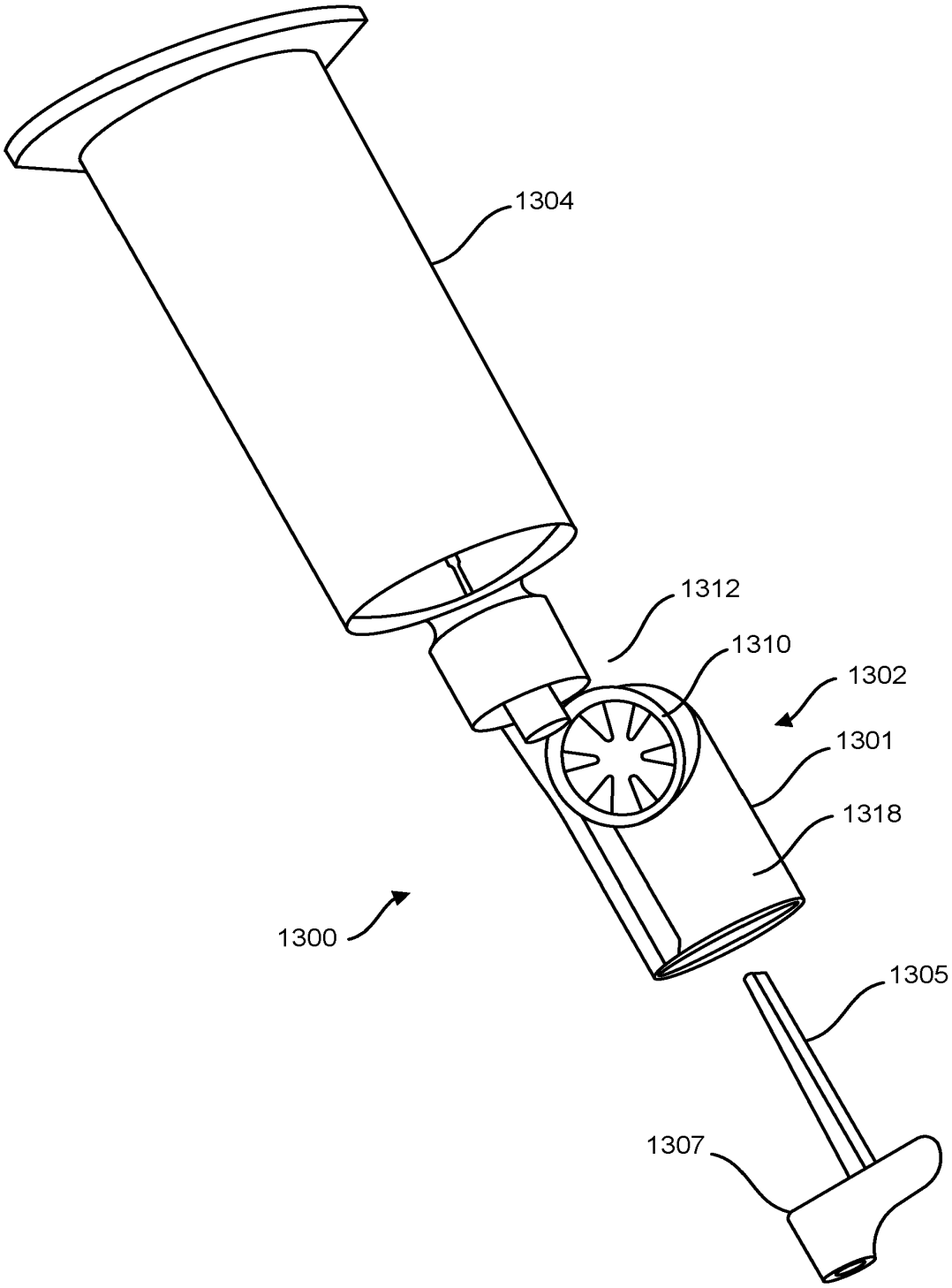


FIG. 13A

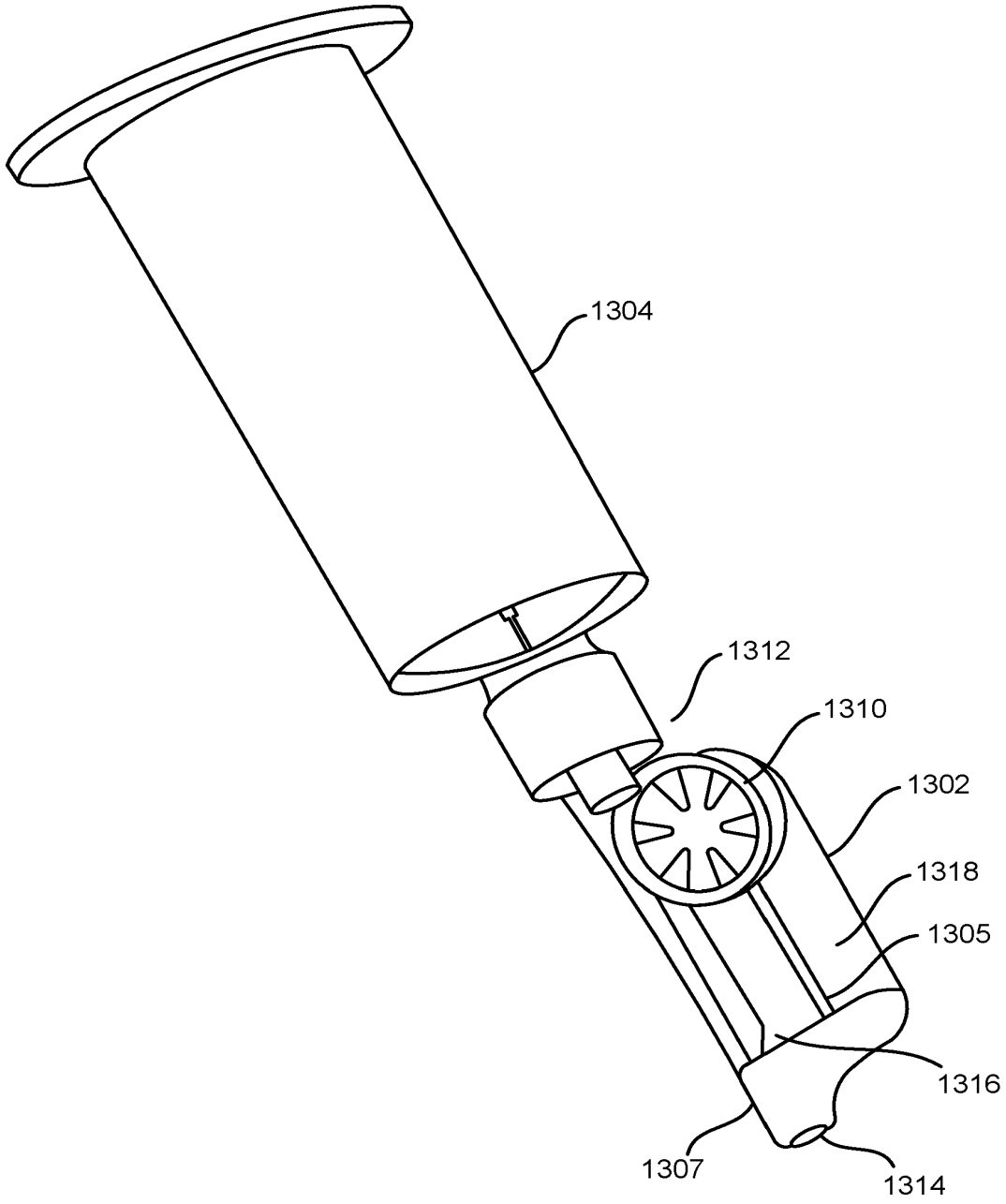


FIG. 13B

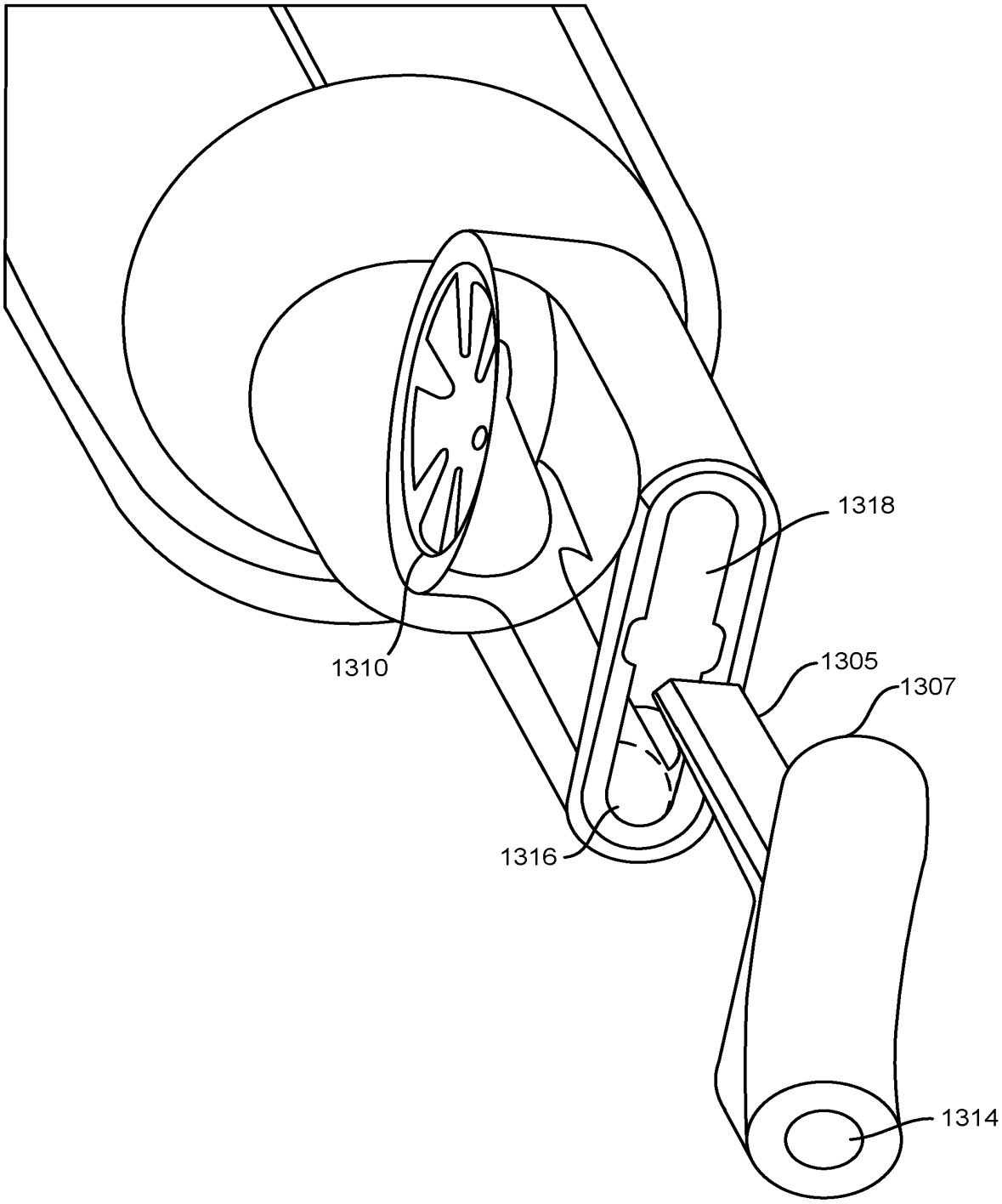


FIG. 13C

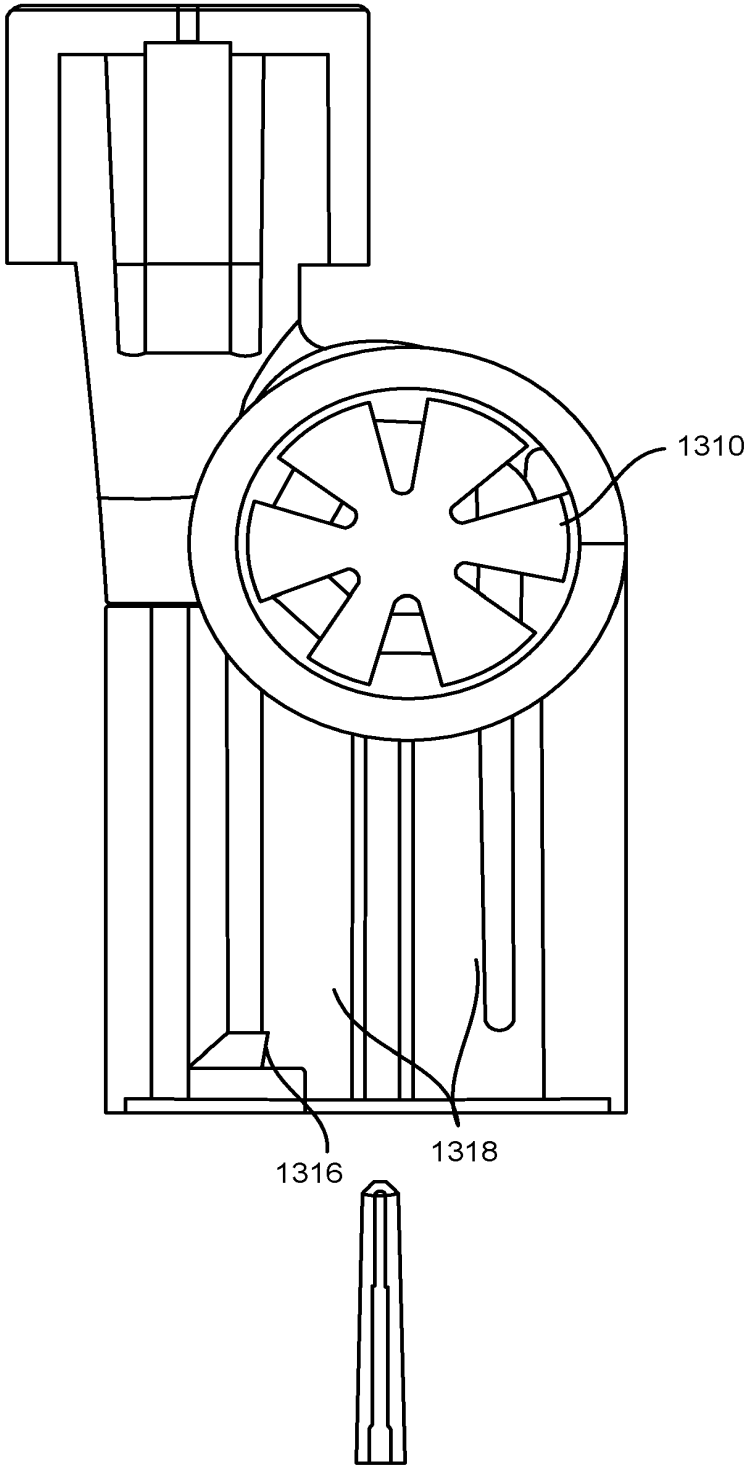


FIG. 13D

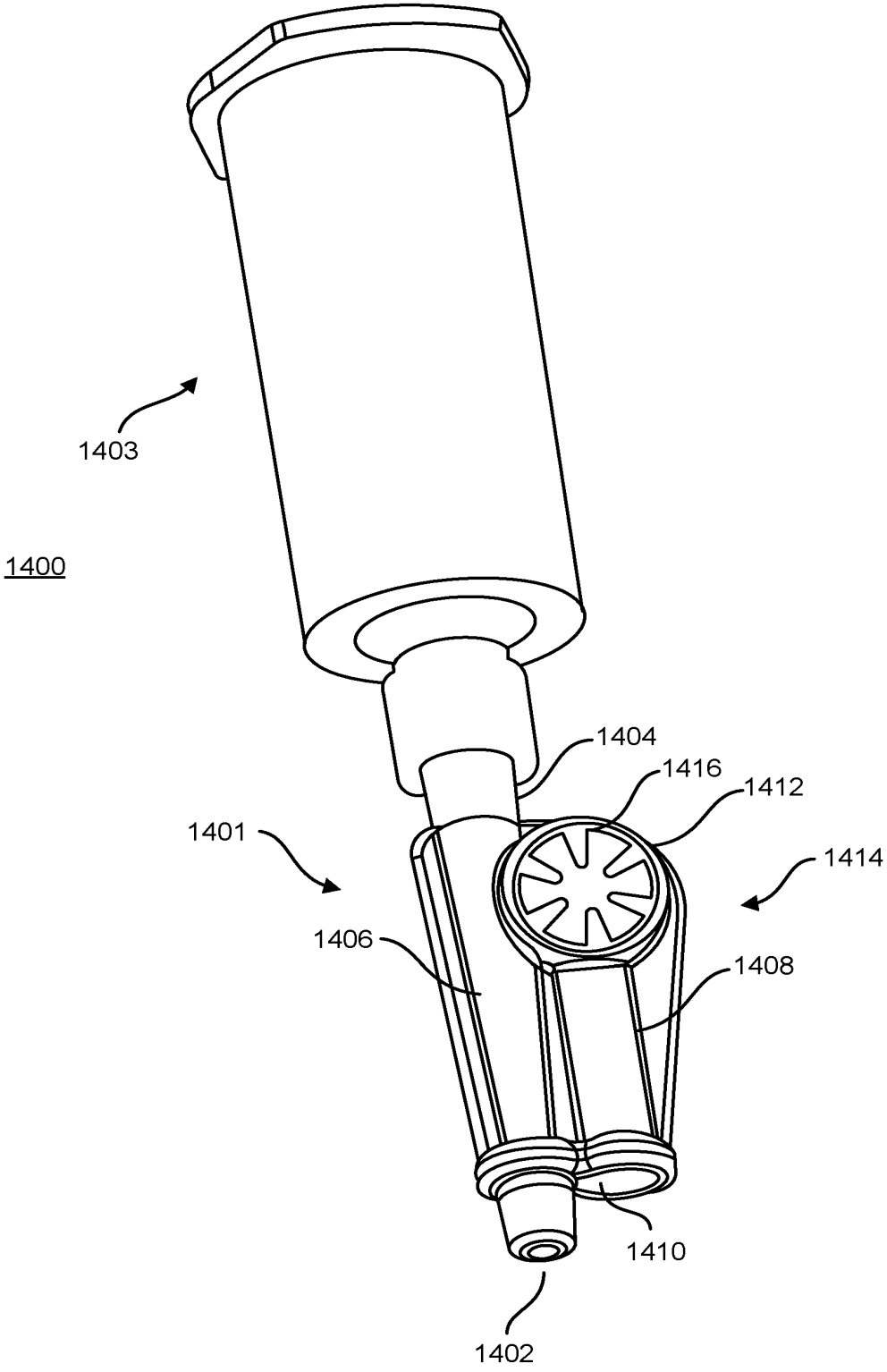


FIG. 14A

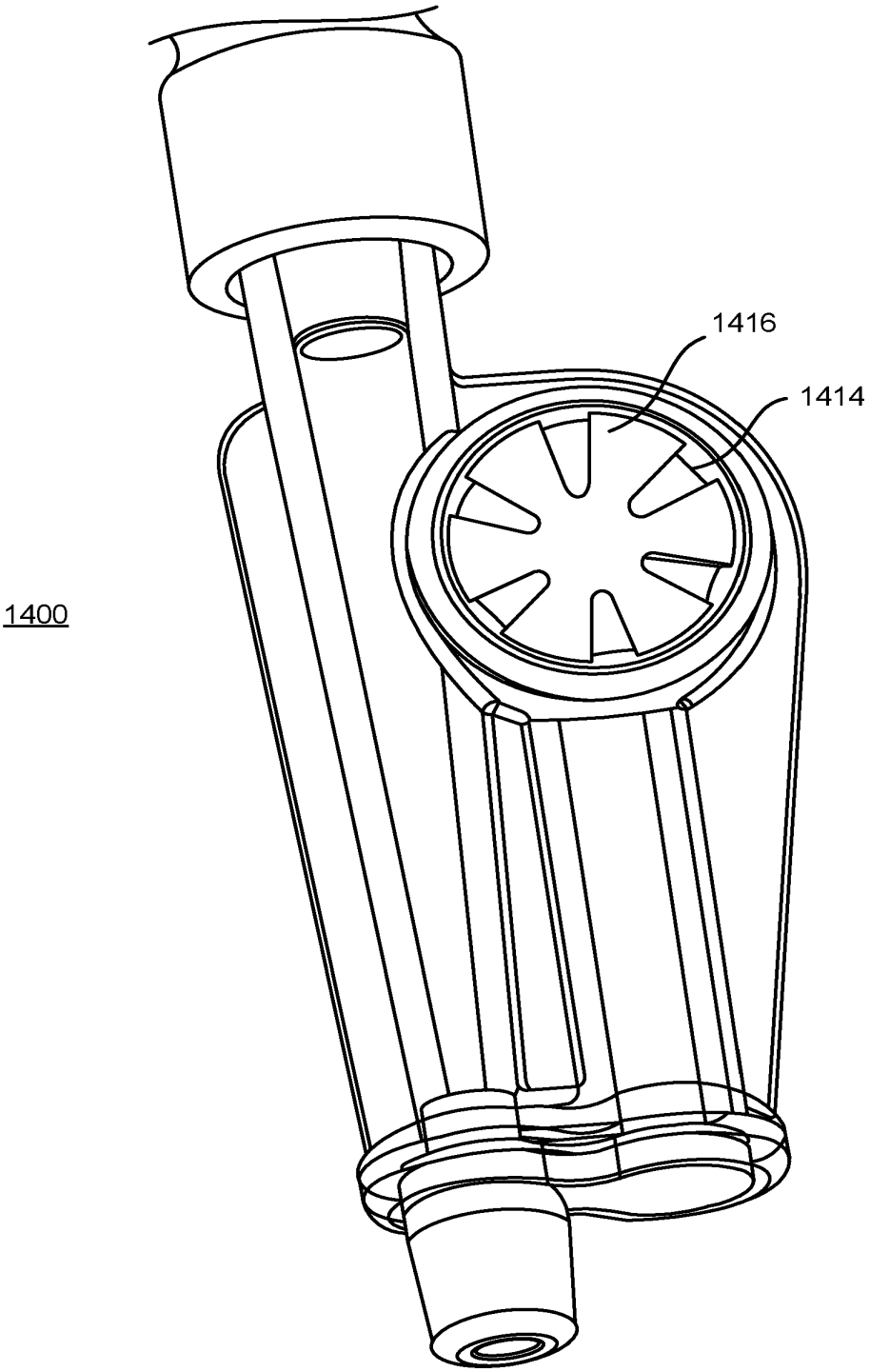


FIG. 14B

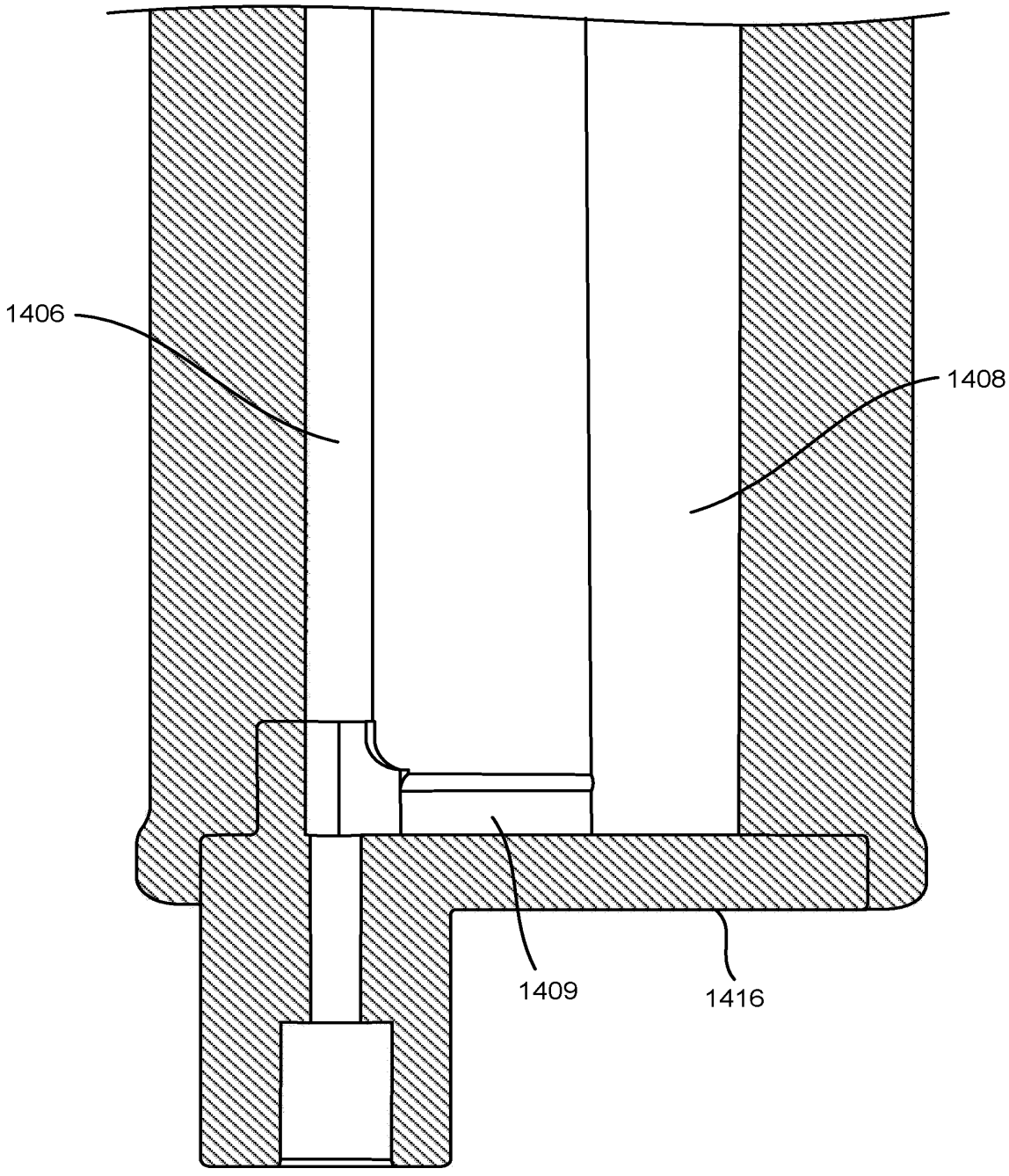


FIG. 14C

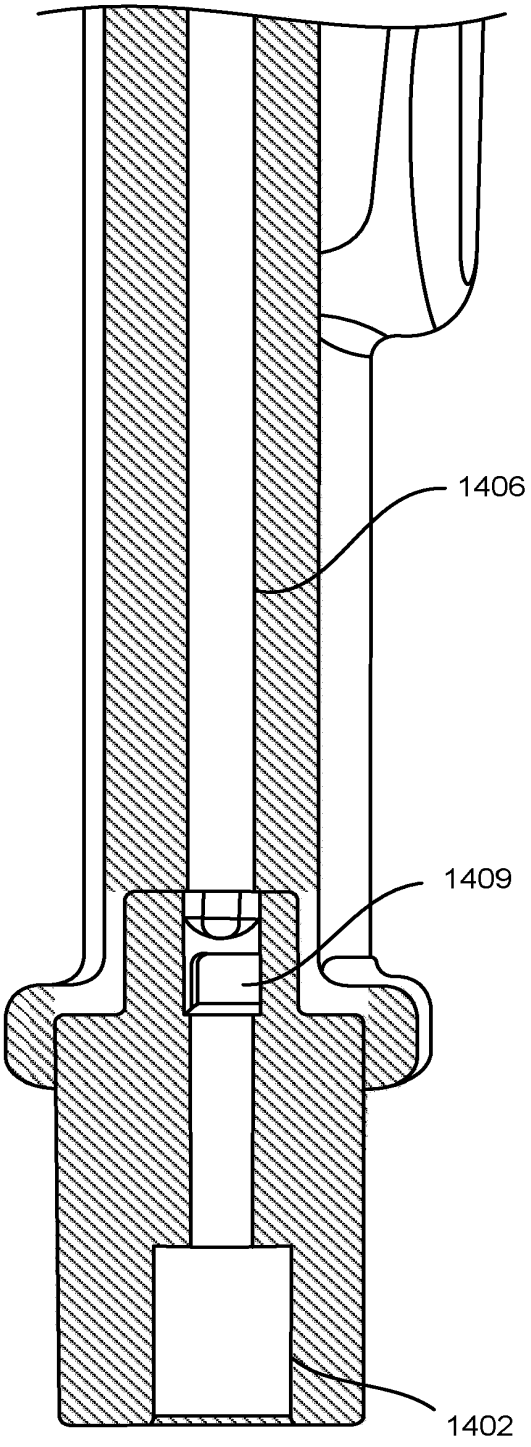


FIG. 14D

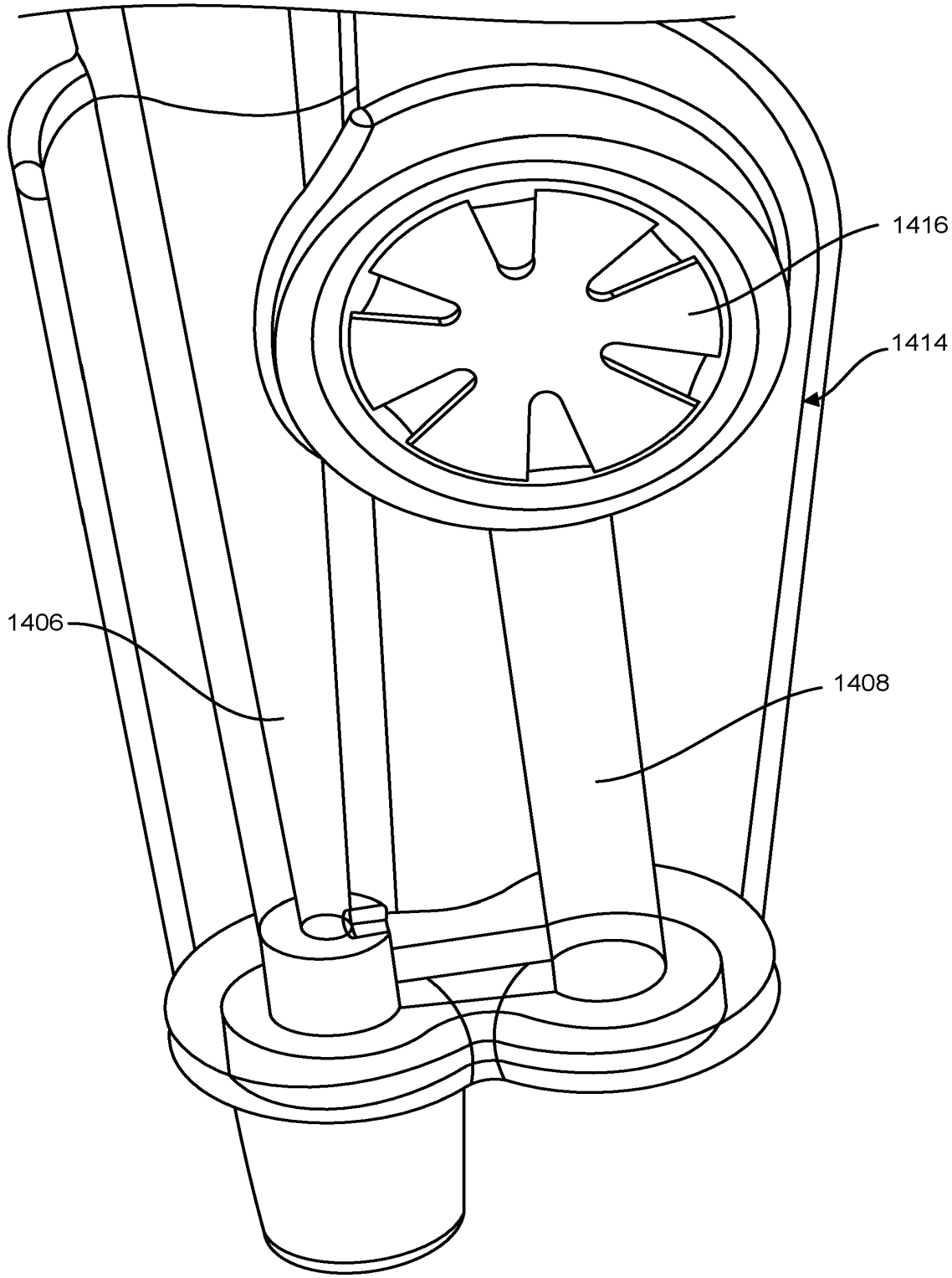


FIG. 14E

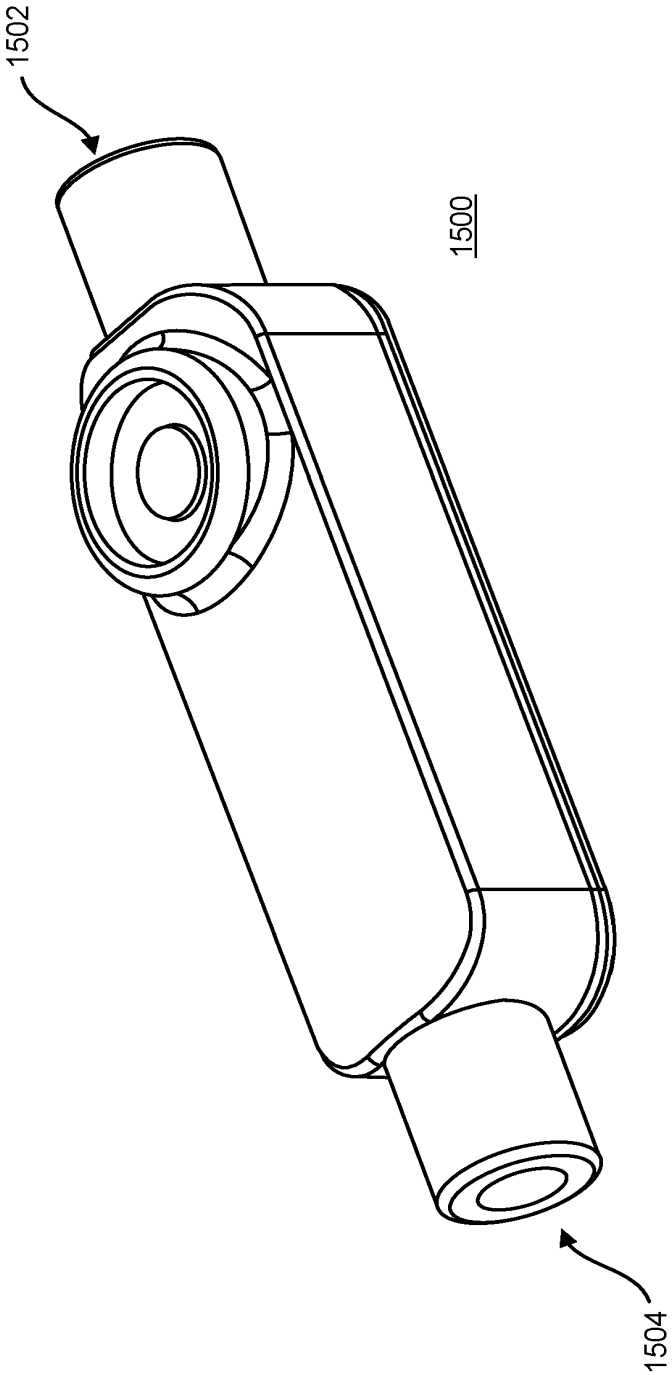


FIG. 15A

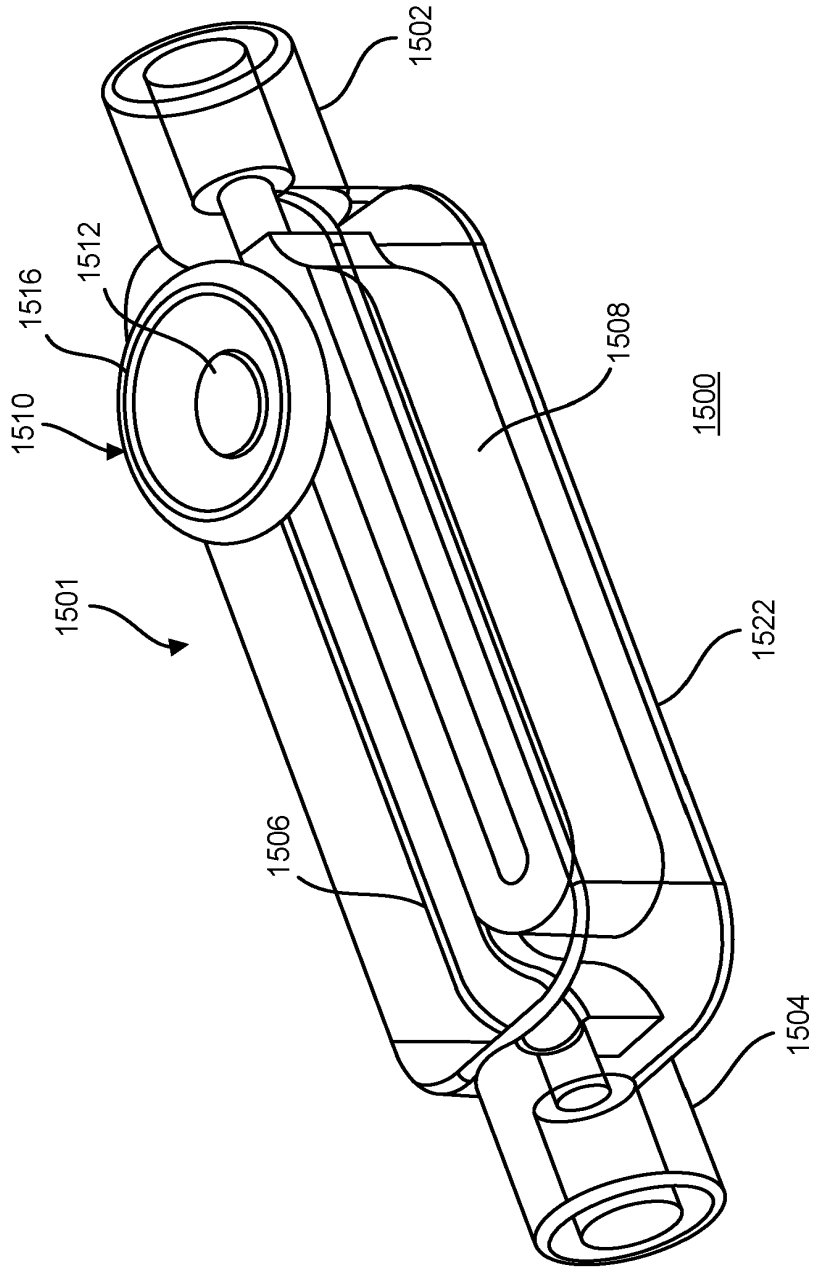


FIG. 15B

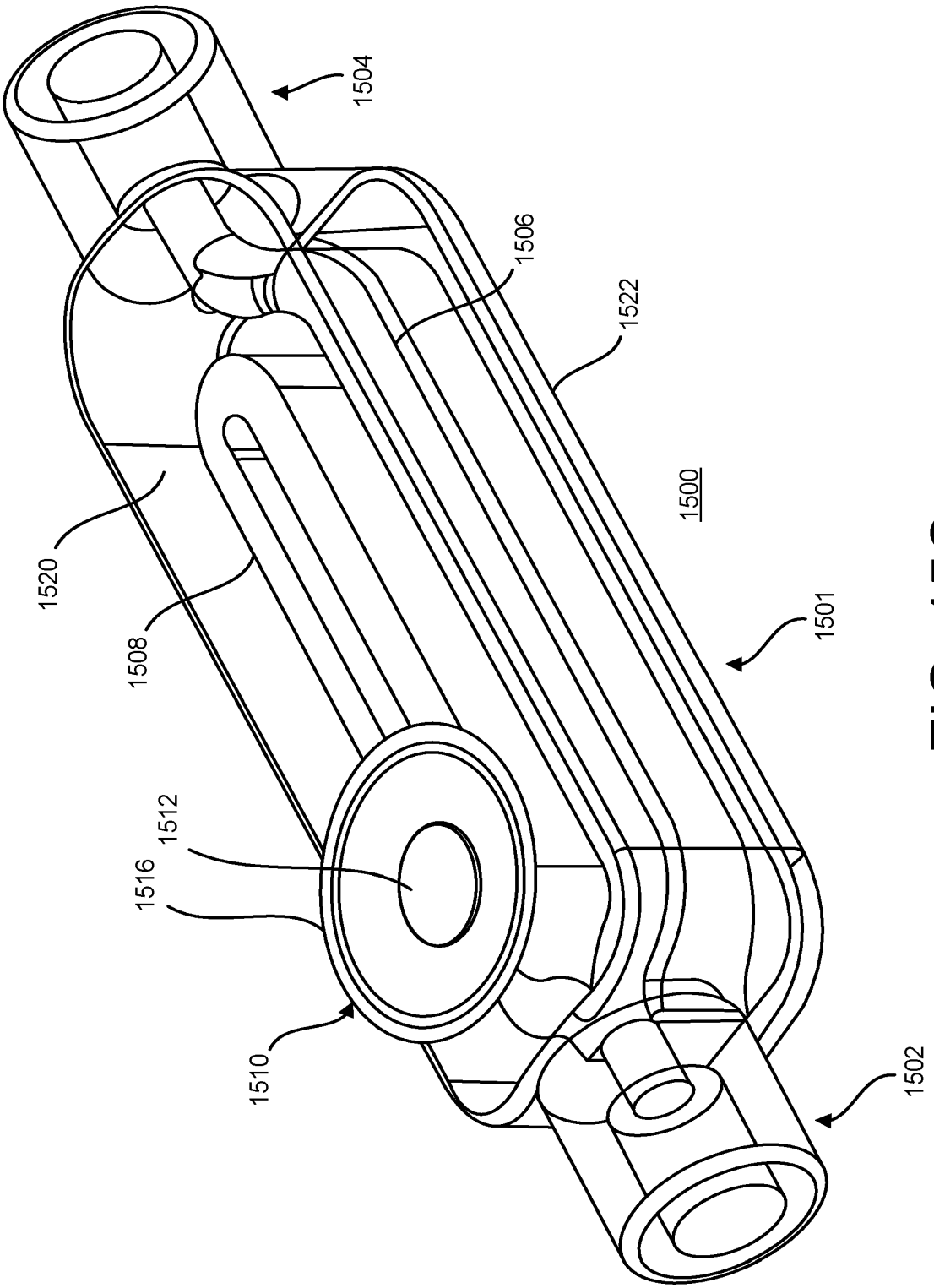


FIG. 15C

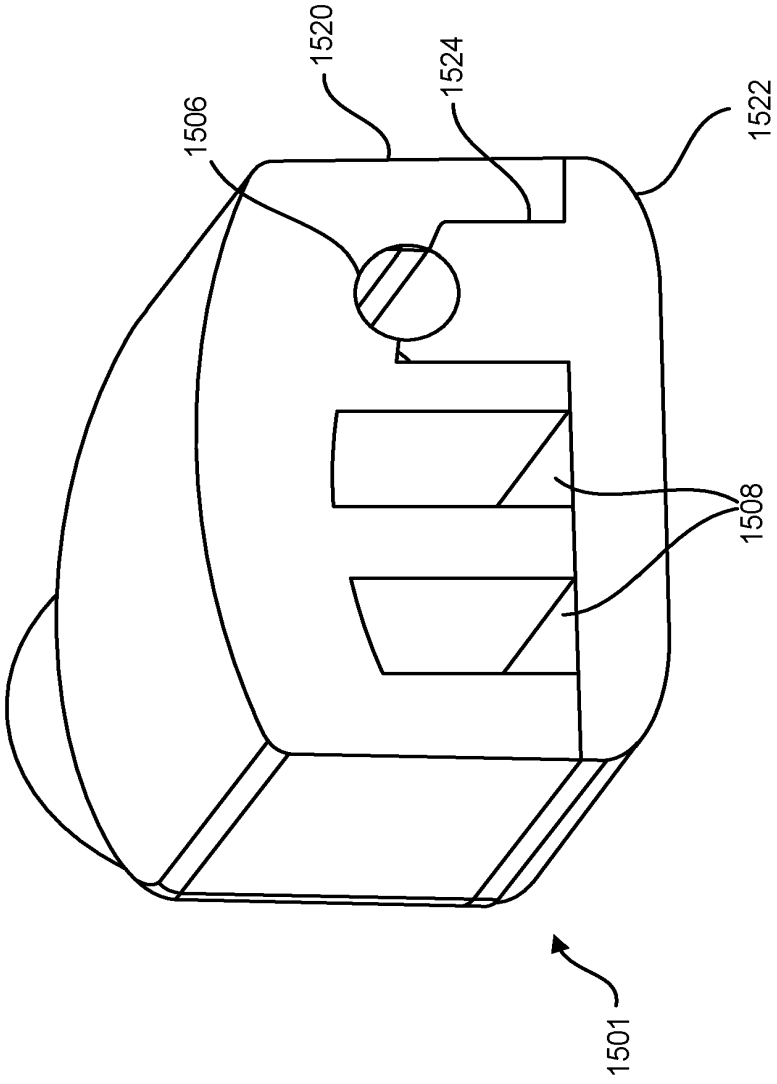


FIG. 15D

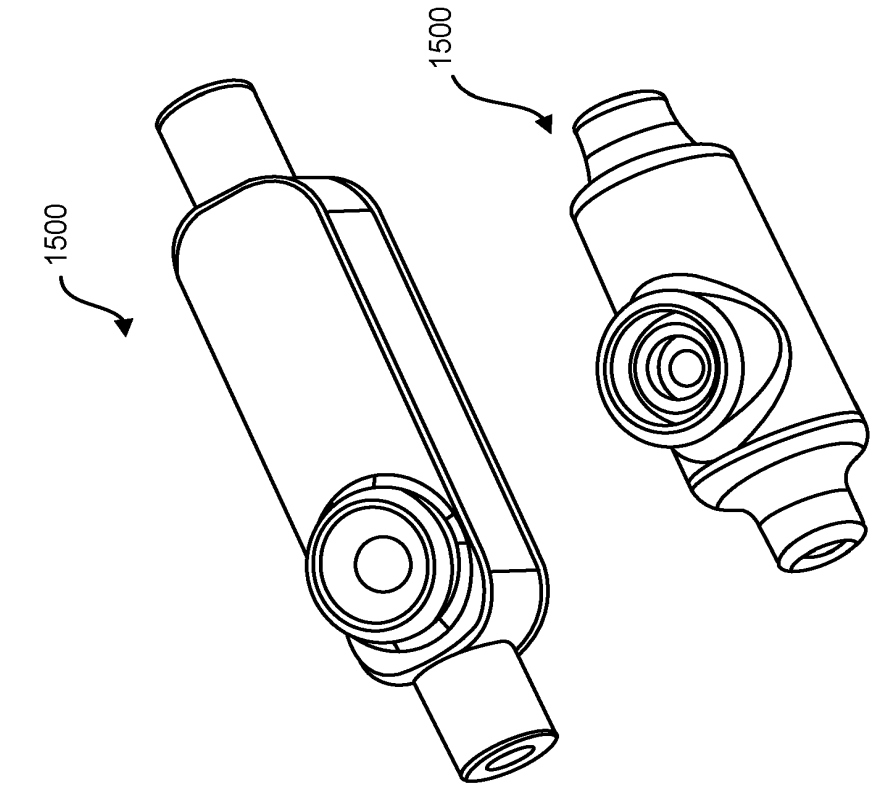


FIG. 15F

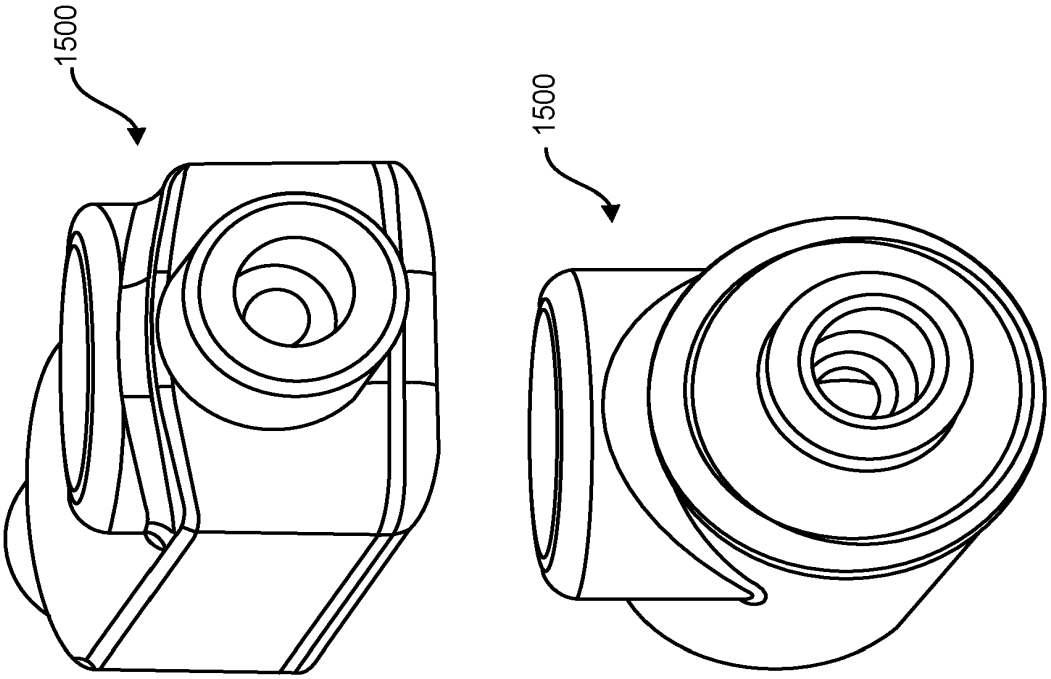


FIG. 15E

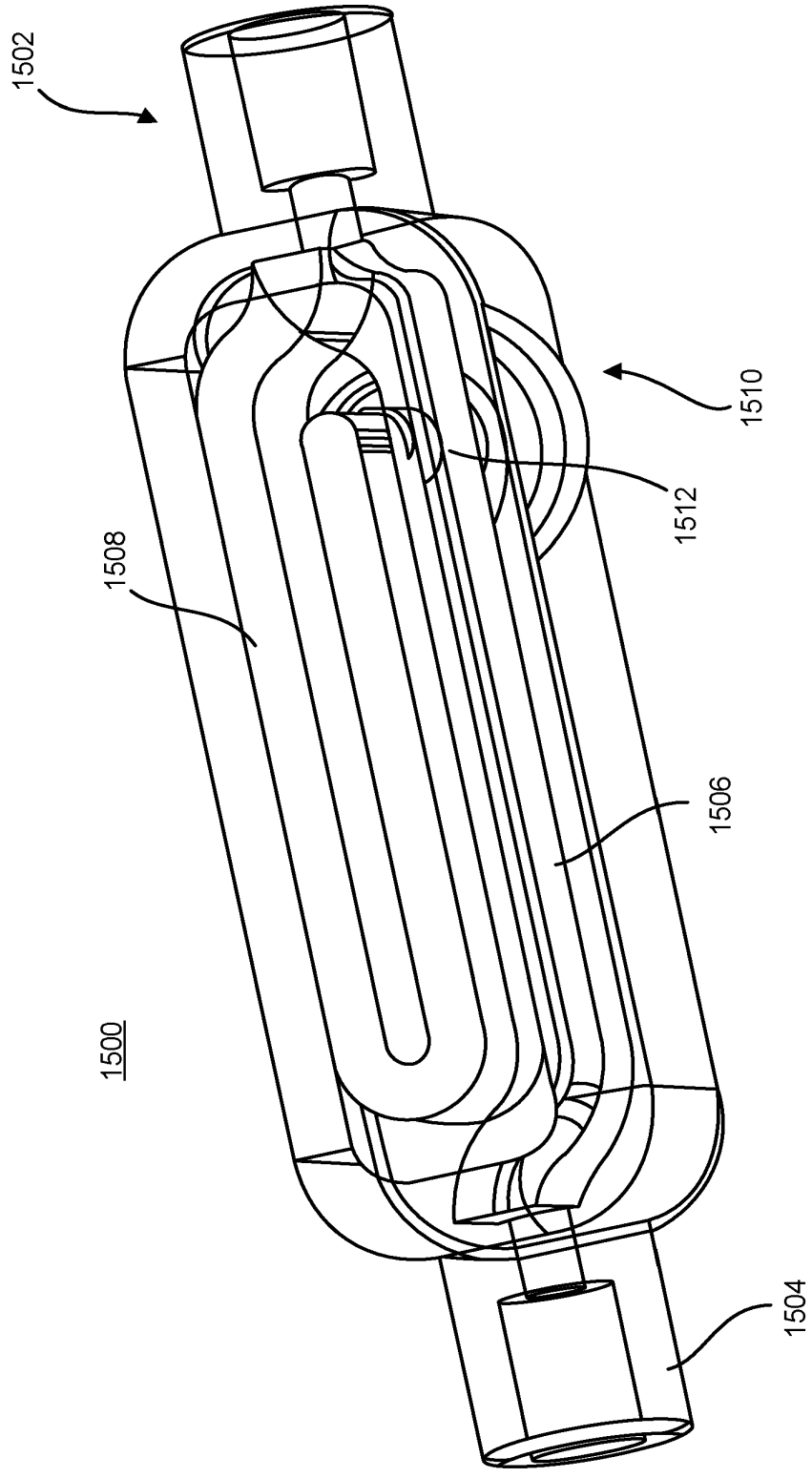


FIG. 15G

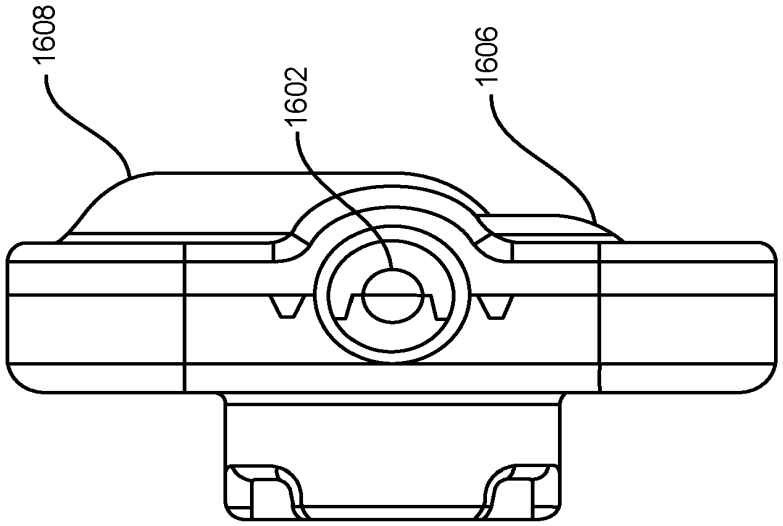


FIG. 16C

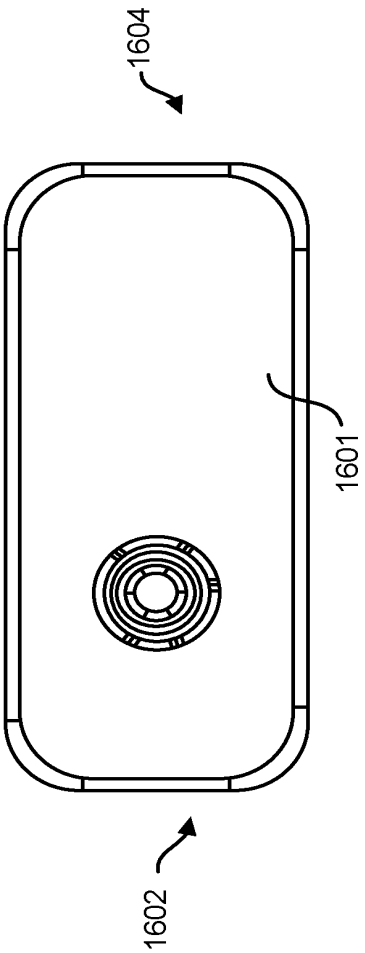


FIG. 16A

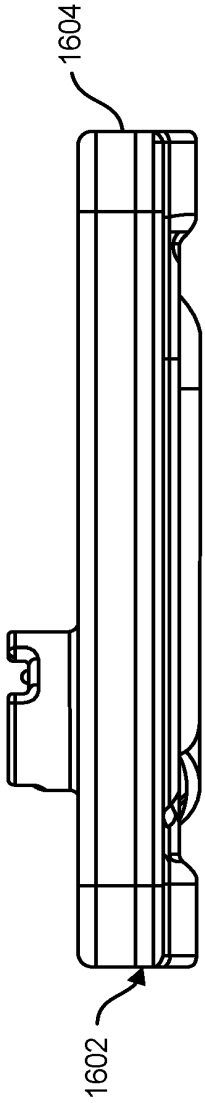


FIG. 16B

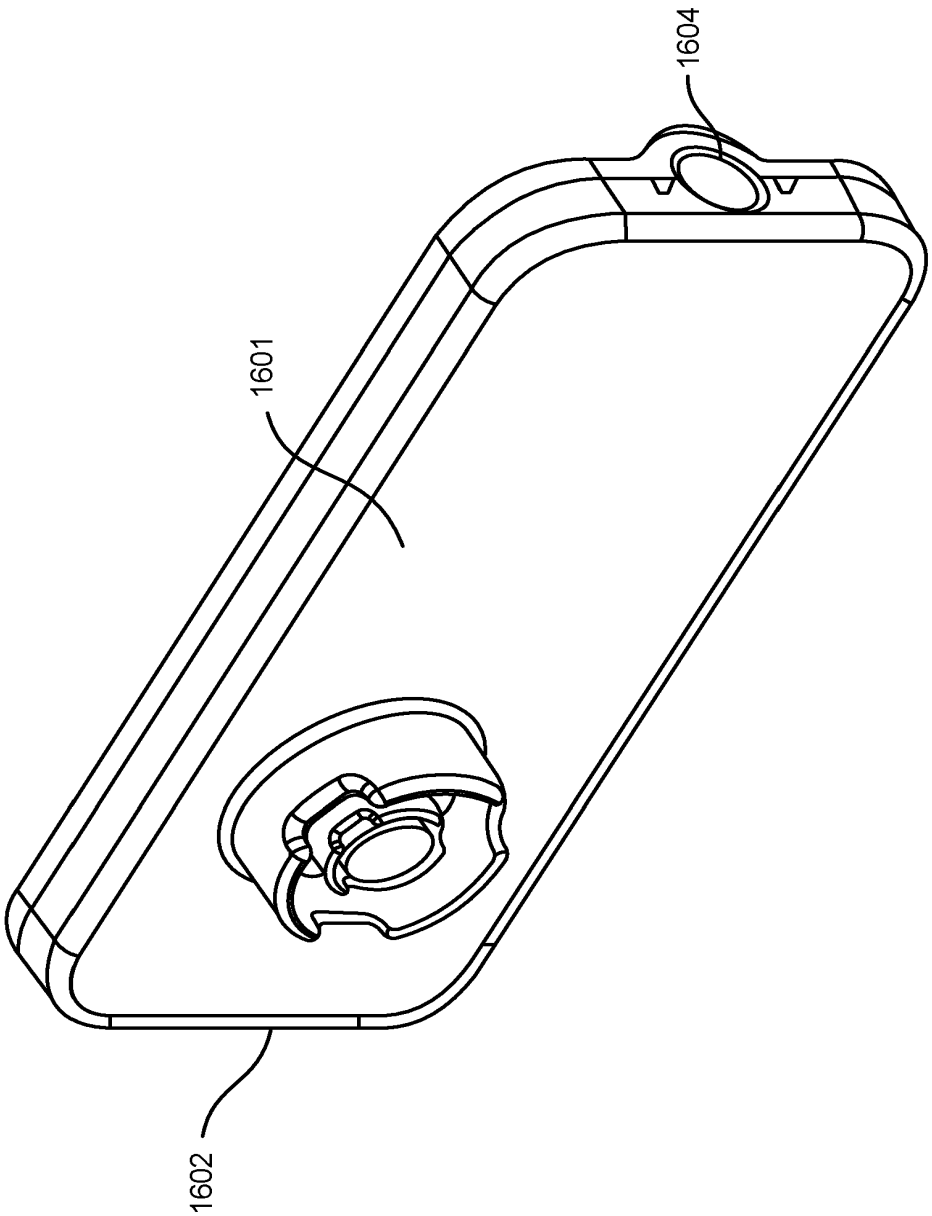


FIG. 16D

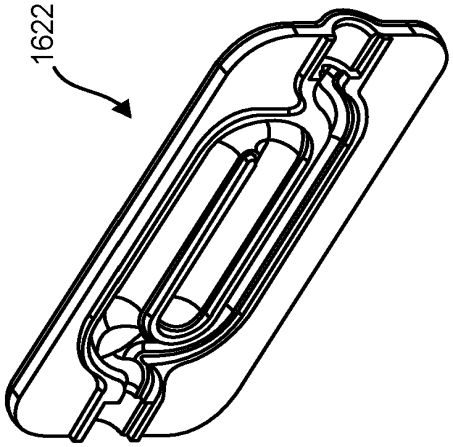


FIG. 17B

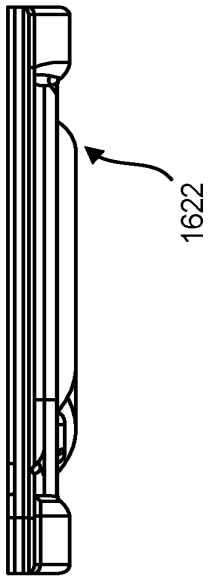


FIG. 17E

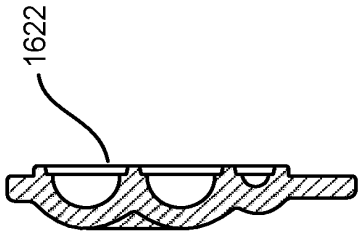


FIG. 17D

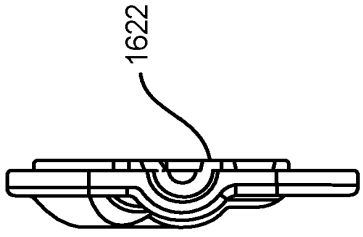


FIG. 17C

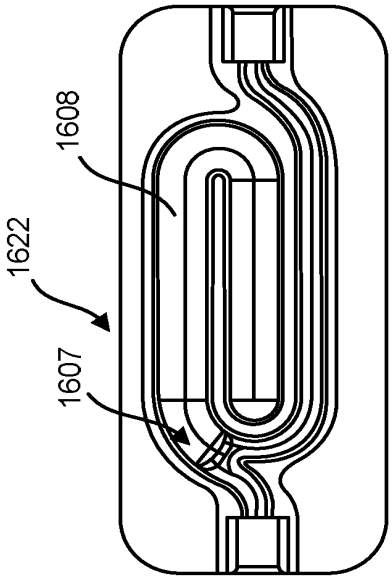


FIG. 17A

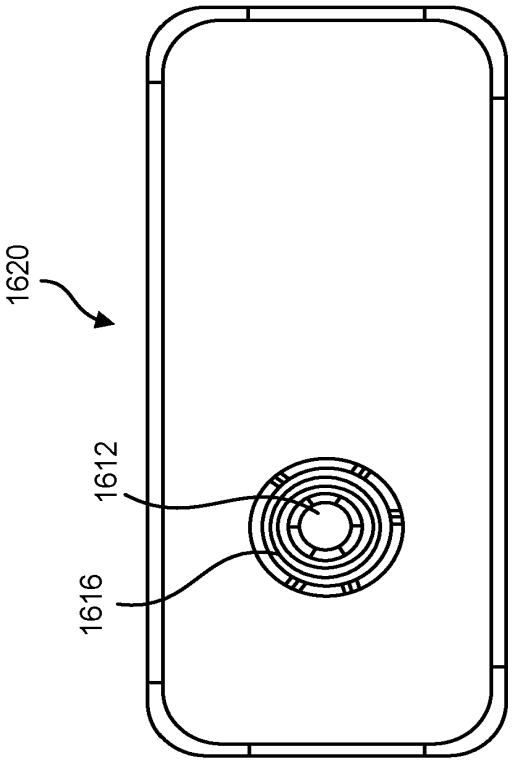


FIG. 18A

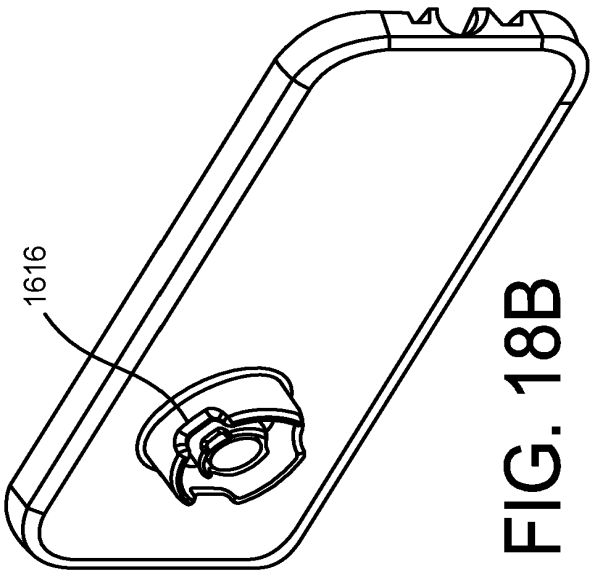


FIG. 18B

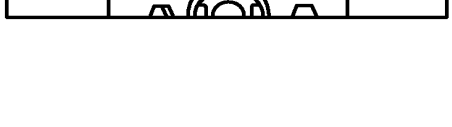


FIG. 18C

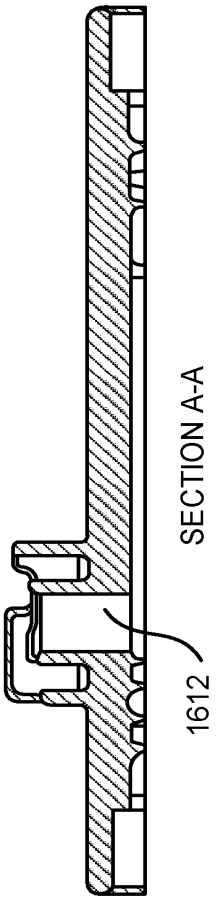


FIG. 18D

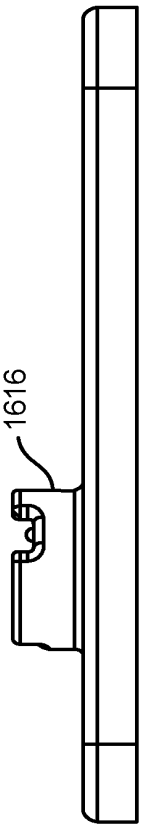


FIG. 18E

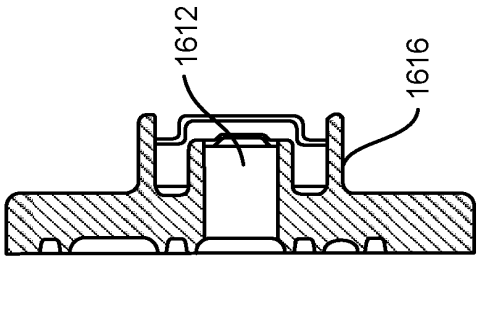


FIG. 18F

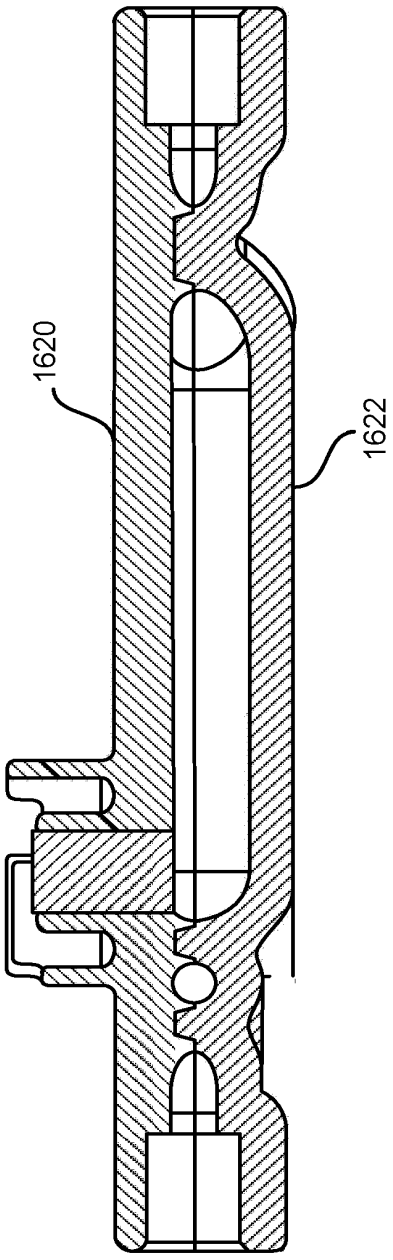


FIG. 19A

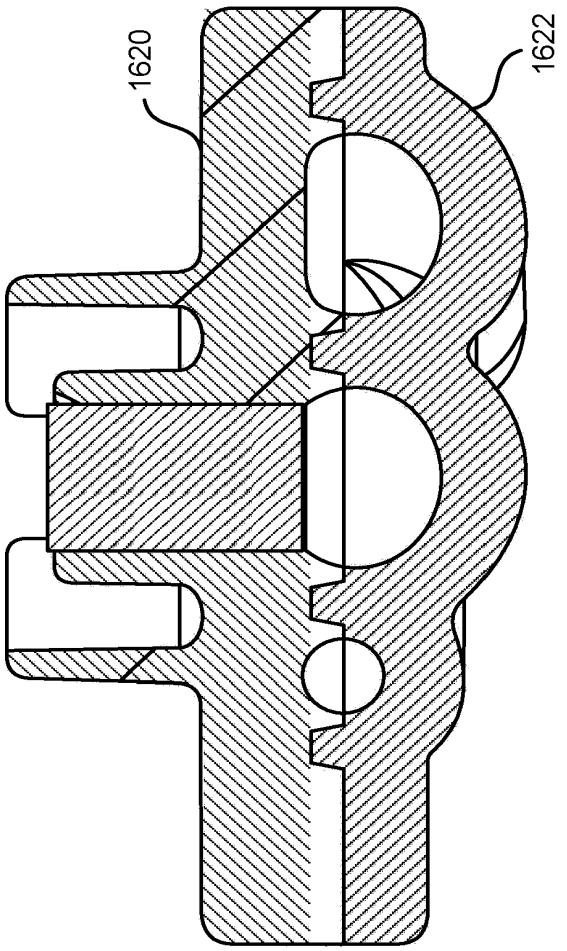


FIG. 19B

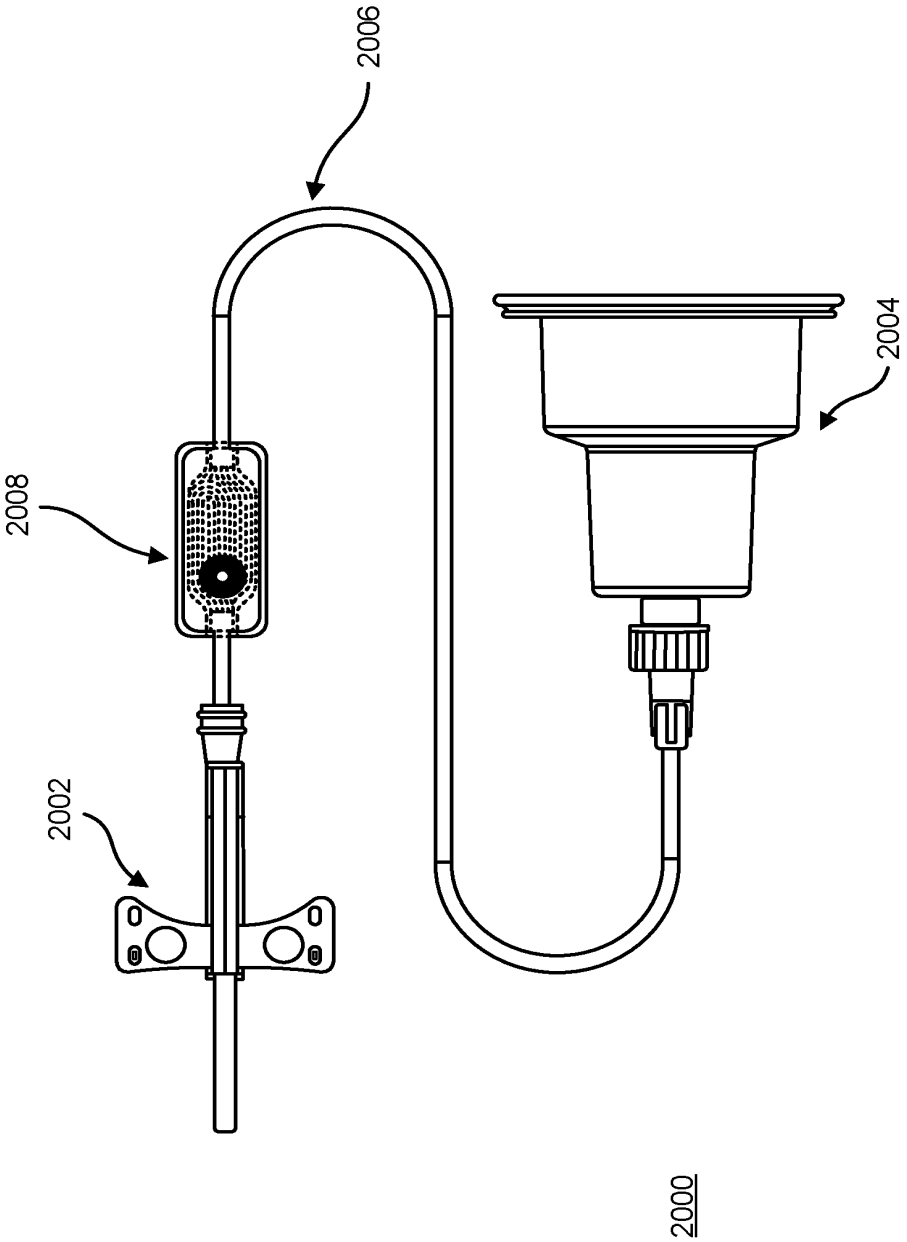


FIG. 20

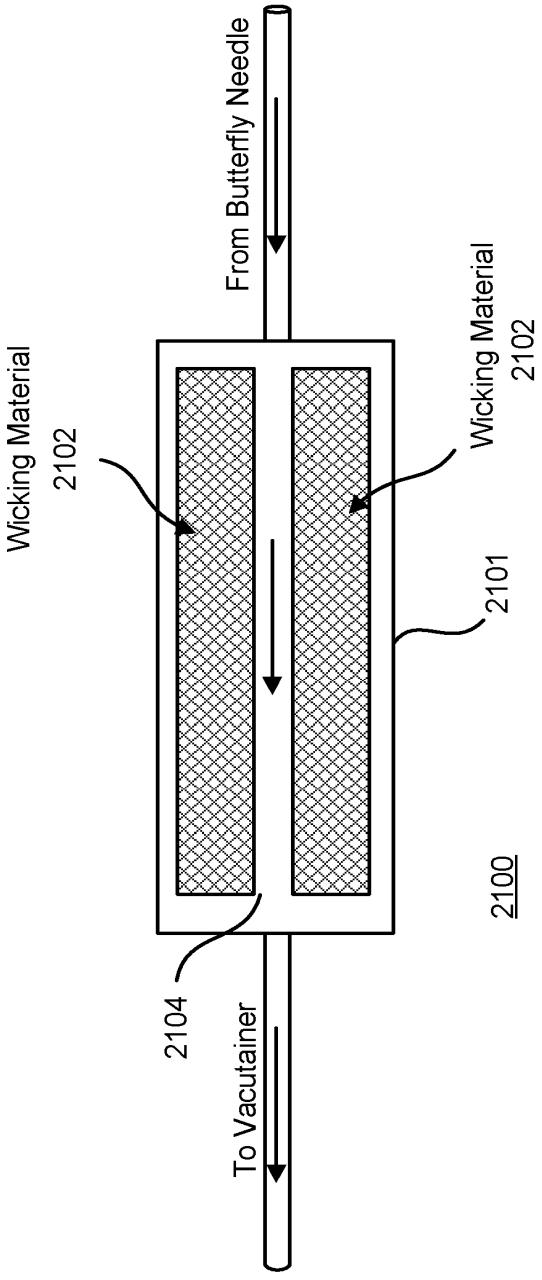

From Butterfly Needle
Wicking Material
2102
Wicking Material
2102
2101
2100
2104
To Vacutainer

FIG. 21

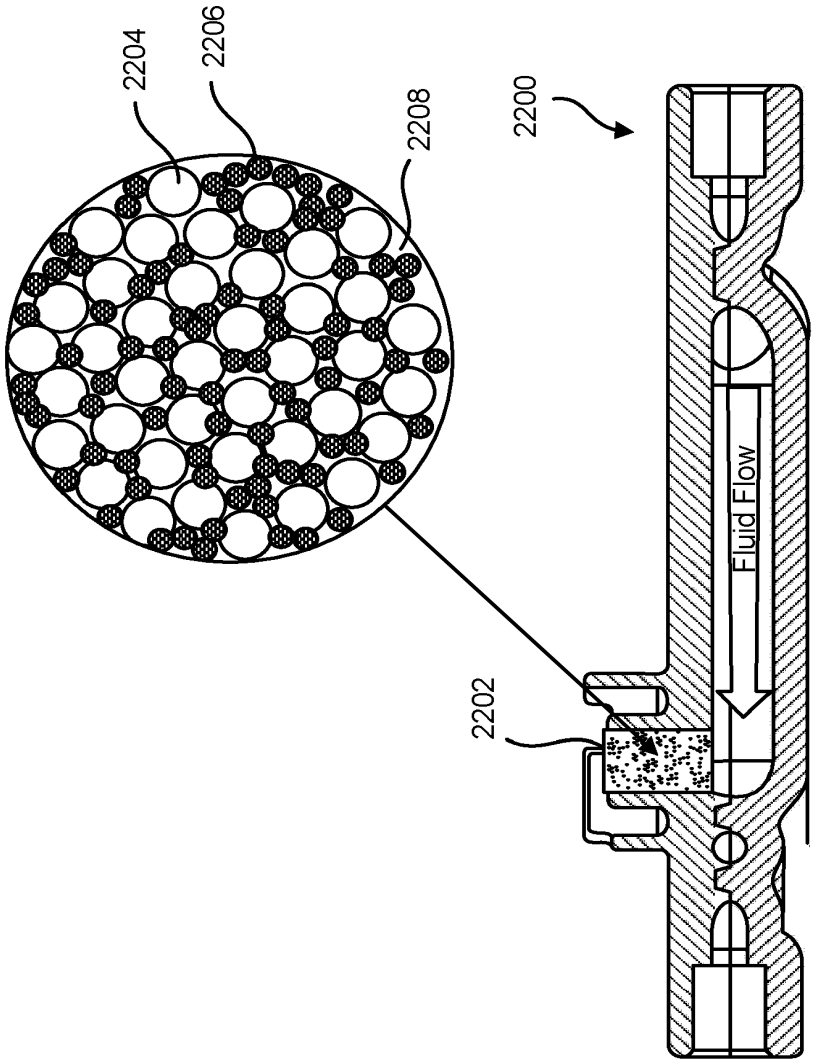


FIG. 22A

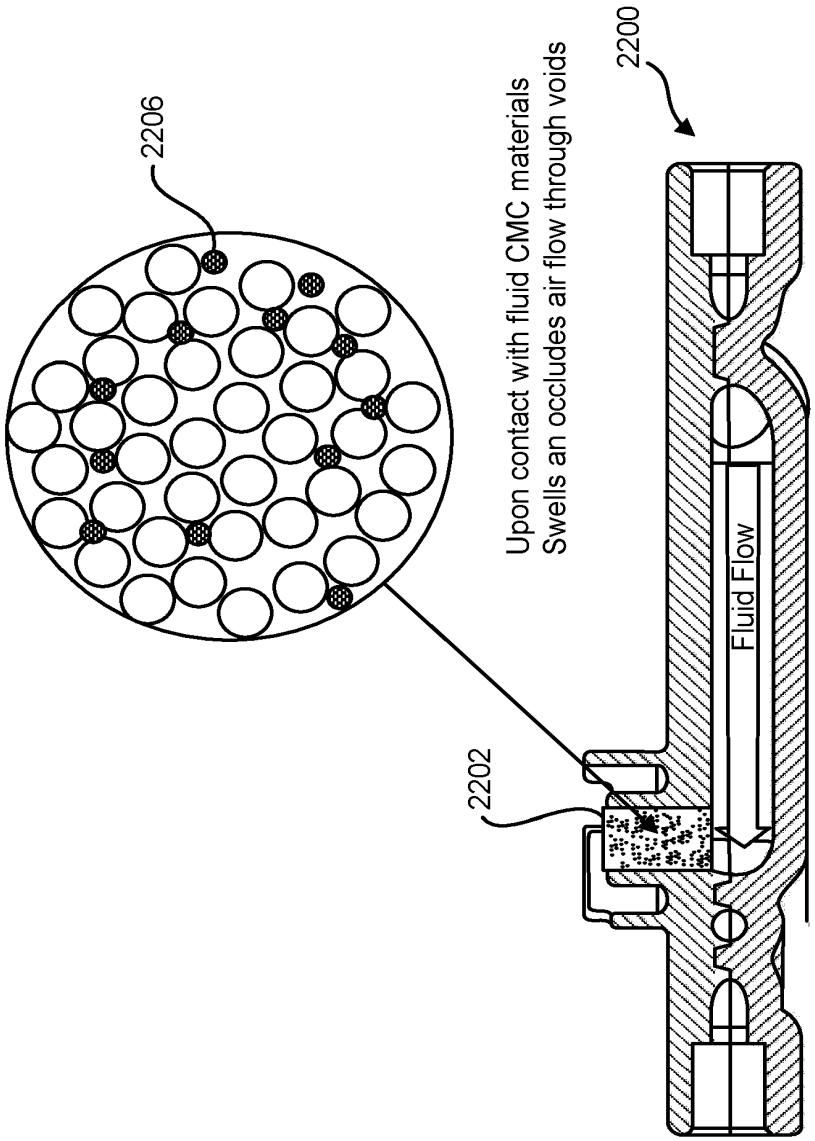

2206
Upon contact with fluid CMC materials
Swells an occludes air flow through voids
2200
2202
Fluid Flow

FIG. 22B

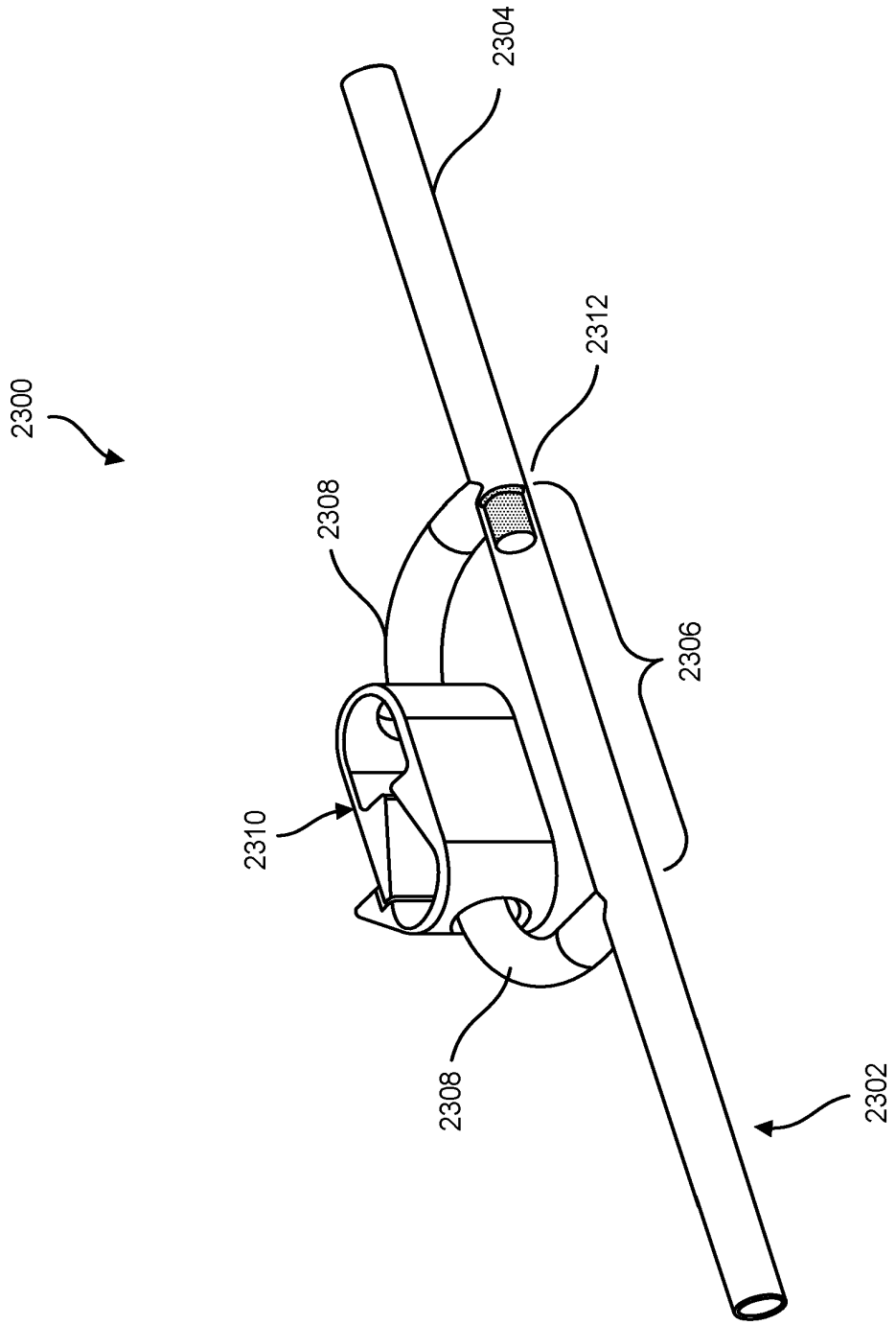


FIG. 23A

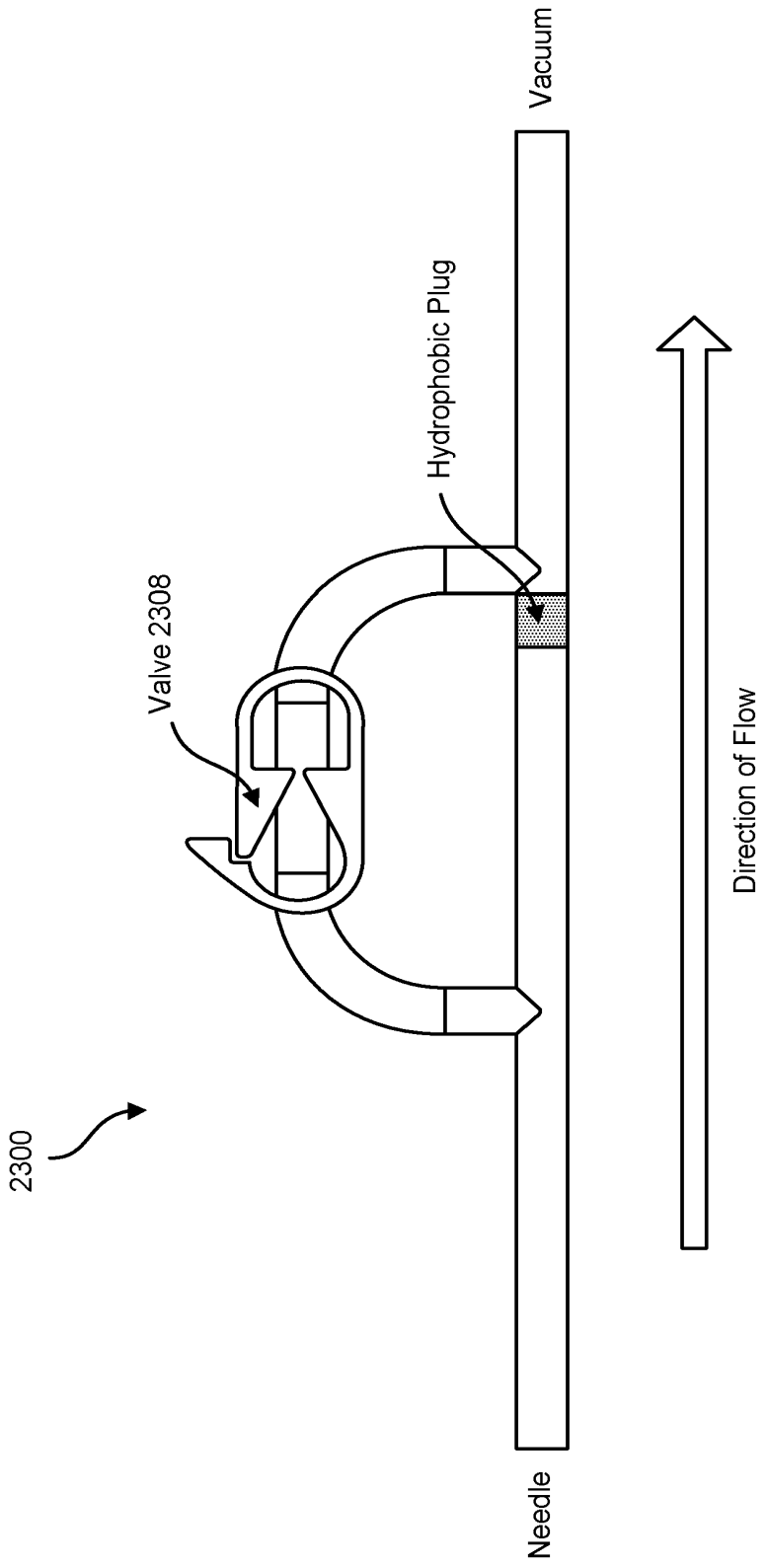

Vacuum
Hydrophobic Plug
Valve 2308
2300
Needle
Direction of Flow

FIG. 23B

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2016/043709

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B5/15 A61B5/153 A61B5/154
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.
X	WO 2011/162772 A1 (CLEARVIEW PATIENT SAFETY TECHNOLOGIES LLC [US]; FISCHEL LLOYD [US]; BR) 29 December 2011 (2011-12-29)	1-5, 7-13, 15-20
A	paragraph [0070] figure 15 abstract	6,14
A	US 2009/227953 A1 (TAN CHEE LEONG [SG] ET AL) 10 September 2009 (2009-09-10) the whole document	1-20
A	JP H08 257018 A (NISSHO KK) 8 October 1996 (1996-10-08) abstract; figures	1-20

-/--

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

[X] See patent family annex.

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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

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
11 October 2016	19/10/2016

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	Schultz, Ottmar

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

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2016/043709

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 4 416 290 A (LUTKOWSKI LAWRENCE [US]) 22 November 1983 (1983-11-22) abstract; figures	1-20
A	US 3 648 684 A (BARNWELL CLEORA W ET AL) 14 March 1972 (1972-03-14) abstract; figures	1-20
A	EP 1 665 986 A1 (BECTON DICKINSON CO [US]) 7 June 2006 (2006-06-07) figures 13,14	1-20
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(54) Title: BLOOD SAMPLE OPTIMIZATION SYSTEM AND BLOOD CONTAMINANT SEQUESTRATION DEVICE AND METHOD

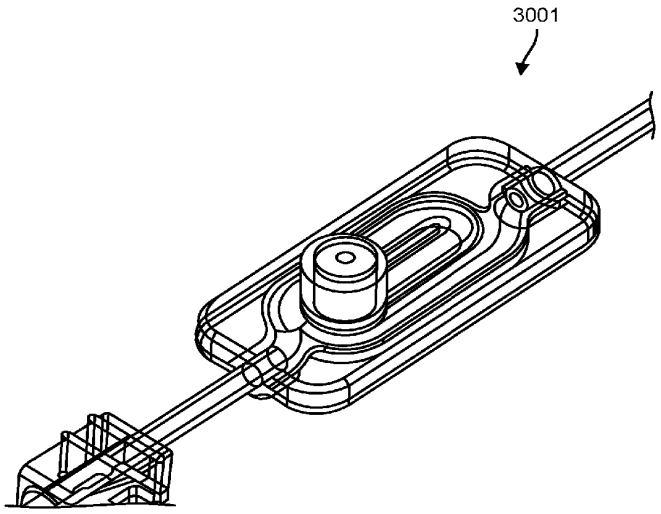


FIG. 30B

(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.

[Continued on next page]

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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.

