

图3F

Inari-2002 - Part 2 of 2
Imperative Care, Inc. v. Inari Medical, Inc.
Page 1653 of 2754 IPR2024-01257

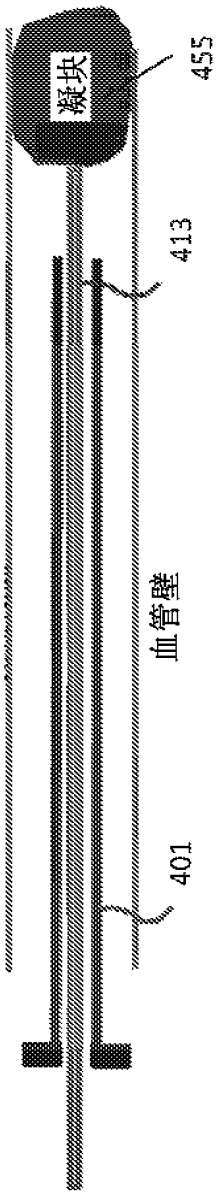


图4A

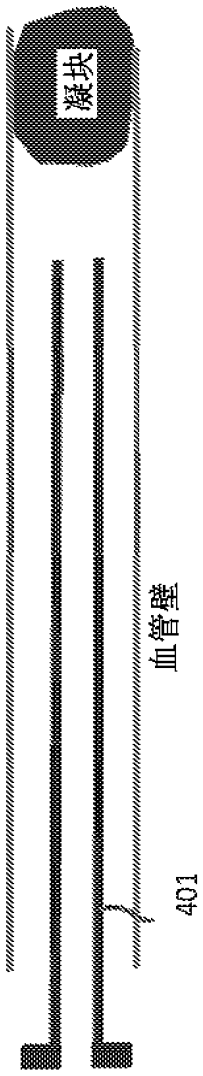


图4B

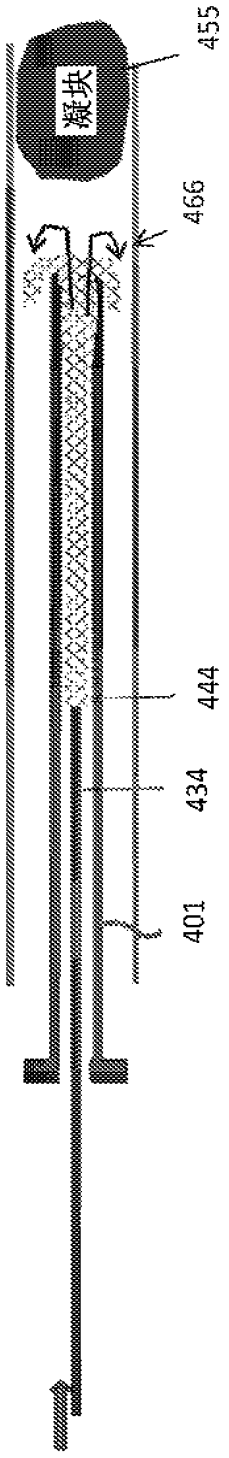


图4C

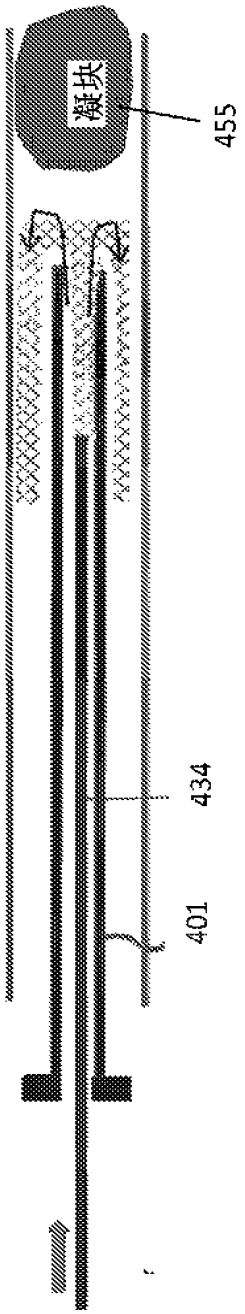


图4D

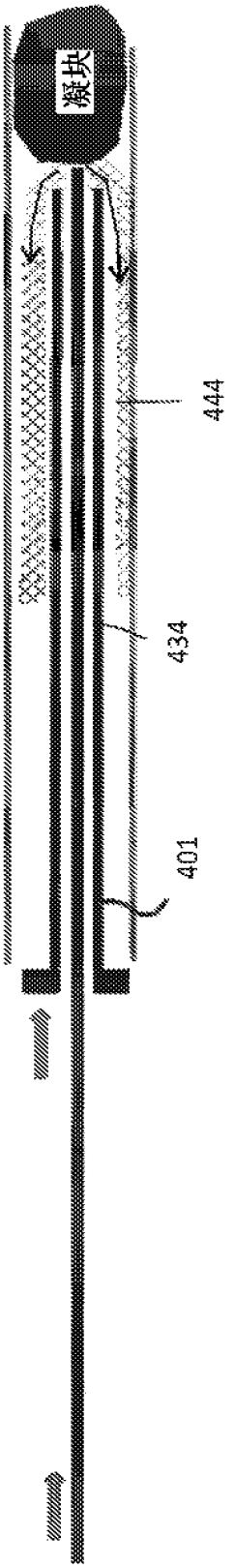


图4E

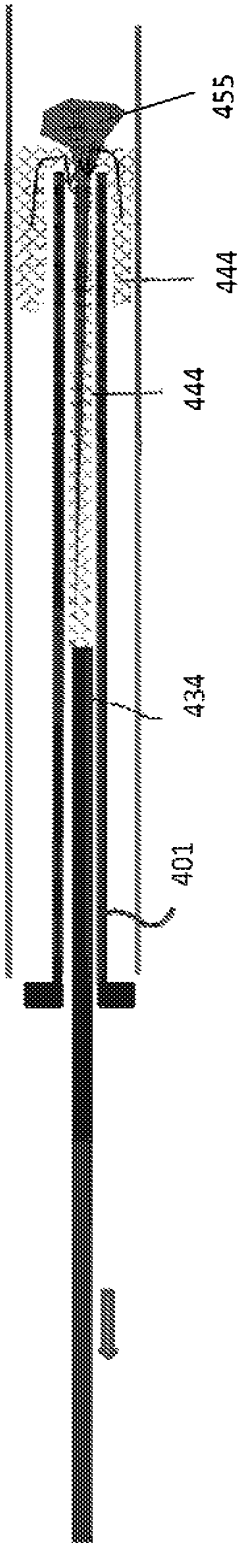


图4F

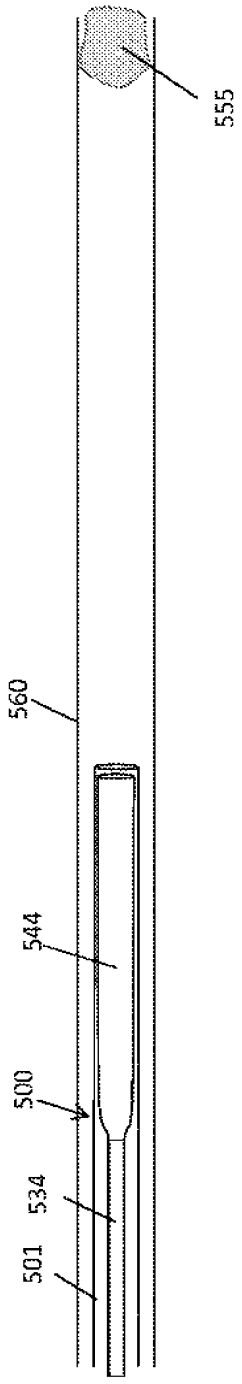


图5A

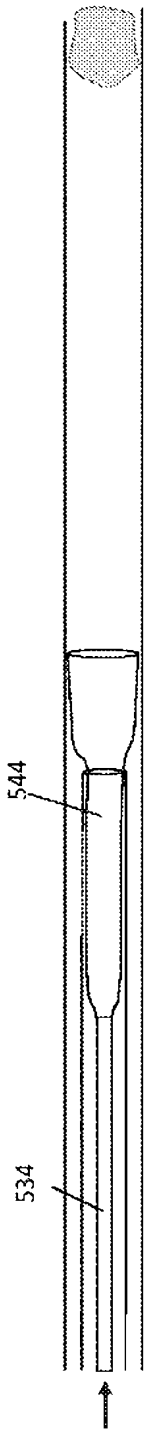


图5B

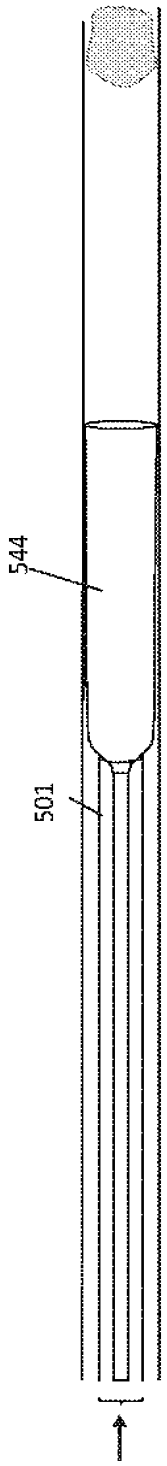


图5C

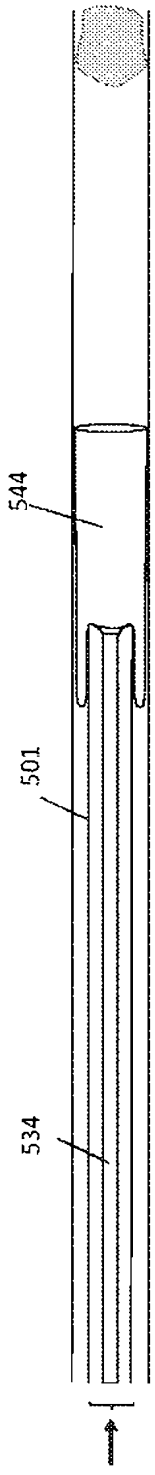


图5D

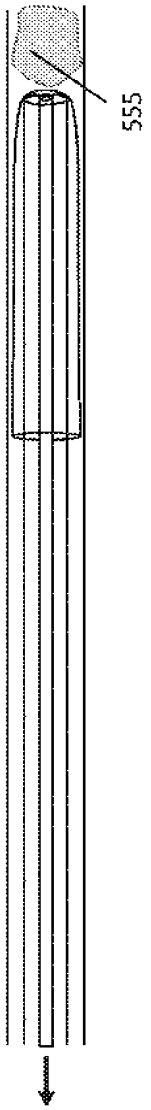


图5E

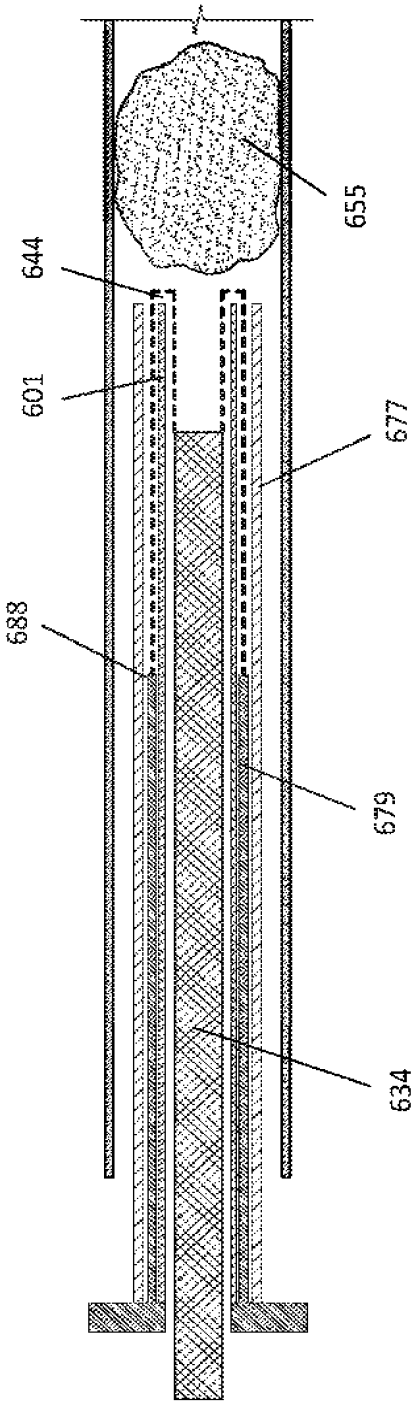


图6A

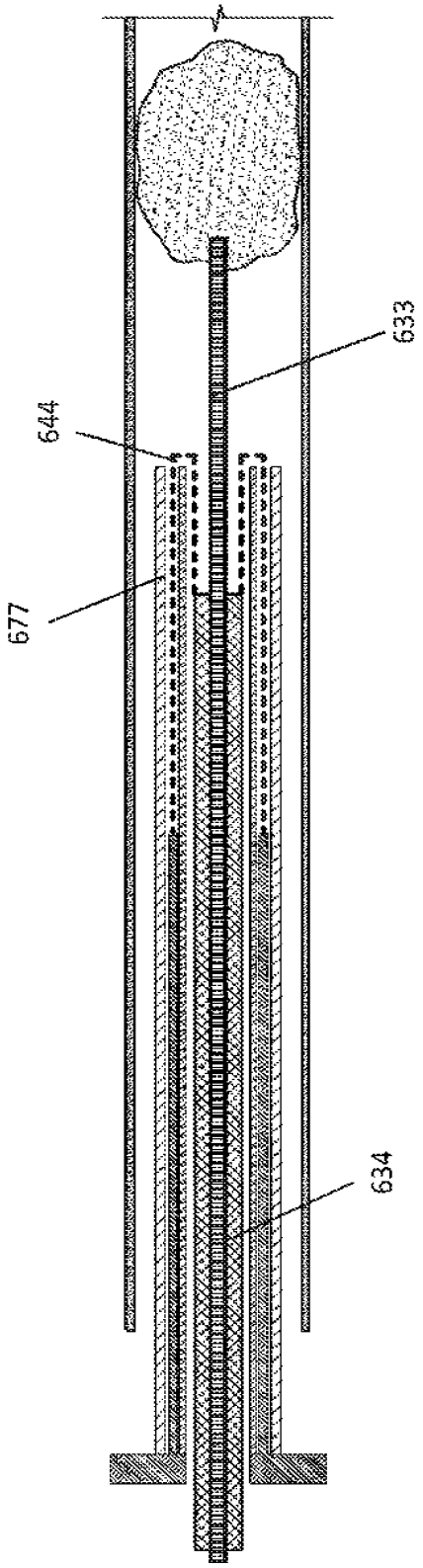


图6B

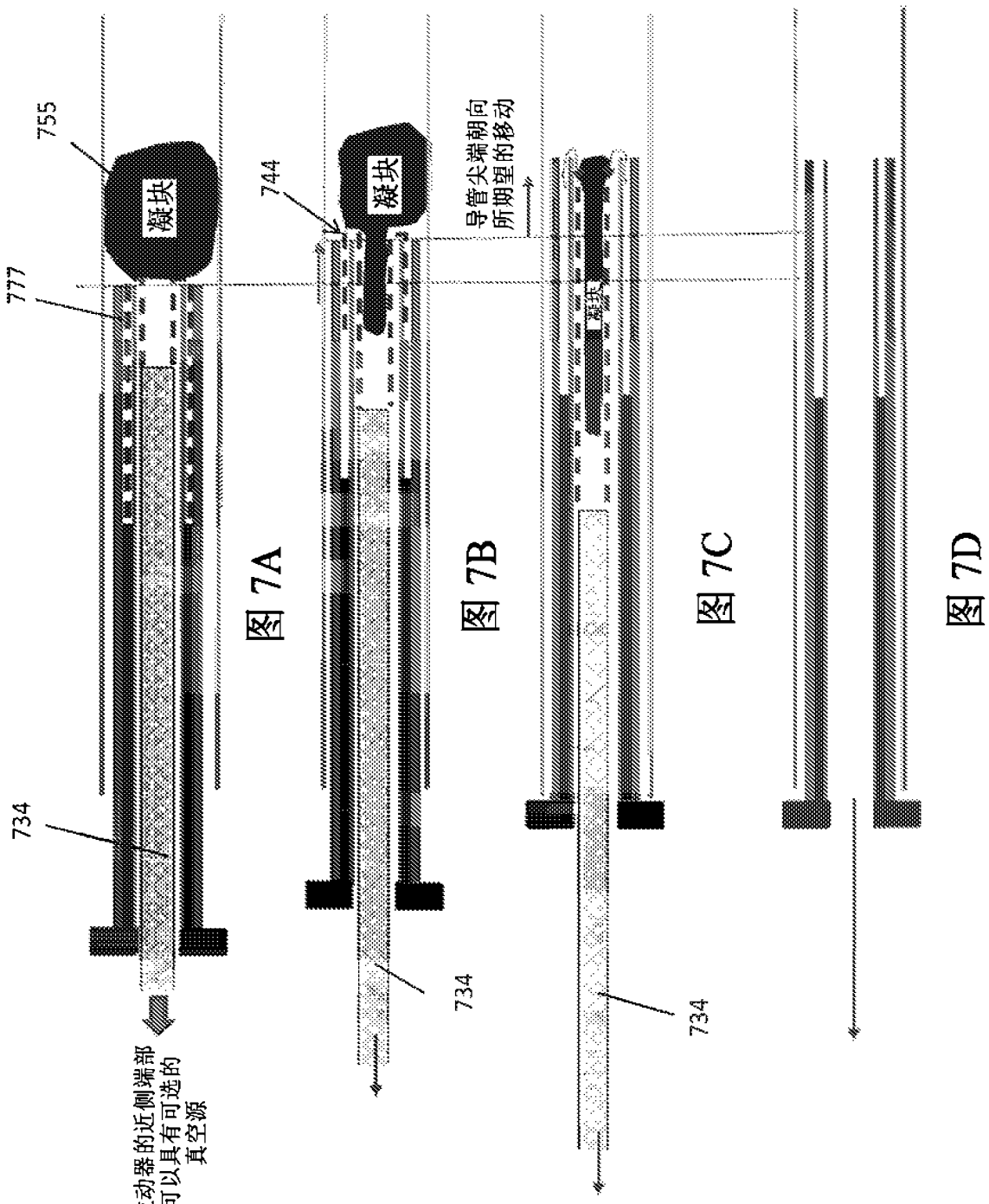


图 7A 图 7B 图 7C 图 7D

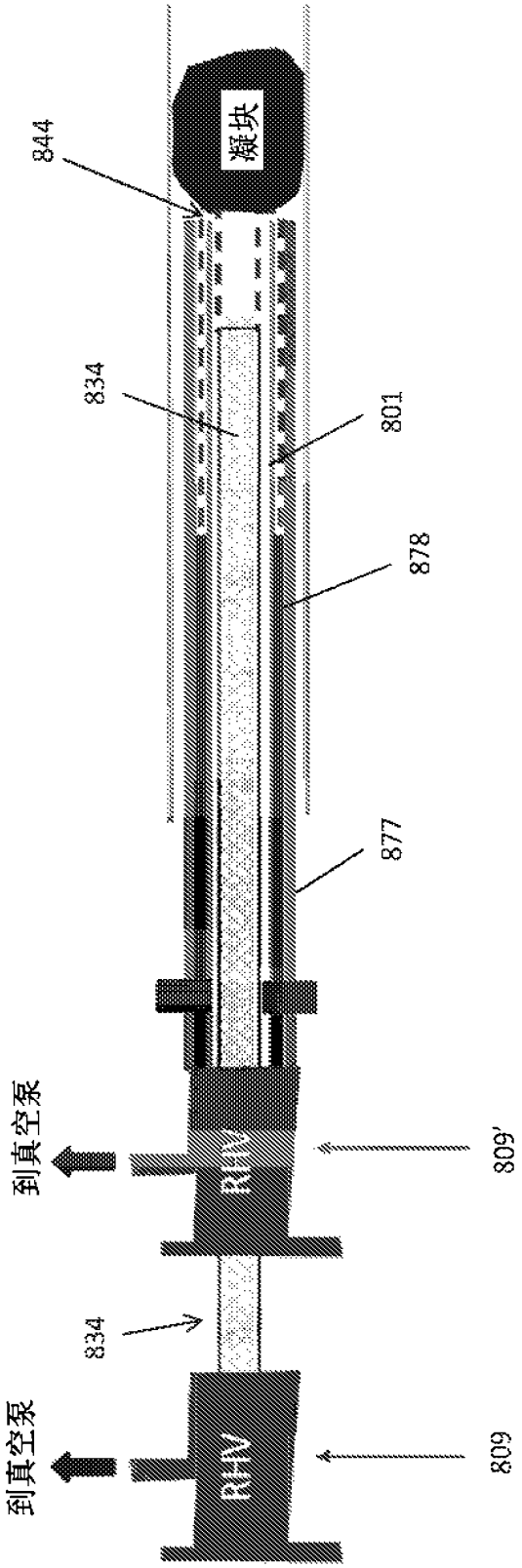


图8

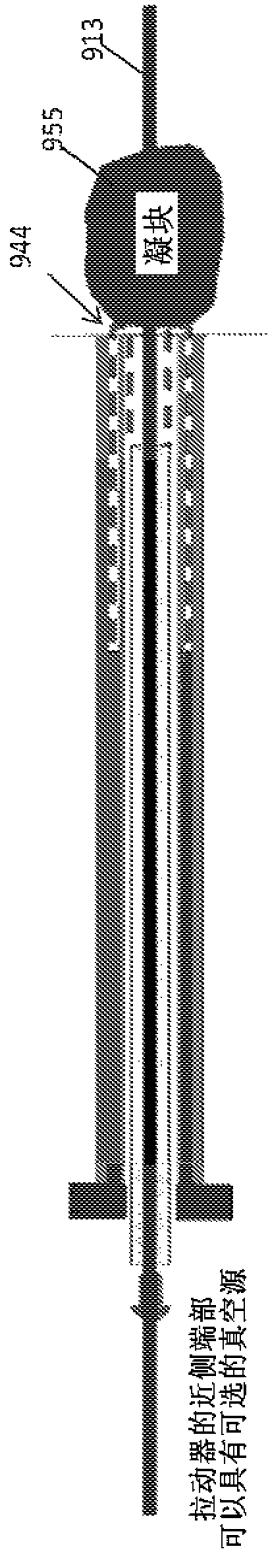


图9A

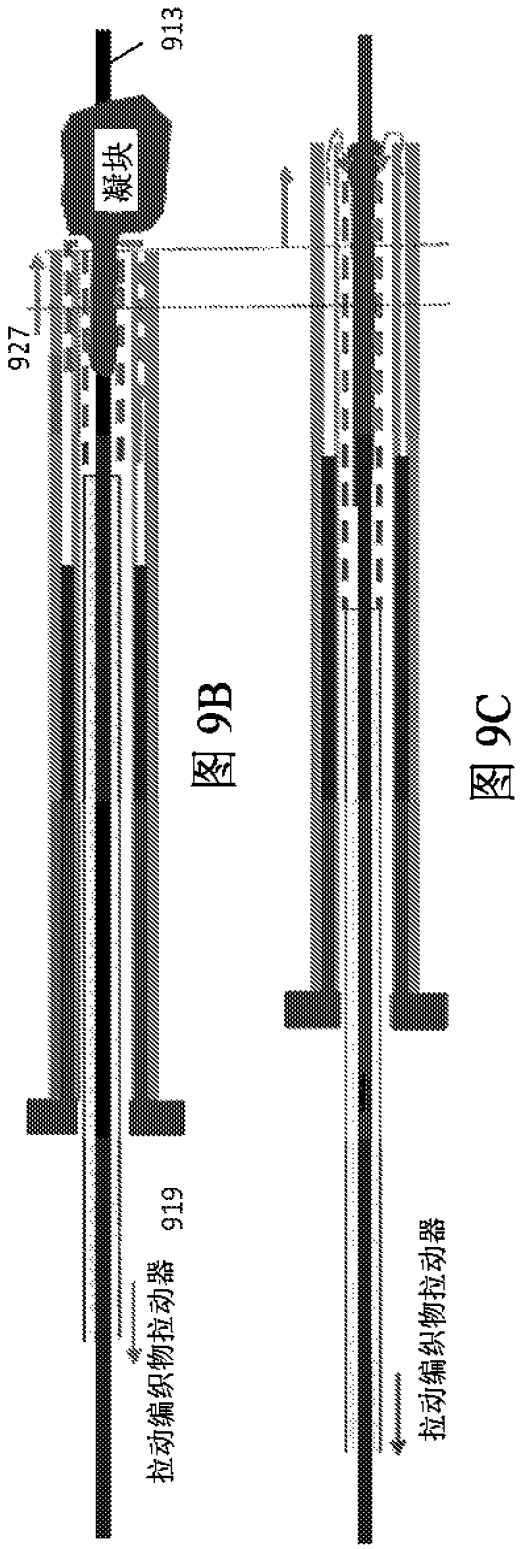


图 9B

图 9C

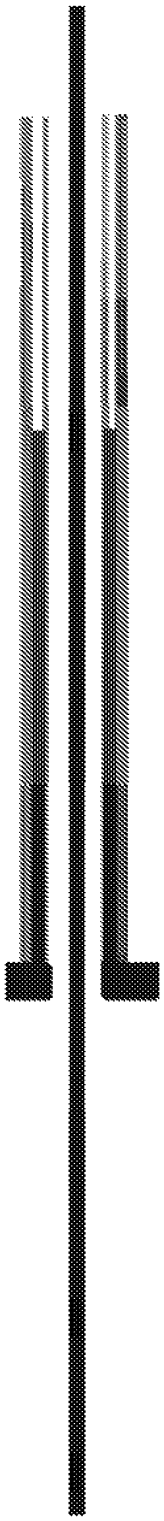


图9D

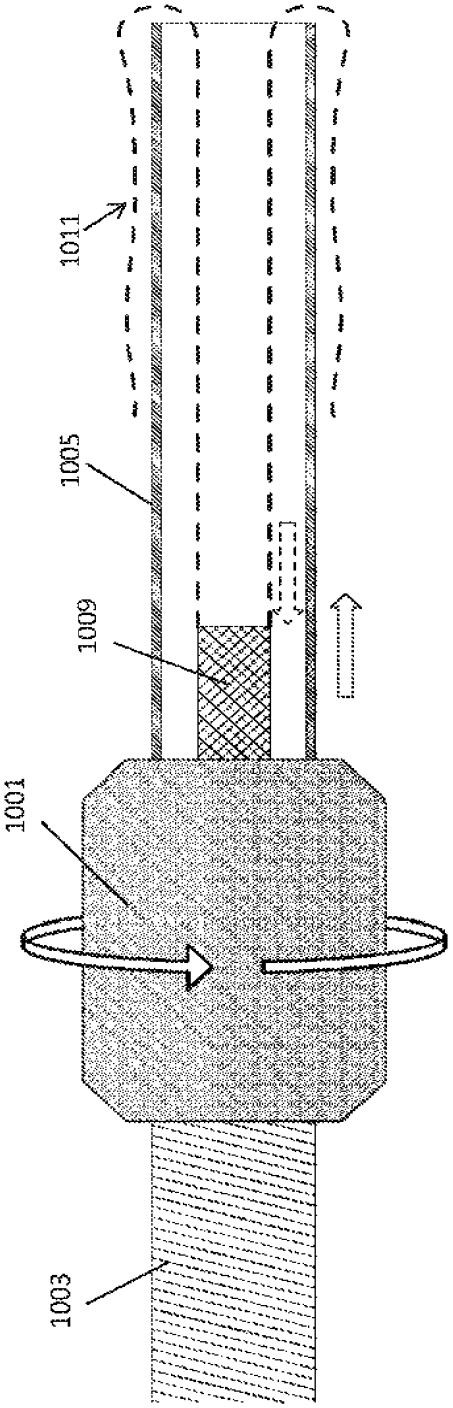


图10A

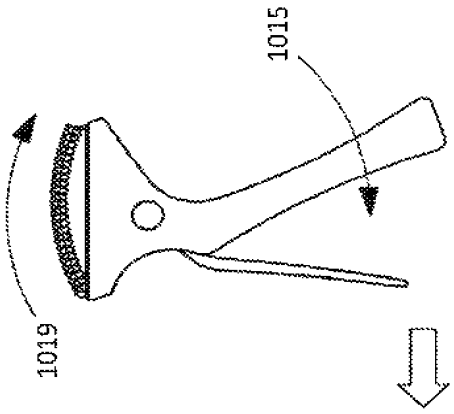


图10B

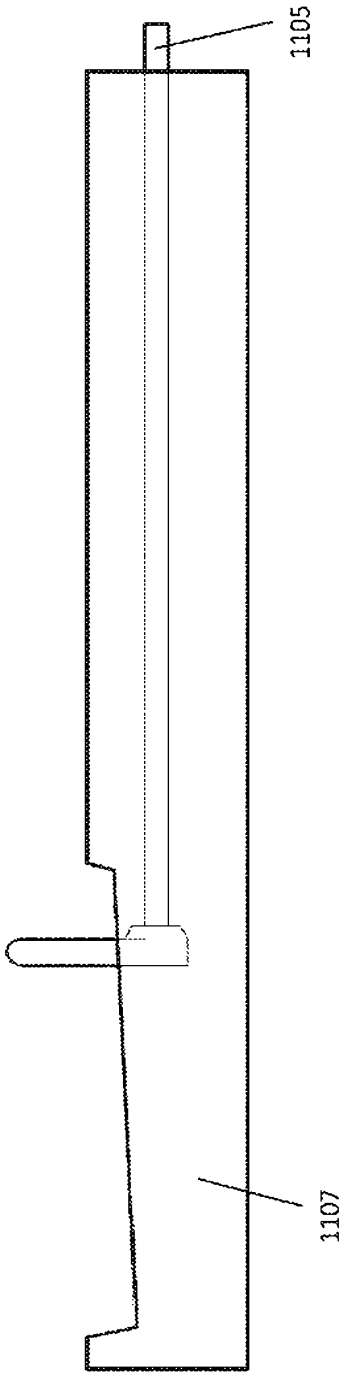


图11A

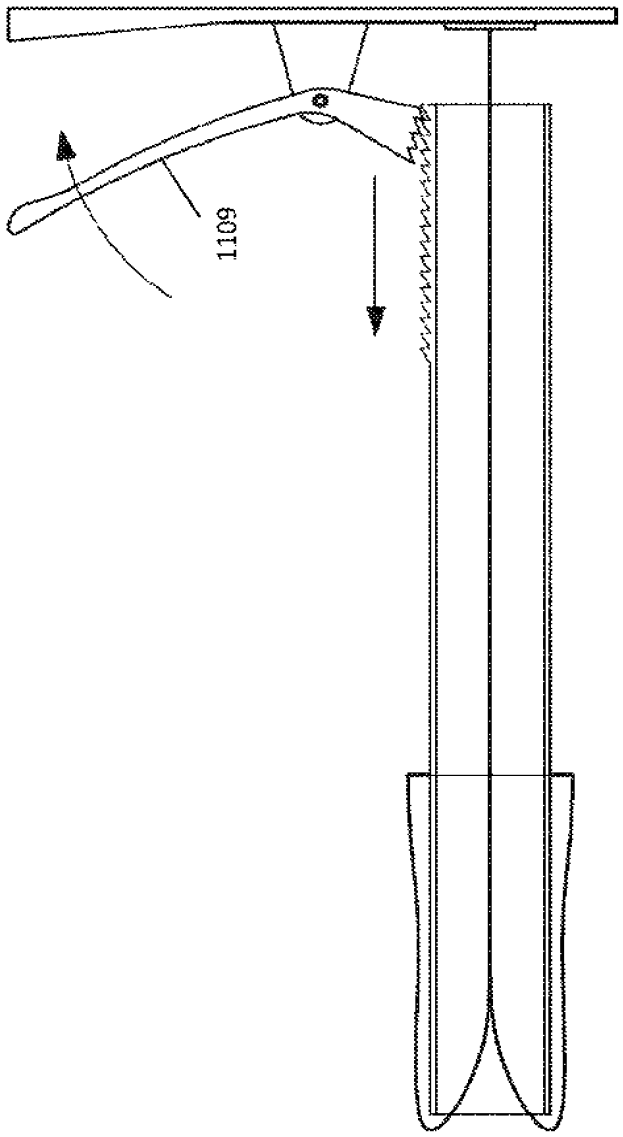


图11B

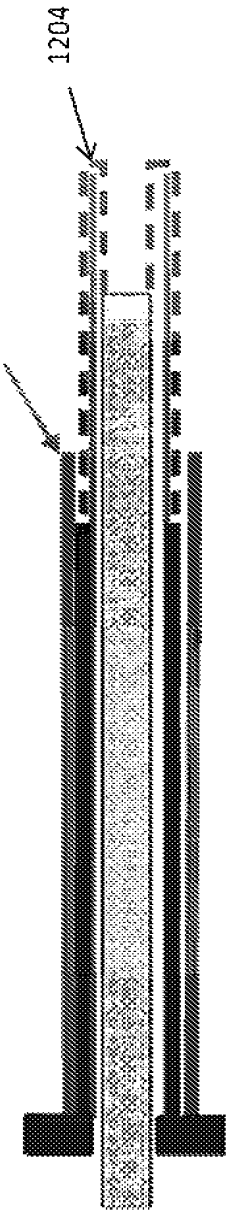


图12A

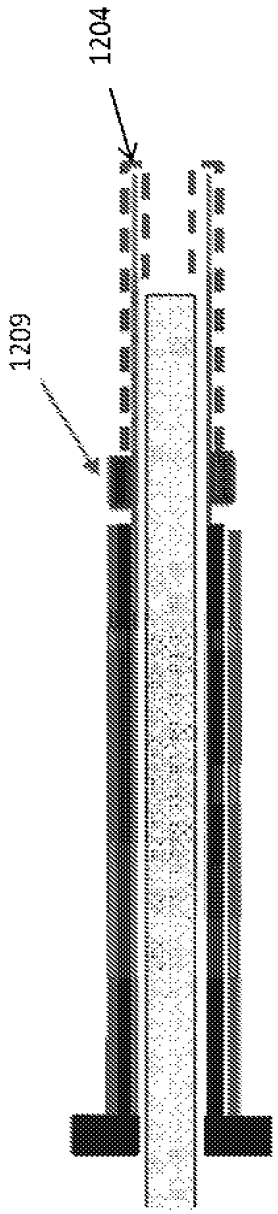


图12B

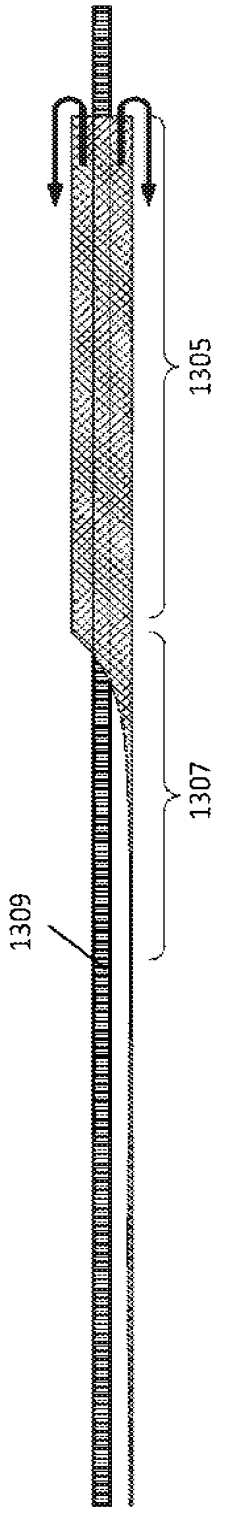


图13A

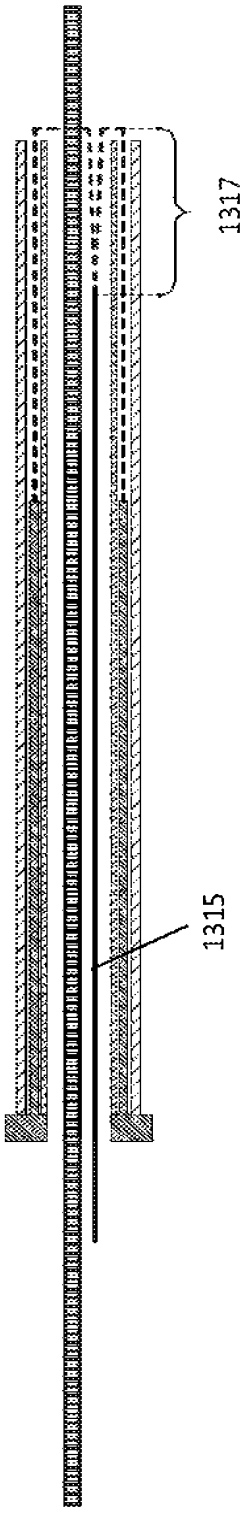


图13B

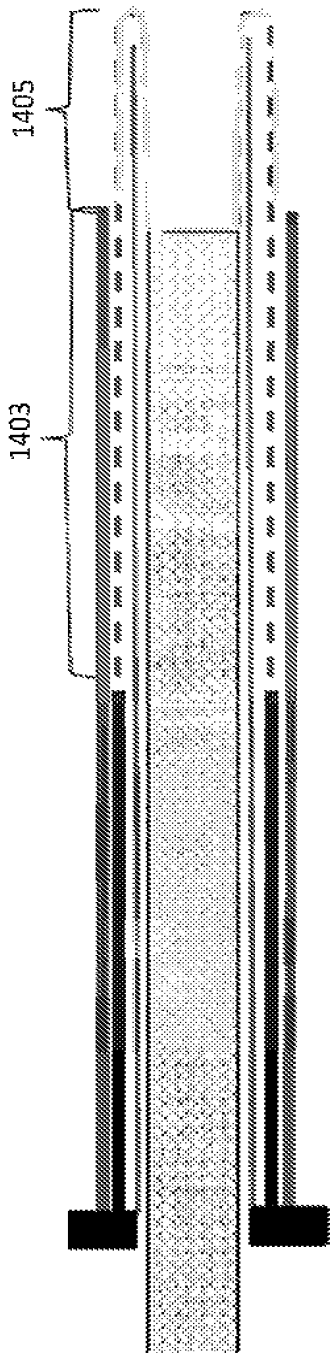


图14

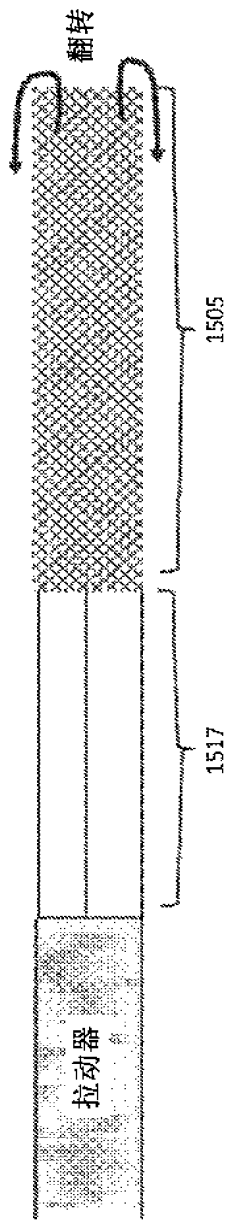


图15A

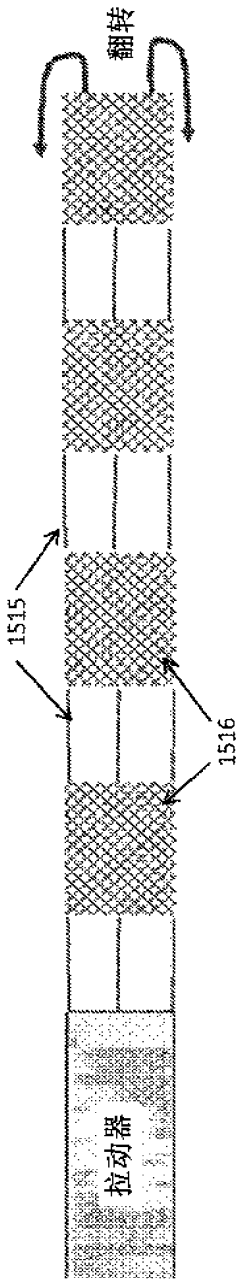


图15B

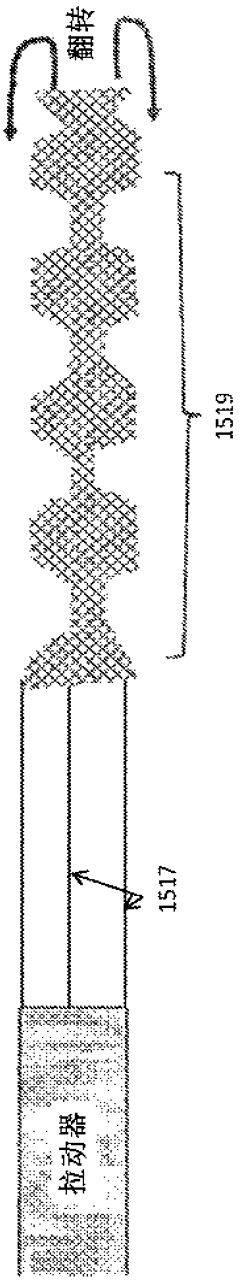


图15C

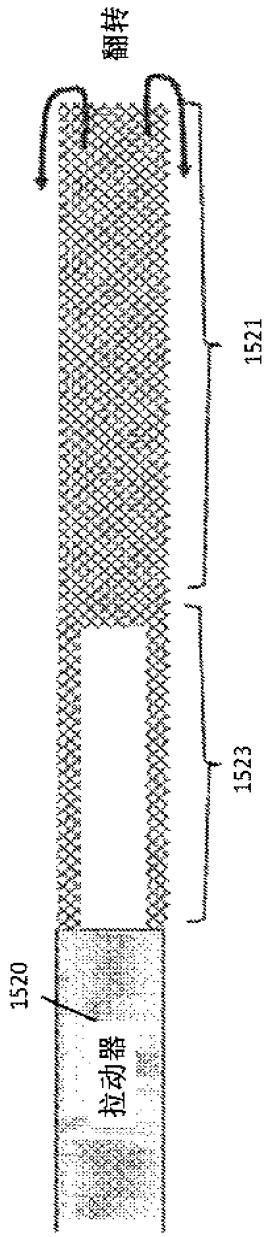


图15D

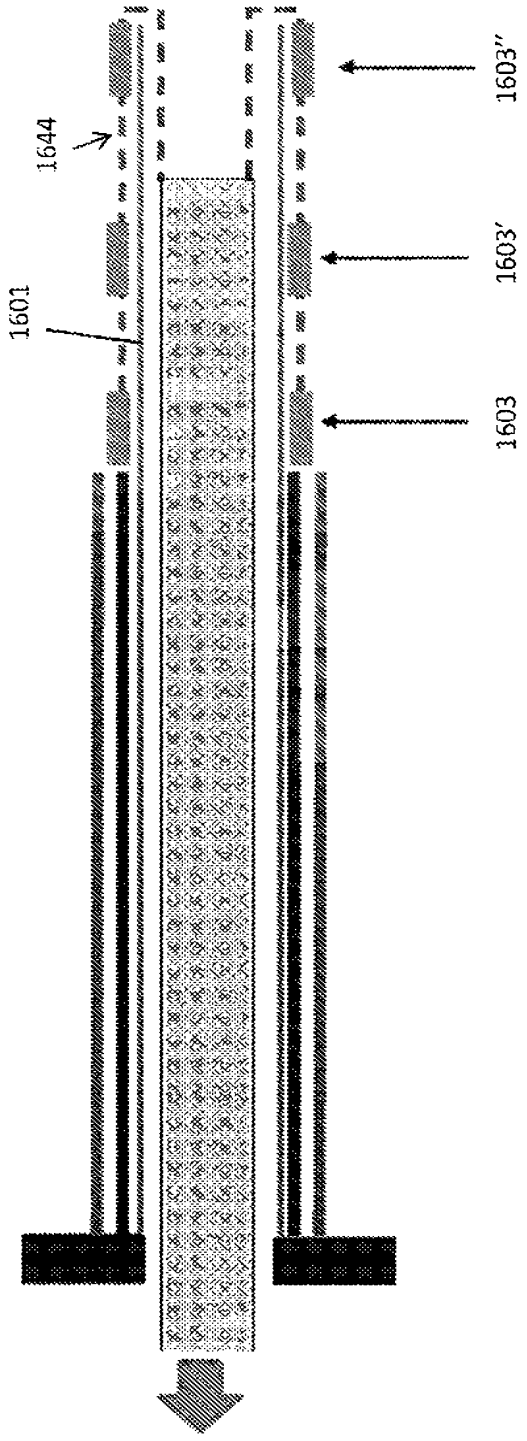


图16

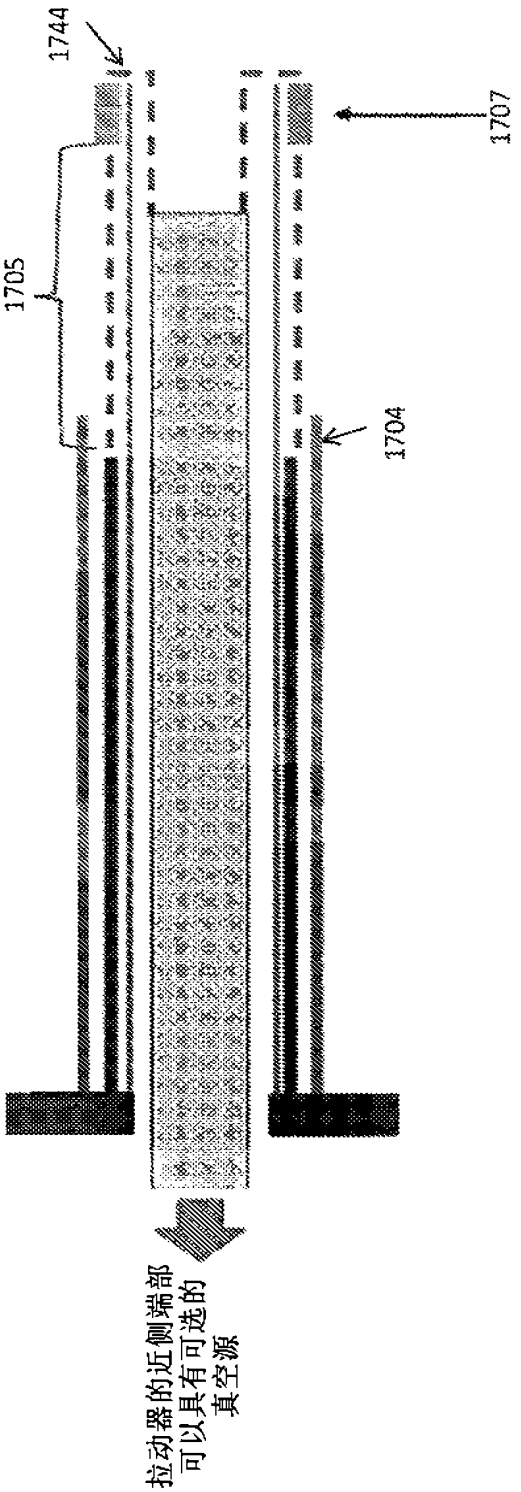


图17

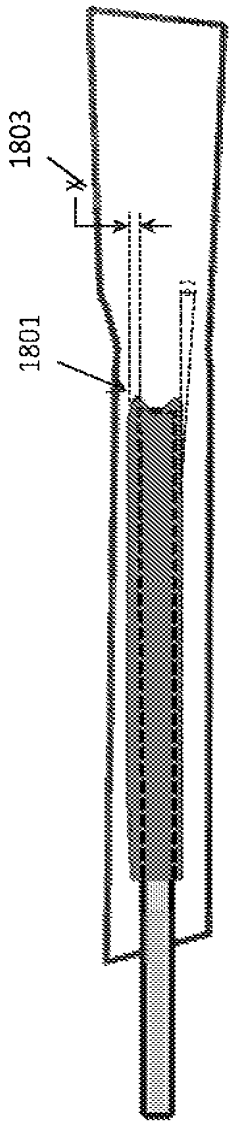


图18A

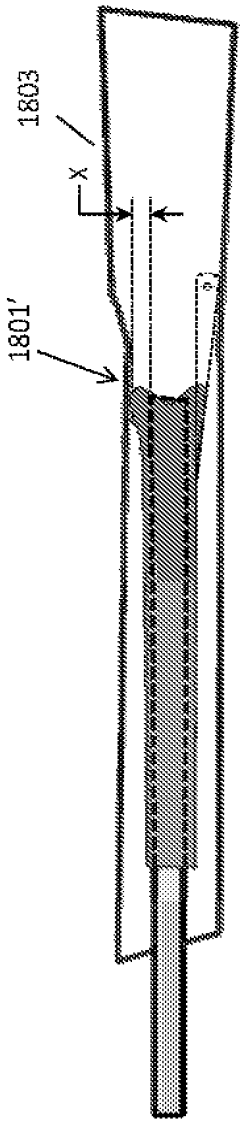


图18B

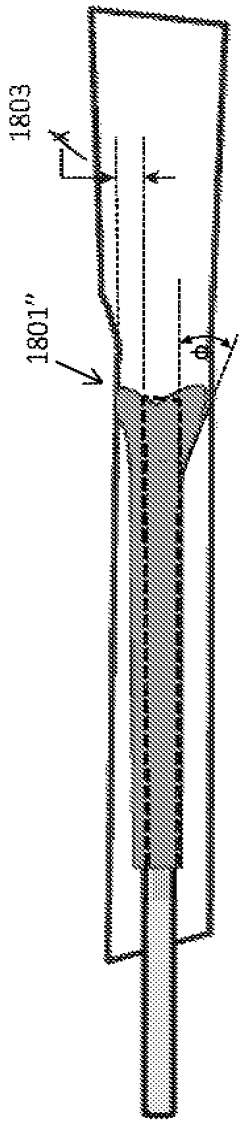


图18C

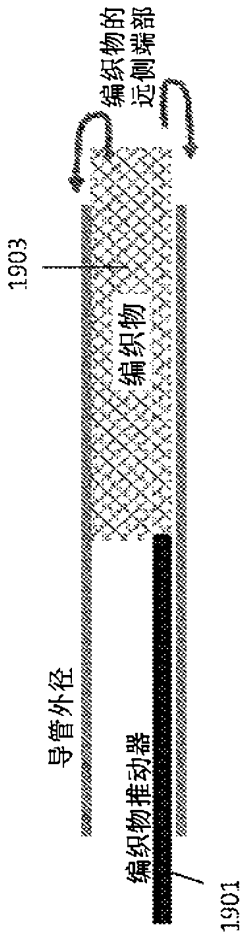


图19A

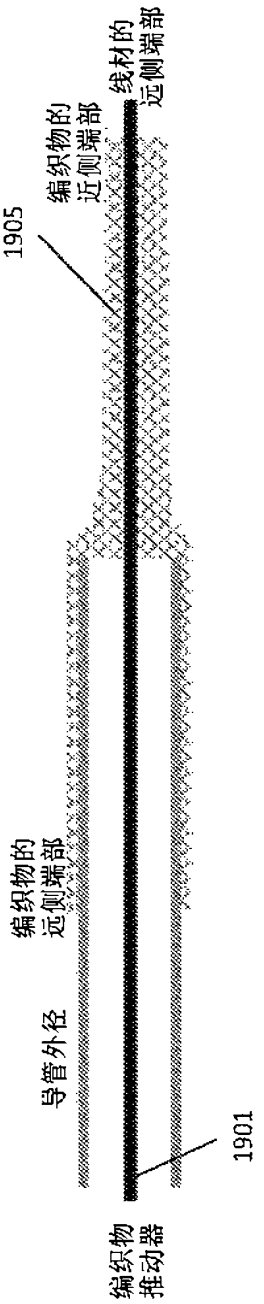


图19B

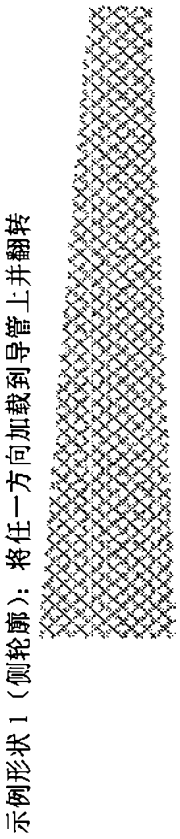


图20A



图20B

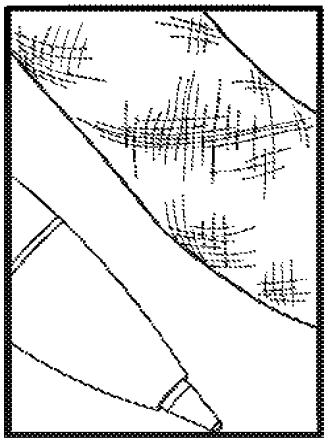


图21A

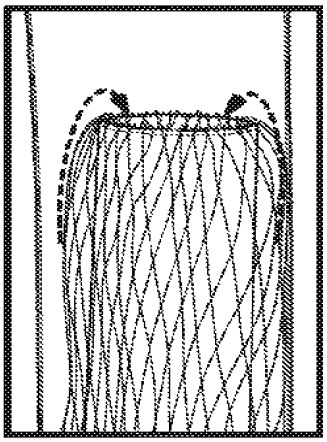


图21B

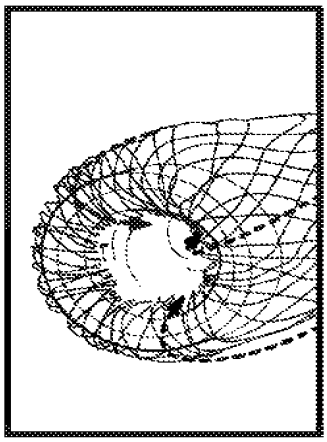


图21C

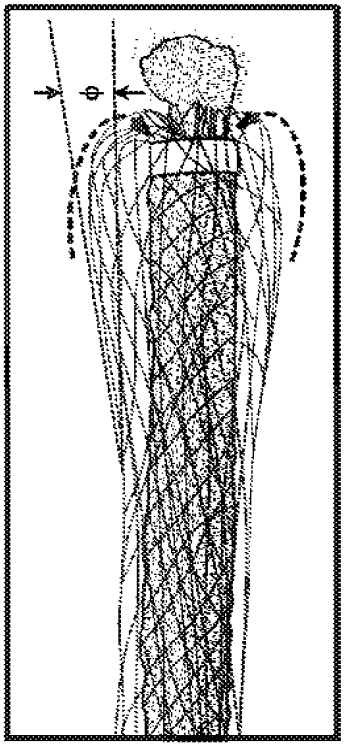


图21D

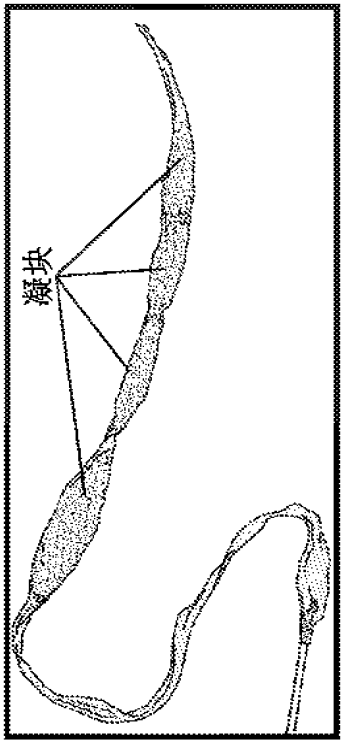


图22

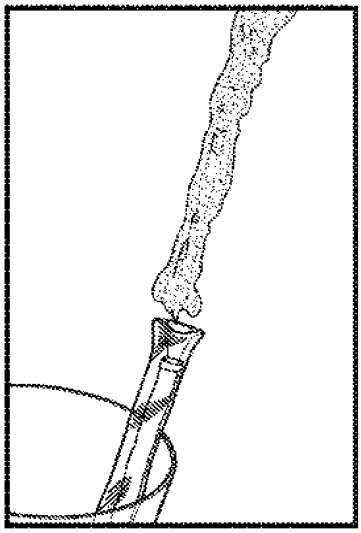


图23A

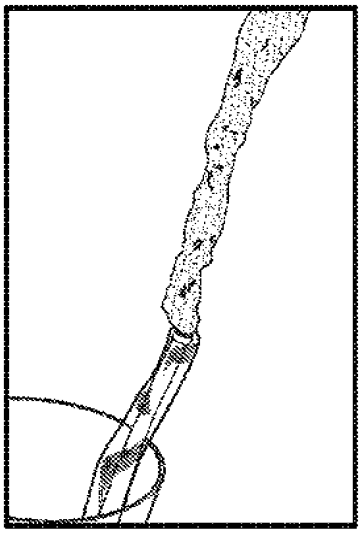


图23B

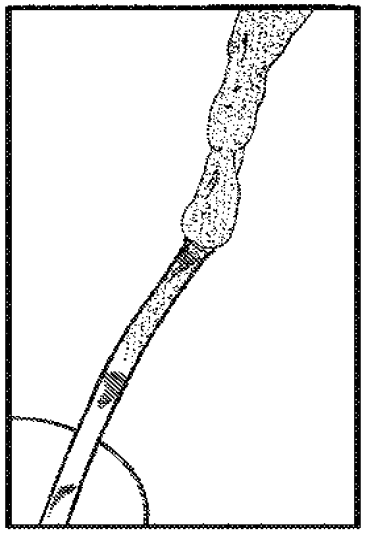


图23C

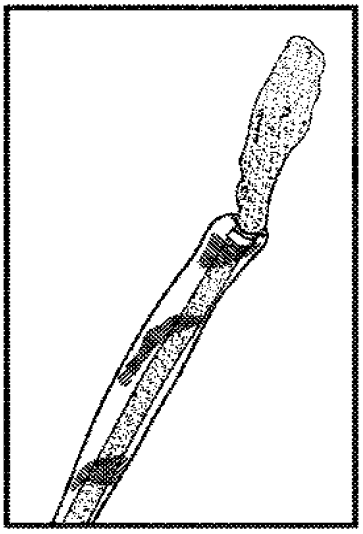


图23D

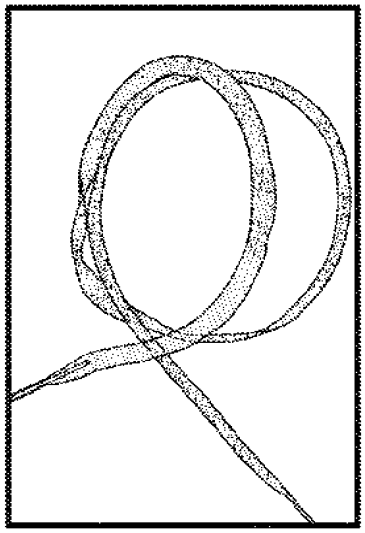


图23E

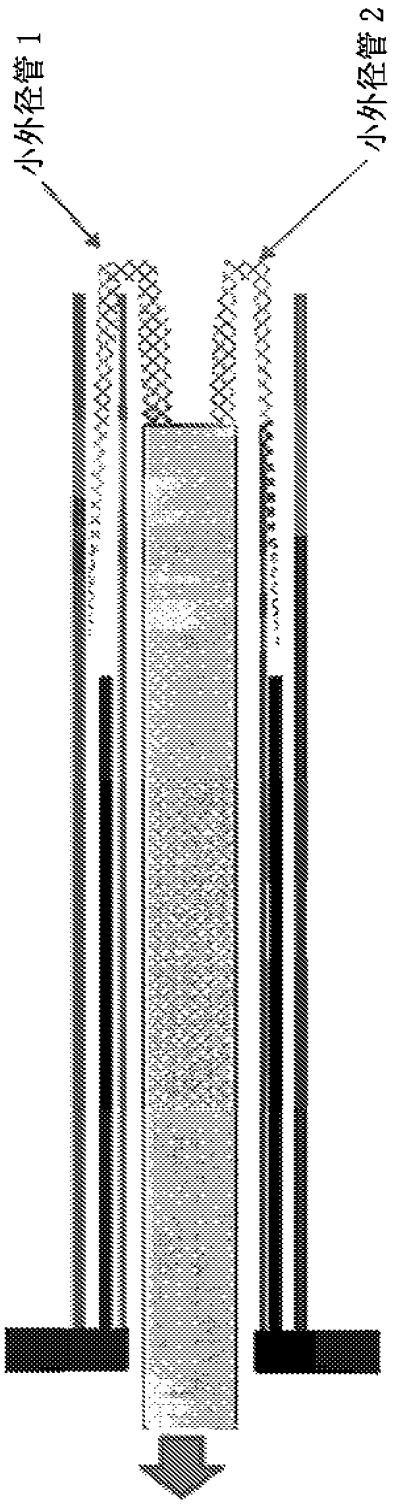


图24

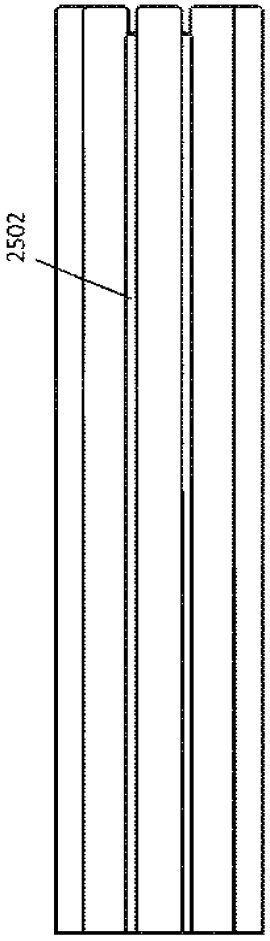


图25A

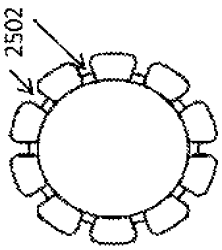


图25B

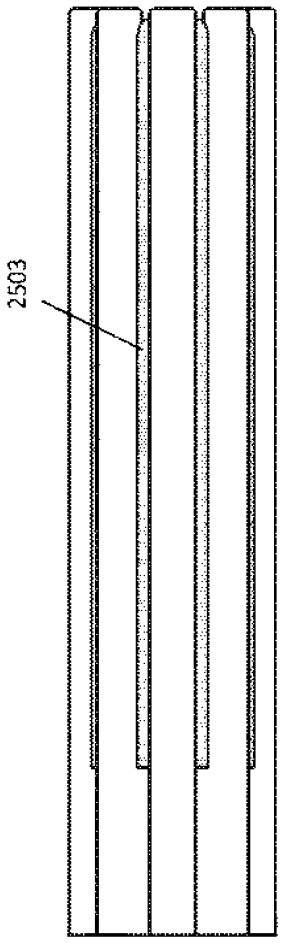


图25C

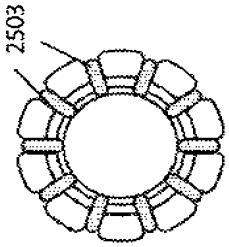


图25D

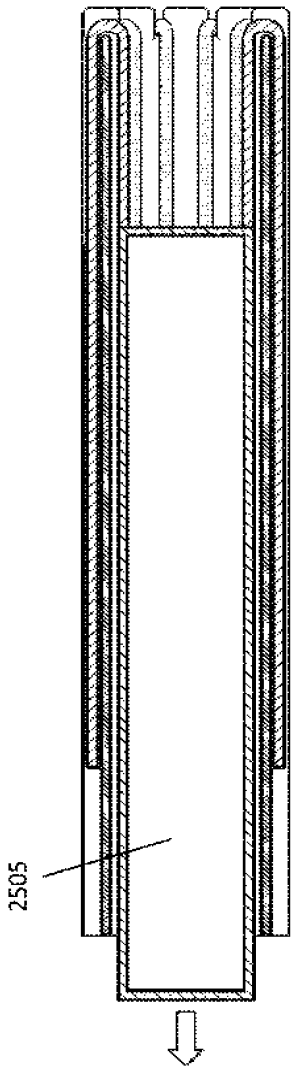


图25E

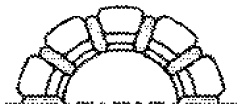


图25F

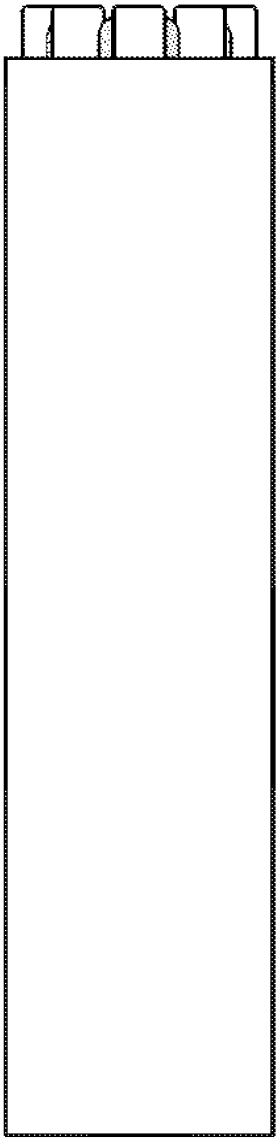


图26A

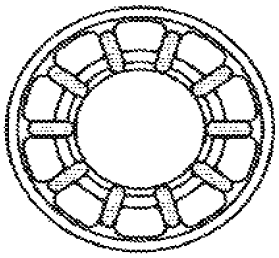


图26B

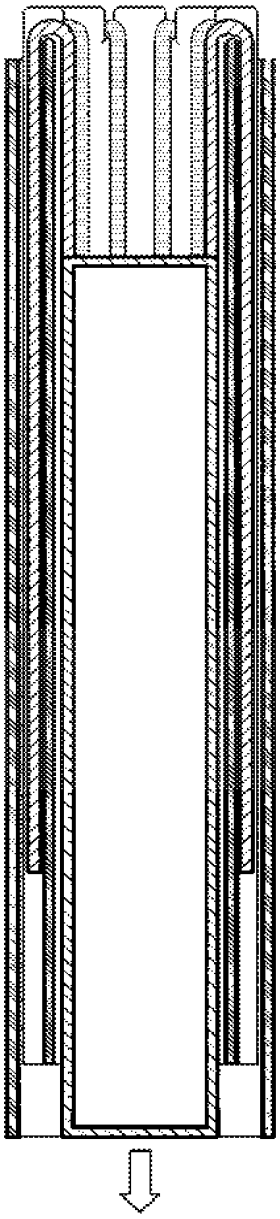


图27A

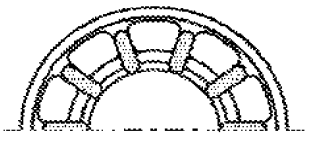


图27B

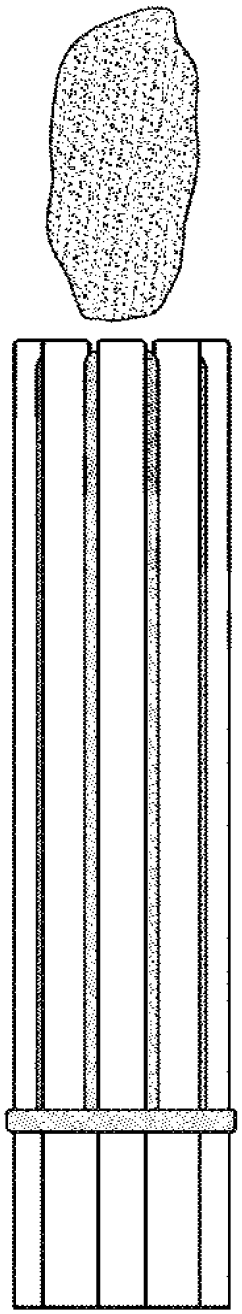


图28

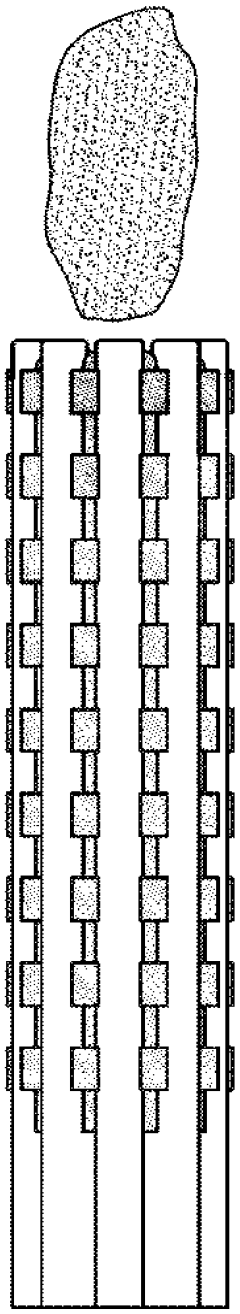


图29



图30A



图30B



图30C

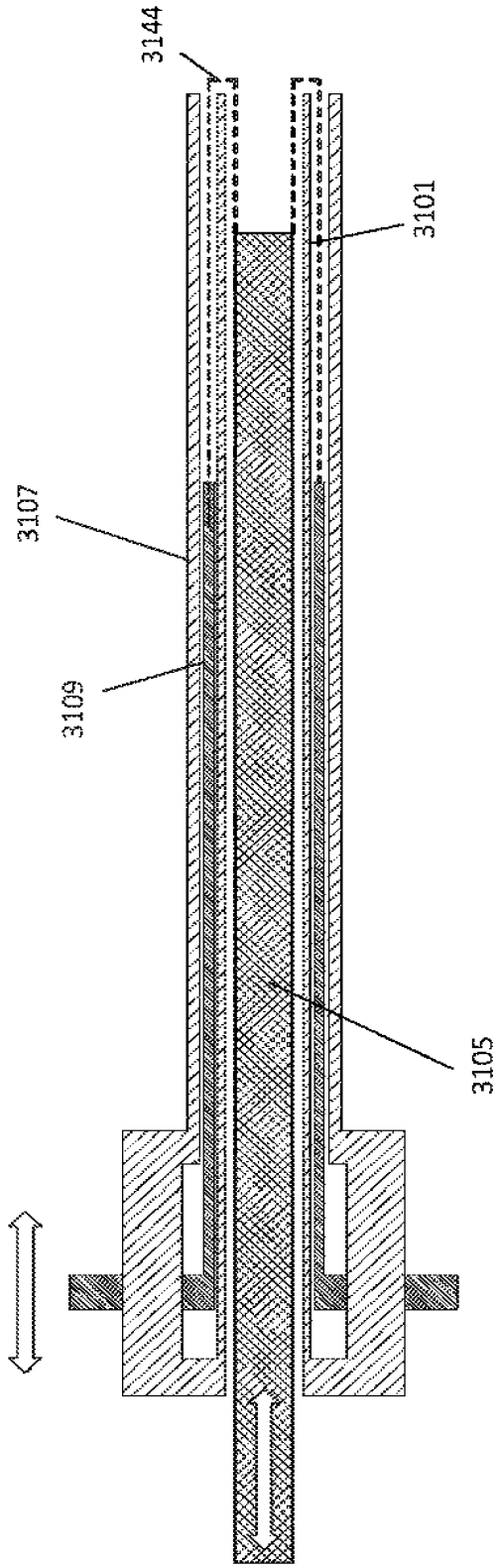


图31

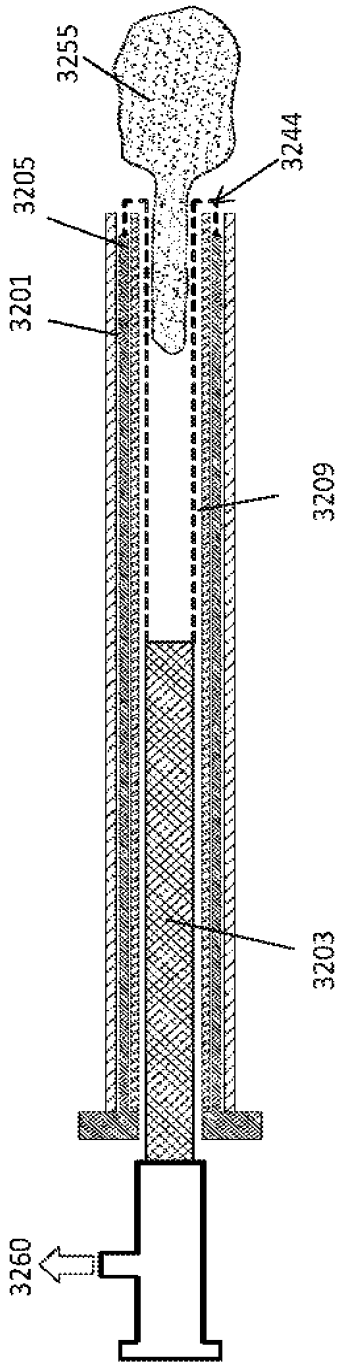


图32

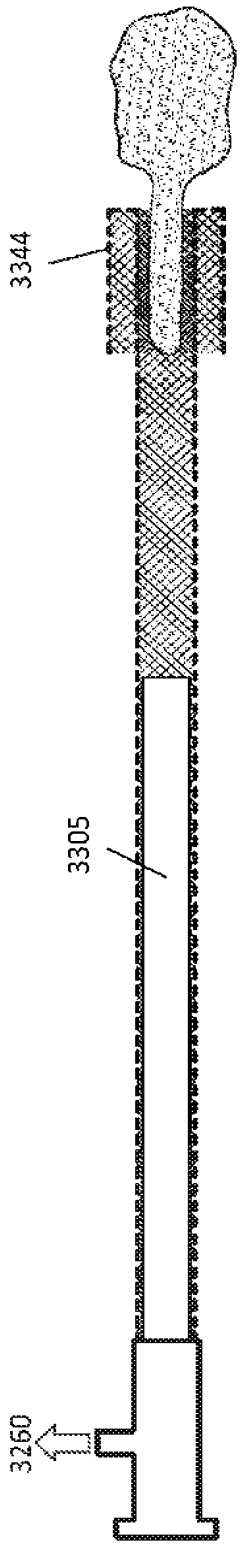


图33

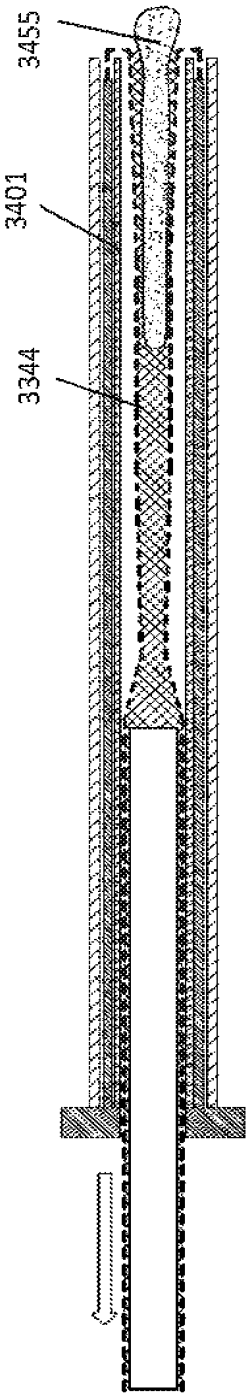


图34

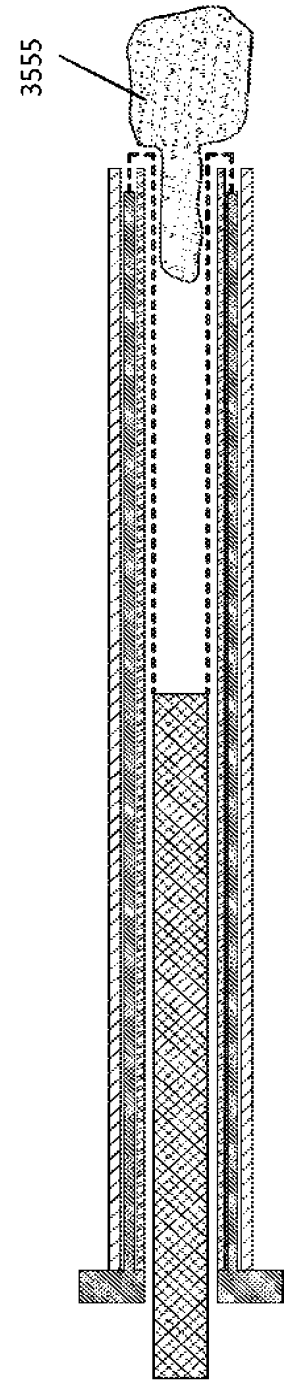


图35A

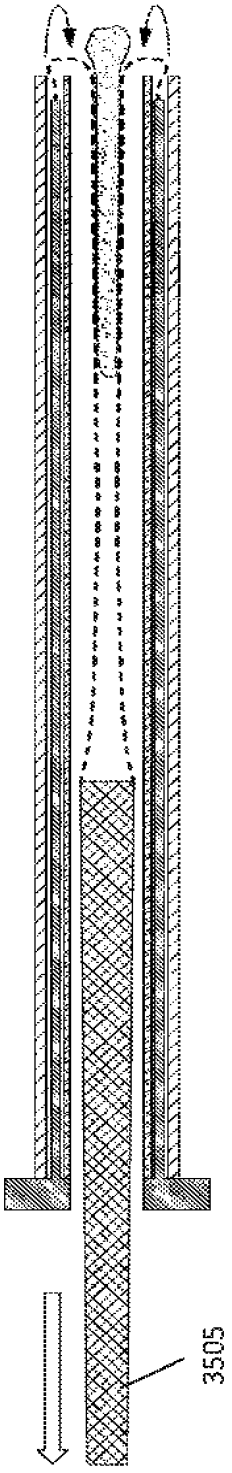


图35B

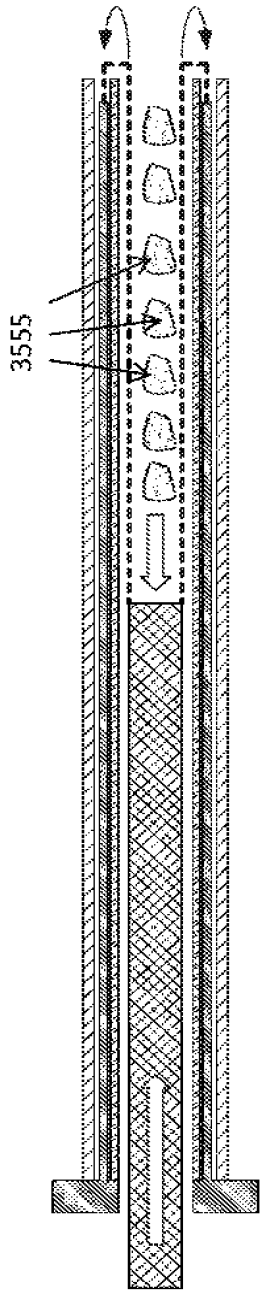


图35C

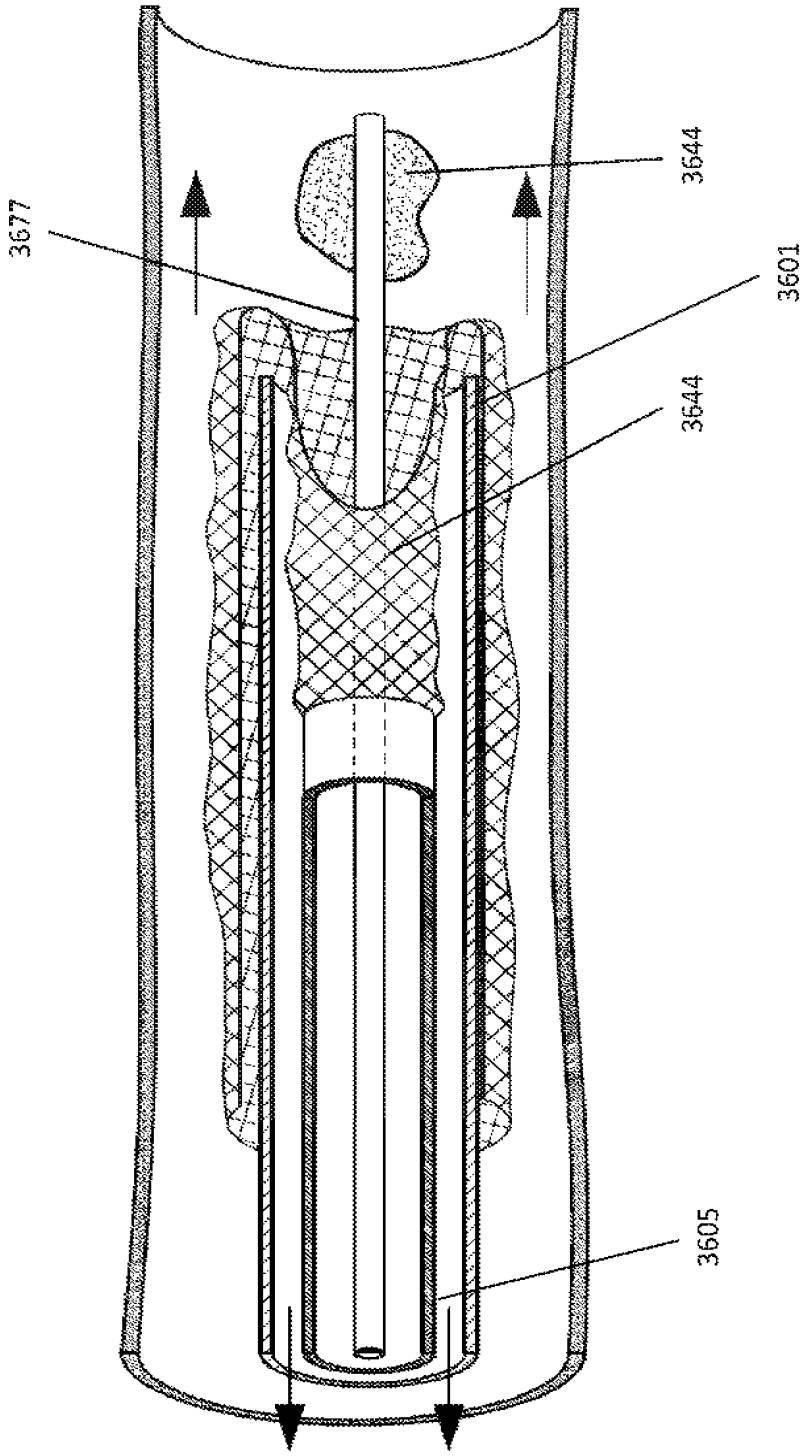


图36

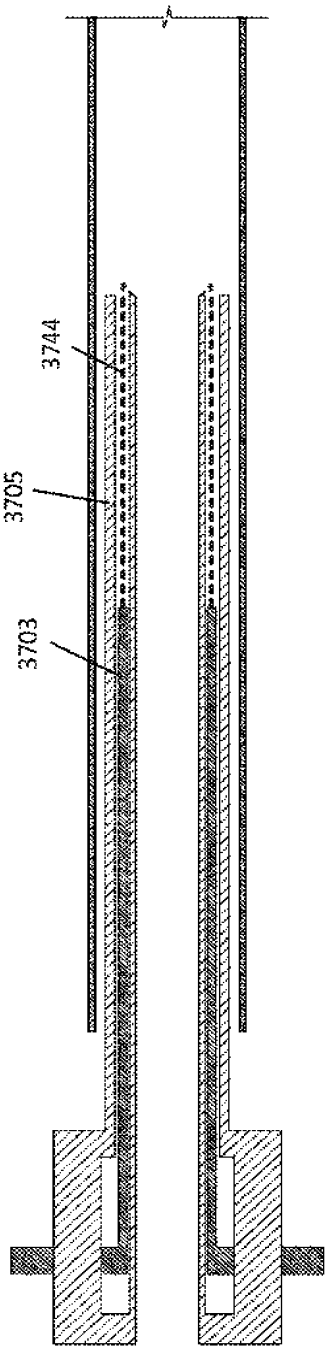


图37A

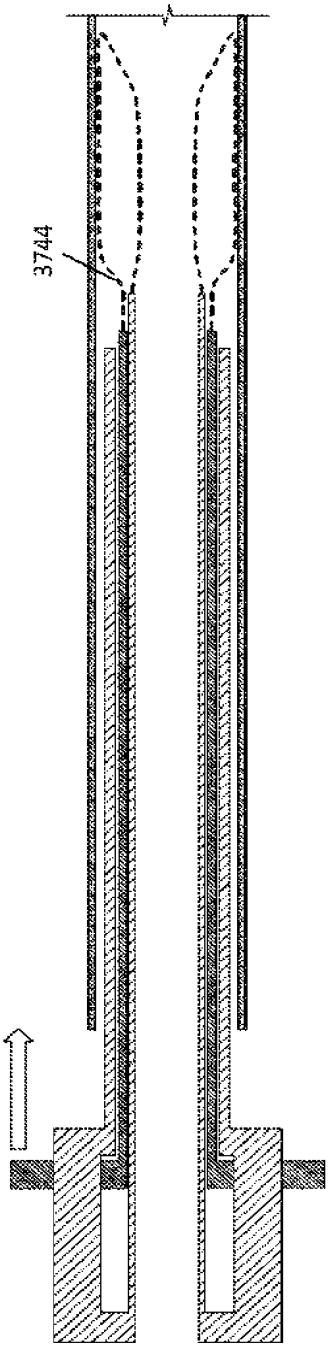


图37B

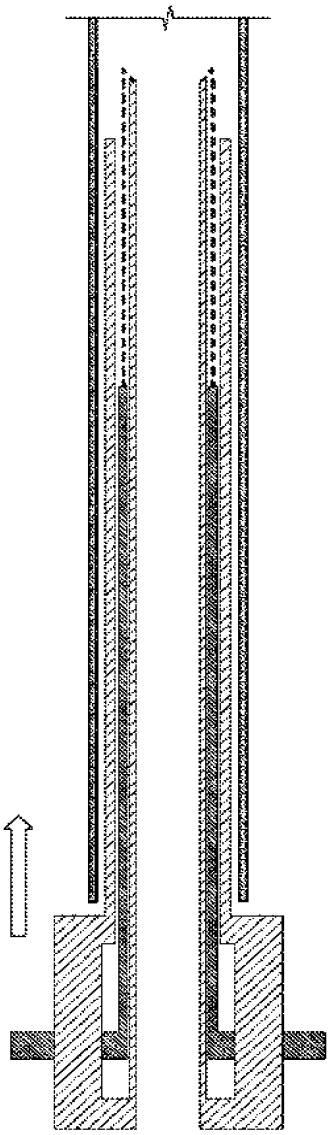


图37C

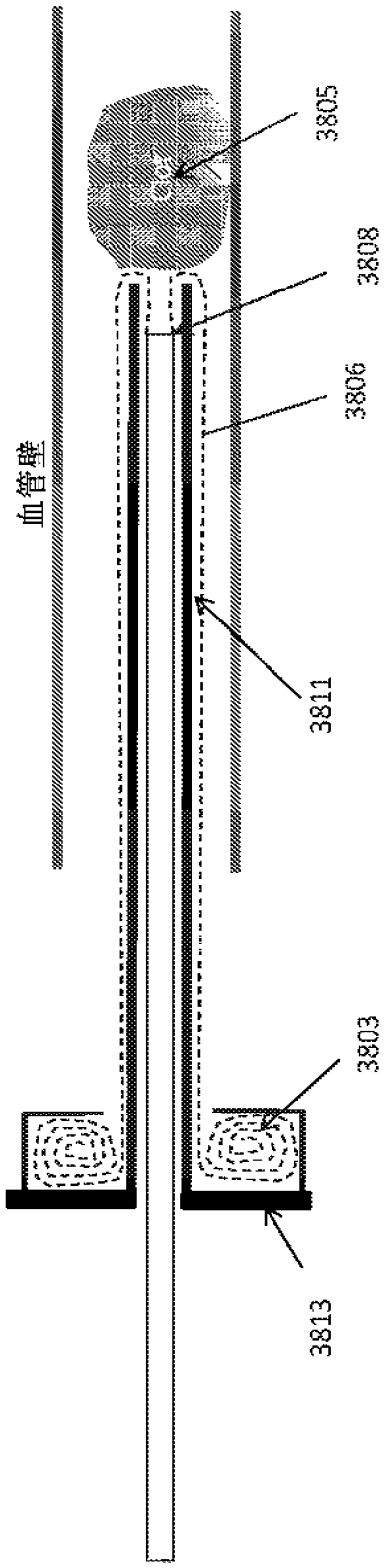


图38A

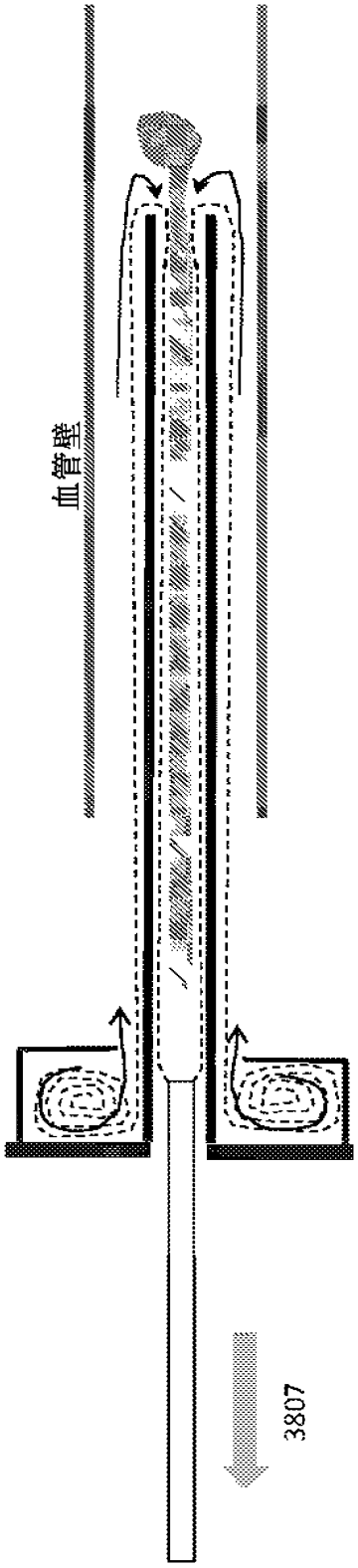


图38B

(19)中华人民共和国国家知识产权局

(12)发明专利

(10)授权公告号 CN 102186427 B
(45)授权公告日 2013.12.18

(21)申请号 200980141805.5

(22)申请日 2009.09.22

(30)优先权数据
61/099,171 2008.09.22 US
61/143,603 2009.01.09 US
61/152,227 2009.02.12 US

(85)PCT申请进入国家阶段日
2011.04.20

(86)PCT申请的申请数据
PCT/US2009/057918 2009.09.22

(87)PCT申请的公布数据
WO2010/034021 EN 2010.03.25

(73)专利权人 浩特斯博尔技术公司
地址 美国加利福尼亚州

(72)发明人 杰弗里·A·克罗里克
胡安·多明戈 达宇施·米尔扎伊
詹姆士·H·德雷赫尔

(74)专利代理机构 北京英赛嘉华知识产权代理有限责任公司 11204
代理人 余朦 王艳春

(51)Int.Cl.
A61B 17/22(2006.01)
A61B 17/50(2006.01)

(56)对比文件
US 7285126 B2,2007.10.23, 说明书第11栏第2段至第13栏第4段,图10-14.
US 2004/0006361 A1,2004.01.08, 全文.
US 2002/0010487 A1,2002.01.24, 全文.