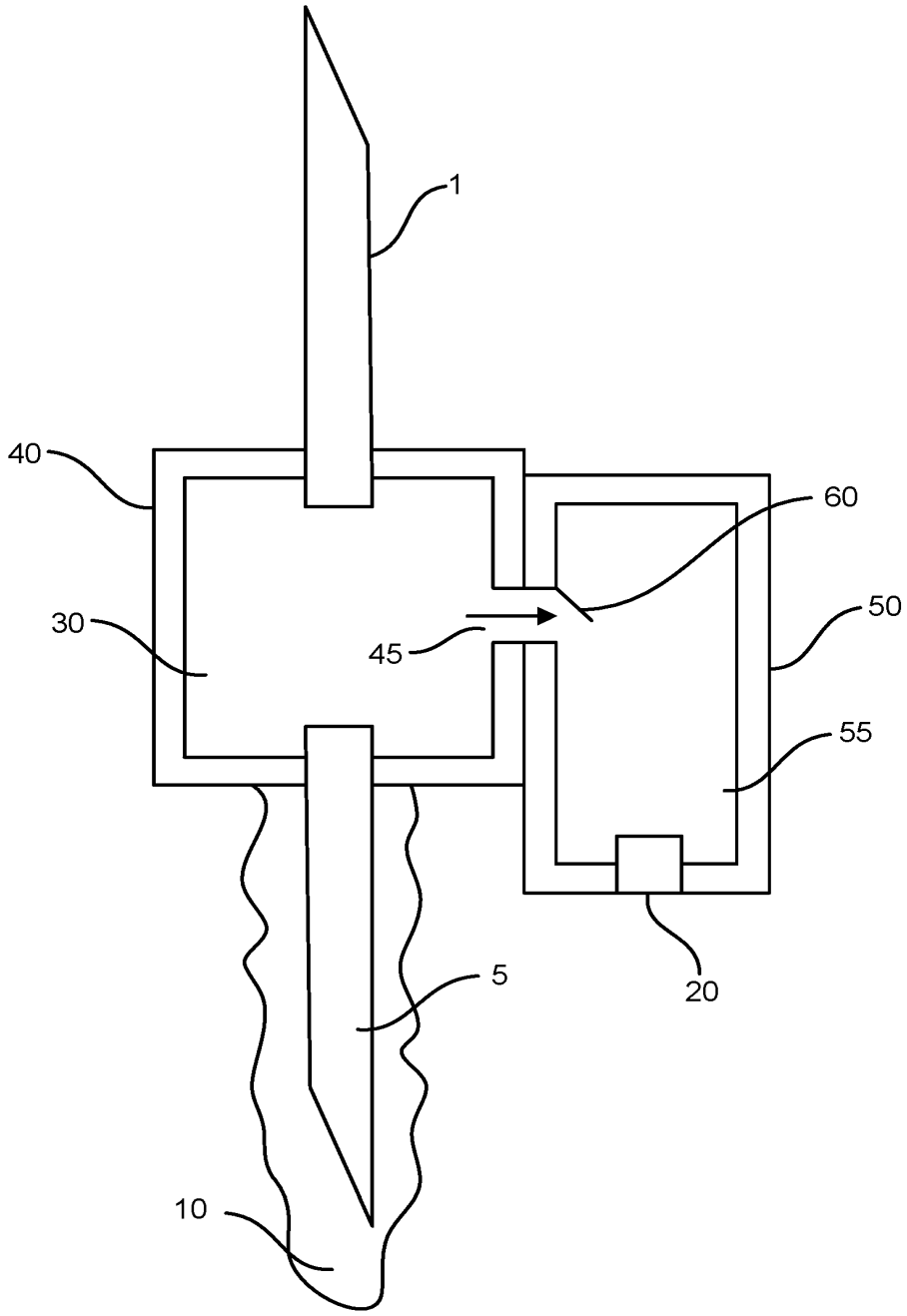


FIG. 1

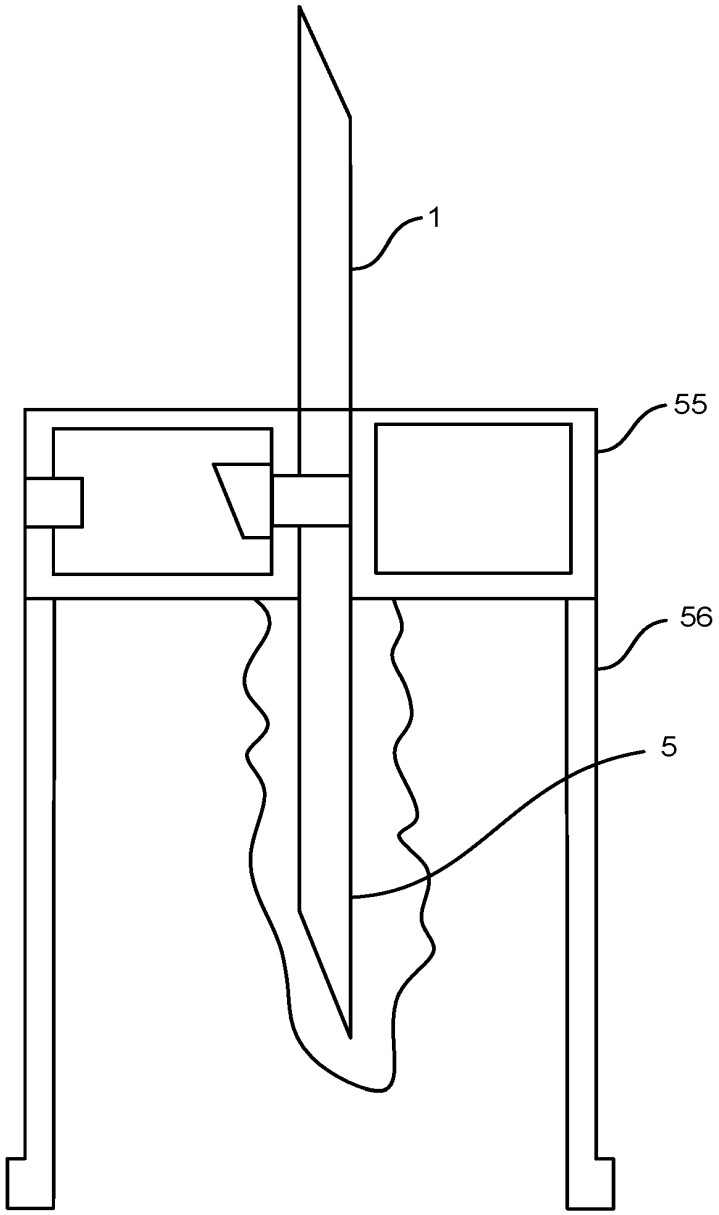


FIG. 2

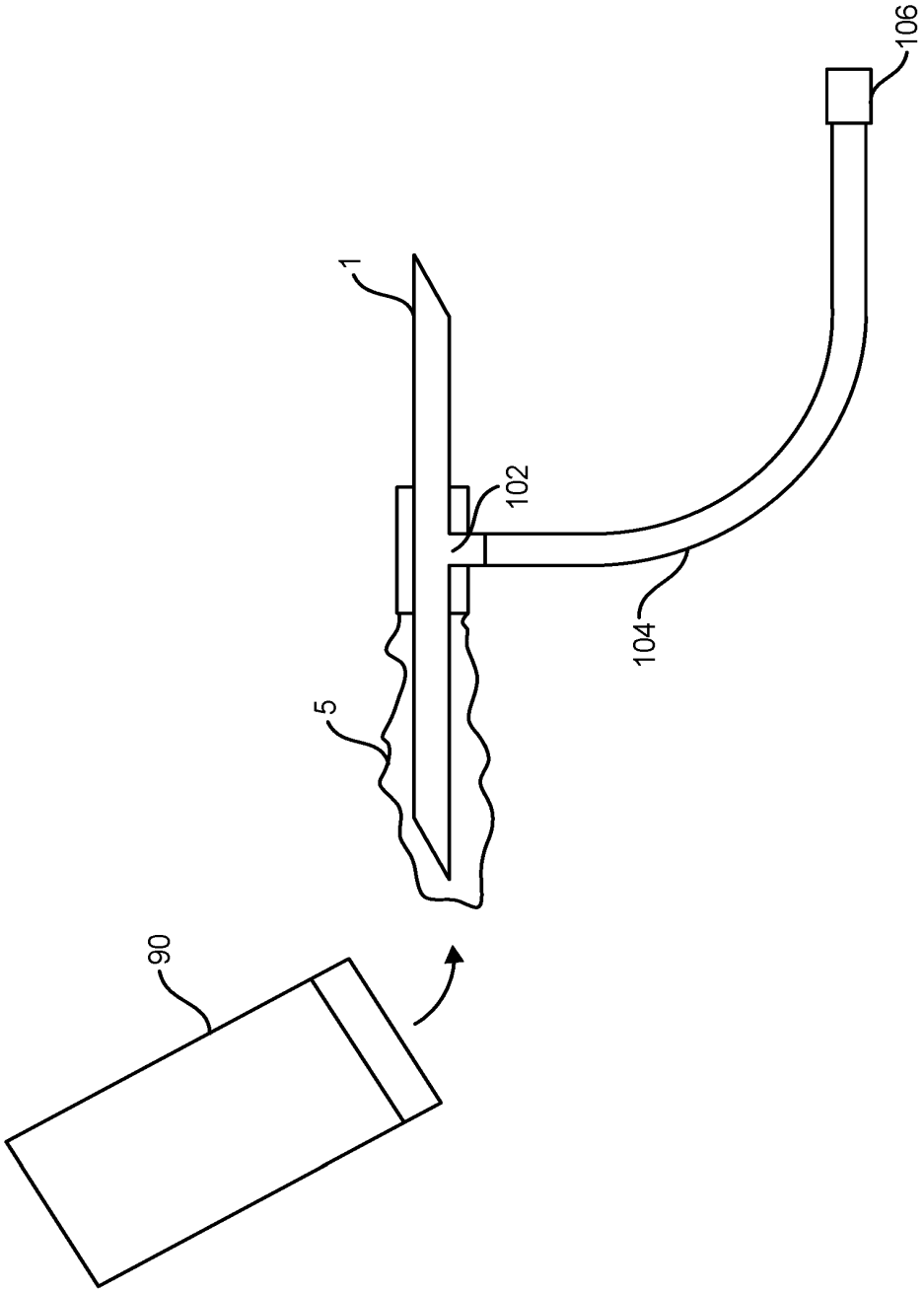


FIG. 3

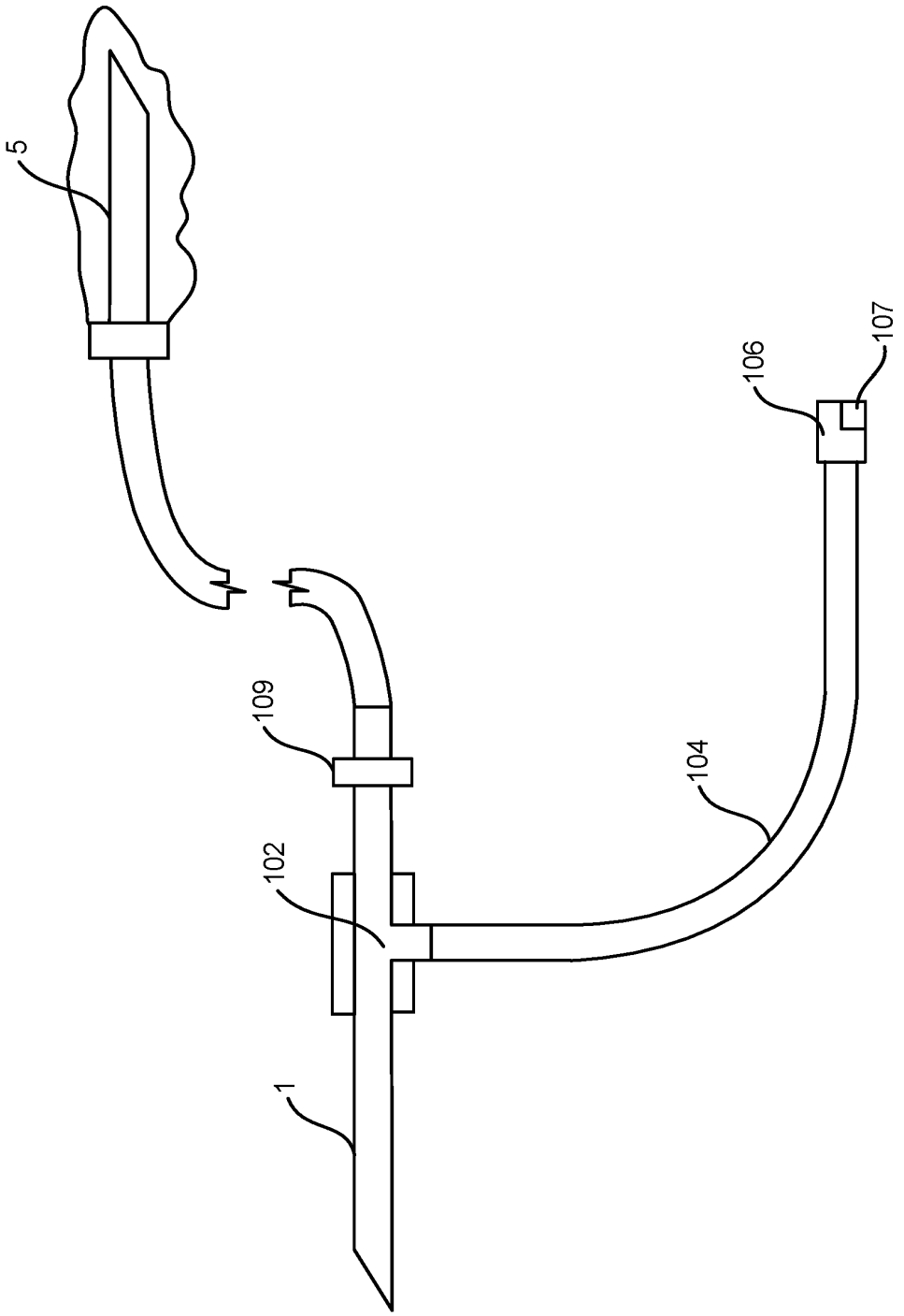


FIG. 4

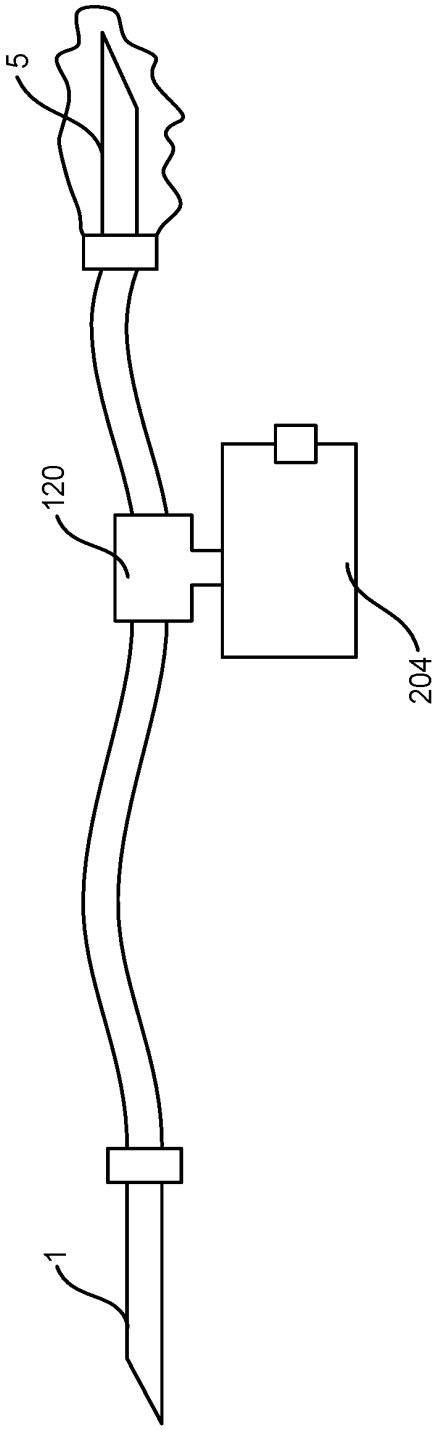


FIG. 5

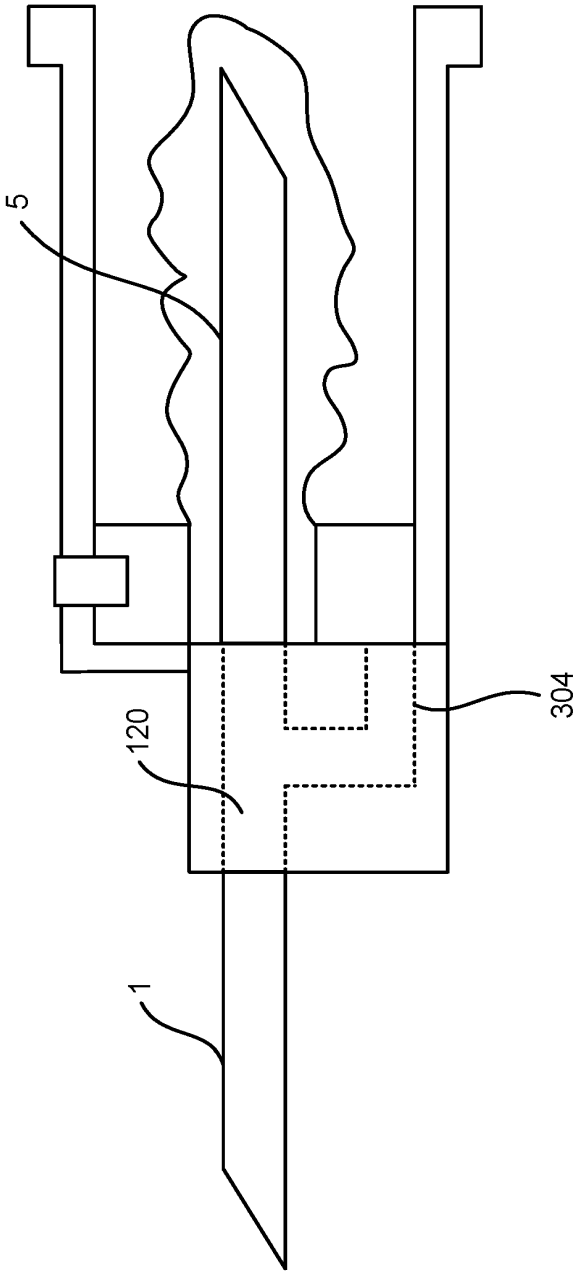


FIG. 6

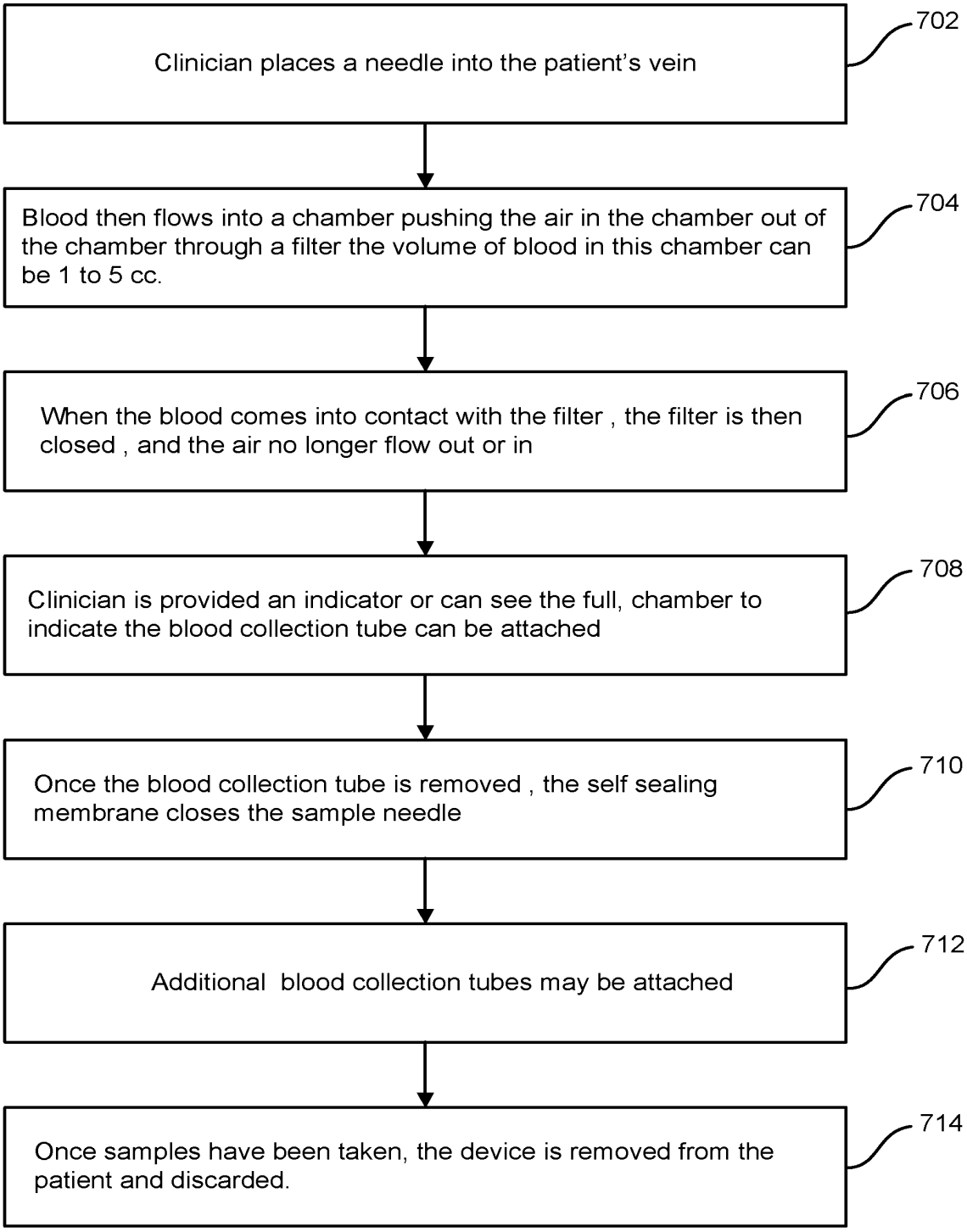

Clinician places a needle into the patient's vein
702
Blood then flows into a chamber pushing the air in the chamber out of the chamber through a filter the volume of blood in this chamber can be 1 to 5 cc.
704
When the blood comes into contact with the filter , the filter is then closed , and the air 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

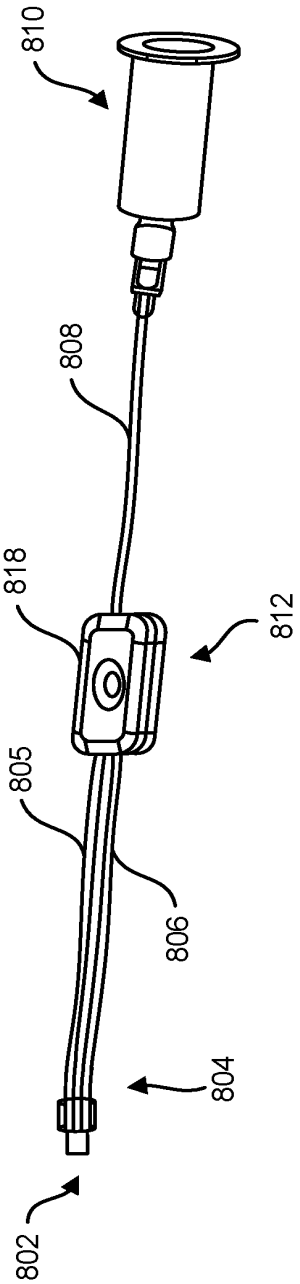


FIG. 8A

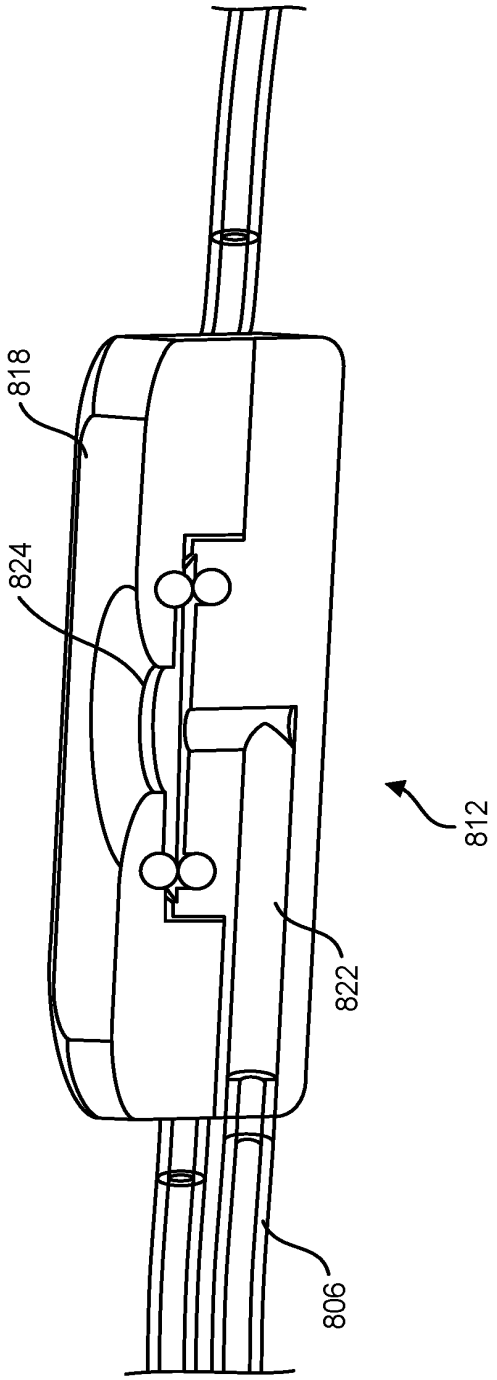


FIG. 8B

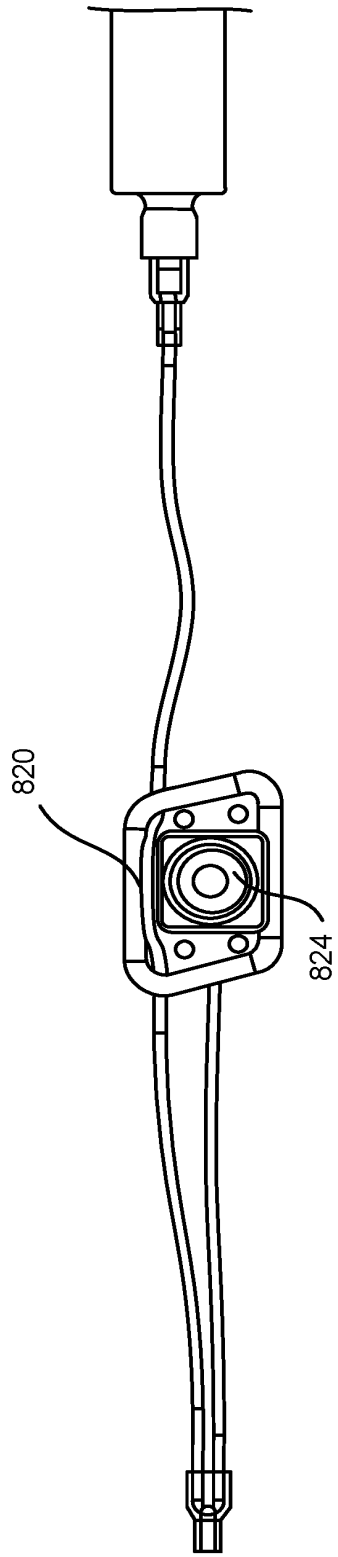


FIG. 8C

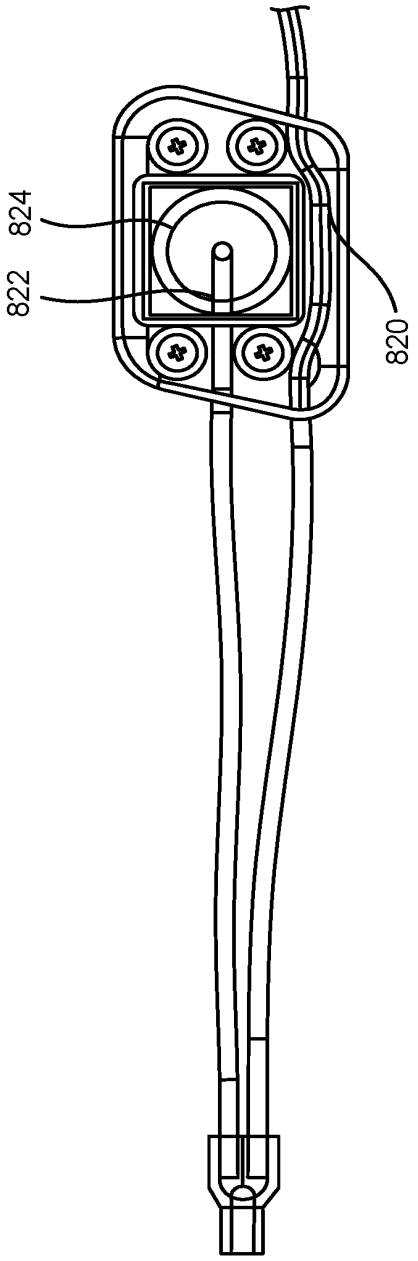


FIG. 8D

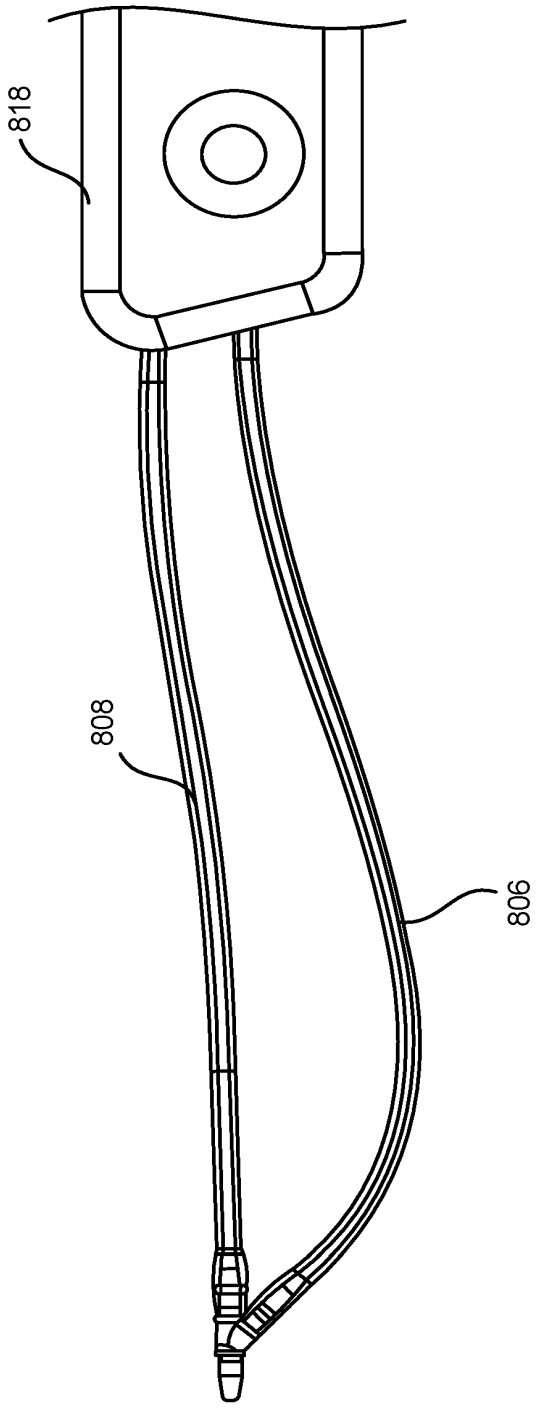


FIG. 8E

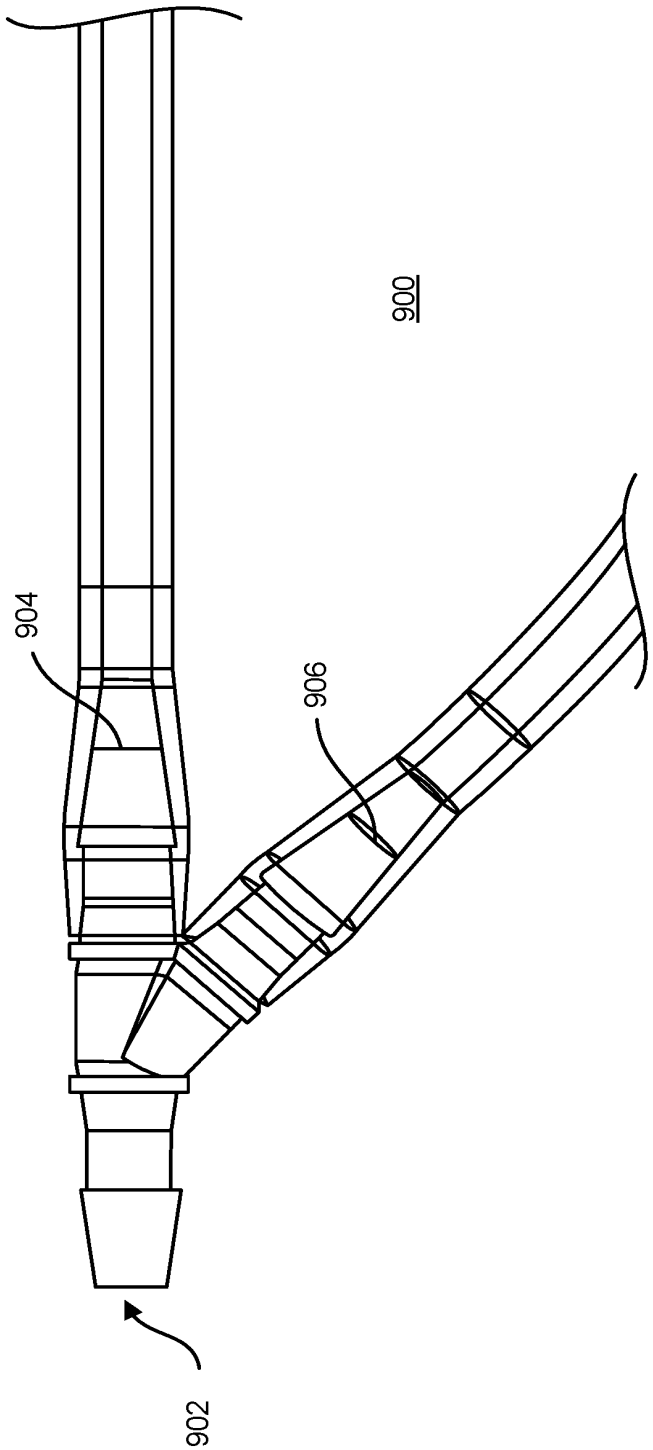


FIG. 9

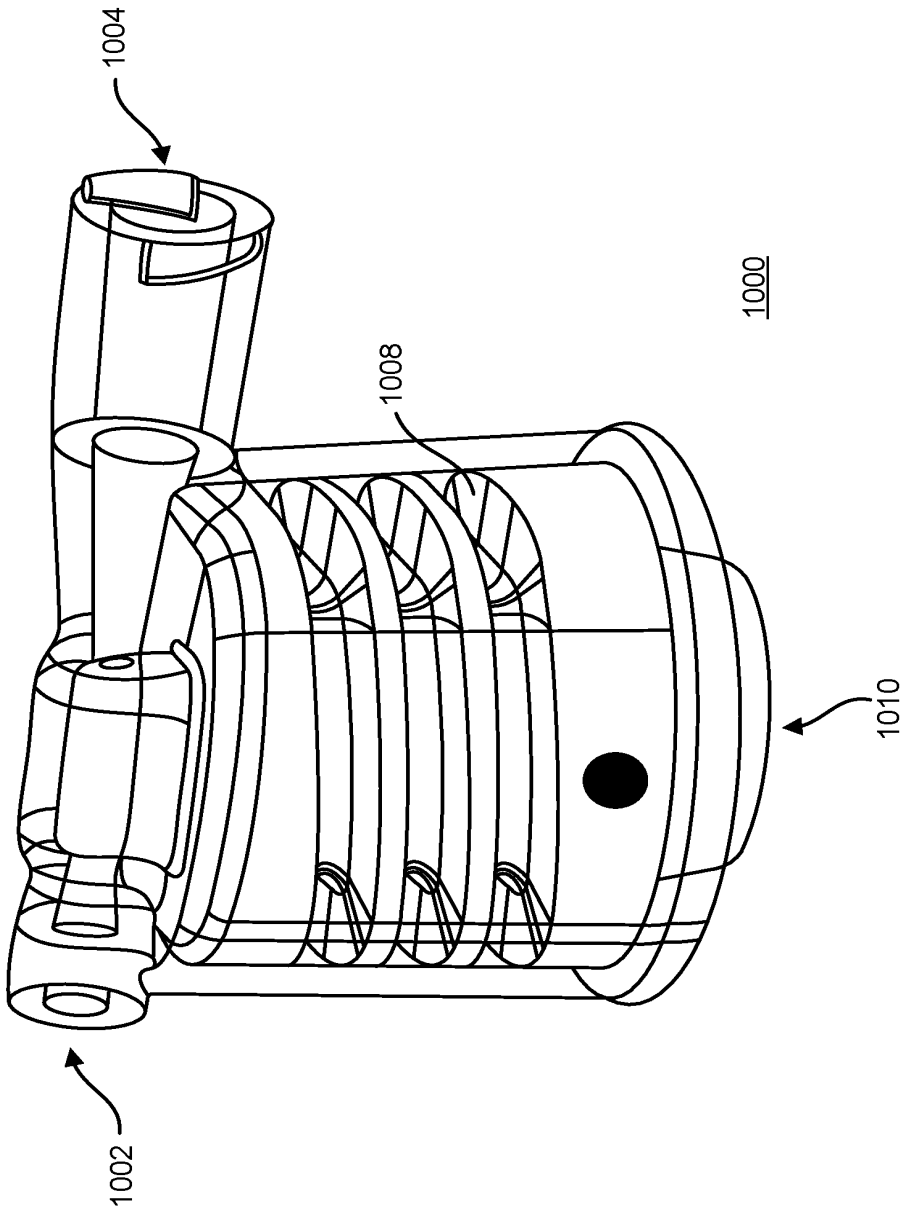


FIG. 10A

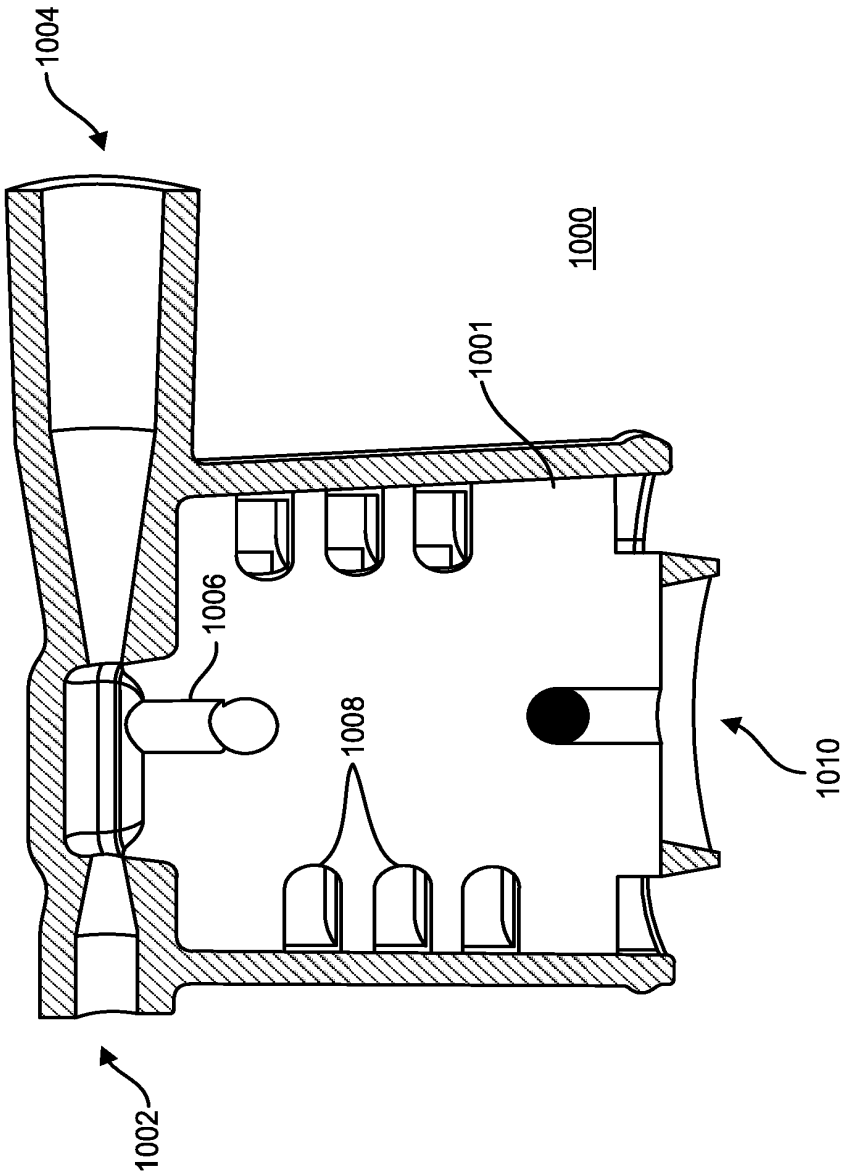


FIG. 10B

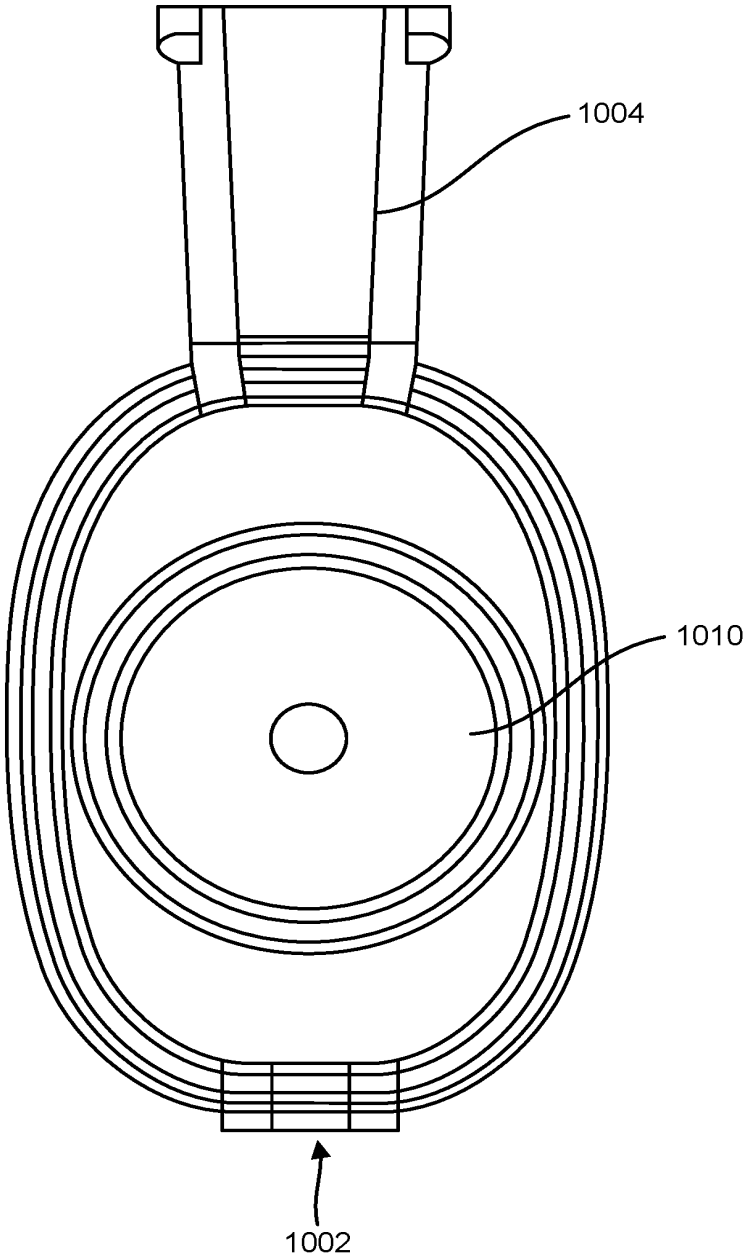


FIG. 10C

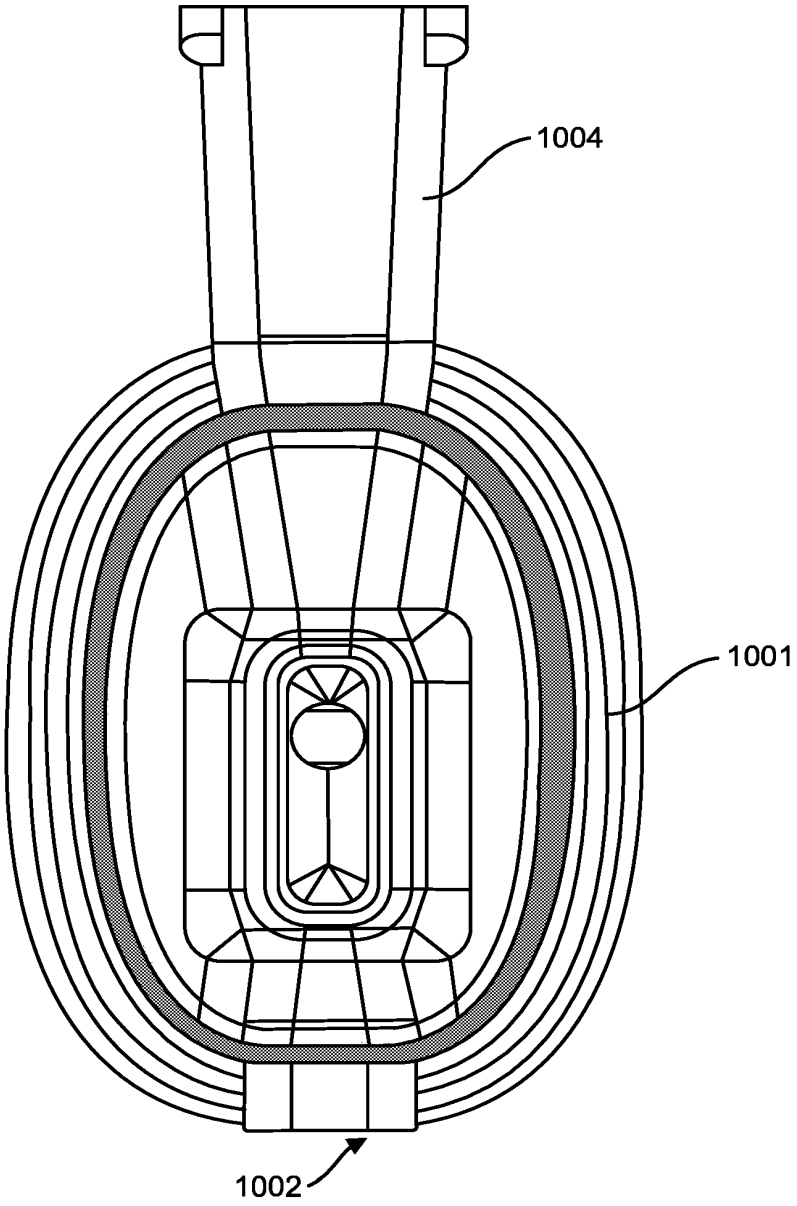


FIG. 10D

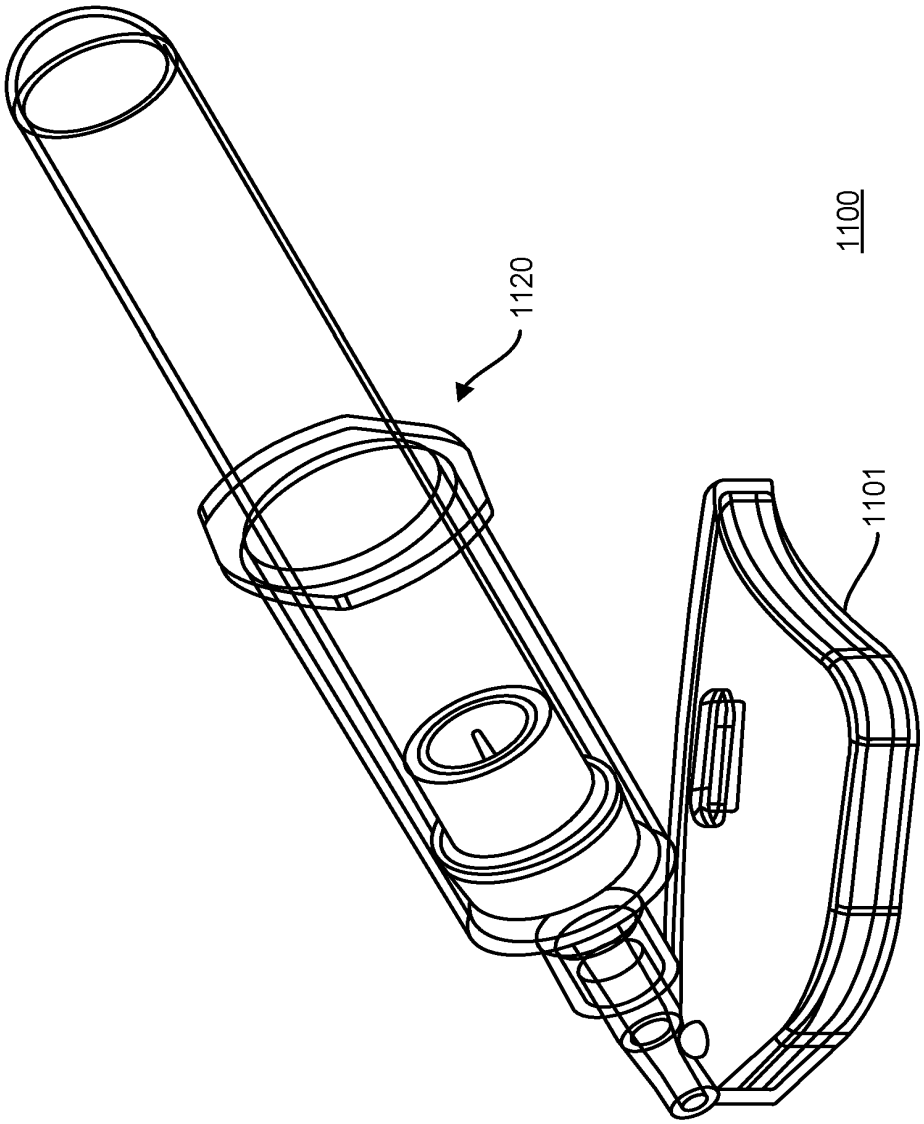


FIG. 11A

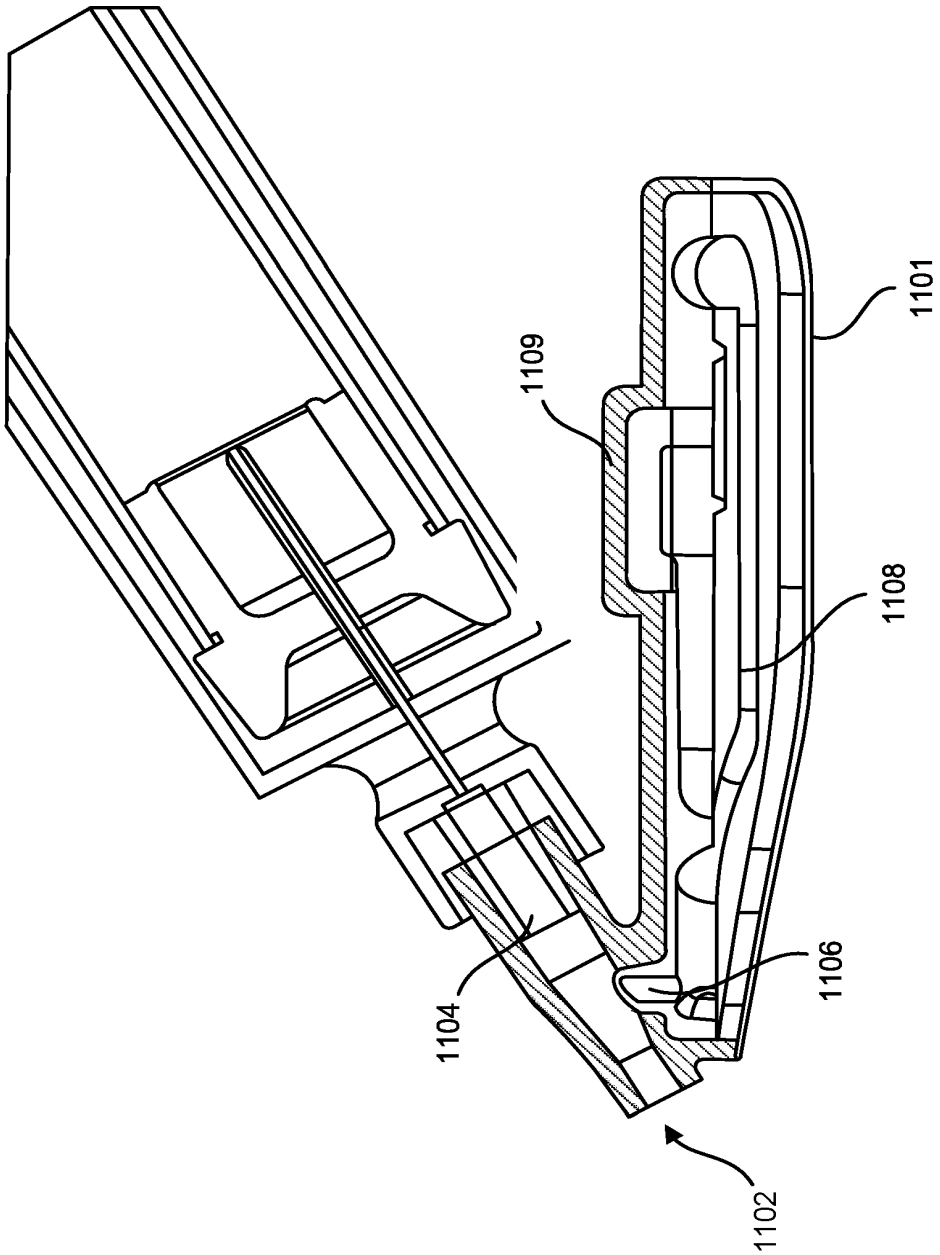


FIG. 11B

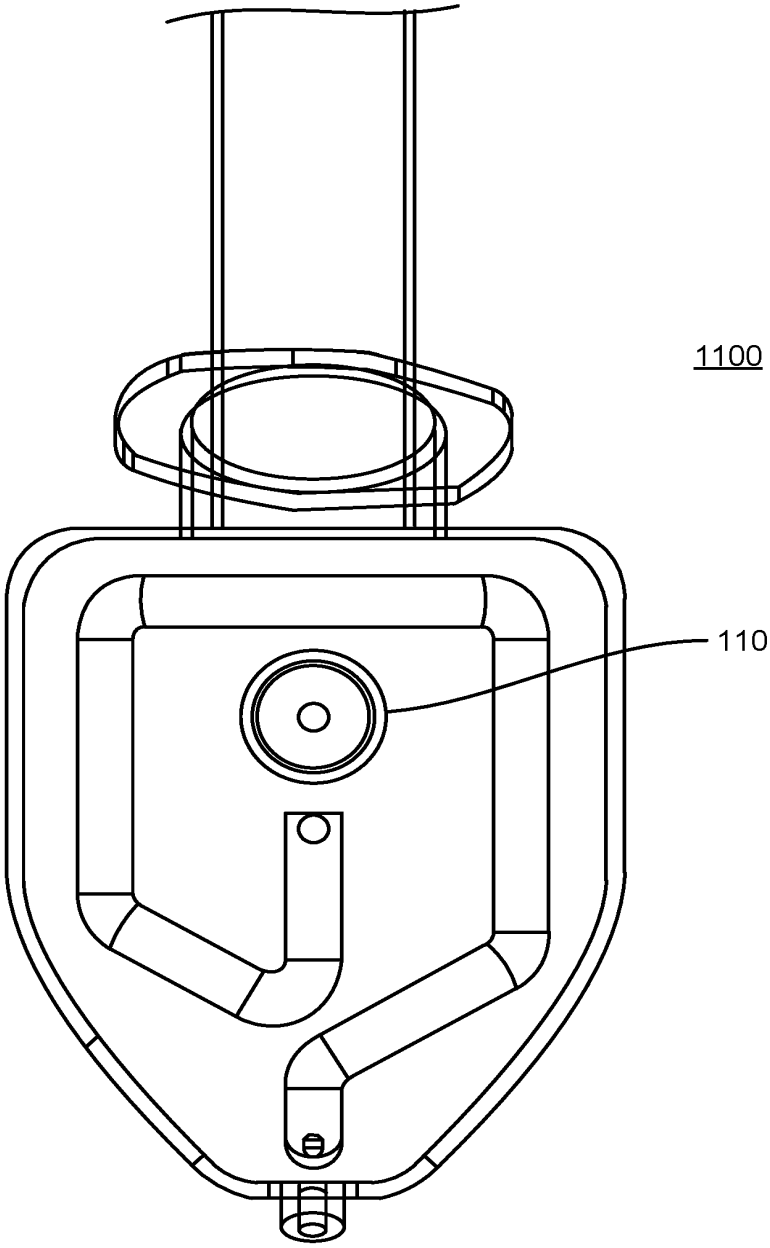


FIG. 11C

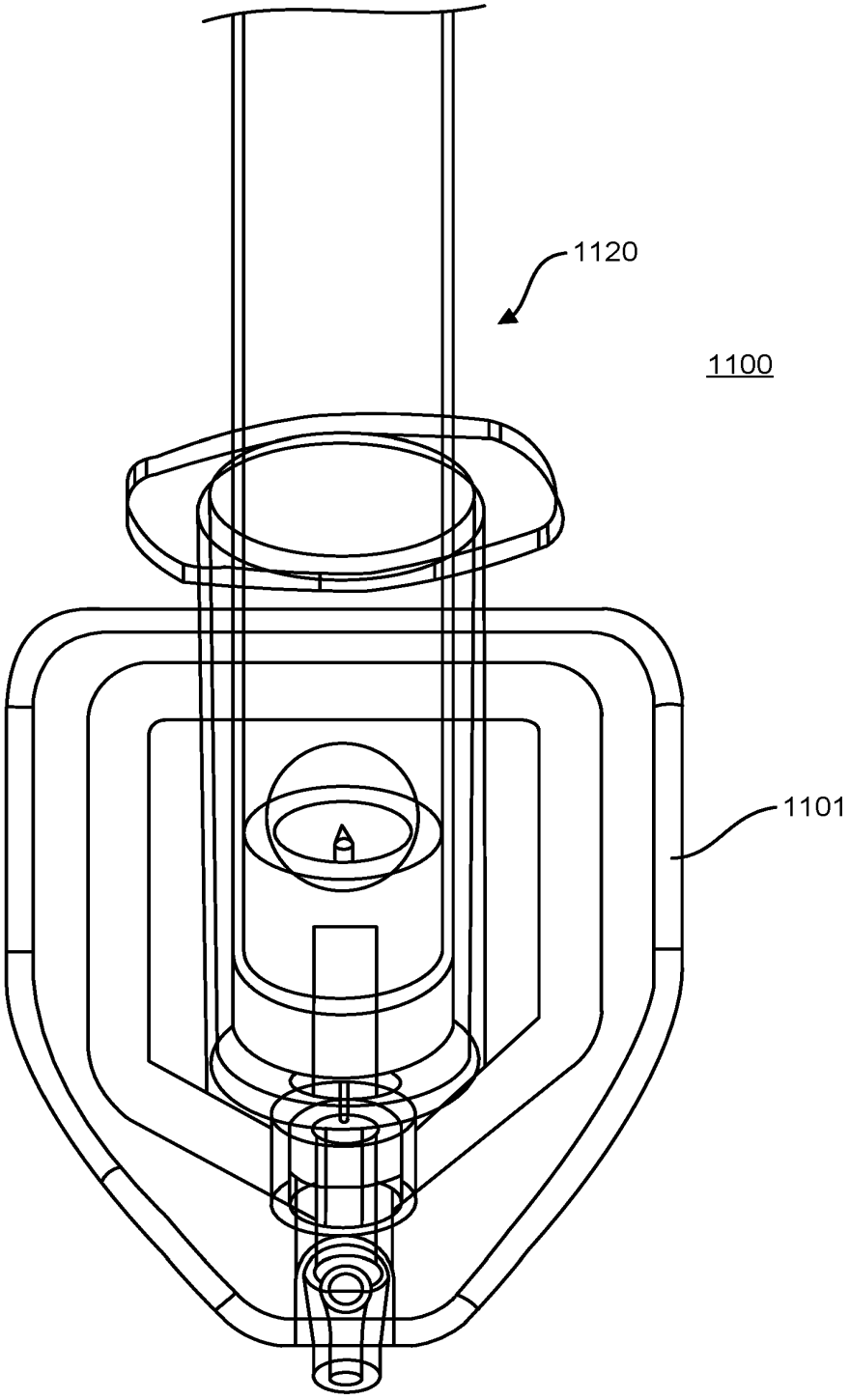


FIG. 11D

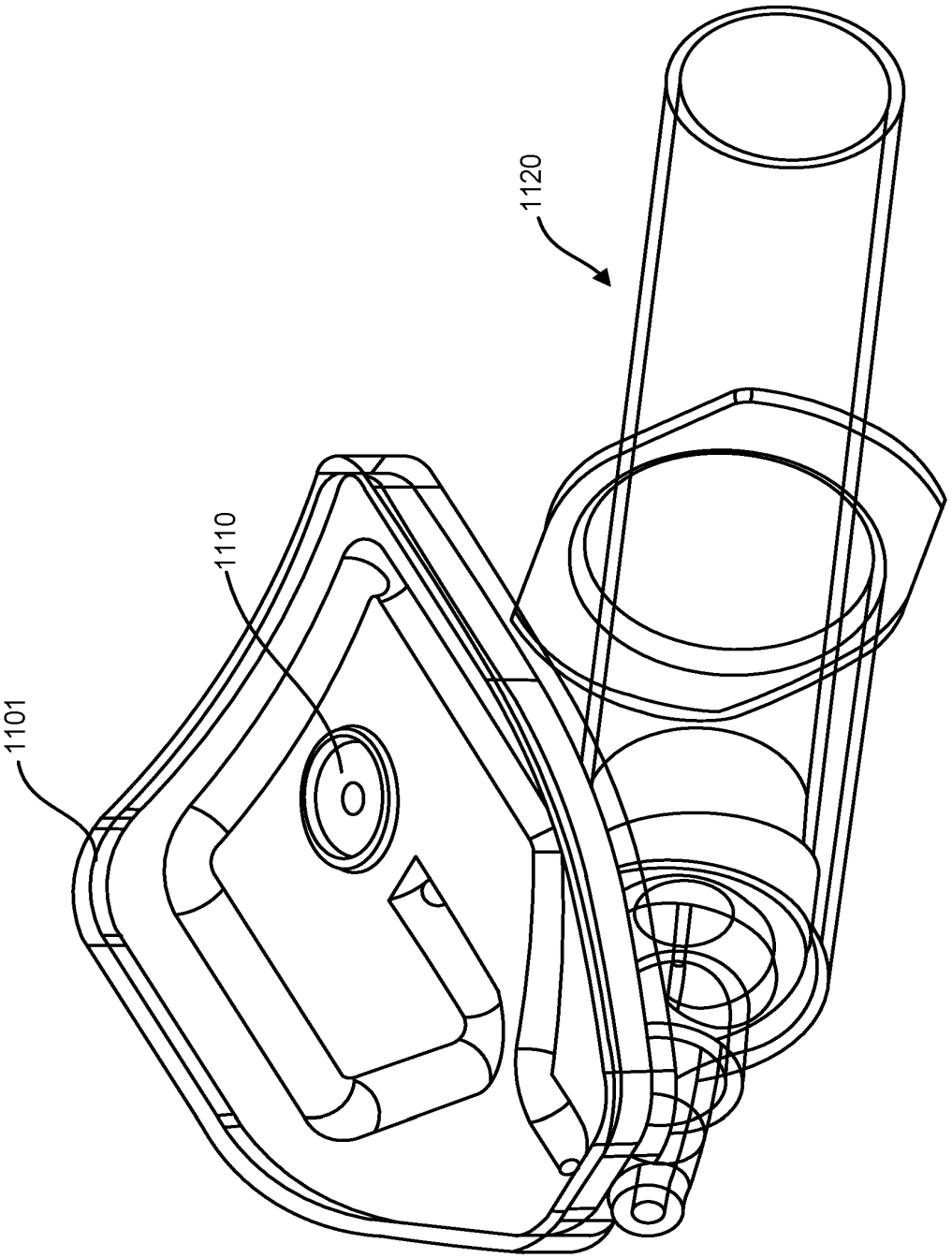


FIG. 11E

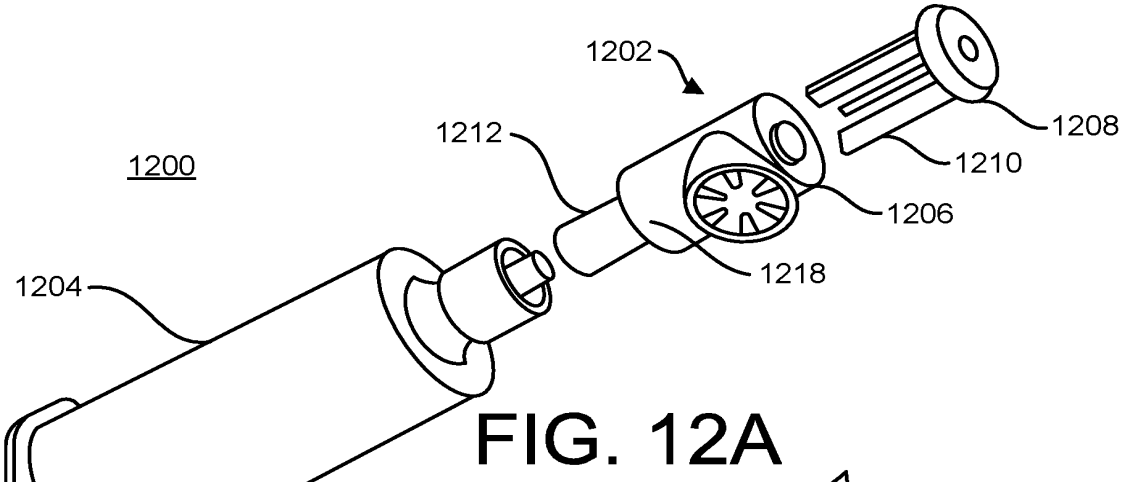


FIG. 12A

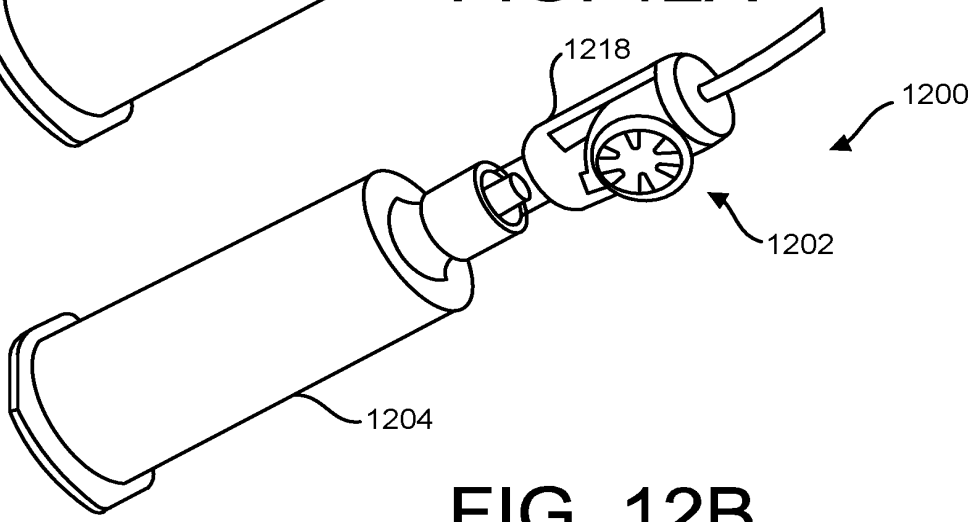


FIG. 12B

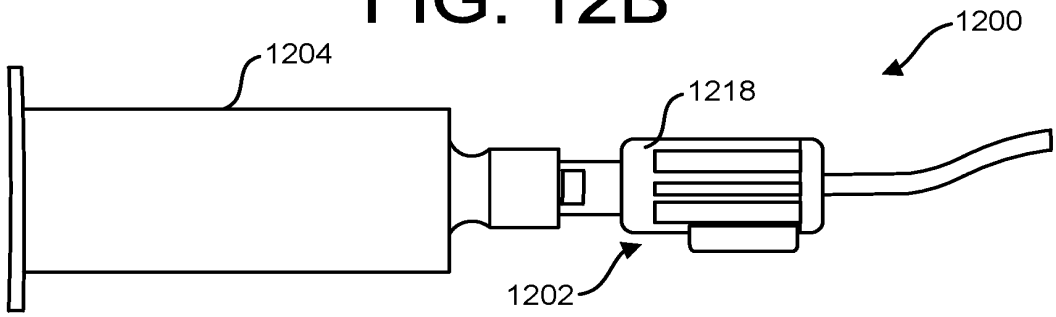


FIG. 12C

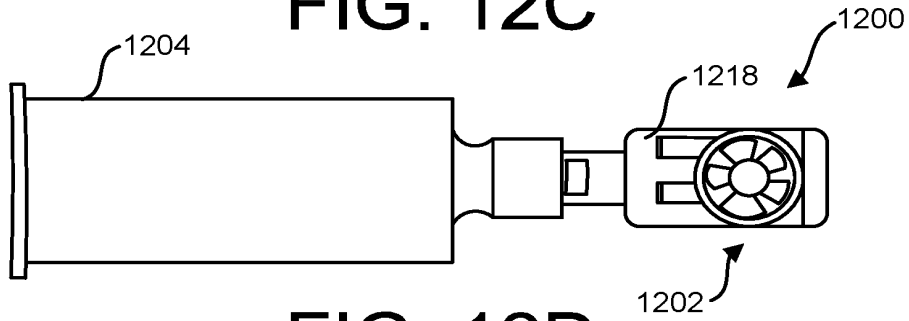


FIG. 12D

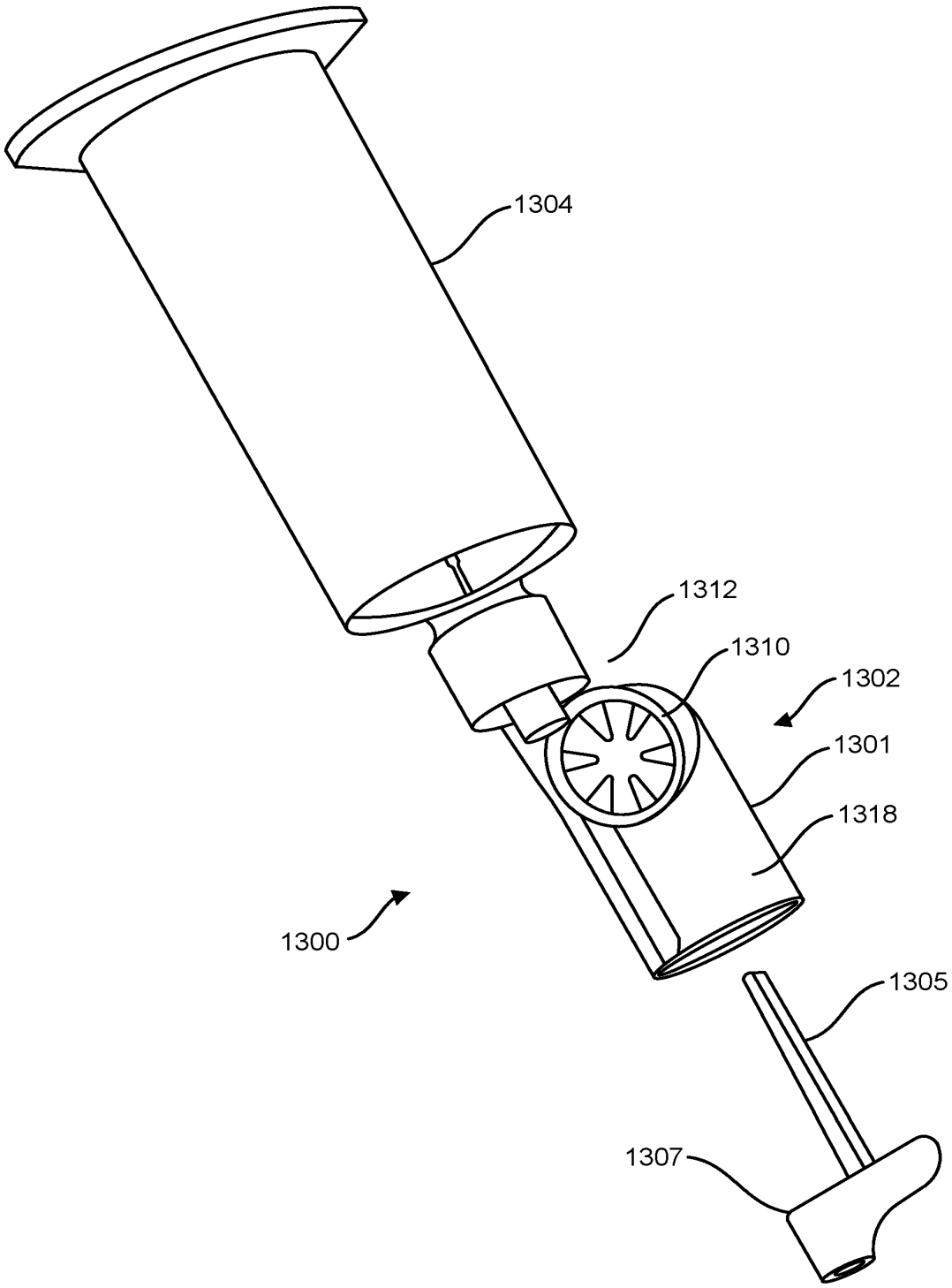


FIG. 13A

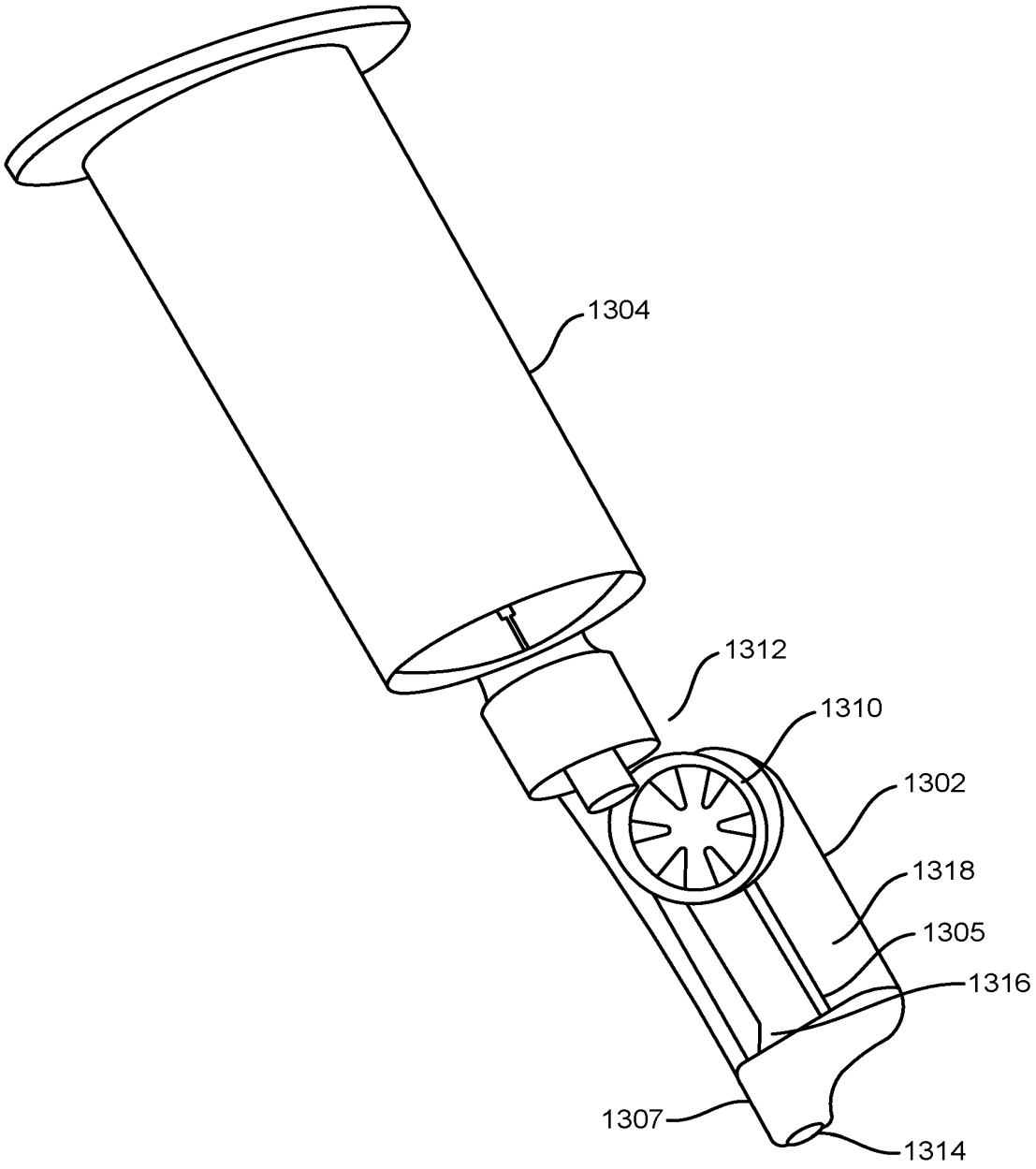


FIG. 13B

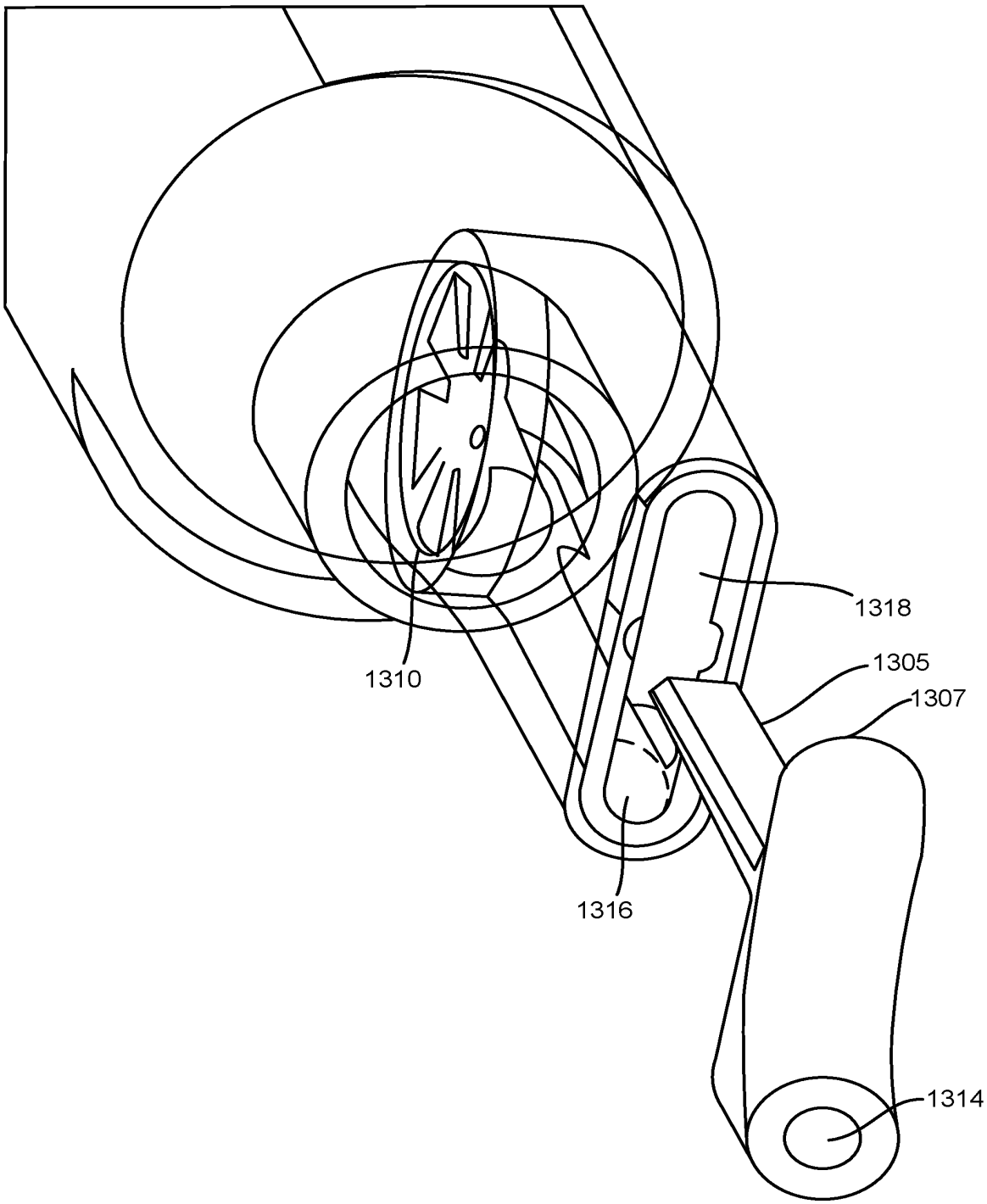


FIG. 13C

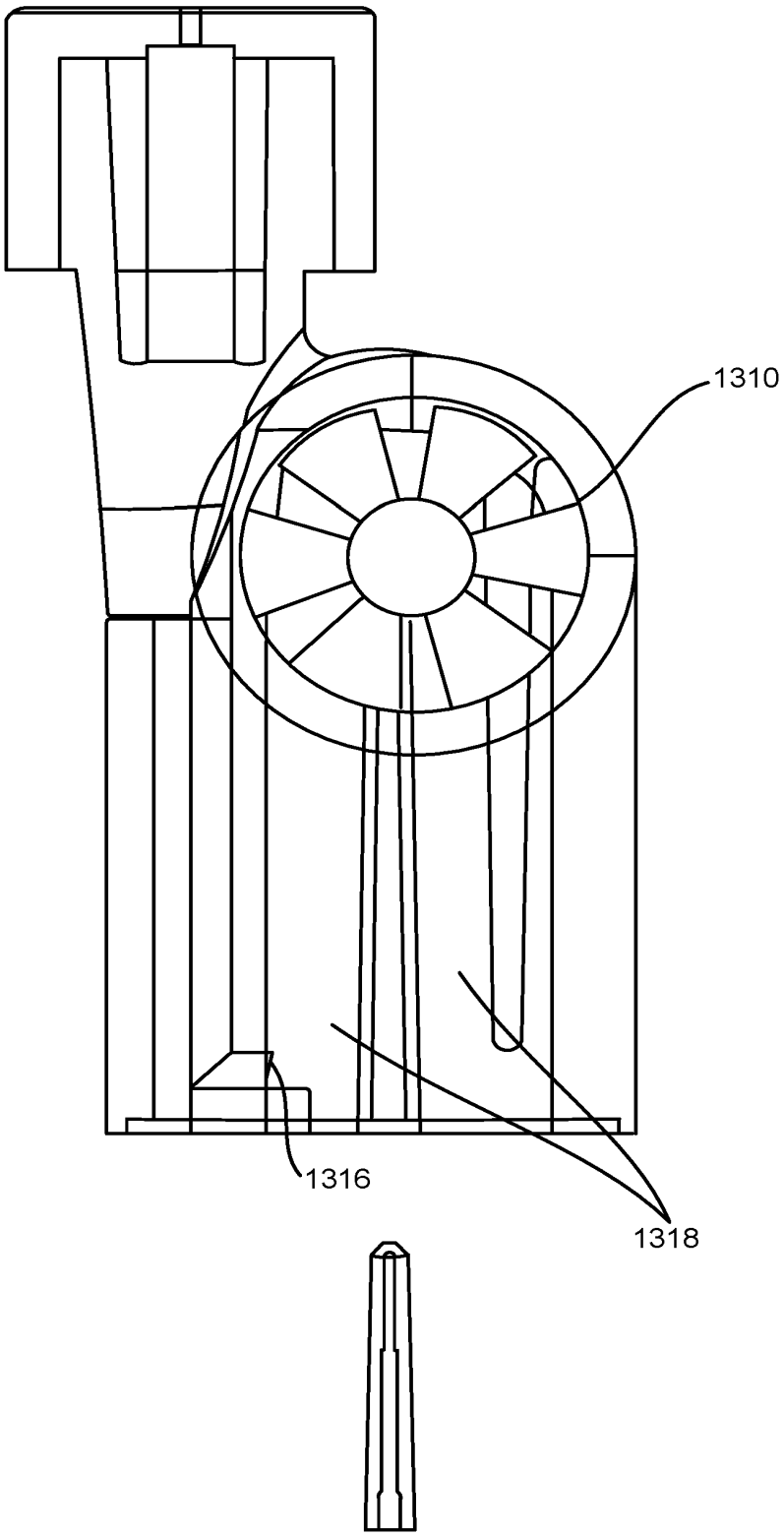


FIG. 13D

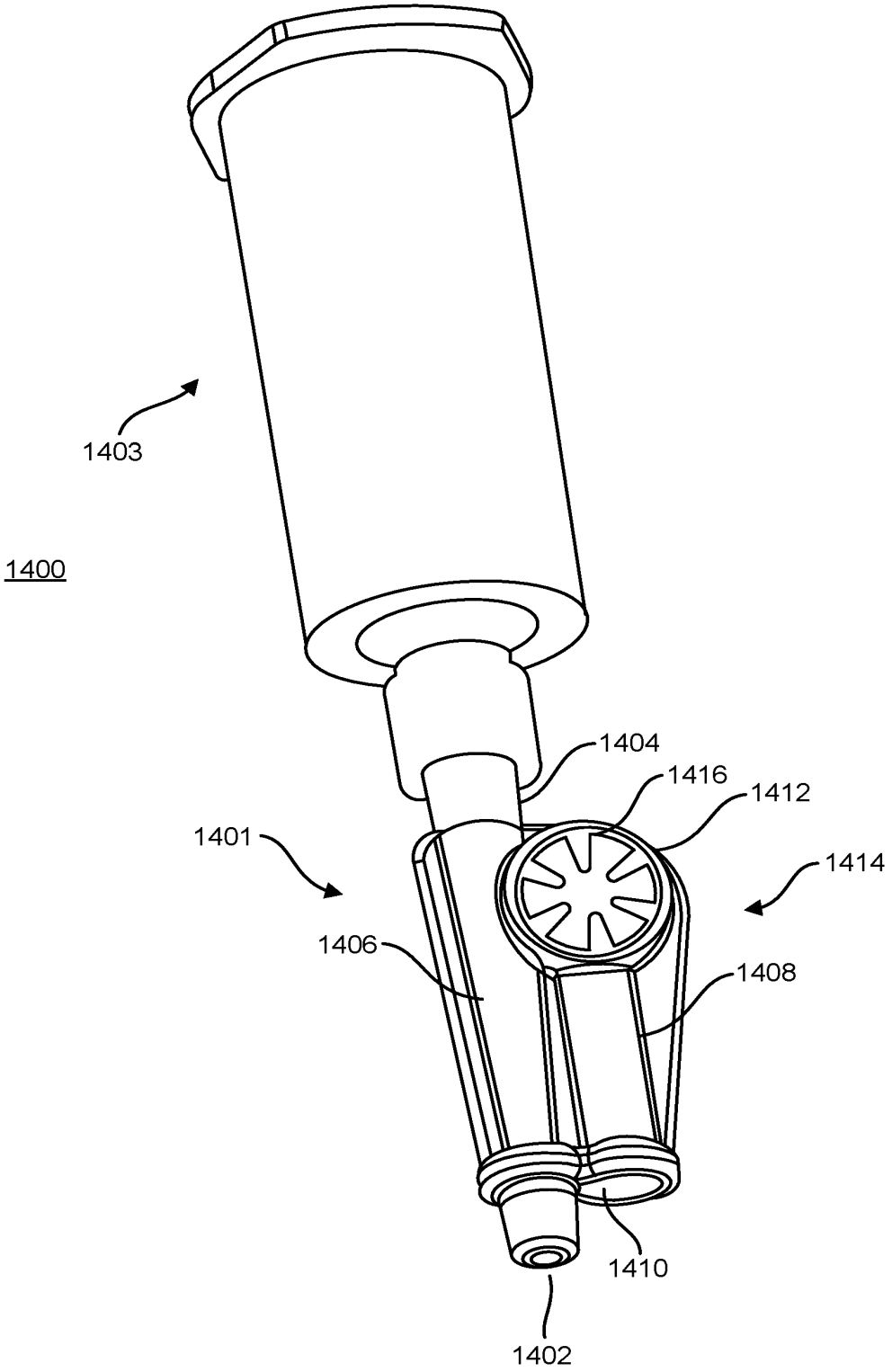


FIG. 14A

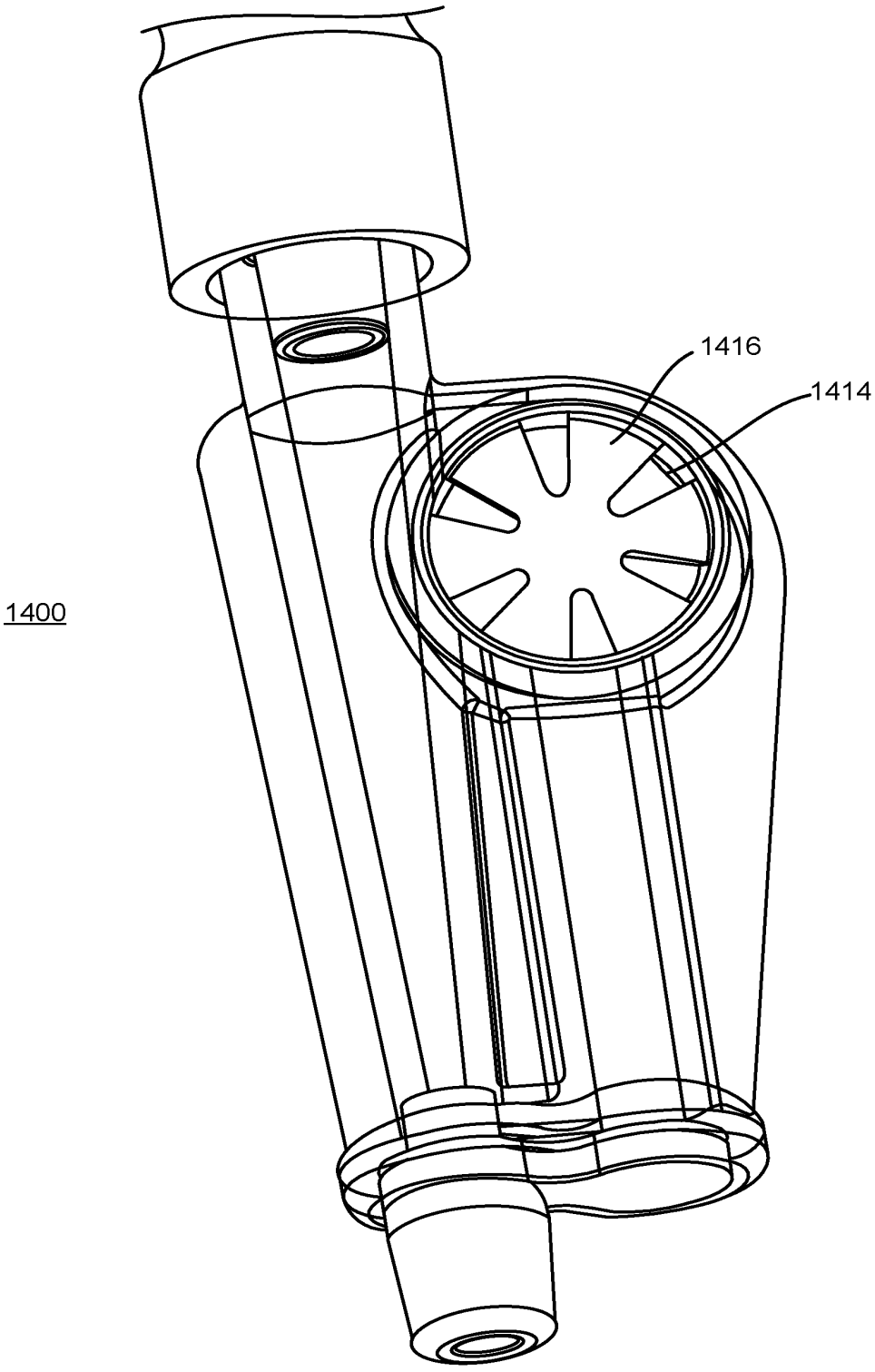


FIG. 14B

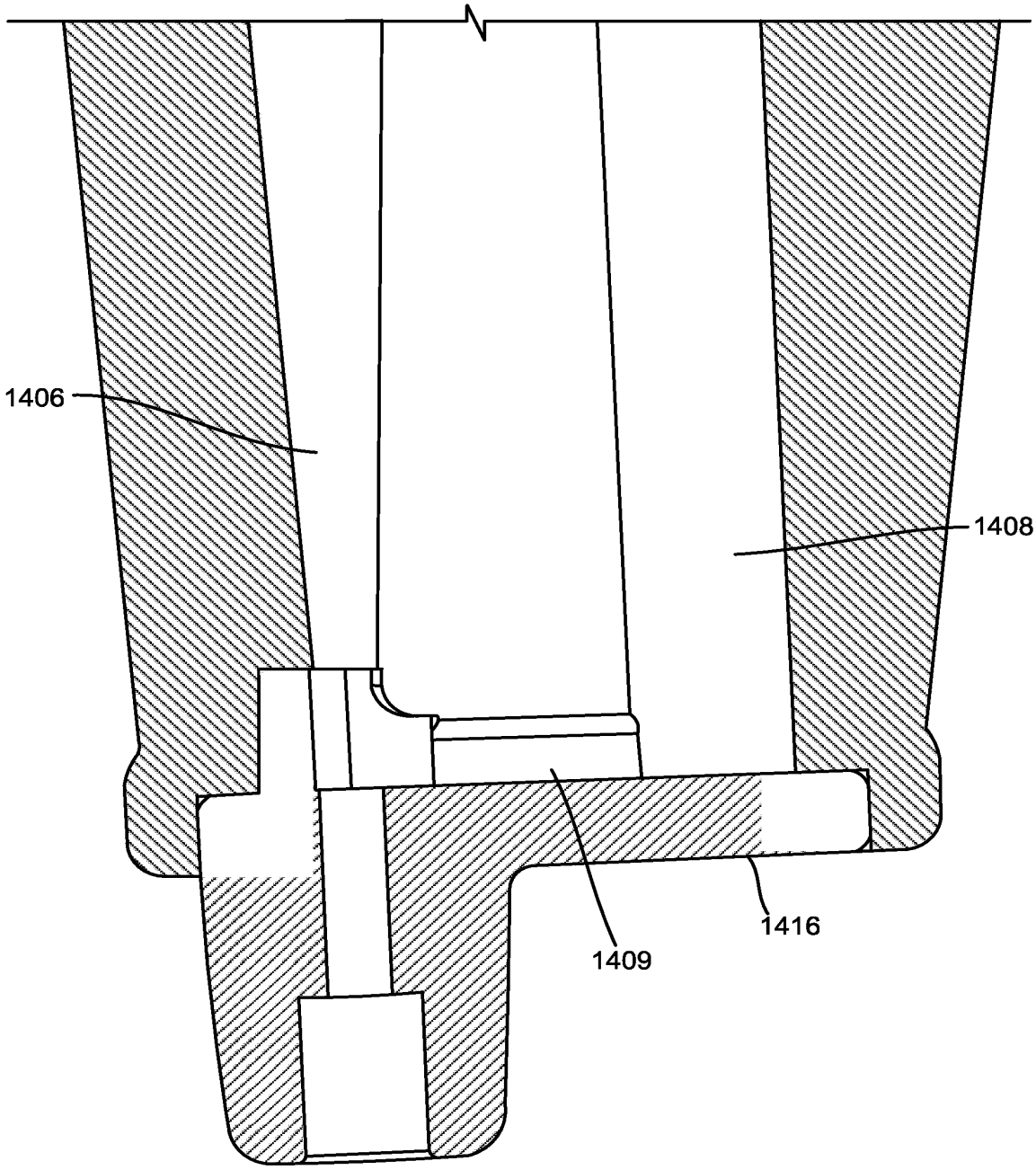


FIG. 14C

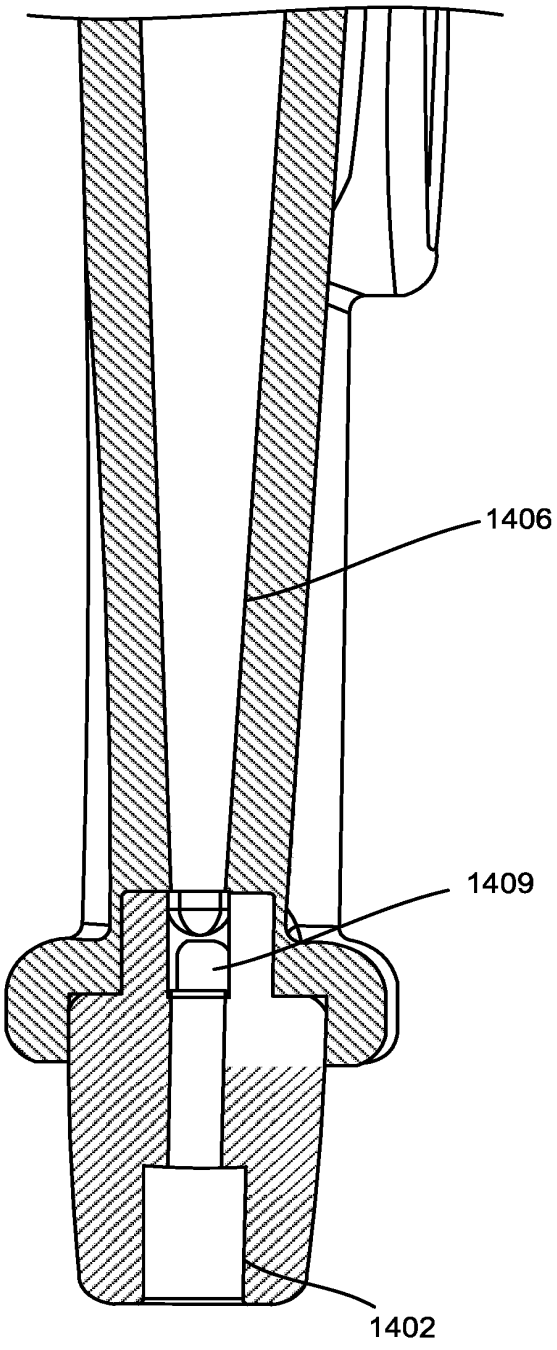


FIG. 14D

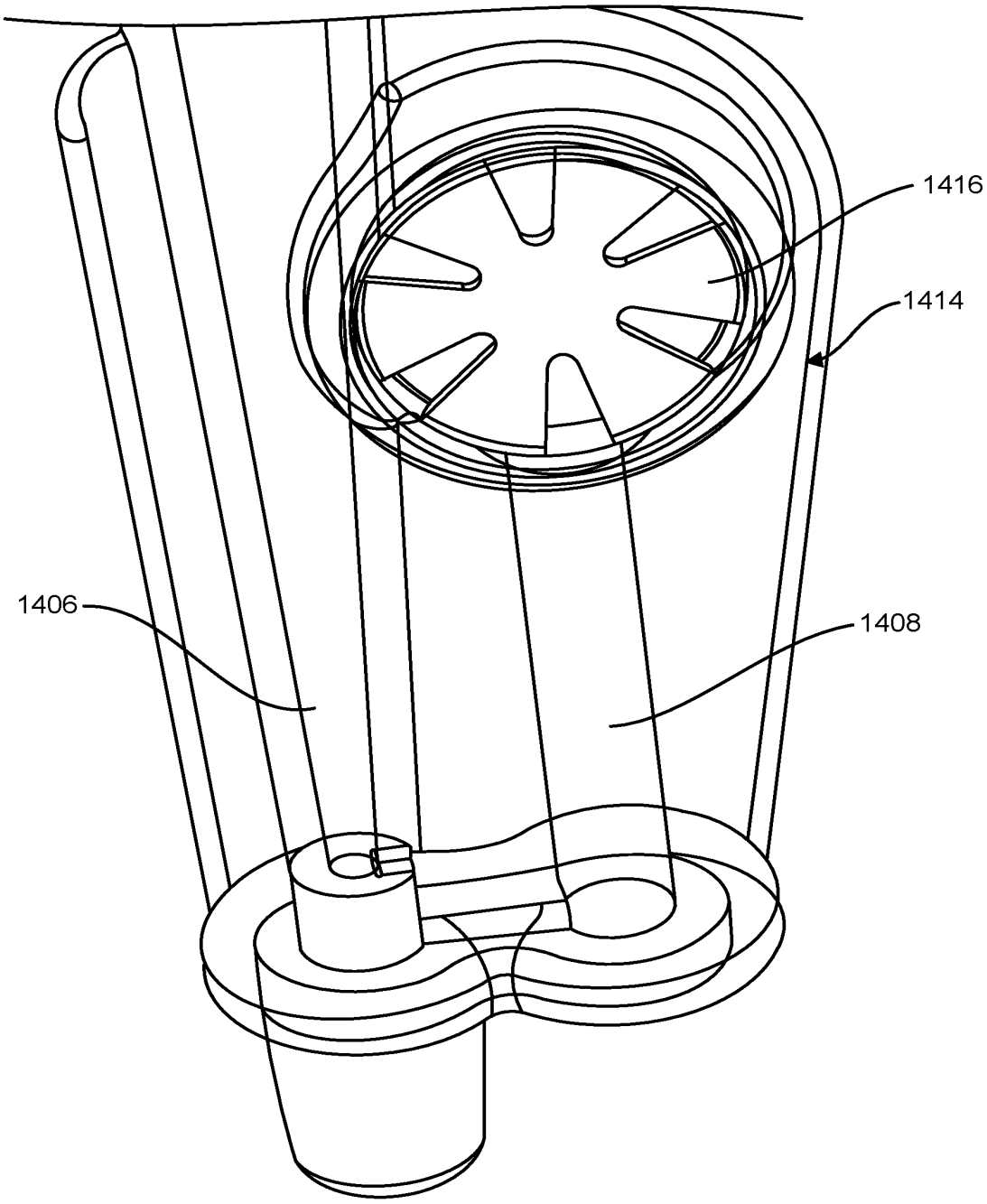


FIG. 14E

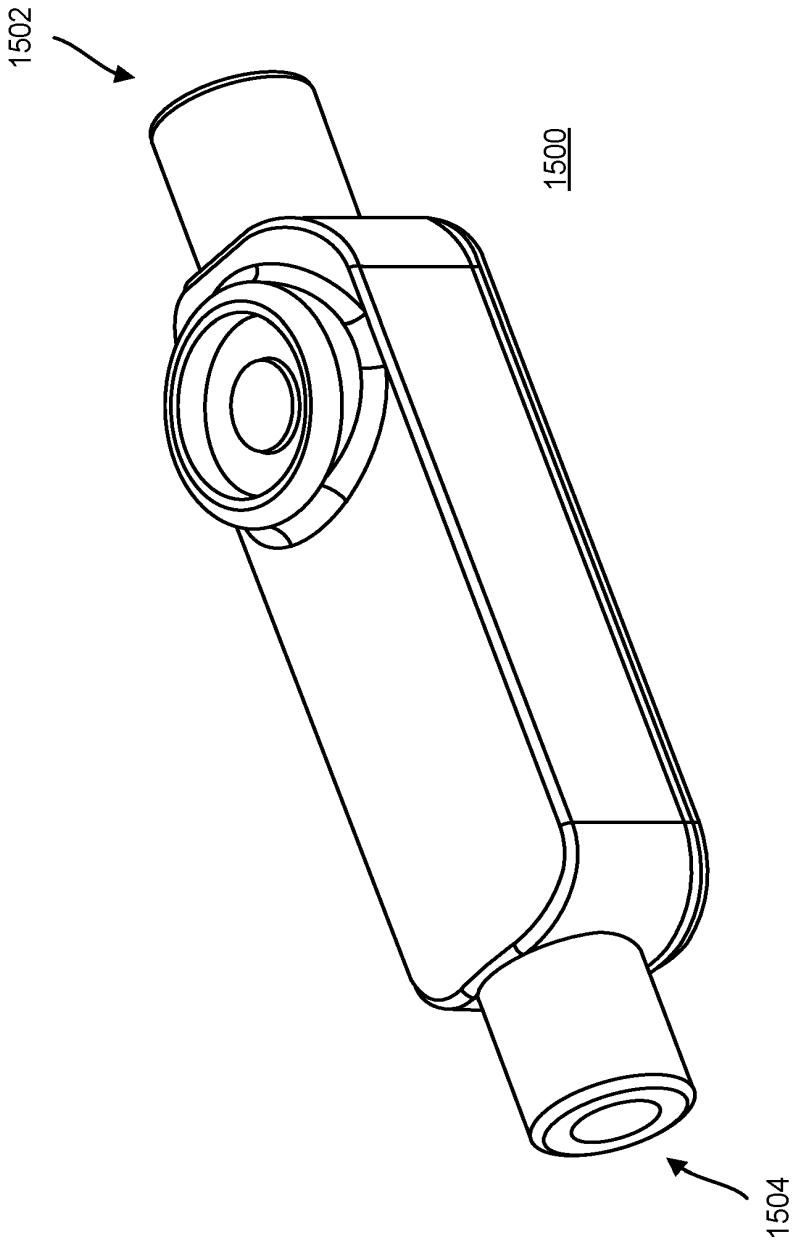


FIG. 15A

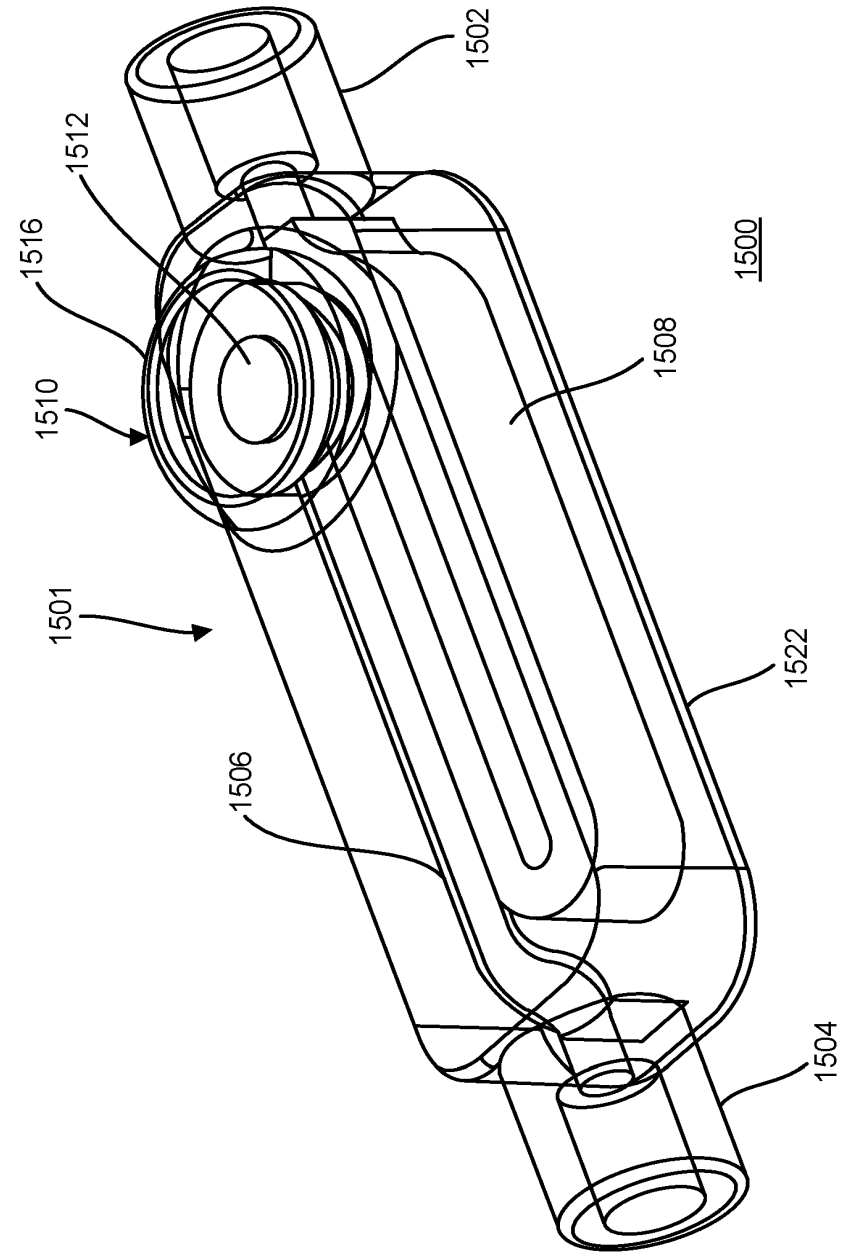


FIG. 15B

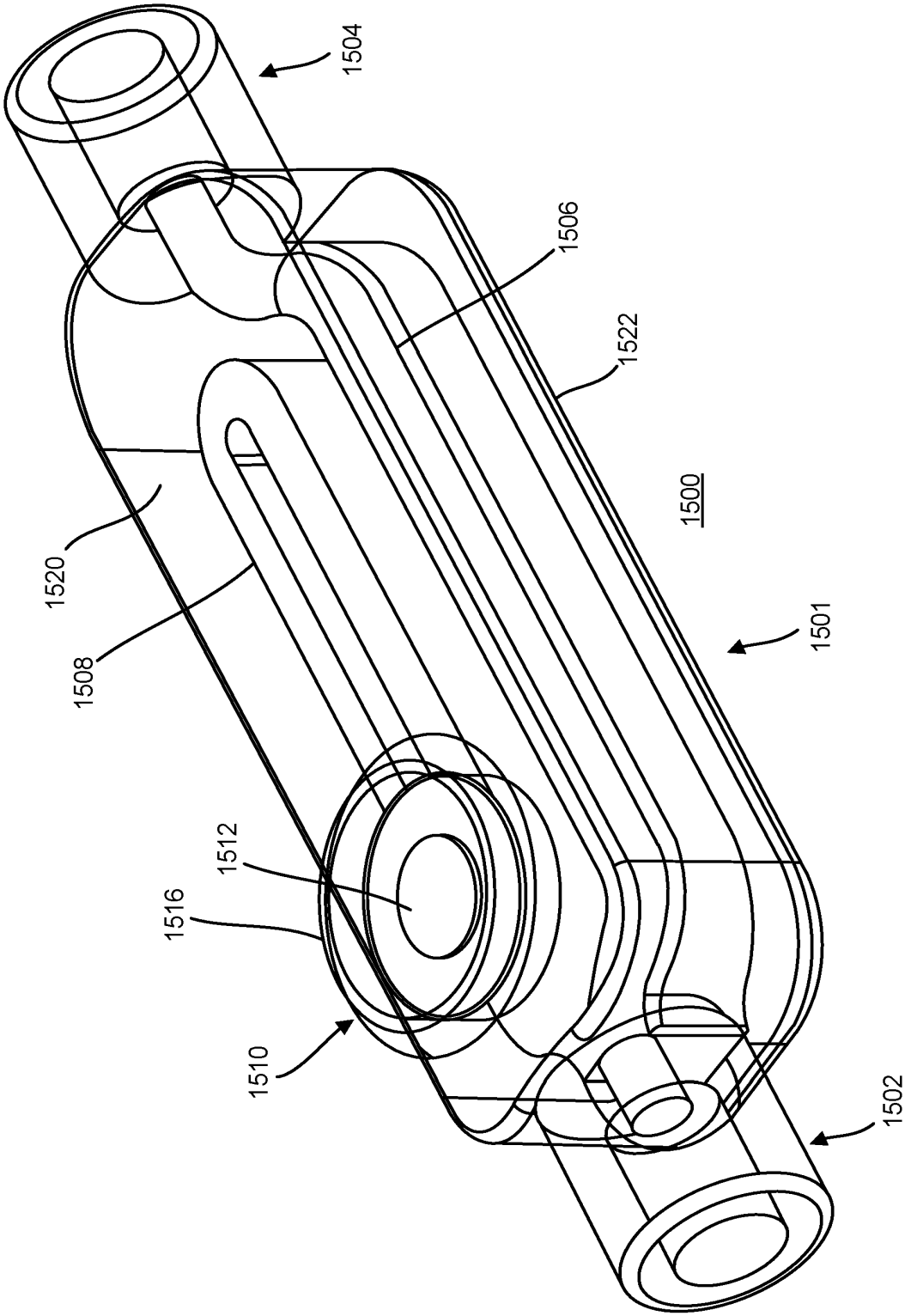


FIG. 15C

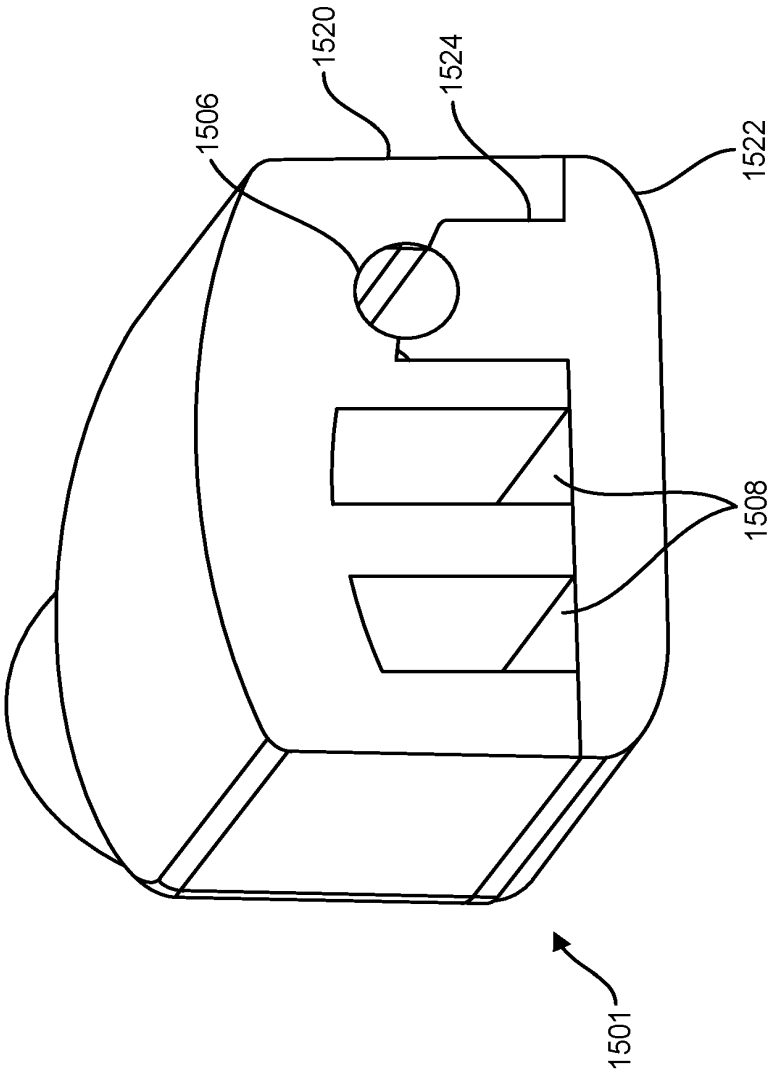


FIG. 15D

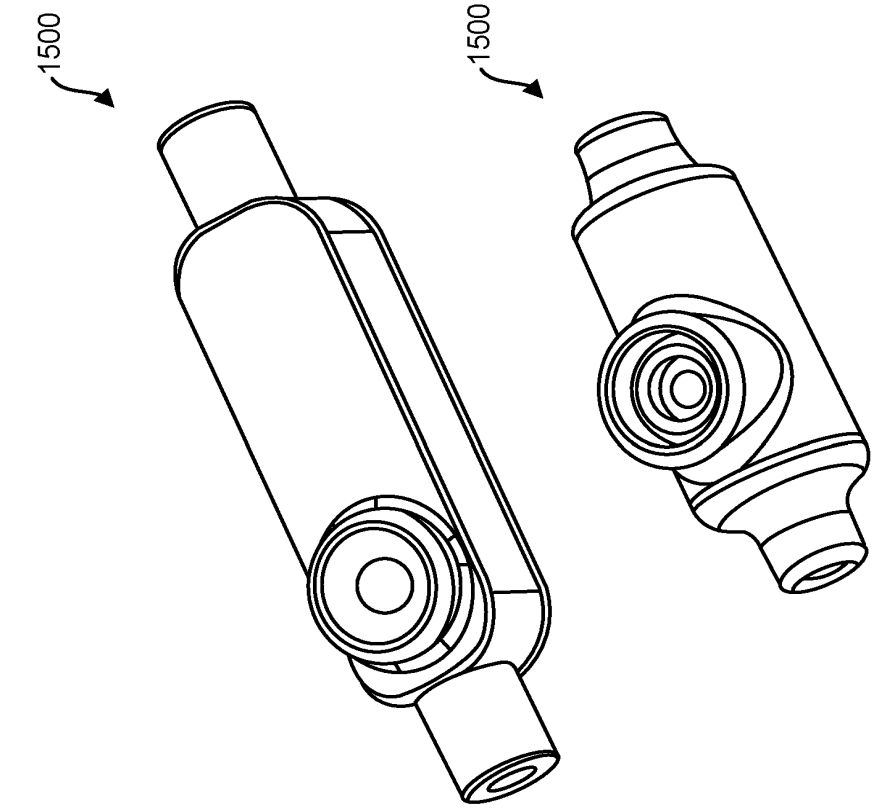


FIG. 15F

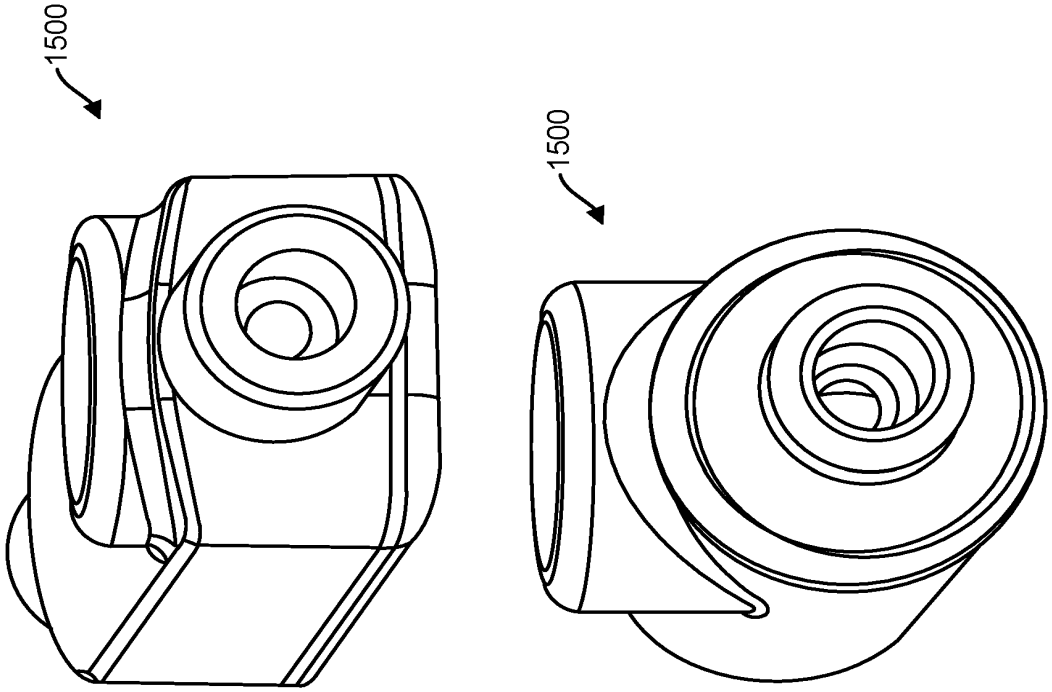


FIG. 15E

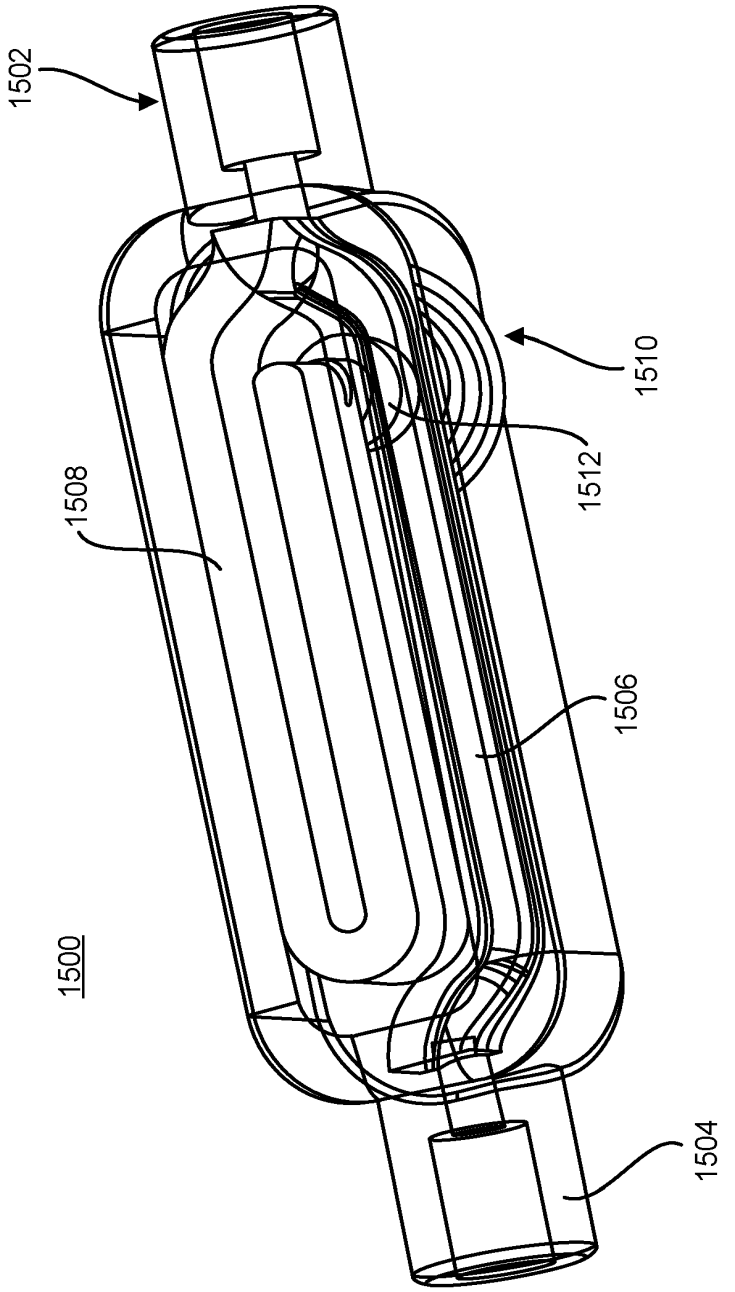


FIG. 15G

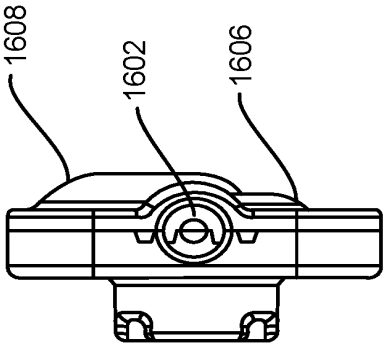


FIG. 16C

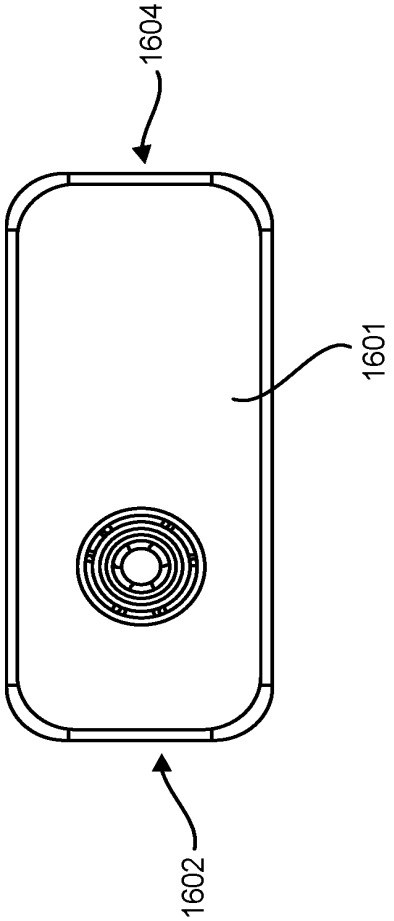


FIG. 16A

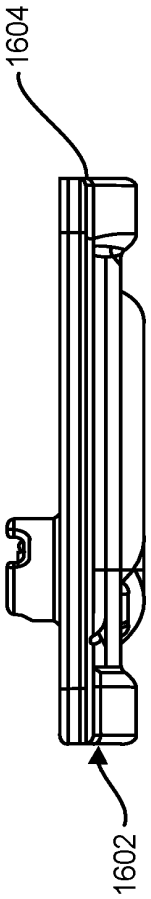


FIG. 16B

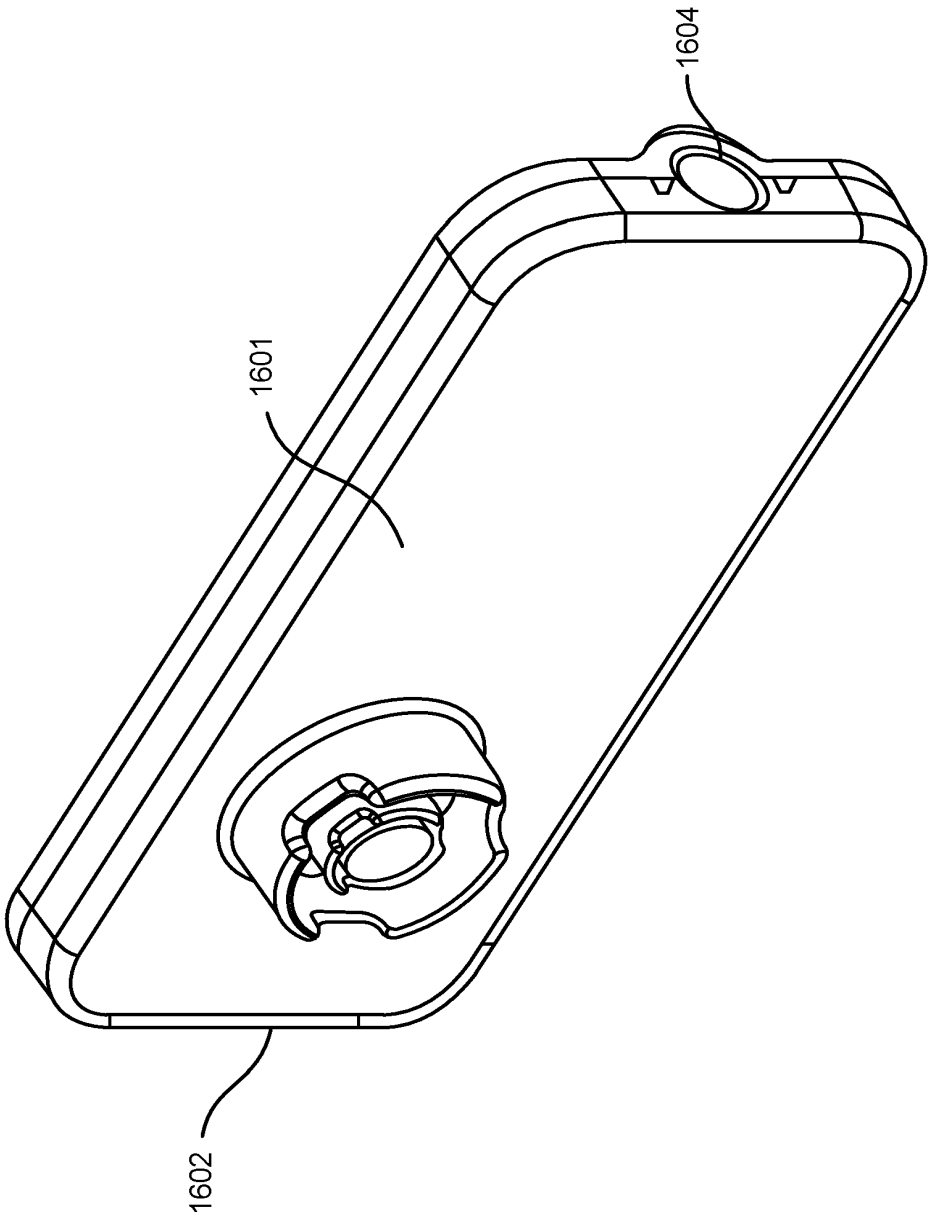


FIG. 16D

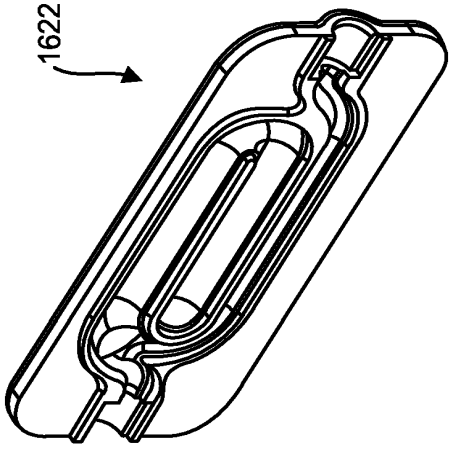


FIG. 17B



FIG. 17E

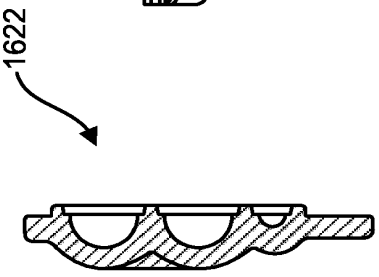


FIG. 17D

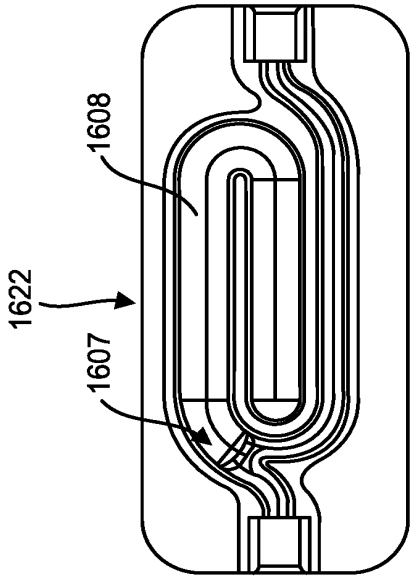


FIG. 17A

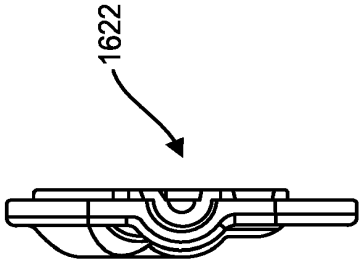


FIG. 17C

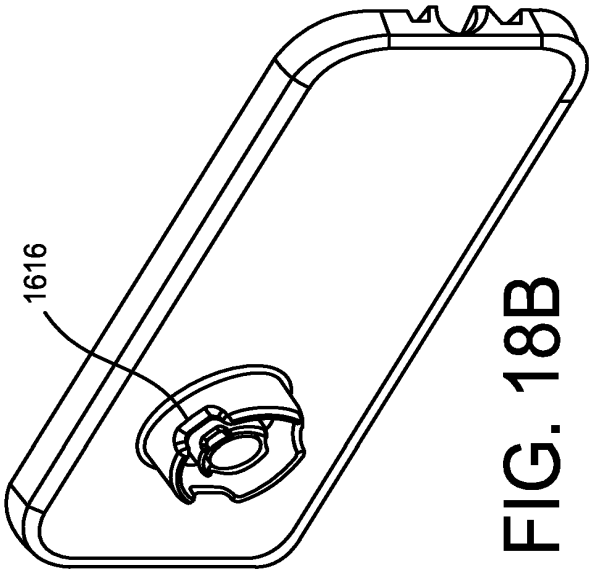


FIG. 18B

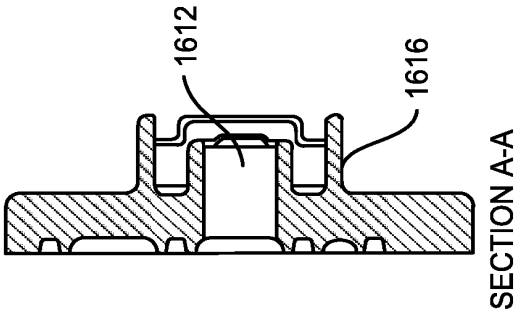


FIG. 18F

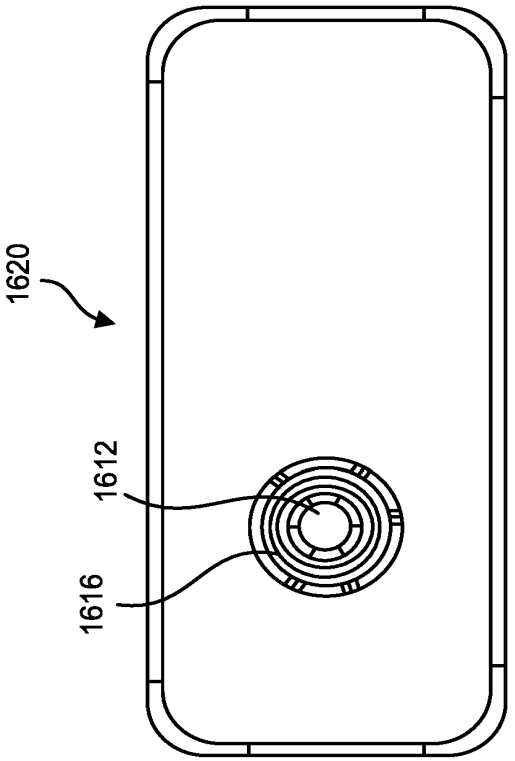


FIG. 18A

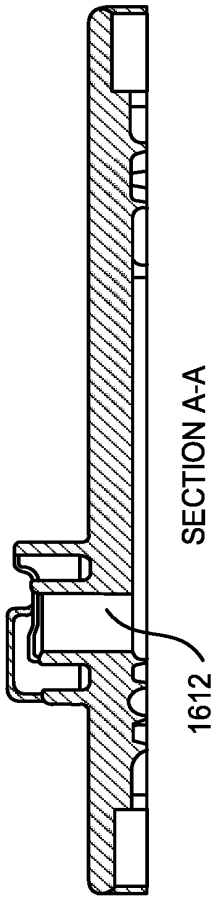


FIG. 18D

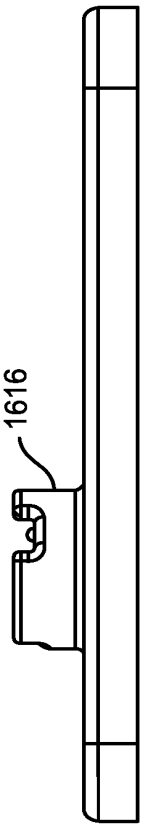


FIG. 18E

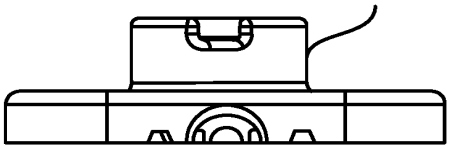


FIG. 18C

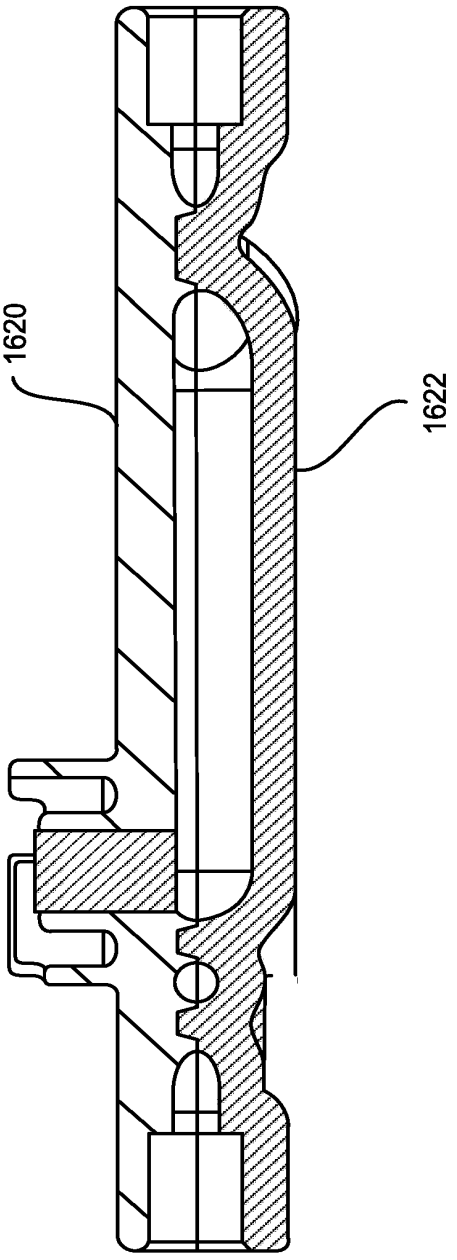


FIG. 19A

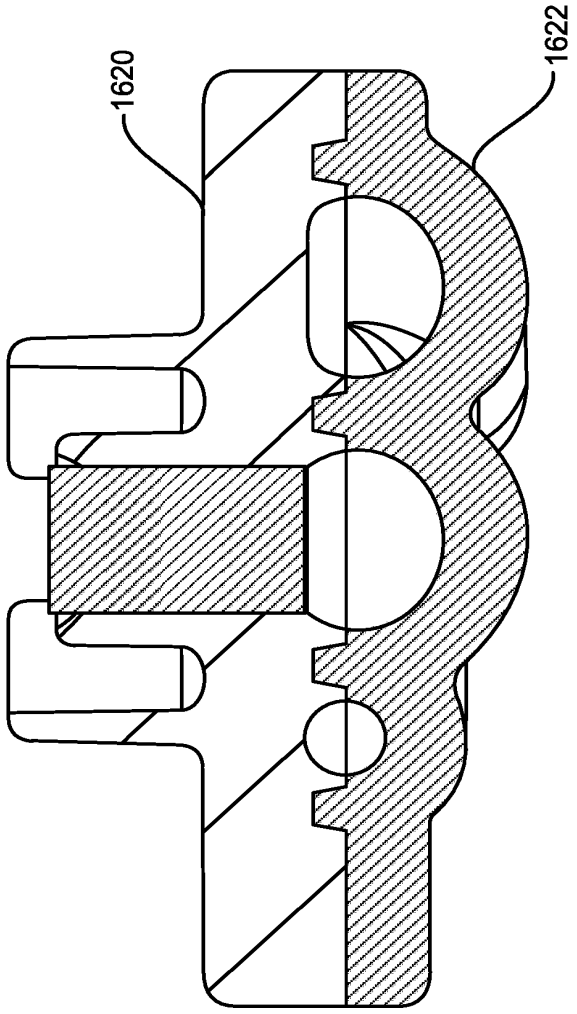


FIG. 19B

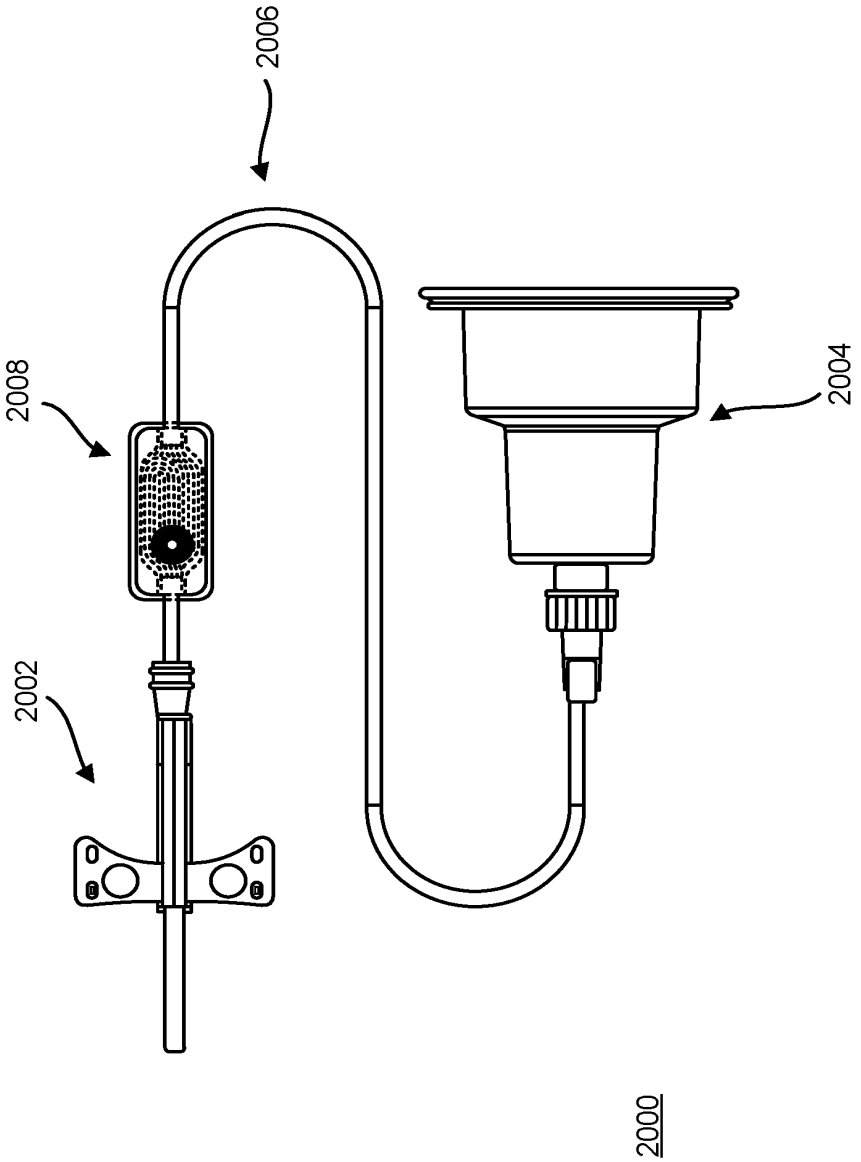


FIG. 20

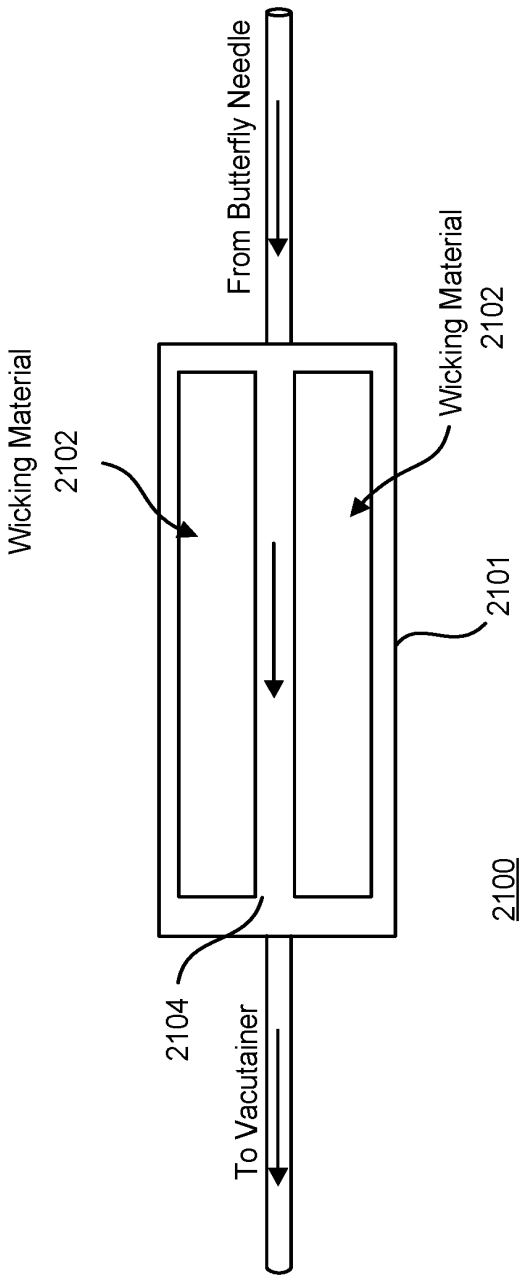

From Butterfly Needle
Wicking Material
2102
Wicking Material
2102
2101
2100
2104
To Vacutainer

FIG. 21

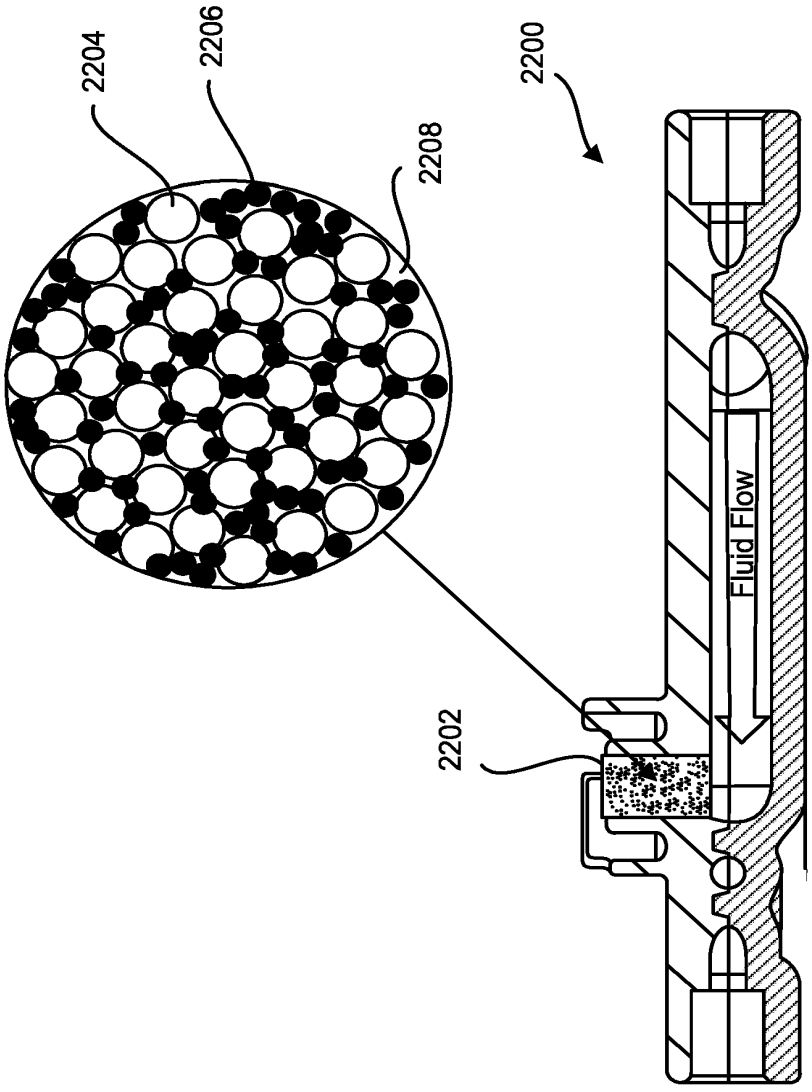


FIG. 22A

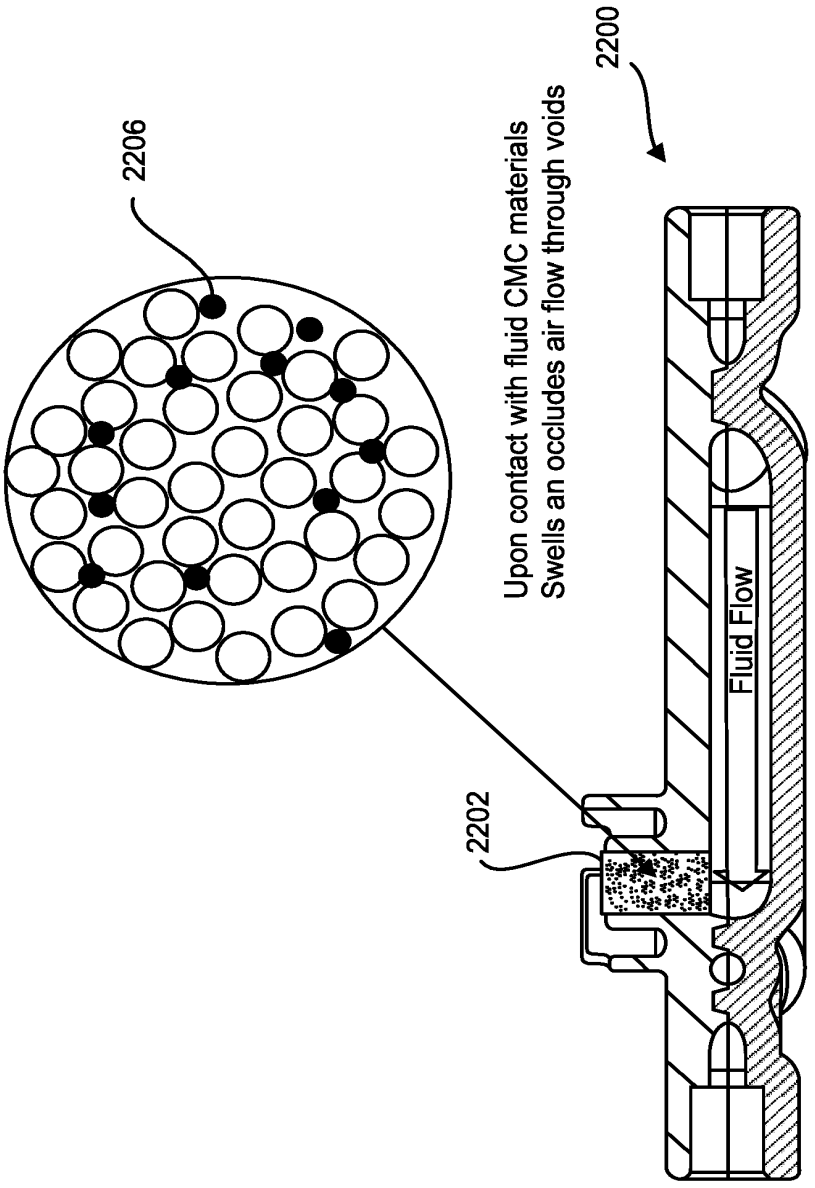

2200
2206
Upon contact with fluid CMC materials
Swells an occludes air flow through voids
Fluid Flow
2202

FIG. 22B

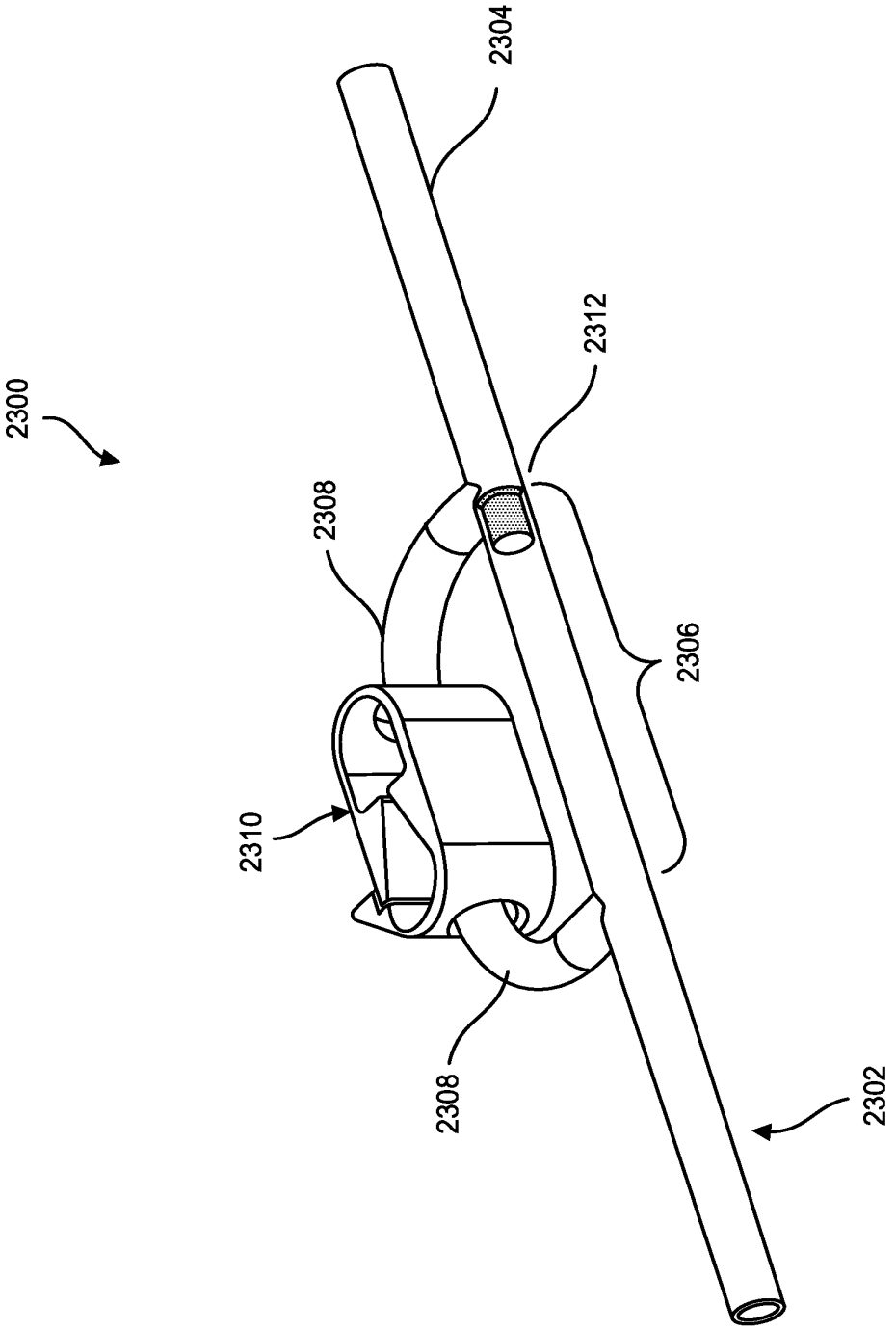


FIG. 23A

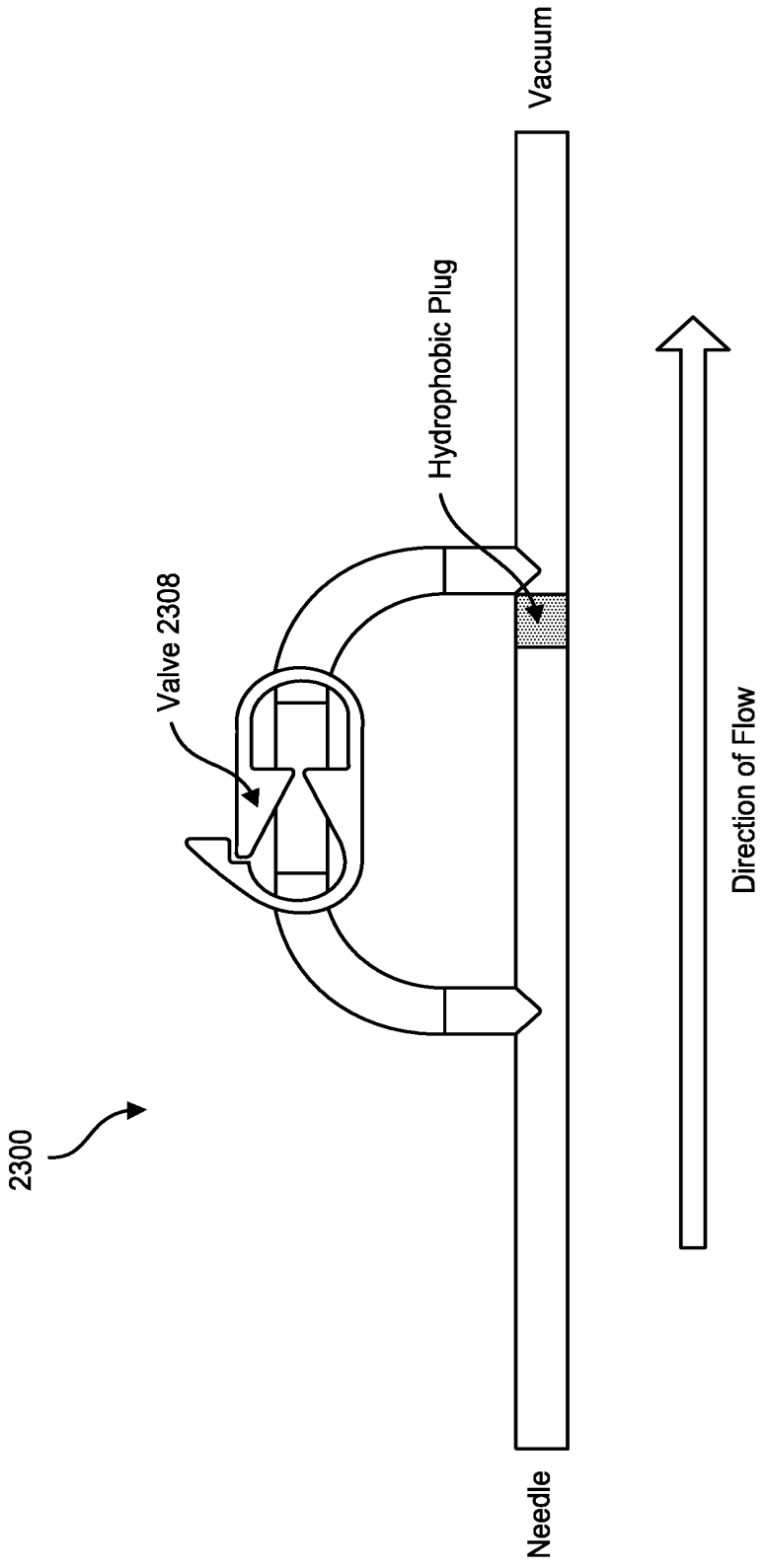

Vacuum
Hydrophobic Plug
Valve 2308
Direction of Flow
2300
Needle

FIG. 23B

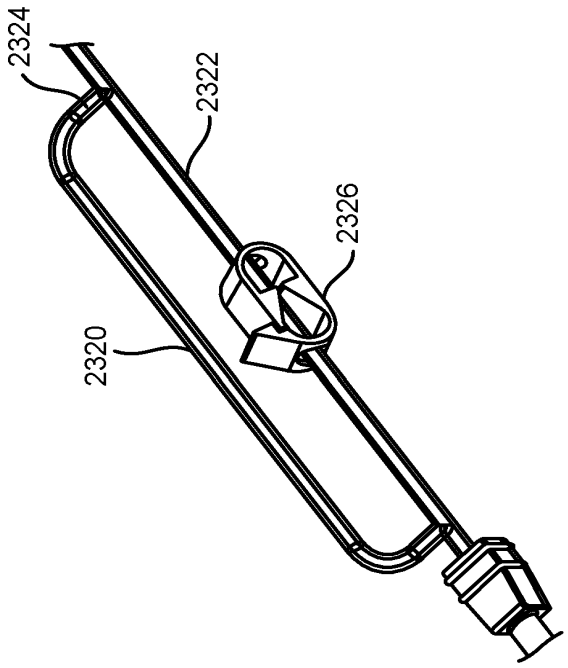


FIG. 23D

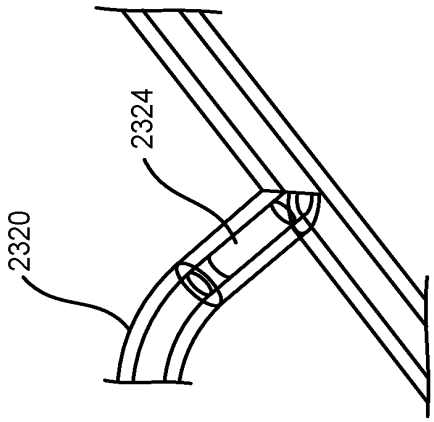


FIG. 23E

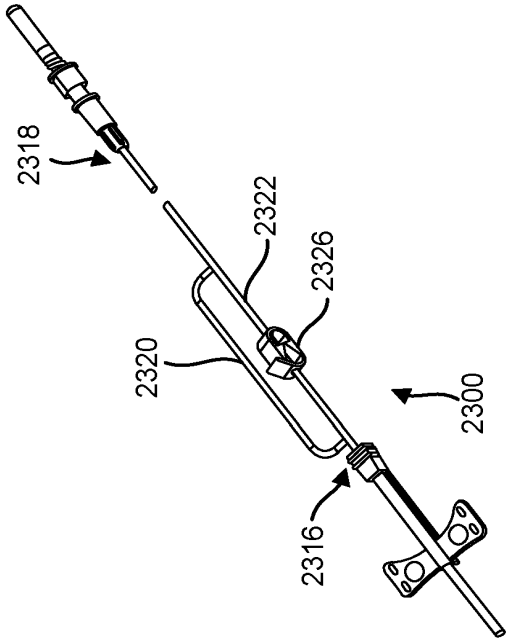


FIG. 23C

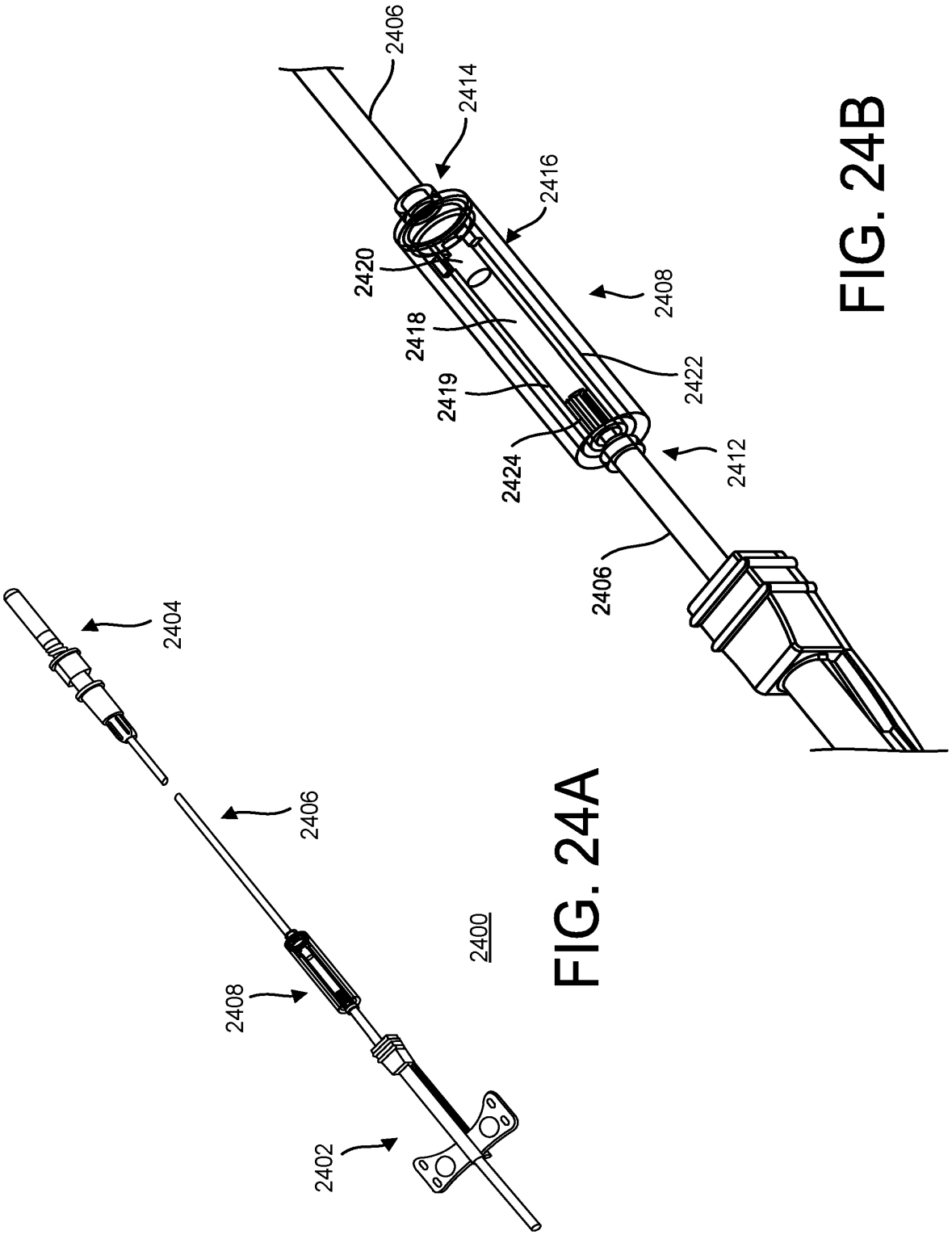


FIG. 24B

FIG. 24A

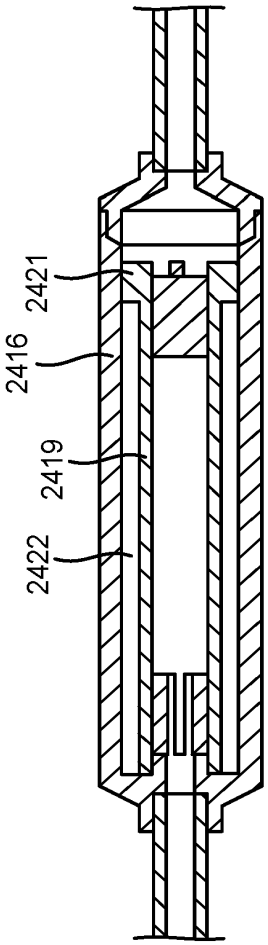


FIG. 24C

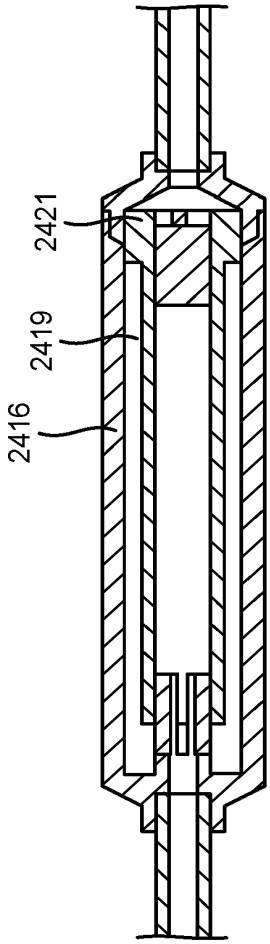


FIG. 24D

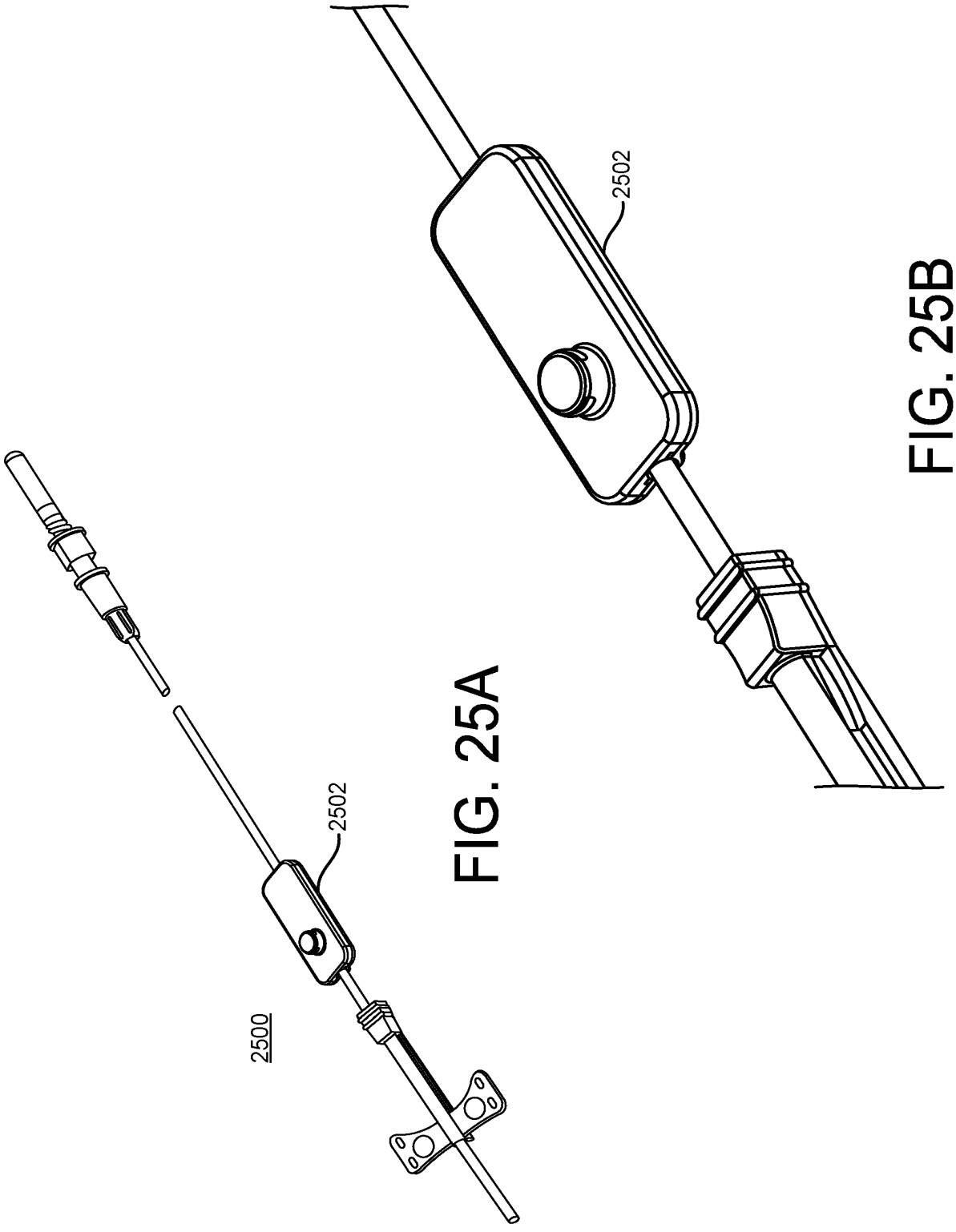


FIG. 25A

FIG. 25B

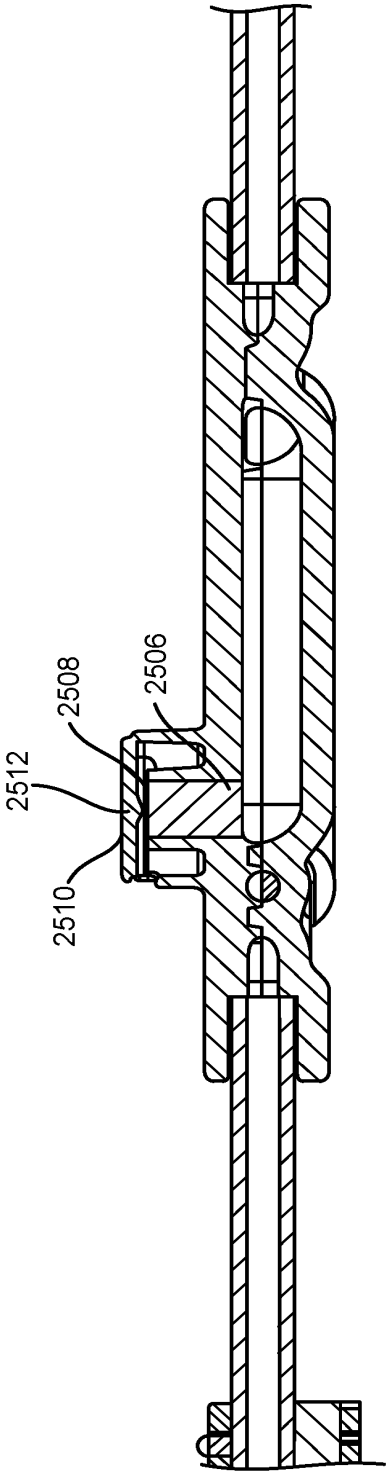


FIG. 25C

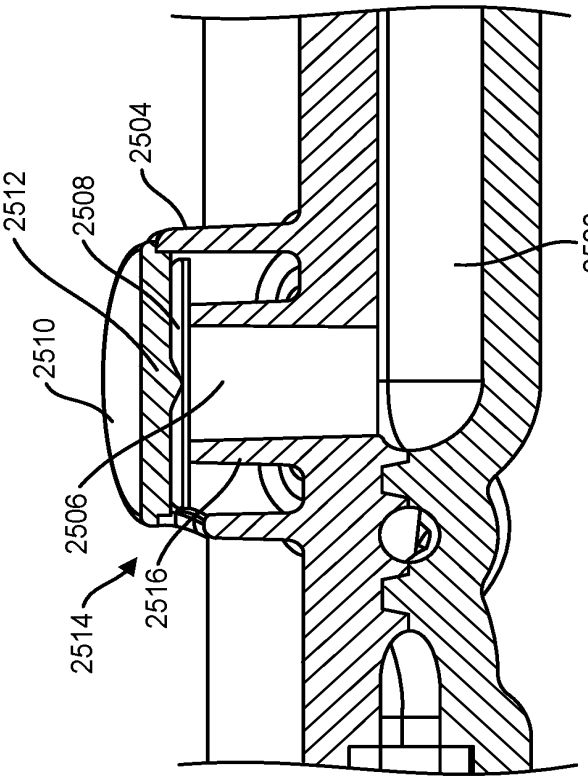


FIG. 25D

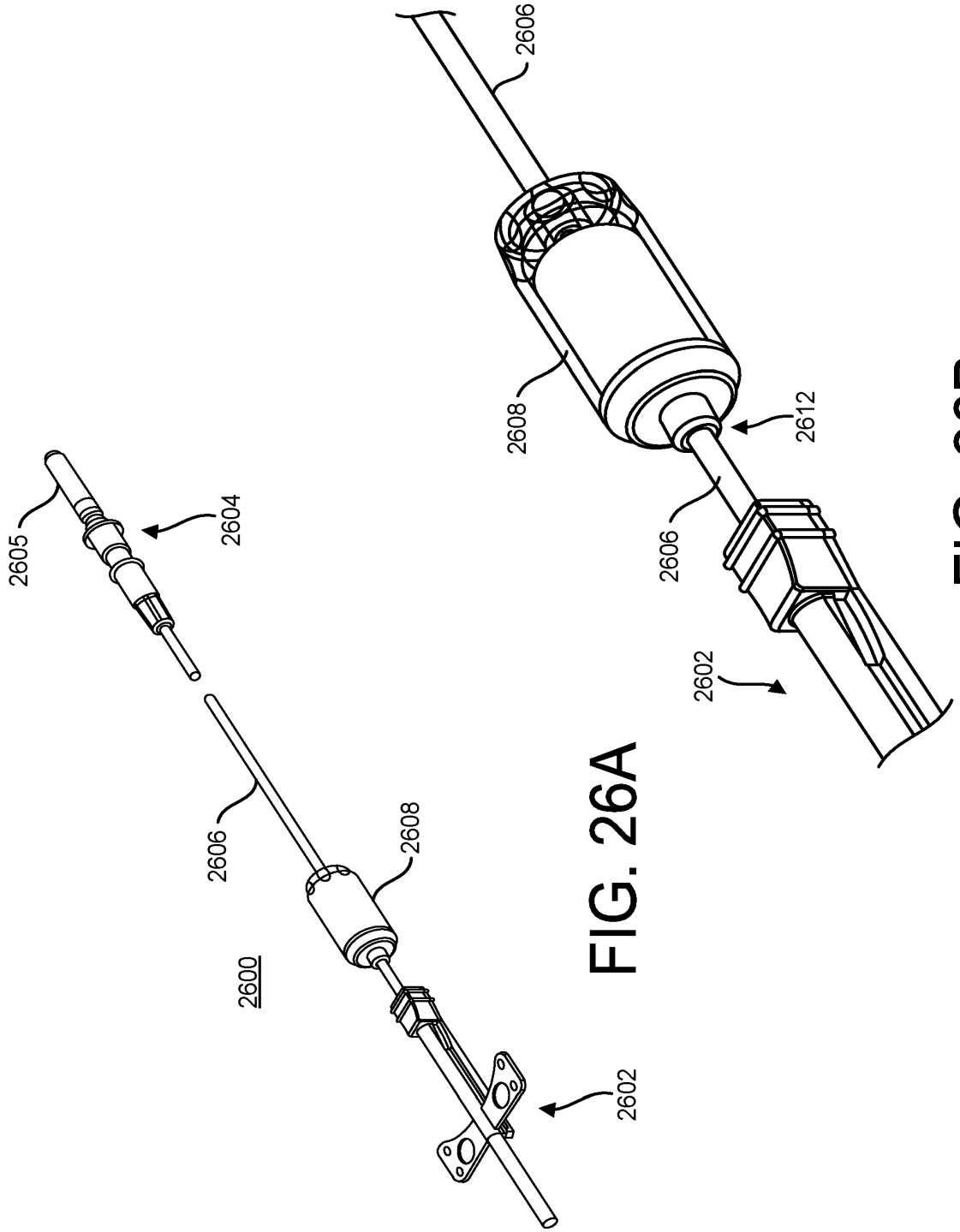


FIG. 26B

FIG. 26A

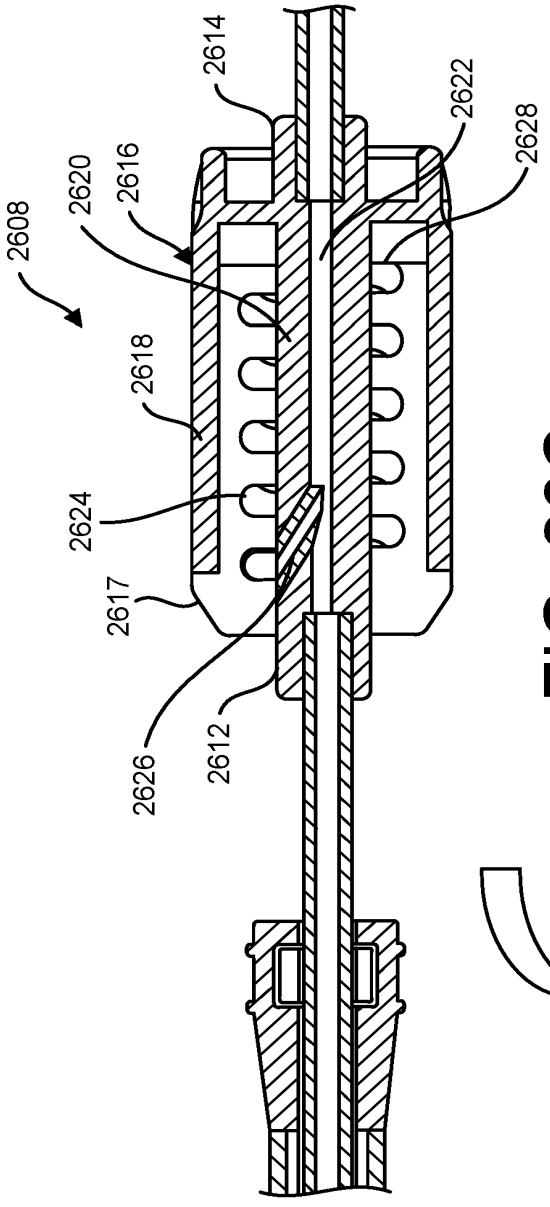


FIG. 26C

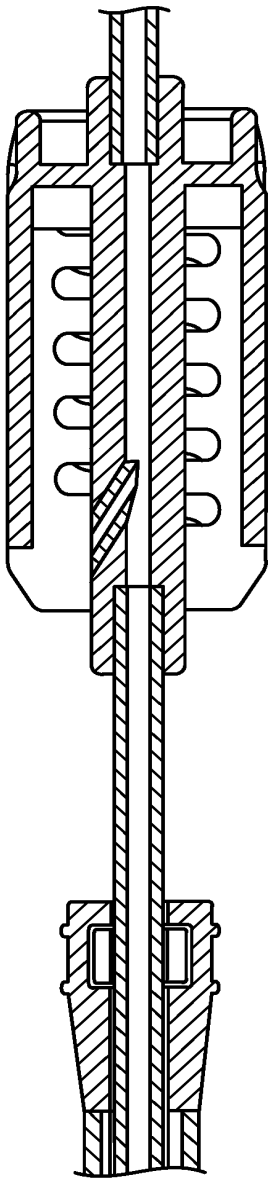


FIG. 26D

Replacement Sheet
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PCT/US2017/068569