审查员 王婷婷

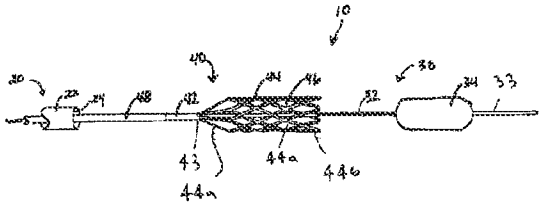
权利要求书1页 说明书13页 附图14页

(54)发明名称

流动恢复系统

(57)摘要

提供了用于移除体腔内的阻塞性物质的装置和方法。所述装置包括从套管可部署的剥离器装置，剥离器装置包括由轴承载且位于约束管内的可扩展笼。该轴相对于约束管可移动，以在体腔内部署和扩展笼，使得笼的开放端被定向为朝向阻塞性物质。笼前进以捕获物质或者通过在物质之外扩展并被收回的可扩展部件将物质引入笼中。笼撤回到约束管内以径向向内地压缩笼。穿过笼中的孔延伸的物质通过约束管的锋利的边缘被削切。然后通过套管从体腔抽吸更小的、被削切的颗粒。



CN 102186427 B

1. 一种用于从体腔移除阻塞性物质的系统，包括：

外部管状部件，包括近端、被确定尺寸以被引入体腔的远端、以及在所述近端与所述远端之间延伸的腔；

阻塞装置，能够从所述管状部件被部署至将要被移除的阻塞性物质之外的位置，所述阻塞装置包括位于其远端上的可扩展部件；以及

剥离器装置，包括在轴的远端上承载的可扩展笼和约束管，所述约束管用于使所述笼保持在收缩形态以允许所述剥离器装置通过管状部件腔被引入到所述体腔中，所述笼在体腔内能够从所述约束管的远端被部署并且能够扩展至扩展形态，所述笼包括与处于所述扩展形态的笼的内部连通的开放端，以将阻塞性物质捕获到所述笼的内部，

其中，所述笼包括管状结构，所述管状结构包括在所述笼的开放端和闭合端之间延伸的壁，所述笼包括在所述开放端与所述闭合端之间延伸的多个支杆，由此在所述壁中限定了多个孔，

所述多个支杆包括通常在所述笼的开放端和闭合端之间轴向延伸的第一组支杆，以及在所述第一组支杆的相邻支杆之间不连续延伸的第二组支杆，从而限定网状壁结构，

所述第一组支杆具有比所述第二组支杆更大的刚性，使得所述笼关于其纵轴在第一方向的旋转引起所述笼径向扩展。

2. 如权利要求 1 所述的系统，其中，所述阻塞装置能够相对于所述剥离器装置移动，使得扩展的可扩展部件将置于所述可扩展部件与所述笼之间的阻塞性物质引导至所述笼的开放端内，以将所述物质捕获到所述笼的内部。

3. 如权利要求 1 所述的系统，其中，所述笼能够在体腔内扩展之后缩回到所述约束管中，使得所述笼的闭合端可滑动地与所述约束管的远端接合并且使得所述笼向所述收缩形态被压缩。

4. 如权利要求 3 所述的系统，其中，所述笼包括管状结构，所述管状结构包括在所述笼的开放端和闭合端之间延伸的壁，所述壁包括限定了期望孔隙尺寸的多个孔，从而当随着所述笼缩回到所述约束管中，所述笼可滑动地与所述约束管的远端接合时，由所述笼捕获的通过所述孔延伸的阻塞性物质通过所述约束管的远端而与所述笼分离。

5. 如权利要求 4 所述的系统，进一步包括真空源，所述真空源连接至所述管状部件的腔，以将与所述笼分离的阻塞性物质抽吸到所述管状部件的腔中。

6. 如权利要求 1 所述的系统，其中，所述剥离器装置的轴包括在其近端和远端之间延伸的腔，以在该腔中可滑动地接纳所述阻塞装置，所述可扩展部件处于收缩形态。

7. 如权利要求 1 所述的系统，进一步包括从所述笼的开放端向远侧延伸的多个远末端。

流动恢复系统

[0001] 相关申请

[0002] 本申请要求共同未决的 2008 年 9 月 22 日提交的第 61/099,171 号美国临时专利申请、2009 年 1 月 9 日提交的第 61/143,603 号美国临时申请和 2009 年 2 月 12 日提交的第 61/152,227 号美国临时专利申请的优先权，其全部公开通过引用明确并入本文。

技术领域

[0003] 本发明通常涉及用于处理患者体腔（例如，管状移植物 (tubulargraft)、主动脉 - 静脉瘘 (aorto-venous fistula)、血管等）内的阻塞性物质（例如，血栓，器官狭窄）和 / 或不期望物质的装置。更具体地，本发明涉及用于移除或以其它方式捕获体腔内的血栓或其它阻塞性物质的装置，以及制造和使用这种装置的方法。

背景技术

[0004] 患者脉管系统内的血管或其它体腔内的流动可能由于各种原因而变得缩窄或最终中断。例如，炎症和 / 或细胞增殖可能导致血管逐渐变窄。此外，这种变窄或血管内的其它流动问题可能导致血栓的形成。

[0005] 移除粘附至血管壁的不期望物质（例如，血栓）的一种方法可涉及使装置（例如，Fogarty（福格蒂）栓子清除气囊）前进至附着的阻塞性物质之外的一点，将装置扩展至血管内部的尺寸，然后撤回扩展的装置，以将附着的物质清扫出血管。虽然这种方法经常是成功的，但是也存在一些情况：附着的物质没有脱离血管壁，并且甚至在多次通过后仍然留在血管内。

[0006] 移除附着的物质的另一种方法是推进可以刮擦附着的物质的表面或与附着的物质缠绕在一起的旋转结构，从而迫使附着的物质脱离血管壁。Arrow Treratola 装置具有若干径向向外扩展以接触血管壁的螺 旋线。通过连接至装置的机头中电动机的驱动轴使这些线高速旋转。在操作过程中，当 Treratola 装置前进时，它摩擦血管的内壁。一旦与附着的物质接合 (engage)，装置刮擦该物质的内表面，而且在许多情况下，装置可冲破附着的物质与血管壁之间的界面。在这种情况下，附着的物质可从血管壁脱落，并且缠绕在 Treratola 装置的螺旋线上。

[0007] 虽然这可解决从血管壁移除附着的物质的直接目标，但是往往很难从血管本身移除物质，因为 Treratola 装置没有提供任何方法来解开 (unwind) 或抽吸物质。当 Treratola 装置从血管移除时，它通常通过紧贴的孔，例如导引器套管。任何缠绕在 Treratola 装置上的物质在该 Treratola 装置进入套管时被推落，因此这些物质仍然留在血管中。

[0008] 因此，从主动脉 - 静脉瘘、血管或其它体腔中移除物质的装置和方法是有用的。

发明内容

[0009] 本发明涉及处理患者体腔（例如管状移植物、主动脉 - 静脉瘘、血管等）的装置。更具体地，本发明涉及用于移除或以其它方式捕获体腔内的血栓或其它阻塞性物质的装

置，以及制造和使用这种装置的方法。

[0010] 根据一个实施方式，提供了用于从体腔移除阻塞性物质的系统。所述系统包括外部管状部件，其包括近端、远端、以及在近端与远端之间延伸的腔。任选地，环形可扩展阻塞部件可设置在外部管状部件远端上。该系统还包括剥离器装置，其可插入通过腔并且包括细长轴、连接至细长轴远端的可扩展笼、以及包括具有锋利的边缘的远端开口的约束管，其中，轴和笼相对于约束管轴向可移动。可选地，约束管固定地连接至外部管状部件的内表面，或者约束管可独立于外部管状部件可移动。

[0011] 笼可包括多个孔，并且约束管的远端锋利的边缘被配置为当将笼撤回到约束管时削切通过孔突出的阻塞性物质。任选地，笼的内表面可包括多个向内突出的倒钩。笼可包括远端伸出结构和/或厚支杆以及与厚支杆连接在一起的薄支杆。任选地，一根或多根控制线可连接至 笼的远端伸出结构，其中，控制线可被配置为当笼处于扩展形态时，将伸出结构一起拉向闭合形态。任选地，驱动轴可操作地连接至笼，以使笼在通过体腔前进期间旋转，或者该系统可包括促动器从而手动地旋转笼。在示例性实施方式中，所述远端伸出结构可具有平滑边缘、具有沟槽的边缘或蜿蜒的边缘。

[0012] 在示例性实施方式中，系统可进一步包括具有可扩展处理元件的细长处理部件，可扩展处理元件选择性地可扩展以当笼处于扩展形态时将体腔内的阻塞性物质引入到笼中。细长处理部件可插入通过穿过剥离器装置轴中的腔。可选地，细长处理部件可插入通过邻近剥离器装置轴的外部管状部件腔。任选地，在这个可选实施方式中，笼可包括细长处理部件可通过的不间断的路径或其它开口。

[0013] 根据另一实施方式，提供了用于从体腔移除阻塞性物质的方法，包括将外部管状部件引入到体腔内，外部管状部件包括腔和远端开口。可通过管状部件腔将剥离器装置引入到体腔内。在示例性实施方式中，剥离器装置包括细长轴，连接至细长轴远端的可扩展笼，以及具有远端开口的约束管。通过使细长轴相对于约束管向远侧前进可将可扩展笼部署在约束管远端开口的外部，并且使其在体腔内扩展。可将阻塞性物质捕获到笼内，然后将笼向近侧撤回到约束管中。当笼收缩时，通过笼中的孔突出的物质可被削切，例如，通过约束管远端开口的锋利的边缘被削切。附加地或者可选地，可将削切的物质抽吸到外部管状部件远端开口中。任选地，方法还可包括在外部管状部件远端上扩展阻塞部件，例如以防止阻塞性物质紧邻地经过外部管状部件的远端。

[0014] 在示例性实施方式中，所述方法还可包括将将包括远端可扩展处理元件的细长处理部件引导通过外部管状部件腔并引入到体腔中，使得处于收缩形态的可扩展处理元件位于阻塞性物质的远侧，并且笼被定位在阻塞性物质的近侧。可扩展处理元件可以被扩展并且将可扩展处理元件向近侧朝向可扩展笼撤回，使得阻塞性物质被撤到笼的开放端内。

[0015] 在另一示例性实施方式中，所述方法还可包括使可扩展笼朝向阻塞性物质前进并且在推进期间使笼旋转，直至阻塞性物质缠绕在笼的 远端部。笼的旋转可引起所述阻塞性物质与血管壁分离，并且笼可撤回到约束管中。所述撤回步骤可从笼远端部释放阻塞性物质和/或将阻塞性物质撤到约束管中。任选地，笼可一次或多次地重新部署、扩展和/或撤回，例如以分离阻塞性物质和/或将阻塞性物质撤到笼中。

[0016] 根据另一实施方式，提供了用于从体腔移除阻塞性物质的装置，包括：外部管状部件，包括近端、被确定尺寸以被引入体腔的远端、以及在近端与远端之间延伸的腔；细长轴，

包括近端和远端并且在管状部件腔内轴向可移动；以及可扩展的剥离器笼，包括附接至轴的远端的第一端和第二自由端。当笼被置于管状部件腔内时笼可从收缩形态扩展，当笼从管状部件腔被部署时笼可从扩展形态扩展。

[0017] 在一个实施方式中，笼包括管状结构，管状结构包括在第一端与第二端之间延伸的壁，第二端限定了与处于扩展形态的笼的内部连通的开口，以将阻塞性物质捕获到笼的内部。壁可包括多个支杆 / 孔，使得当笼在将阻塞性物质捕获到笼内之后撤回到管状部件腔时，管状部件的远端可滑动地与笼的壁接合，或者以其它方式分离由笼捕获的穿过孔延伸的阻塞性物质，并且将笼压缩回到收缩形态。

[0018] 根据又一实施方式，提供了用于从体腔移除阻塞性物质的系统，包括：外部管状部件，包括近端、被确定尺寸以被引入体腔的远端、以及在近端与远端之间延伸的腔；阻塞装置，从管状部件可被部署至将要被移除的阻塞性物质之外的位置，阻塞装置包括位于其远端上的可扩展部件；以及剥离器装置。剥离器装置可包括轴的远端上承载的可扩展笼以及用于使笼保持在收缩形态的约束管，例如以允许将剥离器装置通过管状部件引入体腔中。笼可从约束管的远端可部署并且在体腔内可扩展至扩展形态。在一个实施方式中，笼可包括与处于扩展形态的笼的内部连通的开放端，以将阻塞性物质捕获到笼的内部。

[0019] 考虑下面结合附图的描述，本发明的其它方面和特征将会变得显而易见。

附图说明

[0020] 应理解的是，图中所示的示例性装置不必按照比例绘制，主要用于强调而非说明所示实施方式的各个方面和特征。

[0021] 图 1 是包括从进入套管可部署的剥离器装置和闭塞装置的流动恢复系统的示例性实施方式的侧视图；

[0022] 图 2A 是可包含在图 1 的系统中的进入套管的截面侧视图，该图包括位于进入套管的远端上的可扩展部件；

[0023] 图 2B 是可包含在图 1 的系统中的进入套管的可选实施方式的截面侧视图，该图包括位于进入套管的远端上的可扩展部件；

[0024] 图 3 是可包含在图 1 的系统中的剥离器装置的笼的内表面的细部；

[0025] 图 4A 和图 4B 是可包含在图 1 的系统的剥离器装置中的约束管的示例性实施方式的截面侧视图；

[0026] 图 5 是进入装置的可选实施方式的截面侧视图，该进入装置包括可包含在图 1 系统中的整合的约束管；

[0027] 图 6 是包括从进入套管可部署的剥离器装置和闭塞装置的流动恢复系统的另一示例性实施方式的侧视图；

[0028] 图 7 至图 10 示出了患者身体内体腔的截面视图，其示出了移除体腔内阻塞性物质的方法；

[0029] 图 11A 和图 11B 分别是处于扩展形态和收缩形态的剥离器装置的另一示例性实施方式的透视图；

[0030] 图 12A 是可以并入图 11A 和图 11B 的剥离器装置笼的平面样式的俯视图；

[0031] 图 12B 是图 12A 的平面样式的一部分的细部；

[0032] 图 13 是图 11A 和图 11B 中所示的剥离器装置笼沿方向 A 旋转的详细透视图；

[0033] 图 14A 和图 14B 是剥离器装置笼的另一示例性实施方式的截面图，该剥离器装置包括控制线，分别用于在开放结构与闭合结构之间引导笼的远端；

[0034] 图 14C 是图 14A 和图 14B 的剥离器装置笼的可选示例性实施方式的截面图，该剥离器装置包括控制线以及围绕控制线的套管，以在开放结构与闭合结构之间引导笼；

[0035] 图 15A 至图 15C 是可设置在剥离器装置笼（如图 11A 和图 11B 中所示的笼）上的远末端的可选实施方式的侧视图；以及

[0036] 图 16A 至图 16H 是患者身体内体腔的截面视图，其示出了移除体腔内阻塞性物质的另一方法。

具体实施方式

[0037] 转到附图，图 1 示出了用于处理体腔的装置 10 的示例性实施方式，装置 10 例如用于从体腔（诸如血管、主动脉 - 静脉瘘、管状移植物等）内移除血栓、血块、物体、碎片和 / 或其它不期望的或阻塞性物质。通常，装置 10 包括外部进入套管或其它管状部件 20、以及任选地阻塞装置 30 和剥离器 (macerator) 装置 40，它们一起可提供流动恢复系统，例如以从患者身体的体腔内移除阻塞性物质。另外，这种系统可包括一个或多个未示出的附加部件，例如，一根或多根导引线 (guidewire)、注射器或膨胀介质和 / 或真空的其它源等。

[0038] 套管 20 可以是细长的管状体（例如，导引器或手术 (procedure) 套管），包括近端（未示出）、被确定尺寸以被引入体腔内的远端 22、以及在近端与远端 22 之间延伸的腔 24。套管 20 可被配置为经皮置于体腔内，例如包括圆的或其它基本上无损伤的末端，从而便于推入到患者身体内的体腔内和 / 或沿着患者身体内的体腔前进。

[0039] 套管 20 可具有沿着其长度基本均匀的结构，或可选地，该结构可以是变化的。例如，套管 20 的近端部可以是基本刚性或半刚性的以通过推动或以其它方式操纵近端来方便装置 10 的前进。附加地或可选地，套管 20 的远端部可以是柔性的，例如以便于折弯和 / 或在弯曲的解剖结构中前进而不存在扭结或弯曲变形的高风险。在示例性实施方式中，形成套管 20 的材料可以是诸如金属、塑料（例如 PEEK、GrilamedL25 等）、或复合材料。套管 20 的长度可约在 5cm 至 130cm 之间，外径约在 1.6 毫米至 2.0 毫米之间，腔 24 的直径可约在 1.4 毫米与 1.8 毫米之间。

[0040] 任选地，套管 20 可在近端（未示出）上包括握柄或套筒 (hub)。如下进一步描述，握柄可成形为便于握住或操纵装置 10 或装置 10 的单独部件。另外，握柄可包括与例如围绕剥离器装置 40 和 / 或阻塞装 置 30 的腔 24 连通的端口，例如以将流体注入腔 24 和 / 或从腔 24 抽吸物质。如下进一步描述，例如，注射器、真空管线等可连接至端口，以抽吸容纳在套管 20 的腔 24 内和 / 或在体腔内邻近远端 22 放置的阻塞性物质。

[0041] 任选地，套管 20 可包括由远端 22 承载的可扩展 (expandable) 部件或其它阻塞元件，例如以在体腔内固定套管 20 和 / 或密封体腔以防止在手术期间流体流过远端 22。例如，图 2A 示出了体腔 50 内的套管 20'，该套管 20' 包括位于其远端 22' 上的可扩展部件 26'。如果需要，可扩展部件 26' 可以是柔性气囊（例如由柔性材料制成，其可根据运送到气囊 26' 中的膨胀介质的量成比例地弹性扩展）、半柔性气囊或非柔性气囊（例如 PTA 气囊）。在这个实施方式中，套管 20' 可包括从套管 20' 的近端延伸到远端 22' 且与气囊 26' 的内

部连通的膨胀腔（未示出）。诸如具有盐溶液或其它流体的注射器等的膨胀介质和/或真空的源（未示出）可连接至套管 20' 的近端，以经由膨胀腔将膨胀介质运送到气囊 26' 中和/或从气囊 26' 中抽吸流体，例如，以便于在手术后使气囊收缩。可选地，可扩展部件 26' 可以是以机械或其它方式可扩展的，例如，包括可扩展框架、或者在膜（未示出）内或以其它方式连接至膜（未示出）的其它结构。

[0042] 可扩展部件 26' 可从低轮廓、收缩形态（例如，抵靠套管 20' 的外表面布置以便于套管 20' 的引入）扩展，并且可从高轮廓、扩展形态扩展，例如以与其内引入套管 20' 的体腔 50 的内表面接合或以其它方式接触。在扩展形态中，可扩展部件 26' 可在体腔 50 内提供基本的流体密封，例如以防止沿着体腔 50 的大量生理流动，否则其可能允许松散物质的颗粒移动经过套管 20 进入患者身体的其它部位，在那里颗粒可能造成伤害。附加地或可选地，可扩展部件 26' 还可基本上固定和/或稳定体腔 50 内的套管，例如，以防止在处理过程中体腔 50 内的套管 20' 因疏忽而移动。

[0043] 在使用过程中，在套管 20' 被引入时，可扩展部件 26' 可保持低轮廓形态，然后一旦套管 20' 被定位在正被处理的体腔 50 内，则可扩展部件 26' 扩展至高轮廓形态。当阻塞性物质从体腔 50 经由套管 20' 或 装置 10 的其它部件移除时，可扩展部件 26' 可保持扩展状态，如下进一步描述。一旦体腔 50 被充分处理，则可扩展部件 26' 可收缩以恢复体腔 50 内的生理流动。

[0044] 在图 2B 中所示的可替换实施方式中，可提供包括可扩展部件 26" 的进入套管 20"，可扩展部件 26" 延伸到套管 20" 的远端 22" 之外以为套管 20" 提供可扩展的远末端。因此，可扩展部件 26" 可提供从增大的远末端向套管 20" 的腔 24" 的圆锥形过渡或其它过渡，例如，如果需要，可在可扩展部件 26" 的远末端内或邻近可扩展部件 26" 的远末端执行阻塞性物质的剥离。在剥离期间，阻塞性物质的颗粒可在套管 20" 的腔 24" 内或者邻近套管 20" 的腔 24" 释放。在 2009 年 8 月 8 日提交的第 PCT/US09/53237 号申请中可得到进入套管 20" 和/或可扩展部件 26" 的更多信息，该申请的全部公开通过引用明确并入本文。

[0045] 回到图 1，阻塞装置 30 通常包括轴或其它细长部件 32，其包括近端（未示出）和远端 33，远端 33 被确定尺寸以被引导例如经由腔 24 穿过套管 20，并且在远端 33 上承载有可扩展的阻塞或处理部件 34。通常，阻塞部件 34 从收缩形态（未示出）（例如，其尺寸适合被引导通过套管 20 的腔 24）扩展，并从扩展形态（图 1 所示）扩展，以与体腔的壁接合或以其它方式接触，其中阻塞部件 34 在体腔内扩展。在示例性实施方式中，阻塞部件 34 可以是可扩展成基本上球形或圆筒形的气囊，例如柔性气囊、半柔性气囊或非柔性气囊。在这个实施方式中，轴 32 可包括与阻塞部件 34 的内部连通的膨胀腔（未示出），例如，以选择性地扩展和收缩阻塞部件 34。任选地，阻塞部件 34 可包括芯线和/或螺旋结构（未示出），例如使得阻塞部件可在扩展形态中采用螺旋形。在 2009 年 7 月 2 日提交的第 12/497,135 号共同未决申请中公开了可用于阻塞部件 30 的示例性装置，该申请的全部公开通过引用明确地并入本文。可选地，如果需要，阻塞部件 34 可包括框架或其它机械上可扩展的结构（未示出）。

[0046] 继续参照图 1，剥离器装置 40 通常包括轴或其它细长部件 42，其包括近端（未示出）和远端 43、以及在远端 43 上承载的可扩展笼 44，远端 43 被确定尺寸以适配于套管 20 的腔 24 内。任选地，如下进一步 描述，轴 42 可包括腔或其它轨道（未示出），以可滑动地

容纳通过该腔或其它轨道的阻塞部件 30。附加地或可选地，如下进一步描述，轴 42 可包括一个或多个附加腔（未示出），例如用于接收导引线或其它轨（也未示出），一个或多个促动器线或线缆（也未示出）等。

[0047] 如图所示，笼 44 是开放的或多孔的可扩展结构，其包括连接至轴 42 的闭合的近端或第一端 44a 以及开放的远端或第二端 44b，例如，以在笼 44 内容纳接收的阻塞性物质，如下进一步描述。通常，笼 44 包括在第一端 44a 与第二端 44b 之间和 / 或围绕笼 44 的外周延伸的多个支杆 (struts)44a，由此例如至少邻近第一端 44a 限定了包括多个孔 46 的圆筒形外壁或其它管状外壁。支杆 44a 和 / 或孔 46 可被确定尺寸以适应笼 44 的扩展和 / 或收缩，和 / 或限定期望的孔隙尺寸，一旦比期望孔隙尺寸大的颗粒被捕获到笼 44 内，则该期望的孔隙尺寸防止该颗粒逃脱，如下进一步描述。

[0048] 笼 44 从例如适于低轮廓、收缩形态（未示出）（以适于被引导通过套管 20）和高轮廓、扩展形态（图 1 所示）扩展，在高轮廓、扩展形态中，笼 44 径向向外扩展，例如以接触的体腔的壁，其中笼 44 在体腔内被部署 (deploy) 和 / 或扩展。任选地，如图 3 所示，笼 44 可包括从支杆 44a 径向向内突出的多个倒钩或其它特征 41，例如以与被捕获到笼 44 内的阻塞性物质接合和 / 或对其提供附加的牵引力，如下进一步描述。

[0049] 笼 44 可由例如能够在收缩形态与扩展形态之间弹性或塑性地变化一次或多次的多种材料形成。例如，笼 44 可由弹性或超弹性材料形成，例如金属（如不锈钢、镍钛合金等）、塑料或复合材料。在示例性实施方式中，笼 44 可由管形成，该管的一个或多个部分通过激光切割、蚀刻、机械切割等被移除以限定支杆 44a 和 / 或孔 46。可选地，笼 44 可由片形成，该片的一个或多个部分也通过激光切割、蚀刻、机械切割、冲压等被移除以限定支杆 44a 和 / 或孔 46，该片可例如通过焊接、钎焊、用粘接剂粘合、熔化等将片的边缘附接在一起以卷成管状形状。

[0050] 然后，例如通过绕着闭合端 44a 压接、粘接剂粘合、熔接、缠绕轴环、线或其它材料等，绕着轴 42 的远端 43 基本上永久地附接闭合 端 44a，从可使笼 44 附接至轴 42。因此，闭合端 43 可固定在收缩形态，而笼 44 的其余部分可自由地从收缩形态扩展至扩展形态。在示例性实施方式中，笼 44 可由超弹性材料形成，该超弹性材料可被加热处理以将扩展形态设计到笼 44 中，并且允许笼 44 被弹性压缩并保持在收缩形态。

[0051] 因此，在图 1 所示的实施方式中，笼 44 可以是自扩展结构，例如，径向向内弹性地可压缩至收缩形态，而偏移 (bias) 以向扩展形态扩展。可选地，笼 44 可例如通过剥离器装置 40 近端上连接至笼 44 的促动器（未示出）进行机械地扩展和收缩。

[0052] 为了将自扩展笼 44 维持在收缩形态，例如在被引导通过套管 20 期间或者从套管 20 被部署之前，剥离器装置 40 可包括绕着轴 42 可滑动地布置的约束管 48。约束管 48 可以是细长的管状体，包括近端（未示出）、远端 48a、以及在近端与远端 48a 之间延伸的腔 49，腔 49 被确定尺寸以接收轴 42 和处于收缩形态的笼 44。可选地，可围绕笼 44 设置其它可移动的约束件，以将笼 44 维持在收缩形态，直至期望在体腔内部署笼 44 并使其扩展，其它可移动的约束件例如为围绕笼 44 缠绕的一根或多根可移除的线、撕开的套等（未示出）。

[0053] 约束管 48 的远端 48a 可被确定尺寸以可滑动地布置在套管 20 内，例如，以容纳剥离器装置 40 被引导通过套管 20 的腔 24。约束管 48、轴 42 和笼 44 可轴向地相对彼此移动，例如，以允许笼 44 被收回到约束管 48 内和 / 或从约束管 48 被部署。因此，例如在通过套

管 20 将笼 44 引入体腔期间，约束管 48 可将笼 44 维持在收缩形态，并允许笼 44 从约束管 48 被部署，使得笼 44 呈现扩展形态。

[0054] 轴 42 和 / 或约束管 48 的近端（未示出）可延伸或以其它方式连接至套管 20 的近端，并且可从套管 20 的近端被驱动。例如，套管 20 可在其近端上包括握柄或套筒（未示出），该握柄或套筒可包括一个或多个促动器以从套管 20 的远端 22 推动剥离器装置 40，和 / 或使笼 44 从约束管 48 被部署以及用约束管 48 包覆笼 44。轴 42 和 / 或约束管 48 可延伸到握柄内，或者在轴 42 和 / 或约束管 48 与握柄上的一个或多个促动器之间可连接有一个或多个线缆、线、杆、或其它促动器元件（未 示出）。

[0055] 例如，第一促动器（例如滑动器、按钮、转盘等）可设置在握柄（未示出）上，以相对于套管 20 推动和 / 或收回整个剥离器装置 40，例如以使笼 44 从套管 20 的远端 22 被部署但仍然被约束管 48 所包覆。然后例如另一滑动器、按钮、转盘等（也未示出）的第二促动器可被激活，以例如通过相对于约束管 48 推动轴 42 和笼 44 或者在基本上不移动笼 44 的情况下收回约束管 48，从而露出笼 44。在上面通过引用并入的第 12/497,135 号申请中公开了可设置在装置 10 上的示例性握柄和 / 或促动器。

[0056] 可选地，套管 20 和剥离器装置 40 可以是结构上分离的装置，并且剥离器装置 40 可例如经由套管 20 近端的端口或其它开口被引入到套管 20 中。例如，握柄或套筒（未示出）可设置在套管 20 的近端上，握柄或套筒包括与腔 24 连通的端口（未示出），在腔 24 中可容纳剥离器装置 40 和 / 或其它装置的引入。任选地，端口可包括一个或多个密封件（例如止血密封件），在其内可容纳接收的剥离器装置 40，并且提供基本地流体密封以防止体液从腔 24 漏出。在这个可选实施方式中，剥离器装置 40 本身可包括位于其近端上的握柄或套筒（未示出），该握柄或套筒包含一个或多个促动器（也未示出）以与上文所述的促动器相似的方式相对于约束管 48 操纵轴 42 和笼。

[0057] 任选地，以类似方式，阻塞装置 30 可连接至套管 20 和 / 或剥离器装置 40，例如用装置 10 的握柄上的一个或多个促动器（未示出）来部署和 / 或撤回阻塞装置 30。可选地，阻塞装置 30 可以是与套管 20 和 / 或剥离器装置 40 分离的装置，并且剥离器装置 40 可包括用于接收阻塞装置 20 的端口，例如与上述端口相似。

[0058] 任选地，如图 4A 和图 4B 所示，约束管 48 可被配置以便于移除由笼 44 捕获的过量物质。例如，约束管 48 的远端 48a 可包括滑动或以其它方式与笼支杆 44a 相互作用的一个或多个特征，例如以当笼 44 在将阻塞性物质捕获到笼 44 内之后撤回到约束管 48 中时，切除延伸到笼孔 46 外的过量物质。因此，当笼 44 进入约束管 48 并且向收缩形态压缩时，约束管 48 的远端 48a 上的特征可削切或以其它方式切除突 出到笼孔 46 外的过量物质。

[0059] 在图 4A 中所示的示例性实施方式中，约束管 48 的远端 48a 可包括围绕与腔 49 连通的远端开口 43 延伸的锋利的边缘 47，锋利的边缘 47 适于削切可能通过笼 44 的孔 46 突出的过量的阻塞性物质。在图 4A 中所示的示例性实施方式中，锋利的边缘 47 可以是单地 (single-ground) 边缘，例如在撤回期间，锋利的边缘 47 可沿着笼 44 的外表面削切以切割或以其它方式分离通过孔 46 延伸的阻塞性物质。可选地，如图 4B 所示，约束管 48' 可被设置为包括围绕远端开口 43' 延伸的双地 (double-ground) 边缘 47'。双地锋利的边缘 47' 可以以与单地边缘 47 类似的方式切割过量的阻塞性物质，但是由于笼进入约束管 48' 的腔 49'，所以双地锋利的边缘 47' 更加抗损。例如，由于切割边缘 47' 的直径稍稍大于约束管

48' 的腔 49' 本身的直径，所以在笼 44 的撤回期间，切割边缘 47' 可以不接触笼 44 的外表面，而是与笼 44 保持微小的间隔。

[0060] 在图 5 中所示的可选实施方式中，可以省略图 4A 和图 4B 中示出的约束管 48，套管 60 可用于在笼 44 被引入期间将笼 44（未示出）约束在收缩形态和 / 或在笼 44 的撤回期间移除过量物质。与前面的实施方式类似，套管 60 包括近端（未示出）、远端 62、以及在近端与远端 62 之间延伸的腔 64。与前面的实施方式不同，套管 60 包括并入到远端 64（例如在腔 64 内）中的约束管 48"。约束管 48"可以是相对短的管状体，其在腔 64 中以短距离延伸并且包括围绕远端开口 43" 的露出且锋利的边缘 47"，例如单地或双地边缘，与前面的实施方式类似。约束管 48"可以基本上永久地附接在腔 64 内或例如通过用粘接剂粘合、干涉配合 (interference fit)、熔接、声波焊接等的其它方式连接至远端 62，从而提供从远端开口 43" 到腔 64 的过渡。

[0061] 在使用过程中，笼 44 可从腔 64 被推进并且离开远端开口 43"，于是笼 44 可自由地向扩展形态扩展。在将不期望物质捕获到笼 44 内之后（如本文的其它地方进一步描述），笼 44 可通过远端开口 43" 撤回到套管 60 中，于是当笼 44 收缩时，穿过笼 44 的孔 46 延伸的过量阻塞性物质可通过锋利的边缘 47" 被切割或以其它方式分离。

[0062] 在其它可选的实施方式中，图 1 所示的套管 20 可用于在引入和 / 或撤回期间约束笼 44，并且约束管 48 完全可以省略。与前面的实施方式不同，然而，当笼 44 撤回到套管 20 时，由于套管 20 与被引导通过套管 20 的约束管 48 相比直径相对较大，所以笼 44 可以不收缩成较小的尺寸。在这个可选的实施方式中，在笼 44 撤回到套管 20 之后，阻塞性物质的一部分可能留在笼 44 中。换句话说，剥离器装置笼 44 可用于在不切除过量阻塞性物质的情况下捕捉并移除阻塞性物质。可选地，套管 20 本身可包括锋利的远端边缘（未示出），或者锋利的末端可附接到套管 20 的远端 22（也未示出），例如以在笼 44 的撤回期间切割过量的阻塞性物质，而笼 44 内的阻塞性物质被撤回到套管 20 中笼 44 内。

[0063] 进一步参照图 1，在示出的实施方式中，剥离器装置 40 的轴 42 包括腔以可滑动地接收阻塞装置 30 的轴 32，例如，使得剥离器装置 40 和阻塞装置 30 具有同心、相对彼此伸缩的布置。可选地，如图 6 所示，可以设置装置 10'，其中，剥离器装置 40 和阻塞装置 30 被设置为相对于外套管 20 并排布置。在这个可替换的实施方式中，套管 20、阻塞装置 30 和剥离器装置 40 可以以与上述实施方式类似的方式构造。任选地，剥离器装置 40 可包括笼 44，笼 44 包括由笼 44 的支杆 44a 限定的不间断路径 45，该不间断路径 45 沿着笼 44 的至少一部分轴向地延伸，以容纳穿过笼 44 的阻塞装置 30，并且允许笼 44 基本上完全闭合到收缩形态。

[0064] 在这个实施方式中，阻塞装置 30 和剥离器装置 40 可被接纳在套管 20 的共同腔 24 中，如图 6 所示。可选地，套管 20 可包括彼此相邻布置的分离的腔（未示出），每个腔用于接收阻塞装置 30 和剥离器装置 40 中的一个。除此以外，装置 10' 的结构和操作可以与参照图 1 的装置 10 所描述的结构和操作相似。

[0065] 转到图 7 至图 10，示出了在体腔 50 内移除物质（例如血栓或其它阻塞性物质 52）的示例性方法。体腔 50 可以是例如在相邻动脉与静脉之间连通的患者胳膊内的血管、主动脉 - 静脉瘘、管状移植物、异种移植物等。可选地，本文所述的装置和方法可用于处理患者身体内 的其它位置，例如患者的脉管系统或其它体腔。虽然结合图 7 至图 10 示出并描述

了图 1 所示的装置 10，但是应该意识到的是，本文所述方法可以使用本文所述的任意装置和系统来执行。

[0066] 通常，该方法可涉及捕获扩展的阻塞部件 34 与扩展的笼 44 之间的血栓或其它阻塞性物质，例如，使得该物质可由笼 44 捕获，碎成更小颗粒，在笼 44 内被移除，和 / 或通过套管 20 从体腔 50 抽出。最初，如图 7 所示，套管 20 可例如通过常规方法从进入位置经皮引入到体腔 50 中，并且被操纵以在体腔 50 内定位套管 20 的远端 22，邻近阻塞性物质 52 并且与其间隔。任选地，如果套管 20 包括位于远端 22 上的可扩展部件，例如如图 2A 或 2B 所示的气囊 26、26'，那么在远端 22 被置于体腔 50 内的期望位置之后，可扩展部件（未示出）可以在任意时间扩展，例如以防止套管 20 的随后移动和 / 或基本上密封体腔 50 以防止流体紧邻套管 20 流过。

[0067] 附加地或可选地，例如在将套管 20 的远端 22 引入到体腔 50 中之后的任何时间，可将抽吸应用于套管 20 的腔 24。例如，注射器或真空管线可连接到套管 20 的近端，并且被激活以将基本持续的真空应用到腔 24 以将体腔 50 内的松散物质拉到腔 24 中。

[0068] 然后将阻塞装置 30 从套管 20 引入到体腔 50 中，并且使处于低轮廓结构（未示出）的阻塞部件 34 前进穿过物质 52。例如，阻塞装置 30 可被加载到套管 20 的腔 24 中并且经过套管 20 的长度进入到体腔 50 中，或者阻塞装置 30 可在手术和仅在从套管 20 被部署之前被整合到或预加载到套管 20 中。可选地，阻塞装置 30 的远末端可充分小和 / 或尖锐以自由地穿过物质 52，和 / 或可以是圆的或其它基本上无创伤的以沿着体腔 50 的壁经过物质 52。一旦阻塞部件 34 被定位在物质 52 之外的远侧，那么阻塞部件 34 被扩展到如图 7 所示的高轮廓状态。

[0069] 接下来，参照图 8，剥离器装置 40 可从套管 20 被部署，例如在阻塞装置 30 的轴 32 的上方或邻近阻塞装置 30 的轴 32。可推进剥离器装置 40 直至笼 44（在约束管 48 内维持在收缩形态）布置在物质 52 的与扩展的阻塞部件 34 相反的近侧或者与扩展的阻塞部件 34 相反地邻近物质 52。因此，阻塞性物质 52 的一侧可被阻塞部件 34 限制，并 且其另一侧被剥离器装置 40 限制。一旦笼 44 在体腔 50 内被定位，笼 44 就可在体腔 50 内扩展，例如通过使笼从约束管 48 被部署，于是笼 44 可如图 8 所示弹性径向向外扩展以接触体腔的壁。

[0070] 转向图 9，然后阻塞装置 30 可向近侧朝向笼 44 被收回，以朝向剥离器装置笼 44 拉动体腔 50 内的物质 52 并使其进入剥离器装置笼 44，如图所示。可选地，笼 44 可朝向阻塞装置 30 前进以将物质 52 捕获到笼 44 中，通过阻塞部件 34 防止物质 52 离开笼向远侧移动。如上所述，如果笼 44 包括例如如图 3 所示的倒钩 41，那么倒钩 41 可部分刺入或以其它方式与被捕获到笼 44 内的物质 52 接合，例如以防止物质 52 相对于笼 44 移动。

[0071] 任选地，阻塞装置 30 和 / 或剥离器装置 40 可包括锁定机构，例如一个或多个协作制动装置、凸片或其它特征（未示出），当阻塞装置 30 已经被放置在距笼 44 预定距离的位置处（例如如图 9 所示，基本上邻近笼 44 使得阻塞装置 30 基本上封住笼 44 内的阻塞性物质 52）时，锁定机构可基本上相对于笼 44 固定阻塞装置 30。可选地，锁定机构可设置在装置 10 的近端上，例如在握柄（未示出）上，该锁定机构可被锁定和解锁以选择性地相对于笼 44 固定阻塞装置 30。随着锁定机构的接合，阻塞装置 30 可以不被引导向远侧远离笼 44，例如使得阻塞装置 30 的随后运动与笼 44 的运动连接在一起。

[0072] 转向图 10，然后剥离器装置笼 44 和扩展的阻塞部件 34 可向近侧朝向套管 20 被引

导，例如，直至笼 44 进入约束管 48。如果在此之前没有应用真空，那么真空源可被激活以将体腔 50 内释放的物质抽吸到套管 24 的腔 24 中，如图所示。当笼 44 被拉回到约束管 48 时，笼 44 可径向向内被压缩，由此迫使物质 52 的一个或多个部分穿过笼 44 的孔 46。通过孔 46 露出的物质 52 的一个或多个部分可被削切，例如通过约束管 48 的锋利的远端边缘 47、47'（未示出，见图 4A 和图 4B）被削切，以在体腔 50 内使物质 52 碎成很多更小的颗粒 53。松散颗粒 53 可以从体腔 50 例如通过抽吸穿过套管腔 24 被移除，如图所示。注意的是，减小的颗粒尺寸可随着笼 44 中孔 46 的尺寸而变化。因此，可选择笼孔 46 的尺寸，以将物质 52 的颗粒尺寸减小至所需的最大横 截面，例如使得减小的直径的颗粒 53 可以可靠地通过套管 20 被移除，而基本上不存在堵塞套管腔 24 的风险。

[0073] 在一个实施方式中，当笼 44 撤回到约束管 48 中（在约束管 48 中笼 44 的内部空间最小）时，笼 44 可被压缩至收缩形态，从而通过笼 44 的孔 46 挤压基本上所有被捕获的物质 52。然后将挤压和 / 或削切的颗粒 53 抽吸到套管 20 的腔 24 中。可选地，笼 44 可在收缩形态中具有充足的内部空间，使得当笼 44 完全撤回到约束管 48 中时，至少一些被捕获的物质可留在笼 44 内。

[0074] 随着笼 44 完全撤回到约束管 48 中，剥离器装置 40 和阻塞装置 30 可撤回到套管 20 中，并且装置 10 从患者身体被移除。可选地，阻塞装置 30 可被收缩并且使阻塞装置 30 前进穿过体腔 50 内阻塞性物质的另一部分（未示出）。在这个可选实施方式中，然后可例如通过重复上述步骤重新部署剥离器装置 40 以捕获并移除物质。可选地，如果需要，整个装置 10 可被引入到另一体腔（未示出）内，并且阻塞装置 30 和剥离器装置 40 被重新部署以捕获和 / 或移除患者身体的其它区域中的阻塞性物质。

[0075] 一旦足够的物质已经被移除，那么阻塞装置 30 的阻塞部件 34 可被收缩，并且阻塞装置 30 可撤回到剥离器装置 40 中，或者如果剥离器装置 40 已经撤回到套管 20 中，那么阻塞装置 30 可撤回到套管 20 中。套管 20 内的抽吸可以是不连续的，套管 20 上的可扩展部件可被收缩（如果设置在套管 20 上），并且套管 20 可从体腔 50 撤出。

[0076] 转向图 11A 至图 13，示出了剥离器笼 144 的另一实施方式，其可包括在本文所描述的任意装置和 / 或系统中。通常，剥离器笼 144 包括闭合的近端或第一端 144a 和开放的远端或第二端 144b，与前面的笼 44 相似。笼 144 可包括在第一端 144a 与第二端 144b 之间和 / 或绕着笼 144 的外周延伸的多个支杆 116、118，由此限定了包括多个孔 146 的圆筒形外壁或其它管状外壁，与前面的笼 44 相似。

[0077] 笼 144 的闭合端 144a 可包括轴环 (collar) 部分 141，其可附接至剥离器装置轴 42（未示出，见例如图 1），而笼 144 开放的远端 143 可包括多个向远侧伸出的元件或远末端 112。例如，图 11A 示出了处 于扩展形态的笼 144，其中，例如由于轴环部分 141 附接至轴（未示出）所以轴环部分 141 保持被压缩，并且笼 144 限定了从闭合端 144a 向开放端 144b 延伸的基本上连续的直径。图 11B 示出了处于压缩形态的笼 144，例如其中，笼 144 可被约束或以其它方式压缩在轴的周围和 / 或在约束管（也未示出）内。

[0078] 与图 1 的笼 44 不同，如在图 12A 和图 12B 中最佳见到的，笼 144 包括至少两种不同类型的支杆 116，118。例如，笼 144 可包括多个较厚的支杆 116，其沿着笼 144 的长度基本连续地延伸，例如在第一端 144a 与第二端 144b 之间的第一螺旋结构中。此外，笼 144 可包括多个较薄的支杆 118，其可与相邻的厚支杆 116 连接在一起。如图所示，与厚支杆 116

不同，薄支杆 118 不是基本连续的，而是可以不连续模式螺旋地和 / 或圆周地围绕笼 44 延伸。任选地，薄支杆 118 还可具有弯曲或其它特征，例如相对变薄或穿孔的部分，这允许薄支杆 118 与厚支杆 116 相比相对容易弯曲。孔 146 可由厚支杆 116 与薄支杆 118 之间的间隔限定，从而限定了笼 144 所需的孔隙尺寸。可通过与前面所述的材料和方法相似的材料和方法来形成笼 144。

[0079] 笼 144 的开放端 144b 上的远末端 112 可以为笼 144 提供基本无损伤的远端，例如以防止刺穿其内部署有笼 144 的体腔的壁或对其造成其它伤害。附加地或可选地，远末端 112 可以足够的柔韧以允许远末端 112 在使用过程中螺旋地扭转和 / 或彼此互锁。图 15A 至图 15C 示出了远末端的可选结构，可在笼 144 上设置远末端，例如以便于与体腔内的阻塞性物质接合和 / 或移除体腔内的阻塞性物质。例如，图 15A 示出了远末端 112a 的示例性实施方式，远末端 112a 包括具有平滑前缘 125 的基本直的结构。

[0080] 可选地，图 15B 示出了远末端 112b 的另一示例性实施方式，远末端 112b 包括沿着远末端 112b 的长度间隔分布的一系列槽或凹口 126，例如其可允许远末端 112b 互相缠绕和 / 或与捕获的或通过远末端 112b 以其它方式接合的阻塞性物质缠绕，以便于移除，如下面参照图 16A 至 16H 的进一步描述。例如，当笼 144 旋转时，远末端 112b 和阻塞性物质可缠绕在一起，例如使得其它远末端 112b 和 / 或阻塞性物 质的一个或多个部分可进入槽 126，并且远末端 112b 彼此互锁。图 15C 示出了远末端 112c 的又一示例性实施方式，远末端 112c 包括蜿蜒的样式 (pattern)127。在这个实施方式中，蜿蜒的样式 127 的内弯部 128 可提供使远末端 112c 和 / 或阻塞性物质可缠绕在一起的多个区域，例如与图 15A 的远末端 112a 中所示的提供平滑边缘 125 相比。

[0081] 图 11A 至图 13 中所示的笼 144 的一个优势是，笼 144 可便于部署笼 144 和 / 或使笼 144 前进进入或穿过体腔内的阻塞性物质。与此相反，图 1 中所示的笼 44 一旦在体腔内被部署则通常保持静止，例如，而阻塞装置 40 被收回以将阻塞性物质收到笼 44 中。例如，图 11A 至图 13 的笼 144 可便于将物质 52 拉到笼 144 的开放端 144a 内和 / 或使阻塞性物质与体腔 50 的壁分离。

[0082] 在向远侧前进过程中，笼 144 可例如通过手动或通过连接到装置 10 的握柄（未示出）中的电动机的驱动轴（见例如图 1）同时前进和旋转。这可导致在笼 144 前进时，笼 144 的远末端 112 沿着体腔 50 的内壁例如以螺旋方式行进。当遇到血栓或其它阻塞性物质时，远末端 112 可在物质 52 与体腔 50 的壁之间穿过，从而将物质 50 定位在笼 144 内。

[0083] 笼 144 的远末端 112 可便于分离物质和 / 或将物质捕获到笼 144 内。例如远末端 112 的边缘可提供这样的笼 144 的远侧前缘，即其不是基本光滑的圆柱体，而是限定了起伏的表面。因此，当笼 144 旋转时，笼 144 的远末端 112 可通过重复与物质 52 接触而起到锯的作用，这可增加物质 52 从体腔 50 的壁脱落和 / 或被捕获到笼 144 内的机会。为了进一步确保笼 144 的前缘在不期望物质与体腔 50 的壁之间穿过，远末端 112 和 / 或支杆 116、118 的边缘还可起到沿着体腔 50 的壁削切的刀片的作用以将附着的物质拉到笼 144 中。因此，支杆 116、118 可切割或以其它方式分离体腔 50 与阻塞性物质 52 之间的界面。

[0084] 远末端 112 可被形成使得它们基本符合笼 144 的圆柱形形状，例如虽然可选地远末端 112 可径向向外偏移，但是限定了与扩展的笼 144 的其余部分类似的直径，例如以确保远末端 112 在体腔 50 的壁与阻塞性物质 52 之间穿过和 / 或加强远末端 112 与体腔 50 的

壁的接合。可选 地，远末端 112 可偏移以径向向内延伸，例如相对于装置 10 的中心纵轴横向地向内延伸，例如以防止伤害体腔 50 壁的高风险。

[0085] 此外，支杆 116、118 的不同厚度和 / 或形状可提供这样的笼 144，根据笼 40 的旋转方向，笼 144 以不同方式响应。例如，图 13 中的箭头“A”表示笼 144 旋转的第一方向。如果在这个旋转期间笼 144 与体腔 50 壁（未示出）接触的部分中遇到阻力，那么可能发生扭曲。由于厚支杆 116 具有较高的抗弯曲性而薄支杆 118 容易弯曲，所以扭曲可能不会折弯厚支杆 116，但是可能导致薄支杆 118 弯曲成以在相邻的支杆 116、118 之间限定更大的角度，并且使笼 144 径向向外扩展。这可增加剥离器笼 144（例如，厚支杆 116 的前缘）与体腔 50 的壁之间的接触力，从而可增加从体腔 50 的壁移除阻塞性物质并且将阻塞性物质捕获到笼 144 内的机会。可选地，厚支杆 116 的前缘可包括锋利的边缘或其它特征，这可增强切割或与体腔 50 内附着的物质的其它接合。

[0086] 如果笼 144 在与“A”相反的第二方向旋转，那么由于薄支杆 118 的低断裂强度，扭曲可能导致薄支杆 118 弯曲以减小相邻的支杆 116、118 之间的角度，并且笼 144 可能不会以与第一方向类似的方式径向向外扩展。关于旋转方向的这种各向异性可能是有用的，因为笼 144 可在“A”方向前进和旋转以与阻塞性物质接合并使附着的阻塞性物质与血管壁分离，例如，使物质进入笼 144。扭曲还可引起笼 144 向外扩展以更好地附着或接合血管壁。如果笼 144 遇到过多的阻力，那么笼 144 可沿第二方向旋转，例如以释放阻力而不引起径向扩展。根据薄支杆 118 与厚支杆 116 之间的刚度差，笼 144 在第二方向的旋转还可引起笼 144 径向地收缩以进一步便于释放。

[0087] 转向图 14A 至图 14C，示出了可扩展笼 144 的又一个实施方式，其可包括选择性地打开和 / 或闭合笼 144 的开放远端 143 的促动机构。例如，通过例如使用连接至每个远末端 112 的控制元件（例如，一个或多个线或细丝 114）径向向内收缩远末端 112，可基本上闭合笼 144 的开放远端 143。可选地，单一控制元件（未示出）可穿过每个远末端 112，例如圆周地且连续地穿过多个远末端中的孔（未示出），使得 控制元件上的向近侧的拉力可使远末端 122 折弯或以其它方式径向向内引导远末端 122。任选地，如果需要，可提供锁定机构（未示出）以将远末端 122 固定在闭合的方向。可选地，远末端 122 可彼此互锁，例如如上所述，以将远末端 122 固定在闭合的方向。

[0088] 图 14A 示出了远端 143 开放，笼 144 处于扩展形态，例如控制元件 114 松驰并且远末端 112 偏移至基本上轴向开放的结构。图 14B 示出了远末端 112 弯曲或以其它方式向内朝向闭合形态被引导，例如在向近侧的拉力被施加到控制元件 114 之后。远末端 112 的结构通过提供例如变薄的支杆宽度、变薄的支杆厚度、穿孔部分等（未示出）的一个或多个优选的弯曲特征可有助于这种弯曲，以提供远末端 112 的铰接区域。在可选实施方式中，如图 14C 所示，管状部件 113 可在控制元件 114 上前进以引起远末端 112 径向向内弯曲。

[0089] 图 14B 和图 14C 中所示的闭合结构可允许被捕获到笼 144 内的阻塞性物质被基本上保留在其内，例如，不需要本文其它地方所述的可扩展的阻塞部件 34。在这些可选实施方式中，笼 144 可简单地撤回到约束管或者进入套管（未示出）中，从而径向向内压缩笼 144。当笼被压缩（例如如上所述被抽吸）时，随着远末端 112 的闭合，所捕获的物质不会简单地从笼 144 的远端 143 逃脱，而是保留在笼 144 内通过孔 146 突出（在图 14B 和 14C 中未示出）。可选地，所捕获的物质可以也如上所述随着笼 144 撤回到约束管或套管中。

[0090] 转向图 16A 至图 16H，示出了另一示例性方法，例如通过图 11A 至图 13 所示的笼 144 从血管或其它体腔 150 内移除阻塞性物质。与前述实施方式相似，可经由进入套管和 / 或约束管 148 将笼 144 引入体腔 150。如图 16A 所示，笼 144 已经在体腔 150 内被部署和扩展，使得开放的远端 143 邻近待移除的阻塞性物质 152 布置。一旦笼 144 完全扩展，笼 144 就可在体腔内朝向阻塞性物质 152 前进和旋转。

[0091] 转向图 16B，笼 144 的远端 143 可与物质 152 接合，例如使得远末端 112 在一定程度上在物质 152 与体腔 152 的壁之间穿过，但是当它们与物质 152 缠绕在一起时还可以自由变形。任选地，在笼 144 前进之前，阻塞装置（未示出）可被引导通过物质 152 并且阻塞部件在 物质 152 之外扩展。因此，在笼 144 前进时，阻塞部件可防止物质 152 远离笼 144 向远侧移动。

[0092] 另外参照图 16C，当笼 144 进一步旋转时，远末端 112 可至少部分地绕着物质 152 缠绕或者绕着彼此缠绕，由此在笼 144 与物质 152 之间产生机械接合。然后可将笼 144 的进一步旋转传递至物质 152，这样可引起物质 152 扭转和 / 或以其它方式脱离体腔 150 的壁。在缠绕和进一步旋转之后，被缠绕的物质 152 可完全从体腔 150 的壁移除，如图 16D 所示。

[0093] 如图 16E 所示，与前述实施方式类似，然后可将笼 144 撤回到进入套管和 / 或约束管 148，从而将笼 144 径向向内地压缩至收缩形态。由于笼 144 的远末端 112 基本上是直的并且在它们的远端上是自由的（即，笼 144 在其远端上是开放端并且未附接至芯线），所以当笼 144 撤回到进入套管 20 时，远末端 112 可松开并且物质 152 被释放。因此，如图所示，分离的物质 152 可在体腔 50 内保持松驰。

[0094] 此后，如图 16F 所示，笼 144 可从约束管 148 或套管被重新部署，并且再次通过邻近松散物质 152 布置的开放端 143 扩展。然后例如通过阻塞装置 134 将物质 152 拉入笼 144 的开放端 143，阻塞装置 134 可以是之前在物质 152 之外部署的相同装置，或者是在重新部署笼 144 之前或之后被引入到体腔 150 中且位于物质 152 之外的不同装置。

[0095] 参照图 16G，然后将其内具有捕获的物质 152 的笼 144 撤回到套管 20 或约束管（未示出）中，与前面的实施方式类似。如本文其它地方所讨论的，当笼 144 被压缩时，通过笼 144 的孔 146 突出的任何物质都可被削切或以其它方式分离，例如以确保笼 144 不会在套管 20 的末端被卡住。如图 16H 所示，笼 144 可完全撤回到套管 20 中，并且物质 152 的任何剩余松散颗粒可通过套管腔被抽吸，与前面的实施方式类似。例如，如上所述，可通过套管 20 随时将真空应用到体腔 150 内以抽吸体腔 150 内的松散颗粒，例如当笼 144 使物质与体腔 150 的壁分离时或者在其之后被释放的。这些步骤中的任意步骤都可根据需要重复多次，以移除任何剩余物质。

[0096] 应理解，对于具体实施方式来说，文中的任何实施方式所示的元 件或部件都是示例性的，并且可用于或结合至文中所公开的其它实施方式。

[0097] 虽然本发明可以进行各种修改、和替换形式，但其具体实施例已在附图中示出并在文中详细描述。然而，应理解，本发明并不限制于所公开的具体形式或方法，相反，本发明包括落入所附权利要求范围内的所有修改、等同和替代。

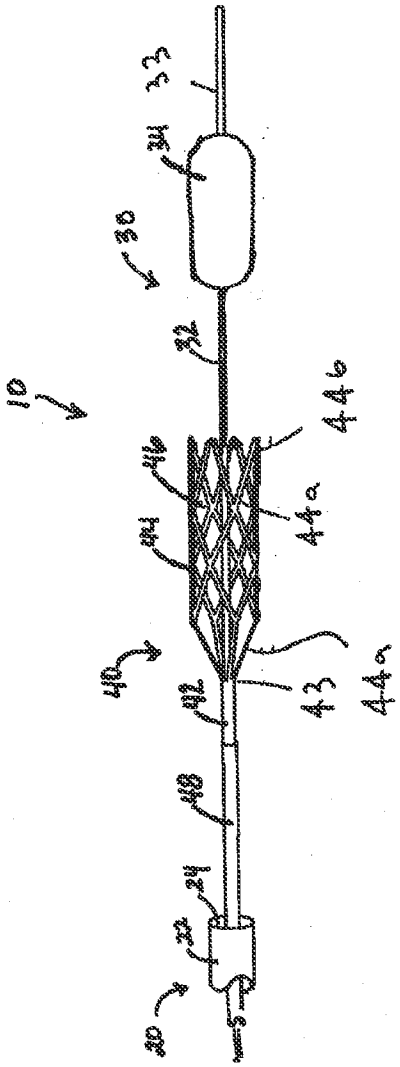

10
32
34
30
22
46
46a
46b
44
44a
40
42
43
44c
48
24
22
20

图 1

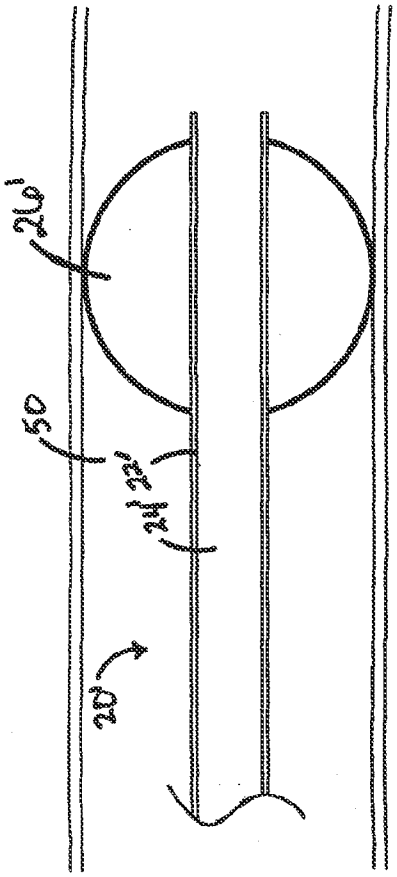

210'
50
24'
22'
20'

图 2A

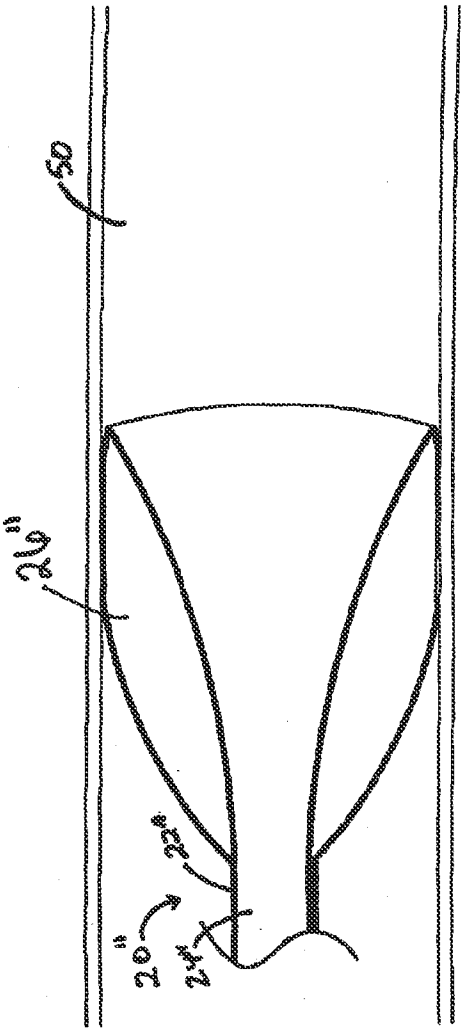


图 2B

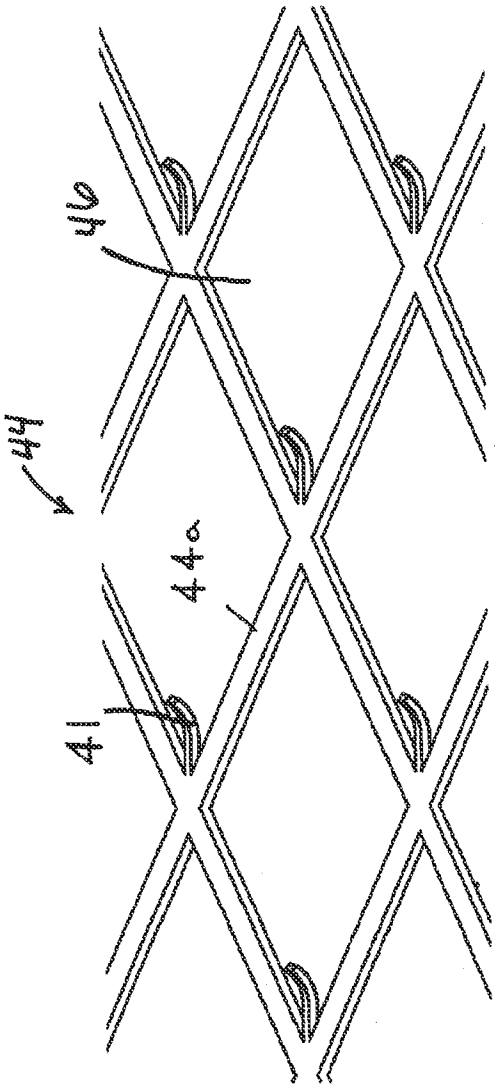


图 3

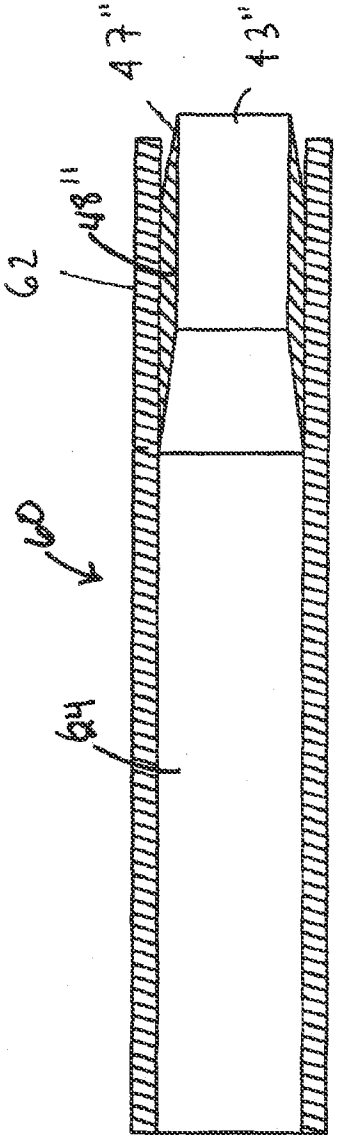


图 5

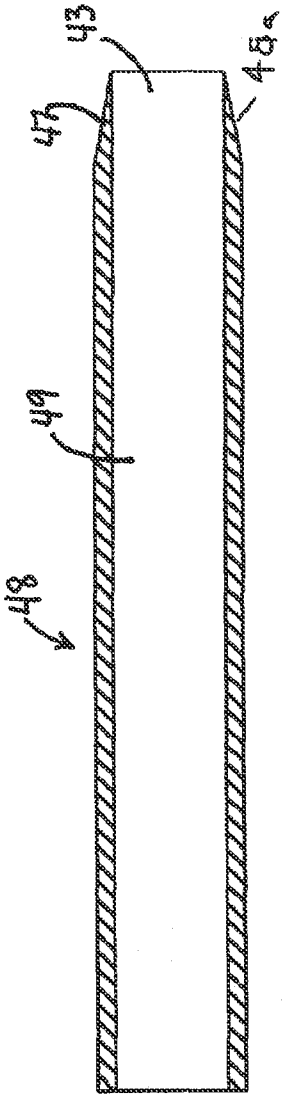


图 4A

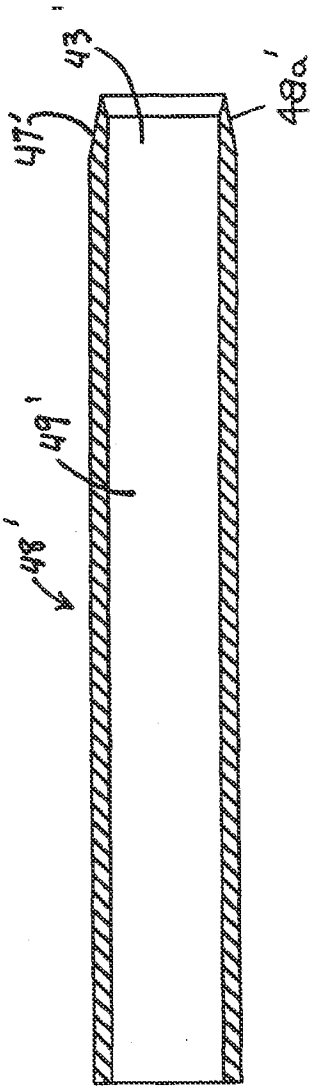


图 4B

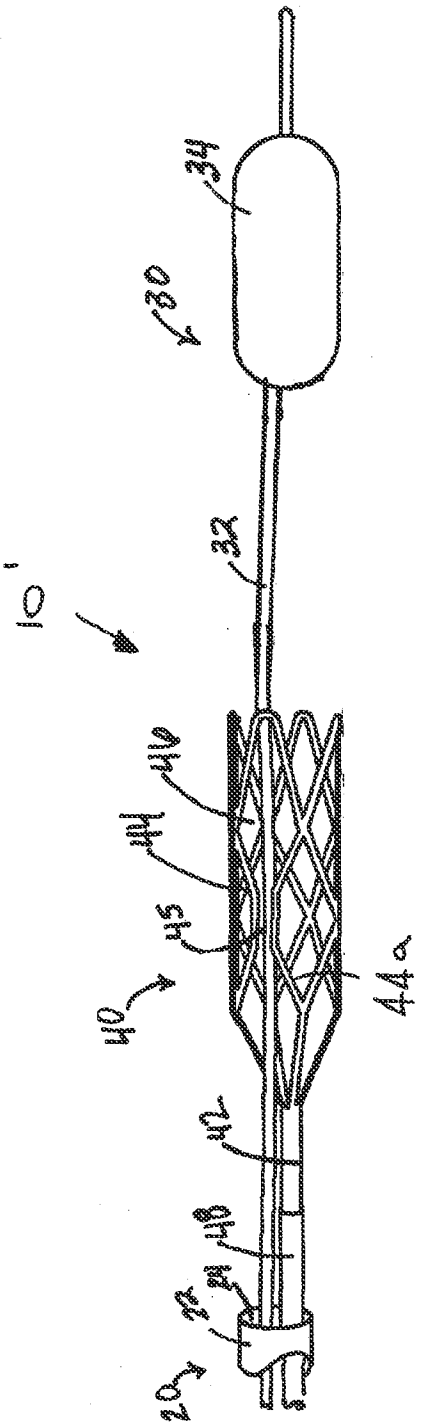


图 6

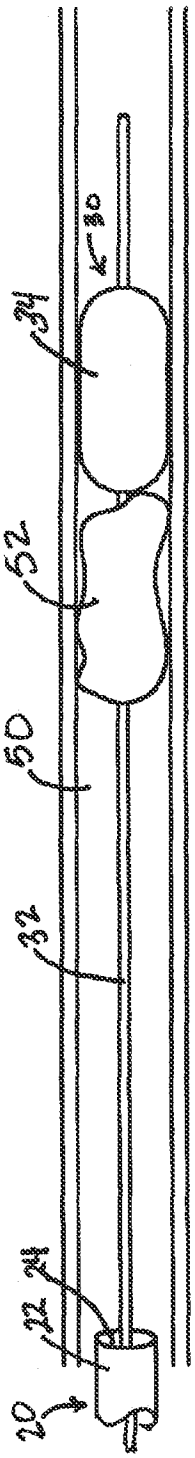


图 7

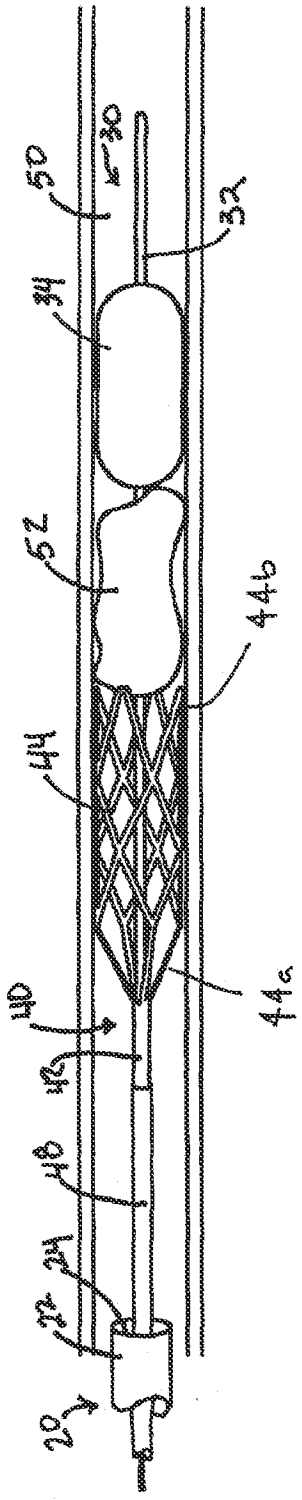

50
30
32
34
52
44b
44
44c
40
42
46
24
22
20

图 8

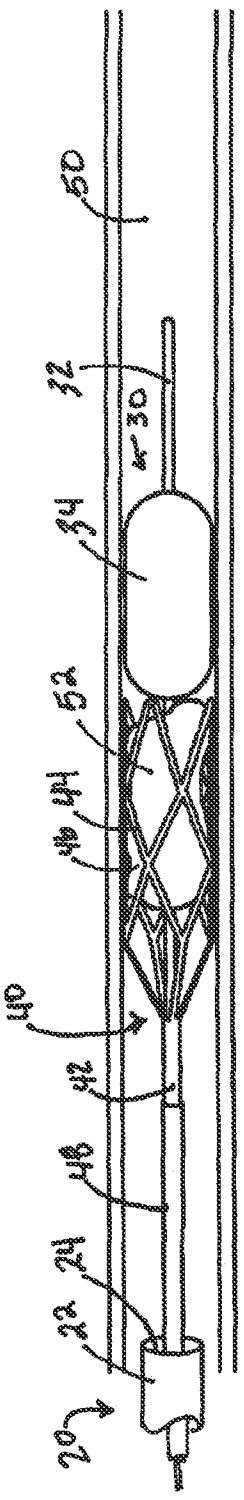

50
12
30
34
52
44
40
42
46
24
22
20

图 9

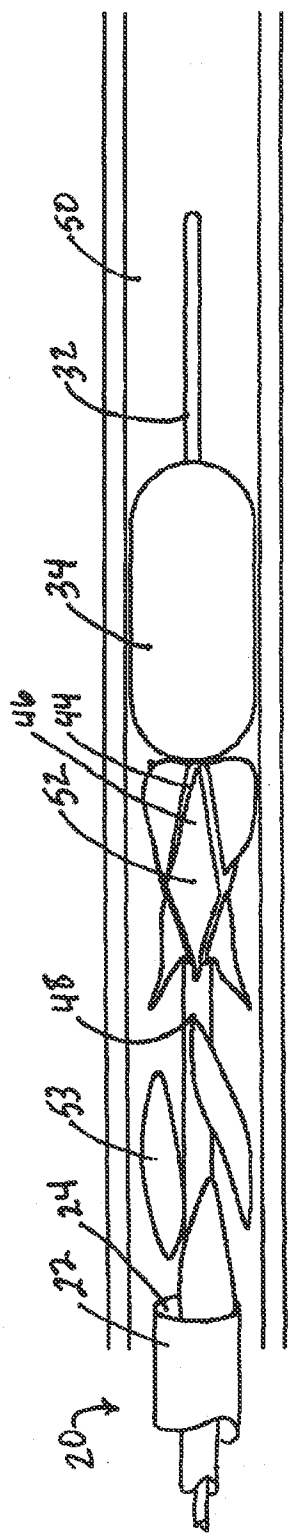

50
32
34
46b
44
52
46
53
24
22
20

图 10

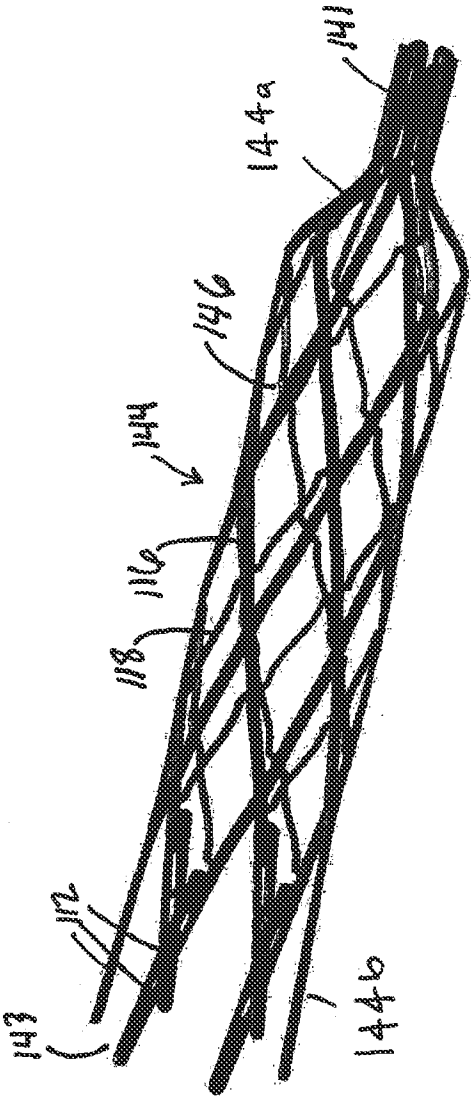

141
144a
146
144
116
118
112
143
144b

图 11A

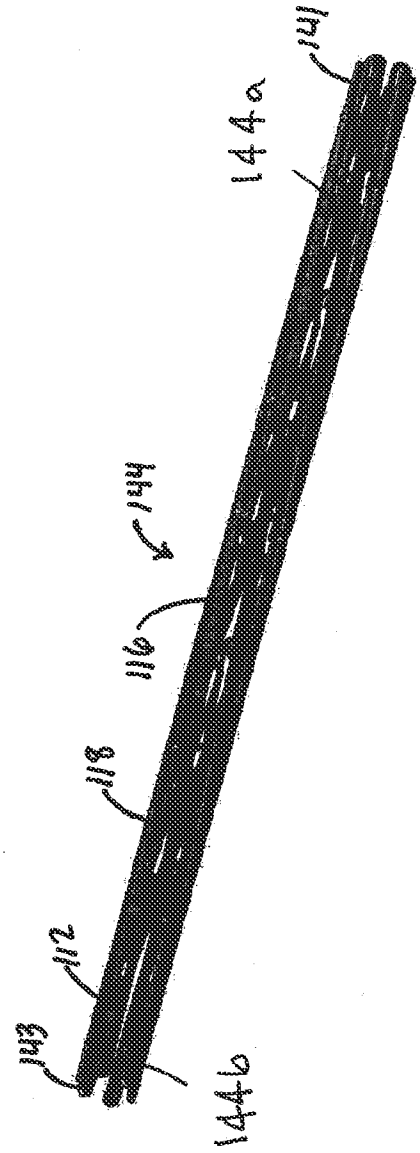

141
144a
144
116
118
112
143
144b

图 11B

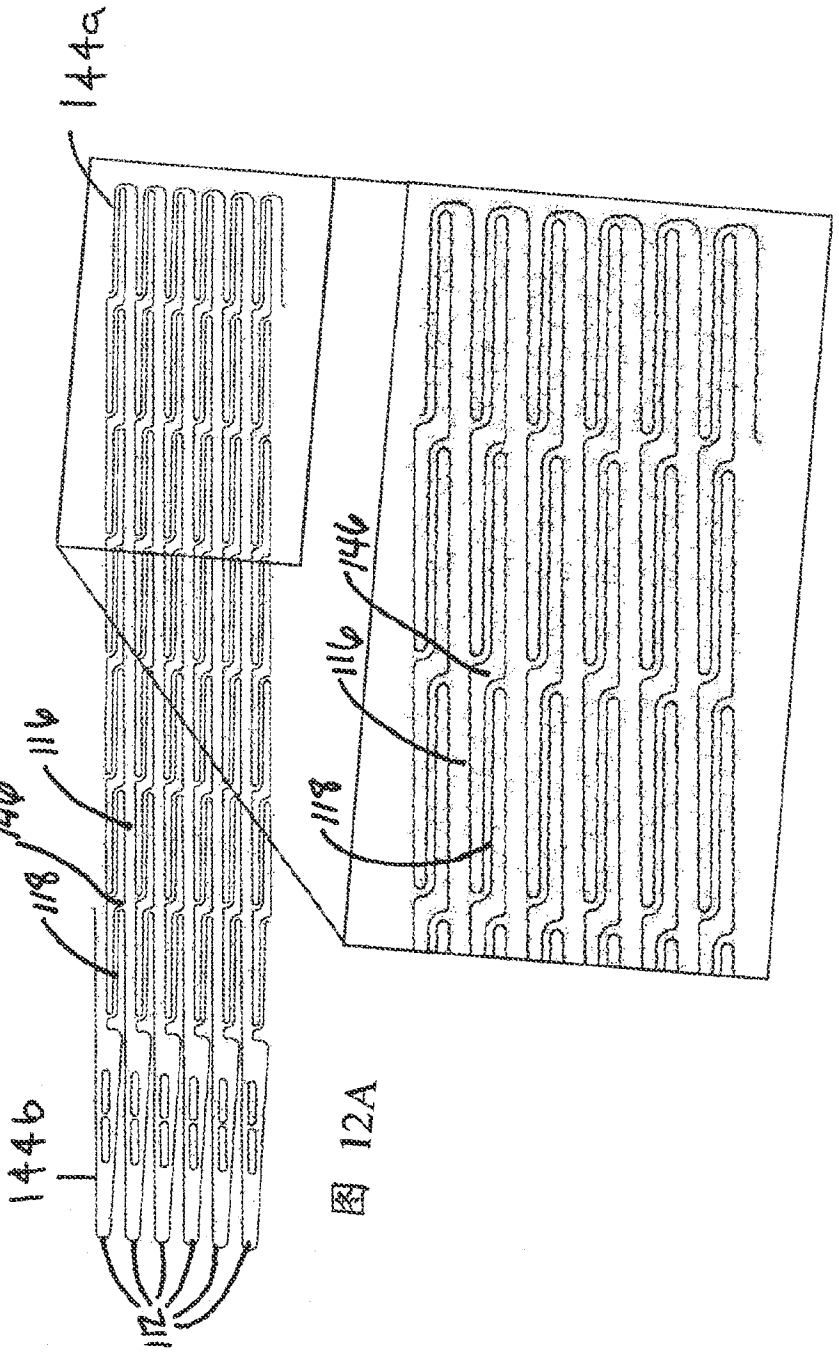


图 12A

图 12B

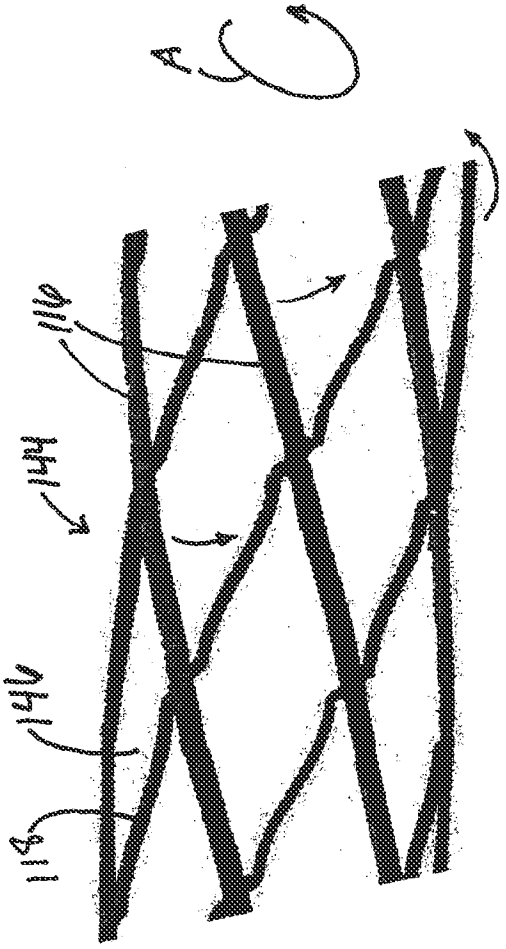


图 13

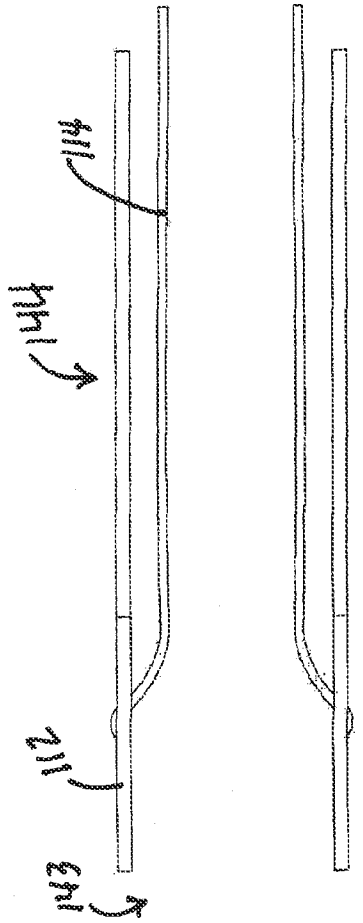


图 14A

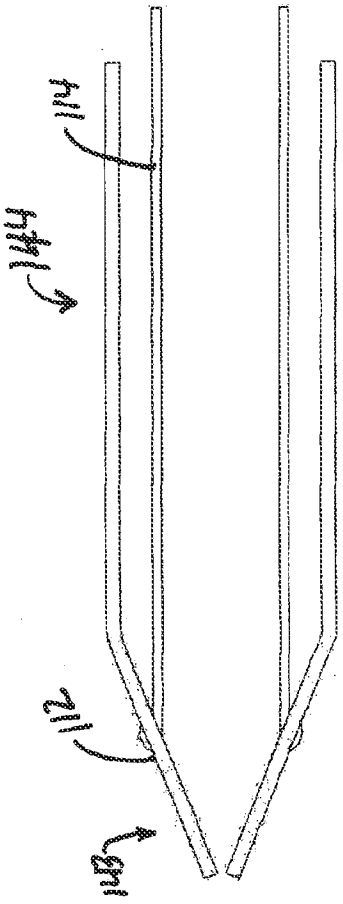


图 14B

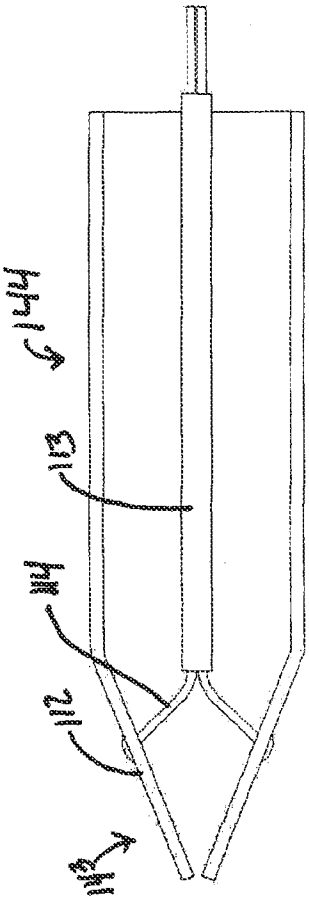


图 14C

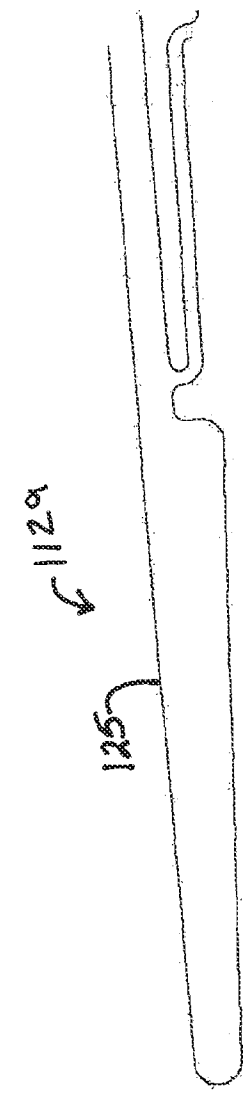


图 15A

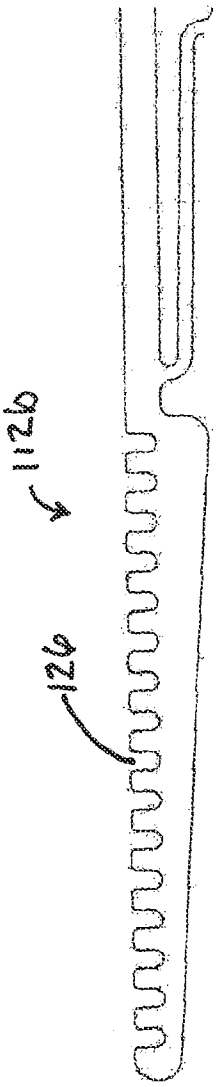


图 15B

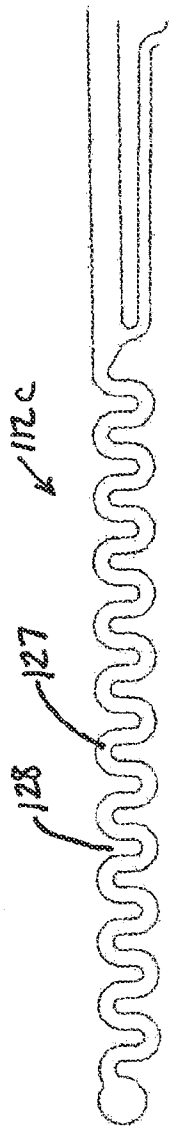


图 15C

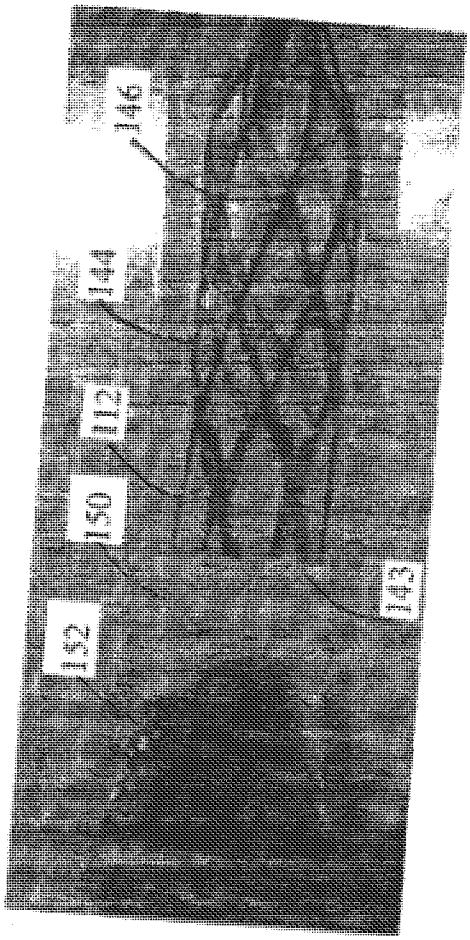


图 16A

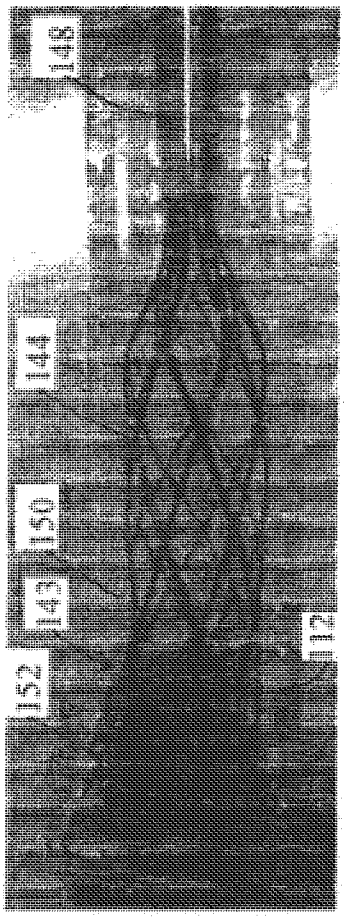


图 16B

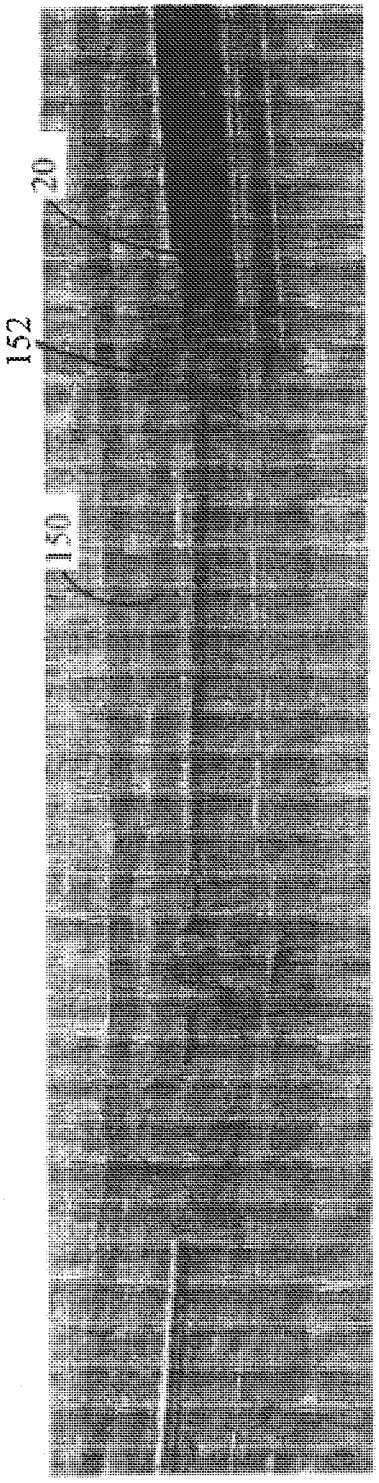


图 16E

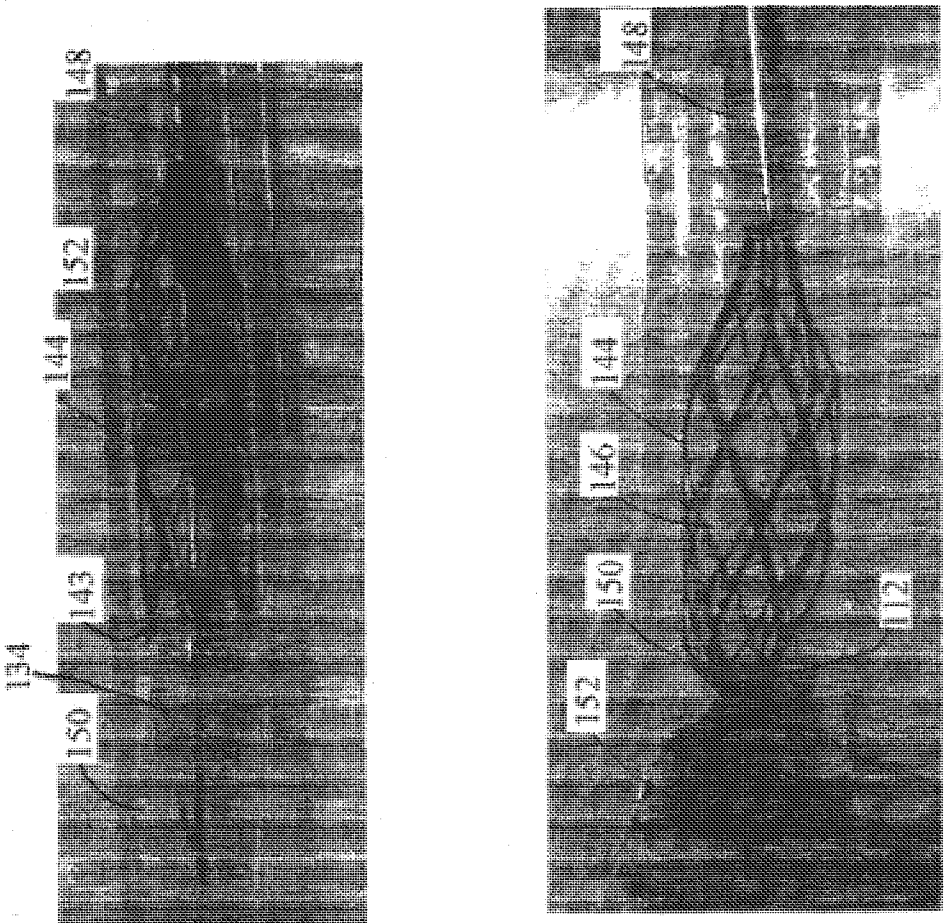


图 16C

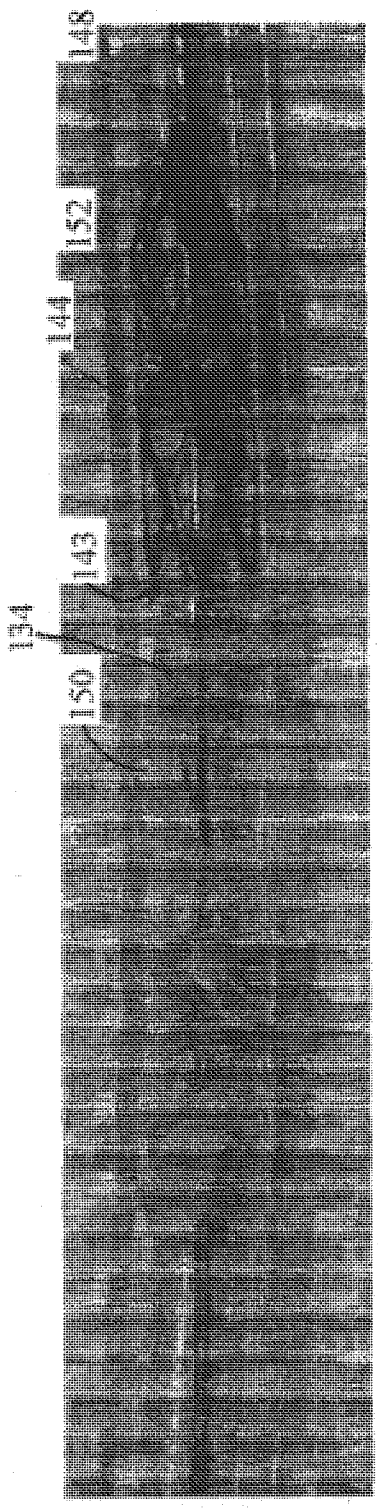


图 16F

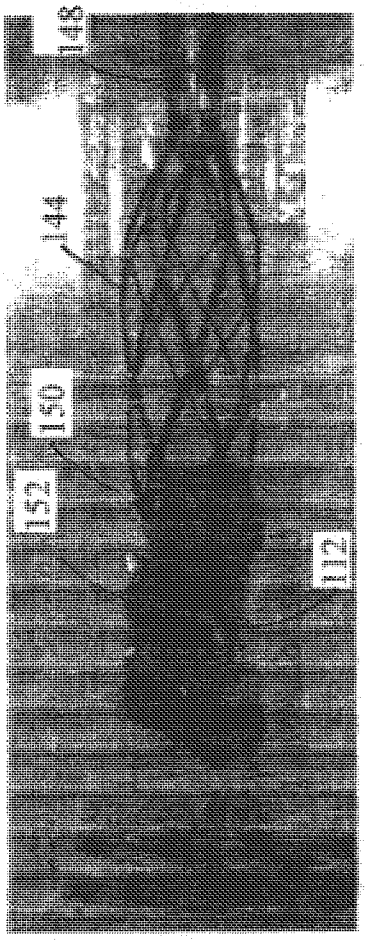


图 16D

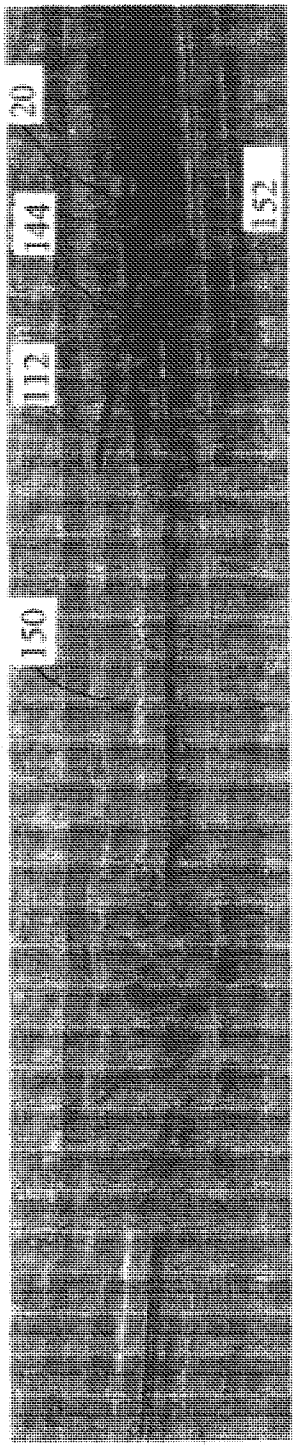


图 16G

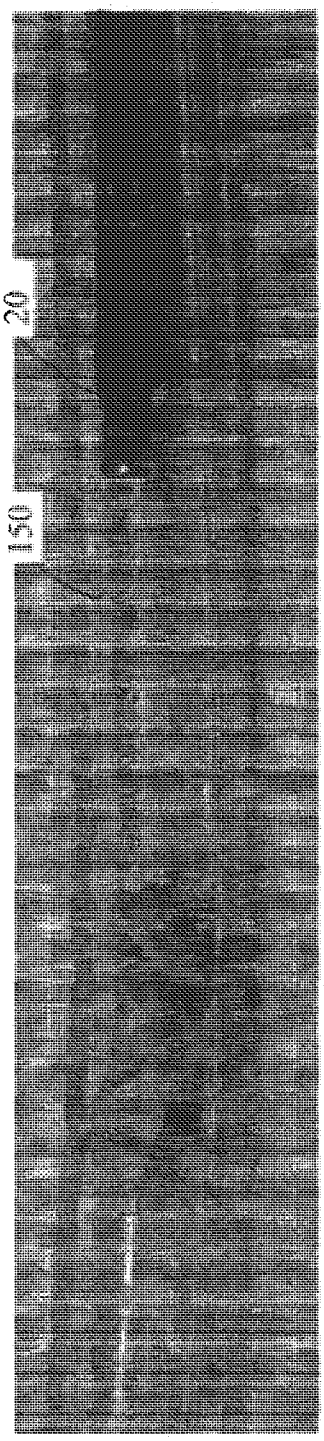


图 16H

Patent Translate
Powered by EPO and Google

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.

DESCRIPTION CN110652845A

Multilayer catheter main body and its catheter assembly

[0001]

Technical field

[0002]

The present invention mainly relates to a multi-layer catheter body and its catheter assembly for guiding, operating or distally supporting for neurovascular applications.

In particular, the catheter body provides excellent distal flexibility and proximal stability for tracking inside the neurovascular, as well as excellent external and internal smoothness for implant delivery.

[0003]

Background technique

[0004]

Almost every neurovascular device placement or treatment occurs on or above the neck.

Therefore, catheters used in the neurovascular system must be able to traverse tortuous blood vessels.

When designing catheters for neurovascular applications, engineers must strike a balance between functionality and structure, with the basic goals of tracking, flexibility, pushability, and torque (transmittance or torsion) of the catheter.

[0005]

PTFE material has excellent wear resistance and high smoothness, and is an ideal choice for the inner wall of the catheter.

When the medical device is pushed through the tight catheter lumen, the smooth lumen surface of the PTFE inner layer reduces the friction between the medical device and the catheter. Dip coating and extrusion are two common methods for manufacturing PTFE liners. The conversion plating method is a method to obtain a polytetrafluoroethylene lining. This process can be performed on the mandrel as part of the catheter body construction process. Once the coating is cured, additional components of the catheter, such as nylon sheath, braided tubing, are built on the cured dip coating mandrel. Although the dip coating process seems to be a simple process from the beginning, it has some limitations. The dip coating may have an uneven surface that resembles orange peel. Sometimes there are many cross-section lines on the surface of the dip coating, which is called flutter, which is caused by the vibration during the dip coating process. The surface of the dip coating may also have pits, depressions, or even holes in the cured layer, which are caused by contaminants (including moisture) during the dip coating process. These defects will negatively affect the smoothness of the catheter lumen and seriously affect the use of the catheter. Although these defects can be solved in different ways, the high precision of the dip coating process usually brings greater cost and time.

[0006]

Extrusion of PTFE tubing is another way to make the inner layer of PTFE tubing.

Although extruded PTFE has the lowest coefficient of friction, a typical extruded PTFE tube has a wall thickness of about 0.001". This wall thickness may result in an increase in the overall rigidity of the catheter, which is not an ideal method to pass through tortuous passages in the nerves and blood vessels.

[0007]

The ideal neurovascular catheter should have the smallest outer diameter to transport medical devices/implants through small blood vessels and the largest inner diameter

This eventually leads to the need for the inner layer of ultra-thin catheters. However, with the ultra-thin inner layer of the catheter, engineers need to incorporate the catheter body supporting components, such as the metal wire layer covering the inner layer of the catheter, the braided mesh layer or the coil layer, to enhance the pushability and bending resistance of the catheter. In order to maintain the integrity of the catheter structure, a minimum contact pressure is required between the wire layer and the inner layer of the catheter. Generally, such a minimum contraction pressure will increase the roughness of the inner surface of the inner layer of the catheter and significantly reduce the smoothness of the inner surface.

[0008]

Therefore, it is necessary to develop a new catheter for neurovascular to meet the high standards of pushability, trackability, flexibility and torsion speed, and a large cavity is needed to achieve maximum extraction. Section flow, smaller outer diameter allows the catheter to penetrate into smaller blood vessels without causing additional vascular damage to the target treatment site; smooth outer surface, and extremely high inner surface smoothness to reduce fibrin.

[0009]

Summary of the invention

[0010]

The purpose of the present invention is to provide a multi-layer catheter body and catheter assembly for the delivery and placement of medical equipment.

The invention can meet the goals of high standards of pushability, trackability, flexibility and bendability, and at the same time has a large cavity to achieve the maximum suction flow; a smaller outer diameter enables the catheter to go deeper in the blood vessel, it will not cause additional blood vessel damage to the target treatment location; the outer surface is smooth; at the same time, it has a very high inner surface smoothness.

[0011]

In the first aspect of the present invention, a multilayer catheter body is provided. The catheter body is used to deliver and place medical devices. The catheter body includes an inner layer, a first intermediate layer, and a second intermediate layer in order from the inside to the outside. And the outer layer, the inner layer is a thin-walled tube, and the tube lumen of the inner layer has a smooth wall surface, the first middle layer is a coil layer, and the first middle layer is wound by flat wire; The ratio of the width to the thickness of the flat wire is at least 2:1, the second middle layer is a braided layer, and the second middle layer is braided by metal wires, the hardness of the distal end of the outer layer is less than that of the outer layer. The hardness of the proximal end of the outer layer; the outer layer is bonded to the inner layer through the wire gap between the first intermediate layer and the second intermediate layer.

[0012]

In another preferred embodiment, the outer layer is composed of multiple materials, wherein a material with soft hardness is used as the distal end of the outer layer, a material with medium hardness is used as the middle section of the outer layer, and a material with hard hardness is used as the proximal part of the outer layer.

[0013]

In another preferred embodiment, the ratio of the outer diameter of the inner layer of the catheter body to its wall thickness is at least 10:1.

[0014]

In another preferred embodiment, the smallest inner diameter of the inner layer of the catheter body is 0.6 mm.

[0015]

In another preferred embodiment, the maximum thickness of the flat wire of the first intermediate layer is 0.30 mm.

[0016]

In another preferred embodiment, the minimum width of the flat wire of the first intermediate layer is 0.08 mm.

[0017]

In another preferred embodiment, the first intermediate layer covers at least 30% of the outer surface of the inner layer.

[0018]

In another preferred embodiment, the maximum thickness of the second intermediate layer is 0.035 mm.

[0019]

In another preferred embodiment, the wall thickness of the catheter body is at least 0.03 mm.

[0020]

In another preferred example, the wall thickness of the catheter body is 0.03-0.3mm, preferably, 0.05-0.2mm, more preferably, 0.07-0.15mm.

[0021]

In another preferred embodiment, the inner layer and the outer layer have the same length.

[0022]

In another preferred embodiment, the first intermediate layer is formed by winding at least two wires in the same direction.

[0023]

In another preferred embodiment, the first intermediate layer is formed by winding at least two wires in opposite directions.

[0024]

In another preferred embodiment, the second intermediate layer covers at least the proximal end and the intermediate section of the first intermediate layer.

[0025]

In a second aspect of the present invention, a catheter assembly is provided. The catheter assembly includes the above-mentioned multilayer catheter body and a catheter proximal end control mechanism. The catheter proximal end control mechanism is used to control the advancement, retreat, and Reverse.

In addition, the catheter proximal control mechanism can be used for the introduction and connection of other medical devices. For example, other channels can be opened for placing guide wires or micro catheters or implant delivery devices and other delivery devices, and can also be used with pressure extension tubes etc. The connection is made, and the thrombus and other suction are carried out under the action of external suction.

[0026]

In another preferred embodiment, the second intermediate layer is at least 20 mm shorter than the first intermediate layer.

[0027]

In another preferred embodiment, the first intermediate layer and the second intermediate layer are sandwiched between the inner layer and the outer layer.

[0028]

In another preferred embodiment, the second intermediate layer is located between the first intermediate layer and the outer layer.

[0029]

In another preferred embodiment, the ratio of the outer diameter to the inner diameter of the catheter body is at least 1.2:1.

[0030]

It should be understood that within the scope of the present invention, the above-mentioned technical features of the present invention and the technical features specifically described in the following (such as the embodiments) can be combined with each other to form a new or preferred technical solution.

Due to space limitations, I will not repeat them one by one here.

[0031]

Description of the drawings

[0032]

In order to explain the embodiments of the present invention or the technical solutions in the prior art more clearly, the following will briefly introduce the drawings that need to be used in the description of the embodiments or the prior art. Obviously, the drawings in the following description are only These are some embodiments of the present invention. For those of ordinary skill in the art, other drawings can be obtained based on these drawings without creative work.

[0033]

Figure 1A is a front view of a catheter assembly with a catheter body and a catheter proximal control mechanism according to an embodiment of the present invention.

[0034]

Fig. 1B is a perspective view of a main structure of a multilayer catheter according to an embodiment of the present invention.

[0053]

131, 231-Materials coil.

[0054]

detailed description

[0055]

After extensive and in-depth research and extensive screening, the inventor developed a multilayer catheter body and catheter assembly for the delivery and placement of medical equipment for the first time. Compared with the prior art, the catheter body of the present invention has Good torque and torsion resistance (anti-winding) characteristics, with a flexible distal part that can reach the predetermined treatment position, and provide treatment without damaging the surrounding blood vessels, and in the smallest possible outer contour and as large as possible A delicate balance is maintained between the lumens to facilitate the delivery of medical implants and move in the lumens of other catheters to attract and occlude occluded blood vessels. In addition, the body of the catheter can be visible under X-ray fluoroscopy, which is convenient for the operator. Based on observations, the present invention has been completed.

[0056]

the term

[0057]

As used herein, the term "lumen" refers to pipes, delivery tubes, or general tubular spaces or cavities in the body, including veins, arteries, blood vessels, capillaries, intestines, and the like.

The term "lumen" can also refer to a tubular space in a tube, sheath, hollow needle, tube, or the like.

[0058]

As used herein, the term "proximal" refers to being close to the operator (less entry into the human body), and "distal" refers to being away from the operator (further into the human body).

When positioning a medical device in a patient, "distal" refers to the direction relatively far away from the catheter insertion position, and "proximal" refers to the direction relatively close to the catheter insertion position.

[0059]

As used herein, the term "silk" can be a strand, a rope, a fiber, a yarn, a filament, a cable, a thread, or the like, and these terms can be used interchangeably.

[0060]

As used herein, the term "sheath" can also be described as "catheter", therefore, these terms can be used interchangeably.

[0061]

The invention provides a multi-layered catheter body and a catheter assembly for delivering and placing medical equipment. It is a catheter body and a catheter assembly with a specific structure.

[0062]

Typically, the catheter body includes an inner layer, a first middle layer, a second middle layer, and an outer layer.

The first intermediate layer is composed of flat wires with a width-to-thickness ratio of at least 2:1.

The material of the outer jacket layer includes a distal end portion of the outer sleeve formed of a soft material, a middle section portion of the outer sleeve formed of a medium-hard material, and a distal end portion of the outer sleeve formed of a high-hardness material.

[0063]

According to an embodiment of the present invention, the ratio of the outer diameter to the thickness of the inner layer of the catheter body is at least 30:1.

The maximum inner diameter of the inner layer is 6.4mm.

According to an embodiment of the present invention, the maximum thickness of the first intermediate layer of the catheter body is 0.05 mm.

According to another embodiment of the present invention, the minimum width of the first intermediate layer of the catheter body is 0.08 mm.

[0064]

According to an embodiment of the present invention, the first intermediate layer of the catheter body covers at least 30% of the outer cavity surface of the inner layer.

In another embodiment, the coverage area between the first intermediate layer of the catheter body and the outer cavity surface of the inner catheter wire is between 30-75%, depending on the required stiffness.

Those skilled in this technology should know that the smaller the coverage area between the first intermediate layer and the inner layer, the more flexible the entire catheter.

[0065]

According to an embodiment of the present invention, the maximum thickness of the second braided intermediate layer of the catheter body is 0.05 mm.

[0066]

According to an embodiment of the present invention, the inner layer of the catheter has the same length as the outer jacket layer of the catheter body.

According to another embodiment of the present invention, the first intermediate layer and the second braided intermediate layer are encapsulated in the inner layer of the catheter and the outer sheath layer.

[0067]

According to an embodiment of the present invention, the outer sheath layer is connected to the inner layer through the gap between the filaments forming the first intermediate layer (30) and the second woven intermediate layer.

[0068]

According to an embodiment of the present invention, the first intermediate layer of the catheter body is composed of at least two filaments wound in the same direction.

According to another embodiment of the present invention, the first intermediate layer of the catheter body is composed of at least two reverse-wound filaments.

[0069]

According to an embodiment of the present invention, the second woven middle layer (40) is located between the first middle layer and the outer jacket layer.

According to another embodiment of the present invention, the second woven middle layer is placed at least at the proximal end and the middle of the first middle layer.

According to another embodiment of the present invention, the second woven middle layer is at least 20 mm shorter than the first middle layer.

[0070]

according to an embodiment of the present invention, the ratio of the outer diameter of the catheter body to the inner cavity diameter is at least 1.2:1.

[0071]

The main advantages of the present invention include

[0072]

(a) Have a large cavity to achieve maximum contrast flow.

[0073]

(b) With a smaller outer diameter, the catheter can penetrate into smaller blood vessels without causing additional blood vessel damage to the target treatment site.

[0074]

(c) It has extremely high outer surface smoothness and inner surface smoothness, which is easy to push.

[0075]

(d) With a developing ring, it is convenient to track the position of the catheter.

[0076]

(e) The distal end has good flexibility, the proximal end has good stability, and is more flexible.

[0077]

(1) The catheter has good flexural resistance and is easy to pass through tortuous distal blood vessels.

[0078]

(2) It has excellent anti-collapse performance and can resist external suction and external pressure.

[0079]

The following description and figures list some specific details to provide an understanding of various embodiments of the current patent.

Those with ordinary skills in related technologies should understand that they can practice other embodiments of existing patents without requiring one or more of the details described herein.

Therefore, the applicant does not intend to limit or in any way limit the scope of the claims appended to these details.

Although in the following disclosure, various processes are described with reference to steps and sequences, these steps and the sequence of steps should not be regarded as necessary conditions for practicing all embodiments of the present invention.

[0080]

Unless specifically described otherwise, all numbers expressing quantities, metrics, and other attributes or parameters used in the specifications and claims should be understood as being modified by the word "about" in all embodiments.

Therefore, unless otherwise stated, it should be understood that the numerical parameters specified in the following specifications and appended claims are approximate values.

At least, it should not try to limit the application of the principle of equivalence to the scope of the claims, but should read the numerical parameters based on the number of significant figures reported and the application of general rounding techniques.

[0081]

It should be understood that when these words, such as "composition" (and any tense composition), "have" (and any tense have), "include" (and any tense include) or "include" (and any tense) when used, it specifically refers to the existence of the stated characteristics, integers, steps, operations, elements, and/or components, but does not exclude one or more other characteristics, integers, steps, operations, elements, components, and / Or the existence or addition of its group.

[0082]

We will further understand that although terms such as first, second, and third can be used to describe various limitations, elements, components, regions, layers and/or sections, these limitations, elements, components, regions, layers and/or sections should not be restricted by these terms.

These terms are only used to distinguish one limitation, element, component, region, layer or section from another limitation, element, component, region, layer or section.

Therefore, the first limitation, element, component, region, layer or section discussed below may be referred to as the second limitation, element, component, region, layer or section without departing from the currently applied patent.

[0083]

It is further understood that when an element is referred to as being "on", "attached to", "connected" or "coupled" to another element, it can be directly located at or above the other element, or connected or coupled to another element or one or more intermediate elements.

In contrast, when an element is said to be "directly on", "directly attached to", "directly connected" or "directly coupled" to another element, there are no intervening elements.

Other terms used to describe the relationship between elements should be interpreted in a similar way (for example, "between" and "directly between", "nearby" and "directly neighbor", etc.).

[0084]

To further understand, when the first element is called "within", "above" and/or "inside" the second element, the first element can be located in: the internal space of each element within a part of the second element (for example, in the wall of the second element); located on the external and/or internal surface of the second element; and a combination of one or more of them.

[0085]

Space-related terms, such as "below", "below", "lower", "above", "upper", etc., can be used to describe one element and/or feature and another element and/or the relationship between features, as shown in the figure.

It is further understood that the spatially related terms are intended to include different orientations of the equipment in use and/or operation, and at the same time include the orientations shown in the figures.

For example, if the device in the graphic is turned over, elements described as "below" and/or "below" other elements or characteristics will be "above" other elements or characteristics.

The device can be oriented in other directions (for example, rotated 90 degrees or other orientations), and correspondingly interpreted in spatially relative terms.

[0086]

The term "reduction" and similar words used here mean a reduction in quantity, including reduction to zero.

Reducing the likelihood of occurrence should include preventing occurrence.

[0087]

The term "and/or" as used herein shall be regarded as a specific disclosure of each characteristic or component of two specified characteristics or components, one of which has or does not have the other.

For example, "A and/or B" should be considered as specific disclosures of (i) A, (ii) B, and (iii) A and B, as if listed separately here.

[0088]

The term "diameter" used here to describe a non-circular geometry should be regarded as an approximation of the diameter of an imaginary circle of the described geometry.

For example, when describing the cross-section, such as the cross-section of a member, the term "diameter" should be used to indicate the diameter of an imaginary circle having the same cross-sectional area as the cross-section of the member.

[0089]

The "major axis" and "minor axis" of the component used herein respectively refer to the length and diameter of the smallest volume imaginary cylinder that can completely surround the component.

[0090]

For the sake of clarity, certain features of the invention described in the context of separate embodiments may also be provided in combination in a single embodiment.

On the contrary, for the sake of brevity, various features of the invention described in the context of a single embodiment may also be provided separately or in any suitable sub-combination.

For example, all the features listed in any statement (whether independent or dependent) can be combined in any given way.

[0091]

Example

[0092]

This embodiment relates to a single-lumen, large-caliber, thin-walled catheter.

The catheter structure of this embodiment provides excellent distal end flexibility, excellent proximal pushability and torsion, superior external smoothness and superior inner surface smoothness.

[0093]

As shown in Figures 1A-1B, the catheter body (10) has a four-layer structure.

The inner layer (30) of the catheter body (10) is a full-length ultra-thin inner layer of the catheter, wherein the inner cavity (21) extends from one end to the other end.

The first intermediate layer (30) of the catheter body (10) includes a flat coil (31) wound on the outer surface (24) of the inner layer of the inner catheter.

The second intermediate layer (40) of the catheter body (10) includes braided wires placed on the outer surface of the first intermediate layer (30).

The outer layer (50) of the catheter body (10) includes a tube placed on the outer surface of the second middle layer (40) of the catheter body (10). The outer layer (50) melts and flows through the two middle layers (30, 40),) And adheres to the inner layer (20) of the catheter body (10).

In addition, according to an embodiment of the patent, the outer layer (50) and the inner layer (20) of the catheter body (10) actually have the same length, and the two middle layers (30, 40) of the catheter body (10) are slightly shorter than The outer layer (50) and the inner layer (20) can be encapsulated between the outer layer (50) and the inner layer (20).

[0094]

Continuing to refer to Figure 1A, a radiopaque imaging ring is fixed at the distal end of the catheter body (10) assembly, and the imaging ring is visible under fluorescence.

Figure 1A also shows that the proximal end (14) of the catheter body is connected to the proximal end control mechanism (8) of the catheter.

The design of the specific proximal control mechanism can vary according to the expected application.

Therefore, FIG. 1A is only an example for the purpose of explaining the present invention.

[0095]

According to an embodiment of the present invention, the general length of the catheter body (10) is 1150-1400mm, the outer diameter is 1.4-2.7mm, and the inner diameter is 1.3-2.3mm.

Those skilled in the art should understand that the overall length and dimensions of the catheter body (10) assembly can be easily modified to suit specific applications.

Therefore, the numbers disclosed here should be regarded as references and should not be regarded as limited to the range shown.

[0096]

1B, according to an embodiment of the present invention, the inner layer (20) of the catheter body (10) has a tubular profile, and its inner cavity (21) extends from one end to the other end.

According to an embodiment of the present invention, the inner layer (20) of the catheter body (10) has a length of 1150-1400mm, an outer diameter of 1.75-1.85mm, an inner diameter of 1.70-1.80mm, and a wall thickness of 0.013-0.032mm. The ratio of diameter to inner diameter is 1.018-0.015.

According to one embodiment of the present invention, when the medical device/implant passes through the catheter, the inner layer (20) of the catheter body (10) directly contacts the medical device/implant.

The inner layer (20) of the catheter body (10) provides sufficient lubricity and reduces the force required to push the device/implant through the inner cavity (21).

According to an embodiment of the present invention, the ratio of the wall thickness to the inner diameter of the inner layer (20) of the catheter body (10) disclosed in the present invention is 0.007-0.017.

[0097]

According to an embodiment of the present invention, the inner layer (20) of the catheter body (10) is made of extruded PTFE (polytetrafluoroethylene).

In another embodiment, the inner layer (20) of the catheter body (10) is made of expanded polytetrafluoroethylene, which is also called ePTFE.

The ePTFE inner layer (20) is made by carefully expanding polytetrafluoroethylene using a non-standard manufacturing process, such as heating the extruded polytetrafluoroethylene to a desired temperature, and then expanding its inner diameter on a mandrel.

Such a post-extrusion process will produce an enlarged inner diameter and ultra-thin tubular walls with microscopic pores.

The prepared ePTFE inner layer (20) has the physical properties of air permeability, softness and flexibility, and feels smooth and elastic, like a film.

The ePTFE inner layer (20) also has high tensile strength, chemical inertness, watertightness under low pressure, low dielectric constant, and good radial expansion and UV resistance.

[0098]

Those skilled in the art should understand that although the purpose of the extruded and expanded polytetrafluoroethylene tube described here is to explain the present invention, the inner layer (20) of the catheter body (10) can be made of other materials, such as FEP (fluorine Ethylene propylene), HDPE (high density polyethylene), LDPE (low density polyethylene), PET (polyethylene terephthalate), PP (polypropylene), polyamide/block polyether polyamide. Any manufacturing process known in this field, such as direct extrusion and/or post-extrusion axial stretching and/or radial expansion, is adopted to realize ultra-thin cavity wall.

[0099]

Continuing to refer to Fig. 1B, the first intermediate layer (30) of the catheter body (10) includes a coil (31) wound on the outer surface of the inner layer (20) of the catheter.

The first intermediate layer (30) is added on the inner layer (20) of the catheter as a support, which increases the circumferential strength and enhances the lateral flexibility of the distal end, and the bending resistance is better.

According to one embodiment, the wire used to compose the first intermediate layer (30) of the catheter body (10) is in a flat form.

Those skilled in the art should understand that FIG. 1B is to illustrate and explain the four-layer structure of the catheter body according to an embodiment of the present invention.

Figure 1B does not actually show the length or relative length of the layers of the catheter body.

[0100]

That is, as shown in FIG. 2A, the cross-sectional width of the wire (100) is greater than its thickness.

Therefore, in this embodiment, the inner layer (20) of the catheter body (10) has the largest contact area with the first intermediate layer (30).

Since the inner layer (20) of the catheter body (10) has an ultra-thin wall thickness, the larger the contact area between the first intermediate layer (30) and the outer surface of the inner layer (20), the smoother the inner cavity of the inner layer (20).

Those skilled in the art should understand that under the same coil width, the thicker the coil, the better its bending resistance.

Therefore, a design balance must be achieved between bending resistance and the overall profile of the small catheter body (10).

[0101]

According to an embodiment in Fig. 2A, the width of the coil (31) is 0.03-0.11 mm, and the thickness is 0.02-0.05 mm.

In one embodiment, the width of the coil (31) is 0.003" and the thickness is 0.0015".

According to another embodiment of the present invention, the cross-sectional area of the wire (100) forming the first intermediate layer (30) is 0.001-0.007 mm2, and the width-to-thickness ratio is at least 2:1.

According to one embodiment, the first intermediate layer (30) covers at least 36% of the area of the outer surface of the inner layer (20).

According to another embodiment of the present invention, the pitch of the coil (31) is 0.10-0.23mm, and the minimum gap between each spiral turn is 0.025mm.

In another embodiment, the coil (31) can be left-handed or right-handed.

[0102]

According to another embodiment of the present invention, the first intermediate layer (30) is a [illegible] pitch.

[illegible]
Click on a word or select text for partial translation.

According to another embodiment of the present invention, the wire (100) forming the first [illegible] constant thickness and width throughout its length.