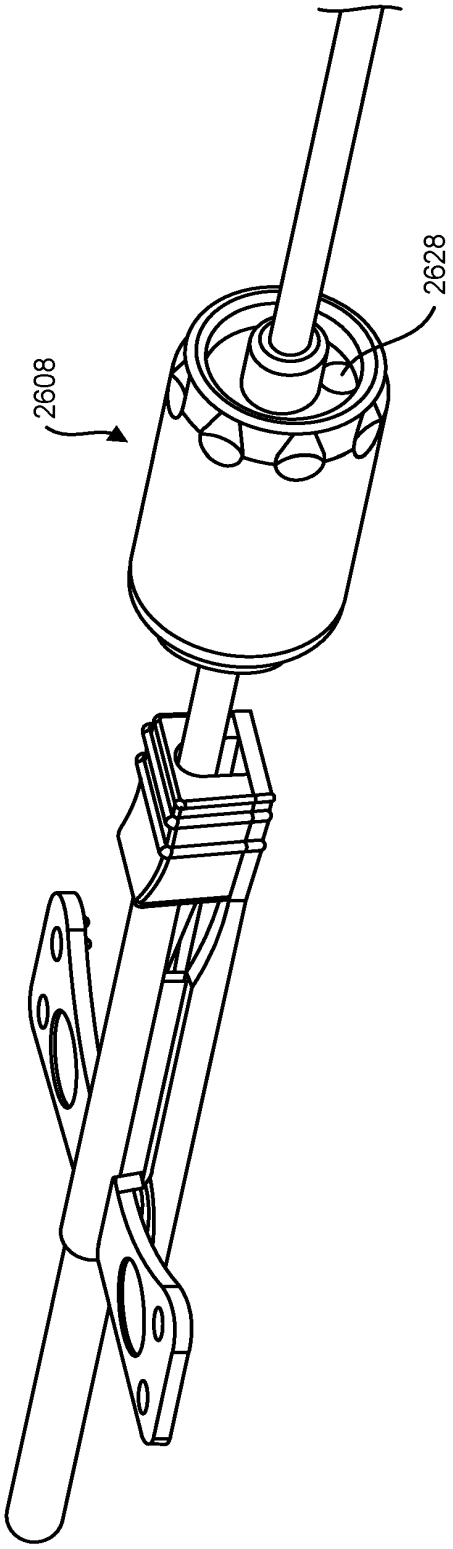


FIG. 26E

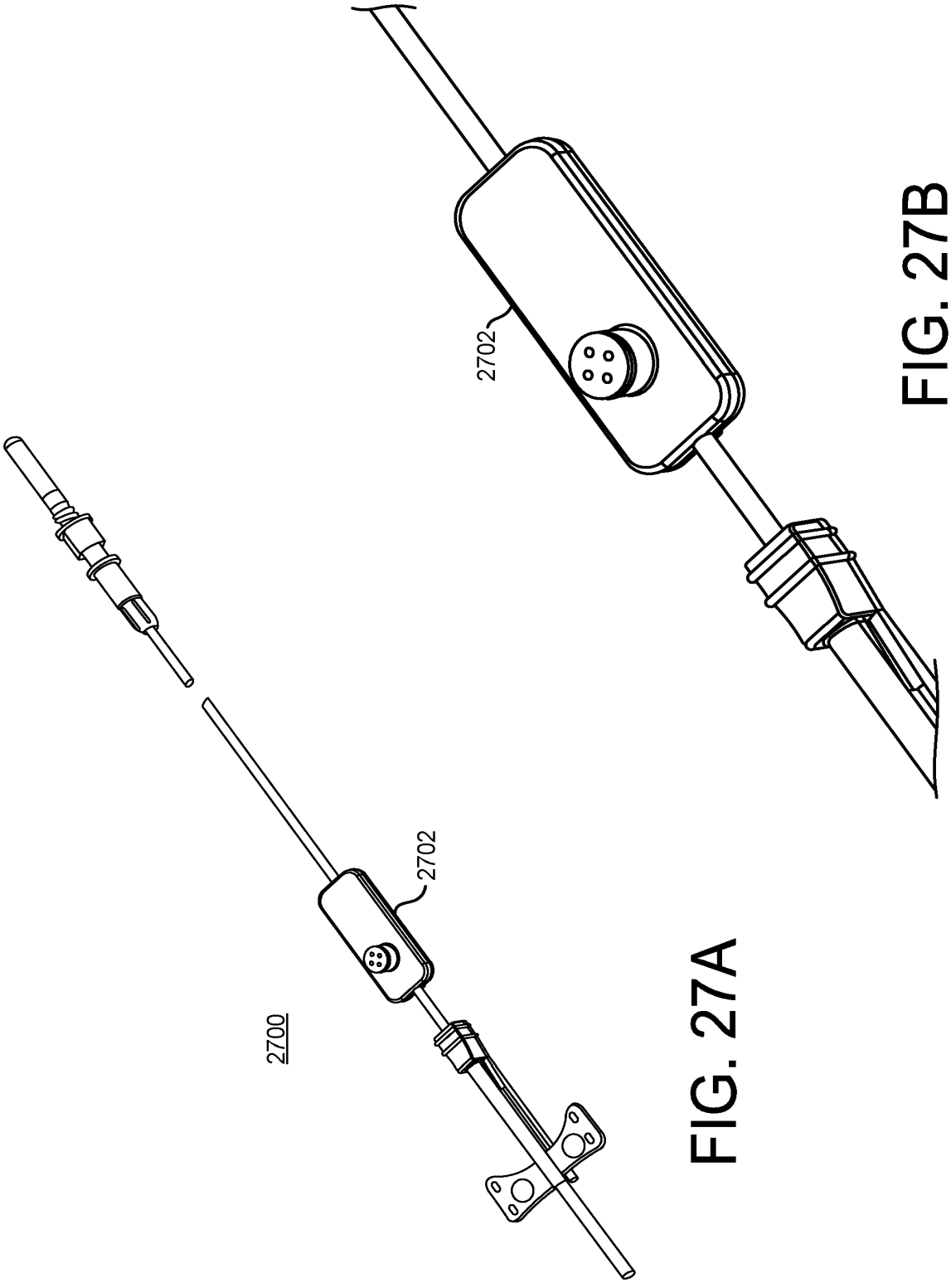


FIG. 27B

FIG. 27A

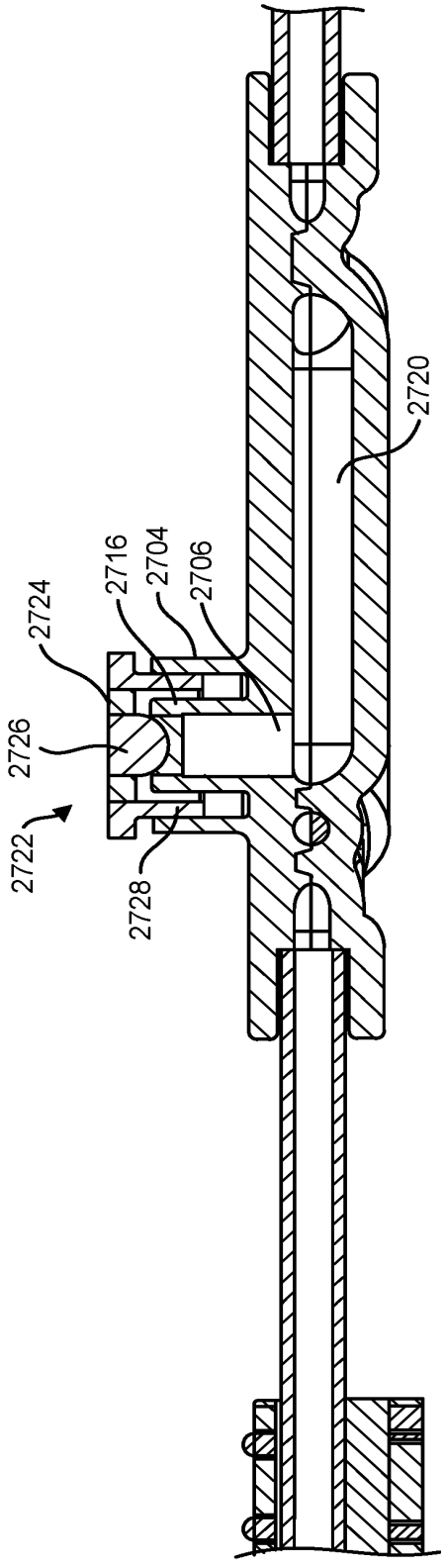


FIG. 27C

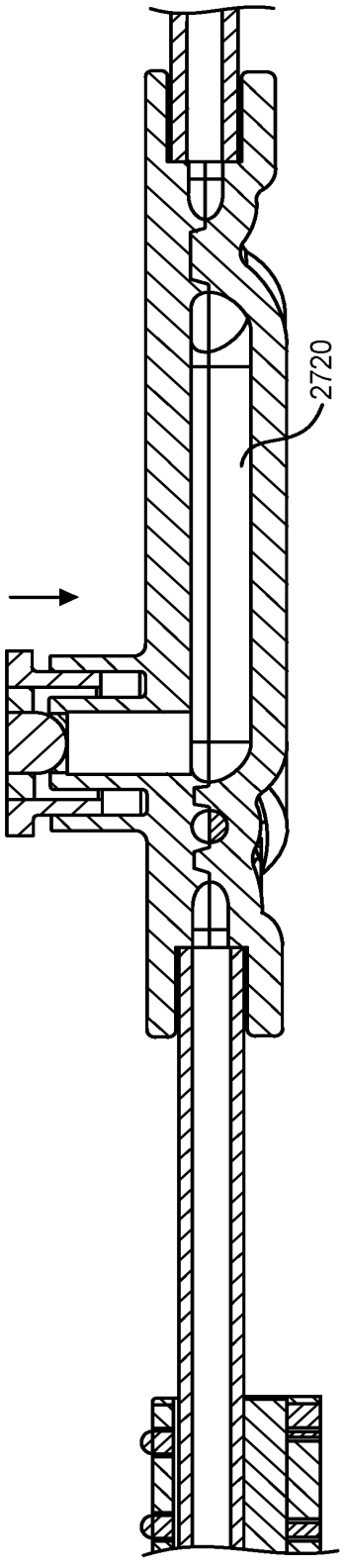


FIG. 27D

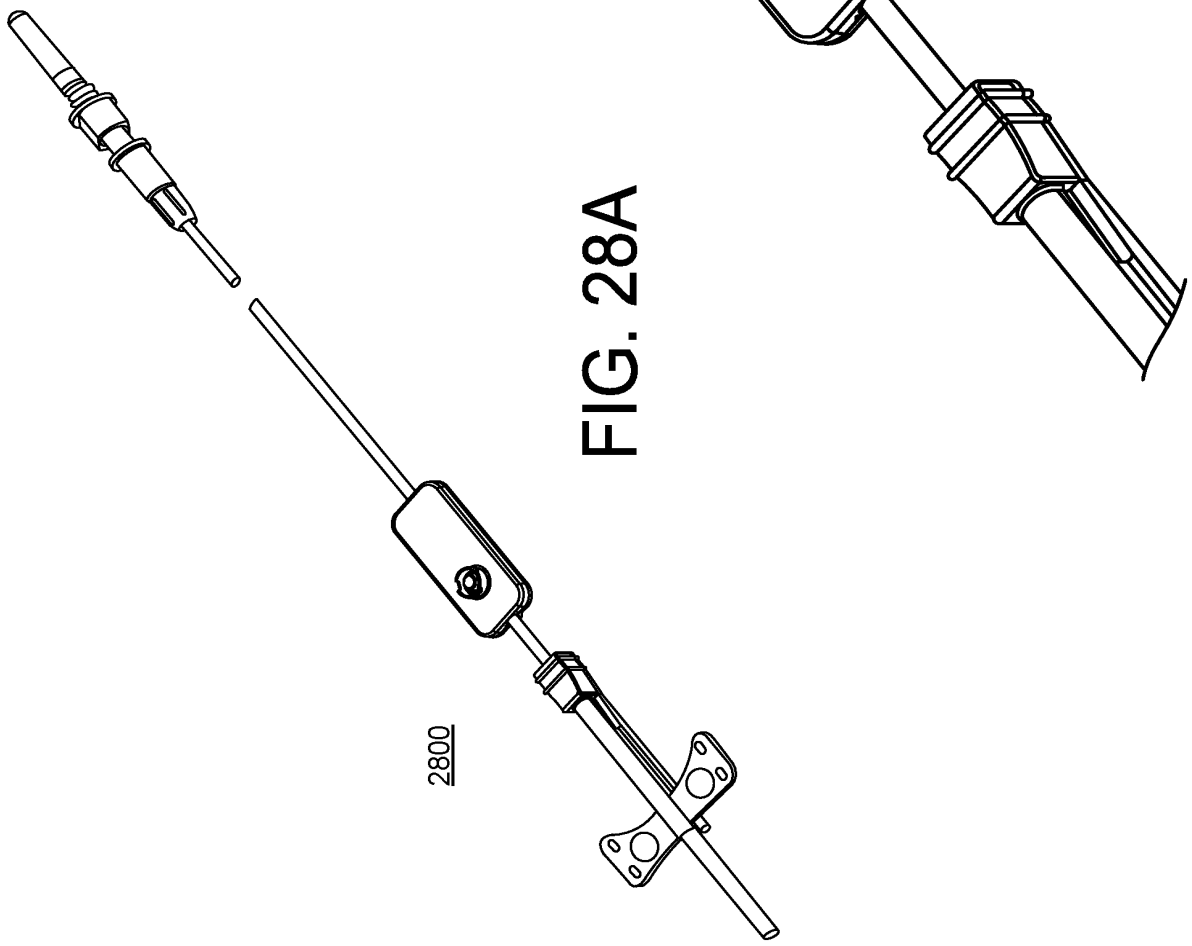


FIG. 28A

FIG. 28B

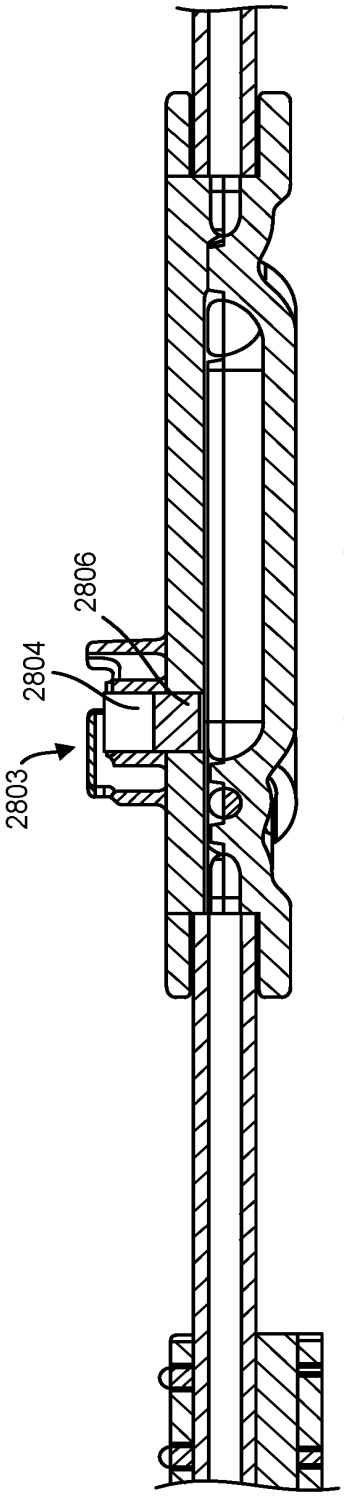


FIG. 28C

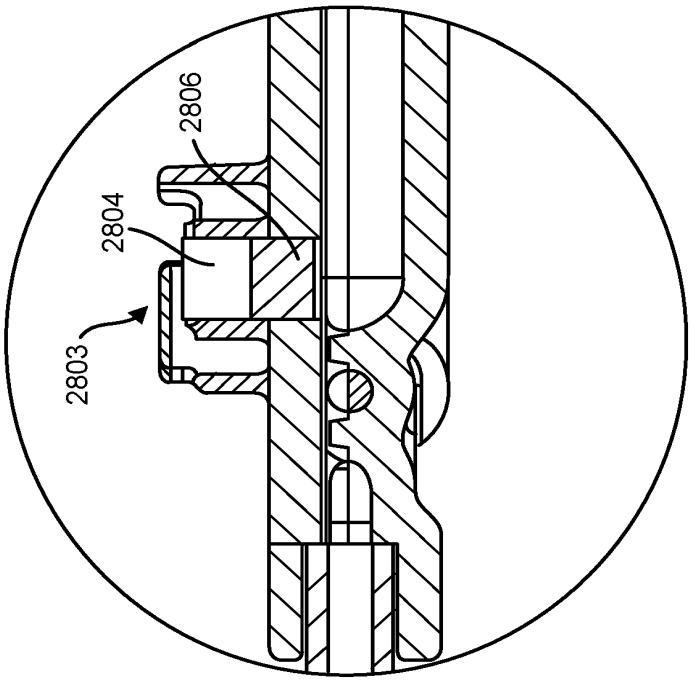


FIG. 28D

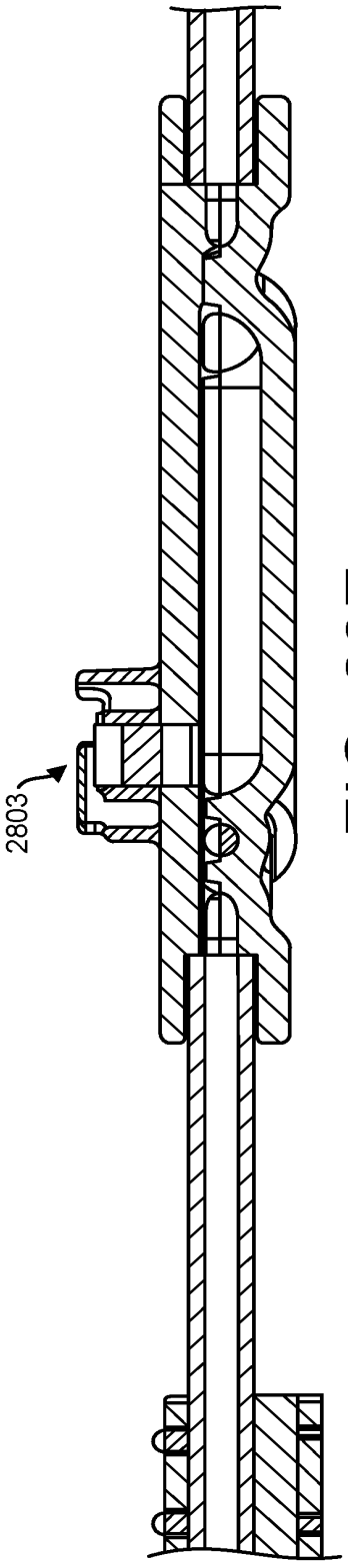


FIG. 28E

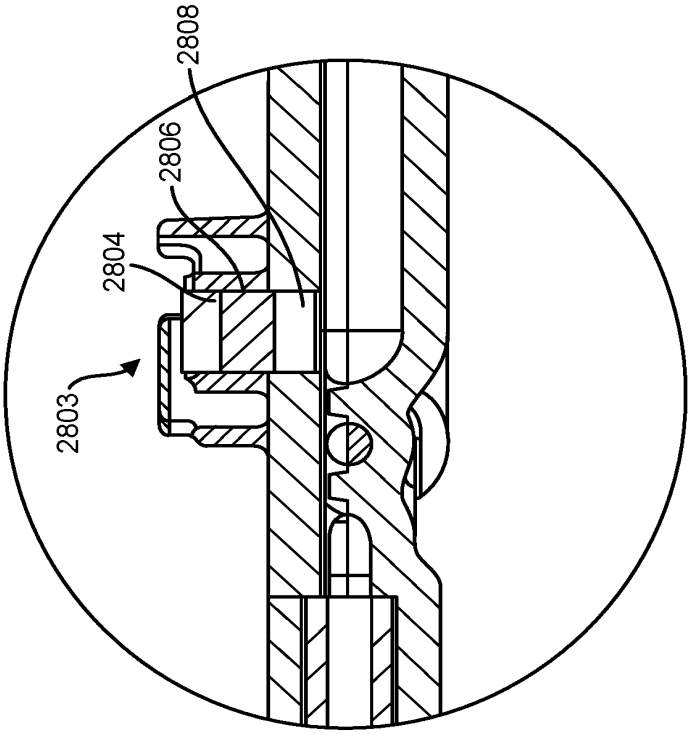


FIG. 28F

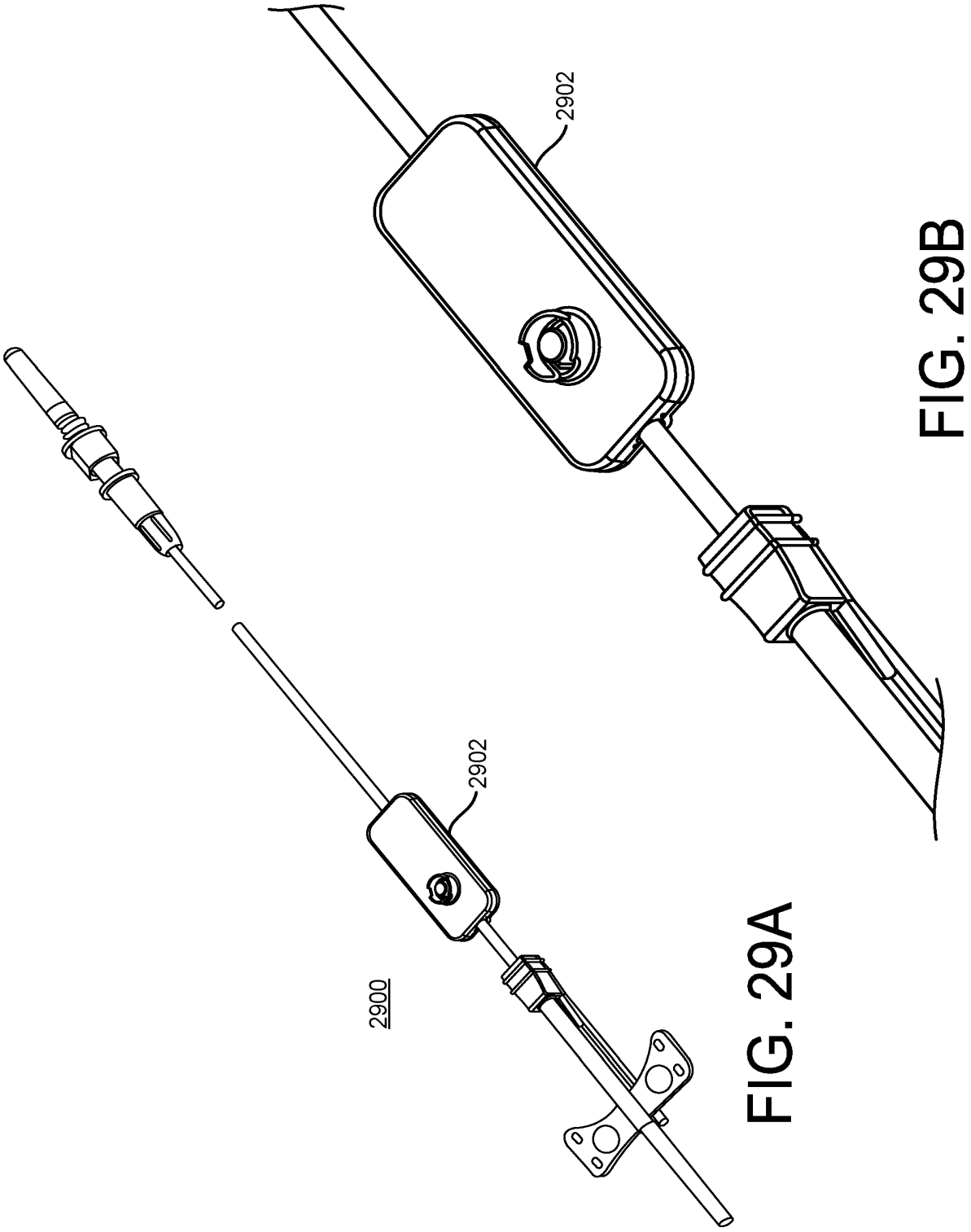


FIG. 29B

FIG. 29A

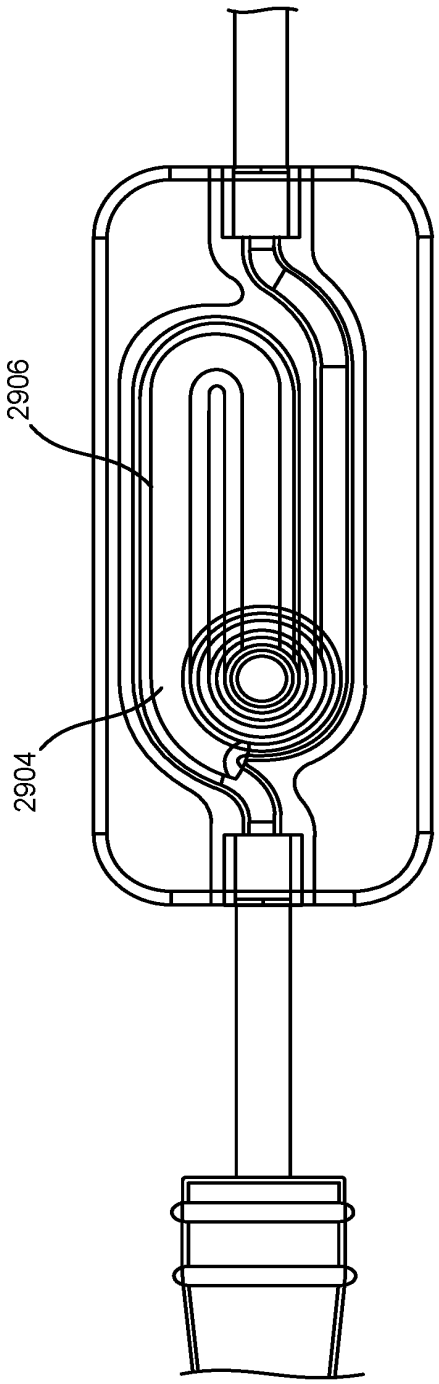


FIG. 29C

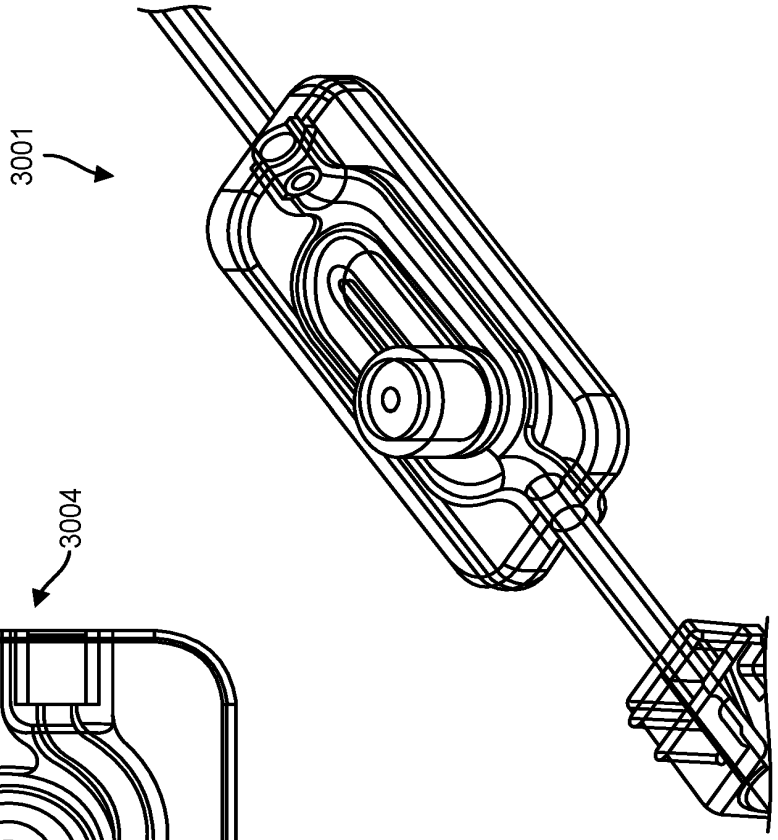


FIG. 30B

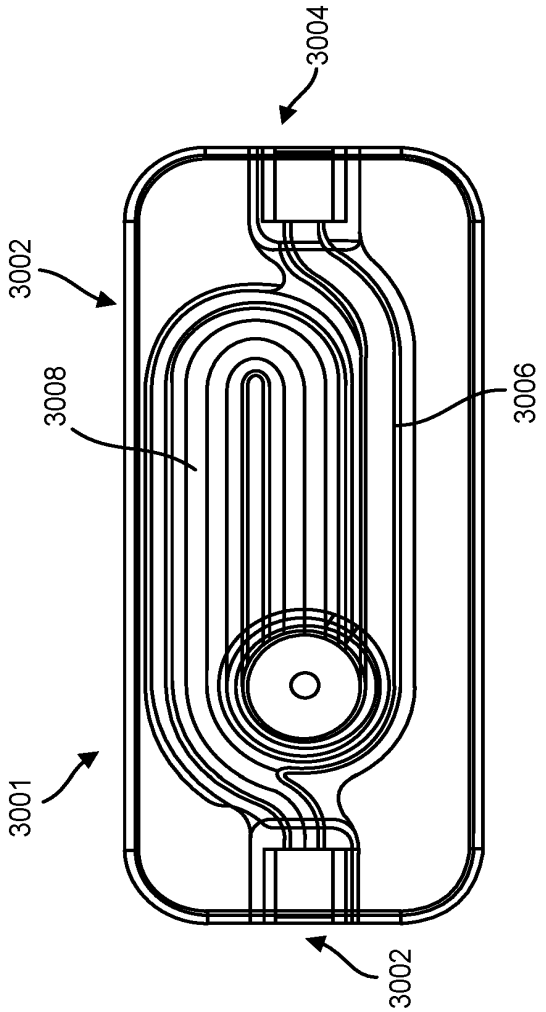


FIG. 30A

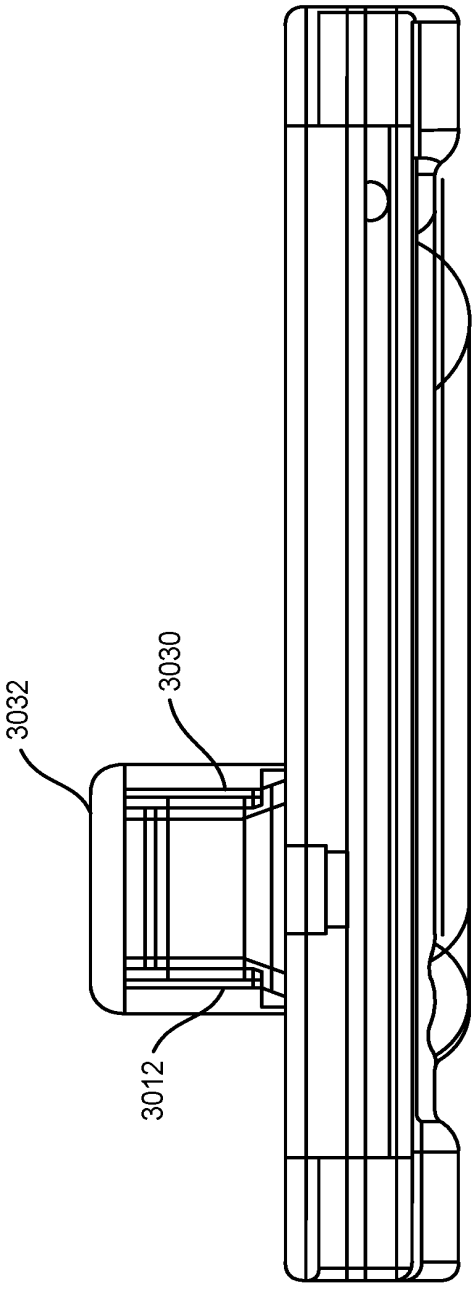


FIG. 30C

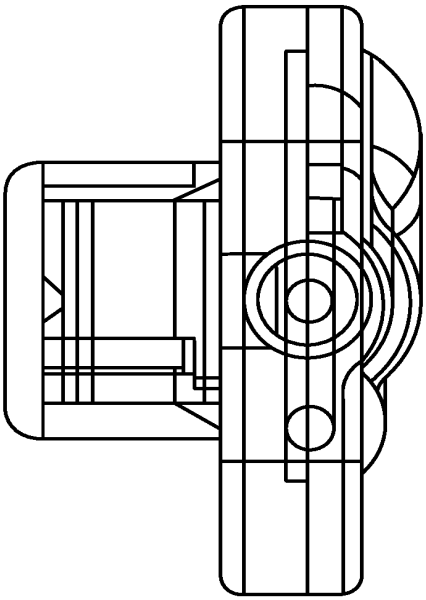


FIG. 30D

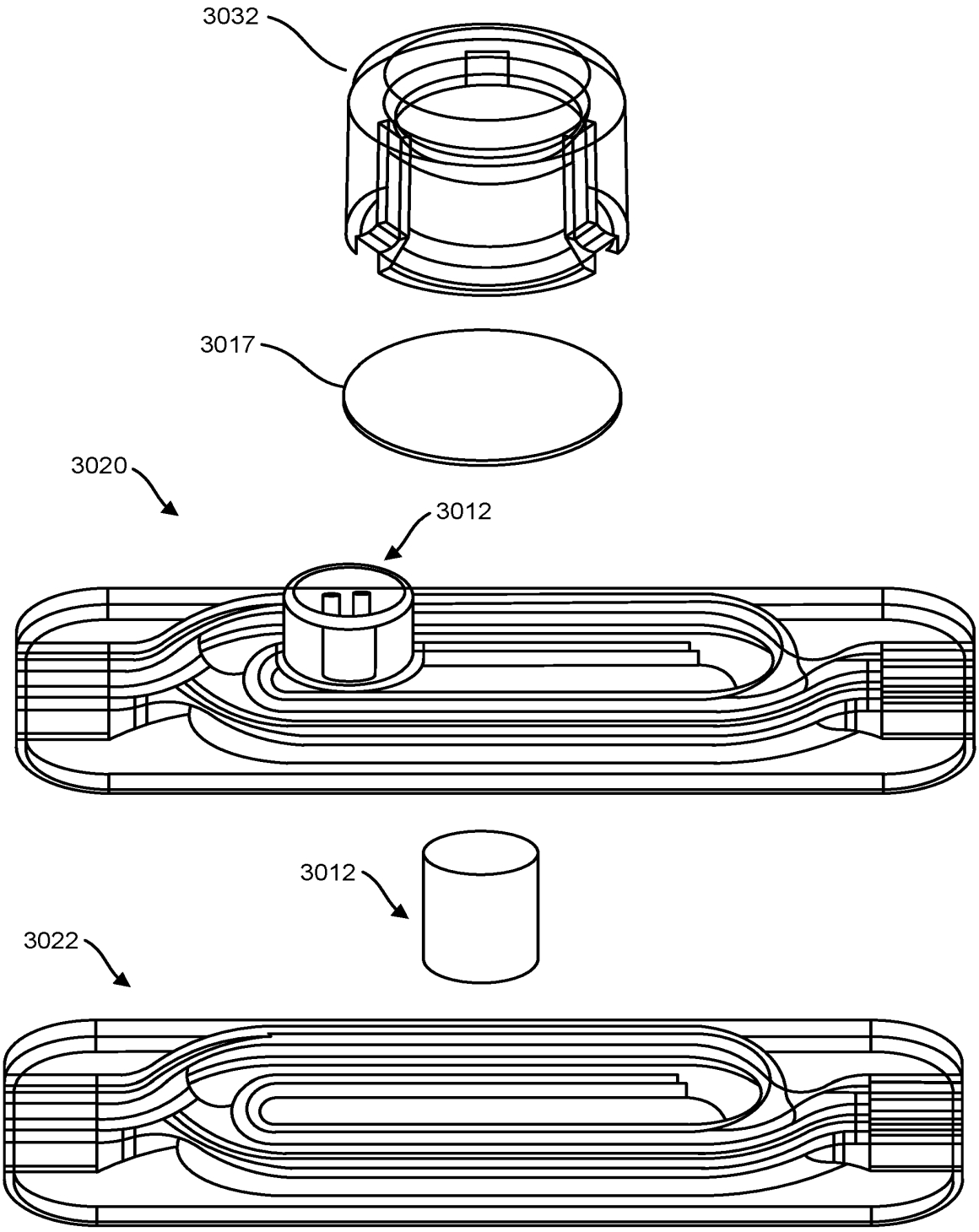


FIG. 30E

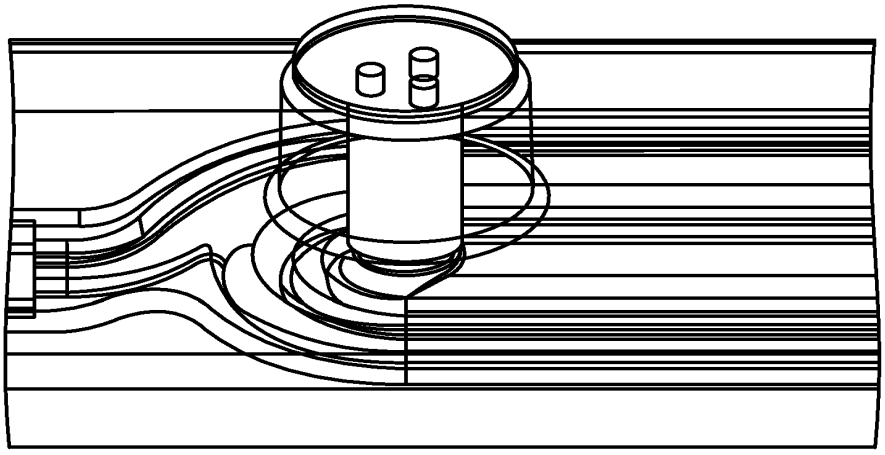


FIG. 30F

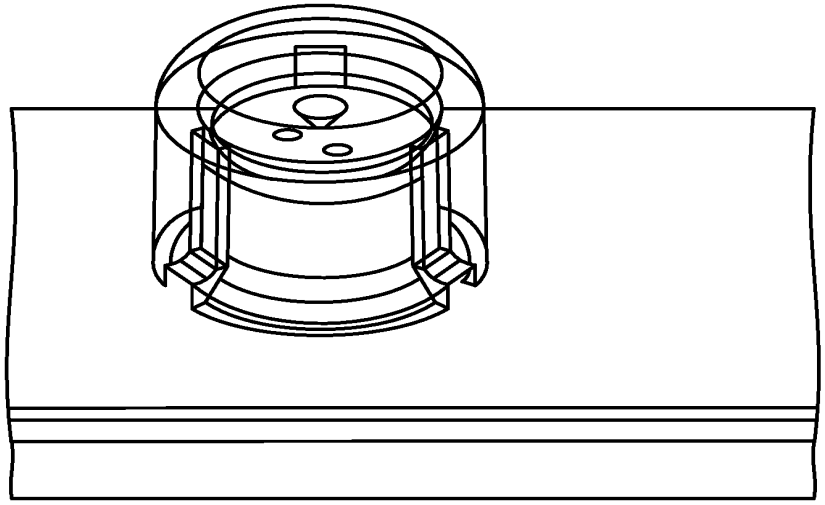


FIG. 30G

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.

* 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
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

1

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

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
US 2014039348 A1	06-02-2014	US 2014039348 A1	06-02-2014
		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
		US 2015367069 A1	24-12-2015
		WO 2014058945 A1	17-04-2014
US 4813433 A	21-03-1989	NONE	
US 2013317391 A1	28-11-2013	US 2013317391 A1	28-11-2013
		US 2015099996 A1	09-04-2015
		US 2015351678 A1	10-12-2015
WO 2013181352 A1	05-12-2013	AU 2013267448 A1	18-12-2014
		AU 2017216493 A1	07-09-2017
		CA 2875118 A1	05-12-2013
		CN 104902817 A	09-09-2015
		CN 107736901 A	27-02-2018
		EP 2854643 A1	08-04-2015
		EP 3173021 A1	31-05-2017
		JP 6242386 B2	06-12-2017
		JP 2015519145 A	09-07-2015
		JP 2018034009 A	08-03-2018
		US 2014155781 A1	05-06-2014
		US 2015351679 A1	10-12-2015
		WO 2013181352 A1	05-12-2013

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EXHIBIT H

PTO/AIA/14 (11-15)
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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	MGMD-012/01US 316052-MGMD
	Application Number	
Title of Invention	SYSTEMS AND METHODS FOR SAMPLE COLLECTION WITH REDUCED HEMOLYSIS	

The application data sheet is part of the provisional or nonprovisional application for which it is being submitted. The following form contains the bibliographic data arranged in a format specified by the United States Patent and Trademark Office as outlined in 37 CFR 1.76.
This document may be completed electronically and submitted to the Office in electronic format using the Electronic Filing System (EFS) or the document may be printed and included in a paper filed application.

Secrecy Order 37 CFR 5.2:

☐ Portions or all of the application associated with this Application Data Sheet may fall under a Secrecy Order pursuant to 37 CFR 5.2 (Paper filers only. Applications that fall under Secrecy Order may not be filed electronically.)

Inventor Information:

Inventor 1 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Gregory	J.	Bullington	

Residence Information (Select One) ◉ US Residency ○ Non US Residency ○ Active US Military Service

City	State/Province	Country of Residence
Bellevue	WA	US

Mailing Address of Inventor:

Address 1	5825 134th Place SE
Address 2	

City	State/Province	Postal Code	Country
Bellevue	WA	98006	US

Inventor 2 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Richard	G.	Patton	

Residence Information (Select One) ◉ US Residency ○ Non US Residency ○ Active US Military Service

City	State/Province	Country of Residence
Seattle	WA	US

Mailing Address of Inventor:

Address 1	2561 Magnolia Blvd. W
Address 2	

City	State/Province	Postal Code	Country
Seattle	WA	98199	US

Inventor 3 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Shan	E.	Gaw	

Residence Information (Select One) ◉ US Residency ○ Non US Residency ○ Active US Military Service

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	MGMD-012/01US 316052-MGMD
	Application Number	
Title of Invention	SYSTEMS AND METHODS FOR SAMPLE COLLECTION WITH REDUCED HEMOLYSIS	

City	Seattle	State/Province	WA	Country of Residence	US

Mailing Address of Inventor:

Address 1	4027 Sunnyside Ave. N		
Address 2			
City	Seattle	State/Province	WA
Postal Code	98103	Country	US

Inventor 4 — Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Jay	M.	Miazga	

Residence Information (Select One) ◉ US Residency ○ Non US Residency ○ Active US Military Service

City	Seattle	State/Province	WA	Country of Residence	US

Mailing Address of Inventor:

Address 1	4025 McKinley Pl. N		
Address 2			
City	Seattle	State/Province	WA
Postal Code	98103	Country	US

Inventor 5 — Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Jed		McCann	

Residence Information (Select One) ◉ US Residency ○ Non US Residency ○ Active US Military Service

City	Seattle	State/Province	WA	Country of Residence	US

Mailing Address of Inventor:

Address 1	7321 22nd Ave. NW		
Address 2			
City	Seattle	State/Province	WA
Postal Code	98117	Country	US

Inventor 6 — Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Paul		Goldenbaum	

Residence Information (Select One) ◉ US Residency ○ Non US Residency ○ Active US Military Service

City	San Antonio	State/Province	TX	Country of Residence	US

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	MGMD-012/01US 316052-MGMD
	Application Number	
Title of Invention	SYSTEMS AND METHODS FOR SAMPLE COLLECTION WITH REDUCED HEMOLYSIS	

Mailing Address of Inventor:

Address 1	4218 Black Rock		
Address 2			
City	San Antonio	**State/Province**	TX
Postal Code	78253	**Country** i	US

All Inventors Must Be Listed - Additional Inventor Information blocks may be generated within this form by selecting the **Add** button. Add

Correspondence Information:

Enter either Customer Number or complete the Correspondence Information section below.
For further information see 37 CFR 1.33(a).

☐ **An Address is being provided for the correspondence Information of this application.**

Customer Number	58249		
Email Address	zpatdcdocketing@cooley.com	Add Email	Remove Email

Application Information:

Title of the Invention	SYSTEMS AND METHODS FOR SAMPLE COLLECTION WITH REDUCED HEMOLYSIS		
Attorney Docket Number	MGMD-012/01US 316052-MGMD	**Small Entity Status Claimed**	☒
Application Type	Provisional		
Subject Matter	Utility		
Total Number of Drawing Sheets (if any)	36	**Suggested Figure for Publication (if any)**	

Filing By Reference:

Only complete this section when filing an application by reference under 35 U.S.C. 111(c) and 37 CFR 1.57(a). Do not complete this section if application papers including a specification and any drawings are being filed. Any domestic benefit or foreign priority information must be provided in the appropriate section(s) below (i.e., "Domestic Benefit/National Stage Information" and "Foreign Priority Information").

For the purposes of a filing date under 37 CFR 1.53(b), the description and any drawings of the present application are replaced by this reference to the previously filed application, subject to conditions and requirements of 37 CFR 1.57(a).

Application number of the previously filed application	Filing date (YYYY-MM-DD)	Intellectual Property Authority or Country

Publication Information:

☐ Request Early Publication (Fee required at time of Request 37 CFR 1.219)

☐ **Request Not to Publish.** I hereby request that the attached application not be published under 35 U.S.C. 122(b) and certify that the invention disclosed in the attached application **has not and will not** be the subject of an application filed in another country, or under a multilateral international agreement, that requires publication at eighteen months after filing.

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	MGMD-012/01US 316052-MGMD
	Application Number	
Title of Invention	SYSTEMS AND METHODS FOR SAMPLE COLLECTION WITH REDUCED HEMOLYSIS	

Representative Information:

Representative information should be provided for all practitioners having a power of attorney in the application. Providing this information in the Application Data Sheet does not constitute a power of attorney in the application (see 37 CFR 1.32).
Either enter Customer Number or complete the Representative Name section below. If both sections are completed the customer Number will be used for the Representative Information during processing.

Please Select One:	● Customer Number	US Patent Practitioner	○ Limited Recognition (37 CFR 11.9)
Customer Number	68249		

Domestic Benefit/National Stage Information:

This section allows for the applicant to either claim benefit under 35 U.S.C. 119(e), 120, 121, 365(c), or 386(c) or indicate National Stage entry from a PCT application. Providing benefit claim information in the Application Data Sheet constitutes the specific reference required by 35 U.S.C. 119(e) or 120, and 37 CFR 1.78.
When referring to the current application, please leave the "Application Number" field blank.

Prior Application Status			Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)

Additional Domestic Benefit/National Stage Data may be generated within this form by selecting the **Add** button. Add

Foreign Priority Information:

This section allows for the applicant to claim priority to a foreign application. Providing this information in the application data sheet constitutes the claim for priority as required by 35 U.S.C. 119(b) and 37 CFR 1.55. When priority is claimed to a foreign application that is eligible for retrieval under the priority document exchange program (PDX)[i] the information will be used by the Office to automatically attempt retrieval pursuant to 37 CFR 1.55(i)(1) and (2). Under the PDX program, applicant bears the ultimate responsibility for ensuring that a copy of the foreign application is received by the Office from the participating foreign intellectual property office, or a certified copy of the foreign priority application is filed, within the time period specified in 37 CFR 1.55(g)(1).

Remove

Application Number	Country[i]	Filing Date (YYYY-MM-DD)	Access Code[i] (if applicable)

Additional Foreign Priority Data may be generated within this form by selecting the **Add** button. Add

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	MGMD-012/01US 316052-MGMD
	Application Number	
Title of Invention	SYSTEMS AND METHODS FOR SAMPLE COLLECTION WITH REDUCED HEMOLYSIS	

Statement under 37 CFR 1.55 or 1.78 for AIA (First Inventor to File) Transition Applications

☐ This application (1) claims priority to or the benefit of an application filed before March 16, 2013 and (2) also contains, or contained at any time, a claim to a claimed invention that has an effective filing date on or after March 16, 2013.
NOTE: By providing this statement under 37 CFR 1.55 or 1.78, this application, with a filing date on or after March 16, 2013, will be examined under the first inventor to file provisions of the AIA.

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	MGMD-012/01US 316052-MGMD
	Application Number	
Title of Invention	SYSTEMS AND METHODS FOR SAMPLE COLLECTION WITH REDUCED HEMOLYSIS	

Authorization or Opt-Out of Authorization to Permit Access:

When this Application Data Sheet is properly signed and filed with the application, applicant has provided written authority to permit a participating foreign intellectual property (IP) office access to the instant application-as-filed (see paragraph A in subsection 1 below) and the European Patent Office (EPO) access to any search results from the instant application (see paragraph B in subsection 1 below).

Should applicant choose not to provide an authorization identified in subsection 1 below, applicant **must opt-out** of the authorization by checking the corresponding box A or B or both in subsection 2 below.

NOTE: This section of the Application Data Sheet is **ONLY** reviewed and processed with the **INITIAL** filing of an application. After the initial filing of an application, an Application Data Sheet cannot be used to provide or rescind authorization for access by a foreign IP office(s). Instead, Form PTO/SB/39 or PTO/SB/69 must be used as appropriate.

1. Authorization to Permit Access by a Foreign Intellectual Property Office(s)

A. Priority Document Exchange (PDX) - Unless box A in subsection 2 (opt-out of authorization) is checked, the undersigned hereby **grants the USPTO authority** to provide the European Patent Office (EPO), the Japan Patent Office (JPO), the Korean Intellectual Property Office (KIPO), the State Intellectual Property Office of the People's Republic of China (SIPO), the World Intellectual Property Organization (WIPO), and any other foreign intellectual property office participating with the USPTO in a bilateral or multilateral priority document exchange agreement in which a foreign application claiming priority to the instant patent application is filed, access to: (1) the instant patent application-as-filed and its related bibliographic data, (2) any foreign or domestic application to which priority or benefit is claimed by the instant application and its related bibliographic data, and (3) the date of filing of this Authorization. See 37 CFR 1.14(h)(1).

B. Search Results from U.S. Application to EPO - Unless box B in subsection 2 (opt-out of authorization) is checked, the undersigned hereby **grants the USPTO authority** to provide the EPO access to the bibliographic data and search results from the instant patent application when a European patent application claiming priority to the instant patent application is filed. See 37 CFR 1.14(h)(2).

The applicant is reminded that the EPO's Rule 141(1) EPC (European Patent Convention) requires applicants to submit a copy of search results from the instant application without delay in a European patent application that claims priority to the instant application.

2. Opt-Out of Authorizations to Permit Access by a Foreign Intellectual Property Office(s)

☐ A. Applicant **DOES NOT** authorize the USPTO to permit a participating foreign IP office access to the instant application-as-filed. If this box is checked, the USPTO will not be providing a participating foreign IP office with any documents and information identified in subsection 1A above.

☐ B. Applicant **DOES NOT** authorize the USPTO to transmit to the EPO any search results from the instant patent application. If this box is checked, the USPTO will not be providing the EPO with search results from the instant application.

NOTE: Once the application has published or is otherwise publicly available, the USPTO may provide access to the application in accordance with 37 CFR 1.14.

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	MGMD-012/01US 316052-MGMD
	Application Number	
Title of Invention	SYSTEMS AND METHODS FOR SAMPLE COLLECTION WITH REDUCED HEMOLYSIS	

Applicant Information:

Providing assignment information in this section does not substitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.

Applicant 1 — Remove

If the applicant is the inventor (or the remaining joint inventor or inventors under 37 CFR 1.45), this section should not be completed. The information to be provided in this section is the name and address of the legal representative who is the applicant under 37 CFR 1.43; or the name and address of the assignee, person to whom the inventor is under an obligation to assign the invention, or person who otherwise shows sufficient proprietary interest in the matter who is the applicant under 37 CFR 1.46. If the applicant is an applicant under 37 CFR 1.46 (assignee, person to whom the inventor is obligated to assign, or person who otherwise shows sufficient proprietary interest) together with one or more joint inventors, then the joint inventor or inventors who are also the applicant should be identified in this section.

Clear

Assignee	Legal Representative under 35 U.S.C. 117	Joint Inventor
◉ Person to whom the inventor is obligated to assign.	Person who shows sufficient proprietary interest	

If applicant is the legal representative, indicate the authority to file the patent application, the inventor is:

Name of the Deceased or Legally Incapacitated Inventor:

If the Applicant is an Organization check here. ☒

Organization Name	Magnolia Medical Technologies, Inc.		
Mailing Address Information For Applicant:			
Address 1	2001 Sixth Avenue		
Address 2	Suite 1630		
City	Seattle	**State/Province**	WA
Country	US	Postal Code	98121
Phone Number		Fax Number	
Email Address			

Additional Applicant Data may be generated within this form by selecting the Add button. Add

Assignee Information including Non-Applicant Assignee Information:

Providing assignment information in this section does not substitute for compliance with any requirement of part 3 of Title 37 of CFR to have an assignment recorded by the Office.

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	MGMD-012/01US 316052-MGMD
	Application Number	
Title of Invention	SYSTEMS AND METHODS FOR SAMPLE COLLECTION WITH REDUCED HEMOLYSIS	

Assignee 1

Complete this section if assignee information, including non-applicant assignee information, is desired to be included on the patent application publication. An assignee-applicant identified in the "Applicant Information" section will appear on the patent application publication as an applicant. For an assignee-applicant, complete this section only if identification as an assignee is also desired on the patent application publication.

Remove

If the Assignee or Non-Applicant Assignee is an Organization check here. ☐

Prefix	Given Name	Middle Name	Family Name	Suffix

Mailing Address Information For Assignee including Non-Applicant Assignee:

Address 1			
Address 2			
City		State/Province	
Country i		Postal Code	
Phone Number		Fax Number	
Email Address			

Additional Assignee or Non-Applicant Assignee Data may be generated within this form by selecting the Add button. Add

Signature:

Remove

NOTE: This Application Data Sheet must be signed in accordance with 37 CFR 1.33(b). **However, if this Application Data Sheet is submitted with the INITIAL filing of the application and either box A or B is not checked in subsection 2 of the "Authorization or Opt-Out of Authorization to Permit Access" section, then this form must also be signed in accordance with 37 CFR 1.14(c).**

This Application Data Sheet **must** be signed by a patent practitioner if one or more of the applicants is a **juristic entity** (e.g., corporation or association). If the applicant is two or more joint inventors, this form must be signed by a patent practitioner, **all** joint inventors who are the applicant, or one or more joint inventor-applicants who have been given power of attorney (e.g., see USPTO Form PTO/AIA/81) on behalf of **all** joint inventor-applicants.

See 37 CFR 1.4(d) for the manner of making signatures and certifications.

Signature	/Michael D. Wintemitz/			Date (YYYY-MM-DD)	2016-11-18
First Name	Michael	Last Name	Wintemitz	Registration Number	73102

Additional Signature may be generated within this form by selecting the Add button. Add

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Application Data Sheet 37 CFR 1.76	Attorney Docket Number	MGMD-012/01US 316052-MGMD
	Application Number	
Title of Invention	SYSTEMS AND METHODS FOR SAMPLE COLLECTION WITH REDUCED HEMOLYSIS	

This collection of information is required by 37 CFR 1.76. 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 23 minutes to complete, including gathering, preparing, and submitting the completed application data sheet 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.**

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 records.

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 CooperationTreaty.

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.

SYSTEMS AND METHODS FOR SAMPLE COLLECTION WITH REDUCED HEMOLYSIS

Background

[1001] Embodiments described herein relate generally to the parenteral procurement of bodily-fluid samples, and more particularly to systems and methods for parenterally procuring bodily-fluid samples, such as blood, with reduced hemolysis.

[1002] Health care practitioners routinely draw bodily-fluids from a patient for various testing and/or donation purposes. In some instances, the process of obtaining the bodily-fluids, and in particular, blood, can result in a degradation and/or breakdown of portions and/or constituents contained in the bodily-fluid. Specifically, hemolysis of red blood cells (i.e., a rupturing of the red blood cells and the release of cytoplasm) during blood draw is a known problem in the field of phlebotomy and/or medical testing. Hemolysis of blood is the most common pre-analytical source of error in clinical testing, accounting for nearly 60% of all rejected samples (Bonini P, Plebani M, Ceriotti F, Rubboli F (2002). Errors in laboratory medicine. *Clinical Chemistry*, 48, 691-698; and Plebani M, Carraro P (1997). Mistakes in a stat laboratory: types and frequency. *Clinical Chemistry*, 43, 1348-1351). Moreover, hemolyzed sample rates from hospital emergency rooms can be as high as 30% (Grant M (2003). The effect of blood drawing techniques and equipment on the hemolysis of ED laboratory blood samples. *Journal of Emergency Nursing*, 29 (2), 116-121, and Soderberg J, Jonsson PA, Wallin O, Grankvist K, Hultdin J (2009). Hemolysis index—an estimate of pre-analytical quality in primary health care. *Clinical Chemistry and Laboratory Medicine*, 47, 940-944). In some know blood draw systems, the arrangement and/or coupling of multiple devices to form a fluid flow path from a patient to, for example, a sample reservoir or container, shear stress exerted on or within the red blood cells, exposure time, and/or the like can lead to an increased likelihood of hemolysis within a sample volume.

[1003] Thus, a need exists for systems and methods for sample collection with reduced hemolysis.

Summary

[1004] Systems and methods for parenterally procuring bodily-fluid samples, such as blood, with reduced hemolysis are described herein. In some embodiments, a collection system has a proximal end portion, a distal end portion, and an inner surface defining a fluid flow path therethrough. The distal end portion is configured to be placed in fluid communication with a patient. The proximal end portion is configured to be placed in fluid communication with a fluid reservoir. The fluid flow path defined by the inner surface is associated with at least one flow characteristic configured to limit a stress within the flow of the bodily-fluid between the distal end portion and the proximal end portion.

Brief Description of the Drawings

[1005] FIG. 1 is a schematic illustration of a bodily-fluid collection device according to an embodiment.

[1006] FIG. 2 is a perspective view of a needle included in a bodily-fluid collection device according to an embodiment.

[1007] FIG. 3 is an enlarged view of a portion of the needle of FIG. 2, identified by the region A_1.

[1008] FIGS. 4-6 are illustrations of a needle used to deliver a cannula to a portion of the body according to an embodiment.

[1009] FIG. 7 is a perspective view of a portion of a needle included in a bodily-fluid collection device according to another embodiment.

[1010] FIG. 8 is a perspective view of a portion of a bodily-fluid collection device according to an embodiment.

[1011] FIG. 9 is a cross-sectional view of the bodily-fluid collection device of FIG. 8, taken along the line 9-9.

[1012] FIG. 10 is an enlarged view of a portion of the bodily-fluid collection device of FIG. 9, identified by the region A_2.

[1013] FIG. 11 is a front view of a portion of a bodily-fluid collection device according to an embodiment.

[1014] FIG. 12 is a cross-sectional view of the portion of the bodily-fluid collection device of FIG. 11, taken along the line 12-12.

[1015] FIG. 13 is an enlarged view of a portion of the bodily-fluid collection device of FIG. 12, identified by the region A_3.

[1016] FIG. 14 is a cross-sectional view of a portion of a bodily-fluid collection device according to another embodiment.

[1017] FIG. 15 is an enlarged view of a portion of the bodily-fluid collection device of FIG. 14, identified by the region A_4.

[1018] FIG. 16 is a cross-sectional view of a portion of a bodily-fluid collection device according to another embodiment.

[1019] FIG. 17 is a cross-sectional view of a portion of a bodily-fluid collection device according to another embodiment.

[1020] FIG. 18 is a perspective view of a portion of a bodily-fluid collection device according to an embodiment.

[1021] FIG. 19 is an exploded view of the portion of the bodily-fluid collection device of FIG. 18.

[1022] FIG. 20 is a cross-sectional view of the portion of the bodily-fluid collection device of FIG. 18, taken along the line 20-20.

[1023] FIG. 21 is a perspective view of a restrictor included in a bodily-fluid collection device according to an embodiment.

[1024] FIG. 22 is a cross-sectional view of the restrictor of FIG. 21, taken along the line 22-22.

[1025] FIG. 23 is a top view of a baffle included in the restrictor of FIG. 21.

[1026] FIG. 24 is a cross-sectional view of the baffle of FIG. 23, taken along the line 24-24.

[1027] FIG. 25 is a perspective view of a restrictor included in a bodily-fluid collection device according to an embodiment.

[1028] FIG. 26 is a cross-sectional view of the restrictor of FIG. 25, taken along the line 26-26.

[1029] FIG. 27 is a perspective view of an adapter included in a bodily-fluid collection device according to an embodiment.

[1030] FIG. 28 is a cross-sectional view of the adapter of FIG. 27, taken along the line 28-28.

[1031] FIG. 29 is a front view of a portion of the adapter of FIG. 27.

[1032] FIG. 30 is a cross-sectional view of the portion of the adapter illustrated in FIG. 29, taken along the line 30-30.

[1033] FIG. 31 is a perspective view of the portion of the adapter illustrated in FIG. 29 coupled to a fluid reservoir according to an embodiment.

[1034] FIG. 32 is an exploded view of the fluid reservoir of FIG. 31.

[1035] FIG. 33 is a cross-sectional view of the portion of the adapter and the fluid reservoir illustrated in FIG. 31, taken along the line 33-33.

[1036] FIG. 34 is a cross-sectional view of an adapter coupled to a fluid reservoir according to another embodiment.

[1037] FIG. 35 is a cross-sectional view of an adapter coupled to a fluid reservoir according to another embodiment.

[1038] FIG. 36 is a cross-sectional view of an adapter coupled to a fluid reservoir according to another embodiment.

[1039] FIG. 37 is a perspective view of an adapter coupled to a fluid reservoir according to another embodiment.

[1040] FIG. 38 is a cross-sectional view of the adapter and the fluid reservoir of FIG. 37, taken along the line 38-38.

[1041] FIG. 39 is a perspective view of an adapter coupled to a fluid reservoir according to another embodiment.

[1042] FIG. 40 is a perspective view of an adapter coupled to a fluid reservoir according to another embodiment.

[1043] FIGS. 41 and 42 are cross-sectional views of the adapter and the fluid reservoir of FIG. 40, taken along the line 41-41, in a first configuration and a second configuration, respectively.

[1044] FIG. 43 is a perspective view of an adapter and a fluid reservoir according to another embodiment.

[1045] FIG. 44 is a cross-sectional view of the adapter and the fluid reservoir of FIG. 43, taken along the line 44-44.

[1046] FIGS. 45-47 are cross-sectional views of an adapter and a fluid reservoir each according to a different embodiment.

[1047] FIG. 48 is a perspective of an adapter included in a bodily-fluid collection device according to another embodiment.

[1048] FIG. 49 is a cross-sectional view of the adapter of FIG. 48, taken along the line 49-49.

[1049] FIG. 50 is a perspective view of a fluid reservoir included in a bodily-fluid collection device according to an embodiment.

[1050] FIG. 51 is a cross-sectional view of the adapter illustrated in FIG. 49 coupled to the fluid reservoir illustrated in FIG. 50, taken along the line 51-51 in FIG. 50.

[1051] FIG. 52 is a perspective view of a fluid reservoir included in a bodily-fluid collection device according to another embodiment.

[1052] FIG. 53 is a cross-sectional view of the fluid reservoir of FIG. 52, taken along the line 53-53.

[1053] FIG. 54 is a perspective view of a fluid reservoir included in a bodily-fluid collection device according to another embodiment.

[1054] FIG. 55 is an exploded view of a plunger included in the fluid reservoir of FIG. 54.

[1055] FIG. 56 is a cross-sectional view of the fluid reservoir of FIG. 54, taken along the line 56-56.

[1056] FIG. 57 is a perspective view of a fluid reservoir included in a bodily-fluid collection device according to another embodiment.

[1057] FIG. 58 is a cross-sectional view of the fluid reservoir of FIG. 57, taken along the line 58-58.

[1058] FIG. 59 is a front view of a fluid reservoir included in a bodily-fluid collection device according to another embodiment.

[1059] FIG. 60 is a cross-sectional view of a fluid reservoir included in a bodily-fluid collection device according to another embodiment.

[1060] FIG. 61 is a perspective view of an adapter included in a bodily-fluid collection device according to another embodiment.

[1061] FIG. 62 is an exploded view of the adapter of FIG. 61.

[1062] FIG. 63 is a cross-sectional view of the adapter of FIG. 61, taken along the line 63-63.

[1063] FIG. 64 is a perspective view of an adapter included in a bodily-fluid collection device according to another embodiment.

[1064] FIG. 65 is an exploded view of the adapter of FIG. 64.

[1065] FIG. 66 is a cross-sectional view of the adapter of FIG. 65, taken along the line 66-66.

[1066] FIG. 67 is a perspective view of an adapter included in a bodily-fluid collection device according to another embodiment.

[1067] FIG. 68 is a cross-sectional view of the adapter of FIG. 67, taken along the line 68-68.

[1068] FIG. 69 is a perspective view of an adapter included in a bodily-fluid collection device according to another embodiment.

[1069] FIG. 70 is an exploded view of the adapter of FIG. 69.

[1070] FIG. 71 is a cross-sectional view of the adapter of FIG. 69, taken along the line 71-71.

Detailed Description

[1071] Systems and methods for parenterally procuring bodily-fluid samples, such as blood, with reduced hemolysis are described herein. In some embodiments, a collection system has a proximal end portion, a distal end portion, and an inner surface defining a fluid flow path therethrough. The distal end portion is configured to be placed in fluid communication with a patient. The proximal end portion is configured to be placed in fluid communication with a fluid reservoir. The fluid flow path defined by the inner surface is associated with at least one flow characteristic configured to limit a stress within the flow of the bodily-fluid between the distal end portion and the proximal end portion.

[1072] As used in this specification and the appended claims, the singular forms "a," "an" and "the" include plural referents unless the context clearly dictates otherwise. Thus, for example, the term "a member" is intended to mean a single member or a combination of members, "a material" is intended to mean one or more materials, or a combination thereof.

[1073] As used 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. Moreover, while the embodiments and/or devices herein are specifically described as reducing, limiting, inhibiting, and/or substantially preventing hemolysis of blood withdrawn therethrough, any of the embodiments and/or devices can be used for controlling a flow of any suitable bodily-fluid (e.g., such as those listed above) when withdrawn from the body of a patient through that device.

[1074] 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 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).

[1075] As used herein, the terms "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.

[1076] As used herein, the terms "about," "approximately," and "substantially" when used in connection with a numerical value is intended to convey that the value so defined is nominally the value stated. Said another way, the terms about, approximately, and substantially when used in connection with a numerical value generally include the value stated plus or minus a given tolerance. For example, in some instances, a suitable tolerance can be plus or minus 10% of the value stated; thus, about 0.5 would include 0.45 and 0.55, about 10 would include 9 to 11, about 1000 would include 900 to 1100. In other instances, a suitable tolerance can be plus or minus an acceptable percentage of the last significant figure in the value stated. For example, a suitable tolerance can be plus or minus 10% of the last significant figure; thus, about 10.1 would include 10.09 and 10.11, approximately 25 would include 24.5 and 25.5. Such variance can result from manufacturing tolerances or other practical considerations (such as, for example, tolerances associated with a measuring instrument, acceptable human error, or the like).

[1077] As used herein, the term "laminar" refers to an organized and/or orderly fluid flow in parallel layers without lateral mixing, crosscurrents, eddy currents, and/or the like. More generally, the term "laminar" is intended to convey a flow of fluid that is smooth and/or free of turbulence. Moreover, the term "substantially" when used in connection with "laminar" is intended to convey that a fluid flow so defined is nominally a laminar fluid flow. As one example, a portion of a fluid transfer device defining a lumen that is described as facilitating and/or otherwise causing a "substantially laminar" fluid flow therethrough is intended to

convey that, although laminar fluid flow is desirable, some non-laminar flow can occur. Such variances (e.g., turbulence or the like) can result from manufacturing tolerances, or other practical considerations. Thus, a fluid having a "substantially laminar" flow includes such non-laminar flow characteristics within an industry-accepted tolerance. For example, while it may be desirable that a bodily-fluid transfer device transfer a laminar flow of blood therethrough a "substantially laminar flow" of blood can be 99% laminar, 95% laminar, 90% laminar, or any other acceptable tolerance thereof.

[1078] The embodiments described herein can be formed or constructed of one or more biocompatible materials. Examples of suitable biocompatible materials include metals, glasses, ceramics, or polymers. Examples of suitable metals include pharmaceutical grade stainless steel, gold, titanium, nickel, iron, platinum, tin, chromium, copper, and/or alloys thereof. A polymer material may be biodegradable or non-biodegradable. Examples of suitable biodegradable polymers include polylactides, polyglycolides, polylactide-co-glycolides (PLGA), polyanhydrides, polyorthoesters, polyetheresters, polycaprolactones, polyesteramides, poly(butyric acid), poly(valeric acid), polyurethanes, and/or blends and copolymers thereof. Examples of non-biodegradable polymers include nylons, polyesters, polycarbonates, polyacrylates, polymers of ethylene-vinyl acetates and other acyl substituted cellulose acetates, non-degradable polyurethanes, polystyrenes, polyvinyl chloride, polyvinyl fluoride, poly(vinyl imidazole), chlorosulphonate polyolefins, polyethylene oxide, and/or blends and copolymers thereof.

[1079] In some current phlebotomy procedures, blood is drawn from a patient using multiple components that are physically and fluidically coupled to define a fluid flow path between the patient and a collection device and/or fluid reservoir used to capture the bodily-fluid sample. In some such systems, however, the physical and/or fluidic interfaces formed between the components can result in turbulent regions and/or eddy currents within the flow of the blood, which in turn, can result in a stress within the flow that is sufficient to sheer, rupture, and/or otherwise damage the red blood cells. In addition, the process of drawing blood from a patient often involves exposing the blood to a negative pressure differential produced, for example, by placing an evacuated container (e.g., a Vacutainer ™) in fluid communication with a portion of the body. In some instances, the pressure differential can increase an internal stress within a flow of blood to an extent that results in hemolysis of the red blood cells. In other instances, the pressure differential can be attributed to the physical

exertion associated with a clinician actuating, for example, a syringe with a force sufficient to rupture the red blood cells during the collection process. A number of factors (for example, small veins, dehydration, veins with scar tissue, presence of sclerosis, and/or the like) can make vascular access a challenge. In such cases, excess negative pressure exerted during the collection process can result in hemolysis.

[1080] While such a negative pressure differential often facilitates withdraw of the blood, it also can produce a relatively high shear stresses within the red blood cells and/or a relatively high flow velocity of the blood through a flow path defined between the patient and the fluid reservoir (e.g., evacuated container). As a result, the red blood cells contained within the flow of blood can be damaged as the cells pass through the physical and/or fluidic interfaces formed between different components of a transfer device. In some instances, the relatively high velocity of the blood flow as the blood enters the containers can result in the blood impacting an inner surface of the container with a force sufficient to damage the red blood cells and/or other components of the blood. In addition, exposure time of a needle and/or catheter within the vein can result in hemolysis of the red blood cells.

[1081] Thus, to mitigate the risk of hemolysis of a sample volume of blood, various portions of a fluid flow path between the patient and the sample reservoir can be optimized. Such optimization can be done holistically (i.e., a system wide optimization) or done piecemeal (i.e., optimization of at least one potential source of hemolysis). By way of example, in some instances, any of the embodiments described herein, can be used independently to mitigate the risk of hemolysis at a specific point along a fluid flow path between a patient and a sample reservoir. That is to say, the embodiments described herein can be characterized by the potential source of hemolysis that the embodiments, so characterized, mitigate. For example, the embodiments described herein generally address six potential categories, portions, and/or sources of hemolysis along a fluid flow path between a patient and a fluid reservoir. Namely, the embodiments described herein can be used to mitigate the risk of hemolysis otherwise associated with (1) blood flow from, for example, a vein into a puncture member, needle, cannula, and/or the like, (2) blood flow through changing geometries and/or physical and fluidic interfaces; (3) blood flow rates and/or velocity within the fluid flow path; (4) blood flow from an adapter, puncture member, needle, cannula, and/or the like into a fluid reservoir; (5) blood flow exposure to a negative

pressure differential within a fluid reservoir, and (6) blood flow through a multi-lumen adapter and/or the like.

[1082] FIG. 1 is a schematic illustration of a portion of a bodily-fluid collection device 100, according to an embodiment. Generally, the bodily-fluid collection device 100 (also referred to herein as "fluid collection device," "collection device," or "device") can be used to percutaneously withdraw bodily-fluid from a patient. In some instances, the device 100 can be used to withdraw a volume of blood from a patient that is to be used as a biological sample for testing and/or assays associated with medical diagnosis and/or treatment. In other instances, the device 100 can be used to withdraw a volume of blood for collection purposes such as, for example, blood donation or the like. More particularly, the device 100 is configured to limit, inhibit, and/or substantially prevent hemolysis of at least a portion of the blood drawn therethrough, as described in further detail herein.

[1083] The device 100 has a proximal end portion 101 and a distal end portion 102 and defines a lumen 104 therethrough. More specifically, the device 100 includes an inner surface 103 that defines the lumen 104. The device 100 can be any suitable device or group of devices (e.g., a system including multiple devices). In some embodiments, for example, the device 100 can be a needle, a cannula, a trocar, a catheter, and/or the like. In such embodiments, the distal end portion 102 of the device 100 can include a sharpened, angled, or beveled edge configured to puncture the cutaneous layer of the body to place the lumen 104 in fluid communication with, for example, a vascular structure and/or the like. The proximal end portion 101 of the device 100 can be physically and/or fluidically coupled to any other suitable device such as, for example, a collection reservoir (not shown in FIG. 1). As such, the lumen 104 defined by the device 100 defines fluid pathway through which blood can flow from the patient to an intermediary collection device and/or directly to the collection reservoir.

[1084] As described above, in some embodiments, the device 100 is configured to reduce, limit, inhibit, and/or substantially prevent hemolysis of blood withdrawn from the body and through the device. For example, in embodiments in which the device 100 is a needle, cannula, catheter, and/or the like, the distal end portion 102 of the device 100 can include rounded edges and/or a substantially smooth contour. As such, the constituents of the blood (e.g., the red blood cells or "erythrocytes") can flow relatively smoothly into the lumen

104 (e.g., in response to a negative pressure differential produced, for example, by a syringe and/or an evacuated container coupled thereto) substantially without being damaged.

[1085] Moreover, in some embodiments, the shape, size, and/or contour of the inner surface 103 can selectively control the flow of blood through the device 100. By way of example, in some embodiments, the inner surface 103 can form a substantially smooth contour, which can facilitate a laminar flow of the blood therethrough. In addition, the inner surface 103 can have a contour that can selectively control an amount of negative pressure within a region of the lumen 104. For example, in some embodiments, the inner surface 103 can have a diameter that is varied along the length of the device 100. That is to say, a first portion of the inner surface 103 can have a diameter that is different from a diameter of a second portion of the inner surface 103 and thus, can reduce, constrict, limit, and/or otherwise control a flow of blood therethrough. In some such embodiments, the first portion of the inner surface 103 can be disposed between the second portion of the inner surface 103 and a third portion of the inner surface 103 having a diameter greater than or equal to the diameter of the second portion of the inner surface 103. In such embodiments, a region of the lumen 104 having a relatively larger diameter can be associated with a larger pressure than a region of the lumen 104 having a relatively smaller diameter, while conversely, a velocity associated with the region of the lumen 104 having the relatively larger diameter is less than a velocity associated with the region of the lumen having the relatively smaller diameter based on the simplified Bernoulli's Equation mathematically represented by equation 1 below:

$$P_1 + {}^1/_2\,\rho V_1^2 = P_2 + {}^1/_2\,\rho V_2^2 \qquad \text{Equation 1}$$

wherein P is pressure within the lumen, ρ is density of the fluid, and V is velocity of the fluid.

[1086] While described above as being a needle, catheter, cannula, trocar, and/or the like, in other embodiments, the device 100 can be any suitable component included in a fluid transfer system. For example, the device 100 can be an adapter, a locking mechanism, a cannula, a coupling mechanism, a port, an inlet, and outlet, and/or the like. By way of example, in some embodiments, the device 100 can be an adapter configured to be physically and fluidically coupled to at least one other device such as, for example, a needle. Thus, the adapter (i.e., the device 100) can have an inner surface with a contour that can control a flow of bodily-fluid therethrough. Moreover, an interface between the device 100 and the needle

(and/or any other suitable device) can be arranged to reduce turbulence of a flow of bodily-fluid therebetween, as described in further detail herein.

[1087] In some embodiments, the device 100 can be coupled to a fluid reservoir or container (e.g., at the proximal end portion 101). As such, the contour of the inner surface 103 of the device 100 can control a flow of bodily-fluid therethrough (as described above), while the orientation of the device 100 relative to the fluid reservoir or container can control and/or direct the flow of bodily-fluid through the proximal end portion 101 toward an inner surface of the fluid reservoir to, for example, reduce a force associated with a portion of the flow of bodily-fluid impacting the inner surface. In some embodiments, the device 100 can be an insert or the like at least partially disposed within the fluid reservoir or container.

[1088] Although not shown in FIG. 1, in some embodiments, the device 100 can be used with (e.g., physically and fluidically coupled to) a device or mechanism configured to modulate a negative pressure within a fluid reservoir or container. For example, in some embodiments, the device 100 can be coupled to a syringe or the like configured to transition between a first configuration and a second configuration to produce a negative pressure within an inner volume. As such, a rate at which the syringe can be transitioned from the first configuration (e.g., associated with a plunger in a distal position) to the second configuration (e.g., associated with the plunger in a proximal position) can be constrained (e.g., limited, inhibited, slowed, governed, controlled, etc.), thereby reducing a negative pressure exerted through the lumen 104 of the device, as described in further detail herein.

[1089] While the device 100 is described above as including a surface, mechanism, portion, etc. configured to reduce hemolysis of a volume of blood in a mechanical manner (e.g., reducing pressure and/or turbulence within a flow path via a contour, restrictor, or the like; reducing forces associated with a portion of the volume of blood impacting a surface of a fluid reservoir via a coupling mechanism, interface, etc.; reducing damage to constituents in the volume of blood by limiting or eliminating sharp edges, corners, etc.; and/or the like), in other embodiments, the device can be configured to chemically modify one or more characteristics associated with the volume of blood. For example, in some embodiments, the inner surface 103 of the device 100 can be coated with a chemical configured to limit lysis of erythrocytes (red blood cells) by strengthening or weakening a cell wall of the erythrocytes. More specifically, in some embodiments, the device 100 can be configured to introduce a chemical into a flow of blood that can, for example, increase a rigidity of the cell wall of

erythrocytes (e.g., decrease flexibility), which in turn, can reduce a likelihood of lysis of the erythrocytes (e.g., hemolysis of the blood) as the blood flows through the device 100. In other embodiments, the device 100 can be configured to introduce a chemical into a flow of blood that can, for example, decrease a rigidity of the cell wall of erythrocytes (e.g., increase flexibility), which in turn, can reduce a likelihood of lysis of the erythrocytes as the blood flows through the device 100.

[1090] While described above as coating the inner surface 103 with the chemical configured to modify a characteristic of the cell wall of the erythrocytes, in other embodiments, the device 100 can include any suitable device, mechanism, and/or method for introducing such a chemical to the volume of blood flowing therethrough. For example, the device 100 can include a chamber containing such a chemical, a baffle impregnated with such a chemical, a dispensing or dispersing device (e.g., sprayer or the like) configured to dispense a volume of such a chemical, impregnation of the chemical directly into the material used to produce the device 100 and/or any other suitable means for introducing such a chemical.

[1091] FIGS. 2-7 illustrate embodiments configured to mitigate the risk of hemolysis as a volume of blood flows from the patient (e.g., a vein of a patient) and into a lumen-defining device such as a needle or the like. Specifically, FIGS. 2 and 3 illustrate a puncture member 210 coupled to an adapter 220 according to an embodiment. The puncture member 210 has a proximal end portion 211 and a distal end portion 212 and defines a lumen 213 therebetween. The proximal end portion 211 of the puncture member 210 is physically and fluidically coupled to a distal end portion 222 of the adapter 220, as described above with reference to FIG. 1. More specifically, the proximal end portion 211 of the puncture member 210 is coupled to the adapter 220 such that an interface therebetween forms a substantially smooth and/or continuous surface. Said another way, the interface between the puncture member 210 and the adapter 220 can be such that a transition between the lumen 213 of the puncture member 210 and a lumen (not shown in FIGS. 2-6) defined by the adapter is substantially smooth and/or continuous (i.e., does not introduce a discontinuity such as a change in alignment and/or diameter), as described in further detail herein.

[1092] The distal end portion 212 of the puncture member 210 is configured to be inserted through the cutaneous layer of the patient to transfer fluid to and/or from the patient. For example, the distal end portion 212 can be inserted into a vein of a patient and the adapter 220 can be coupled to a fluid reservoir and/or intermediary collection device configured to

receive a volume of blood from the patient via the lumen 213. More specifically, as shown in FIGS. 2 and 3, the distal end portion 212 of the puncture member 210 is sharpened, angled, and/or beveled, which facilitates the insertion of the puncture member 210 into the body. The lumen 213 of the puncture member 210 extends through the distal end portion 212, thereby defining an opening 214 that places the lumen 213 in fluid communication with, for example, a vascular structure (e.g., a vein) within which the distal end portion 212 is disposed. Furthermore, as shown in FIG. 3, a distal edge 215 of the puncture member 210 defining the opening 214 is substantially rounded, smoothed, contoured, blunted, and/or the like. In other words, the distal edge 215 defining the opening 214 forms a substantially round corner. Thus, blood drawn through the opening 214 and into the lumen 213 can flow past the distal edge 214 with reduced damage to, for example, the constituents of the blood (e.g., the erythrocytes) that would otherwise result from contact with a sharper, more abrupt, substantially orthogonal, and/or otherwise non-rounded distal edge 215.

[1093] In some instances, a puncture member can be used to deliver and/or place a portion of a catheter in a desired lumen within the body of a patient. For example, as shown in FIGS. 4-6, a puncture member 310 can be used to place a stented catheter and/or the like within a vein V. The puncture member 310 can be substantially similar to the puncture members 210 and/or 310 described above and thus, the puncture member is not described in further detail herein. As shown in FIG. 4, a user (e.g., a phlebotomist, nurse, technician, physician, doctor, etc.) can manipulate a portion of the puncture member 310 (e.g., either directly or indirectly) to place at least a distal end portion 312 of the puncture member 310 within a lumen defined by the vein V. Once disposed in the vein V, a guidewire 316 can be advanced through the lumen defined by the puncture member 310, as shown in FIG. 4. With the guidewire 316 positioned within the vein V, the user can advance an introducer catheter 317 and, for example, a stented catheter 318 along the guide wire 316 to dispose a distal end portion of at least the introducer catheter 317 within the lumen of the vein V, as indicated by the arrow AA in FIG. 5. In some instances, the stented catheter 318 can be inserted into the vein V concurrently with the introducer catheter 317. In other instances, the stented catheter 318 can be advanced within the introducer catheter 317 after the distal end portion of the introducer catheter 317 is disposed in the vein 317.

[1094] With the distal end portion of the stented catheter 318 disposed in the vein V, the guidewire 316 and the introducer catheter 317 can be moved in the proximal direction (i.e.,

withdrawn from the vein V), as indicated by the arrow BB in FIG. 6. In some embodiments, as the introducer catheter 317 is withdrawn from the vein V, the distal end portion of the stented catheter 318 can transition from a first configuration to a second configuration. For example, the stented catheter 318 can be in a collapsed configuration (e.g., the first configuration) when disposed in the introducer catheter 317 (FIG. 5) such that a diameter of the stented catheter 318 is substantially uniform. When the introducer catheter 318 is withdrawn from the vein (FIG. 6), the distal end portion of the stented catheter 318 can expand and/or otherwise reconfigure such that a diameter of the distal end portion of the stented catheter 318 is greater than a diameter of a portion of the stented catheter 318 still disposed in the introducer catheter 317.

[1095] In some embodiments, the distal end portion of the stented catheter 318 can expand to an extent that places an outer surface of the stented catheter 318 in close proximity to or directly in temporary contact with an inner surface of the vein V defining the lumen. As such, blood can be withdrawn from the vein V into a fluid reservoir (not shown in FIGS. 4-6) via a lumen defined by the stented catheter 318. Moreover, with the distal end portion of the stented catheter 318 in close proximity to or directly in contact with the inner surface of the vein, the stented catheter 318 can inhibit, limit, and/or substantially prevent a collapse of at least a portion of the vein V (e.g., in response to a negative pressure differential between the vein V and the fluid reservoir (not shown). In some embodiments, the arrangement of at least the distal end portion of the stented catheter 318, when in the second configuration, can allow a flow of blood to enter the stented catheter 318 substantially without damaging the constituents of the blood, as described above with reference to FIGS. 2 and 3. While the puncture member 310 is described above as being retracted once the stented catheter 318 is placed in a desired position with the vein, in other embodiments, the puncture member 310 need not be retracted. As such, the stented catheter 318 can be, for example, a sleeve or the like disposed about the distal end portion 312 of the puncture member 310 to control a flow of blood entering the lumen of the puncture member 310. Moreover, as described above with reference to the puncture member 210, a surface of the puncture member 310 and/or the stented catheter 318 defining a distal opening can be substantially rounded, smoothed, contoured, blunted, and/or the like. In other words, a distal edge of the puncture member 310 and/or stented catheter 318 defining the distal opening forms a substantially round corner. Thus, blood drawn through the opening can flow past the distal edge with reduced damage to

the erythrocytes that would otherwise result from contact with a sharper, more abrupt, substantially orthogonal, and/or otherwise non-rounded distal edge 215.

[1096] While described above as placing a stented catheter, in other embodiments, a puncture member can be used to place any suitable catheter and/or cannula. For example, FIG. 7 illustrates a puncture member 410 and a catheter 418 according to another embodiment. The puncture member 410 can be used, for example, to place at least a portion of the catheter 418 within a lumen defined by the body (e.g., a vein). As shown in FIG. 7, a distal end portion 412 of the puncture member 410 can include a substantially rounded distal edge 415, as described above with reference to the puncture member 210. In this manner, a flow of blood can flow past the distal edge 415 to enter a lumen 413 defined by the puncture member 410. Similarly, the catheter 418 can include a distal edge 418A that is substantially rounded. As shown in FIG. 7, the distal end portion 412 of the puncture member 410 extends beyond the distal edge 418A of the catheter 418. In some embodiments, the distal end portion 412 of the puncture member 410 can form and/or can define a recessed portion 419 or the like that corresponds with a position at or near the distal edge 418A of the catheter 418. In this manner, when the puncture member 410 is inserted into, for example, a vein of a patient, an opening in the vein defined by the puncturing can be a diameter that is substantially the same as an outer diameter of the catheter 418. As such, the catheter 418 can be positioned within the vein without rupturing and/or otherwise dilating the opening in the vein. In some instances, once the catheter 418 is disposed in the lumen defined by the vein, the puncture member 410 can be retracted through the catheter 418 while at least a distal end portion of the catheter 418 remains within the vein. In such instances, the substantially rounded distal edge 418A can reduce and/or can substantially prevent hemolysis of a volume of blood flowing to the catheter 418, as described above with reference to the puncture member 310 in FIGS. 2 and 3.

[1097] While the puncture members 210, 310, and 410 are particularly shown and described above, in other embodiments, any suitable puncture member can be coupled to any compatible adapter, which in turn, can place the puncture member in fluid communication with a fluid collection device. For example, FIGS. 8-17 illustrate embodiments configured to mitigate the risk of hemolysis as a volume of blood flows through changing geometries and/or physical and fluidic interfaces of one or more adapters. Specifically, FIGS. 8-10 illustrate a puncture member 510 coupled to an adapter 520, according to another

embodiment. In some embodiments, the puncture member 510 and the adapter 520 can be and/or can form, for example, a butterfly needle or the like. More specifically, the puncture member 510 has a proximal end portion 511 and a distal end portion 512 and defines a lumen 513 therethrough. The proximal end portion 511 is coupled to the adapter 520, as described in further detail herein. The distal end portion 512 of the puncture member 510 can be any suitable configuration. For example, the distal end portion 512 of the catheter 510 can be substantially similar to or the same as the distal end portion 212 of the catheter 210 described above with reference to FIGS. 2 and 3. That is to say, the arrangement of the distal end portion 512 of the catheter 510 can limit and/or substantially prevent damage (e.g., hemolysis) to blood as blood flow past the distal end portion 512 and into the lumen 513.

[1098] The adapter 520 has a proximal end portion 521, a distal end portion 522, and an inner surface 523. As described above, the adapter 520 can have an overall shape substantially similar to known butterfly needles. While shown in FIG. 8 as being substantially cylindrical with varying diameters, the adapter 520 can be any suitable shape, size, or configuration such as square, rectangular, polygonal, and/or any other non-cylindrical shape. In this manner, the overall shape of the adapter 520 can facilitate the handling of the transfer device 520 by including similar geometric features as known butterfly needles. The distal end portion 522 of the adapter 520 is physically and fluidically coupled to the proximal end portion 511 of the puncture member 510, as described in further detail herein. The proximal end portion 521 of the adapter 520 can be any suitable configuration. In some embodiments, the proximal end portion 521 can be a port and/or a portion of a locking mechanism. For example, in this embodiment, the proximal end portion 521 of the adapter 520 is a locking mechanism configured as a male portion of a Luer Lok ®. Moreover, in this embodiment, such a locking mechanism is disposed at a proximal end portion of a cannula configured to extend between the proximal end portion 521 and the distal end portion 522 of the adapter 520. In other embodiments, the adapter 520 is monolithically formed without a cannula between the proximal end portion 521 and the distal end portion 522. Although the proximal end portion 521 is described as including a locking mechanism, in other embodiments, the proximal end portion 521 can be any suitable configuration configured to interface with any suitable device such that blood flows in a substantially laminar, smooth, and/or non-turbulent flow between the adapter 520 and the device.

[1099] As shown in FIGS. 9 and 10, the inner surface 523 of the adapter 520 defines a lumen 524 extending through the proximal end portion 521 and the distal end portion 522. In some embodiments, the arrangement of the inner surface 523 can reduce, inhibit, and/or substantially prevent, for example, hemolysis of a volume of blood flowing within the lumen 524. More specifically, as shown in FIG. 10, the distal end portion 522 of the adapter 520 is coupled to the proximal end portion 511 of the puncture member 510 such that the lumen 513 of the puncture member 510 is substantially aligned with and substantially the same diameter as the lumen 524 of the adapter 520. That is to say, the proximal end portion 511 of the puncture member 510 is coupled to the distal end portion 522 of the adapter 520 such that a substantially smooth and/or continuous transition is defined between the lumen 513 of the puncture member 510 and the lumen 524 of the adapter 520. Similarly, in embodiments including the cannula extending between the end portions, a distal end portion of the cannula can be coupled to the distal end portion 522 of the adapter 520 in such a manner as to define a substantially smooth transition therebetween.

[1100] In addition, the inner surface 523 of the adapter 520 defines a tapered portion that extends between the puncture member 510 and the cannula. Expanding further, a first portion of the inner surface 523 (e.g., a more proximal portion) defines a first diameter that is substantially the same as an inner diameter defined by the cannula, while a second portion of the inner surface (e.g., a more distal portion) defines a second diameter, smaller than the first diameter, that is substantially the same as an inner diameter defined by the lumen 513 of the puncture member 510. As shown in FIG. 10, the tapered portion can form a substantially smooth transition between, for example, the first diameter and the second diameter. In some instances, such a smooth transition, for example, from the first diameter to the second diameter can facilitate, produce, encourage, and/or force a substantially laminar flow (e.g., consistent, uniform, non-turbulent, uninterrupted, smooth, etc.) of a volume of bodily-fluid (e.g., blood) through the lumen 524. Moreover, the smooth or substantially uniform transitions between the puncture member 510 and the adapter 520 and/or the smooth or substantially uniform transitions between the various components of the adapter 520 can reduce eddy currents (i.e., circulating currents often resulting from a discontinuity) or the like within the flow of blood. Thus, when the distal end portion 512 of the puncture member 510 is disposed in a vein or the like and the proximal end portion 521 (e.g., a locking mechanism) is physically and fluidically coupled to a fluid reservoir, a volume of blood can flow within the lumens 513 and 524 from the patient to the fluid reservoir with reduced damage to the

constituents of the blood (e.g., hemolysis of the erythrocytes) that might otherwise occur as a result of misaligned interfaces and/or discontinuities; abrupt changes in diameter; turbulence and/or eddy currents within a flow of blood therethrough; and/or the like.

[1101] While the adapter 520 is particularly shown and described above with reference to FIGS. 8-10, in other embodiments, an adapter can be any suitable configuration and can be arranged within a system of components to form a physical and/or fluidic interface therebetween. For example, FIGS. 11-13 illustrate a first adapter 620 coupled to a second adapter 630 according to an embodiment. The first adapter 620 has a proximal end portion 621, a distal end portion 622 and an inner surface 623. The inner surface 623 of the first adapter 620 defines a lumen 624 extending through its proximal end portion 621 and its distal end portion 622.

[1102] As shown in FIGS. 12 and 13, the inner surface 623 of the first adapter 620 includes and/or otherwise forms a shoulder 625. More specifically, the shoulder 625 formed by the inner surface 623 is associated with a change in diameter of the inner surface 623. As shown in FIG. 13, the shoulder 625 forms a substantially annular discontinuity that has substantially rounded corners or edges. In this manner, the transition from a diameter of the inner surface 623 proximal to the shoulder 625 to a diameter of the inner surface distal to the shoulder 625 can be relatively smooth rather than forming a relatively sharp, abrupt, and/or orthogonal corner (e.g., shoulder). As such, the arrangement of the shoulder 625 can limit, inhibit, and/or substantially prevent hemolysis of blood as the blood flows within the lumen 624 past the shoulder 625.

[1103] The second adapter 630 has a proximal end portion 631, a distal end portion 632, and an inner surface 633. The inner surface 633 of the second adapter 630 defines a lumen 624 extending through its proximal end portion 631 and its distal end portion 632. As shown in FIGS. 11-13, a portion of the second adapter 630 can be inserted into a portion of the lumen 624 defined by the first adapter 620 to couple the second adapter 630 to the first adapter 620. In some embodiments, the first adapter 620 and the second adapter 630 can form a friction fit and/or the like, which in turn, can define a substantially fluid tight seal therebetween. Thus, the second adapter 630 can be inserted into the first adapter 620 to couple the second adapter 630 thereto.

[1104] Similarly, the distal end portion 632 of the second adapter 630 is configured to reduce, limit, and/or substantially prevent hemolysis of blood as the blood flow therethrough. Specifically, as shown in FIG. 13, a distal most surface of the second adapter 630 and the inner surface 633 of the second adapter 630 form a rounded corner 635 and/or smooth transition therebetween. The rounded corner 635 formed by the second adapter 630 defines a relatively smooth transition from an outer diameter of the second adapter 630 (e.g., at the distal end) to an inner diameter of the second adapter 630 (e.g., at the distal end) rather than forming a relatively sharp, abrupt, and/or orthogonal corner. In some embodiments, a radius of curvature associated with the rounded corner 635 of the second adapter 630 can be substantially similar to a radius of curvature associated with the shoulder 625 of the first adapter 620. Thus, when the second adapter 630 is disposed within the first adapter 620, a volume of bodily-fluid (e.g., blood) can flow through the lumen 624 of the first adapter 620 and the lumen 634 of the second adapter 630 to be disposed within a fluid reservoir or the like. Moreover, the arrangement of the shoulder 625 of the first adapter 620 and the rounded corner 635 of the second adapter 630 can, for example, reduce, limit, and/or substantially prevent hemolysis of blood flowing therethrough that might otherwise result from contact substantially abrupt, sharp, and/or orthogonal corners or the like. In addition, the arrangement of the shoulder 625 of the first adapter 620 and the rounded corner 635 of the second adapter 630 can facilitate, produce, encourage, and/or otherwise result in a substantially laminar flow through the lumens 624 and 634, respectively (e.g., with little turbulence, eddy currents, etc.).

[1105] Although the first adapter 620 and the second adapter 630 are shown in FIGS. 11-13 as each forming substantially rounded corners and/or shoulders, in other embodiments, a first adapter and a second adapter can be coupled together to form an interface therebetween having any suitable arrangement and/or configuration. For example, FIGS. 14 and 15 illustrate a first adapter 720 coupled to a second adapter 730 according to another embodiment. The first adapter 720 has a proximal end portion 721, a distal end portion 722 and an inner surface 723. The inner surface 723 of the first adapter 720 defines a lumen 724 extending through its proximal end portion 721 and its distal end portion 722. Furthermore, the inner surface 723 includes and/or otherwise forms a shoulder 725. In this embodiment, the shoulder 725 is associated with a change in diameter of the inner surface 723. As shown in FIG. 15, the shoulder 725 forms a substantially annular discontinuity with a substantially orthogonal corner. Said another way, the shoulder 725 has a substantially non-rounded

corner (e.g., has no radius of curvature of a nominal radius of curvature) that defines an edge or the like.

[1106] The second adapter 730 has a proximal end portion 731, a distal end portion 732, and an inner surface 733. The inner surface 733 of the second adapter 730 defines a lumen 724 extending through its proximal end portion 731 and its distal end portion 732. As shown in FIGS. 14 and 15, a portion of the second adapter 730 can be inserted into a portion of the lumen 724 defined by the first adapter 720 to couple the second adapter 730 to the first adapter 720. As shown in FIG. 14, the distal most surface of the second adapter 730 and the inner surface 733 of the second adapter 730 form a substantially orthogonal corner 735 (e.g., a substantially non-rounded corner, as described above). In some embodiments, the first adapter 720 and the second adapter 730 can be substantially similar to known adapters (e.g., each adapter forms relatively abrupt and/or substantially orthogonal corners and/or edges).

[1107] While such corners, discontinuities, and/or edges are described above as a potential source of blood hemolyzation, in this embodiment, a gasket 726 is disposed between and in contact with the shoulder 725 of the first adapter 720 and the distal surface of the second adapter 730, as shown in FIG. 15. The gasket 726 can be, for example, an elastomeric gasket and/or the like that is in contact with the distal surface of the second adapter 730 and the shoulder 725 of the first adapter 720 to define a substantially fluid tight seal therebetween. Moreover, the gasket 726 defines an opening and/or lumen therethrough that can have a size and/or diameter substantially similar to the size and/or diameter of the lumens 724 and 734. Thus, the arrangement of the gasket 726 can reduce a magnitude of the discontinuities formed by the shoulder 725 of the first adapter 720 and the distal end of the second adapter 730. As a result, the gasket 726 disposed between the shoulder 725 of the first adapter 720 and the distal surface of the second adapter 730 can, for example, reduce, limit, and/or substantially prevent hemolysis of blood flowing therethrough that might otherwise result from relatively large changes and/or discontinuities in the diameters of the inner surfaces 723 and 733, respectively. In addition, the gasket 726 can facilitate, produce, encourage, and/or otherwise result in a substantially laminar flow of fluid through the lumens 724 and 734, respectively (i.e., with little to no turbulence, eddy currents, etc.).

[1108] In some embodiments, the gasket 726 can be configured to restrict, limit, reduce, and/or otherwise control a flow of blood and/or a pressure exerted therethrough. For example, while the gasket 726 is described above as having substantially the same size and/or

diameter as the lumens 724 and 734, in other embodiments, the gasket 726 can have a size and/or diameter that is greater than or less than the diameter of the lumens 724 and 734. Specifically, in some embodiments, the size and/or diameter of the gasket 726 can be less than the diameter of the lumens 724 and 734 and, as such, the gasket 726 can restrict, constrict, reduce, limit, and/or otherwise control a flow of blood therethrough. In some embodiments, such a reduction and/or restriction of the blood flowing through the gasket 726 can reduce a likelihood of hemolysis of the blood resulting from, for example, a flow rate and/or a large pressure differential between a volume having a relatively high pressure disposed on a first side of the gasket 726 and a volume having a relatively low pressure disposed on a second side of the gasket 726.

[1109] FIG. 16 illustrates a portion of a first adapter 820 coupled to a portion of a second adapter 830 according to another embodiment. The first adapter 820 has a proximal end portion 821 configured to be coupled to a distal end portion 832 of the second adapter 830, as described in further detail herein. Although only the proximal end portion 821 of the first adapter 820 is shown in FIG. 16, the first adapter 820 can be similar in size and/or shape as the first adapters 620 and/or 720, unless otherwise expressed. The first adapter 820 includes an inner surface 823 that defines a lumen 824 extending through at least its proximal end portion 821. As shown in FIG. 16, the inner surface 823 of the first adapter 820 includes and/or otherwise forms a shoulder 825. The shoulder 825 formed by the inner surface 823 is associated with a change in diameter of the inner surface 823. More specifically, the shoulder 825 is associated with and/or forms a tapered or chamfered portion of the inner surface 823, as described in further detail herein.

[1110] Although only the distal end portion 832 of the second adapter 830 is shown in FIG. 16, the second adapter 830 can be any suitable shape, size, or configuration. For example, the distal end portion 832 of the second adapter 830 can form and/or can include a locking mechanism or the like while a proximal end portion (not shown in FIG. 16) can be coupled to and/or can form any suitable portion of a fluid collection device such as, for example, a fluid reservoir, a conduit, a flow control mechanism, and/or the like. In this embodiment, the distal end portion 832 of the second adapter 830 includes and/or forms a locking mechanism configured to form a threaded coupling with, for example, the proximal end portion 821 of the first adapter 820. In other embodiments, the distal end portion 832 of the second adapter 830 can be any suitable configuration.

[1111] As shown in FIG. 16, the second adapter 830 includes an inner surface 833 that defines a lumen 834 extending through at least its distal end portion 832. Moreover, the distal end portion 832 of the second adapter 830 includes and/or forms a distal surface 835 that is substantially tapered or chamfered. In some embodiments, the distal surface 835 of the second adapter 830 can have a size, shape, angle, etc. that substantially corresponds with the shoulder 825 defined by the first adapter 820. Thus, when the first adapter 820 is coupled to the second adapter 830 (e.g., via a threaded coupling or the like), the distal surface 835 of the second adapter 830 can be brought into contact with the shoulder 825 of the first adapter 820. Moreover, the arrangement of the first adapter 820 and the second adapter 830 is such that when the distal surface 835 of the second adapter 830 is placed in contact with the shoulder 825 of the first adapter 820, the inner surfaces 833 and 823, respectively, are brought into alignment, as shown in FIG. 16. In this manner, the inner surfaces 823 and 833 can form a substantially continuous surface having, for example, a substantially constant diameter. Thus, by reducing and/or substantially eliminating a discontinuity otherwise associated with the physical and fluidic coupling of the first adapter 820 and the second adapter 830, blood can flow within the lumens 824 and 834 of the adapters 820 and 830, respectively, with little or substantially no hemolysis of the blood flowing therethrough.

[1112] Although the inner surfaces 823 and 833 of the first adapter 820 and the second adapter 830, respectively, are described above as having a substantially constant diameter, in other embodiments, a diameter of each inner surface 823 and 833 can be varied. Such arrangement, however, is such that the inner surfaces 823 and 833 form a substantially smooth transition between, for example, a smaller diameter and a larger diameter. Thus, the substantially smooth transition in the diameters of the inner surfaces 823 and 833 can still facilitate a substantially laminar flow therethrough, which in some instances, can limit and/or substantially prevent hemolysis of blood flowing from the first adapter 820 and through the second adapter 830.

[1113] While the flow of bodily-fluid (i.e., blood) is described above as first flowing through the first adapter 820 and then flowing through the second adapter 930, in other embodiments, the flow through a set of adapters can be reversed. For example, FIG. 17 illustrates a first adapter 920 and a second adapter 930 according to another embodiment. The first adapter 920 has a distal end portion 922 configured to be coupled to a proximal end portion 931 of the second adapter 930, as described in further detail herein. Although only

the distal end portion 922 of the first adapter 920 is shown in FIG. 17, the first adapter 920 can be similar in size and/or shape as the first adapters 620 and/or 720, unless otherwise expressed. The first adapter 920 includes an inner surface 923 that defines a lumen 924 extending through at least its distal end portion 922. As shown in FIG. 17, a portion of the second adapter 930 is inserted into the lumen 924, as described in further detail herein.

[1114] Although only the proximal end portion 931 of the second adapter 930 is shown in FIG. 17, the second adapter 930 can be any suitable shape, size, or configuration. For example, the proximal end portion 931 of the second adapter 930 can form and/or can include a locking mechanism or the like while a proximal end portion (not shown in FIG. 17) can be coupled to and/or can form any suitable portion of a fluid collection device such as, for example, a puncture member, a needle, a conduit, a flow control mechanism, and/or the like. In this embodiment, the proximal end portion 931 of the second adapter 930 includes and/or forms a locking mechanism configured to form a threaded coupling with, for example, the distal end portion 922 of the first adapter 920. In other embodiments, the proximal end portion 931 of the second adapter 930 can be any suitable configuration.

[1115] As shown in FIG. 17, the second adapter 930 includes an inner surface 933 that defines a lumen 934 extending through at least its proximal end portion 931. Moreover, a region of the proximal end portion 931 of the second adapter 930 is disposed within the lumen 924 of the first adapter 920. For example, the inner surface 923 of the first adapter 920 has a diameter that corresponds to an outer diameter associated with the region of the proximal end portion 931 of the second adapter 930. Thus, as shown in FIG. 17, the diameter defined by the inner surface 923 of the first adapter 920 is greater than a diameter defined by the inner surface 933 of the second adapter 930, as described in further detail herein.

[1116] The proximal end portion 931 of the second adapter 930 includes and/or forms a proximal surface 935 with a substantially rounded corner and/or smooth transition. For example, the proximal surface 935 formed by the second adapter 930 defines a relatively smooth transition from an inner diameter of the second adapter 930 (e.g., defined by the inner surface 933) to an outer diameter of the second adapter 930 (e.g., at the distal end) rather than forming a relatively sharp, abrupt, and/or orthogonal corner. When a portion of the second adapter 930 is disposed within the lumen 923 of the first adapter 920, a volume of bodily-fluid (e.g., blood) can flow through the lumen 934 of the second adapter 930 and into the lumen 924 of the first adapter 920. Thus, the arrangement of the proximal surface 935 of the

second adapter 930 can, for example, facilitate, produce, encourage, and/or otherwise result in a substantially laminar flow of a volume of bodily-fluid (i.e., blood) as the volume flows from the lumen 934 of the second adapter 930 into the lumen 924 of the first adapter 920. Specifically, the proximal surface 935 of the second adapter 930 allows for a gradual transition from the diameter associated with the lumen 934 of the second adapter 930 (i.e., the smaller diameter) to the diameter associated with the lumen 924 of the first adapter 920 (i.e., the larger diameter). Such a smooth transition can, for example, reduce eddy currents and/or other forms of turbulence that can otherwise result from a substantially abrupt change in diameter or the like. Thus, the arrangement of the first adapter 920 and the second adapter 930 can allow a volume of blood to expand as the flow of blood exits the lumen 934 of the second adapter 930, which in some instances, can reduce, limit, and/or substantially prevent hemolysis of blood flowing therethrough.

[1117] While the first adapters 620, 720, 820, and 920 are shown and described above as receiving and/or otherwise being directly coupled to the second adapters 630, 730, 830, and 930, respectively, in other embodiments, a first adapter can be indirectly coupled to a second adapter via an intervening structure. In such embodiments, the intervening structure can define a lumen that can place the first adapter in fluid communication with the second adapter. Moreover, the intervening structure can limit, modulate, and/or control a flow rate of a volume of fluid (i.e., blood) therethrough. For example, FIGS. 18-26 illustrate embodiments configured to mitigate the risk of hemolysis otherwise associated with a relatively high flow rate and/or velocity along a fluid flow path that exceeds known shear force and exposure time limits that can rupture red blood cells. Specifically, FIGS. 18-20 illustrate a first adapter 1020 indirectly coupled to a second adapter 1030 via a restrictor 1050, according to an embodiment. The first adapter 1020 includes a proximal end portion 1021, a distal end portion 1022, and an inner surface 1023. The inner surface 1023 defines a lumen 1024 extending through the proximal end portion 1021 and the distal end portion 1022 (see e.g., FIG. 20). In some embodiments, the first adapter 1020 can be substantially similar to and/or the same as the first adapter 720 described above with reference to FIGS. 14 and 15. Thus, aspects of the first adapter 1020 are not described in further detail herein.

[1118] The second adapter 1030 has a proximal end portion 1031, a distal end portion 1032, and an inner surface 1033. The inner surface 1033 of the second adapter 1030 defines a lumen 1024 extending through its proximal end portion 1031 and its distal end portion 1032

(see e.g., FIG. 20). In some embodiments, the second adapter 1030 can be substantially similar to and/or the same as the second adapter 730 described above with reference to FIGS. 14 and 15. Thus, aspects of the second adapter 1030 are not described in further detail herein.

[1119] The restrictor 1050 has a proximal end portion 1051, a distal end portion 1052, and an inner surface 1053. The inner surface 1053 of the restrictor 1050 defines a lumen 1054 extending through its proximal end portion 1051 and its distal end portion 1052 (see e.g., FIG. 20). In this embodiment, the restrictor 1050 is coupled between the first adapter 1020 and the second adapter 1030 to define a fluid pathway therebetween (e.g., via the lumen 1054). More specifically, the restrictor 1050 can include any suitable interface, locking mechanism, surface, etc. at or near the proximal end portion 1051 and the distal end portion 1052 configured to couple the restrictor 1050 to the first adapter 1020 or the second adapter 1030. As shown in FIGS. 18-20, the restrictor 1050 includes a locking mechanism or the like at its distal end portion 1052 that is configured to couple the distal end portion 1052 of the restrictor 1050 to the proximal end portion 1021 of the first adapter 1020. For example, in some embodiments, the distal end portion 1052 of the restrictor 1050 can include a threaded female Luer Lok ® configured to form a threaded coupling with a corresponding threaded male Luer Lok ® of the first adapter 1020, as shown in FIG. 20.

[1120] As shown in FIGS. 19 and 20, the proximal end portion 1051 of the restrictor 1050 receives the second adapter 1030. For example, as described above with reference to the first adapter 620 and the second adapter 630 in FIGS. 11-13, a portion of the second adapter 1030 is inserted through the proximal end portion 1051 of the restrictor 1050 to be disposed in the lumen 1054. In some embodiments, the restrictor 1050 and the second adapter 1030 can form a friction fit and/or the like, which in turn, can define a substantially fluid tight seal therebetween. In other embodiments, the proximal end portion 1051 of the restrictor 1050 and the distal end portion 1032 of the second adapter 1030 can include any suitable coupling and/or locking mechanism configured to couple the second adapter 1030 to the restrictor 1050 (e.g., as described above with reference to the coupling between the first adapter 1020 and the restrictor 1050).

[1121] As shown in FIGS. 19 and 20, the restrictor 1050 or the first adapter 1020 includes a gasket 1026 configured to minimize a discontinuity between the lumen 1024 of the first adapter 1020 and the lumen 1054 of the restrictor 1050 when coupled. Similarly, the

second adapter 1030 or the restrictor 1050 includes a gasket 1036. The gaskets 1026 and 1036 can be substantially similar in form and function to the gasket 726 shown and described above with reference to FIGS. 14 and 15. Thus, the gaskets 1026 and 1036 are disposed within the lumen 1024 of the first adapter 1020 and the lumen 1054 of the restrictor 1050, respectively. The arrangement of the gaskets 1026 and 1036 can reduce a magnitude of the discontinuities formed between the inner surfaces 1023, 1033, and 1053 of the first adapter 1020, the second adapter 1030, and the restrictor 1050, respectively, which in turn, can reduce, limit, and/or substantially prevent hemolysis of blood flowing therethrough, as described in detail above. In some embodiments, the gaskets 1026 and 1036 can be configured to restrict and/or reduce a pressure and/or a flow rate associated with the first adapter 1020, the second adapter 1030, and/or the restrictor 1050, as described above with reference to the gasket 726. In some instances, restricting and/or reducing the pressure and/or flow rate associated with the first adapter 1020, the second adapter 1030, and/or the restrictor 1050 (e.g., via the gaskets 1026 and 1036) can, for example, limit shear forces and/or exposure time experienced by red blood cells as the red blood cells flow through the first adapter 1020, the second adapter 1030, and the restrictor 1050, and/or the interfaces therebetween.

[1122] The inner surface 1053 of the restrictor 1050 is configured to control a flow of fluid through the lumen 1053. For example, as shown in FIG. 20, the inner surface 1053 of the restrictor 1050 includes a choke portion 1055 or the like. In some embodiments, the choke portion 1055 corresponds to a portion of the inner surface 1053 having a reduced diameter relative to the other portions of the inner surface 1053. More specifically, the choke portion 1055 forms a relatively smooth transition (e.g., a gradual change) from a region of the inner diameter 1053 associated with a first diameter to a region (i.e., the choke portion 1055) associated with a second diameter, smaller than the first diameter. Thus, the choke portion 1055 restricts, controls, and/or reduces a flow of fluid therethrough.

[1123] Expanding further, the reduction in the diameter of the inner surface 1053 at or along the choke portion 1055 selectively controls a pressure within the lumen 1054. For example, in some embodiments, the second adapter 1030 can be fluidically coupled (e.g., either directly or indirectly) to an evacuated container or the like, resulting in a negative pressure within the lumens 1034, 1054, and 1024. Thus, the reduced diameter associated with the choke portion 1055 results in a reduced pressure differential between the lumen 1024

of the first adapter 1020 (i.e., at a time directly before the exposure to the negative pressure) and a portion of the lumen 1054 of the restrictor 1050 that is distal to the choke portion 1055. As such, when the first adapter 1020 is in fluid communication with, for example, a vascular structure (e.g., via a needle, catheter, cannula, etc.), a magnitude of the negative pressure exerted on or in the vascular structure is reduced, thereby limiting, reducing, and/or substantially preventing hemolysis of blood as it flows into the lumen 1024 defined by the first adapter 1020. Moreover, the smooth transition in the diameter of the inner surface 1053 from the first diameter to the second diameter (associated with the choke portion 1055), facilitates, encourages, and/or otherwise results in a substantially laminar flow through the lumen 1054 of the restrictor 1050.

[1124] While the restrictor 1050 is particularly shown and described above with reference to FIGS. 18-20, in other embodiments, a restrictor, configured to control a flow of fluid therethrough, can be any suitable configuration. For example, FIGS. 21-24 illustrate a restrictor 1150 according to another embodiment. The restrictor 1150 has a proximal end portion 1151, a distal end portion 1152, and an inner surface 1153. The inner surface 1153 of the restrictor 1150 defines a inner volume 1154 extending through its proximal end portion 1151 and its distal end portion 1152 (see e.g., FIG. 22). Although not shown in FIGS. 21-24, the restrictor 1150 can be disposed between two components of a fluid transfer device to define a fluid flow path therethrough. For example, in some embodiments, the proximal end portion 1151 can be coupled to an adapter such as, for example, the second adapter 1030, described above with reference to FIGS. 18-20. Similarly, the distal end portion 1152 can be coupled to an adapter such as, for example, the first adapter 1020, described above. As such, the proximal end portion 1151 and the distal end portion 1152 can be substantially similar to or the same as the proximal end portion 1051 and the distal end portion 1052, respectively, of the restrictor 1050 and thus, are not described in further detail herein.

[1125] As shown in FIGS. 22-24, the restrictor 1150 includes a baffle 1156 disposed in the inner volume 1154. The baffle 1156 can be any suitable shape, size, or configuration. For example, in this embodiment, the baffle 1156 is substantially rectangular (see e.g., FIG. 20) with a size that substantially corresponds to the inner volume 1154 of the restrictor 1150, as described in further detail herein. The baffle 1156 includes an inner surface 1157 that defines an inner volume 1158. As shown in FIG. 24, the inner surface 1157 of the baffle 1156 defines a gradual bow toward the center of the baffle 1156. More specifically, the

arrangement of the inner surface 1157 is such that a distance between opposite sides of the baffle 1156 gradually varies as the inner surface 1157 extends outward from a longitudinal centerline CL (shown in FIG. 22) of the baffle 1156. For example, in this embodiment, a distance between opposite portions of the inner surface 1157 gradually increases from a first distance, at a first position associated with a perimeter of the inner surface 1157, to second distance, at a second position disposed between the perimeter of the inner surface 1157 and the longitudinal centerline CL, and then gradually decreases from the second distance to a third distance, at a position associated with and/or near the longitudinal center CL. In this manner, the baffle 1156 can selectively control a flow of fluid through the inner volume 1158, as described in further detail herein.

[1126] Referring back to FIG. 22, in this embodiment, an outer surface of the baffle 1156 is in contact with the inner surface 1153 of the restrictor 1150 when disposed in the inner volume 1154. In some embodiments, the outer surface of the baffle 1156 and the inner surface 1153 of the restrictor 1150 define a friction fit or the like that forms a substantially fluid tight seal. As such, the arrangement of the baffle 1156 and the inner surface 1153 of the restrictor 1150 can limit, inhibit, and/or substantially prevent a flow of fluid between the outer surface of the baffle 1156 and the inner surface 1153 of the restrictor 1150. More specifically, the inner volume 1158 of the baffle 1156 defines a fluid flow path that places a first portion of the inner volume 1154, which is distal to the baffle 1156, in fluid communication with a second portion of the inner volume 1154, which is proximal to the baffle 1156. In this manner, the arrangement of the inner surface 1157 of the baffle 1156 can restrict, inhibit, guide, limit, choke, and/or otherwise control a flow of fluid through the restrictor 1150. Moreover, the smooth or gradual change in distance between opposite portions of the inner surface 1157 of the baffle (as described above) facilitates, encourages, and/or otherwise results in a substantially laminar flow through the inner volume 1154 of the restrictor 1150.

[1127] Although not shown in FIGS. 21-24, in some embodiments, the inner volume 1158 of the baffle 1156 can include a medium disposed therein. For example, in some embodiment, the baffle 1156 can include a substantially porous material or the like that can slow and/or filter a flow of fluid (e.g., blood) therethrough. In other embodiments, the user can manipulate the restrictor 1150 to modify and/or control a flow of fluid through the restrictor 1150. For example, in some instances, the user can exert a force on a portion of the

restrictor 1150 sufficient to deform that portion. As such, a portion of the force can correspondingly deform the baffle 1156, which in turn, can change a contour of the inner surface 1157. Thus, the user can exert a force on the restrictor 1150 to, for example, increase, decrease, or otherwise control a flow of fluid through the baffle 1156. By way of example, a user can exert a force of the restrictor 1150 to reduce a distance between opposite portions of the inner surface 1157, which in turn, can reduce a negative pressure differential produced by an evacuated container being placed in fluid communication with the restrictor 1150.

[1128] FIGS. 25 and 26 illustrate a restrictor 1250 according to another embodiment. The restrictor 1250 has a proximal end portion 1251, a distal end portion 1252, and an inner surface 1253. The inner surface 1253 of the restrictor 1250 defines a inner volume 1254 extending through its proximal end portion 1251 and its distal end portion 1252 (see e.g., FIG. 26). As described above, the restrictor 1250 can be physically and fluidically coupled between, for example, a pair of components of a fluid transfer device to restrict and/or otherwise control a flow of fluid therebetween. For example, although not shown in FIGS. 25-26, the proximal end portion 1251 can be coupled to an adapter such as, for example, the second adapter 1030, described above with reference to FIGS. 18-20. Similarly, the distal end portion 1252 can be coupled to an adapter such as, for example, the first adapter 1020, as described above. In this manner, the proximal end portion 1251 and the distal end portion 1252 can be substantially similar to or the same as the proximal end portion 1051 and the distal end portion 1052, respectively, of the restrictor 1050 and thus, are not described in further detail herein.

[1129] The restrictor 1250 includes and/or defines a set of chambers 1259, as shown in FIG. 26. More specifically, the restrictor 1250 includes a set of walls that can form, for example, a set of semi-spherical portions, which in turn, result in the inner surface 1253 defining the set of chambers 1259. Thus, the chambers 1259 are, for example, a set of semi-spherical portions of the inner volume 1254. As shown in FIG. 26, the chambers 1259 are serially arranged along a longitudinal centerline CL of the restrictor 1250. In some embodiments, the size and/or shape of each chamber 1259 can vary. For example, as shown in FIG. 26, the chamber 1259 disposed at or near the proximal end portion 1251 of the restrictor 1250 is smaller than the adjacent chamber 1259. In other embodiments, the size and/or shape of each chamber 1259 can be substantially uniform. With the inner surface 1253 defining the semi-spherical chambers 1259, a diameter of the inner volume 1254 (e.g.,

associated with a cross-sectional shape of the inner surface 1253) is varied along a length of the longitudinal centerline CL. For example, a diameter of the inner volume 1254 gradually increases or decreases in an alternating manner between a relatively smaller diameter, associated with a position along the longitudinal centerline substantially between adjacent chambers 1259 and a relatively larger diameter, associated with a position along the longitudinal centerline substantially in the center of a given chamber 1259.

[1130] In some embodiments, the arrangement of the chambers 1259 selectively controls a pressure within the inner volume 1254. For example, in some embodiments, the proximal end portion 1251 of the restrictor 1250 can be fluidically coupled (e.g., either directly or indirectly) to an evacuated container or the like, resulting in a negative pressure within the inner volume 1254. Thus, the alternating increase and decrease corresponding to each chamber 1259 results in a changing pressure differential along the longitudinal centerline CL. In some embodiments, such an alternating arrangement can, for example, act as a peristaltic pump or the like. Thus, the restrictor 1250 can draw a fluid through the inner volume 1254 via a pressure differential that is at least partially controlled by the arrangement of the inner surface 1253. That is to say, while an evacuated container is the source of a negative pressure, the arrangement of the chambers 1259 at least partially controls a pressure differential between the proximal end portion 1251 and the distal end portion 1252. In this manner, hemolysis of blood can be reduced and/or substantially prevented, which might otherwise occur in response to a shear force produced by a relatively rapid and/or relatively large pressure drop associated with placing an evacuated container in fluid communication with a vascular structure. Moreover, the smooth and/or gradual transitions in the diameter of the inner surface 1253 associated with the chambers 1259, facilitates, encourages, and/or otherwise results in a substantially laminar flow through the inner volume 1254 of the restrictor 1250.

[1131] Although not shown, any of the restrictors 1050, 1150, and/or 1250 can be fluidically coupled (either directly or indirectly) to and/or monolithically formed with an adapter configured to engage a fluid reservoir such as an evacuated container. In some embodiments, such adapters can include an inner surface configured to reduce discontinuities or the like within a portion of a fluid flow path and/or otherwise configured to facilitate a substantially laminar fluid flow therethrough, as described in detail above. Moreover, the adapters can engage any suitable fluid reservoir or container. For example, FIGS. 27-44

illustrate embodiments (i.e., adapters and fluid reservoirs) configured to mitigate the risk of hemolysis as blood flow from an adapter, a puncture member, a needle, a cannula, and/or the like into a fluid reservoir. Specifically, FIGS. 27-33 illustrate an adapter 1330 configured to engage a fluid reservoir 1360 (FIGS. 29-33) according to an embodiment. The adapter 1330 has a proximal end portion 1331, a distal end portion 1332, and an inner surface 1333. The inner surface 1333 defines a lumen 1334 extending through the proximal end portion 1331 and the distal end portion 1332 (see e.g., FIG. 27). As shown in FIGS. 27 and 28, in some embodiments, the adapter 1330 can include and/or can be coupled to a shroud 1343. In such embodiments, the shroud 1343 can define an inner volume 1344 within which a portion of a fluid reservoir can be disposed. In other embodiments, the adapter 1330 need not include and/or need not be coupled to the shroud 1343.

[1132] The adapter 1330 can be any suitable shape, size, or configuration. For example, as shown in FIGS. 29 and 30, the distal end portion 1332 of the adapter 1330 includes and/or is coupled to a lock mechanism or the like. In this embodiment, the distal end portion 1332 includes and/or forms a female portion of a Luer Lok ® or the like. Thus, the distal end portion 1332 of the adapter 1330 can be coupled to a corresponding male portion of a Luer Lok ® or the like, as described above with reference to the distal end portion 1052 of the restrictor 1050 shown in FIG. 20. The proximal end portion of the adapter 1330 includes and/or is coupled to a puncture member 1338 defining a lumen 1339 in fluid communication with the lumen 1334 of the adapter 1330. The puncture member 1338 can be any suitable configuration. For example, in some embodiments, the puncture member 1338 is a needle. As shown in FIG. 30, the puncture member 1325 is disposed within a sheath 1341. More specifically, the sheath 1341 is at least temporarily disposed about the puncture member 1338 and is configured to limit and/or substantially prevent an accidental contact with the puncture member 1338. Furthermore, the sheath 1341 can maintain the puncture member 1338 in a substantially sterile environment prior to use and can selectively control a flow of bodily-fluid through the puncture member 1338, as described in further detail herein.

[1133] As shown in FIG. 30, a diameter of the inner surface 1333 at or near the distal end portion 1332 is larger than a diameter of the puncture member 1338. In this manner, the inner surface 1333 forms and/or defines a smooth transition from a larger diameter at or near the distal end portion 1332 to a smaller diameter at or near the puncture member 1338. In some instances, such a smooth transition from the larger diameter to the smaller diameter can

facilitate, produce, encourage, and/or force a substantially laminar flow of a volume of bodily-fluid (e.g., blood) through the lumen 1334. Moreover, the smooth transition can reduce eddy currents or the like within the flow of blood that can otherwise result from a relatively abrupt change in diameter or the like. Thus, a volume of blood can flow within the lumens 1334 and 1339 with reduced damage to the constituents of the blood (e.g., hemolysis of the erythrocytes) that might otherwise occur as a result of misaligned interfaces and/or discontinuities; abrupt changes in diameter; turbulence and/or eddy currents within a flow of blood therethrough; and/or the like.

[1134] As described above, the adapter 1330 is configured to couple to and/or otherwise engage a fluid reservoir 1360. The fluid reservoir 1360 can be any suitable shape, size, or configuration. For example, in this embodiment, the fluid reservoir 1360 is an evacuated container such as a Vacutainer™, a BacT/ALERT® SN, a BacT/ALERT® FA, and/or any other type of container, vial, bottle, reservoir, etc. As shown in FIGS. 31-33, the fluid reservoir 1360 includes a proximal end portion 1361 and a distal end portion 1362, and defines an inner volume 1364. The distal end portion 1362 includes a port 1363 through which the puncture member 1338 can be inserted to place the inner volume 1364 of the fluid reservoir 1360 in fluid communication with the lumen 1334 of the adapter 1330. For example, in some embodiments, the port 1363 can be a self-healing septum or the like. Thus, the port 1363 can be substantially in a sealed configuration prior to insertion of, for example, the puncture member 1338 and subsequently, can transition from an open configuration to the sealed configuration when, for example, the puncture member 1338 is removed from the port 1363.

[1135] In some embodiments, a fluid reservoir can include a flow control member or the like disposed in its inner volume. For example, as shown in FIGS. 32 and 33, the fluid reservoir 1360 includes a flow control member 1367 disposed within the inner volume 1364. In this embodiment, the flow control member 1367 can be, for example, an insert or funnel that defines a channel 1368 configured to receive a flow of fluid from the lumen 1339 of the puncture member 1338. More specifically, as shown in FIG. 33, a first end of the flow control member 1367 can be disposed adjacent to and/or can be coupled to the port 1363 and a second end, opposite the first end, can extend toward an inner surface of the fluid reservoir 1360. In this manner, the second end of the flow control member 1367 can be adjacent to the inner surface of the fluid reservoir 1360 such that an axis associated with a portion of the

channel 1368 at or near the second end is substantially parallel to and/or otherwise directed toward the inner surface of the fluid reservoir 1360.

[1136] In use, the adapter 1330 and/or the fluid reservoir 1360 can be manipulated to insert the puncture member 1338 through the port 1363 of the fluid reservoir 1360. As such, the sheath 1341 disposed about the puncture member 1338 can deform to allow the puncture member 1338 to be inserted through the port 1363. With the fluid reservoir 1360 being an evacuated container, the insertion of the puncture member 1338 is such that a negative pressure within the fluid reservoir 1360 is exerted through the lumen 1334 of the adapter 1330 (e.g., via the lumen 1339 of the puncture member 1338). Thus, when the distal end portion 1332 is fluidically coupled (either directly or indirectly) to a device or member in fluid communication with the body of a patient, the negative pressure draws a volume of bodily-fluid (e.g., blood) from the patient and into the fluid reservoir 1360. More specifically, the distal end portion 1332 of the adapter 1330 can be coupled (either directly or indirectly) to any suitable adapter, restrictor, and/or needle described herein to receive a flow of, for example, blood from the patient with reduced or substantially no hemolyzation of the blood. Furthermore, by disposing the flow control member 1367 in the inner volume 1364, a flow of blood can be directed within the channel 1338 toward the inner surface, which in turn, can decrease a force otherwise associated with an impact of the volume of blood contacting the inner surface. Thus, hemolysis of the blood associated with such a contact is reduced or substantially prevented.

[1137] While the adapter 1330 is shown in FIGS. 31-33 as not including and/or not be coupled to the shroud 1343, in other embodiments, the adapter 1330 can be coupled to the shroud 1343 when engaging the fluid reservoir 1360. Furthermore, while the flow control member 1367 is particularly shown in FIG. 33, in some embodiments, a second end of a flow control member can extend within the inner volume 1364 to a position adjacent to and/or substantially abutting a bottom or proximal surface (i.e., a surface opposite the port 1363). In other embodiments, a flow control member can extend in a spiral or helical manner from the port 1363. As such, a second end of the flow control member can be substantially tangential to the inner surface of the fluid reservoir and thus, fluid exiting a channel defined by the flow control member can flow along a circumference of the inner surface (e.g., tangent to the inner surface).

[1138] In other embodiments, a fluid reservoir can include any suitable flow control member. For example, FIG. 34 illustrates a fluid reservoir 1460 according to another embodiment. The fluid reservoir 1460 includes a proximal end portion 1461 and a distal end portion 1462, and defines an inner volume 1464. The distal end portion 1462 includes a port 1463 configured to receive, for example, a puncture member 1438 of an adapter 1430, as described in detail above with reference to FIGS. 31-33. The inner volume 1464 of the fluid reservoir 1460 includes and/or houses a flow control member 1467 operable to control a flow of fluid from, for example, the adapter 1430 into the inner volume 1464, as described in further detail herein. The fluid reservoir 1460 can be any suitable shape, size, or configuration. For example, in this embodiment, the fluid reservoir 1460 is an evacuated container such as a Vacutainer™, a BacT/ALERT® SN, a BacT/ALERT® FA, and/or any other type of container, vial, bottle, reservoir, etc. In some embodiments, the fluid reservoir 1460 can be substantially similar to or the same as the fluid reservoir 1360 described above with reference to FIGS. 31-33. Thus, such similar aspects of the fluid reservoir 1460 are not described in further detail herein.

[1139] The fluid reservoir 1460 can differ from the fluid reservoir 1360, however, in the arrangement of the flow control member 1467. More specifically, while the flow control member 1367 is shown in FIG. 33 as tapering to a substantially uniform diameter as the flow control member 1367 extends away from the port 1363, in this embodiment, the flow control member 1467 has a varying diameter as the flow control member 1467 extends away from the port 1463. In this manner, a channel 1468 defined by the flow control member 1467 has a cross-sectional area and/or diameter that is dependent on, for example, a position along a longitudinal centerline CL defined by the flow control member 1467. For example, the channel 1468 can have a first diameter at a first end portion nearest to the port 1463, a second diameter at an end portion opposite the first end portion, and a third diameter at a portion disposed therebetween. As shown in FIG. 34, the end portions of the flow control member 1467 can be flared or the like such that the first diameter and the second diameter are each greater than the third diameter. Said another way, the diameter of the channel 1468 can taper along the longitudinal centerline CL from a larger diameter associated with the end portions of the flow control member 1467 to a smaller diameter at or near a center portion of the flow control member 1467.

[1140] With the fluid reservoir 1460 being an evacuated container or the like, a pressure (i.e., a negative pressure) within the channel 1468 is dependent on a position along the longitudinal centerline CL. That is to say, the pressure within the channel 1468 is dependent on the diameter of the channel 1468, in which a larger diameter is associated with a larger pressure. In a similar manner, the velocity of a flow of bodily-fluid (e.g., blood) within the channel 1468 is also dependent on the diameter of the channel 1468, however, such dependency is inverse to that associated with the pressure (i.e., a larger diameter is associated with less velocity). Thus, as blood (or other bodily-fluid) flows through the channel 1468, the increase in diameter at the end portion of the flow control member 1467 opposite the port 1463 results in a decrease in velocity associated with the flow of bodily-fluid therethrough. As such, a force otherwise associated with a volume of blood contacting an inner surface of the fluid reservoir 1460 is reduced, which in turn, can reduce and/or substantially prevent hemolysis of the volume of blood. Moreover, the diameter of the channel 1468 can be such that a pressure within the channel 1468 is maintained below a threshold that can otherwise result in hemolysis of blood flowing therethrough.

[1141] While the flow control members 1367 and 1467 are shown and described above as controlling a flow of, for example, blood through the channels 1368 and 1468, respectively, in other embodiments, a fluid reservoir can include a flow control member having any suitable configuration. For example, FIG. 35 illustrates a fluid reservoir 1560 according to another embodiment. The fluid reservoir 1560 includes a proximal end portion 1561 and a distal end portion 1562, and defines an inner volume 1564. The distal end portion 1562 includes a port 1563 configured to receive, for example, a puncture member 1538 of an adapter 1530, as described in detail above with reference to FIGS. 31-33. The inner volume 1564 of the fluid reservoir 1560 includes and/or houses a flow control member 1565 operable to control a flow of fluid from, for example, the adapter 1530 into the inner volume 1564, as described in further detail herein. The fluid reservoir 1560 can be any suitable shape, size, or configuration. For example, in this embodiment, the fluid reservoir 1560 is an evacuated container such as a Vacutainer™, a BacT/ALERT® SN, a BacT/ALERT® FA, and/or any other type of container, vial, bottle, reservoir, etc. In some embodiments, the fluid reservoir 1560 can be substantially similar to or the same as the fluid reservoir 1360 described above with reference to FIGS. 31-33. Thus, such similar aspects of the fluid reservoir 1560 are not described in further detail herein.

[1142] As shown in FIG. 35, the flow control member 1565 is disposed within the inner volume 1564 at or near the port 1563. In this embodiment, the flow control member 1565 is a baffle insert or the like. Specifically, the flow control member 1565 forms and/or includes an angled baffle having a set of substantially parallel angled surfaces configured to direct a flow of blood or other bodily-fluid. For example, the puncture member 1538 of the adapter 1530 can be inserted through the port 1563 to place a distal end portion of the puncture member 1538 within the flow control member 1565. As such, when a flow of blood is expelled and/or drawn through a lumen defined by the puncture member 1538 (e.g., via a negative pressure differential produced by the evacuated container), the flow of blood contacts at least one angled surface of the flow control member 1565. Thus, the blood can flow along the angled surface toward an inner surface of the fluid reservoir 1560. By diverting, guiding, and/or otherwise directing the flow of blood to the inner surface, a force is reduced, which can otherwise result from an impact of the volume of blood contacting the inner surface. Thus, hemolysis of the blood associated with such a contact is reduced or substantially prevented.

[1143] While the flow control member 1565 is shown and described as forming and/or including a set of parallel angled surfaces configured to direct a flow of bodily-fluid toward the inner surface of the fluid reservoir 1560, in other embodiments, a flow control member can be any suitable baffle or the like. For example, in some embodiments, a flow control member can be an angled baffle or the like having a set of angled surfaces with an alternating orientation or the like. By way of example, a flow control member can include a first set of angled surfaces with a cross-sectional orientation (as shown in FIG. 35) that forms a 30° with a given plane and a second set of angled surfaces with a cross-sectional orientation that forms a 150° orientation with the given plane (i.e., a mirrored orientation), with each angled surface of the first set being disposed between two angled surfaces of the second set (or vice versa). In some embodiments, a baffle can include a set of surfaces that are each substantially V-shaped or U-shaped.

[1144] In other embodiments, a flow control member can be an absorbent or porous baffle or the like that can fill at least a portion of an inner volume of a fluid reservoir. In this manner, a flow of blood can be expelled or drawn from a lumen of an adapter (e.g., a lumen of a puncture member or the like) and absorbed by the absorbent baffle. In such embodiments, a volume of blood can be subsequently released or expelled from the absorbent

baffle via a centripetal or centrifugal action and/or the like. In some embodiments, a flow control member can be a baffle including a set of angled surfaces with an absorbent material disposed therebetween.

[1145] While the flow control members 1367, 1467, and 1565 are shown as independent components disposed within the fluid reservoirs 1360, 1460, and 1560, respectively, in other embodiment, a fluid reservoir can include a flow control member that is integral with another portion of the fluid reservoir such as, for example, a port. For example, FIG. 36 illustrates a fluid reservoir 1660 according to another embodiment. The fluid reservoir 1660 can be any suitable shape, size, or configuration. For example, in this embodiment, the fluid reservoir 1660 is an evacuated container such as a Vacutainer™, a BacT/ALERT® SN, a BacT/ALERT® FA, and/or any of type of container, vial, bottle, reservoir, etc. In some embodiments, the fluid reservoir 1660 can be substantially similar to or the same as the fluid reservoir 1360 described above with reference to FIGS. 31-33. Thus, such similar aspects of the fluid reservoir 1660 are not described in further detail herein.

[1146] The fluid reservoir 1660 includes a proximal end portion 1661 and a distal end portion 1662, and defines an inner volume 1664. The distal end portion 1662 includes a port 1663 configured to receive, for example, a puncture member 1638 of an adapter 1630, as described in detail above with reference to FIGS. 31-33. The port 1663 in this embodiment, however, includes an inner surface 1665 configured to control a flow of fluid into the inner volume 1664 of the fluid reservoir 1660. As shown in FIG. 36, the inner surface 1665 of the port 1663 has a varied diameter that forms a constriction disposed between a proximal end portion and a distal end portion of the port 1663. For example, in some embodiments, the inner surface 1665 can form a constriction or otherwise can have a reduced diameter at or near a center of the port 1663 (i.e., at or near a midpoint between the proximal end portion and the distal end portion of the port).

[1147] In some embodiments, the inner surface 1665 can have a reduced diameter at a position that is proximal to the puncture member 1638 when the adapter 1630 is engaged with the fluid reservoir 1660. Similarly stated, the arrangement of the fluid reservoir 1660 and the adapter 1630 is such that when the adapter 1630 engages the fluid reservoir 1660, the puncture member 1638 is disposed in a distal position relative to a portion of the inner surface 1665 associated with the smallest diameter. Thus, the arrangement of the inner surface 1665 of the port 1663 can, for example, result in a venturi effect within a volume of

bodily-fluid as the volume of bodily-fluid flows from the puncture member 1638 into the port 1663. In other words, with the inner surface 1665 forming a constriction and/or reduction in diameter, a pressure associated with a volume on opposite sides of the constriction and/or reduction in diameter can be controlled. For example, the fluid reservoir 1660, being an evacuated container, defines a negative pressure within a portion of the inner volume 1664 proximal to the portion of the inner surface 1665 having the reduced diameter. In some embodiments, the constriction and/or reduced diameter formed by the inner surface 1665 results in a corresponding decrease in pressure associated with the reduced diameter. Thus, by selectively controlling a portion of the inner surface 1665 that is distal to the reduced diameter (i.e., selectively increasing the diameter of the inner surface 1665) a pressure within a volume distal to the reduced diameter can be less than, for example, the pressure within the volume proximal to the reduced diameter. Thus, hemolysis within a flow of blood is reduced or substantially prevented that might otherwise result from a rapid exposure to the negative pressure differential produced by the fluid reservoir 1660.

[1148] While the flow control members 1367, 1467, 1565, and the port 1663 are shown and described above as receiving and/or otherwise guiding a flow of bodily-fluid (e.g., blood) into the inner volumes 1364, 1464, 1564, 1664, respectively, in some embodiments, an adapter can be arranged to selectively direct a flow of bodily-fluid into a fluid reservoir. For example, FIGS. 37 and 38 illustrate an adapter 1760, according to another embodiment. The adapter 1760 is configured for selective engagement with a fluid reservoir 1760 to deliver a flow of bodily-fluid into an inner volume 1764. The adapter 1760 includes at least a shroud 1743 and a puncture member 1768. Although not shown in FIGS. 37 and 38, an inner surface of the adapter 1760 can be substantially similar to or the same as the inner surface 1363 of the adapter 1360 described above with reference to FIG. 30. That is to say, the adapter 1760 can include an inner surface that defines a substantially smooth transition between, for example, a lumen associated with an inlet of the adapter 1760 (e.g., a catheter, cannula, and/or locking mechanism) and a lumen of the puncture member 1768, thereby reducing and/or substantially preventing hemolysis of blood flowing therethrough.

[1149] As shown in FIG. 38, the arrangement of the adapter 1760 is such that the puncture member 1768 is disposed at non-orthogonal orientation relative to the shroud 1743. More specifically, at least a portion of the puncture member 1768 extends within an inner volume 1744 of the shroud 1743 and toward an inner surface. Thus, when the fluid reservoir

1760 is inserted into the inner volume 1744 of the shroud 1743, the puncture member 1768 punctures a port 1763 of the fluid reservoir 1760 (e.g., substantially similar to the port 1363 of the fluid reservoir 1360 described above with reference to FIGS. 31-33) at a substantially non-orthogonal angle. For example, the fluid reservoir 1760 can be inserted into the inner volume 1743 of the shroud 1744 with a substantially parallel or orthogonal orientation relative thereto. As the fluid reservoir 1760 is moved in the distal direction, the port 1763 is brought into contact with the puncture member 1768 and with the fluid reservoir 1760 parallel or orthogonal to the shroud 1743, the puncture member 1768 punctures the port 1763 at an angle associated with the orientation of the puncture member 1768 relative to the shroud (e.g., non-orthogonal). Therefore, as shown in FIG. 38, an end portion of the puncture member 1768 can be adjacent to, in contact with, and/or otherwise near an inner surface of the reservoir 1760 defining the inner volume 1764. In this manner, directing the flow of blood to the inner surface reduces a force, which can otherwise result from an impact of the volume of blood contacting the inner surface. Thus, hemolysis of the blood associated with such a contact is reduced or substantially prevented.

[1150] In some embodiments, the adapter 1730 can be configured to engage, for example, a standard fluid reservoir such as, for example, a Vacutainer ™ or the like. That is to say, in some embodiments, the adapter 1730 is configured to be compatible with existing fluid reservoirs without modifications being made thereto. In other embodiments, a fluid reservoir can have any suitable configuration. For example, FIG. 39 illustrates an adapter 1830 physically and fluidically coupled to a fluid reservoir 1860 according to another embodiment. The adapter 1830 can be any suitable adapter such as, for example, the adapter 1330 described above with reference to FIGS. 29 and 30. In this manner, the adapter 1830 includes a puncture member 1838 configured to puncture a port or the like of the fluid reservoir 1860, as described in further detail herein.

[1151] The fluid reservoir 1860 includes a proximal end portion 1861 and a distal end portion 1862, and defines an inner volume (not shown in FIG. 39). The distal end portion 1862 includes a port 1863 configured to receive, for example, the puncture member 1838 of the adapter 1830, as described in detail above with reference to FIGS. 31-33. The port 1863 in this embodiment, however, is disposed in a substantially horizontal position. More specifically, in some embodiments, the port 1863 can be disposed in a substantially tangential arrangement relative to, for example, an inner surface of the fluid reservoir 1860. Thus,

when the puncture member 1838 is inserted through the port 1863, an end portion of the puncture member 1838 can be placed adjacent to, at, or substantially near a portion of the inner surface of the fluid reservoir 1860, as described above with reference to the adapter 1730 and fluid reservoir 1760. Similarly stated, the arrangement of the port 1863 can be such that when the puncture member 1838 is inserted therethrough, at least the end portion of the puncture member 1838 (not shown in FIG. 39) is in a tangential orientation relative to the inner surface of the fluid reservoir 1860. In this manner, directing a flow of blood to the inner surface reduces a force, which can otherwise result from an impact of the volume of blood contacting the inner surface. Thus, hemolysis of the blood associated with such a contact is reduced or substantially prevented.

[1152] While a flow of bodily-fluid (e.g., blood) into the fluid reservoirs 1360, 1460, 1560, 1660, 1760, and 1860 is described above as being passively controlled by, for example, the flow control members 1367, 1467, 1565, the port 1663, the adapter 1730, and/or the port 1863, respectively, in other embodiments, a flow of bodily-fluid into a fluid reservoir can be actively controlled. That is to say, while the flow of bodily-fluid into the fluid reservoirs 1360, 1460, 1560, 1660, 1760, 1860 is controlled without user intervention (i.e., beyond the intervention of coupling the adapters 1330, 1430, 1530, 1660, 1760, and 1860 to the fluid reservoirs 1360, 1460, 1560, 1660, 1760, and 1860 respectively), in other embodiments, a user can manipulate an adapter and/or fluid reservoir to actively control a flow of fluid into the fluid reservoir. For example, FIGS. 40-42 illustrate an adapter 1930 and a fluid reservoir 1960, according to another embodiment. The fluid reservoir 1960 can be any suitable reservoir that defines an inner volume 1964 configured to receive a flow of bodily-fluid such as, for example, an evacuated container or the like. More specifically, as described above with reference to the fluid reservoir 1360 in FIGS. 31-33, the fluid reservoir 1960 includes a port 1963 through which a portion of the adapter 1930 can be inserted to gain access to the inner volume 1964, as described in further detail herein.

[1153] As shown in FIGS. 40-42, the adapter 1930 includes a proximal end portion 1931 and a distal end portion 1932, and defines an inner volume 1934. Although not shown, the distal end portion 1932 of the adapter 1930 can be coupled to any suitable lumen-defining device such as a needle, cannula, catheter, and/or sterile flexible tubing. In some embodiments, the distal end portion 1932 can include a locking mechanism or the like that can physically and fluidically couple the adapter 1930 to any suitable corresponding device

and/or component. The proximal end portion 1931 of the adapter 1930 receives a portion of the fluid reservoir 1960. For example, as shown in FIGS. 41 and 42, at least a portion of the port 1963 is inserted through the proximal end portion 1931 of the adapter 1930 to be disposed within a portion of the inner volume 1934.

[1154] As shown in FIGS. 41 and 42, the adapter 1930 further includes a cannula 1935 and an actuator 1945. Specifically, the cannula 1935 extends through the proximal end portion 1931 and the distal end portion 1932 of the adapter 1930, thereby defining a fluid pathway through the adapter 1930. The cannula 1935 can be any suitable shape, size, or configuration. For example, in some embodiments, the cannula 1935 is a substantially flexible tube formed of a biocompatible plastic or the like. In this manner, at least a portion of the cannula 1935 can be manipulated (e.g., by the actuator 1945) to bend, flex, kink, and/or otherwise reconfigure the cannula 1935, as described in further detail herein. The arrangement of the cannula 1935 can be such that when the fluid reservoir 1960 is inserted into the inner volume 1934 of the adapter 1930, an end portion of the cannula 1935 punctures the port 1963 of the fluid reservoir 1960 and thus, places the inner volume 1964 of the fluid reservoir 1960 in fluid communication with a lumen defined by the cannula 1935. Thus, a negative pressure within the fluid reservoir 1960 (e.g., the fluid reservoir 1960 is an evacuated container) exerts or draws suction through the lumen defined by the cannula 1935, as described in further detail herein.

[1155] The actuator 1945 of the adapter 1930 can be any suitable configuration. For example, as shown in FIGS. 41 and 42, the actuator 1945 can be a trigger or the like coupled to the adapter 1930 via a pivot point, pin, axle, etc. More specifically, a first portion of the actuator 1945 extends from and/or beyond an outer surface of the adapter 1930 and a second portion is disposed within the inner volume 1934 defined by the actuator 1930. Thus, a user (e.g., a phlebotomist, doctor, technician, nurse, etc.) can actuate the actuator 1945 by pivoting the actuator 1945 relative to the adapter 1930. In this manner, a portion of the actuator 1945 disposed in the inner volume 1934 of the adapter 1930 can be increased or decreased, for example, by exerting a force or removing a force, respectively, on the actuator 1945 (i.e., pivoting the actuator 1945 relative to the adapter 1930).

[1156] As shown, the portion of the actuator 1945 disposed within the inner volume 1934 of the adapter 1930 defines an opening 1946 through which the cannula 1935 can extend. Therefore, actuating the actuator 1945 (e.g., pivoting the actuator 1945 relative to the adapter

1930) results in a corresponding manipulation of a portion of the cannula 1935. For example, in some instances, while the actuator 1945 is in a first configuration, the position of the opening 1946 relative to the adapter 1930 can be such that the cannula 1935 (disposed therein) is pulled, bent, bowed, deformed, kinked, etc. Such deformation of the cannula 1935 can result in, for example, a constriction and/or pinching of the cannula 1935, which in turn, can constrict and/or at least partially obstruct the lumen defined by the cannula 1935, as shown in FIG. 41.

[1157] Conversely, a force can be exerted to actuate the actuator 1945, thereby pivoting the actuator 1945 relative to the adapter 1930. As described above, such pivoting motion can, for example, increase a portion of the actuator 1945 disposed in the inner volume 1934, which in turn, can change the position and/or orientation of the opening 1946 relative to the adapter 1930. Thus, the repositioning and/or reorienting of the opening 1946 actively (e.g., by exerting a force) or passively (e.g., by removing or reducing an existing force) reconfigures at least the portion of the cannula 1935 disposed therein. For example, as shown in FIG. 42, when the actuator 1945 is placed in the second configuration, the cannula 1935 can be substantially straight or substantially undeformed. Thus, the lumen defined by the cannula 1935 is substantially unobstructed and/or otherwise not constricted by the actuator 1945.

[1158] In use, when the fluid reservoir 1960 is placed in fluid communication with the lumen defined by the cannula 1935 (see e.g., FIGS. 41 and 42), the negative pressure and/or suction (described above) within the lumen of the catheter 1935 can be modulated by actuating the actuator 1945 between its first configuration, associated with a smaller amount of suction, and its second configuration, associated with a larger amount of suction. Moreover, when the distal end portion 1932 of the adapter 1930 is placed in fluid communication with the body of a patient (e.g., either directly or indirectly via a lumen-defining device, a needle, etc.), the negative pressure within the fluid reservoir 1960 draws blood, or other bodily-fluids, through the lumen defined by the cannula 1935 and into the inner volume 1964. In this manner, actuating the actuator 1945 to control or modulate the amount of suction or negative pressure within the lumen of the cannula 1935 can reduce a magnitude of negative pressure that would otherwise be exerted on the flow of blood. Thus, hemolysis of the blood is reduced or substantially prevented that might otherwise result from a rapid exposure to a negative pressure differential produced by the fluid reservoir 1960.

[1159] Although the lumen of the cannula 1935 is shown in FIG. 41 as being partially constricted when the actuator 1945 is in its first configuration, in other embodiments, the actuator 1945 can deform the cannula 1935 a sufficient amount to result in a substantially complete constriction of the lumen. Moreover, while not shown in FIGS. 40-42, in some embodiments, the actuator 1945 can include and/or can be operably coupled to a bias member such as a spring or the like. As such, the bias member can exert a force that at least temporarily maintains the actuator 1945 in, for example, the first configuration until an actuating force is exerted on the actuator 1945, which is sufficient to overcome the force of the bias member.

[1160] While the adapter 1930 is shown and described above as controlling a flow of bodily-fluid into the fluid reservoir 1960 by manipulating the cannula 1935, in other embodiments, an adapter can control a flow of bodily-fluid into a fluid reservoir in any suitable manner. For example, FIGS. 43 and 44 illustrate an adapter 2030 and a fluid reservoir 2060, according to another embodiment. The fluid reservoir 2060 can be any suitable reservoir that defines an inner volume 2064 configured to receive a flow of bodily-fluid such as, for example, an evacuated container or the like. More specifically, as described above with reference to the fluid reservoir 1360 in FIGS. 31-33, the fluid reservoir 2060 includes a port 2063 through which a portion of the adapter 2030 can be inserted to gain access to the inner volume 2064, as described in further detail herein.

[1161] As shown in FIGS. 43 and 44, the adapter 2030 includes a proximal end portion 2031 and a distal end portion 2032. The proximal end portion 2031 of the adapter 2030 is open and/or defines an opening configured to receive at least a portion of the port 2063 of the fluid reservoir 2060. The distal end portion 2032 of the adapter 2030 includes a port 2033 or the like that can be coupled to any suitable lumen-defining device such as a cannula, catheter, and/or sterile flexible tubing (not shown in FIGS. 43 and 44). In some embodiments, the distal end portion 2032 can include a locking mechanism or the like fluidically coupled to the port 2033 and configured to physically and fluidically couple the adapter 2030 to any suitable corresponding device and/or component.

[1162] As shown in FIG. 44, the adapter 2030 includes a puncture member 2038 that extends from a surface of the adapter 2030 to, for example, puncture the port 2063 of the fluid reservoir 2060. Furthermore, the adapter 2030 defines a lumen 2036 that extends through a portion of the adapter 2030 to fluidically couple the port 2033 to the puncture

member 2038. Thus, the puncture member 2038 can puncture the port 2063 of the fluid reservoir 2060 to place the inner volume 2064 of the fluid reservoir 2060 in fluid communication with, for example, the port 2033 of the adapter 2030, which in turn, can be in fluid communication (e.g., either directly or indirectly via an intervening structure) a portion of the body of a patient. Moreover, a negative pressure within the fluid reservoir 2060 (e.g., the fluid reservoir 2060 is an evacuated container) exerts or draws suction through the lumen 2036 and the port 2033 of the adapter 2030 to, for example, draw a flow of bodily-fluid from the patient through the adapter 2030 and into the inner volume 2064 of the fluid reservoir 2060.

[1163] As shown in FIGS. 43 and 44, the arrangement of the adapter 2030 is such that the fluid reservoir 2060 is in a substantially vertical orientation when coupled to the adapter 2030. Thus, when a volume of bodily-fluid (e.g., blood) is expelled from the puncture member 2038, in response to the negative pressure within the fluid reservoir 2060, the bodily-fluid flows in a substantially vertical direction from a lower position to an upper position. While the fluid reservoir 2060 defines a negative pressure that produces a suction force operable in drawing a flow of bodily-fluid from the puncture member 2038, the bodily-fluid expelled therefrom is also exposed to a substantially opposing force associated with gravitational acceleration (i.e., approximately 9.81 meters-per-second-squared ($^{m}/_{s^2}$)). Thus, when a volume of blood is drawn through the adapter 2030 and into the inner volume 2064 of the fluid reservoir 2060, the force associated with gravity acts to slow a velocity of the flow of blood within the inner volume 2064. As such, hemolysis of blood is reduced and/or substantially prevented that can otherwise result from a force associated with a volume of blood impacting an inner surface of the fluid reservoir 2060 defining the inner volume 2064.

[1164] While the adapters and fluid reservoirs described above with reference to FIGS. 27-44 control and/or direct a flow of fluid (i.e., blood) into a fluid reservoir to, for example, reduce hemolysis, in some embodiments, the arrangement of a fluid reservoir and/or an adapter can be such that a negative pressure operable in drawing a volume of blood into the fluid reservoir can be configured modulated and/or controlled. For example, FIGS. 45-60 illustrate embodiments configured to mitigate the risk of hemolysis associated with blood flow to a negative pressure differential within a fluid reservoir. Specifically, FIG. 45 illustrates an adapter 2130 and a fluid reservoir 2160 according to another embodiment. The adapter 2130 can be any suitable adapter such as, for example, the adapter 1330 described

above with reference to FIGS. 29 and 30. In this manner, the adapter 2130 includes a puncture member 2138 configured to puncture a port or the like of the fluid reservoir 2160, as described in further detail herein. The fluid reservoir 2160 includes a proximal end portion 2161 and a distal end portion 2162, and defines an inner volume 2164. The proximal end portion 2161 includes a port 2163A configured to receive, for example, an output member (e.g., a needle, puncture member, cannula, etc.) from, for example, a vacuum source or the like, as described in further detail herein. Similarly, the distal end portion 2162 includes a port 2163 configured to receive, for example, the puncture member 2138 of the adapter 2130, as described in detail above with reference to FIGS. 31-33. In some embodiments, the ports 2163A and 2163 can be substantially similar in form and/or function. In some embodiments, the port 2163A disposed at or near the proximal end portion 2161, for example, can include a frangible seal, a self-healing port, a one-way valve, and/or the like.

[1165] As shown in FIG. 45, the fluid reservoir 2160 includes an elastomeric member 2178 (and/or any other suitable member or material) disposed within the inner volume 2164. The elastomeric member 2178 is in contact with an inner surface of the fluid reservoir 2160 (defining at least a portion of the inner volume 2164) to form a substantially fluid tight seal therebetween. Thus, a portion of the inner volume 2164 that is proximal to the elastomeric member 2178 is substantially fluidically isolated from a portion of the inner volume 2164 that is distal to the elastomeric member 2178. In some embodiments, the portion of the inner volume 2164 disposed between the elastomeric member 2178 and the port 2163 (i.e., disposed at the distal end portion 2162 of the fluid reservoir 2160) can define, for example, a negative pressure, prior to the insertion of the puncture member 2138 through the port 2163. In other embodiments, both portions of the inner volume 2164 (e.g., on either side of the elastomeric member 2178) define a negative pressure, prior to the insertion of the puncture member 2138 through the port 2163. In still other embodiments, the inner volume 2164, in its entirety, need not define a negative pressure, prior to the insertion of the puncture member 2138 through the port 2163.

[1166] As shown in FIG. 45, the plunger 2145 can "float" and/or otherwise be disposed in a substantially fixed position within the inner volume 2164 prior to the port 2163A being fluidically coupled to a vacuum source (not shown in FIG. 45). Moreover, the arrangement of the fluid reservoir 2160 is such that when the actuator 2130 engages the fluid reservoir 2160, the puncture member 2138 is in a distal position relative to the elastomeric member

2178 and thus, substantially fluidically isolated from the portion of the inner volume 2164 that is proximal to the elastomeric member 2178. In a similar manner, the fluid reservoir 2160 can be manipulated such that an outlet of a vacuum source (not shown in FIG. 45) punctures and/or is otherwise inserted through the port 2163A to be placed in fluid communication with the portion of the inner volume 2164 proximal to the elastomeric member 2178. Thus, a user can actuate the vacuum source (e.g., via an electric switch, a pre-charged negative pressure created in a manufacturing process, mechanical actuation, and/or the like), such that the vacuum source draws a vacuum (e.g., a suction force) through its output and into the portion of the inner volume 2164 proximal to the elastomeric member 2178.

[1167] In some instances, the suction force and/or negative pressure can be sufficient to overcome a friction force between the elastomeric member 2178 and the inner surface, thereby resulting in a movement of the elastomeric member 2178 within the inner volume 2164 towards the port 2163A. The movement of the elastomeric member 2178 results in a change in volume associated with the portions of the inner volume 2164 disposed on either side of the elastomeric member 2178. In some instances, the increase in volume of the portion of the inner volume 2164 distal to the elastomeric member 2178 results in a negative pressure that is sufficient to draw a flow of bodily-fluid through the puncture member 2138 and into the inner volume 2164. As such, in some instances, a rate and/or magnitude of the vacuum drawn by the vacuum source can be controlled to, for example, change a characteristic associated with a pressure difference within the inner volume 2164 of the fluid reservoir 2160 and, for example, the adapter 2130. Thus, hemolysis of the blood is reduced or substantially prevented that might otherwise result from a rapid exposure to a negative pressure differential produced by the fluid reservoir 2160.

[1168] While the elastomeric member 2178 is shown and described above as "floating" within the inner volume 2164, in other embodiments, a fluid reservoir can include an elastomeric member and/or the like that is coupled to a plunger. For example, FIG. 46 illustrates an adapter 2230 and a fluid reservoir 2260 according to another embodiment. The adapter 2230 can be any suitable adapter such as, for example, the adapter 1330 described above with reference to FIGS. 29 and 30. In this manner, the adapter 2230 includes a puncture member 2238 configured to puncture a port or the like of the fluid reservoir 2260, as described in further detail herein.

[1169] The fluid reservoir 2260 includes a proximal end portion 2261 and a distal end portion 2262, and defines an inner volume 2264. The proximal end portion 2261 includes a port 2263A configured to be coupled to, for example, a vacuum source or the like, as described in further detail herein. Similarly, the distal end portion 2262 includes a port 2263 configured to receive the puncture member 2238 of the adapter 2230, as described in detail above with reference to FIGS. 31-33. In some embodiments, the ports 2263A and 2263 can be substantially similar in form and/or function. In some embodiments, the port 2263A disposed at or near the proximal end portion 2261, for example, can include a frangible seal, a self-healing port, a one-way valve, a locking mechanism, and/or the like. Thus, the port 2263A can physically and fluidically couple to a corresponding outlet port of a vacuum source (not shown in FIG. 46). For example, in some embodiments, an outlet port of a vacuum source and the port 2263A can form a threaded coupling or the like. In such embodiments, when the vacuum source is actuated, the port 2263A can be transitioned from a first, substantially sealed configuration to a second, substantially open configuration.

[1170] As shown in FIG. 46, the fluid reservoir 2260 includes a plunger 2275 disposed within the inner volume 2264. The plunger 2275 includes and/or is coupled to an elastomeric member 2278 disposed within the inner volume 2264. The elastomeric member 2278 is in contact with an inner surface of the fluid reservoir 2260 (defining at least a portion of the inner volume 2264) to form a substantially fluid tight seal therebetween. Thus, a portion of the inner volume 2264 that is proximal to the elastomeric member 2278 is substantially fluidically isolated from a portion of the inner volume 2264 that is distal to the elastomeric member 2278, as described above with reference to the elastomeric member 2178 in FIG. 46. In this embodiment, at least a portion of the plunger 2275 is movably disposed within a support member 2264A extending from a surface of the fluid reservoir 2260. As shown, the support member 2264A can, for example, divide the inner volume into a first portion and a second portion. Moreover, the support member 2264A can include a seal or the like that is in contact with an outer surface of the plunger to form a substantially fluid tight seal therebetween. Thus, the first portion of the inner volume 2264 can be substantially isolated from the second portion of the inner volume 2264.

[1171] The arrangement of the fluid reservoir 2260 is such that when the actuator 2230 engages the fluid reservoir 2260, the puncture member 2238 is in a distal position relative to the elastomeric member 2278 and thus, substantially fluidically isolated from the portion of

the inner volume 2264 that is proximal to the elastomeric member 2278. A user can similarly manipulate the fluid reservoir to couple the port 2263A to an outlet of a vacuum source (not shown in FIG. 46). In this manner, the portion of the inner volume 2264 that is proximal to the support member 2264A is placed in fluid communication with the vacuum source. Thus, a user can actuate the vacuum source (e.g., via an electric switch, a pre-charged negative pressure created in a manufacturing process, mechanical actuation, and/or the like) such that the vacuum source draws a vacuum (e.g., a suction force) through its output and into the portion of the inner volume 2264 proximal to the support member 2264A.

[1172] In some instances, the suction force and/or negative pressure can be sufficient to move the plunger 2275 within the inner volume 2264 towards the port 2263A. The movement of the plunger 2275 results in a corresponding movement of the elastomeric member 2278 and thus, changes a volume associated with the portions of the inner volume 2264 disposed on either side of the elastomeric member 2278. In some instances, the increase in volume of the portion of the inner volume 2264 distal to the elastomeric member 2278 results in a negative pressure that is sufficient to draw a flow of bodily-fluid through the puncture member 2238 an into the inner volume 2264. As such, in some instances, a rate and/or magnitude of the vacuum drawn by the vacuum source can be controlled to, for example, change a characteristic associated with a pressure difference within the inner volume 2264 of the fluid reservoir 2260 and, for example, the adapter 2230. Thus, hemolysis of the blood is reduced or substantially prevented that might otherwise result from a rapid exposure to a negative pressure differential produced by the movement of the plunger 2375 within the fluid reservoir 2260.

[1173] In some embodiments, the arrangement of the plunger 2275 and the support member 2264A can, for example, maintain a sterility of a portion of the inner volume 2264 distal to the support member 2264A. Specifically, as described above, the support member 2264A can include the seal that engages the outer surface of the plunger 2275 to fluidically isolate a portion of the inner volume 2264 proximal to the support member 2264A from a different portion of the inner volume 2264 distal to the support member 2264A. As such, when the port 2263A is placed in fluid communication with the vacuum source (not shown in FIG. 46), the portion of the inner volume 2264 proximal to the support member 2264A can be exposed, for example, to a non-sterile environment (e.g., associated with the vacuum source), while the sterility of the portion of the inner volume 2264 is maintained.

[1174] FIG. 47 illustrates an adapter 2330 and a fluid reservoir 2360 according to another embodiment. The adapter 2330 can be any suitable adapter such as, for example, the adapter 1330 described above with reference to FIGS. 29 and 30. In this manner, the adapter 2330 includes a puncture member 2338 configured to puncture a port or the like of the fluid reservoir 2360, as described in further detail herein.

[1175] The fluid reservoir 2360 includes a proximal end portion 2361 and a distal end portion 2362, and defines an inner volume 2364. The proximal end portion 2361 includes a port 2363A configured to be coupled to, for example, a vacuum source or the like, as described in further detail herein. Similarly, the distal end portion 2362 includes a port 2363 configured to receive the puncture member 2338 of the adapter 2330, as described in detail above with reference to FIGS. 31-33. As shown in FIG. 47, the fluid reservoir 2360 includes a plunger 2375 disposed within the inner volume 2364. The plunger 2375 includes and/or is coupled to an elastomeric member 2378 disposed within the inner volume 2364. The elastomeric member 2378 is in contact with an inner surface of the fluid reservoir 2360 (defining at least a portion of the inner volume 2364) to form a substantially fluid tight seal therebetween. As such, the fluid reservoir 2360 can be substantially similar to the fluid reservoir 2260 described above with reference to FIG. 46.

[1176] The fluid reservoir 2360 can differ from the fluid reservoir 2260, however, by including a bias member 2377 (e.g., a linear spring, a torsion spring, a leaf spring, a compression member, and/or the like) disposed about and in contact with a portion of the plunger 2375. In this manner, when the port 2363A is physically and fluidically coupled to an outlet of a vacuum source (not shown in FIG. 47) and the vacuum source is actuated, the vacuum source draws a vacuum (e.g., a suction force) through its output and into the portion of the inner volume 2364. Thus, the vacuum source can exert a suction force within a portion of the inner volume 2364 that results in a proximal movement of the plunger 2375. The arrangement of the bias member 2377, however, is such that the bias member 2377 exerts a reaction force in response to the movement of the plunger 2375. As such, the bias member 2377 can at least partially control a movement of the plunger 2375 within the inner volume 2364, for example, to reduce speed at which the plunger 2375 is moved. Thus, hemolysis of the blood is reduced or substantially prevented that might otherwise result from a rapid exposure to a negative pressure differential produced by the movement of the plunger 2375 within the fluid reservoir 2360.

[1177] While the adapters in the embodiments above have been shown and described as being physically and/or fluidically coupled to a corresponding fluid reservoir configured as an evacuated container, in other embodiments, an adapter can be configured to physically and/or fluidically couple to any suitable fluid reservoir and/or any suitable intervening structure. For example, FIGS. 49 and 50 illustrate an adapter 2430 according to another embodiment. The adapter 2430 can be any suitable shape or size and can be configured to be placed in fluid communication with any suitable fluid reservoir. For example, as described in further detail herein with reference to FIGS. 51 and 52, in some instances, the adapter 2430 can be physically and fluidically coupled to a fluid reservoir 2460 configured as, for example, a syringe or the like.

[1178] As shown in FIGS. 49 and 50, the adapter 2430 has a proximal end portion 2431 and a distal end portion 2432. In this embodiment, the distal end portion 2432 of the adapter 2430 includes, for example, a locking mechanism (e.g., a Luer Lok® or the like) that can physically and fluidically couple the adapter 2430 to a corresponding locking mechanism of any other suitable device such as, for example, an extension set or the like. In other embodiments, the distal end portion 2432 can be any suitable configuration such as, for example, a port, a septum, and/or the like. In a similar manner, the proximal end portion 2431 of the adapter 2430 includes, for example, a locking mechanism (e.g., a Luer Lok® or the like) that can physically and/to fluidically couple the adapter 2430 to, for example, the fluid reservoir 2460, as described in further detail herein.

[1179] The adapter 2430 includes a delivery member 2438 that extends from a portion of adapter 2430 toward the proximal end portion 2431. The delivery member 2438 defines a lumen 2439 extending at least partially through the delivery member 2438. More specifically, in this embodiment, the lumen 2439 extends through the distal end portion 2432 of the adapter 2430 but does not extend through the proximal end portion 2431. Similarly stated, the lumen 2439 does not extend through a proximal surface of the delivery member 2438. For example, as shown in FIGS. 49 and 50, the delivery member 2438 can have a substantially rounded or hemispherical proximal surface that is substantially closed and/or continuous. Alternatively, the delivery member 2438 defines at least one opening 2440 disposed along a circumference of the delivery member 2438 at a position distal to, for example, the proximal surface. Thus, while the delivery member 2438 does not define an

opening though a proximal most surface, opening(s) 2440 place a proximal end portion of the lumen 2439 in fluid communication with a volume outside of the delivery member 2438.

[1180] As described above, the adapter 2430 can be physically and fluidically coupled to the fluid reservoir 2460 (see e.g., FIG. 52). The fluid reservoir 2460 can be any suitable shape, size, or configuration. For example, in this embodiment, the fluid reservoir 2460 is a syringe or the like, as shown in FIG. 51. The fluid reservoir 2460 has a proximal end portion 2461 and a distal end portion 2462 and defines an inner volume 2464. The distal end portion 2462 is configured to be physically and fluidically coupled to an adapter such as, for example, the adapter 2430. For example, the distal end portion 2462 can include a locking mechanism (e.g., a Luer Lok® or the like) configured to be physically and fluidically coupled to the proximal end portion 2431 (e.g., the corresponding locking member included therein) of the adapter 2430. Moreover, when the adapter 2430 is coupled to the fluid reservoir 2460, the delivery member 2438 is at least partially disposed in the inner volume 2464 of the fluid reservoir 2460 and as such, the opening(s) 2440 defined by the delivery member 2438 place the lumen 2439 of the adapter 2430 in fluid communication with the inner volume 2464 of the fluid reservoir 2460, as described in further detail herein.

[1181] As shown in FIGS. 51 and 52, the proximal end portion 2461 movably receives a plunger 2475 that is at least partially disposed in the inner volume 2464, as described in further detail herein. As shown in FIG. 52, the fluid reservoir 2460 includes a seal member 2479 disposed within the inner volume 2464. More specifically, the seal member 2479 is disposed within a proximal portion of the inner volume 2464 and about a portion of the plunger 2475. As such, the seal member 2479 forms a substantially fluid tight seal between an inner surface of the fluid reservoir 2460 and an outer surface of the seal member 2479 and an outer surface of the plunger 2475 and an inner surface of the seal member 2479. Furthermore, the seal member 2479 defines an opening 2479A extending therethrough that can place a portion of the inner volume 2464 proximal to the seal member 2479 in fluid communication with a portion of the inner volume 2464 distal to the seal member 2479. The arrangement of the fluid reservoir 2460 is such that the seal member 2479 is maintained in a substantially fixed position when the plunger 2475 is moved within the inner volume 2464, as described in further detail herein.

[1182] As shown in FIG. 52, the plunger 2475 has a proximal end portion 2476 and a distal end portion 2477. The distal end portion 2477 of the plunger 2475 includes and/or is

coupled to an elastomeric member 2478 or the like. For example, in some embodiments, the elastomeric member 2478 can form a substantially fluid tight seal with an inner surface of the fluid reservoir 2460. As described above, the plunger 2475 is movably disposed within the inner volume 2464 of the fluid reservoir 2460. More specifically, the plunger 2475 can be moved within the inner volume 2464 in an axial direction between a first position (e.g., a distal position) and a second position (e.g., a proximal position) relative to the fluid reservoir 2460. For example, in some embodiments, the plunger 2475 can be disposed in a distal position relative to the fluid reservoir 2460 prior to use. A user can then manipulate the fluid reservoir 2460 and/or the plunger 2475 to move the plunger 2474 in a proximal direction within the inner volume 2464. With the elastomeric member 2478 in contact with the inner surface of the fluid reservoir 2460, the proximal movement of the plunger 2475 relative to the fluid reservoir 2460 produces a negative pressure within a portion of the inner volume 2464 that is distal to the elastomeric member 2478.

[1183] When the adapter 2430 is coupled to the fluid reservoir 2460 (as shown in FIG. 52), the negative pressure within the portion of the inner volume 2464 results in a suction through the lumen 2439 of the delivery member 2438. Thus, when the distal end portion 2431 of the adapter 2430 is coupled to a device or other intervening structure, which in turn, is in fluid communication with a portion of the body and/or intervening device (e.g. catheter, fluid reservoir, etc.), the suction force within the lumen 2439 can draw a bodily-fluid (e.g., blood) through the lumen 2439 and into the inner volume 2464 of the fluid reservoir 2460. Moreover, the arrangement of the seal member 2479 within the inner volume 2464 can reduce, limit, modulate, and/or otherwise at least partially control a rate at which the plunger 2479 can be moved within the inner volume 2464. For example, with the elastomeric member 2478 forming a substantially fluid tight seal with the inner surface of the fluid reservoir 2460, the proximal movement of the plunger 2464 reduces and/or compresses a volume defined between the elastomeric member 2478 and the seal member 2479, which in turn, increases a pressure within that volume. Therefore, with the seal member 2479 similarly forming a substantially fluid tight seal with the inner surface of the fluid reservoir 2460 and with an outer surface of the plunger 2475, air within the volume between the seal member 2479 and the elastomeric member 2478 is forced through the opening 2479A defined by the seal member 2479, thereby limiting the rate at which the plunger 2479 is moved within the inner volume 2464. As such, a negative pressure and/or a suction force drawn through the lumen 2439 of the adapter 2430 is correspondingly controlled and/or modulated.

[1184] As described above, in some embodiments, the arrangement of the delivery member 2438 can also limit and/or otherwise modulate a pressure and/or a suction force within the lumen 2439. In this manner, when withdrawing a volume of blood, hemolysis of the blood flowing through the lumen 2439 and into the inner volume 2464 of the fluid reservoir 2460 is reduced or substantially prevented. Specifically, the arrangement opening(s) 2440 and the lumen 2439 of the delivery member 2438 can, for example, reduce a negative pressure within the lumen 2439 and/or can slow a flow of blood delivered to the inner volume 2464 of the fluid reservoir 2460 to an extent that can reduce and/or substantially prevent hemolysis of the blood that can otherwise result from, inter alia, a volume of blood being exposed to a rapid pressure drop or the like. In addition, the arrangement of an inner surface defining the lumen 2439 can, for example, reduce turbulence, eddy currents, and/or any other disturbance that can otherwise result from a discontinuity or the like.

[1185] While the fluid reservoir 2460 is particularly shown and described above with reference to FIGS. 51 and 52, in other embodiments, any suitable fluid reservoir can be coupled to, for example, the adapter 2430 to receive a volume of blood with reduced hemolysis of its constituents. For example, FIGS. 53 and 54 illustrate a fluid reservoir 2560 according to another embodiment. In this embodiment, the fluid reservoir 2560 is, for example, a syringe or the like having a proximal end portion 2561 and a distal end portion 2562 and defining an inner volume 2564. The distal end portion 2562 is configured to be physically and fluidically coupled to an adapter such as, for example, the adapter 1530, as described in detail above.

[1186] The proximal end portion 2561 of the fluid reservoir 2560 is substantially open and receives at least a portion of a plunger 2575. Moreover, the proximal end portion 2561 of the fluid reservoir 2560 includes an actuator 2570 that is operable in moving the plunger 2575 within the inner volume 2564. For example, as shown in FIGS. 53 and 54, the fluid reservoir 2560 includes a protrusion 2569 to which the actuator 2570 is pivotally coupled. More specifically, the actuator 2570 includes a first end portion 2571, a second end portion 2572, and a pivot portion 2573 disposed therebetween. The second end portion 2572 of the actuator 2570 is coupled to a portion of the plunger 2575, as described in further detail herein. The pivot portion 2573 is coupled to the protrusion 2569 via, for example, a pin, an axle, a rod, and/or the like configured to allow the actuator 2570 to pivot about the protrusion

2569 (e.g., about an axis defined by the protrusion 2569) in response to a force exerted on the first end portion 2571. In this manner, the actuator 2570 can be arranged, for example, as a trigger or the like which when actuated, is operable in moving the plunger 2575 relative to the fluid reservoir 2560, as described in further detail herein.

[1187] As shown in FIG. 54, the plunger 2575 has a proximal end portion 2576 and a distal end portion 2577. The distal end portion 2577 of the plunger 2575 includes and/or is coupled to an elastomeric member 2578 or the like. For example, in some embodiments, the elastomeric member 2578 can form a substantially fluid tight seal with an inner surface of the fluid reservoir 2560. As described above, the plunger 2575 is movably disposed within the inner volume 2564 of the fluid reservoir 2560. More specifically, the proximal end portion 2576 of the plunger 2575 is coupled to the second end portion 2572 of the actuator 2570 such that an actuation of the actuator 2570 results in a movement of the plunger 2570 within the inner volume 2564.

[1188] For example, a user can exert a force on the first end portion 2571 (e.g., with his or her thumb or finger) of the actuator 2570, which in turn, results in a pivoting motion about the protrusion 2569 that places the first end portion 2571 in a position closer to an outer surface of the fluid reservoir 2560 and places the second end portion 2572 in a corresponding position farther away from the fluid reservoir 2560. In other words, the pivoting of the actuator 2570 about the protrusion 2569 moves the second end portion 2572 in a proximal direction. Moreover, the trigger arrangement of the actuator 2570 (as described above) defines a range of motion through which the actuator 2570 can pivot and thus, defines a range of motion through which the plunger 2575 is moved in the proximal direction (i.e., a stroke length). As such, the user can serially actuate the actuator 2570 to move the plunger 2575 a desired distance in the proximal direction.

[1189] With the elastomeric member 2578 of the plunger 2575 forming a substantially fluid tight seal with the inner surface of the fluid reservoir 2560, the proximal movement of the plunger 2575 relative to the fluid reservoir 2560 produces a negative pressure within a portion of the inner volume 2564 that is distal to the elastomeric member 2578. Thus, when the fluid reservoir is coupled to an adapter and/or any other suitable lumen-defining device in fluid communication with the body of a patient, the negative pressure results in a suction force within that lumen that can draw a bodily-fluid (e.g., blood) through the lumen and into the inner volume 2564 of the fluid reservoir 2560. Moreover, by limiting the stroke length

(as described above) of the plunger 2575, a rate at which the plunger 2575 can be moved within the inner volume 2564 is reduced, limited, modulated, and/or otherwise at least partially controlled. As a result, a negative pressure and/or a suction force drawn through, for example, the lumen of the lumen-defining device is correspondingly controlled and/or modulated. Therefore, by limiting the stroke of the plunger 2575, a negative pressure within the inner volume 2564 of the fluid reservoir 2560 and/or a rate at which blood (or other bodily-fluid) flows into the inner volume 2564 can be controlled to an extent that can reduce and/or substantially prevent hemolysis of the blood that can otherwise result from, inter alia, a volume of blood being exposed to a rapid pressure drop or the like.

[1190] While the actuator 2570 is particularly shown in FIGS. 52 and 53, in other embodiments, the actuator 2570 can be any suitable device, mechanism, and/or member that is operative in moving the plunger 2575 within the fluid reservoir 2560. For example, while actuator 2570 is described above as being actuated by a user's thumb or finger, in other embodiments, and actuator can include a first end portion that extends a given length of the fluid reservoir as to be engaged by a user's palm or more than one finger (e.g., each finger excluding the thumb of the user). In other embodiments, a fluid reservoir can include an actuator that is a switch, a push button, a toggle, and/or the like configured to close an electric circuit or the like when actuated. Thus, when the electric circuit is closed, a current can flow through the electric circuit, for example, to a mechanism (e.g., including an electric motor) configured to move a plunger within the fluid reservoir.

[1191] FIGS. 54-56 illustrate a fluid reservoir 2660 according to another embodiment. The fluid reservoir 2660 can be any suitable shape, size, or configuration. For example, in this embodiment, the fluid reservoir 2660 is a syringe or the like, as shown in FIG. 54. The fluid reservoir 2660 has a proximal end portion 2661 and a distal end portion 2662 and defines an inner volume 2664 (see e.g., 56). The distal end portion 2662 is configured to be physically and fluidically coupled to an adapter (not shown in FIGS. 54-56) such as, for example, the adapter 2430 described above with reference to FIGS. 48-51.

[1192] The proximal end portion 2661 of the fluid reservoir 2660 movably receives a plunger 2675 that is at least partially disposed in the inner volume 2664. As shown in FIGS. 55 and 56, the plunger 2675 has a proximal end portion 2676 and a distal end portion 2677. The distal end portion 2677 of the plunger 2675 includes and/or is coupled to an elastomeric member 2678 or the like. For example, in some embodiments, the elastomeric member 2678

can form a substantially fluid tight seal with an inner surface of the fluid reservoir 2660, as described in detail above. The proximal end portion 2676 of the plunger 2675 is coupled to an actuator 2670. For example, in some embodiments, at least a portion of the actuator 2670 can be hollow and configured to be movably disposed (e.g., in an axial direction) about the proximal end portion 2676 of the plunger 2675. Expanding further, the proximal end portion 2676 of the plunger 2675 includes a set of protrusions 2676A or the like (e.g., tabs, pins, bumps, etc.) configured to engage and/or otherwise disposed in a corresponding set of openings 2670A when the actuator 2670 is disposed about the proximal end portion 2676. In some embodiments, each protrusion 2676A can include an indicator or the like that can be viewable when disposed in a corresponding opening 2670A of the actuator 2670, as described in further detail herein.

[1193] As shown in FIGS. 55 and 56, the plunger 2675 includes a bias member 2674 (e.g., a linear spring, a torsion spring, and/or the like) disposed between the proximal end portion 2676 and the actuator 2670. In this manner, the bias member 2674 can, for example, maintain the actuator 2670 is a substantially fixed position relative to the proximal end portion 2676 until a force is exerted on the actuator 2670 or the plunger 2675 that is sufficient to overcome a force exerted by the bias member 2674. For example, in some embodiments, a user can manipulate the fluid reservoir 2660 to fluidically couple the distal end portion 2662, for example, to an adapter (e.g., the adapter 2430), which in turn can be directly or indirectly coupled to a device in fluid communication with a portion of the body. Thus, the inner volume 2664 of the fluid reservoir 2660 is placed in fluid communication with the portion of the body. With the fluid reservoir 2660 in fluid communication with the portion of the body, the user can manipulate the actuator 2670, for example, to move the plunger 2675 within the inner volume 2664. For example, a user can exert a force on the actuator 2670 to move the actuator 2670 and the plunger 2675 in the proximal direction relative to the fluid reservoir 2660. The arrangement of the bias member 2674 can be such that at least a portion of the force exerted by the user on the actuator 2670 transitions the bias member 2674 from a first configuration (e.g., a compressed configuration) to a second configuration (e.g., an extended configuration). Thus, the bias member 2674 can absorb at least a portion of the force (e.g., an excess portion of force above a predetermined threshold), exerted by the user, that would otherwise be exerted on the plunger 2675. In this manner, a rate at which the plunger 2675 is moved within the inner volume 2664 can be at least partially controlled and/or otherwise limited, which in turn, can reduce and/or substantially prevent hemolysis of the blood drawn

into the inner volume 2664 that can otherwise result from, inter alia, a volume of blood being exposed to a rapid pressure drop or the like.

[1194] In some embodiments, the arrangement of the protrusions 2676A of the proximal end portion 2676 within the openings 2670A of the actuator 2670, for example, can define a range of motion of the actuator 2670 relative to the plunger 2675 (e.g., can prevent a movement of the actuator 2675 beyond a predetermined threshold relative to the plunger 2675. In some embodiments, the protrusions 2676A can each include an indicator or the like that are viewable through the openings 2670A and therefore, can provide an indication to the user associated with the movement of the actuator 2670 relative to the plunger 2675. For example, in some embodiments, when a force is exerted on the actuator 2670 that is greater than a predetermined threshold, the actuator 2670 can be moved relative to the plunger 2675 and at least a portion of the force can transition the bias member 2674 from its first configuration to its second configuration. Thus, when the bias member 2674 is in its second configuration (e.g., an extended configuration), the actuator 2670 can be in a position relative to the plunger 2675 that is associated with at least a portion of the indicator of the protrusions 2676A being viewable through the openings 2670A. As such, the indicators can provide a visual indication of when a force exerted by the user exceeds a predetermined threshold. In some embodiments, the arrangement of the protrusions 2676A and the openings 2670A can be such that when a force exerted on the actuator 2670 exceeds the predetermined threshold, the plunger 2675 and/or the actuator 2670 also provide an auditory (e.g., a clicking sound) or a haptic indication.

[1195] While the actuators 2570 and 2670 are particularly shown and described above, in other embodiments, a fluid reservoir can include any suitable actuator operable in moving a plunger within an inner volume of the fluid reservoir. For example, FIGS. 57 and 58 illustrate a fluid reservoir 2760 according to another embodiment. The fluid reservoir 2760 can be any suitable shape, size, or configuration. For example, in this embodiment, the fluid reservoir 2760 is a syringe or the like, as shown in FIG. 57. The fluid reservoir 2760 has a proximal end portion 2761 and a distal end portion 2762 and defines an inner volume 2764 (see e.g., 56). The distal end portion 2762 is configured to be physically and fluidically coupled to an adapter (not shown in FIGS. 57 and 58) such as, for example, the adapter 2430 described above with reference to FIGS. 48-51. The proximal end portion 2761 of the fluid reservoir 2760 movably receives a plunger 2775 that is at least partially disposed in the inner

volume 2764. As shown in FIG. 58, the plunger 2775 has a proximal end portion 2776 and a distal end portion 2777. The distal end portion 2777 of the plunger 2775 includes and/or is coupled to an elastomeric member 2778 or the like, as described in detail herein. The proximal end portion 2776 of the plunger 2775 is coupled to an actuator 2770 operable in moving the plunger 2775 relative to the fluid reservoir 2760.

[1196] The actuator 2770 can be any suitable shape, size, or configuration. For example, as shown in FIGS. 57 and 58, the actuator 2770, in this embodiment, is a dial rotatably coupled to the fluid reservoir 2760 and the plunger 2775. More specifically, the actuator 2770 can be disposed about the proximal end portion 2761 of the fluid reservoir 2760 such that the actuator 2770 can rotate relative thereto without, for example, unthreading or removing the actuator 2770 from the fluid reservoir 2760. In other words, the actuator 2770 can be coupled to the proximal end portion 2761 of the fluid reservoir 2760 for rotational motion while substantially preventing a linear motion of the actuator 2770 relative to the fluid reservoir 2760. As shown in FIG. 58, an outer surface of the plunger 2775 includes and/or otherwise forms a set of continuous threads 2775A arranged in a helical manner along a length of the plunger 2775 (e.g., substantially the entire length). Moreover, a portion of the plunger 2775 is configured to extend through, for example, a threaded opening defined by the actuator 2770. Thus, the set of threads 2775A engage a surface of the actuator 2770 to define a threaded coupling therebetween, which can allow the plunger 2775 to be moved in an axial direction within the inner volume 2764 of the fluid reservoir 2760.

[1197] Specifically, in use, the fluid reservoir 2760 can be manipulated to couple the distal end portion 2762 to an adapter or other device in fluid communication with a portion of the body, thereby placing the inner volume 2764 of the fluid reservoir 2760 in fluid communication with the portion of the body and/or intervening device (e.g. catheter, etc.). With the inner volume 2764 in fluid communication with the portion of the body, the actuator 2770 can be rotated relative to the fluid reservoir 2760, which in turn, results in the threads 2775A being advanced along a surface of the actuator 2770. Thus, the plunger 2775 is moved in an axial direction (e.g., a proximal direction) within the inner volume 2764, which in turn, increases a portion of the inner volume 2764 that is distal to the elastomeric member 2778. Such an increase results in, for example, a negative pressure within the portion of the inner volume 2764 distal to the elastomeric member 2778 and therefore, a suction force is exerted that is operable in drawing a bodily-fluid (i.e., blood) into the inner volume 2764 of

the fluid reservoir 2760. In some embodiments, the arrangement of the actuator 2770 and the plunger 2775 (i.e., the threaded coupling) limits a rate at which the plunger 2775 is moved within the inner volume 2764. In this manner, limiting the rate at which the plunger 2775 is moved within the inner volume 2764 can reduce and/or substantially prevent hemolysis of the blood drawn into the inner volume 2764 that can otherwise result from, inter alia, a volume of blood being exposed to a rapid pressure drop or the like.

[1198] While the actuator 2770 is shown and described above as forming a threading coupling with the plunger 2775, in other embodiments, a fluid reservoir can include an actuator that is monolithically formed with a plunger. For example, FIG. 59 illustrates a fluid reservoir according to another embodiment. The fluid reservoir 2860 has a proximal end portion 2861 and a distal end portion 2862 and defines an inner volume 2864. The distal end portion 2862 is configured to be physically and fluidically coupled to an adapter (not shown in FIG. 59) such as, for example, the adapter 2430 described above with reference to FIGS. 48-51. In this embodiment, the fluid reservoir 2860 includes an outer surface that defines a set of continuous threads arranged in a helical manner along a length of the fluid reservoir 2860, as described above with reference to the plunger 2775 in FIG. 58.

[1199] The fluid reservoir 2860 is rotatably coupled to an actuator 2870. The actuator 2870 includes a proximal end portion 2871, a distal end portion 2872, and a plunger 2875. The actuator 2870 further includes an inner surface that defines a set of continuous threads 2899 (e.g., female threads or grooves) arranged in a helical manner along a length of the inner surface. In this manner, the actuator 2870 can be disposed about the fluid reservoir 2860 such that the set of threads 2860A of the fluid reservoir 2860 are disposed within the corresponding set of threads 2899 of the actuator 2870, while the plunger 2875 extends from the proximal end portion 2871 of the actuator 2870 within the inner volume 2864 of the fluid reservoir 2860. Moreover, as shown in FIG. 59, a distal end portion 2877 of the plunger 2875 includes and/or is coupled to an elastomeric member 2878 configured to form a substantially fluid tight seal with an inner surface of the fluid reservoir 2860, as described in detail herein.

[1200] Thus, in use, the fluid reservoir 2860 can be manipulated to couple the distal end portion 2862 to an adapter or other device in fluid communication with a portion of the body, thereby placing the inner volume 2864 of the fluid reservoir 2860 in fluid communication with the portion of the body. With the inner volume 2864 in fluid communication with the

portion of the body, the actuator 2870 can be rotated relative to the fluid reservoir 2860, which in turn, results in the threads 2899 of the actuator 2870 being advanced along the corresponding threads 2860A of the fluid reservoir 2860. Thus, the actuator 2870 can be moved in the proximal direction relative to the fluid reservoir 2860, which results in the plunger 2875 being moved in an axial direction (e.g., a proximal direction) within the inner volume 2864. As such, a portion of the inner volume 2864 that is distal to the elastomeric member 2878 is increased. Such an increase results in, for example, a negative pressure within the portion of the inner volume 2864 distal to the elastomeric member 2878 and therefore, a suction force is exerted that is operable in drawing a bodily-fluid (i.e., blood) into the inner volume 2864 of the fluid reservoir 2860. In some embodiments, the arrangement of the actuator 2870 and the fluid reservoir 2860 (i.e., the threaded coupling) limits a rate at which the plunger 2875 is moved within the inner volume 2864. In this manner, limiting the rate at which the plunger 2875 is moved within the inner volume 2864 can reduce and/or substantially prevent hemolysis of the blood drawn into the inner volume 2864 that can otherwise result from, inter alia, a volume of blood being exposed to a rapid pressure drop or the like.

[1201] FIG. 60 illustrates a fluid reservoir 2960 according to another embodiment. The fluid reservoir 2960 can be any suitable shape, size, or configuration. For example, in this embodiment, the fluid reservoir 2960 can be configured to receive a portion of an actuator 2970 (e.g., arranged as a syringe or the like), as described in further detail herein. The fluid reservoir 2960 has a first chamber 2990 and a second chamber 2991, which are formed unitarily (e.g., joined at a proximal end portion of the fluid reservoir 2960. The first chamber 2990 includes a proximal end portion 2961 and a distal end portion 2962 and defines an inner volume 2964. The distal end portion 2962 is configured to be physically and fluidically coupled to an adapter such as, for example, the adapter 2430 described above with reference to FIGS. 48-51. The proximal end portion 2961 movably receives a first plunger 2975 of the actuator 2970, which is at least partially disposed in the inner volume 2964, as described in further detail herein. In this manner, the first chamber 2990 is configured to receive and at least temporarily store a volume of bodily-fluid, as described in further detail herein.