However, in another embodiment of the present invention, in order to obtain the ideal maneuverability of the catheter body (10) while maintaining the flexibility of the distal end of the catheter body (10), the spiral coil (31) is placed near the catheter body (10). The pitch of the tip is small, and the pitch of the distal end of the catheter body (10) is larger, and a gradual change is realized at the transition.

In another embodiment of the present invention, the wire (100) forming the spiral coil (31) has a larger width at the proximal end of the catheter body (10) while maintaining the same thickness of the wire. The distal end of) has a smaller width and achieves a gradual change at the transition.

[0103]

Those skilled in the art should understand that round coil. When the flat coil has the same cross-sectional area as the round coil, the bending resistance of the two coils is equivalent, but the flat coil can reduce the wall thickness by at least 33%.

Therefore, the embodiments of the present invention provide a nominal increase in the radial profile of the catheter.

In other words, the present invention provides the greatest possibility of reducing the outer diameter of the catheter as much as possible while maintaining the size of the inner diameter.

[0104]

According to an embodiment of the present invention, the flat wire (100) forming the first intermediate layer (30) may be formed of stainless steel, tungsten, cobalt-chromium alloy and other materials.

In another embodiment, the flat wire (100) forming the first intermediate layer (30) may be formed of a superelastic material such as Nitinol.

In one embodiment, when the catheter is entangled during use, the Nitinol may allow the first intermediate layer (30) to restore its pre-configured circular tubular shape.

[0105]

Figure 2A shows a single wire spiral coil (31).

Those skilled in the art should know that multi-wire coils (131, 231) can also be incorporated into the structure of the first intermediate layer (30).

For example, as shown in FIG. 2B, the multi-wire coil (131) forming the first intermediate layer (30) can be composed of two wires (110, 120), each wire is made of a different material and wound in the same direction.

In this way, the first intermediate layer (30) can possess the mechanical properties of the complementary strength of the two materials.

In another embodiment, as shown in Fig. 2C, the multi-wire coil (231) constituting the first intermediate layer (30) can be composed of two wires (130, 140), and each wire is made of a different material and wound in opposite directions.

According to one embodiment, as shown in the two embodiments of Figs. 2B-2C, the two wires (130, 140) can be wound alternately so that they are basically in the same layer.

In another embodiment, one wire can be wound around a coil formed by another wire.

Those skilled in the art should know that the structure of each wire (110, 120, 130, 140), including its width, thickness, coil pitch and winding angle, can be adjusted individually to achieve the best results.

According to one embodiment, the multi-wire coil (131, 231) includes 2-4 wires.

In another embodiment, the multi-wire coil (131, 231) can be wound left-handed or right-handed.

In another embodiment, the pitch of the multi-wire coil (131, 231) may be 0.07-0.6 mm.

In other embodiments, the width of the wire used for the multi-wire coil is 0.04-0.15 mm, and the thickness is 0.03-0.08 mm.

[0106]

Continuing to refer to FIG. 1B, according to one of the embodiments, the second intermediate layer (40) is placed outside the first intermediate layer (30).

The second intermediate layer (40) is made of tubular braided metal wires (41).

The tubular braided metal wire (41) strengthens the axial and torsion control of the catheter main body (10), and reduces or almost eliminates the delay caused by the clinician's pushing, pulling or rotating operation.

[0107]

Fig. 3 shows an embodiment of a weaving pattern.

According to an embodiment of the present invention, the tubular braided metal wire (41) as the second intermediate layer (40) is composed of 16 wires, which is a conventional braiding pattern.

In another embodiment, the second intermediate layer (40) is composed of 16 wires and has a conventional diamond weaving pattern, which can provide better torsion and flexural properties than the conventional weaving pattern.

Those skilled in the art should understand that the weaving pattern and the number of threads can be changed.

Therefore, the content disclosed here should not be taken as limiting the scope of the present invention.

[0108]

According to one embodiment, the second intermediate layer (40) is placed outside the first intermediate layer (30), as shown in Fig. 1B.

According to one embodiment, the thickness of the conventional second intermediate layer (40) is 0.025-0.088 mm, and the thickness of each braided wire used is 0.013-0.0038 mm.

According to an embodiment of the present invention, the length of the second intermediate layer (40) is 1150-1400 mm, which is substantially equal to the length of the first intermediate layer (30).

According to another embodiment, the length of the second intermediate layer (40) is 1100-1350 mm, which is much smaller than the length of the first intermediate layer (30), and the second intermediate layer (40) only covers the first intermediate layer (30). The middle and proximal end portions of the first intermediate layer (30) do not cover the distal end portion.

But according to another embodiment, the second intermediate layer (40) is 2 cm shorter than the first intermediate layer (30) at the distal end of the first intermediate layer (30), as shown in Fig. 1B.

[0109]

Continuing to refer to Fig. 1B, according to one embodiment, the outer layer (50) of high molecular polymer is placed on the outside of the second intermediate layer (40) to form the outer layer of the catheter.

According to one embodiment, the outer layer (50) has an original tubular configuration and is placed outside the second intermediate layer (40).

Then the entire catheter shaft (10) assembly is subjected to a reflow soldering process, and a composite catheter body (10) is formed by melting the outer layer (50) and/or the inner layer material.

According to one embodiment, the material of the outer layer (50) melts and flows into the gaps between the braided wires of the second middle layer (40) and the first middle layer (30), and adheres to the inner layer (20) of the catheter shaft (10).

Those skilled in the art should understand that the temperature used to melt the outer layer (50) to form a bond with the inner layer (20) of the catheter body (10) is balanced to allow sufficient material to flow through the gap between the wires. In addition, grooves and narrow channels will not be introduced into the lumen surface of the inner layer (20) of the catheter shaft (10), and the grooves and narrow channels will affect the smoothness of the catheter lumen.

[0110]

According to one embodiment, the outer layer (50) is made of a single material, such as nylon or Pebax, and has a stable hardness.

According to another embodiment, the outer layer (50) has a hardness of 25-60D (Shore 25-60D), a length of 80-930 mm, an outer diameter of 2.0-2.5 mm, and a wall thickness of 0.025-0.13 mm.

According to one embodiment, the outer layer (50) covers the entire length of the two intermediate layers (30, 40) and the entire length of the inner layer (20) of the catheter shaft (10).

[0111]

Reference is now made to Figure 8, which shows another embodiment of the outer layer (50).

According to one embodiment, the outer layer (50) is composed of multiple sections, each of which is a material of different hardness.

For example, as shown in Fig. 8, the distal portion of the outer layer (50) is made of an ultra-low hardness material, such as TPU with a hardness of about 80A (HS).

The proximal part of the outer layer (50) is made of a relatively high hardness material, such as nylon with a hardness of about 70D (HS).

The transition section between the distal end and the proximal end of the outer layer (50) is made of a relatively high hardness material, such as Pebax with a hardness in the range of 35D-82D. Therefore, the low-hardness distal outer layer enables the catheter body (10) assembly to have excellent elasticity to pass through tortuous small blood vessels. The high-hardness proximal section of the outer layer (50) enables the catheter shaft (10) to have rigidity and excellent maneuverability. The transition section realizes the gradual transformation from the distal super soft section to the proximal rigid and support section.

[0112]

Continuing to refer to Figure 4, according to one embodiment, the length of the distal section of the outer layer (50) is 100-200mm, the length of the transition section of the outer layer (50) is 10-30mm, and the length of the proximal section of the outer layer (50) is 1000-1100mm.

According to one embodiment, the distal section, the transition section and the proximal section of the outer layer (50) all have approximately the same thickness.

[0113]

According to another embodiment of the present invention, additional coatings can be added to the catheter composition described in the present invention.

For example, a hydrophilic coating is added to obtain a smooth surface so that the catheter can be transported more easily in the blood vessel.

[0114]

Even if not specifically described above, those skilled in the art should understand that one or more radiopaque marking points can facilitate visualization by imaging equipment (for example, fluoroscope, X-ray, CT scan, nuclear magnetic resonance, ultrasound imaging).

A marking point as disclosed herein can be applied to any part of the catheter shaft (10) of the present invention. A radiopaque marking point can be attached, forged, crimped, or otherwise arranged and fixed on the catheter shaft (10) or on the surface thereof. The radiopaque marking points can be made of tantalum, tungsten, platinum, platinum, iridium, gold, or alloys of these materials or other materials known to those skilled in the art. The radiopaque marking points can also be composed of a variety of paramagnetic materials, which include one or more elements with atomic numbers of 21-29, 42, 44, and 58-70, such as chromium (B), magnesium (B), iron (B), iron (B), cobalt (B), copper (B), nickel (B), praseodymium (B), ruthenium (B), samarium (B), ytterbium (B), gadolinium (B) terbium (B), dysprosium (B), holmium (B), erbium (B) or other MRI visible materials known to those skilled in the art.

[0115]

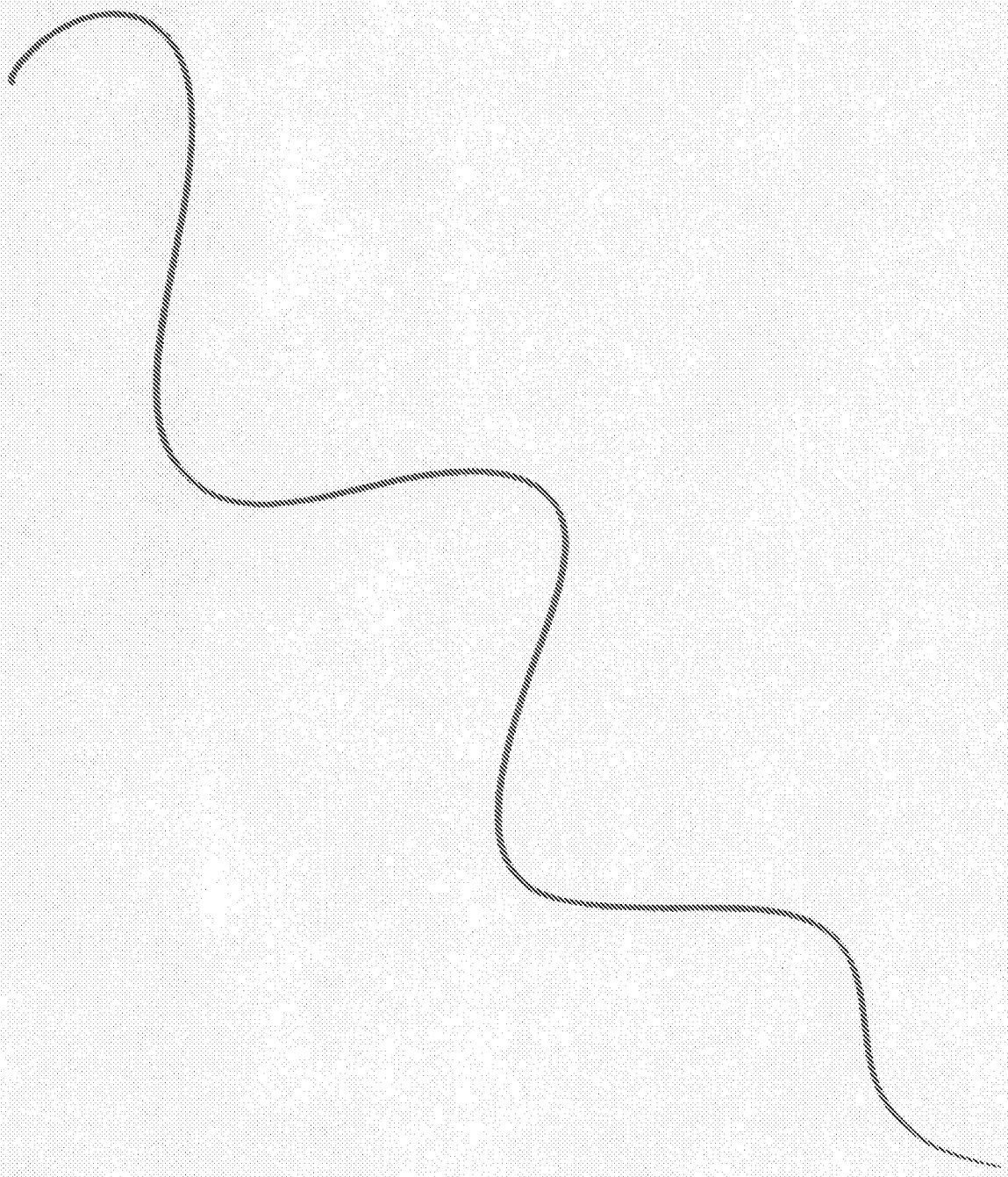
Those skilled in the art should understand that even though most of the exemplary embodiments of the catheter body (10) described above are suitable for intracranial vascular applications, the exemplary embodiments of the present invention can also be used for any other suitable partially occlusive interventional applications.

For example, the exemplary embodiments of the present invention can be used for delivery of vascular occlusion devices, stents, aspiration, stent thrombus extractors for the treatment of ischemic stroke, and the like. In other examples, the exemplary embodiments of the present invention can be used to accurately deliver implants into blood vessels, such as cerebral blood vessels, open blood vessels, or other locations.

[0116]

The foregoing description and related drawings present a number of current representative embodiments.

Based on the foregoing teachings, various modifications and alternative designs will be apparent to those skilled in the art without departing from the spirit of the present invention or beyond the scope of the present invention, and the scope is defined by the appended claims rather than the foregoing description indicates. All changes and changes falling within the equivalent scope and meaning of the present invention are deemed to be included in the scope of the present invention.



(19)中华人民共和国国家知识产权局

(12)发明专利申请

(10)申请公布号 CN 110652645 A
(43)申请公布日 2020.01.07

(21)申请号 201911114807.7
(22)申请日 2019.11.14
(30)优先权数据
62/886,322 2019.08.13 US
(71)申请人 上海沃比医疗科技有限公司
地址 201318 上海市浦东新区天雄路166弄2号楼2层201室
(72)发明人 冯骋骋 林·丁 杰罗姆·克洛伊 钱承 尼尔·白 丹·丁
(74)专利代理机构 上海一平知识产权代理有限公司 31266
代理人 徐迅 祝蓬君
(51)Int.Cl.
A61M 25/00(2006.01)
A61M 25/01(2006.01)
A61F 2/962(2013.01)

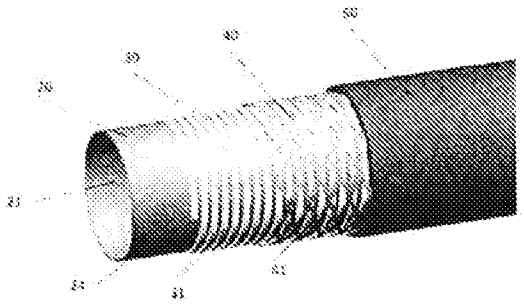
权利要求书1页 说明书9页 附图3页

(54)发明名称

多层导管主体及其导管组件

(57)摘要

本发明提供了一种多层导管主体及其导管组件，用于输送和放置医疗器械，以及抽吸去除堵塞。该导管主体由内到外依次包括内层、第一中间层、第二中间层以及外层；内层为一薄壁管，内层的管内腔具有光滑的壁面；第一中间层为线圈层，第一中间层由扁丝绕制而成，扁丝的宽度和厚度之比为至少为2:1；第二中间层为编织层，第二中间层由金属丝编织而成；外层远端的硬度小于外层近端的硬度；外层通过第一中间层和第二中间层的丝间隙粘接到内层上。本发明可以满足高标准的推送性、可追踪性、柔韧性和可扭性的目标，可以实现大的抽吸流量，能够深入到更小的血管中，而不会对目标治疗位置造成额外的损伤；具有极高的内表面顺滑性和外表面顺滑性。



CN 110652645 A

1.一种多层导管主体，其特征在于，所述导管主体用于输送和放置医疗器械，所述导管主体由内到外依次包括内层、第一中间层、第二中间层以及外层；

所述内层为一薄壁管，所述内层的管内腔具有光滑的壁面；

所述第一中间层为线圈层，所述第一中间层由扁丝绕制而成，所述扁丝的宽度和厚度之比为至少为2:1；

所述第二中间层为编织层，所述第二中间层由金属丝编织而成；

所述外层远端的硬度小于所述外层近端的硬度；

所述外层通过所述第一中间层和所述第二中间层的丝间隙粘接到所述内层上。

2.如权利要求1所述的导管主体，其特征在于，所述导管主体的内层的外径与其壁厚比至少为10:1。

3.如权利要求1所述的导管主体，其特征在于，所述第一中间层的扁丝的最大厚度为0.06mm。

4.如权利要求1所述的导管主体，其特征在于，所述第一中间层覆盖至少30%的所述内层的外表面。

5.如权利要求1所述的导管主体，其特征在于，所述第二中间层的最大厚度为0.066mm。

6.如权利要求1所述的导管主体，其特征在于，所述导管主体的壁厚至少为0.03mm。

7.如权利要求1所述的导管主体，其特征在于，所述第一中间层由至少两根丝沿相同方向缠绕而成。

8.如权利要求1所述的导管主体，其特征在于，所述第一中间层由至少两根丝沿相反方向缠绕而成。

9.如权利要求1所述的导管主体，其特征在于，所述第二中间层至少覆盖所述第一中间层的近端和中间段。

10.如权利要求1所述的导管主体，其特征在于，所述导管主体的外径和内径之比至少为1.2:1。

多层导管主体及其导管组件

技术领域

[0001] 本发明主要涉及一种用于神经血管应用的导引、抽吸或远端支撑的多层导管主体及其导管组件。特别地，该导管主体提供了卓越的远端柔韧性和近端稳定性用于在神经血管内部跟踪，以及优秀的外部顺滑性和内部顺滑性以用于植入物的输送。

背景技术

[0002] 几乎每一种神经血管装置的放置或治疗都发生在颈部或颈部以上。因此，神经血管系统内使用的导管必须能够穿越曲折的血管。在设计用于神经血管的导管时，工程师必须在功能性和结构性之间取得平衡，并以导管的可跟踪性、灵活性、推送性和扭矩(透过率或扭转力)为基本目标。

[0003] 聚四氟乙烯材料具有卓越的耐磨性和高顺滑性，是导管内壁的理想选择。当推送医疗设备通过紧的导管内腔时，聚四氟乙烯内层光滑的内腔表面减少了医疗设备和导管之间的摩擦。浸渍涂层和挤压是制造聚四氟乙烯内衬的两种常用方法。浸镀法是获得聚四氟乙烯内衬的一种方法。这个过程可以在作为导管主体构建过程的一部分的芯轴上进行。一旦涂层固化，导管的附加组件，例如尼龙护套、编织管，就建立在固化浸渍涂层芯轴上。浸涂工艺虽然从一开始看起来是一个简单的过程，但也有一些局限性。浸渍涂层可能存在不均匀地类似于橘子皮的表面。有时浸渍涂层表面会出现许多横截面线，称为颤振，这是由于浸渍涂层过程中的振动造成的。浸渍涂层的表面也可能有凹坑、凹陷、甚至固化层中的刺，其是由浸渍涂层过程中的污染物(包括水分)造成的。这些缺陷都会对导管腔内的顺滑性产生负面影响，严重影响导管的使用。虽然这些缺陷可以用不同的方法来解决，但浸涂工艺的高精度通常会带来更大的成本和时间。

[0004] 挤压聚四氟乙烯管是制造聚四氟乙烯导管内层的另一种方法。虽然挤压聚四氟乙烯具有最低的摩擦系数，但一个典型的挤压聚四氟乙烯管壁厚约0.001″。这种壁厚可能导致导管整体刚性的增加，这不是一个理想的方法来穿过神经血管内曲折的通路。

[0005] 理想的神经血管导管应该有最小的外径来通过细小的血管，最大的内径来运送医疗器械/植入物。这不可避免地导致对超薄导管内层的需求。然而，伴随超薄的导管内层，工程师需要纳入导管主体支撑组件，如覆盖导管内层的金属丝层，编织网管层或线圈层，以增强导管的推送性和抗弯折性。为了保持导管结构的完整性，金属丝层和导管内层之间需要最小的接触压力。通常，这样的最小收缩压力会导致导管内层的内表面粗糙度增加，并显著降低内表面顺滑性。

[0006] 因此，有必要研制一种新的用于神经血管的导管，以满足高标准的推送性、可追踪性、柔韧性和可扭性的目标，同时需要一个大的腔体来实现最大限度的抽吸流量；更小的外径使导管能够深入到更小的血管中，而不会对目标治疗位置造成额外的血管损伤；外表面顺滑，同时具有极高的内表面顺滑性，以减少用力。

发明内容

[0007] 本发明的目的在于提供一种用于输送和放置医疗设备的多层导管主体及其导管组件，本发明可以满足高标准的推送性、可追踪性、柔韧性和可扭性的目标，同时具有大的腔体来实现最大限度的抽吸流量、更小的外径使导管能够深入到更小的血管中，而不会对目标治疗位置造成额外的血管损伤；外表面顺滑；同时具有极高的内表面顺滑性。

[0008] 在本发明的第一方面提供了一种多层导管主体，所述导管主体用于输送和放置医疗器械，所述导管主体由内到外依次包括内层、第一中间层、第二中间层以及外层；所述内层为一薄壁管，所述内层的管内腔具有光滑的壁面；所述第一中间层为线圈层，所述第一中间层由扁丝绕制而成，所述扁丝的宽度和厚度之比为至少为2:1；所述第二中间层为编织层，所述第二中间层由金属丝编织而成；所述外层远端的硬度小于所述外层近端的硬度；所述外层通过所述第一中间层和所述第二中间层的丝间隙粘接到所述内层上。

[0009] 在另一优选例中，所述外层由多种材料组成，其中硬度软的材料作为外层远端，硬度中等的材料作为外层中间段，以及硬度硬的材料作为外层近端部分。

[0010] 在另一优选例中，所述导管主体的内层的外径与其壁厚比至少为10:1。

[0011] 在另一优选例中，所述导管主体的内层的最小内径为0.8mm。

[0012] 在另一优选例中，所述第一中间层的扁丝的最大厚度为0.06mm。

[0013] 在另一优选例中，所述第一中间层的扁丝的最小宽度为0.08mm。

[0014] 在另一优选例中，所述第一中间层覆盖至少30%的所述内层的外表面。

[0015] 在另一优选例中，所述第二中间层的最大厚度为0.066mm。

[0016] 在另一优选例中，所述导管主体的壁厚至少为0.03mm。

[0017] 在另一优选例中，所述导管主体的壁厚为0.03~0.3mm；优选地，0.06~0.2mm；更佳地，0.07~0.18mm。

[0018] 在另一优选例中，所述内层和所述外层的长度相同。

[0019] 在另一优选例中，所述第一中间层由至少两根丝沿相同方向缠绕而成。

[0020] 在另一优选例中，所述第一中间层由至少两根丝沿相反方向缠绕而成。

[0021] 在另一优选例中，所述第二中间层至少覆盖所述第一中间层的近端和中间段。

[0022] 在本发明的第二方面提供了一种导管组件，所述导管组件包括上述的多层导管主体和导管近端控制机构，所述导管近端控制机构用于操控所述导管主体前进、后退和扭转。此外，所述导管近端控制机构可用于其它医疗器械的导入和连接，例如，可以开设其他通道用于放置导丝或微导管或植入物输送件等输送装置，也可与压力延长管等进行连接，在外界抽吸力的作用下进行血栓等抽吸。

[0023] 在另一优选例中，所述第二中间层至少比所述第一中间层短20mm。

[0024] 在另一优选例中，所述第一中间层和第二中间层被封闭在所述内层和所述外层之间。

[0025] 在另一优选例中，所述第二中间层位于所述第一中间层和所述外层之间。

[0026] 在另一优选例中，所述导管主体的外径和内径之比至少为1.2:1。

[0027] 应理解，在本发明范围内中，本发明的上述各技术特征和在下文(如实施例)中具体描述的各技术特征之间都可以互相组合，从而构成新的或优选的技术方案。限于篇幅，在此不再一一累述。

附图说明

[0028] 为了更清楚地说明本发明实施例或现有技术中的技术方案，下面将对实施例或现有技术描述中所需要使用的附图做简单地介绍，显而易见地，下面描述中的附图仅仅是本发明的一些实施例，对于本领域普通技术人员来讲，在不付出创造性劳动的前提下，还可以根据这些附图获得其他的附图。

[0029] 图1A是根据本发明的一个实施例的具有导管主体和导管近端控制机构的导管组件的主视图；

[0030] 图1B是根据本发明的一个实施例的多层导管主体结构的透视图；

[0031] 图2A是根据本发明的一个实施例的导管主体的第一中间层的主视图；

[0032] 图2B是根据本发明的另一个实施例的导管主体的第一中间层的主视图；

[0033] 图2C是根据本发明的又一个实施例的导管主体的第一中间层的透视图；

[0034] 图3是根据本发明的一个实施例的导管主体的第二中间层的主视图；

[0035] 图4是根据本发明的一个实施例的导管主体的外层的透视图。

[0036] 各附图中，各标示如下：

[0037] 8-导管近端控制机构；

[0038] 10-导管主体；

[0039] 14-导管主体的近端；

[0040] 20-内层；

[0041] 21-内腔；

[0042] 24-内层的外表面；

[0043] 30-第一中间层；

[0044] 31-线圈；

[0045] 40-第二中间层；

[0046] 41-管状编织金属丝；

[0047] 50-外层；

[0048] 100、110、120、130、140-线；

[0049] 131、231-多线线圈。

具体实施方式

[0050] 本发明人经过广泛而深入的研究，通过大量筛选，首次开发了一种用于输送和放置医疗设备的多层导管主体及其导管组件，与现有技术相比，本发明的导管主体内具有良好的扭矩和抗扭(抗缠绕)特性，具有能够到达预定治疗位置的灵活的远端部分，并在不损伤周围血管的情况下提供治疗，且在尽可能小的外部轮廓和尽可能大的内腔之间保持一个微妙的平衡，以便输送医用植入物，在其他导管内腔移动以吸引疏通闭塞的血管，此外，这种导管主体在X射线透视下还可以是可见的，便于操作者观察，在此基础上完成了本发明。

[0051] 术语

[0052] 如本文所用，术语"内腔"是指主体体内的管道、输送管或一般的管状空间或腔体，包括静脉、动脉、血管、毛细血管、肠道等。"内腔"一词也可以指导管内、鞘、空心针、管或类似物中的管状空间。

[0053] 如本文所用，术语"近端"是指靠近操作者（较少进入人体），"远端"是指远离操作者（较远进入人体），在患者体内定位医疗器械时，"远端"指相对远离导管插入位置的方向，"近端"指相对靠近导管插入位置的方向。

[0054] 如本文所用，术语"丝"可以是一股线、一根绳子、一根纤维、一根纱线、一根细丝、一根电缆、一根线或类似的东西，这些术语可以互换使用。

[0055] 如本文所用，术语"臂"也可以描述为"导管"，因此，这些术语可以互换使用。

[0056] 本发明提供了一种用于输送和放置医疗设备的多层导管主体及其导管组件，它是一种具有特定结构的导管主体及其导管组件。

[0057] 典型地，所述导管主体包括内层、第一中间层、第二中间层和外层。第一中间层由宽厚比至少为2:1的扁丝构成。所述外套层的材料，包括柔软材料形成的外套管远端部分、中等硬度材料形成的外套管中段部分和高硬度材料形成的外套管近端部分。

[0058] 根据本发明的一个实施例，导管主体的内层的外径与厚度比至少为10:1。内层的最小内径为0.8mm。根据本发明的一个实施例，导管主体的第一中间层的最大厚度为0.06mm。根据本发明的另一个实施例，导管主体的第一中间层的最小宽度为0.08mm。

[0059] 根据本发明的一个实施例，所述导管主体的第一中间层至少覆盖所述内层的外腔表面的30%的区域。在另一个实施例中，根据所需的刚度，导管主体的第一中间层与内导管线的外腔表面之间的覆盖面积在30-75%之间。熟练掌握这门技术的人应该知道，第一中间层与内层之间的覆盖面积越小，整个导管就越灵活。

[0060] 根据本发明的一个实施例，导管主体的第二编织中间层的最大厚度为0.03mm。

[0061] 根据本发明的一个实施例，导管内层与导管主体的外夹套层长度相同。根据本发明的另一个实施例了第一中间层和第二编织中间层封装在导管内层和外护套层内。

[0062] 根据本发明的一个实施例，外护套层通过形成第一中间层（30）和第二编织中间层的丝之间的间隙与内层连接。

[0063] 根据本发明的一个实施例，导管主体的第一中间层由至少两根沿同一方向缠绕的丝构成。根据本发明的另一个实施例，导管主体的第一中间层由至少两根反向缠绕的丝构成。

[0064] 根据本发明的一个实施例，所述第二编织中间层（40）位于第一中间层和外夹套层之间。根据本发明的另一个实施例，第二编织中间层至少置于第一中间层的近端和中部。根据本发明的另一个实施例，第二编织中间层至少比第一中间层短20毫米。

[0065] 根据本发明的一个实施例，导管主体的外径与内腔直径之比至少为1.2:1。

[0066] 本发明的主要优点包括：

[0067] (a)具有大的腔体来实现最大限度的抽吸流量；

[0068] (b)具有更小的外径使导管能够深入到更小的血管中，而不会对目标治疗位置造成额外的血管损伤；

[0069] (c)具有极高的外表面顺滑性和内表面顺滑性，便于推送；

[0070] (d)具有显影环，便于追踪导管位置；

[0071] (e)远端柔韧性好，近端稳定性好，更加灵活；

[0072] (f)导管抗折性能好，便于通过迂曲的远端血管；

[0073] (g)具有优良的抗塌陷性能，可以抵抗内部抽吸力和外部压力。

[0074] 下面的描述和图中列出了一些具体的细节，以提供对当前专利的各种实施例的理解。那些在相关技术中具有普通技能的人要明白，他们可以实践现有专利的其他实施例，而不需要本文描述的一个或多个细节。因此，申请人无意限制或以任何方式限制附加在这些细节上的权利要求范围。虽然在接下来的披露中，各种过程都是参照步骤和顺序来描述的，但这些步骤和步骤的顺序不应该被作为实践本发明所有实施例的必要条件。

[0075] 除非另有具体描述，否则在规范和权利要求书中使用的所有表示数量、度量和其他属性或参数的数字都应被理解为在所有实施例中都被"大约"一词修饰。因此，除非另有说明，应了解下列规格书和所附权利要求中规定的数值参数是近似值。至少，不应试图将等同原则的适用限制在权利要求的范围内，而应根据所报告的有效数字的数目和一般圆整技术的应用来读取数值参数。

[0076] 要明白当这些字，如"组成"（和任何时态的组成），"有"（和任何时态的有），"包括"（和任何时态的包括）或"包含"（和任何时态的包含）被使用时，特指所陈述的特性，整数，步骤，操作，元素，和/或组件的存在，但不排除一个或多个其他特性、整数、步骤、操作、元素、组件和/或其分组的存在或添加。

[0077] 我们将进一步理解，尽管第一、第二，第三等术语可用于描述各种限制、元素、组件、区域、层和/或节，但这些限制、元素，组件、区域、层和/或节不应受这些术语的限制。这些术语仅用于区分一个限制、元素、组件、区域、层或节与另一个限制、元素、组件、区域、层或节。因此，下面讨论的第一个限制、元素，组件、区域、层或节可以称为第二个限制、元素、组件、区域、层或节，而不偏离当前应用的专利。

[0078] 进一步的理解是，当一个元素被称为"在……之上"、"附加于"、"连接"或"耦合"到另一个元素时，它可以直接位于或离于另一个元素，或者连接或耦合到另一个元素或一个或多个中间元素。相比之下，当一个元素被称为"直接在……之上"、"直接附加于"、"直接连接"或"直接耦合"到另一个元素时，则不存在中间元素。用于描述元素之间关系的其他词汇应该以类似的方式解释（例如，"介于……之间"与"直接介于……之间"、"邻近"与"直接近邻"等）。

[0079] 进一步理解，当第一个元素被称为"在……之内"，"在……之上"和/或"在……内部"于第二个元素，第一个元素可以位于：第二个元素的内部空间，第二个元素的一部分内（例如，在第二个元素壁内）；位于第二元素的外部和/或内部表面；以及其中一个或多个的组合。

[0080] 空间相关术语，如"在……之下"，"在下面"、"较低的"、"在……上面"、"上部的"等，可用于描述一个元素和/或特征与另一个元素和/或特征之间的关系，如图中所示。进一步的理解是，空间相关术语是为了包括在使用和/或操作中的设备的不同方向，同时包括图中所示的方向。例如，如果将图形中的设备翻转过来，则描述为"在下面"和/或"在……之下"其他元素或特性的元素将位于"在……上面"其他元素或特性。该装置可以朝向其他方向（例如旋转90度或其他方向），并相应地用空间相关术语来解释。

[0081] 这里使用的术语"减少"等类似词汇，含义包括数量的减少，包括减少到零。减少发生的可能性应包括预防发生。

[0082] 此处使用的术语"和/或"应被视为两个指定特性或组件的每个特性或组件的特定披露，其中一个具有或不具有另一个。例如，"A和/或B"应被视为（i）A、（ii）B和（iii）A和B的

具体披露，就像这里单独列出的一样。

[0083] 这里用来描述非圆几何体的术语"直径"应被视为近似所描述几何体的假想圆的直径。例如，在描述横截面时，如构件的横截面，应采用"直径"一词来表示与所述构件横截面具有相同横截面积的假想圆的直径。

[0084] 这里使用的组件的"长轴"和"短轴"分别是指能够完全环绕组件的最小体积假想圆柱体的长度和直径。

[0085] 为清楚起见，本发明在单独实施例的上下文中描述的某些特征也可以组合在单个实施例中提供。相反，为简洁起见，在单个实施例的上下文中描述的本发明的各种特征也可以单独提供或以任何适当的子组合形式提供。例如，任何声明中列出的所有特性(不管是独立的还是非独立的)都可以以任何给定的方式组合在一起。

[0086] 实施例

[0087] 本实施例涉及一种单腔、大口径、壁薄的导管。本实施例的导管结构提供了优异的远端柔顺性、优异的近端推送性和扭转性、优越的外部顺滑性和优越的内表面顺滑性。

[0088] 如图1A-1B所示，导管主体(10)为四层结构。导管主体(10)的内层(20)为全长的超薄导管内层，其中内腔(21)从一端延伸到另一端。所述导管主体(10)的第一中间层(30)包括绕在所述内导管内层的外表面(24)上的扁平线圈(31)。所述导管主体(10)的第二中间层(40)包括置于第一中间层(30)外表面上的编织丝。导管主体(10)的外层(50)包括一个放置在导管主体(10)的第二中间层(40)外表面的管子，外层(50)融化后流过两个中间层(30、40)并与导管主体(10)的内层(20)粘附在一起。此外，根据专利的一个实施例，导管主体(10)的外层(50)和内层(20)通常有相同的长度，导管主体(10)的两个中间层(30、40)略短于外层(50)和内层(20)，以便于能够封装在外层(50)和内层(20)之间。

[0089] 继续参阅图1A，在导管主体(10)组件的远端固定有一个不透射线的显影环，该显影环在荧光下可视。图1A还显示导管主体的近端(14)与导管近端控制机构(8)相连。具体的近端控制机构的设计可以根据预期的应用情况而异。因此，图1A只是一个例子，目的是解释本发明。

[0090] 根据本发明的一个实施例，导管主体(10)的一般长度为1100~1400mm，外径为1.4~2.7mm，内径为1.2~2.3mm。本领域技术人员应该了解导管主体(10)总成的总长度和尺寸可以很容易地修改以适合特定的应用。因此，此处披露的数字应被视为参考，不应被视为仅限于所示出的范围。

[0091] 参照图1B，根据本发明的一个实施例，导管主体(10)的内层(20)具有管状轮廓，其内腔(21)从一端延伸到另一端。根据本发明的一个实施例，导管主体(10)的内层(20)的长度为1150~1400mm，外径为1.75~1.85mm，内径为1.73~1.83mm，壁厚为0.013~0.032mm，外径和内径之比为1.014~0.015。根据本发明的一个实施例，当医疗设备/植入物通过导管时，导管主体(10)的内层(20)直接与医疗设备/植入物接触。所述导管主体(10)的内层(20)提供了足够的润滑性，减小推动设备/植入物通过内腔(21)所需的力。根据本发明的一个实施例，本发明公开的导管主体(10)的内层(20)的壁厚与内径之比为0.007~0.017。

[0092] 根据本发明的一个实施例，导管主体(10)的内层(20)由挤压的(extruded)PTFE(聚四氟乙烯)制成。在另一个实施例中，导管主体(10)的内层(20)由膨胀聚四氟乙烯制成，其也被称为ePTFE。ePTFE内层(20)是通过使用非标准制造工艺小心膨胀聚四氟乙烯制成

的，例如将挤压的聚四氟乙烯加热到所需的温度，然后在芯轴上扩大其内径。这样的后挤压工艺将产生一个扩大的内径和超薄管状壁与微观孔隙。所制得的ePTFE内层(20)具有透气、柔软、柔韧的物理特性，手感光滑有弹性，像一层膜。ePTFE内层(20)还具有高线性强度、化学惰性、在低压下保持水密，具有低介电常数、并具有良好的径向膨胀和抗紫外线性能。

[0093] 本领域技术人员应该理解，尽管此处描述的挤压的和膨胀的聚四氟乙烯管的目的是解释本发明，导管主体(10)的内层(20)可以由其他材料，如FEP(氟化乙烯丙烯)、HDPE(高密度聚乙烯)、LDPE(低密度聚乙烯)、PET(聚对苯二甲酸乙二醇酯)、PP(聚丙烯)、聚酰胺/嵌段聚醚聚酰胺，采用该领域已知的任何制造工艺，如直接挤压和/或后挤压轴向拉伸和/或径向膨胀等工艺，实现超薄腔壁。

[0094] 继续参照图1B，导管主体(10)的第一中间层(30)包括绕在导管内层(20)的外表面上的线圈(31)。在导管内层(20)上增加第一中间层(30)作为支撑，在增加周向强度的同时，增强远端侧向柔顺性，抗弯性更佳。根据一个实施例，用于组成导管主体(10)第一中间层(30)的线为扁平形态。本领域技术人员应理解图1B是为了说明和解释本发明的一个实施例的导管主体的四层结构。图1B并不实际表示导管主体各层的长度或相对长度。

[0095] 也就是说，如图2A所示，线(100)的横截面宽度大于其厚度。因此，本实施中导管主体(10)的内层(20)与第一中间层(30)有最大接触面积。由于导管主体(10)的内层(20)具有超薄壁厚，第一中间层(30)与内层(20)的外表面接触面积越大，内层(20)的内腔越光滑。本领域技术人员应该了解，在相同的线圈宽度下，线圈越厚，其抗弯折性能越好。因此，必须在抗弯折性和小的导管主体(10)整体轮廓之间实现设计平衡。

[0096] 根据图2A中的一个实施例，线圈(31)的宽度为0.04-0.11mm，厚度为0.02-0.06mm。在一个实施例中，线圈(31)的宽度为0.003″，厚度为0.0015″。根据本发明的另一个实施例，形成第一中间层(30)的线(100)的横截面积为0.001-0.007mm^2，宽厚比至少为2:1。根据一个实施例，第一中间层(30)至少覆盖所述内层(20)的外表面38%的面积。根据本发明的另一个实施例，线圈(31)的螺距为0.12-0.25mm，每个螺旋距间的最小间隙为0.025mm。在另一个实施例中，线圈(31)可以为左旋，也可以为右旋。

[0097] 根据本发明的另一个实施例，第一中间层(30)是具有恒定螺距的螺旋线圈(31)。根据本发明的另一个实施例，形成第一中间层(30)的线(100)在其整个长度中具有恒定的厚度和宽度。然而在本发明的另一个实施例中，为了在保持导管主体(10)远端柔顺性的同时获得导管主体(10)理想的可操纵性，螺旋线圈(31)在导管主体(10)的近端的螺距较小，在导管主体(10)的远端的螺距较大，且在过度处实现渐进的变化。在本发明的另一个实施例中，在保持线的厚度相同情况下，形成螺旋线圈(31)的线(100)在导管主体(10)的近端有较大的宽度，在导管主体(10)的远端有较小的宽度，并在过度处实现渐进的变化。

[0098] 本领域技术人员应该理解圆线圈，当扁平线圈拥有和圆线圈相同的横截面积时，两种线圈的抗弯折性能相当，但扁平线圈可以减少至少33%的壁厚。因此，本发明中的实施例提供了导管径向剖面的最小增加量。换句话说，本发明提供了在保持内径大小的同时，尽可能的减小导管的外径的一个最大可能。

[0099] 根据本发明的一个实施例，形成第一中间层(30)的扁线(100)可以用不锈钢、钨、钴铬合金和其他材料形成。在另一个实施例中，形成第一中间层(30)的扁线(100)可由镍钛等超弹性材料形成。在一个实施例中，当导管在使用过程中纠缠时，镍钛可以允许第一中间

层(30)恢复其预先配置的圆形管腔形状。

[0100] 图2A示出了单线螺旋线圈(31)。本领域技术人员应该知道，多线线圈(131、231)也可以被纳入到第一中间层(30)的构造中。例如，如图2B所示，形成第一中间层(30)的多线线圈(131)可以由两根线(110、120)组成，每根线采用不同的材料，向同一方向绕制而成。这样，第一中间层(30)就可以拥有两种材料的综合强度的力学性能。另一个实施例如图2C所示，构成第一中间层(30)的多线线圈(231)可由两根导线(130、140)组成，每根导线采用不同的材料，向相反方向绕制。根据一个实施例，如图2B-2C的两个实施例所示，两根导线(130、140)可以交替缠绕，使它们基本上处于同一层。在另一个实施例中，一根线可以绕在另一根线形成的线圈上。本领域技术人员应该知道，每根线(110、120、130、140)的结构，包括它的宽度、厚度、线圈的螺距和绕制的角度，都可以单独调整，以达到最佳的效果。根据一个实施例，多线线圈(131、231)包括2-4根线。在另一个实施例中，多线线圈(131、231)可以左旋或右旋绕制。在另一个实施例中，多线线圈(131、231)的螺距可为0.07-0.5mm。在其他实施例中，用于多线线圈的导线的宽度为0.04-0.11mm，厚度为0.02-0.06mm。

[0101] 继续参照图1B，根据其中一个实施例，第二中间层(40)置于第一中间层(30)的外部。第二中间层(40)由管状编织金属丝(41)而成。所述管状编织金属丝(41)加强了导管主体(10)的轴向和扭转控制，减少或几乎消除临床医生推拉或旋转操作所产生的延迟。

[0102] 图3示出了一种编织模式实施例。根据本发明的一个实施例，作为第二中间层(40)的管状编织金属丝(41)由16根丝组成，为常规编织模式。在另一个实施例中，第二中间层(40)由16根丝组成并且为常规钻石编织模式，其可以提供比常规编织模式更好的扭转和抗折性能。本领域技术人员应该理解编织模式和丝数可以改变。所以在此披露的内容不应该作为限制本发明包含的范围。

[0103] 根据一个实施例，第二中间层(40)置于第一中间层(30)的外侧，如图1D所示。根据一个实施例，常规的第二中间层(40)的厚度为0.025-0.066mm，其使用的每根编织丝的厚度为0.013-0.0033mm。根据本发明的一个实施例，第二中间层(40)长度为1150-1400mm，基本等同第一中间层(30)的长度。根据另一个实施例，第二中间层(40)的长度为1100-1350mm，远小于第一中间层(30)的长度，这种第二中间层(40)仅覆盖第一中间层(30)的中间和近端部分，没有覆盖第一中间层(30)的远端部分。但是根据另一个实施例，第二中间层(40)在第一中间层(30)的远端处比第一中间层(30)短2cm，如图1B所示。

[0104] 继续参考图1B，根据一个实施例，高分子聚合物外层(50)放在第二中间层(40)外形成导管外层。根据一个实施例，外层(50)为原始管状配置，置于在第二中间层(40)外。然后整个导管轴(10)组件经受回流焊接过程，由此外层(50)和/或内层材料融化形成一根复合的导管主体(10)。根据一个实施例，外层(50)材料融化并流到第二中间层(40)的编织丝间隙以及第一中间层(30)，并黏附到导管轴(10)的内层(20)。本领域技术人员应该理解用于熔化外层(50)以与导管主体(10)的内层(20)形成粘结的温度是平衡的，以允许足够的材料流过金属丝之间的间隙，并且不会在导管轴(10)的内层(20)的内腔表面引入凹槽和狭道，凹槽和狭道则会影响导管内腔的顺滑性。

[0105] 根据一个实施例，外层(50)由单种材料，如尼龙或Pebax制成，有稳定的硬度。根据另一个实施例，外层(50)的硬度为25-80D(Shore 25-80D)，长度为20-500mm，外径为2.0-2.5mm，壁厚为0.025-0.13mm。根据一个实施例，外层(50)覆盖了两个中间层(30、40)的全长

和导管轴(10)的内层(20)的全长。

[0106] 现在参考图4，其示出了另外一个外层(50)的实施例。根据一个实施例，外层(50)有多段组成，每段为不同硬度的材料。例如，如图4所示，外层(50)的远端部分由超低硬度材料制成，如硬度约60A(HS)的TPU。外层(50)的近端部分由相对较高硬度的材料制成，如硬度约75D(HS)的尼龙。外层(50)的远端和近端中间的过渡段，是由相对高硬度的材料制成，如硬度在30D-63D范围内的Pebax。因此，低硬度远端外层使导管主体(10)组件具有优异的弹性，以穿过迂曲的小血管。外层(50)高硬度的近端段使导管轴(10)具有刚性和优异的操控性。过渡段实现了由远端超软段到近端刚性和支撑段渐变的转化。

[0107] 继续参考图4，根据一个实施例，外层(50)的远端段长为100-200mm，外层(50)的过渡段长度为10-30mm，外层(50)的近端段长为1000-1200mm。根据一个实施例，外层(50)的远端段、过渡段和近端段都有大致相同的厚度。

[0108] 根据本发明的另一个实施例，可以将附加的涂层添加到本发明中描述的导管组成中。例如，添加亲水涂层，以获得光滑表面，从而使得导管可以更轻松地在血管内输送。

[0109] 即使在上文中没有具体描述，本领域技术人员应该理解一个或多个不透射线标记点可有助于通过影像设备(例如荧光镜，X射线，CT扫描，核磁共振，超声成像)可视化。如本文披露的一个标记点可以施加到本发明的导管轴(10)任何部位。一个不透射线标记点可以粘接、锻打、压握或者其他方式安置、固定在到导管轴(10)内或其表面。不透射线标记点可以由钽、钨、铂、铱、铑、金、或这些材料的合金或其他本领域技术人员已知的材料制成。不透射线标记点也可以由多种顺磁性材料组成，该顺磁性材料包括一种或多种原子数为21-29、42、44以及58-70的元素，如铬(III)、镁(II)、铁(III)、铁(II)、钴(II)、铜(II)、镍(II)、锆(III)、锰(III)，钐(III)、锝(III)、钒(III)、钬(III)、钛(III)、铒(III)或者其他本领域技术人员知晓的核磁可见材料。

[0110] 本领域技术人员应该理解，即使以上表述的关于导管主体(10)的大多数示例实施例适用于颅内血管应用，本发明的示例实施例也可以用于任何其他合适的微创伤介入应用。例如，本发明的示例实施例可用于输送血管封堵装置，支架，抽吸(aspiration)，治疗缺血性中风的支架取栓器等等。在其它示例中，本发明的示例实施例可被用于精准输送植入物进入血管，如脑血管，畅通的血管，或者其他部位。

[0111] 前面的描述和相关附图提出了多个当前代表性的实施例。根据前述教导，在不脱离本发明的精神或超出本发明的范围的情况下，各种修改和替代设计对于本领域技术人员将是显而易见的，所述范围是由所附权利要求限定而不是由前述说明指示。所有落入本发明等同范围和意义下的改变和变化都被视为包含在本发明的范围内。

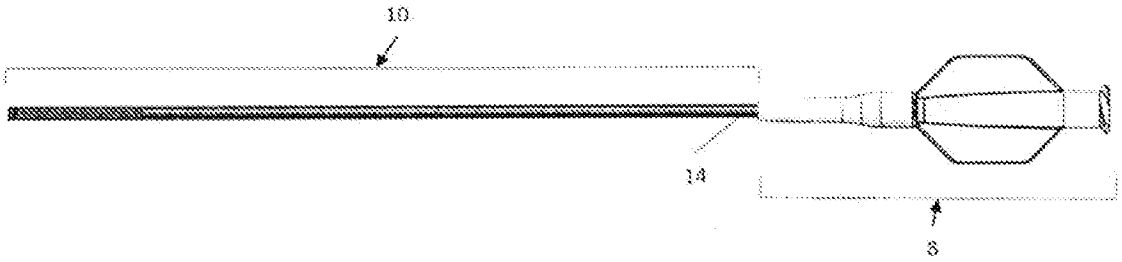


图1A

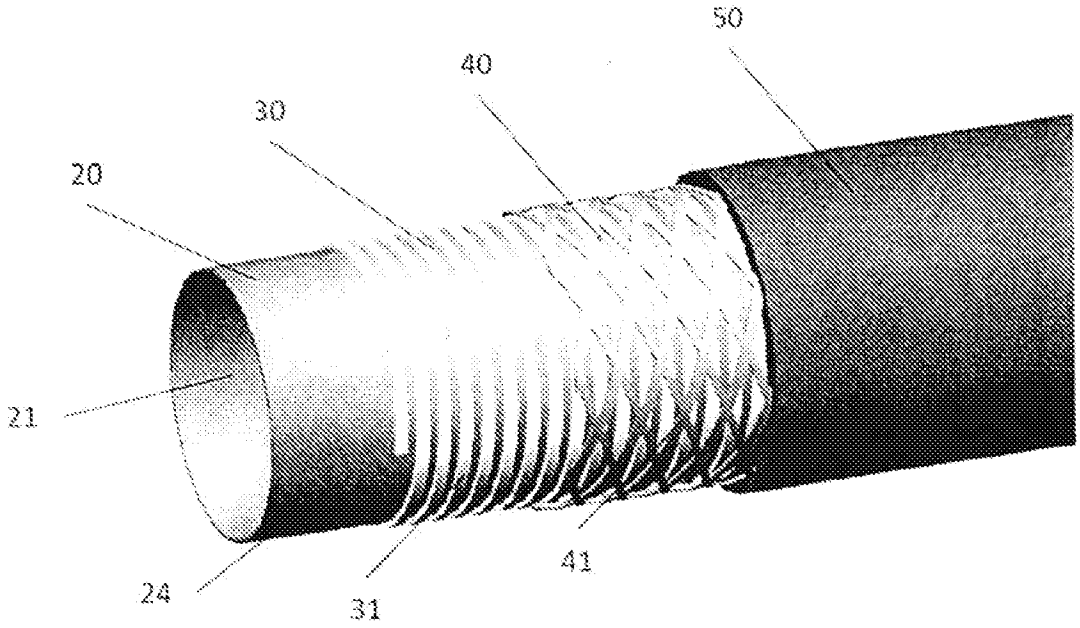


图1B

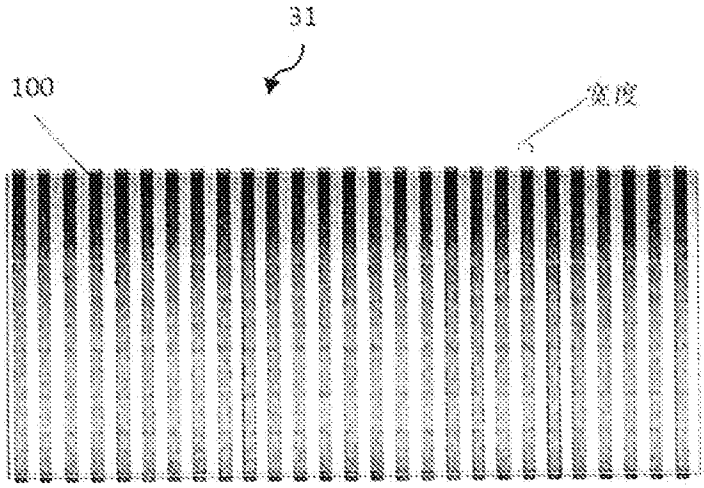


图2A

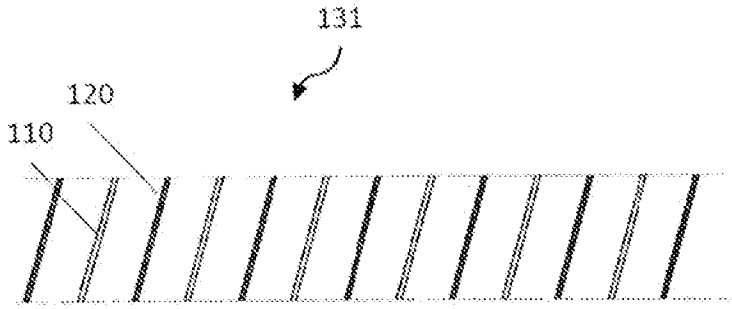


图2B

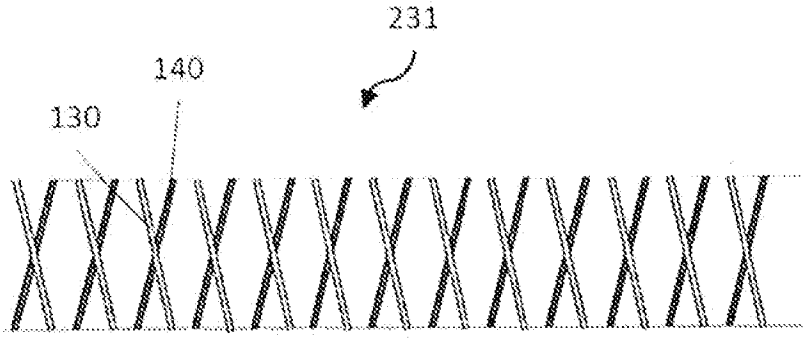


图2C

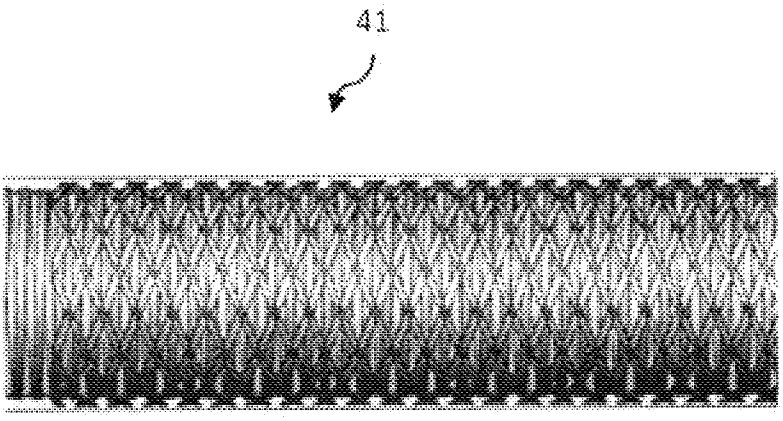


图3

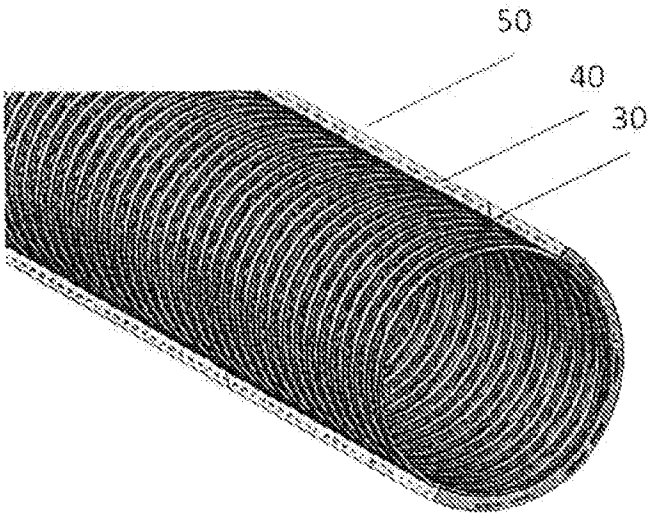


图4

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
6 April 2017 (06.04.2017)

WIPO | PCT

(10) International Publication Number
WO 2017/058280 A1

(51) International Patent Classification:
A61F 2/01 (2006.01)

(21) International Application Number:
PCT/US2016/017982

(22) International Filing Date:
15 February 2016 (15.02.2016)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:

62/284,300	28 September 2015 (28.09.2015)	US
62/284,752	8 October 2015 (08.10.2015)	US
62/245,560	23 October 2015 (23.10.2015)	US

(71) Applicant: **GW MEDICAL LLC** [US/US]; 5849 Corte Margarita, Pleasanton, CA 94566 (US).

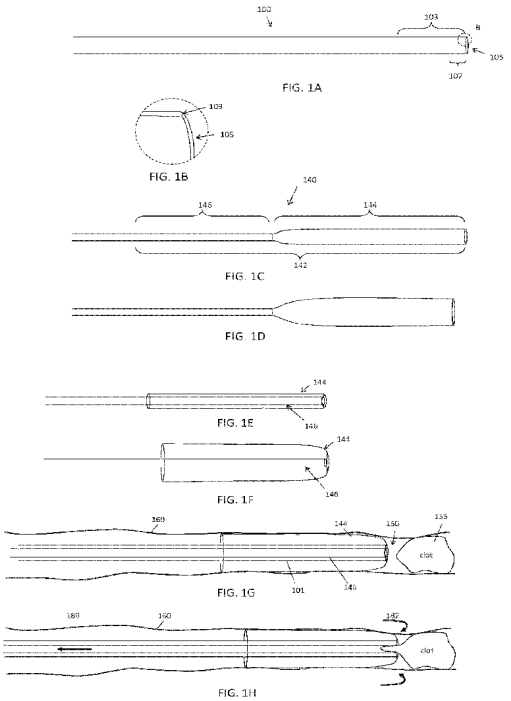
(72) Inventors: **GREENHALGH, E., Skott**; 5849 Corte Margarita, Pleasanton, CA 94566 (US). **WALLACE, Michael, P.**; 5849 Corte Margarita, Pleasanton, CA 94566 (US).

(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).

[Continued on next page]

(54) Title: MECHANICAL THROMBECTOMY APPARATUSES AND METHODS



(57) Abstract: Methods and apparatuses for mechanically removing objects from a body. In particular, described herein are thrombectomy methods and mechanical thrombectomy apparatuses for removal of blood clots from within a lumen of a blood vessel.

WO 2017/058280 A1

Published:

— *with international search report (Art. 21(3))*

MECHANICAL THROMBECTOMY APPARATUSES AND METHODS

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] This patent application claims priority to each of the following provisional patent applications, each of which is herein incorporated by reference in its entirety: U.S. Provisional Patent Application No. 62/284,300, filed September 28, 2015; U.S. Provisional Patent Application No. 62/284,752, filed October 8, 2015; and U.S. Provisional Patent Application No. 62/245,560, filed October 23, 2015.

INCORPORATION BY REFERENCE

[0002] All publications and patent applications mentioned in this specification are herein incorporated by reference in their entirety to the same extent as if each individual publication or patent application was specifically and individually indicated to be incorporated by reference.

FIELD

[0003] The apparatuses and methods described herein relate to mechanical removal of objects from within a body. In particular, described herein are mechanical thrombectomy apparatuses and methods.

BACKGROUND

[0004] It is often desirable to remove tissue from the body in a minimally invasive manner as possible, so as not to damage other tissues. For example, removal of tissue (e.g., blood clots) from the vasculature may improve patient conditions and quality of life.

[0005] Many vascular system problems stem from insufficient blood flow through blood vessels. One causes of insufficient or irregular blood flow is a blockage within a blood vessel referred to as a blood clot, or thrombus. Thrombi can occur for many reasons, including after a trauma such as surgery, or due to other causes. For example, a large percentage of the more than 1.2 million heart attacks in the United States are caused by blood clots (thrombi) which form within a coronary artery.

[0006] When a thrombus forms, it may effectively stop the flow of blood through the zone of formation. If the thrombus extends across the interior diameter of an artery, it may cut off the flow of blood through the artery. If one of the coronary arteries is 100% thrombosed, the flow of blood is stopped in that artery, resulting in a shortage of oxygen carrying red blood cells, e.g., to supply the muscle (myocardium) of the heart wall. Such a thrombosis is unnecessary to prevent loss of blood but can be undesirably triggered within an artery by damage to the arterial wall from atherosclerotic disease. Thus, the underlying disease of atherosclerosis may not cause acute oxygen deficiency (ischemia) but can trigger acute ischemia via induced thrombosis. Similarly, thrombosis of one of the carotid arteries can lead to stroke because of insufficient oxygen supply to vital nerve centers in the cranium. Oxygen deficiency reduces or prohibits muscular activity, can cause chest pain (angina pectoris), and can lead to

death of myocardium which permanently disables the heart to some extent. If the myocardial cell death is extensive, the heart will be unable to pump sufficient blood to supply the body's life sustaining needs. The extent of ischemia is affected by many factors, including the existence of collateral blood vessels and flow which can provide the necessary oxygen.

[0007] Clinical data indicates that clot removal may be beneficial or even necessary to improve outcomes. For example, in the peripheral vasculature, inventions and procedures can reduce the need for an amputation by 80 percent. The ultimate goal of any modality to treat these conditions of the arterial or venous system is to remove the blockage or restore patency, quickly, safely, and cost effectively. This may be achieved by thrombus dissolution, fragmentation, thrombus aspiration or a combination of these methods.

[0008] Catheter directed thrombectomy and thrombolysis are commonly perceived to be less traumatic, less likely to decrease the morbidity and mortality associated with conventional surgical techniques. In recent years, direct administration of chemical lysing agents into the coronary arteries has shown to be of some benefit to patients who have thrombosed coronary arteries. In this procedure, a catheter is placed immediately in front of the blockage and a drip of streptokinase is positioned to be directed at the upstream side of the thrombus. Streptokinase is an enzyme which is able in time to dissolve the fibrin molecule. This procedure can take several hours and is not always successful in breaking up the thrombus. Furthermore, it can lead to downstream thrombus fragments (emboli) which can lead to blockage of small diameter branches. U.S. Pat. No. 4,646,736 discloses a thrombectomy device that permits rapid removal of an obstructive thrombus. However, the device is characterized by small catheter tip size and thus is unable to exert significant total force on clot masses. Also, a clot which is not in good position of purchase on a vessel wall in the "line of fire" of the rotating wire is not fibrinectomized. This is especially true of clots floating free in the blood stream, since it is virtually impossible to revolve within these clots in the absence of a constraint such as fingers.

[0009] Further disadvantages to this thrombectomy device include the difficulty of keeping the clot in the space above the wire during all degrees of rotation as the wire is moved sideways during rotation, which is sometimes necessary to sweep the arterial lumen. In fact, sweeping out an entire arterial lumen with a rotating wire is virtually impossible in all but the smallest, i.e., less than 1.5 mm diameter, arteries. An additional and serious possible disadvantage is that fragments of the clot may be embolized downstream.

[0010] Another approach for capturing emboli is described in U.S. patent application 2015/0005781. This application describes a catheter with a basket extending from the distal end. An actuator, such as a rod or cable, can be pulled proximally to retract the basket into the catheter. Unfortunately, the basket occludes the inside of the lumen, preventing the concurrent use with a positioning and/or supporting guidewire, and the basket must be held in or near the distal end of the catheter. Depending on the stiffness of the material (e.g., clot) being removed, retrieval of the basket often collapses the distal end of the catheter, preventing its use, and the basket can be difficult to pull into the catheter, particularly when holding a clot. This may result in sheering the clot. Finally the basket must be preloaded into the distal

end of the catheter prior to insertion into the vessel, and preloading may be both difficult and time consuming, and may risk disrupting the device prior to deployment.

[0011] Thus, there is a definite need for a thrombectomy device, and particularly a mechanical thrombectomy device that can be more effective in removing tissue such as clots from within a body. Described herein are apparatuses (devices, systems and kit) and methods of using them, that may address the needs and problems discussed above.

SUMMARY OF THE DISCLOSURE

[0012] In general, described herein are medical apparatuses, including medical devices and systems including these medical devices, and methods of operating these medical devices, for collecting objects, including but not limited to blood clots (thrombi), tissue (biopsies, small tumors, polyps, calcifications, kidney stones, etc.). The apparatuses described herein typically include an elongate catheter having a lumen and a distal end and with a distal end opening into the lumen. The catheter may be low-profile neurovascular catheters (e.g., microcatheters, insertion catheters, etc.) having any appropriate diameter (e.g., <1 Fr, 1Fr-6Fr, 1Fr-9 Fr, etc.). A flexible tractor assembly or portion (e.g., which may be referred to herein as a flexible tractor tube or simply a flexible tube) is typically positioned and longitudinally slideable within the catheter, and arranged so that the distal end region ("distal tractor region") doubles back over the distal end of the catheter. The flexible tube ("tractor tube") is generally elongate and hollow and configured to slide and invert over the distal end opening when a first end of the flexible tube is pulled proximally within the catheter. The distal end forming the distal tractor region may be tubular or not (e.g., it may be formed of strips of material, etc.). The combined catheter and flexible tractor assembly also forms a guidewire lumen through the catheter and the flexible tube that is configured to pass a guidewire.

[0013] In use, a guidewire may be configured to slide through the apparatus (and may form part of the apparatus) to allow positioning and in some variations support, typically without interfering with the operation of the tractor tube drawing an object such as a blood clot into the body of the catheter.

[0014] In addition to the catheter having a flexible tractor tube that is arranged within the catheter and inverted or doubled over the distal end of the catheter, the apparatuses described herein may include one or more features or elements that permit these devices to operate within a vasculature without collapsing, particularly at their distal ends, despite applying a pulling moment over the distal edge/opening of the preferably quite soft distal end. Further, these apparatuses may be adapted to minimize the force required to withdraw the distal tractor region into the catheter and invert over the distal end opening of the catheter, without damaging or weakening the distal tractor region, preventing a failure mode in which the flexible tractor tube within the apparatus breaks, binds up, jams or tangles on its self or with the catheter. For example, as will be described in greater detail below, any of these apparatuses may include a selectively lubricious region at or near the distal end of the catheter. The catheter end may be shaped to allow inverting of the flexible tractor region of the distal end of the tube. In addition, the end profile of the catheter (e.g., the distal-most 5 mm, 4 mm, 3 mm, 2mm, 1mm, etc.)

may have an arrangement of stiffnesses (e.g., durometers) that prevent collapse/buckling of the catheter. Alternatively or additionally, the flexible tractor tube may be adapted for "sweeping" as much of the vessel around the catheter to collect objects from within the vessel while still allowing relatively low-force retraction into the catheter and inverting over the distal end of the catheter. The tractor portion of the flexible tube, which may refer to a distal portion of the tube within the catheter, may generally include a distal expandable (first) end region that is adjacent, either immediately adjacent or separated by a spacer region, to a second less-expandable (or non-expandable) end region. The second end region is proximal (when both the first end region and the second end regions are drawn into the catheter) to the first end region. The flexible tractor tube may extend all the way through the catheter to a proximal end and/or proximal handle, or it may end before the proximal end of the catheter and be connected to a puller. The puller may be another, possible less flexible tube, or a wire, rod, string, etc. The flexible tractor tube is generally configured to have a lumen through it (e.g., central lumen or radially offset lumen) through which a guidewire may be passed, passing through the apparatus, including the catheter and the flexible tractor tube. The flexible tractor tube may generally be operated (e.g., pulled proximally and in some variations pushed distally) while a guidewire is within this lumen.

[0015] The apparatus may be pre-loaded for deployment of the distal tractor region and capture of an object within a vessel, or in some variations it may be loaded *in vivo*, after or during positioning a guidewire and/or the catheter within a blood vessel. For example, in some variations, the apparatus may be adapted for use *in vivo* by holding the distal tractor region retracted into the catheter until the catheter is within the vessel, and preferably near the object to be removed. Once positioned, the distal tractor region of the flexible tube within the catheter may be distally extended from the catheter, expanded to form the capture shape that can be drawn and inverted over the distal end of the catheter either with or without advancing the catheter distally. Thus, the distal tractor portion may be safely and securely delivered to the necessary site within the lumen without risk to damage to the apparatus or the body.

[0016] For example, a method of performing a mechanical thrombectomy to remove a clot from a blood vessel may include: advancing a distal end of a catheter through the blood vessel towards the clot; exposing a distal tractor region of a tube that is within the catheter from the distal end of the catheter, wherein the distal tractor region comprises an expandable first end region and a less expandable second end region proximal to the expandable first end region; allowing the expandable first end region to expand within the blood vessel; positioning the distal end of the catheter so that a distal end region of the catheter is between the less expandable second end region and the expandable first end region of the distal tractor region while the expandable first end region is doubled over the less expandable second end region; and drawing the clot into the catheter by rolling the expandable first end region rolls over the distal end of the catheter so that the expandable first end region inverts as the expandable first end region is pulled into the catheter.

[0017] The step of advancing the distal end of the catheter through the blood vessel towards the clot may include advancing over a guidewire, as mentioned. The catheter may be slid distally over the guidewire or extended distally (or retracted proximally) with the guidewire. The inner (tractor) tube may

be held within the catheter (e.g., near the distal end, a middle region, or near the proximal end) or in some variations it may be inserted after positioning the catheter within the vessel. The distal end of the catheter may be positioned at, near or adjacent the object to be removed (e.g., the clot), or it may be separated by a predetermined distance, e.g., to allow space for the apparatus to set up by extending the distal tractor region out of the distal end of the catheter and expand in preparation for withdrawing the object into the catheter.

[0018] Thus, once positioned, the apparatus may be deployed by exposing the distal tractor region and positioning the distal end of the catheter and in some variations the guidewire, to allow the object to be captured and drawn into the catheter. The distal tractor region may be exposed by pulling the catheter proximally while either holding the flexible tube including the distal tractor region stationary (e.g., relative to the blood vessel) and/or by extending the flexible tube distally.

[0019] As mentioned, the flexible tube may include a distal tractor region that includes a first end region that is expandable. This end region is generally porous (e.g., formed of a mesh, knit, woven, or other material, including solid material having multiple openings therethrough) and adapted to grab the object (e.g. clot) to be removed. This first end region is generally expandable to between about 1.3x and about 10x the inner diameter of the catheter (e.g., between about 1.5 and about 7x, between about 1.5x and about 5x, between about 1.5 and about 4x, between about 1.5x and about 3x, etc.). This first distal end region forming the tractor portion is generally adjacent to the second end region that is less expandable (or not substantially expandable). The second region may extend proximally all the way down the catheter, or partially down the catheter. In general, the first end region of the tractor portion is exposed from out of the catheter and used to capture the clot or other object; the second end region may be exposed during positioning but may otherwise remain within the catheter during operation.

[0020] Thus, exposing a distal tractor region of a tube that is within the catheter from the distal end of the catheter may include extending or pushing the distal tractor region out of the distal end of the catheter. In some variations the distal tractor region is pre-formed so that the first expandable distal end region is doubled over the second distal end region; in other variations the first distal end region is in-line, distal to, the less expandable second distal end region. The catheter may then be moved distally so that a distal end region of the catheter (including the distal end) is extended in a gap radially between the expanded expandable first end region of the distal tractor region and the less-expandable second end region.

[0021] In any of the variations in which the distal tractor region is pushed out of the distal end of the catheter, e.g., during this initial *in vivo* set up phase, the flexible tube, and particularly the distal tractor region, may be configured or otherwise adapted to allow pushing out of catheter without binding up. Binding within the catheter of an expandable tube may occur if the expandable first end region in particular becomes caught on the inner walls of the catheter, preventing deployment. In some variations the expandable first end region is configured as a mesh tubular member having filaments (e.g. Nitinol, polymeric, etc.) having between about 24 to 144 stands, having a thickness of 0.0005 inches to 0.005 in diameter, wherein the mesh tubular member extends in a longitudinal axis, further wherein the mesh

tubular member has a length that is greater than 5 cm, forms a braid angle between crossing strands in a direction of the longitudinal axis of about 35 degrees or less when being pulled and inverted around the distal end of the catheter and expands to a diameter of greater than 1.5 times an inner diameter of the catheter outside of the catheter when unconstrained. Within this configuration, the tubular member has been found to be pushable.

[0022] In other variations, when the expandable first distal end region is pushed or extended out of the distal end of the catheter, it may be configured (e.g., pre-shaped, shape-set, etc.) to invert over the distal end of the catheter and expand. The catheter may be moved distally, aiding in pushing this expandable first end region of the distal tractor region proximally relative to the outside of the catheter.

[0023] In any of these methods, the distal tractor region may include the expandable first end region and a less expandable second end region proximal to the expandable first end region, and the expandable first end region is permitted to expand within the blood vessel.

[0024] Thus, towards the end of the deployment phase, the distal end of the catheter is typically positioned so that the distal end region of the catheter is radially between the less expandable second end region and the expandable first end region of the distal tractor region while the expandable first end region is doubled over the less expandable second end region.

[0025] Thereafter, an object (e.g., clot) may be drawn into the catheter by rolling the expandable first end region over the distal end of the catheter so that the expandable first end region inverts as the expandable first end region is pulled into the catheter.

[0026] As mentioned, positioning may include distally advancing the distal end of the catheter so that the distal end region of the catheter is between the less expandable second end region and the expandable first end region of the distal tractor region.

[0027] A guidewire may be used with any of the methods described herein. For any of the methods described herein may include advancing a guidewire within the blood vessel to the clot, wherein advancing the distal end of the catheter comprises advancing the catheter over the guidewire through the blood vessel until the distal end of the catheter is proximate to the clot. The guidewire may be inserted into or through the clot, or it may be positioned just before the clot. The guidewire may be left in during clot removal, or it may be partially or completely withdrawn first. For example, any of these methods may include advancing a guidewire within the blood vessel to the clot, wherein advancing the distal end of the catheter comprises advancing the catheter over the guidewire through the blood vessel until the distal end of the catheter is proximate to the clot, further wherein drawing the clot into the catheter comprises advancing the catheter towards the clot over the guidewire while rolling the expandable first end region over the distal end of the catheter.

[0028] Drawing the clot into the catheter generally includes rolling the distal tractor region (e.g., the expandable first end region) over the distal end of the catheter. The apparatus may also be moved distally during actuation of the distal tractor region. For example, drawing the clot into the catheter may include withdrawing the tube proximally (to roll the distal tractor region over the distal end) and/or withdrawing the tube proximally while advancing the catheter distally.

[0029] In any of these methods, drawing the clot into the catheter may include withdrawing the tube proximally while advancing the catheter distally, wherein the tube is withdrawn at a different rate than the catheter is advanced. It may be beneficial in some configurations to advance the catheter distally more rapidly than the tube (distal tractor region) is drawn proximally. In some variations, the catheter may be advanced more slowly than the tube (distal tractor region) is withdrawn proximally. Alternatively in some variations, they are moved at the same rate. The rate of motion may be determined for the flexible tube by looking at the proximal motion (e.g., of the second end region) within the catheter.

[0030] In general the expandable first end region of the distal tractor region is expandable and may form a distal-facing mouth or lip that can engage with an object such as a clot. The mouth of lip of the expandable tractor region may form a tangent angle or roll angle (as described below in greater detail in reference to FIGS. 18 and 21D) with respect to the long axis of the catheter outer diameter (OD) in the range of 5-60 degrees and preferable at least 10 degrees (e.g., 10°-60°, 10°-50°, 10°-45°, etc.). As long as the roll angle is at least 10 degrees with the tube is retracted into the catheter, the tube should not bind or jam on the catheter tip. The mesh tube may be constructed by modifying is stiffness to ensure the roll angle in greater than 10 degrees. Alternatively or in combination to maintaining a minimum roll angle it may be desirable to maintain a physical space or gap between the tube material ID and the O.D of the catheter (as described in greater detail in FIG. 18, below) at the catheters most distal tip. The gap may need to be greater than, e.g., 0.1, mm 0.2 mm, 0.3 mm, 0.4 mm, 0.5 mm, 0.7 mm, 0.8 mm, 0.9 mm, 1.0 mm, etc. to ensure the tube rolls around the distal end of the catheter when the tube is retracted. The expanded material (e.g., a mesh, woven, braided, kitted, perforated, etc. material) may be allowed to expand within the blood vessel by itself. Thus the expandable first region may be self-expandable. The expandable first end region of the distal tractor region may be pre-biased to expand. In some variation a shape memory material (e.g., shape memory alloy) is used. In some variations a biasing element is included in or integral to the expandable first end region to expand so that the distal tractor region. The expandable first end region may expand to make contact with an intima of the blood vessel. In some variations the apparatus may be configured (e.g., sized, including sizing the expandable first end region) so that the distal-most end of the distal tractor region makes contact with the vessel lumen. Thus, any of the variations described herein may additionally or alternatively include a biasing element such as a loop, ring, scaffold, or the like to push the expandable distal end region open so that it can make contact with the vessel by applying an increased radial force to expand it open. In some variations this opening bias (loop, helix, ring, etc.) is located at or near the distal end of the expandable first end region of the distal tractor region.

[0031] Any of the variations described herein may include an expandable catheter tip. For example, in some variation the durometer of the catheter tip may be sufficiently soft to compress proximally when the distal tractor region is drawn proximally into the catheter; compressing the distal tip axially may expand it slightly (e.g., so that it may flare out) at the distal end.

[0032] As mentioned, exposing the distal tractor region of the tube that is within the catheter from the distal end of the catheter may comprise pushing the distal tractor region out of the distal end of the

catheter. Alternatively or additionally, exposing the distal tractor region of the tube that is within the catheter out of the distal end of the catheter may comprise pulling the catheter proximally. For example, exposing the distal tractor region of the tube that is within the catheter from the distal end of the catheter may comprise pushing the distal tractor region out of the distal end of the catheter to expose the expandable first end region already inverted over the less expandable second end region.

[0033] In some variations, exposing the distal tractor region of the tube that is within the catheter from the distal end of the catheter comprises extending the expandable first end region out of the distal end of the catheter so that the expandable first end region inverts over the distal end of the catheter as the expandable first end region is extended.

[0034] The expandable first end region of the distal tractor region may be any appropriate length, and any portion of this length (all of it, 90%, 80%, 70%, 60%, 50%, 40%, etc.) may be exposed during this set-up period. For example, in some variations, exposing the distal tractor region of the tube may comprise exposing at least 5 mm of the expandable first end. The expandable first end region may be, e.g. 5 mm or greater (e.g., 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 25, 30, 35, 40, 45, 50, 55, 60, 70, 80, 90, 100, 110, 120, 130, 140, 150, 200, 300, 400, 500 mm, etc. between about 5 mm and 500 mm, between about any lower value of 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 25, 30, 35, 40, 45, 50, 55, 60, 70, 80, 90, 100, 110, 120, 130, 140, 150, 200 mm and any larger value of 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 25, 30, 35, 40, 45, 50, 55, 60, 70, 80, 90, 100, 110, 120, 130, 140, 150, 200, 300, 400, 500 mm, where the lower value is always lower than the larger value). In any of these variations, when exposing the distal tractor region, either just the expandable first distal end region may be exposed out of the catheter (e.g., when pushing the expandable distal end region out distally and allowing it to invert over the distal end of the catheter) or both the expandable first distal end region and the less expandable second distal end region may all or partially exposed. For example, exposing at least 1 cm of the expandable first end region and at least 1 cm of the less expandable second end region. The expandable first end region may be inverted (doubled back) over the less expandable second end region.

[0035] As mentioned, the expandable first end region may comprise any appropriate material that is both expandable and able to grip the object (e.g., clot). For example the expandable first end region of the distal tractor region may comprise a mesh that is coupled adjacent to the less expandable second end region. For example the expandable first end region may be one or more of: a woven material, a mesh braided material, a knitted material, or a film material with multiple openings therethrough. The less expandable second end region may be made of the same material or it may be made of a different material. The less expandable second end region may have the same structure (e.g., woven, etc.) or it may have a different structure, including a less-expandable variation of the structure of the expandable first end region. For example the less expandable second end region may be a non-porous (e.g. non-woven, non-knitted, etc. or solid material) or less porous (e.g., tightly woven, small pore size knitted holes, tight braid). In some variation the less expandable second end region may include a transition region between the expandable first end region (e.g., having an intermediate expandability) and a non-expandable portion

of the second end region. In general, the less expandable second end portion of the distal tractor region include non-expandable structures and materials.

[0036] A method of performing a mechanical thrombectomy to remove a clot from a blood vessel may include: advancing a distal end of a catheter through the blood vessel towards the clot; exposing a distal tractor region of a tube that is within the catheter from the distal end of the catheter, wherein the distal tractor region comprises an expandable first end region and a less expandable second end region proximal to the expandable fist end region and configured so that the expandable first end region is inverted over the less expandable second end region; allowing the expandable first end region to expand within the blood vessel so that the distal end region of the catheter is between the less expandable second end region and the expandable first end region of the distal tractor region; and drawing the clot into the catheter by advancing the catheter distally and withdrawing the tube proximally within the catheter so that the expandable first end region rolls over the distal end of the catheter and inverts as the expandable first end region is pulled into the catheter.

[0037] As mentioned, the expandable first end region may be inverted over the less expandable second end region before exposing the distal tractor region. Alternatively, exposing the distal tractor region may include inverting the expandable distal end region over the less expandable second end region as the distal tractor region is exposed. In general, exposing the distal tractor region of the tube that is within the catheter from the distal end of the catheter may include pushing the distal tractor region out of the distal end of the catheter. Exposing the distal tractor region of the tube that is within the catheter out of the distal end of the catheter may include pulling the catheter proximally.

[0038] A method of performing a mechanical thrombectomy to remove a clot from a blood vessel may include: advancing a distal end of a catheter through the blood vessel towards the clot; exposing a distal tractor region of a tube that is within the catheter out of the distal end of the catheter, wherein the distal tractor region comprises an expandable first end region and a less expandable second end region, wherein exposing comprises extending the expandable first end region out of the distal end of the catheter so that the expandable first end region inverts over the distal end of the catheter as the expandable first end region is extended; allowing the expandable first end region to expand within the blood vessel as it is extended out of the distal end of the catheter so that a distal end region of the catheter is between the less expandable second end region and the expandable first end region; and drawing the clot into the catheter by withdrawing the tube proximally within the catheter so that the expandable distal end region rolls over the distal end of the catheter, collapses, and inverts as the expandable distal end region is pulled into the catheter. Exposing the distal tractor region of the tube that is within the catheter from the distal end of the catheter may include pushing the distal tractor region out of the distal end of the catheter. Alternatively or additionally, exposing the distal tractor region of the tube that is within the catheter out of the distal end of the catheter may include withdrawing the catheter proximally relative to the distal tractor region of the tube.

[0039] Also described herein are mechanical thrombectomy devices for removing a clot from a vessel, the device comprising: a catheter having a distal end and a distal end opening, wherein the catheter

has an inner diameter and an outer diameter; a distal tractor region of a tube within the catheter, wherein the distal tractor region comprises an expandable distal end region and a less expandable distal end region proximal to the expandable distal end region, the distal tractor region configured so that the expandable distal end region is inverted over the less expandable distal end region; a guidewire lumen through the catheter and the tube, including the distal tractor region, wherein the guidewire lumen is configured to pass a guidewire; and a proximal handle coupled to the tube and configured to cause relative motion between the catheter and the tube such that the distal tractor region is released from within the inner diameter of the catheter so that the expandable distal end region may expand to a diameter that is greater than the outer diameter so that the catheter may be advanced between the expandable distal end region and the less expandable distal end region and the tube may be drawn proximally to pull the expandable distal end region over the distal end of the catheter so that the expandable distal end region rolls into the distal end of the catheter, inverts, collapses and is drawn into the catheter.

[0040] For example, a mechanical thrombectomy device for removing a clot from a vessel may include: a catheter having a distal end and a distal end opening, wherein the catheter has an inner diameter and an outer diameter; a tube having a distal tractor region within the catheter, wherein the distal tractor region comprises an expandable distal end region and a less expandable distal end region that is proximal to the expandable distal end region, further wherein the expandable distal end region is biased to invert over the less expandable distal end region as it is exposed from the distal end of the catheter; a guidewire lumen through the catheter and the tube, including the distal tractor region, wherein the guidewire lumen is configured to pass a guidewire; and a proximal handle coupled to the tube and configured to cause relative motion between the catheter and the tube such that the distal tractor region is released from within the inner diameter of the catheter so that the expandable distal end region may expand to a diameter that is greater than the outer diameter and the tube may be drawn proximally to pull the expandable distal end region over the distal end of the catheter so that the expandable distal end region rolls into the distal end of the catheter, inverts, collapses and is drawn into the catheter.

[0041] Also generally described herein are mechanical thrombectomy apparatuses. For example, described herein are mechanical thrombectomy apparatus for removing a clot from a vessel, including: a catheter having a distal end and a distal end opening; a flexible tube extending within the catheter and doubling back over the distal end of the catheter, wherein the flexible tube is configured to slide and invert over the distal end opening when a first end of the flexible tube is pulled proximally within the catheter; and a guidewire lumen through the catheter and the flexible tube that is configured to pass a guidewire.

[0042] A mechanical thrombectomy apparatus for removing a clot from a vessel may include: a catheter having a distal end and a distal end opening, wherein the distal end opening has a durometer that is greater than a durometer of a region immediately proximal to the distal end, further wherein the distal end opening has a rounded lip profile; a flexible tube extending within the catheter and doubling back over the distal end of the catheter, wherein the flexible tube is configured to invert over the distal end opening when a first end of the flexible tube is pulled proximally within the catheter; and a guidewire

lumen through the catheter and the flexible tube configured to pass a guidewire. The catheter distal end durometer may be greater than 60A shore hardness or greater than 40D shore hardness.

[0043] A mechanical thrombectomy apparatus for removing a clot from a vessel that include: an inner catheter having a distal end and a distal end opening; a flexible tube extending though the catheter and doubling back over the distal end of the inner catheter, wherein the flexible tube is configured to invert over the distal end opening when a first end of the flexible tube is pulled proximally within the inner catheter; an outer catheter extending over the inner catheter and flexible tube; a lubricious region of the flexible tube extending between a distal end of the outer catheter and the distal end opening of the inner catheter, wherein the majority of the flexible tube is not lubricious; and a guidewire lumen through the catheter and the flexible tube configured to pass a guidewire.

[0044] A mechanical thrombectomy apparatus for removing a clot from a vessel may include: an inner catheter having a distal end and a distal end opening; a flexible tube extending though the catheter and doubling back over the distal end of the inner catheter, wherein the flexible tube is configured to invert over the distal end opening when a first end of the flexible tube is pulled proximally within the inner catheter; a releasable attachment between the flexible tube and an outer surface of the catheter, configured to release when the flexible tube is pulled with a predetermined force (e.g., that is greater than 0.01 N); and a guidewire lumen through the catheter and the flexible tube configured to pass a guidewire.

[0045] A mechanical thrombectomy apparatus for removing a clot from a vessel may include: a catheter having a distal end, a distal end opening and an inner diameter; a flexible tube extending through the catheter and doubling back over the distal end of the catheter, wherein the flexible tube is configured to invert over the distal end opening when a first end of the flexible tube is pulled proximally within the catheter, the flexible tube having a low Poisson's ratio, such that the flexible tube has a diameter of greater than half the inner diameter of the catheter when pulled proximally within the catheter with sufficient force to invert over the distal end opening; and a guidewire lumen through the catheter and the flexible tube configured to pass a guidewire. The flexible tubes having a low Poisson's ratio may be less than 0.5 or in the range of 0.05 to 0.5 or 0.1 to 0.3.

[0046] As already mentioned above the flexible tube typically includes the distal tractor region having an expandable first end region and a less- (or non-) expandable second end region proximally adjacent to the first end region. Thus, the flexible tube may comprise a mesh tube.

[0047] In general, the catheters forming part of the apparatuses described herein are highly flexible, as would be appropriate for the tortious paths taken, e.g. by neurovascular catheters. In some variations, the aggregate stiffness of the assembled apparatus (having the flexible tube wrapped over the distal end and ready for operation) is within a predetermined percentage (e.g., within 10%, within 12%, within 15%, within 16%, within 17%, within 18%, within 19%, within 20%, within 25%, within 30%, etc.) of the original stiffness of the catheter without the flexible tube. For example, the flexible tube extending through the catheter and doubling back over the distal end of the catheter may increases the stiffness of a distal 5cm of the catheter by less than a predetermined percentage (e.g., 15%) of the stiffness of the distal

5 cm of the catheter without the flexible tube extending therethrough and doubling back over the distal end of the catheter.

[0048] In any of the variations described herein, the distal tractor region of the flexible tube is adapted to grab an object, e.g., clot. In particular, the flexible tube may be porous or have at least one porous section having a pore pattern having a longitudinal separation between pores of less than a predetermined distance (e.g., about 0.005 inches) in width. As used in this example "pores" includes windows, openings, gaps, etc. between strands of mesh (weave, etc.) as well as pores formed through a solid sheet of material. In general, for woven (and particularly braided) expandable first end region materials, smaller filaments may be better at grabbing, and therefore smaller pore sizes may be preferred. The optimal sizing may depend on the material, including filament size, pore percentage, size of the spacing of pores, pore diameters, etc. For example, in some variations it is beneficial to have a porosity of greater than >60% (greater than 70%, greater than 75%, greater than 80%, greater than 85%, etc., between 60-95, 65-95, 70-95%, etc.) and a fiber diameter (for woven materials) that is <0.005. The effective pore size of the flexible tubular member required to make sure the clot or foreign body is grabbed may range from 50 to 1000 micrometers (μm), or in the range of 100-200μm, 100-300μm, 100-500μm or 500-1000 μm. The flexible tubular member may have a variety of pore sizes along its length.

[0049] In general, as used herein a woven material includes any material formed by weaving multiple strands of material in an interlacing pattern (e.g., interlacing strands, filaments, lengths of material, etc.). A mesh is one type of woven material. A woven material is typically more stretchable/expandable in certain directions (on the bias directions) depending on the elasticity of the material forming the weave. Woven materials are typically run in parallel or nearly parallel paths. A knitted material may be more flexible and generally refers to a single path or course that is meandering, forming loops that may be symmetrically arranged and interlocking. Woven material may be highly stretchable/flexible. Knitted constructs tend to be less stretchable but yet still highly flexible.

[0050] In any of the apparatuses described herein, and particularly the pre-loaded or pre-formed versions, the apparatus may include a releasable attachment between the flexible tube and an outer surface of the catheter, configured to release when the flexible tube is pulled with a force that is greater than a predetermined force threshold. For example, the releasable force threshold may be greater than about 0.001 N, greater than about 0.005 N, greater than about 0.01 N, greater than about 0.03 N, greater than about 0.05 N, greater than about 0.08 N, greater than about 0.1 N, greater than about 0.3 N, greater than about 0.5 N, etc.).

[0051] In any of the apparatuses described herein, the flexible tube may comprise a plurality of strips of flexible material, wherein the strips are arranged in parallel with the long axis of the flexible tube. Alternatively or additionally, in any of these variations, the distal end opening may comprise a plurality of notches or channels into which fibers or strips forming the flexible tube are drawn as the flexible tube inverts over the distal end opening.

[0052] In any of the apparatuses described herein, the flexible tube may comprise a polymeric tube having a plurality of holes therethrough. For example, the flexible tube may comprise a distal end, a

proximal end and a body region there between, wherein the body region transitions from a more flexible distal end to a stiffer proximal end.

[0053] As mentioned above, in any of the variations described herein, the distal end of the catheter (e.g., the distal opening region) may be adapted to prevent collapsing when inverting the distal tractor region over the catheter opening but still be soft enough to provide appropriate use for neurovascular applications. For example, any of the apparatuses described herein may have a durometer at the distal end (e.g., at the distal end opening/rim) that is greater than a durometer of a region immediately proximal to the distal end. Any of these distal end openings may have a rounded lip profile. In general, though the durometer of the distal end region may decrease (becoming 'softer') the durometer of the very distal end (the opening) may be high. This, along with a rounded end shape, may reduce the force needed to invert the distal tractor region (e.g., the expandable first end region) as it is drawn into the catheter, while preventing collapse of the distal end region of the catheter.

[0054] Any of the apparatuses described herein may also include a handle adapted to draw the flexible tube proximally relative to the catheter. The handle may be attached or attachable to the catheter and/or the flexible tube and may include separate controls for actuating each independently or, more preferably, in a coordinated manner (or toggle between these two modes). For example, any of these apparatuses may include a drive handle coupled to a proximal end region of the catheter, wherein the drive handle comprises a control configured to coordinate advancing of the catheter distally while retracting the flexible tube proximally when actuated.

[0055] Any of these apparatuses may also include an outer catheter extending over the catheter and flexible tube. The outer catheter may extend over the catheter and the flexible tube and may keep an external portion of the distal tractor region (outside of the catheter) collapsed until it has been delivered. Any of these apparatuses may include a lubricious region of the flexible tube extending between a distal end of the outer catheter and the distal end opening, wherein the majority of the flexible tube is not lubricious. This lubricious region may reduce the initial force required to start actuating the apparatus.

[0056] In any of the apparatuses described herein, the flexible tube may be configured to invert over the distal end opening when a first end of the flexible tube is pulled proximally within the catheter and the flexible tube may have a low Poisson's ratio such that the flexible tube (which may be a mesh tube) may have a diameter of greater than half the inner diameter of the catheter when pulled proximally within the catheter with sufficient force to invert over the distal end opening.

[0057] Any of these apparatuses may include a puller (e.g., an elongate puller) within the catheter and coupled to a distal end of the flexible tube. The puller is typically configured to draw the flexible tube proximally, though in some variation it may also move it distally. For example, any of these apparatuses may also include an elongate puller within the catheter and coupled to a distal end of the flexible tube, wherein the elongate puller comprises a hypotube having an inner lumen that is continuous with the guidewire lumen though the flexible tube.

[0058] As mentioned, in some variations, the flexible tube comprises a soft outer mesh that is pushable. For example the distal tractor region (and particularly the expandable first end region) may be

formed from 24 to 144 stands, having a thickness of 0.0020 inches or less in diameter, wherein the mesh tubular member extends in a longitudinal axis, further wherein the mesh tubular member has a length that is greater than 5 cm, forms a braid angle between crossing strands in a direction of the longitudinal axis of about 35 degrees or less when being pulled and inverted around the distal end of the catheter and expands to a diameter of greater than 1.5 times an inner diameter of the catheter outside of the catheter when unconstrained.

[0059] When the flexible tube is formed of strands (e.g., woven, braided, etc.) the strands may be formed of any of the following; monofilament polymer, multifilament polymer, NiTi filament, NiTi tube with radiopaque metallic center, Cobalt chromium alloy filament, Cobalt chromium alloy tube with radiopaque metallic center, Nylon, Polyester, Polyethylene terephthalate, and Polypropylene.

[0060] As mentioned, any of these apparatuses may be configured so that the flexible tube (e.g., expandable distal end region) are releasably held onto the catheter. For example any of these apparatuses may include a retaining ring around a distal end region of the flexible tube configured to releasably hold the flexible tube against the catheter.

[0061] In any of these variations, the flexible tube may be shape set to have different diameter when within the catheter after being pulled proximally into the catheter. In general, the flexible tube may include a plurality of woven or one (or more) knitted filaments. In some variations the entire (or majority of the) flexible tube is formed of a woven or knitted filament(s), and the proximal end of the flexible tube may form a tapered opening opposite from a filament or bundle of filaments forming a pull wire. Alternatively or additionally, the flexible tube may be formed from a sleeve of polymer having a thickness less than 0.020 inches, wherein the sleeve comprises a perforation pattern in which the perforations extend through the polymer. The perforation pattern may comprise perforations having a shaped consisting of one or more of: round holes, rectangular holes and zig-zag shapes.

[0062] Any of these apparatuses may include a pull wire coupled to one side of a proximal end of the flexible tube configured to be drawn proximally to pull the flexible tube within the catheter.

[0063] In general, the flexible tube may be any appropriate length. For example, the flexible tube may be between 3 to 200 cm (e.g., between 3 to 150 cm, 3 to 100 cm, 3 to 50 cm, etc.).

[0064] In any of the apparatuses described herein, the flexible tube of the apparatus may be configured so that the flexible tube may be retracted into the catheter by applying less than a predetermined amount of force (e.g., 500 grams of force, 450 grams of force, 400 grams of force, 350 grams of force, 300 grams of force, 250 grams of force, 200 grams of force, 150 grams of force, etc.) to a distal end of the flexible tube.

[0065] In any of these variations, the flexible tube may include a taper between the first end and a second end of the flexible tube. In some variations, the flexible tube may extend within the entire length of the catheter so that a proximal end of the flexible tube is configured to be pulled proximally away from the proximal end of the catheter to slide and invert the flexible tube over the distal end opening.

[0066] Any of the apparatuses described herein may also include a vacuum source. For example any of these apparatuses may include a guidewire vacuum pump coupled to a proximal end of the guidewire

lumen and configured to apply vacuum therethrough. For example, any of these apparatuses may include an outer catheter vacuum pump coupled to a space between the catheter and the flexible tube and configured to apply a vacuum within a lumen of the catheter between an inner wall of the catheter and the flexible tube.

[0067] As mentioned, the apparatus may include a puller, wherein a distal end of the flexible tube is coupled to a distal end of the puller. An outer catheter may be arranged over the catheter adjacent to a proximal end of the flexible tube. Any of these apparatuses may also include a handle having a control configured to coordinate advancing of the outer catheter to push the proximal end of the flexible tube distally and pulling the puller proximally to drawn the proximal end of the flexible tube into the catheter. For example, an apparatus as described herein may include: a puller, wherein a distal end of the flexible tube is coupled to a distal end of the puller; an outer catheter slideably arranged over the catheter coupled to a proximal end of the flexible tube; and a handle having a control configured to coordinate advancing of the outer catheter distally to push the proximal end of the flexible tube distally while pulling of the puller proximally to drawn the proximal end of the flexible tube into the catheter or pulling the outer catheter proximally to pull the proximal end of the flexible tube proximally while pushing of the puller distally to push the proximal end of the flexible tube out of the catheter.

[0068] Also described herein are methods of mechanically removing a thrombectomy including: advancing a guidewire at least to the proximal end of a clot in a blood vessel; advancing a thrombectomy (e.g. clot removal) apparatus distally over the guidewire, wherein the thrombectomy apparatus comprises a catheter having a distal end and a distal end opening and a flexible tube extending along an outer diameter of the catheter and over the distal end of the catheter, so that the guidewire passes through a lumen of the catheter and the flexible tube; pulling the flexible tube proximally from off of the outer diameter of the catheter and into the catheter lumen so that the flexible tube slides and inverts over the distal end opening; and drawing a clot into the inverted flexible tube as the flexible tube is drawn into the catheter.

[0069] A method of mechanically removing a thrombectomy may include: advancing a guidewire adjacent a clot in a blood vessel; advancing a thrombectomy apparatus distally over the guidewire, wherein the thrombectomy apparatus comprises a catheter having a distal end and a distal end opening and a flexible tube extending along an outer diameter of the catheter and over the distal end of the catheter, so that the guidewire passes through a lumen of the catheter and the flexible tube; pulling the flexible tube proximally from off of the outer diameter of the catheter and into the catheter lumen over a rounded lip of the distal end opening of the catheter so that the flexible tube slides and inverts over the distal end opening, wherein the distal end opening has a durometer that is greater than a durometer of a region immediately proximal to the distal end; and drawing a clot into the inverted flexible tube as the flexible tube is drawn into the catheter.

[0070] A method of mechanically removing a thrombectomy may include: advancing a guidewire adjacent a clot in a blood vessel; advancing a thrombectomy apparatus distally over the guidewire, wherein the thrombectomy apparatus comprises an inner catheter having a distal end and a distal end

opening, a flexible tube extending along an outer diameter of the inner catheter and over the distal end of the catheter, and an outer catheter securing a distal end region of the flexible tube against the outer diameter of the inner catheter, so that the guidewire passes through a lumen of the catheter and the flexible tube; pulling the flexible tube proximally from off of the outer diameter of the catheter and into the catheter lumen so that a lubricious proximal leader region of the flexible tube slides and inverts over the distal end opening, until a non-lubricious distal region of the flexible tube is drawn into the inner catheter; and drawing a clot into the inverted flexible tube as the flexible tube is drawn into the catheter.

[0071] A method of mechanically removing a thrombectomy may include: advancing a guidewire adjacent a clot in a blood vessel; advancing a thrombectomy apparatus distally over the guidewire, wherein the thrombectomy apparatus comprises a catheter having a distal end and a distal end opening and a flexible tube extending along an outer diameter of the catheter and over the distal end of the catheter, so that the guidewire passes through a lumen of the catheter and the flexible tube; pulling the flexible tube proximally from off of the outer diameter of the catheter and into the catheter lumen so that the flexible tube slides and inverts over the distal end opening; pulling or pushing the flexible tube distally out of the distal end of the catheter so that the flexible tube slides and inverts over the distal end opening and over the outer diameter of the catheter; and drawing a clot into the inverted flexible tube as the flexible tube is drawn into the catheter.

[0072] In any of the methods described herein, the guidewire may be positioned at least partially within the clot in the blood vessel.

BRIEF DESCRIPTION OF THE DRAWINGS

[0073] The novel features of the invention are set forth with particularity in the claims that follow. A better understanding of the features and advantages of the present invention will be obtained by reference to the following detailed description that sets forth illustrative embodiments, in which the principles of the invention are utilized, and the accompanying drawings of which:

[0074] FIGS. 1A-1H illustrate one variation of an apparatus for mechanically removing an object such as a clot form a body region. FIG. 1A shows a catheter portion of the apparatus; FIG. 1B shows an enlarged view of a distal end (opening) of the catheter; FIG. 1C shows an example of a distal tractor region of a flexible tube (tractor tube), showing the expandable first end region of the flexible tube in a collapsed (non-expended) configuration, while FIG. 1D shows the same distal tractor region with the expandable first end region expanded. FIG. 1E shows an assembled mechanical thrombectomy apparatus with the flexible tube extending through the catheter and doubling back over the distal end of the catheter so that the expandable first end region of the flexible tube (forming part of the distal tractor region) is at least partially outside of the catheter and in a non-expanded state. FIG. 1F shows the apparatus of FIG. 1E with the expandable first end region expanded. FIGS. 1G and 1H illustrate the use of the apparatus of FIGS. 1E and 1F to remove a clot by drawing the flexible tube proximally and/or advancing the catheter distally towards the clot so that the expandable first end region inverts as it is drawn into the distal end of the catheter, pulling the clot into the catheter.

[0075] FIGS. 2A-2D show variations of flexible tubes (tractor tubes) that may be part of the apparatuses described herein. FIG. 2A shows the distal end of the flexible tube including the distal tractor region comprising the expandable first end region at the distal end, adjacent to a less-expandable second end region. In FIG. 2B the expandable first end region is formed of a plurality of woven fibers. In FIG. 2C the expandable first end region is formed of a sheet of material having a plurality of small pores throughout. In FIG. 2D the expandable first end region is doubled over the less-expandable second end region.

[0076] FIGS. 3A-3F illustrate the *in vivo* deployment and operation of one example of a mechanical thrombectomy apparatus. In this example, the distal tractor region is pushed through the catheter after positioning the catheter near a clot until the distal tractor region is exposed from the distal end of the clot (FIGS. 3A-3D) so that the expandable first end region expands to the intima of the vessel; the catheter is then advanced between the expandable first end region and the less-expandable second end region (FIGS. 3D-3E), and the expandable first end region is drawn into the catheter so that it inverts and pulls the clot into the catheter (FIGS. 3E-3F).

[0077] FIGS. 4A-4F illustrate *in vivo* deployment and operation of another example of a mechanical thrombectomy apparatus. In this example, the expandable first end region of the flexible (tractor) tube is deployed after positioning the catheter portion (FIGS. 4A-4B) by extending the expandable first end region out of the distal end of the catheter so that the expandable first end region double-back over the distal end region of the catheter (FIGS. 4C-4D). Once exposed and deployed, the expandable first end region may be drawn back into the catheter with or without advancing the catheter distally to pull the clot into the catheter (FIG. 4F).

[0078] FIGS. 5A-5E illustrate *in vivo* deployment and operation of another example of a mechanical thrombectomy apparatus in which the expandable first end region is extended distally out of the end of the catheter after it has been positioned within the vessel near the clot (FIGS. 5A-5C). Once the expandable first end region has been extended and allowed to expand within the vessel, the catheter and the rest of the flexible tube within the catheter may be advanced distally (FIG. 5D) so that the expandable first end region doubled over the distal end as shown. Thereafter the expandable first end region may be drawn back into the catheter with or without advancing the catheter distally to pull the clot into the catheter (FIG. 5E).

[0079] FIGS. 6A and 6B illustrate a mechanical thrombectomy apparatus including a catheter and flexible tube (tractor tube) extending through the catheter and doubling back over the distal end of the catheter (forming the distal tractor region) and an outer catheter or release protector catheter over the distal tractor region. FIG. 6A shows the apparatus positioned near a clot; FIG. 6B shows the apparatus used with a guidewire through the guidewire lumen of the apparatus for positioning and operating the apparatus.

[0080] FIGS. 7A-7D illustrate operation of a thrombectomy apparatus as shown in FIGS. 6A-6B, showing positioning the distal end/distal tractor region adjacent to the clot (FIG. 7A), then pulling the clot into the catheter (FIGS. 7B-7C) and finally removal of the clot and flexible tractor tube (FIG. 7D).

[0081] FIG. 8 shows a thrombectomy apparatus including an optional vacuum source.

[0082] FIGS. 9A-9D illustrate operation of a thrombectomy apparatus as described herein in combination with a guidewire. The guidewire may pass through the clot completely or partially and the apparatus may be actuated over the guidewire, providing enhanced stability and efficacy.

[0083] FIG. 10A shows one variation of a handle (proximal) handle for actuating an apparatus such as the thrombectomy apparatuses described herein. The handle may be coupled and may, separately or in a coordinated fashion, actuate movement of the catheter and flexible (tractor) tube, including the distal tractor region.

[0084] FIG. 10B shows another example of a proximal handle for an apparatus as described herein, which includes controllers for controlling (separately or together) actuation of the catheter and/or inner flexible tractor tube.

[0085] FIG. 11A shows another example of a proximal handle for an apparatus including a thrombectomy apparatus as described herein.

[0086] FIG. 11B is a mechanical schematic illustrating operation of a handle for an apparatus as described herein.

[0087] FIGS. 12A and 12B illustrate variations in which the expandable first end region of the flexible tractor tube of the apparatus is releasably secured to an outer surface of the catheter; prior to actuation of the apparatus, so that the distal tractor region can be drawn into the distal end of the catheter, the releasable attachment may be detached. In FIG. 12A an outer tubing (e.g., an outer catheter or release protector catheter over the distal tractor region) covers at least the end of the expandable distal end region. In FIG. 12B the expandable first end region of the distal tractor region may include a band, adhesive, weld (e.g., frangible adhesive or other attachment), clap, grasper, or the like, releasably securing the expandable first end region to the outer diameter of the catheter.