[1202] Similarly, the second chamber 2991 includes a proximal end portion 2992 and a distal end portion 2993 and defines an inner volume 2994. The distal end portion 2993 of the second chamber 2991 is closed (i.e., does not define a port or other opening). The proximal

end portion 2992 movably receives a second plunger 2995 of the actuator 2970, which is at least partially disposed in the inner volume 2994, as described in further detail herein. As shown in FIG. 60, the second chamber 2991 has a size and/or shape that are/is smaller than the first chamber 2990. Thus, in some embodiments, the second chamber 2991 can be an auxiliary chamber or the like. For example, with the distal end portion 2993 of the second chamber 2991 being closed and/or sealed, in this embodiment, the second chamber 2991 can act as a dampener or the like configured to dampen a movement of the actuator 2970 relative to the fluid reservoir 2960.

[1203] As described above, the actuator 2970 includes the first plunger 2975 movably disposed in the inner volume 2964 of the first chamber 2990 and the second plunger 2995 movably disposed in the inner volume 294 of the second chamber 2991. As shown in FIG. 60, the first plunger 2975 has a proximal end portion 2976 and a distal end portion 2977. The proximal end portion 2976 of the first plunger 2975 is coupled to and/or otherwise unitarily formed a proximal end portion 2996 of the second plunger 2995. The distal end portion 2977 of the first plunger 2975 includes and/or is coupled to an elastomeric member 2978 or the like. In some embodiments, the elastomeric member 2978 can form a substantially fluid tight seal with an inner surface of the first chamber 2990, as described in detail above. Similarly, the second plunger 2995 has the proximal end portion 2996 and a distal end portion 2997. The proximal end portion 2996 of the second plunger 2995 is coupled to and/or otherwise unitarily formed with the proximal end portion 2976 of the first plunger 2975. The distal end portion 2997 of the second plunger 2995 includes and/or is coupled to an elastomeric member 2998. As described above with reference to the elastomeric member 2978, the elastomeric member 2998 of the second plunger 2995 can form a substantially fluid tight seal with an inner surface of the second chamber 2991. In this manner, the actuator 2970 can be moved relative to the fluid reservoir 2960 to move the first plunger 2975 within the inner volume 2964 of the first chamber 2990 and the second plunger 2995 within the inner volume 2994 of the second chamber 2991 in a substantially concurrent movement, as described in further detail herein.

[1204] In use, for example, the fluid reservoir 2960 can be manipulated to couple the distal end portion 2962 to an adapter or other device in fluid communication with a portion of the body, thereby placing the inner volume 2964 of the fluid reservoir 2960 in fluid communication with the portion of the body and/or intervening device (e.g. catheter, etc.).

Once the inner volume 2964 is placed in fluid communication with the portion of the body, the actuator 2970 can be moved in the proximal direction relative to the fluid reservoir 2960, which in turn, moves the first plunger 2975 within the inner volume 2964. More specifically, with the elastomeric member 2978 of the plunger 2975 forming a substantially fluid tight seal with the inner surface of the fluid reservoir 2960, the proximal movement of the first plunger 2975 relative to the fluid reservoir 2960 produces a negative pressure within a portion of the inner volume 2964 that is distal to the elastomeric member 2978. Thus, when the fluid reservoir is coupled to an adapter and/or any other suitable lumen-defining device in fluid communication with the body of a patient, the negative pressure results in a suction force within that lumen that can draw a bodily-fluid (e.g., blood) through the lumen and into the inner volume 2964 of the fluid reservoir 2960.

[1205] In a similar manner, the proximal movement of the actuator 2970 moves the second plunger 2995 within the inner volume 2994 of the second chamber 2991 substantially concurrently with the first plunger 2975, thereby increasing a portion of the inner volume 2994 that is distal to the elastomeric member 2998. With the elastomeric member 2998 of the second plunger 2995 forming a substantially fluid tight seal with the inner surface of the second chamber 2991, such an increase in the portion of the inner volume 2994 that is distal to the elastomeric results in a negative pressure within that portion of the inner volume 2994. Moreover, with the distal end portion 2993 of the second chamber 2991 being closed and/or sealed, the movement of the second plunger 2995 within the second chamber 2991, for example, can act to dampen the movement of the actuator 2970 relative to the fluid reservoir 2960. Specifically, the increase of the portion of the inner volume 2994 distal to the elastomeric member 2998 produces, for example, a suction force therein that resists the proximal movement of the second plunger 2995. Thus, an effective force exerted on the actuator 2970 to move the first plunger 2975 within the first chamber 2990 and the second plunger 2995 within the second chamber 2991 can be modulated, reduced, limited, and/or otherwise controlled, which in turn, can limit a rate at which the actuator 2970 is moved relative to the fluid reservoir 2960. In other words, the arrangement of the second chamber 2991 and the second plunger 2995 dampen the force exerted on the actuator 2970 and thus, the movement of the actuator 2970 relative to the fluid reservoir 2960. Therefore, by limiting the rate at which the actuator 2970 is moved relative to the fluid reservoir 2960, a negative pressure within the inner volume 2964 of the first chamber 2991 and/or a rate at which blood (or other bodily-fluid) flows into the inner volume 2964 can be controlled to an extent that

can reduce and/or substantially prevent hemolysis of the blood that can otherwise result from, inter alia, a volume of blood being exposed to a rapid pressure drop or the like.

[1206] While the embodiments are shown and described above as defining a single flow path from the patient to a fluid reservoir, in some embodiments, a fluid transfer device and/or system can include, for example, any suitable extension set, Y-adapter, T-adapter, junction, split, and/or the like configured to define more than one fluid flow path. Moreover, in such embodiments, a fluid transfer device and/or system can include any suitable coupling mechanism, lock mechanism, hub, and/or the like configured to couple, for example, a first lumen-defining device to a second lumen-defining device such that hemolysis of a flow of blood therethrough is limited and/or substantially prevented. For example, FIGS. 61-71 illustrate embodiments configured to mitigate the risk of hemolysis as blood flows through a multi-lumen adapter and/or the like. Specifically, FIGS. 61-63 illustrate a hub 3020 configured to receive a lumen-defining device 3080 according to an embodiment.

[1207] The hub 3020 has a proximal end portion 3021, a distal end portion 3022 and an inner surface 3023 defining a lumen 3024 therethrough (see e.g., FIG. 63). The distal end portion 3022 of the hub 3020 includes and/or is coupled to a cannula 3022A and/or other suitable lumen-defining device. Although not shown in FIGS. 61-63, in some embodiments, the cannula 3022A can be coupled to an adapter, a restrictor, locking mechanism, and/or the like. In some embodiments, the cannula 3022A can be, for example, an indwelling cannula with a distal end portion disposed within the body of a patient. In other embodiments, the distal end portion 3022 of the hub 3020 can include and/or can form a locking mechanism configured to physically and fluidically couple the hub 3020 to any suitable device. The proximal end portion 3021 of the hub 3020 includes and/or is coupled to a proximal cap 3027 and an actuator 3045. For example, in some embodiments, the proximal cap 3027 can be coupled to the proximal end portion 3021 via a press fit, a snap fit, a friction fit, a threaded coupling, an adhesive, ultrasonic welding and/or the like. Moreover, the proximal cap 3027 defines an opening 3028 that is, for example, substantially aligned with the lumen 3024 defined by the inner surface 3023. In this manner, a portion of the lumen-defining device 3080 can be inserted through the opening 3028 of the proximal cap 3027 to be disposed within the hub 3020, as described in further detail herein.

[1208] As shown in FIGS. 62 and 63, the actuator 3045 is disposed between the proximal end portion 3021 and the proximal cap 3027. More specifically, the actuator 3045 forms a

substantially annular ring or the like that is movably disposed within a space defined between a proximal surface of the hub 3020 and a distal surface of the proximal cap 3027. In this manner, the actuator 3045 defines an opening 3046 that can be selectively aligned with the opening 3028 of the proximal cap 3027 and the inner surface 3023 of the hub 3020. Moreover, the actuator 3045 includes and/or is coupled to a bias member 3047 (see e.g., FIG. 62), which can exert a force to temporarily maintain the actuator 3045 in a predetermined position relative to the hub 3020, for example, until a force is exerted on the actuator 3045 sufficient to overcome the force exerted by the bias member 3047, as described in further detail herein.

[1209] As shown in FIG. 63, the inner surface 3023 of the hub 3020 defines the lumen 3024 extending through its proximal end portion 3021 and its distal end portion 3022, which is configured to receive a portion of the lumen-defining device 3080. Furthermore, the inner surface 3023 includes and/or otherwise forms a shoulder 3025. In this embodiment, the shoulder 3025 is associated with a change in diameter of the inner surface 3023. For example, a first portion of the inner surface 3023 (e.g., a proximal portion) can have a first diameter that is larger than a diameter of a second portion of the inner surface (e.g., a distal portion). In this manner, the shoulder 3025 can be placed in contact with a surface of the lumen-defining device 3080 when inserted therein, as described in further detail herein.

[1210] The hub 3020 further includes a valve 3026 disposed within the lumen 3024. The valve 3026 can be, for example, a one-valve, a port, and/or the like, which can be transitioned between a first, substantially closed configuration and a second, substantially opened configuration. Thus, when in the first configuration, the valve 3026 can fluidically isolate a portion of the lumen 3024 that is proximal to the valve 3026 from a portion of the lumen 3024 that is distal to the valve 3026. Conversely, when the valve 3026 is in the second configuration, the lumen 3024 can define a fluid flow path substantially through the hub 3020. In some embodiments, the insertion of the portion of the lumen-defining device 3080 can be operable in transitioning the valve 3026 from the first configuration to the second configuration, as described in further detail herein.

[1211] The lumen-defining device 3080 has a proximal end portion 3031, a distal end portion 3032, and a flange 3086. The lumen-defining device 3080 also defines a notch 3085 and a lumen 3083 extending through the proximal end portion 3081 and the distal end portion 3082, as described in further detail herein. As shown in FIGS. 62 and 63, the distal end

portion 3082 of the lumen-defining device 3080 is configured to be inserted through the proximal cap 3027 and the actuator 3045 to be disposed within the hub 3020, as described in further detail herein. Moreover, the lumen-defining device 3080 includes a seal member 3087 disposed about an outer surface of the distal end portion 3082, which is placed in contact with the inner surface 3023 of the hub 3020 which the lumen-defining device 3080 is disposed therein.

[1212] As shown, for example, in FIGS. 61 and 63, the proximal end portion 3081 of the lumen-defining device 3080 is physically and fluidically coupled to a cannula 3088. The cannula 3088 can be any suitable configuration. For example, in this embodiment, the cannula 3088 is a bifurcated cannula having a first portion 3088A and a second portion 3088B (also referred to herein as a "first cannula" and a "second cannula," respectively). The first portion 3088A and second portion 3088B can be physically and fluidically coupled to any suitable device (e.g., at a proximal end). For example, as shown in FIG. 61, the second portion 3088B includes a port or locking mechanism that can physically and fluidically couple the second portion 3088B to, for example, a fluid source and/or the like. Although not shown, the first portion 3088A can include a port or the like substantially similar to that of the second portion 3088B that can physically and fluidically couple the first portion 3088A to, for example, a fluid reservoir and/or the like. In other embodiments, the first portion 3088A and the second portion 3088B can be arranged in any suitable manner and can each be physically and fluidically coupled to any suitable device, mechanism, and/or member included in a fluid transfer system.

[1213] In use, a portion of the lumen-defining device 3080 can be inserted into the hub 3020 to define a fluid flow path between the cannula 3022A, coupled to the distal end portion 3022 of the hub 3020, and the cannula 3088 coupled to the proximal end portion 3081 of the lumen-defining device 3080. More specifically, in some instances, a user can manipulate the hub 3020 by exerting a force on the actuator 3045, thereby moving the actuator 3045 from a first position, in which the opening 3046 of the actuator 3045 is substantially unaligned with the opening 3028 of the proximal cap 3027, to a second position, in which the opening 3046 is aligned with the opening 3028. Thus, with the actuator 3045 in the second position, the opening 3028 of the proximal cap 3027, the opening 3046 of the actuator 3046, and the lumen 3024 of the hub 3020 are sufficiently aligned to allow the distal end portion 3082 of the lumen-defining device 3080 to be inserted through the proximal cap 3027, the actuator

3045, and into the lumen 3024. As shown in FIG. 63, the lumen-defining device 3080 can be inserted into the hub 3020 by a predetermined amount that places the distal end portion 3082 extends through the valve 3026, thereby transitioning the valve 3026 from its first, substantially closed configuration to its second, substantially open configuration. Moreover, a distal surface of the lumen-defining device 3080 in contact with the shoulder 3025, as shown in FIG. 63.

[1214] With the distal surface of the lumen-defining device 3080 in contact with the shoulder 3025, the flange 3086 of the lumen-defining device 3080 is disposed within a recessed surface defined by the proximal cap 3027. In some embodiments, the shape and/or size of the recessed surface and the flange 3086 can be such that the lumen-defining device 3080 is placed into a predetermined radial position such that the lumen 3024 of the hub 3020 and the lumen 3083 of the lumen-defining device 3080 are substantially aligned, as shown in FIG. 63. Moreover, the seal member 3087 disposed about the outer surface at or near the distal end portion 3082 of the lumen-defining device 3080 is placed in contact with the inner surface 3023 of the hub 3020. In this manner, the arrangement of the flange 3086 disposed within the recessed surface of the proximal cap 3027 and the seal member 3087 in contact with the inner surface 3023 of the hub 3020, the lumen-defining device 3080 is placed in a predetermined radial position relative to the hub 3020. For example, in this embodiment, the lumen 3083 of the lumen-defining device 3080 and the lumen 3024 of the hub 3020 form a substantially continuous transition therebetween. That is to say, the lumens 3083 and 3024 are substantially aligned and/or a discontinuity defined therebetween is sufficiently minimized or obviated so as to not produce turbulence within a flow of bodily-fluid therethrough.

[1215] In addition, once the lumen-defining device 3080 is disposed in the desired and/or predetermined position within the hub 3020, the user can remove the force exerted on the actuator 3045. As such, the bias member 3047 can exert a force to move the actuator 3045 from its second position to its first position (e.g., a biased position). Thus, as shown in FIG. 63, the actuator 3045 is moved out of alignment with the hub 3020, resulting in a portion of the actuator 3045 being disposed in the notch 3085 defined by the lumen-defining device 3080, which in turn, can maintain the lumen-defining device 3080 in a substantially fixed position within the hub 3020. In this manner, a user can couple the first portion 3088A or the second portion 3088B of the cannula 3088 to, for example, a fluid reservoir such as those

described herein, which in turn, can exert a suction force (e.g., in response to a negative pressure differential) through the lumen-defining device 3080 and the hub 3020. Therefore, when the cannula 3022A is in fluid communication with the body of a patient (e.g., either directly or indirectly via an intervening structure), a volume of, for example, blood can be withdrawn with a reduced amount of hemolysis. Specifically, the alignment of the lumen 3024 defined by the hub 3020 and the lumen 3083 of the lumen-defining device 3080, for example, can reduce turbulence, eddy currents, and/or any other disturbance that can otherwise result from a discontinuity or the like. Thus, the flow of blood therethrough can be substantially laminar and substantially free of hemolysis.

[1216] Although the valve 3026 is particularly shown and described above with reference to FIGS. 62 and 63, in other embodiments, a hub can include any suitable valve. For example, FIGS. 64-66 illustrate a hub 3120 configured to receive a lumen-defining device 3180 according to another embodiment. The hub 3120 and the lumen-defining device 3080 can be substantially similar in form and/or function as the hub 3020 and the lumen-defining device 3080 described above with reference to FIGS. 61-63. Thus, such similar aspects are not described in further detail herein.

[1217] As shown in FIGS. 64-66, the hub 3120 has a proximal end portion 3121, a distal end portion 3122, and an inner surface 3123 defining a lumen 3124 therethrough (see e.g., FIG. 66). The distal end portion 3122 of the hub 3120 includes and/or is coupled to a cannula 3122A and/or other suitable lumen-defining device. While the hub 3020 is shown and described as being coupled to a single cannula and/or a cannula defining a single lumen, in this embodiment, the hub 3120 is coupled to a bifurcated cannula having a first portion (also referred to herein as "first cannula" or "cannula 3122A") and a second portion 3122B. In other embodiments, the hub 3120 can be coupled to a single cannula and/or a cannula defining a single lumen. The proximal end portion 3121 of the hub 3120 includes and/or is coupled to a proximal cap 3127 and an actuator 3145, as described in detail above. The proximal cap 3127 defines an opening 3128 that is, for example, substantially aligned with the lumen 3124 defined by the inner surface 3123. In this manner, a portion of the lumen-defining device 3180 can be inserted through the opening 3128 of the proximal cap 3127 to be disposed within the hub 3120, as described in further detail herein.

[1218] As shown in FIGS. 65 and 66, the actuator 3145 is disposed between the proximal end portion 3121 and the proximal cap 3128. The actuator 3145 forms a substantially annular

ring or the like that is movably disposed within a space defined between a proximal surface of the hub 3120 and a distal surface of the proximal cap 3127. In addition, the actuator 3145 includes and/or is coupled to a bias member 3147, which can exert a force to temporarily maintain the actuator 3145 in a predetermined position relative to the hub 3120, for example, until a force is exerted on the actuator 3145 sufficient to overcome the force exerted by the bias member 3147. In this manner, the arrangement of the proximal end portion 3121 of the hub 3120, the proximal cap 3127, and the actuator 3145 can be substantially similar to the proximal end portion 3021 of the hub 3020, the proximal cap 3027, and the actuator 3045 described above with reference to FIGS. 62 and 63.

[1219] As shown in FIG. 66, the inner surface 3123 of the hub 3120 defines the lumen 3124 extending through its proximal end portion 3121 and its distal end portion 3122, which is configured to receive a portion of the lumen-defining device 3180. Furthermore, the inner surface 3123 includes a valve and a sealing surface 3125. As shown in FIG. 66, in this embodiment, the valve is a ball valve 3126, which can be transitioned between a first, substantially closed configuration and a second, substantially opened configuration. More specifically, the hub 3120 includes a bias member 3148 in contact with the ball valve 3126. In this manner, the bias member 3148 can exert a force on the ball valve 3126 that places the ball valve 3126 in contact with the sealing surface 3125. Thus, a contact sufficient to maintain a substantially fluid tight seal can be maintained when the ball valve 3126 is in contact with the sealing surface 3125 (e.g., in the first configuration) via a force exerted by the bias member 3148. Conversely, when a force exerted on the ball valve 3126, opposite the force exerted by the bias member 3148, is sufficient to overcome the force exerted by the bias member 3148, the ball valve 3126 can be removed from contact with the sealing surface 3125 and thus, a fluid flow path can be defined therethrough. In some embodiments, the insertion of the portion of the lumen-defining device 3180 can be operable in transitioning the ball valve 3126 from the first configuration to the second configuration, as described in further detail herein.

[1220] The lumen-defining device 3180 has a proximal end portion 3181, a distal end portion 3182, and a flange 3186. The lumen-defining device 3180 also defines a notch 3185 and a lumen 3183 extending through the proximal end portion 3181 and the distal end portion 3182, as described in further detail herein. As shown, for example, in FIGS. 64-66, the proximal end portion 3181 of the lumen-defining device 3180 is physically and fluidically

coupled to a cannula 3188. The cannula 3188 can be any suitable configuration. For example, in this embodiment, the cannula 3188 is a single cannula and/or a cannula that defines a single lumen. In other embodiments, the cannula 3188 can be a bifurcated cannula, as described in detail above with reference to the cannula 3088 in FIG. 61. Moreover, although not shown in FIGS. 64-66, the cannula 3188 can include any suitable port, locking mechanism, and/or the like, as described above.

[1221] As shown in FIGS. 65 and 66, the distal end portion 3182 of the lumen-defining device 3180 is configured to be inserted through the proximal cap 3127 and the actuator 3145 to be disposed within the hub 3120, as described in further detail herein. Moreover, the lumen-defining device 3180 includes a seal member 3187 disposed about an outer surface of the distal end portion 3182, which is placed in contact with the inner surface 3123 of the hub 3120 which the lumen-defining device 3180 is disposed therein. As shown in FIG. 66, the lumen 3183 of defined by the lumen-defining device 3080 at or near the distal end portion 3182 is diverted, for example, into one or more channels and defining a substantially smooth transition therebetween. In some embodiments, the one or more channels, for example, can be offset from the lumen 3183 (e.g., non-coaxial). In other words, each channel is radially offset from a longitudinal centerline CL, as shown in FIG. 66. Thus, when a distal surface of the lumen-defining device 3180 is placed in contact with, for example, the ball valve 3126, the channels and/or the lumen 3183 are/is substantially unobstructed, as described in further detail herein.

[1222] In use, a portion of the lumen-defining device 3180 can be inserted into the hub 3120 to define a fluid flow path between the cannula 3122A, coupled to the distal end portion 3122 of the hub 3120, and the cannula 3188 coupled to the proximal end portion 3181 of the lumen-defining device 3180. More specifically, in some instances, a user can manipulate the hub 3120 by exerting a force on the actuator 3145, thereby moving the actuator 3145 from a first position, in which the opening 3146 of the actuator 3145 is substantially unaligned with the opening 3128 of the proximal cap 3127, to a second position, in which the opening 3146 is aligned with the opening 3128, as described in detail above. As shown in FIG. 66, the lumen-defining device 3180 can be inserted into the hub 3120 by a predetermined amount that places a distal surface of the lumen-defining device 3180 in contact with the ball valve 3126. In this manner, the lumen-defining device 3180 can be inserted into the hub 3180 until the flange 3186 of the lumen-defining device 3180 is disposed within a recessed surface

defined by the proximal cap 3127, thereby aligning the lumen-defining device 3180, as described in detail above. Moreover, the seal member 3187 disposed about the outer surface at or near the distal end portion 3182 of the lumen-defining device 3180 is placed in contact with the inner surface 3123 of the hub 3120. In this manner, the lumen-defining device 3180 can be inserted into a position that removes the ball valve 3126 from the sealing surface 3125, thereby defining a fluid flow path between the lumen 3124 of the hub 3120 and the lumen 3183 (and/or channels) of the lumen-defining device 3180.

[1223] Once the lumen-defining device 3180 is disposed in the desired and/or predetermined position within the hub 3120, the user can remove the force exerted on the actuator 3145. As such, the bias member 3147 can exert a force to move the actuator 3145 from its second position to its first position (e.g., a biased position), resulting in a portion of the actuator 3145 being disposed in the notch 3185 defined by the lumen-defining device 3180. Thus, the actuator 3145 can maintain the lumen-defining device 3180 in a substantially fixed position within the hub 3120, as described in detail above. In this manner, a user can couple the cannula 3188, for example, to a fluid reservoir such as those described herein. Therefore, when the cannula 3122A is in fluid communication with the body of a patient (e.g., either directly or indirectly via an intervening structure), a volume of, for example, blood can be withdrawn with a reduced amount of hemolysis, as described in detail above. Specifically, the alignment of the lumen 3124 defined by the hub 3120 and the channels and/or lumen 3183 of the lumen-defining device 3180, for example, can reduce turbulence, eddy currents, and/or any other disturbance that can otherwise result from a discontinuity or the like. Thus, the flow of blood therethrough can be substantially laminar and substantially free of hemolysis.

[1224] Although the hubs 3020 and 3120 have a proximal end portion including an actuator, in other embodiments, a hub can have any suitable configuration and need not include an actuator. For example, FIGS. 67 and 68 illustrate a hub 3320 configured to receive a lumen-defining device 3280 according to another embodiment. The hub 3220 and the lumen-defining device 3280 can be substantially similar in form and/or function as the hub 3020 and the lumen-defining device 3080 and/or the hub 3120 and the lumen-defining device 3180, described in detail above. Thus, such similar aspects are not described in further detail herein. As shown in FIGS. 67 and 68, the hub 3220 has a proximal end portion 3221, a distal end portion 3222, a secondary port 3289, and an inner surface 3223 defining a

lumen 3224 therethrough (see e.g., FIG. 68). The hub 3220 further includes a valve 3226 disposed within the lumen 3224, as described in further detail herein.

[1225] The distal end portion 3222 of the hub 3220 includes and/or is coupled to a cannula 3222A and/or other suitable lumen-defining device, as described above with reference to the hub 3020 in FIGS. 61-63. The proximal end portion 3221 of the hub 3220 includes and/or is coupled to a proximal cap 3227. As shown in FIGS. 67 and 68, in this embodiment, the proximal cap 3237 can be, for example, a locking mechanism or the like configured to form a treaded coupling with a portion of the lumen-defining device 3280, as described in further detail herein.

[1226] As shown in FIG. 68, the inner surface 3223 of the hub 3220 defines the lumen 3224 extending through its proximal end portion 3221 and its distal end portion 3222, which is configured to receive a portion of the lumen-defining device 3280. Furthermore, the inner surface 3223 includes and/or otherwise forms a shoulder 3225. In this embodiment, the shoulder 3225 is associated with a change in diameter of the inner surface 3223. For example, a first portion of the inner surface 3223 (e.g., a proximal portion) can have a first diameter that is larger than a diameter of a second portion of the inner surface (e.g., a distal portion). In this manner, the shoulder 3225 can be placed in contact with a surface of the lumen-defining device 3280 when inserted therein, as described in detail above with reference to the hub 3020. In some embodiments, the shoulder 3225 can form, for example, a seat or a recessed portion configured to receive a portion of the lumen-defining device 3280.

[1227] The valve 3226 of the hub 3220 can be, for example, a one-valve, a port, and/or the like, which can be transitioned between a first, substantially closed configuration and a second, substantially opened configuration. Thus, when in the first configuration, the valve 3226 can fluidically isolate a portion of the lumen 3224 that is proximal to the valve 3226 from a portion of the lumen 3224 that is distal to the valve 3226. Conversely, when the valve 3226 is in the second configuration, the lumen 3224 can define a fluid flow path substantially through the hub 3220. In some embodiments, the insertion of the distal end portion 3282 of the lumen-defining device 3280 can be operable in transitioning the valve 3226 from the first configuration to the second configuration, as described in further detail herein.

[1228] The secondary port 3289 of the hub 3280 can be any suitable port or the like. For example, in some embodiments, the hub 3220 can be arranged as a T-adapter or the like, in

which the proximal end portion 3221 defines a first port and the secondary port 3289 extends in a substantially perpendicular direction from the first port. In this manner, the secondary port 3289 is in fluid communication with the lumen 3224 defined by the hub 3220 and can be configured to receive and/or deliver a fluid from and/or to the lumen 3224 of the hub 3220. Moreover, the arrangement of the secondary port 3289 is such that when the valve 3226 is in its closed configuration, the secondary port 3289 is fluidically isolated from a portion of the lumen 3224 proximal to the valve 3226.

[1229] The lumen-defining device 3080 has a proximal end portion 3031, a distal end portion 3032, and a flange 3086. The lumen-defining device 3080 also defines a notch 3085 and a lumen 3083 extending through the proximal end portion 3081 and the distal end portion 3082, as described in further detail herein. As shown in FIGS. 62 and 63, the distal end portion 3082 of the lumen-defining device 3080 is configured to be inserted through the proximal cap 3027 and the actuator 3045 to be disposed within the hub 3020, as described in further detail herein. Moreover, the lumen-defining device 3080 includes a seal member 3087 disposed about an outer surface of the distal end portion 3082, which is placed in contact with the inner surface 3023 of the hub 3020 which the lumen-defining device 3080 is disposed therein.

[1230] The lumen-defining device 3280 has a proximal end portion 3281 and a distal end portion 3282, and defines a lumen 3283 therethrough. As shown, for example, in FIG. 68, the proximal end portion 3281 of the lumen-defining device 3280 is physically and fluidically coupled to a cannula 3288. The cannula 3288 can be any suitable configuration. For example, in this embodiment, the cannula 3288 is a single cannula and/or a cannula that defines a single lumen. In some embodiments, the cannula 3288 can be substantially similar to the cannula 3188 described above wither reference to FIGS. 64-66.

[1231] As shown in FIG. 68, the distal end portion 3282 of the lumen-defining device 3280 is configured to be inserted through the proximal cap 3227 to be disposed within the hub 3220. More specifically, a portion of the lumen-defining device 3280 can be inserted into the proximal cap 3227 and configured to form, for example, a threaded coupling or the like. For example, in some embodiments, a portion of an outer surface of the lumen-defining device 3280 can include a set of treads or the like configured to engage a corresponding set of threads included in and/or defined by the proximal cap 3227. Thus, in use, as the lumen-defining device 3280 is inserted through the proximal cap 3227, the proximal cap 3227

and/or the lumen-defining device 3280 can be rotated to form the threaded coupling therebetween. Moreover, the arrangement of the lumen-defining device 3280 can be such that when coupled to the proximal cap 3227, the distal end portion 3282 of the lumen-defining device 3280 extends through the valve 3226. Thus, the valve 3226 is transitioned from its first, substantially closed configuration to its second, substantially open configuration. In some embodiments, the valve 3226 can be configured to form a substantially fluid tight seal about a portion of the lumen-defining device 3280, which in turn, can maintain the secondary port 3289 in fluid isolation from, for example, the lumen 3283 of the lumen-defining device 3280. Moreover, the lumen-defining device 3280 is advanced such that a distal surface of the lumen-defining device 3280 is in contact with the shoulder 3225, as shown in FIG. 68.

[1232] In this embodiment, the arrangement of the lumen-defining device 3280 and the proximal cap 3227 (i.e., the coupling therebetween) is such that the lumen 3283 of the lumen-defining device 3280 and the lumen 3224 of the hub 3220 form a substantially continuous transition therebetween. That is to say, the lumens 3283 and 3224 are substantially aligned and/or a discontinuity defined therebetween is sufficiently minimized or obviated so as to not produce turbulence within a flow of bodily-fluid therethrough. Therefore, when the cannula 3222A is in fluid communication with the body of a patient (e.g., either directly or indirectly via an intervening structure), a volume of, for example, blood can be withdrawn with a reduced amount of hemolysis. Specifically, the alignment of the lumen 3224 defined by the hub 3220 and the lumen 3283 of the lumen-defining device 3280, for example, can reduce turbulence, eddy currents, and/or any other disturbance that can otherwise result from a discontinuity or the like. Thus, the flow of blood therethrough can be substantially laminar and substantially free of hemolysis.

[1233] While the hubs 3020, 3120, and 3220 are shown and described above as receiving the lumen-defining devices 3080, 3180, and 3280 (e.g., a connector), respectively, in other embodiments, a hub can be configured to receive a terminated end of a cannula or the like (e.g., without a connector or other lumen-defining device). For example, FIGS. 69-71 illustrate a hub 3320 configured to receive a cannula 3388 according to another embodiment. The hub 3320 and the lumen-defining device 3080 can be substantially similar in form and/or function as the hub 3020 and the lumen-defining device 3080 and/or the hub 3120 and the

lumen-defining device 3180, described in detail above. Thus, such similar aspects are not described in further detail herein.

[1234] As shown in FIGS. 69-71, the hub 3320 has a proximal end portion 3321, a distal end portion 3322, and an inner surface 3323 defining a lumen 3324 therethrough (see e.g., FIG. 71). The distal end portion 3322 of the hub 3320 includes and/or is coupled to a cannula 3322A and/or other suitable lumen-defining device. In some embodiments, the distal end portion 3322 of the hub 3320 can be substantially similar to the distal end portion 3322 of the hub 3020 described above with reference to FIGS. 61-63. The proximal end portion 3321 of the hub 3320 includes and/or is coupled to a proximal cap 3327, as described in detail above. The proximal cap 3327 defines an opening 3328 that is, for example, substantially aligned with the lumen 3324 defined by the inner surface 3323. In this manner, a portion of the cannula 3388 can be inserted through the opening 3328 of the proximal cap 3327 to be disposed within the hub 3320, as described in further detail herein.

[1235] As shown in FIGS. 70 and 71, the proximal end portion 3321 of the hub 3320 further includes and or is coupled to a first coupling member 3345 and a second coupling member 3349. As described above with reference to the actuator 3145, the first coupling member 3345 is disposed between the proximal end portion 3321 and the proximal cap 3327. The first coupling member 3345 is configured to selective receive a portion of the second coupling member 3349. The second coupling member 3349 is configured to be disposed about a portion of the cannula 3388. Thus, the second coupling member 3349 can be inserted substantially concurrently with the cannula 3388. Moreover, the second coupling member 3349 is configured to engage the first coupling member 3345 disposed within the hub 3320, for example, to at least temporarily maintain the cannula 3388 in a fixed position. For example, in some embodiments, the second coupling portion 3349 can form a snap fit, a press fit, a friction fit, and/or the like when placed in contact with the first coupling member 3345, as described in further detail herein.

[1236] As shown in FIG. 71, the inner surface 3323 of the hub 3320 defines the lumen 3324 extending through its proximal end portion 3321 and its distal end portion 3322, which is configured to receive a portion of the cannula 3388. Furthermore, the inner surface 3323 includes and/or otherwise forms a shoulder 3325. In this embodiment, the shoulder 3325 is associated with a change in diameter of the inner surface 3323. For example, a first portion of the inner surface 3323 (e.g., a proximal portion) can have a first diameter that is larger than

a diameter of a second portion of the inner surface (e.g., a distal portion). In this manner, the shoulder 3325 can be placed in contact with a surface of the cannula 3388 when inserted therein, as described in detail above with reference to the hub 3020.

[1237] The hub 3320 further includes a valve 3326 disposed within the lumen 3324. The valve 3326 can be, for example, a one-valve, a port, and/or the like, which can be transitioned between a first, substantially closed configuration and a second, substantially opened configuration. Thus, when in the first configuration, the valve 3326 can fluidically isolate a portion of the lumen 3324 that is proximal to the valve 3326 from a portion of the lumen 3324 that is distal to the valve 3326. Conversely, when the valve 3326 is in the second configuration, the lumen 3324 can define a fluid flow path substantially through the hub 3320. In some embodiments, the insertion of the portion of the cannula 3388 can be operable in transitioning the valve 3326 from the first configuration to the second configuration, as described in further detail herein.

[1238] In use, a portion of the cannula 3388 can be inserted into the hub 3320 to define a fluid flow path between the cannula 3322A, coupled to the distal end portion 3322 of the hub 3320, and the cannula 3388 coupled to the proximal end portion 3381 of the cannula 3388. More specifically, in some instances, a user can insert an end portion of the cannula 3388 through the second coupling member 3349. Once the second coupling member 3349 is disposed about the cannula 3380, the cannula 3388 can be inserted into the hub 3320 by a predetermined amount that extends, for example, a distal end portion of the cannula 3388 through the valve 3326, thereby transitioning the valve 3326 from its first, substantially closed configuration to its second, substantially open configuration. Moreover, a distal surface of the cannula 3388 in contact with the shoulder 3325, as shown in FIG. 71. As the cannula 3388 is moved into its desired position within the hub 3320, the second coupling member 3349 is inserted through the opening 3328 defined by the proximal cap 3327 and into contact with the first coupling member 3345. Thus, the second coupling member 3349 can engage the first coupling member 3345 to define, for example, a snap fit or the like. In some embodiments, the arrangement of the second coupling member 3349 can be such that when it engages the first coupling member 3349, a space through which the cannula 3388 extends is reduced. As such, the second coupling member 3349 can clamp the cannula 3388 and with the second coupling member 3349 being coupled to the first coupling member 3345, the first coupling member 3345 and the second coupling member 3349 can act to at least

temporarily maintain the cannula 3388 in a substantially fixed position relative to the hub 3320. Although described above as being moved substantially concurrently with the cannula 3388, in other embodiments, the second coupling member 3349 can be moved after the distal surface of the cannula 3388 is placed in contact with the shoulder 3325.

[1239] In some embodiments, the arrangement of the hub 3320 and the cannula 3388 is such that when the cannula 3388 is maintained in the substantially fixed position, the lumen 3324 of the hub 3320 is substantially aligned with a lumen defined by the cannula 3388. For example, in this embodiment, the lumen of the cannula 3388 and the lumen 3324 of the hub 3320 form a substantially continuous transition therebetween. That is to say, the lumens are substantially aligned and/or a discontinuity defined therebetween is sufficiently minimized or obviated so as to not produce turbulence within a flow of bodily-fluid therethrough. In this manner, a user can couple the cannula 3388 to, for example, a fluid reservoir such as those described herein, which in turn, can exert a suction force (e.g., in response to a negative pressure differential) through the cannula 3388 and the hub 3320. Therefore, when the cannula 3322A is in fluid communication with the body of a patient (e.g., either directly or indirectly via an intervening structure), a volume of, for example, blood can be withdrawn with a reduced amount of hemolysis. Specifically, the alignment of the lumen 3324 defined by the hub 3320 and the lumen of the cannula 3388, for example, can reduce turbulence, eddy currents, and/or any other disturbance that can otherwise result from a discontinuity or the like. Thus, the flow of blood therethrough can be substantially laminar and substantially free of hemolysis.

[1240] Although the embodiments are shown and described above as mitigating the risk of hemolysis of a volume of blood at a given point along a fluid flow path between a patient and a fluid reservoir, any embodiment configured to mitigate the risk of hemolysis at a given point along the fluid flow path can be used in conjunction with any suitable embodiment(s) configured to mitigate the risk of hemolysis at a different point along the fluid flow path. In some instances, a fluid transfer device can include any combination of the embodiments described herein, for example, to mitigate the risk of hemolysis otherwise associated with (1) blood flow from, for example, a vein into a puncture member, needle, cannula, and/or the like; (2) blood flow through changing geometries and/or physical and fluidic interfaces; (3) blood flow rates, pressures, and/or velocities within the fluid flow path; (4) blood flow from an adapter, puncture member, needle, cannula, and/or the like into a fluid reservoir; (5) blood

flow exposure to a negative pressure differential within a fluid reservoir; and/or (6) blood flow through a multi-lumen adapter and/or the like.

[1241] While the embodiments are shown and described above as mitigating the risk of hemolysis of a volume of blood during, for example, aspiration, blood draw, and/or any other procedure in which blood is withdrawn from the body, in other instances, any embodiment configured to mitigate the risk of hemolysis described herein, and/or any combination thereof, can be used in any suitable medical device and/or procedure in which it is desirable to reduce hemolysis. For example, any of the embodiments or combinations of the embodiments described herein such as the adapters, puncture members, restrictors, fluid reservoirs, gaskets, etc., and/or characteristics, geometries, and/or features thereof can be used to mitigate the risk of hemolysis in any suitable device and/or during any suitable medical procedure. Such devices and/or procedures can include but are not limited to, mechanical hearts and/or other organs, perfusion machines used, for example, during open-heart surgery, dialysis machines, and/or the like. In some instances, the embodiments and/or combination of embodiments described herein can be used to modulate pressure within such devices, produce a laminar flow through at least a portion of such devices, reduce and/or limit shear stress and/or exposure time experienced by red blood cells, and/or the like.

[1242] Although not shown or described herein, any of the embodiments can be used in a fluid transfer device configured to, for example, divert a predetermined pre-sample volume of bodily-fluid that can contain, for example, externally residing microbes prior to collection of a sample volume of bodily. For example, in some embodiments, the predetermined pre-sample volume can be about a drop or a few drops of blood, about 0.1 mL, about 0.3 mL, about 0.5 mL, about 1.0 mL, about 2.0 mL, about 3.0 mL, about 4.0 mL, about 5.0 mL, about 11.0 mL, about 20 mL, about 50 mL, and/or any volume or fraction of a volume therebetween. In other embodiments, the pre-sample volume can be greater than 50 mL or less than 0.1 mL. In other embodiments, 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 about 3 mL. In some instances, a venipuncture event can result in trauma to the blood flowing within the punctured vein that can at least temporarily hemolyze a portion of the blood. Thus, in some embodiments, the diverted pre-sample volume of blood can include, for example, the hemolyzed portion of the blood. Furthermore, by collecting the

predetermined pre-sample volume, the predetermined sample volume disposed in one or more sample reservoirs can be substantially free-from externally residing microbes.

[1243] Fluid transfer devices configured to divert a predetermined pre-sample volume of bodily-fluid can be any suitable configuration. For example, in some embodiments, such a fluid transfer device can be substantially similar to or the same as the fluid transfer devices described in U.S. Patent No. 8,535,241 entitled, "Fluid Diversion Mechanism for Bodily-Fluid Sampling," filed October 12, 2012; U.S. Patent No. 9,060,724 entitled, "Fluid Diversion Mechanism for Bodily-Fluid Sampling," filed May 29, 2013; U.S. Patent No. 9,155,495 entitled, "Syringe-Based Fluid Diversion Mechanism for Bodily-fluid Sampling," filed December 2, 2013; and/or U.S. Patent Publication No. 2014/0155782 entitled, "Sterile Bodily-Fluid Collection Device and Methods," filed December 4, 2012, the disclosures of which are incorporated herein by reference in their entireties and attached hereto as Exhibit A, Exhibit B, Exhibit C, and Exhibit D, respectively. Moreover, in some embodiments, such transfer devices can be configured to selectively obstruct a needle to prevent hemolyzed blood from entering a lumen defined by the needle during a venipuncture event. Such devices can be substantially similar to and/or the same as those described in U.S. Patent Publication No. 2014/0276578, entitled, "Methods and Apparatus for Selectively Occluding the Lumen of a Needle," filed September 18, 2014, the disclosure of which is incorporated herein by reference in its entirety and attached hereto as Exhibit E.

[1244] In some embodiments, the bodily-fluid transfer devices described herein can include and/or can be partially formed from antisepsis-saturated materials. For example, any of the valves, gaskets, seals, ports, and/or the like can be saturated with, for example, isopropyl alcohol. As such, when various components of a fluid transfer device are coupled and/or otherwise collectively form an interface, the components can be contemporaneously sterilized. In some embodiments, such a device can be substantially similar to or the same as those described in U.S. Patent Publication No. 2015/0246352 entitled, "Apparatus and Methods for Disinfection of a Specimen Container," filed March 3, 2015, the disclosure of which is incorporated herein by reference in its entirety and attached as Exhibit F.

[1245] While the device 100 is described above as including a surface, mechanism, portion, etc. configured to reduce hemolysis of a volume of blood in a mechanical manner (e.g., by mechanically changing one or more characteristics of a flow of blood within a fluid flow path), in other embodiments, any of the devices can be configured to chemically modify

one or more characteristics associated with the volume of blood. For example, in some embodiments, an inner surface of any of the embodiments described herein can be coated with a chemical configured to limit lysis of erythrocytes (red blood cells) by strengthening or weakening a cell wall of the erythrocytes. More specifically, in some embodiments, a can be configured to introduce a chemical into a flow of blood that can, for example, increase a rigidity of the cell wall of erythrocytes (e.g., decrease flexibility), which in turn, can reduce a likelihood of lysis of the erythrocytes (e.g., hemolysis of the blood) as the blood flows through the device. In other embodiments, a device can be configured to introduce a chemical into a flow of blood that can, for example, decrease a rigidity of the cell wall of erythrocytes (e.g., increase flexibility), which in turn, can reduce a likelihood of lysis of the erythrocytes as the blood flows through the device.

[1246] While described above as coating an inner surface of a device with the chemical configured to modify a characteristic of the cell wall of the erythrocytes, in other embodiments, any of the embodiments described herein can include any suitable device, mechanism, and/or method for introducing such a chemical to the volume of blood flowing therethrough. For example, a device can include a chamber containing such a chemical (e.g., a chamber within a Luer lock or the like), a baffle, wipe, valve, porous material (e.g., sintered glass or plastic), etc. impregnated with such a chemical, a dispensing or dispersing device (e.g., sprayer or the like) configured to dispense a volume of such a chemical, and/or any other suitable means for introducing such a chemical. Moreover, a device can include any suitable combination of devices, interfaces, members, mechanisms, etc. included in the embodiments described herein as well as any suitable means for introducing a chemical into a volume of blood flowing through such a device.

[1247] As described above, in some instances, introducing a chemical into a volume of blood (e.g., whole blood) can result in a strengthening of an erythrocyte membrane or outer structure, or in other words, can modify a magnitude of stability associated with the erythrocyte membrane. In some instances, such stabilization can result in an increased resistance to hemolysis caused by mechanical stress, osmotic stress, peroxyl radicals attack, heat, and/or the like. Examples of chemicals that can modify a characteristic associated with an erythrocyte membrane include phloridzin, cremophore (glycerol polyethylene glycol ricinoleate, lidocaine, antioxidants such as reduced glutathione (GSH), N-acetylcysteine, ebselen (2-phenyl-1, 2-benzoselenazol-3-one) and/or albumin, papaya leaf and/or other plant

extracts, tranquilizers and/or antihistamines such as phenothiazine, reserpine, and/or haloperidol, saponins and/or sapogenins, polyamines, anti-inflammatory drugs such as phenylbutazone, methylsergide, and/or indomethacin, and/or any other suitable chemical.

[1248] While various embodiments have been particularly shown and described, various changes in form and details may be made. While embodiments have been described above, it should be understood that they have been presented by way of example only, and not limitation. 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, in some embodiments, a restrictor such as, for example, the restrictor 650 can be used when collecting a bodily-fluid using any of the fluid reservoirs described herein. Similarly, the hub 3020 and lumen-defining device 3080 described above with reference to FIGS. 61-63 can be used with any of the adapters described herein. Moreover, any suitable combination of components described herein can be physically and/or fluidically coupled together to form a bodily-fluid collection device configured, for example, to reduce hemolysis in a withdrawn volume of blood.

[1249] 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. While various components have been described above a being physically and fluidically coupled, in other embodiments, any of the devices and/or embodiments can be, for example, monolithically formed with and/or otherwise joined to any other suitable device and/or embodiment. For example, while the first adapter 1020, the second adapter 1030, and the restrictor 1050 are described above with reference to FIGS. 18-20 as being formed separately and subsequently coupled, in other embodiments, the first adapter 1020 and/or the second adapter 1030 can be monolithically formed with the restrictor 1050. In some instances, such a monolithically formed component can be included in, for example, a pre-assembled and sterile blood collection device and/or the like.

[1250] Where methods and/or events described above indicate certain events and/or procedures occurring in certain order, the ordering of certain events and/or procedures may

be modified. Additionally, certain events and/or procedures may be performed concurrently in a parallel process when possible, as well as performed sequentially as described above.

Abstract

A collection system has a proximal end portion, a distal end portion, and an inner surface defining a fluid flow path therethrough. The distal end portion is configured to be placed in fluid communication with a patient. The proximal end portion is configured to be placed in fluid communication with a fluid reservoir. The fluid flow path defined by the inner surface is associated with at least one flow characteristic configured to limit a stress within the flow of the bodily-fluid between the distal end portion and the proximal end portion.