[0088] FIGS. 13A and 13B illustrate examples of the proximal end region (puller region) of the flexible (e.g., tractor) tube of the apparatuses described herein. FIG. 13A shows an example in which the proximal end of the tractor tube forms a pull wire that is radially offset from the lumen of the tube; a guidewire may still pass through the lumen of the tube (and catheter) for operation of the device, as shown. FIG. 13B shows an example in which the pull wire (or rod, member, etc.) is formed of a separate material than the rest of the flexible tractor tube.

[0089] FIG. 14 illustrates a distal tractor region including a limited lubricious region near a proximal end region of the expandable first end region of the distal tractor region; other portions of the expandable first end region may not be lubricious, nor may other portions of the rest of the distal tractor region.

[0090] FIGS. 15A-15D illustrate flexible (tractor) tubes having shaped expandable first end regions. In particular, these different expandable first end regions may be pre-set to different diameters which may help draw in and/or break the clot up within the catheter. FIG. 15A shows a first example in which the expandable first end regions is coupled to a puller portion by a plurality of pull wires. The expandable first end regions is shown not inverted over the more proximal portion of the flexible tubular member (tractor tube) in these examples. FIG. 15B shows a plurality of expandable end regions connected by a

plurality of pull wires that may not be radially expandable. FIG. 15C shows an expandable first end region having a plurality of pre-set diameters. FIG. 15D shows an expandable first end region coupled to a more proximal puller portion of the tractor tube by two or more bundles of the filaments forming the expandable first end region.

[0091] FIG. 16 illustrates another example of an expandable first end region that includes a plurality of releasable attachments to the outer diameter of the catheter; these releasable attachments (which may be frangible, elastic, etc.) can be released by applying sufficient force to allow the distal tractor region to be pulled into the catheter for actuating the apparatus.

[0092] FIG. 17 illustrates an example in which the expandable first end region is loaded (e.g., spring loaded, compressed, etc.) over the outer diameter of the distal end region of the catheter and releasably locked or otherwise held in place, e.g. by a reliable attachment; this releasable attachment may prevent deployment of the apparatus until actuation, and the loading of the expandable first end region may make it easier for the distal tractor region to invert over the distal end of the catheter to draw a clot into the apparatus.

[0093] FIGS. 18A-18C illustrate examples of expandable first end regions having different stiffnesses.

[0094] FIGS. 19A and 18B illustrate assembly methods for assembling an apparatus as descried herein.

[0095] FIGS. 20A and 20B illustrate exemplary profiles of expandable first end regions that may be used as part of a distal tractor region of an apparatus as described herein.

[0096] FIGS. 21A-21D show examples of apparatuses used to remove clots. FIG. 21A shows an example of an expandable first end region prior to coupling to a catheter. FIG. 21B illustrates the expandable first end region within a vessel (glass tube) being drawn into a catheter by pulling the proximal end of the flexible (tractor) tube. FIG. 21C shows the distal end region of the apparatus including the expandable first end regions doubled over the distal end region of the catheter. FIG. 21D illustrates the apparatus of FIG. 21C drawing a clot into the catheter.

[0097] FIG. 22 shows the expandable first end region of FIG. 21D with the captured clot after drawing it proximally out of the catheter.

[0098] FIGS. 23A-23D illustrate a mechanical thrombectomy apparatus as described herein capturing a blood clot and drawing it into the apparatus.

[0099] FIG. 23E illustrates the clot held within the flexible tractor tube after the flexible tractor tube has been removed from the catheter (e.g., proximally).

[0100] FIG. 24 is another example of an apparatus including a flexible tractor member in which the distal tractor region is formed of a plurality of filaments that are arranged as strips of material (longitudinally parallel) that are not woven or braided. These strips may be filaments, or tubes, etc.

[0101] FIGS. 25A-25F illustrate another variation of a distal tractor region of a flexible tractor assembly in which the expandable first end region (e.g., the distal end region of the distal tractor region) is formed of a plurality of filaments or strips, similar to that shown in FIG. 24; the distal end of the

catheter includes channels, as shown in FIGS. 25A-24B; the strips may fit within these channels, as shown in FIGS. 25C-25D. FIGS. 25E and 25F show sectional views through FIGS. 25C and 25D.

[0102] FIGS. 26A and 26B show a variation of the apparatus of FIGS. 25A-25F with an outer sleeve (e.g., an outer catheter or release protector catheter or other outer sleeve/protector)

[0103] FIGS. 27A and 27B show a sectional view through the apparatus of FIGS. 26A-26B.

[0104] FIG. 28 is an apparatus including a distal tractor region of a flexible tractor assembly having a plurality of longitudinally-parallel (non-woven/braided) filaments or strips in which the distal ends of the filaments or strips are connected to each other by a distal connector.

[0105] FIG. 29 shows a distal tractor region of a flexible tractor assembly in an apparatus in which the longitudinally-parallel (non-woven/braided) filaments or strips include grabbing elements.

[0106] FIGS. 30A-30C illustrate example of filaments/strips with grabbing elements. Grabbing elements (and/or filaments including them) may be used as part of any of the variations described herein, including woven or braided distal tractor regions.

[0107] FIG. 31 illustrates a variation in which the distal tractor region is adapted to be reciprocated (e.g., pushed and pulled) so that the expandable first end region may be draw into and reversed out of the catheter.

[0108] FIG. 32 illustrates another example of an apparatus as described herein in which the distal-most end of the expandable first end region is fixed to a portion of the distal end of the catheter; the rest of the expandable first end region is sufficiently elastic/flexible to be drawn into the catheter (pulling a clot with it). The flexible tractor assembly may then be left retracted and the entire apparatus withdrawn. This example may include an optional vacuum.

[0109] FIG. 33 is another example of an apparatus in which the puller portion of the flexible tractor assembly is formed of the same material as the distal tractor region but may be laminated or otherwise reinforced to have less flexibility/stretchability than the distal tractor region.

[0110] FIG. 34 illustrates another example in which the distal tractor region is adapted to compress the clot when draw into the catheter.

[0111] FIGS. 35A-35C illustrate operation of an apparatus as shown in FIG. 34 in which the clot is drawn into the catheter by withdrawing the expandable first end region of the distal tractor region into the catheter (e.g., pulling on the puller region of the tractor assembly) which compresses the clot (FIGS. 35A-35B); releasing the tractor assembly and/or pushing it distally may further break up the clot and release it from the distal tractor region so that it may be suctioned up proximally with a manual or powered vacuum source (FIG. 35C).

[0112] FIG. 36 illustrates an example of an apparatus and method of use in which drawing the flexible tractor assembly proximally may advance the apparatus distally through the body (e.g., vessel) over a guidewire, which may be treated to engage the distal tractor region.

[0113] FIGS. 37A-37C illustrate an apparatus and method of use in which drawing the flexible tractor assembly proximally may advance the apparatus distally.

[0114] FIGS. 38A and 38B illustrate another variation of an apparatus and method of using the apparatus to remove material from within a vessel, wherein the apparatus is an "infinite" tractor mechanism, in which a large amount of tractor material (e.g., mesh) is stored in an external holding region, wound-up but dispensable over an extended use.

DETAILED DESCRIPTION

[0115] In general, described herein are methods and apparatuses for mechanically removing objects from a body. Although these methods and apparatuses may be adapted for use to remove a variety of objects from a variety of regions of the body, they may be particularly well suited for removal of blood clots from within a lumen of a blood vessel. Thus described herein are mechanical thrombectomy apparatuses (e.g., device and systems).

[0116] The apparatuses described herein (e.g., mechanical thrombectomy apparatus for removing a clot from a vessel) may be assemblies including an elongate catheter having a distal end and a distal end opening, and a flexible tractor assembly at least partially within the catheter, where the distal end region of the tractor assembly is configured as a distal tractor region that at least partially extends within the catheter and doubles back over the distal end of the catheter. The tractor assembly may include a proximate pusher region which is connected to the distal tractor region. The flexible tractor assembly includes an elongate lumen that is configured to allow passage of a guidewire. The flexible tractor assembly is also configured to slide along the long axis within the catheter lumen and invert over the distal end opening of the catheter when the proximal end region is pulled proximally. The tractor assembly may be referred to herein as a flexible tractor assembly, flexible tractor portion, flexible tractor tube, or simply a flexible tube, and is typically positioned and longitudinally slideable within the catheter, and arranged so that the distal end region ("distal tractor region") doubles back over the distal end of the catheter.

[0117] For example, FIG. 1A shows one variation of a catheter that may form part of the apparatuses described herein. In this example, the catheter 100 includes a distal end region 103 that includes a distal end 105. The distal end region may have an increasing softness (measured by durometer, e.g., shore durometer) except that the very distal tip (distal end 105) may be substantially less soft than the region immediately proximate to it. Thus, although the distal tip region (e.g., the distal most x linear dimensions, where x is 10 cm, 7 cm, 5 cm, 4 cm, 3 cm, 2 cm, 1 cm, 9 mm, 8 mm, 7 mm, 6 mm, 5 mm, 4 mm, 3 mm) has an increasing softness/decreasing harness extending from the proximal to distal ends, the very distal end region 107 (e.g., measured as distal most z linear dimensions, where z is 1 cm, 9 mm, 8 mm, 7mm, 6 mm, 5 mm, 4 mm, 3 mm, 2 mm, 1mm, 0.8 mm, 0.5mm, 0.3 mm, 0.2mm, etc., and z is always at least three times less than x) has a hardness that is greater than the hardness of the region immediately proximal to it, and may be as hard or harder than the proximal-most region of the distal tip region.

[0118] The catheter 100 may also be referred to as the inner catheter or the tractor catheter. Any appropriate type of catheter may be used, including microcatheters appropriate for neurovascular use.

[0119] In some variations the distal end 105 of the catheter is adapted so that the distal tractor region may slide and invert over the distal end of the catheter without being caught (binding) or without substantial friction. For example, in some variations the distal tip (end) may be curved or radiused 109 as shown in FIG. 1B, particularly on the outer surface (e.g., the transition from outer diameter to inner diameter). In some variations the distal tip includes one or more channels, as shown and described in FIGS. 25A-28, including channels around the distal-facing edge, to guide the sliding of the distal tractor region.

[0120] FIG. 1C shows an example of a flexible tractor tube 140. In FIG. 1C, the tube is flexible and elongate (having a generally greater length than the catheter 101), and includes a distal tractor region 142 that includes a distal-most expandable first end region 144 that is configured to fold over the immediately proximal region 146, which may be a less-expandable second end region. In general the expandable distal end region is configured to expand to a radial diameter that is between 1.3 and 10 times the diameter of the inner diameter of the catheter when unconstrained. FIG. 1D shows the expandable distal end region of FIG. 1C in an expanded configuration. Thus the expandable distal end region may be biased to expand open. The expandable distal end region may be formed as a mesh, woven or sheet of material and is generally adapted to grasp the object to be removed (e.g., blood clot).

[0121] The flexible tractor tube shown generically in FIG. 1C is shown with the expandable distal end region doubled back over itself (e.g. over the more proximal less-expandable second end region) in FIG. 1E. In FIG. 1E, the expandable distal end region is collapsed, while in FIG. 1F the expandable distal end region is expanded. In general, the expandable distal end region may be distinguished from the proximal less-expandable second end region, however in some variations the entire flexible tractor tube may comprise and expandable material (e.g., mesh, weave, etc.) that is pushed and/or pulled within the catheter and does not include a proximal less-expandable distal end region.

[0122] FIGS. 1G and 1H illustrate the removal of a clot using an apparatus such as the apparatus assembled from the components of FIGS. 1A and 1E. In this example the apparatus is configured as a thrombectomy apparatus including a catheter 101 and a flexible tractor tube that includes an expandable distal end region 144 that extends over the distal end region of the catheter and doubles-over the distal end of the catheter so that the expandable distal end region is continuous with an inner proximal less-expandable (in this example, less-expandable includes non-expandable) second distal end region 146 that extends proximally within the catheter and forms an inner lumen that may pass a guidewire. The proximal end of the flexible tractor tube (not shown) may include a pusher/puller member that may be a rod or other member that is continuous with the distal end region (distal tractor region140). In FIG. 1G the apparatus is shown positioned and deployed within the vessel 160 near the clot 155. The clot may be drawn into the catheter by withdrawing the distal tractor region 140 into the catheter 101, as indicated by the arrow 180 showing pulling of the inner portion of the flexible tractor tube (e.g., using a handle, not shown) resulting in pulling the expandable distal end region into the catheter distal end and inverting the expandable distal end region so that it is pulled into the catheter, shown by arrows 182. The distal end of

the expandable distal end region may be "loose" relative to the outer wall of the catheter, or it may removal attached or in some variations permanently attached.

[0123] In general, positioning these apparatuses and actuating them may be challenging because they must be highly flexible, both before actuating and during operation. For example, in general, the flexible tractor tube must not increase the stiffness/flexibility of the catheter, and particularly the distal end region of the catheter too much, or it may be too difficult and/or dangerous to maneuver, particularly within tortious vessels of the neurovasculature. Described herein are flexible tractor tube portions that increase the stiffness of the last y cm (e.g., distal most 20 cm, 18 cm, 15 cm, 12 cm, 10 cm, 9 cm, 8 cm, 7 cm, 6 cm, 5 cm, 4 cm, 3 cm, 2 cm, 1 cm, etc.) of the catheter less than a predetermined percentage (e.g., less than 10%, 12%, 15%, 18%, 20%, 25%, 30%, etc.). For example, described herein are flexible tractor tube portions that pass through the catheter and double back over the distal end of the catheter but increase the stiffness of a distal 5cm of the catheter by less than 15% of the stiffness of the distal 5 cm of the catheter without the flexible tube extending therethrough and doubling back over the distal end of the catheter.

[0124] For example, FIG. 2A shows a flexible tractor tube 201. In this example, the flexible tractor tube includes a distal tractor region 242 with an expandable first end region 244 and a less-expandable second end region 246 that is distal to a proximal pusher region 201. The entire flexible tractor tube is hollow and may pass a guidewire (not shown). The various regions of the flexible tractor tube may be made of the same material (e.g., a woven, braided, etc. filament or filaments) or they may be made of different materials.

[0125] FIG. 2B shows a flexible tractor tube having a distal tractor region, or at least the expandable first end region 244' formed of a plurality of woven fibers. Alternatively the expandable first end region may be formed of one (or more) knitted fibers, or a combination of woven and knitted fibers. The expandable first end region may be biased open (as shown) by a shape-setting property of the fibers or woven/knitted pattern or by the inclusion of one or more biasing members (e.g., rings, springs, bands, filaments, etc.) that tend to bias at least the distal end region of the expandable first end region open.

[0126] FIG. 2C illustrates another variation of an expandable first end region formed of a sheet of material that includes a plurality of openings (e.g., pores, perforations, passages, windows, etc.). These openings may be any sizes, including non-uniform sizes (e.g. a range of sizes) or uniform sizes. The sizing of these opening through the sheet may depend on the material used, e.g., polymeric material (PTFE), silicone materials, polyurethanes, shape memory alloys, etc. In some variations it is beneficial to have a porosity of greater than >60% (greater than 70%, greater than 75%, greater than 80%, greater than 85%, etc., between 60-95, 65-95, 70-95%, etc.) of the sheet.

[0127] In any of these variations, the distal tractor region is configured so that it may be inverted (e.g., doubled over) itself, as shown in FIG. 2D. In some variations the apparatus may be performed so that the expandable first end region is inverted over the itself and/or over the distal end region of the catheter, or it may be configured so that it can be deployed and inverted over the distal end of the catheter *in vivo* (e.g., within the blood vessel). In general, before the apparatus can be actuated the catheter may be inserted between the expandable first end region and the region proximal to the expandable first end

region on the flexible tractor tube, which may, in some variations, be the less-expandable second distal end region. This space 289 may be held open by a biasing member at or near the distal end of the expandable first end region. As mentioned, this expandable first end region opening biasing member may be a ring, band, spring, coil, or the like, and may be made of a biasing element (e.g., shape-set material, such as a shape memory alloy), rubber or other polymeric material, or the like.

[0128] In vivo deployment of the apparatuses described herein may provide a number of advantages for users operating the apparatus, despite associated challenges. FIGS. 3A-3F illustrates one example of a thrombectomy apparatus that is configured for in vivo deployment. In this example, the apparatus includes a catheter 301 that may be positioned (as with any of the variations described herein) using a guidewire 313. The guidewire may be extend to or into (or through) the object to be removed, shown as clot 355 in FIG. 3A within a blood vessel 360. The catheter of the apparatus may be inserted with or after the guidewire, and the catheter may be positioned near (e.g., adjacent to or immediately adjacent to) the clot with or without the flexible tractor tube at or near the distal end of the catheter. In FIG. 3A the catheter is positioned after the guidewire has been positioned, and, as shown in FIG. 3B, is removed from the vessel. The guidewire may be a wire, smaller catheter or combination of devices that may be positioned (e.g., steered) to and/or through the clot. Following positioning of the catheter, the inner flexible tractor tube 340 including the distal tractor region 342 is pushed through the catheter to the distal end region of the catheter, as shown in FIG. 3C. In this example the distal end of the flexible tractor tube forming the distal tractor region includes an expandable first end region shown as a mesh 344 that is connected to a proximal less-expandable second end region that is continuous with the rest of the flexible tractor tube, at the proximal end (pusher region 305). The braided mesh 344 of the expandable first end region is pre-inverted over the outside of the tubular second end region/pusher region in a collapsed (non-expanded) configuration, and can be slide through the inner lumen of the catheter, and (when the guidewire is left in position or used adjust the position) over the guidewire (not shown). As shown in FIG. 3D, the distal tractor region of the flexible tractor tube may then be exposed to the outside of the catheter by extending (in this example either pushing the flexible tractor tube distally and/or pulling the catheter proximally, allowing the expandable first end region of the distal tractor region (shown as mesh) 344 to expand along the length of the first end region. In FIG. 3D this is shown as a stent-like structure that may expand fully to the intima of the vessel forming a separation between the expandable first end region and the less-expandable (in this case non-expandable) second end region 346. In particular the expansion of the first end region may be greater than 1.3 times the diameter of the inner lumen of the catheter (e.g., greater than 1.5x, greater than 2x, greater than 2.2x, greater than 2.5x, greater than 3x, greater than 3.5x, greater than 4x, greater than 5x, greater than 6x, greater than 7x, greater than 8x, greater than 9x, greater than 10x, etc.).

[0129] In FIG. 3D, the catheter is slid distally between the first and second end regions of the distal tractor region. The clot may then be removed by withdrawing the expandable first end region proximally into the catheter either or both by pulling the flexible tractor tube (e.g., proximal puller region) proximally and/or advancing the catheter distally. In some variations it may be beneficial to both advance the

apparatus and particularly the catheter, while withdrawing the expanded first end region and inverting it into the catheter. The catheter may be advanced more quickly than the flexible tractor tube is withdrawn.

[0130] As shown in FIG. 3F, the clot 355 may be drawn in to the catheter with the expandable first end region.

[0131] Another variation of an *in vivo* deployment method and apparatus is shown in FIGS. 4A-4F. In this example, the self-expanding first end region of the flexible tractor tube is configured to self-expand over end of the catheter as it is pushed out of the catheter so that it will slide over the distal end of the catheter. As described above for FIGS. 3A-3B, the apparatus may be positioned using a guidewire 413 or the like. In FIG. 4A, the catheter 401 is positioned over the guidewire 413 adjacent to the clot 455 to be removed. In FIG. 4B the guidewire may be (optionally) removed, or (preferably) left in place. The flexible tractor tube 434 including the distal tractor region may then be moved distally within the catheter and extended with the expandable first end region 444 out of the distal end so that it inverts 466 over the distal end and slide proximally over the distal end region, as shown in FIG. 4C. This process may be aided by pushing the apparatus distally within the lumen of the vessel, as the expansion of the first end region 444 may help secure it against the wall of the vessel, as shown in FIGS. 4D-4E. Once exposed, the expandable first end region may be withdrawn into the apparatus by pulling the flexible tractor tube 434 proximally and/or advancing the assembly (or at least the catheter) distally, as shown in FIG. 4F. The clot 455 may then be drawn into the apparatus.

[0132] FIGS. 5A-5E illustrate another variation of an *in vivo* deployment and thrombectomy (clot removal) method using a mechanical thrombectomy apparatus. In FIG. 5A, the apparatus 500 including a catheter 501 and an inner flexible tractor tube 534 is advanced (e.g., over a guidewire, not shown) to be near a clot 555. In this example (which may be relevant to any of the methods described herein) the apparatus is positioned with the flexible tractor member having the un-deployed distal tractor region already positioned distally near the distal end region of the apparatus. As shown in FIG. 5B, the expandable first end region 544, which is in a collapsed configuration within the catheter 501 in FIG. 5A, is pushed out of the distal end of the catheter and expands to the walls of the lumen as shown in FIGS. 5B-5C. Once pushed out and expanded, the catheter and the portion of the flexible tractor tube within the catheter may be advanced distally, as shown in FIG. 5D, causing the expandable first end region 544 to invert, doubling over the distal end region of the catheter 501. By FIG. 5E, the apparatus has been deployed near the clot 555 and may be actuated as already described to remove the clot, but pulling the expandable first end region of the distal tractor region into the catheter, so that it inverts and draws the clot into the catheter. The catheter may optionally be simultaneously advanced. Note that the method of in vivo deployment described above may also be used to load an apparatus for insertion into a body in order to position the catheter radially between the expandable first end region and the more proximal portion of the flexible tractor tube.

[0133] FIG. 6A illustrates an example of another variation of a thrombectomy apparatus having a flexible tractor tube 634 with a flexible first (distal) end region 644 formed in this example of a braided (e.g., woven) or knitted material, where the flexible first end region (tractor region) is inverted over the

distal end of a catheter 601 and attached to the proximal end region of the flexible tractor tube 634. As in any of the apparatuses described herein this proximal end region of the flexible tractor tube may be a hypotube, catheter, or laminated weave/mesh or woven material that is pushable/pullable within the catheter and is attached at its distal end to the flexible tractor region (e.g., distal tractor region), including in some variations an expandable first end region. Note that in some variations the distal tractor region (the first end region) may not be expandable but may be just flexible.

[0134] In FIG. 6A, the first end region of the distal tractor region attached to the flexible tractor tube is covered by an outer catheter or sleeve (protector) 677. In this example, the apparatus also includes a mid-catheter 679 between the inner catheter 601 and the protector catheter or sleeve 677. In some variations the flexible first end region 644 may be attached to this mid catheter, including removably attached so that pulling the flexible tractor tube 634 proximally will disengage it and allow the mesh (the flexible first end region 644) to deploy in the vessel. In the variation shown in FIG. 6A the flexible first end region 644 is not attached to the middle catheter 679.

[0135] Any of the apparatuses described herein, including the apparatus shown in FIG. 6A may be used with (and may include) a guidewire 633 as shown in FIG. 6B. FIGS. 7A-7D illustrate the operation of the apparatus shown in FIGS. 6A-6B to remove a clot 755. In this apparatus the proximal end of the flexible tractor tube 734 may be coupled to a vacuum source (not shown) which may be actuated when withdrawing the tractor tube 734 proximally to invert the distal tractor region over the end of the catheter. In FIG. 7A the apparatus is positioned near the clot 755. In FIG. 7B, the distal tractor region is inverted and pulled into the catheter by pulling the flexible tractor tube 734 as shown by the arrow. In this example the distal tractor region is not expanded because it remains covered by the outer sleeve 777, as shown in FIGS. 7B and 7C. The apparatus may be advanced distally toward/over the clot either or both by pushing or by the action of pulling the distal tractor end region (shown in this example as a mesh 744) proximally to invert it over the distal end of the catheter. Once the clot is removed, the apparatus may be withdrawn and pulled out of the vessel, as shown in FIG. 7D.

[0136] As mentioned above, any of these variations may include one or more vacuum sources. FIG. 8 illustrates one example including a vacuum source showing a first optional vacuum source at the proximal end coupled to the lumen of the flexible tractor tube 834. For example, the coupling with the vacuum and the tractor tube 834 may be a rotating hemostatic value (RHV) as shown. In FIG. 8 a second (optional) vacuum connection is made between the (optional) outer catheter 877 and the inner catheter 801 or an (optional) middle catheter 878. Vacuum may be applied at any appropriate portion of the method, including during retraction of the flexible tractor rube 834 to remove the clot.

[0137] As mentioned, any of the apparatuses described herein may include a guidewire and may leave the guidewire in position during the procedure. FIGS. 9A-9D illustrate a method of removing an object (e.g., clot) when leaving a guidewire 913 in position. In this example, the apparatus is similar to the apparatus shown in FIGS. 6A-6B, and may include an optional vacuum source. In FIG. 9A the distal end of the catheter including the inverting portion of the flexible first end region 944 of the distal tractor region 944 is placed adjacent to the clot and actuated by pulling proximally to draw the clot into the

catheter as shown in FIG. 9B. In this example the clot has been penetrated by the guidewire 913, thus the catheter tip with the inverting tractor region may be advanced forward over the guidewire by pushing on the catheter 927 and/or by pulling the tractor tube proximally 919. This may be continued until the entire clot is within the catheter, as shown in FIG. 9C.

[0138] In any of the variations described herein, the apparatus may include one or more markers or may be configured for use with one or more contrast agent to assist in visualizing the methods described. Further any of these methods may include visualization. Visualization may be indirect (e.g., using fluoroscopy or equivalent techniques) or direct, e.g., using one optical fibers for direct visualization down the apparatus (e.g., thought the lumen of the apparatus).

[0139] In FIG. 9D, the tractor tube with the captured object (e.g. clot) may be removed proximally from the apparatus and the removed material may be examined (e.g., via histological/cytological examination). The catheter may be subsequently or simultaneously removed. As mentioned above, when removing the object (e.g., clot) it may be desirable to pull back (proximally) the guidewire at the same time that the flexible tractor tube is pulled back proximally (not shown). In some variations, the distal tractor region (e.g., braided/woven or knitted region) may grab onto the guidewire within the catheter and which may also help propel the apparatus distally over/toward the clot, as described in more detail in FIGS. 36 and 37A-37C, below.

[0140] In general, the rolling effect of the grabber (the distal tractor region) is activated by the motion of the catheter relative to the distal tractor region. If the distal tractor region is fixed proximally and the catheter is advanced, the distal tractor region may have a 1:1 grab ratio. If the distal tractor region is pulled though the catheter, the grabbing effect may be amplified. For example when the distal tractor region is pulled back (by pulling the tractor tube) and inverted into the inner catheter 1 unit to proximally within the catheter as the inner catheter is pushed 1 unit to distally, the grabbing effect is approximately 2x. If the distal tractor region is withdrawn into the inner catheter proximally two units as the inner catheter is advanced distally one unit, the grabbing effect may be approximately 3x. The concurrent motion of the distal tractor region and the catheter may be coordinated by a handle.

[0141] In general, any of the apparatuses described herein may include a handle. The handle may couple with the flexible tractor tube and/or the catheter (e.g., inner catheter) and/or any outer catheter (e.g., protector, sleeve, etc.). The handle may be configured to allow selective, separate actuation of the flexible tractor tube and/or the catheter and/or coordinate motion of these components. FIGS. 10A and 10B illustrate examples of handles that may be used. In FIG. 10A, the handle includes a drive mechanism to pull back the tractor tube, and therefore invert the distal tractor region over the distal end of the catheter and/or advance the catheter relative to the distal tractor region. In FIG. 10A, the handle include rotatable handle 1001couled to a catheter drive 1003. The handle connects to both the catheter 1005 and the inner flexible tractor tube 1009 having a distal tractor region 1011. The handle may be configured so that the ratio of the advancing (distally) of the catheter versus the pull (proximally) of the tractor tube may be selected and/or may depend on a thread pitch of the catheter drive thread or other mechanical mechanism.

[0142] Another variation of a handle is shown in FIG. 10B. In this example the handle may be attached to the tractor tube to pull (or push) 1017 the tractor tube and therefore invert the distal tractor region over the distal end of the catheter, and another portion of the handle may be coupled to the catheter to push/pull the catheter 1015.

[0143] FIG. 11A shows another variation of a handle mechanism 1107 configured to pull the grabber (distal tractor region) of any of the apparatuses described herein by coupling to the proximal end of the tractor tube at an attachment site 1105, and/or advance the catheter by coupling to the proximal end of the catheter. Another example of a handle mechanism is shown schematically in FIG. 11B, showing a levering mechanism 1109 and a coupling to the inner tractor tube that may be fixed or adjustable.

[0144] In any of the apparatuses (e.g., mechanical thrombectomy apparatuses) described herein, the distal tractor region may be preloaded in/on the catheter so that it can be actuated by pulling the tractor rube coupled to the distal tractor region proximally and/or advancing the catheter distally. In pre-loaded variations in which the distal tractor region includes a flexible and/or expandable first end region (e.g., formed of a mesh and/or weave of material) that is doubled over the distal end of the catheter, the apparatus may be adapted to prevent inadvertent dislodging and/or expansion of the first end region before it has been positioned at or near the clot.

[0145] FIGS. 12A and 12B illustrate examples of releasable attachments for the distal tractor regions attached to the outside of the catheter. Any of these attachments may be released by the application of an appropriate amount of force (e.g. pulling force) applied to the proximal end of the flexible tractor tube. For example in FIG. 12A, the outer distal end of the distal tractor region (shown as mesh 1204) is covered by a shoulder or sock extending from an outer catheter or tubing 1203). Similarly in FIG. 12B, the outer distal end of the distal tractor region (shown as mesh 1204) is covered by a separate band, ring, or sock 1209. The distal tractor region may be prevented from collapsing or reducing in diameter when tension (e.g. pulling proximally on the tractor tube) by adding filaments (e.g., in braided or woven variations, additional braid filaments), by adding a coating, by heat setting to a larger diameter, and/or by adding an axial inter-braiding pull wire.

[0146] Any of the variations described herein may include a proximal pull rod or pull wire as part of the flexible tractor tube. Further, the proximal end region of tractor tube may be less flexible than the distal end (distal tractor region). FIGS. 13A and 13B illustrate examples of flexible tractor tubes. In FIG. 13A, the tube includes a proximal taper region in which the distal tractor region 1305 is formed of a material (e.g., mesh/woven material) that tapers proximally 1307 into a pull wire, leaving room for a guidewire 1309 and permitting the distal tractor region to invert over a catheter. The proximal pull-wire portion may be formed of the filaments forming the distal tractor region, e.g., in variations in which the distal tractor region is woven or braided. These filaments may be reinforced, e.g., by other materials such as polymers that help make it stiffer or more compliant. FIG. 13B shows another example in which the proximal end of the flexible tractor tube is formed of a pull wire 1315 that may be a separate material or an extension of the braid wire bundle attached to the distal end of the pull wire and forming the distal tractor region 1317.

[0147] Any of the apparatuses described herein may be treated or adapted to reduce the force required to invert the distal tractor region over the end of the catheter. For example in some variations either the distal end may be treated to be lubricious, or all or a portion of the distal tractor region may be treated to enhance laboriousness. For example, in some variations only a portion of the distal tractor region, e.g., the portion that initially interacts/inverts over the distal end of the catheter is treated; the rest of the distal tractor region is not treated. FIG. 14 shows an example of such an apparatus. In FIG. 14, the proximal-most end 1405 of the expandable and/or flexible first end region (that is positioned outside of the catheter) is treated with a lubricous coating or formed of a lubricious material. The remaining portion (not shown to scale) of the first end region is not as lubricous 1403. Since the more proximal region 1405 is exposed to the vessel and the distal end of the catheter, it may more effectively track the target or allow the apparatus to track the target as well as start inverting over the distal end more effectively. This region may be made lubricious in any appropriate manner, including but not limited to coatings such as hydrophobic/hydrophilic coatings, and forming or including a more lubricious polymeric material (e.g. PTFE).

[0148] In general, any of the distal tractor regions described herein may be adapted to include different profiles, including pre-set to have (e.g., shape-set) profiles that may more readily slide/move over the distal end and/or grab a clot or other target object for removal. For example, FIGS. 15A-15D illustrate tractor tubes having different distal end profiles forming different distal tractor regions. In FIG. 15A for example, the distal tractor region includes a distal-most expandable and/or flexible first end region 1505 that is formed of a braided/mesh or woven material that is connected to proximal end of the tractor tube by a plurality of pull wires. These pull wires 1517 may be formed by the same wires or filaments forming the braided/mesh or woven distal end region. FIG. 15B shows another variation in which a plurality of discrete braided/mesh or woven distal end regions are connected by pull wires 1515; these pull wire regions 1515 may be less-expandable and/or flexible than the braided/mesh or woven regions 1516. In FIG. 15C, the distal end regions are braided/mesh or woven but pre-set to have different diameters. Thus these regions may have different shapes along their length; these shapes may be heat set to better grab or break up clot as they are pulled into the catheter. FIG. 15D illustrates an example of a braid or stent-like first end region 1521 that is connected to hypotube or other more proximal end region of the tractor tube 1520 by the same filaments or bundles of the same filaments forming the braided/mesh or woven distal tractor region 1523.

[0149] Any of the apparatuses described herein may also or alternatively include a plurality of releasable attachments to the outer surface of the catheter securing the distal tractor region (and particularly the distal end portion) to the outer surface. In FIG. 16, three rings 1603, 16.3', 1603'' forming releasable attachment are shown securing the distal end of the distal tractor region 1644 to an outside of a catheter 1601. In this example, a polymer coating/film is attached or integrated with the braid forming the distal tractor region to help prevent it from sliding or slipping off of the catheter prematurely (e.g., until pulled by a user). The apparatus can include multiple attachments, as shown, radially positioned along the length of the catheter to help it stay secure to the outer diameter of the

catheter delivery system. In some variations these releasable attachments are elastic member (e.g., a urethane ring) but may be frangible, and allowed to break to free the distal tractor region.

[0150] FIG. 17 shows another variation in which the releasable attachment is positioned so that a portion of the distal tractor region is spring-loaded (biased) to drive it in rolling over the distal end of the catheter and into the catheter lumen. In FIG. 17, The distal end of the distal tractor region 1704 may be secured (fixed, attached or loose but constrained) and a more proximal end region near the distal end of the catheter may be releasably secured to the catheter 1707. For example, a polymeric coating or film may be attached to the distal tractor region (shown as a braid 1744 in FIG. 17) and coupled to hold a portion of the distal tractor region 1705 between the distal end 1704 and releasable attachment site 1707 in tension (e.g., compressed). Release of the releasable attachment 1707 may then apply a force driving the distal tractor region around the distal end of the catheter, helping pull the clot into the apparatus, and reducing the force necessary to invert the distal tractor region.

[0151] As mentioned above, the material forming the distal tractor region may, and in particular the distal-most flexible and/or expandable first end region may be formed of any appropriate material. For example, the material may comprise a fabric, a weave, a knit, a braided, a sewn, a tube, and/or a flat sheet. The material may have any appropriate thickness, e.g., between 0.0005 to 0.015" wall thickness, and may have pores of any appropriate spacing/dimension (porosity) from low to high porosity. All or a portion of the distal tractor region may be radiopaque or radio transparent. In woven, knitted, braided or sewn variations, the material may be formed of multi- or mono-filaments. Different size filaments can be mixed together (e.g., big and/or small) to change gripping effect by increasing or decreasing fabric surface texture. In some variations the material (including the filaments forming the material) may be polymer based (e.g., PET, Nylon, Polypropylene, PTFE, ePTFE), elastic and non-elastic (e.g., PU, Silicone, rubber, lycra), metal filaments (e.g., Niti, drawn filled Niti indcluding DFT, i.e., Niti with Pt inner core, steel, stainless steel, cobalt chrome, etc.), and mix of metallic and polymer filaments. The ends of the fabric can be laser cut/welded or free cut. In some variations all or part of the distal tractor region includes a film or sheet. The film may be between 0.0005 to 0.008" thick. The film may be formed by tube extrusion or sheet and rolled into a tube. In some variations the film is yarn reinforced. The film may be slotted (e.g., may include holes and/or slits cut to improve gripping or sliding into the catheter. In some variations the film has a textured surface (e.g., textured inner surface that is exposed when inverted). The film may form a tube having ridges and/or rings (radial rings) and/or lines down the length, and/or a saw tooth pattern. A textured inner surface my include a mix of big and small filaments, and/or may be formed of more porous, less dense fabrics.

[0152] In some variation, the visibility of the grabber element is desirable but not required throughout. For example, as mentioned above markers may be located on the device. In some variations it may be desirable to see the entire structure or proximal and distal end of structure. For example, the material could be Nitinol or Nitinol drawn over platinum material (DFT) to enhance visibility.

[0153] Any of the variations may include a rotational auger element in the inside of any of the braid constructs to assist in pulling the clot back to the hub. As mentioned, any of these apparatuses may

include a vacuum source. The addition of the vacuum to the system may aid the ability of the distal tractor region to pull clot/emboli into the catheter. The vacuum applied may be stead/constant, ramped or pulsatile.

[0154] In some variations the apparatus and methods for using them may include a flow stopping proximal balloon (e.g., to be positioned proximal to clot), that may reduce pressure on clot during the procedure.

[0155] The apparatuses and methods described herein may be used to capture biopsy samples (e.g., from breast or any other organs). For example, these apparatuses can be used to remove bigger tissue segments (e.g., cancer, gallbladders, etc.) when a laproscopic procedure is performed.

[0156] When the material forming the distal tractor region is a woven/braided material, the resulting mesh structure may have a braid length ranging from 1 to 100cm long to around the outer diameter (O.D.) of the catheter, with a preferred length of between about 3-30cm.

[0157] In any of these variations, the tractor tube and/or catheter (including the distal tractor region) may be constructed so the distal tractor region may be pulled so that the distal tractor region is drawn (inverted) around the outer diameter of the catheter distal end with a minimal force so the catheter tip does not buckle or significant deform (e.g., snake) in the blood vessel, wherein the pull forces are less than about: 50 grams, 100 grams, 300 grams, 500 grams, 800 gram, 1000 grams, 2 kg, 3 kg, 5 kg, 8 kg, 10 kg, 15 kg, 20 kg, etc.

[0158] In variations in which the grabber (distal tractor region) is constructed as a woven (e.g., braided) structure at least on a distal end (e.g., the expandable and/or flexible first end region), examples of the filaments forming the woven structure may include: NiTi, NiTi-PT DFT wire (NiTi tube over Pt inner), PET, PP, Nylon, Algiloy, SS, hybrid materials. When used, NiTi may be etched to make is very smooth. The number of filament ends may be about: 16, 24, 36, 48, 77, 96, 144 or any number between these integers. Any braid construction may be used. For example, an exemplary braid construction may include 1 over 1 (1x1), 1x2, 2x2, etc. In some variations the filaments forming the woven and/or knitted material comprises a monofilament, e.g., having an outer diameter (O.D.) size of about: 0.0005", 0.00075", 0.001", 0.0015", 0.002", 0.003" or an combination of sizes or diameter size which is between the integers list herein. As mentioned, these apparatuses may be adapted for neuro vasculature used, e.g., assuming 2-3mm vessel inner diameter (ID). For example, an apparatus appropriate for neurovascular applications as described herein may include between 36 to 72 ends of a 0.001"to 0.002" polymer braid annealed to 3-7mm OD. In some variations, the distal tractor region includes 24 braided wires having an OD of 0.0005" by 0.0015" or 0.002" of flat Niti wire, annealed on a 2 mm mandrel, braided at a 45 degree angle. Alternatively in one variation the distal tractor region comprises a braided material formed from 24 wires of a 0.002" thickness Niti wire, annealed on a 2 mm mandrel, braided at a 45 degree angle. In one example, the distal tractor region comprises a braided material including 24 wires 0.002" DFT Niti wire, annealed on a 2 mm mandrel, braided at a 45 degree angle. In one example, the distal tractor region comprises a braided material including 8 ends of 0.003" wire mixed with 8 additional ends of 0.002" Niti wire on a 2 mm mandrel. In one example, the distal tractor region comprises a braided material including

16 ends of 0.002" platinum iridium wire, annealed on a 2 mm mandrel. In one example, the distal tractor region comprises a braided material including 24 ends of PP monofilament, having an outer diameter of 0.002" diameter. In one example, the distal tractor region comprises a braided material including 12 ends of 0.003" PP monofilament. In one example, the distal tractor region comprises a braided material including 16 ends of 0.003" PP mono. In one example, the distal tractor region comprises a braided material including 72 ends, 0.001" PET or PP, 8 mm mandrel, 90 degree braid angle, 1x1. In one example, the distal tractor region comprises a braided material including 36 ends, 0.001" PET or PP, 6 mm mandrel, 75 deg braid angle, 1x1. In one example, the distal tractor region comprises a braided material including 48 ends, 0.002" PET or PP, 8 mm mandrel, 90 degree braid angle, 1x1. In one example, the distal tractor region comprises a braided material including 24 ends, 0.002" PET or PP, 6mm mandrel, 70 degree braid angle, 1x1.

[0159] In variations in which the distal tractor region comprises a mesh, the tubular mesh may be formed from a knit or alternative structure that is constructed so it's radially compression (change in tubular mesh inner diameter, ID) experiences a 5-20% reduction in diameter when the mesh tractor is pulled axially and around the outside of the catheter tip and into the catheter ID. This 5-20% mesh diameter reduction, may aid in grabbing the clot or foreign object when pulling the mesh into the catheter, without generating so much radially compression force that the tubular mesh binds on the catheter tip when pulled and does not easily roll around the catheter tip. In contrast a woven mesh may collapse between 20-60% within the catheter when drawn proximally, which may provide a substantial amount of compression of a clot of other removed material.

[0160] In variations in which the apparatus is configured for use in the peripheral vessels (e.g., having between a 4 to 8mm vessel ID), the distal tractor region may be configured for this application. For example, the distal tractor region may include a braided material having 24 ends of PP, 0.009" PP monofilament formed on a 4 mm mandrel and annealed. The distal tractor region may include a braided material having 48 ends of PP 0.008" mono, 4 mm mandrel annealed. The distal tractor region may include a braided material having 72 ends 0.006" PP mono 4 mm mandrel annealed. The distal tractor region may include a braided material having 36 ends of .004" Niti, 4 mm mandrel annealed. The distal tractor region may include a braided material having 48 ends of 0.004" DFT Niti mandrel annealed.

[0161] In variations in which the apparatus is configured as a biopsy device (e.g., having a 4-12 mm sample size), the apparatus may be a woven material including 72 ends of PP .007" mono formed on a 10 mm mandrel. In some variations, the apparatus (e.g., the distal tractor region) may include 48 ends of 0.004" Niti formed on a 1mm mandrel. In some variations, the apparatus (e.g., the distal tractor region) may include 48 ends of PP 0.008" mono on a 12 mm mandrel.

[0162] In any of the variations described herein the apparatus may be configured to have a relatively low friction. In particular the distal tractor region may have a low friction to allow it to be more easily and/or reliably pulled through the catheter when retracting a clot. As already mentioned above, any of these variations may include a lubricous material and/or coating including using or coating one or more of the following materials on the grabber (distal tractor region): PET, PP, PTFE, ePTFE. When the material

forming the apparatus is a small diameter filament metallic structures, the filaments may be between 0.0005 to 0.003" in diameter. The material may be Niti, Stainless, MP35n, Ti, Platinum, Platinum Iridum, cobalt chromium allowy etc.

[0163] In variations in which the distal tractor region is a mesh (e.g., woven and/or kitted material), the diameter of the distal tractor region relative to the catheter diameter may be depended on the woven/knitted structure. For example, when braided, the ratio may be between 2 to 1 or greater; when warp knit, the ratio is between: 1.5 to 1 or greater. When formed as a lasered tube, the ratio is between 1.1 to 1 or greater. Similarly for braided tube or tape structures, the braid angle inside of the catheter should be between 0 to 45 degrees of the braid angle inside catheter, and between about 20 to 90 degrees of the braid angle outside catheter. In variations in which the distal tractor region includes a knit braid (e.g., a warp knit) tube, the apparatus may include 12 to 16 ends per inch. For an apparatus having a 0.0035" ID catheter: 12 to 16 ends of 20-40D PET multifilament may be used, or 12 to 16 ends of 0.0007 to .003" PET or Polypro or PTFE monofilament, or 12 to 16 ends of .0007 to .002" NITI, stainless, MP35n, etc.

[0164] As mentioned above, in some variations the distal tractor region is formed of ePTFE as a sheet (e.g., formed into a tube or tape). This material may be thin walled (e.g., between 0.0005 to 0.003" thick), think walled (between 0.0005 to 0.002"), and may fold/role over catheter tip. The material may include a 0.001 to 0.004" with lasered pattern that is stent-like.

[0165] Other examples of designs for apparatuses including distal tractor region of different shapes may be a function of catheter ID. For example, in some variations the apparatus may select the catheter ID, number of filaments, diameter/length of filaments, stiffness of bending/rolling stiffness, Poisson's ratio, friction (and/or texture) of the inner surface of the grabber, etc. Smaller diameter catheters may require less mesh filaments or smaller ePTFE tube IDS's than larger diameter catheters. For example, in some variations in which the distal tractor region is braided, the apparatus may include a 0.072" ID catheter having a distal tractor region with 24 to 72 ends of 0.0008" to 0.002 Niti wire, braided on a 6 mm mandrel at a 90 degrees braid angle. In some variations the distal tractor region is formed of 24 to 72 ends of 0.0008" to 0.002 PP monofil, braided on a 6 mm mandrel at a 90 degrees braid angle. In some variations the distal tractor region is formed of a knit braid (assume .072" catheter) and may include 16 ends or 40D PET multifil free warp-knitted, annealed on a 3 mm mandrel. In some variations the distal tractor region is formed of 16 ends of 0.002" PP monofil warp-knitted, annealed on a 3 mm mandrel. In variations having a distal tractor region formed of ePTFe tubes (again, assuming a 0.072" catheter), the distal tractor region may be 0.002" thick, 3mm tube. Alternatively, the distal tractor region may be a 0.002" thick, 3mm tube laser slotted to collapse and grab clot.

[0166] As mentioned, in some variations the apparatus is configured to include a gripping inner mesh surface in the distal tractor region. For example the apparatus may include a laser slotted ePTFE tube having larger diameter braid filaments and/or mixed diameter filaments. In some variations a gripping inner mesh surface may be formed with a knit braid that is a warp knit formed tube. Such a structure may have a natural macro structure to allow mesh rolling and gripping of clot, since filaments

do not enter catheter ID parallel to catheter, but rather they are perpendicular or looped relative to catheter long axis. For examples in which the distal tractor region is formed of an ePTFE laser slotted (sheet of) material, the structure may include slots cut to allow Poisson ratio to effect tube diameter while creating grippy texture to grab clot.

[0167] In general, the effectiveness of the distal tractor region in grabbing a clot may be enhanced by using self-expanding and/or stiffer distal tractor region (e.g., self-expanding and/or flexible first end regions of the distal tractor region). When the first end region of the distal tractor region is formed of a braid, stiffer filaments (e.g., formed of bigger diameter filaments, stiffer materials, larger number of fibers, etc.) may result in more expanded first end regions of the distal tractor region, as illustrated in FIGS. 18A-18C. In FIG. 18A a softer distal tractor region does not expand out beyond the OD of the catheter any substantial distance. FIG. 18B shows a slightly stiffer/more expandable first end region of the distal tractor region. FIG. 18C shows the most expandable distal tractor region 1801, which may optimally expand to the intima of the vessel 1803.

[0168] As shown in FIGS. 18A-18C, the mouth of lip of the expandable tractor region may form a tangent angle or roll angle (ϕ) with respect to the long axis of the catheter OD. This angle may be in the range of approximately 5° to 60° degrees (e.g., 10°-60°, 10°-50°, 10°-45°, 10°-40°, etc., and preferable at least 10 degrees). The inventors have surprisingly found that, in some variations, having a roll angle of at least about 10 degrees (e.g., 10°-60°, 10°-50°, 10°-45°, 10°-40°) with the tube as the tractor region is retracted into the catheter may prevent binding or jamming on the catheter tip. The mesh tube may be modified (e.g., at the distal tip or end region), including by modifying the stiffness and/or shape of the distal tip, to ensure the roll angle in greater than 10 degrees. Alternatively or in combination to maintaining a minimum roll angle it may be desirable to maintain a physical space or gap between the tube material ID and the O.D of the catheter (see, e.g., FIGS. 18A-18C) at the catheters most distal tip. The gap may need to be greater than 0.1 mm, 0.2 mm, 0.3 mm, 0.4 mm, 0.5 mm, 0.7 mm, 0.8 mm, or 1.0mm to ensure the tube rolls around the distal end of the catheter when the tube is retracted.

[0169] In any of these variations, the distal tractor region may be lubricious (e.g., hydrophilic coating, silicone coating, thin urethane or other thin elastomeric coating) as mentioned above. One or more polymeric braid ends may be included to enhance lubricity (e.g., polypropylene, nylon, etc.). Further, the braid angle may be kept small (e.g., less than 70 degrees, 50 degrees, 45 degrees, etc.) to allow better pulling. This angle may be measured when the distal tractor region is rolling around/over the tip of the catheter. Increasing the number of ends of the weave may also prevent locking of the first end region within the catheter, so that gaps/spaces between the braid elements are smaller and less likely to snag on the catheter tip when rolling the distal tractor region over the end of the catheter. Any of these apparatuses may also include an axial element when formed as a braided element that is less likely to collapse or reduce in diameter when pulled, and therefore less likely to hang up on the catheter opening when rolling over the tip. It may also be advantageous to use slightly larger braid filaments when using Niti (e.g., >0.0001" diameter); the greater the diameter, the less likely the braid may deform to lock onto

the catheter tip. As mentioned above, in some variations the distal tractor region may be heat set to automatically roll over the distal end of the catheter when advanced distally.

[0170] FIGS. 19A and 19B illustrate alternative methods for forming the doubled-back configuration of the distal tractor region. In FIG. 19A, the tubular distal tractor region 1903 may be coupled to a puller/pusher 1901 and then inverted over the catheter tip as mentioned above. In FIG. 19B, the tubular braid 1905 is attached distally through the braid to a wire/puller 1901 and pulled to invert it over the distal end of the catheter.

[0171] In general, the first end region of the distal tractor region may have any appropriate shape (refer to FIGS. 15A-15D). FIGS. 20A and 20B illustrate examples of tapered woven braids that may form the distal tractor region. In. FIG. 20A, the braid has a tapered side profile that may be attached to a puller (proximal end of the flexible tractor tube) and inverted. Any of the braids described herein may include a marker wire (e.g., DFT, gold, Pt, Pt iridium, etc.) to help with visualization (e.g., fluoroscopically). In FIG. 20B, the mesh is tapered more abruptly than in FIG. 20A.

[0172] As described above, in general, any of the catheters described herein may be adapted for use with these apparatuses. For example an appropriate catheter may be highly flexible with a good column stiffness (e.g., will not shorten in length when advanced distally). The catheter can have a high angle braid reinforcing element. For example, the catheter may have a high angle braid through proximal to distal end (70-85 degrees, small wire Niti, Stainless, cobalt chrome, MP35N, flat or round wire), and a lower braid angle for the distal 1 to 5 cm of the catheter. This will allow the id of the catheter to expand when axial compression is applied, and/or under an internal expanding force (e.g., clot).

[0173] In general, any of these catheters may include a changing stiffness/compliance. For example, the proximal third (1/3) may be stiffer; the middle section may be less stiff, and the distal 20% (1/5) may be the least stiff. Further, the distal tip of the catheter may have an appropriate radius (curve) as described in FIGS. 1A and 1B. In general, the radius should be smooth and round, and not square. In addition, the distal tip of the catheter may be made of a hard enough material (~72D or harder) to allow braid to roll and not grab onto tip. For example, the catheter tip may have a hard metallic structure to reduce friction (e.g., stainless steel, Pt, etc.). The less the catheter tip compresses/buckles when pulling the distal tractor region, the better. In some variations the catheter includes an additional reinforcement such as a braid reinforcement rather than a coil reinforcement, to prevent braid buckling for the last 5-10 cm of the catheter. Thus, as described herein, in some variations, the tip of the catheter may be made of a lubricous and/or hard material to help reduce the braid to catheter tip friction when the braid is pulled or pushed around the catheter tip. Lubricous materials may include flour-polymers like PTFE, FEP and/or hydrophilic coatings. Hard materials like Nylons, or metallics like stainless steel, Platinum and PT iridium alloys could be used at the tip and fused/attached to softer materials proximally. If a hard tip is put on the distal end of the catheter tip it may be short in length (e.g., < 5mm and preferably < 3mm) so it does not adversely affect catheter tracking.

[0174] FIGS. 21A-21D show examples of apparatuses used to remove clots. In this example, the distal tractor region was formed of a fine Denier PET mesh of approximately 72 ends that is 10 mm

(expanded) diameter pulled down onto a 0.071" catheter, as shown in FIGS. 21A and 21B. FIG. 21A shows an example of an expandable first end region prior to coupling to a catheter. FIG. 21B illustrates the expandable first end region within a vessel (glass tube) being drawn into a catheter by pulling the proximal end of the flexible (tractor) tube. FIG. 21C shows the distal end region of the apparatus including the expandable first end regions doubled over the distal end region of the catheter. FIG. 21D illustrates the apparatus of FIG. 21C drawing a clot into the catheter.

[0175] Another example examined a distal tractor region formed from a 6 mm braid having 72 ends and 0.001" diameter filaments rolling into and doubled over a 0.071" ID catheter. A 'medium hard' 5 mm clot that was 20 cm long was successfully removed. FIG. 22 shows the expandable first end region of FIG. 21D with the captured clot after drawing it proximally out of the catheter.

[0176] FIGS. 23A-23D illustrate a mechanical thrombectomy apparatus as described herein capturing a blood clot and drawing it into the apparatus. FIG. 23E illustrates the clot held within the flexible tractor tube after the flexible tractor tube has been removed from the catheter (e.g., proximally).

[0177] In some variations described herein the distal tractor region is not formed of a woven or knitted material, but is instead composed of strip or bundles of longitudinally arranged (e.g., in parallel or near-parallel arrangement). For example, FIG. 24 is another example of an apparatus including a flexible tractor member in which the distal tractor region is formed of a plurality of filaments that are arranged as strips of material (longitudinally parallel) that are not woven or braided. These strips may be filaments, or tubes, etc.

[0178] FIGS. 25A-25F illustrate another variation of a distal tractor region of a flexible tractor assembly in which the expandable first end region (e.g., the distal end region of the distal tractor region) is formed of a plurality of filaments or strips, similar to that shown in FIG. 24; the distal end of the catheter includes channels, as shown in FIGS. 25A-24B; the strips may fit within these channels, as shown in FIGS. 25C-25D. FIGS. 25E and 25F show sectional views through FIGS. 25C and 25D. FIGS. 25A, 25C and 25E show side views and FIGS. 25B, 25D and 25F show axial views. In this example, the catheter tip includes channels 2502 into which the filaments/strips 2503 run. The strips forming the distal tractor region are attached to the more proximate puller region of the flexible tractor tube 2505, shown in FIG. 25E.

[0179] FIGS. 26A and 26B show a variation of the apparatus of FIGS. 25A-25F with an outer sleeve (e.g., an outer catheter or release protector catheter or other outer sleeve/protector)

[0180] FIGS. 27A-27B show a sectional view through the apparatus of FIGS. 26A-26B.

[0181] FIG. 28 is an apparatus including a distal tractor region of a flexible tractor assembly having a plurality of longitudinally-parallel (non-woven/braided) filaments or strips in which the distal ends of the filaments or strips are connected to each other by a distal connector.

[0182] FIG. 29 shows a distal tractor region of a flexible tractor assembly in an apparatus in which the longitudinally-parallel (non-woven/braided) filaments or strips include grabbing elements.

[0183] FIGS. 30A-30C illustrate example of filaments/strips with grabbing elements. Grabbing elements (and/or filaments including them) may be used as part of any of the variations described herein,

including woven or braided distal tractor regions. Other options for filaments/strips with grabbing elements may include braided strips, mesh/woven strips, and micro-coils.

[0184] In any of these configuration described herein, the apparatus may be adapted to allow reciprocation of the distal tractor region, cycling from outside to inside and back outside of the distal end of the catheter. For example, FIG. 31 illustrates a variation in which the distal tractor region is adapted to be reciprocated (e.g., pushed and pulled) so that the expandable first end region may be draw into and reversed out of the catheter. In this example, the tractor tube (puller) 3105 is attached to the distal tractor region 3144 that may be attached (and in some variations is not attached) to a second catheter 3109 over the inner catheter 3101. The mid-catheter 3109 can be coupled to the puller 3105 and the two reciprocated together so that the braid reciprocated back and forth inside of the catheter 3101. This may help break up a clot, which may be particularly when used with suction.

[0185] FIG. 32 illustrates another example of an apparatus as described herein in which the distal-most end 3205 of the flexible first end region of the distal tractor region is non-releasably fixed to the distal end of the outside of the catheter 3201; the rest of the expandable first end region 3209 is sufficiently elastic/flexible to be drawn into the catheter (pulling a clot 3255 with it). The flexible tractor assembly may then be left retracted and the entire apparatus withdrawn. This example may include an optional vacuum 3260.

[0186] FIG. 33 is another example of an apparatus in which the puller portion 3305 of the flexible tractor assembly is formed of the same material as the distal tractor region 3344 but may be laminated or otherwise reinforced to have less flexibility/stretchability than the distal tractor region.

[0187] FIG. 34 illustrates another example in which the distal tractor region 3444 is adapted to compress the clot 3455 when draw into the catheter 3401. FIGS. 35A-35C illustrate operation of an apparatus as shown in FIG. 34 in which the clot 3455 is drawn into the catheter by withdrawing the expandable first end region of the distal tractor region into the catheter (e.g., pulling on the puller region 3505 of the tractor assembly) which compresses the clot (FIGS. 35A-35B); releasing the tractor assembly and/or pushing it distally may further break up the clot and release it from the distal tractor region so that it may be sectioned up proximally (FIG. 35C).

[0188] FIG. 36 illustrates an example of an apparatus and method of use in which drawing the flexible tractor assembly proximally may advance the apparatus distally through the body (e.g., vessel) over a guidewire, which may be treated to engage the distal tractor region. In this example, the apparatus may be configured to pull the inner tractor tube (catheter 3605) which has the mesh forming the distal tractor region 3644 attached to its distal end and inverting over the distal end of the catheter 3601. Pulling the flexible tractor tube 3605 makes the braid roll over the opening of the catheter 3601. The mesh/braid forming the distal tractor region (e.g., the first end region of the distal tractor region) is constructed to collapse in diameter when tensile loads are applied to this structure and lock/grab onto inner wire (guidewire 3677). This inner guidewire may have a tacky, rough or knobby surface aid mesh/braid grabbing onto wire. As the mesh/braid grabs onto the guidewire, the tractor tube, as a

reactionary force, will be driven forward in the vessel. Alternatively the user will be able to easily advance outer catheter 3601 forward through vessel while pulling back on the tractor tube.

[0189] FIGS. 37A-37C illustrate another apparatus and method of use in which drawing the flexible tractor assembly proximally may advance the apparatus distally. In FIG. 37A, the distal tractor region 3744 is attached to a middle catheter 3703 (an optional outer catheter 3705 may be included) and the opposite end of the distal tractor region 3744 is bonded to the distal end of the inner catheter 3701 within the inner diameter of this catheter. In FIG. 37B the inner catheter is advanced distally, expanding the distal tractor region both laterally and forward. As shown in FIG. 37C, the outer and inner catheters may then be pushed distally to move the apparatus more distally.

[0190] In some variations the distal and flexible tractor region may be held pre-loaded outside of the catheter, e.g., in a roll or bundle, over the distal end region of the catheter, so that it can be gradually pulled out of the external storage region and rolled and inverted over the distal end of the catheter. An example of one such variation is shown in FIGS. 38A and 38B. this exemplary apparatus may be used to remove material from within a vessel as shown in FIG. 38B, and may be referred to as an "infinite" tractor mechanism because a large amount (e.g., greater than 50 cm, greater than 60 cm, greater than 70 cm, greater than 80 cm, greater than 90 cm, greater than 100 cm, greater than 150 cm, 200 cm, greater than 300 cm, greater than 400 cm, greater than 500 cm, etc.) of tractor material (e.g., mesh) may be stored in an external holding region, wound-up but dispensable over an extended use.

[0191] In FIG. 38A, the apparatus may include the catheter (inner catheter) 3811 and the distal tractor region 3806 is formed of a mesh that is rolled up 3803 in a housing region 3813 proximal to the distal end of the catheter. The clot 3805 may be drawn into the catheter by pulling the distal tractor region proximally within the catheter. Because a great deal of distal tractor region may be stored and withdrawn proximally, this variation may be useful for very long procedures or where there is a lot of material to be removed.

[0192] This variation may allow a user to unroll a long length of mesh, which may be advantageous for more rigid tools, such as, for example, a rigid hypotube during surgery, for example, removing fat in a liposuction procedure, removing clot in an intracerebral hemorrhage or a larger peripheral vascular clot.

[0193] As mentioned above, in any of the variations described herein, the distal tractor member may be a woven (e.g., knit) or braided mesh material. The mesh may be a knit material, including, for example a weft knit, circular knit, warp braid knit, and/or braid knit.

[0194] When a feature or element is herein referred to as being "on" another feature or element, it can be directly on the other feature or element or intervening features and/or elements may also be present. In contrast, when a feature or element is referred to as being "directly on" another feature or element, there are no intervening features or elements present. It will also be understood that, when a feature or element is referred to as being "connected", "attached" or "coupled" to another feature or element, it can be directly connected, attached or coupled to the other feature or element or intervening features or elements may be present. In contrast, when a feature or element is referred to as being "directly connected", "directly attached" or "directly coupled" to another feature or element, there are no

intervening features or elements present. Although described or shown with respect to one embodiment, the features and elements so described or shown can apply to other embodiments. It will also be appreciated by those of skill in the art that references to a structure or feature that is disposed "adjacent" another feature may have portions that overlap or underlie the adjacent feature.

[0195] Terminology used herein is for the purpose of describing particular embodiments only and is not intended to be limiting of the invention. For example, as used herein, the singular forms "a", "an" and "the" are intended to include the plural forms as well, unless the context clearly indicates otherwise. It will be further understood that the terms "comprises" and/or "comprising," when used in this specification, specify the presence of stated features, steps, operations, elements, and/or components, but do not preclude the presence or addition of one or more other features, steps, operations, elements, components, and/or groups thereof. As used herein, the term "and/or" includes any and all combinations of one or more of the associated listed items and may be abbreviated as "/".

[0196] Spatially relative terms, such as "under", "below", "lower", "over", "upper" and the like, may be used herein for ease of description to describe one element or feature's relationship to another element(s) or feature(s) as illustrated in the figures. It will be understood that the spatially relative terms are intended to encompass different orientations of the device in use or operation in addition to the orientation depicted in the figures. For example, if a device in the figures is inverted, elements described as "under" or "beneath" other elements or features would then be oriented "over" the other elements or features. Thus, the exemplary term "under" can encompass both an orientation of over and under. The device may be otherwise oriented (rotated 90 degrees or at other orientations) and the spatially relative descriptors used herein interpreted accordingly. Similarly, the terms "upwardly", "downwardly", "vertical", "horizontal" and the like are used herein for the purpose of explanation only unless specifically indicated otherwise.

[0197] Although the terms "first" and "second" may be used herein to describe various features/elements (including steps), these features/elements should not be limited by these terms, unless the context indicates otherwise. These terms may be used to distinguish one feature/element from another feature/element. Thus, a first feature/element discussed below could be termed a second feature/element, and similarly, a second feature/element discussed below could be termed a first feature/element without departing from the teachings of the present invention.

[0198] Throughout this specification and the claims which follow, unless the context requires otherwise, the word "comprise", and variations such as "comprises" and "comprising" means various components can be co-jointly employed in the methods and articles (e.g., compositions and apparatuses including device and methods). For example, the term "comprising" will be understood to imply the inclusion of any stated elements or steps but not the exclusion of any other elements or steps.

[0199] As used herein in the specification and claims, including as used in the examples and unless otherwise expressly specified, all numbers may be read as if prefaced by the word "about" or "approximately," even if the term does not expressly appear. The phrase "about" or "approximately" may be used when describing magnitude and/or position to indicate that the value and/or position described is

within a reasonable expected range of values and/or positions. For example, a numeric value may have a value that is +/- 0.1% of the stated value (or range of values), +/- 1% of the stated value (or range of values), +/- 2% of the stated value (or range of values), +/- 5% of the stated value (or range of values), +/- 10% of the stated value (or range of values), etc. Any numerical values given herein should also be understood to include about or approximately that value, unless the context indicates otherwise. For example, if the value "10" is disclosed, then "about 10" is also disclosed. Any numerical range recited herein is intended to include all sub-ranges subsumed therein. It is also understood that when a value is disclosed that "less than or equal to" the value, "greater than or equal to the value" and possible ranges between values are also disclosed, as appropriately understood by the skilled artisan. For example, if the value "X" is disclosed the "less than or equal to X" as well as "greater than or equal to X" (e.g., where X is a numerical value) is also disclosed. It is also understood that the throughout the application, data is provided in a number of different formats, and that this data, represents endpoints and starting points, and ranges for any combination of the data points. For example, if a particular data point "10" and a particular data point "15" are disclosed, it is understood that greater than, greater than or equal to, less than, less than or equal to, and equal to 10 and 15 are considered disclosed as well as between 10 and 15. It is also understood that each unit between two particular units are also disclosed. For example, if 10 and 15 are disclosed, then 11, 12, 13, and 14 are also disclosed.

[0200] Although various illustrative embodiments are described above, any of a number of changes may be made to various embodiments without departing from the scope of the invention as described by the claims. For example, the order in which various described method steps are performed may often be changed in alternative embodiments, and in other alternative embodiments one or more method steps may be skipped altogether. Optional features of various device and system embodiments may be included in some embodiments and not in others. Therefore, the foregoing description is provided primarily for exemplary purposes and should not be interpreted to limit the scope of the invention as it is set forth in the claims.

[0201] The examples and illustrations included herein show, by way of illustration and not of limitation, specific embodiments in which the subject matter may be practiced. As mentioned, other embodiments may be utilized and derived there from, such that structural and logical substitutions and changes may be made without departing from the scope of this disclosure. Such embodiments of the inventive subject matter may be referred to herein individually or collectively by the term "invention" merely for convenience and without intending to voluntarily limit the scope of this application to any single invention or inventive concept, if more than one is, in fact, disclosed. Thus, although specific embodiments have been illustrated and described herein, any arrangement calculated to achieve the same purpose may be substituted for the specific embodiments shown. This disclosure is intended to cover any and all adaptations or variations of various embodiments. Combinations of the above embodiments, and other embodiments not specifically described herein, will be apparent to those of skill in the art upon reviewing the above description.

CLAIMS

What is claimed is:

1. A method of performing a mechanical thrombectomy to remove a clot from a blood vessel, the method comprising:

advancing a distal end of a catheter through the blood vessel towards the clot;

exposing a distal tractor region of a tube that is within the catheter from the distal end of the catheter, wherein the distal tractor region comprises an expandable first end region and a less expandable second end region proximal to the expandable first end region;

allowing the expandable first end region to expand within the blood vessel;

positioning the distal end of the catheter so that a distal end region of the catheter is between the less expandable second end region and the expandable first end region of the distal tractor region while the expandable first end region is doubled over the less expandable second end region; and

drawing the clot into the catheter by rolling the expandable first end region over the distal end of the catheter so that the expandable first end region inverts as the expandable first end region is pulled into the catheter.

2. The method of claim 1, wherein positioning comprises distally advancing the distal end of the catheter so that the distal end region of the catheter is between the less expandable second end region and the expandable first end region of the distal tractor region.

3. The method of claim 1, further comprising advancing a guidewire within the blood vessel to the clot, wherein advancing the distal end of the catheter comprises advancing the catheter over the guidewire through the blood vessel until the distal end of the catheter is proximate to the clot.

4. The method of claim 1, further comprising advancing a guidewire within the blood vessel to the clot, wherein advancing the distal end of the catheter comprises advancing the catheter over the guidewire through the blood vessel until the distal end of the catheter is proximate to the clot, further wherein drawing the clot into the catheter comprises advancing the catheter towards the clot over the guidewire while rolling the expandable first end region over the distal end of the catheter.

5. The method of claim 1, wherein drawing the clot into the catheter comprises withdrawing the tube proximally.

6. The method of claim 1, wherein drawing the clot into the catheter comprises withdrawing the tube proximally while advancing the catheter distally.

7. The method of claim 1, wherein drawing the clot into the catheter comprises withdrawing the tube proximally while advancing the catheter distally, wherein the tube is withdrawn at a different rate than the catheter is advanced.

8. The method of claim 1, wherein allowing the expandable first end region to expand within the blood vessel comprises allowing a biasing element in the expandable first end region to expand so that the distal tractor region makes contact with an intima of the blood vessel.

9. The method of claim 1, wherein exposing the distal tractor region of the tube that is within the catheter from the distal end of the catheter comprises pushing the distal tractor region out of the distal end of the catheter.

10. The method of claim 1, wherein exposing the distal tractor region of the tube that is within the catheter out of the distal end of the catheter comprises pulling the catheter proximally.

11. The method of claim 1, wherein exposing the distal tractor region of the tube that is within the catheter from the distal end of the catheter comprises pushing the distal tractor region out of the distal end of the catheter to expose the expandable first end region already inverted over the less expandable second end region.

12. The method of claim 1, wherein exposing the distal tractor region of the tube that is within the catheter from the distal end of the catheter comprises extending the expandable first end region out of the distal end of the catheter so that the expandable first end region inverts over the distal end of the catheter as the expandable first end region is extended.

13. The method of claim 1, wherein exposing the distal tractor region of the tube comprises exposing at least 5 mm of the expandable first end region and at least 5 mm of the less expandable second end region.

14. The method of claim 1, wherein exposing the distal tractor region comprises exposing at least 1 cm of the expandable first end region inverted over at least 1 cm of the less expandable second end region.

15. The method of claim 1, wherein the expandable first end region comprises a mesh that is coupled adjacent to the less expandable second end region.

16. The method of claim 1, wherein the expandable first end region comprises one or more of: a woven material, a mesh braided material, a knitted material, or a film material with multiple openings therethrough.

17. The method of claim 1, wherein advancing comprises advancing the distal end of the catheter through the blood vessel to position the distal end adjacent to the clot.

18. A method of performing a mechanical thrombectomy to remove a clot from a blood vessel, the method comprising:

advancing a distal end of a catheter through the blood vessel towards the clot;

exposing a distal tractor region of a tube that is within the catheter from the distal end of the catheter, wherein the distal tractor region comprises an expandable first end region and a less expandable second end region proximal to the expandable fist end region and configured so that the expandable first end region is inverted over the less expandable second end region;

allowing the expandable first end region to expand within the blood vessel so that the distal end region of the catheter is between the less expandable second end region and the expandable first end region of the distal tractor region; and

drawing the clot into the catheter by advancing the catheter distally and withdrawing the tube proximally within the catheter so that the expandable first end region rolls over the distal end of the catheter and inverts as the expandable first end region is pulled into the catheter.

19. The method of claim 18, wherein the expandable first end region is inverted over the less expandable second end region before exposing the distal tractor region.

20. The method of claim 18,wherein the exposing the distal tractor region comprises inverting the expandable distal end region over the less expandable second end region as the distal tractor region is exposed.

21. The method of claim 18, further comprising, before exposing the distal tractor region, advancing a guidewire within the blood vessel to the clot and advancing the catheter over the guidewire through the blood vessel until a distal end of the catheter is proximate to the clot.

22. The method of claim 18, further comprising, before exposing the distal tractor region, advancing a guidewire within the blood vessel to the clot and advancing the catheter over the guidewire

through the blood vessel until a distal end of the catheter is proximate to the clot and leaving the guidewire in place while drawing the clot into the catheter.

23. The method of claim 18, wherein exposing the distal tractor region of the tube that is within the catheter from the distal end of the catheter comprises pushing the distal tractor region out of the distal end of the catheter.

24. The method of claim 18, wherein exposing the distal tractor region of the tube that is within the catheter out of the distal end of the catheter comprises pulling the catheter proximally.

25. The method of claim 18, wherein exposing the distal tractor region of the tube comprises exposing at least 5 mm of the expandable first end region and at least 5 mm of the less expandable second end region.

26. The method of claim 18, wherein the expandable first end region of the distal tractor region comprises a mesh that is coupled adjacent to the less expandable second end region.

27. The method of claim 18, wherein the expandable first end region comprises one or more of: a woven material, a mesh braided material, or a film material with multiple openings therethrough.

28. A method of performing a mechanical thrombectomy to remove a clot from a blood vessel, the method comprising:

advancing a distal end of a catheter through the blood vessel towards the clot;

exposing a distal tractor region of a tube that is within the catheter out of the distal end of the catheter, wherein the distal tractor region comprises an expandable first end region and a less expandable second end region, wherein exposing comprises extending the expandable first end region out of the distal end of the catheter so that the expandable first end region inverts over the distal end of the catheter as the expandable first end region is extended;

allowing the expandable first end region to expand within the blood vessel as it is extended out of the distal end of the catheter so that a distal end region of the catheter is between the less expandable second end region and the expandable first end region; and

drawing the clot into the catheter by withdrawing the tube proximally within the catheter so that the expandable distal end region rolls over the distal end of the catheter, collapses, and inverts as the expandable distal end region is pulled into the catheter.

29. The method of claim 28, further comprising advancing a guidewire within the blood vessel to the clot, wherein advancing the distal end of the catheter comprises advancing the catheter over the guidewire through the blood vessel until a distal end of the catheter is proximate to the clot.

30. The method of claim 28, wherein exposing the distal tractor region of the tube that is within the catheter from the distal end of the catheter comprises pushing the distal tractor region out of the distal end of the catheter.

31. The method of claim 28, wherein exposing the distal tractor region of the tube that is within the catheter out of the distal end of the catheter comprises withdrawing the catheter proximally relative to the distal tractor region of the tube.

32. The method of claim 28, wherein exposing the distal tractor region of the tube comprises exposing at least 5 mm of the expandable first end region and at least 5 mm of the less expandable second end region.

33. The method of claim 28, wherein the expandable first end region comprises a mesh that is coupled adjacent to the less expandable second end region.

34. The method of claim 28, wherein the expandable first end region comprises one or more of: a woven material, a mesh braided material, or a film material with multiple openings therethrough.

35. A mechanical thrombectomy apparatus for removing a clot from a vessel, the apparatus comprising:

a catheter having a distal end and a distal end opening;

a flexible tube extending within the catheter and doubling back over the distal end of the catheter, wherein the flexible tube is configured to slide and invert over the distal end opening when a first end of the flexible tube is pulled proximally within the catheter; and

a guidewire lumen through the catheter and the flexible tube that is configured to pass a guidewire.

36. A mechanical thrombectomy apparatus for removing a clot from a vessel, the apparatus comprising:

a catheter having a distal end and a distal end opening, wherein the distal end opening has a **durometer that is greater than a durometer of a region immediately proximal to the distal end**, further wherein the distal end opening has a rounded lip profile;

a flexible tube extending within the catheter and doubling back over the distal end of the catheter, wherein the flexible tube is configured to invert over the distal end opening when a first end of the flexible tube is pulled proximally within the catheter; and

a guidewire lumen through the catheter and the flexible tube configured to pass a guidewire.

37. A mechanical thrombectomy apparatus for removing a clot from a vessel, the apparatus comprising:

an inner catheter having a distal end and a distal end opening;

a flexible tube extending though the catheter and doubling back over the distal end of the inner catheter, wherein the flexible tube is configured to invert over the distal end opening when a first end of the flexible tube is pulled proximally within the inner catheter;

an outer catheter extending over the inner catheter and flexible tube;

a **lubricious region of the flexible tube extending between a distal end of the outer catheter and the distal end opening of the inner catheter**, wherein the majority of the flexible tube is not lubricious; and

a guidewire lumen through the catheter and the flexible tube configured to pass a guidewire.

38. A mechanical thrombectomy apparatus for removing a clot from a vessel, the apparatus comprising:

an inner catheter having a distal end and a distal end opening;

a flexible tube extending though the catheter and doubling back over the distal end of the inner catheter, wherein the flexible tube is configured to invert over the distal end opening when a first end of the flexible tube is pulled proximally within the inner catheter;

a releasable attachment between the flexible tube and an outer surface of the catheter, configured to release when the flexible tube is pulled with a predetermined force that is greater than 0.01 N; and

a guidewire lumen through the catheter and the flexible tube configured to pass a guidewire.

39. A mechanical thrombectomy apparatus for removing a clot from a vessel, the apparatus comprising:

a catheter having a distal end, a distal end opening and an inner diameter;

a flexible tube extending through the catheter and doubling back over the distal end of the catheter, wherein the flexible tube is configured to invert over the distal end opening

when a first end of the flexible tube is pulled proximally within the catheter, the **flexible tube having a low Poisson's ratio**, such that the flexible tube has a diameter of greater than half the inner diameter of the catheter when pulled proximally within the catheter with sufficient force to invert over the distal end opening; and

a guidewire lumen through the catheter and the flexible tube configured to pass a guidewire.

40. The apparatus of claims 35, 36, 37, 38 and 39, wherein the flexible tube comprises a mesh tube.

41. The apparatus of claims 35, 36, 37, 38 and 39, wherein the flexible tube extending through the catheter and doubling back over the distal end of the catheter increases the stiffness of a distal 5cm of the catheter by less than 15% of the stiffness of the distal 5 cm of the catheter without the flexible tube extending therethrough and doubling back over the distal end of the catheter.

42. The apparatus of claims 35, 36, 37, 38 and 39, wherein the flexible tube has at least one porous section having a pore pattern having a longitudinal separation between pores of less than about 0.005 inches in width.

43. The apparatus of claims 35, 36, 37 and 39, further comprising a releasable attachment between the flexible tube and an outer surface of the catheter, configured to release when the flexible tube is pulled with a force that is greater than a predetermined force threshold.

44. The apparatus of claim 43, wherein the releasable force threshold is 0.01 N.

45. The apparatus of claims 35, 36, 37, 38 and 39, wherein the flexible tube comprises a plurality of strips of flexible material, wherein the strips are arranged in parallel.

46. The apparatus of claims 35, 36, 37, 38 and 39, wherein the distal end opening comprises a plurality of notches or channels into which fibers or strips forming the flexible tube are drawn as the flexible tube inverts over the distal end opening.

47. The apparatus of claims 35, 36, 37, 38 and 39, wherein the flexible tube comprises a polymeric tube having a plurality of holes therethrough.

48. The apparatus of claims 35, 36, 37, 38 and 39, wherein the flexible tube comprises a distal end, a proximal end and a body region there between, wherein the body region transitions from a more flexible distal end to a stiffer proximal end.

49. The apparatus of claims 35, 37, 38 and 39, wherein the distal end opening has a durometer that is greater than a durometer of a region immediately proximal to the distal end, further wherein the distal end opening has a rounded lip profile

50. The apparatus of claims 35, 36, 37, 38 and 39, further comprising a handle adapted to draw the flexible tube proximally relative to the catheter.

51. The apparatus of claims 35, 36, 38 and 39, further comprising an outer catheter extending over the catheter and flexible tube.

52. The apparatus of claims 35, 36, 38 and 39, further comprising an outer catheter extending over the catheter and flexible tube and a lubricious region of the flexible tube extending between a distal end of the outer catheter and the distal end opening, wherein the majority of the flexible tube is not lubricious.

53. The apparatus of claims 35, 36, 37 and 38, wherein the flexible tube is configured to invert over the distal end opening when a first end of the flexible tube is pulled proximally within the catheter wherein the flexible tube has a low Poisson's ratio such that the flexible mesh tube has a diameter of greater than half the inner diameter of the catheter when pulled proximally within the catheter with sufficient force to invert over the distal end opening.

54. The apparatus of claims 35, 36, 37, 38 and 39, further comprising an elongate puller within the catheter and coupled to a distal end of the flexible tube.

55. The apparatus of claims 35, 36, 37, 38 and 39, further comprising an elongate puller within the catheter and coupled to a distal end of the flexible tube, wherein the elongate puller comprises a hypotube having an inner lumen that is continuous with the guidewire lumen though the flexible tube.

56. The apparatus of claims 35, 36, 37, 38 and 39, wherein the flexible tube comprises a soft outer mesh member formed from 48 to 144 stands, having a thickness of 0.0020 inches or less in diameter, wherein the mesh tubular member extends in a longitudinal axis, further wherein the mesh tubular member has a length that is greater than 5 cm, forms a braid angle between crossing strands in a direction of the longitudinal axis of about 35 degrees or less when being pulled and inverted around the distal end of the catheter and expands to a diameter of greater than 1.5 times an inner diameter of the catheter outside of the catheter when unconstrained.

57. The apparatus of claim 56, where the strand is formed of any of the following; monofilament polymer, multifilament polymer, NiTi filament, NiTi tube with radiopaque metallic center, Nylon, Polyester, Polyethylene terephthalate, and Polypropylene, .

58. The apparatus of claims 35, 36, 37, 38 and 39, further comprising a drive handle coupled to a proximal end region of the catheter, wherein the drive handle comprises a control configured to coordinate advancing of the catheter distally while retracting the flexible tube proximally when actuated.

59. The apparatus of claims 35, 36, 37, 38 and 39, further comprising a retaining ring around a distal end region of the flexible tube configured to hold the flexible tube against the catheter.

60. The apparatus of claims 35, 36, 37, 38 and 39, wherein the flexible tube is shape set to have different diameter when within the catheter after being pulled proximally into the catheter.

61. The apparatus of claims 35, 36, 37, 38 and 39, wherein the flexible tube comprises a plurality of woven or knitted filaments.

62. The apparatus of claims 35, 36, 37, 38 and 39, wherein the flexible tube comprises a plurality of woven or knitted filaments, and further wherein the proximal end of the flexible tube forms a tapered opening opposite from a bundle of filaments forming a pull wire.

63. The apparatus of claims 35, 36, 37, 38 and 39, wherein the flexible tube is formed from a sleeve of polymer having a thickness less than 0.020 inches, wherein the sleeve comprises a perforation pattern in which the perforations extend through the polymer.

64. The apparatus of claim 63, wherein the perforation pattern comprises perforations having a shaped consisting of one or more of: round holes, rectangular holes and zig-zag shapes.

65. The apparatus of claims 35, 36, 37, 38 and 39, further comprising a pull wire coupled to one side of a proximal end of the flexible tube configured to be drawn proximally to pull the flexible tube within the catheter.

66. The apparatus of claims 35, 36, 37, 38 and 39, wherein the flexible tube is 3 to 50 cm.

67. The apparatus of claims 35, 36, 37, 38 and 39, wherein the flexible tube of the apparatus is configured so that the flexible tube may be retracted into the catheter by applying less than 300 grams of force to a distal end of the flexible tube.

68. The apparatus of claims 35, 36, 37, 38 and 39, wherein the flexible tube comprises a taper between the first end and a second end of the flexible tube.

69. The apparatus of claims 35, 36, 37, 38 and 39, wherein the flexible tube extends within the entire length of the catheter so that a proximal end of the flexible tube is configured to be pulled proximally away from the proximal end of the catheter to slide and invert the flexible tube over the distal end opening.

70. The apparatus of claim 35, 36, 37, 38 and 39, further comprising a guidewire vacuum pump coupled to a proximal end of the guidewire lumen and configured to apply vacuum therethrough.

71. The apparatus of claims 35, 36, 37, 38 and 39, further comprising an outer catheter vacuum pump coupled to a space between the catheter and the flexible tube and configured to apply a vacuum within a lumen of the catheter between an inner wall of the catheter and the flexible tube.

72. The apparatus of claims 35, 36, 37, 38 and 39, further comprising a puller, wherein a distal end of the flexible tube is coupled to a distal end of the puller and an outer catheter arranged over the catheter adjacent to a proximal end of the flexible tube, further comprising a handle having a control configured to coordinate advancing of the outer catheter to push the proximal end of the flexible tube distally and pulling the puller proximally to drawn the proximal end of the flexible tube into the catheter.

73. The apparatus of claims 35, 36, 37, 38 and 39, further comprising:

a puller, wherein a distal end of the flexible tube is coupled to a distal end of the puller;

an outer catheter slideably arranged over the catheter coupled to a proximal end of the flexible tube; and

a handle having a control configured to coordinate advancing of the outer catheter distally to push the proximal end of the flexible tube distally while pulling of the puller proximally to drawn the proximal end of the flexible tube into the catheter or pulling the outer catheter proximally to pull the proximal end of the flexible tube proximally while pushing of the puller distally to push the proximal end of the flexible tube out of the catheter.

74. A method of mechanically removing a thrombectomy, the method comprising:

advancing a guidewire at least to the proximal end of a clot in a blood vessel;

advancing a thrombectomy apparatus distally over the guidewire, wherein the thrombectomy apparatus comprises a catheter having a distal end and a distal end opening and a flexible tube extending along an outer diameter of the catheter and over the distal end of the

catheter, so that the guidewire passes through a lumen of the catheter and the flexible tube;

pulling the flexible tube proximally from off of the outer diameter of the catheter and into the catheter lumen so that the flexible tube slides and inverts over the distal end opening; and

drawing a clot into the inverted flexible tube as the flexible tube is drawn into the catheter.

75. A method of mechanically removing a thrombectomy, the method comprising:

advancing a guidewire adjacent a clot in a blood vessel;

advancing a thrombectomy apparatus distally over the guidewire, wherein the thrombectomy apparatus comprises a catheter having a distal end and a distal end opening and a flexible tube extending along an outer diameter of the catheter and over the distal end of the catheter, so that the guidewire passes through a lumen of the catheter and the flexible tube;

pulling the flexible tube proximally from off of the outer diameter of the catheter and into the catheter lumen over a rounded lip of the distal end opening of the catheter so that the flexible tube slides and inverts over the distal end opening, wherein the distal end opening has a durometer that is greater than a durometer of a region immediately proximal to the distal end; and

drawing a clot into the inverted flexible tube as the flexible tube is drawn into the catheter.

76. A method of mechanically removing a thrombectomy, the method comprising:

advancing a guidewire adjacent a clot in a blood vessel;

advancing a thrombectomy apparatus distally over the guidewire, wherein the thrombectomy apparatus comprises an inner catheter having a distal end and a distal end opening, a flexible tube extending along an outer diameter of the inner catheter and over the distal end of the catheter, and an outer catheter securing a distal end region of the flexible tube against the outer diameter of the inner catheter, so that the guidewire passes through a lumen of the catheter and the flexible tube;

pulling the flexible tube proximally from off of the outer diameter of the catheter and into the catheter lumen so that a lubricious proximal leader region of the flexible tube slides and inverts over the distal end opening, until a non-lubricious distal region of the flexible tube is drawn into the inner catheter; and

drawing a clot into the inverted flexible tube as the flexible tube is drawn into the catheter.

77. A method of mechanically removing a thrombectomy, the method comprising:

advancing a guidewire adjacent a clot in a blood vessel;

advancing a thrombectomy apparatus distally over the guidewire, wherein the thrombectomy apparatus comprises a catheter having a distal end and a distal end opening and a flexible

tube extending along an outer diameter of the catheter and over the distal end of the catheter, so that the guidewire passes through a lumen of the catheter and the flexible tube;

pulling the flexible tube proximally from off of the outer diameter of the catheter and into the catheter lumen so that the flexible tube slides and inverts over the distal end opening;

pulling or pushing the flexible tube distally out of the distal end of the catheter so that the flexible tube slides and inverts over the distal end opening and over the outer diameter of the catheter; and

drawing a clot into the inverted flexible tube as the flexible tube is drawn into the catheter.

78. The method of claims 74, 75, 76, and 77, wherein the guidewire is positioned at least partially within the clot in the blood vessel.

79. A mechanical thrombectomy device for removing a clot from a vessel, the device comprising:

a catheter having a distal end and a distal end opening, wherein the catheter has an inner diameter and an outer diameter;

a distal tractor region of a tube within the catheter, wherein the distal tractor region comprises an expandable distal end region and a less expandable distal end region proximal to the expandable distal end region, the distal tractor region configured so that the expandable distal end region is inverted over the less expandable distal end region;

a guidewire lumen through the catheter and the tube, including the distal tractor region, wherein the guidewire lumen is configured to pass a guidewire; and

a proximal handle coupled to the tube and configured to cause relative motion between the catheter and the tube such that the distal tractor region is released from within the inner diameter of the catheter so that the expandable distal end region may expand to a diameter that is greater than the outer diameter so that the catheter may be advanced between the expandable distal end region and the less expandable distal end region and the tube may be drawn proximally to pull the expandable distal end region over the distal end of the catheter so that the expandable distal end region rolls into the distal end of the catheter, inverts, collapses and is drawn into the catheter.

80. A mechanical thrombectomy device for removing a clot from a vessel, the device comprising:

a catheter having a distal end and a distal end opening, wherein the catheter has an inner diameter and an outer diameter;

a tube having a distal tractor region within the catheter, wherein the distal tractor region comprises an expandable distal end region and a less expandable distal end region that is proximal to the expandable distal end region, further wherein the expandable distal

end region is biased to invert over the less expandable distal end region as it is exposed from the distal end of the catheter;

a guidewire lumen through the catheter and the tube, including the distal tractor region, wherein the guidewire lumen is configured to pass a guidewire; and

a proximal handle coupled to the tube and configured to cause relative motion between the catheter and the tube such that the distal tractor region is released from within the inner diameter of the catheter so that the expandable distal end region may expand to a diameter that is greater than the outer diameter and the tube may be drawn proximally to pull the expandable distal end region over the distal end of the catheter so that the expandable distal end region rolls into the distal end of the catheter, inverts, collapses and is drawn into the catheter.

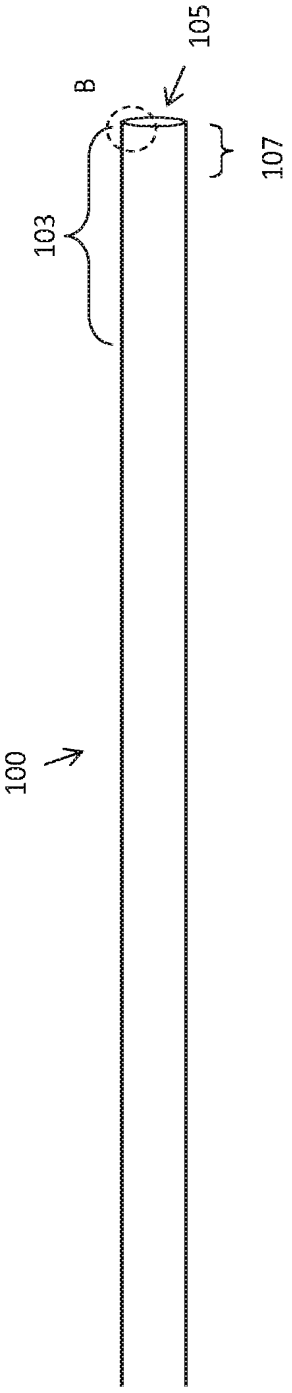


FIG. 1A

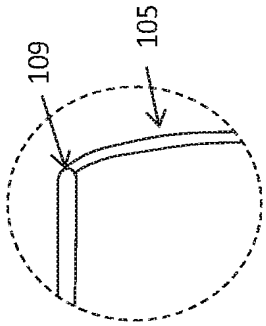


FIG. 1B

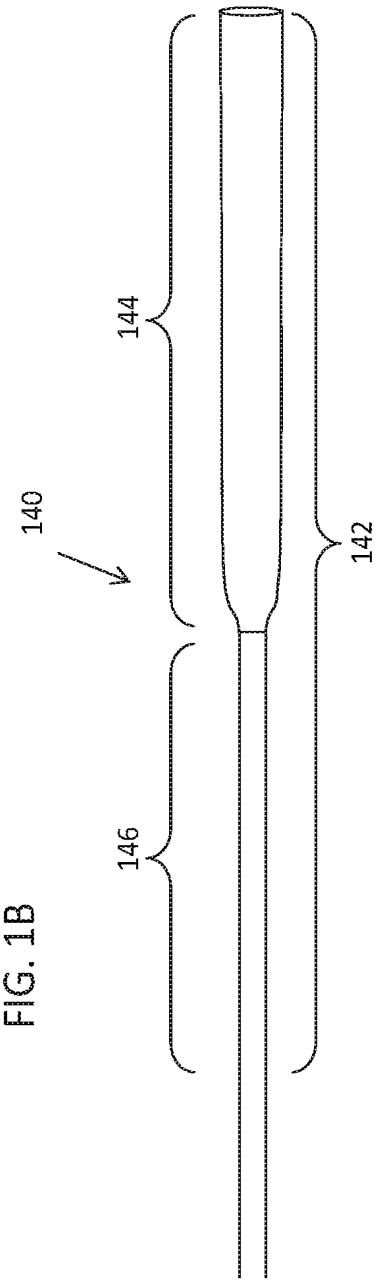


FIG. 1C

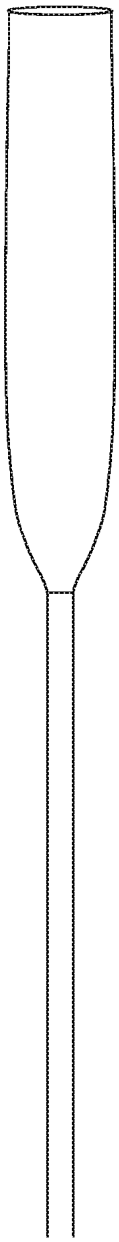


FIG. 1D

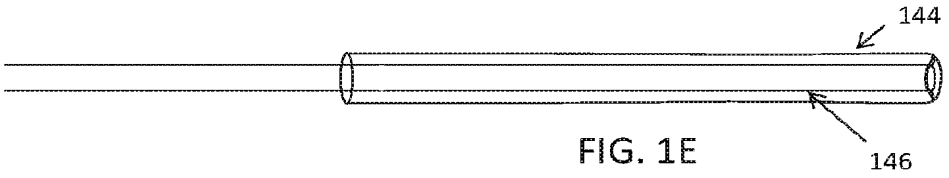


FIG. 1E

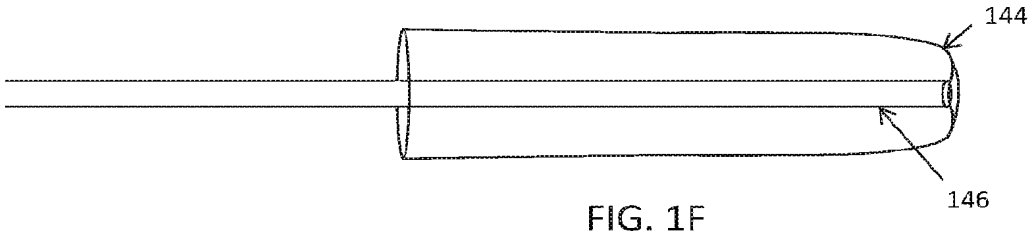


FIG. 1F

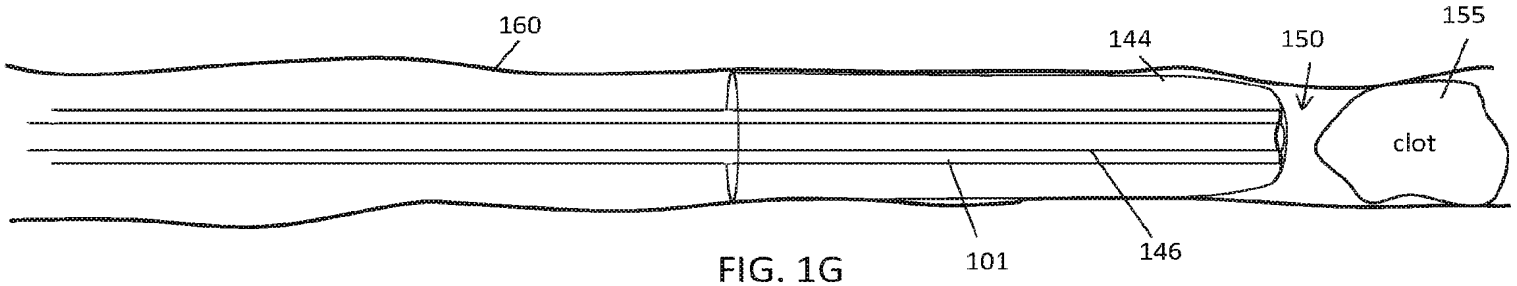


FIG. 1G

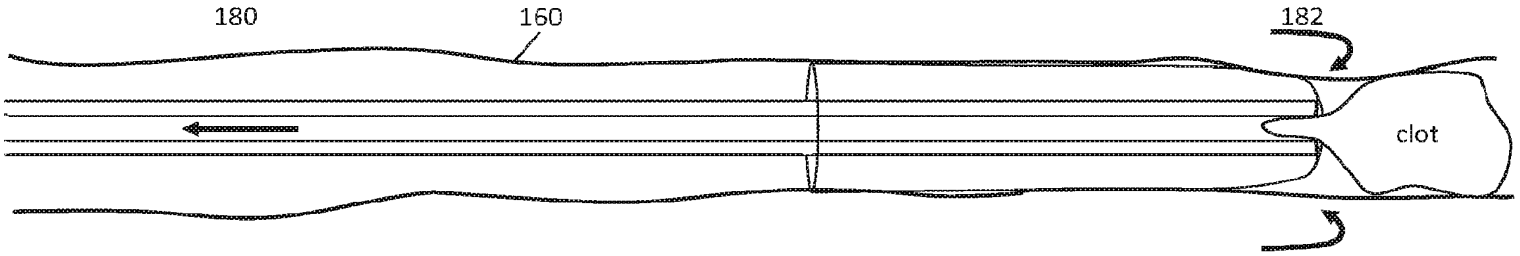


FIG. 1H

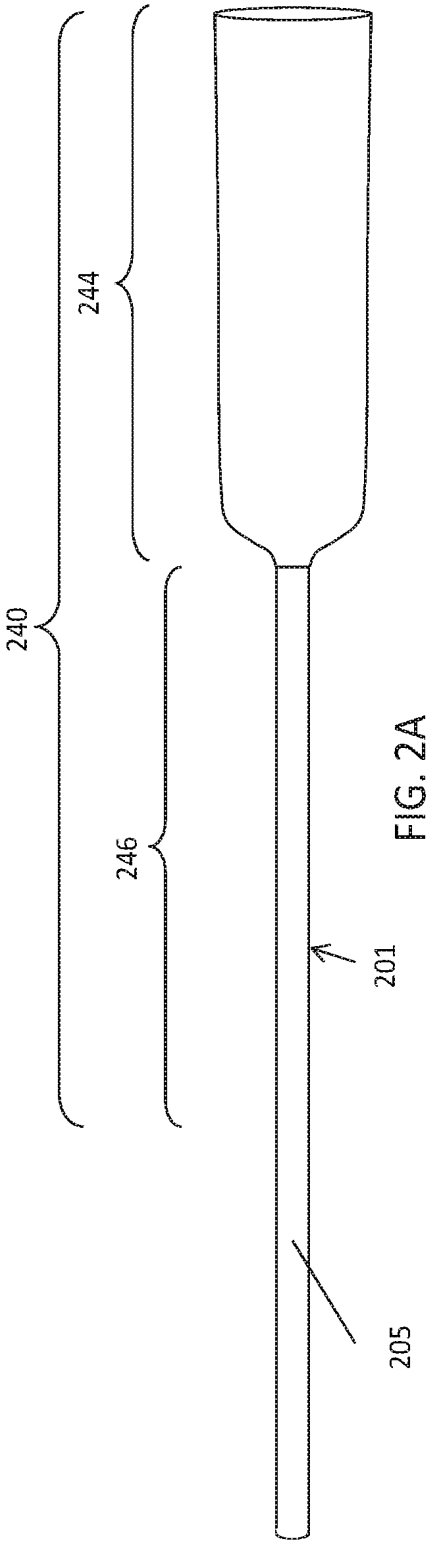


FIG. 2A

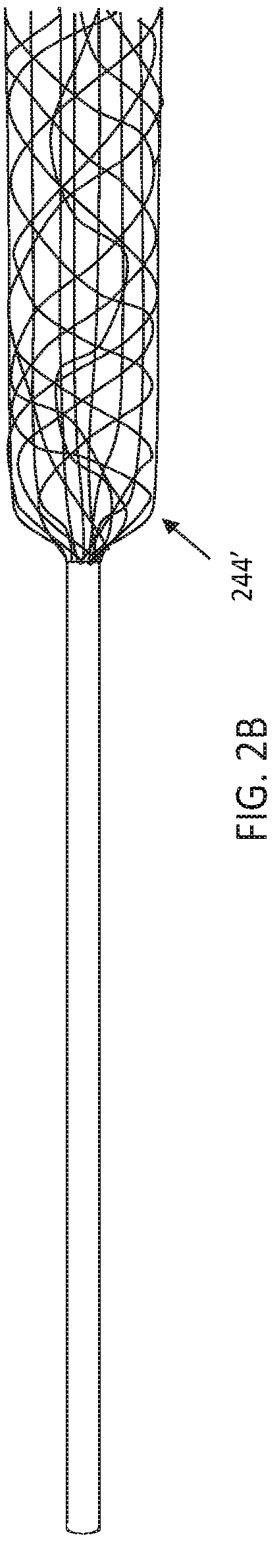


FIG. 2B

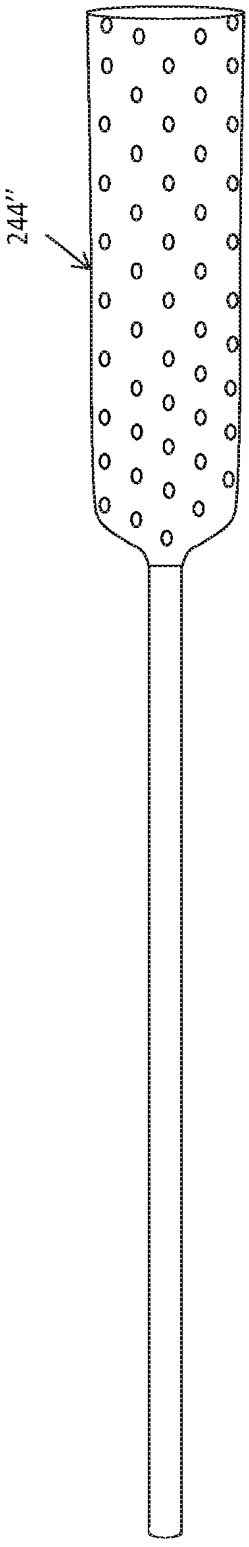


FIG. 2C

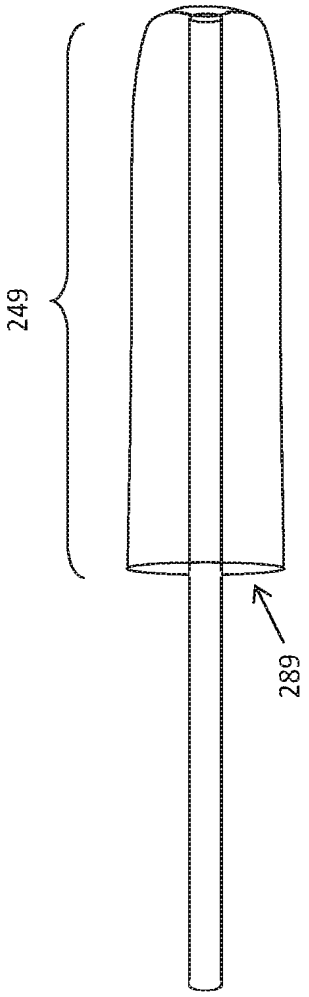


FIG. 2D

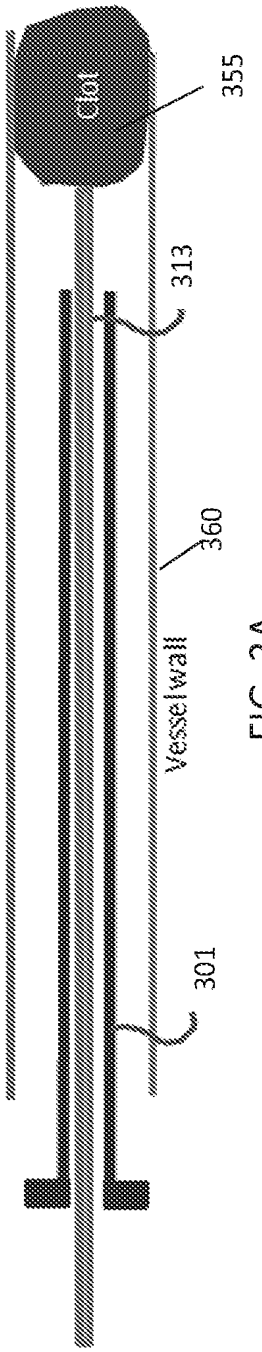


FIG. 3A

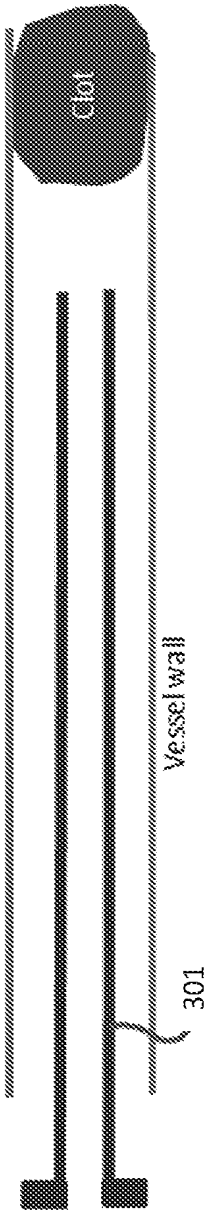


FIG. 3B

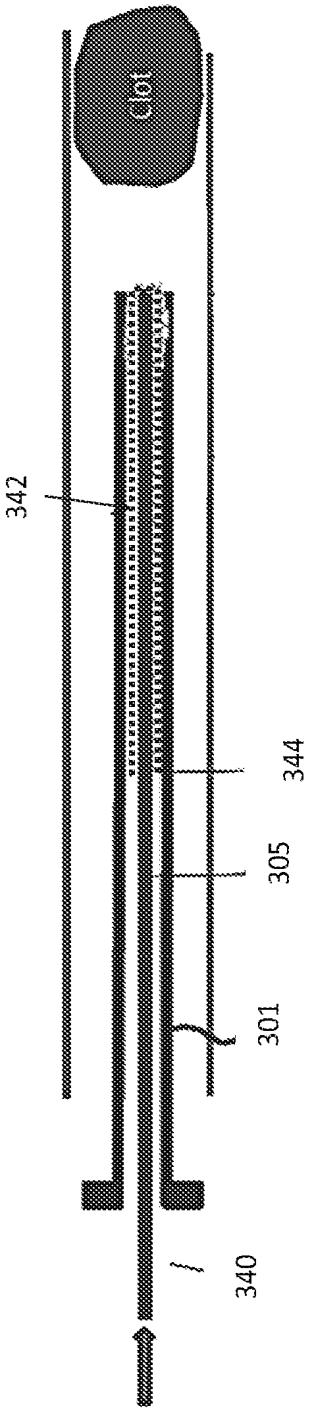


FIG. 3C

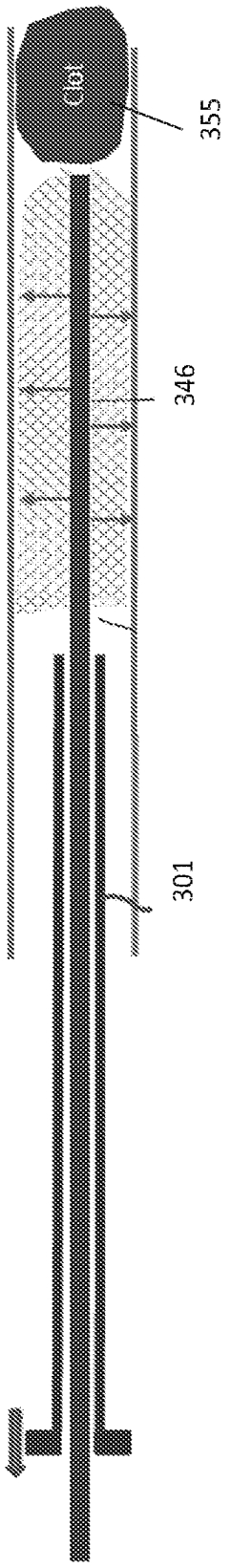


FIG. 3D

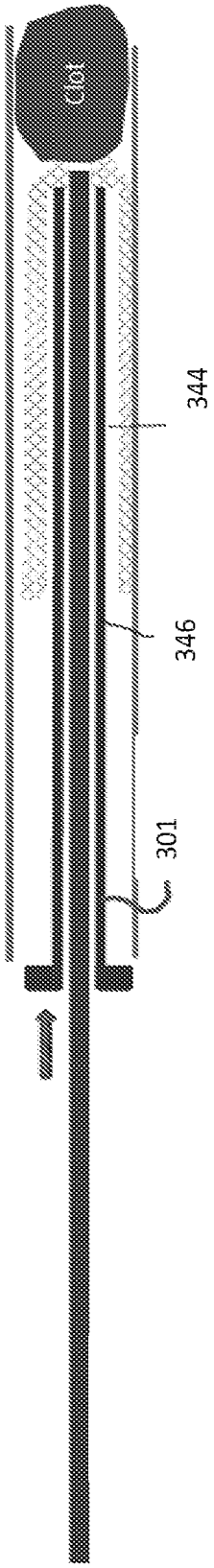


FIG. 3E

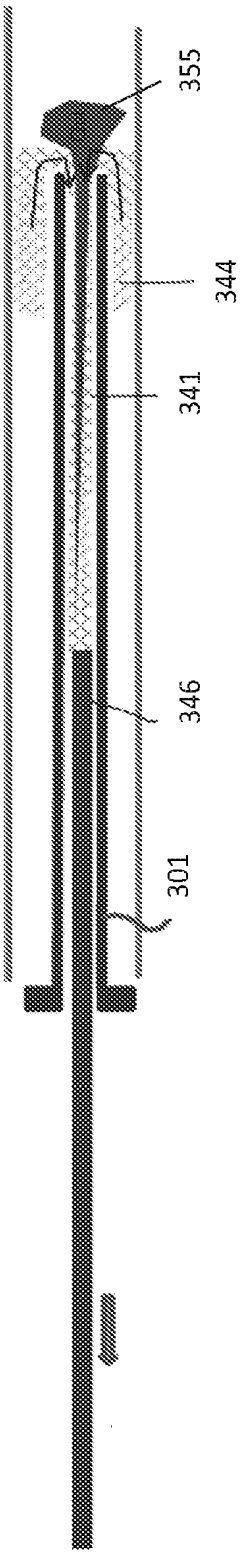


FIG. 3F

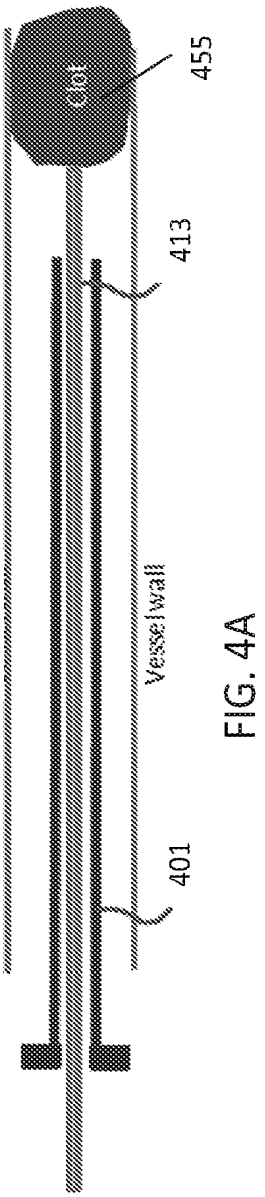


FIG. 4A

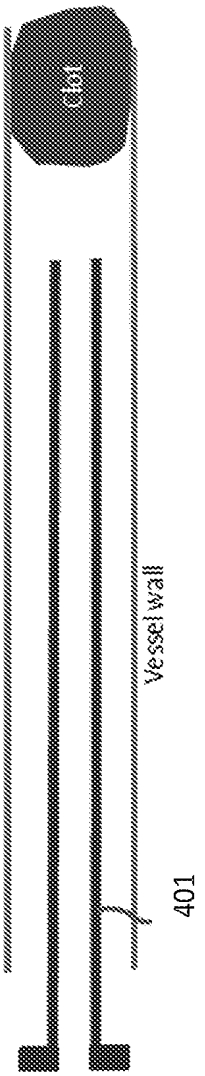


FIG. 4B

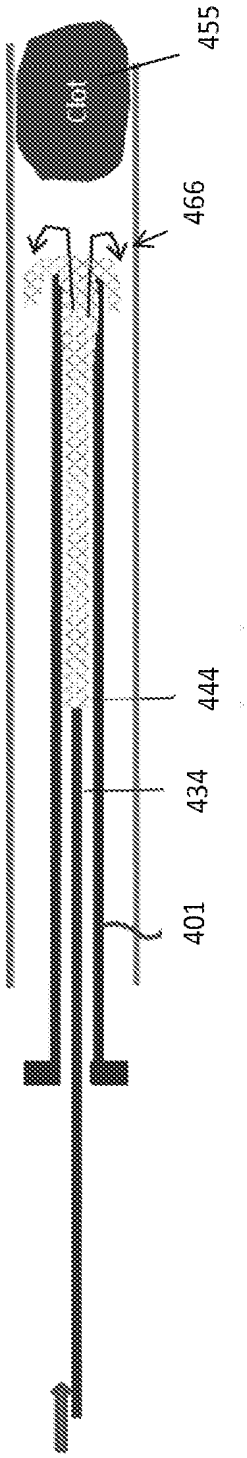


FIG. 4C

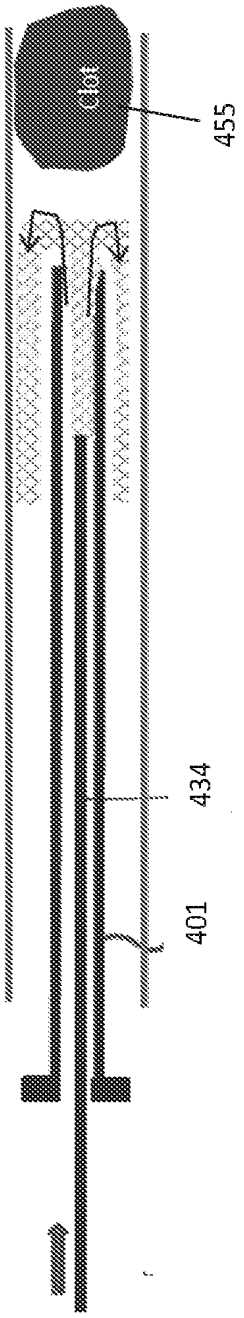


FIG. 4D

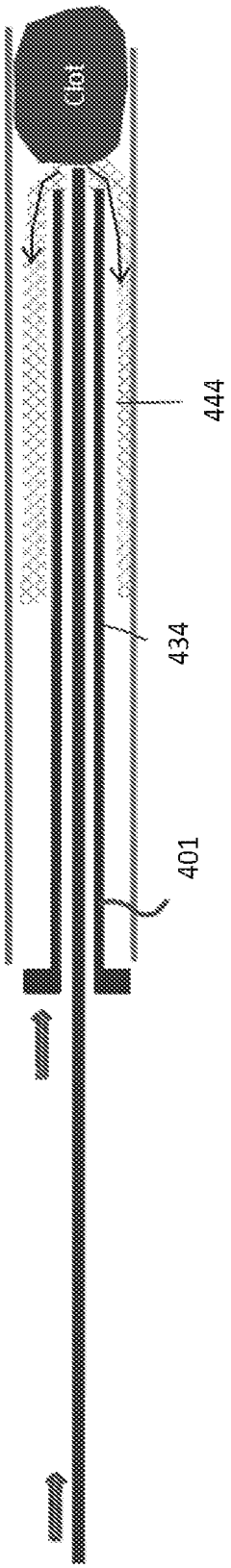


FIG. 4E

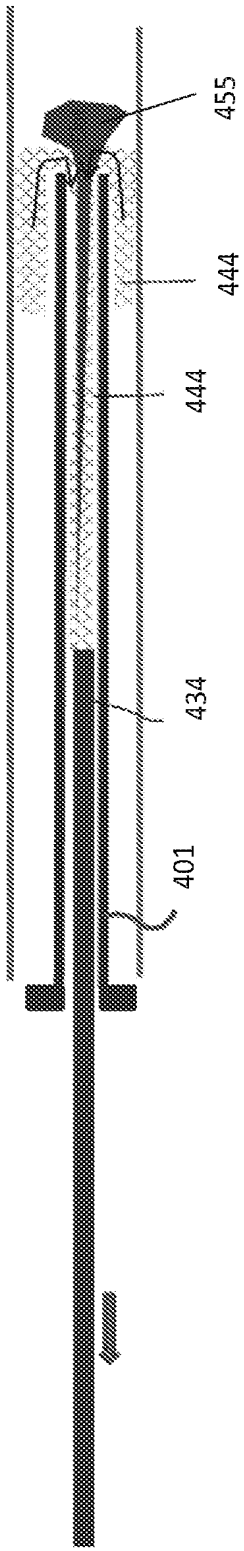


FIG. 4F

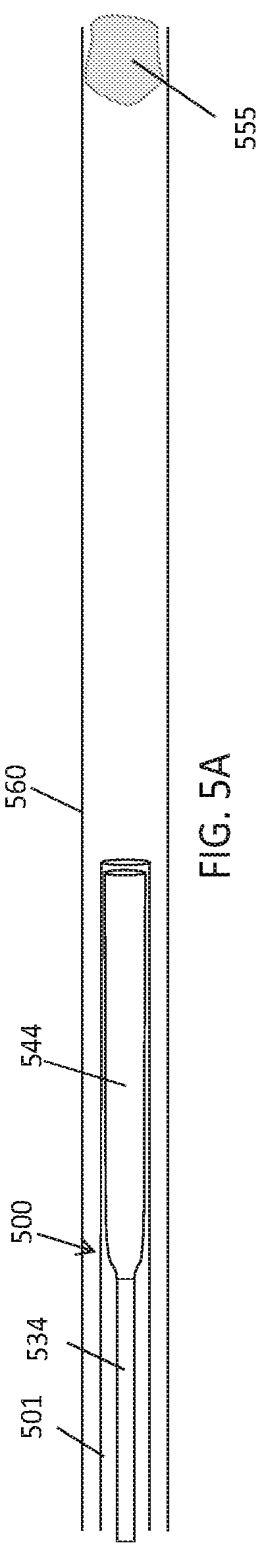


FIG. 5A

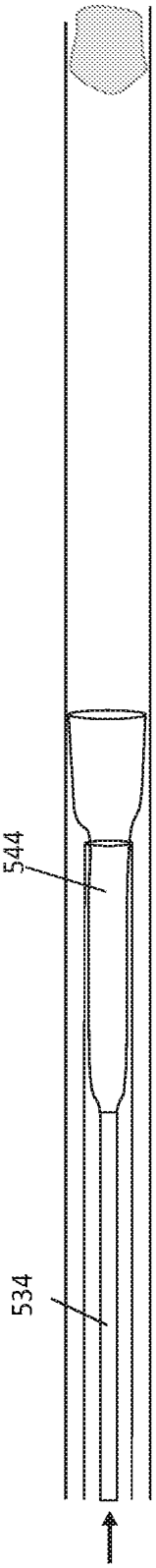


FIG. 5B

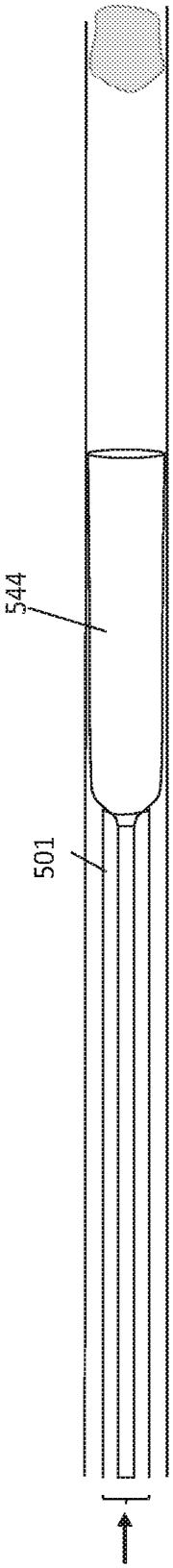


FIG. 5C

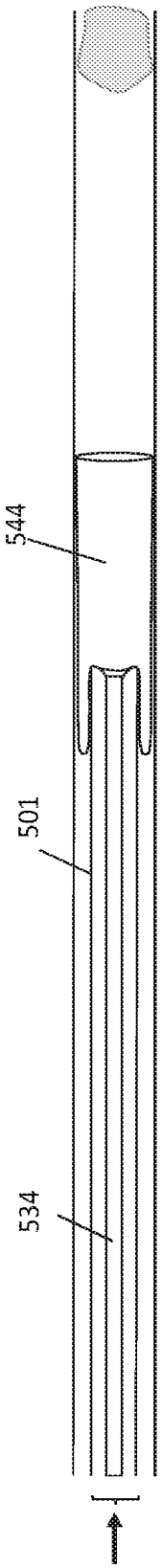


FIG. 5D

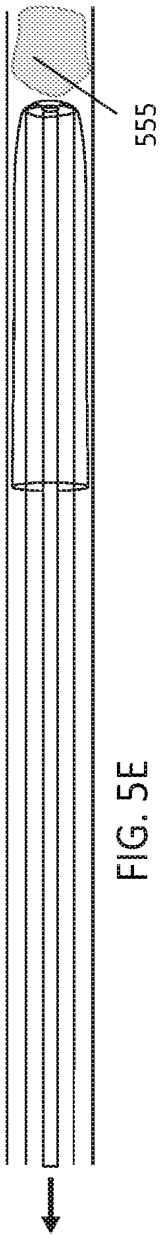


FIG. 5E

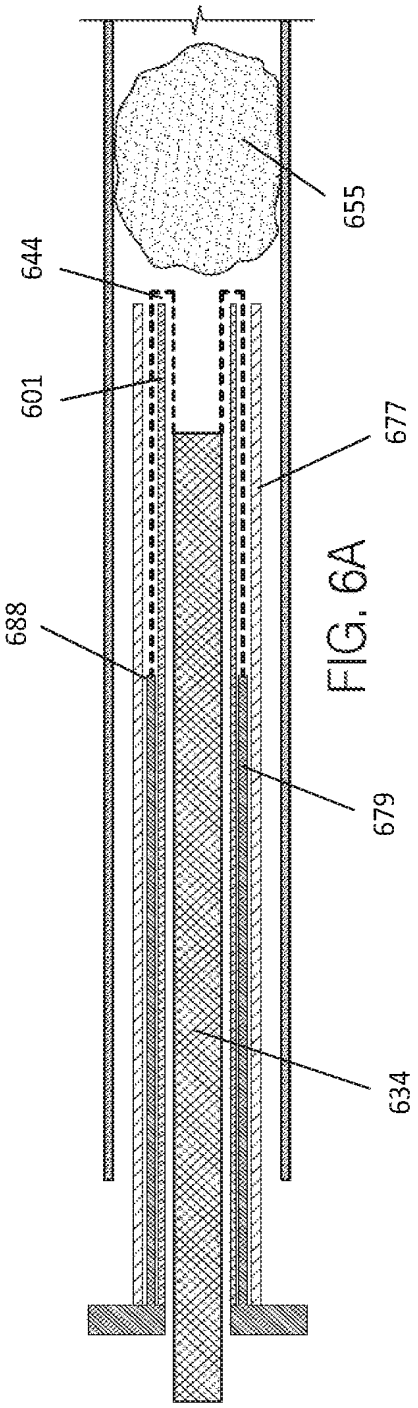


FIG. 6A

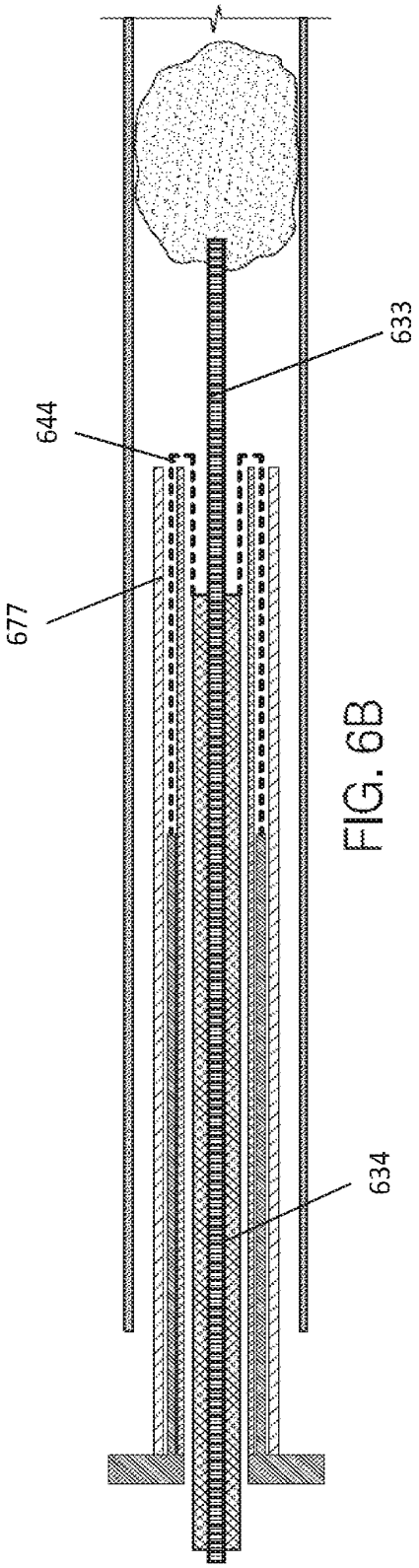


FIG. 6B

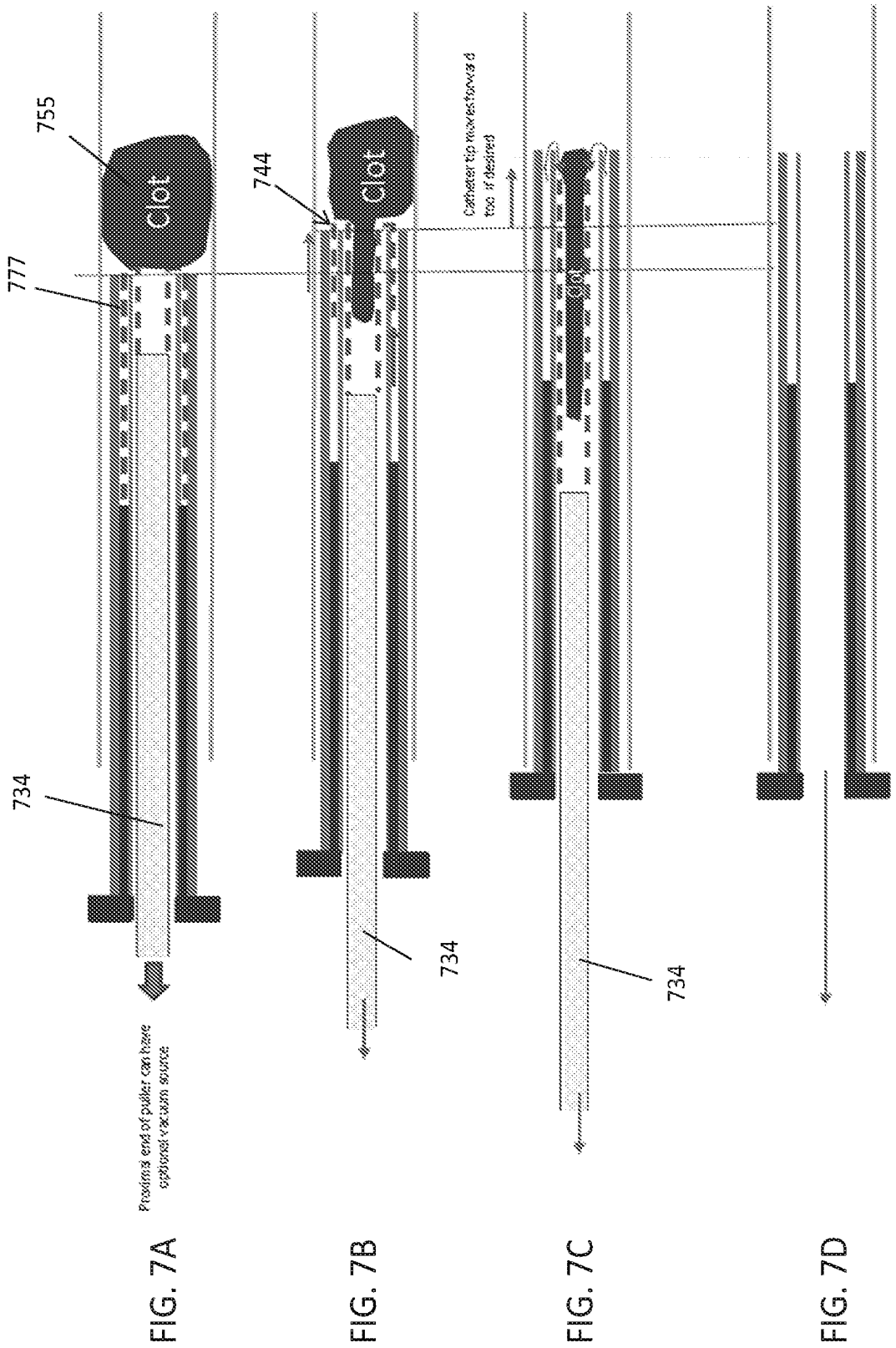


FIG. 7A FIG. 7B FIG. 7C FIG. 7D

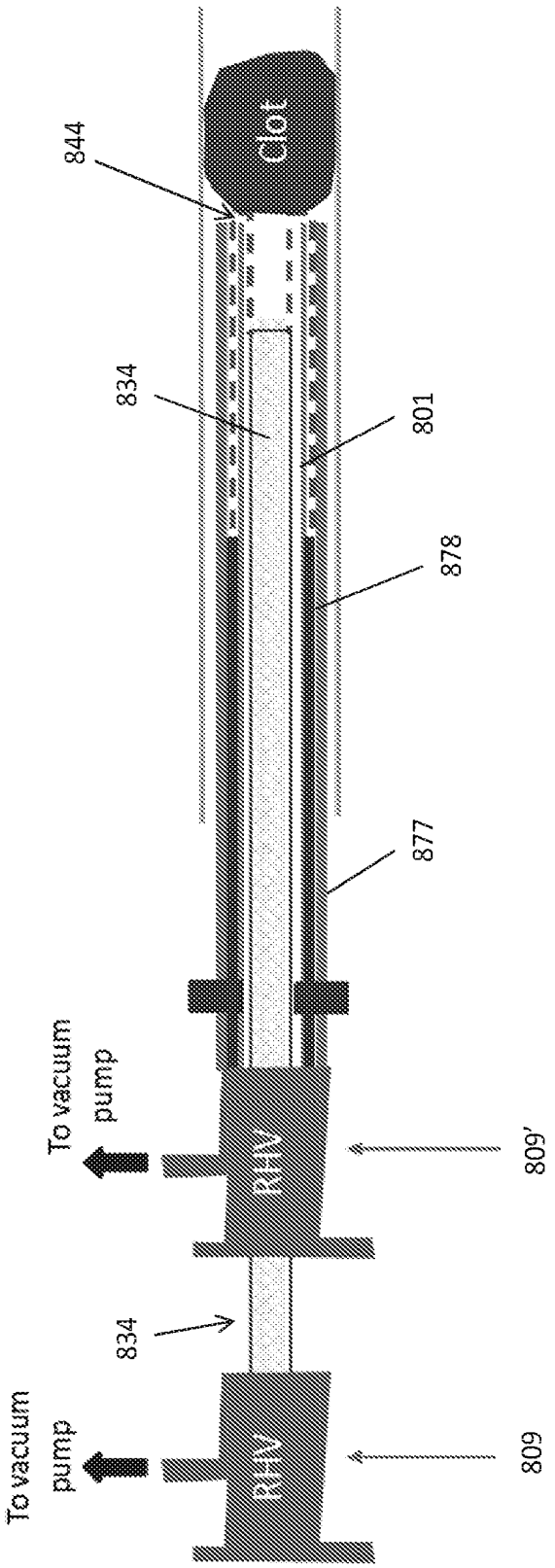

844
Clot
834
801
878
877
To vacuum pump
RHV
809'
834
To vacuum pump
RHV
809

FIG. 8

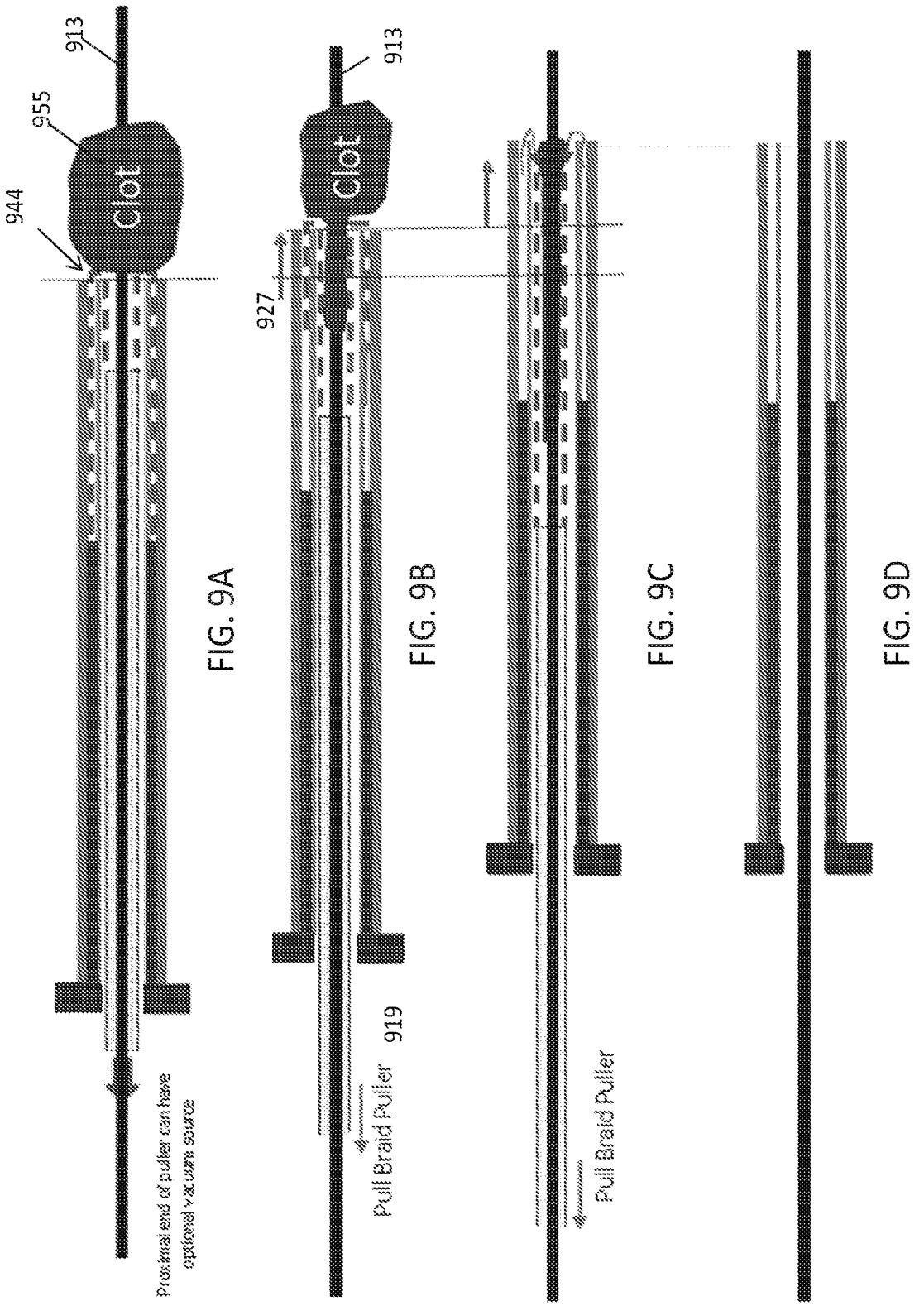


FIG. 9A

FIG. 9B

FIG. 9C

FIG. 9D

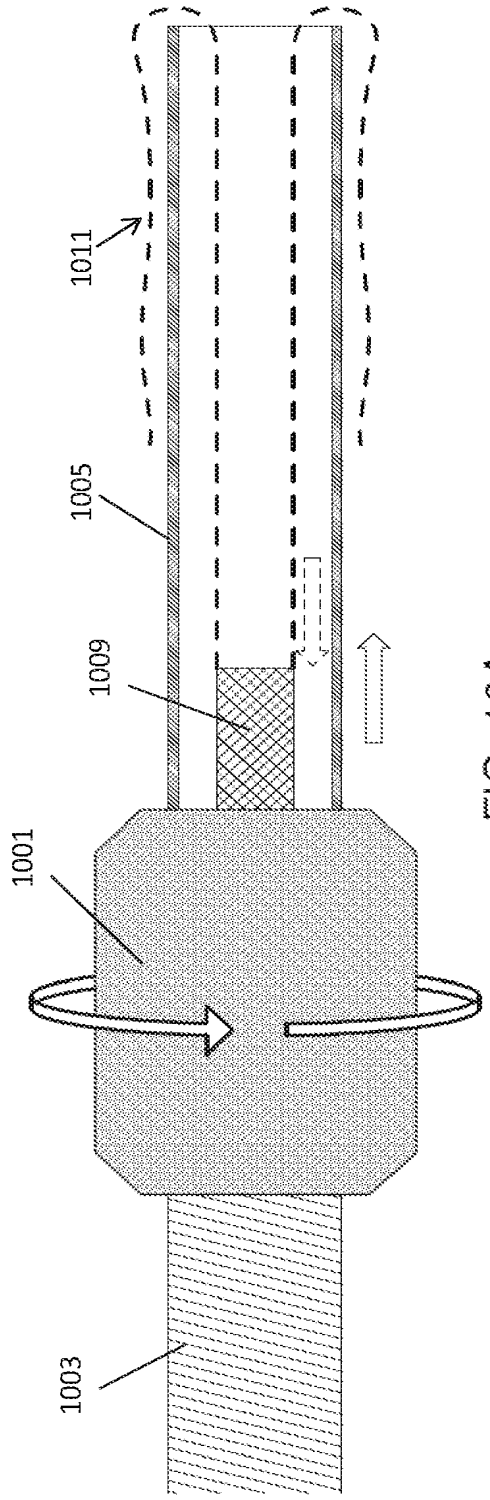


FIG. 10A

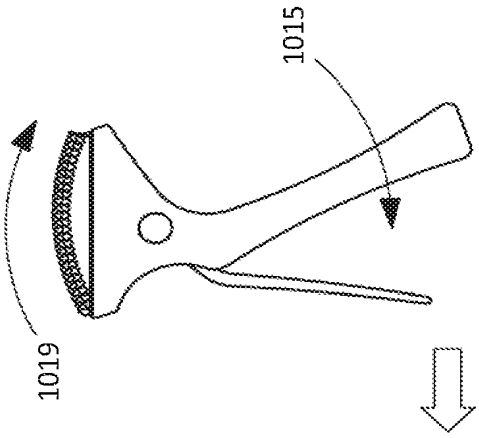


FIG. 10B

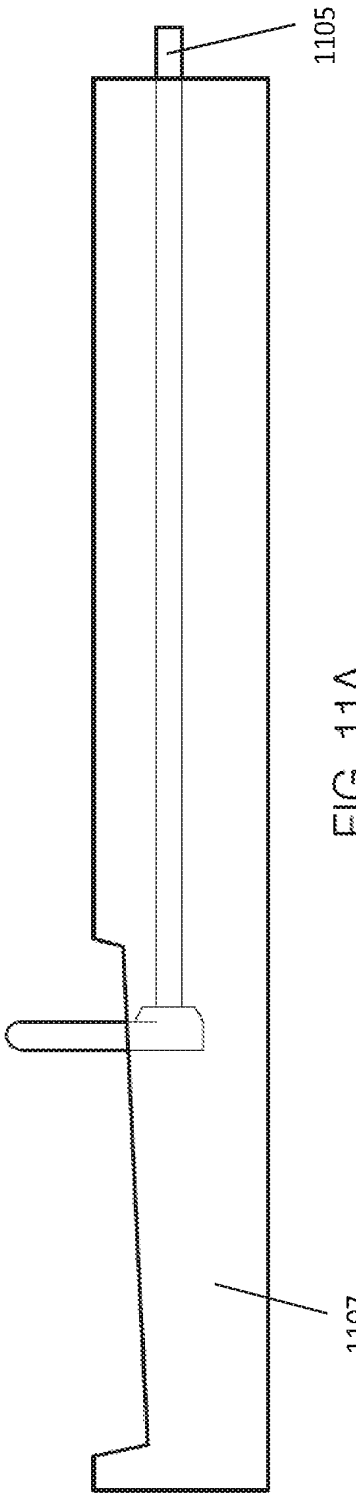


FIG. 11A

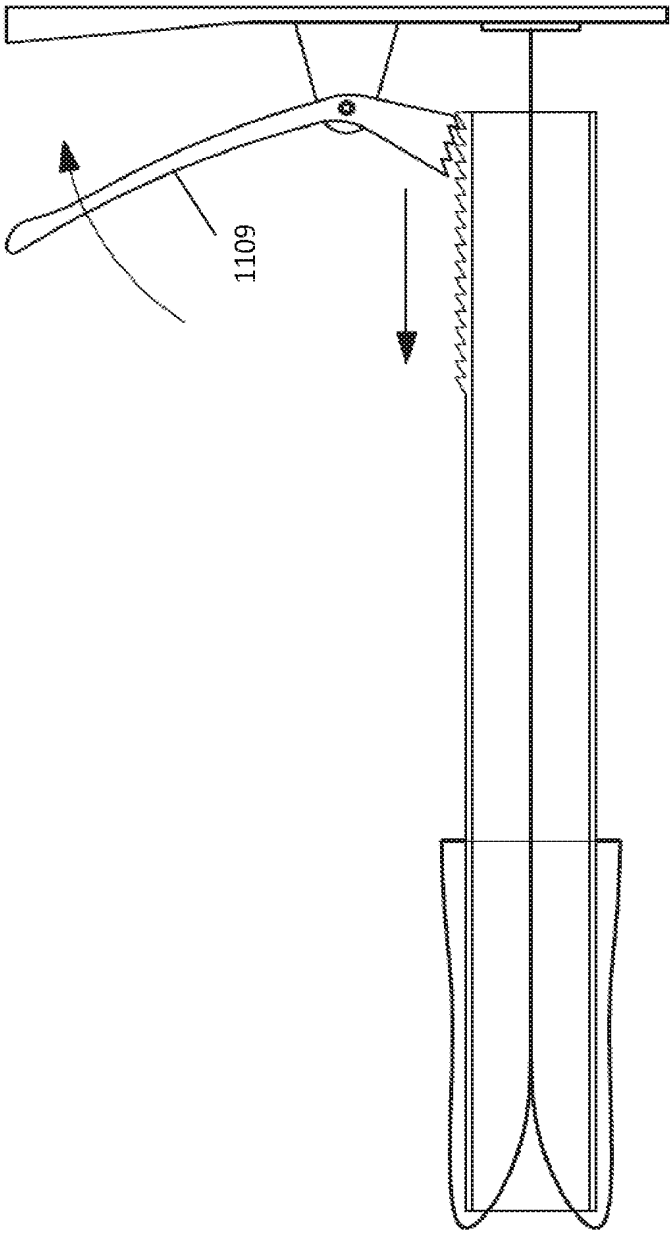


FIG. 11B

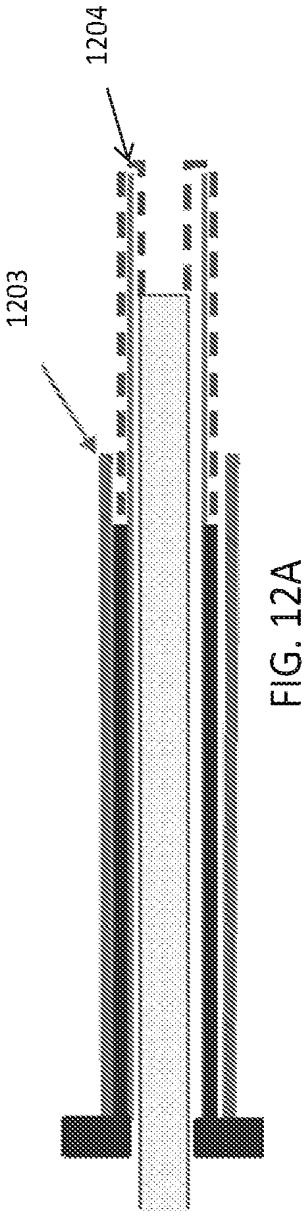


FIG. 12A

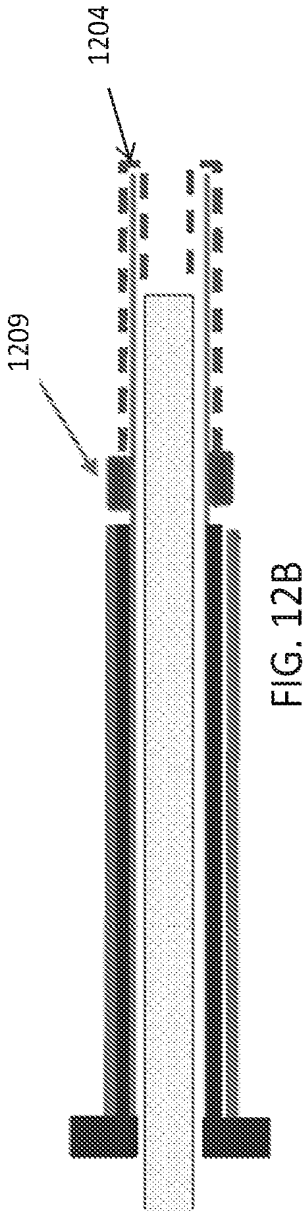


FIG. 12B

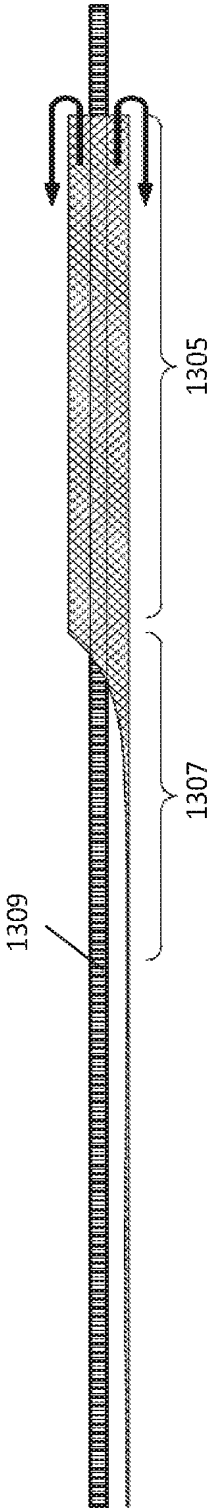


FIG. 13A

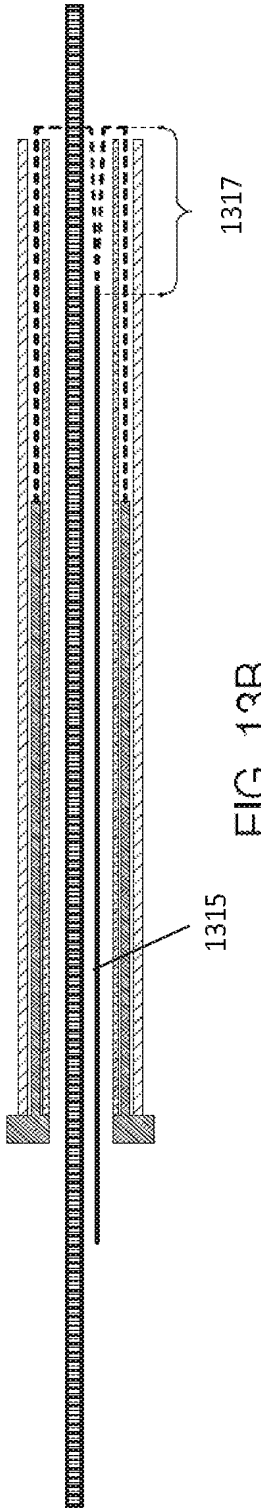


FIG. 13B

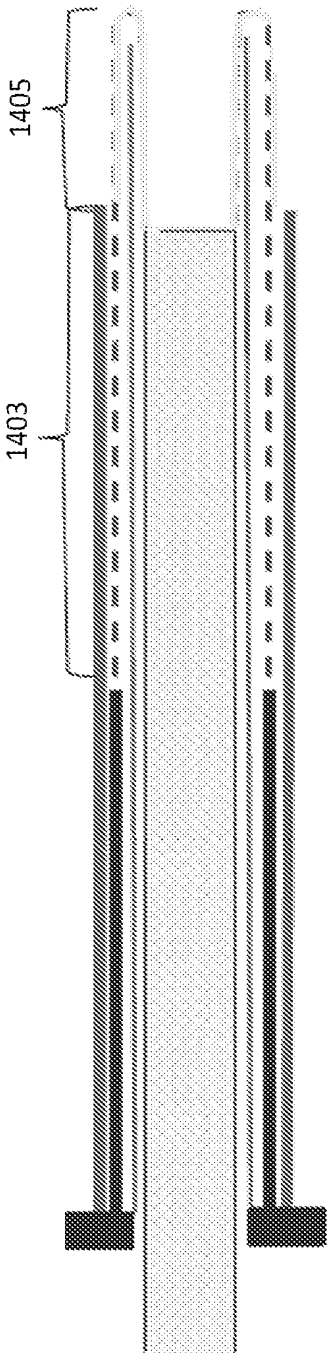


FIG. 14

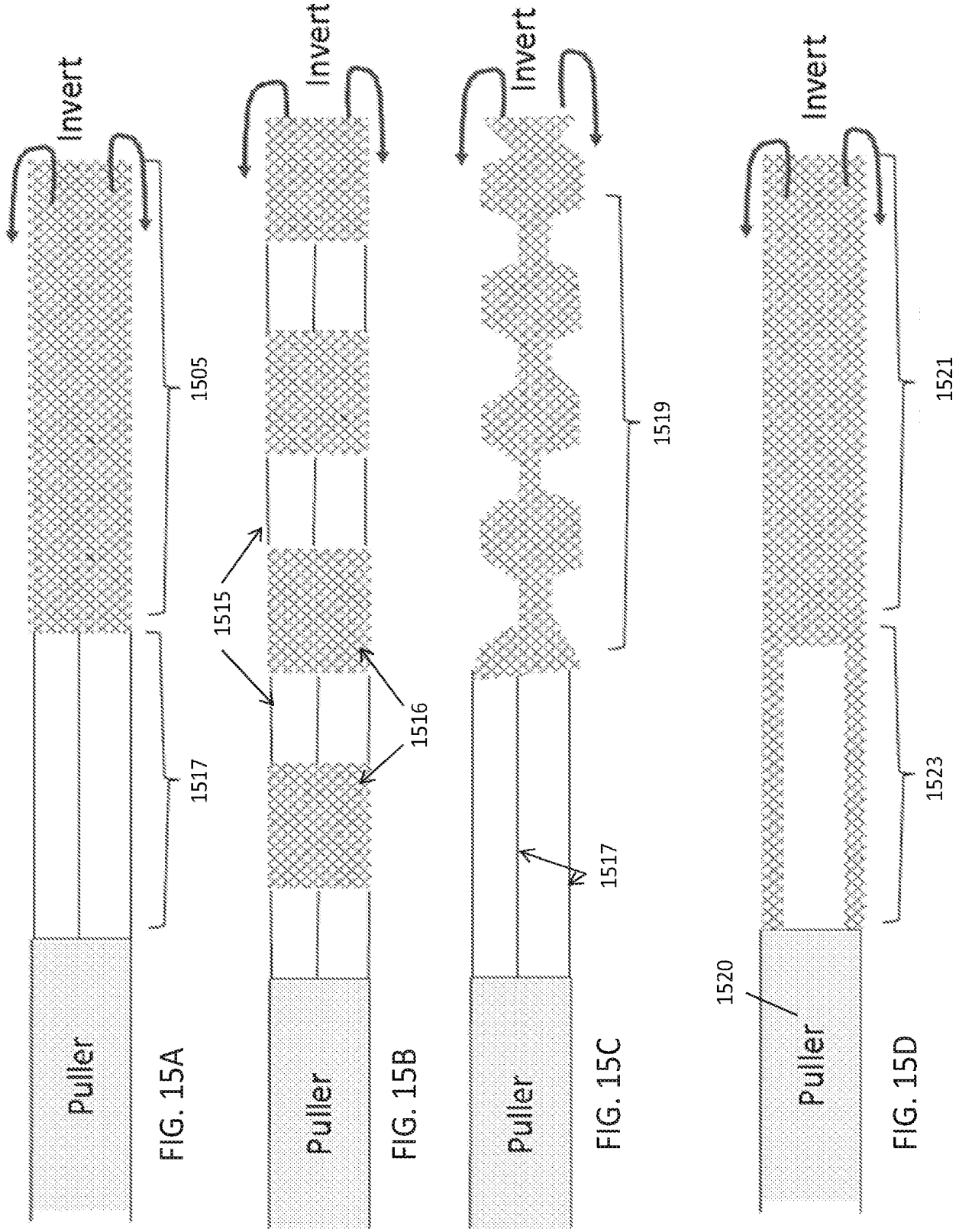


FIG. 15A FIG. 15B FIG. 15C FIG. 15D

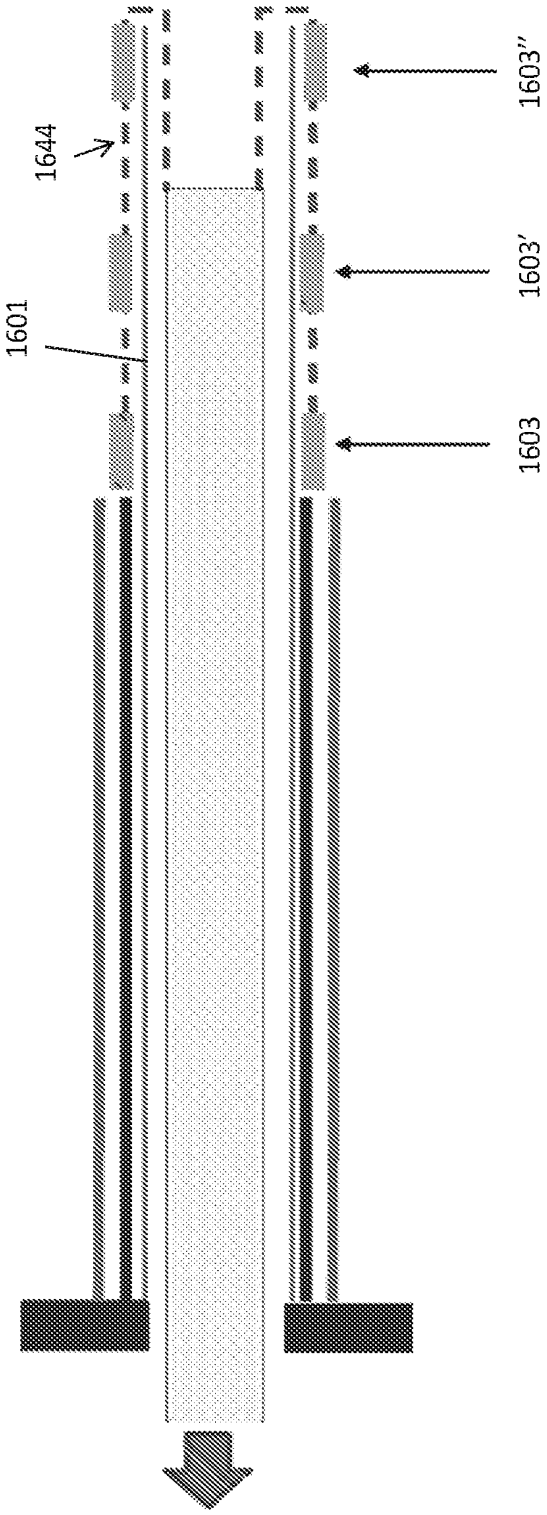

1644
1601
1603''
1603'
1603

FIG. 16

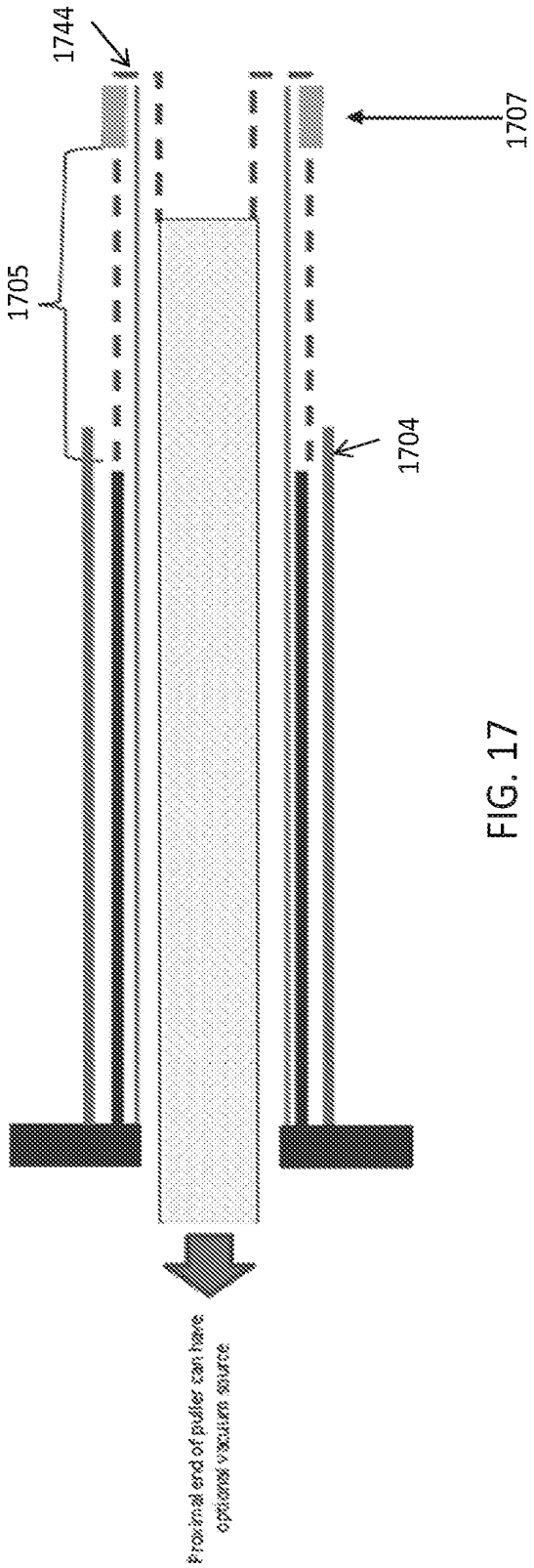

1744
1705
1707
1704
Proximal end of puller can have optional vacuum source

FIG. 17

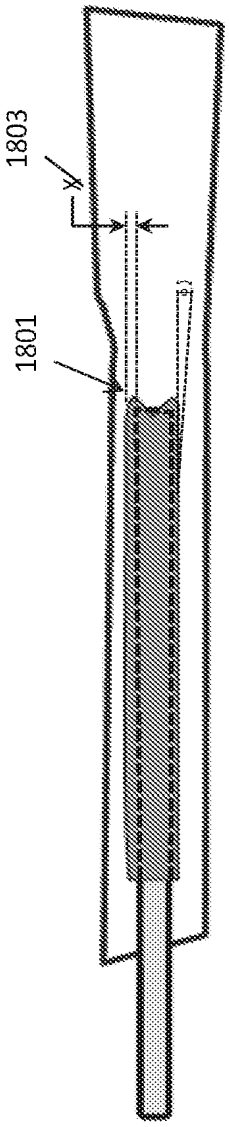


FIG. 18A

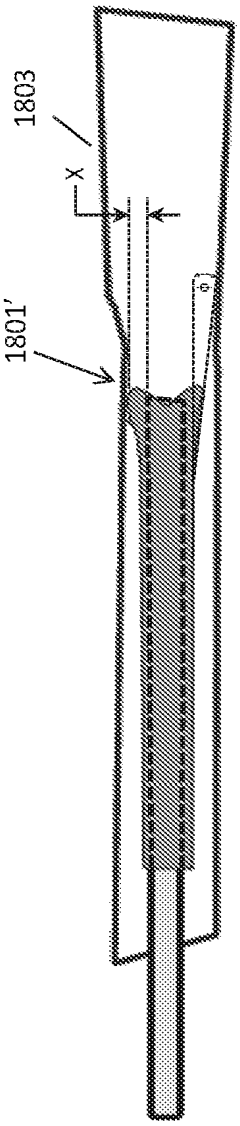


FIG. 18B

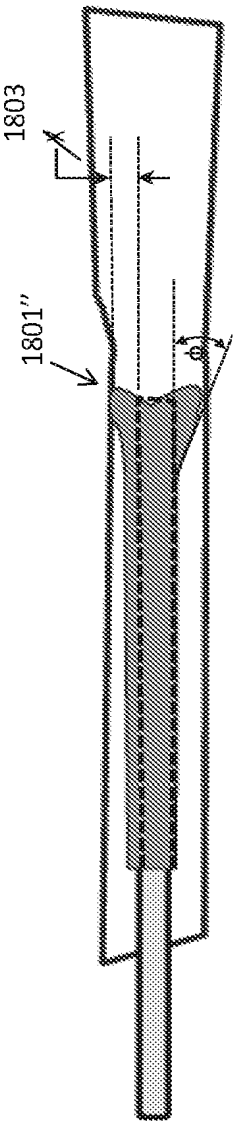


FIG. 18C

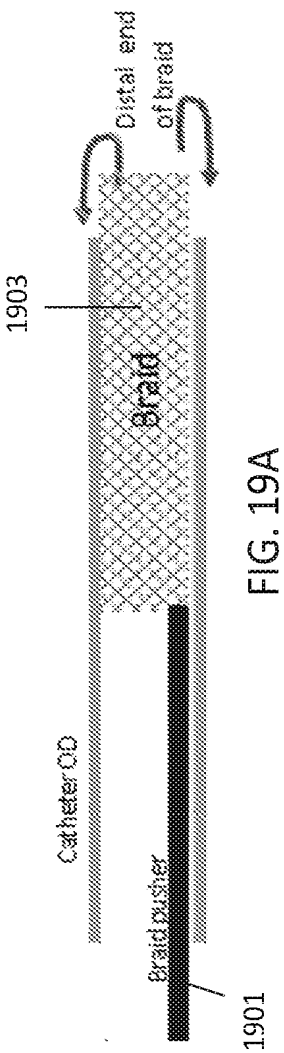


FIG. 19A

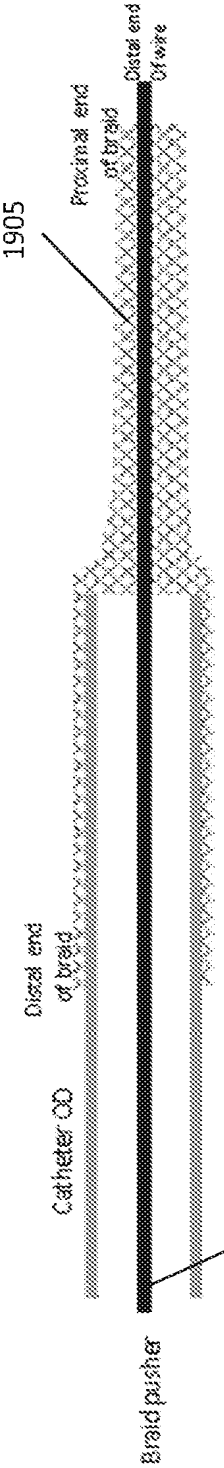


FIG. 19B

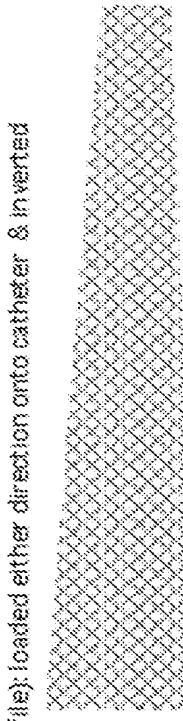


FIG. 20A

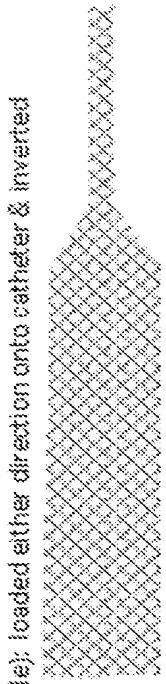


FIG. 20B

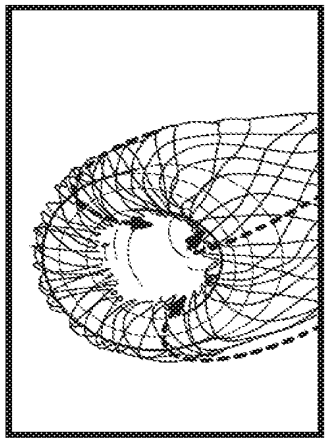


FIG. 21C

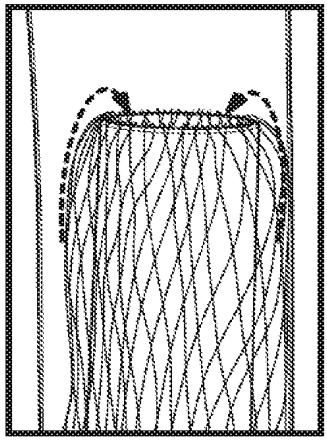


FIG. 21B

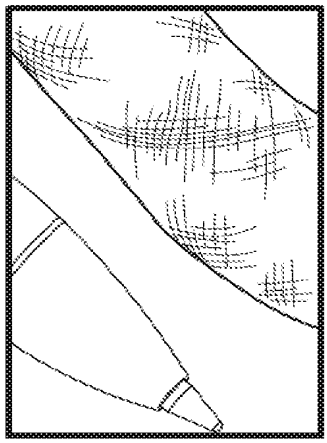


FIG. 21A

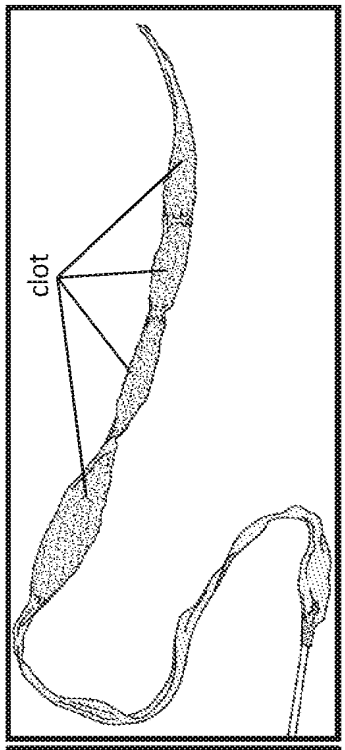


FIG. 22

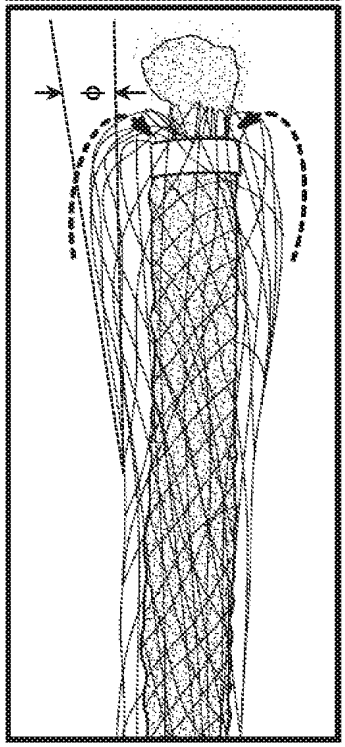


FIG. 21D

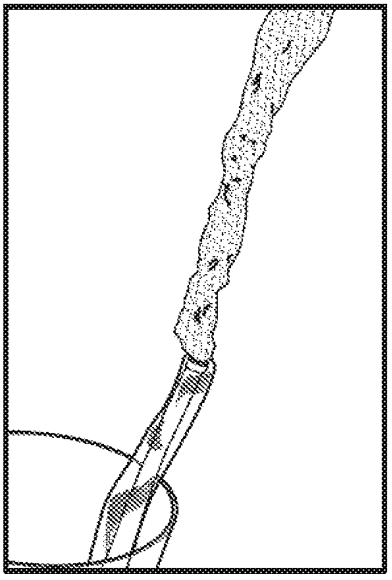


FIG.23B

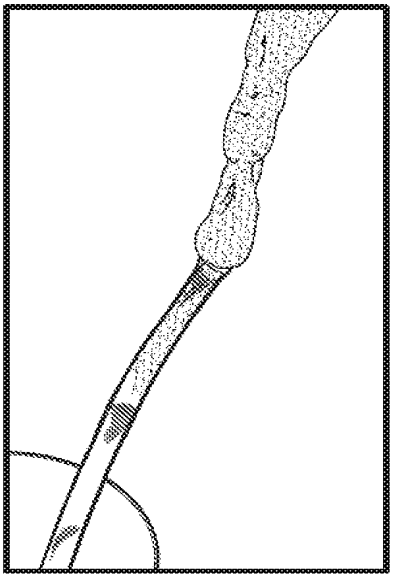


FIG. 23C

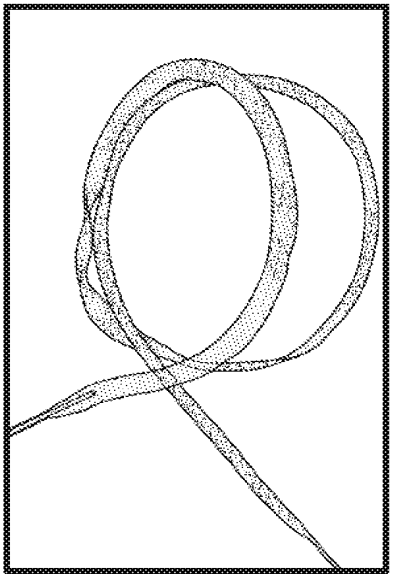


FIG.23E

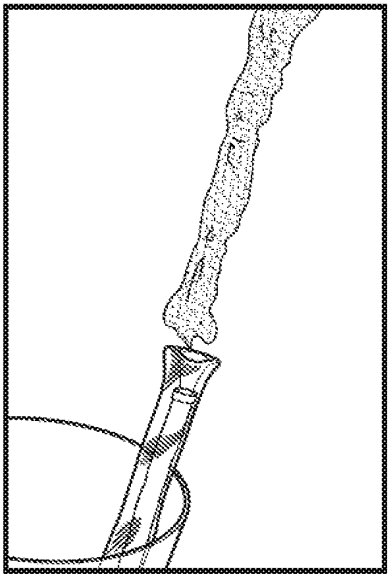


FIG.23A

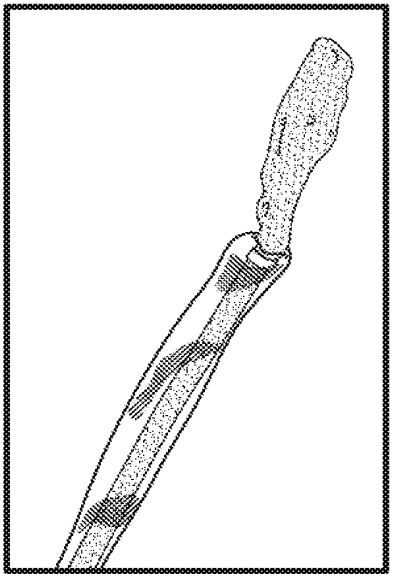


FIG.23D

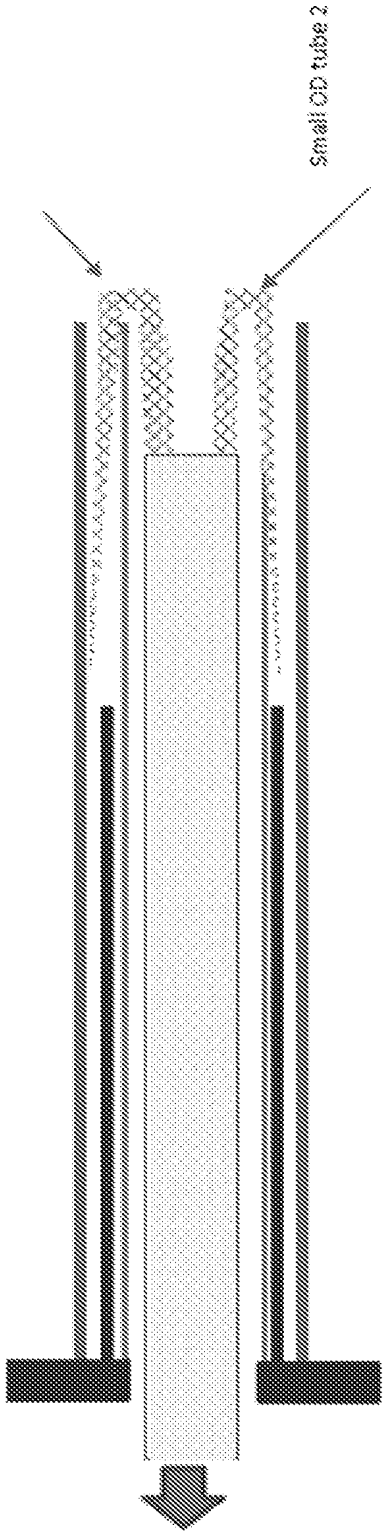


FIG. 24

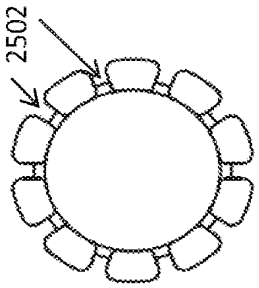


FIG. 25B

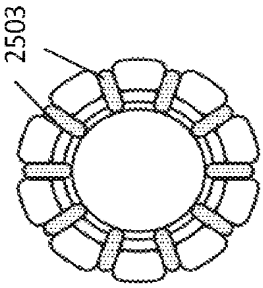


FIG. 25D

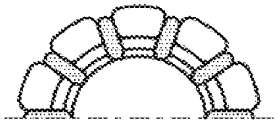


FIG. 25F

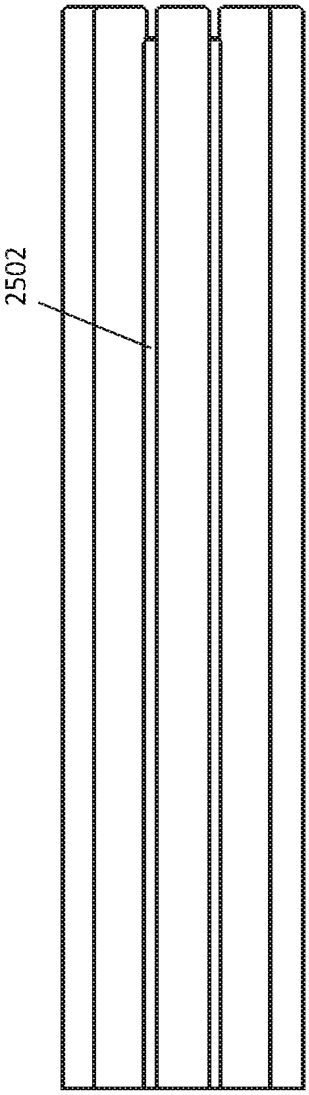


FIG. 25A

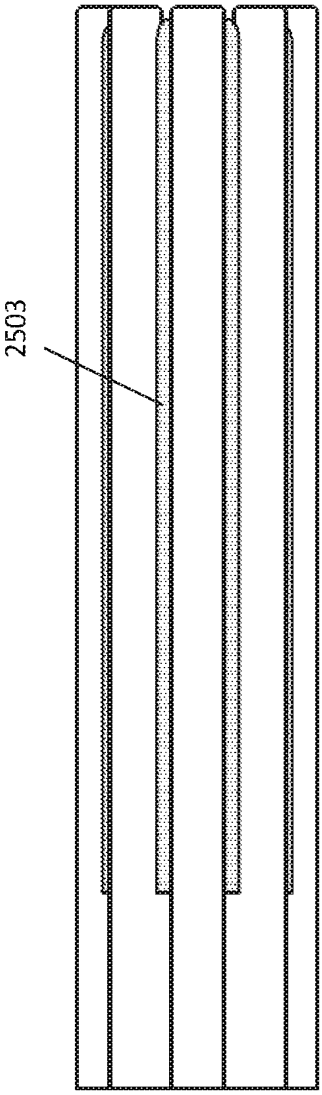


FIG. 25C

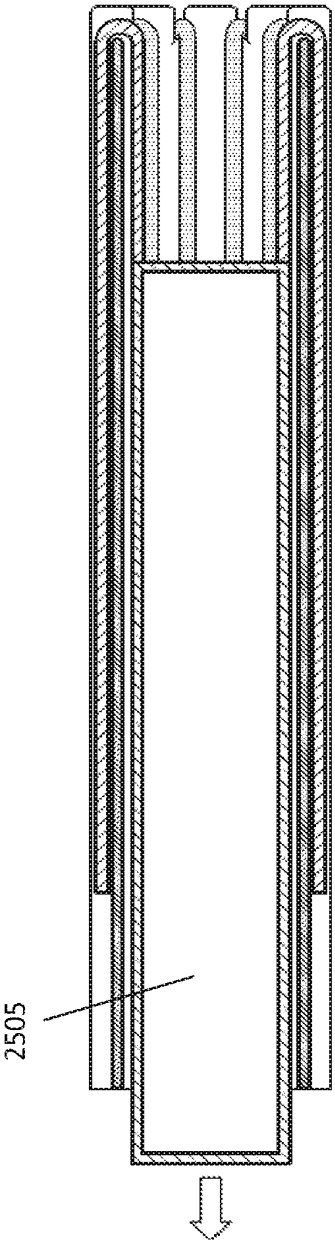


FIG. 25E

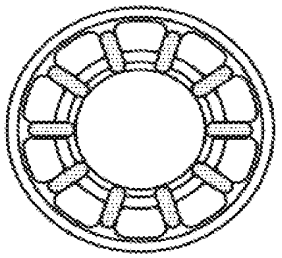


FIG. 26B

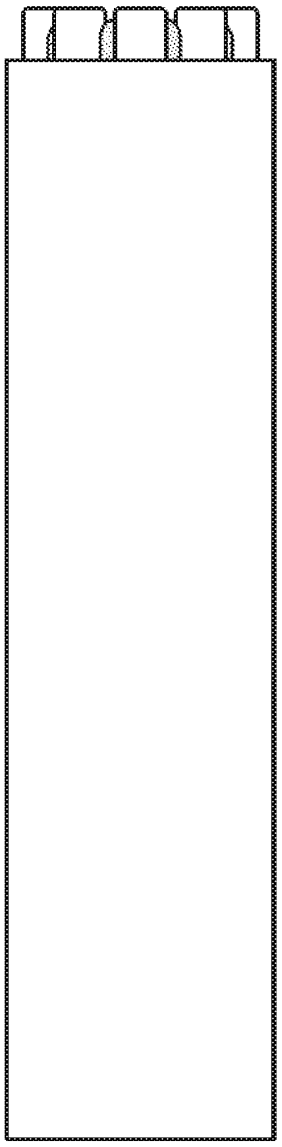


FIG. 26A

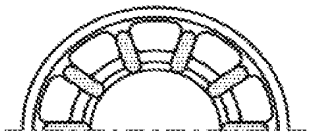


FIG. 27B

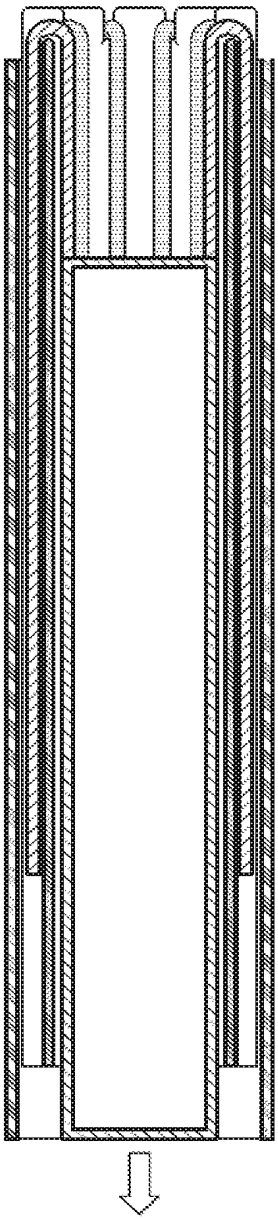


FIG. 27A

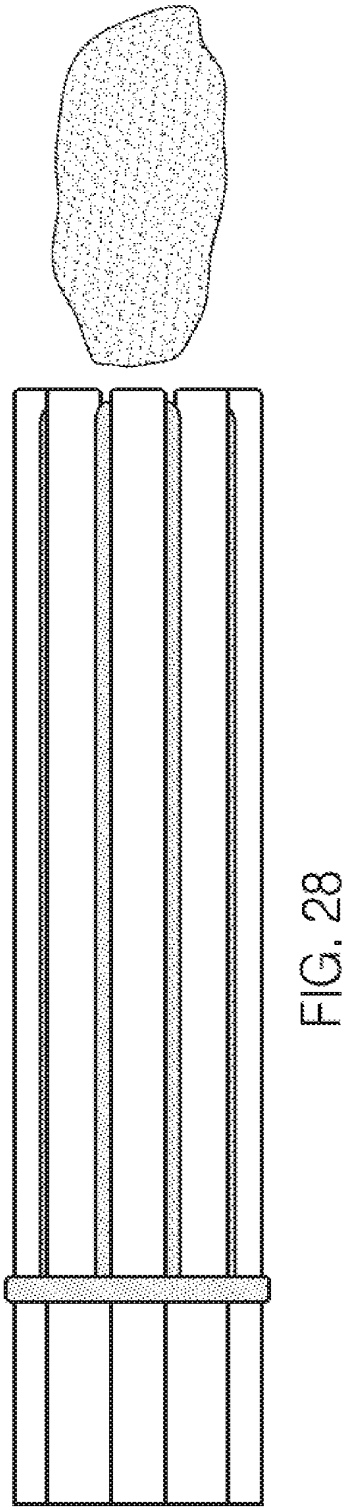


FIG. 28

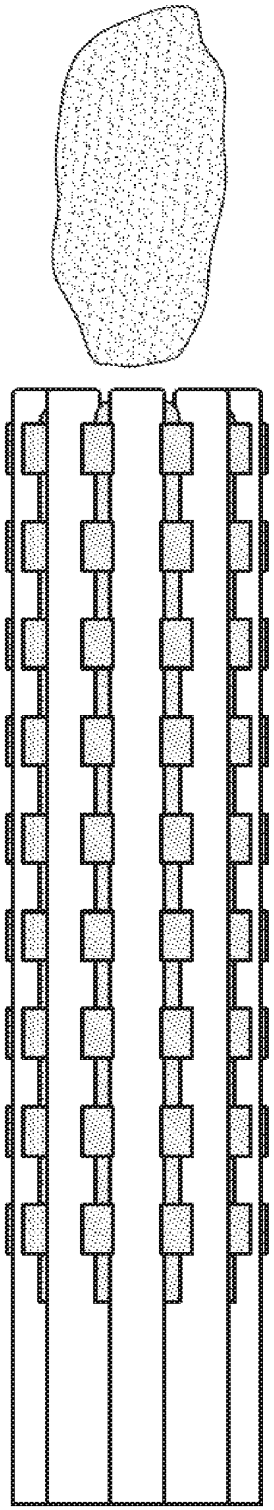


FIG. 29

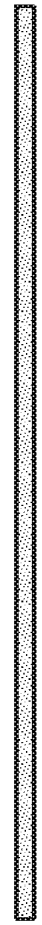


FIG. 30A

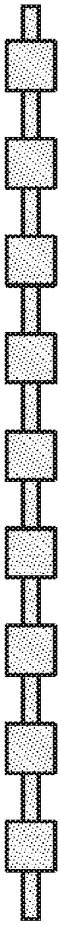


FIG. 30B

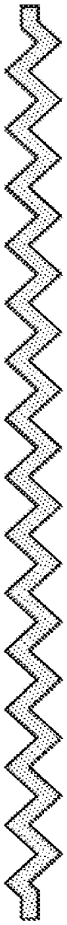


FIG. 30C

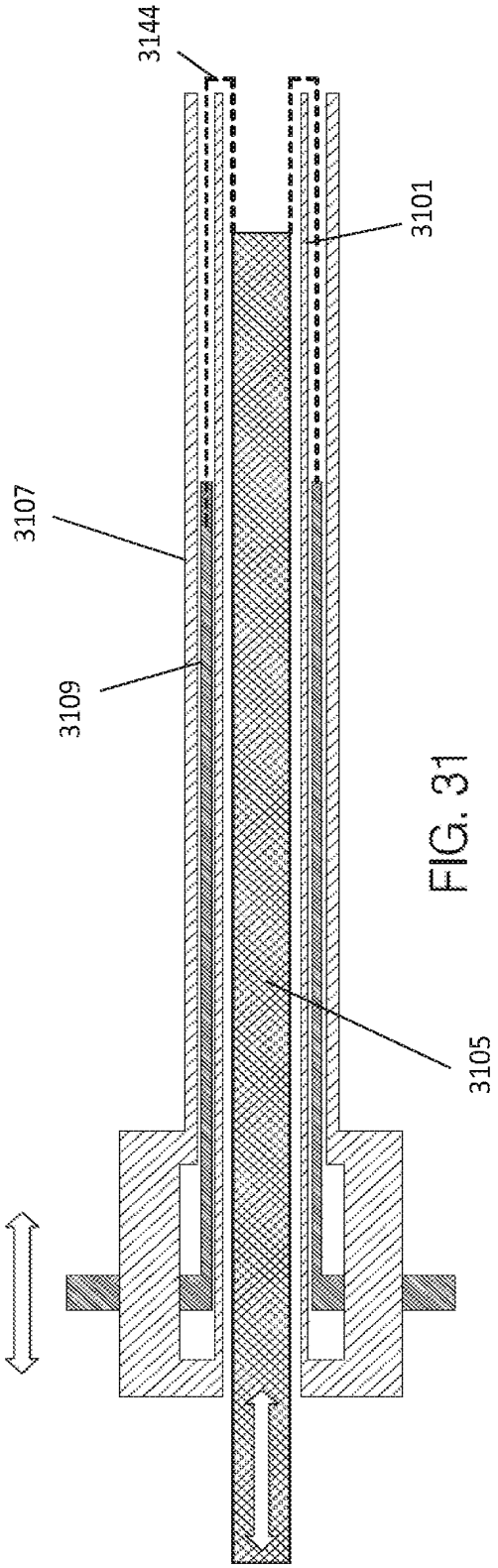


FIG. 31

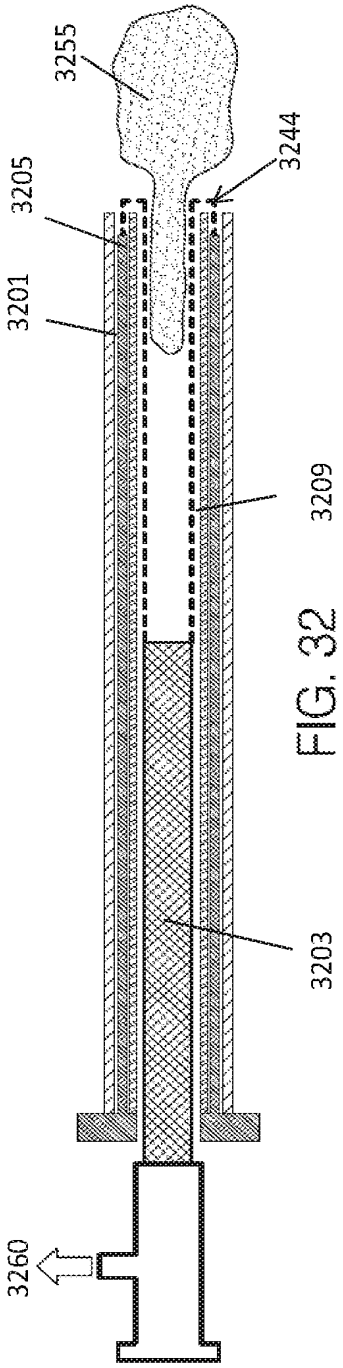


FIG. 32

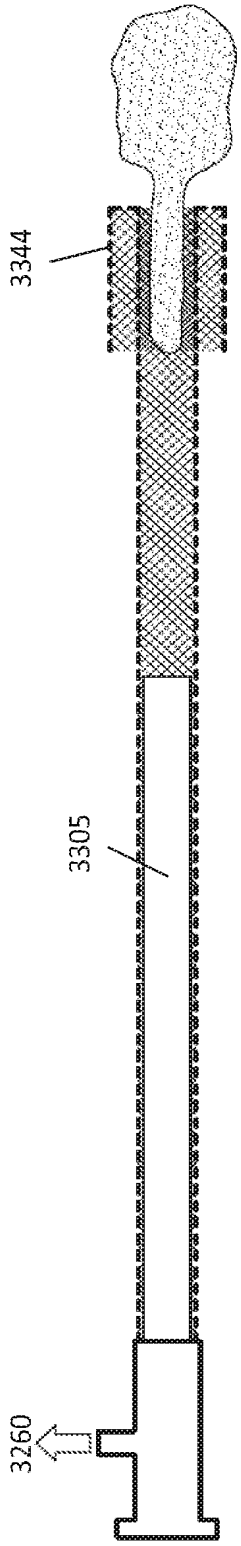


FIG. 33

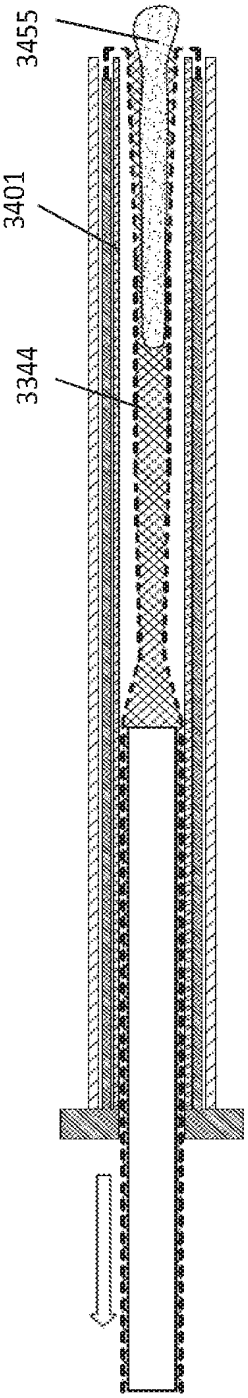


FIG. 34

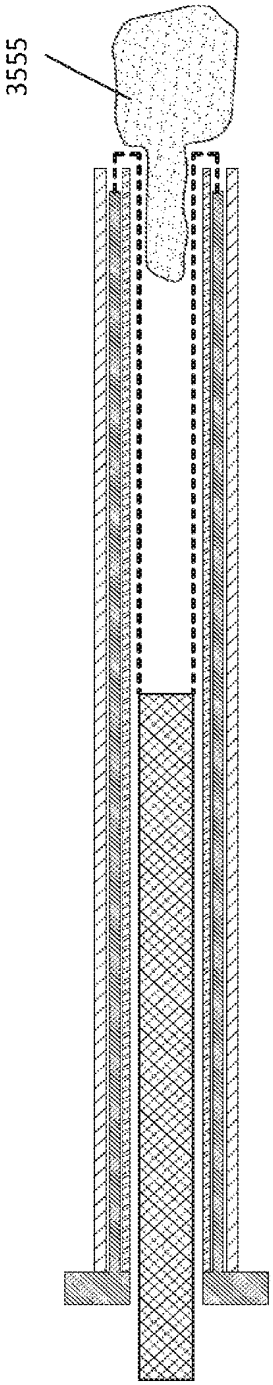


FIG. 35A

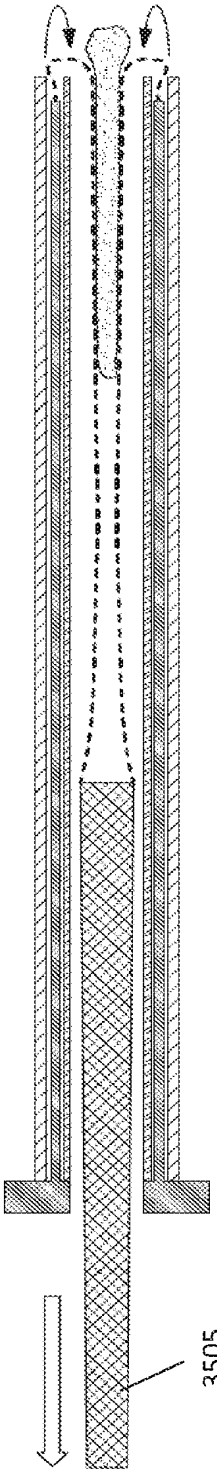


FIG. 35B

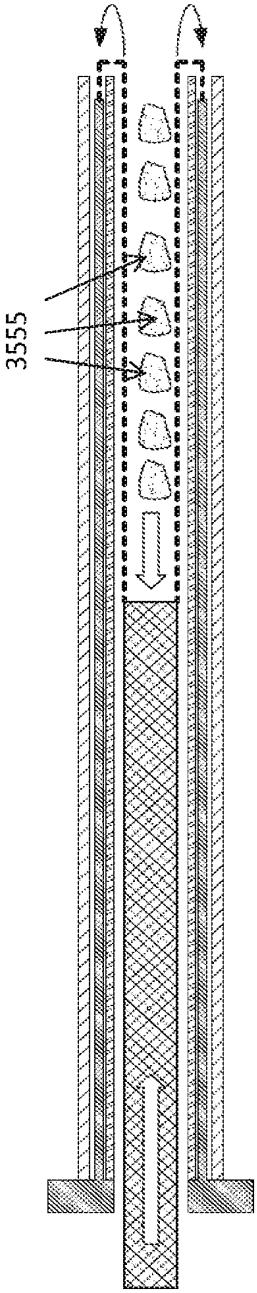


FIG. 35C

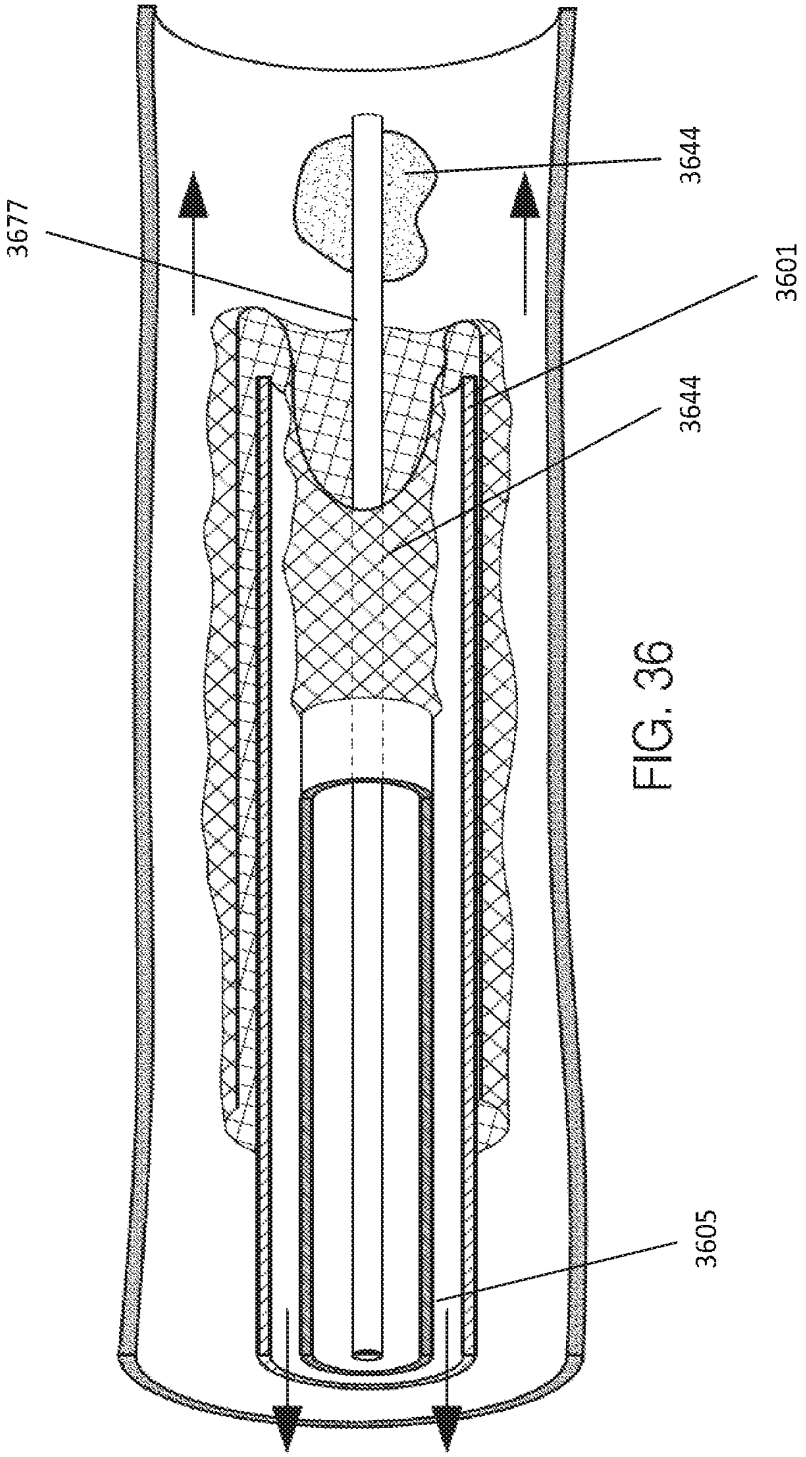


FIG. 36

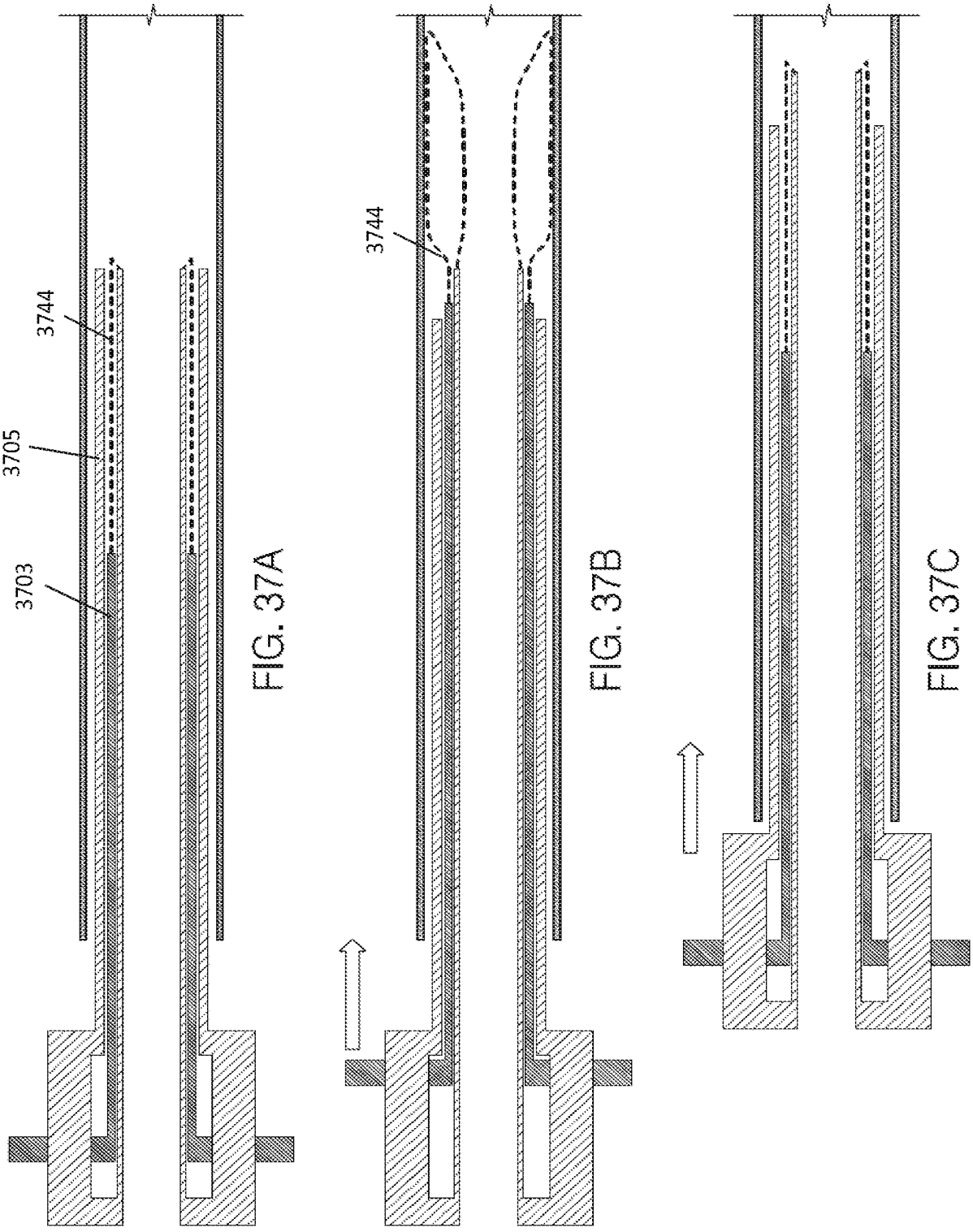


FIG. 37A

FIG. 37B

FIG. 37C

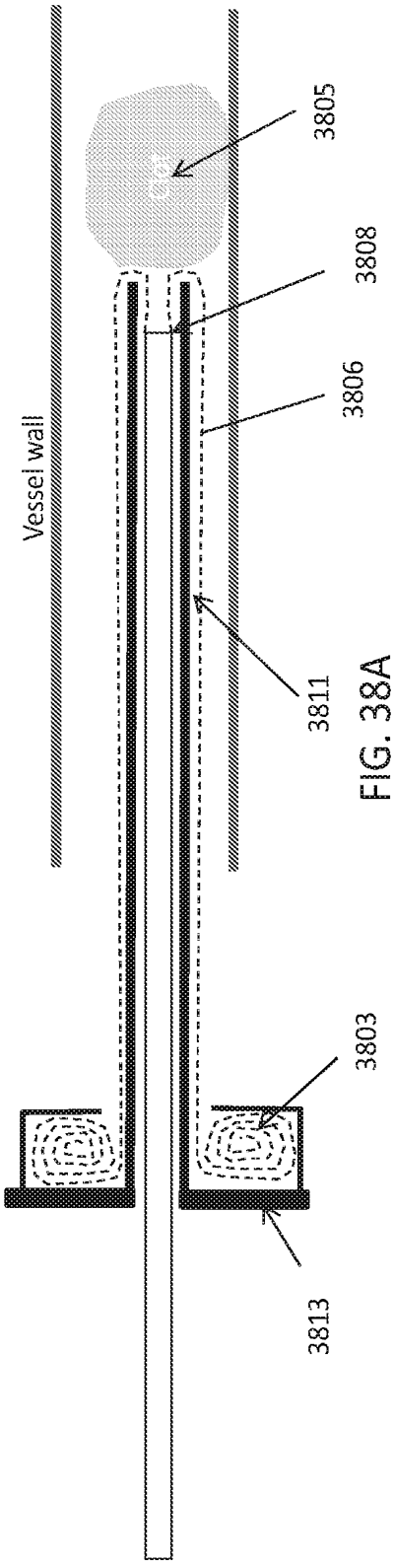


FIG. 38A

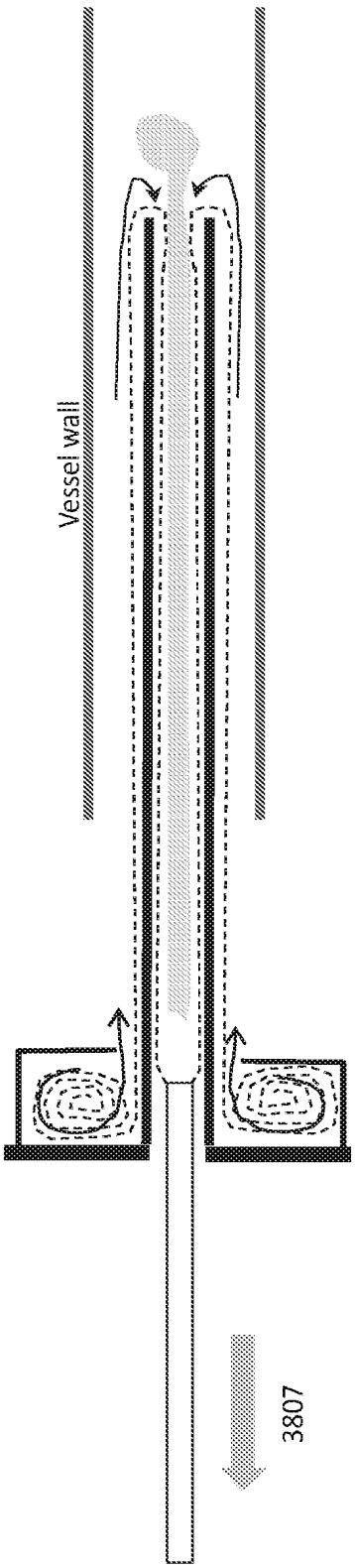


FIG. 38B

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 16/17982

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61F 2/01 (2016.01)
CPC - A61B 17/221, A61F 2/01, A61B 2017/22038, A61B 2017/22079, A61B 2017/22081
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) - A61F 2/01 (2016.01)
CPC - A61B 17/221, A61F 2/01, A61B 2017/22038, A61B 2017/22079, A61B 2017/22081

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
(CPC) 606/200, 159, 127; (CPC) A61B 2017/221*; A61F 2/013, 2002/01*
(Search term limited; see below)

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
PubWest (PGPB, USPT, EPAB, JPAB); Google; PatBase (All);
Search Terms: thrombectomy, embolectomy, remov*, captur*, thromb*, clot*, emboli*, plaque*, invert*, inversion, evert*, intussuscept*, mesh, net, basket, smooth*, round*, edge, tip, end, stiff*, reinforc*, snag*, expand*,

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X -- Y -- A	US 2015/0005781 A1 (LUND-CLAUSEN et al.) 01 January 2015 (01.01.2015) Entire document, especially Abstract, para[0003], para[0036]- para0042] and FIGS. 1-3.	1-2 5-20, 23-28, 30-34 --- 3-4, 21-22, 29, 35-39, 74-76, 79-80 --- 77
Y -- A	US 2010/0249815 A1 (JANTZEN et al.) 30 September 2010 (30.09.2010) Entire document, especially Abstract, para[0029] and FIGS. 1-4.	3-4, 21-22, 29, 35-39, 74-76, 79-80 --- 77
Y	US 2006/0293696 A1 (FAHEY et al.) 28 December 2006 (28.12.2006) Entire document, especially Abstract, para[0018], para[0125]- para[0126].	36, 75
A	US 2013/0317589 A1 (MARTIN et al.) 28 November 2013 (28.11.2013) Entire document.	1-39, 74-77, 79-80
A	US 2010/0030256 A1 (DUBRUL et al.) 04 February 2010 (04.02.2010) Entire document.	1-39, 74-77, 79-80
A	US 2003/0083693 A1 (DANIEL et al.) 01 May 2003 (01.05.2003) Entire document.	1-39, 74-77, 79-80
A	US 2007/0149996 A1 (COUGHLIN) 28 June 2007 (28.06.2007) Entire document.	1-39, 74-77, 79-80
A	US 2007/0112374 A1 (PAUL et al.) 17 May 2007 (17.05.2007) Entire document.	1-39, 74-77, 79-80

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

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
26 April 2016	06 MAY 2016
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 W. Young PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

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

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 16/17982

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.: 40-73, 78
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:

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.:

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.

PCT WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61B 17/22

A1

(11) International Publication Number: **WO 98/33443**

(43) International Publication Date: 6 August 1998 (06.08.98)

(21) International Application Number: PCT/US98/01894

(22) International Filing Date: 3 February 1998 (03.02.98)

(30) Priority Data:
08/794,011 3 February 1997 (03.02.97) US

(71) Applicant *(for all designated States except US)*: ANGIO-GUARD, INC. [US/US]; 735 Aran Drive, Roswell, GA 30076 (US).

(72) Inventor; and
(75) Inventor/Applicant *(for US only)*: YADAV, Jay, S. [US/US]; 735 Aran Drive, Roswell, GA 30076 (US).

(74) Agents: DIPPERT, William, H. et al.; Cowan, Liebowitz & Lataman, P.C., 1133 Avenue of the Americas, New York, NY 10036–6799 (US).

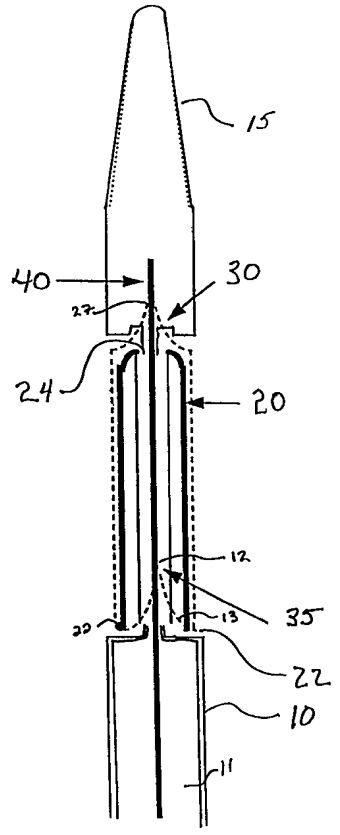
(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, GM, GW, HU, ID, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).

Published
With international search report.

(54) Title: VASCULAR FILTER

(57) Abstract

A removable vascular filter for blocking micro–emboli, and macro–emboli while allowing the continued perfusion of blood comprising a filter membrane (20), wherein the free end of the membrane sits tightly against the guide wire (10) when the filter membrane is in a collapsed state, and wherein the filter has a means for deploying the filter membrane in the interior of a lumen which is comprised of cables or spines (30) operable with a movable core (40), or fibers inside the guide wire which transitions the filter membrane from the collapsed state to the deployed state. The filter membrane is comprised of a fine mesh material which has a pore size capable of blocking emboli while allowing continued blood flow.



FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	**ES**	Spain	**LS**	Lesotho	**SI**	Slovenia
AM	Armenia	**FI**	Finland	**LT**	Lithuania	**SK**	Slovakia
AT	Austria	**FR**	France	**LU**	Luxembourg	**SN**	Senegal
AU	Australia	**GA**	Gabon	**LV**	Latvia	**SZ**	Swaziland
AZ	Azerbaijan	**GB**	United Kingdom	**MC**	Monaco	**TD**	Chad
BA	Bosnia and Herzegovina	**GE**	Georgia	**MD**	Republic of Moldova	**TG**	Togo
BB	Barbados	**GH**	Ghana	**MG**	Madagascar	**TJ**	Tajikistan
BE	Belgium	**GN**	Guinea	**MK**	The former Yugoslav Republic of Macedonia	**TM**	Turkmenistan
BF	Burkina Faso	**GR**	Greece			**TR**	Turkey
BG	Bulgaria	**HU**	Hungary	**ML**	Mali	**TT**	Trinidad and Tobago
BJ	Benin	**IE**	Ireland	**MN**	Mongolia	**UA**	Ukraine
BR	Brazil	**IL**	Israel	**MR**	Mauritania	**UG**	Uganda
BY	Belarus	**IS**	Iceland	**MW**	Malawi	**US**	United States of America
CA	Canada	**IT**	Italy	**MX**	Mexico	**UZ**	Uzbekistan
CF	Central African Republic	**JP**	Japan	**NE**	Niger	**VN**	Viet Nam
CG	Congo	**KE**	Kenya	**NL**	Netherlands	**YU**	Yugoslavia
CH	Switzerland	**KG**	Kyrgyzstan	**NO**	Norway	**ZW**	Zimbabwe
CI	Côte d'Ivoire	**KP**	Democratic People's Republic of Korea	**NZ**	New Zealand		
CM	Cameroon			**PL**	Poland		
CN	China	**KR**	Republic of Korea	**PT**	Portugal		
CU	Cuba	**KZ**	Kazakstan	**RO**	Romania		
CZ	Czech Republic	**LC**	Saint Lucia	**RU**	Russian Federation		
DE	Germany	**LI**	Liechtenstein	**SD**	Sudan		
DK	Denmark	**LK**	Sri Lanka	**SE**	Sweden		
EE	Estonia	**LR**	Liberia	**SG**	Singapore		

VASCULAR FILTER

FIELD OF THE INVENTION

The present invention relates to the treatment of vascular disease of either surgery or percutaneous angioplasty and stenting. More particularly, the invention relates to a device that reduces macro- and micro-embolism during the treatment of vascular stenosis.

BACKGROUND OF THE INVENTION

A variety of surgical and non-surgical angioplasty procedures have been developed for removing obstructions from blood vessels. Balloon angioplasty utilizes a balloon-tipped catheter which may be inserted within a stenosed region of the blood vessel. By inflation of the balloon, the stenosed region is dilated. Surgery involves either removing the plaque from the artery or attaching a graft to the artery so as to bypass the obstructing plaque. Other techniques, such as atherectomy, have also been proposed. In atherectomy, a rotating blade is used to shave plaque from an arterial wall.

One problem common with all of these techniques is the accidental release of portions of the plaque or thrombus, resulting in emboli which can lodge elsewhere in the vascular system. Such emboli are, of course, extremely dangerous to the patient, frequently causing severe impairment of the distal circulatory bed. Depending upon the vessel being treated, this may result in a stroke or myocardial infarction or limb ischemia.