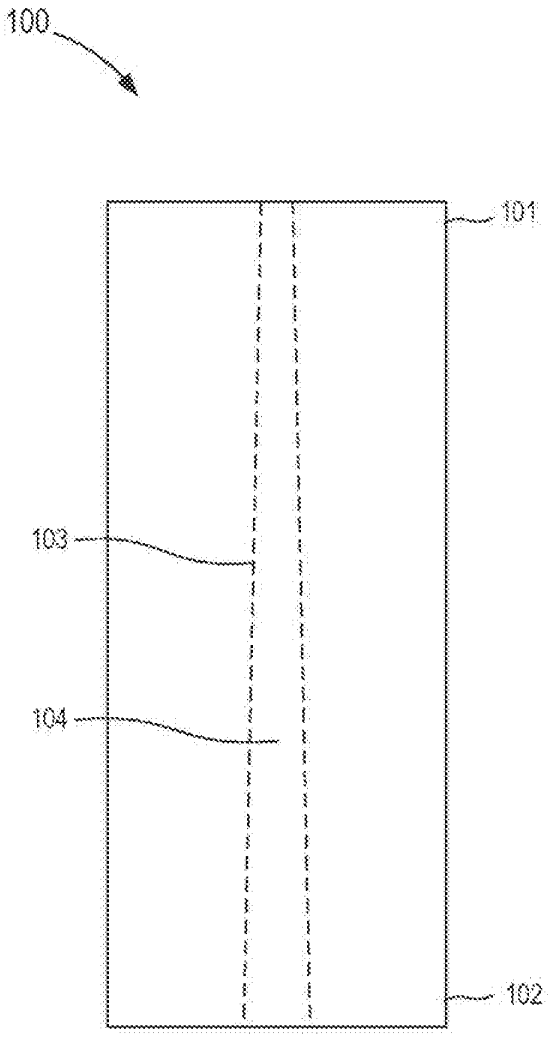


FIG. 1

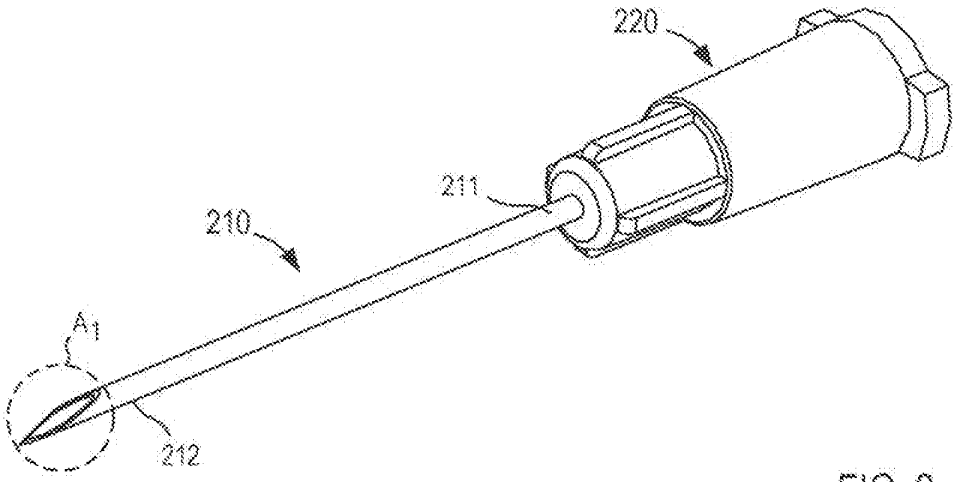


FIG. 2

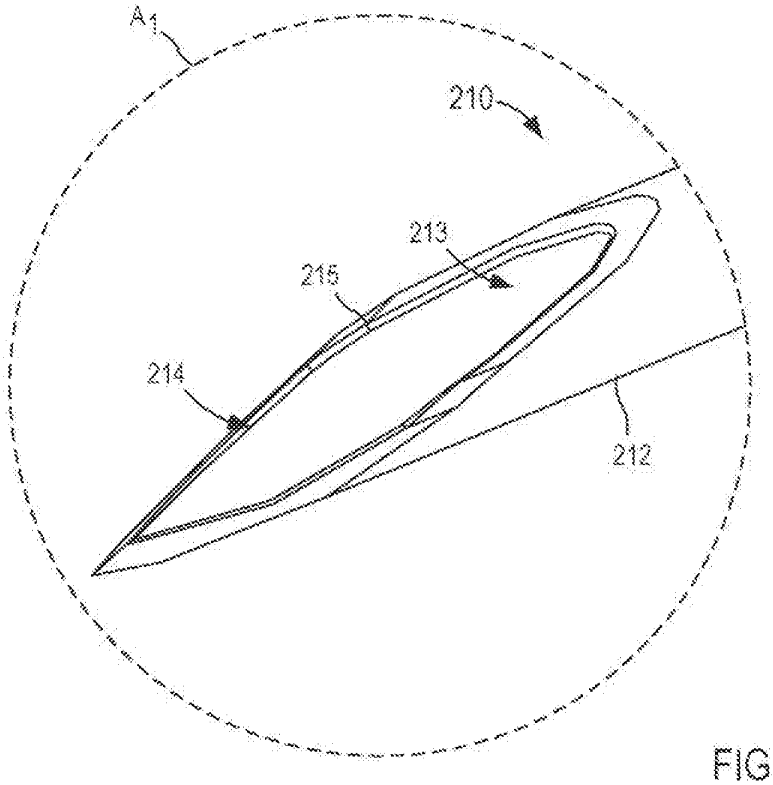


FIG. 3

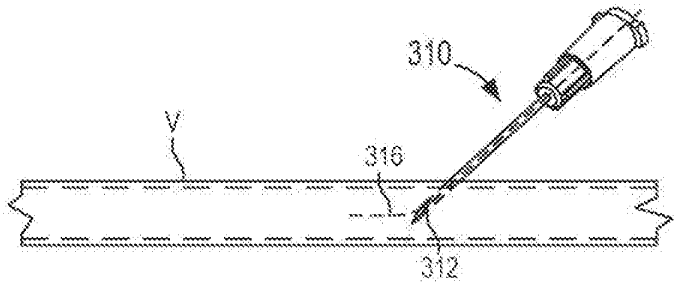


FIG. 4

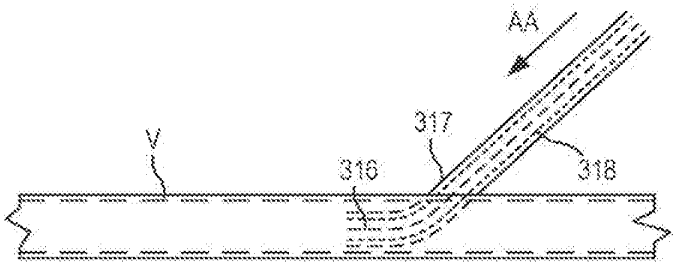


FIG. 5

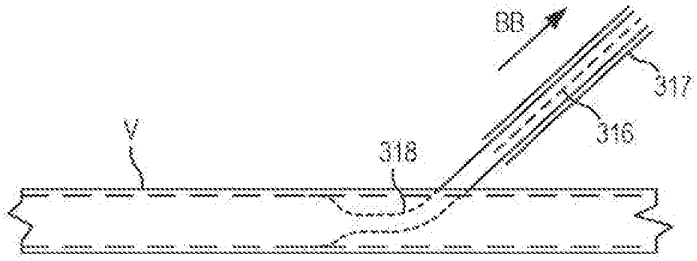


FIG. 6

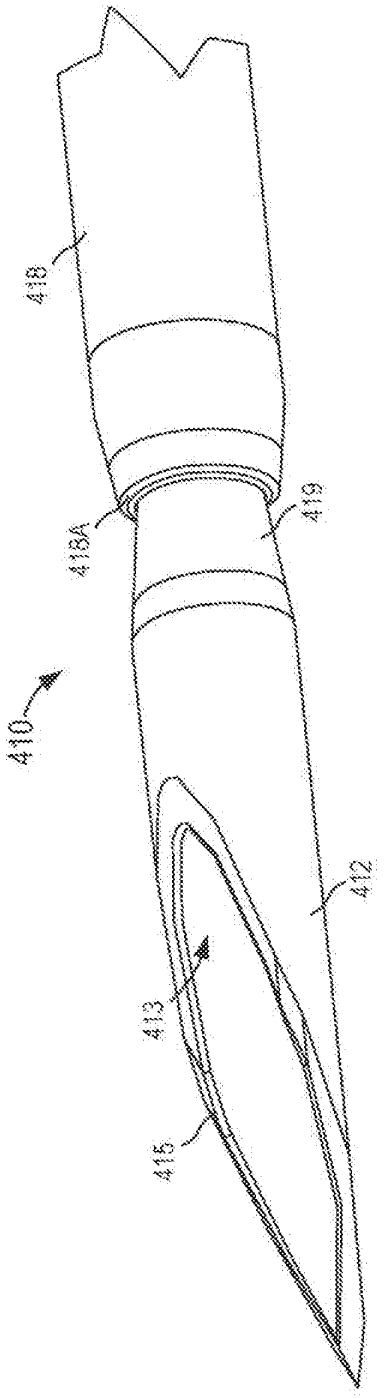


FIG. 7

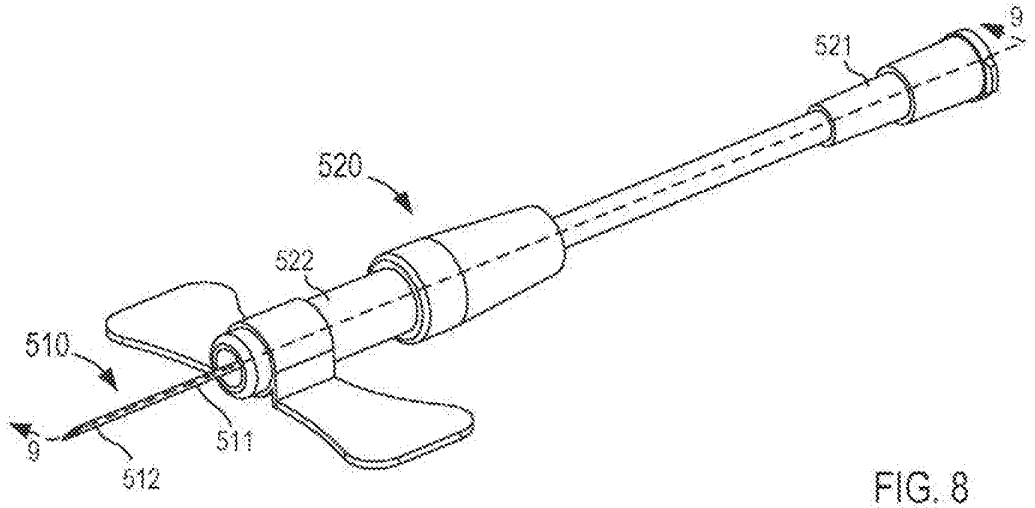


FIG. 8

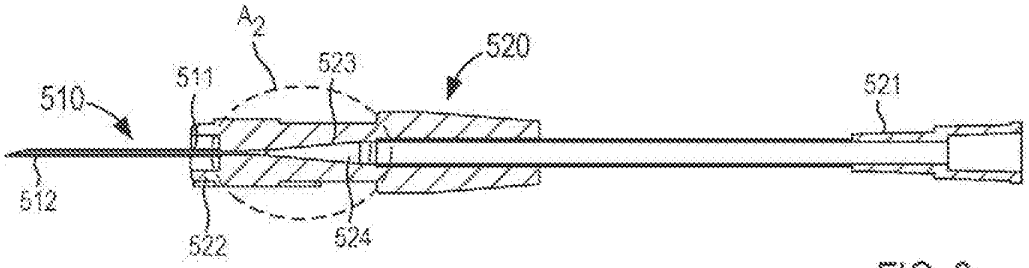


FIG. 9

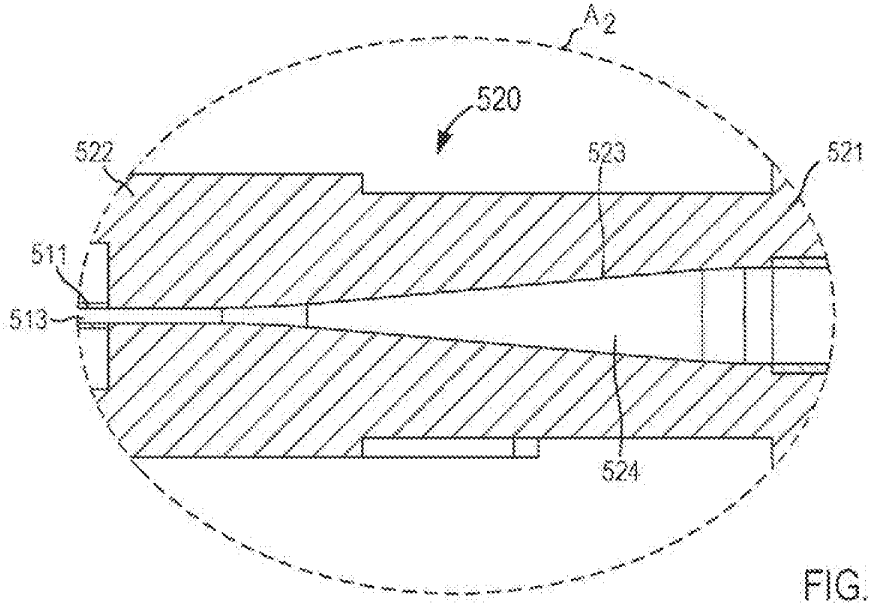


FIG. 10

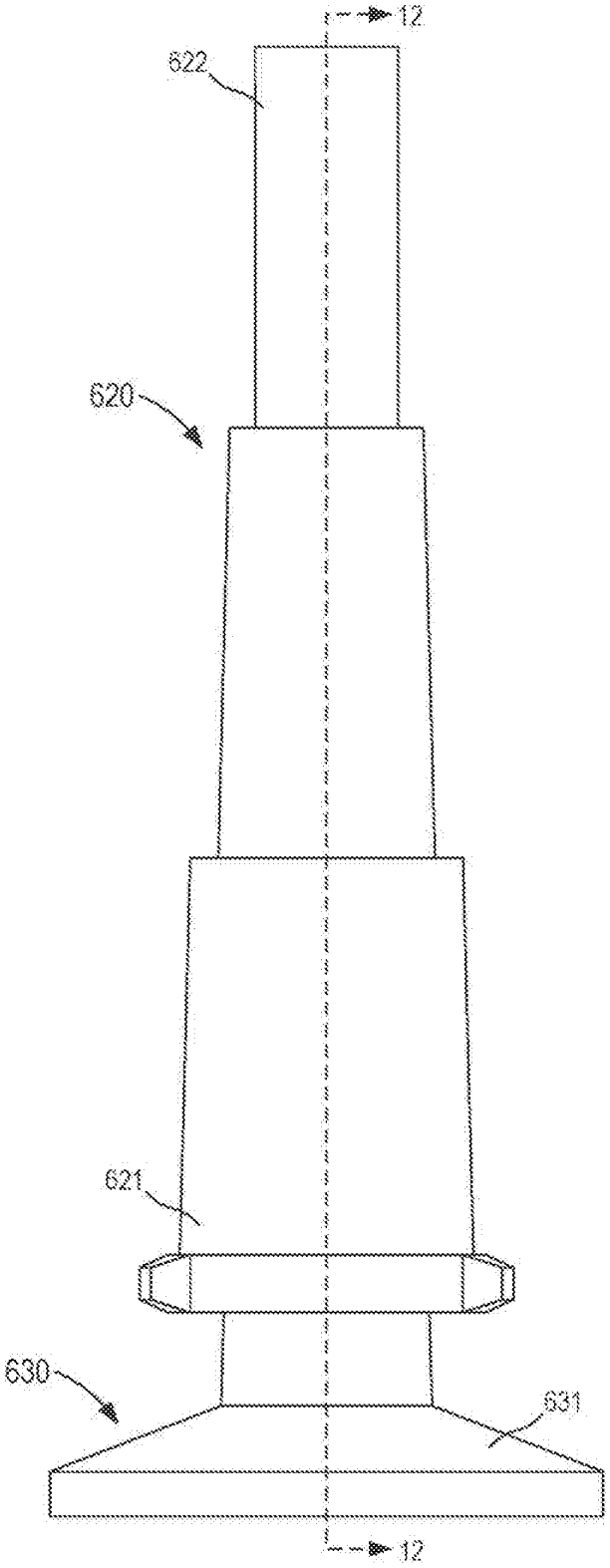


FIG. 11

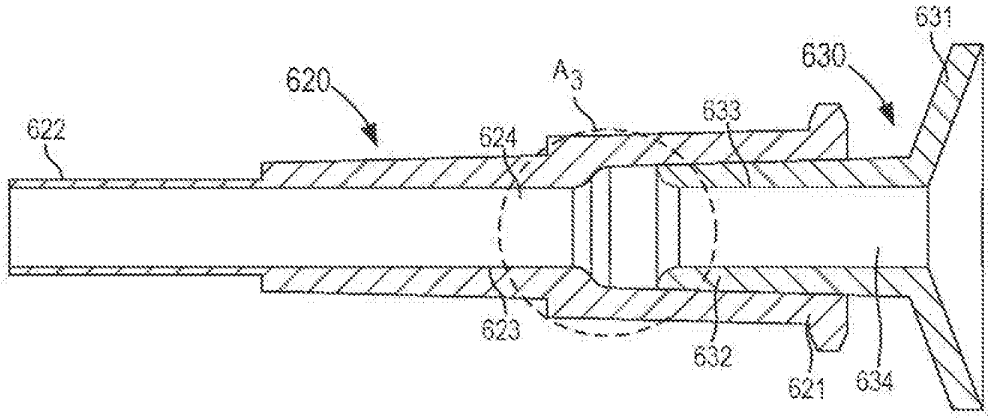

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FIG. 12

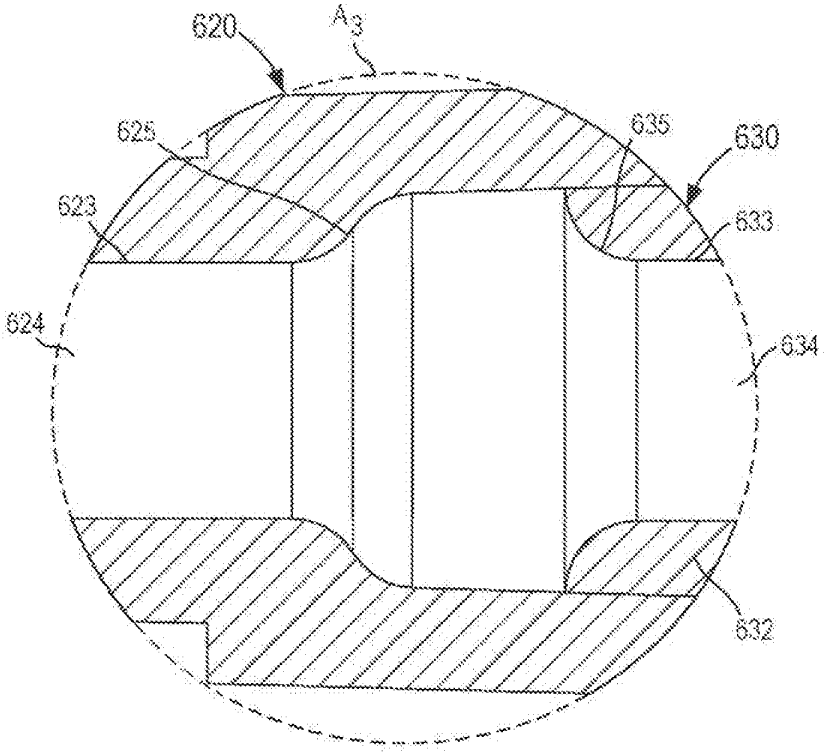

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FIG. 13

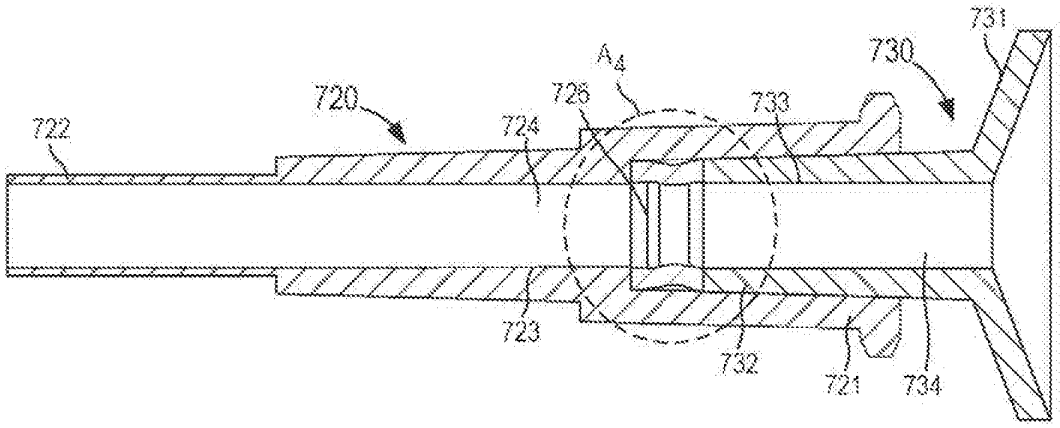

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FIG. 14

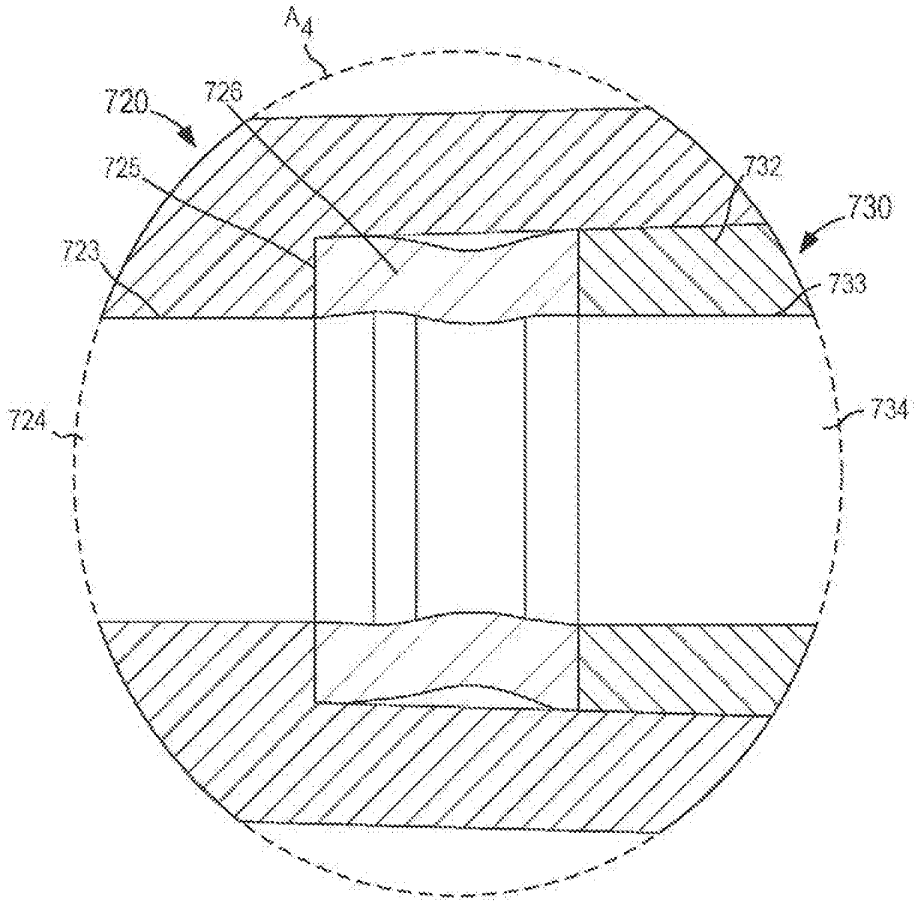

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FIG. 15

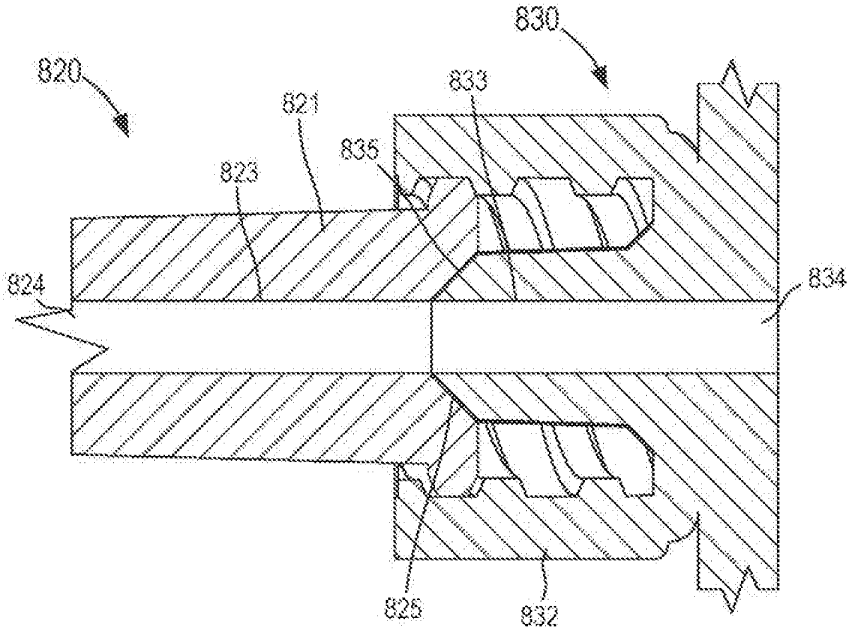

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FIG. 16

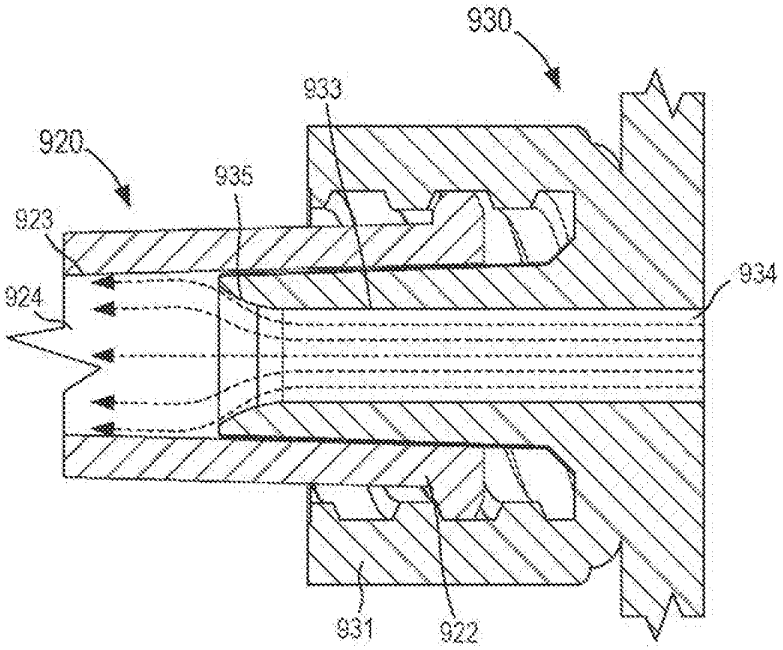

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FIG. 17

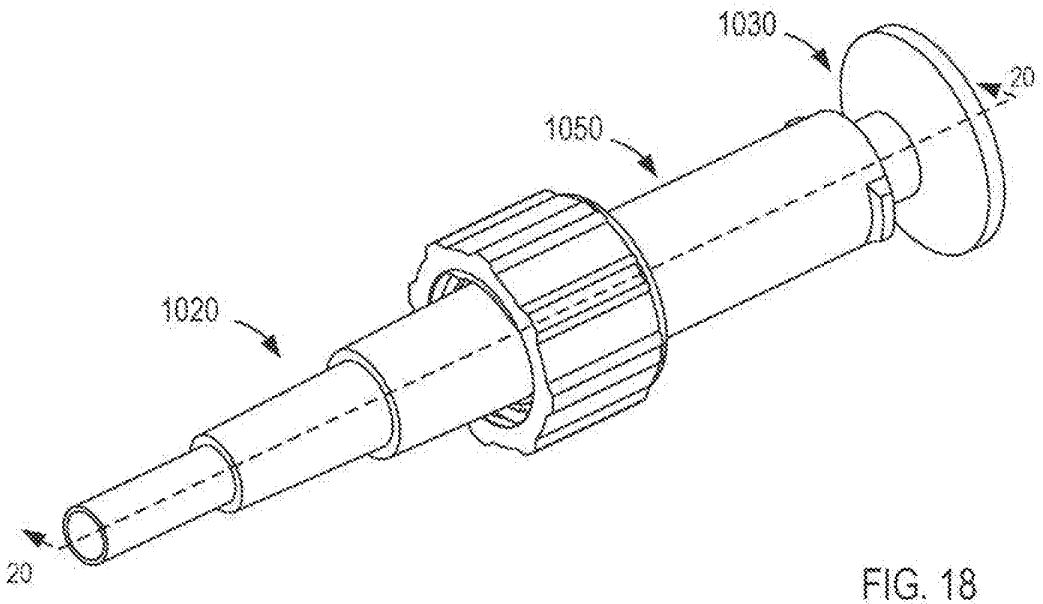

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FIG. 18

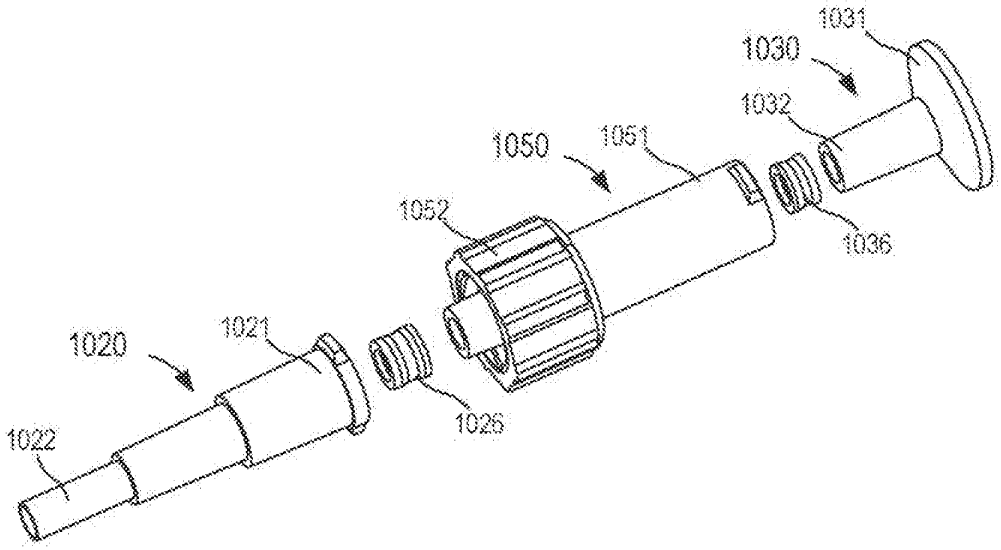

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FIG. 19

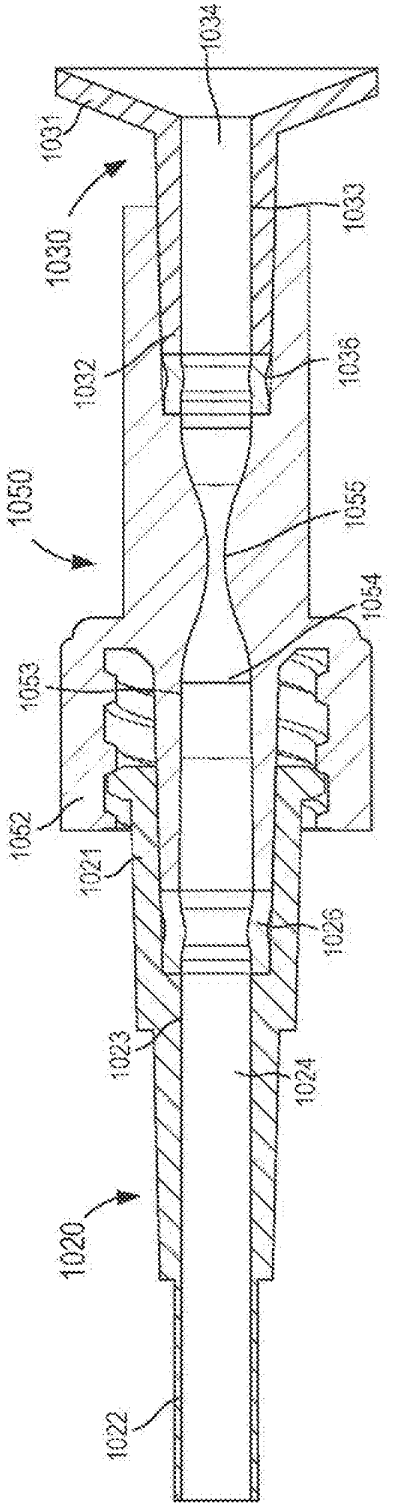

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FIG. 20

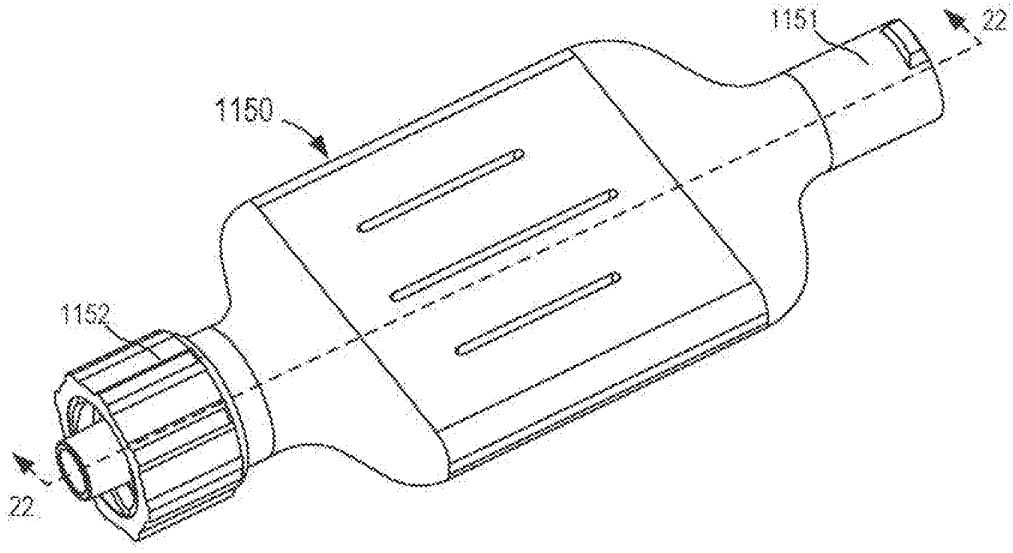


FIG. 21

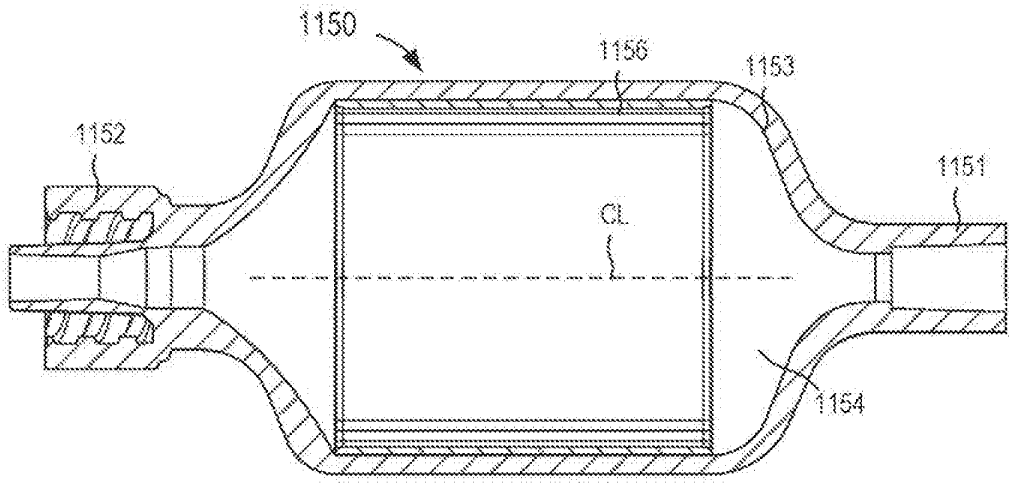


FIG. 22

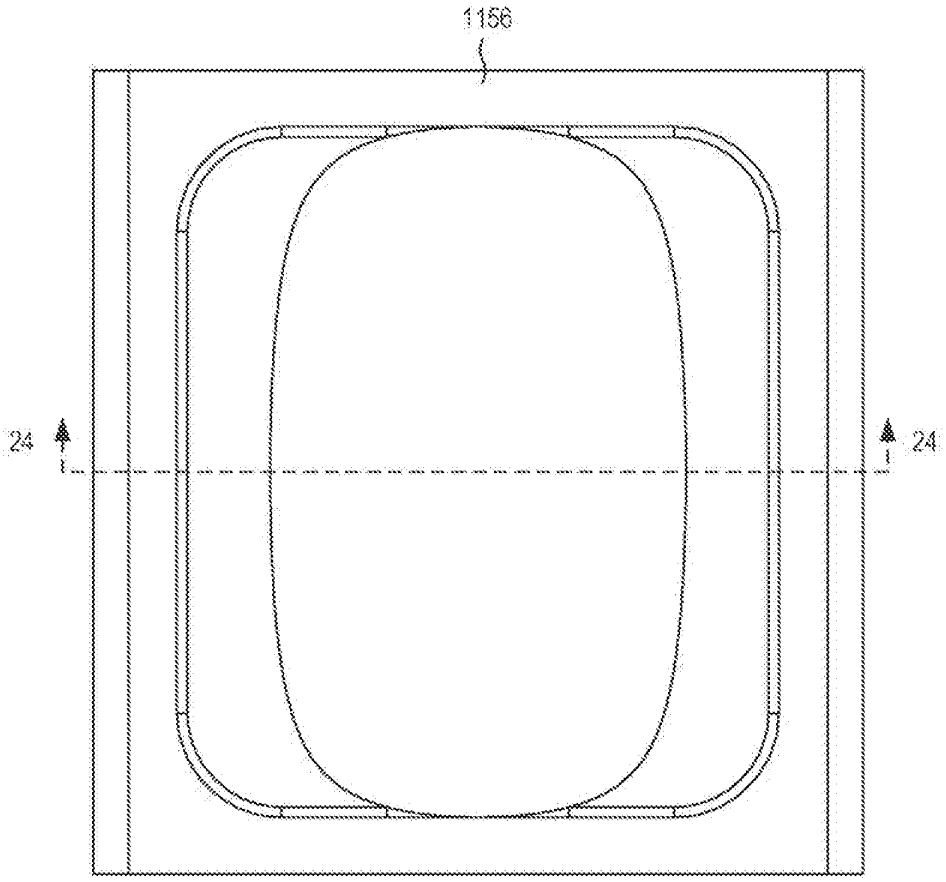


FIG. 23

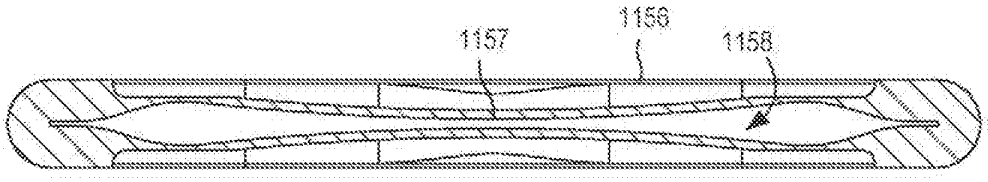


FIG. 24

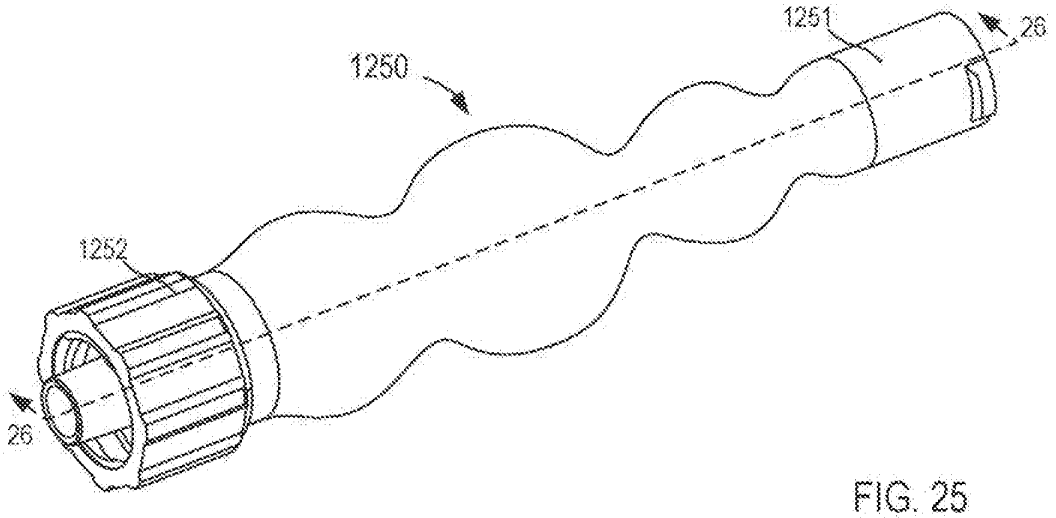

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FIG. 25

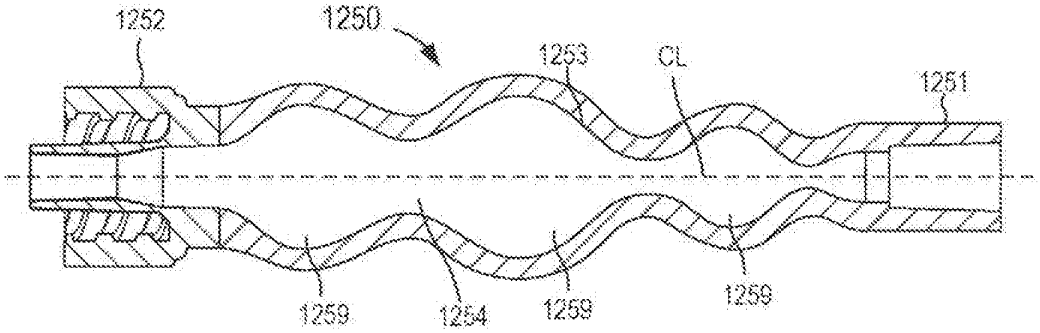

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FIG. 26

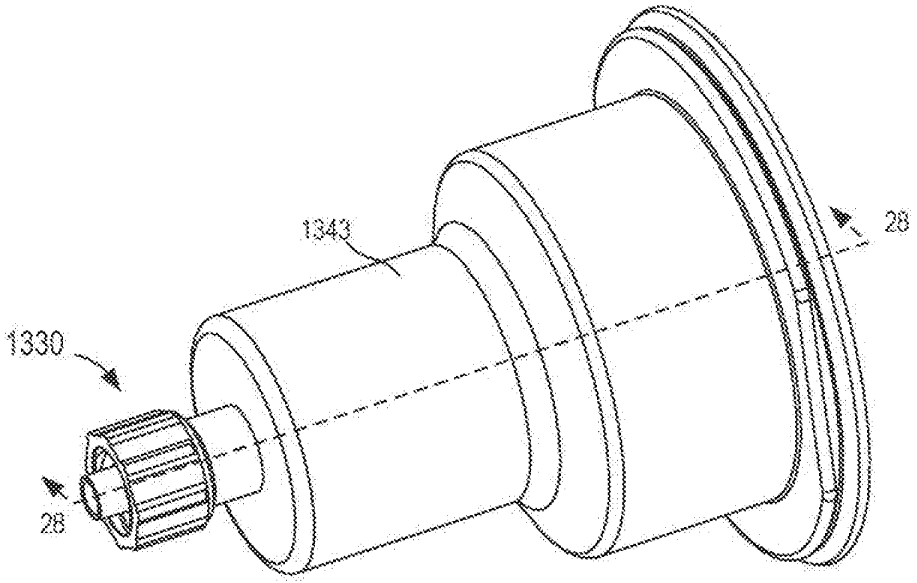


FIG. 27

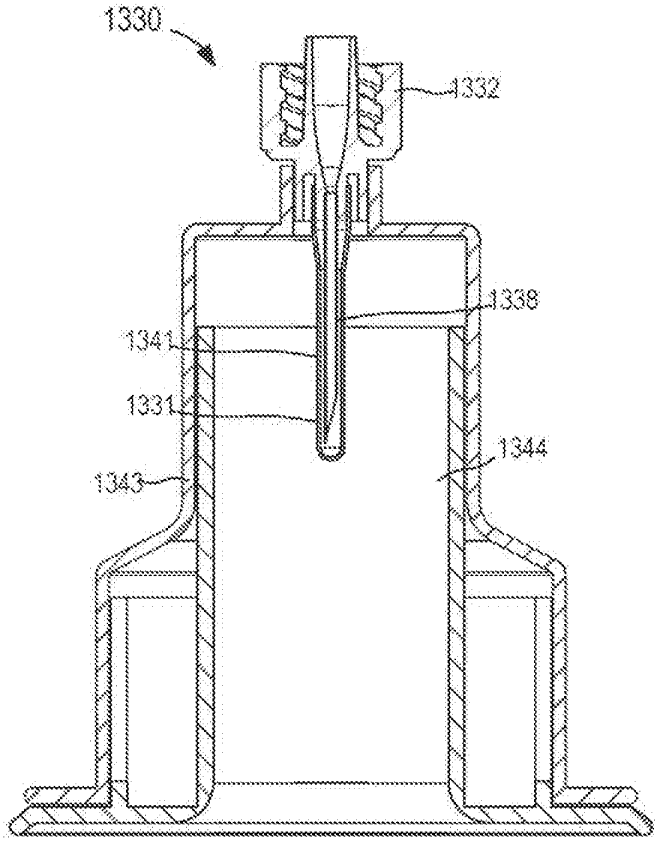


FIG. 28

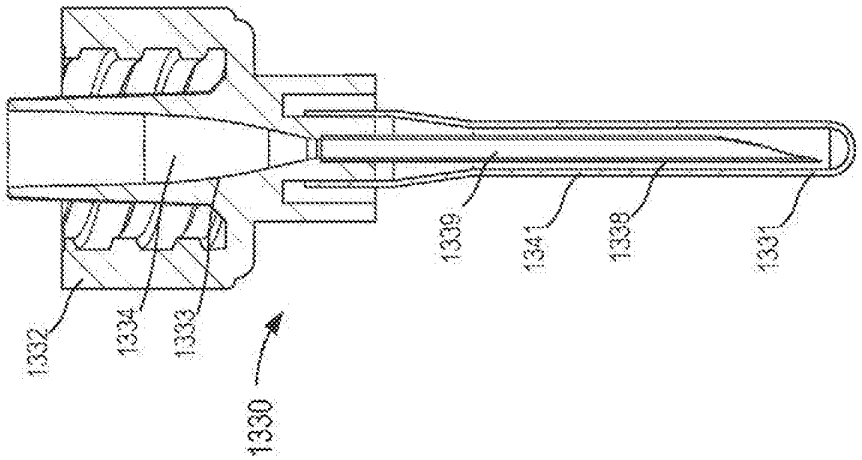


FIG. 30

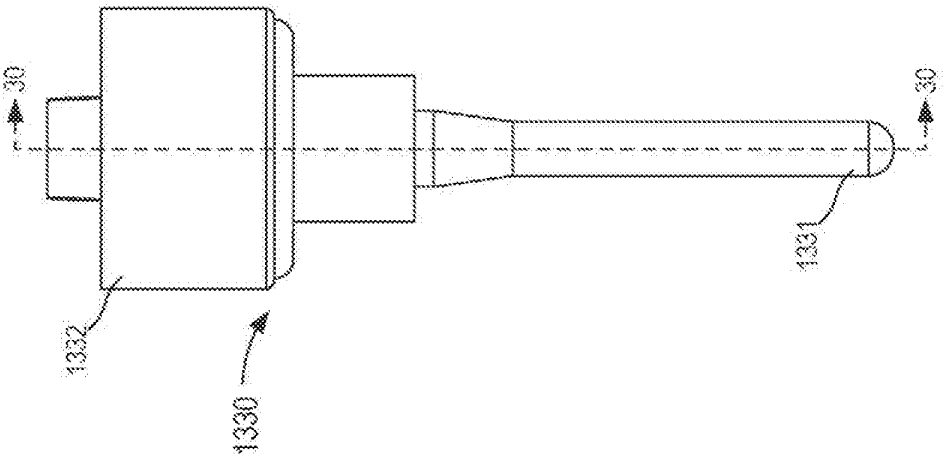


FIG. 29

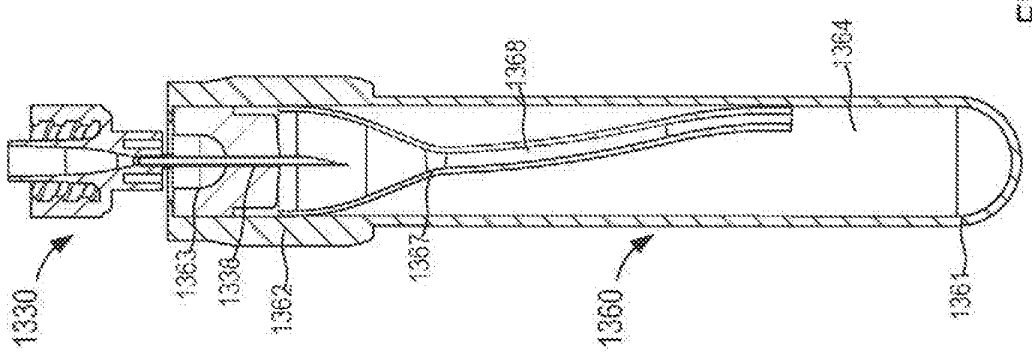


FIG. 33

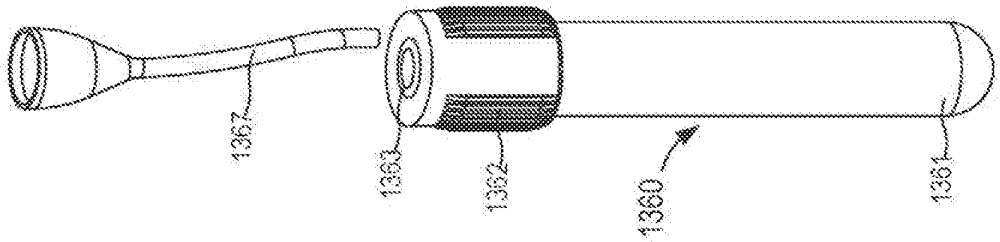


FIG. 32

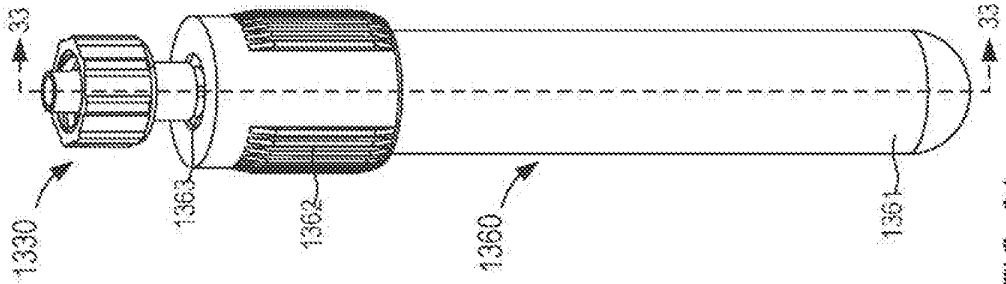


FIG. 31

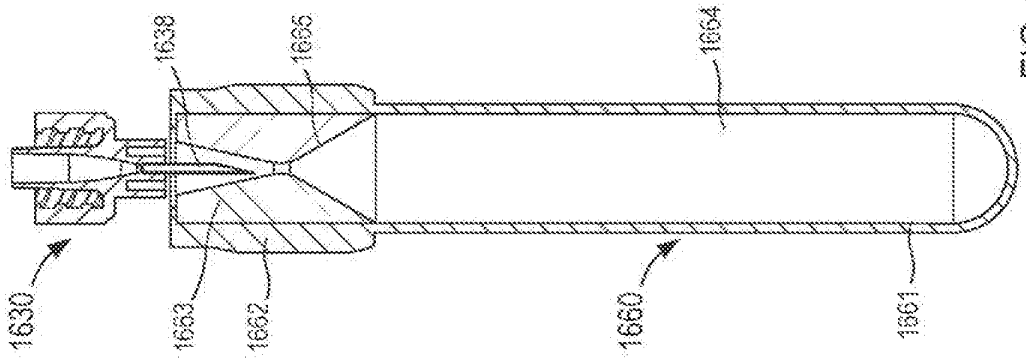


FIG. 36

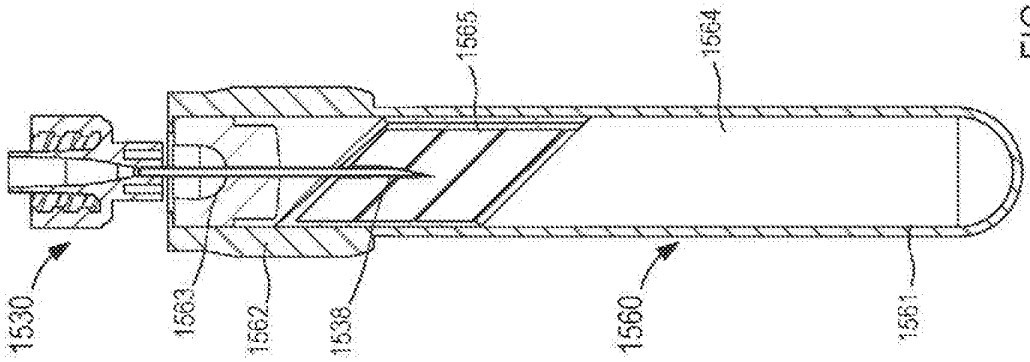


FIG. 35

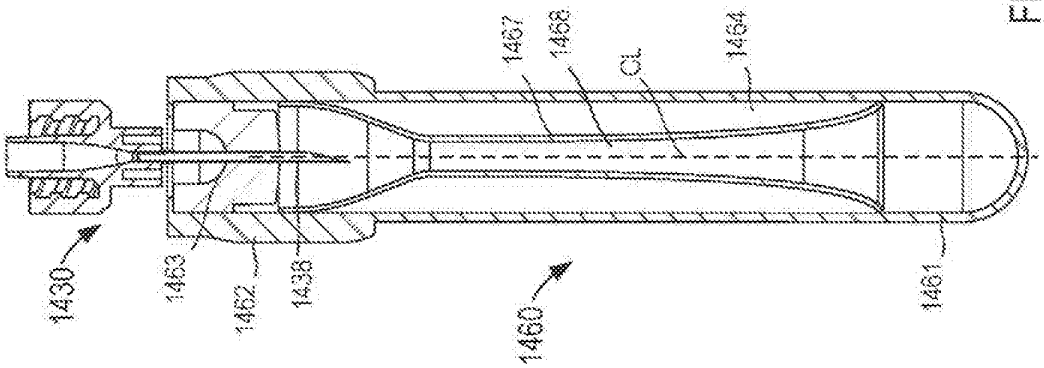


FIG. 34

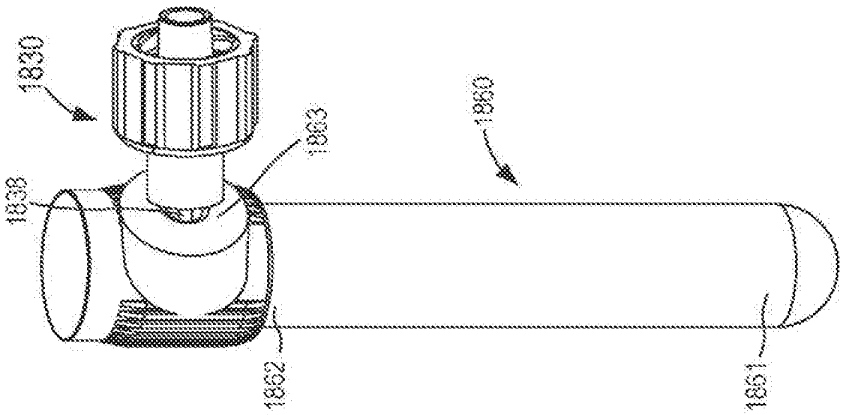


FIG. 39

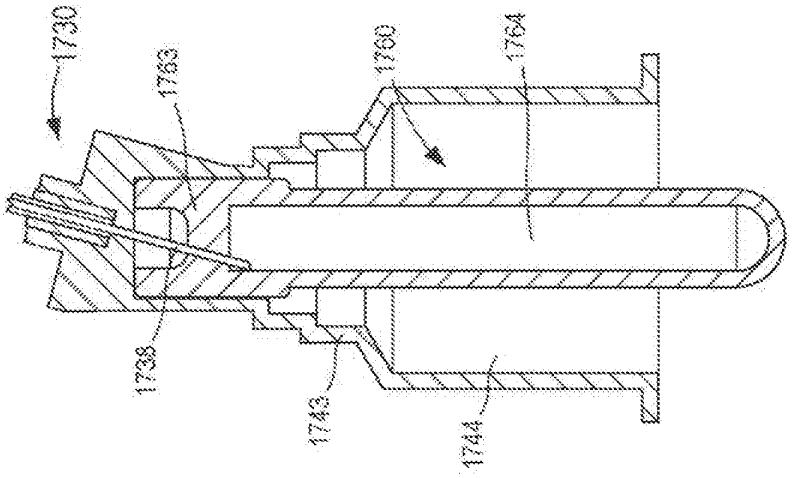


FIG. 38

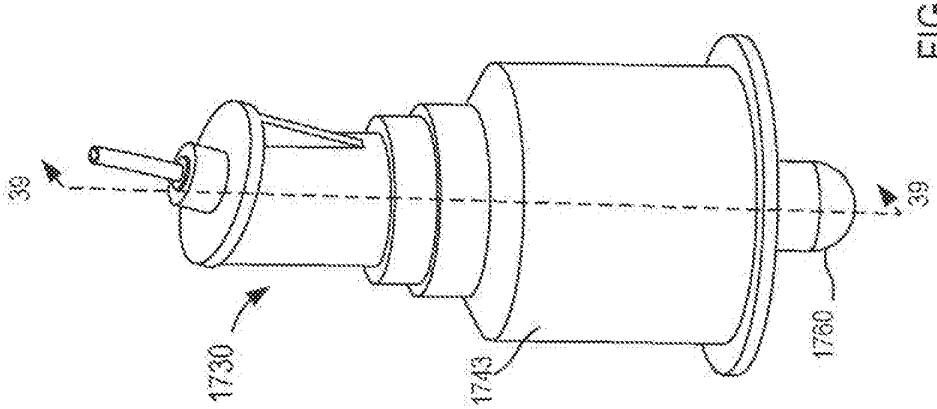


FIG. 37

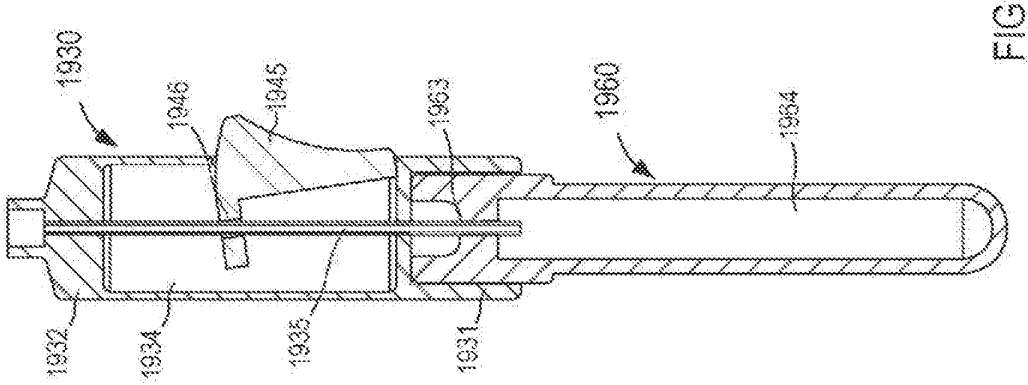


FIG. 42

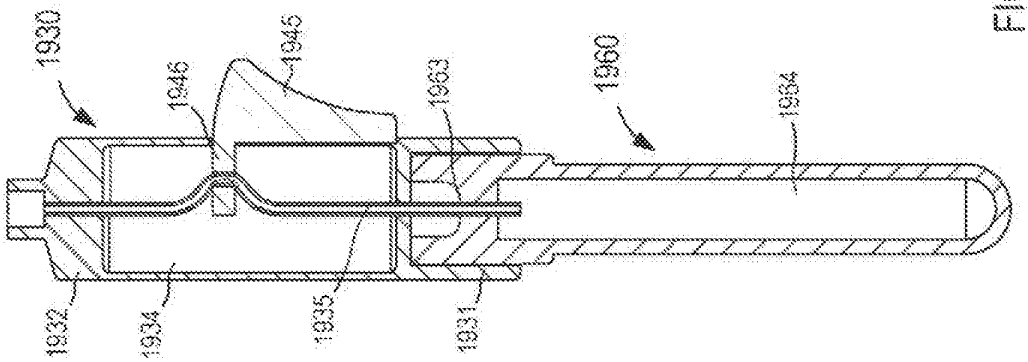


FIG. 41

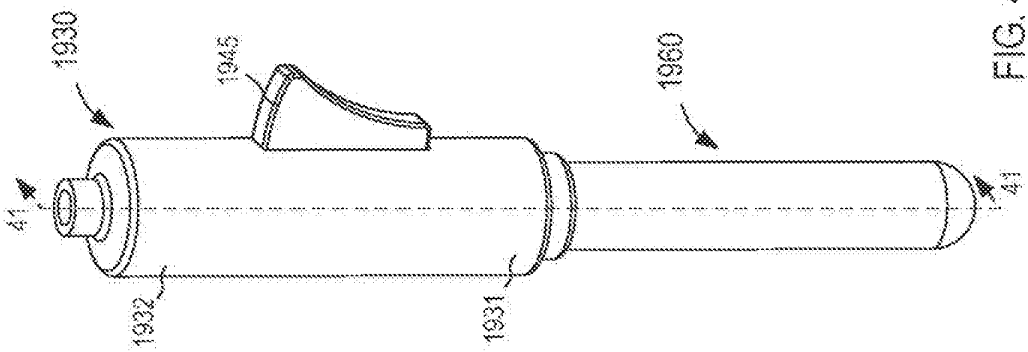


FIG. 40

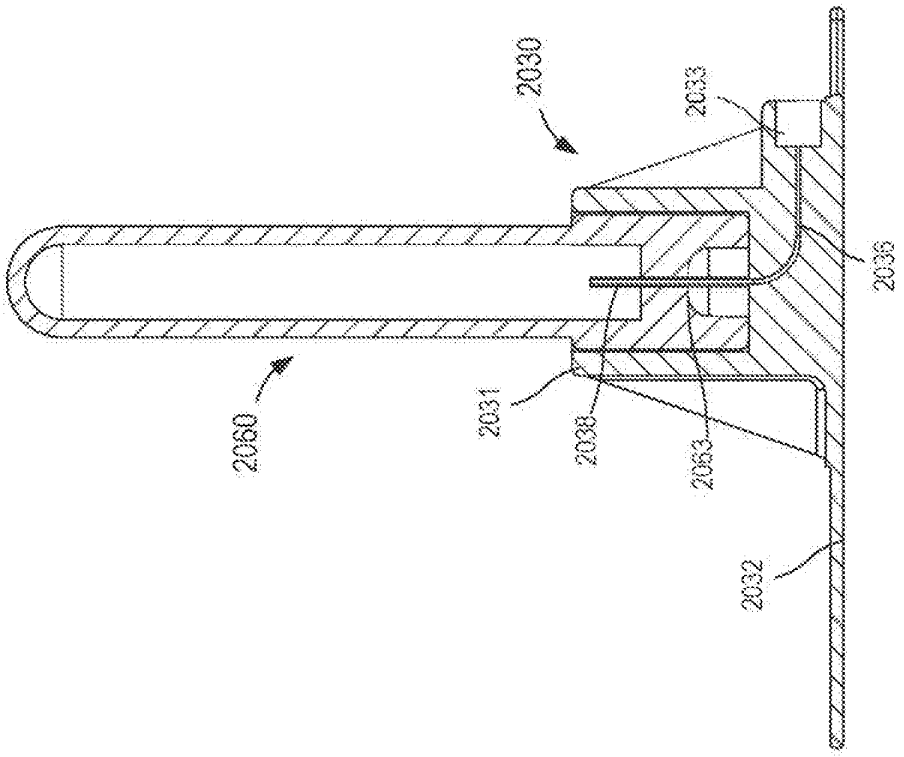

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FIG. 44

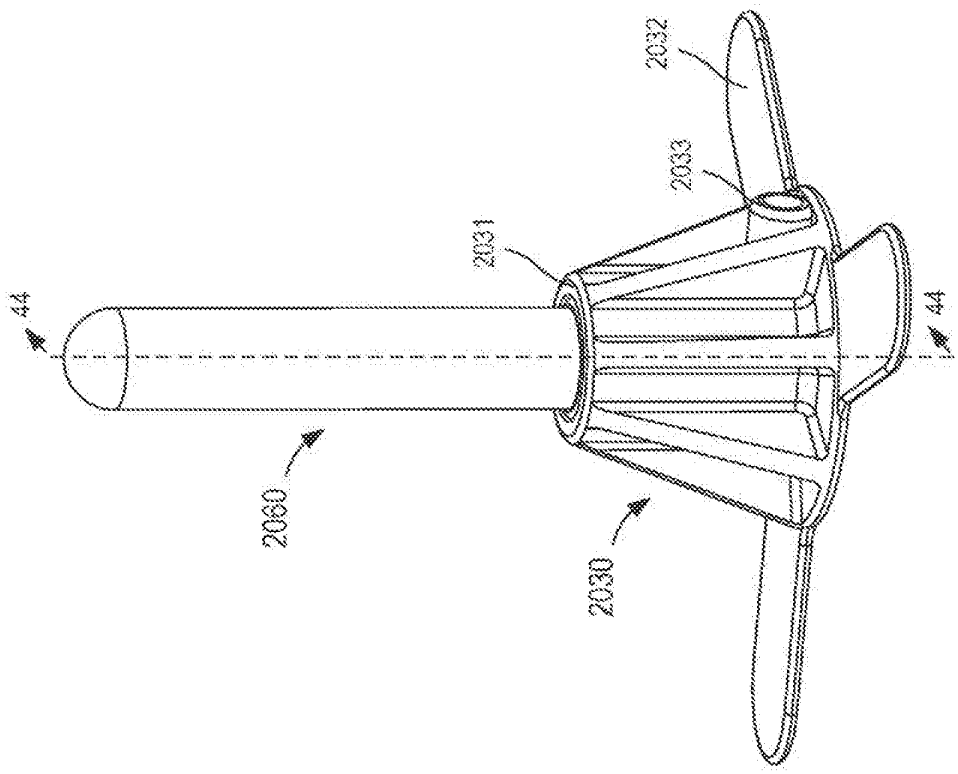

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FIG. 43

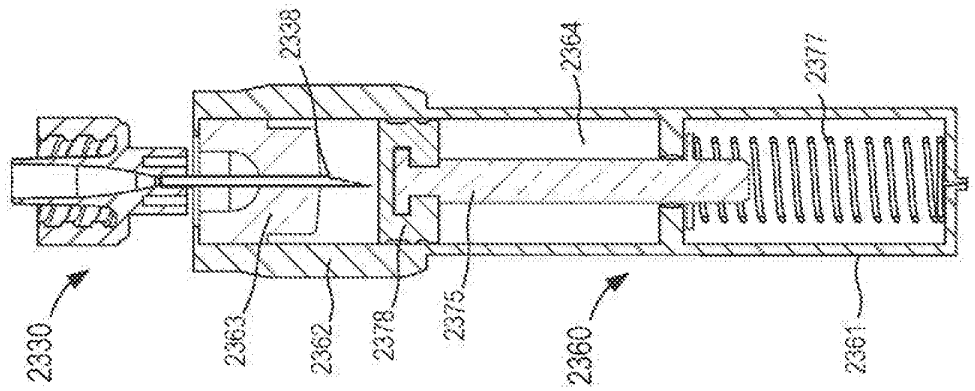


FIG. 47

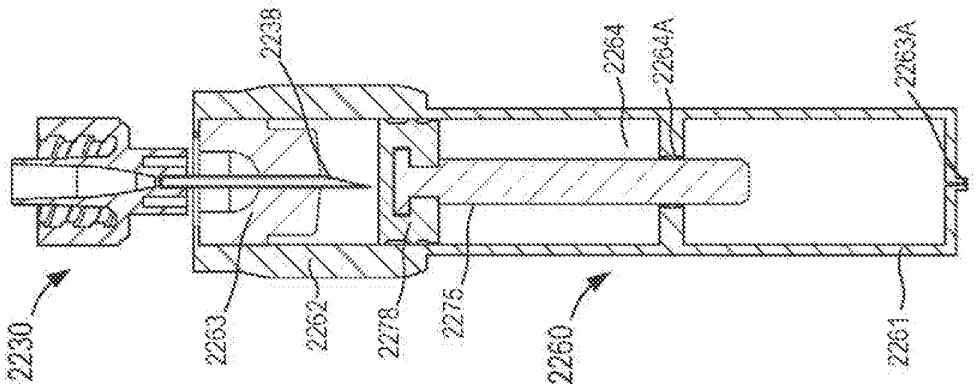


FIG. 46

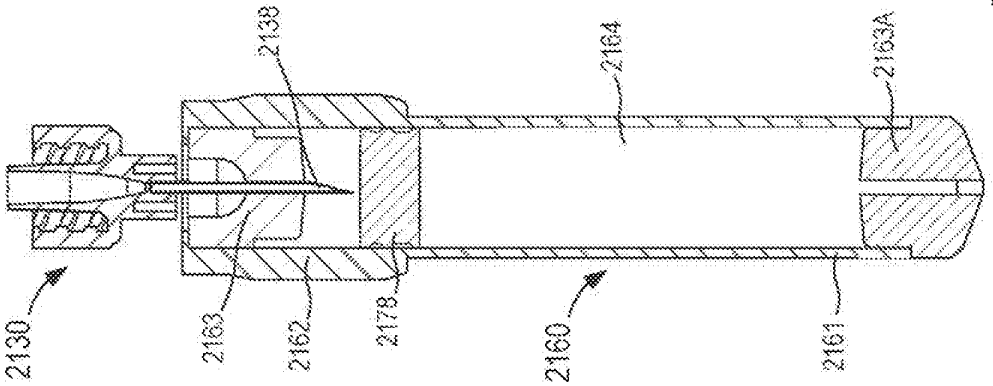


FIG. 45

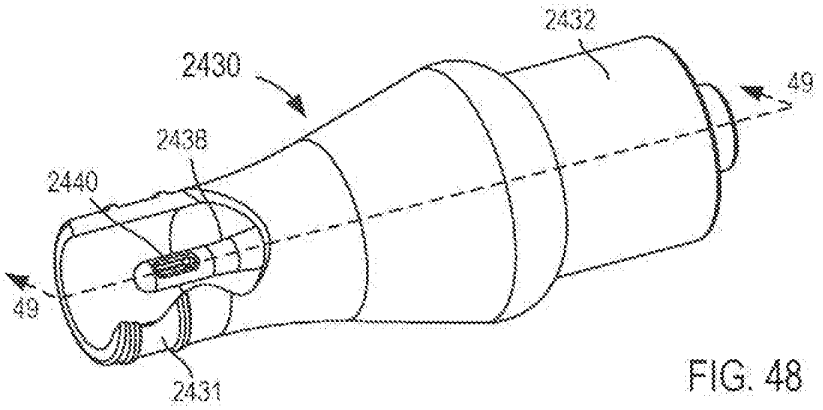


FIG. 48

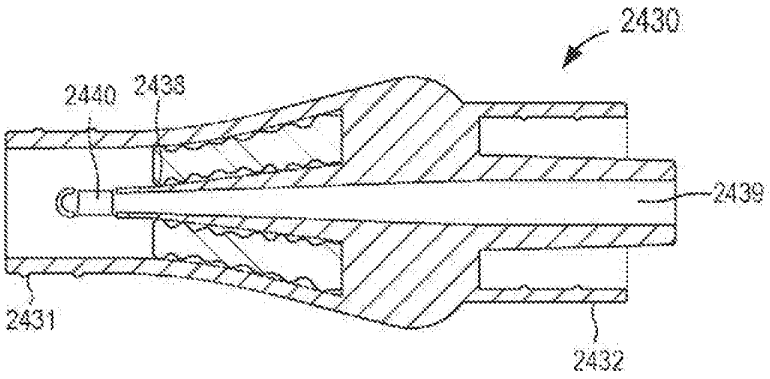


FIG. 49

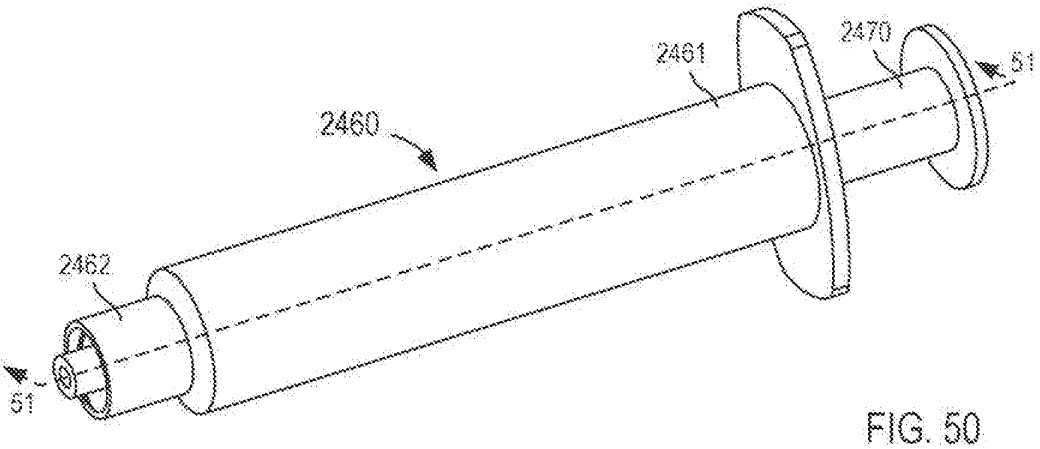


FIG. 50

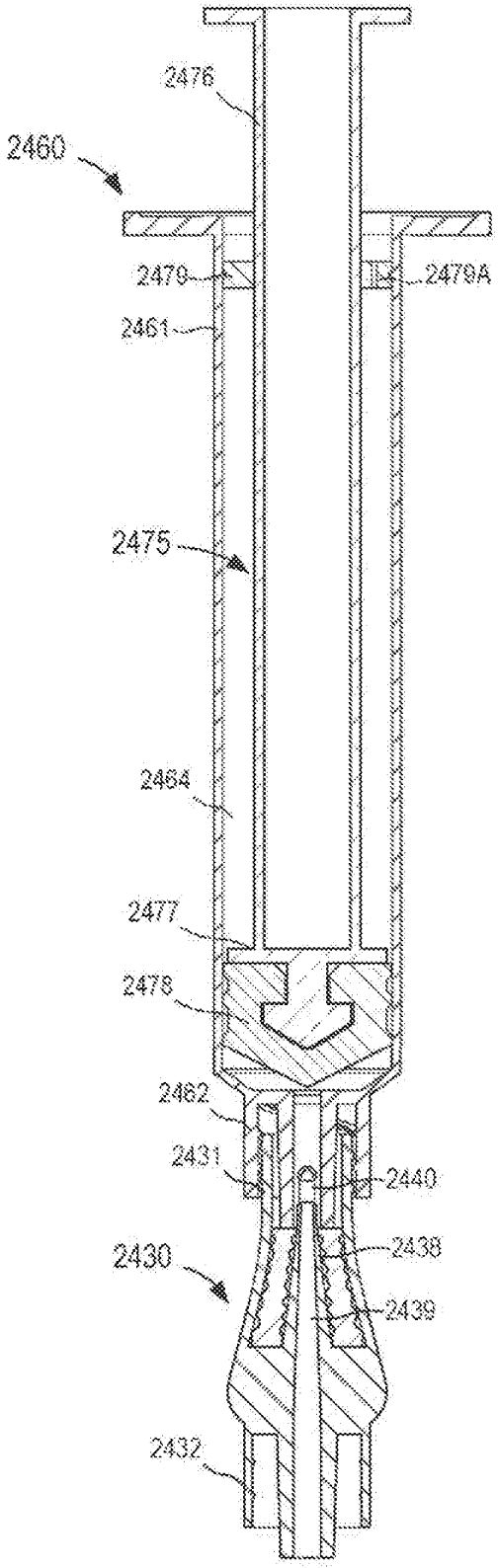

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FIG. 51

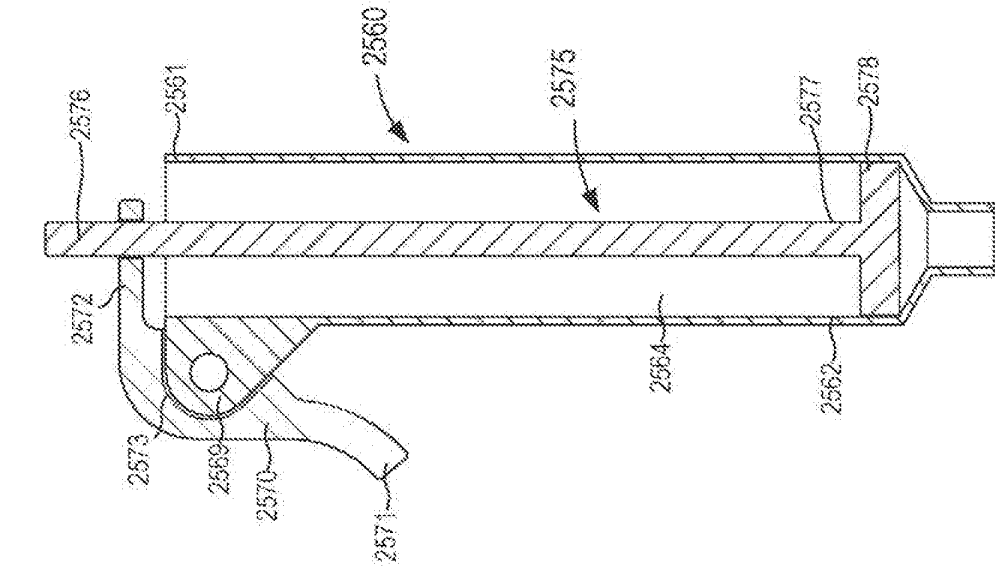

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FIG. 53

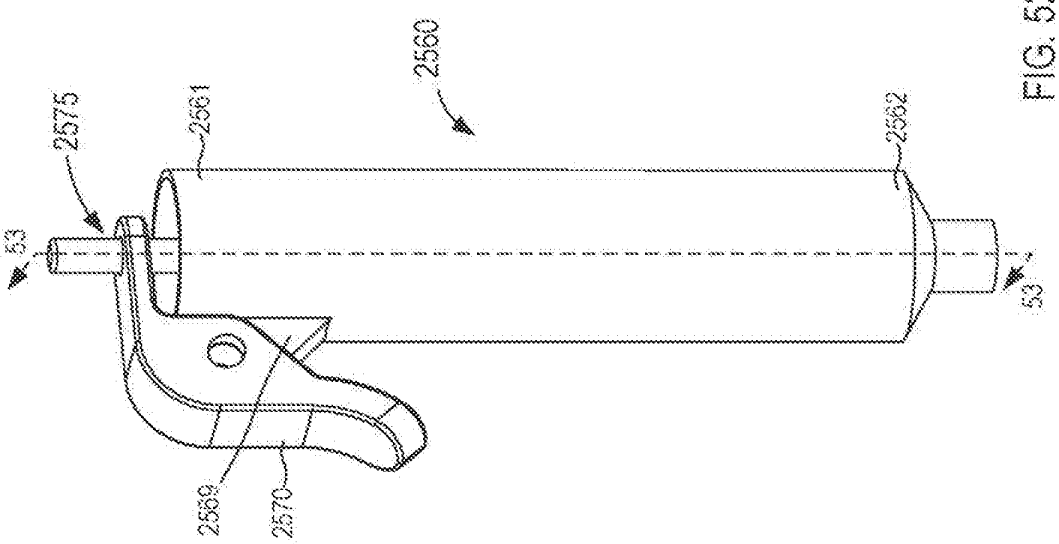

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FIG. 52

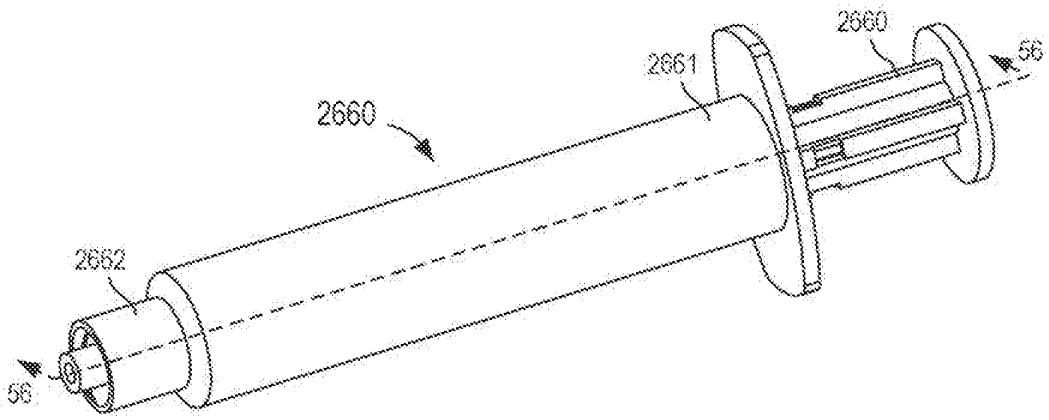

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FIG. 54

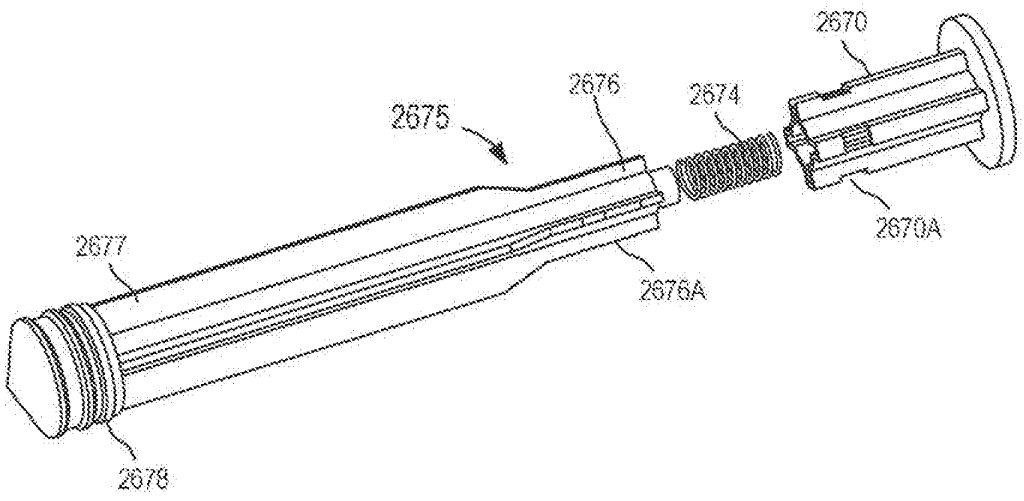

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FIG. 55

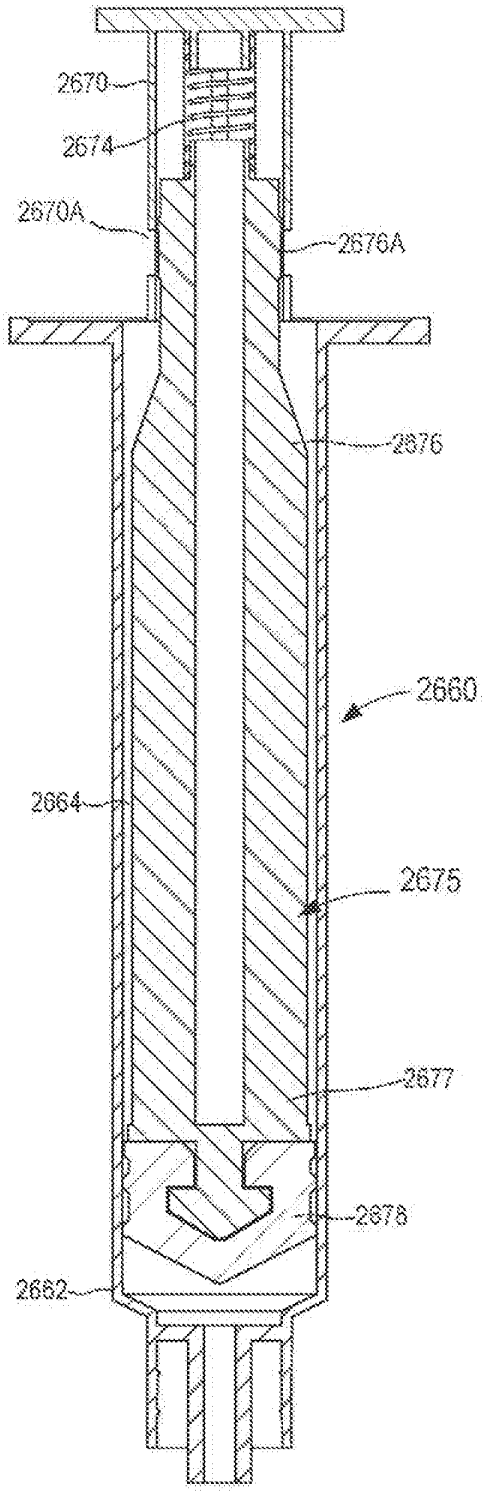


FIG. 56

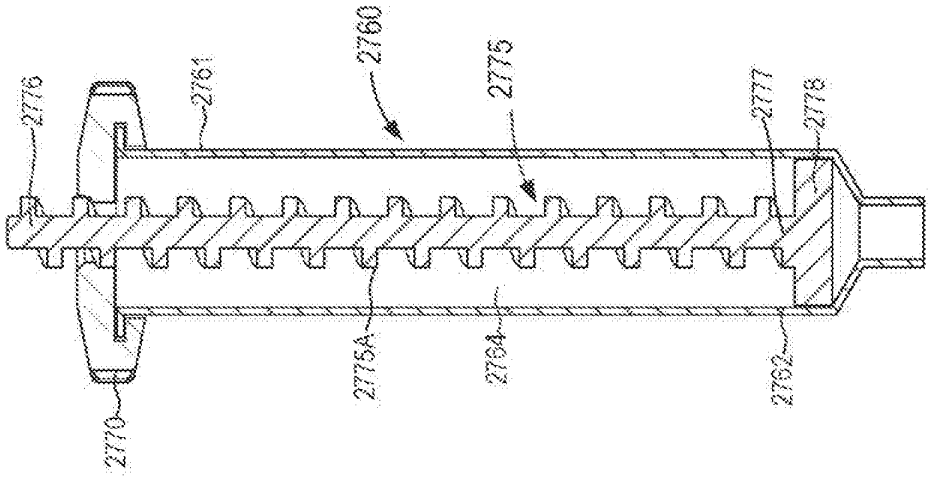

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FIG. 58

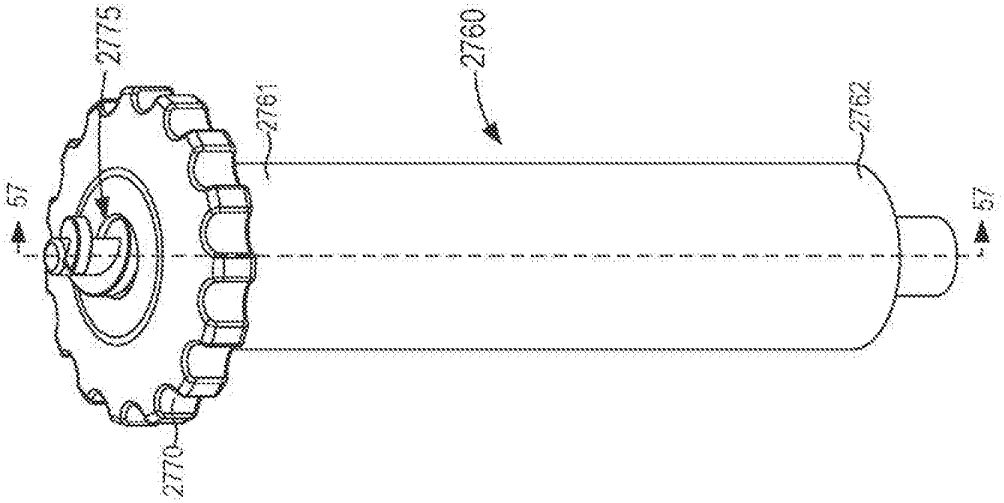

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FIG. 57

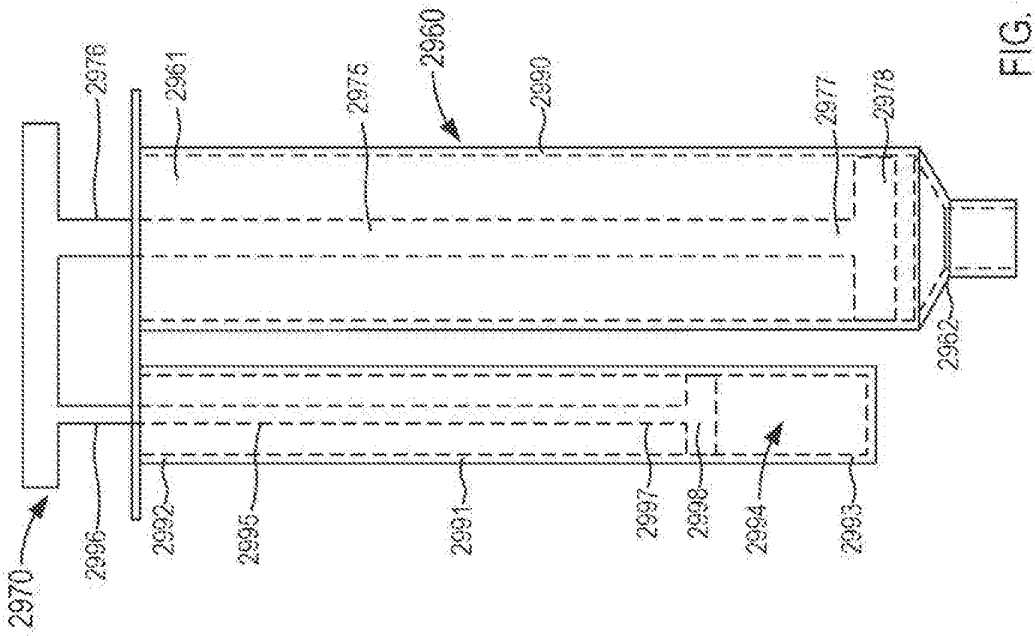

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FIG. 60

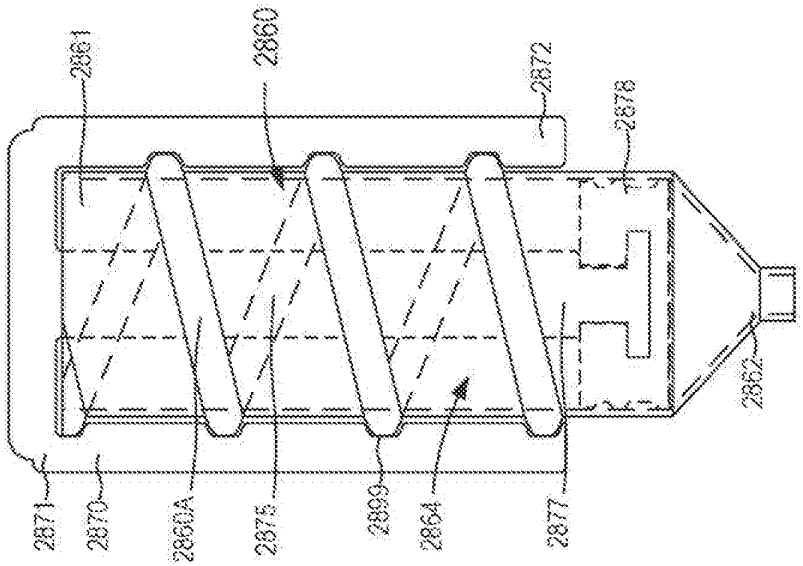

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FIG. 59

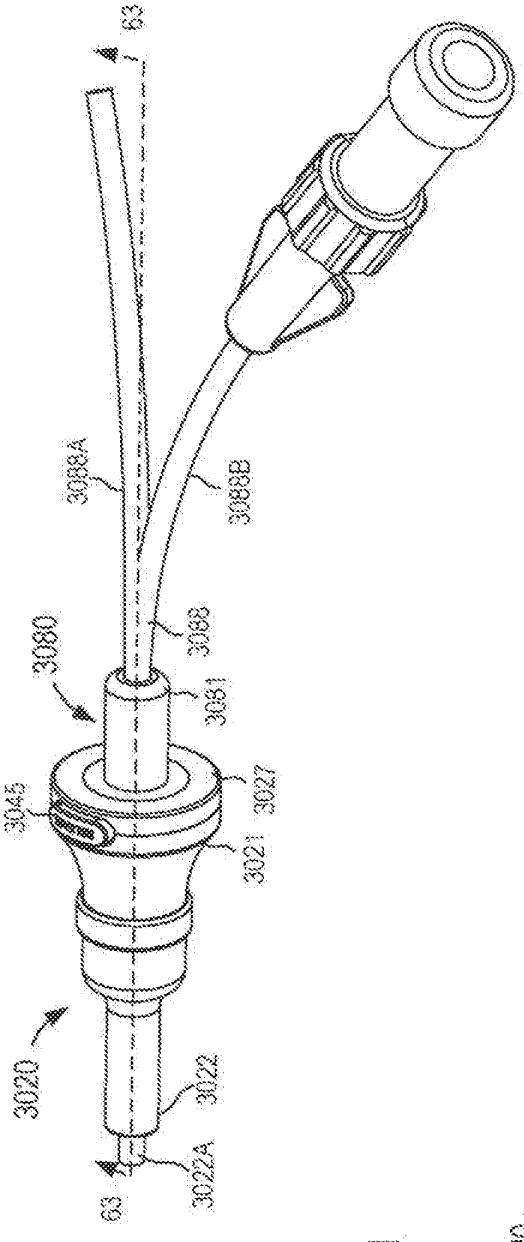

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FIG. 61

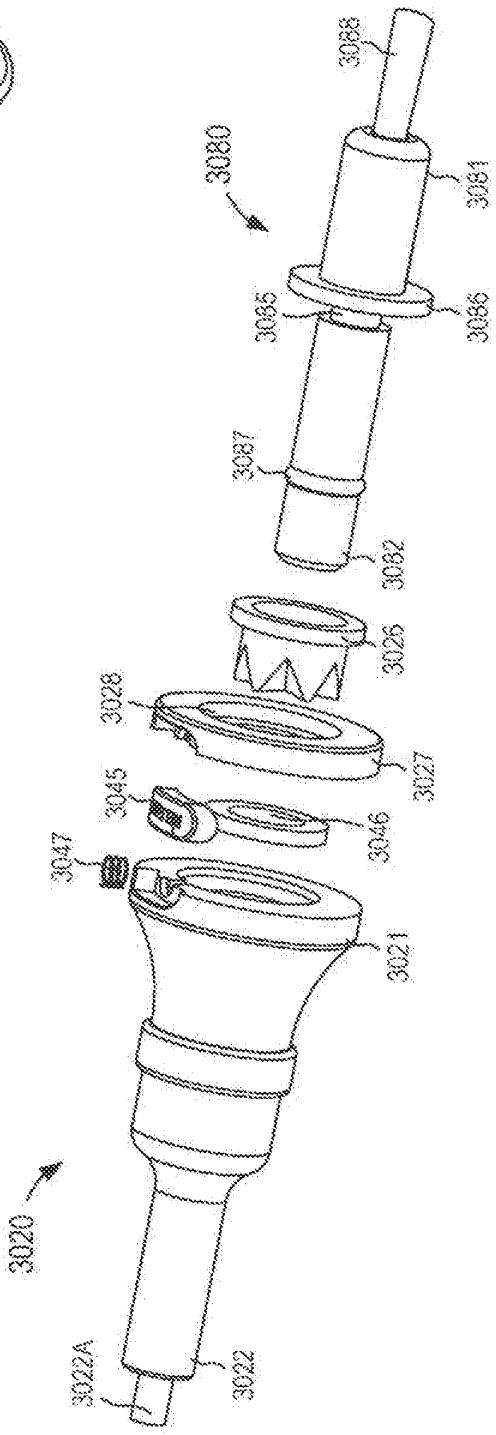

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FIG. 62

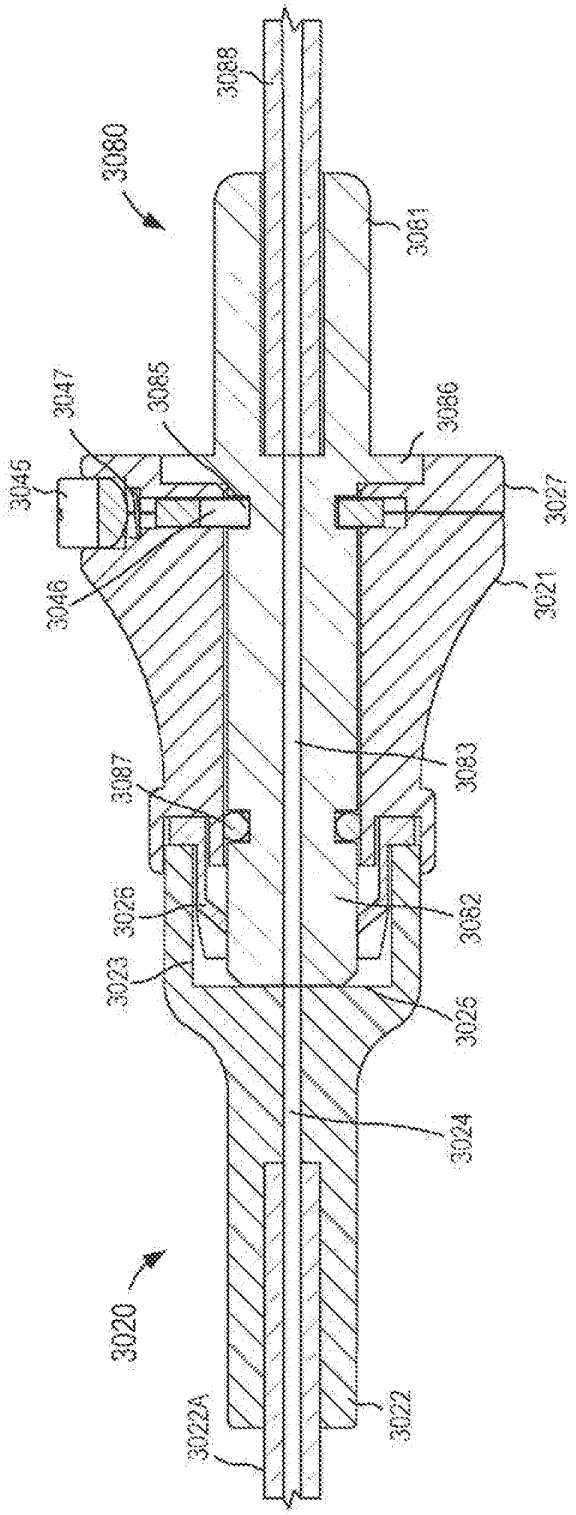

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FIG. 63

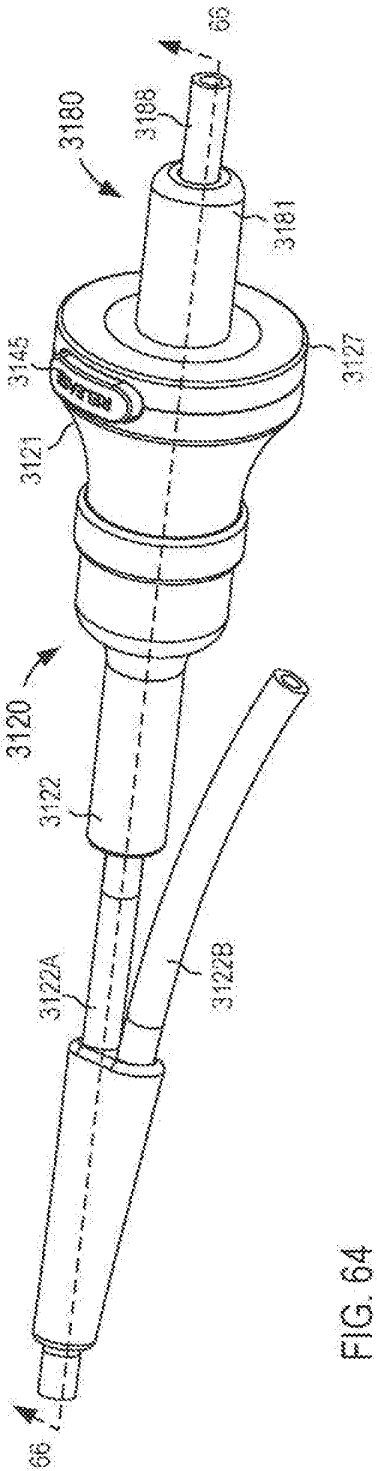

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FIG. 64

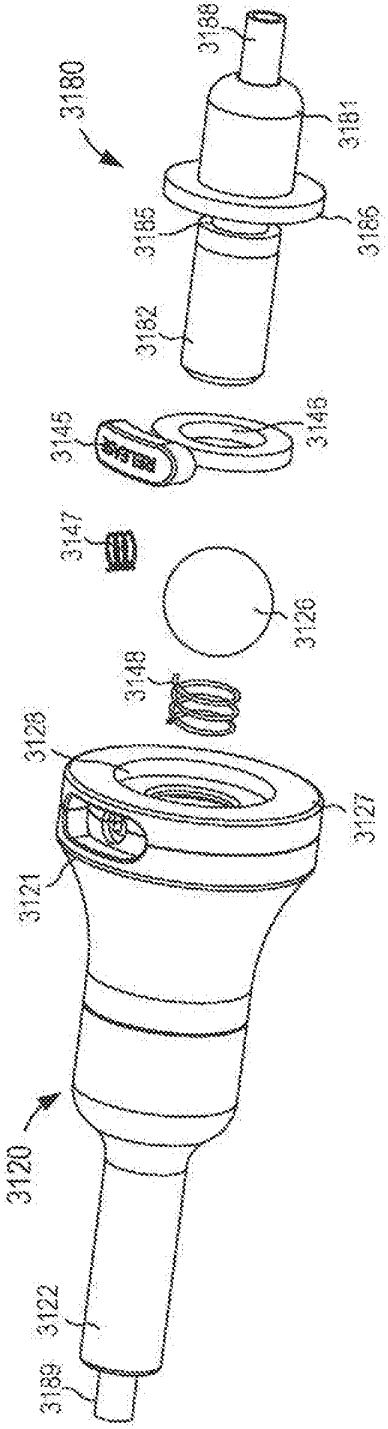

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FIG. 65

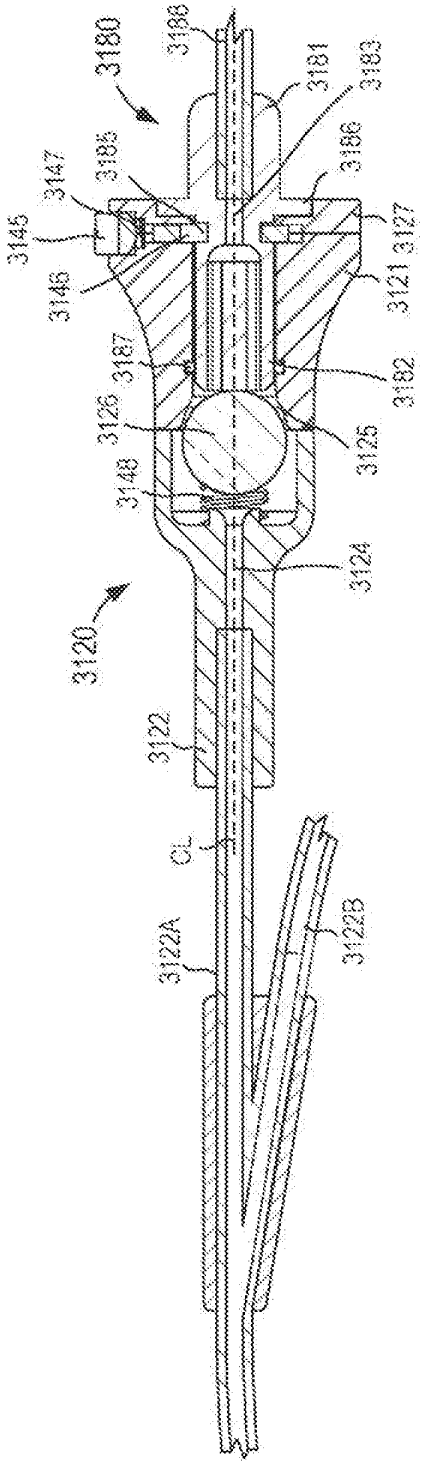

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FIG. 66

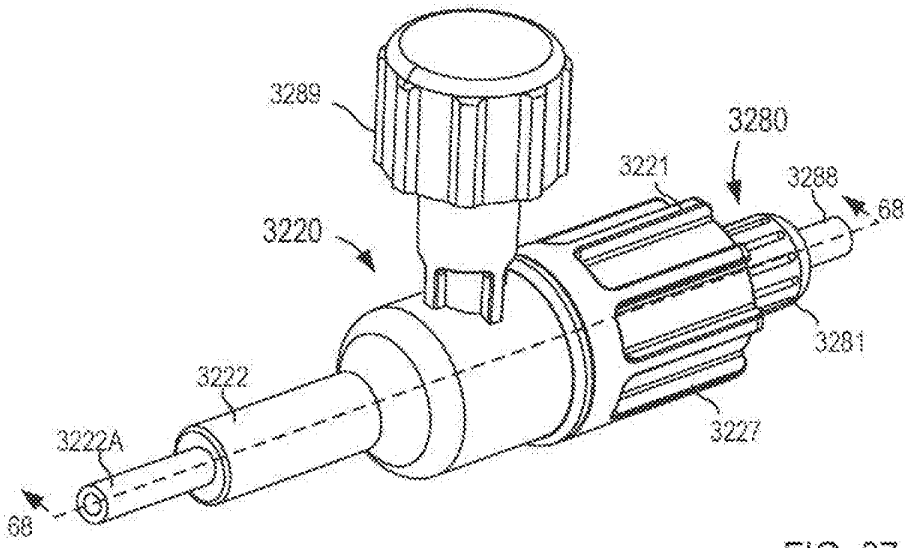

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FIG. 67

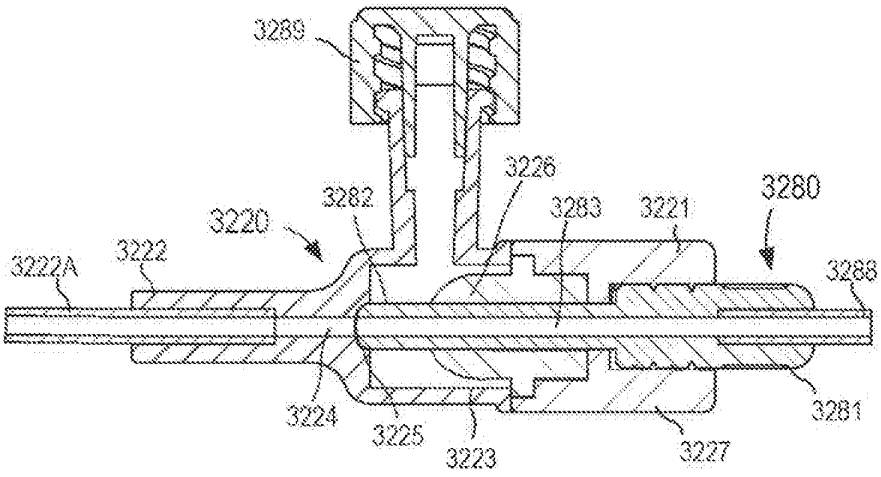

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FIG. 68

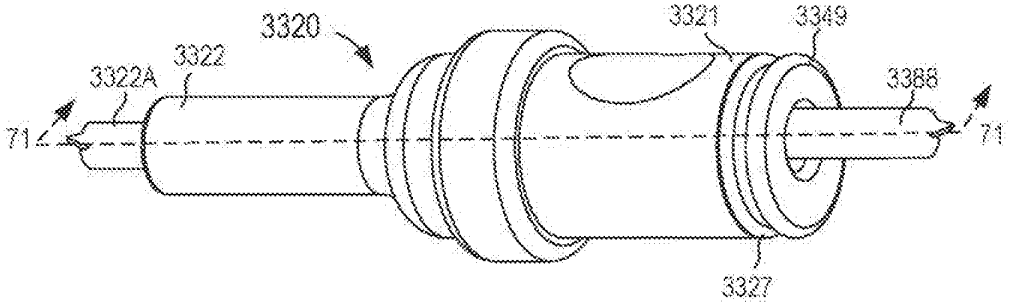

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FIG. 69

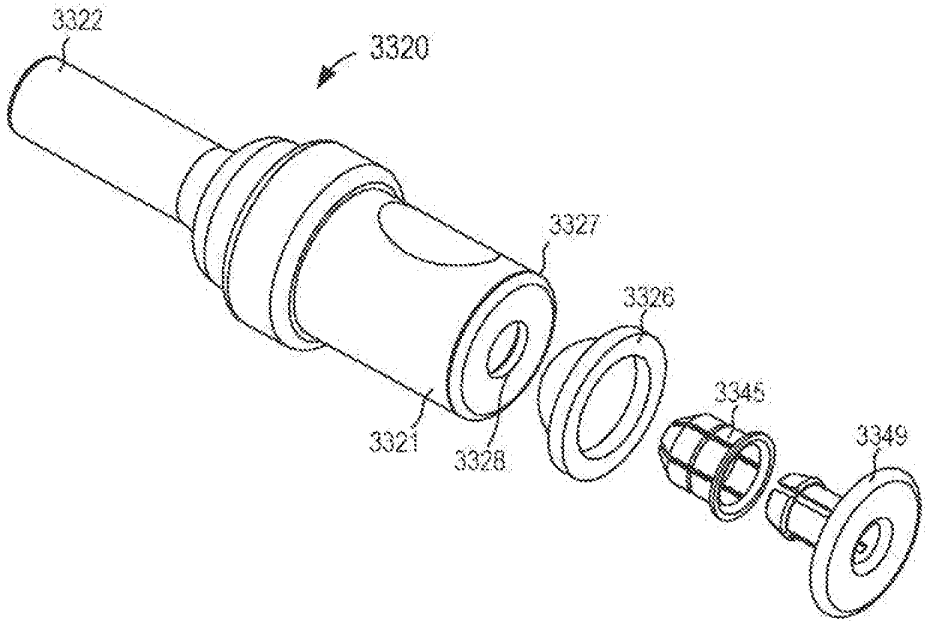

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FIG. 70

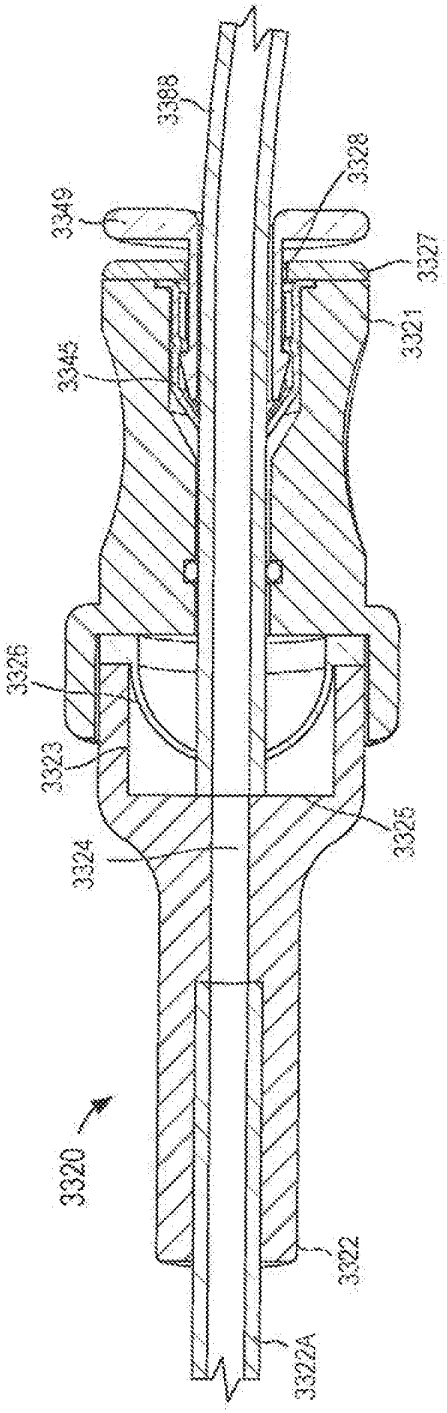

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FIG. 71

PTO/SB/08a (02-18)
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(Not for submission under 37 CFR 1.99)

Application Number	16208559
Filing Date	2018-12-04
First Named Inventor	Bobby E. ROGERS
Art Unit	3791
Examiner Name	Tse W CHEN
Attorney Docket Number	KURIN2CON3

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	2	5401262	A	1995-03-28	Karwoski et al.	

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	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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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	16208559
	Filing Date	2018-12-04
	First Named Inventor	Bobby E. ROGERS
	Art Unit	3791
	Examiner Name	Tse W CHEN
	Attorney Docket Number	KURIN2CON3

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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		Date Considered	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	16208559
	Filing Date	2018-12-04
	First Named Inventor	Bobby E. ROGERS
	Art Unit	3791
	Examiner Name	Tse W CHEN
	Attorney Docket Number	KURIN2CON3

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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)	2020-07-01
Name/Print	James S. Nolan	Registration Number	53,393

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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.

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.

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference		FOR FURTHER ACTION
KURIN4PCT		see Form PCT/ISA/220 as well as, where applicable, item 5 below.
International application No.	International filing date *(day/month/year)*	(Earliest) Priority Date *(day/month/year)*
PCT/US 20/23617	19 March 2020 (19.03.2020)	13 March 2020 (13.03.2020)
Applicant KURIN, INC.		

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. 35

☐ 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.

Pending processing

Form PCT/ISA/210 (first sheet) (July 2019)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 20/23617

A. CLASSIFICATION OF SUBJECT MATTER

IPC - A61B 5/15, A61B 5/153, A61B 5/154, A61B 5/157 (2020.01)

CPC - A61B 5/15003, A61B 5/150213, A61B 5/150251, A61B 5/150992, A61B 5/150206, A61B 5/150221, A61B 5/150946

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)
See Search History document

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

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

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 2018/0177445 A1 (Kurin, Inc.) 28 June 2018 (28.06.2018), entire document	1-4, 10-12, 18 --- 5-9, 13-17, 19-20
Y	US 4,349,035 A (Thomas et al.) 14 September 1982 (14.09.1982), entire document	5-6, 8-9, 13-14, 16-17, 19-20
Y	US 5,401,262 A (Karwoski et al.) 28 March 1995 (28.03.1995), entire document	5, 7, 13, 15
A	US 2018/0271425 A1 (Kurin, Inc.) 27 September 2018 (27.09.2018), entire document	1-20
A	US 2018/0353117 A1 (Magnolia Medical Technologies, Inc.) 13 December 2018 (13.12.2018), entire document	1-20

Online processing

☐ 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
"D" document cited by the applicant in the international application
"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
07 JUNE 2020	19 JUN 2020
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. 571-273-8300	Authorized officer Lee Young Telephone No. PCT Helpdesk: 571-272-4300

Form PCT/ISA/210 (second sheet) (July 2019)

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To: JAMES SCOTT NOLAN
P.O. BOX 371710
SAN DIEGO, CA 92110

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing *(day/month/year)*	19 JUN 2020

Applicant's or agent's file reference	FOR FURTHER ACTION
KURIN4PCT	See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US 20/23617	19 March 2020 (19.03.2020)	13 March 2020 (13.03.2020)

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

IPC - A61B 5/15, A61B 5/153, A61B 5/154, A61B 5/157 (2020.01)

CPC - A61B 5/15003, A61B 5/150213, A61B 5/150251, A61B 5/150992, A61B 5/150206, A61B 5/150221, A61B 5/150946

Applicant KURIN, INC.

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

- ☒ 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
- ☒ 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/US	Date of completion of this opinion	Authorized officer
Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-8300	07 JUNE 2020	Lee Young PCT Help Desk Telephone No. 571-272-4300

Form PCT/ISA/237 (cover sheet) (revised January 2019)

Electronic Processing

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 20/23617

Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established 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)).

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(b)).

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:

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 forming part of the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

5. Additional comments:

Pending processing

Form PCT/ISA/237 (Box No. I) (revised January 2019)

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 20/23617

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	5-9, 13-20	YES
	Claims	1-4, 10-12	NO
Inventive step (IS)	Claims	none	YES
	Claims	1-20	NO
Industrial applicability (IA)	Claims	1-20	YES
	Claims	none	NO

2. Citations and explanations:
Claims 1-4 and 10-12 lack novelty under PCT Article 33(2) as being anticipated by US 2018/0177445 A1 to Kurin, Inc. (hereinafter Kurin).

Regarding claim 1, Kurin teaches a blood sequestration device (see fig. 30A-G; para [0156]) comprising; an inlet path (fig. 30A see inlet path 3002; para [0156]); an outlet path (fig. 30A see outlet path 3004; para [0158]); a sequestration chamber (fig. 30A see sequestration chamber 3008; para [0160]) connected with the inlet path by a junction (fig. 30A see junction 3007; para [0160]; see fig. 17A-B) and being configured to receive a first portion of blood through the inlet path (para [0160]; para [0163]-[0164]), the sequestration chamber having a vent that allows air to be displaced by the first portion of blood (fig. 30A-D see vent 3010; para [0161]; para [0163]-[0165]), the junction being configured to inhibit a return to the inlet path of any of the first portion of blood received by the sequestration chamber (intended use - see para [0160] "the diverter junction 3007 is configured such that the flow out of the inlet port 3002 is preferentially directed toward the sequestration chamber 3008" - since the junction is configured to direct flow away from the inlet port, it is thereby considered capable of inhibiting a return to the inlet path of any of the first portion of blood received by the sequestration chamber; see para[0156], [0160]-[0161], [0061],[0067]); and a sampling channel connected between the inlet path and the outlet path (fig. 30A see sampling channel 3006; para [0159]-[0160]), 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 (para [0160]-[0170]).

Regarding claim 2, Kurin teaches the blood sequestration device in accordance with claim 1, wherein the junction is angled from the inlet path toward the sequestration chamber (fig. 30A; fig. 17A see junction 3007 is angled from the inlet path to the sequestration chamber; para [0160]) .

Regarding claim 3, Kurin teaches the blood sequestration device in accordance with claim 1, wherein the junction has a cross-sectional area that is smaller than a cross-sectional area of the inlet path (fig. 30A; fig. 17A see junction 3007 has a cross-sectional area closest to the inlet path that is smaller than a cross-sectional area of the inlet path below where it meets the junction; para [0160]).

Regarding claim 4, Kurin teaches the blood sequestration device in accordance with claim 1, wherein the junction has a cross-sectional area that is larger than a cross-sectional area of the inlet path (fig. 30A; fig. 17A see junction 3007 has a cross-sectional area near the sequestration chamber 3008 that is larger than a cross-sectional area of the inlet path where the inlet path opens to the junction; para [0160]; para [0163] junction cross-sectional area widens towards the sequestration chamber to direct blood).

Regarding claim 10, Kurin teaches the blood sequestration device in accordance with claim 1, wherein the vent includes two or more vent apertures (para [0161] vent 3010 comprises air permeable blood barrier 3012 as previously described; para [0060] air permeable blood barrier may comprise a mesh, a mesh inherently comprises two or more vent apertures).

Regarding claim 11, Kurin teaches a blood sequestration device (see fig. 30A-G; para [0156]) comprising; a housing (fig. 30A see housing 3001; para [0161]) having in inlet port (fig. 30A see inlet path 3002 has port opening in housing 3001; para [0156; para [0161]) and an outlet port (fig. 30A see outlet path 3004 has outlet opening in housing 3001; para [0159]; para [0161]), the housing containing: an inlet path connected to the inlet port (fig. 30A see inlet path 3002; para [0156]); an outlet path connected with the outlet port (fig. 30A see outlet path 3004; para [0158]); a sequestration chamber (fig. 30A see sequestration chamber 3008; para [0160]) connected with the inlet path by a junction (fig. 30A see junction 3007; para [0160]; see fig. 17A-B) and being configured to receive a first amount of blood through the inlet path (para [0160]; para [0163]-[0164]), the sequestration chamber having a vent that allows air to be displaced by the first portion of blood (fig. 30A see vent 3010; para [0161]; para [0163]-[0165]), the vent further being further configured to close upon the sequestration chamber being filled with the first portion of blood (para [0161] vent 3010 comprises air permeable blood barrier 3012 as previously described; para [0060]; para [0160]-[0170]), the junction being configured to inhibit a return of the first portion of blood out of the sequestration chamber (intended use - see para [0160] "the diverter junction 3007 is configured such that the flow out of the inlet port 3002 is preferentially directed toward the sequestration chamber 3008" - since the junction is configured to direct flow away from the inlet port, is is thereby considered capable of inhibiting a return to the inlet path of any of the first portion of blood received by the sequestration chamber; see also para[0156],[0160]-[0161],[0061],[0067]); and a sampling channel connected between the inlet path and the outlet path (fig. 30A see sampling channel 3006; para [0159]-[0160]), the sampling channel being configured to convey subsequent amounts of blood between the inlet path and the outlet path after the first portion of blood is received by the sequestration chamber (para [0160]-[0170]).

-*-Continued in Supplemental Box-*-

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 20/23617

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

Regarding claim 18, the claim language is confusing and lacks clarity. Specifically, the recitation "the patient needle and the sample needle", lack proper antecedent basis. In order to give meaning to this claim and to give proper antecedent basis, based on the specification (para [0063]), this recitation has been interpreted as the following: "and a blood sequestration device connected along the blood sampling pathway between a patient needle and a sample needle, wherein the venipunture apparatus includes the patient needle and the reservoir includes the sample needle".

Pending processing

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 20/23617

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.
Continuation of:
-*-Box V.2 - Citations and Explanations-*-

Regarding claim 12, Kurin teaches the blood sequestration device in accordance with claim 11, wherein the vent further comprises a closure mechanism that inhibits air from reentering the sequestration chamber after it has been displaced (para [0161] vent 3010 comprises air permeable blood barrier 3012 as previously described; para [0060]).

Claim 18 lacks an inventive step under PCT Article 33(3) as being obvious over Kurin.

Regarding claim 18, Kurin teaches a blood sample optimization system (fig. 30A-G; para [0156]) comprising: a blood sampling system (para [0156]) comprising: a venipuncture apparatus configured for venipuncture of a patient to access a sample of blood of a patient (para [0156] inlet port 3002 with opening connects to patient needle, needle is a suitable venipuncture apparatus); a blood sampling pathway connected with the venipuncture apparatus for conveying the sample of blood (fig. 30A see system 3000 comprises blood sampling pathway from inlet 3002 to outlet 3004 through sampling channel 3006; para [0156]); and a reservoir (fig. 30A see reservoir 3004; para [0158]); and a blood sequestration device connected along the blood sampling pathway between a patient needle and the reservoir (see fig. 30A-G; para [0156]), wherein the venipunture apparatus includes the patient needle (para [0156] inlet port 3002 with opening connects to patient needle), the blood sequestration device comprising: an inlet path connected with the patient needle (fig. 30A see inlet path 3002; para [0156]); an outlet path connected with the reservoir (fig. 30A see outlet path through outlet reservoir 3004; para [0158]); a sequestration chamber (fig. 30A see sequestration chamber 3008; para [0160]) connected with the inlet path by a junction (fig. 30A see junction 3007; para [0160]; see fig. 17A-B) and being configured to receive a first portion of blood through the inlet path (para [0160]; para [0163]-[0164]), the sequestration chamber having a vent that allows air to be displaced by the first portion of blood (fig. 30A see vent 3010; para [0161]; para [0163]-[0165]), the junction being configured to inhibit a return to the inlet path of any of the first portion of blood received by the sequestration chamber (intended use - see para [0160] "the diverter junction 3007 is configured such that the flow out of the inlet port 3002 is preferentially directed toward the sequestration chamber 3008" - since the junction is configured to direct flow away from the inlet port, is is thereby considered capable of inhibiting a return to the inlet path of any of the first portion of blood received by the sequestration chamber; see para[0156], [0160]-[0161], [0061],[0067]); and a sampling channel connected between the inlet path and the outlet path (fig. 30A see sampling channel 3006; para [0159]-[0160]), 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 (para [0160]-[0170]); but Kurin does not explicitly teach wherein the reservoir is configured for receiving an evacuated blood collection tube to collect and contain at subsequent portion of the sample of blood, nor wherein reservoir and connected outlet path comprise a sample needle. However, in another embodiment, Kurin teaches a sample needle at an outlet path of a blood sample collection device facilitates connection to an evacuated blood collection tube to collect and contain at subsequent portion of the sample of blood (fig. 1 see sample needle 5; para [0065]; see fig. 7). Combining embodiments is within the ordinary skill of a person within the art. Accordingly, it would have been obvious to a person having ordinary skill in the art to have provided a sample needle such that the reservoir is configured for receiving an evacuated blood collection tube to collect and contain at subsequent portion of the sample of blood in order to provide blood collection means with the blood sampling device.

Claims 5-6, 8-9, 13-14, 16-17 and 19-20 lack an inventive step under PCT Article 33(3) as being obvious over Kurin in view of US 4,349,035 A to Thomas et al. (hereinafter Thomas).

Regarding claim 5, Kurin teaches the blood sequestration device in accordance with claim 1, but does not explicitly teach wherein the junction includes one or more passive structures configured to inhibit a return to the inlet path of any of the first portion of blood received by the sequestration chamber. However, in similar art, Thomas teaches a blood collection device (see fig. 1; column 4, ln 20-24) comprising an inlet path (fig. 5 see cannula 19; column 4, ln 23-38) and a chamber connected by a junction (fig. 4-5 see junction 22 leads to chamber 21; column 4, ln 23-38). Kurin further teaches wherein the junction includes one or more passive structures configured to inhibit a return to the inlet path of any of the first portion of blood received by the sequestration chamber (fig. 4-5 see junction 22 comprises one-way valve to prevent backflow; column 4, ln 32-38). Passive structures for preventing backflow are well known in the art for improved blood collection by preventing contaminated blood from returning to a patient. Accordingly, it would have been obvious to a person having ordinary skill in the art to have included a passive structure as taught by Thomas in the device taught by Kurin in order to prevent return flow to the patient for improved blood sampling.

Regarding claim 6, Kurin in view of Thomas teaches the blood sequestration device in accordance with claim 5, and Kurin modified by Thomas further teaches wherein the one or more passive structures include a conical baffle having a tapered end directed toward the sequestration chamber (see Thomas fig. 4-5 passive structure tapers to a point towards chamber, thus restricting flow; see column 5, ln 13 -17).

Regarding claim 8, Kurin in view of Thomas teach the blood sequestration device in accordance with claim 5, and Kurin modified by Thomas further teaches wherein the one or more passive structures include a divider wall extending across a cross-section of the junction (see Thomas fig. 4-5 divider wall 25; column 6, ln 7-13).

-*-Continued in next Supplemental Box-*-

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 20/23617

Supplemental Box

In case **the space in any of the preceding boxes is not sufficient.**
Continuation of:
-*-Supplemental Box - Box V.2 - Citations and Explanations-*-

Regarding claim 9, Kurin in view of Thomas teach the blood sequestration device in accordance with claim 5, and Kurin modified by Thomas further teaches wherein the one or more passive structures include a flow director extending from an inner surface of the junction (see Thomas fig. 4-5 valve 22 is a flow director; column 4, ln 23-38; column 5, ln 13-17), the flow director being configured to control a flow of blood (see Thomas column 4, ln 23-28 flow director valve 22 controls flow by directing into chamber 21 and preventing backflow).

Regarding claim 13, Kurin teaches the blood sequestration device in accordance with claim 11, but does not explicitly teach wherein the junction includes one or more passive structures configured to inhibit a return to the inlet path of any of the first portion of blood received by the sequestration chamber. However, in similar art, Thomas teaches a blood collection device (see fig. 1; column 4, ln 20-24) comprising an inlet path (fig. 5 see cannula 19; column 4, ln 23-38) and a chamber connected by a junction (fig. 4-5 see junction 22 leads to chamber 21; column 4, ln 23-38). Kurin further teaches wherein the junction includes one or more passive structures configured to inhibit a return to the inlet path of any of the first portion of blood received by the sequestration chamber (fig. 4-5 see junction 22 comprises one-way valve to prevent backflow; column 4, ln 32-38). Passive structures for preventing backflow are well known in the art for improved blood collection by preventing contaminated blood from returning to a patient. Accordingly, it would have been obvious to a person having ordinary skill in the art to have included a passive structure as taught by Thomas in the device taught by Kurin in order to prevent return flow to the patient for improved blood sampling.

Regarding claim 14, Kurin in view of Thomas teach the blood sequestration device in accordance with claim 13, and Kurin modified by Thomas further teaches wherein the one or more passive structures include a conical baffle having a tapered end directed toward the sequestration chamber (see Thomas fig. 4-5 passive structure tapers to a point towards chamber, thus restricting flow; see column 5, ln 13 -17).

Regarding claim 16 Kurin in view of Thomas teach the blood sequestration device in accordance with claim 13, and Kurin modified by Thomas further teaches wherein the one or more passive structures include a divider wall extending across a cross-section of the junction. (see Thomas fig. 4-5 divider wall 25; column 6, ln 7-13).

Regarding claim 17 Kurin in view of Thomas teach the blood sequestration device in accordance with claim 13, and Kurin modified by Thomas further teaches wherein the one or more passive structures include a flow director extending from an inner surface of the junction (see Thomas fig. 4-5 valve 22 is a flow director; column 4, ln 23-38; column 5, ln 13-17), the flow director being configured to control a flow of blood (see Thomas column 4, ln 23-28 flow director valve 22 controls flow by directing into chamber 21 and preventing backflow).

Regarding claim 19, Kurin teaches the blood sample optimization system in accordance with claim 18, but does not explicitly teach wherein the junction of the blood sequestration device includes one or more passive structures configured to inhibit a return to the inlet path of any of the first portion of blood received by the sequestration chamber. However, in similar art, Thomas teaches a blood collection device (see fig. 1; column 4, ln 20-24) comprising an inlet path (fig. 5 see cannula 19; column 4, ln 23-38) and a chamber connected by a junction (fig. 4-5 see junction 22 leads to chamber 21; column 4, ln 23-38). Kurin further teaches wherein the junction includes one or more passive structures configured to inhibit a return to the inlet path of any of the first portion of blood received by the sequestration chamber (fig. 4-5 see junction 22 comprises one-way valve to prevent backflow; column 4, ln 32-38). Passive structures for preventing backflow are well known in the art for improved blood collection by preventing contaminated blood from returning to a patient. Accordingly, it would have been obvious to a person having ordinary skill in the art to have included a passive structure as taught by Thomas in the device taught by Kurin in order to prevent return flow to the patient for improved blood sampling.

Regarding claim 20, Kurin in view of Thomas teach the blood sample optimization system in accordance with claim 19, and Kurin modified by Thomas further teaches wherein the one or more passive structures includes a wall extending from an inner surface of the junction to control a flow of the first portion of blood (see Thomas fig. 4-5 divider wall 25; column 6, ln 7-13).

-*-Continued in next Supplemental Box-*-

Pending Provisional

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 20/23617

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.
Continuation of:
-*-Supplemental Box - Box V.2 - Citations and Explanations-*-

Claim 5, 7 and 13, 15 lack an inventive step under PCT Article 33(3) as being obvious over Kurin in view of US 5,401,262 A to Karwoski et al. (hereinafter Karwoski).

Regarding claim 5, Kurin teaches the blood sequestration device in accordance with claim 1, but does not explicitly teach wherein the junction includes one or more passive structures configured to inhibit a return to the inlet path of any of the first portion of blood received by the sequestration chamber. However, in similar art, Karwoski teaches a blood collection device (see fig. 1; column 4, ln 20-40). Karwoski further teaches wherein a pathway of the blood collection devices includes one or more passive structures configured to inhibit a return to an inlet path of any of a sample of blood (fig. 1 see baffles 112a-f direct flow through pathway and assist in fluid retention; column 18, ln 1-24; column 21, ln 55-65). Passive structures for preventing backflow are well known in the art for improved blood collection by preventing contaminated blood from returning to a patient. Accordingly, it would have been obvious to a person having ordinary skill in the art to have included a passive structures as taught by Karwoski in the device taught by Kurin in order to prevent return flow to the patient for improved blood sampling.

Regarding claim 7, Kurin in view of Karwoski teach the blood sequestration device in accordance with claim 5, and Kurin modified by Karwoski further teaches wherein the one or more passive structures include two or more staggered baffles extending from an inner surface of the junction (Karwoski fig. 1 see baffles 112a-f direct flow through pathway and assist in fluid retention; column 18, ln 1-24; column 21, ln 55-65).

Regarding claim 13, Kurin teaches the blood sequestration device in accordance with claim 11, wherein the junction includes one or more passive structures configured to inhibit a return to the inlet path of any of the first portion of blood received by the sequestration chamber. However, in similar art, Karwoski teaches a blood collection device (see fig. 1; column 4, ln 20-40). Karwoski further teaches wherein a pathway of the blood collection devices includes one or more passive structures configured to inhibit a return to an inlet path of any of a sample of blood (fig. 1 see baffles 112a-f direct flow through pathway and assist in fluid retention; column 18, ln 1-24; column 21, ln 55-65). Passive structures for preventing backflow are well known in the art for improved blood collection by preventing contaminated blood from returning to a patient. Accordingly, it would have been obvious to a person having ordinary skill in the art to have included a passive structures as taught by Karwoski in the device taught by Kurin in order to prevent return flow to the patient for improved blood sampling.

Regarding claim 15, Kurin in view of Karwoski teach the blood sequestration device in accordance with claim 13, and Kurin modified by Karwoski further teaches wherein the one or more passive structures include two or more staggered baffles extending from an inner surface of the junction (Karwoski fig. 1 see baffles 112a-f direct flow through pathway and assist in fluid retention; column 18, ln 1-24; column 21, ln 55-65).

Claims 1-20 have industrial applicability as defined by PCT Article 33(4) because the subject matter can be made or used by industry.

Pending processing

Form PCT/ISA/237 (Supplemental Box) (revised January 2019)

SEARCH HISTORY

Application Number	PCT/US 20/23617
Search Conducted By	EAW
Search Approved By	SCL

CPC/IPC Classifications Searched	IPC(8): A61B 5/15, A61B 5/153, A61B 5/154, A61B5/157 (2020.01) CPC: A61B 5/15003, A61B 5/150213, A61B 5/150251, A61B 5/150992, A61B 5/150206, A61B 5/150221, A61B 5/150946
Date Conducted	7 June 2020 (07.06.2020)

Documentation Searched	IPC(8): A61B 5/15, A61B 5/153, A61B 5/154, A61B5/157 (2020.01) CPC: (keyword limited; see below)
Search Terms Used	baffle*, prevent*, inhibit*, back*, return*, sequestration*, flow*, blood*, sample*, restrict*
Date Conducted	7 June 2020 (07.06.2020)

Electronic Database Searched	PatBase
Files Searched	Full-text: AU BE BR CA CH CN DE DK EP ES FI FR GB IN JP KR SE TH TW US WO Bibliographic: (European) AT BA BE BG CH CS CY CZ DD DK EE ES FI GE GR HR HU IE IS IT LT LU LV MC MD MT NL NO PL PT RO RS SE SI SK SM TR UA YU (Asia) EA GC HK ID IL IN KZ MN MY PH RU SG SU TH TJ TW UZ VN (North America) CA CR CU DO GT HN MX NI PA SV TT (South America) AR BR CL CO EC PE UY (Australasia) AU NZ (Africa) AP DZ EG KE MA MW OA ZA ZM ZW
Date Conducted	7 June 2020 (07.06.2020)
Search Logic:	

Search 1: PA=(Kurin inc) (Results 5)

Search 2: PN=(US2018/0177445) (Results 1)

Search 3: ctb 2 or ctf 2 (Results 5)

Search 4: CPC=(A61B5/15003) (Results 2650)

Search 5: 4 and ft=(baffle%) (Results 36)

Search 6: 4 and ft=((prevent* or inhibit*) near (back* or return*)) (Results 226)

Search 7: 6 and ft=(sequestration) (Results 3)

Search 8: 6 and ft=(flow*) (Results 182)

Search 9: IPC=(A61B5/15 or A61B5/153 or A61B5/154 or A61B5/157) (Results 13750)

Search 10: CPC=(A61B5/15003 or A61B5/150213 or A61B5/150251 or A61B5/150992 or A61B5/150206 or A61B5/150221 or A61B5/150946) (Results 3410)

Search 11: 9 or 10 (Results 14204)

Search 12: 11 and ft=(sequestration) (Results 32)

Search 13: 11 and ft=((prevent* or inhibit*) near (back* or return*)) (Results 535)

Search 14: 13 and ft=(blood* near sample*) (Results 335)

Search 15: 14 not 8 (Results 198)

Search 16: ft=(sequestration* and baffle* and blood*) (Results 170)

Search 17: 16 not (14 or 8) (Results 170)

Search 18: ft=(blood* and sequestration* and (restrict* near flow*)) (Results 176)

Electronic Database Searched	Google
Files Searched	Patents
Date Conducted	7 June 2020 (07.06.2020)

Search Logic:

blood sampling sequestration device prevent backflow

blood sampling sequestration device baffle directs flow

blood sampling collection device prevent backflow

blood sampling device valve restricts backflow controls flow

blood sequestration junction prevents backflow blood sequestration junction flow restriction

Electronic Database Searched	Google
Files Searched	Web
Date Conducted	7 June 2020 (07.06.2020)
Search Logic:	
blood sampling sequestration device prevent backflow blood sampling sequestration device baffle directs flow blood sampling collection device prevent backflow blood sampling device valve restricts backflow controls flow blood sequestration junction prevents backflow blood sequestration junction flow restriction	

Electronic Acknowledgement Receipt

EFS ID:	39909609
Application Number:	16208559
International Application Number:	
Confirmation Number:	1020
Title of Invention:	BLOOD SAMPLE OPTIMIZATION SYSTEM AND BLOOD CONTAMINANT SEQUESTRATION DEVICE AND METHOD
First Named Inventor/Applicant Name:	Bobby E. Rogers
Customer Number:	158174
Filer:	James Scott Nolan/KETHYA TEUK
Filer Authorized By:	James Scott Nolan
Attorney Docket Number:	KURIN2CON3
Receipt Date:	03-JUL-2020
Filing Date:	04-DEC-2018
Time Stamp:	20:35:11
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	no

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Information Disclosure Statement (IDS) Form (SB08)	KURIN2CON3_IDS.pdf	1053407 7ec53f679f5785eb91316ef16780ec81156f076c	no	4

Warnings:

Information:					
2	Non Patent Literature	NPL_KURIN4PCT_ISRWO.pdf	668278 dacf2ee561c200a8cd675c74ba2ee76214716cb6	no	12
Warnings:					
Information:					
			Total Files Size (in bytes):	1721685	

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 a 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.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/208,559	12/04/2018	Bobby E. Rogers	KURIN2CON3	1020

158174 7590 04/05/2021

Kurin, Inc.
P.O. Box 371710
San Diego, CA 92137

EXAMINER	
ABOUELELA, MAY A	

ART UNIT	PAPER NUMBER
3791	

NOTIFICATION DATE	DELIVERY MODE
04/05/2021	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

Office Action Summary	Application No. 16/208,559	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 12/04/2018.