Vascular filters or embolism traps for implantation into the vena cava of a patient are well known, being illustrated by, for example, U.S. Patents. Nos. 4,727,873 and 4,688,553. Additionally, there is a substantial amount of medical literature describing various designs of vascular filters and reporting the results of the clinical and experimented use thereof. See, for example, the article by Eichelter & Schenk entitled "Prophylaxis of Pulmonary Embolism," Archives of

Surgery, Vol. 97, August 1968, pp. 348 et seq. See, also, the article by Greenfield, et al., entitled "A New Intracaval Filter Permitting Continued Flow and Resolution of Emboli", Surgery, Vol. 73, No. 4, pp. 599-606 (1973).

Vascular filters are used, often during a postoperative period, when there is a perceived risk of a patient encountering a pulmonary embolus resulting from clots generated at the surgical site or the like. As a typical use of vascular filters, the filter is mounted in the vena cava to catch large emboli passing from the surgical site to the lungs.

The vascular filters of the prior art are usually permanently implanted in the venous system of the patient, so that even after the need for the filter has abated, the filter remains in place for the lifetime of the patient, absent surgical removal. U.S. Pat. No. 3,952,747 describes a stainless steel filtering device which is permanently implanted transvenously within the inferior vena cava. The filtering device is intended to treat recurrent pulmonary embolism. U.S. Pat. No. 4,873,978 describes a catheter device comprising a catheter body having a strainer mounted at it distal end. The strainer is shiftable between an opened configuration where it extends substantially across the blood vessel to entrap passing emboli, and a closed configuration where it retains the captured emboli during removal of the catheter. A mechanism actuable at the proximate end of the catheter body allows selective opening and closing of the strainer. Typically, the strainer is a collapsible cone having an apex attached to a wire running from the distal end to the proximate end of the catheter body.

Permanent implantation is often deemed medically undesirable, but it has been done because vascular filters are implanted in patients primarily in response to potentially life threatening situations. Accordingly, the disadvantages of permanent implantations of a vascular filter are often accepted.

To avoid permanent implantation, it would be highly desirable to provide an apparatus and method for preventing

embolisms associated with conventional surgery and angioplasty procedures. In particular, it would be desirable to provide a device which could be located within the vascular system to collect and retrieve portions of plaque and thrombus which have dislodged during the surgery or angioplasty procedure.

OBJECT OF THE INVENTION

It is an object of this invention to provide a vascular filter for reducing macro- and micro-embolism.

It is also an object of the invention to provide a vascular filter which is readily removable from the vascular system, or elsewhere, of a patient when the filter is no longer needed.

It is a further object of the invention to provide a vascular filter having a configuration which does not require hooks to penetrate and grip the blood vessel walls, so that the implantation results in less blood vessel injury.

It is a yet further object of the invention to provide a vascular filter of very low profile which is part of a guidewire and can be used in small vessels

These and other objects of the invention will become more apparent from the description below.

SUMMARY OF THE INVENTION

The present invention generally relates to the surgical and interventional treatment of vascular disease. For example, during angioplasty and stenting of carotid stenosis, there is occurrence of macro- and micro-embolism which increases the risk of a minor or major stroke. The device of the present invention for reducing macro- and micro-embolism is very useful in helping to prevent the risk of stroke. However, this device would also be useful in any angioplasty or surgical procedure where embolization is a risk.

The filters of the present invention will decrease embolism while allowing brain, or other distal tissue, perfusion. The filters are incorporated into a guidewire which

is used for the entire procedure from crossing a lesion to deploying a stent. The filter consists of a thin membrane attached to the guidewire and supported by fine metal spines. The filter membrane has a pore size such that blood flow is not impeded when the filter membrane is expanded but micro- and macro-emboli are blocked. The attachments of the filter membrane to the guidewire allow expansion of the filter membrane with a firm fit inside the artery. Expansion of the filter membrane is aided by the forward flow of blood against the filter. The attachments also allow for collapse of the filter membrane at the end of the procedure so it fits tightly against the guidewire and can be withdrawn through the guide catheter. The filter design results in a very low profile so that the initial crossing of the lesion is minimally traumatic. Also, the small diameter and small profile facilitate use of the device in small or larger arteries with minimal or no obstruction of blood flow.

BRIEF DESCRIPTION OF THE DRAWINGS

The above and other objects and advantages of the invention will be apparent upon consideration of the following detailed description, taken in conjunction with the accompanying drawings, in which the reference characters refer to like parts throughout and in which:

Fig. 1 is a lateral, partly cross-sectional view of the distal end of a guidewire of one embodiment of the invention with the filter membrane in a collapsed position;

Fig. 2 is a lateral, partly cross-sectional view of the distal end of a guidewire of Fig. 1 with the filter membrane in an expanded, deployed position;

Fig. 3 is a proximal end-on view of the filter membrane shown in Fig. 2;

Fig. 4 is a lateral, partly cross-sectional view of another embodiment of the invention;

Fig. 5A is a lateral, partly cross-sectional view of a further embodiment of the invention;

Fig. 5B is a lateral, partly cross-sectional view of the embodiment of the invention shown in Fig. 5A with the filter membrane in an expanded, deployed position;

Fig. 6 is a partly cross-sectional view of a control handle for the invention;

Fig. 7 is a partly cross-sectional view of another embodiment of the invention;

Fig. 8 is a partial cross-sectional view of an embodiment of the invention wherein the filter membrane has curved supports;

Fig. 9 is a partial cross-sectional view of yet another embodiment of the invention wherein the filter membrane has a spiral wire;

Fig. 10 is a top, cross-sectional view of the embodiment of the invention shown in Fig. 9;

Fig. 11 is a partial cross-sectional view of another embodiment of the invention having inflatable support spines; and

Figs. 12 and 13 represent partial cross-sectional views of another embodiment of the invention in collapsed and deployed positions, respectively.

DETAILED DESCRIPTION OF THE INVENTION

The present invention relates to a vascular filter for use in percutaneous angioplasty and stenting and provides for the prevention of distal embolism during endovascular procedures. Further, the filter device of the invention allows for distal perfusion while preventing embolism.

The device consists of a thin, perforated filter membrane which is capable of blocking emboli and which is attached to the distal end of a guidewire. The device preferably uses thin fibers which are moveable and are attached to the filter membrane to deploy and collapse the filter membrane. The invention also contemplates the use of metal spines or inflatable spines attached to the filter membrane to deploy the

filter membrane. The fibers or spines can also be attached to a moveable core which is slidable within the guidewire and is used to deploy and collapse the filter membrane.

The filter membrane deploys in an umbrella-like fashion with the unattached edge of the membrane moving upward, i.e., distally, and outward until it is in firm contact with an artery wall. When the filter membrane is deployed, it spans the cross-sectional area of the vessel lumen being treated for a stenosis such as carotid stenosis, or another condition likely to produce emboli.

The invention can perhaps be appreciated better by referring to the drawings. Fig. 1 illustrates a lateral, cross-sectional view of a distal end of a guidewire 10 with a filter membrane 20 attached thereto. Fig. 1 shows guidewire 10 with a shapeable, tapered soft tip 15 at its extreme distal end which provides flexibility and maneuverability to guidewire 10. The filter membrane in Fig. 1 is in a collapsed position. Filter membrane 20 has a fixed portion 24 which is movably attached to guidewire 10, and filter membrane 20 lies adjacent guidewire 10 proximal to fixed portion 24 when filter membrane 20 is in the collapsed state. A moveable core 40 runs through a center lumen 11 of guidewire 10 and preferably extends distally a short distance beyond fixed portion 24 of filter membrane 20. Deploying wires or fibers 30 are each firmly attached at one end 27 to moveable core 40 distal to fixed portion 21 of filter membrane 20. The deploying fibers 30 are attached at their other ends to filter membrane 20 at attachment points 22.

Collapsing fibers 35 are each firmly attached at one end 12 to the portion of moveable core wire 40 which is interior to filter membrane 20 when it is in the collapsed state. Collapsing fibers 35 are each attached at their other end 13 to filter membrane 20 at attachment points 22. Accordingly, collapsing fibers 35 lie interior to filter membrane 20 when filter membrane 20 is in the collapsed state.

Filter membrane 20 is deployed when the operator pulls moveable core 40 proximally through the interior of guidewire

10. Prior to retraction of moveable core 40, deploying fibers 30 are sufficiently relaxed so as not to create any tension at filter membrane attachment points 22. Upon retraction of moveable core 40, tension is created in deploying fibers 30.

There will preferably be from 2 to 6 each of evenly-spaced deploying fibers 30 and collapsing fibers 35, 3 or 4 being most preferred. The deploying fibers 30 and collapsing fibers 35 can be made of any flexible, medically acceptable material, including stainless steel, nitinol, or another metal or metallic alloy or a non-metallic substance such as graphite or a suitable polymer. In addition, guidewire 10 and moveable core 40 can be made from similar materials, as would be appreciated by those skilled in the art. Typically, guidewire 10 could have an external diameter of from about 0.014 mm to about 0.035 mm, a wall thickness of from about 0.002 mm to about 0.010 mm, and a length of from about 25 cm to about 300 cm. Also, moveable core 40 could have a diameter of from about 0.003 mm to about 0.010 mm and a length of from about 30 cm to about 350 cm.

Fig. 2 illustrates the filter device of the invention in a deployed position on the inside of an artery wall 60. Moveable core 40 is in a retracted state, i.e., pulled proximally through the interior of guidewire 10. Tension is created in deploying fibers 30, and filter membrane 20 extends to a deployed position where the outer edge 14 of filter membrane 20 contacts artery wall 60. In this deployed position, collapsing fibers 35 are in a relaxed state and extend from filter membrane attachment points 22 to fixed attachment points 28 on moveable core 40.

The flow of blood in Fig. 2 is toward the distal end of guidewire 10. As such, the force of the flow of blood pushes on deployed filter membrane 20 and helps to maintain filter membrane 20 in the deployed position.

For withdrawal of guidewire 10 and the filter device, filter membrane 20 is collapsed so that it sits tightly against guidewire 10. This is accomplished by extending moveable core 40 distally through guidewire 10, thus relaxing deploying

fibers 30 and creating tension in collapsing fibers 35. The tension in collapsing fibers 35 collapses the filter membrane 20, allowing it to fit tightly against guidewire 10 in recess 16 as depicted in FIG. 1.

Fig. 3 illustrates the filter device of the invention from a distal end view in Fig. 2 with filter membrane 20 deployed. Guidewire 10 is centrally located, and structural wires 50 are seen extending from guidewire 10 to the outer edge 14 of filter membrane 20. These wires 50 provide structural integrity and rigidity to filter membrane 20. Fig. 3 depicts four, evenly-spaced structural wires 50, but there can be more or less structural wires 50. Preferably there are from two to six structural wires 50, which may be spaced regularly or irregularly. The wires 50 may preferably be comprised of stainless steel or another medically acceptable metal or alloy.

Filter membrane 20 of the invention is preferably a mesh such as that depicted in Fig. 3. The mesh should have pores of a size sufficient to block and capture any micro- and macro-emboli which may flow downstream from the site where the stenosis is being treated, but large enough such that blood flow is not impeded. The mesh used in the filter device of the invention can have a pore size of from about 20 to about 300 microns, preferably from about 30 to about 100 microns, more preferably from about 40 to 60 microns. Moreover, the size of filter membrane 20, i.e., the distance from guidewire 10 to free ends 22, is such as to allow a firm fit between filter membrane 20 and artery wall 60. The diameter of filter membrane 20 will be directly related to the artery being treated, with typical diameters ranging from about 2 mm to about 40 mm, most preferably from about 2 mm to about 20 mm.

The membrane can be comprised of fabric or non-fabric meshes, such as those used in known hemodialysis filters or heart-lung bypass machine filters. Suitable materials include polymers or physiologically acceptable metals or alloys.

In alternative embodiments of the invention shown in Figs. 4, 5A and 5B, filter membrane 20 will be suspended between from two to six, preferably three or four, thin metal wires 51 which

serve as spines for filter membrane 20. Wires 51 may be comprised of stainless steel or another metallic alloy, nitinol, or another shape-memory material. Wires 51 will be constructed so that they assume a 90° angle with guidewire 10 when they are in an unconstrained state. This will result in expansion of the filter membrane 20 to a position normal to guidewire 10. A set of thin fibers 17 are attached at attachment points 18 to filter membrane outer edge 14 and are used to collapse filter membrane 20.

Fig. 4 shows an embodiment of this invention in which metal wires 51 are allowed to regain their 90° angle unconstrained state by use of a moveable core 40 that runs through guidewire 10. Prior to retraction of moveable core 40, fibers 17 are sufficiently tensed so as to restrain wires 51. Upon retraction of moveable core 40, tension in fibers 17 is released and wires 51 are allowed to revert to their relaxed shape, which will result in expansion of filter membrane 20 to a position normal to guidewire 10.

Figs. 5A and 5B show an embodiment of the invention wherein wires 51 are restrained by fibers 17 that run through guidewire 10 and that are controlled at a remote location. In Fig. 5A, there is sufficient tension in fibers 17 to maintain wires 51 in a constrained position. In Fig. 5B, tension in fibers 17 has been relaxed such that wires 51 are allowed to revert to their relaxed shape, which will result in expansion of filter membrane 20 to a position normal to guidewire 10.

Fig. 6 depicts a control handle especially suitable for the embodiment of the invention shown in Figs. 5A and 5B. The proximal end 32 of guidewire 10 is rotatably attached to handle 33, such that rotation of handle 33 causes handle 33 to move distally or proximally relative to proximal guidewire end 32. For example, handle 33 may have threads 34 which engage threads 35 on guidewire proximal end 32. Fibers 17 attached to filter membrane 20 are secured in a base 36 of handle 33. Then, as handle 33 is turned, the fibers 17 move distally or proximally to open or close filter membrane 20.

As handle 33 is turned clockwise in the direction of arrow A and fibers 17 are allowed to move distally in the direction of arrow C, the tension on the filter membrane fibers 17 decreases and wires 51 are allowed to assume their natural 90° angle with respect to the guidewire, resulting in opening of filter membrane 20. Similarly, when handle 33 is turned counter-clockwise in the direction of arrow B and fibers 17 are pulled proximally in the direction of arrow D, the tension on filter fibers 17 increases, causing filter membrane 20 to collapse tightly against guidewire 10. Of course, the direction of turn of handle 33 as discussed above can be reversed, as long as threads 34,35 are properly formed to allow appropriate movement of handle 33 relative to guidewire proximal end 32.

In yet another embodiment of the invention, shown in Fig. 11, filter membrane 20 can be supported by inflatable spines 135 supporting the filter membrane 20. Spines 135 supporting the filter membrane 20 are from two to six hollow plastic tubes which are inflatable using, for example, a standard balloon angioplasty inflation device or endoflator in fluid connection through channel 137 with spines 135. Inflation of spines 135 causes them to become rigid and deploys filter membrane 20. The underside of the filter membrane is attached to very thin fibers 17 which are attached to moveable core 40 inside hollow guidewire 10. Filter membrane 20 is collapsed by deflating the spines 135 and withdrawing the moveable core 40 in the direction of arrow E until the membrane 20 fits tightly against guidewire 10.

A catheter-based configuration is also possible, as shown in FIG. 7. In this design, the guidewire is not part of the filter catheter; the guidewire and filter catheter are two separate components. The filter catheter has an entry hole for the guidewire below the attachment of the filter membrane and the guidewire exits out the end of the filter catheter. The filter catheter could be designed to accommodate a variety of guidewire sizes, most commonly a 0.014 inch guidewire. The advantages of this design are that a variety of guidewires

could be used; the lesion could be crossed with the guidewire prior to crossing with the filter catheter; the filter catheter could be removed from the artery without removing the guidewire; and the filter catheter could be made smaller.

In the embodiment of the invention shown in Fig. 7 a catheter 101 comprises a longitudinally extending lumen 103, which has an annular recess 105 adjacent the distal end of catheter 101. Positioned within recess 105 is a filter 107 comprised of structural wires 109 and a filter membrane 111. The distal end of each of wires 109 is attached at point 113 in recess 105. Fibers 117 extend from the proximal ends 119 of wires 109 proximally to a control means such as described in Fig. 6.

Catheter 101 contains guidewire port 125 located proximal to recess 105. It is intended that in use the distal portion 128 of a guidewire 127 will be threaded into the distal end 129 of catheter 101 and out through port 125.

Alternatively, and not shown here, a catheter 101 could comprise a longitudinally extending lumen and a shorter tracking lumen that extends from distal end 129 to a point proximal to recess 105. The distal end of guidewire 127 would then be threaded into the distal opening of the tracking lumen and out the proximal end of the tracking lumen.

Spiral or curved structural wires may be used to deploy the filter membrane instead of straight wires. Fig. 8 illustrates the use of four curved wires 120. The angulation of the filter attachment point of wires 120 relative to their guidewire attachment has the effect of wrapping the filter fabric around the guidewire in the undeployed state. This leads to a lower profile for the undeployed filter.

Figs. 9 and 10 illustrate the use of a single spiral structural wire 130 which is attached to the filter 107. As tension fiber 131 is released, wire 130 unwinds and deploys filter 107 in a conical configuration. This configuration has the simplicity of using a single wire and, when the tension on fiber 131 is increased, allows filter 107 to be wrapped very

tightly around the guidewire shaft 131, resulting in filter 107 having a low profile in its undeployed state.

Another modification shown in Figs. 12 and 13 comprises a retractable sheath 140 at the distal end of guidewire 142 which covers filter membrane 144 in the collapsed state. Sheath 140, the distal portion of which is affixed to guidewire tip 146, which is affixed to the distal end of moveable core 148, would prevent an edge 150 of filter membrane 144 from becoming entangled in an artery or guide catheter as it was being withdrawn from a patient.

More specifically, when guidewire 142 with tapered tip 146 is inserted percutaneously into a patient, sheath 140 covers collapsed filter membrane 144. After the filter membrane is determined by fluoroscopy to be in proper position, moveable core 148 is pushed distally to cause sheath 140 to "release" filter membrane 144, which has spines 152, to cause filter membrane 144 to deploy, as shown in Fig. 13.

It will be seen that the objects set forth above, among those made apparent from the preceding description, are efficiently attained and, since certain changes may be made in carrying out the method and in the apparatus set forth without departing from the spirit and scope of the invention, it is intended that all matter contained in the above description and shown in the accompanying drawings shall be interpreted as illustrative and not in a limiting sense.

It is also to be understood that the following claims are intended to cover all of the generic and specific features herein and described and all statements of the scope of the invention which, as a matter of language, might be said to fall therebetween.

ITEM LISTING

No.	Item
10	Guidewire
11	Guidewire lumen
12	End of collapsing fiber
13	End of collapsing fiber
14	Filter membrane outer edge
15	Guidewire soft tip
17	Collapsing fiber
18	Attachment point
20	Filter membrane
22	Filter membrane attachment point
24	Filter membrane fixed portion
27	Fiber attachment point
28	Fiber attachment point
30	Deploying fibers
32	Guidewire proximal end
33	Handle
34	Handle threads
35	Guidewire proximal end threads
36	Handle base
40	Moveable core wire
50	Structural wires
51	Deploying wires
60	Artery wall
101	Catheter
103	Lumen
105	Recess
107	Filter mesh structure
109	Filter wire
111	Mesh
113	Attachment point
117	Deployment collapse wire
120	Curved filter structural wires
125	Guidewire port
127	Guidewire

128	Guidewire distal end
129	Spiral wire
131	Fiber
132	Guidewire shaft
135	Inflatable spines
137	Inflation channel
140	Sheath
142	Guidewire
144	Filter member
146	Tapered guidewire tip
148	Moveable core
150	Filter membrane edge
152	Filter membrane spine

I claim:

1. A removable vascular filter device for blocking micro-and macro-emboli while allowing continued perfusion of blood, comprising:

a guidewire having distal and proximal portions, wherein there is a recess in the distal portion, the recess having distal and proximal ends,

a filter membrane having a fixed inner portion and a free outer portion, wherein the fixed inner portion is movably attached toward the distal end of the guidewire recess and wherein the free outer portion is positioned in the recess when the filter membrane is in a collapsed state; and

a deploying means for causing the filter membrane to assume a position substantially normal to the longitudinal axis of the guidewire.

2. The vascular filter of Claim 1, wherein the filter membrane is comprised of a porous mesh.

3. The vascular filter of Claim 2, wherein the pore size of the porous mesh is from about 40 to about 300 microns.

4. The vascular filter of Claim 1, wherein the guidewire is hollow and wherein the deploying means comprises a moveable core, the moveable core being slidably positioned in the interior of the guidewire.

5. The vascular filter of Claim 4, wherein the deploying means further comprises deploying fibers each having first and second ends and said filter membrane further comprises an outer edge, and wherein said deploying fibers are each attached at a first end to the moveable core and are attached at a second end to the outer edge of the filter membrane.

6. The vascular filter of Claim 4, wherein the moveable core creates a tension in the deploying fibers when it slides proximally in relation to the guidewire, and said tension causes the filter membrane to expand outwardly until the outer edge of the filter membrane is in firm contact with the lumen wall.

7. The vascular filter of Claim 5 further comprising a means for collapsing the filter membrane from a deployed state to a collapsed state.

8. The vascular filter of Claim 7, wherein the collapsing means further comprises collapsing fibers each having first and second ends, wherein said collapsing fibers are each attached at a first end to the moveable core and are further attached at a second end to the outer edge of the filter membrane.

9. The vascular filter of Claim 8, wherein the moveable core creates a tension in the collapsing fibers when it slides distally in relation to the guidewire, and said tension causes the filter membrane to collapse tightly against the guidewire.

10. The vascular filter of Claim 1, wherein the guidewire has a lumen extending distally from the proximal portion of the guidewire to at least the recess.

11. The vascular filter of Claim 1, wherein the guidewire has a tapered distal tip.

12. A removable vascular filter device for blocking micro-and macro-emboli while allowing continued perfusion of blood, comprising:

a guidewire having distal and proximal portions, wherein there is a recess in the distal portion, the recess having distal and proximal ends,

a filter membrane having a fixed inner portion and a free outer portion, wherein the fixed inner portion is attached toward the distal end of the guidewire recess and wherein the free outer portion is positioned in the recess when the filter membrane is in a collapsed state, and wherein the filter membrane in an unstressed position assumes a position substantially normal to the longitudinal axis of the guidewire, and

means for collapsing the filter membrane from a deployed state to a collapsed state.

13. The vascular filter of Claim 12, wherein the filter membrane comprises wires which assume a 90° angle with respect to the longitudinal axis of the guidewire in an unconstrained state.

14. The vascular filter of Claim 12, wherein the filter membrane comprises from 2 to 6 arcing wires.

15. The vascular filter of Claim 13, wherein the filter membrane comprises a single spiral wire.

16. The vascular filter of Claim 12, wherein the collapsing means comprises collapsing fibers each having first and second ends, wherein said collapsing fibers are each attached at a first end to the outer edge of the filter membrane and the second end of each fiber extends proximally through the guidewire to an actuator.

17. The vascular filter of Claim 16, wherein the actuator is a handle or shaft that can be rotated clockwise or counter-clockwise to release or collapse the filter membrane.

18. The vascular filter of Claim 12, wherein the filter membrane comprises a set of inflatable spines, said spines being hollow plastic tubes.

19. The vascular filter of Claim 18 which further comprises an inflator for inflating the spines, wherein said inflator is in fluid communication with said spines, which become rigid upon inflation.

20. The vascular filter of Claim 19, where the means of inflation is an endoflator.

21. The vascular filter of Claim 12, wherein the guidewire has a lumen extending distally from the proximal portion of the guidewire to at least the recess.

22. The vascular filter of Claim 12, wherein the guidewire has a tapered distal tip.

23. The vascular filter of Claim 12, which also comprises a sheath positioned concentric to the collapsed filter membrane, wherein said membrane causes the filter

member to be in a collapsed state but can be moved distally to allow the filter member to extend radially.

24. The vascular filter of Claim 23, wherein the sheath has proximal and distal portions and is attached at its distal end to a distal guidewire tip that is affixed to a moveable core extending proximally through the guidewire.

25. A removable vascular filter device for blocking micro-and macro-emboli while allowing continued perfusion of blood, comprising:

a catheter having distal and proximal portions, wherein there is a recess in the distal portion, the recess having distal and proximal ends, and the catheter has a longitudinally extending lumen;

a filter membrane having a fixed inner portion and a free outer portion, wherein the fixed inner portion is movably attached toward the distal end of the catheter recess, wherein the free outer portion is positioned in the recess when the filter membrane is in a collapsed state, and wherein the filter membrane is unstressed and extends substantially normal to the outer surface of the catheter; and

a collapsing means for causing the filter membrane to collapse into the catheter recess,

wherein the outer surface of the catheter has a guidewire port for receipt of a guidewire.

26. The vascular filter of Claim 25, wherein the filter membrane comprises a porous mesh.

27. The vascular filter of Claim 26, wherein the pore size of the porous mesh is from about 40 to about 300 microns.

28. The vascular filter of Claim 25, wherein the collapsing means comprises fibers each having first and second ends and said filter membrane further comprises an outer edge, and wherein said collapsing fibers are each attached at a first end to a control mechanism and are attached at a second end to the outer edge of the filter membrane.

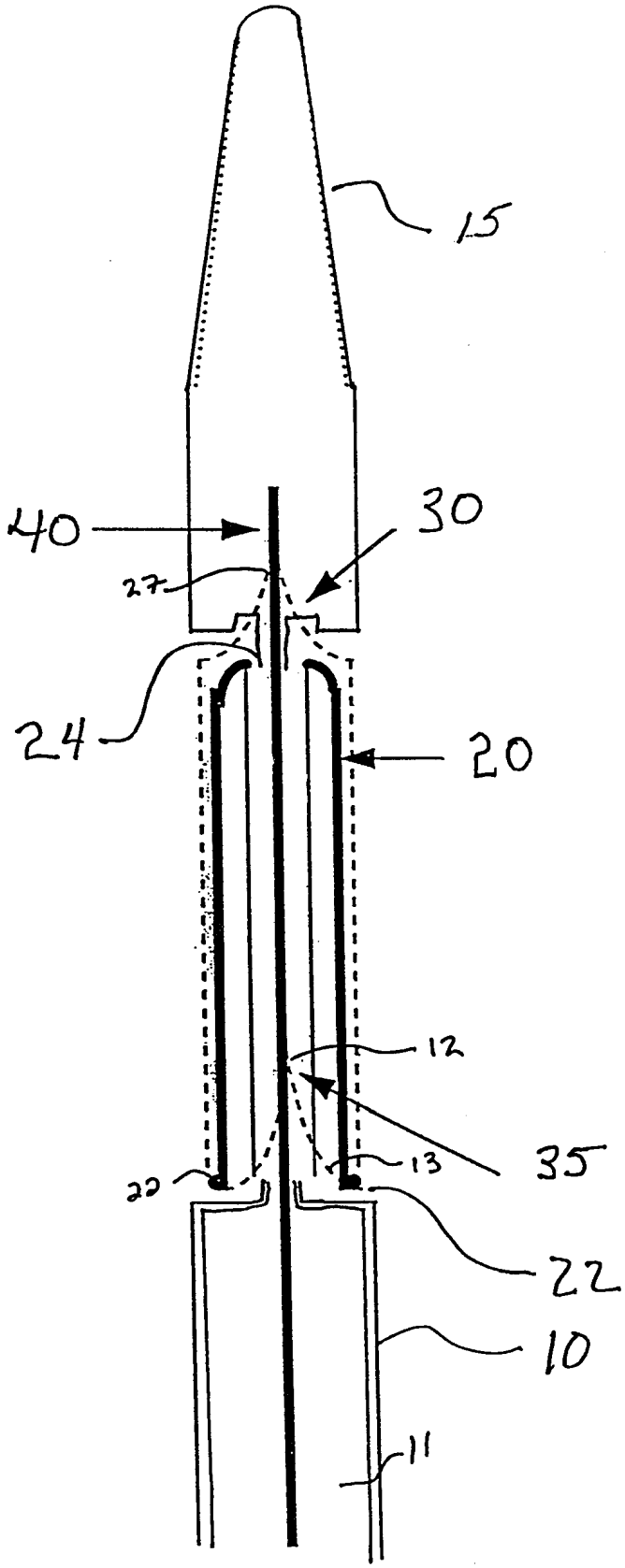


FIG. 1

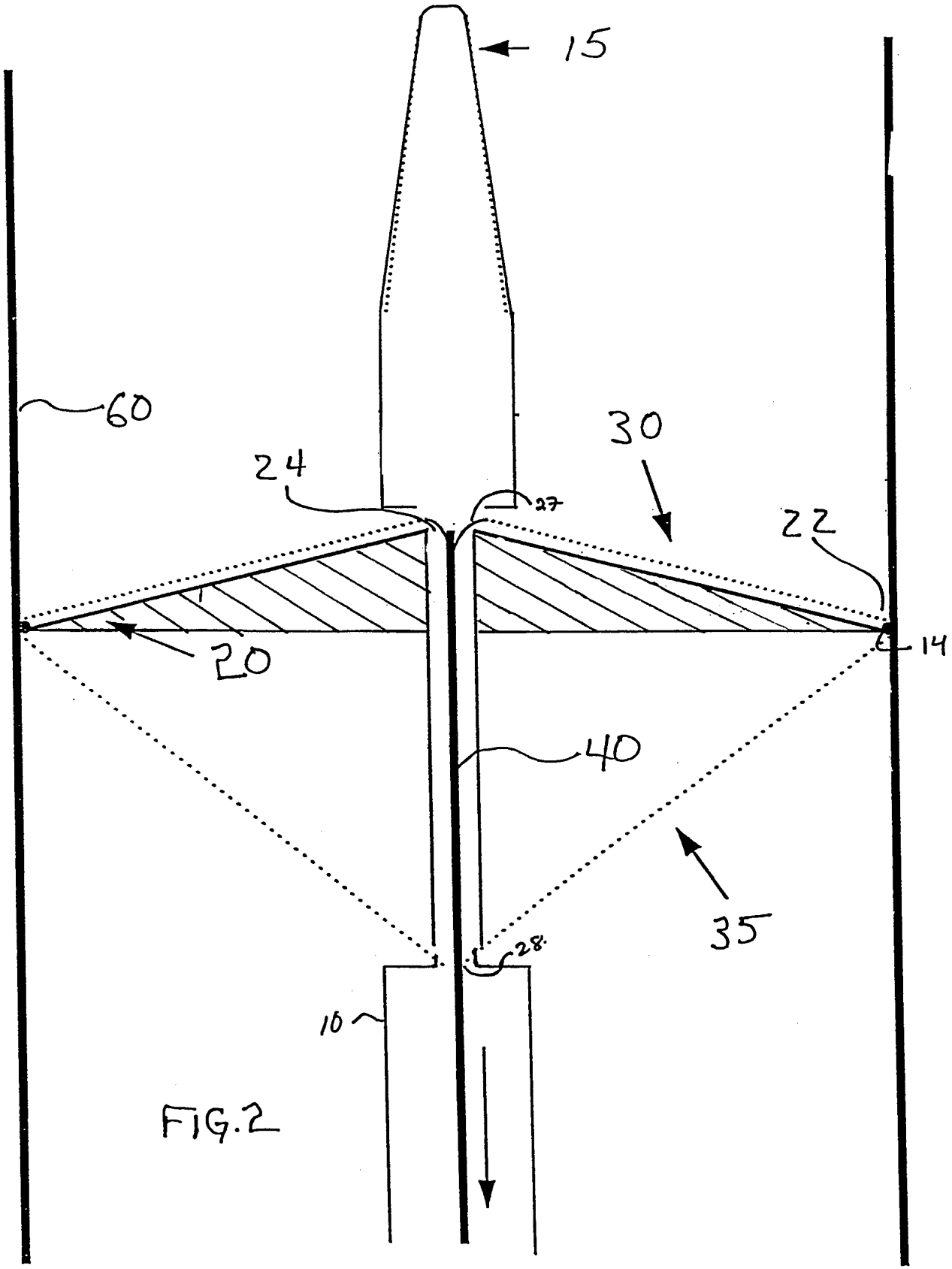


FIG.2

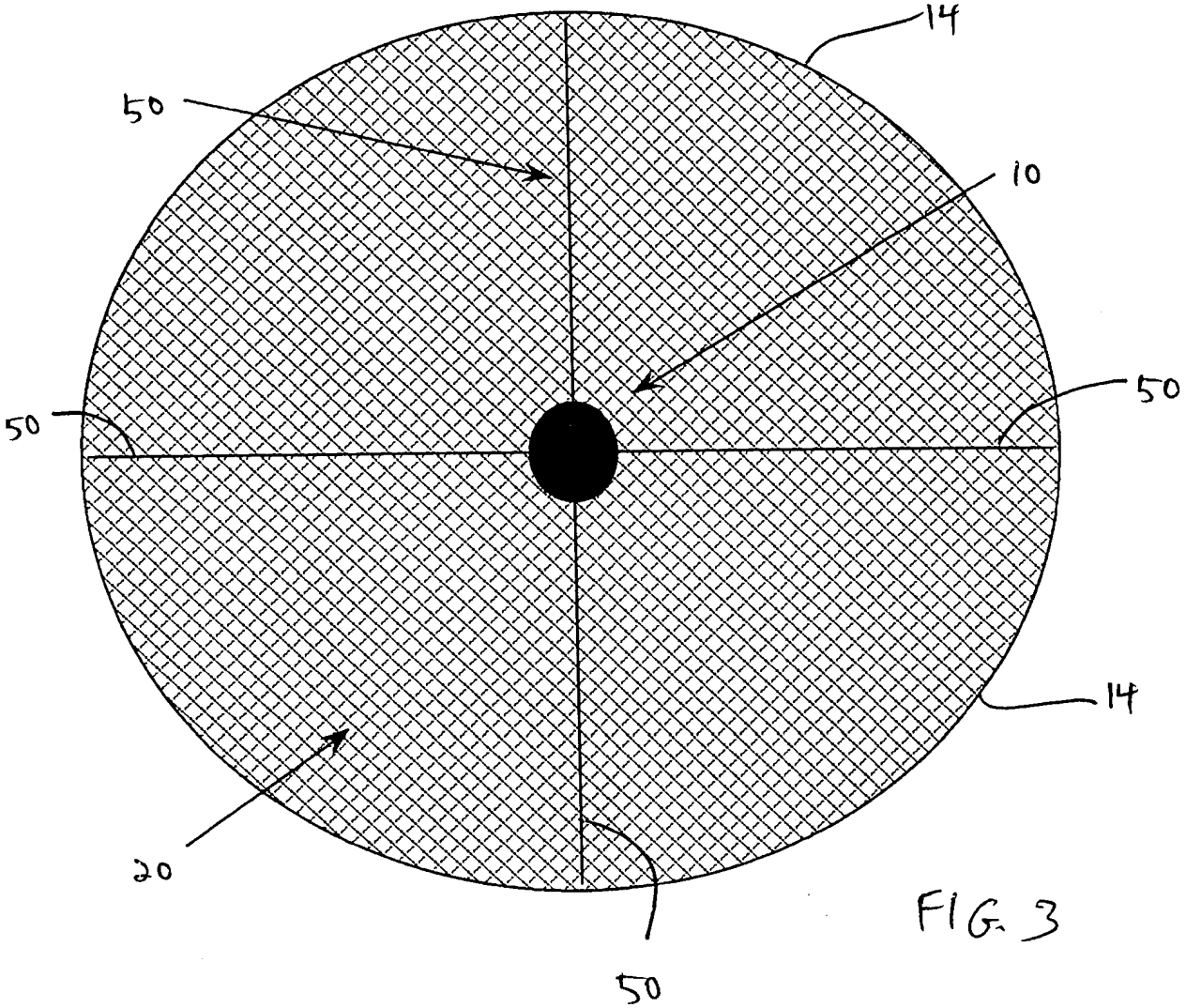


FIG. 3

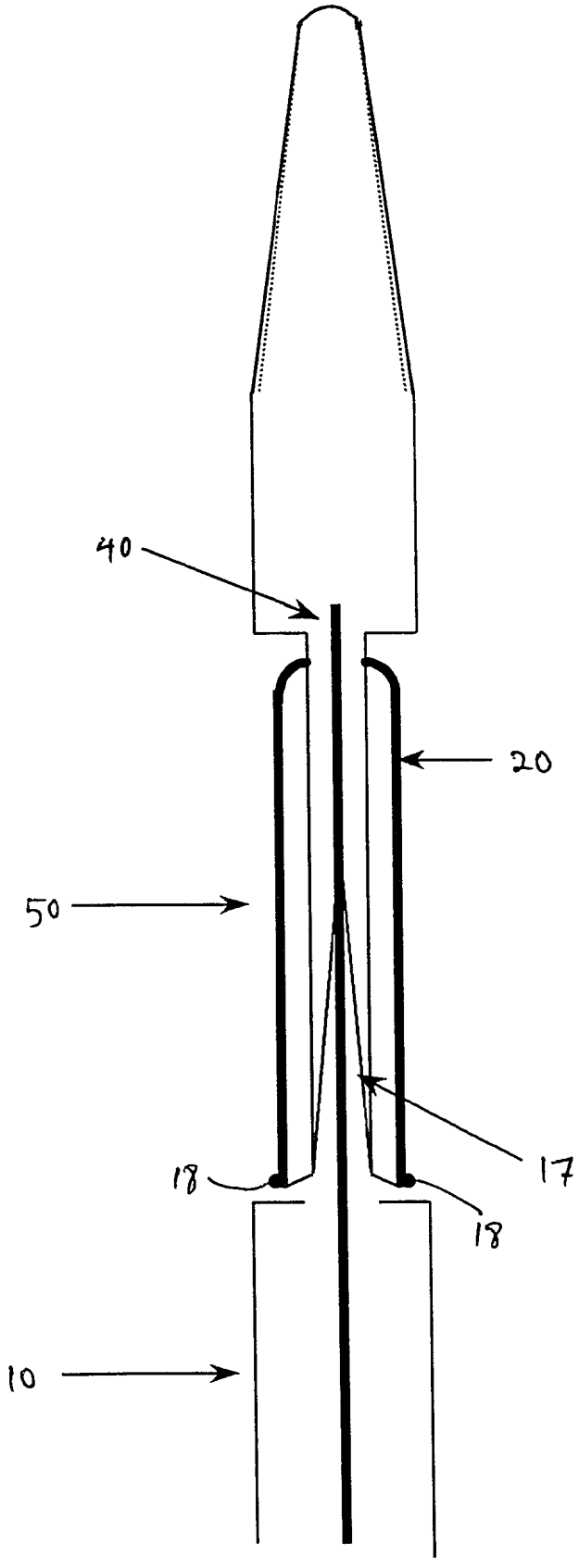


FIG. 4

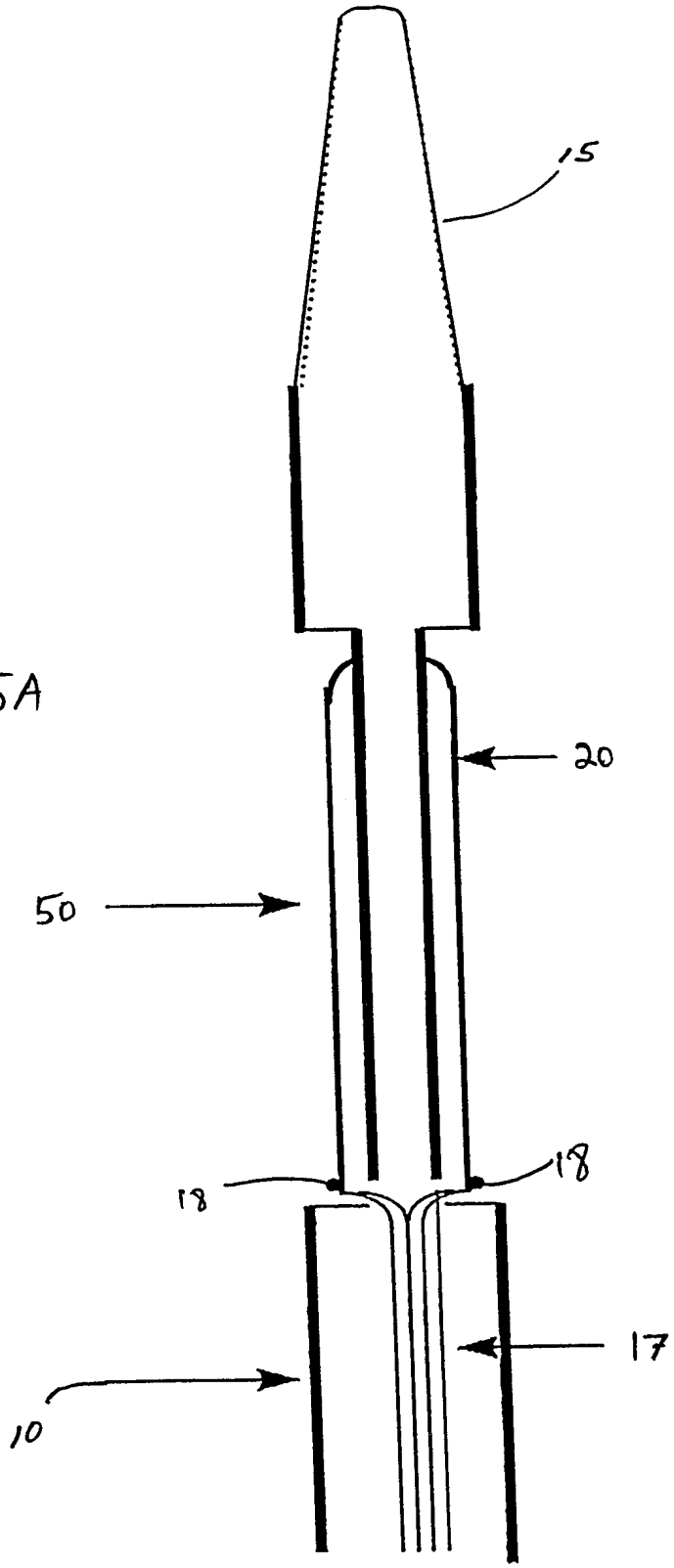


Fig. 5A

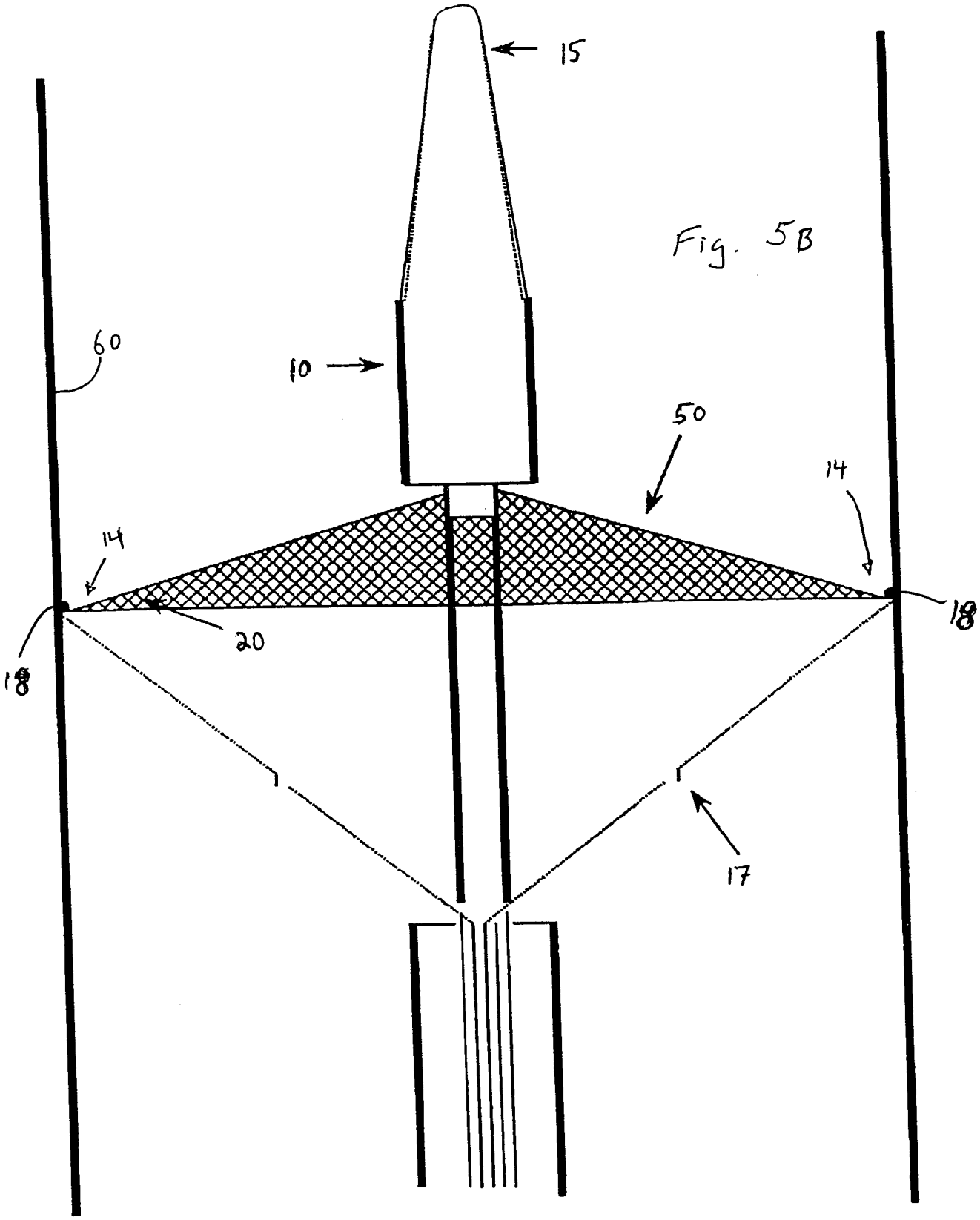


Fig. 5B

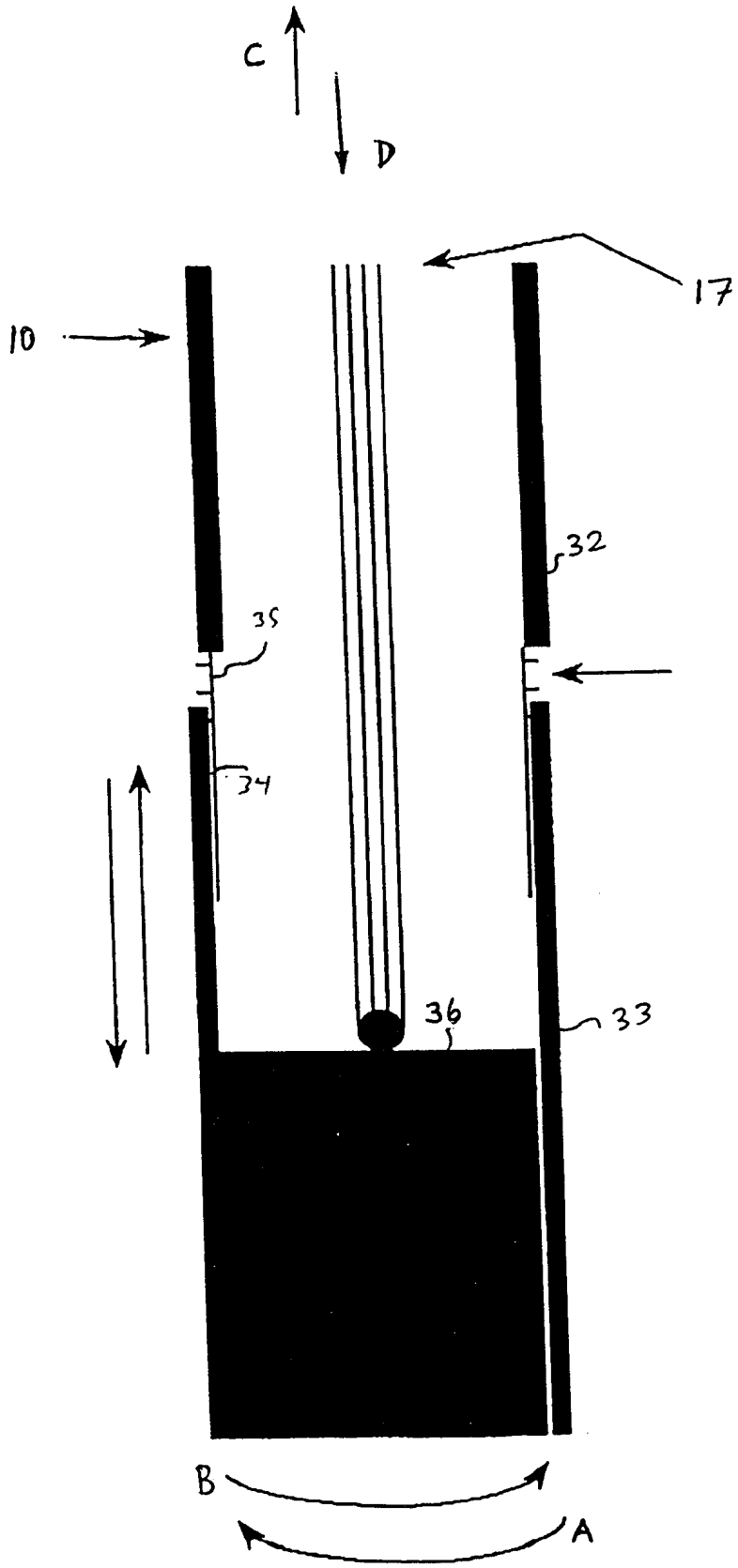


Fig. 6

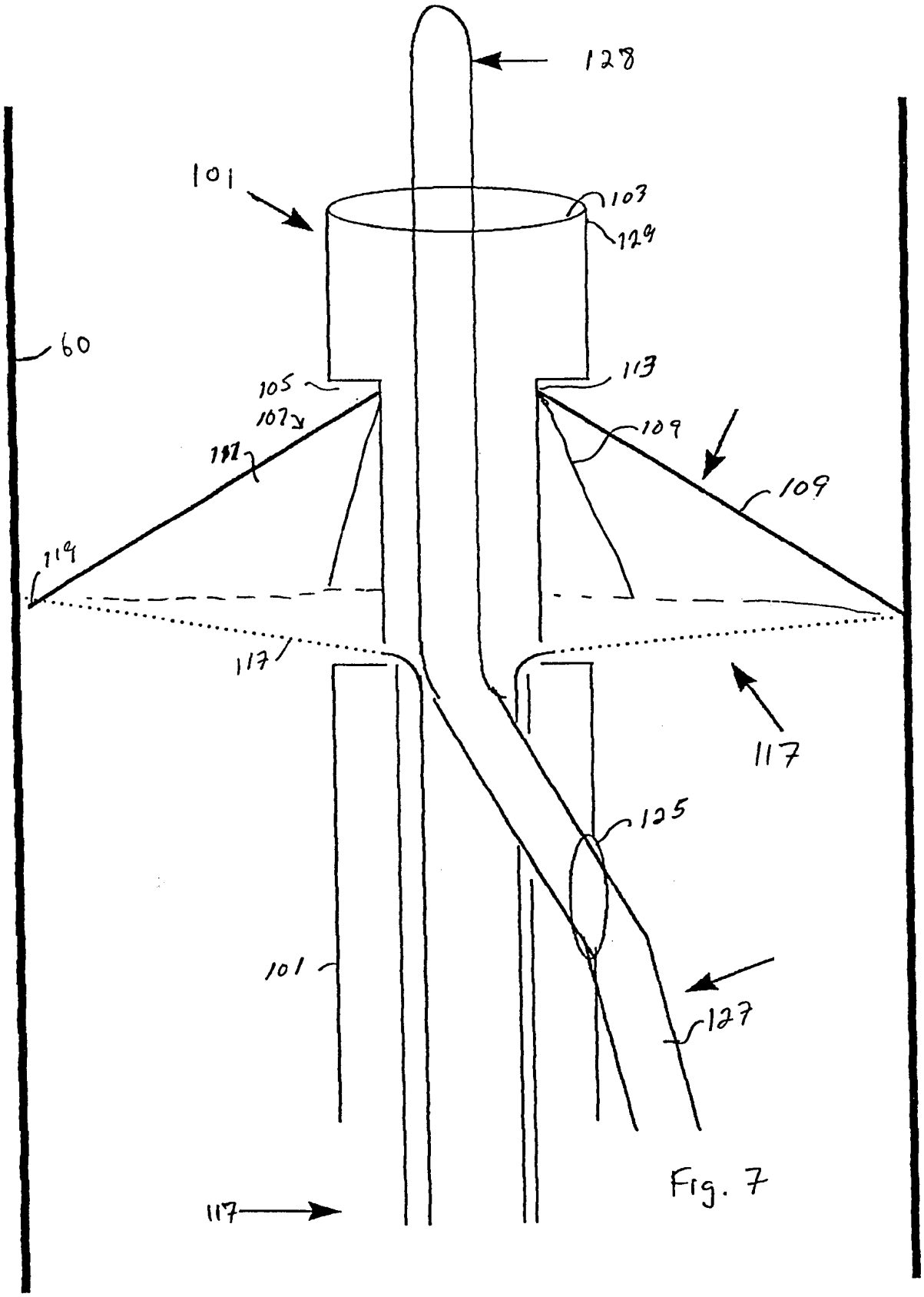

128
101
103
129
60
113
105
107
111
109
109
119
117
117
125
101
127
117

Fig. 7

FIG. 8

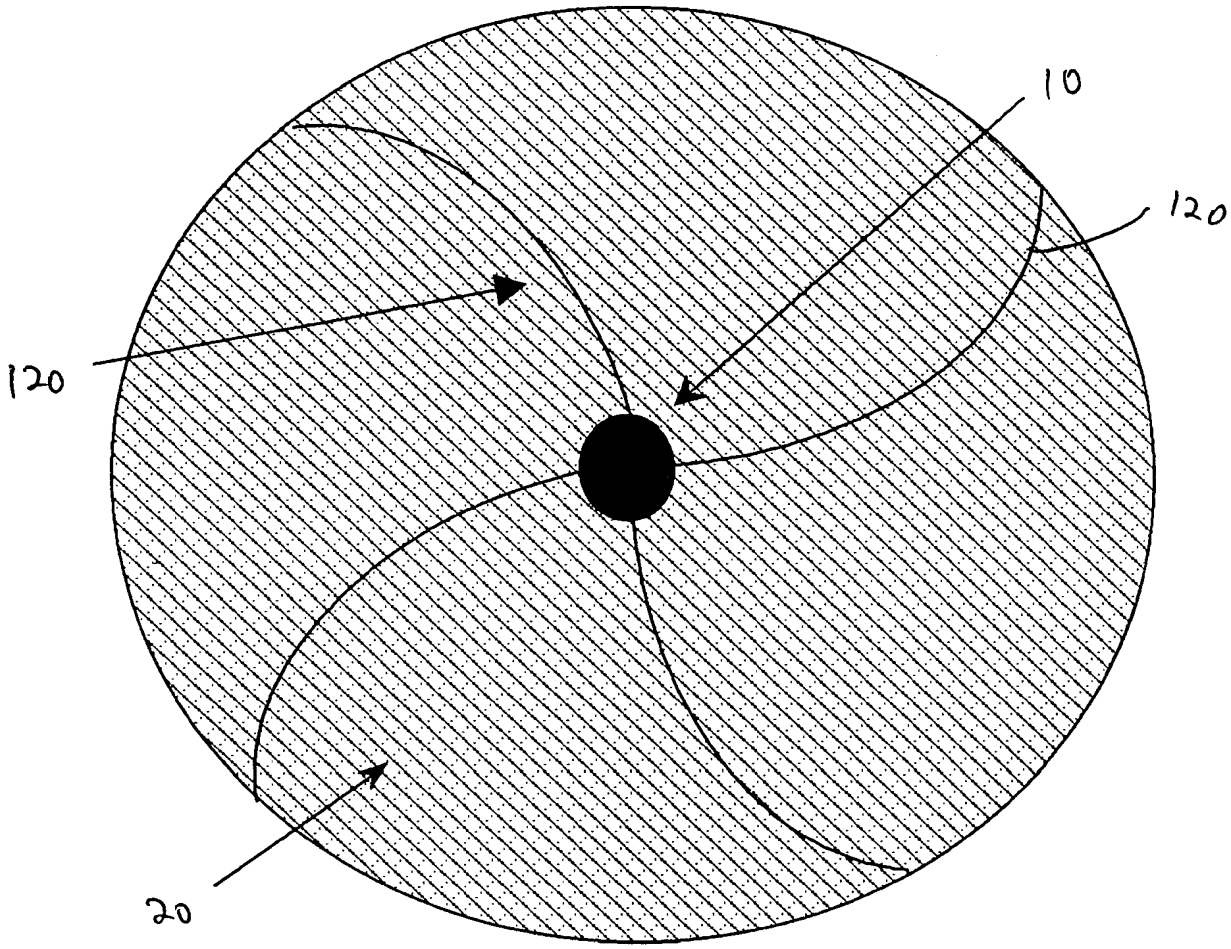


FIG. 9

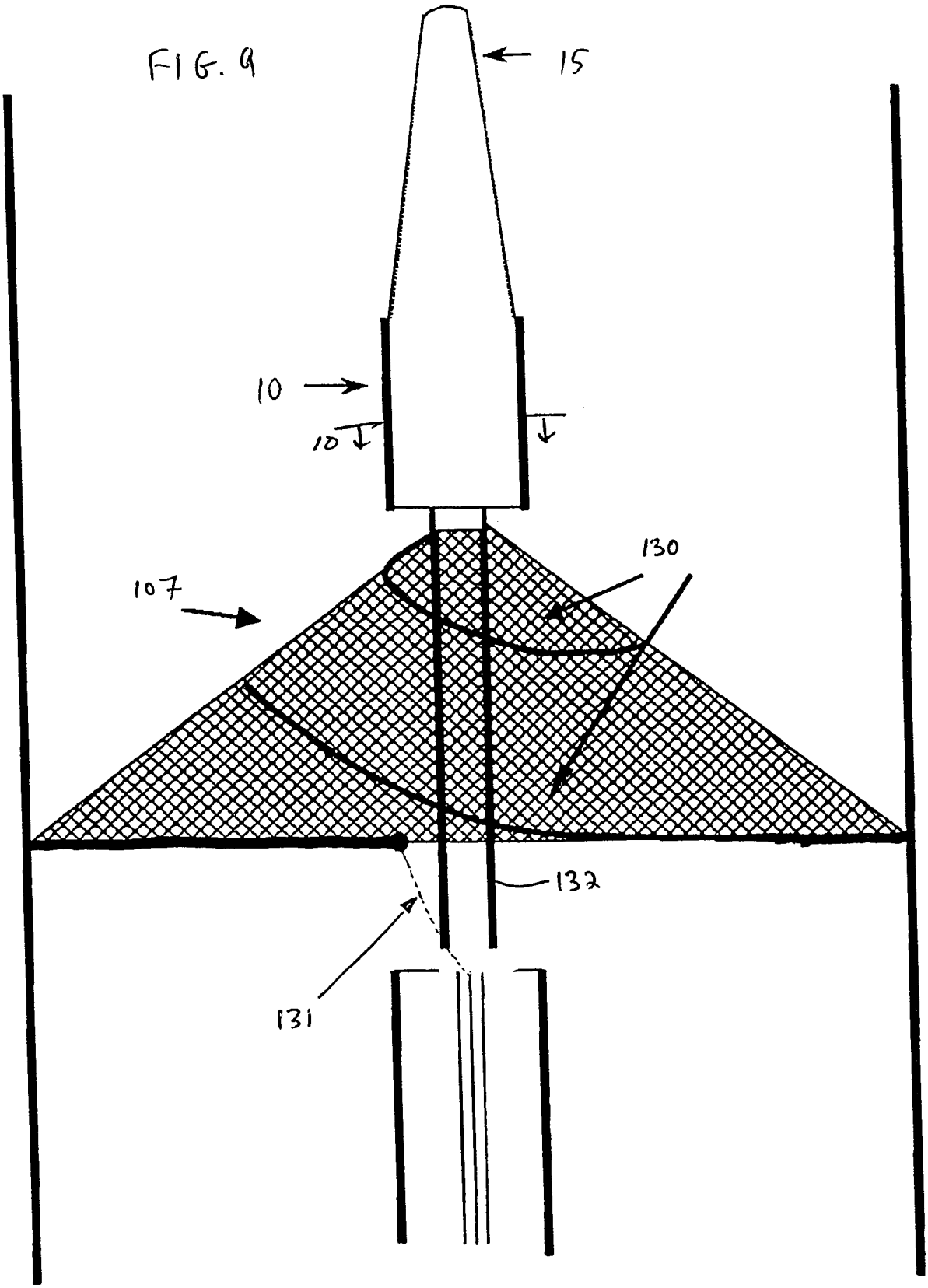
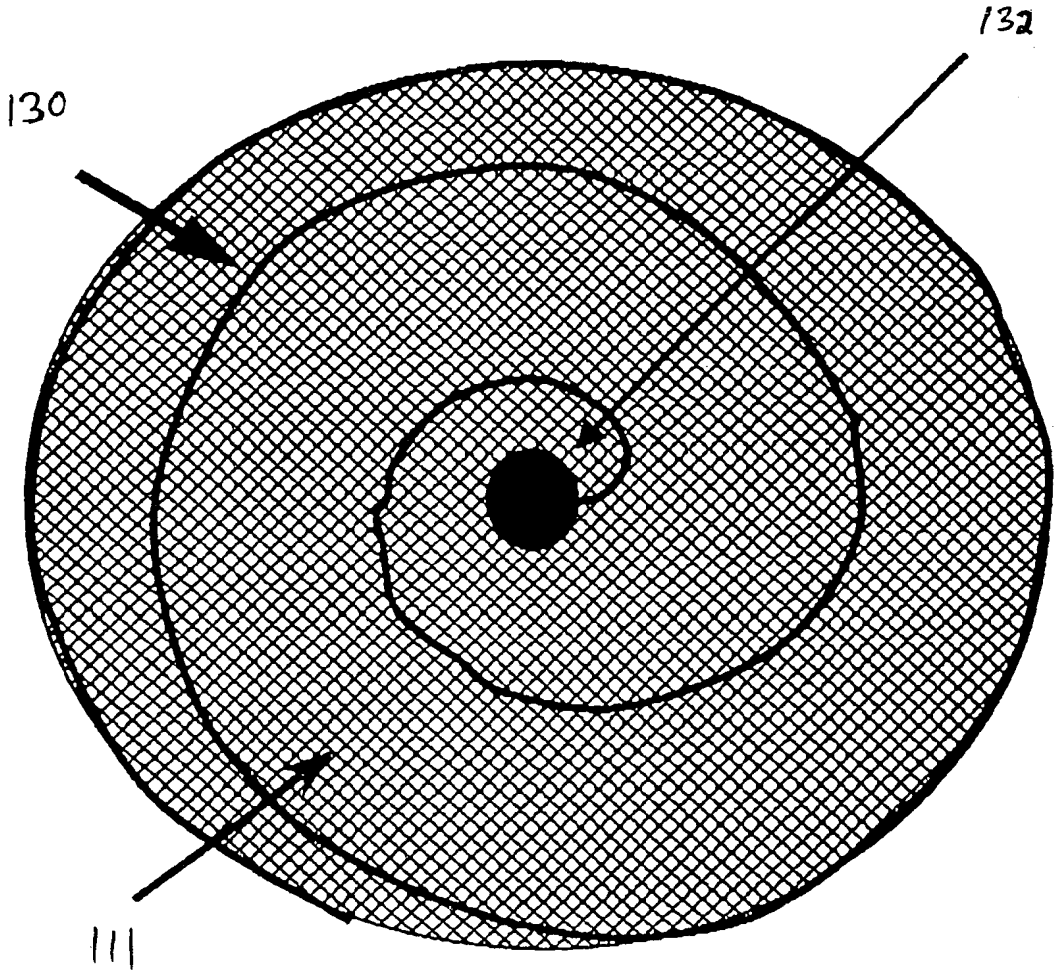


FIG. 10



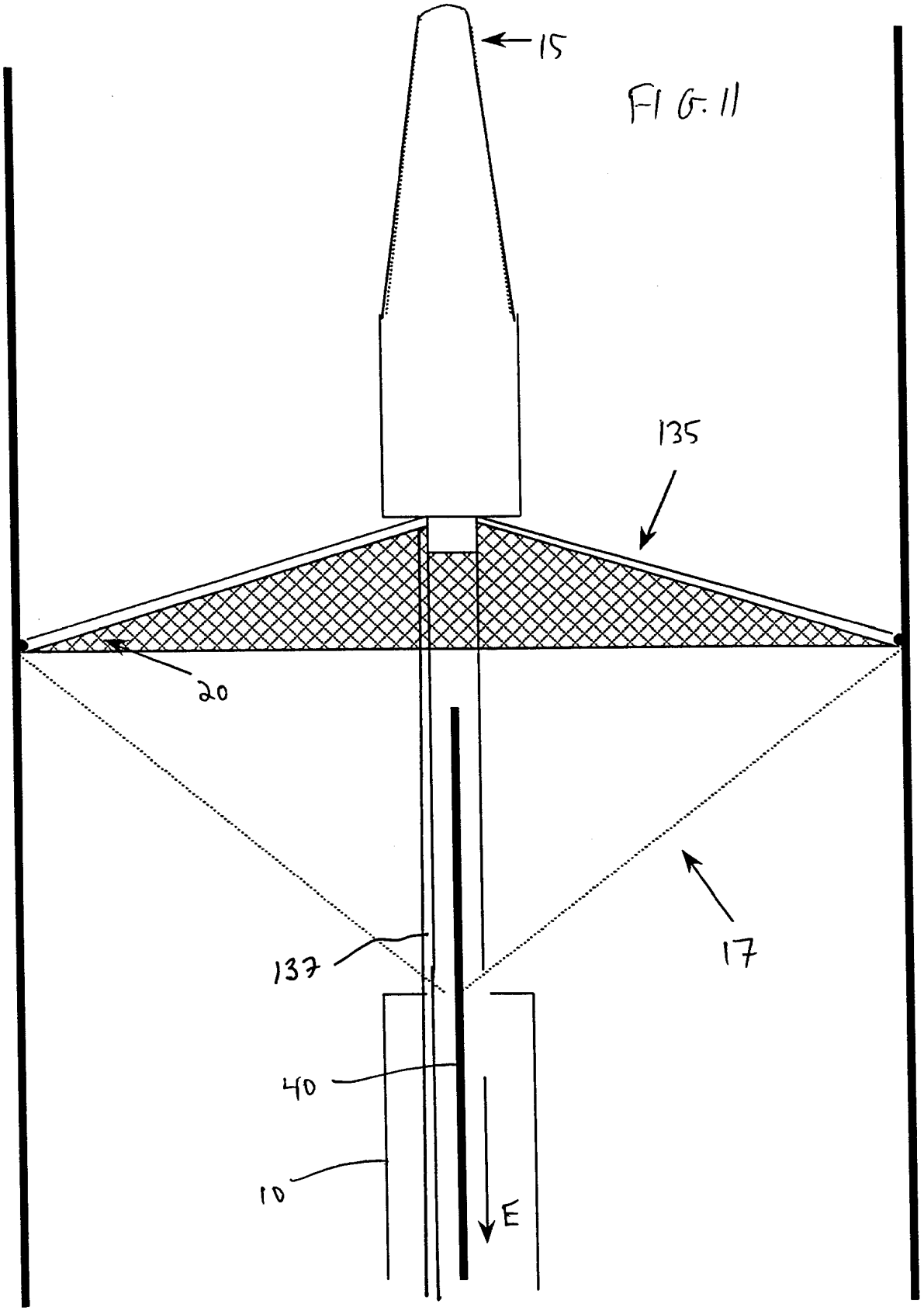


FIG. 11

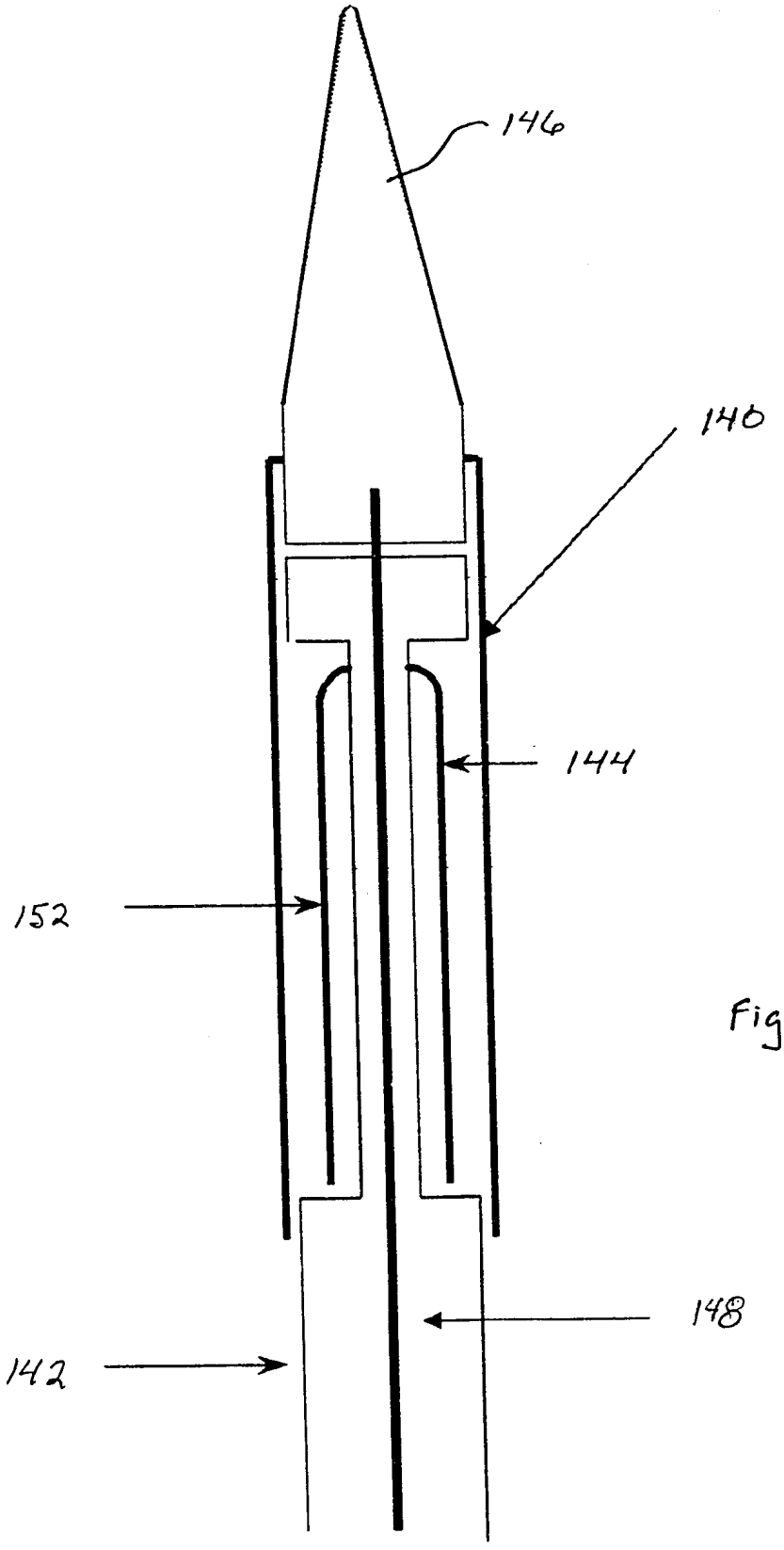


Fig. 12

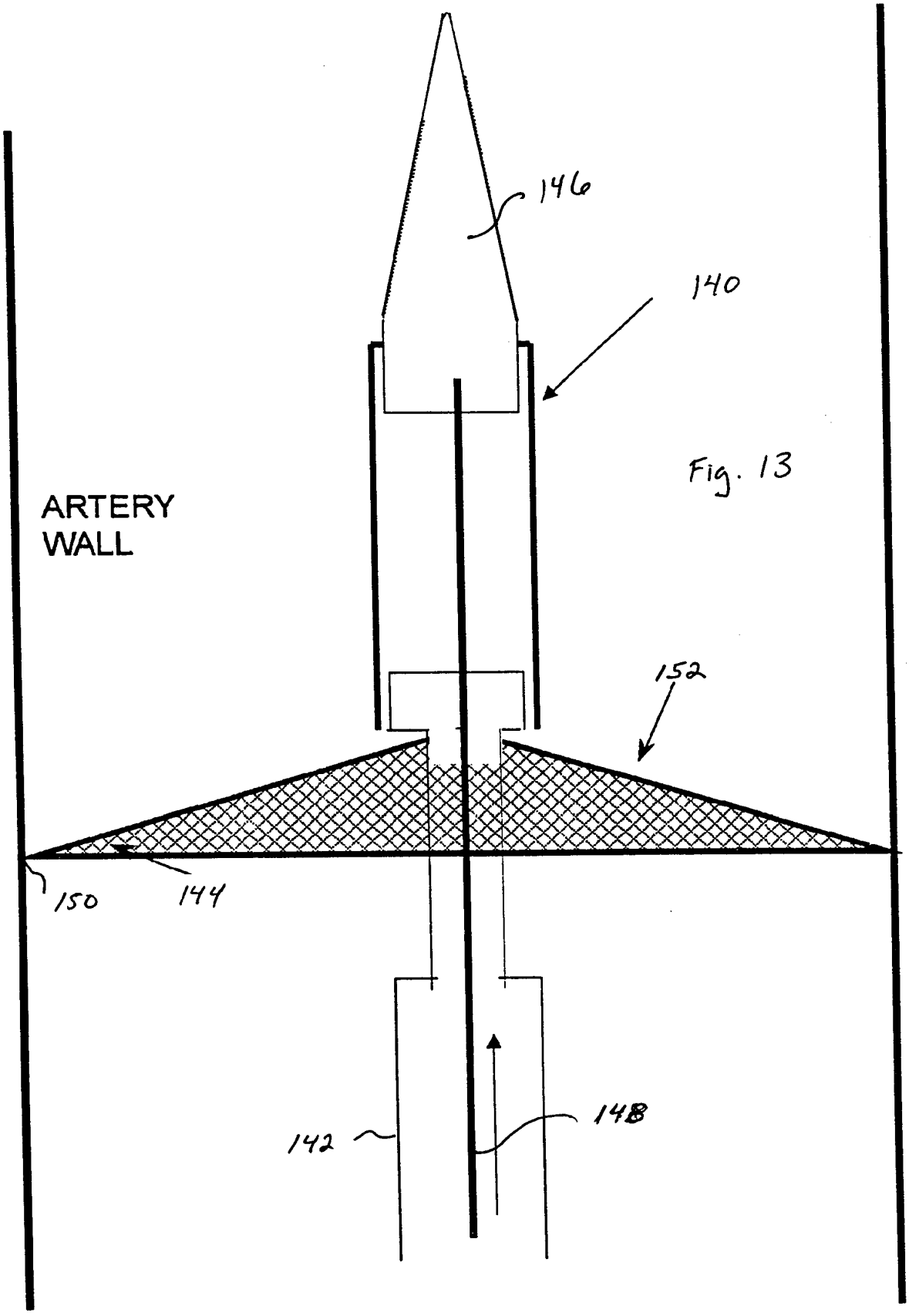


Fig. 13

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US98/01894

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61B 17/22
US CL :606/200

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. : 606/200

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 4,723,549 A (WHOLEY et al) 09 February 1988, entire document.	1-3 --- 4-19
Y	US 5,053,008 A (BAJAJ) 01 October 1991, entire document.	4-19

☐ 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 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
21 APRIL 1998

Date of mailing of the international search report
07 MAY 1998

Name and mailing address of the ISA/US
Commissioner of Patents and Trademarks
Box PCT
Washington, D.C. 20231
Facsimile No. (703) 305-3230

Authorized officer
MICHAEL THALER
Telephone No. (703) 308-2981

Form PCT/ISA/210 (second sheet)(July 1992)★

PCT WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) **International Patent Classification** 6 :
A61F 2/01, A61M 29/02

A1

(11) **International Publication Number:** **WO 98/51237**

(43) **International Publication Date:** 19 November 1998 (19.11.98)

(21) **International Application Number:** PCT/US98/10220

(22) **International Filing Date:** 15 May 1998 (15.05.98)

(30) **Priority Data:**

60/046,777	16 May 1997 (16.05.97)	US
60/057,439	2 September 1997 (02.09.97)	US

(81) **Designated States:** CA, JP, European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

Published
With international search report.

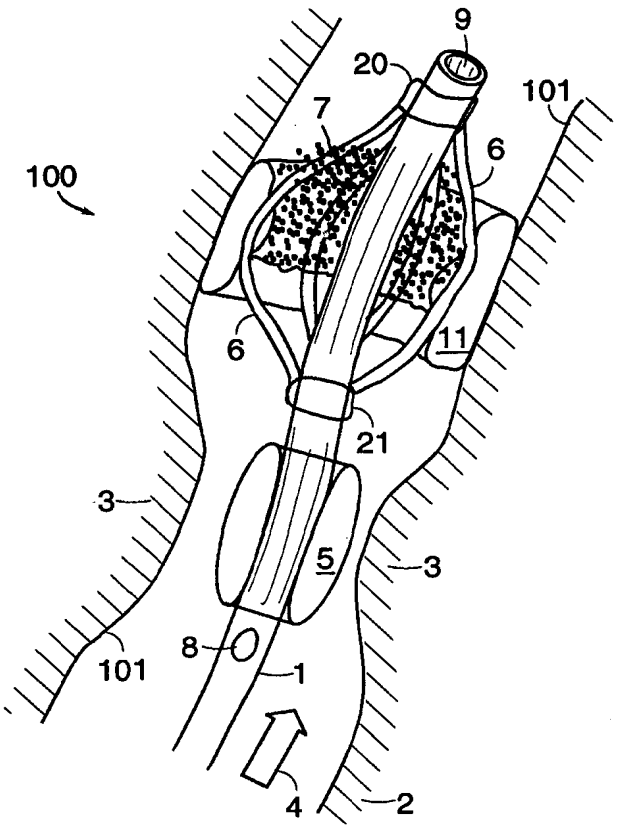
(71)(72) **Applicants and Inventors:** GERTLER, Jonathan [US/US]; 16 Greenridge Road, Weston, MA 02193 (US). KAMM, Roger [US/US]; 31 Nonesuch Road, Weston, MA 02193 (US).

(74) **Agents:** SUNSTEIN, Bruce, D. et al.; Bromberg & Sunstein LLP, 125 Summer Street, Boston, MA 02110–1618 (US).

(54) **Title:** CATHETER–FILTER SET HAVING A COMPLIANT SEAL

(57) **Abstract**

A catheter–filter set in an embodiment may be used in a vas through which a biological fluid may flow. This embodiment includes a tubular member, having a lumen disposed along its length and an insertion end for insertion into the vas. The lumen defines a longitudinal axis and a radial direction perpendicular thereto. The embodiment also has a filter, coupled to the tubular member and having a circumference, for trapping undesired particles. Finally, the embodiment includes a resilient member, having compliance in the radial direction, disposed circumferentially about the filter and, when deployed in the vas, forms a seal against the interior wall of the vas. Other embodiments are also provided.



FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	**ES**	Spain	**LS**	Lesotho	**SI**	Slovenia
AM	Armenia	**FI**	Finland	**LT**	Lithuania	**SK**	Slovakia
AT	Austria	**FR**	France	**LU**	Luxembourg	**SN**	Senegal
AU	Australia	**GA**	Gabon	**LV**	Latvia	**SZ**	Swaziland
AZ	Azerbaijan	**GB**	United Kingdom	**MC**	Monaco	**TD**	Chad
BA	Bosnia and Herzegovina	**GE**	Georgia	**MD**	Republic of Moldova	**TG**	Togo
BB	Barbados	**GH**	Ghana	**MG**	Madagascar	**TJ**	Tajikistan
BE	Belgium	**GN**	Guinea	**MK**	The former Yugoslav Republic of Macedonia	**TM**	Turkmenistan
BF	Burkina Faso	**GR**	Greece			**TR**	Turkey
BG	Bulgaria	**HU**	Hungary	**ML**	Mali	**TT**	Trinidad and Tobago
BJ	Benin	**IE**	Ireland	**MN**	Mongolia	**UA**	Ukraine
BR	Brazil	**IL**	Israel	**MR**	Mauritania	**UG**	Uganda
BY	Belarus	**IS**	Iceland	**MW**	Malawi	**US**	United States of America
CA	Canada	**IT**	Italy	**MX**	Mexico	**UZ**	Uzbekistan
CF	Central African Republic	**JP**	Japan	**NE**	Niger	**VN**	Viet Nam
CG	Congo	**KE**	Kenya	**NL**	Netherlands	**YU**	Yugoslavia
CH	Switzerland	**KG**	Kyrgyzstan	**NO**	Norway	**ZW**	Zimbabwe
CI	Côte d'Ivoire	**KP**	Democratic People's Republic of Korea	**NZ**	New Zealand		
CM	Cameroon			**PL**	Poland		
CN	China	**KR**	Republic of Korea	**PT**	Portugal		
CU	Cuba	**KZ**	Kazakstan	**RO**	Romania		
CZ	Czech Republic	**LC**	Saint Lucia	**RU**	Russian Federation		
DE	Germany	**LI**	Liechtenstein	**SD**	Sudan		
DK	Denmark	**LK**	Sri Lanka	**SE**	Sweden		
EE	Estonia	**LR**	Liberia	**SG**	Singapore		

CATHETER-FILTER SET HAVING A COMPLIANT SEAL

Technical Field

The present invention relates to catheter-filter sets, including those for use in angioplasty and other procedures.

Background Art

A large number of medical procedures utilize catheters. A catheter is defined herein and within the appended claims as a tubular, flexible instrument for insertion into a body cavity. Catheters may facilitate the withdrawal or introduction of fluids or other substances and may, in combination with other coupled components, perform a variety of other useful functions.

Catheters coupled with inflatable balloons provide the means to facilitate the unblocking of and the relief of constriction within various body passageways and vessels. Such angioplasty procedures can replace other more invasive surgical procedures and provide acceptable solutions to correct life threatening conditions. However, these procedures carry a risk of serious secondary problems associated with the transmission of unwanted material downstream of the operative site. Any material, such as plaque built up in arterial vessels, which does not adhere to the interior vas wall or is in another way removed from the vessel following treatment becomes a likely source of downstream blockage. In arterial angioplasty, embolic ischemic damage distal to the angioplasty site is a major complication of the procedure. Mobile arterial plaque is a major factor linked with ischemic stroke or end organ/limb infarction. In particular, carotid

artery angioplasty is not a favored practice at present due to the risk of emboli and resulting stroke.

Some catheters coupled with downstream filtering capability have been previously disclosed. Several utilize wire mesh filters which are generally not compliant and do not accommodate localized changes in vessel diameter and shape which may be caused by on-going fluid flow restoration and pulsatility. Other designs contain deployment structures which may make insertion prior to and retraction after completion of a procedure problematic or unduly risky.

Typical prior art catheter arrangements are disclosed in United States patents 4,723,549; 4,794,928; 5,662,671; and 5,695,519. These documents are hereby incorporated herein by reference.

Summary of the Invention

Various embodiments of the present invention solve problems of the prior art by providing radial compliance to accommodate localized changes in vessel diameter and shape which may be caused by on-going fluid flow restoration and pulsatility. Furthermore, some embodiments of the invention provide a device that is biased to return to its lowest profile condition in the absence of active operator input to facilitate making arterial angioplasty, particularly in the cerebral and coronary beds, more fail-safe. Various embodiments of the invention avoid asperities or protrusions which can traumatize or otherwise damage or irritate interior vas walls. Similarly various embodiments provide for cushioning of the filter element against the vas wall when it is deployed. This cushioning effect is balanced with the requirement of effective sealing of the vas to prevent any unwanted downstream flow of matter.

Accordingly, in a first embodiment of the invention there is provided a catheter-filter set for use in a vas through which a biological fluid may flow. This embodiment includes a tubular member, having a lumen disposed along its length and an insertion end for insertion into the vas. The lumen defines a longitudinal axis and a radial direction perpendicular thereto. The embodiment also has a filter, coupled to the tubular member and having a circumference, for trapping undesired particles. (Unless the context otherwise requires, the term

"particles" as used in this description and the accompanying claims refers to substances to be removed from a vas, and may include thrombotic material.) Finally, the embodiment includes a resilient member, having compliance in the radial direction, disposed circumferentially about the filter and, when deployed in the vas, forming a seal against the interior wall of the vas. In further embodiments, the resilient member may be inflatable, such as a balloon, or alternatively may be an O-ring or sleeve. The outer surface of the resilient member may form the seal with the interior wall or may otherwise effectuate the seal. In a related embodiment the resilient member is a balloon having an anterior for receiving an inflation fluid and a shape so that when the balloon is inflated there is provided a passageway permitting fluid flow through the filter. In accordance with another related embodiment, the balloon is toroidal in shape and may have anisotropic elasticity so that during inflation its interior cross-section expands relatively less than its radial extent. Alternatively or in addition, the catheter-filter set may include an elastic member coupled to the balloon and the tubular member for causing the balloon to be radially confined when not deployed. In yet another variation, regardless whether a balloon is utilized, the filter has a stowed position where the filter is radially confined and disposed in the lumen so that the catheter-filter set may be inserted into and removed from the vas, and a deployed position, where the filter is radially expanded.

Various embodiments of the present invention have a range of potential applications. The application of embodiments to angioplasty procedures wii be apparent to those skilled in the art. In addition, through either standard open technique or laparoscopic technique, retrieval of common duct stones in the biliary tree is facilitated by catheter passage utilizing embodiments herein. Similarly, through either standard open technique or cystographic technique, retrieval of ureteral and bladder duct stones is, also, facilitated by catheter passage via endoscopic or surgical methods. A catheter coupled with an inflatable balloon may also be utilized to effect balloon sphincteroplasty and stone retrieval. Embodiments herein provide improved devices to effectively retrieve such stones and to avoid their further passage or migration downstream.

Embodiments herein may also employable as a temporary filtering device for the vena cava. In the process of lytic treatment for deep venous thrombosis, there is a risk of clot (thrombus) breaking loose and causing pulmonary embolism, a potentially fatal event. Although filters exist for vena cava use, these are permanent structures with attendant long term morbidity. Having an effective and retractable filter which is in place only for the time of significant risk, *i.e.*, during deep venous clot lysis, would allow protection from pulmonary embolism and avoidance of the long term sequelae of a permanent filter insertion.

Discussion of medical procedures and associated devices in this description may focus, for example, upon arterial (blood circulation), biliary, and ureteral systems. This focus in no way limits the applicability of embodiments herein to any and all other uses for catheters with filtration capability known to those skilled in the art.

In another embodiment, there is provided a catheter-filter set having a tubular member, which has a first lumen disposed along its length, an insertion end for insertion into and a retraction end for retraction out of the vas. The lumen defines a longitudinal axis and a radial direction perpendicular thereto. The embodiment also has a filter, coupled to the tubular member proximal to the insertion end, wherein the filter has a stowed position and a deployed position, and a non-inflatable actuator, coupled to the filter, for causing the filter to move from the stowed position to the deployed position, wherein, absent operation of the actuator, the filter is biased to be in the stowed position. In a related embodiment, the set also includes a vas conditions-modifying element located upstream from the filter; this element may be an angioplasty balloon. In yet another related embodiment, the tubular member has a second lumen having an inlet upstream from the vas conditions-modifying element and an outlet downstream from the filter, permitting unimpeded, downstream fluid flow to bypass the filter. In further embodiment, the set has a plurality of resilient ribs, each rib having a first end coupled to the tubular member, each rib also coupled to the filter, the ribs having a stowed condition in which they are parallel to the

longitudinal axis and a deployed condition in which at least a portion of each rib is disposed radially outward from the tubular member. Each rib may have a second end slidably mounted on the tubular member and coupled to the actuator. The catheter-filter set may further include a resilient member, having compliance in the radial direction, disposed circumferentially about the filter and, when deployed in the vas, forming a seal against the interior wall of the vas.

In another embodiment in accordance with the present invention, there is provided a catheter-filter set having:

a. a tubular member, having a lumen disposed along its length, an insertion end for insertion into and a retraction end for retraction out of the vas, the lumen defining a longitudinal axis and a radial direction perpendicular thereto; and

b. a filter, coupled to the tubular member proximal to the insertion end, wherein the filter has a stowed position wherein the filter is radially confined and disposed in the lumen so that the catheter-filter set may be inserted into and removed from the vas, and a deployed position, wherein the filter is radially expanded.

Brief Description of the Drawings

Figs. 1A and 1B are longitudinal views of a catheter-filter set, in the deployed and the stowed conditions, respectively, used in a vas as part of an angioplasty device and using a toroidal balloon according to an embodiment of the invention.

Figs. 2A and 2B are longitudinal views of a portion of a catheter-filter set, in the stowed and the deployed conditions, respectively, illustrating generally filter deployment according to an embodiment of the invention utilizing ribs for structuring the filter.

Figs. 3A and 3B are longitudinal views of a catheter-filter set, in accordance with a tether deployment embodiment of the invention, showing stowed and deployed conditions, respectively.

Figs. 4A and 4B are longitudinal views of a catheter-filter set, in accordance with a balloon deployment embodiment of the invention, showing stowed and deployed conditions, respectively.

Fig. 5 is a longitudinal view of a catheter-filter set in accordance with an embodiment using balloon deployment wherein elastic bands bias the set in a stowed condition.

Figs. 6A and 6B are stowed and deployed conditions respectively of an embodiment similar to that of Figs. 4A and 4B, but wherein the ribs are normally twisted in a stowed condition, in which the embodiment is biased.

Fig. 7A is a cross-sectional view of a catheter-filter set in the deployed condition illustrating a balloon deployment design according to an embodiment of the invention in which the balloon has a passageway to permit fluid flow therethrough. Figs. 7B and 7C are longitudinal views of the same embodiment in the stowed and the deployed conditions, respectively.

Fig. 8A is a cross-sectional view of a catheter-filter set according to an embodiment of the invention, using for deployment a balloon 11 that is asymmetrically disposed with respect to the tubular member. Fig. 8B is a longitudinal view of the same embodiment in the deployed condition. Fig. 8C shows detail of the catheter-balloon interface.

Fig. 9 is a view of a catheter-filter set according to an embodiment of the invention utilizing a retractable O-ring.

Fig. 10 is a perspective view of a catheter-filter set according to an embodiment of the invention that is similar to the embodiment of Fig. 9, but utilizing a sleeve in lieu of the O-ring.

Fig. 11A is a perspective view of a catheter-filter set according to an embodiment of the invention utilizing a tethered O-ring, shown in the deployed condition. Fig. 11B is a longitudinal view of the same embodiment in the stowed condition.

Detailed Description of Specific Embodiments

Various embodiments of the catheter-filter set described herein address a number of shortcomings inherent in previous designs. Some desirable features

for the filter portion of the set are that it be easily confined in a radial direction for ease of set insertion and removal, that it be capable of capturing and safely removing all particles flowing downstream in a vas, and additionally, it should be designed so as to minimize the risk of accidental deployment and to collapse into position for removal in the event of failure. It should be atraumatic to the native vas wall and should accommodate changes in vas diameter.

Figs. 1A and 1B are longitudinal views of a catheter-filter set, in the deployed and the stowed conditions, respectively, used in a vas as part of an angioplasty device and using a toroidal balloon according to an embodiment of the invention. Fig. 1A shows a catheter **1** inserted into a vas **2**. The vas may be constricted or otherwise blocked at a location **3**. Downstream fluid flow is indicated by arrow **4**. An angioplasty balloon **5** affixed to the catheter and inflatable (by means well known in the art) is positioned proximate to location **3**. During and after the angioplasty balloon **5** inflation process, unwanted particles may flow downstream from location **3**. A plurality of resilient ribs **6** (four are shown in this view) are coupled to the catheter **1** by two collars, one collar **20** at a downstream end and the other collar **21** at an opposing, upstream end of the catheter. In this embodiment, one of collars **20** and **21** is fixed relative to the catheter **1** and the other of the collars is free to slide along the catheter **1**. The ribs **6** and both collars **20** and **21** are positioned at a location downstream from location **3** and the angioplasty balloon **5**. A filter **7** is shown attached to the ribs **6** and to the catheter **1**. A toroidal balloon **11**, which is distinct from the angioplasty balloon **5**, is attached to the ribs **6**. In this embodiment, the toroidal balloon **11** is mounted approximately midway along the length of the ribs **6** and positioned radially outward from the catheter **1**. (The filter **7** is represented in this figure and figures below by a dot or hash pattern; for clarity of representation, the dot or hash pattern is not shown to occupy the entire region occupied by the filter. It will be understood, however, that when deployed the filter, together with any accompanying structure, such as the balloon **11**, will occupy the entire cross section of the vas so as to operate in an effective manner known in the art.)

Fig. 1B shows that, in accordance with the embodiment in the stowed condition, the ribs parallel to the longitudinal axis of the catheter **1** facilitating set **100** insertion into and retraction out of the vas **2** minimizing trauma to the vas wall **101**. During insertion and retraction of set **100** and catheter **1** into and out of the vas **2**, the uninflated toroidal balloon **11** is collapsed and radially confined against the ribs **6** and the uninflated angioplasty balloon **5** is collapsed against the catheter **1**. As illustrated in Fig. 1A, when the toroidal balloon **11** is inflated (in accordance with means well known in the art), one of collars **20** and **21** slides toward the other collar causing at least a portion of each of the ribs **6** and the filter **7** to be disposed radially outward from the catheter **1**. The toroidal balloon **11** effectively spans any radial distance between, on the one hand, the vas wall **101**, and on the other hand, the ribs **6** with the expanded filter **7**. The toroidal balloon **11** thus forms a compliant seal between the set **100** and the vas wall **101**.

After this compliant seal has been established, the angioplasty balloon **5** may then be inflated to unblock the vas **2** at location **3**. The deployed filter **7** may then capture unwanted particles flowing downstream during and after operation and subsequent deflation of the angioplasty balloon **5**. After the procedure, the toroidal balloon **11** is deflated, and the set **100** returns to the position shown in Fig. 1B for retraction from the vas **2**. Unwanted particles are trapped within the filter **7** and are safely removed from the vas **2** upon retraction of the set **100**. Additionally, biasing components (for example, as discussed below in connection with later figures) may be used in connection with the set **100** to insure the return to the position shown in Fig. 1B after deflation of the toroidal balloon **11**. These components may include, and are not limited to, elastic bands coupled to one or more elements of the ribs **6**, the filter **7**, and collars **20** and **21**.

Also shown in Fig. 1A, an inlet port **8** is provided by the catheter **1** at a location upstream from the angioplasty balloon **5** and an outlet port **9** is provided downstream from the filter **7**. The ports are in communication with a lumen of the catheter; the lumen may be the same as the lumen used for other purposes or may be a separate dedicated lumen. The result of this structure is an auto-perfusion pathway from inlet port **8** through a catheter lumen to the outlet port **9**

to permit the unimpeded flow of a quantity of fluid during the time in which the medical procedure is being performed. The feature is advantageous when deleterious results may occur from even short intervals of downstream fluid starvation or depletion. Hypoperfusion during angioplasty balloon inflation is primarily relevant to the cerebral and coronary beds. Carotid artery angioplasty, in which the brain is immediately downstream from the location **3**, is a prime example of a procedure benefiting from an auto-perfusion pathway. In many arterial applications, given the normal magnitude of blood pressures, there may be provided a lumen having an internal diameter of 1 to 2 mm. Even when blood flow is not as high as normal, the reduced rate of flow may nevertheless significantly reduce the risk of tissue damage caused by a complete interruption of flow in the cerebral and coronary beds.

Figs. 2A and 2B are longitudinal views of a portion of a catheter-filter set, in the stowed and the deployed conditions, respectively, illustrating generally filter deployment according to an embodiment of the invention utilizing ribs **6** for structuring the filter **7**. Fig. 2A shows the ribs **6** and the filter **7** coupled to and juxtaposed with the catheter **1** in conjunction with the downstream collar **20**. In Fig. 2B the ribs **6**, which are resilient, are expanded radially from the catheter **1** to form a convex shape. The expanded ribs **6** support the filter **7** as shown. Preferably, the ribs **6** are free from asperities. The ribs **6** may be made of any resilient material with sufficient rigidity to support and to enable deployment of the filter **7**. The number of ribs **6** may be selected to be sufficiently large to facilitate a seal of the filter **7** with the interior wall of the vas **2** but not so numerous as to significantly obstruct fluid flow or convenient operation of the set. In the embodiment of Figs. 2A and 2B, the ribs **6** are disposed radially outward from the filter **7**. In other embodiments of the invention, the ribs **6** may be disposed radially inward from the filter **7**, so that, when stowed, the resilient ribs **6** lie immediately adjacent to the catheter **1**. Such other embodiments may deploy in a fashion analogous to opening of an umbrella. The ribs **6** may have one free end as in Figs. 2A and 2B, or be coupled to the catheter **1** at both ends and bow in the middle for deployment as for example in Figs 1A and 1B. The

filter **7** may beneficially be made of a porous, compliant material in a manner known in the art. Suitable materials may include, but are not limited to, woven nylon, plastic resins such as PTFE sold under the Teflon trademark by Dupont of Wilmington, Delaware, other woven polymer, porous silicone rubber and latex rubber. Suitable materials are sufficiently porous to permit a small downstream flow of fluid yet capable of collecting any dangerous particles. For example, calculations suggest that, for an arterial application, a woven material with a fiber porosity of 90% and a spacing of 200 microns may pose little impediment to normal blood flow while trapping undesirable particles..

Figs. 3A and 3B are longitudinal views of a catheter-filter set, in accordance with a tether deployment embodiment of the invention, showing stowed and deployed conditions, respectively. As shown in Fig. 3B, the ribs **6** of this embodiment are attached to the catheter **1** at both ends by collars **20** and **21**. The upstream end collar **21** is free to slide along the catheter **1** while the downstream end collar **20** is fixed. Collar **21** is tethered with line **30** so that an operator can, by applying an upstream force to line **30** slide collar **21** downstream toward collar **20.** This action urges the ribs **6** to form a convex shape and to expand radially from the catheter **1**. As Figs. 3A and 3B show, tethering may be accomplished by attaching one end of line **30** to collar **21**, feeding the line **30** through a port **31** provided by the catheter **1** at a position downstream from collar **21.** The line passes into a lumen of the catheter and exits the catheter **1** upstream at its retraction end. The ribs **6** may expand to the full radial extent of the vas **2**. Other material, as discussed in connection with other figures, may be coupled to the ribs **6** proximate to their approximate midpoint in length to provide better sealing action and cushioning at the interface with the vas wall **101**. (For example, the toroidal balloon of Figs. 1A and 1B may be employed; alternatively, any suitable resilient sleeve or O-ring may be utilized.) The ribs **6** will return to the stowed position of Fig. 3A, in accordance with the embodiment of the invention, with the elimination of the applied upstream force on line **30**. This provides a set **100** which is biased to remain in and revert to the stowed position. Such bias provides for assured collapsibility upon retraction and offers

a high degree of fail-safe operation by minimizing the chance of accidental deployment.

Another embodiment according to the invention provides a filter deployment technique using an inflatable toroidal balloon **11** with ribs **6** which have their upstream end uncoupled to the catheter **1**. The stowed position is shown in Fig. 4A; the deployed position in Fig. 4B. Operation of this embodiment is similar to that of Figs. 1A and 1B with respect to the use of a toroidal balloon and to that of Figs. 2A and 2B with respect to the ribs **6**. A tube **40** is provided for inflation fluid communication between a lumen disposed within the catheter **1** and the toroidal balloon **11**. The opposing ends of tube **40** are, respectively, inserted and remain within ports **41**, provided by the catheter **1**, and **42**, provided by the toroidal balloon **11**. The ends of tube **40** may be secured in the ports **41** and **42** with adhesives or using other methods in a manner known in the art. The uninflated toroidal balloon **11**, as shown in Fig. 4A is coupled to the upstream ends of the ribs **6** and juxtaposed with the catheter **1**. As shown in Fig. 4B, with inflation of the toroidal balloon **11**, the resilient ribs **6** expand radially from the catheter **1** to form a convex shape supporting the filter **7**. At its most radially outward extent, the inflated toroidal balloon **11** effects a compliant seal between the set **100** and the vas wall **101**. The toroidal balloon **11** may be made by wrapping fiber around it so that its expansion will be constrained in such a way that the diameter of its inflatable cross-section increases to a lesser degree than its radial (perpendicular to the catheter axis) dimension. In fact, this mode of inflation can be produced by any material that is anisotropic having a high stiffness (or Young's modulus) in the direction of the fiber wrapping and a low stiffness in the direction perpendicular to the wrapping. The inflation of the toroidal balloon provides the necessary structural rigidity needed to withstand the forces associated with downstream fluid flow (in particular, arterial blood flow) while the set **100** is in the deployed condition.

Fig. 5 is a longitudinal view of a catheter-filter set in accordance with an embodiment using balloon deployment wherein elastic bands **50** are employed to bias the set in a stowed condition. The bands **50** are coupled to an upstream collar

51 and a second downstream collar 52. Both collars 51 and 52 are coupled to the catheter 1; the second downstream collar 52 is positioned at a distance farther downstream along the catheter 1 than collar 20 to which optional ribs 6 may be coupled. This embodiment provides a set 100 which is biased to revert to the stowed condition. On deflation of the toroidal balloon 11, the bands 50 act to force the balloon 11, the ribs 6, and the filter 7, with any entrapped particles within, to revert to the stowed condition for safe retraction.

Figs. 6A and 6B are stowed and deployed conditions respectively of an embodiment similar to that of Figs. 4A and 4B, but wherein the ribs are normally twisted in a stowed condition, in which the embodiment is biased. The ribs 6 (which are here differently shaded to permit differentiation in the figure), when in a relaxed, unstressed configuration, fit snugly about the catheter 1 bore in a helical arrangement, as shown in Fig. 6A. The filter 7 is gathered together inside the ribs while the cushioning balloon 11 lies outside the ribs 6 but deflated into a collapsed configuration. The ribs 6 in this embodiment are attached at both the upstream and downstream ends to collars 21 and 20 respectively. The collars 21 and 20 are constrained so as to prevent movement in the longitudinal direction, but the downstream collar 20 can be rotated by rotation of a stiff line 60 threaded through a lumen 61 of the catheter 1. Rotation of the downstream collar 20 causes the ribs 6 to bow outward into the deployed position illustrated in Fig. 6B. Once deployed, the balloon 11 can be inflated to provide a resilient seal against the interior wall of the vas 101 while maintaining an open space between the balloon 11 and catheter 1 for fluid flow. Bowing of the ribs deploys the filter 7 attached to the inner surface of the balloon 11 so that it can function as a trap for debris released from an upstream site. Retraction of the ribs 6 occurs when the stiff line 60 is allowed to rotate back to its original position and the balloon 11 is deflated. The filter set is therefore biased closed in that when pressure is relieved from the balloon 11 and the torque exerted on the stiff line 60 is released, the ribs 6 and filter 7 revert to their stowed position.

Fig. 7A is a cross-sectional view of a catheter-filter set in the deployed condition illustrating a balloon deployment design according to an embodiment

of the invention in which the balloon has a passageway to permit fluid flow therethrough. Figs. 7B and 7C are longitudinal views of the same embodiment in the stowed and the deployed conditions, respectively. In this embodiment, the inflation balloon **11** takes on the shape of two "Ds" back-to-back. The advantage of this embodiment is that the catheter **1** passes directly through the inflatable portion of the balloon **11**, avoiding the need for a separate inflation line that might be prone to rupture because of its small diameter. Fig. 7A shows the balloon in a view along the axis of the vas **2** looking in the downstream direction. The catheter **1** can be seen passing through at the center, and is sealed to the balloon at the points where it passes through the balloon membrane. The catheter has a port inside the balloon **11** that is used for balloon inflation. The filter **7** is seen in Fig. 7A through the openings in the balloon **11** through which the fluid is free to flow. Fig. 7B shows the balloon **11** in the retracted or stowed position. Elastic bands **50** hold the deflated balloon **11**, so that it is radially confined, tight against the catheter **1**. The filter **7** is gathered together and held against the catheter **1** in part by the elastic bands **50**. Deployment is accomplished by inflation of the balloon **11**, a process that forces the balloon **11** into its double-D shape shown in longitudinal view in Fig. 7C. The inflated balloon **11** of Fig. 7C forms a flexible seal against the vas wall **101** and deploys the filter **7**. The filter in this embodiment is firmly tethered to the catheter at its downstream end to aid in gathering the filter **7** to the catheter on balloon deflation. The balloon **11** is made from a flexible but relatively inextensible polymer so that on inflation, it takes the shape shown.

Fig. 8A is a cross-sectional view of a catheter-filter set according to an embodiment of the invention, using for deployment a balloon **11** that is asymmetrically disposed with respect to the tubular member. Fig. 8B is a longitudinal view of the same embodiment in the deployed condition. Fig. 8C shows detail of the catheter-balloon interface. This embodiment increases the area available for flow through the "doughnut hole" of the balloon **11** and, like the embodiment of Figs. 7A through 7C, avoids the need for a separate inflation tube connecting the balloon **11** with the catheter **1**. In this embodiment, the

catheter **1** passes through the toroidal balloon **11** at location **80** on its circumference; a seal is provided between the balloon **11** and the catheter so that the balloon can be inflated through a port as in the embodiment of Figure 7. In the stowed position, shown in Figure 8A, an elastic band **50** attached to the balloon 11 at a point diametrically opposite to the inflation site **80** draws the balloon **11** in the upstream direction. When and as the balloon **11** is deflated, it and filter **7** are collapsed radially against the catheter 1 bore under the force of the elastic band **50**. Additional elastic bands may be optionally used on the downstream side to help gather together the filter **7** on deflation. The filter is deployed by inflation of balloon **11** through the port at location **80** as illustrated in Figure 8B. Balloon inflation also seals the balloon **11** in a flexible manner against the wall of the vas. In the process of balloon inflation, the catheter **1** is displaced off center toward the wall of the vas so as to increase the area available for flow. All flow still passes through the filter **7**.

Fig. 9 is a perspective view of a catheter-filter set according to an embodiment of the invention utilizing a retractable O-ring. The downstream end of the catheter **1** is pictured at a location downstream of a suitable vas-modifying element. The filter **7** is fastened to an O-ring **90** which in turn, is coupled to a set of resilient ribs **6** (four of which are shown). When in the deployed position (shown) the ribs **6** are pushed out of the downstream end of the catheter **1**. The resilience of the O-ring **90** (optionally, in combination with shape memory of the ribs **6**) causes the ribs **6** to separate as the O-ring **90** deploys into its natural circular shape, producing a seal against the wall of the vas. In so doing, the O-ring **90** expands the filter **7** so that it can trap debris released from an upstream location. The filter **7** is returned to its original undeployed position by retracting the ribs **6** into the catheter **1**, exerting a radially-inward force on the O-ring **90**, causing it to buckle into a

multi-lobed pattern with outside radial dimension much smaller than in the deployed position. The ribs **6** can be drawn into the catheter **1** by means of a stiff tether line **91** attached to the ribs **6** at their upstream end **92** within the catheter lumen. The tether line **91** must be sufficiently rigid that it can exert the force

needed to deploy the filter **7** and the O-ring **90**. For ease of retrieval, the filter **7** can be sheathed by a second catheter that slides on the outer bore of the catheter **1**, slipping over the buckled O-ring **90** and filter **7**.

Fig. 10 is a perspective view of a catheter-filter set according to an embodiment of the invention that is similar to the embodiment of Fig. 9, but utilizing a cylindrical sleeve **93** in lieu of the O-ring **90**. An advantage of the sleeve is that the filter **7** can be entirely contained within the sleeve **93** when the ribs and filter are in the retracted position, thus eliminating the necessity for a second catheter.

Fig. 11A is a perspective view of a catheter-filter set according to an embodiment of the invention utilizing a tethered O-ring, shown in the deployed condition. Fig. 11B is a longitudinal view of the same embodiment in the stowed condition. This embodiment shows that an O-ring **191** may be employed in situations in which the filter **7** is attached upstream of the end of the catheter **1**. Deployment, in this embodiment, is accomplished when the operator relaxes the force applied by the line **121** which passes through the wall of the catheter **1** at point **122**. The line **121** is attached to a collar **21** that can slide freely along the bore of the catheter **1**. When force is relaxed, the resilience of the O-ring **191** that exerts a tension in a plurality of tether lines **200** (two are shown) pulls the collar **21** in the downstream direction. The O-ring **191**, selected to be of an outer diameter when fully extended slightly larger than the normal diameter of the vas, provides a flexible seal against the wall of the vas when the tension force in tethers **200** is reduced. A filter **7** is attached around the circumference of the O-ring **191** and is deployed when the O-ring is allowed to expand to fill the vas. The O-ring **191** is also attached to a plurality of additional tethers **201** (two are shown) that are rigidly fixed to the downstream collar **20**. All tether lines **200** and **201** are inextensible and, in this embodiment, are attached at points distributed roughly equidistant around the circumference of the O-ring **191.** To retract and stow the filter, the operator pulls on the line **121** and the O-ring buckles into the configuration shown in Figure 11B due to the alternating

attachments of the tether lines **200** and **201**. The buckling of the O-ring **191** also helps to gather together the filter **7**.

Although the invention has been described with reference to several preferred embodiments, it will be understood by one of ordinary skill in the art that various modifications can be made without departing from the spirit and the scope of the invention, as set forth in the claims hereinbelow.

What is claimed is:

1. A catheter-filter set for use in a vas through which a biological fluid may flow, the vas having an interior wall, the fluid flow defining downstream and upstream directions, there being a risk of the presence of undesired particles in the fluid, the catheter-filter set comprising:

a. a tubular member, having a lumen disposed along its length and an insertion end for insertion into the vas, the lumen defining a longitudinal axis and a radial direction perpendicular thereto;

b. a filter, coupled to the tubular member and having a circumference, for trapping undesired particles; and

c. a resilient member, having compliance in the radial direction, disposed circumferentially about the filter and, when deployed in the vas, forming a seal against the interior wall.

2. A catheter-filter set according to claim 1, wherein the resilient member is an O-ring.

3. A catheter-filter set according to claim 1, wherein the resilient member is a sleeve.

4. A catheter-filter set according to claim 1, wherein the resilient member is a balloon having an interior for receiving an inflation fluid and a shape so that when the balloon is inflated there is provided a passageway permitting fluid flow through the filter.

5. A catheter-filter set according to claim 4, further comprising an elastic member coupled to the balloon and the tubular member for causing the balloon to be radially confined when not deployed.

6. A catheter-filter set according to claim 4, wherein the balloon is toroidal and its interior has a cross-section.

7. A catheter-filter set according to claim 6, wherein the resilient balloon has anisotropic elasticity so that during inflation its interior cross-section expands relatively less than its radial extent.

8. A catheter filter set according to claim 1, such that the filter has a stowed position where the filter is radially confined and disposed in the lumen so that

the catheter-filter set may be inserted into and removed from the vas, and a deployed position, where the filter is radially expanded.

9. A catheter-filter set for use in a vas through which a biological fluid may flow, the vas having an interior wall, the fluid flow defining downstream and upstream directions, there being a risk of the presence of undesired particles in the fluid, the catheter-filter set comprising:

a. a tubular member, having a first lumen disposed along its length, an insertion end for insertion into and a retraction end for retraction out of the vas, the lumen defining a longitudinal axis and a radial direction perpendicular thereto;

b. a filter, coupled to the tubular member proximal to the insertion end, wherein the filter has a stowed position wherein the filter is radially confined so that the catheter-filter set may be inserted into and removed from the vas, and a deployed position, wherein the filter is radially expanded; and

c. a non-inflatable actuator, coupled to the filter, for causing the filter to move from the stowed position to the deployed position;

wherein, absent operation of the actuator, the filter is biased to be in the stowed position.

10. A catheter-filter set according to claim 9, further comprising:

d. a vas conditions-modifying element, associated with the tubular member and located upstream from the filter.

11. A catheter-filter set according to claim 9 wherein element (d) is an angioplasty balloon.

12. A catheter-filter set according to claim 9, wherein the tubular member has a second lumen, the second lumen having an inlet upstream from the vas conditions-modifying element and an outlet downstream from the filter, permitting unimpeded, downstream fluid flow to bypass the filter.

13. A catheter-filter set according to claim 12, wherein the second lumen has a diameter of from approximately 1 mm to approximately 2 mm.

14. A catheter-filter set according to claim 9, further comprising:

d. a plurality of resilient ribs, each rib having a first end coupled to the tubular member, each rib also coupled to the filter, the ribs having a stowed condition in which they are parallel to the longitudinal axis and having a deployed condition in which at least a portion of each rib is disposed radially outward from the tubular member.

15. A catheter-filter set according to claim 14, wherein the filter, in the deployed position, has a maximum radial extent and each rib, in the deployed condition, radially extends a distance less than the maximum radial extent of the filter.

16. A catheter-filter set according to claim 14, wherein each rib has a second end slidably mounted on the tubular member and coupled to the actuator.

17. A catheter-filter set according to claim 16, wherein each rib is coupled to a collar slidably mounted on the tubular member.

18. A catheter-filter set according to claim 14, further comprising:

e. a vas conditions-modifying element, associated with the tubular member and located upstream from the filter.

19. A catheter-filter set according to claim 18 wherein element (e) is an angioplasty balloon.

20. A catheter-filter set according to claim 18, wherein the tubular member has a second lumen, the second lumen having an inlet upstream from the vas conditions-modifying element and an outlet downstream from the filter, permitting unimpeded, downstream fluid flow to bypass the filter.

21. A catheter-filter set according to claim 20, wherein the second lumen has a diameter of from approximately 1 mm to approximately 2 mm.

22. A catheter-filter set according to claim 9, further comprising:

d. a resilient member, having compliance in the radial direction, disposed circumferentially about the filter and, when deployed in the vas, forming a seal against the interior wall.

23. A catheter-filter set according to claim 22, further comprising:

e. a plurality of resilient ribs, each rib having a first end coupled to the tubular member, each rib also coupled to the filter, the ribs having a

stowed condition in which they are parallel to the longitudinal axis and having a deployed condition in which at least a portion of each rib is disposed radially outward from the tubular member.

24. A catheter-filter set according to claim 23, wherein the filter, in the deployed position, has a maximum radial extent and each rib, in the deployed condition, radially extends a distance less than the maximum radial extent of the filter.

25. A catheter-filter set according to claim 23, wherein each rib has a second end slidably mounted on the tubular member and coupled to the actuator.

26. A catheter-filter set according to claim 25, wherein each rib is coupled to a collar slidably mounted on the tubular member.

27. A catheter-filter set according to claim 23, further comprising:

f. a vas conditions-modifying element, associated with the tubular member and located upstream from the filter.

28. A catheter-filter set according to claim 27 wherein element (f) is an angioplasty balloon.

29. A catheter-filter set according to claim 23, wherein the tubular member has a second lumen, the second lumen having an inlet upstream from the vas conditions-modifying element and an outlet downstream from the filter, permitting unimpeded, downstream fluid flow to bypass the filter.

30. A catheter-filter set according to claim 29, wherein the second lumen has a diameter of from approximately 1 mm to approximately 2 mm.

31. A catheter-filter set according to claim 22, wherein the resilient member is an O-ring.

32. A catheter-filter set according to claim 22, wherein the resilient member is a sleeve.

33. A catheter-filter set according to claim 22, wherein the resilient member is a resilient balloon having an interior for receiving an inflation fluid and a shape so that when the resilient balloon is inflated there is provided a passageway permitting fluid flow through the filter.

34. A catheter-filter set according to claim 33, wherein the resilient balloon is toroidal and its interior has a cross-section.

35. A catheter-filter set according to claim 34, wherein the resilient balloon has anisotropic elasticity so that during inflation its interior cross-section expands relatively less than its radial extent.

36. A catheter-filter set for use in a vas through which a biological fluid may flow, the vas having an interior wall, the fluid flow defining downstream and upstream directions, there being a risk of the presence of undesired particles in the fluid, the catheter-filter set comprising:

a. a tubular member, having a lumen disposed along its length, an insertion end for insertion into and a retraction end for retraction out of the vas, the lumen defining a longitudinal axis and a radial direction perpendicular thereto; and

b. a filter, coupled to the tubular member proximal to the insertion end, wherein the filter has a stowed position wherein the filter is radially confined and disposed in the lumen so that the catheter-filter set may be inserted into and removed from the vas, and a deployed position, wherein the filter is radially expanded.

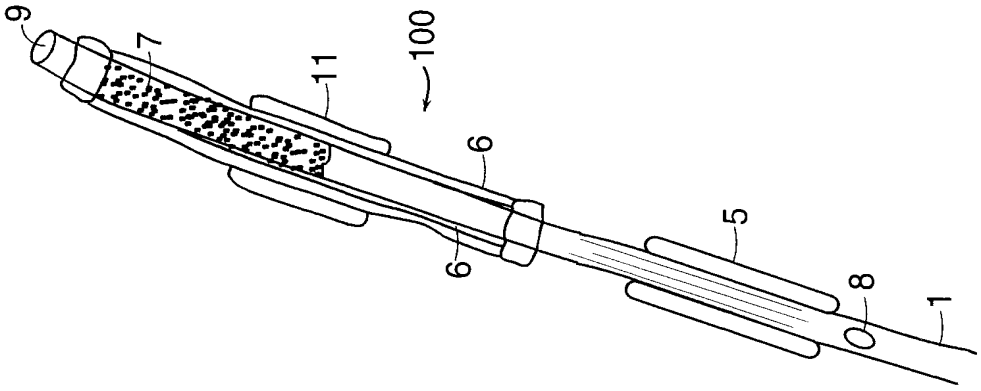


FIG. 1B

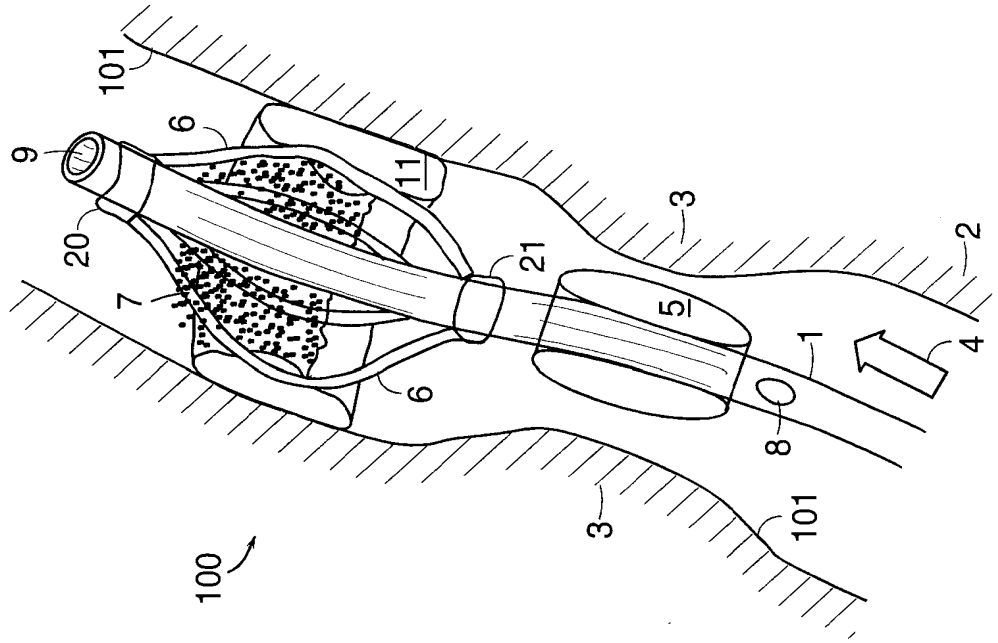


FIG. 1A

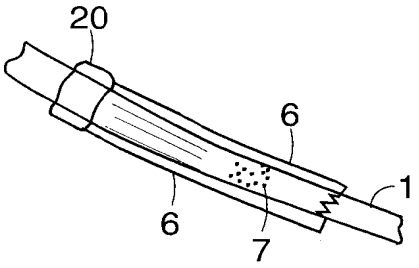


FIG. 2A

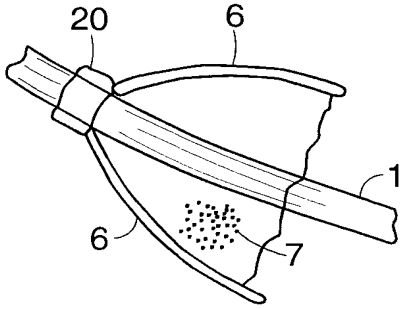


FIG. 2B

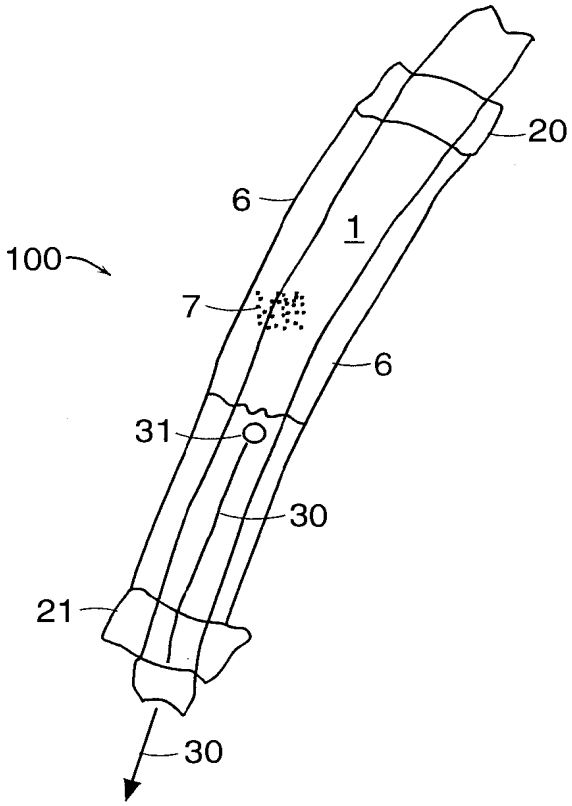


FIG. 3A

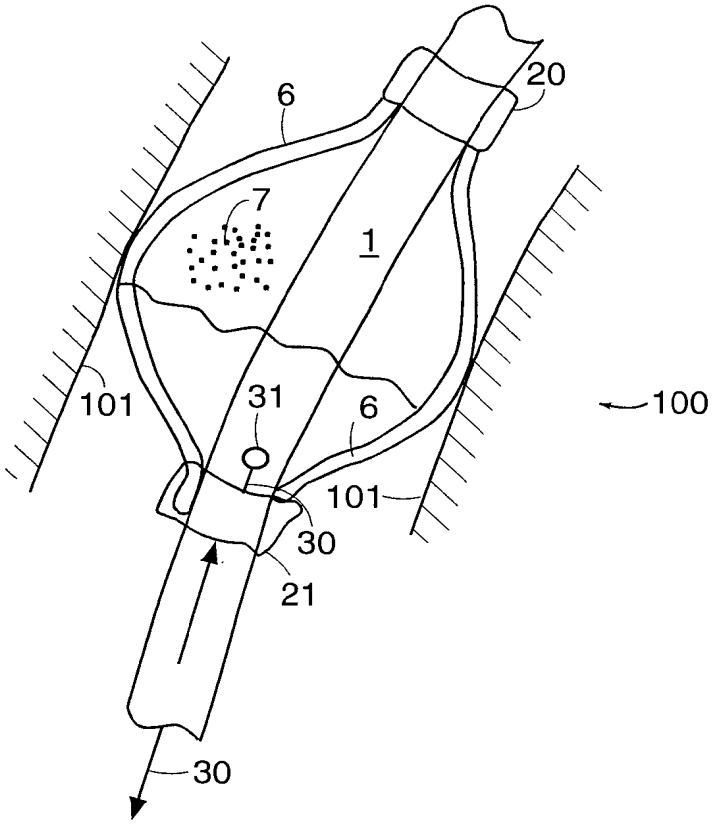


FIG. 3B

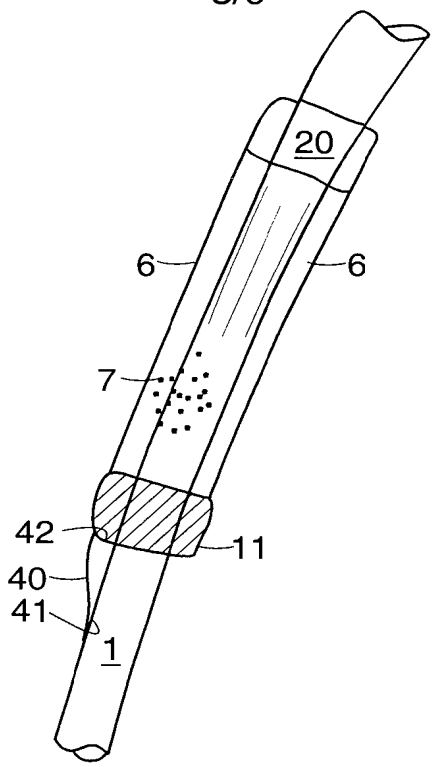


FIG. 4A

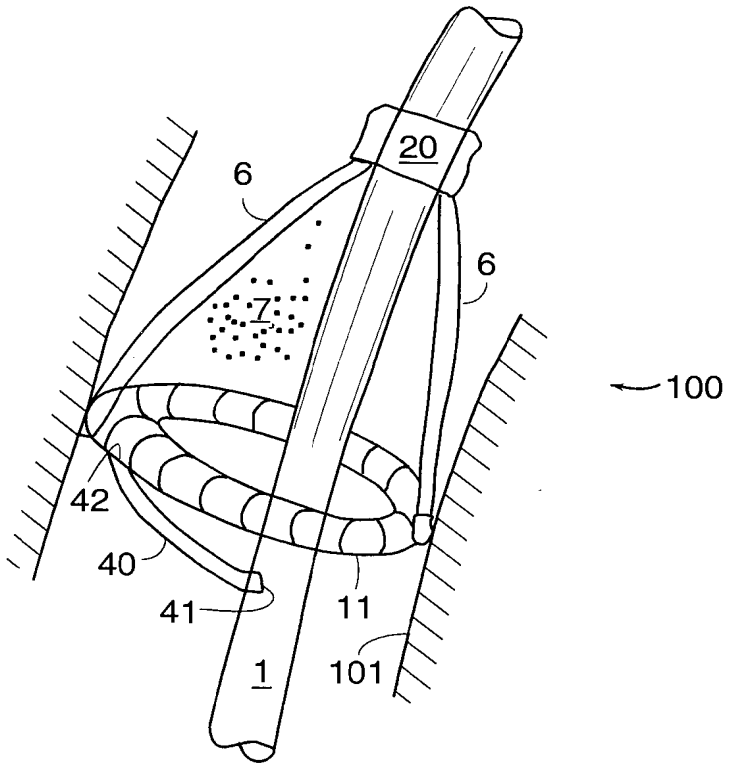


FIG. 4B

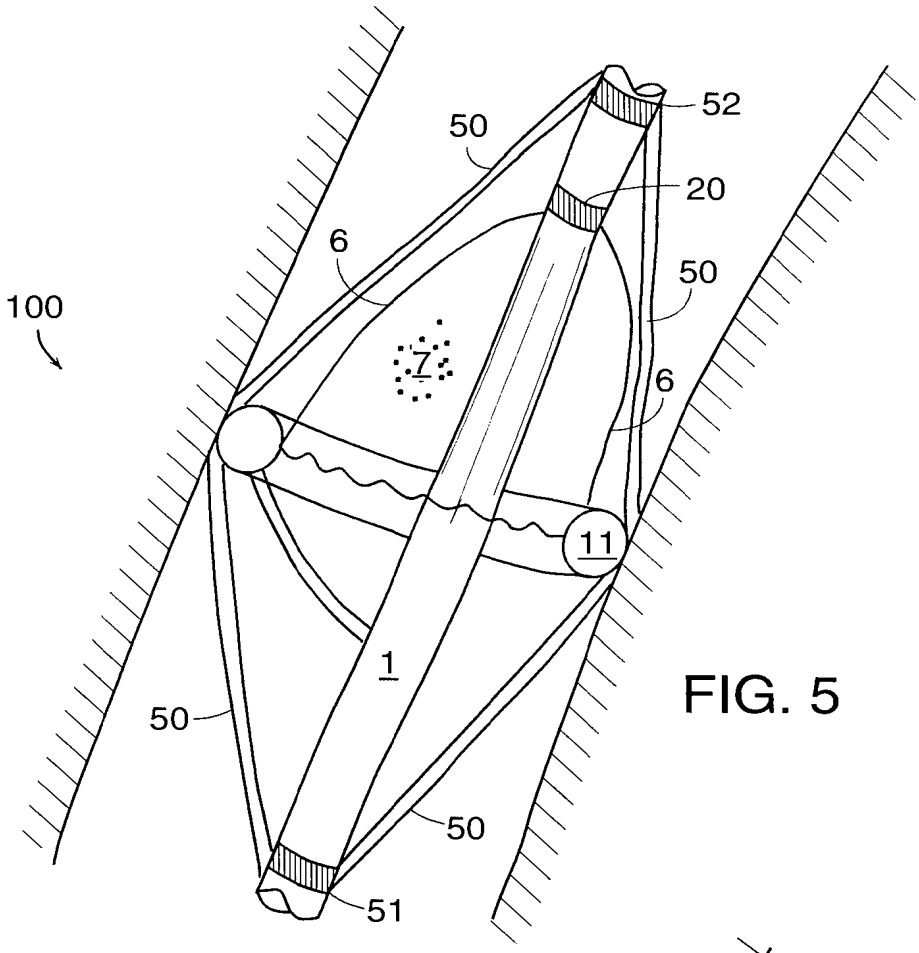


FIG. 5

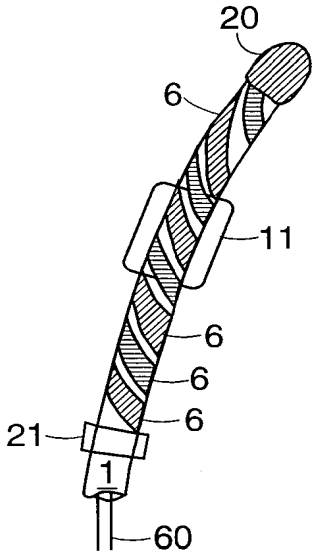


FIG. 6A

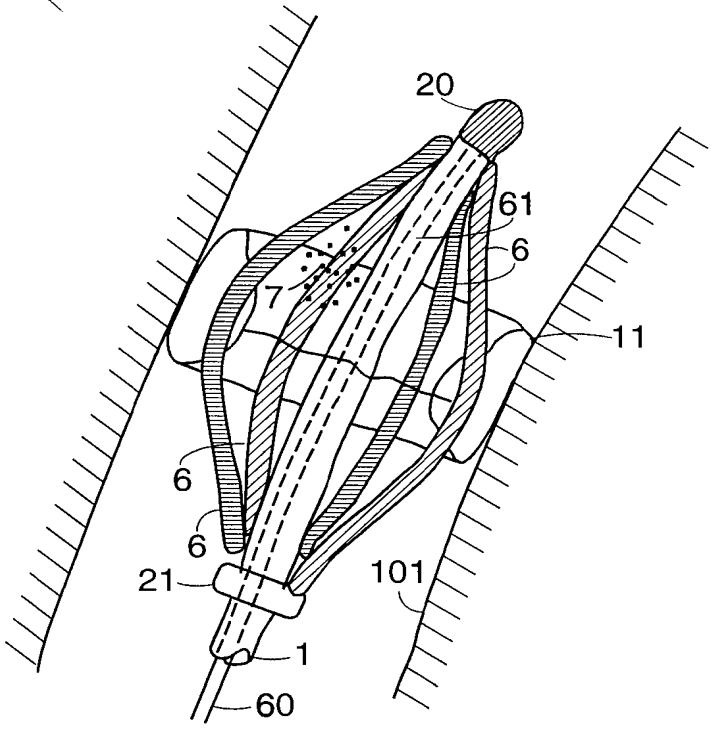


FIG. 6B

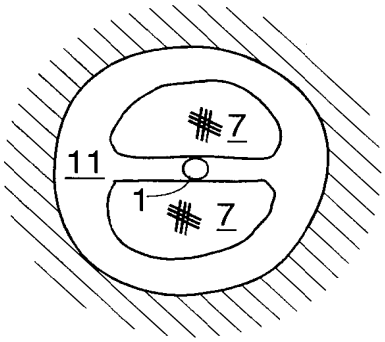


FIG. 7A

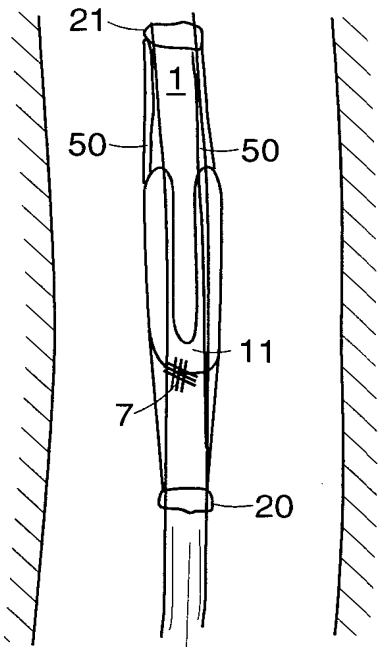


FIG. 7B

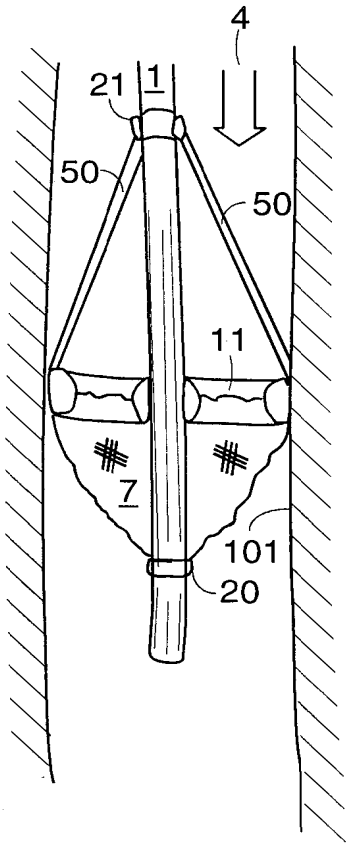


FIG. 7C

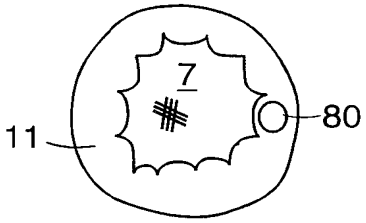


FIG. 8A

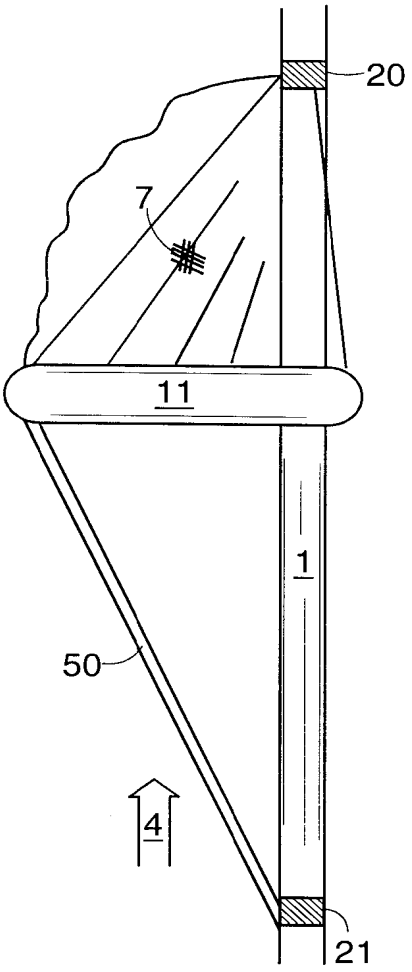


FIG. 8B

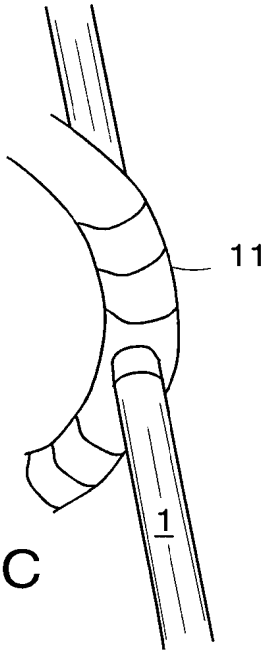


FIG. 8C

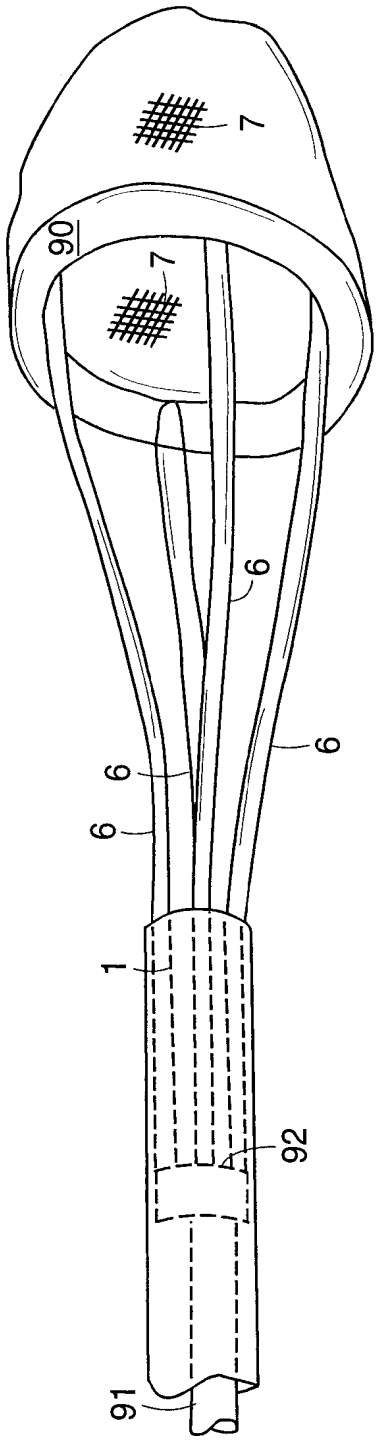


FIG. 9

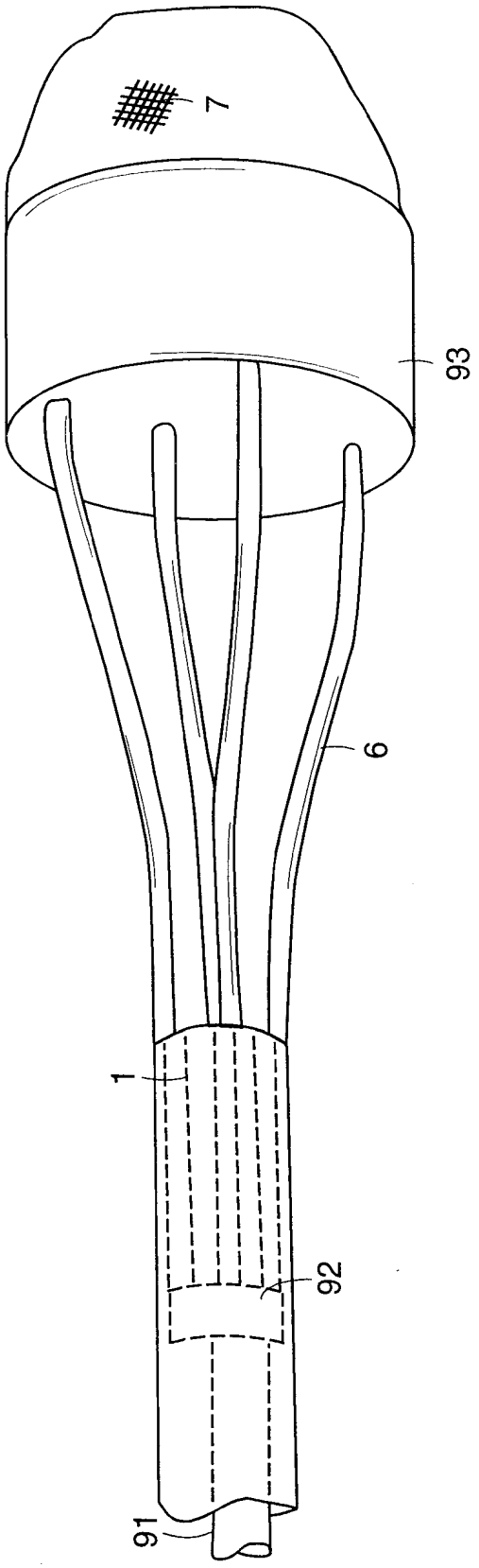


FIG. 10

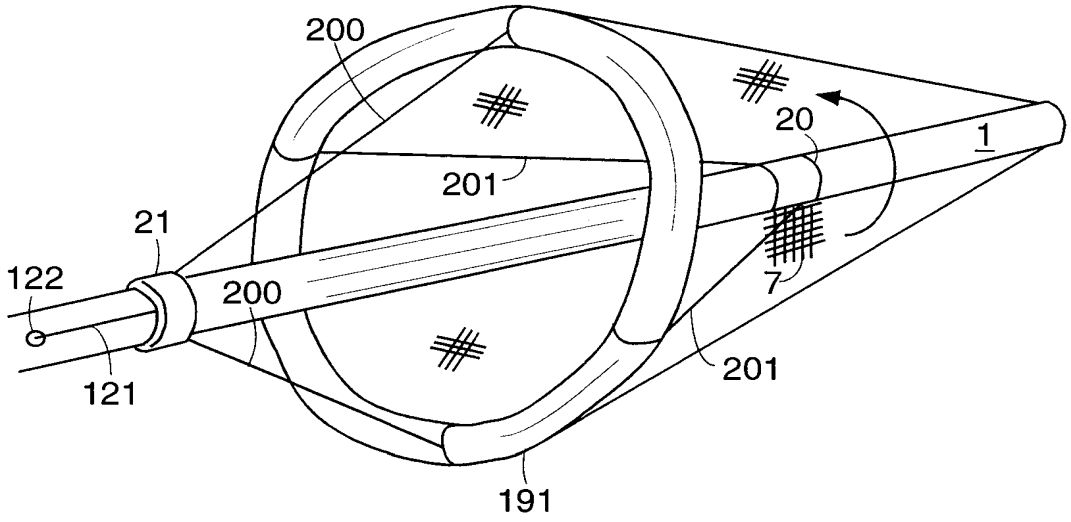


FIG. 11A

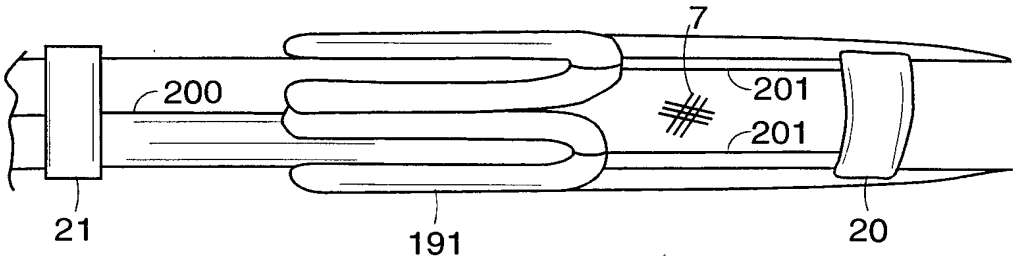


FIG. 11B

INTERNATIONAL SEARCH REPORT

In..ational Application No
PCT/US 98/10220

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61F2/01 A61M29/02

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 6 A61F A61B

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	WO 95 05209 A (TECH. DEV. CENTER) 23 February 1995 see page 13, line 29 - page 15, line 11 see page 7, line 6 - line 10; figures 1,13-15	1-4,6-8, 36 5,9-35
Y	US 4 723 549 A (WHOLEY ET AL.) 9 February 1988 cited in the application see column 3, line 2 - line 66; figures 1-6	5,9-35

-/--

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

[X] Patent family members are listed in annex.

° Special categories of cited documents :

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

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

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

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

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

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

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

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

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
21 August 1998	02/09/1998

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, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Moers, R

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 98/10220

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
X	DATABASE WPI Week 8122 8 July 1981 Derwent Publications Ltd., London, GB; AN 78-70163A XP002075206 & SU 764 684 A (CHELY MED. INST.) see abstract; figures 1-5	1-3,9,36
X A	US 5 053 008 A (BAJAJ) 1 October 1991 see column 7, line 55 - column 8, line 47; figures 1-4	1,36 3,7,32, 35
A	US 5 470 314 A (WALINSKY PAUL) 28 November 1995 see column 7, line 13 - line 18	7,35

Form PCT/ISA/210 (continuation of second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Information on patent family members

Ir. .ational Application No
PCT/US 98/10220

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9505209 A	23-02-1995	AU 7567394 A	14-03-1995
US 4723549 A	09-02-1988	NONE	
US 5053008 A	01-10-1991	NONE	
US 5470314 A	28-11-1995	NONE	

PCT WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61M 29/00

A1

(11) International Publication Number: **WO 98/39053**

(43) International Publication Date: 11 September 1998 (11.09.98)

(21) International Application Number: PCT/US98/02961

(22) International Filing Date: 26 February 1998 (26.02.98)

(30) Priority Data:

08/813,794	6 March 1997 (06.03.97)	US
08/943,358	3 October 1997 (03.10.97)	US

(81) Designated States: CA, JP, European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

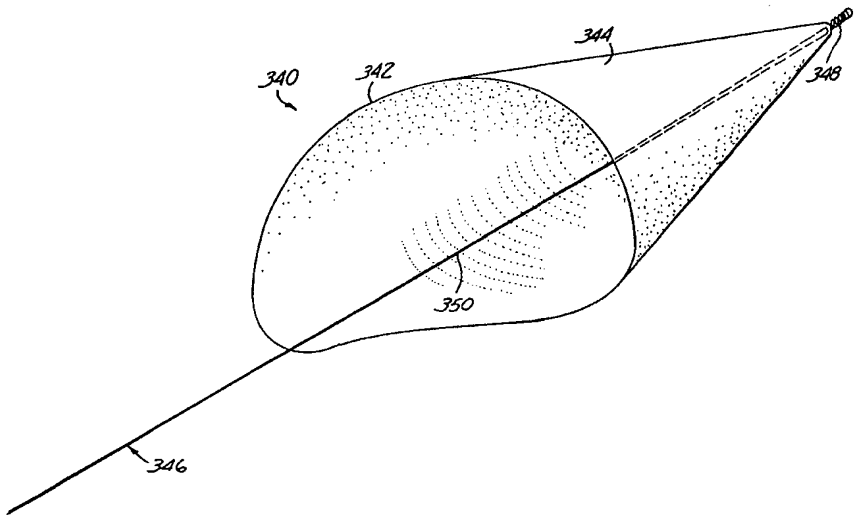
Published
With international search report.

(71) Applicant: SCIMED LIFE SYSTEMS, INC. [US/US]; One Scimed Place, Maple Grove, MN 55311–1566 (US).

(72) Inventors: DANIEL, John, M., K.; 701 Oak Park Lane #61, Hopkins, MN 55343 (US). BROOME, Thomas, E.; 511 Sunnyside Lane, Hopkins, MN 55343 (US). HOLTAN, David, J.; 5175 Nalmark Avenue, Rogers, MN 55374 (US). CASSELL, Robert, L.; 14398 – 91st Street N.E., Otsego, MN 55330 (US). ADAMS, Daniel, O.; 1145 Tonkawa Road South, Orono, MN 55356 (US).

(74) Agents: KELLY, Joseph, R.; Westman, Champlin & Kelly, P.A., International Centre, Suite 1600, 900 Second Avenue South, Minneapolis, MN 55402–3319 (US) et al.

(54) Title: DISTAL PROTECTION DEVICE AND METHOD



(57) Abstract

An emboli capturing system (366) captures emboli in a body lumen. A first elongate member (346) has a proximal end and a distal end. An expandable emboli capturing device (344) is mounted proximate the distal end of the first elongate member (346), and is movable between a radially expanded position and a radially contracted position. When in the expanded position, the emboli capturing device (344) forms a basket with a proximally opening mouth (368). A second elongate member (376) has a proximal and a distal end with a lumen extending therebetween. The lumen is sized to slidably receive a portion of the first elongate member (346). An expandable delivery device (378) is mounted to the distal end of the second elongate member (376) and is movable from a radially retracted position to a radially expanded position. The delivery device has a receiving end (382) configured to receive the emboli capturing device (344), and retains at least the mouth (368) of the emboli capturing device (344) in a radially retracted position.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	**ES**	Spain	**LS**	Lesotho	**SI**	Slovenia
AM	Armenia	**FI**	Finland	**LT**	Lithuania	**SK**	Slovakia
AT	Austria	**FR**	France	**LU**	Luxembourg	**SN**	Senegal
AU	Australia	**GA**	Gabon	**LV**	Latvia	**SZ**	Swaziland
AZ	Azerbaijan	**GB**	United Kingdom	**MC**	Monaco	**TD**	Chad
BA	Bosnia and Herzegovina	**GE**	Georgia	**MD**	Republic of Moldova	**TG**	Togo
BB	Barbados	**GH**	Ghana	**MG**	Madagascar	**TJ**	Tajikistan
BE	Belgium	**GN**	Guinea	**MK**	The former Yugoslav Republic of Macedonia	**TM**	Turkmenistan
BF	Burkina Faso	**GR**	Greece			**TR**	Turkey
BG	Bulgaria	**HU**	Hungary	**ML**	Mali	**TT**	Trinidad and Tobago
BJ	Benin	**IE**	Ireland	**MN**	Mongolia	**UA**	Ukraine
BR	Brazil	**IL**	Israel	**MR**	Mauritania	**UG**	Uganda
BY	Belarus	**IS**	Iceland	**MW**	Malawi	**US**	United States of America
CA	Canada	**IT**	Italy	**MX**	Mexico	**UZ**	Uzbekistan
CF	Central African Republic	**JP**	Japan	**NE**	Niger	**VN**	Viet Nam
CG	Congo	**KE**	Kenya	**NL**	Netherlands	**YU**	Yugoslavia
CH	Switzerland	**KG**	Kyrgyzstan	**NO**	Norway	**ZW**	Zimbabwe
CI	Côte d'Ivoire	**KP**	Democratic People's Republic of Korea	**NZ**	New Zealand		
CM	Cameroon			**PL**	Poland		
CN	China	**KR**	Republic of Korea	**PT**	Portugal		
CU	Cuba	**KZ**	Kazakstan	**RO**	Romania		
CZ	Czech Republic	**LC**	Saint Lucia	**RU**	Russian Federation		
DE	Germany	**LI**	Liechtenstein	**SD**	Sudan		
DK	Denmark	**LK**	Sri Lanka	**SE**	Sweden		
EE	Estonia	**LR**	Liberia	**SG**	Singapore		

DISTAL PROTECTION DEVICE AND METHOD

BACKGROUND OF THE INVENTION

The present invention deals with an emboli capturing system. More specifically, the present invention deals with an emboli capturing system and method for capturing embolic material in a blood vessel during an atherectomy or thrombectomy procedure.

Blood vessels can become occluded (blocked) or stenotic (narrowed) in one of a number of ways. For instance, a stenosis may be formed by an atheroma which is typically a harder, calcified substance which forms on the lumen walls of the blood vessel. Also, the stenosis can be formed of a thrombus material which is typically much softer than an atheroma, but can nonetheless cause restricted blood flow in the lumen of the blood vessel. Thrombus formation can be particularly problematic in a saphenous vein graft (SVG).

Two different procedures have developed to treat a stenotic lesion (stenosis) in vasculature. The first is to deform the stenosis to reduce the restriction within the lumen of the blood vessel. This type of deformation (or dilatation) is typically performed using balloon angioplasty.

Another method of treating stenotic vasculature is to attempt to completely remove either the entire stenosis, or enough of the stenosis to relieve the restriction in the blood vessel. Removal of the stenotic lesion has been done through the use of radio frequency (RF) signals transmitted via conductors, and through the use of lasers, both of which treatments are meant to ablate (i.e., super heat and vaporize) the stenosis. Removal of the stenosis has also been accomplished using thrombectomy or atherectomy. During

thrombectomy and atherectomy, the stenosis is mechanically cut or abraded away from the vessel.

Certain problems are encountered during thrombectomy and atherectomy. The stenotic debris which is separated from the stenosis is free to flow within the lumen of the vessel. If the debris flows distally, it can occlude distal vasculature and cause significant problems. If it flows proximally, it can enter the circulatory system and form a clot in the neural vasculature, or in the lungs, both of which are highly undesirable.

Prior attempts to deal with the debris or fragments have included cutting the debris into such small pieces (having a size on the order of a blood cell) that they will not occlude vessels within the vasculature. However, this technique has certain problems. For instance, it is difficult to control the size of the fragments of the stenotic lesion which are severed. Therefore, larger fragments can be severed accidentally. Also, since thrombus is much softer than an atheroma, it tends to break up easier when mechanically engaged by a cutting instrument. Therefore, at the moment that the thrombus is mechanically engaged, there is a danger that it can be dislodged in large fragments which would occlude the vasculature.

Another attempt to deal with debris severed from a stenosis is to remove the debris, as it is severed, using suction. However, it may be necessary to pull quite a high vacuum in order to remove all of the pieces severed from the stenosis. If a high enough vacuum is not used, all of the severed pieces will not be removed. Further, when a high vacuum is used, this can tend to cause the vasculature to collapse.

A final technique for dealing with the fragments of the stenosis which are severed during atherectomy is to place a device distal to the stenosis during atherectomy to catch the pieces of the stenosis as they are severed, and to remove those pieces along with the capturing device when the atherectomy procedure is complete. Such capture devices have included expandable filters which are placed distal of the stenosis to capture stenosis fragments. Problems are also associated with this technique. For example, delivery of such devices in a low profile, pre-deployment configuration can be difficult. Further, some devices include complex and cumbersome actuation mechanisms. Also, retrieving such capture devices, after they have captured emboli, can be difficult as well.

SUMMARY OF THE INVENTION

An emboli capturing system captures emboli in a body lumen. A first elongate member has a proximal end and a distal end. An expandable emboli capturing device is mounted proximate the distal end of the first elongate member, and is movable between a radially expanded position and a radially contracted position. When in the expanded position, the emboli capturing device forms a basket with a proximally opening mouth. A second elongate member has a proximal and a distal end with a lumen extending therebetween. The lumen is sized to slidably receive a portion of the first elongate member. An expandable delivery device is mounted to the distal end of the second elongate member and is movable from a radially retracted position to a radially expanded position. The delivery device has a receiving end configured to receive the emboli capturing device,

and retains at least the mouth of the emboli capturing device in a radially retracted position.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 shows a distal protection device of the present invention in a deployed position.

FIG. 2 shows the distal protection device shown in FIG. 1 in a collapsed position.

FIG. 3 shows an end view of a portion of the distal protection device shown in FIGS. 1 and 2.

FIG. 4 shows a cross-sectional view of a portion of the distal protection device shown in FIGS. 1-3 in the deployed position.

FIG. 5 shows a second embodiment of the distal protection device according to the present invention in a deployed position.

FIG. 6 shows an end view of the distal protection device shown in FIG. 5.

FIG. 7 shows a cross-sectional view of the distal protection device shown in FIGS. 5 and 6 in the collapsed position.

FIG. 8 shows a third embodiment of a distal protection device according to the present invention in a deployed position.

FIG. 9 is a side sectional view of an alternate embodiment illustrating how the expandable members of the present invention are attached to a guidewire.

FIG. 10 is a sectional view taken along section lines 10-10 in FIG. 9.

FIGS. 11A and 11B show a fourth and fifth embodiment, respectively, of a distal protection device according to the present invention in a deployed position.

FIG. 12 illustrates the operation of a distal protection device in accordance with the present invention.

FIGS. 13A-17B show additional embodiments of distal protection devices which expand and collapse based on movement of a mechanical actuator.

FIGS. 18A-18D illustrate an additional embodiment of a distal protection device which is deployed and collapsed using a rolling flap configuration.

FIG. 19 illustrates another embodiment in accordance with the present invention in which the protection device is deployed using fluid pressure and a movable collar.

FIGS. 20A and 20B illustrate another aspect of the present invention in which two longitudinally movable members used to deploy the distal protection device are disconnectably locked to one another.

FIGS. 21A-21C illustrate another embodiment in accordance with the present invention in which the protection device is formed with a shape memory alloy frame and an attached filter or mesh mounted to the frame.

FIGS. 22A-22C illustrate another embodiment in accordance with the present invention in which the distal protection devices shown in FIGS. 21A-21C are delivered and deployed.

FIGS. 23A-23E illustrate another embodiment in accordance with the present invention in which the distal protection devices shown in FIGS. 21A-21C are retrieved.

FIGS. 24A-24C illustrate another embodiment in accordance with the present invention in which the

distal protection devices shown in FIGS. 21A-21C are retrieved.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

FIG. 1 illustrates protection device 10 in a deployed position within the lumen of a blood vessel 12. Protection device 10 preferably includes hollow guidewire 14 (or a hypotube having the same general dimensions as a guidewire) having a coil tip 16, and a capturing assembly 18. Capturing assembly 18, in the embodiment shown in FIG. 1, includes an inflatable and expandable member 20 and mesh 22.

An interior of expandable member 20 is preferably coupled for fluid communication with an inner lumen of guidewire 14 at a distal region of guidewire 14. When deployed, inflatable member 20 inflates and expands to the position shown in FIG. 1 such that capturing assembly 18 has an outer periphery which approximates the inner periphery of lumen 12.

Mesh 22 is preferably formed of woven or braided fibers or wires, or a microporous membrane, or other suitable filtering or netting-type material. In one preferred embodiment, mesh 22 is a microporous membrane having holes therein with a diameter of approximately 100 μm. Mesh 22 can be disposed relative to inflatable member 20 in a number of different ways. For example, mesh 22 can be formed of a single generally cone-shaped piece which is secured to the outer or inner periphery of inflatable member 20. Alternatively, mesh 22 can be formed as a spiral strip which is secured about the outer or inner periphery of inflatable member 20 filling the gaps between the loops of inflatable member 20. Alternatively, mesh 22 can be formed of a number of discrete pieces which are assembled onto inflatable member 20.

Hollow guidewire 14 preferably has a valve 24 coupled in a proximal portion thereof. During operation, a syringe is preferably connected to the proximal end of guidewire 14, which preferably includes a fluid hypotube. The syringe is used to pressurize the fluid such that fluid is introduced through the lumen of hollow guidewire 14, through valve 24, and into inflatable member 20. Upon being inflated, inflatable member 20 expands radially outwardly from the outer surface of guidewire 14 and carries mesh 22 into the deployed position shown in FIG. 1. In this way, capturing assembly, or filter assembly, 18 is deployed distally of stenosis 26 so that stenosis 26 can be severed and fragmented, and so the fragments from stenosis 26 are carried by blood flow (indicated by arrow 28) into the basket or chamber formed by the deployed filter assembly 18. Filter assembly 18 is then collapsed and removed from vessel 12 with the fragments of stenosis 26 contained therein.

FIG. 2 illustrates protection device 10 with filter assembly 18 in the collapsed position. Similar items to those shown in FIG. 1 are similarly numbered. FIG. 2 illustrates that mesh 22 is easily collapsible with inflatable member 20. In order to collapse filter assembly 18, fluid is preferably removed from inflatable member 20 through the lumen of hollow guidewire 14 and through two-way valve 24. This can be done using the syringe to pull a vacuum, or using any other type of suitable fluid removal system.

Inflatable member 20 is preferably formed of a material having some shape memory. Thus, when inflatable member 20 is collapsed, it collapses to approximate the outer diameter of hollow guidewire 14. In one preferred embodiment, inflatable member 20 is

formed of a resilient, shape memory material such that it is inflated by introducing fluid under pressure through the lumen in hollow guidewire 14 into inflatable member 20. When pressure is released from the lumen in hollow guidewire 14, inflatable member 20 is allowed to force fluid out from the interior thereof through two-way valve 24 and to resume its initial collapsed position. Again, this results in filter assembly 18 assuming its collapsed position illustrated in FIG. 2.

FIG. 3 illustrates a view taken from the distal end of device 10 with mesh 22 removed for clarity. FIG. 3 shows that, when inflatable member 20 is deployed outwardly, mesh 22 (when deployed between the loops of inflatable member 20) forms a substantially lumen-filling filter which allows blood to flow therethrough, but which provides a mechanism for receiving and retaining stenosis fragments carried into mesh 22 by blood flow through the vessel.

FIG. 3 also shows that inflatable member 20 preferably has a proximal end portion 29 which is connected to the outer periphery of guidewire 14. Although end 29 need not be connected to guidewire 14, it is preferably connected using adhesive or any other suitable connection mechanism. By fixedly connecting proximal end portion 29 to guidewire 14, this increases the stability of the filter assembly 18 upon deployment.

FIG. 4 is a cross-sectional view of a portion of protection device 10. FIG. 4 shows protection device 10 with filter assembly 18 in the expanded or deployed position. FIG. 4 also better illustrates that guidewire 14 is hollow and has a longitudinal lumen 30 extending therethrough. Longitudinal lumen 30 is connected in fluid communication with an interior of inflatable member 20 through aperture 32 which is provided in the

wall of guidewire 14. FIG. 4 also shows that, in one preferred embodiment, a core wire 34 extends through lumen 30 from a proximal end thereof where it is preferably brazed to a portion of a hypotube which may be connected to the proximal portion of guidewire 14. The core wire 34 extends to the distal end of guidewire 14 where it is connected to coil tip 16. In one preferred embodiment, coil tip 16 is brazed or otherwise welded or suitably connected to the distal portion of core wire 34.

FIG. 4 further shows that, in the preferred embodiment, inflatable member 20 inflates to a generally helical, conical shape to form a basket opening toward the proximal end of guidewire 14. FIG. 4 further illustrates, in the preferred embodiment, mesh 22 has a distal portion 38 which is connected to the exterior surface of guidewire 14, at a distal region thereof, through adhesive 36 or any other suitable connection mechanism.

FIG. 5 illustrates a second embodiment of a distal protection device 40 in accordance with the present invention. Device 40 includes hollow guidewire 42, filter assembly 44 and coil tip 16. Filter assembly 44 includes a plurality of inflatable struts 46 and mesh 47. Each strut 46 has a distal end 48 and proximal end 50. Inflatable struts 46 also have an interior which is coupled in fluid communication, through distal end 48 thereof, with the lumen in hollow guidewire 42. Struts 46 are preferably configured such that, upon being inflated, the proximal ends 50 deploy radially outwardly away from the outer surface of hollow guidewire 42 to assume a dimension which approximates the inner dimension of lumen 58 in which they are inserted.

Mesh 47, as with mesh 22 shown in FIG. 1, is deployed either on the outer or inner surface of inflatable struts 46, such that, when the inflatable struts 46 are deployed radially outwardly, mesh 47 forms a generally conical basket opening toward the proximal end of hollow guidewire 42. As with the embodiment shown in FIG. 1, mesh 47 can be applied to either the outer or the inner surface of struts 46. It can be applied to struts 46 as one unitary conical piece which is adhered about distal ends 48 of struts 46 using adhesive (or about the distal end of guidewire 42 using adhesive) and secured to the surface of the struts 46 also using adhesive. Alternatively, mesh 47 can be applied to struts 46 in a plurality of pieces which are individually or simultaneously secured to, and extend between, struts 46.

FIG. 6 is an end view of distal protection device 40 shown in FIG. 5 taken from the distal end of distal protection device 40. When struts 46 are deployed outwardly, mesh 47 forms a substantially lumen-filling filter which allows blood to flow therethrough, but which provides a mechanism for receiving and retaining stenosis fragments from stenosis 56 carried into mesh 47 by blood flow through the vessel.

FIG. 7 is a cross-sectional view of a portion of distal protection device 40 shown in FIGS. 5 and 6. FIG. 7 shows filter assembly 44 in the collapsed position in which it approximates the outer diameter of guidewire 42. FIG. 7 also shows that, in the preferred embodiment, the distal ends 48 of struts 46 are in fluid communication with an inner lumen 52 in hollow guidewire 42 through apertures 54 in the wall of guidewire 42.

FIG. 8 illustrates another embodiment of a distal protection device 60 in accordance with the

present invention. Distal protection device 60 is similar to those shown in other figures, and similar items are similarly numbered. However, distal protection device 60 includes hollow guidewire 63 which has a lumen in fluid communication with an interior of a pair of inflatable struts 62. Inflatable struts 62 have an inner surface 64 which is generally concave, or hemispherical, or otherwise appropriately shaped such that it extends about a portion of the outer surface of hollow guidewire 63. Mesh portions 66 extend between the inflatable struts 62 so that inflatable struts 62 and mesh portions 66, when deployed outwardly as shown in FIG. 8, form a basket shape which opens toward the proximal end of hollow guidewire 63.

FIG. 9 illustrates another system for attaching inflatable struts to a hollow guidewire for a distal protection device 70 in accordance with the present invention. Distal protection device 70 is similar to the distal protection devices shown in the previous figures in that a plurality of inflatable struts 72 are provided and preferably have a mesh portion extending therebetween. For the sake of clarity, the mesh portion is eliminated from FIG. 9. However, it will be understood that, when deployed, distal protection device 70 forms a generally basket-shaped filter assembly which opens toward the proximal end of hollow guidewire 74.

In the embodiment shown in FIG. 9, hollow guidewire 74 has a distal end 75 which is open. An endcap 76 is disposed about the distal end 75 of hollow guidewire 74 and defines an internal chamber or passageway 78. Endcap 76 has a proximal end 80 which has openings therein for receiving the ends of inflatable struts 72. Thus, in order to inflate

inflatable struts 72, the operator pressurizes fluid within the lumen of hollow guidewire 74 forcing fluid out through distal end 75 of hollow guidewire 74, through passageway 78, and into inflatable struts 72. In order to collapse distal protection device 70, the operator draws a vacuum which pulls the fluid back out of inflatable struts 72, through passageway 78 and, if necessary, into the lumen of hollow guidewire 74.

FIG. 10 is an end view of endcap 76 taken along lines 10-10 in FIG. 9. FIG. 10 shows that proximal end 80 of endcap 76 preferably includes a first generally central aperture 82 for receiving the distal end of hollow guidewire 74. Aperture 82 is sized just larger than, or approximating, the outer diameter of hollow guidewire 74 such that it fits snugly over the distal end 75 of hollow guidewire 74. Endcap 76 is then fixedly connected to the distal end 75 of hollow guidewire 74 through a friction fit, a suitable adhesive, welding, brazing, or another suitable connection technique.

FIG. 10 also shows that proximal end 80 of endcap 76 includes a plurality of apertures 84 which are spaced from one another about end 80. Apertures 84 are sized to receive open ends of inflatable struts 72. In the preferred embodiment, inflatable struts 72 are secured within apertures 84 using a suitable adhesive, or another suitable connection technique. Also, in the preferred embodiment, spring tip 16 is embedded in, or otherwise suitably connected to, endcap 76.

FIGS. 11A and 11B show two other preferred embodiments of a distal protection device in accordance with the present invention. FIG. 11A shows distal protection device 90 which includes hollow guidewire 92 having a lumen running therethrough, inflatable member

94 and mesh portion 96. FIG. 11A shows that inflatable member 94, when inflated, forms a ring about the outer surface of hollow guidewire 92. The ring has an inner periphery 98 which is spaced from the outer surface of hollow guidewire 92 substantially about the entire radial periphery of hollow guidewire 92. Mesh portion 96 extends between the outer surface of hollow guide 92 and the inner periphery 98 of inflatable member 94. Thus, a substantially disc-shaped filter assembly is provided upon deployment of distal protection device 90. As with the other embodiments, deployment of distal protection device 90 is accomplished by providing fluid through the inner lumen of hollow guidewire 92 into an interior of inflatable member 94 which is in fluid communication with the inner lumen of hollow guidewire 92.

In one preferred embodiment, end 100 of inflatable member 94 is coupled to a coupling portion 102 of inflatable member 94 such that stability is added to inflatable member 94, when it is inflated.

FIG. 11B illustrates another distal protection device 104 which includes a hollow guidewire 106 and an inflatable member 108. Device 104 is similar to distal protection device 90 except that, rather than having only a single inflatable ring upon deployment of distal protection device 104, a plurality of generally equal-diameter rings are formed into a helix shape. In the preferred embodiment, distal protection device 104 includes a mesh sleeve 110 which extends about the outer or inner surface of the helix formed by inflatable member 108. In one embodiment, mesh sleeve 110 is connected to the outer surface of hollow guidewire 106 in a region 112 proximate, but distal of, inflatable member 108. In another preferred embodiment, the

proximal end of mesh sleeve 110 is connected to the outer perimeter of inflatable member 108. Thus, distal protection device 104 forms a generally basket-shaped filter assembly which opens toward a proximal end of guidewire 106.

As with the other embodiments, both distal protection device 90 shown in FIG. 11A and distal protection device 104 shown in FIG. 11B are preferably collapsible. Therefore, when collapsed, the distal protection devices 90 and 104 preferably have an outer dimension which approximates the outer dimension of hollow guidewires 92 and 106, respectively. Further, as with the other embodiments, distal protection devices 90 and 104 can either be biased in the deployed or collapsed positions, and deployment and collapse can be obtained either by pulling a vacuum, or pressurizing the fluid within the lumen of the hollow guidewires 92 and 106.

FIG. 12 illustrates the use of a distal protection device in accordance with the present invention. For the sake of clarity, the present description proceeds with respect to distal protection device 10 only. Device 10 is shown filtering stenosis fragments from the blood flowing through the lumen of vessel 12. FIG. 12 also shows a dilatation device 120 which can be any suitable dilatation device for dilating, cutting, fragmenting, or abrading, portions of stenosis 26. In the preferred embodiment, device 120 is used in an over-the-wire fashion over hollow guidewire 14. Thus, filter assembly 18 is first advanced (using guidewire 14) distal of stenosis 26. Then, filter assembly 18 is deployed outwardly to the expanded position. Dilatation device 120 is then advanced over guidewire 14 to stenosis 26 and is used to fragment or

abrade stenosis 26. The fragments are received within the basket of filter assembly 18. Filter assembly 18 is then collapsed, and filter assembly 18 and dilatation device 120 are removed from vessel 12. Alternatively, dilatation device 120 can be removed first and filter assembly 18 is then removed along with guidewire 14.

It should be noted that the stenosis removal device (or atherectomy catheter) 120 used to fragment stenosis 26 can be advanced over guidewire 14. Therefore, the device according to the present invention is dual functioning in that it captures emboli and serves as a guidewire. The present invention does not require adding an additional device to the procedure. Instead, the present invention simply replaces a conventional guidewire with a multi-functional device.

FIGS. 13A-17B illustrate embodiments of various distal protection devices wherein deployment and contraction of the distal protection device is accomplished through a mechanical push/pull arrangement.

FIGS. 13A and 13B illustrate a distal protection device 122. FIG. 13A shows device 122 in an undeployed position and FIG. 13B shows device 122 in a deployed position. Distal protection device 122 includes a slotted Nitinol tube 124 which has a lumen 126 extending therethrough. Tube 124 has a plurality of slots 128 at a distal region thereof. The distal portion of slots 128 are covered by mesh 130 which, in the preferred embodiment, is a flexible microporous membrane. Device 122 also preferably includes a mandrel 132 which extends through the inner lumen 126 of tube 124 and is attached to the distal end of tube 124. In the preferred embodiment, mandrel 132 is attached to the distal end of tube 124 by an appropriate adhesive, brazing, welding, or another suitable connection

technique. Tube 124 also has, on its inner periphery in a proximal region thereof, a plurality of locking protrusions 134. Lock protrusions 134 are preferably arranged about a proximal expandable region 136 disposed on mandrel 132.

In order to deploy device 122 into the deployed position shown in FIG. 13B, the operator preferably first advances tube 124 distally of the lesion to be fragmented. In the preferred embodiment, tube 124 has a size on the order of a guidewire, such as a 0.014 inch outer diameter. Therefore, it easily advances beyond the stenosis to be fragmented. The operator then pushes on the proximal region of tube 124 and pulls on the proximal end of mandrel 132. This causes two things to happen. First, this causes the struts formed by slots 128 to expand radially outwardly, and carry with them, microporous membrane 130. Thus, microporous membrane 130 forms a generally basket-shaped filter assembly which opens toward the proximal end of tube 124. In addition, proximal expandable member 136 expands and engages protrusions 134. This locks device 122 in the deployed and expanded position. In order to move the device 122 to the collapsed position, the physician simply pushes on mandrel 132 and pulls on the proximal end of tube 124. This causes device 122 to return to the undeployed position shown in FIG. 13A.

It should be noted that device 122 can optionally be provided with a stainless steel proximal hypotube attachment. Also, the struts defined by slots 128 can be expanded and retracted using a fluid coupling instead of a mandrel. In other words, the proximal end of tube 124 can be coupled to a pressurizable fluid source. By making slots 128 very thin, and pressurizing the fluid, the struts expand outwardly. Further, by

pulling vacuum on the pressurizable fluid, the struts collapse.

FIG. 14A illustrates distal protection device 140 which is similar to that shown in FIGS. 13A and 13B, except that the struts 142 are formed of a metal or polymer material and are completely covered by mesh 144. Mesh 144 includes two mesh portions, 146 and 148. Mesh portion 146 is proximal of mesh portion 148 on device 140 and is a relatively loose mesh which will allow stenosis fragments to pass therethrough. By contrast, mesh 148 is a fairly tight mesh, or a microporous membrane, (or simply loose mesh portion 146 with a microporous membrane or other suitable filter material bonded or cast or otherwise disposed thereover) which does not allow the fragments to pass therethrough and therefore captures and retains the fragments therein. The mesh portions can provide a memory set which, in the relaxed position, is either deployed or collapsed.

FIG. 14B illustrates a device 150 which is similar to device 140 shown in FIG. 14A, except struts 142 are eliminated and the two mesh portions 146' and 148' are simply joined together at a region 152. Also, the two mesh portions 146' and 148' are not two different discrete mesh portions but are formed of the same braided mesh material wherein the braid simply has a different pitch. The wider pitch in region 146' provides a looser mesh, whereas the narrower pitch in region 148' provides a tighter mesh that traps the embolic material.

FIG. 14C illustrates a distal protection device 160 which is similar to that shown in FIG. 14A. However, rather than simply providing a slotted tube, distal protection device 160 includes a plurality of struts 162 on a proximal region thereof and a plurality

of struts 164 on the distal region thereof. Struts 162 are spaced further apart than struts 164 about the periphery of protection device 160. Therefore, struts 162 define openings 166 which are larger than the openings 168 defined by struts 164 and allow stenosis fragments to pass therethrough. Also, struts 164 have secured to the interior surface thereof a filter or mesh portion 170. When deployed, filter portion 170 forms a substantially basket-shaped filter device opening toward the proximal region of tube 172.

FIG. 15 illustrates the operation of another distal protection device 176. Distal protection device 176 includes a tube 178 and a push/pull wire 180. Tube 178 has, at the distal end thereof, a filter assembly 182. Filter assembly 182 includes a plurality of preferably metal struts 184 which have a microporous membrane, or other suitable mesh 186 disposed thereon. Tube 178 also preferably includes end cap 188 and umbrella-like expansion structure 190 disposed at a distal region thereof. Expansion structure 190 is connected to the distal region of tube 178 and to metal struts 184 such that, when push/pull wire 180 is pulled relative to tube 178, expansion member 190 exerts a radial, outwardly directed force on struts 184 causing them to expand radially outwardly relative to the outer surface of tube 178. This causes microporous membrane or mesh 186 to be deployed in a manner opening toward the proximal end of tube 178 to catch embolic material. Struts 184 can also be formed of an appropriate polymer material.

FIGS. 16A and 16B illustrate a protection device in accordance with another embodiment of the present invention. FIG. 16A illustrates distal protection device 192. Device 192 includes guidewire

194, actuator wire 196, and filter assembly 198. Filter assembly 198 includes an expandable ring 200, such as an expandable polymer or metal or other elastic material, which has attached thereto mesh 202. Mesh 202 is also attached to guidewire 194 distally of ring 200. Actuator wire 196 is attached to sleeve or sheath 204 which is positioned to fit about the outer periphery of expandable ring 200, when expandable ring 200 is in the collapsed position.

Thus, when sheath 204 is moved distally of expandable ring 200, expandable ring 200 has shape memory which causes it to expand into the position shown in FIG. 16A. Alternatively, when sheath 204 is pulled proximally by pulling actuator wire 196 relative to guidewire 194, sheath 204 collapses ring 200 and holds ring 200 in the collapsed position within sheath 204. Manipulating wires 194 and 196 relative to one another causes device 192 to move from the deployed position to the collapsed position, and vice versa.

FIG. 16B is similar to device 192 except that, instead of having an expandable ring 200 connected at one point to wire 194, distal protection device 206 includes expandable member 208 which is formed of an elastic coil section of wire 194. Thus, elastic coil section 208 has a shape memory which causes it to expand into the generally helical, conical shape shown in FIG. 16B. However, when sheath 204 is pulled proximally relative to expandable member 208, this causes sheath 204 to capture and retain expandable member 208 in a collapsed position. When sheath 204 is again moved distally of expandable member 208, expandable member 208 returns to its expanded position shown in FIG. 16B carrying with it mesh 210 into a deployed position. In the preferred embodiment, sheath 204 is formed of a

suitable polymer material and expandable member 208 and expandable ring 200 are preferably formed of Nitinol.

FIGS. 17A and 17B illustrate the operation of another distal protection device 212. Protection device 212 includes guidewire 214 and filter assembly 216. In the preferred embodiment, filter assembly 216 includes a wire braid portion 218 which extends from a distal region of guidewire 214 proximally thereof. Braid portion 218 is formed of braided filaments or fibers which have a shape memory causing them to form a deployed, basket-shaped filter, such as that shown in FIG. 17A, in the unbiased position. Braided portion 218 terminates at its proximal end in a plurality of eyelets 220. One or more cinch wires 222 are preferably threaded through eyelets 220. By pushing on guidewire 214 and pulling on cinch wires 222, the operator is able to cinch closed, and pull proximally, the proximal portion of mesh 218. This causes mesh 218 to collapse tightly about the outer surface of wire 214.

Therefore, during operation, the operator holds mesh 218 in the collapsed position and inserts protection device 212 distally of the desired stenosis. The operator then allows cinch wire 222 to move distally relative to guidewire 214. This allows mesh 218 to open to the deployed position shown in FIG. 17A which has an outer diameter that approximates the inner diameter of the lumen within which it is disposed. Filter assembly 216 is then disposed to capture embolic material from blood flowing therethrough. Once the embolic material is captured, the operator again moves cinch wire 222 proximally relative to guidewire 214 to collapse filter assembly 216 and capture and retain the embolic material in filter assembly 216. The device 212 is then removed.

FIG. 17B shows distal protection device 212 except that in the embodiment shown in FIG. 17B, protection device 212 is not disposed distally of the stenosis, but rather proximally. This results, for example, in an application where the blood flow is proximal of the stenosis rather than distal. Further, in the embodiment shown in FIG. 17B, guidewire 214 is preferably hollow and the cinch wire 222 extends through the lumen therein. By pushing on guidewire 214, a force is exerted on mesh 218 in the distal direction. This causes cinch wire 222 to tightly close the distal opening in filter assembly 216 and to collapse mesh portion 218. By contrast, by allowing cinch wire 222 to move distal relative to hollow guidewire 214, mesh portion 218 expands and filter assembly 216 is deployed as shown in FIG. 17B.

FIGS. 18A and 18B illustrate a distal protection device 250 in accordance with another aspect of the present invention. Device 250 includes inner wire 252 and outer tube 254. In the preferred embodiment, inner wire 252 is a core wire and outer tube 254 has a lumen 256 therein large enough to accommodate longitudinal movement of inner wire 252 therein. Also, in the preferred embodiment, inner wire 252 has, coupled to its distal end 258, a spring tip 260.

Device 250 includes expandable mesh or braid portion 262. Expandable portion 262 has a proximal end 264 which is attached to the distal end 266 of tube 254. Also, expandable member 262 has a distal end 268 which is attached to the distal end 258 of inner wire 252.

Expandable member 262 is preferably a mesh or braided material which is coated with polyurethane. In one preferred embodiment, a distal portion of expandable member 262 has a tighter mesh than a proximal portion

thereof, or has a microporous membrane or other suitable filtering mechanism disposed thereover. In another preferred embodiment, expandable member 262 is simply formed of a tighter mesh or braided material which, itself, forms the filter. FIG. 18A illustrates device 250 in a collapsed, or insertion position wherein the outer diameter of mesh portion 262 closely approximates the outer diameters of either inner wire 252 or outer tube 254.

FIG. 18B illustrates device 250 in the deployed position in which expandable member 262 is radially expanded relative to the collapsed position shown in FIG. 18A. In order to deploy device 250, the outer tube 254 is moved distally with respect to inner wire 252 such that the distal ends 266 and 258 of wires 254 and 252 move longitudinally toward one another. Relative movement of ends 266 and 258 toward one another causes the mesh of expandable member 262 to buckle and fold radially outwardly. Thus, the outer diameter of expandable member 262 in the deployed position shown in FIG. 18B closely approximates the inner diameter of a vessel within which it is deployed.

FIG. 18C illustrates device 250 in a partially collapsed position. In FIG. 18C, the distal end 266 of outer tube 254 and the distal end 258 of inner wire 252 are moved even closer together than they are as shown in FIG. 18B. This causes expandable mesh portion 262 to fold over itself and form a rolling, proximally directed flap 270. As longitudinal movement of inner wire 252 proximally with respect to outer tube 254 continues, mesh portion 262 continues to fold over itself such that the rolling flap portion 270 has an outer radial diameter which continues to decrease. In other words, expandable mesh portion 262 continues to fold over

itself and to collapse over the outer periphery of outer tube 254.

FIG. 18D illustrates device 250 in a fully collapsed position in which it retains emboli captured therein. In FIG. 18D, the distal end 266 of outer tube 254 has been advanced as far distally as it can relative to the distal end 258 of inner wire 252. This causes expandable mesh portion 262 to fold all the way over on itself such that it lies against, and closely approximates the outer diameter of, outer tube 254. Device 250 thus captures any emboli filtered from the vessel within which it was deployed, and can be removed while retaining that embolic material.

FIG. 19 illustrates device 280 which depicts a further aspect in accordance with the present invention. Device 280 includes outer tube 282, core wire 284, transition tube 286, movable plunger 288, expandable member 290, fixed collar 292 and bias member 294.

In the preferred embodiment, tube 282 comprises a proximal hypotube which is coupled to a plunger that selectively provides fluid under pressure through an inflation lumen 296. Inner wire 284 is preferably a tapered core wire which terminates at its distal end in a spring coil tip 298 and which is coupled at its proximal end 300 to transition tube 286. Transition tube 286 is preferably an outer polymer sleeve either over hypotube 282, or simply disposed by itself and coupled to a hypotube 282. Transition tube 286 is capable of withstanding the inflation pressure provided by the fluid delivered through the inflation lumen 296.

Movable collar 288 is preferably slidably engageable with the interior surface of transition tube

286 and with the exterior surface of core wire 284, and is longitudinally movable relative thereto. Slidable collar 288 has, attached at its distal end, bias spring 294 which is preferably coiled about core wire 284 and extends to fixed collar 292. Fixed collar 292 is preferably fixedly attached to the exterior surface of a distal portion of core wire 284.

Expandable member 290 is preferably formed, at a proximal portion thereof, of either discrete struts, or another suitable frame (such as a loose mesh) which allows blood and embolic material to flow therethrough. The proximal end 302 of expandable member 290 is coupled to a distal region of movable collar 288. The distal portion of expandable member 290 is preferably formed of a filtering material which is suitable for allowing blood flow therethrough, but which will capture embolic material being carried by the blood.

In one preferred embodiment, spring 294 is biased to force collars 288 and 292 away from one another. Thus, as spring 294 urges collars 288 and 292 away from one another, collar 288 retracts within transition tube 286 pulling expandable member 290 into a collapsed position about core wire 284. However, in order to deploy collapsible member 290 as shown in FIG. 19, the operator preferably actuates a plunger (not shown) which delivers pressurized fluid through lumen 296. The pressurized fluid enters transition tube 286 and travels about the outer periphery of inner core wire 284, thus forcing movable collar 288 to move distally along core wire 284. This overcomes the spring force exerted by spring 294 thus causing collars 288 and 292 to move toward one another, relatively. This motion causes expandable member 290 to buckle and expand outwardly to the deployed position shown in FIG. 19.

Expandable member 290 is collapsed by releasing the pressure applied through lumen 296 (i.e., by causing the plunger to move proximally). This allows spring 294 to again urge collars 288 and 292 away from one another to collapse expandable member 290. In an alternative embodiment, the frame supporting expandable member 290 is imparted with a memory (such as a heat set, or a thermally responsive material which assumes a memory upon reaching a transition temperature) such that the resting state of the frame supporting expandable member 290 is in a collapsed position. This eliminates the need for spring 294. The expandable member 290, in that preferred embodiment, is expanded using the hydraulic pressure provided by the pressurized fluid introduced through lumen 296, and it is collapsed by simply allowing the memory in expandable member 290 to force fluid from transition tube 286 back through lumen 296.

FIGS. 20A and 20B illustrate another aspect in accordance with the present invention. A device 310 includes a mesh portion 312 supported by a frame 314. Expansion of frame 314 to the radially expanded position shown in FIG. 20A is driven by an expandable member, such as a balloon, 316 which is coupled to frame 314. Balloon 316 is coupled to a distal end of a distal hypotube 318, which is formed of a suitable material, such as nitinol. It should be noted that the distal tip of hypotube 318 includes a spring tip 320.

Distal hypotube 318 is shown coupled to a proximal hypotube 322 which has a tapered portion 324 therein. In the preferred embodiment, proximal hypotube 322 is formed of a suitable material, such as stainless steel. A plunger 326 is longitudinally movable within

the lumen of both proximal hypotube 322 and distal hypotube 318.

Frame 314, and consequently mesh portion 312, are deployed by the operator moving plunger 326 distally within the lumens of hypotubes 318 and 322. This causes pressurized fluid to enter balloon 316, thereby inflating balloon 316 and driving deployment of frame 314 and mesh 312. In order to collapse frame 314 and mesh 312, the operator preferably moves plunger 326 proximally within the lumens of tubes 318 and 322 to withdraw fluid from within balloon 316. Alternatively, mesh 312 or frame 314 can have a memory set which is either in the inflated or collapsed position such that the operator need only affirmatively move frame 314 and mesh 312 to either the deployed or collapsed position, whichever is opposite of the memory set.

In either case, it is desirable that the operator be able to lock plunger 326 in a single longitudinal position relative to hypotubes 318 and 322. Thus, device 310 includes a locking region 328.

FIG. 20B illustrates locking region 328 in greater detail. FIG. 20B illustrates that, in locking region 328, plunger 326 has a plurality of grooves 330 formed in the outer radial surface thereof. Also, in accordance with the present invention, FIG. 20B illustrates that one of hypotubes 318 or 322 has an inwardly projecting portion 332. In one preferred embodiment, inwardly projecting portion 332 includes an inwardly extending, deflectable, annular rim which extends inwardly from either hypotube 318 or 322. In another preferred embodiment, the inwardly projecting portion 332 includes a plurality of discrete fingers which extend inwardly from one of hypotubes 318 or 322

and which are angularly displaced about the interior periphery of the corresponding hypotube 318 or 322.

In operation, as the operator advances plunger 326 distally within the lumens of hypotubes 318 and 322, inwardly projecting portion 332 rides along the exterior periphery of plunger 326 until it encounters one of grooves 330. Then, inwardly projecting portion 332 snaps into the groove 330 to lock plunger 326 longitudinally relative to tubes 318 and 322.

It should be noted that, in the preferred embodiment, both inwardly projecting portions 332 and grooves 330 are formed such that, when gentle pressure is exerted by the operator on plunger 326 relative to hypotubes 318 and 322, projection portions 332 follow the contour of grooves 330 up and out of grooves 330 so that plunger 326 can again be freely moved within the lumens of hypotubes 318 and 322. Thus, the relative interaction between projecting portions 332 and grooves 330 provides a ratcheting type of operation wherein plunger 326 can be releasably locked into one of a plurality longitudinal positions relative hypotubes 318 and 322, since a plurality of grooves 330 are provided. Plunger 326 can be moved back and forth longitudinally within the lumens of hypotubes 318 and 322 in a ratcheting manner and can be locked into one of a plurality of relative longitudinal positions because there are a plurality of grooves 330 in the exterior of plunger 326. It should also be noted, however, that in another preferred embodiment, a plurality of sets of inwardly projecting portions 332 are provided along the inner longitudinal surface of hypotubes 318 and/or 322. In that case, only a single groove 330 needs to be formed in the exterior surface of plunger 326, and the same type of ratcheting locking operation is obtained.

In the preferred embodiment, at least the exterior of hypotubes 318 and 322, and preferably the exterior of plunger 326, are tapered. This allows device 310 to maintain increased flexibility. It should also be noted that, in the preferred embodiment, hypotubes 318 and 322 are preferably sized as conventional guidewires.

FIG. 21A illustrates a protection device in accordance with another embodiment of the present invention. FIG. 21A illustrates distal protection device 340. Device 340 is similar to devices 192 and 206 shown in FIGS. 16A and 16B. However, in the preferred embodiment, device 340 includes hoop-shaped frame 342, filter portion 344, and wire 346. Hoop-shaped frame 342 is preferably a self-expanding frame formed of a wire which includes a shape memory alloy. In a more preferred embodiment hoop-shaped frame 342 is formed of a nitinol wire having a diameter in a range of approximately 0.002 - 0.004 inches.

Filter portion 344 is preferably formed of a polyurethane material having holes therein such that blood flow can pass through filter 344, but emboli (of a desired size) cannot pass through filter 344 but are retained therein. In one preferred embodiment, filter material 344 is attached to hoop-shaped frame 342 with a suitable, commercially available adhesive. In another preferred embodiment, filter 344 has a proximal portion thereof folded over hoop-shaped frame 342, and the filter material is attached itself either with adhesive, by stitching, or by another suitable connection mechanism, in order to secure it about hoop-shaped frame 342. This connection is preferably formed by a suitable adhesive or other suitable connection mechanism.

Also, the distal end of filter 344 is preferably attached about the outer periphery of wire 346, proximate coil tip 348 on wire 346.

In one preferred configuration, filter 344 is approximately 15 mm in longitudinal length, and has a diameter at its mouth (defined by hoop-shaped frame 342) of a conventional size (such as 4.0 mm, 4.5 mm, 5 mm, 5.5 mm, or 6 mm). Of course, any other suitable size can be used as well.

Also, in the preferred configuration, filter 344 is formed of a polyurethane material with the holes laser drilled therein. The holes are preferably approximately 100 μm in diameter. Of course, filter 344 can also be a microporous membrane, a wire or polymer braid or mesh, or any other suitable configuration.

Wire 346 is preferably a conventional stainless-steel guidewire having conventional guidewire dimensions. For instance, in one embodiment, wire 346 is a solid core wire having an outer diameter of approximately 0.014 inches and an overall length of up to 300 cm. Also, in the preferred embodiment, wire 346 has a distal end 350, in a region proximate filter 344, which tapers from an outer diameter at its proximal end which is the same as the outer diameter of the remainder of wire 346, to an outer diameter of approximately 0.055 inches at its distal end. At distal region 350, guidewire 346 is preferably formed of stainless steel 304.

Of course, other suitable guidewire dimensions and configurations can also be used. For example guidewires having an outer diameter of approximately 0.018 inches may also be used. For other coronary applications, different dimensions may also be used, such as outer diameters of approximately 0.010 inches to

0.014 inches. Further, it will be appreciated that the particular size of wire 346 will vary with application. Applications involving neural vasculature will require the use of a smaller guidewire, while other applications will require the use of a larger guidewire. Also, wire 346 can be replaced by a hollow guidewire, or hypotube of similar, or other suitable dimensions.

In addition, in order to make wire 342, hoop 346, or filter 344 radiopaque, other materials can be used. For example, radiopaque loaded powder can be used to form a polyurethane sheath which is fitted over wire 346 or hoop 342, or which is implemented in filter 344. Also, hoop 342 and wire 346 can be gold plated in order to increase radiopacity. Also, marker bands can be used on wire 346 or filter 344 to increase the radiopacity of the device.

In operation, hoop 342 (and thus filter 344) is preferably collapsed to a radially contracted position which more closely approximates the outer diameter of wire 346. Methods of performing this contraction are described later in the specification. Once retracted to a more low profile position, wire 346 is manipulated to position hoop 342 and filter 344 distal of a restriction to be treated. Then, the restraining force which is used to restrain hoop 342 in the predeployment, low profile position is removed, and the superelastic properties of nitinol hoop 342 (or the shape memory properties of another shape memory alloy) are utilized in allowing hoop 342 to assume its shape memory position. This causes hoop 342 to define a substantially lumen filling mouth to filter 344 which is positioned distal of the restriction to be treated.

A suitable dilatation device is then advanced over wire 346 and is used to treat the vascular

restriction. Emboli which are carried by blood flow distal of the restriction are captured by filter 344. After the dilatation procedure, filter 344, along with the emboli retained therein, are retrieved from the vasculature. Various retrieval procedures and devices are described later in the specification.

By allowing hoop-shaped frame 342 to be unattached to wire 346, and only connected to wire 346 through filter 344 (or other super structure used to support filter 344), wire 346 is allowed to substantially float within hoop 342. This configuration provides some advantages. For instance, hoop 342 can better follow the vasculature without kinking or prolapsing (i.e., without collapsing upon itself). Thus, certain positioning or repositioning of filter 344 can be accomplished with less difficulty.

FIG. 21B illustrates a protection device 352 in accordance with another embodiment of the present invention. Protection device 352 is similar to protection device 340, and similar items are similarly numbered. However, rather than having simply a hoop-shaped frame 342 to support filter 344, and drive filter 344 into its expanded and deployed position, device 352 includes frame 354 which includes a hoop-shaped portion 356, and a pair of tails 358 and 360.

Tails 358 and 360 extend proximally from hoop-shaped portion 356 to an attachment region 362. In the preferred embodiment, tails 358 and 360 are attached to wire 346 at attachment region 362 by soldering, welding, brazing, adhesive, or any other suitable attachment mechanism. In the embodiment shown in FIG. 21B, attachment sleeve 364, formed of a weldable material, is attached at its inner periphery to tails 358 and 360.

Sleeve 364 is then attached, using welding or brazing, to wire 346.

By providing tails 358 and 360, frame 354 is directly connected to wire 346. However, tails 358 and 360 are provided so that the point of attachment of frame 354 to wire 346 is located several millimeters proximal of hoop-shaped portion 356. This provides some additional structural integrity to frame 354, but still allows frame 354 to substantially float about wire 346 in the region of hoop-shaped frame portion 356.

FIG. 21C illustrates a protection device 366 in accordance with another embodiment of the present invention. Protection device 366 is similar to protection devices 340 and 352 shown in FIGS. 21A and 21B, and similar items are similarly numbered. However, device 366 includes hoop-shaped frame 368. Frame 368 is similar to frame 342 shown in FIG. 21A. However, unlike frame 342, hoop 368 does not allow wire 346 to float freely therein. Instead, hoop 368 is directly attached to wire 346 at attachment point 370. This causes hoop-shaped frame 368 and filter 344 to reside eccentrically about wire 346.

FIGS. 22A-22C illustrate one preferred embodiment for delivering one of devices 340, 352 and 366. For the sake of clarity, only device 352 is illustrated in FIGS. 22A-22C.

FIG. 22A illustrates delivery device 372. In the preferred embodiment, delivery device 372 includes proximal hub 374, shaft 376, and distal retaining section 378. Also, in one preferred embodiment, device 372 also includes marker band 380. In the preferred embodiment, delivery device 372 is similar to a conventional balloon catheter in that proximal hub 374 is a conventional hub, and shaft 376 is a conventional

balloon catheter shaft. Further, distal retaining section 378 is preferably a conventional angioplasty balloon having an inflated diameter of approximately 1.5 - 2.0 millimeters, but having its distal end cutoff such that the distal end 382 of balloon 378 is open.

Prior to insertion of device 372 into the vasculature, hoop-shaped frame 354 is retracted into its low profile deployment position and is withdrawn through end 382 into balloon 378. Then, the distal end of balloon 378 is exposed to heat to heat shrink or heat set the distal end of balloon 378 around the radially retracted device 352. Device 372, including device 352, is then inserted in the vasculature either through a preplaced guide catheter, along with a guide catheter, or simply without a guide catheter utilizing coil tip 348.

In any case, once device 372 is properly placed such that balloon 378 is located distal of the restriction to be treated, distal protection device 352 is then removed from within heat collapsed balloon 378. In one preferred embodiment, the physician simply accomplishes longitudinal movement of wire 346 relative to catheter 376. For instance, the physician may simply hold wire 346 longitudinally in place and withdraw catheter 376 proximally relative to wire 346 by pulling on hub 374. This causes balloon 378 to move proximally relative to device 352, and thereby to expose device 352 to the vasculature.

FIG. 22B illustrates another preferred embodiment for removing device 352 from within balloon 378. In the embodiment shown in FIG. 22B, syringe 384, which contains fluid, is inserted into coupling 386 in hub 374. The physician then introduces pressurized fluid into the lumen of catheter 376. The pressurized

fluid advances down the lumen of catheter 376 to the distal end where it encounters collapsed balloon 378. The pressure exerted on balloon 378 by the pressurized fluid causes balloon 378 to open radially. Then, the physician withdraws catheter 376 relative to device 352 thereby exposing device 352 to the vasculature.

In any case, once device 352 is no longer restrained by balloon 378, device 352 assumes its shape memory position in the vasculature, as illustrated in FIG. 22C. Thus, device 352 substantially forms a lumen-filling basket or filter which allows blood to pass distally therethrough, but which retains or captures embolic material carried by the blood flow. The physician then simply removes device 372 from the vasculature, leaving device 352 in place during subsequent procedures. In one preferred embodiment, shaft 376 includes a predefined slit or score from a region just proximal of marker band 380 to, or through, hub 374. Thus, as the physician removes device 372, it can be peeled away from device 352. Also, or alternatively, device 372 can be provided with an aperture in shaft 376 near its distal end. The proximal end of wire 346 will thus lie outside of shaft 376. Wire 346 can enter shaft 376 through the aperture and extend through the distal end of shaft 376. This also facilitates easier withdrawal of device 372 over wire 346.

FIGS. 23A-23E illustrate one preferred embodiment for retrieving one of the devices 340, 352 and 366 described in FIGS. 21A-21C. For the sake of clarity, only device 352 is illustrated in FIGS. 23A-23E. FIG. 23A illustrates retrieval device 388. Retrieval device 388 is preferably formed of proximal shaft 390, mesh portion 392, and end cap 394. Items

390, 392 and 394 preferably each have lumens therein to define a passageway for receiving wire 346. Also, wire 346 may optionally be provided with an positive stop 396 (which can be embodied as a radiopaque marker band). Optional stop 396 may also simply be an annular ring attached to wire 346 proximate to filter 344, or may be any other suitable stop.

Proximal shaft 390 is preferably simply a polymer or nitinol tube sized and configured to track over wire 346. End cap 394 is also preferably formed to track over wire 346, but also contains radiopaque material to serve as a distal marker band for retrieval device 388. Mesh 392 is preferably a braid or mesh formed of wire or polymer material having sufficient flexibility that it can be deflected as described below.

Mesh 392 preferably has a proximal end coupled to proximal shaft 390, by adhesive, welding, or other suitable attachment mechanisms. Mesh 392 also preferably includes a distal end connected to end cap 394, also by a suitable connection mechanism.

In order to retrieve filter 344, which likely contains embolic material, device 388 is inserted in the low profile position shown in FIG. 23A, over wire 346, to a position proximate filter 344. Then, device 388 is advanced toward filter 344, until end cap 394 abuts positive stop 396, or the hoop-shaped frame 354. Continued advancement of proximal shaft 390 relative to wire 346 causes compression of mesh 392. This results in a radial expansion of an intermediate portion of mesh 392 (between the proximal and distal ends of mesh 392). The radial expansion of mesh portion 392 is illustrated in FIG. 23B.

By continuing to advance proximal shaft 390 relative to wire 346, the intermediate portion of mesh

392 is configured to bend over on itself such that it is axially displaced toward filter 344, in the direction generally indicated by arrows 398 in FIG. 23C. In the preferred embodiment, mesh 392 is sized and configured such that, with continued advancement of proximal shaft 390 relative to wire 346, this action continues as shown in FIGS. 23D and 23E until the intermediate portion of mesh 392 encompasses at least the mouth of filter 344. Also, in the preferred embodiment, the intermediate portion of mesh 392, when driven as described above, engages and contracts the mouth of filter 344 to a lower profile position, such as that shown in FIG. 23E. In yet another preferred embodiment, mesh 392 is sized and configured to substantially engulf the entire filter 344.

Once at least the mouth of filter 344 is encompassed by mesh 392, device 388, along with device 352, are simply withdrawn from the vasculature. In one preferred embodiment in which a guide catheter is used, devices 388 and 352 are simply withdrawn either into the guide catheter and the guide catheter is removed with those devices, simultaneously, or devices 388 and 352 are removed from the guide catheter prior to removal of the guide catheter. In another preferred embodiment, in which no guide catheter is used, devices 388 and 352 are simply removed from the vasculature simultaneously.

It will also be appreciated, of course, that rather than providing device 388 with a single proximal tube 390 and end cap 394, a second actuation tube or wire can also be provided which is attached to end cap 394, and which extends back through the lumen in proximal tube 390 and is longitudinally movable relative to proximal shaft 390. In that way, the actuation wire or elongate member can be used to pull cap 394 closer to

the distal portion of proximal shaft 390 in order to accomplish the action illustrated in FIGS. 23A-23E. This feature is also illustrated in FIGS. 18A-18D which illustrate the mesh portion folded proximally rather than distally.

FIGS. 24A-24C illustrate another preferred embodiment in accordance with the present invention, for retrieving any of the distal protection devices 340, 352 or 366 shown in FIGS. 21A-21C. For the sake of clarity, only device 352 is illustrated in FIGS. 24A-24C.

FIG. 24A illustrates retrieval device 400. Retrieval device 400 preferably includes retrieval sheath 402, proximal locking device 404, dilator sheath 405, and nose cone 406. In the preferred embodiment, retrieval sheath 402 is preferably formed of polyether block amide (PEBAX) material having an outer diameter of approximately six French (i.e., approximately 2 mm) and having a shore D hardness of approximately 40. Also, retrieval sheath 402 preferably has a wall thickness of approximately 0.004 inches. Dilator sheath 405, and nose cone 406, are preferably formed of low density polyethylene, or high density polyethylene. Sheath 405 preferably has an outer diameter which is approximately equal to the inner diameter of sheath 402. In addition, the inner diameter of sheath 405 and nose cone 406 is preferably just large enough to fit over, and track over, wire 346. Nose cone 406 preferably has a proximal portion which is either attached to, or formed integrally with, sheath 405. The outer diameter of the proximal portion of nose cone 406 is also approximately the same as the outer diameter of sheath 405. However, nose cone 406 also preferably has a distal portion which tapers, or reduces along preferably a smooth curve, to

an outer diameter which terminates at the inner diameter of nose cone 406.

Proximal locking device 404 is preferably any suitable, and commercially available, locking device which can be configured to lock dilator sheath 405 to guidewire 346.

In order to retrieve device 352 from the vasculature, device 400 is preferably advanced over guidewire 346 to a position shown in FIG. 24B, in which the distal portion of nose cone 406 is closely proximate, or adjacent to, either optional stop 396 or the mouth of filter 344. Then, proximal locking device 404 is actuated to lock dilator sheath 405 to wire 346 so that wire 346 and dilator sheath 405 (as well as nose cone 406) can be moved as a unitary piece.

Next, wire 346 (and hence dilator sheath 405 and nose cone 406) are withdrawn longitudinally relative to retrieval sheath 402. This causes the mouth of filter 344 to enter within the distal opening in retrieval sheath 402. This results in device 352 being positioned relative to sheath 402 as shown in FIG. 24C. Of course, wire 346, dilator sheath 405 and nose cone 406 can be withdrawn further into sheath 402 such that the entire filter 344, and wire tip 348, are disposed within the lumen of sheath 402.

In any case, once at least the mouth of filter 344 is within sheath 402, device 352 is configured to be removed from the vasculature. This can be accomplished by either removing dilator sheath 405, nose cone 406 and device 352 as a unitary piece, leaving sheath 402 in place for later removal, or by removing sheath 402 with the remainder of the system, either through a guide catheter or simply through the vasculature, simultaneously. Also, where a guide catheter is used,

device 352 and device 400 can be removed through the guide catheter leaving the guide catheter in place, or the guide catheter can be removed simultaneously with the other devices 352 and 400.

It should be noted that all of the devices according to the present invention can optionally be coated with an antithrombotic material, such as heparin (commercially available under the tradename Duraflow from Baxter), to inhibit clotting.

Thus, in accordance with one preferred embodiment of the present invention, the superelastic properties of nitinol are used to form a frame at least in the area of the mouth of the distal protection filter. Thus, the distal protection device can be deployed, retrieved, and re-deployed any number of times without incurring plastic deformation. In addition, in other preferred embodiments in accordance with the present invention, various deployment and retrieval techniques and systems are provided which address various problems associated with such systems.

Although the present invention has been described with reference to preferred embodiments, workers skilled in the art will recognize that changes may be made in form and detail without departing from the spirit and scope of the invention.

WHAT IS CLAIMED IS:

1. An emboli capturing system for capturing emboli in a body lumen, comprising:

a first elongate member having a proximal end and a distal end;

an expandable emboli capturing device mounted proximate the distal end of the first elongate member, the emboli capturing device being movable between a radially expanded position and a radially retracted position, the expandable emboli capturing device forming a basket with a proximally opening mouth when in the radially expanded position;

a second elongate member having a proximal end and a distal end and a lumen extending between the proximal and distal ends,the lumen being sized to slidably receive a portion of the first elongate member therein; and

an expandable delivery device mounted to the distal end of the second elongate member and being movable from a radially retracted position to a radially expanded position, the delivery device having a receiving end configured to receive the emboli capturing device, the delivery device retaining at least the mouth of the emboli capturing device in the radially retracted position when the delivery device is in the radially retracted position, the emboli capturing device being longitudinally movable out from within the delivery device when the

delivery device is in the radially expanded position.

2. The emboli capturing system of claim 1 and further comprising:

a retrieval device, configured to be longitudinally movable relative to the emboli capturing device in the body lumen and having a receiving end configured to receive at least the mouth of the emboli capturing device when the emboli capturing device is in the radially expanded position.

3. The emboli capturing system of claim 2 wherein the retrieval device comprises the expandable delivery device in the radially expanded position.

4. The emboli capturing system of claim 2 wherein the receiving end of the retrieval device is contractible from a radially expanded position to a radially contracted position to at least partially collapse the emboli capturing device therein.

5. The emboli capturing system of claim 4 wherein the retrieval device comprises:

a third elongate member having proximal and distal ends and a lumen extending therebetween, the lumen being sized to slidably receive at least a portion of the first elongate member therein, the lumen at the distal end of the third elongate member forming the receiving end and being sized to receive a most radially expanded portion of the emboli capturing device; and

a fourth elongate member movable within the lumen of the third elongate member, the

fourth elongate member having an intermediate region sized to substantially fill the receiving end and a distal tip having an outer diameter less than an outer diameter of the intermediate region.

6. The emboli capturing system of claim 5 wherein the distal tip of the fourth elongate member is configured with an aperture therein sized to track over the first elongate member.

7. The emboli capturing system of claim 6 wherein the fourth elongate member is formed in a substantially conical shape between the distal tip thereof and the intermediate region thereof.

8. The emboli capturing system of claim 2 wherein the retrieval device includes:

a third elongate member having proximal and distal ends and a lumen extending therebetween, the lumen being sized to slidably receive at least a portion of the first elongate member; and

a mesh sleeve having a first end coupled to the third elongate member, a second end distal of the first end and an intermediate portion between the first and second ends, the mesh sleeve being configured such that relative longitudinal movement of one of the first and second ends thereof relative to another of the first and second ends thereof drives movement of the mesh portion from a radially retracted position, to a radially expanded position in which the intermediate

portion expands radially outward relative to the first and second ends, and to a collapsed position in which the mesh sleeve bends such that the intermediate portion is displaced in a direction toward one of the first and second ends of the mesh sleeve.

9. The emboli capturing system of claim 8 wherein the retrieval device is configured such that sufficient longitudinal movement of the emboli capturing device toward the mesh sleeve causes the emboli capturing device to drive the second end of the mesh sleeve toward the first end of the mesh sleeve.

10. The emboli capturing system of claim 9 wherein the mesh sleeve is sized to encompass at least the mouth of the emboli capturing device as the mesh sleeve moves from the radially expanded position to the collapsed position.

11. The emboli capturing system of claim 2 wherein the retrieval device includes:

a third elongate member having proximal and distal ends and a lumen extending therebetween, the lumen being sized to slidably receive at least a portion of the first elongate member;

a fourth elongate member longitudinally movable relative to the third elongate member; and

a mesh sleeve having a first end coupled to the third elongate member and a second end coupled to the fourth elongate member and an intermediate portion between the first and second ends, the mesh sleeve being configured such that

relative longitudinal movement of one of the third and fourth elongate members relative to another of the third and fourth elongate members drives movement of the mesh portion from a radially retracted position, to a radially expanded position in which the intermediate portion expands radially outward relative to the first and second ends, and to a collapsed position in which the mesh sleeve bends such that the intermediate portion is displaced in a direction toward one of the first and second ends of the mesh sleeve.

12. The emboli capturing system of claim 1 wherein the receiving end of the delivery device is defined by a portion of a dilatation balloon.

13. The emboli capturing system of claim 1 wherein the receiving end of the delivery device is thermally shrunk over at least the mouth of the emboli capturing device to retain the emboli capturing device in the radially contracted position during delivery.

14. The emboli capturing system of claim 1 wherein the receiving end of the delivery device is movable from the radially retracted position to the radially expanded position by delivery of pressurized fluid through the lumen in the second elongate member.

15. The emboli capturing system of claim 1 wherein the emboli capturing device is a self-expanding device biased in the radially expanded position.

16. The emboli capturing system of claim 15 wherein the emboli capturing device includes:

a frame formed of a shape memory alloy; and

a filter portion supported by the frame, the filter portion being configured to permit blood flow therethrough and to capture emboli carried by blood flow therethrough.

17. The emboli capturing system of claim 16 wherein the filter portion has a first end connected to the first elongate member and a second end connected to the frame and wherein the frame comprises:

a loop disposed about the first elongate member to define the mouth of the emboli capturing device.

18. The emboli capturing system of claim 17 wherein the loop is directly connected to the first elongate member.

19. The emboli capturing system of claim 17 wherein the shape memory alloy comprises an alloy having superelastic properties.

20. The emboli capturing system of claim 19 wherein the shape memory alloy includes nitinol.

21. The emboli capturing system of claim 20 wherein the emboli capturing device is substantially conical in shape.

22. The emboli capturing system of claim 21 wherein the filter portion comprises a polyurethane member having a plurality of holes therein.

23. The emboli capturing system of claim 1 wherein the first elongate member comprises a guidewire.

24. A method of capturing emboli carried by flow of fluid through a body lumen, the method comprising:

providing a first elongate member having a proximal end and a distal end;

providing an expandable emboli capturing device mounted proximate the distal end

of the first elongate member, the emboli capturing device being movable between a radially expanded position and a radially retracted position, the expandable emboli capturing device defining a proximally opening mouth when in the radially expanded position;

providing a second elongate member having a proximal end and a distal end and a lumen extending between the proximal and distal ends, the lumen being sized to slidably receive a portion of the first elongate member therein;

providing an expandable delivery device mounted to the distal end of the second elongate member and being movable from a radially retracted position to a radially expanded position, the delivery device having a receiving end configured to receive the emboli capturing device, the delivery device retaining at least the mouth of the emboli capturing device in the radially retracted position when the delivery device is in the radially retracted position;

inserting the expandable delivery device into the lumen with the mouth of the emboli capturing device retained in the radially retracted position within the delivery device;

expanding the expandable delivery device into the radially expanded position; and

longitudinally moving the delivery device relative to the emboli capturing device

to remove the emboli capturing device from within the delivery device.

25. The method of claim 24 and further comprising:

providing a retrieval device, configured to be longitudinally movable relative to the emboli capturing device in the body lumen and having a receiving end configured to receive at least the mouth of the emboli capturing device when the emboli capturing device is in the radially expanded position; and

longitudinally moving the delivery device relative to the emboli capturing device such that at least the mouth of the emboli capturing device is in the receiving end of the retrieval device.

26. The method of claim 25 wherein the receiving end of the retrieval device is contractible from a radially expanded position to a radially contracted position, and further comprising:

contracting the receiving end of the retrieval device to at least partially collapse the emboli capturing device therein.

27. The method of claim 26 wherein providing a retrieval device comprises:

providing a third elongate member having proximal and distal ends and a lumen extending therebetween, the lumen being sized to slidably receive at least a portion of the first elongate member therein, the lumen at the distal end of the third elongate member forming the

receiving end and being sized to receive a most radially expanded portion of the emboli capturing device;

providing a fourth elongate member movable within the lumen of the third elongate member, the fourth elongate member having an intermediate region sized to substantially fill the receiving end and a distal tip having an outer diameter less than an outer diameter of the intermediate region;

advancing the third and fourth elongate members over the first elongate member, with the intermediate region of the fourth elongate member positioned within the third elongate member to fill the receiving end thereof, to a point proximate the emboli capturing device;

withdrawing the distal tip of the fourth elongate member within the lumen of the third elongate member; and

positioning at least the mouth of the emboli capturing device within the receiving end of the retrieval device.

28. The method of claim 27 and further comprising:

withdrawing the first, third, and fourth elongate members from the body lumen.