☐ 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) 1-26 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) 1-26 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 12/04/2018 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 and 07/03/2020. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Objections

3. Claim 6 is objected to because of the following informalities: the phrase "and and a sampling channel" in lines 7-8. Appropriate correction is required.

4. Claim 20 is objected to because of the following informalities: the phrase "and and a sampling channel" in lines 9-10. Appropriate correction is required.

Claim Rejections - 35 USC § 101

5. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Section 33(a) of the America Invents Act reads as follows:

> Notwithstanding any other provision of law, no patent may issue on a claim directed to or encompassing a human organism.

Claims rejected under 35 U.S.C. 101 and section 33(a) of the America Invents Act as being directed to or encompassing a human organism. See also *Animals - Patentability*, 1077 *Off. Gaz. Pat. Office* 24 (April 21, 1987) (indicating that human organisms are excluded from the scope of patentable subject matter under 35 U.S.C. 101).

Claim 1 recite the limitation "an inlet port for receiving the blood". The current claim language positively recites a body part of a human being, thus claiming non-statutory subject matter. In order to overcome this rejection, the claimed subject matter should be "adapted to" or "configured to" receive the blood

Double Patenting

6. 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 1-26 are provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-20 of copending Application No.15/855439, claims 1-20 of copending Application No.16/819033, claims 1-16 of Patent Application No.10010282, claims 1-23 of Patent Application No.10143412, and claims 1-16 of Patent Application No.9820682. Although the claims at issue are not identical, they are not patentably distinct from each other because the copending application and the instance application are claiming a common subject matter including: a blood

sequestration device for sequestering blood conveyed from a patient, the blood sequestration device comprising; an inlet port for receiving the blood; an outlet port; a sequestration chamber; a junction connected between the inlet port, the sequestration 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 sequestration such that a second portion of blood is allowed to bypass the sequestration chamber and the first portion of blood sequestered therein to be directed into the sampling channel toward the outlet port.

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 on 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 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 https://ppair-my.uspto.gov/pair/PrivatePair. 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.

/MAY A ABOUELELA/
Primary Examiner, Art Unit 3791

Notice of References Cited	Application/Control No. 16/208,559	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	A61M39/045	1/1
*	C	US-8568371-B2	10-2013	Siopes; William	A61M39/26	604/256
*	D	US-8540663-B2	09-2013	Davey; Christopher T.	A61M1/30	604/43
*	E	US-8523826-B2	09-2013	Layton, Jr.; Russell K.	A61M39/16	604/237
*	F	US-20160174888-A1	06-2016	Berthier; Erwin	A61B5/150412	600/575
*	G	US-8197420-B2	06-2012	Patton; Richard G.	A61B10/0051	600/579
*	H	US-4057050-A	11-1977	Sarstedt; Walter	A61B5/15003	600/578
*	I	US-20050240161-A1	10-2005	Crawford, Jamieson William McLean	A61B5/150641	604/264
*	J	US-20040147855-A1	07-2004	Marsden, Stewart	A61B5/150572	600/576
*	K	US-8864684-B2	10-2014	Bullington; Gregory J.	A61B5/150221	600/579
*	L	US-8535241-B2	09-2013	Bullington; Gregory	A61B5/150099	600/579
*	M	US-20130317391-A1	11-2013	Bullington; Gregory J.	A61B5/150099	600/575

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	CPC Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

Notice of References Cited	Application/Control No. 16/208,559	Applicant(s)/Patent Under Reexamination Rogers et al.	
	Examiner MAY A ABOUELELA	Art Unit 3791	Page 2 of 4

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	CPC Classification	US Classification
*	A	US-20050004524-A1	01-2005	Newby, C. Mark	A61M5/3243	604/164.08
*	B	US-20030105414-A1	06-2003	Leong, Alvin Tan Chee	A61B5/150389	600/576
*	C	US-5749857-A	05-1998	Cuppy; Michael J.	A61M25/0606	604/161
*	D	US-9060724-B2	06-2015	Bullington; Gregory J.	A61B5/153	1/1
*	E	US-9204864-B2	12-2015	Bullington; Gregory J.	A61B5/150099	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.	A61B5/1545	600/577
*	H	US-3874367-A	04-1975	Ayres; Waldemar A.	A61B5/1545	600/579
*	I	US-3886930-A	06-1975	Ryan; George R.	A61B5/150389	600/577
*	J	US-4106497-A	08-1978	Percarpio; Edward P.	A61B5/150351	600/579
*	K	US-4154229-A	05-1979	Nugent; Edward L.	A61B5/154	600/577
*	L	US-4207870-A	06-1980	Eldridge; William N.	F16K15/148	137/197
*	M	US-4412548-A	11-1983	Hoch; Louis	A61B5/150389	600/577

FOREIGN PATENT DOCUMENTS

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	N					
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	S					
	T					

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Notice of References Cited	Application/Control No. 16/208,559	Applicant(s)/Patent Under Reexamination Rogers et al.	
	Examiner MAY A ABOUELELA	Art Unit 3791	Page 3 of 4

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	CPC Classification	US Classification
*	A	US-5222502-A	06-1993	Kurose; Katsutoshi	A61B5/15003	600/576
*	B	US-5520193-A	05-1996	Suzuki; Issei	A61B5/150396	600/577
*	C	US-20100057004-A1	03-2010	Christensen; Kelly D.	A61M25/0606	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.	A61B5/155	435/379
*	F	US-20040054333-A1	03-2004	Theeuwes, Felix	A61M5/14276	604/248
*	G	US-9022951-B2	05-2015	Bullington; Gregory	A61B5/150251	600/579
*	H	US-6569117-B1	05-2003	Ziv; David	A61M39/02	604/164.01
*	I	US-3741197-A	06-1973	Sanz; Manuel C.	A61B5/150793	600/583
*	J	US-20100010372-A1	01-2010	BROWN; LEROY R.	A61B5/150389	600/573
*	K	US-8603009-B2	12-2013	Tan; Alvin Chee Leong	A61B5/15003	600/573
*	L	US-20080319346-A1	12-2008	Crawford; Jamieson	A61B5/1545	600/577
*	M	US-20080167577-A1	07-2008	Weilbacher; Eugene E.	A61B5/150572	600/576

FOREIGN PATENT DOCUMENTS

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	N					
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	P					
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	R					
	S					
	T					

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Notice of References Cited	Application/Control No. 16/208,559	Applicant(s)/Patent Under Reexamination Rogers et al.	
	Examiner MAY A ABOUELELA	Art Unit 3791	Page 4 of 4

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	CPC Classification	US Classification
*	A	US-20080086085-A1	04-2008	Brown; Leroy R.	A61B5/150572	604/122
*	B	US-9877675-B2	01-2018	Baid; Rishi	A61B5/150488	1/1
*	C	US-4444203-A	04-1984	Engelman; Allan	A61M25/0693	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.	A61M25/0631	600/434
*	F	US-9022950-B2	05-2015	Bullington; Gregory	A61B5/15003	600/579
*	G	US-9155495-B2	10-2015	Bullington; Gregory J.	A61B5/155	1/1
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	J					
	K					
	L					
	M					

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	CPC Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
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	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16/208,559	Rogers et al.
	Examiner	**Art Unit**
	MAY A ABOUELELA	3791

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

CLAIMS

☐ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	03/02/2021								
	1	✓								
	2	✓								
	3	✓								
	4	✓								
	5	✓								
	6	✓								
	7	✓								
	8	✓								
	9	✓								
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	22	✓								
	23	✓								
	24	✓								
	25	✓								
	26	✓								

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16/208,559	Rogers et al.
	Examiner	Art Unit
	MAY A ABOUELELA	3791

CPC - Searched*		
Symbol	Date	Examiner
A61B5/150992 or A61B5/15003 or A61B5/150213 or A61B5/150389 or A61B5/150473 or A61B5/150572 or A61B5/154 or A61B5/153 or A61M39/0693 or A61M39/04 or A61B5/150221 or A61M2039/0633 or A61M2039/0202 or A61M2039/068	03/02/2021	MA

CPC Combination Sets - Searched*		
Symbol	Date	Examiner

US Classification - Searched*			
Class	Subclass	Date	Examiner
600	573, 576, 577, 583	03/02/2021	MA
604	164.01	03/02/2021	MA

* See search history printout included with this form or the SEARCH NOTES box below to determine the scope of the search.

Search Notes		
Search Notes	Date	Examiner
inventor name search, east text search, class/subclass search	03/02/2021	MA

Interference Search			
US Class/CPC Symbol	US Subclass/CPC Group	Date	Examiner

/MAY A ABOUELELA/ Primary Examiner, Art Unit 3791	

Bibliographic Data

Application No: 16/208,559

Foreign Priority claimed: ○ Yes ◉ No

35 USC 119 (a-d) conditions met: ☐ Yes ☑ No ☐ Met After Allowance

Verified and Acknowledged: /MAY A ABOUELELA/ Examiner's Signature | Initials

Title: BLOOD SAMPLE OPTIMIZATION SYSTEM AND BLOOD CONTAMINANT SEQUESTRATION DEVICE AND METHOD

FILING or 371(c) DATE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
12/04/2018	600	3791	KURIN2CON3
RULE			

APPLICANTS

Kurin, Inc., San Diego, CA,

INVENTORS

Bobby E. Rogers, San Diego, CA, UNITED STATES

Gino Kang, Irvine, CA, UNITED STATES

John Detloff, San Diego, CA, UNITED STATES

CONTINUING DATA

This application is a CON of 15994559 05/31/2018 PAT 10143412

15994559 is a CON of 15140448 04/27/2016 PAT 10010282

15140448 has PRO of 62318194 04/04/2016

15140448 has PRO of 62238636 10/07/2015

15140448 has PRO of 62196797 07/24/2015

FOREIGN APPLICATIONS

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12/21/2018

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STATE OR COUNTRY

UNITED STATES

ADDRESS

Kurin, Inc.
P.O. Box 371710
San Diego, CA 92137
UNITED STATES

FILING FEE RECEIVED

$1,395

Doc code: IDS
Doc description: Information Disclosure Statement (IDS) Filed

PTO/SB/08a (02-18)
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Application Number	16208559
Filing Date	2018-12-04
First Named Inventor	Bobby E. ROGERS
Art Unit	3791
Examiner Name	Tse W CHEN
Attorney Docket Number	KURIN2CON3

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	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.	

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /M.A.A/

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	9	4057050	A	1977-11-08	Sarstedt	
	10	4106497	A	1978-08-15	Percarpio	
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	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.	
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	26	8603009	B2	2013-12-10	Tan et al.	
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	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.	
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	33	9820682	B2	2017-11-21	Rogers 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	20020004647	A1	2002-01-10	Leong	
	2	20030105414	A1	2003-06-05	Leong	
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	7	20050004524	A1	2005-01-06	Newby et al.	
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	10	20050240161	A1	2005-10-27	Crawford	
	11	20070088279	A1	2007-04-19	Shue et al.	
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	13	20080167577	A1	2008-07-10	Weilbacher et al.	
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	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.	
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	28	20170020427	A1	2017-01-26	Rogers et al.	

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	Attorney Docket Number	KURIN2CON3

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	34	20190159711	A1	2019-05-30	Rogers et al.	

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Examiner Initial*	Cite No	Foreign Document Number[3]	Country Code[2] i	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	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.		☒
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	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.		☐

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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.	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	

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	Art Unit	3791
	Examiner Name	Tse W CHEN
	Attorney Docket Number	KURIN2CON3

	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.	

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EXAMINER SIGNATURE

Examiner Signature	/MAY A ABOUELELA/	Date Considered	03/02/2021

*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

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Art Unit	3791
Examiner Name	Tse W CHEN
Attorney Docket Number	KURIN2CON3

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

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See attached certification statement.

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☒ A certification statement is not submitted herewith.

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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.

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Name/Print	James S. Nolan	Registration Number	53393

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	1	4349035	A	1982-09-14	Thomas et al.	
	2	5401262	A	1995-03-28	Karwoski et al.	

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	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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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)		
	Application Number	16208559
	Filing Date	2018-12-04
	First Named Inventor	Bobby E. ROGERS
	Art Unit	3791
	Examiner Name	Tse W CHEN
	Attorney Docket Number	KURIN2CON3

	1							

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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.	T[5]
	1	International Search Report and Written Opinion dated 19 June 2020, for PCT application no. PCTUS2020/023617.	

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Examiner Signature	/MAY A ABOUELELA/	Date Considered	03/02/2021

*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)		
	Application Number	16208559
	Filing Date	2018-12-04
	First Named Inventor	Bobby E. ROGERS
	Art Unit	3791
	Examiner Name	Tse W CHEN
	Attorney Docket Number	KURIN2CON3

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)	2020-07-01
Name/Print	James S. 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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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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To: kurin@virtualipsupport.com,jsnolan1@hotmail.com,eofficeaction@appcoll.com
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Cc: PAIR_eOfficeAction@uspto.gov
Subject: Private PAIR Correspondence Notification for Customer Number 158174

Apr 05, 2021 03:47:01 AM

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Kurin, Inc.
P.O. Box 371710
San Diego, CA 92137
UNITED STATES

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Application	Document	Mailroom Date	Attorney Docket No.
16208559	CTNF	04/05/2021	KURIN2CON3
	892	04/05/2021	KURIN2CON3
	1449	04/05/2021	KURIN2CON3
	1449	04/05/2021	KURIN2CON3

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TERMINAL DISCLAIMER TO OBVIATE A PROVISIONAL DOUBLE PATENTING REJECTION OVER A PENDING "REFERENCE" APPLICATION	Docket Number (Optional) KURIN2CON3

In re Application of: Bobby E. ROGERS et al.

Application No.: 16/208,559

Filed: 2018-12-04

For: BLOOD SAMPLE OPTIMIZATION SYSTEM AND BLOOD CONTAMINANT SEQUESTRATION DEVICE AND METHOD

The applicant, Kurin, Inc., owner of 100 percent interest in the instant application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application which would extend beyond the expiration date of the full statutory term of any patent granted on pending **reference** Application Number 16/819,033, filed, 3/13/2020, as the term of any patent granted on said **reference** application may be shortened by any terminal disclaimer filed prior to the grant of any patent on the pending **reference** application. The applicant hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and any patent granted on the **reference** application are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assigns.

In making the above disclaimer, the applicant does not disclaim the terminal part of any patent granted on the instant application that would extend to the expiration date of the full statutory term of any patent granted on said **reference** application, "as the term of any patent granted on said **reference** application may be shortened by any terminal disclaimer filed prior to the grant of any patent on the pending **reference** application," in the event that: any such patent granted on the pending **reference** application expires for failure to pay a maintenance fee, is held unenforceable, is found invalid by a court of competent jurisdiction, is statutorily disclaimed in whole or terminally disclaimed under 37 CFR 1.321, has all claims canceled by a reexamination certificate, is reissued, or is in any manner terminated prior to the expiration of its full statutory term as shortened by any terminal disclaimer filed prior to its grant.

Check either box 1 or 2 below, if appropriate.

1. ☐ The undersigned is the applicant. If the applicant is an assignee, the undersigned is authorized to act on behalf of the assignee.

I hereby acknowledge that any willful false statements made are punishable under 18 U.S.C. 1001 by fine or imprisonment of not more than five (5) years, or both.

2. ☒ The undersigned is an attorney or agent of record. Reg. No. 53393

/JSN/	2021-07-06
Signature	Date
James Scott Nolan	
Typed or printed name	
Attorney for Applicant	858-212-2638
Title	Telephone Number

☑ Terminal disclaimer fee under 37 CFR 1.20(d) is included.

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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.

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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.
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).
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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.
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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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TERMINAL DISCLAIMER TO OBVIATE A DOUBLE PATENTING REJECTION OVER A "PRIOR" PATENT	Docket Number (Optional) KURIN2CON3

In re Application of: Bobby E. ROGERS et al.

Application No.: 16/208,559

Filed: 2018-12-04

For: BLOOD SAMPLE OPTIMIZATION SYSTEM AND BLOOD CONTAMINANT SEQUESTRATION DEVICE AND METHOD

The applicant, Kurin, Inc., owner of 100 percent interest in the instant application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application which would extend beyond the expiration date of the full statutory term of **prior patent** No. 10,143,412 as the term of said **prior patent** is presently shortened by any terminal disclaimer. The applicant hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and the **prior patent** are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assigns.

In making the above disclaimer, the applicant does not disclaim the terminal part of the term of any patent granted on the instant application that would extend to the expiration date of the full statutory term of the **prior patent**, "as the term of said **prior patent** is presently shortened by any terminal disclaimer," in the event that said **prior patent** later:

expires for failure to pay a maintenance fee;
is held unenforceable;
is found invalid by a court of competent jurisdiction;
is statutorily disclaimed in whole or terminally disclaimed under 37 CFR 1.321;
has all claims canceled by a reexamination certificate;
is reissued; or
is in any manner terminated prior to the expiration of its full statutory term as presently shortened by any terminal disclaimer.

Check either box 1 or 2 below, if appropriate.

1. ☐ The undersigned is the applicant. If the applicant is an assignee, the undersigned is authorized to act on behalf of the assignee.

I hereby acknowledge that any willful false statements made are punishable under 18 U.S.C. 1001 by fine or imprisonment of not more than five (5) years, or both.

2. ☒ The undersigned is an attorney or agent of record. Reg. No. 53393

/JSN/ — Signature
2021-07-06 — Date

James Scott Nolan — Typed or printed name

Attorney for Applicant — Title
858-212-2638 — Telephone Number

☑ Terminal disclaimer fee under 37 CFR 1.20(d) included.

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This collection of information is required by 37 CFR 1.321. 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 1.11 and 1.14. This collection is estimated to take 12 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, 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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TERMINAL DISCLAIMER TO OBVIATE A PROVISIONAL DOUBLE PATENTING REJECTION OVER A PENDING "REFERENCE" APPLICATION	Docket Number (Optional) KURIN2CON3

In re Application of: Bobby E. ROGERS et al.

Application No.: 16/208,559

Filed: 2018-12-04

For: BLOOD SAMPLE OPTIMIZATION SYSTEM AND BLOOD CONTAMINANT SEQUESTRATION DEVICE AND METHOD

The applicant, Kurin, Inc., owner of 100 percent interest in the instant application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application which would extend beyond the expiration date of the full statutory term of any patent granted on pending **reference** Application Number 15/855,439, filed, 12/27/2017, as the term of any patent granted on said **reference** application may be shortened by any terminal disclaimer filed prior to the grant of any patent on the pending **reference** application. The applicant hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and any patent granted on the **reference** application are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assigns.

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2. ☒ The undersigned is an attorney or agent of record. Reg. No. 53393

/JSN/	2021-07-06
Signature	Date
James Scott Nolan	
Typed or printed name	
Attorney for Applicant	858-212-2638
Title	Telephone Number

☑ Terminal disclaimer fee under 37 CFR 1.20(d) is included.

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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)).
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.

PTO/AIA/26 (04-14)
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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TERMINAL DISCLAIMER TO OBVIATE A DOUBLE PATENTING REJECTION OVER A "PRIOR" PATENT	Docket Number (Optional) KURIN2CON3

In re Application of: Bobby E. ROGERS et al.

Application No.: 16/208,559

Filed: 2018-12-04

For: BLOOD SAMPLE OPTIMIZATION SYSTEM AND BLOOD CONTAMINANT SEQUESTRATION DEVICE AND METHOD

The applicant, Kurin, Inc., owner of 100 percent interest in the instant application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application which would extend beyond the expiration date of the full statutory term of **prior patent** No. 9,820,682 as the term of said **prior patent** is presently shortened by any terminal disclaimer. The applicant hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and the **prior patent** are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assigns.

In making the above disclaimer, the applicant does not disclaim the terminal part of the term of any patent granted on the instant application that would extend to the expiration date of the full statutory term of the **prior patent**, "as the term of said **prior patent** is presently shortened by any terminal disclaimer," in the event that said **prior patent** later:

expires for failure to pay a maintenance fee;
is held unenforceable;
is found invalid by a court of competent jurisdiction;
is statutorily disclaimed in whole or terminally disclaimed under 37 CFR 1.321;
has all claims canceled by a reexamination certificate;
is reissued; or
is in any manner terminated prior to the expiration of its full statutory term as presently shortened by any terminal disclaimer.

Check either box 1 or 2 below, if appropriate.

1. ☐ The undersigned is the applicant. If the applicant is an assignee, the undersigned is authorized to act on behalf of the assignee.

I hereby acknowledge that any willful false statements made are punishable under 18 U.S.C. 1001 by fine or imprisonment of not more than five (5) years, or both.

2. ☒ The undersigned is an attorney or agent of record. Reg. No. 53393

/JSN/ — Signature
2021-07-06 — Date

James Scott Nolan — Typed or printed name

Attorney for Applicant — Title
858-212-2638 — Telephone Number

☑ Terminal disclaimer fee under 37 CFR 1.20(d) included.

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

This collection of information is required by 37 CFR 1.321. 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 1.11 and 1.14. This collection is estimated to take 12 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, 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 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.
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PTO/AIA/26 (04-14)
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TERMINAL DISCLAIMER TO OBVIATE A DOUBLE PATENTING REJECTION OVER A "PRIOR" PATENT	Docket Number (Optional) KURIN2CON3

In re Application of: Bobby E. ROGERS et al.

Application No.: 16/208,559

Filed: 2018-12-04

For: BLOOD SAMPLE OPTIMIZATION SYSTEM AND BLOOD CONTAMINANT SEQUESTRATION DEVICE AND METHOD

The applicant, Kurin, Inc., owner of 100 percent interest in the instant application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application which would extend beyond the expiration date of the full statutory term of **prior patent** No. 10,010,282 as the term of said **prior patent** is presently shortened by any terminal disclaimer. The applicant hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and the **prior patent** are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assigns.

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expires for failure to pay a maintenance fee;
is held unenforceable;
is found invalid by a court of competent jurisdiction;
is statutorily disclaimed in whole or terminally disclaimed under 37 CFR 1.321;
has all claims canceled by a reexamination certificate;
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Check either box 1 or 2 below, if appropriate.

1. ☐ The undersigned is the applicant. If the applicant is an assignee, the undersigned is authorized to act on behalf of the assignee.

I hereby acknowledge that any willful false statements made are punishable under 18 U.S.C. 1001 by fine or imprisonment of not more than five (5) years, or both.

2. ☒ The undersigned is an attorney or agent of record. Reg. No. 53393

/JSN/ — Signature
2021-07-06 — Date

James Scott Nolan — Typed or printed name

Attorney for Applicant — Title
858-212-2638 — Telephone Number

☑ Terminal disclaimer fee under 37 CFR 1.20(d) included.

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Electronic Patent Application Fee Transmittal

Application Number:	16208559
Filing Date:	04-Dec-2018
Title of Invention:	BLOOD SAMPLE OPTIMIZATION SYSTEM AND BLOOD CONTAMINANT SEQUESTRATION DEVICE AND METHOD
First Named Inventor/Applicant Name:	Bobby E. Rogers
Filer:	James Scott Nolan/KETHYA TEUK
Attorney Docket Number:	KURIN2CON3

Filed as Small Entity

Filing Fees for Utility under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Miscellaneous:				
STATUTORY OR TERMINAL DISCLAIMER	2814	5	170	850
		Total in USD ($)		**850**

Electronic Acknowledgement Receipt

EFS ID:	43175053
Application Number:	16208559
International Application Number:	
Confirmation Number:	1020
Title of Invention:	BLOOD SAMPLE OPTIMIZATION SYSTEM AND BLOOD CONTAMINANT SEQUESTRATION DEVICE AND METHOD
First Named Inventor/Applicant Name:	Bobby E. Rogers
Customer Number:	158174
Filer:	James Scott Nolan/KETHYA TEUK
Filer Authorized By:	James Scott Nolan
Attorney Docket Number:	KURIN2CON3
Receipt Date:	06-JUL-2021
Filing Date:	04-DEC-2018
Time Stamp:	18:00:04
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	$850
RAM confirmation Number	E202176I00373830
Deposit Account	
Authorized User	
The Director of the USPTO is hereby authorized to charge indicated fees and credit any overpayment as follows:	

File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Amendment/Req. Reconsideration-After Non-Final Reject	KURIN2CON3_RespNFOA_Final.pdf	191082 c42beaaaa5b8b53f1af9249135539622145d54fb	no	8
Warnings:					
Information:					
2	Terminal Disclaimer Filed	KURIN2CON3_TD_033_Final.pdf	264201 c66d6cd24e71f666092b12853ac8a7a33ff889e7	no	2
Warnings:					
Information:					
3	Terminal Disclaimer Filed	KURIN2CON3_TD_412_Final.pdf	173213 1cbddede99f24ce57331d7ae8662f0d0d0acadc5	no	2
Warnings:					
Information:					
4	Terminal Disclaimer Filed	KURIN2CON3_TD_439_Final.pdf	259792 f13217d89f100dde3008210bb5f50957b9b4142b	no	2
Warnings:					
Information:					
5	Terminal Disclaimer Filed	KURIN2CON3_TD_682_Final.pdf	173277 9f756c911e5d755d2e912172ea48419aa330a8c5	no	2
Warnings:					
Information:					
6	Terminal Disclaimer Filed	KURIN2CON3_TD_282_Final.pdf	155683 e8a2f2e8af1898a4ac666d232f0146d77c17171c	no	2
Warnings:					
Information:					

7	Fee Worksheet (SB06)	fee-info.pdf	30733 0800eef8c1cbf685ec3100069727caf36a65ca6c	no	2
Warnings:					
Information:					
			Total Files Size (in bytes):	1247981	

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New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for a 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.

PATENT
Attorney Docket No.: KURIN2CON3

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application:	Confirmation No.: 1020
Inventor: Bobby E. Rogers	Group Art Unit: 3791
Application No.: 16/208,559	Examiner: ABOUELELA, MAY A
Filed: December 4, 2018	Customer No.: 158174
Title: BLOOD SAMPLE OPTIMIZATION SYSTEM AND BLOOD CONTAMINANT SEQUESTRATION DEVICE AND METHOD	

FILED ELECTRONICALLY BY EFS-Web

RESPONSE TO NON-FINAL OFFICE ACTION

Mail Stop AMENDMENT
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Commissioner,

This is in response to the Non-Final Office Action electronically transmitted April 5, 2021. The three-month shortened statutory period to respond to this Office Action expires on July 5, 2021. Accordingly, this paper is timely filed. Please consider the following remarks, and amend the above-identified application as follows:

Amendments to the Claims begin on page 2 of this paper.
Remarks begin on page 7 of this paper.

AMENDMENTS TO THE CLAIMS

The following listing of claims will replace all prior versions, and listings, of claims in the application.

Listing of Claims:

1. (Currently Amended) A blood sequestration device for sequestering blood conveyed from a patient, the blood sequestration device comprising;

an inlet port ~~for receiving~~ configured to receive the blood conveyed from the patient;

an outlet port;

a sequestration chamber having a vent that includes an air permeable blood barrier; and

a sampling channel having a distal end connected with the outlet port;

a junction connected between the inlet port, the sequestration 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 sequestration chamber to displace air therein through the air permeable blood barrier and to be sequestered in the sequestration chamber, and such that a second portion of blood is allowed to bypass the sequestration chamber and the first portion of blood sequestered therein to be directed into the sampling channel toward the outlet port.

2. (Original) The blood sequestration device in accordance with claim 1, wherein the air permeable blood barrier includes an air permeable material that at least partially seals upon contact with blood.

3. (Original) The blood sequestration device in accordance with claim 1, further comprising a housing that defines at least a part of each of the inlet port, the outlet port, the sequestration chamber, and the sampling channel.

4. (Original) The blood sequestration device in accordance with claim 3, wherein the sequestration chamber includes a sequestration channel defined in the housing.

5. (Original) The blood sequestration device in accordance with claim 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 port, the outlet port, the sequestration chamber, and the sampling channel.

6. (Currently Amended) A blood sequestration device connected with a blood sampling pathway having a patient needle or catheter and a sample collection device, the blood sequestration device comprising:

an inlet port connected with the patient needle or catheter;

an outlet port connected with the sample collection device;

a sequestration chamber having a vent that includes an air permeable blood barrier; and

[[and]] a sampling channel having a distal end connected with the outlet port;

each of the sequestration chamber and the sampling channel being connected with the inlet port via a junction that is sized and configured such that a first portion of blood flows into the sequestration chamber to displace air therein through the air permeable blood barrier and to be sequestered in the sequestration chamber, and a second portion of blood is allowed to bypass the sequestration chamber and the first portion of blood sequestered therein to be directed into the sampling channel toward the outlet port and the sample collection device.

7. (Original) The blood sequestration device in accordance with claim 6, further comprising a housing that at least partially houses and defines the inlet port, the outlet port, the sequestration chamber, and the sampling channel.

8. (Original) The blood sequestration device in accordance with claim 6, wherein the inlet port is connected with the patient needle or catheter via a first portion of the blood sampling pathway.

9. (Original) The blood sequestration device in accordance with claim 6, wherein the outlet port is connected with the sample collection device via a second portion of the blood sampling pathway.

10. (Original) The blood sequestration 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 blood.

11. (Original) The blood sequestration device in accordance with claim 7, wherein the sequestration chamber includes a sequestration channel defined in the housing.

12. (Original) The blood sequestration device in accordance with claim 11, 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.

13. (Original) A bodily fluid sequestration device comprising;

an inlet port;

an outlet port connected with the inlet port;

a sequestration chamber connected with the inlet port via a junction, the sequestration chamber having a vent that includes an air permeable bodily fluid barrier that at least partially seals upon contact with bodily fluid; and

a housing that houses and defines the inlet port, the outlet port, and the sequestration chamber, the sequestration chamber and the junction configured to direct a first portion of bodily fluid from the inlet port into the sequestration chamber toward the air permeable bodily fluid barrier and to displace air in the sequestration chamber;

whereupon at least partially sealing of the air permeable blood barrier enables sequestration of the first portion of bodily fluid in the sequestration chamber, and enables a second portion of bodily fluid from the inlet port to bypass the sequestration chamber via the junction and the first portion of bodily fluid, toward the outlet port.

14. (Original) The bodily fluid sequestration device in accordance with claim 13, wherein the air permeable bodily fluid barrier includes an air permeable material that seals upon contact with the bodily fluids.

15. (Original) The bodily fluid sequestration device in accordance with claim 13, wherein the sequestration chamber includes a sequestration channel defined in the housing.

16. (Original) The bodily fluid sequestration device in accordance with claim 13, further comprising a sampling pathway connected with the inlet port, wherein the sampling pathway conveys the second portion of bodily fluid from the inlet port to the outlet port via the junction.

17. (Original) The bodily fluid sequestration device in accordance with claim 13, 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, and the sequestration chamber.

18. (Original) The bodily fluid sequestration device in accordance with claim 13, further comprising a sampling channel having a proximal end connected with the inlet port via the junction.

19. (Original) The blood sequestration device in accordance with claim 18, 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.

20. (Currently Amended) A blood sequestration system comprising:

a blood sampling pathway having a patient catheter and a sample collection device; and

a blood sequestration device connected on the blood sampling pathway, the blood sequestration device comprising:

an inlet port connected with the patient catheter;

an outlet port connected with the sample collection device;

a sequestration chamber having a vent that includes an air permeable blood barrier; and

[[and]] a sampling channel having a distal end connected with the outlet port;

each of the sequestration chamber and the sampling channel being connected with the inlet port via a junction that is sized and configured such that a first portion of blood flows into the sequestration chamber to displace air therein through the air permeable blood barrier and to be sequestered in the sequestration chamber, and a second portion of blood is allowed to bypass the sequestration chamber and the first portion of blood sequestered therein to be directed into the sampling channel toward the outlet port and the sample collection device.

21. (Original) The blood sequestration system in accordance with claim 20, further comprising a housing that houses and defines the inlet port, the outlet port, the sequestration chamber, and the sampling channel.

22. (Original) The blood sequestration system in accordance with claim 20, wherein the inlet port is connected with the patient catheter via a first portion of the blood sampling pathway.

23. (Original) The blood sequestration system in accordance with claim 20, wherein the outlet port is connected with the sample collection device via a second portion of the blood sampling pathway.

24. (Original) The blood sequestration system in accordance with claim 20, wherein the air permeable blood barrier includes an air permeable material that seals at least partially upon contact with blood.

25. (Original) The blood sequestration system in accordance with claim 24, wherein the sequestration chamber includes a sequestration channel defined in the housing.

26. (Original) The blood sequestration device in accordance with claim 25, 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.

REMARKS

Claims 1-26 are pending. Claims 1, 6 and 20 have been amended. No claims have been added. All claims are fully supported by the specification as originally filed. Allowance of the current claims is requested in light of the foregoing remarks. No new matter has been added.

Claim Objections

Claim 6 is objected to because of the following informalities: the phrase "and and a sampling channel" in lines 7-8. Claim 6 has been amended to delete the second “and”.

Claim 20 is objected to because of the following informalities: the phrase "and and a sampling channel" in lines 9-10. Claim 20 has been amended to delete second “and”.

Claim Rejections – 35 USC § 101

Claim 1 recites the limitation "an inlet port for receiving the blood". The Office states that the current claim language positively recites a body part of a human being, thus claiming non-statutory subject matter. In order to overcome this rejection, claim 1 has been amended to recite the “an inlet port ~~for receiving~~ configured to receive the blood conveyed from the patient,” as suggested by the Examiner.

Double Patenting Rejection

Claims 1-26 are provisionally rejected on the ground of nonstatutory double patenting as being unpatentable over: claims 1-20 of copending Application No.15/855439; claims 1-20 of copending Application No.16/819033; claims 1-16 of Patent Application No. 10010282; claims 1-23 of Patent Application No.10143412; and claims 1-16 of Patent Application No.9820682. Applicant submits herewith terminal disclaimers to overcome this rejection.

CONCLUSION

Accordingly, this application should be in condition for allowance, and notice to that effect is respectfully requested. If the Examiner believes that it would facilitate prosecution, Applicant respectfully requests that the Examiner contact the undersigned attorney at 858-212-2638

In the event this paper is not timely filed, Applicant petitions for an appropriate extension of time.

Respectfully submitted,

Date: July 6, 2021

/JSN/

P.O. Box 371710
San Diego, California 92137
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James Scott Nolan
Attorney for Applicant
Registration No.: 53393

Application Number	Application/Control No.	Applicant(s)/Patent under Reexamination	
* 16/208,559 *	16/208,559	Rogers et al.	
	Examiner	**Art Unit**	
	ABOUELELA, MAY A	3791	

Document Code - DISQ	**Internal Document - DO NOT MAIL**

TERMINAL DISCLAIMER	☑ APPROVED	☐ DISAPPROVED
Date Filed: 06 July 2021	**This patent is subject to a Terminal Disclaimer**	

Approved/Disapproved by:

/FELICIA D ROBERTS/

Technology Center: OPLC

Telephone: (571)272-0550

5 TDs approved with this filing date

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

158174 7590 07/28/2021

Kurin, Inc.
P.O. Box 371710
San Diego, CA 92137

EXAMINER
ABOUELELA, MAY A

ART UNIT	PAPER NUMBER
3791	

DATE MAILED: 07/28/2021

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/208,559	12/04/2018	Bobby E. Rogers	KURIN2CON3	1020

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	$600	$0.00	$0.00	$600	10/28/2021

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 and an extra copy of the form should be submitted. 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)

158174 7590 07/28/2021
Kurin, Inc.
P.O. Box 371710
San Diego, CA 92137

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.
16/208,559	12/04/2018	Bobby E. Rogers	KURIN2CON3	1020

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nonprovisional	SMALL	$600	$0.00	$0.00	$600	10/28/2021

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/SB/122) attached.

❑ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-09 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
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P.O. Box 1450
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/208,559	12/04/2018	Bobby E. Rogers	KURIN2CON3	1020

158174 7590 07/28/2021

Kurin, Inc.
P.O. Box 371710
San Diego, CA 92137

EXAMINER	
ABOUELELA, MAY A	
ART UNIT	PAPER NUMBER
3791	

DATE MAILED: 07/28/2021

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. 16/208,559	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 07/06/2021.
   ☐ 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 1-26 . 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 _____.

/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 disclaimers filed on 07/06/2021 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of pending U.S Application No.16/819033, and 15/855439, and U.S Patent Application No. 9820682, 10143412, and 10010282 have been reviewed and are accepted. The terminal disclaimer has been recorded.

Allowable Subject Matter

3. Claims 1-26 are allowed.

4. 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 sequestration device for sequestering blood conveyed from a patient, the blood sequestration device comprising; an inlet port configured to receive the blood conveyed from the patient; an outlet port; a sequestration chamber; and a sampling channel having a distal end connected with the outlet port; a junction connected between the inlet port, the sequestration 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 sequestration chamber to displace air therein through the air permeable blood barrier and to be sequestered in the sequestration chamber.

The prior art does not teach, disclose and/or fairly suggest the sequestration 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 sequestration 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 on 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 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 https://ppair-my.uspto.gov/pair/PrivatePair. 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.

/MAY A ABOUELELA/
Primary Examiner, Art Unit 3791

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16/208,559	Rogers et al.
	Examiner	**Art Unit**
	MAY A ABOUELELA	3791

CPC						
Symbol					**Type**	**Version**
A61B	/	5	/	150992	F	2013-01-01
A61M	/	39	/	04	I	2013-01-01
A61B	/	5	/	150221	I	2013-01-01
A61B	/	5	/	15003	I	2013-01-01
A61B	/	5	/	150213	I	2013-01-01
A61B	/	5	/	150389	I	2013-01-01
A61B	/	5	/	150473	I	2013-01-01
A61B	/	5	/	150572	I	2013-01-01
A61B	/	5	/	154	I	2013-01-01
A61B	/	5	/	153	I	2013-01-01
A61M	/	39	/	0693	I	2013-01-01
A61M	/	2039	/	0202	A	2013-01-01
A61M	/	2039	/	068	A	2013-01-01
A61M	/	2039	/	0633	A	2013-01-01

CPC Combination Sets							
Symbol					**Type**	**Set**	**Ranking**	**Version**
	/		/					

NONE		**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	26	
/MAY A ABOUELELA/ Primary Examiner, Art Unit 3791	08 July 2021	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	15C

U.S. Patent and Trademark Office — Part of Paper No.: 20210708

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16/208,559	Rogers et al.
	Examiner	**Art Unit**
	MAY A ABOUELELA	3791

INTERNATIONAL CLASSIFICATION					
CLAIMED					
A61B	/	5	/	00	
NON-CLAIMED					
	/		/		

US ORIGINAL CLASSIFICATION	
CLASS	**SUBCLASS**
600	573

CROSS REFERENCES(S)						
CLASS	**SUBCLASS (ONE SUBCLASS PER BLOCK)**					
600	576	577				

NONE		**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	26	
/MAY A ABOUELELA/ Primary Examiner, Art Unit 3791	08 July 2021	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	15C

U.S. Patent and Trademark Office — Part of Paper No.: 20210708

Issue Classification	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16/208,559	Rogers et al.
	Examiner	**Art Unit**
	MAY A ABOUELELA	3791

☑ Claims renumbered in the same order as presented by applicant ☐ CPA ☑ T.D. ☐ R.1.47

CLAIMS

Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original
	1		10		19										
	2		11		20										
	3		12		21										
	4		13		22										
	5		14		23										
	6		15		24										
	7		16		25										
	8		17		26										
	9		18												

NONE		**Total Claims Allowed:**	
(Assistant Examiner)	(Date)	26	
/MAY A ABOUELELA/ Primary Examiner, Art Unit 3791	08 July 2021	O.G. Print Claim(s)	O.G. Print Figure
(Primary Examiner)	(Date)	1	15C

U.S. Patent and Trademark Office — Part of Paper No.: 20210708

Index of Claims	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16/208,559	Rogers et al.
	Examiner	Art Unit
	MAY A ABOUELELA	3791

✓	Rejected	-	Cancelled	N	Non-Elected	A	Appeal
=	Allowed	÷	Restricted	I	Interference	O	Objected

CLAIMS

☑ Claims renumbered in the same order as presented by applicant ☐ CPA ☑ T.D. ☐ R.1.47

CLAIM		DATE								
Final	Original	03/02/2021	07/08/2021							
	1	✓	=							
	2	✓	=							
	3	✓	=							
	4	✓	=							
	5	✓	=							
	6	✓	=							
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	16	✓	=							
	17	✓	=							
	18	✓	=							
	19	✓	=							
	20	✓	=							
	21	✓	=							
	22	✓	=							
	23	✓	=							
	24	✓	=							
	25	✓	=							
	26	✓	=							

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16/208,559	Rogers et al.
	Examiner	Art Unit
	MAY A ABOUELELA	3791

CPC - Searched*		
Symbol	**Date**	**Examiner**
A61B5/150992 or A61B5/15003 or A61B5/150213 or A61B5/150389 or A61B5/150473 or A61B5/150572 or A61B5/154 or A61B5/153 or A61M39/0693 or A61M39/04 or A61B5/150221 or A61M2039/0633 or A61M2039/0202 or A61M2039/068	03/02/2021	MA
updated as above	07/08/2021	MA

CPC Combination Sets - Searched*		
Symbol	**Date**	**Examiner**

US Classification - Searched*			
Class	**Subclass**	**Date**	**Examiner**
600	573, 576, 577, 583	03/02/2021	MA
604	164.01	03/02/2021	MA
updated as above		07/08/2021	MA

* See search history printout included with this form or the SEARCH NOTES box below to determine the scope of the search.

Search Notes		
Search Notes	**Date**	**Examiner**
inventor name search, east text search, class/subclass search	03/02/2021	MA
updated as above	07/08/2021	MA

/MAY A ABOUELELA/ Primary Examiner, Art Unit 3791	

Search Notes	Application/Control No.	Applicant(s)/Patent Under Reexamination
	16/208,559	Rogers et al.
	Examiner	Art Unit
	MAY A ABOUELELA	3791

Interference Search			
US Class/CPC Symbol	US Subclass/CPC Group	Date	Examiner
as above		07/08/2021	MA

/MAY A ABOUELELA/ Primary Examiner, Art Unit 3791	

EAST Search History

EAST Search History (Prior Art)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L1	182	(("ROGERS") near3 ("Bobby")).INV.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2021/07/08 14:22
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L3	4,684	2 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4 or collect$4))	US-PGPUB; USPAT	OR	OFF	2021/07/08 15:28
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L9	211	8 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4 or collect$4))	US-PGPUB; USPAT	OR	OFF	2021/07/08 16:19
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L22	163	19 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4 or collect$4))	US-PGPUB; USPAT	OR	OFF	2021/07/08 16:27
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L24	1,736	(600/573).CCLS.	US-PGPUB; USPAT	OR	OFF	2021/07/08 16:37
L25	1,363	24 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4 or collect$4))	US-PGPUB; USPAT	OR	OFF	2021/07/08 16:37
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L27	136	26 and (vent$4 near4 air)	US-PGPUB; USPAT	OR	OFF	2021/07/08 16:38
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L29	711	28 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4 or collect$4))	US-PGPUB; USPAT	OR	OFF	2021/07/08 16:41
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S9	7	S4 and (blood near4 sequest$5)	US-PGPUB; USPAT	OR	OFF	2016/12/21 17:42
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S19	265,030	(blood near4 (sequest$5 or sampl$4))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2016/12/21 19:09
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S65	1	("15140443").PN.	US-PGPUB; USPAT	OR	OFF	2017/09/27 13:28
S66	1	("20080145933").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2017/09/27 13:51
S67	9	("2008/0145933").URPN.	USPAT	OR	OFF	2017/09/27 13:55
S68	1	("20040054333").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2017/09/27 13:59
S69	1	("20120109034").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2017/09/27 14:37
S70	1	("20100228206").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2017/09/27 14:39
S71	3	("2010/0228206").URPN.	USPAT	OR	OFF	2017/09/27 14:47
S72	66	(("ROGERS") near3 ("Bobby")).INV.	US-PGPUB; USPAT	OR	OFF	2017/09/28 13:41
S73	4	S72 and (blood near4 (sequest$5 or sampl$4))	US-PGPUB; USPAT	OR	OFF	2017/09/28 13:42
S74	1,733	(600/573).CCLS.	US-PGPUB; USPAT	OR	OFF	2017/09/28 13:58
S75	845	S74 and (blood near4 (sequest$5 or sampl$4))	US-PGPUB; USPAT	OR	OFF	2017/09/28 13:58
S76	9	S75 and ((vent$4 near4 air) and flash$6)	US-PGPUB; USPAT	OR	OFF	2017/09/28 13:59
S77	86	("2007/0083162").URPN.	USPAT	OR	OFF	2017/09/28 13:59
S78	1	("15140443").PN.	US-PGPUB; USPAT	OR	OFF	2017/09/28 13:59
S79	9	("2008/0145933").URPN.	USPAT	OR	OFF	2017/09/28 14:04
S80	1,258	(600/583).CCLS.	US-PGPUB; USPAT	OR	OFF	2017/09/28 14:20
S81	1,071	S80 and (blood near4 (sequest$5 or sampl$4))	US-PGPUB; USPAT	OR	OFF	2017/09/28 14:20
S82	78	S81 and (vent$4 near4 air)	US-PGPUB; USPAT	OR	OFF	2017/09/28 14:21
S83	282,596	(blood near4 (sequest$5 or sampl$4))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO;	OR	OFF	2017/09/28 16:01

			DERWENT; IBM_TDB			
S84	6,183	S83 AND ((A61B10/0096 OR A61B5/150022).CPC.)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2017/09/28 16:01
S85	387	S84 and (vent$4 near4 air)	US-PGPUB; USPAT	OR	OFF	2017/09/28 16:01
S86	362	S85 and @ad<"20150724"	US-PGPUB; USPAT	OR	OFF	2017/09/28 16:02
S87	12	("2005/0010189").URPN.	USPAT	OR	OFF	2017/09/28 16:03
S88	1,363	(604/164.01).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2017/09/28 16:04
S89	74	S88 and (blood near4 (sequest$5 or sampl$4))	US-PGPUB; USPAT	OR	OFF	2017/09/28 16:05
S90	21	("3965910" | "3996923" | "4131127" | "4301811" | "4450854" | "4506691" | "4819684" | "5147333" | "5393035" | "5636975").PN. OR ("6569117").URPN.	US-PGPUB; USPAT; USOCR	OR	OFF	2017/09/28 16:09
S91	499	(435/294.1).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2017/09/28 16:12
S92	18	S91 and (blood near4 (sequest$5 or sampl$4))	US-PGPUB; USPAT	OR	OFF	2017/09/28 16:12
S93	9	("2008/0145933").URPN.	USPAT	OR	OFF	2017/09/28 16:13
S95	67	(("ROGERS") near3 ("Bobby")).INV.	US-PGPUB; USPAT	OR	OFF	2018/01/09 16:23
S96	1,258	(600/583).CCLS.	US-PGPUB; USPAT	OR	OFF	2018/01/09 16:25
S97	4	S96 and ((vent$4 near4 air) and flash$6)	US-PGPUB; USPAT	OR	OFF	2018/01/09 16:25
S98	3	S97 and (blood near4 (sequest$5 or sampl$4))	US-PGPUB; USPAT	OR	OFF	2018/01/09 16:26
S99	1,733	(600/573).CCLS.	US-PGPUB; USPAT	OR	OFF	2018/01/09 16:50
S100	13	S99 and ((vent$4 near4 air) and flash$6)	US-PGPUB; USPAT	OR	OFF	2018/01/09 16:50

S101	255	("1779451" | "2004050" | "2700385" | "2836942" | "2854976" | "2953243" | "3021942" | "3073307" | "3074542" | "3255873" | "3294231" | "3323523" | "3329146" | "3333682" | "3367488" | "3382865" | "3485239" | "3537452" | "3585984" | "3610240" | "3658061" | "3664879" | "3817240" | "3828775" | "3859998" | "3874367" | "3886930" | "3890971" | "3904033" | "3934722" | "3968876" | "4106497" | "4108175" | "4113090" | "4139009" | "4154229" | "4166450" | "4175008" | "4193400" | "4207870" | "4269186" | "4300678" | "4312362" | "4317445" | "4340068" | "4375849" | "4398544" | "4409990" | "4412548" | "4416290" | "4416291" | "4418703" | "4430082" | "4436098" | "4444203" | "4592744" | "4634428" | "4643722" | "4659330" | "4664249" | "4664654" | "4671408" | "4679571" | "4681567" | "4695274" | "4702738" | "4723943" | "4728320" | "4728321" | "4731059" | "4735311" | "4735618" | "4737144" | "4738663" | "4743233" | "4746008" | "4747836" | "4747837" | "4772272" | "4778453" | "4781697" | "4782841" | "4788986" | "4790828" | "4793484" | "4795432" | "4795443" | "4801295" | "4804372" | "4813426" | "4816022" | "4816024" | "4819659" | "4820277" | "4826490" | "4826491" | "4838871" | "4842587" | "4844089" | "4846796" | "4850968" | "4850976" | "4850977" | "4850978" | "4850994" | "4850996" | "4858607" | "4863434" | "4863435" | "4863436" | "4865592" | "4867746" | "4872552" | "4874383" | "4874384" | "4883469" | "4886072" | "4886503" | "4888001" | "4892107" | "4892521" | "4894052" | "4900309" | "4909791" | "4909792").PN. OR ("4921096" | "4927018" | "4944397" | "4966591" | "4971068" | "4976699" | "4982842" | "5011475" | "5011479" | "5030207" | "5032116" | "5033476" | "5055102" | "5069225" | "5078693" | "5078698" | "5092845" | "5112327" | "5116325" | "5120319" | "5122121" | "5135509" | "5137518" | "5139489" | "5151089" | "5154285" | "5181523" | "5188611" | "5197954" | "5201794" | "5207653" | "5217025" | "5222502" |	US-PGPUB; USPAT; USOCR	OR	OFF	2018/01/09 16:51

		"5232454" | "5232455" | "5242411" | "5242417" | "5277311" | "5290246" | "5295969" | "5303713" | "5306259" | "5312369" | "5401251" | "5405332" | "5423765" | "5450856" | "5462534" | "5485854" | "5486163" | "5490841" | "5496281" | "5509907" | "5520193" | "5533984" | "5542932" | "5584816" | "5599313" | "5599318" | "5603699" | "5632732" | "5643219" | "5662617" | "5665075" | "5669889" | "5693022" | "5697914" | "5702369" | "5733265" | "5755701" | "5807351" | "5830190" | "5836920" | "5885249" | "5893844" | "5913846" | "5984895" | "5993426" | "6059737" | "6077244" | "6077253" | "6080137" | "6096006" | "6110160" | "6120482" | "6156010" | "6190370" | "6261263" | "6511439" | "6533760" | "6964658" | "7160267" | "RE31086").PN. OR ("7615033").URPN.				
S102	215	S101 and @ad<"20150724"	US-PGPUB; USPAT	OR	OFF	2018/01/09 16:51
S103	1,347	(604/164.01).CCLS.	US-PGPUB; USPAT	OR	OFF	2018/01/09 17:11
S104	17	S103 and ((vent$4 near4 air) and flash$6)	US-PGPUB; USPAT	OR	OFF	2018/01/09 17:11
S105	19	("2009/0312711").URPN.	USPAT	OR	OFF	2018/01/09 17:11
S106	11	("2007/0106220").URPN.	USPAT	OR	OFF	2018/01/09 17:11
S107	288,967	(blood near4 (sequest$5 or sampl$4))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2018/01/09 17:16
S108	6,321	S107 AND ((A61B10/0096 OR A61B5/150022).CPC.)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2018/01/09 17:16
S109	121	S108 and ((vent$4 near4 air) and flash$6)	US-PGPUB; USPAT	OR	OFF	2018/01/09 17:17
S110	448	(435/294.1).CCLS.	US-PGPUB; USPAT	OR	OFF	2018/01/09 17:31

S111	6	S110 and ((vent$4 near4 air) and flash$6)	US-PGPUB; USPAT	OR	OFF	2018/01/09 17:31
S113	71	(("ROGERS") near3 ("Bobby")).INV.	US-PGPUB; USPAT	OR	OFF	2018/07/24 13:31
S114	0	("15140443").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2018/07/24 13:38
S115	2	(15/140443).APP.	US-PGPUB; USPAT; USOCR	OR	OFF	2018/07/24 13:38
S116	2	(15/140448).APP.	US-PGPUB; USPAT; USOCR	OR	OFF	2018/07/24 13:40
S117	1,735	(600/573).CCLS.	US-PGPUB; USPAT	OR	OFF	2018/07/24 13:56
S118	854	S117 and (blood near4 (sequest$5 or sampl$4))	US-PGPUB; USPAT	OR	OFF	2018/07/24 13:56
S119	91	S118 and (vent$4 near4 air)	US-PGPUB; USPAT	OR	OFF	2018/07/24 13:57
S120	1,258	(600/583).CCLS.	US-PGPUB; USPAT	OR	OFF	2018/07/24 14:06
S121	1,074	S120 and (blood near4 (sequest$5 or sampl$4))	US-PGPUB; USPAT	OR	OFF	2018/07/24 14:06
S122	80	S121 and (vent$4 near4 air)	US-PGPUB; USPAT	OR	OFF	2018/07/24 14:06
S123	301,210	(blood near4 (sequest$5 or sampl$4))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2018/07/24 14:11
S124	6,556	S123 AND ((A61B10/0096 OR A61B5/150022).CPC.)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2018/07/24 14:11
S125	3,664	S124 and @ad<"20150724"	US-PGPUB; USPAT	OR	OFF	2018/07/24 14:12
S126	12,749	"19" and ((vent$4 near4 air) and flash$6)	US-PGPUB; USPAT	OR	OFF	2018/07/24 14:12
S127	117	S125 and ((vent$4 near4 air) and flash$6)	US-PGPUB; USPAT	OR	OFF	2018/07/24 14:12

S128	1,348	(604/164.01).CCLS.	US-PGPUB; USPAT	OR	OFF	2018/07/24 14:16
S129	75	S128 and (blood near4 (sequest$5 or sampl$4))	US-PGPUB; USPAT	OR	OFF	2018/07/24 14:17
S130	1	("20120291564").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2018/07/24 14:21
S131	448	(435/294.1).CCLS.	US-PGPUB; USPAT	OR	OFF	2018/07/24 14:25
S132	18	S131 and (blood near4 (sequest$5 or sampl$4))	US-PGPUB; USPAT	OR	OFF	2018/07/24 14:25
S133	98	("20020002349" | "20020183651" | "20030055381" | "20030208151" | "20040010228" | "20040054333" | "20040147855" | "20050004524" | "20050240161" | "20050245885" | "20050281713" | "20060287639" | "20080108954" | "20080145933" | "2707953" | "3013557" | "3098016" | "3382865" | "3405706" | "3494351" | "3577980" | "3648684" | "3848579" | "3937211" | "4057050" | "4133863" | "4166450" | "4340067" | "4370987" | "4444203" | "4459997" | "4509534" | "4657160" | "4676256" | "4865583" | "4890627" | "4988339" | "5009847" | "5097842" | "5108927" | "5122129" | "5269317" | "5330464" | "5360011" | "5429610" | "5450856" | "5507299" | "5577513" | "5762633" | "5865812" | "5882318" | "5922551" | "6016712" | "6057105" | "6159164" | "6210909" | "6364890" | "6387086" | "6403381" | "6626884" | "6692479" | "6746420" | "6913580" | "7044941" | "7087047" | "7335188" | "7744573" | "8197420" | "8231546" | "8337418").PN. OR ("8535241").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2018/07/24 14:44
S135	23	("4166450").PN. OR ("4412548").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2018/07/24 14:48
S136	307	("2913000" | "3817240" | "3859998" | "3864979" | "4016879" | "4046144").PN. OR ("4207870").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2018/07/24 14:48
S137	4	("2007/0088279").URPN.	USPAT	OR	ON	2018/07/24 14:48
S138	1	(14/990763).APP.	US-PGPUB; USPAT; USOCR	OR	OFF	2018/07/24 14:58

S139	9	(blood and sequest$5 and junction and first and portion and sampl$4).clm.	US-PGPUB; USPAT	OR	ON	2018/07/24 15:07
S140	1	(15/287421).APP.	US-PGPUB; USPAT; USOCR	OR	OFF	2018/07/25 21:39
S141	2	(14/055232).APP.	US-PGPUB; USPAT; USOCR	OR	OFF	2018/07/26 11:56
S142	2	(15/140443).APP.	US-PGPUB; USPAT; USOCR	OR	OFF	2019/11/07 15:24
S143	1	(15/893518).APP.	US-PGPUB; USPAT; USOCR	OR	OFF	2019/11/07 15:25
S144	34	("20020004647" | "20030105414" | "20040054333" | "20040073171" | "20040147855" | "20050004524" | "20050240161" | "20070088279" | "20080145933" | "20100057004" | "20130317391" | "20160174888" | "3817240" | "3874367" | "3886930" | "4057050" | "4106497" | "4154229" | "4207870" | "4412548" | "5222502" | "5520193" | "5749857" | "6569117" | "8197420" | "8523826" | "8535241" | "8540663" | "8568371" | "8864684" | "9022951" | "9060724" | "9138572" | "9204864").PN.	US-PGPUB; USPAT	OR	ON	2019/11/07 17:53
S145	272	((("ROGERS") near3 ("Bobby")) OR (("KANG") near3 ("Gino")) OR (("STROUP") near3 ("David")) OR (("COCHRAN") near3 ("Jonas")) OR (("DEPTALA") near3 ("Arthur")) OR (("DETLOFF") near3 ("John")) OR (("POGUE") near3 ("Lonnie")) OR (("MACOWSKI") near3 ("Brian")) OR (("GARRETT") near3 ("Chad"))).INV.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2019/11/07 17:57
S146	9	S145 and (blood near4 sequest$5)	US-PGPUB; USPAT	OR	OFF	2019/11/07 17:58
S147	34	("20020004647" | "20030105414" | "20040054333" | "20040073171" | "20040147855" | "20050004524" | "20050240161" | "20070088279" | "20080145933" | "20100057004" | "20130317391" | "20160174888" | "3817240" | "3874367" | "3886930" | "4057050" | "4106497" | "4154229" | "4207870" | "4412548" | "5222502" | "5520193" | "5749857" | "6569117" |	US-PGPUB; USPAT	OR	ON	2019/11/07 18:26

		"8197420" | "8523826" | "8535241" | "8540663" | "8568371" | "8864684" | "9022951" | "9060724" | "9138572" | "9204864").PN.				
S148	5	S147 and ((vent$4 near4 air) and flash$6)	US-PGPUB; USPAT	OR	OFF	2019/11/07 18:29
S149	6	("2010/0057004").URPN.	USPAT	OR	ON	2019/11/07 18:40
S150	0	S149 and ((vent$4 near4 air) and flash$6)	US-PGPUB; USPAT	OR	OFF	2019/11/07 19:20
S151	1,258	(600/583).CCLS.	US-PGPUB; USPAT	OR	OFF	2019/11/07 19:21
S152	4	S151 and ((vent$4 near4 air) and flash$6)	US-PGPUB; USPAT	OR	OFF	2019/11/07 19:21
S153	1,766	(600/573).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2019/11/07 19:21
S154	13	S153 and ((vent$4 near4 air) and flash$6)	US-PGPUB; USPAT	OR	OFF	2019/11/07 19:21
S155	811	(600/576).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2019/11/07 19:22
S156	48	S155 and ((vent$4 near4 air) and flash$6)	US-PGPUB; USPAT	OR	OFF	2019/11/07 19:22
S157	1,351	(604/164.01).CCLS.	US-PGPUB; USPAT	OR	OFF	2019/11/07 19:43
S158	17	S157 and ((vent$4 near4 air) and flash$6)	US-PGPUB; USPAT	OR	OFF	2019/11/07 19:43
S159	448	(435/294.1).CCLS.	US-PGPUB; USPAT	OR	OFF	2019/11/07 19:43
S160	6	S159 and ((vent$4 near4 air) and flash$6)	US-PGPUB; USPAT	OR	OFF	2019/11/07 19:44
S161	333,030	(blood near4 (sequest$5 or sampl$4))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2019/11/07 19:44
S162	6,981	S161 AND ((A61B10/0096 OR A61B5/150022).CPC.)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2019/11/07 19:44

S163	139	S162 and ((vent$4 near4 air) and flash$6)	US-PGPUB; USPAT	OR	OFF	2019/11/07 19:44
S164	117	S163 and @ad<"20150724"	US-PGPUB; USPAT	OR	OFF	2019/11/07 19:45
S165	1	S146 and (enclos$3 near4 mechanism)	US-PGPUB; USPAT	OR	OFF	2019/11/07 19:51
S166	1	("7637875").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2019/11/08 16:57
S167	1	(15/139716).APP.	US-PGPUB; USPAT; USOCR	OR	OFF	2019/11/11 12:09
S168	1	(15/520430).APP.	US-PGPUB; USPAT; USOCR	OR	OFF	2019/11/12 11:02
S169	1	("7637875").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2019/11/12 12:11
S170	1	("20120253321").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2019/11/12 12:13
S171	1	(15/861959).APP.	US-PGPUB; USPAT; USOCR	OR	OFF	2019/11/12 12:14
S172	1	("4207870").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2019/12/09 14:17
S173	1	("5749857").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2019/12/09 15:14
S174	1	("20080167577").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2019/12/09 15:19
S175	4	("2008/0167577").URPN.	USPAT	OR	ON	2019/12/09 15:30
S176	1	("8197420").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2019/12/09 15:31
S177	39	(US-20040073171-$ or US-20160174888-$ or US-20050240161-$ or US-20040147855-$ or US-20130317391-$ or US-20050004524-$ or US-20030105414-$ or US-20020004647-$ or US-20100057004-$ or US-20070088279-$ or US-20080145933-$ or US-20040054333-$ or US-20100010372-$ or US-	US-PGPUB; USPAT	OR	ON	2019/12/09 15:37

		20080319346-$ or US-20080167577-$).did. or (US-9138572-$ or US-8568371-$ or US-8540663-$ or US-8523826-$ or US-8197420-$ or US-4057050-$ or US-8864684-$ or US-8535241-$ or US-5749857-$ or US-9060724-$ or US-9204864-$ or US-3817240-$ or US-3874367-$ or US-3886930-$ or US-4106497-$ or US-4154229-$ or US-4207870-$ or US-4412548-$ or US-5222502-$ or US-5520193-$ or US-9022951-$ or US-6569117-$ or US-3741197-$ or US-8603009-$).did.				
S178	8	("20040054333" | "8197420" | "9855001" | "9861306" | "10045724" | "10028687" | "8337418" | "10028689").PN.	US-PGPUB; USPAT	OR	ON	2019/12/09 15:42
S179	100	("20020002349" | "20020183651" | "20030055381" | "20040010228" | "20040054333" | "20040147855" | "20050004524" | "20050240161" | "20050245885" | "20050281713" | "20060287639" | "2707953" | "3013557" | "3098016" | "3382865" | "3405706" | "3494351" | "3577980" | "3648684" | "3848579" | "3937211" | "4057050" | "4133863" | "4166450" | "4340067" | "4370987" | "4444203" | "4459997" | "4509534" | "4676256" | "4865583" | "4890627" | "4988339" | "5009847" | "5097842" | "5108927" | "5122129" | "5269317" | "5360011" | "5429610" | "5450856" | "5507299" | "5577513" | "5762633" | "5882318" | "5922551" | "6016712" | "6057105" | "6159164" | "6210909" | "6364890" | "6387086" | "6403381" | "6692479" | "6746420" | "6913580" | "7044941" | "7087047").PN. OR ("8197420").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2019/12/09 15:43
S180	70	S179 and (blood near4 (sequest$5 or sampl$4 or flash$4))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2019/12/09 15:43
S181	43	S180 and @ad<"20120530"	US-PGPUB; USPAT	OR	OFF	2019/12/09 15:44
S182	270	((("BULLINGTON") near3 ("Gregory")) OR (("PATTON") near3 ("Richard")) OR	US-PGPUB; USPAT;	OR	ON	2019/12/09 16:13

		(("MIAZGA") near3 ("Jay")) OR (("GAW") near3 ("Shan"))).INV.	USOCR; EPO; JPO; DERWENT			
S183	335,813	(blood near4 (sequest$5 or sampl$4))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2019/12/09 16:22
S184	7,259	S183 AND ((A61B10/0096 OR A61B5/150022).CPC.)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2019/12/09 16:22
S185	325	("2913000" | "3817240" | "3859998" | "3864979" | "4016879" | "4046144").PN. OR ("4207870").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2019/12/09 16:33
S186	594	S184 and (flash$6 and seal$4)	US-PGPUB; USPAT	OR	OFF	2019/12/09 16:40
S187	476	S186 and @ad<"20120530"	US-PGPUB; USPAT	OR	OFF	2019/12/09 16:40
S188	1,735	(600/573).CCLS.	US-PGPUB; USPAT	OR	OFF	2019/12/09 17:14
S189	1,123	S188 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4))	US-PGPUB; USPAT	OR	OFF	2019/12/09 17:15
S190	1,013	S189 and @ad<"20120530"	US-PGPUB; USPAT	OR	OFF	2019/12/09 17:15
S191	10	S190 and ((vent$4 near4 air) and flash$6)	US-PGPUB; USPAT	OR	OFF	2019/12/09 17:16
S192	1,259	(600/583).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2019/12/09 17:23
S193	1,143	S192 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4))	US-PGPUB; USPAT	OR	OFF	2019/12/09 17:23
S194	1,038	S193 and @ad<"20120530"	US-PGPUB; USPAT	OR	OFF	2019/12/09 17:23
S195	3	S194 and ((vent$4 near4 air) and flash$6)	US-PGPUB; USPAT	OR	OFF	2019/12/09 17:23
S196	811	(600/576).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2019/12/09 17:24
S197	618	S196 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4))	US-PGPUB; USPAT	OR	OFF	2019/12/09 17:24

S198	557	S197 and @ad<"20120530"	US-PGPUB; USPAT	OR	OFF	2019/12/09 17:24
S199	1	(15/854273).APP.	US-PGPUB; USPAT; USOCR	OR	OFF	2019/12/09 17:25
S200	1,351	(604/164.01).CCLS.	US-PGPUB; USPAT	OR	OFF	2019/12/09 17:31
S201	219	S200 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4))	US-PGPUB; USPAT	OR	OFF	2019/12/09 17:33
S202	199	S201 and @ad<"20120530"	US-PGPUB; USPAT	OR	OFF	2019/12/09 17:33
S203	448	(435/294.1).CCLS.	US-PGPUB; USPAT	OR	OFF	2019/12/09 17:36
S204	44	S203 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4))	US-PGPUB; USPAT	OR	OFF	2019/12/09 17:37
S205	1	(15/508871).APP.	US-PGPUB; USPAT; USOCR	OR	OFF	2019/12/10 11:58
S206	342,199	(blood near4 (sequest$5 or sampl$4))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2020/03/16 12:53
S207	4,239	S206 AND ((A61B10/0096 OR A61B5/150022).CPC.)	US-PGPUB; USPAT	OR	OFF	2020/03/16 12:53
S208	146	S207 and ((vent$4 near4 air) and flash$6)	US-PGPUB; USPAT	OR	OFF	2020/03/16 12:54
S209	101	S208 and @ad<"20120530"	US-PGPUB; USPAT	OR	OFF	2020/03/16 12:55
S210	1,735	(600/573).CCLS.	US-PGPUB; USPAT	OR	OFF	2020/03/16 13:38
S211	1,123	S210 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4))	US-PGPUB; USPAT	OR	OFF	2020/03/16 13:38
S212	1,013	S211 and @ad<"20120530"	US-PGPUB; USPAT	OR	OFF	2020/03/16 13:39
S213	22	S212 and (((vent$4 or open$5 or hole or aperture) near4 air) and flash$6)	US-PGPUB; USPAT	OR	OFF	2020/03/16 13:39
S214	108	("20020193748" | "20030093009" | "20030105414" | "20030220614" | "20030229315" | "20040059302" | "20040092872" | "20040193120" | "20050004524" | "20050065482" | "20050124944" | "20050187493" | "20050245868" | "20050245869" |	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/16 13:46

		"20050245870" | "20050245879" | "20050245885" | "20060036219" | "20060224122" | "20070106220" | "20070106224" | "20070167914" | "20080086085" | "20080177202" | "20080319345" | "20080319346" | "20090204026" | "20100262038" | "4106497" | "4207870" | "4305406" | "4572210" | "4573976" | "4641663" | "4795443" | "4840619" | "4894055" | "4900307" | "4994046" | "5015241" | "5195985" | "5215534" | "5222502" | "5242417" | "5246428" | "5256153" | "5295970" | "5303713" | "5312372" | "5336199" | "5348544" | "5356392" | "5411492" | "5439449" | "5466223" | "5501675" | "5542932" | "5599313" | "5662617" | "5665075" | "5672161" | "5676658" | "5702369" | "5704920" | "5733265" | "5755522" | "5957892" | "5984899" | "6149629" | "6224576" | "6254575" | "6261263" | "6298541" | "6344032" | "6436086" | "6440104" | "6524277" | "6533760" | "6592556" | "6623456" | "6635032" | "6648855" | "6695819" | "6699217" | "6712792" | "6780169" | "6837877" | "6869415" | "6984223" | "7001363" | "7128726" | "7147624" | "7160267" | "7163526" | "7223258" | "7226432" | "7396343" | "7428773" | "7537581" | "7766879" | "D422700" | "D442280" | "D604836" | "D604837" | "D604838" | "D604839" | "D605287").PN. OR ("8603009").URPN.				
S215	26	S214 and (((vent$4 or open$5 or hole or aperture) near4 air) and flash$6)	US-PGPUB; USPAT	OR	OFF	2020/03/16 13:47
S216	27	("2008/0319346").URPN.	USPAT	OR	ON	2020/03/16 13:47
S217	23	("2003/0105414").URPN.	USPAT	OR	ON	2020/03/16 13:48
S218	1,258	(600/583).CCLS.	US-PGPUB; USPAT	OR	OFF	2020/03/16 13:52
S219	1,143	S218 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4))	US-PGPUB; USPAT	OR	OFF	2020/03/16 13:52
S220	25	S219 and (((vent$4 or open$5 or hole or aperture) near4 air) and flash$6)	US-PGPUB; USPAT	OR	OFF	2020/03/16 13:52
S221	353,695	((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4))	US-PGPUB; USPAT	OR	OFF	2020/03/16 13:54

S222	3,643	S221 and (((vent$4 or open$5 or hole or aperture) near4 air) and flash$6)	US-PGPUB; USPAT	OR	OFF	2020/03/16 13:55
S223	1,926	S222 and @ad<"20120530"	US-PGPUB; USPAT	OR	OFF	2020/03/16 13:55
S224	785	S223 and ((blood or fluid$4) near4 (sequest$5 or flash$4))	US-PGPUB; USPAT	OR	OFF	2020/03/16 13:56
S225	7,046	(600/300).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2020/03/16 14:32
S226	14	S225 and ((blood or fluid$4) near4 (sequest$5 or flash$4))	US-PGPUB; USPAT	OR	OFF	2020/03/16 14:35
S227	1,352	(604/164.01).CCLS.	US-PGPUB; USPAT	OR	OFF	2020/03/16 14:36
S228	135	S227 and ((blood or fluid$4) near4 (sequest$5 or flash$4))	US-PGPUB; USPAT	OR	OFF	2020/03/16 14:36
S229	19	S228 and (((vent$4 or open$5 or hole or aperture) near4 air) and flash$6)	US-PGPUB; USPAT	OR	OFF	2020/03/16 14:36
S230	448	(435/294.1).CCLS.	US-PGPUB; USPAT	OR	OFF	2020/03/16 14:47
S231	3	S230 and ((blood or fluid$4) near4 (sequest$5 or flash$4))	US-PGPUB; USPAT	OR	OFF	2020/03/16 14:47
S232	19	("2008/0145933").URPN.	USPAT	OR	ON	2020/03/16 14:48
S233	795	(600/576).CCLS.	US-PGPUB; USPAT	OR	OFF	2020/03/16 14:58
S234	71	S233 and ((blood or fluid$4) near4 (sequest$5 or flash$4))	US-PGPUB; USPAT	OR	OFF	2020/03/16 14:58
S235	57	S234 and @ad<"20120530"	US-PGPUB; USPAT	OR	OFF	2020/03/16 14:59
S236	371	(600/577).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2020/03/16 15:12
S237	11	S236 and ((blood or fluid$4) near4 (sequest$5 or flash$4))	US-PGPUB; USPAT	OR	OFF	2020/03/16 15:12
S238	45	("20040054333" | "20050240161" | "4412548" | "5749857" | "8197420" | "9855001" | "9861306" | "20020004647" | "20100057004" | "3741197" | "20040073171" | "3874367" | "4057050" | "4106497" | "8197420" | "8535241" | "8540663" | "8603009" | "8864684" | "10045724" | "3817240" | "10028687" | "20030105414" | "5222502" | "5520193" | "6569117" | "8568371" | "20040147855" | "20070088279" | "20080145933" | "20100010372" |	US-PGPUB; USPAT	OR	OFF	2020/03/16 15:13

		"3886930" | "8523826" | "9060724" | "9204864" | "8337418" | "20050004524" | "20080167577" | "20080319346" | "20130317391" | "4154229" | "9022951" | "10028689" | "20160174888" | "4207870" | "9138572").PN.				
S239	6	("2008/0167577").URPN.	USPAT	OR	ON	2020/03/16 15:13
S240	118	("3500828" | "3670729" | "3714945" | "3977400" | "3994293" | "3995619" | "4106491" | "4200096" | "4468224" | "4531987" | "4549554" | "4735215" | "4828548" | "4874373" | "4893635" | "4894052" | "4907599" | "4944308" | "4994042" | "5129884" | "5400798").PN. OR ("5749857").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2020/03/16 15:15
S241	6	("2008/0167577").URPN.	US-PGPUB; USPAT	OR	ON	2020/03/16 15:15
S242	274	((("BULLINGTON") near3 ("Gregory")) OR (("PATTON") near3 ("Richard")) OR (("MIAZGA") near3 ("Jay")) OR (("GAW") near3 ("Shan"))).INV.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2020/03/16 15:25
S243	61	S242 and ((blood or fluid$4) near4 (sequest$5 or flash$4))	US-PGPUB; USPAT	OR	OFF	2020/03/16 15:25
S244	1	(15/854273).APP.	US-PGPUB; USPAT; USOCR	OR	OFF	2020/03/16 15:47
S245	0	(14/502498).APP.	US-PGPUB; USPAT; USOCR	OR	OFF	2020/03/16 16:11
S246	1	("20110082383").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2020/03/16 16:24
S247	1	("8150506").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2020/03/16 16:24
S252	1	(15/057214).APP.	US-PGPUB; USPAT; USOCR	OR	OFF	2020/03/17 11:28
S253	348,964	(blood near4 (sequest$5 or sampl$4))	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2020/06/10 17:22

S254	7,453	S253 AND ((A61B10/0096 OR A61B5/150022).CPC.)	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2020/06/10 17:22
S255	155	S254 and ((vent$4 near4 air) and flash$6)	US-PGPUB; USPAT	OR	OFF	2020/06/10 17:23
S256	77	(("ROGERS") near3 ("Bobby")).INV.	US-PGPUB; USPAT; USOCR	OR	OFF	2020/06/10 17:35
S257	343,953	(blood same (sequest$5 or sampl$4))	US-PGPUB; USPAT	OR	OFF	2020/06/10 17:40
S258	11	S256 and (blood same (sequest$5 or sampl$4))	US-PGPUB; USPAT	OR	OFF	2020/06/10 17:41
S259	1	("5749857").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2020/06/10 17:50
S260	121	("3500828" | "3670729" | "3714945" | "3977400" | "3994293" | "3995619" | "4106491" | "4200096" | "4468224" | "4531987" | "4549554" | "4735215" | "4828548" | "4874373" | "4893635" | "4894052" | "4907599" | "4944308" | "4994042" | "5129884" | "5400798").PN. OR ("5749857").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2020/06/10 18:19
S261	32	S260 and (blood near4 (sequest$5 or sampl$4))	US-PGPUB; USPAT	OR	OFF	2020/06/10 18:20
S262	1	("3648684").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2020/06/10 18:38
S263	1	("4056101").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2020/06/10 18:38
S264	329	(600/577).CCLS.	US-PGPUB; USPAT	OR	OFF	2020/06/10 18:39
S265	11	S264 and ((blood or fluid$4) near4 (sequest$5 or flash$4))	US-PGPUB; USPAT	OR	OFF	2020/06/10 18:39
S266	29	("2008/0319346").URPN.	USPAT	OR	ON	2020/06/10 18:40
S267	812	(600/576).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2020/06/10 18:40
S268	72	S267 and ((blood or fluid$4) near4 (sequest$5 or flash$4))	US-PGPUB; USPAT	OR	OFF	2020/06/10 18:40

S269	1,767	(600/573).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2020/06/10 18:44
S270	31	S269 and ((blood or fluid$4) near4 (sequest$5 or flash$4))	US-PGPUB; USPAT	OR	OFF	2020/06/10 18:45
S271	77	("4676249" | "4787891" | "4850960" | "4874382" | "4886067" | "4886500" | "4900307" | "4904242" | "4917102" | "4950252" | "4955862" | "5046508" | "5116353" | "5125718" | "5129884" | "5163911" | "5217435" | "5290244" | "5295974" | "5314503" | "5318585" | "5330432" | "5360410" | "5366441" | "5376075" | "5395337" | "5531692" | "5695475" | "5695479" | "5702367" | "5735813" | "5749857" | "5788654" | "5800395" | "5846226" | "5871470" | "5882342" | "5919172" | "5935108" | "5935113" | "5989220" | "6050976" | "6077244" | "6099504" | "6126641" | "6162195").PN. OR ("6398743").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2020/06/10 18:46
S272	18	S271 and ((blood or fluid$4) near4 (sequest$5 or flash$4))	US-PGPUB; USPAT	OR	OFF	2020/06/10 18:46
S273	1	(15/893518).APP.	US-PGPUB; USPAT; USOCR	OR	OFF	2020/06/10 18:48
S274	7,050	(600/300).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2020/06/10 18:49
S275	14	S274 and ((blood or fluid$4) near4 (sequest$5 or flash$4))	US-PGPUB; USPAT	OR	OFF	2020/06/10 18:49
S276	1,259	(600/583).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2020/06/10 18:51
S277	7	S276 and ((blood or fluid$4) near4 (sequest$5 or flash$4))	US-PGPUB; USPAT	OR	OFF	2020/06/10 18:51
S278	1,368	(604/164.01).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2020/06/10 18:52
S279	135	S278 and ((blood or fluid$4) near4 (sequest$5 or flash$4))	US-PGPUB; USPAT	OR	OFF	2020/06/10 18:52
S280	499	(435/294.1).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2020/06/10 19:08
S281	3	S280 and ((blood or fluid$4) near4 (sequest$5 or flash$4))	US-PGPUB; USPAT	OR	OFF	2020/06/10 19:08

S282	20	("2008/0145933").URPN.	USPAT	OR	ON	2020/06/10 19:08
S286	1	("10045704").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2020/06/10 20:56
S287	1	("10143412").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2021/03/01 21:16
S288	1	("10010282").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2021/03/01 21:17
S289	100	((("ROGERS") near3 ("Bobby")) OR (("KANG") near3 ("Gino")) OR (("DETLOFF") near3 ("John"))).INV.	US-PGPUB; USPAT; USOCR; EPO; JPO; DERWENT	OR	ON	2021/03/01 21:17
S290	2	(15/140443).APP.	US-PGPUB; USPAT; USOCR	OR	OFF	2021/03/01 21:36
S291	1	(15/855439).APP.	US-PGPUB; USPAT; USOCR	OR	OFF	2021/03/01 21:39
S292	180	(("ROGERS") near3 ("Bobby")).INV.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	OFF	2021/03/02 12:19
S293	11	S292 and (blood near4 sequest$5)	US-PGPUB; USPAT	OR	OFF	2021/03/02 12:20
S294	2	(15/140443).APP.	US-PGPUB; USPAT; USOCR	OR	OFF	2021/03/02 12:47
S295	1	(15/855439).APP.	US-PGPUB; USPAT; USOCR	OR	OFF	2021/03/02 12:49
S296	1	("20020048170").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2021/03/02 13:36
S297	1	("20040174525").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2021/03/02 13:49
S298	1	("10045704").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2021/03/02 15:09

S299	27,321	(A61B5/150992 or A61B5/15003 or A61B5/150213 or A61B5/150389 or A61B5/150473 or A61B5/150572 or A61B5/154 or A61B5/153 or A61M39/0693 or A61M39/04 or A61B5/150221 or A61M2039/0633 or A61M2039/0202 or A61M2039/068).cpc.	US-PGPUB; USPAT; USOCR; FPRS; EPO; JPO; DERWENT; IBM_TDB	OR	ON	2021/03/02 15:17
S300	4,594	S299 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4 or collect$4))	US-PGPUB; USPAT	OR	OFF	2021/03/02 15:27
S301	3,762	S300 and @ad<"20150724"	US-PGPUB; USPAT	OR	OFF	2021/03/02 15:28
S302	257	S301 and (air near4 permeab$4)	US-PGPUB; USPAT	OR	OFF	2021/03/02 15:29
S303	420	S301 and ((air or gas$4) near4 permeab$4)	US-PGPUB; USPAT	OR	OFF	2021/03/02 15:29
S304	1	("20110167658").PN.	US-PGPUB; USPAT; USOCR	OR	OFF	2021/03/02 15:30
S305	5	("2015/0306288").URPN.	USPAT	OR	ON	2021/03/02 16:15
S306	1	(16/208559).APP.	US-PGPUB; USPAT; USOCR	OR	OFF	2021/03/02 16:32
S307	2	("2009/0043225").URPN.	USPAT	OR	ON	2021/03/02 16:49
S308	1,736	(600/573).CCLS.	US-PGPUB; USPAT	OR	OFF	2021/03/02 17:00
S309	1,363	S308 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4 or collect$4))	US-PGPUB; USPAT	OR	OFF	2021/03/02 17:00
S310	73	S309 and ((air or gas$4) near4 permeab$4)	US-PGPUB; USPAT	OR	OFF	2021/03/02 17:01
S311	73	S310 and @ad<"20150724"	US-PGPUB; USPAT	OR	OFF	2021/03/02 17:01
S312	812	(600/576).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2021/03/02 17:34
S313	711	S312 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4 or collect$4))	US-PGPUB; USPAT	OR	OFF	2021/03/02 17:34
S314	58	S313 and ((air or gas$4) near4 permeab$4)	US-PGPUB; USPAT	OR	OFF	2021/03/02 17:34
S315	58	S314 and @ad<"20150724"	US-PGPUB; USPAT	OR	OFF	2021/03/02 17:34

S316	371	(600/577).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2021/03/02 17:42
S317	277	S316 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4 or collect$4))	US-PGPUB; USPAT	OR	OFF	2021/03/02 17:42
S318	20	S317 and ((air or gas$4) near4 permeab$4)	US-PGPUB; USPAT	OR	OFF	2021/03/02 17:43
S319	336	("2913000" | "3817240" | "3859998" | "3864979" | "4016879" | "4046144").PN. OR ("4207870").URPN.	US-PGPUB; USPAT; USOCR	OR	ON	2021/03/02 17:44
S320	210	S319 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4 or collect$4))	US-PGPUB; USPAT	OR	OFF	2021/03/02 17:44
S321	196	S320 and @ad<"20150724"	US-PGPUB; USPAT	OR	OFF	2021/03/02 17:44
S322	1,259	(600/583).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2021/03/02 17:48
S323	1,208	S322 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4 or collect$4))	US-PGPUB; USPAT	OR	OFF	2021/03/02 17:48
S324	73	S323 and ((air or gas$4) near4 permeab$4)	US-PGPUB; USPAT	OR	OFF	2021/03/02 17:48
S325	73	S324 and @ad<"20150724"	US-PGPUB; USPAT	OR	OFF	2021/03/02 17:49
S326	1,368	(604/164.01).CCLS.	US-PGPUB; USPAT; USOCR	OR	OFF	2021/03/02 17:59
S327	271	S326 and ((blood or fluid$4) near4 (sequest$5 or sampl$4 or flash$4 or collect$4))	US-PGPUB; USPAT	OR	OFF	2021/03/02 18:00
S328	10	S327 and ((air or gas$4) near4 permeab$4)	US-PGPUB; USPAT	OR	OFF	2021/03/02 18:00
S329	268	S327 and @ad<"20150724"	US-PGPUB; USPAT	OR	OFF	2021/03/02 18:00

EAST Search History (Interference)

Ref #	Hits	Search Query	DBs	Default Operator	Plurals	Time Stamp
L39	6	(port and sequest$5 and junction and chamber and sampl$4 and vent and barrier).clm.	US-PGPUB; USPAT	OR	OFF	2021/07/08 16:49

S94	1	(port and sequest$5 and junction and chamber and sampl$4 and vent and barrier).clm.	US-PGPUB; USPAT	OR	OFF	2017/09/28 16:15
S112	3	(port and sequest$5 and chamber and sampl$4 and vent and barrier).clm.	US-PGPUB; USPAT	OR	OFF	2018/01/09 17:39
S248	4	(blood and fluid$4 and inlet and outlet and port and reservoir and allow and initial$4 and sequest$5).clm.	US-PGPUB; USPAT	OR	OFF	2020/03/16 15:30
S249	4	(blood and fluid$4 and inlet and outlet and port and reservoir and allow$4 and initial$4 and sequest$5).clm.	US-PGPUB; USPAT	OR	OFF	2020/03/16 15:30
S250	495	(blood and fluid$4 and allow$4 and initial$4).clm.	US-PGPUB; USPAT	OR	OFF	2020/03/16 15:31
S251	107	(blood and fluid$4 and allow$4 and initial$4 and subsequent$4).clm.	US-PGPUB; USPAT	OR	OFF	2020/03/16 15:31
S283	9	((blood or fluid$4) and sequestrat$4 and chamber and sampl$4 and vent$4 and air$4).clm.	US-PGPUB; USPAT	OR	OFF	2020/06/10 18:31
S284	530	((blood or fluid$4) and chamber and sampl$4 and vent$4 and air$4).clm.	US-PGPUB; USPAT	OR	OFF	2020/06/10 18:31
S285	84	((blood or fluid$4) and chamber and cap and sampl$4 and vent$4 and air$4).clm.	US-PGPUB; USPAT	OR	OFF	2020/06/10 18:32

7/8/2021 4:51:14 PM
C:\Users\mabouelela\Documents\EAST\Workspaces\15140443 BLOOD OPTIMIZATION AND SEQUESTRATION.wsp

Bibliographic Data

Application No: 16/208,559

Foreign Priority claimed: ○ Yes ◉ No

35 USC 119 (a-d) conditions met: ☐ Yes ☑ No ☑ Met After Allowance

Verified and Acknowledged: /MAY A ABOUELELA/ (Examiner's Signature) | M.A.A (Initials)

Title: BLOOD SAMPLE OPTIMIZATION SYSTEM AND BLOOD CONTAMINANT SEQUESTRATION DEVICE AND METHOD

FILING or 371(c) DATE	CLASS	GROUP ART UNIT	ATTORNEY DOCKET NO.
12/04/2018	600	3791	KURIN2CON3
RULE			

APPLICANTS

Kurin, Inc., San Diego, CA,

INVENTORS

Bobby E. Rogers, San Diego, CA, UNITED STATES

Gino Kang, Irvine, CA, UNITED STATES

John Detloff, San Diego, CA, UNITED STATES

CONTINUING DATA

This application is a CON of 15994559 05/31/2018 PAT 10143412

15994559 is a CON of 15140448 04/27/2016 PAT 10010282

15140448 has PRO of 62318194 04/04/2016

15140448 has PRO of 62238636 10/07/2015

15140448 has PRO of 62196797 07/24/2015

FOREIGN APPLICATIONS

IF REQUIRED, FOREIGN LICENSE GRANTED**

12/21/2018

**** SMALL ENTITY ****

STATE OR COUNTRY

UNITED STATES

ADDRESS

Kurin, Inc.
P.O. Box 371710
San Diego, CA 92137
UNITED STATES

FILING FEE RECEIVED

$1,395

To: kurin@virtualipsupport.com,jsnolan1@hotmail.com,eofficeaction@appcoll.com
From: PAIR_eOfficeAction@uspto.gov
Cc: PAIR_eOfficeAction@uspto.gov
Subject: Private PAIR Correspondence Notification for Customer Number 158174

Jul 28, 2021 03:40:59 AM

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Application	Document	Mailroom Date	Attorney Docket No.
16208559	NOA	07/28/2021	KURIN2CON3

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Monday - Friday 6:00 a.m. to 12:00 a.m.

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PATENT APPLICATION INFORMATION RETRIEVAL SYSTEM

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), by mail or fax, or via EFS-Web.

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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)

158174 7590 07/28/2021
Kurin, Inc.
P.O. Box 371710
San Diego, CA 92137

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.

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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.

[redacted] (Typed or printed name)
[redacted] (Signature)
[redacted] (Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/208,559	12/04/2018	Bobby E. Rogers	KURIN2CON3	1020

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	$600	$0.00	$0.00	$600	10/28/2021

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/SB/122) attached.

☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-09 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 James Scott Nolan
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: Kurin, Inc.

(B) RESIDENCE: (CITY and STATE OR COUNTRY): San Diego, CA

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 _____

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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.

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Authorized Signature /JSN/ Date October 22, 2021

Typed or printed name James Scott Nolan Registration No. 53393

Electronic Patent Application Fee Transmittal

Application Number:	16208559
Filing Date:	04-Dec-2018
Title of Invention:	BLOOD SAMPLE OPTIMIZATION SYSTEM AND BLOOD CONTAMINANT SEQUESTRATION DEVICE AND METHOD
First Named Inventor/Applicant Name:	Bobby E. Rogers
Filer:	James Scott Nolan/KETHYA TEUK
Attorney Docket Number:	KURIN2CON3

Filed as Small Entity

Filing Fees for Utility under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
Pages:				
Claims:				
Miscellaneous-Filing:				
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
UTILITY APPL ISSUE FEE	2501	1	600	600

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Extension-of-Time:				
Miscellaneous:				
			Total in USD ($)	**600**

Electronic Acknowledgement Receipt	
EFS ID:	44104156
Application Number:	16208559
International Application Number:	
Confirmation Number:	1020
Title of Invention:	BLOOD SAMPLE OPTIMIZATION SYSTEM AND BLOOD CONTAMINANT SEQUESTRATION DEVICE AND METHOD
First Named Inventor/Applicant Name:	Bobby E. Rogers
Customer Number:	158174
Filer:	James Scott Nolan/KETHYA TEUK
Filer Authorized By:	James Scott Nolan
Attorney Docket Number:	KURIN2CON3
Receipt Date:	26-OCT-2021
Filing Date:	04-DEC-2018
Time Stamp:	18:02:22
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	$600
RAM confirmation Number	E20210PI03520723
Deposit Account	
Authorized User	
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File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Issue Fee Payment (PTO-85B)	2021-10-22-KURIN2CON3-Issue-Fee-Transmittal-EFS.pdf	242242 e596b1ce74dd8e3ae2a5957d929a6731651f45ae	no	1
Warnings:					
Information:					
2	Fee Worksheet (SB06)	fee-info.pdf	38217 9bb94979884ed006bfd7aa0a430000b57a3cb0b0	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	280459		

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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.

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
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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	16208559
Filing Date	2018-12-04
First Named Inventor	Bobby E. ROGERS
Art Unit	3791
Examiner Name	Tse W CHEN
Attorney Docket Number	KURIN2CON3

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	4349035	A	1982-09-14	Thomas et al.	
	2	5401262	A	1995-03-28	Karwoski et al.	

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	1	20180271425	A1	2018-09-27	Kurin, Inc.	
	2	20180177445	A1	2018-06-28	Kurin, Inc.	
Change(s) applied to document, /DM/ 7/30/2021	3	20180353117	A1	2018-12-13	~~Magnolia Medical Technologies, Inc.~~ Bullington, et al.	

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APPLICATION NO.	ISSUE DATE	PATENT NO.	ATTORNEY DOCKET NO.	CONFIRMATION NO.
16/208,559	11/30/2021	11185266	KURIN2CON3	1020

158174 7590 11/10/2021

Kurin, Inc.
P.O. Box 371710
San Diego, CA 92137

ISSUE NOTIFICATION

The projected patent number and issue date are specified above.

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)
(application filed on or after May 29, 2000)

The Patent Term Adjustment is 426 day(s). Any patent to issue from the above-identified application will include an indication of the adjustment on the front page.

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

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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 Application Assistance Unit (AAU) of the Office of Patents Stakeholder Experience (OPSE), Stakeholder Support Division (SSD) at (571)-272-4200.

INVENTOR(s) (Please see PAIR WEB site http://pair.uspto.gov for additional inventors):

Bobby E. Rogers, San Diego, CA;
Gino Kang, Irvine, CA;
John Detloff, San Diego, CA;

APPLICANT(s) (Please see PAIR WEB site http://pair.uspto.gov for additional applicants):

Kurin, Inc., San Diego, CA;

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IR103 (Rev. 10/09)

To: kurin@virtualipsupport.com,jsnolan1@hotmail.com,eofficeaction@appcoll.com
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Cc: PAIR_eOfficeAction@uspto.gov
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Nov 11, 2021 04:18:13 AM

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Application	Document	Mailroom Date	Attorney Docket No.
16208559	ISSUE.NTF	11/10/2021	KURIN2CON3

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