29. The method of claim 25 wherein providing the retrieval device includes:

providing a third elongate member having proximal and distal ends and a lumen extending therebetween, the lumen being sized to slidably receive at least a portion of the first elongate member;

providing a mesh sleeve having a first end coupled to the third elongate member, a second end distal of the first end and an intermediate portion between the first and second ends, the mesh sleeve being configured such that relative longitudinal movement of one of the first and second ends thereof relative to another of the first and second ends thereof drives movement of the mesh portion from a radially retracted position, to a radially expanded position in which the intermediate portion expands radially outward relative to the first and second ends, and to a collapsed position in which the mesh sleeve bends such that the intermediate portion is displaced in a direction toward one of the first and second ends of the mesh sleeve;

advancing the third elongate member into the body lumen over the first elongate member to a point proximate the mouth of the emboli capturing device; and

accomplishing relative longitudinal movement of the emboli capturing device and the mesh sleeve toward one another, driving the second end of the mesh sleeve toward the first end of the mesh sleeve such that the mesh sleeve encompasses at least the mouth of the emboli capturing device as the mesh sleeve moves from the radially expanded position to the collapsed position.

30. The method of claim 24 wherein expanding comprises:

delivering pressurized fluid through the lumen in the second elongate member.

SUBSTITUTE SHEET (rule 26)

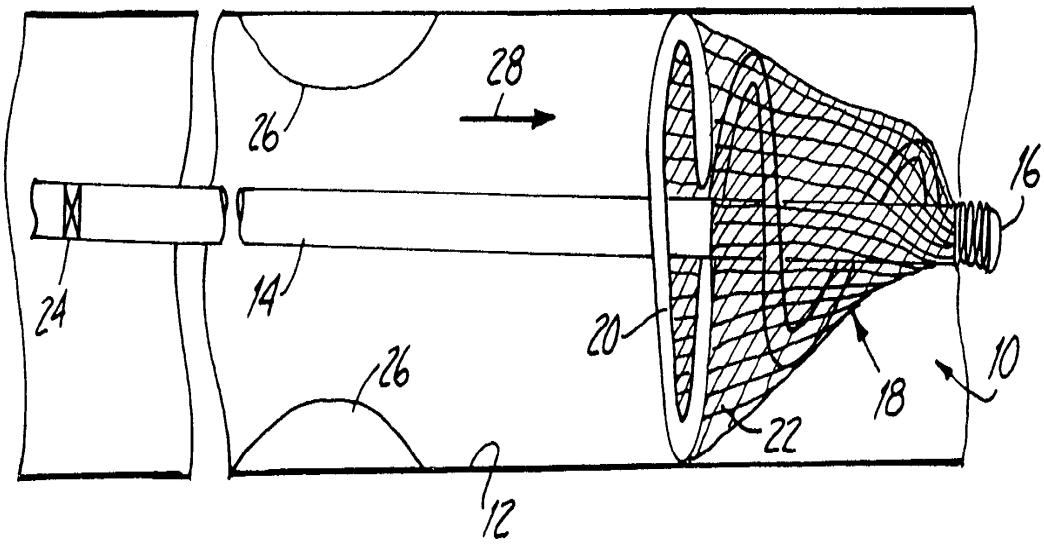


Fig.1

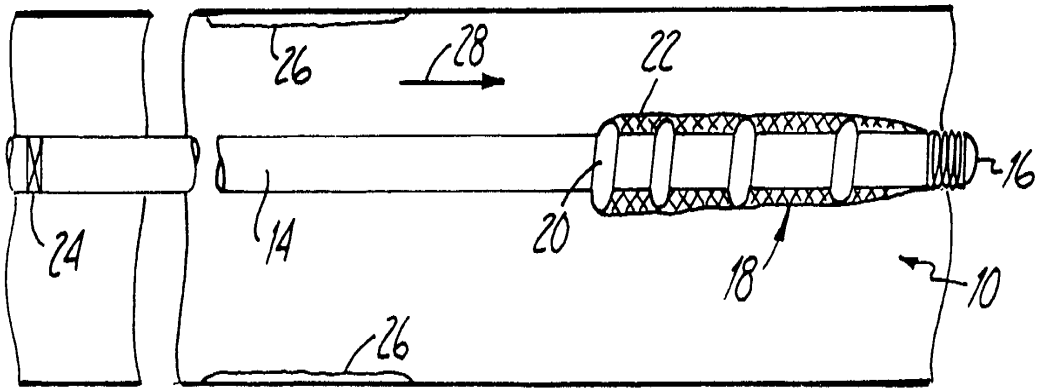


Fig.2

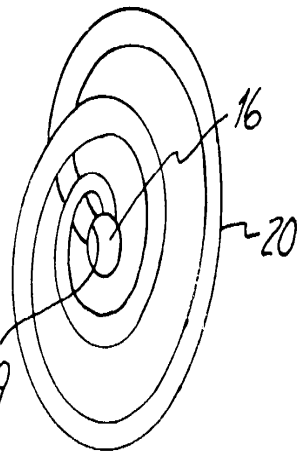


Fig.3

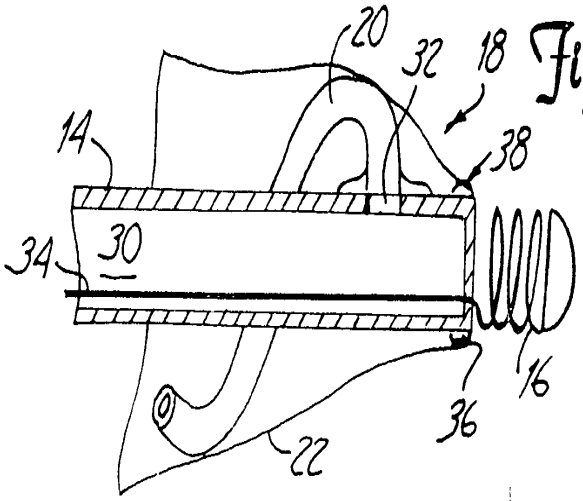


Fig.4

SUBSTITUTE SHEET (rule 26)

Fig.5

Fig.6

Fig.7

Fig.8

SUBSTITUTE SHEET (rule 26)

Fig. 9

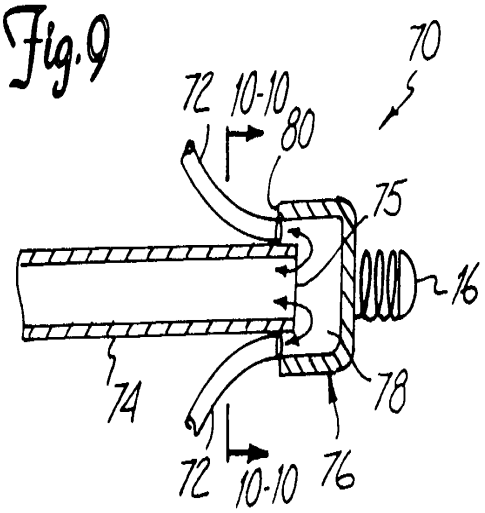
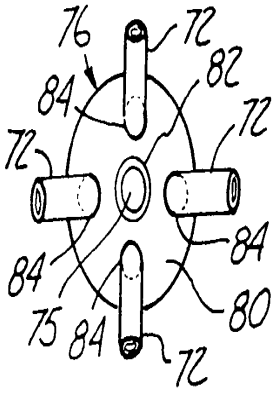


Fig. 10



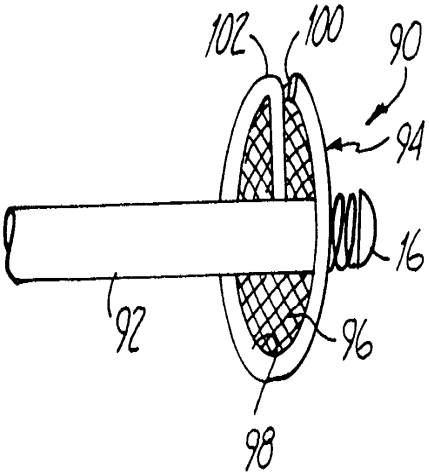


Fig. 11A

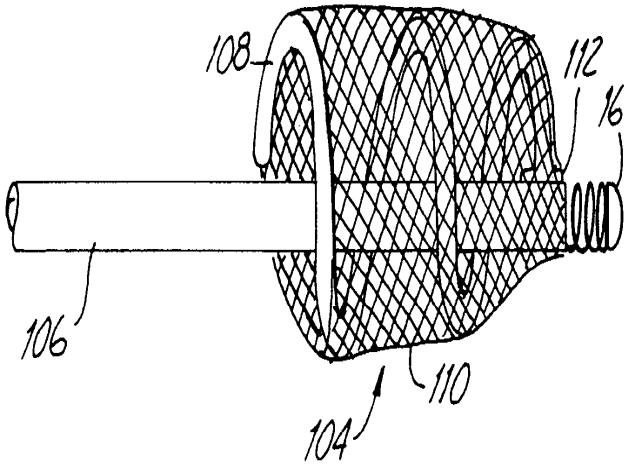


Fig. 11B

SUBSTITUTE SHEET (rule 26)

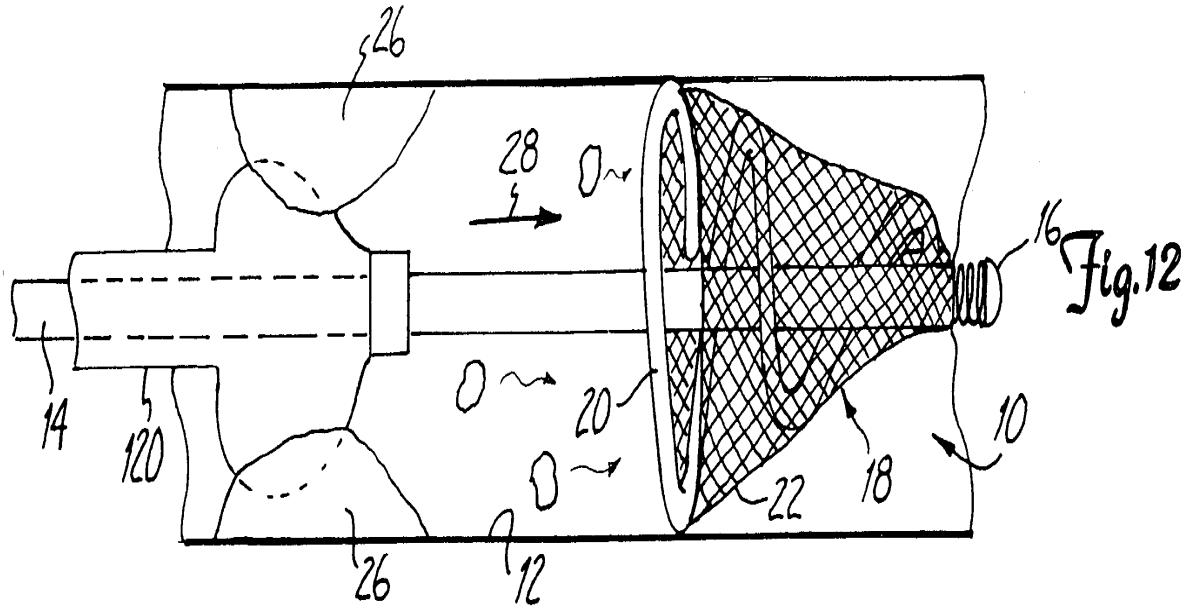


Fig.12

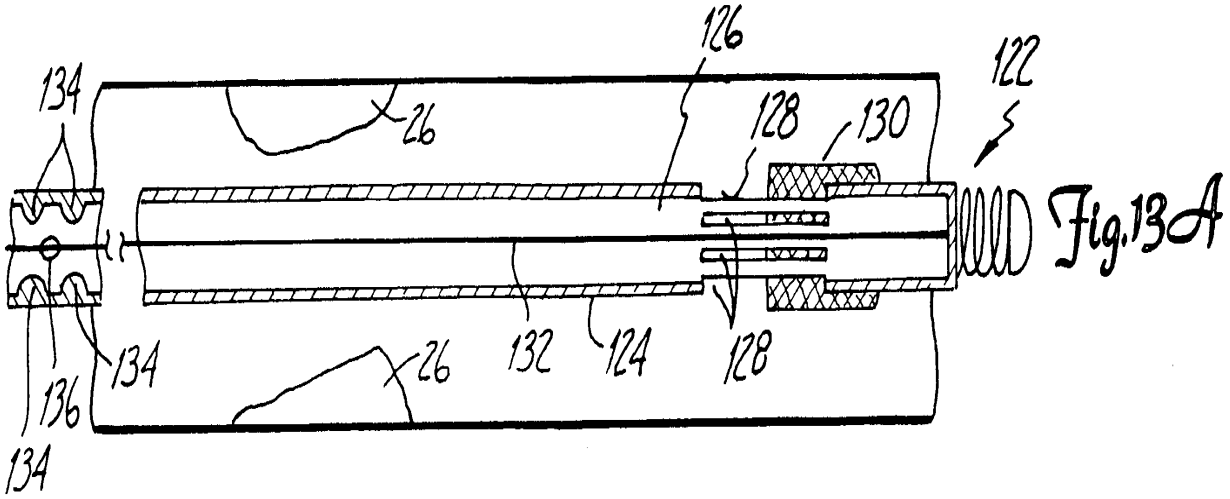


Fig.13A

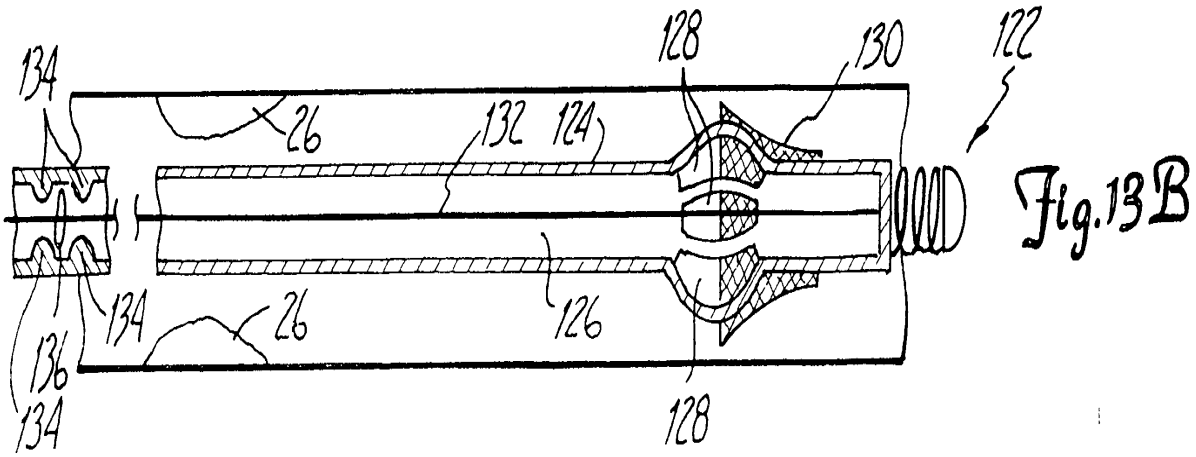


Fig.13B

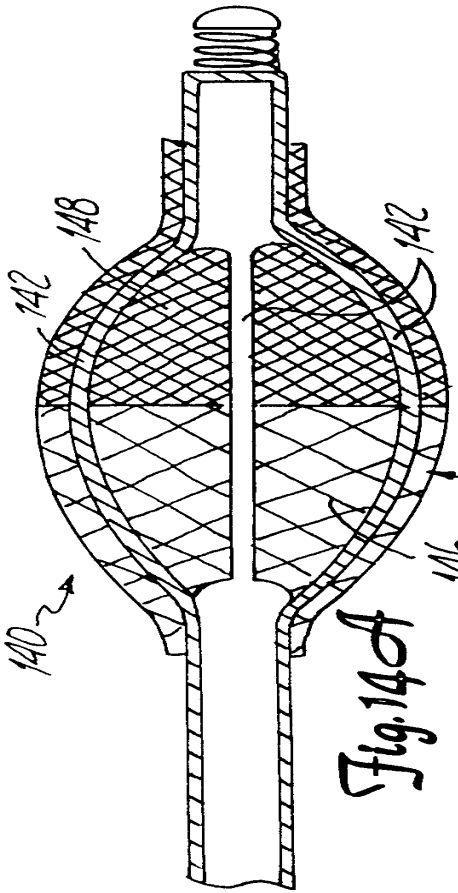


Fig. 14A

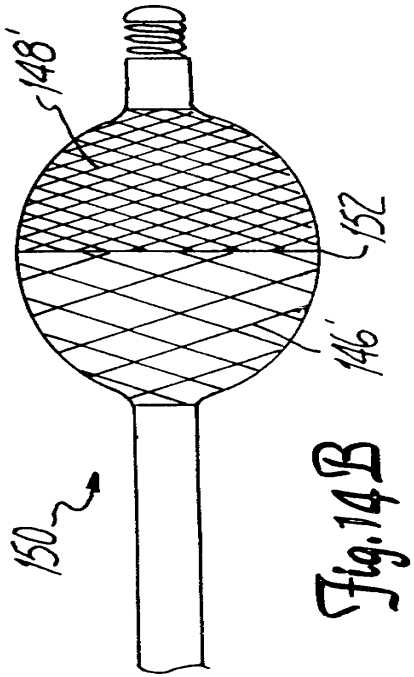


Fig. 14B

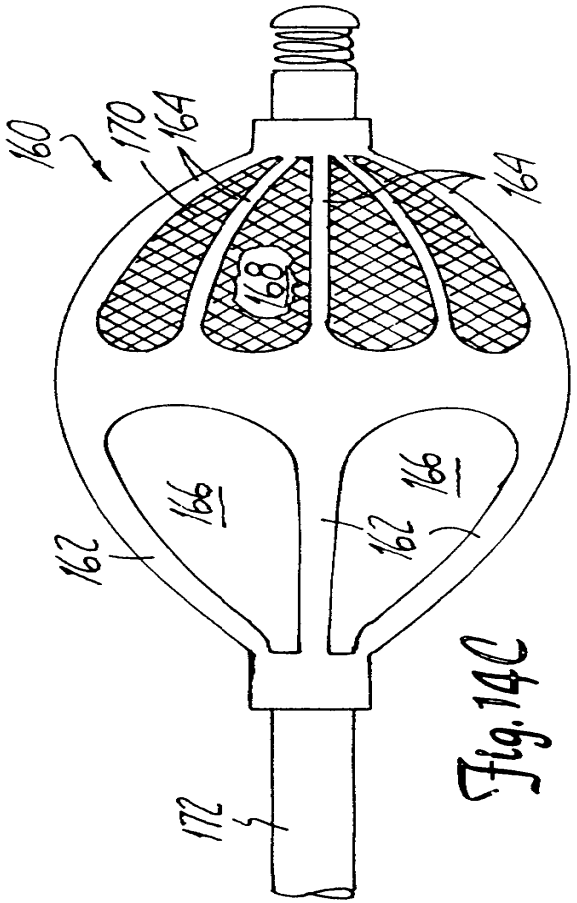


Fig. 14C

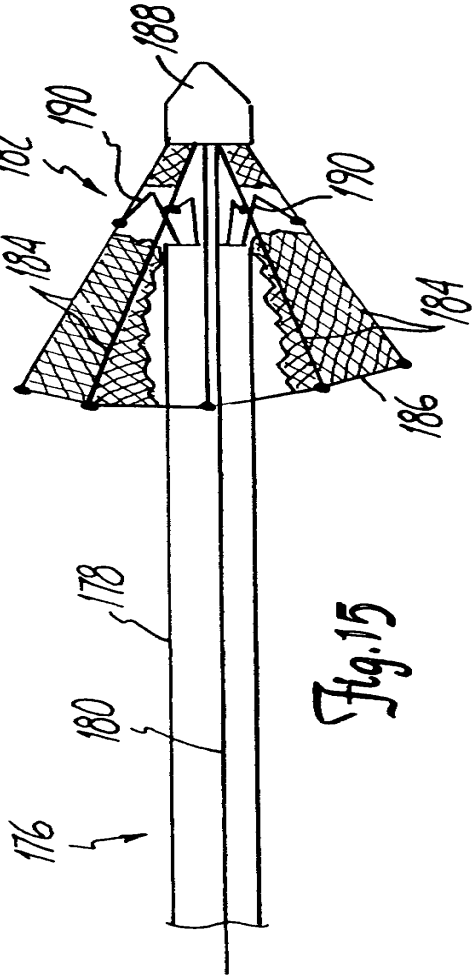


Fig. 15

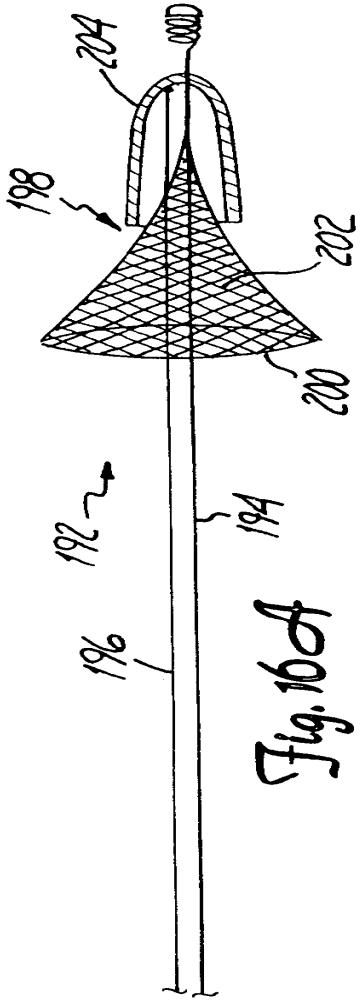


Fig. 16A

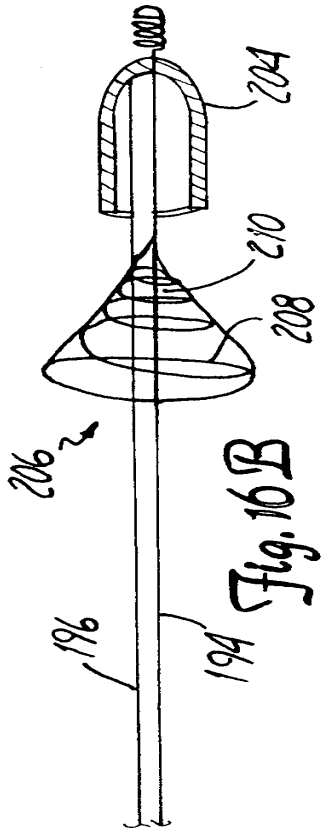


Fig. 16B

Page 1996 of 2754

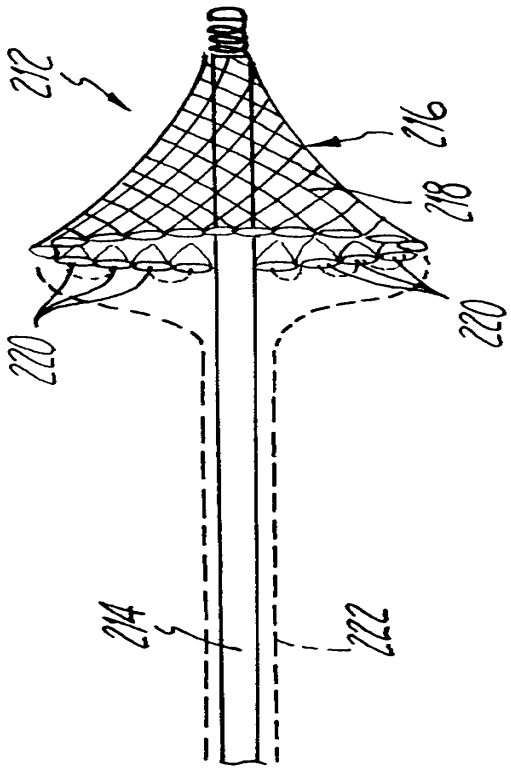


Fig. 17A

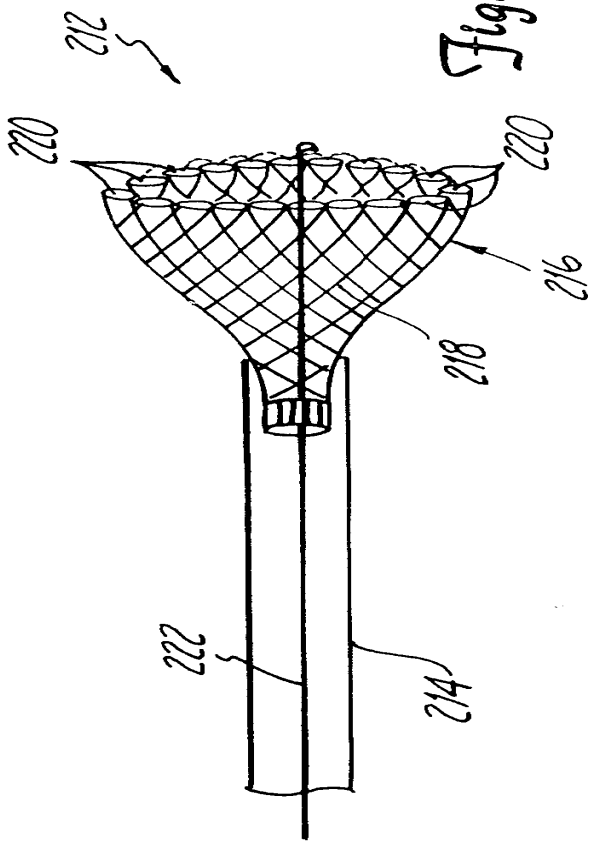


Fig. 17B

Page 1997 of 2754

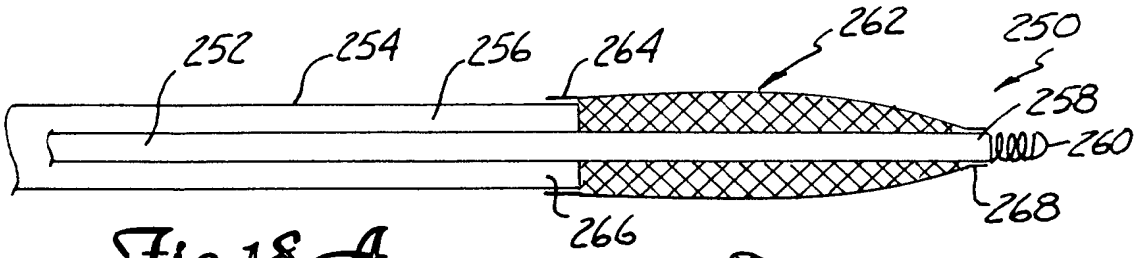


Fig. 18A

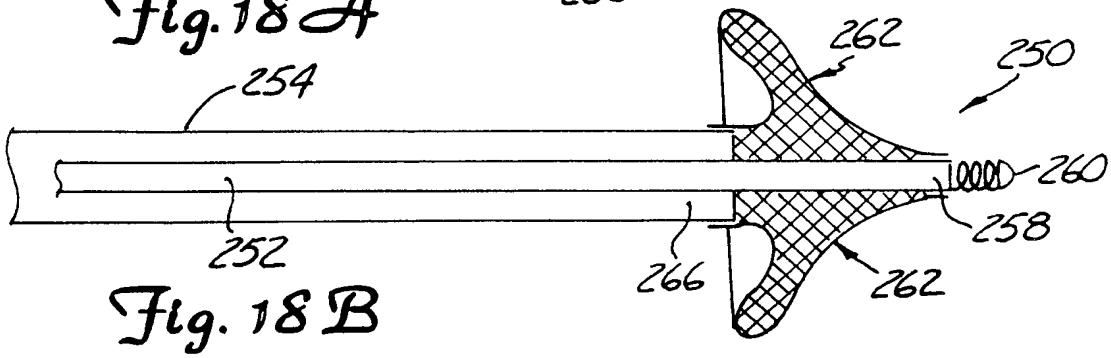


Fig. 18B

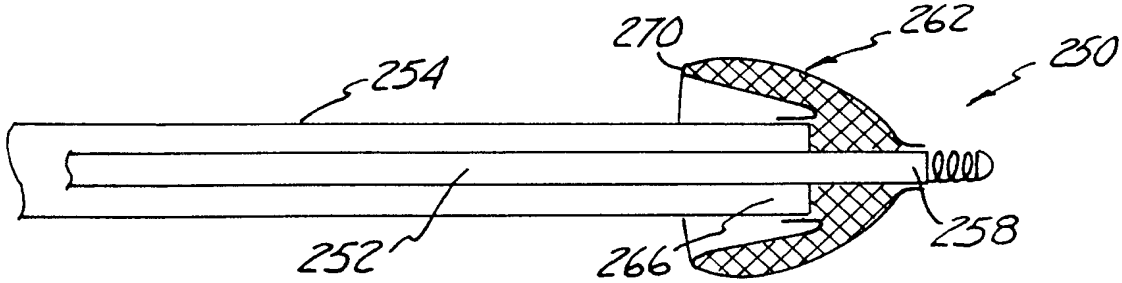


Fig. 18C

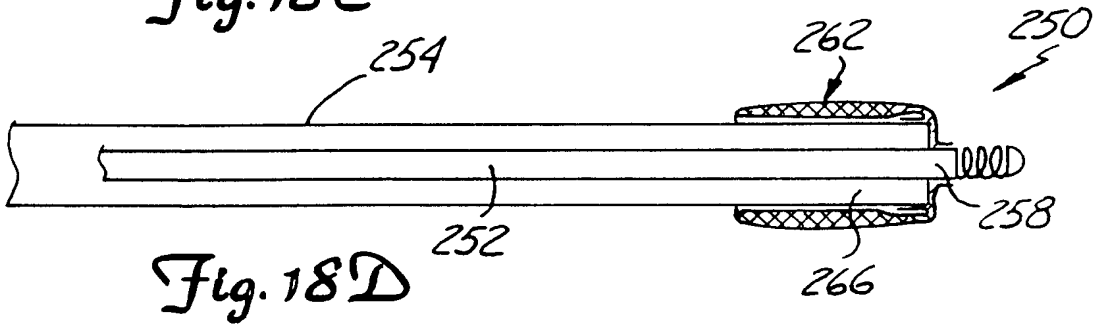


Fig. 18D

SUBSTITUTE SHEET (rule 26)

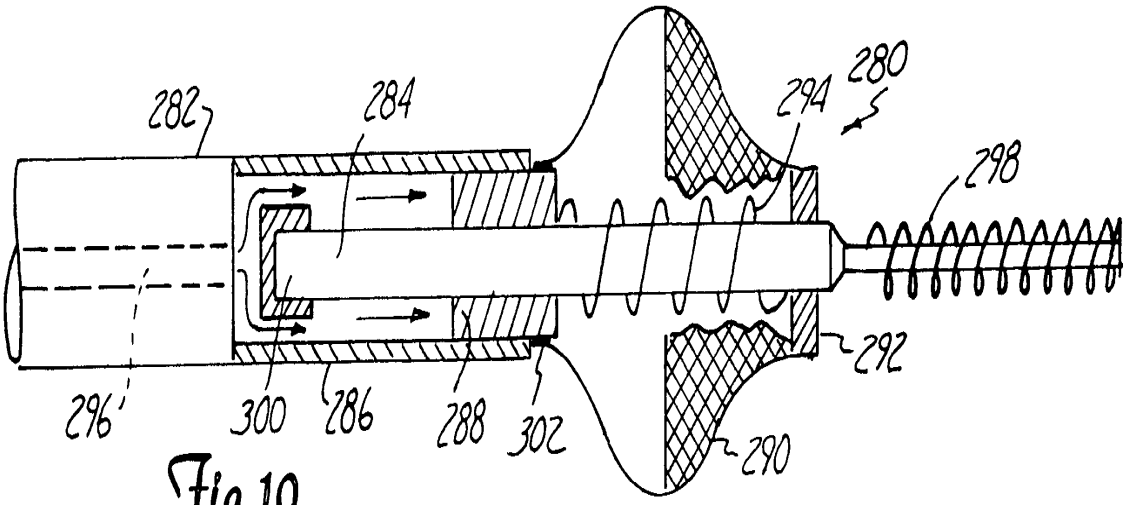


Fig. 19

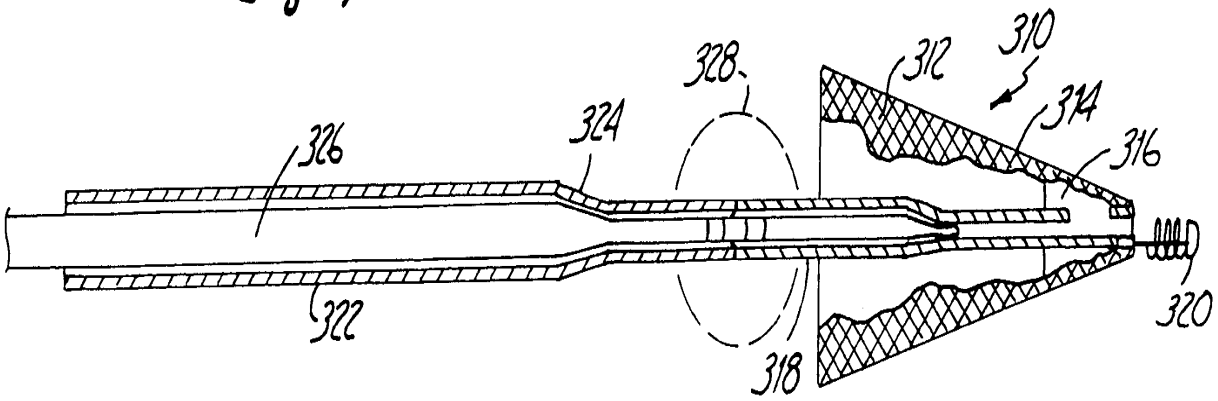


Fig. 20A

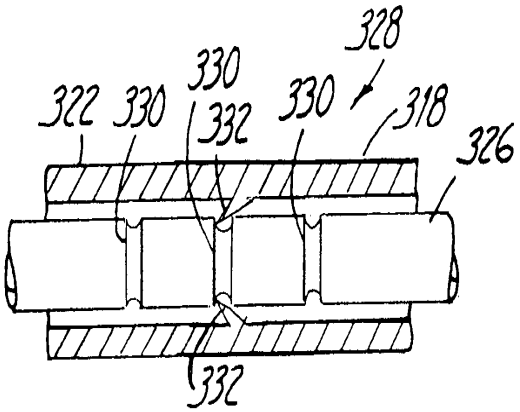


Fig. 20B

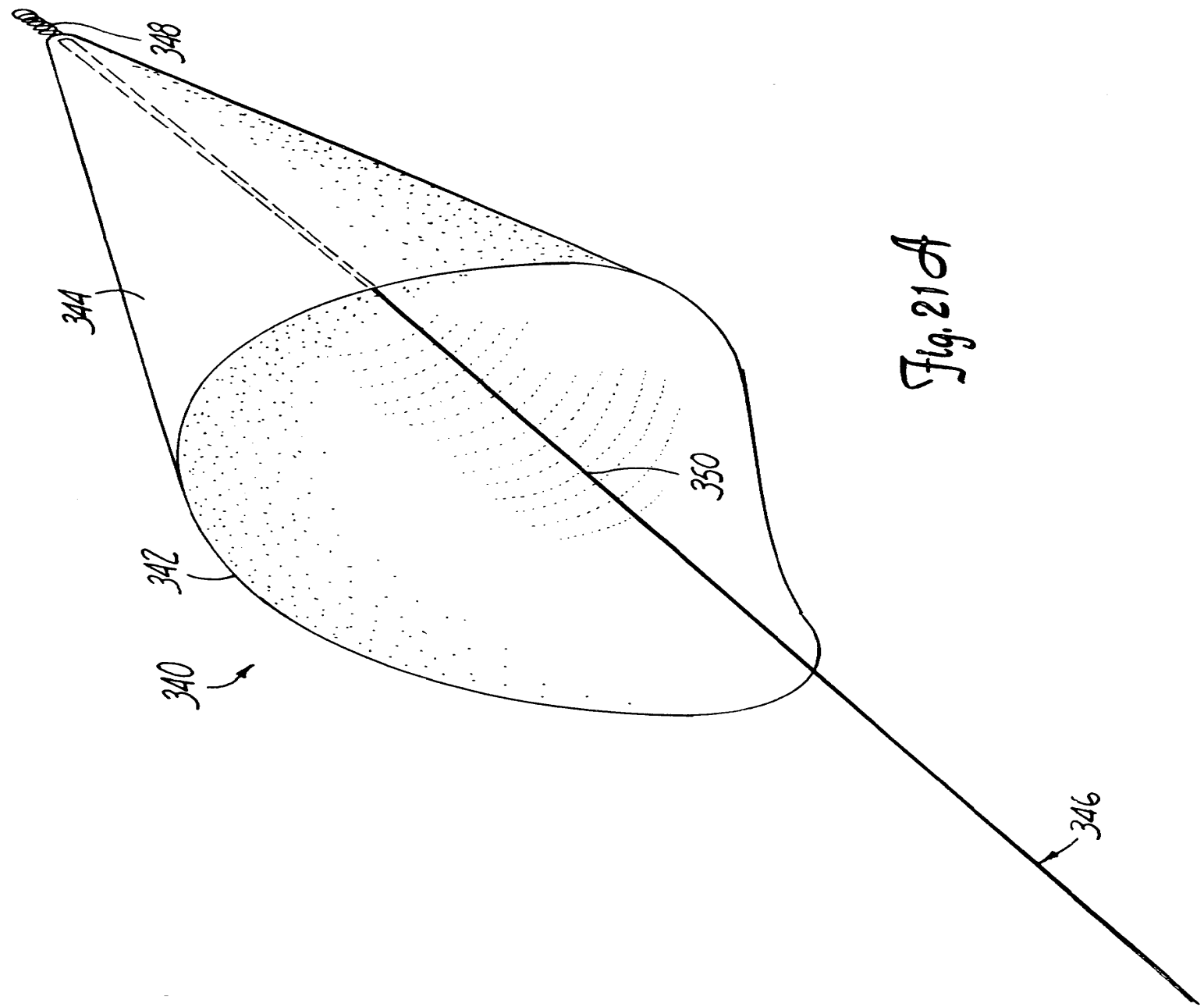


Fig. 21A

Page 2000 of 2754

Fig. 21B

SUBSTITUTE SHEET (rule 26)

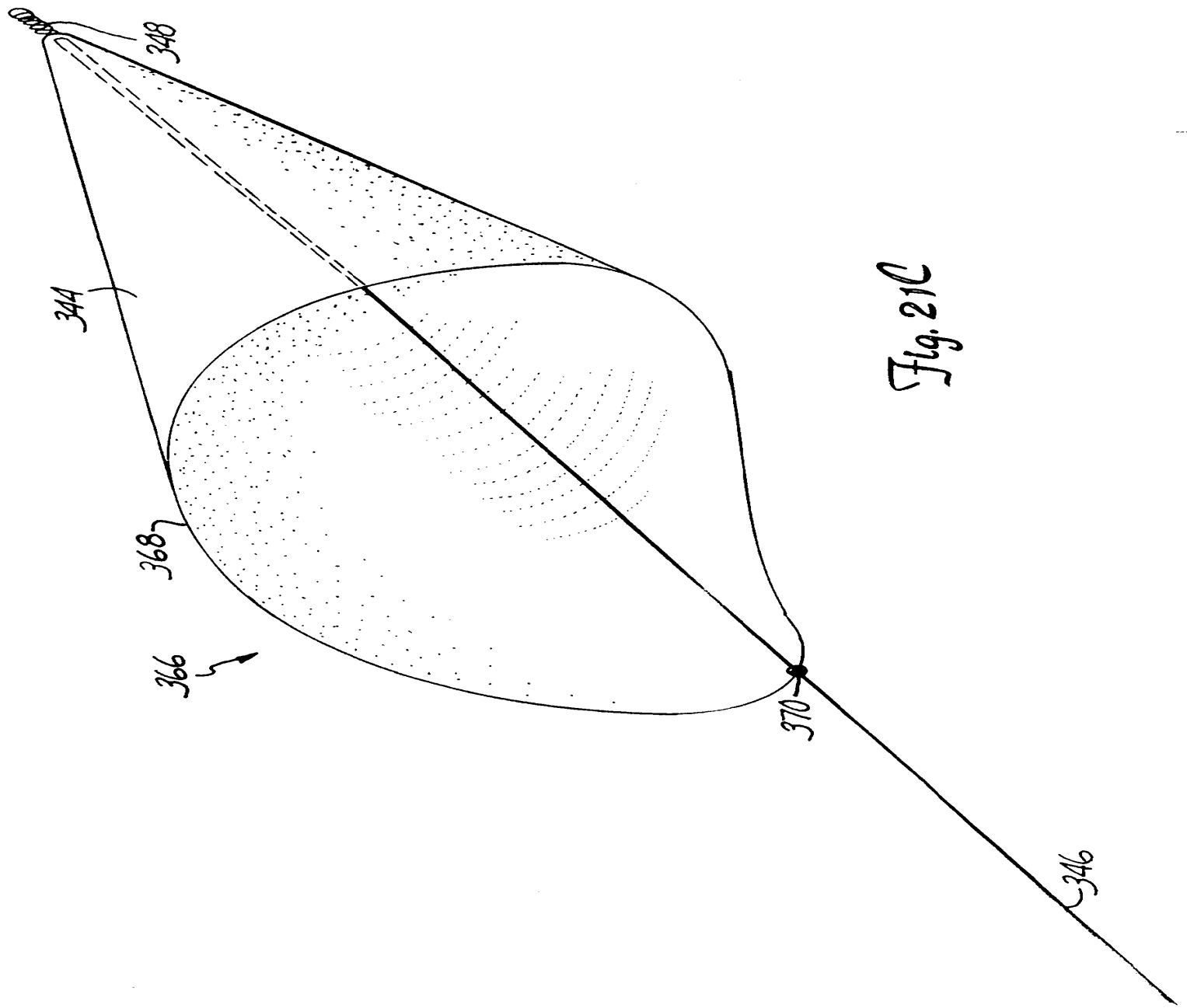


Fig. 21C

Page 2002 of 2754

SUBSTITUTE SHEET (rule 26)

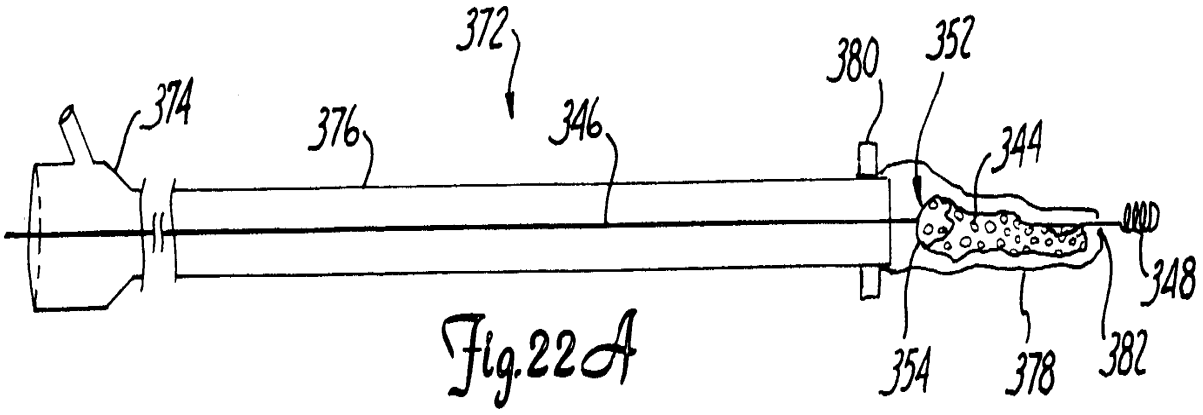


Fig. 22A

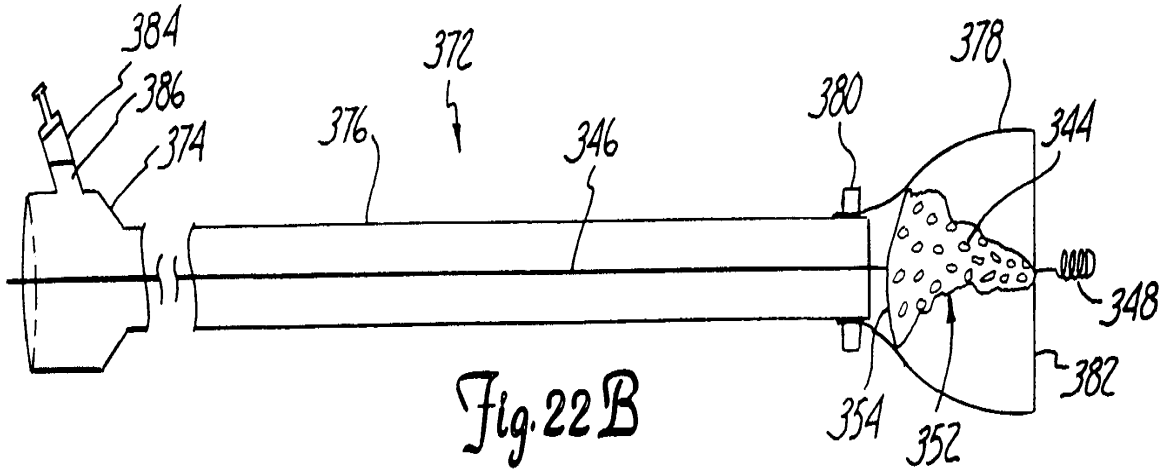


Fig. 22B

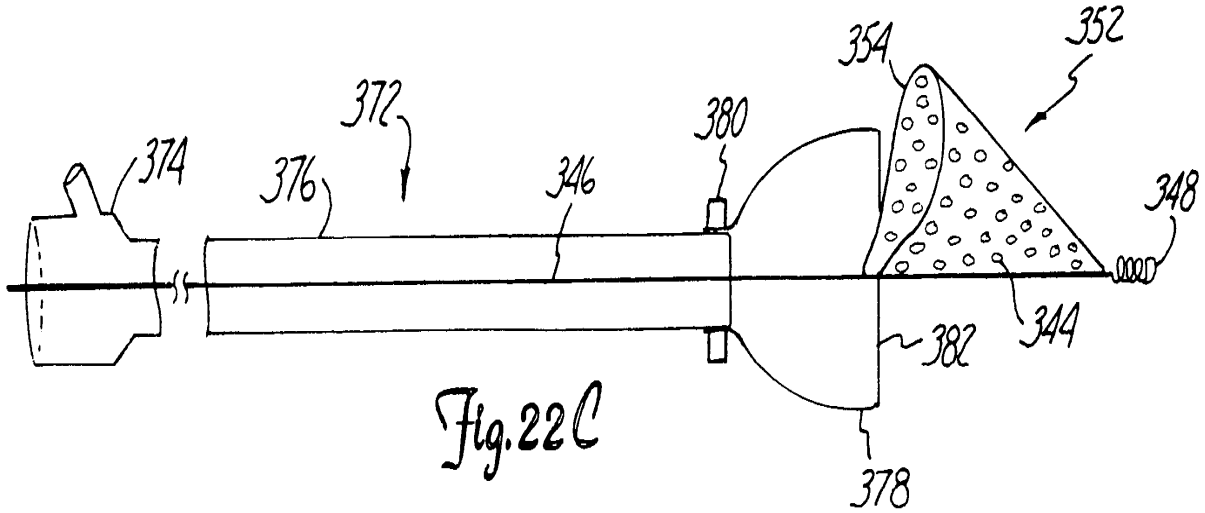


Fig. 22C

SUBSTITUTE SHEET (rule 26)

Fig. 23A

Fig. 23B

Fig. 23C

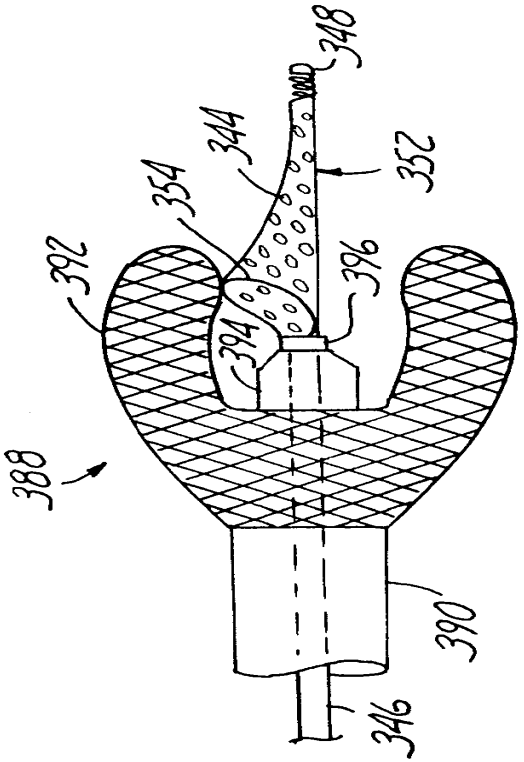


Fig. 23D

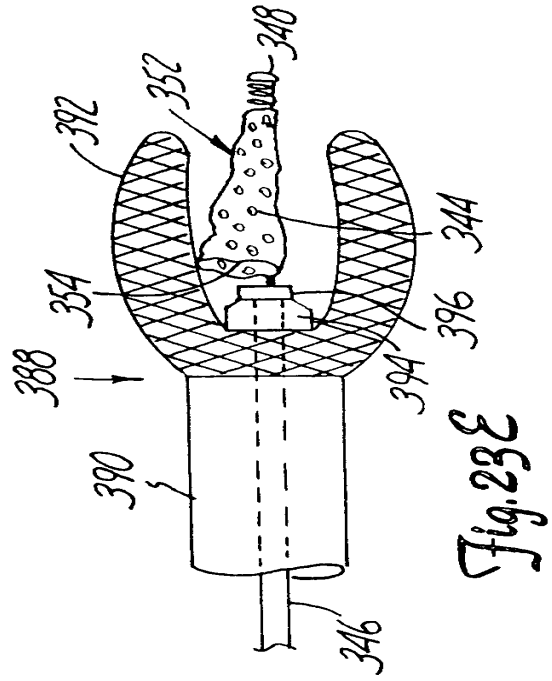
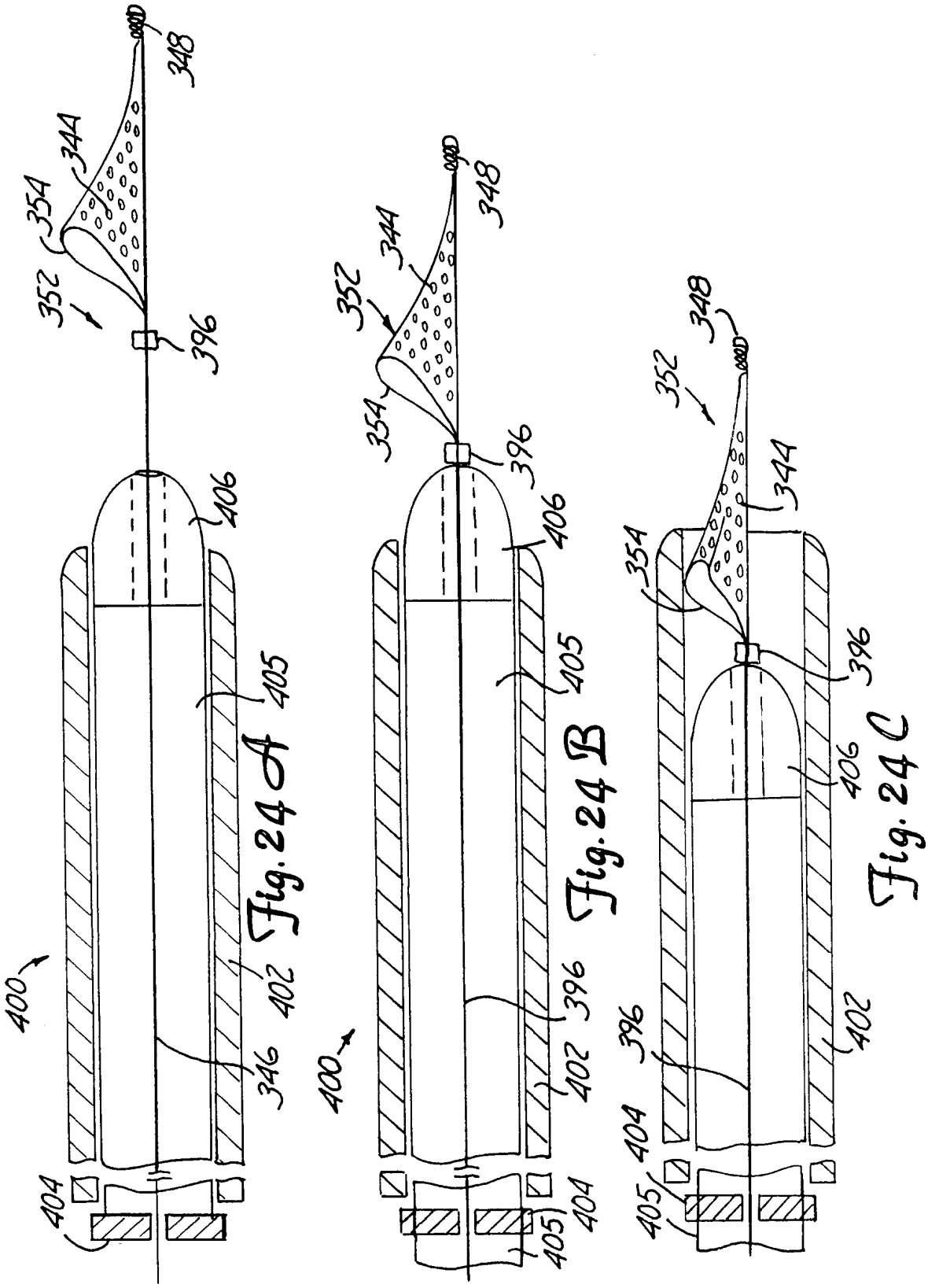


Fig. 23E


348
344
354
352
396
406
405
400
402
346
404
Fig. 24 A
348
344
352
354
396
406
405
400
396
402
404
405
Fig. 24 B
348
352
344
354
396
406
396
402
404
405
Fig. 24 C

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US98/02961

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61M 29/00
US CL :604/22; 606/194, 198, 200
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. : 604/22, 104; 606/159, 180, 191, 194, 195, 198, 200

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.
A	US 5,102,415 A (GUENTHER ET AL) 07 APRIL 1992, COL. 2 LINES 1-61.	1-30
A	US 4,723,549 A (WHOLEY ET AL) 09 FEBRUARY 1988, COL. 2 LINES 3-36.	1-30
A	US 5,071,407 A (TERMIN ET AL) 10 DECEMBER 1991, COL. 2 LINES 20-68, AND COL. 3 LINES 1-57.	1-30

☐ 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 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 02 JUNE 1998	Date of mailing of the international search report 23 JUN 1998
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer GARY JACKSON Telephone No. (703) 308-4302

Form PCT/ISA/210 (second sheet)(July 1992)★

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
2 July 2009 (02.07.2009)

PCT

(10) International Publication Number
WO 2009/082513 A1

(51) International Patent Classification:
A61M 37/00 (2006.01)

(21) International Application Number:
PCT/US2008/072352

(22) International Filing Date: 6 August 2008 (06.08.2008)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
61/015,301 20 December 2007 (20.12.2007) US

(71) Applicant *(for all designated States except US)*: **VORTEX MEDICAL** [US/US]; 50 Loring Drive, Norwell, MA 02061 (US).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **AKLOG, Lishan** [US/US]; 6216 East Shea Blvd., Scottsdale, AZ 85254 (US). **GLENNON, Michael** [US/US]; 50 Loring Drive, Norwell, MA 02061 (US).

(74) Agent: **PHAM, Chinh, H.**; Greenberg Trauig, LLP, One International Place, Boston, MA 02110 (US).

(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, BR, BW, BY, BZ, CA, CH, 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, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, 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, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MT, NL, NO, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:
— *with international search report*

(54) Title: SYSTEMS AND METHODS FOR REMOVING UNDESIRABLE MATERIAL WITHIN A CIRCULATORY SYSTEM

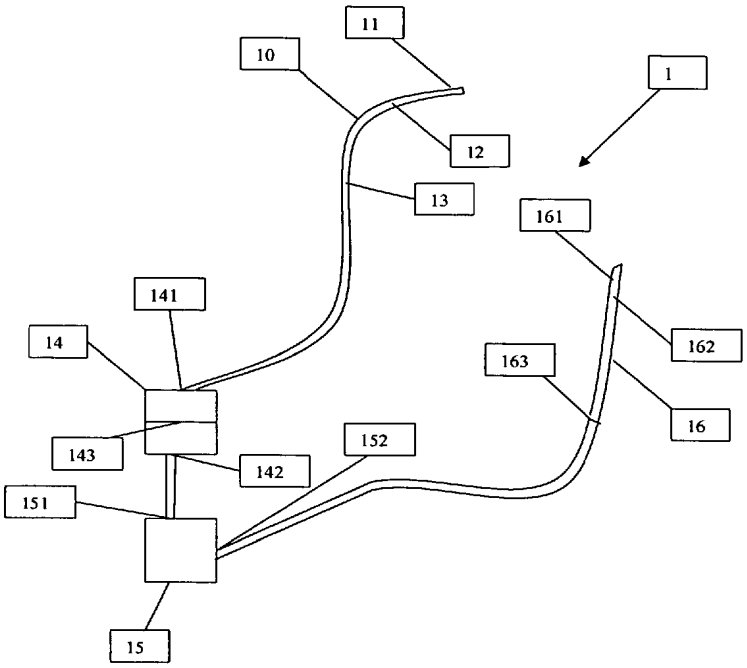


Fig. 1

(57) Abstract: A system for removing undesirable material from vessels and from chambers within the heart is provided. The system includes a suction cannula for removing the undesirable material from a site of interest within a patient. A filter device may be provided for capturing the undesirable material and removing it from the fluid flow. The system also includes pump for generating the necessary suction force through the suction cannula to dislodge the undesirable material from the site of interest and for generating a sufficient driving force to direct the fluid flow downstream within the system. The system further includes a reinfusion cannula for introducing fluid removed from the site of interest back into a patient. A method for removing undesirable material from vessels and from heart chambers is also provided.

WO 2009/082513 A1

SYSTEMS AND METHODS FOR REMOVING UNDESIRABLE MATERIAL WITHIN A CIRCULATORY SYSTEM

TECHNICAL FIELD

[0001] The present invention relates to systems and methods for removing undesirable materials from a site of interest within the circulatory system. More particularly, the present invention relates to systems and methods for removing substantially *en bloc* clots, thrombi, and emboli, among others, from within heart chambers, as well as medium to large vessels, while reinfusing fluid removed from the site of interest back into the patient to minimize fluid loss.

BACKGROUND ART

[0002] Many of the most common and deadly diseases afflicting mankind result from or in the presence of undesirable material, most notably blood clots, in the blood vessels and heart chambers. Examples of such diseases include myocardial infarction, stroke, pulmonary embolism, deep venous thrombosis, atrial fibrillation, infective endocarditis, etc. The treatment of some of these conditions, which involve smaller blood vessels, such as myocardial infarction and stroke, has been dramatically improved in recent years by targeted mechanical efforts to remove blood clots from the circulatory system. Other deadly conditions, which involve medium to large blood vessels or heart chambers, such as pulmonary embolism (1/2 million deaths per year) or deep venous thrombosis (2-3 million cases per year) have not benefited significantly from such an approach. Present treatment for such conditions with drugs or other interventions is not sufficiently effective. As a result, additional measures are needed to help save lives of patients suffering from these conditions.

[0003] The circulatory system can be disrupted by the presence of undesirable material, most commonly blood clots, but also tumor, infective vegetations, and foreign bodies, etc. Blood clots can arise spontaneously within the blood vessel or heart chamber (thrombosis) or be carried through the circulation from a remote site and lodge in a blood vessel (thromboemboli).

[0004] In the systemic circulation, this undesirable material can cause harm by obstructing a systemic artery or vein. Obstructing a systemic artery interferes with the

delivery of oxygen-rich blood to organs and tissues (arterial ischemia) and can ultimately lead to tissue death or infarction. Obstructing a systemic vein interferes with the drainage of oxygen-poor blood and fluid from organs and tissues (venous congestion) resulting in swelling (edema) and can occasionally lead to tissue infarction.

[0005] Many of the most common and deadly human diseases are caused by systemic arterial obstruction. The most common form of heart disease, such as myocardial infarction, results from thrombosis of a coronary artery following disruption of a cholesterol plaque. The most common causes of stroke include obstruction of a cerebral artery either from local thrombosis or thromboemboli, typically from the heart. Obstruction of the arteries to abdominal organs by thrombosis or thromboemboli can result in catastrophic organ injury, most commonly infarction of the small and large intestine. Obstruction of the arteries to the extremities by thrombosis or thromboemboli can result in gangrene.

[0006] In the systemic venous circulation, undesirable material can also cause serious harm. Blood clots can develop in the large veins of the legs and pelvis, a common condition known as deep venous thrombosis (DVT). DVT arises most commonly when there is a propensity for stagnated blood (long-haul air travel, immobility) and clotting (cancer, recent surgery, especially orthopedic surgery). DVT causes harm by (1) obstructing drainage of venous blood from the legs leading to swelling, ulcers, pain and infection and (2) serving as a reservoir for blood clot to travel to other parts of the body including the heart, lungs (pulmonary embolism) and across a opening between the chambers of the heart (patent foramen ovale) to the brain (stroke), abdominal organs or extremities.

[0007] In the pulmonary circulation, the undesirable material can cause harm by obstructing pulmonary arteries, a condition known as pulmonary embolism. If the obstruction is upstream, in the main or large branch pulmonary arteries, it can severely compromise total blood flow within the lungs and therefore the entire body, resulting in low blood pressure and shock. If the obstruction is downstream, in large to medium pulmonary artery branches, it can prevent a significant portion of the lung from participating in the exchange of gases to the blood resulting low blood oxygen and build up of blood carbon dioxide. If the obstruction is further downstream, it can

cut off the blood flow to a smaller portion of the lung, resulting in death of lung tissue or pulmonary infarction.

[0008] The presence of the undesirable material within the heart chambers can cause harm by obstructing flow or by serving as a reservoir for emboli to other organs in the body. The most common site for obstruction within the heart is in the heart valves. Infective vegetations, a condition known as endocarditis, can cause partial obstruction to flow across a valve before destroying the valve. Patients with prosthetic valves, especially mechanical valves, are particularly prone to valve thrombosis and obstruction. The heart chambers are the most common source of emboli (cardioemboli) to the systemic circulation, including stroke. Emboli tend to arise from areas that are prone to stagnation of blood flow under pathologic conditions. The left atrial appendage in patients with atrial fibrillation is prone to thrombosis, as well as the left ventricular apex in patients with acute myocardial infarction or dilated cardiomyopathy. Infected vegetations or thrombi on the heart valves are also common sources of emboli. Undesirable material such as blood clots and infected vegetations can reside in the chambers of the right heart (atrium and ventricle), often associated with prosthetic material such as pacemaker leads or long-term indwelling catheters.

[0009] The most effective treatment for conditions resulting from the presence of blood clots or other undesirable materials within the circulation is, of course, to stabilize or eliminate the material before it has embolized. Alternatively, if obstruction to flow has already occurred but before the obstruction has caused permanent harm (infarction, shock, death), the material can be eliminated by utilizing biologic or mechanical means.

[00010] Biologic treatments involve the delivery of agents to the material, which either dissolve the material or, at a minimum, stabilize it until the body can eliminate it. In the case of infective vegetations, antimicrobial agents can, over time, decrease the chances of embolization. In the case of blood clots, the agents include 1) anticoagulant agents (heparin, warfarin, etc.) which prevent propagation of blood clots; and 2) more potent thrombolytic agents (streptokinase, urokinase, tPA, etc,) which actively dissolve clots. The agents are usually delivered systemically, i.e., into a peripheral or central vein and allowed to circulate throughout the body.

Thrombolytic agents can also be delivered through a catheter directly to the blood clot which can increase its effectiveness by increasing local concentrations but this does not completely eliminate the absorption into systemic circulation throughout the body.

[00011] Thrombolytic agents have been shown to increase survival in patients with hemodynamically significant pulmonary embolism as documented by echocardiographic evidence of right ventricular strain. The use of thrombolytic agents is the standard of care in this subgroup of patients with a high 20-25% early mortality. They are commonly used in to dissolve clots in other blood vessels including arteries to heart, abdominal organs and extremities.

[00012] There are two primary disadvantages to thrombolytic agents. First, every cell in the body is exposed to the agent which can lead to serious and often life threatening bleeding complications in remote areas such as the brain and stomach. The risk of major bleeding complications can be as high as 25% and the risk of often fatal bleeding into the brain can go up to 3%. Second, blood clots undergo a process called organization where the soft gel-like red/purple clot is transformed into a firmer, whitish clot by the cross-linking of proteins such as fibrin. Organized clots are much less amenable to treatment with thrombolytic agents. Thromboemboli, such as pulmonary emboli, can contain a significant amount of organized clot since the thrombus frequently developed at its original site (e.g., the deep veins of the legs) over a long period of time prior to embolizing to the remote site (e.g., the lungs).

[00013] Mechanical treatments involve the direct manipulation of the material to eliminate the obstruction. This can involve aspiration, maceration, and compression against the vessel wall, or other types of manipulation. The distinct advantage of mechanical treatment is that it directly attacks the offending material and eliminates the vascular obstruction independent of the specific content of the offending material. Mechanical treatments, if feasible, can usually prove to be superior to biologic treatments for vascular obstruction. Procedural success rates tend to be higher. The best example of this advantage is in the treatment of acute myocardial infarction. Although thrombolytic therapy has had a major impact on the management of patient with myocardial infarction, this option is now relegated to a distant second choice. The clear standard of care today for an acute myocardial infarction is an emergency percutaneous coronary intervention during which the coronary artery obstruction is

relieved by aspiration, maceration or balloon compression of the offending thrombus. This mechanical approach has been shown to decrease the amount of damaged heart tissue and improve survival relative to the thrombolytic biological approach.

[00014] Mechanical treatment, however, has played a limited role in the removal of blood clots found in larger blood vessels such as pulmonary arteries and heart chambers. Surgical pulmonary embolectomy involves opening the pulmonary artery and removing the offending clot under direct vision. This operation has been performed for nearly 100 years, but did not become practical until the introduction of the heart lung machine. Even then, it was generally relegated to a salvage procedure in moribund patients in whom all other options had been exhausted because of the inherent danger in the surgery and the recovery period. While surgical pulmonary embolectomy is very effective in completely evacuating pulmonary emboli whether soft-fresh and firm-organized clot, it is an invasive procedure.

[00015] Recent data has shown that the early outcomes with surgical pulmonary embolectomy are excellent, at least as good as thrombolytic treatment, as long as the procedure is performed in a timely fashion before the patient becomes very ill or suffers a cardiac arrest. The long term outcomes of patients surviving surgical pulmonary embolectomy have always been very good. Although these data have generated a renewed interest in performing surgical pulmonary embolectomy, its use remains limited because of the invasiveness of the procedure. Although minimally invasive approaches have been described, the standard procedure requires a 20-25cm incision through the sternal bone and placing the patient on cardiopulmonary bypass (the heart-lung machine).

[00016] Catheter-based removal of blood clots from larger blood vessels (e.g., pulmonary arteries) and heart chambers has had limited success, at least compared to smaller blood vessels (e.g., coronary arteries). Catheter pulmonary embolectomy, where the pulmonary emboli are removed percutaneously using one of several techniques, has been around for nearly 30 years but few patients currently receive these therapies. These techniques can be subdivided into three categories. With fragmentation thrombectomy, the clot is broken into smaller pieces, most of which migrate further downstream, decreasing the central obstruction but resulting in a "no-reflow" phenomenon. It is sometimes used in combination with thrombolytics which

preclude their use as an alternative to thrombolytics. With the rheolytic thrombectomy, high velocity saline jets create a Venturi effect and draw the fragments of the clot into the catheter. Finally the aspiration techniques draw the clot into a catheter via suction. With a Greenfield embolectomy, the catheter with the attached clot is repeatedly drawn out of the vein. All of these techniques rely on catheters which are small compared to the size of the clots and blood vessels. Their limited success is likely related to their inability to achieve a complete en-bloc removal of the material without fragmentation.

[00017] The experience with catheter-based treatment of deep venous thrombus has also had limited success. The operator must use relatively small catheters to remove or break up large amounts of well embedded clot. This procedure is therefore time-consuming, inefficient and ultimately not very effective in removal of the whole clot.

[00018] It is clear that all of the therapeutic options available to patients with clot or other undesirable material in medium or large blood vessels, such as those with pulmonary embolism, have serious limitations. Anticoagulation only limits propagation of clot, it does not remove it. Thrombolytic therapy is not targeted, carries a real risk of major bleeding, and is not very effective in firm/organized clots. Catheter embolectomy uses technology developed for small blood vessels, does not scale well to material residing in medium and large vessels or heart chambers, and thus is not very effective. Surgical embolectomy is highly effective but highly invasive. There is a real need for a direct mechanical treatment that is as effective as surgical embolectomy but can be performed using endovascular techniques.

[00019] Current efforts to apply existing catheter embolectomy technologies to medium to large blood vessels and heart chambers encounter at least two obstacles: fragmentation and excessive blood loss. Techniques which depend on fragmentation of the material tend to be inefficient and ineffective in medium to large blood vessels and heart chambers because the flow of blood will carry a significant portion of the fragmented material away before it can be captured in the catheter. On the other hand, techniques which depend on aspiration of undesirable material will result in excessive blood loss as the size of the catheter increases.

[00020] A need therefore exists for a system and method to endovascularly remove undesirable material residing in medium to large blood vessels and heart chambers with minimal fragmentation and without excessive blood loss.

SUMMARY OF THE INVENTION

[00021] The present invention relates generally to systems and methods for removing undesirable material residing in vessels, such as blood vessels, or within chambers of the heart. More specifically, the subject invention relates to systems and methods for using a cannula to remove substantially *en bloc*, from a site of obstruction or interest, an undesirable material, such as blood clots, embolisms and thromboembolisms, without significant fragmentation and without excessive fluid loss. In addition, the systems and methods of the present invention may simultaneously reinfuse aspirated (i.e., removed) and filtered fluid, such as blood, back into the patient on a substantially continuous basis to minimize any occurrences of fluid loss and/or shock. The subject invention may be particularly useful, but may not be limited to, the removal of blood clots, tumors, infective vegetations and foreign bodies from medium to large blood vessels and heart chambers.

[00022] In one embodiment, a system for removing an undesirable material from within a vessel is provided. The system includes a first cannula having a distal end and an opposing proximal end. The distal end of the first cannula, in an embodiment, may include or may be deployable to a diameter relatively larger than that of the proximal end. The first cannula may be designed for maneuvering within the vessel to a site of interest, such that an undesirable material can be captured substantially *en bloc* through the distal end and removed along the first cannula away from the site. The system may also include a pump, in fluid communication with the proximal end of the first cannula, so as to provide a sufficient suction force for removing the undesirable material from the site of interest. The system may further include a second cannula in fluid communication with the pump, so that fluid removed from the site of interest by the first cannula can be directed along the second cannula and reinfused through a distal end of the second cannula. In one embodiment, the distal end of the second cannula may be situated in spaced relation to the distal end of the first cannula. The system may also be provided with a filter device positioned in fluid

communication with the first cannula. The filter device, in an embodiment, may act to entrap or capture the undesirable material and remove it from the fluid flow. The system may further be provided with a reservoir in fluid communication with the filter device. The reservoir may act to transiently collect fluid being directed from the filter device and to provide a source of fluid for reinfusion by the second cannula. A second filter may also be included in fluid communication between the pump and the second cannula, so as to remove, prior to reinfusion, any debris that may have escaped from the filter device from the fluid flow.

[00023] In another embodiment, there is provided a method for removing an undesirable material from within a vessel. The method includes initially maneuvering a first cannula having a distal end and an opposing proximal end to a site of interest within the vessel, such that the distal end of the first cannula is positioned adjacent the undesirable material. Next, a second cannula, in fluid communication with the first cannula, may be positioned such that its distal end can be situated in spaced relation to the distal end of the first cannula. Thereafter, a suction force may be provided through the distal end of the first cannula to the site of interest, so as to remove, through the distal end of the first cannula, the undesirable material substantially *en bloc* from the site of interest. Subsequently, any fluid removed along with the undesirable material may be reinfused, through the distal end of the second cannula, to a location in spaced relation from the distal end of the first cannula. The suction and reinfusion of blood can occur, in an embodiment, continuously for a desired duration to minimize fluid loss in the patient. Alternatively, the step of suctioning an undesirable material can occur at an intermittent pulse for a desired duration following reinfusion of the removed fluid.

[00024] In a further embodiment, an apparatus for removing an undesirable material from within a vessel is provided. The apparatus includes an elongated tube having a distal end through which an undesirable material can be captured, a pathway extending along the tube to provide a passage for transporting the undesirable material from the distal end, and a proximal end in opposing relations to the distal end through which the undesirable material can exit. The apparatus also includes a funnel situated at the distal end of the tube, and designed for deployment between an flared open position and a collapsed closed position, so as to better engage and capture the

undesirable material. The apparatus further includes a mechanism positioned about a distal portion of the tube, which mechanism, upon actuation, can deploy the funnel between the closed position and the open position. In one embodiment, the funnel includes a plurality of strips, with each strip being pivotally coupled at one end to the distal end of the tube. The funnel may also include a substantially impermeable membrane extending across a space between adjacent strips, such that the membrane, in connection with the strips define the shape of the funnel. The mechanism, in an embodiment, includes a balloon positioned circumferentially about the tube at a location proximal to the funnel, and an attachment mechanism provided with one end attached to the funnel and an opposite end attached to the balloon. By design, upon expansion of the balloon, the attachment mechanism can pull on the funnel to deploy it into a flared open position. The apparatus may also include a jacket positioned circumferentially about the distal end of the tube, and extending from the funnel to the balloon to protect the vessel from potential irritation that may be caused by the balloon and the strips defining the funnel. As the jacket may be attached to the funnel and the balloon, in one embodiment, the jacket may act as the mechanism for deploying the funnel into a flared open position upon expansion of the balloon.

BRIEF DESCRIPTION OF THE DRAWINGS

[00025] These and other features and advantages of the present invention will become more apparent from the following detailed descriptions taken in conjunction with the accompanying drawings wherein like reference characters denote corresponding parts throughout the several views.

[00026] Fig. 1 illustrates system for removing an undesirable material from within a vessel in accordance with one embodiment of the present invention.

[00027] Figs. 2A-H illustrate a distal end of a suction cannula in operation in connection with the system shown in Fig. 1.

[00028] Figs. 3A-B illustrate an alternate distal end of a suction cannula used in connection with the system shown in Fig. 1.

[00029] Figs. 4A-E illustrate a variety of cannulas for use in connection with the system shown in Fig. 1.

[00030] Fig. 5 illustrates a port through which another device may be introduced within a suction cannula used in connection with the system shown in Fig. 1.

[00031] Fig. 6 illustrates a system for removing an undesirable material from within a vessel in accordance with another embodiment of the present invention.

[00032] Fig. 7 illustrates a system of the present invention being deployed within a patient for removing an undesirable material from a site of interest.

DETAILED DESCRIPTION OF SPECIFIC EMBODIMENTS

[00033] As noted above, existing catheter techniques may not be effective in removing undesirable material, such as clots, from medium and large size blood vessels or from heart chambers, because these catheters tend to be small relative to the material to be removed. As a result, the material often needs to be fragmented in order to fit within the catheter. However, with fragmentation, the chances of the fragments being carried away in the bloodstream increases, resulting in downstream obstruction. If the catheter is enlarged to accommodate the larger structure and material, such a catheter may aspirate an unacceptable volume of blood, resulting in excessive fluid loss and/or shock in the patient.

[00034] The present invention overcomes the deficiencies of existing devices and techniques and can act to remove substantially *en bloc* (i.e., wholly or entirely) undesirable material, such as thrombi and emboli, from the vasculature, including medium to large size blood vessels, and from heart chambers. Vessels from which the undesirable material may be removed, in accordance with an embodiment of the present invention, include, for example, those within the pulmonary circulation (e.g., pulmonary arteries), systemic venous circulation (e.g., vena cavae, pelvic veins, leg veins, neck and arm veins) or arterial circulation (e.g., aorta or its large and medium branches). The heart chambers may be, for example, in the left heart (e.g., the left ventricular apex and left atrial appendage), right heart (e.g., right atrium and right ventricle), or on its valves. The present invention can also act to remove tumors, infective vegetations and other foreign.

[00035] Although reference is made to medium and large vessels, it should be appreciated that the systems and methods, hereinafter disclosed, can be scaled and adapted for use within smaller vessels within the body, if desired.

[00036] Referring now to Fig. 1, there is illustrated a system 1 for removing an undesirable material, substantially *en bloc*, from an obstruction site or site of interest within the vasculature, and for reinfusion of fluid removed (i.e., suctioned or aspirated) from the site of interest back into a patient, in order to minimize fluid loss within the patient. System 1, in an embodiment, may be provided with a first or suction cannula 10 for capturing and removing *en bloc* the undesirable material from the site of interest, such as that within a blood vessel or a heart chamber. Cannula 10, in an embodiment, may be an elongated tube and may include a distal end 11 through which the undesirable material can be captured and removed. Cannula 10 may also include a lumen or pathway 12 extending along a body portion of cannula 10. Pathway 12, in one embodiment, provides a passage along which the captured material and aspirated circulatory fluid, such as blood, that may be captured therewith may be transported and directed away from the site of interest. Cannula 10 may further include a proximal end 13 in opposing relations to the distal end 11, and through which the captured material may exit from the cannula 10.

[00037] Since cannula 10 may be designed for introduction into the vasculature, for instance, through a peripheral blood vessel, and may need to subsequently be maneuvered therealong to the site of interest, cannula 10, in an embodiment, may be made from a pliable material. In addition, as cannula 10 may be used to introduce a suction force to the site of interest for capturing the undesirable material, cannula 10 may be made from a sufficiently stiff material or may be reinforced with a sufficiently stiff material, so as not to collapse under a suction force. In one embodiment, cannula 10 may be constructed from a biocompatible material, such as polyvinyl chloride, polyethylene, polypropylene, polyurethane, Pebax®, silicone, or a combination thereof.

[00038] In certain instances, it may be desirable to maneuver cannula 10 to the site of interest using image guidance, for example, using fluoroscopy or echocardiography. In order to permit cannula 10 to be visualized, cannula 10, in an embodiment, may also include a radioopaque material or any material capable of being visualized.

[00039] To better engage and capture the undesirable material substantially *en bloc* and without significant fragmentation, the distal end 11 of cannula 10 may be designed to have a diameter that can be relatively larger than that of the proximal end

13. In one embodiment, as illustrated in Figs. 2A-D, distal end 11 of cannula 10 may be in the shape of a funnel 20, and may be provided with a diameter, for example, approximately at least three times that of pathway 12. Of course, depending on the surgical procedure being implemented, the ratio between the diameter of funnel 20 and pathway 12 can be varied, if so desired. Funnel 20, with its design, may be placed directly at a site of interest 23 to engage undesirable material 24 (Fig. 2C), or spatially away from the site of interest 23 to capture the undesirable material 24 (Fig. 2D). In a situation where the distal end 11 may be situated spatially away from the site of interest, by providing distal end 11 with funnel 20, a vortex effect may be generated during suctioning to better direct the undesirable material into the funnel 20. It is believed that fluid flowing into funnel 20 can often exhibit a laminar flow circumferentially along the interior surface of the funnel 20 to generate a vortex flow into the distal end 11 of suction cannula 10. Thus, in the presence of a vortex flow, such a flow can act to direct the undesirable material toward the distal end 11 to allow the material to subsequently be pulled into the distal end by suctioning.

[00040] To provide a funnel shaped distal end, cannula 10 may include, in an embodiment, a sheath 21 circumferentially situated about distal end 11 of cannula 10. Sheath 21, as illustrated, may be designed to slide toward as well as away from the distal end 11 of cannula 10. In that way, when the distal end 11 is positioned at the site of interest 23, and sheath 21 is retracted (i.e., slid away from the distal end 11), funnel 20 may be exposed and expanded into the desired shape in order to engage undesirable material 24. To collapse funnel 20, sheath 21 may be advanced toward the distal end 11 and over the funnel 20. Thereafter, cannula 10 may be maneuvered from the site of interest 23.

[00041] In order to enhance capture and removal of the undesirable material 24, looking now at Figs. 2E-G, cannula 10 may be designed to allow introduction of a catheter 25 with balloon 26 to the site of interest. In an example where the undesirable material 24 may be entrapped within funnel 20, catheter 25 with balloon 26 may be directed along the lumen or pathway 12 of cannula 10 and into funnel 20. Once catheter 25 has been advanced past the undesirable material 24 within funnel 20, balloon 26 may be inflated to a size sufficient to pull on the undesirable material entrapped within funnel 20. As balloon 26 is pulled down the funnel 20 towards

pathway 12, balloon 26 can dislodge the entrapped material and can eventually partially or substantially occlude a pathway 12, distal to the undesirable material 24, which in essence occludes the fluid communication between cannula 10 and the vessel. The suction force within pathway 12, as a result, can be enhanced to better remove the undesirable material. Similarly, as shown in Fig. 2H, in a situation where undesirable material 24 may be firmly lodged in the vessel at the site of interest 23 and the suction applied by cannula 10, spatially situated away from the site of interest 23, may insufficient to dislodge the undesirable material 24, catheter 25 and balloon 26 may be advanced past the distal end of cannula 10 and past the undesirable material 24 at the site of interest 23. Once past the undesirable material 24 the balloon 26 may be inflated and as balloon is withdrawn back towards the distal end 11 of cannula 10, it can dislodge the undesirable material and allow the suction to draw it into the distal end of cannula 10. Of course, this approach can also be applied when cannula 10 is situated directly at the site of interest 23 and the suction force may be insufficient to dislodge the undesirable material 24.

[00042] In another embodiment, looking now at Figs. 3A-B, funnel 20 located at distal end 11 of cannula 10 may be created by providing a plurality of independent strips 31, each coupled at one end to distal end 11 of cannula 10. In the embodiment shown in Fig. 3A, three strips 31 are illustrated. However, it should be appreciated that two or more strips 31 may be used, if so desired. Strips 31, in an embodiment, may be designed to pivot between a closed position, where strips 31 may be substantially adjacent one another, and an open position, where strips may be flared into a funnel 20, shown in Fig. 3A. To deploy strips 31, and thus funnel 20, between an open and closed position, cannula 10 may include a balloon 33 positioned circumferentially about cannula 10 and proximal to strips 31. In addition, an attachment mechanism, such as a string 34 or any similar mechanisms (e.g., rod, chain etc.), may be provided for each of the strips 31, with one end attached to one strip 31 and an opposite end attached to balloon 33. In this way, when balloon 33 is inflated and expands radially, balloon 33 may pull on each attachment mechanism 34, so as to deploy strips 31 into a flared open position. Balloon 33, in one embodiment, may be inflated through opening 37 through the use of any fluid, including water, air, or radioopaque contrast material. It should be noted that securing of the attachment mechanism to the strips

31 and balloon 33 can be accomplished using any methods or mechanisms known in the art. For instance, adhesives, knots, or soldering etc. may be used. Moreover, to the extent desired, strips 33 and balloon 31 may be designed to expand to a diameter larger than that of the vessel within which cannula 10 is being deployed. In that way, cannula 10 may be securely positioned at the site of interest for removal of the undesirable material substantially *en bloc*.

[00043] To better capture the undesirable material and direct it into the cannula 10, a membrane 35 may be placed across a space between adjacent strips 31 when the strips 31 are in the open position. In one embodiment, a continuous membrane 35 may be used to circumferentially stretch across each of the space between adjacent strips 31. Membrane 35 may also act to enhance suction at the site of interest, as it can cover up any open space between the strips 31. To that end, membrane 35, in an embodiment, may be made from a non-permeable material. It should be appreciated that membrane 35 and strips 31, as illustrated, together define funnel 20 at distal end 11 of cannula 10.

[00044] Furthermore, to protect the vessel from irritation or damage that may be caused by the presence of balloon 33 and/or strips 31, jacket 36, as shown in Fig. 3B, may be provided circumferentially about the distal 11 of cannula 10. In an embodiment, jacket 36 may extend substantially from a tip of each strip 31 to balloon 33. Jacket 36, however, can be affixed anywhere along each strip 31, if necessary. Since jacket 36 attaches at one end to strips 31 and at an opposite end to balloon 33, jacket 36, in an embodiment, may be used instead of attachment mechanism 34 to deploy strips 31 into an open position when balloon 33 is expanded. Of course, jacket 36 may also be used in conjunction with attachment mechanism 34 to deploy strips 31 into an open position. Furthermore, in one embodiment, jacket 36 may be lengthened, so that the end connected to strips 31 may instead be pulled over strips 31, into funnel 20, and attached substantially to a base of each strips 31 (i.e., base of funnel 20). With such a design, membrane 35 may not be necessary, as jacket 36 may serve the purpose of membrane 35 to cover the space between each of strips 31. In such an embodiment, at least that portion of jacket 36 extending over strips 31 and into the base funnel 20 can be impermeable.

[00045] In certain instances, balloon 33 may act to enhance the suction force being applied at the site of interest when removing the undesirable material. For instance, when cannula 10 is deployed downstream of the undesirable material, rather than substantially adjacent to the undesirable material, within a vessel having a venous circulation (i.e., flow toward the heart), balloon 33, when expanded radially, can substantially occlude the vessel, such that collateral fluid flow within the vessel can be minimized, thereby increasing the suction force that can be applied to the undesirable material. Additionally, the occlusion of such a vessel by balloon 33 can better direct the material being removed into the funnel 20 and prevent the material from being carried by the flow of blood past the funnel.

[00046] Alternatively, when cannula 10 is deployed upstream of the undesirable material within a vessel having an arterial circulation (i.e., flow away from the heart), rather than substantially adjacent to the undesirable material, balloon 33, when expanded radially, can substantially occlude the vessel, such that pressure being exerted on the downstream material by the fluid flow can be lessened. By lessening the pressure on the material to be removed, the suction force being applied at the site of interest can act to remove the material more easily.

[00047] As suction cannula 10 may be made from a pliable material, in order to efficiently direct it along a vessel to the site of interest, cannula 10 may be reinforced with wire or other material to optimize maneuverability within the vessel without kinking. Referring now to Fig. 4A, suction cannula 10 may, in addition to pathway 12, be provided with one or more additional pathway or lumen 41. In this multi-lumen design, pathway 12 may act, as noted above, to provide a passage along which the captured material may be transported and directed away from the site of interest. Lumen 41, on the other hand, can provide a passage along which a fluid can be directed to inflate balloon 33 through opening 37 (Figs. 3A-B). In certain embodiments, lumen 41 may also be used to accommodate other devices, such as other catheters or surgical instruments, for use in connection with a variety of purposes. For example, a device may be inserted and advanced along lumen 41 through the distal end 11 of suction cannula 10 to dislodge the undesirable material. An angiography catheter can be inserted and advanced along lumen 41 through the distal end 11 of suction cannula 10 to perform an angiogram to confirm the location

of the undesirable material or confirm that it has been successfully removed. A balloon embolectomy catheter can be inserted along lumen 41 toward the distal end 11 of suction cannula 10 to remove any material which may have clogged the cannula or past the any undesirable material firmly lodged in the vessel to draw it into the cannula. Although illustrated with such a multi-lumen design, any other multi-lumen design may be possible.

[00048] To introduce other devices, such as catheter 25 with balloon 26, into lumen 41 or pathway 12, cannula 10 may be provided with a port 51, as shown in Fig. 5, located at the proximal end 13 of cannula 10. It should be appreciated that in the embodiment where cannula 10 has only pathway 12 (i.e., single lumen cannula), port 51 may similarly be provided at the proximal end 13 of cannula 10 to allow the introduction of other devices into pathway 12.

[00049] Cannula 10 of the present invention may be of any sufficient size, so long as it can be accommodated within a predetermined vessel, such as a medium to large size blood vessel. The size of cannula 10 may also be determined by the size of the undesirable material to be removed, so long as the undesirable material can be removed substantially *en bloc* without significant fragmentation. In one embodiment, suction cannula 10 may be designed to remove at least 10 cm^3 of undesirable material substantially *en bloc*. Of course, cannula 10 can be scaled and adapted for use within smaller vessels in the body and for removing a relatively smaller volume or amount undesirable material, if so desired.

[00050] Looking again at Fig. 1, system 1 can also include filter device 14 in fluid communication with the proximal end 13 of cannula 10. Filter device 14, in one embodiment, may include an inlet 141 through which fluid removed from the site of interest along with the captured undesirable material can be directed from cannula 10. Filter device 14 may also include an outlet 142 through which filtered fluid from within device 14 may be directed downstream of system 1. To prevent the undesirable material captured from the site of interest from moving downstream of system 1, filter device 14 may further include a permeable sheet 143 positioned within the fluid flow between the inlet 141 and the outlet 142.

[00051] Permeable sheet 143, in an embodiment, may include a plurality of pores sufficiently sized, so as to permit fluid from the site of interest to flow therethrough,

while preventing any undesirable material captured from the site of interest from moving downstream of system 1. Examples of permeable sheet 143 includes coarse netting, fine netting, a screen, a porous filter, a combination thereof, or any other suitable filter material capable of permitting fluid to flow through while impeding movement of the captured undesirable material. It should be noted that, rather than just one, a plurality of permeable sheets 143 may be used. Alternatively, one permeable sheet 143 may be folded to provide multiple surfaces, similar to an accordion, for use in connection with filter device 14. By using a plurality of permeable sheets 143 or by folding sheet 143, the number of filtration surfaces through which the fluid must flow increases to enhance filtration and further minimize any occurrence of any undesirable material from moving downstream of system 1.

[00052] Although a permeable sheet 143 is described, it should be appreciated that filter device 14 may be of provided with any design capable of entrapping the undesirable material, while allowing fluid to move therethrough. To that end, filter device 14 may include a mechanical trap to remove the undesirable material from the fluid flow. Such a mechanical trap may be any trap known in the art and may be used with or without permeable sheet 143.

[00053] Still looking at Fig. 1, system 1 may also be provided with a pump 15 designed to generate negative pressure, so as to create a necessary suction force through cannula 10 to pull any undesirable material from the site of interest. In one embodiment, pump 15 may include an intake port 151 in fluid communication with outlet 142 of filter device 14. Intake port 151, as illustrated, may be designed to receive filtered fluid from filter device 14. Pump 15 may also be designed to generate the positive pressure, so as to create a necessary driving force to direct fluid through exit port 152 and downstream of system 1 for reinfusion of fluid removed from the site of interest back into the body. In an embodiment, the suction force and the drive force may be generated by pump 15 simultaneously and may take place continuously or intermittently for a set duration. Pump 15, as it should be appreciated, may be any commercially available pump, including those for medical applications and those capable of pumping fluids, such as blood. Examples of such a pump includes a kinetic pump, such as a centrifugal pump, and an active displacement pump, such as a rollerhead pump.

[00054] In an alternate embodiment, an independent vacuum device (not shown), may be provided for generating the necessary suction force at the site of interest, while a pump 15 may act to generate the necessary driving force for reinfusion purposes. In such an embodiment, pump 15 may be in fluid communication with the filter device 14, while the vacuum device may be in fluid communication with suction cannula 10 upstream to the filter device 14. The independent pump 15 and vacuum device may operate intermittently for a set duration, and if desired, either the vacuum device or pump 15 may operate continuously, while the other operates intermittently.

[00055] Downstream of pump 15, system 1 may further include a second or reinfusion cannula 16 in fluid communication with the exit port 152 of pump 15. Reinfusion cannula 16, in an embodiment, may be designed to permit filtered fluid, directed from filter device 14 by way of pump 15, to be reinfused back into a patient at a desired site. To that end, reinfusion cannula 16 may be designed for placement within the same or different vessel within which suction cannula 10 may be located.

[00056] Reinfusion cannula 16, in one embodiment, may be an elongated tube and includes a distal end 161 through which cleansed or filtered fluid can be reinfused back into the body. In an embodiment, distal end 161 of reinfusion cannula 16 may be designed so that it can be situated in spaced relation to the distal end 11 of the suction cannula 10 when system 1 is in operation. Reinfusion cannula 16 may also include a lumen or pathway 162 extending along its body portion to provide a passage along which the filtered fluid, such as blood, may be transported to a reinfusion site. Reinfusion cannula 16 may further include a proximal end 163 in opposing relations to the distal end 161, and through which the filtered fluid from pump 15 may enter into the cannula 16.

[00057] Furthermore, similar to suction cannula 10, since reinfusion cannula 16 may be designed for introduction into the vasculature, and may need to be maneuvered therealong, reinfusion cannula 16, in one embodiment, may be made from a pliable material. In one embodiment, reinfusion cannula 16 may be constructed from a biocompatible material, such as polyvinyl chloride, polyethylene, polypropylene, polyurethane, Pebax®, silicone, or a combination thereof. In certain instances, it may be desirable to maneuver reinfusion cannula 16 to the reinfusion site using image guidance, for example, using fluoroscopy or echocardiography. To permit reinfusion

cannula 16 to be visualized, reinfusion cannula 16, in an embodiment, may also be made to include a radioopaque material.

[00058] Since reinfusion cannula 16 may be made from a pliable material, in order to efficiently direct it along a vessel to the reinfusion site, reinfusion cannula 16 may be reinforced to optimize maneuverability within the vessel without kinking. Moreover as shown in Fig. 4B, reinfusion cannula 16 may be provided with one or more additional lumens. With a multi-lumen design, lumen 162, as noted above, may act to provide a passage along which the filtered fluid may be transported and directed to the reinfusion site. Lumen 42, on the other hand, can provide a passage through which a guide wire can be inserted to assist in the guiding the reinfusion cannula 16 to the reinfusion site, or through which other instruments and devices may be inserted for various surgical procedures. With such a multi-lumen design, reinfusion cannula 16 can serve as an introducer sheath by providing lumen 42 through which these instruments can pass, while filtered blood can be reinfused through lumen 162. Although illustrated with such a multi-lumen design, any other multi-lumen design may be possible.

[00059] Although illustrated as a separate component from suction cannula 10, in certain embodiments, the reinfusion cannula 16 may be designed to be substantially integral with suction cannula 10. In one embodiment, as illustrated in Fig. 4C, reinfusion cannula 16 may be incorporated as part of a double or multi- lumen introducer sheath 43 for insertion into the same vessel within which the suction cannula 10 may be situated. In particular, suction cannula 10 may be inserted and maneuvered through one lumen 44 of sheath 43, while reinfusion cannula 16 may be in fluid communication with lumen 45 of sheath 43. In such an embodiment, lumen 45 may include a distal end 451 in spaced relations to the distal end 11 of cannula 10, so that cleansed or filtered fluid may be introduced to the reinfusion site away from the site of interest where the distal end 11 of cannula 10 may be positioned.

[00060] Alternatively, as illustrated in Fig. 4D, reinfusion cannula 16 may be incorporated as part of a double or multi- lumen introducer sheath 43 where the reinfusion cannula 16 and the suction cannula 10 may be concentrically aligned along a shared axis A. In the embodiment shown in Fig. 4D, reinfusion cannula 16 may have a diameter that can be relatively larger than that of suction cannula 10. To that

end, reinfusion cannula 16 can accommodate suction cannula 10 within pathway 162 of the reinfusion cannula 16, and allow suction cannula 10 to extend from within pathway 162, such that the distal end 11 of suction cannula 10 may be positioned in spaced relations relative to the distal end 161 of reinfusion cannula 16. The spaced relations between distal end 161 and distal end 11 allows filtered fluid to be introduced to the reinfusion site away from the site of interest, where the removal of the undesirable material may be occurring.

[00061] In another embodiment, reinfusion cannula 16 and suction cannula 10 can be integrated into a single multi-lumen suction-reinfusion cannula 46, as shown in Fig. 4E. In the embodiment shown in Fig. 4E, multi-lumen cannula 46 may include a distal suction port 461 through which undesirable material from the site of interest can be removed, and a proximal reinfusion port 462 through which cleansed or filtered fluid may be reinfused back into the body. The spaced relations between the suction port 461 and reinfusion port 462 allows filtered fluid to be introduced to the reinfusion site away from the site of interest where the removal of the undesirable material may be occurring.

[00062] In an embodiment, the size of the reinfusion cannula, whether independent from the suction cannula, part of a multi-lumen introducer sheath, part of a multi-lumen combined suction-reinfusion cannula, or in concentric alignment with the suction cannula, may be designed so that it can handle a relatively rapid reinfusion of large volumes of fluid by pump 15.

[00063] With reference now to Fig. 6, system 1 may also include a reservoir 61. Reservoir 61, in one embodiment, may be situated in fluid communication between filter device 14 and pump 15, and may act to transiently collect fluid filtered from the site of interest, prior to the filtered fluid being directed into reinfusion cannula 16. By providing a place to transiently collect fluid, reservoir 61 can allow the rate of suctioning (i.e., draining, aspirating) to be separated from rate of reinfusing. Typically, the rate of reinfusion occurs at substantially the same rate of suctioning, as the volume of fluid suctioned from the site of interest gets immediately directed along the system 1 and introduced right back to the reinfusion site in a patient. However, the availability of a volume of transiently collected fluid in reservoir 61 now provides a source from which the amount or volume of fluid being reinfused back into the

patient can be adjusted, for example, to be less than that being suctioned from the site of interest, as well as the rate at which fluid can be reinfused back into the patient, for example, at a relatively slower rate in comparison to the rate of suctioning. Of course, if so desired or necessary, the reinfusion rate and volume can be adjusted to be higher, relative to the rate and volume of suction.

[00064] In accordance with one embodiment of the present invention, reservoir 61 may be a closed or an open container, and may be made from a biocompatible material. In an embodiment where reservoir 61 may be a closed container, system 1, likewise, will be a closed system. As a result, pump 15 may be used as both a suction source and a driving force to move fluid from the site of interest to the reinfusion site. In such an embodiment, pump 15 can generate a suction force independently of or alternately with a driving force to allow reservoir 61 collect filtered fluid from filter device 14. In one embodiment, pump 15 may be provided with a gauge in order to measure a rate of flow of the fluid being reinfused.

[00065] Alternatively, where reservoir 61 may be an open container, reservoir 61, in such an embodiment, may be designed to accommodate both a volume of fluid, typically at the bottom of reservoir 61, and a volume of air, typically at the top of reservoir 61, to provide an air-fluid interface within reservoir 61. As a result, using pump 15 in fluid communication with reservoir 61 may not provide the needed driving force and/or suction force to adequately remove the undesirable material and to subsequent reinfuse fluid back into a patient. To address this, system 1, in an embodiment, may include a separate and independent vacuum source, in fluid communication with the volume of air at the top of reservoir 61, for providing the necessary suction force from the top area of reservoir 61 where air exists, through filter device 14, through the distal end 11 of cannula 10, and to the site of interest. A port provided above the fluid level within reservoir 61 may be provided to allow the independent vacuum source to be in fluid communication with the volume of air within reservoir 61. Pump 15, on the other hand, may be in fluid communication with the volume of fluid within reservoir 61, and may act to generate the necessary driving force for reinfusion purposes.

[00066] It should be appreciated that although shown as separate components, to the extent desired, reservoir 61 and filter device 14 may be combined as a single unit.

[00067] Still referring to Fig. 6, system 1 may further include a second filter device 62 positioned in fluid communication between pump 15 and reinfusion cannula 16. Second filter device 62 may act to remove any debris or material (e.g., ranging from smaller than microscopic in size to relatively larger) that may have escaped and moved downstream from filter device 14, so that the fluid may be substantially cleansed prior to reinfusion. In an embodiment, second filter device 62 may include a porous membrane 63 whose pores may be measurably smaller than that in filter device 14, but still capable of allowing fluid to flow therethrough.

[00068] Since fluid such as blood needs to be filtered through system 1, it should be noted that system 1 and its components may be made from a biocompatible material to minimize any adverse reaction when fluid removed from the site of interest gets reinfused back into the body.

[00069] In operation, system 1 of the present invention may be introduced into the vasculature, preferably through a peripheral blood vessel, to remove undesirable material, such as a clot, emboli, or thrombi, substantially *en bloc* and without significant fragmentation, and subsequently reinfusing fluid removed from the site of interest back into a patient. In particular, system 1 and its components disclosed above can collectively form a substantially closed circuit through which fluid and an undesirable material from a site of interest can be removed by suction, cleared of the undesirable material, filtered to remove any additional debris, and actively introduced back into a patient at a reinfusion site.

[00070] With reference now to Fig. 7, there is shown one embodiment of the system of the present invention being utilized for removal of an undesirable material within a patient 700. System 70, as illustrated, includes a suction cannula 71, filter device 72, pump 73, second filter device 74 and reinfusion cannula 75. It should be appreciated that depending on the procedure and to the extent desired, system 70 may not need all of the components shown, or may need other components in addition to those shown.

[00071] In general the method of the present invention, in one embodiment, includes, initially accessing a first blood vessel 701 either by surgical dissection or percutaneously with, for instance, a needle and guide wire. The first blood vessel through which suction cannula 71 may be inserted into patient 700 can be, in an embodiment, any blood vessel that can be accessed percutaneously or by surgical

dissection such as femoral vein, femoral artery or jugular vein. Next, suction cannula 71 may be inserted into the first blood vessel 701 over the guide wire, and advanced toward a site of interest 702, for instance, in a second vessel or a heart chamber 703 where an undesirable material 706 may be residing. The second blood vessel or heart chamber, in an embodiment, can be the main pulmonary artery, branch pulmonary arteries, inferior vena cavae, superior vena cavae, deep veins of the pelvic, legs, arms or neck, aorta, or any other medium to large blood vessel for which the use of a cannula is suitable for removing undesirable material without causing undesirable damage to the blood vessel. In addition, the advancement of suction cannula 71 may be gauged or documented by fluoroscopic angiography, echocardiography or other suitable imaging modality.

[00072] In the case of pulmonary embolism, the suction cannula 71 may normally be introduced through the femoral, jugular or subclavian vein. Alternatively, the suction cannula 71 may be introduced, if desired, directly into the cardiac chambers using a minimally invasive surgical or endoscopic, thoracoscopic, or pericardioscopic approach.

[00073] Thereafter, a third blood vessel 704 may be accessed either by surgical dissection or percutaneously with, for example, a needle and guide wire. Subsequently, reinfusion cannula 75 may be inserted into the third blood vessel 703 using an open or over the guide wire technique. The third blood vessel through which the reinfusion cannula 75 may be inserted, in one embodiment, can be any large vein, such as the femoral vein or jugular vein. Reinfusion cannula 75 may then be advanced toward a reinfusion site, for example, within a fourth blood vessel 705. The fourth blood vessel, in one embodiment, can be the femoral vein, iliac vein, inferior vena cava, superior vena cava or right atrium.

[00074] Once reinfusion cannula 75 is in place and components of system 70 have connected, pump 73 may be activated, and suction cannula 71 may then be placed against and in substantial engagement with the undesirable material 706 at the site of interest 702 for removal by suctioning through the suction cannula 71. The undesirable material 706 and circulatory fluid removed from the site of interest 702 may thereafter be directed along suction cannula 71 into filter device 72 where the undesirable material 706 can be entrapped and removed from the fluid flow. The

resulting filtered fluid may next be directed downstream by way of pump 73 into the second filter device 74, where any debris or material (e.g., ranging from smaller than microscopic in size to relatively larger) that may have escaped and moved downstream from filter device 74 can be further captured and removed from the fluid flow prior to reinfusion. The resulting cleansed fluid may then be directed into the reinfusion cannula 75 and introduced back into the patient 700.

[00075] It should be appreciated that in certain instances, prior to connecting the suction cannula 71 and the reinfusion cannula 75, system 70 may need to be primed with fluid to minimize or eliminate any air and/or air bubbles from the system prior to the initiation of suction and reinfusion. To that end, the suction cannula 71 and reinfusion cannula 75 can be primed separately with fluid or by allowing blood to backfill the cannulae after insertion. The remaining components of the system 70 including all tubing, the filter device 72, the pump 73 and any other components of system 70 may also need to be primed with fluid prior to connecting them to the cannulae. In one embodiment, this can be achieved by temporarily connecting these components in fluid communication with other as a closed circuit and infusing fluid through a port, similar to port 51 in Fig. 5, while providing another port through which air can be displaced. Once these components have been fully primed with fluid, the circuit can be detached and connected to the primed suction cannula 71 and reinfusion cannula 75 in the appropriate configuration. Examples of a priming fluid include crystalloid, colloid, autologous or heterologous blood, among others.

[00076] During operation, pump 73, in one embodiment, may remain activated so that suction and continuous reinfusion of blood can occur continuously for a desired duration or until the removal of the undesirable material has been confirmed, for instance, by visualizing the captured undesirable material in the filter device 72. Alternatively pump 73 can be activated intermittently in short pulses, either automatically or manually by an operator (e.g., surgeon, nurse or any operating room attendant), for a desired duration or until the removal of the undesirable material has been confirmed by visualization of the material within filter device 72.

[00077] It should be appreciated that since suction cannula 71 may be deployed within any vessel within patient 700, depending on the procedure, in addition to being placed substantially directly against the undesirable material at the site of interest, suction

cannula 71 may be deployed at a location distant from the site of interest where direct engagement with the undesirable material may not be possible or desired.

[00078] In a situation where the suction cannula 71 is positioned within a vessel exhibiting a venous flow and at a distant location from the undesirable material, it may be desirable to place the distal end of suction cannula 71 downstream of the undesirable material, so that the fluid flow can push the undesirable material from the site of interest into suction cannula 71 during suction. To the extent there may be some difficulties with suctioning the undesirable material from its location, if necessary, a catheter may be deployed through suction cannula 71 and to the site of interest, where the undesirable material may be dislodged location for subsequent removal.

[00079] On the other hand, when suction cannula 71 is positioned within a vessel exhibiting arterial flow and at a distant location from the undesirable material, it may be necessary to place the distal end of suction cannula 71 upstream of the undesirable material for the purposes of removal, even though the undesirable material must move against the fluid flow in order to enter into the suction cannula 71. In such a situation, since the fluid flow in the vessel tends to exert a pressure against the undesirable material at the site of interest, and thus may make the undesirable material difficult to remove, suction cannula 71 may include a flow occlusion mechanism, similar to balloon 33 shown in Fig. 3. When expanded radially, the mechanism can substantially occlude the vessel, such that pressure being exerted on the downstream material by the fluid flow can be lessened. By lessening the pressure on the undesirable material to be removed, the suction force being applied at the site of interest can act to remove the material more easily. Again, if necessary, a catheter may be deployed through suction cannula 71 and to the site of interest, where the undesirable material may be dislodged or drawn back into the cannula to facilitate its removal.

[00080] The method of the present invention may also utilize a fluid reservoir, similar to reservoir 61 shown in Fig. 6, in connection with system 70. Such a reservoir may be placed in fluid communication between filter device 72 and pump 73. The reservoir, in an embodiment, may be an independent reservoir or may be integrated with filter device 72 as a single unit, similar to that shown in Fig. 7. By utilizing a

reservoir, a volume of transiently collected fluid may be used to independently control the rate or volume of suctioning (i.e., draining, aspirating) and/or the rate or volume of reinfusion.

[00081] In an embodiment where the reservoir may be an open container, it should be appreciated that system 70 may not be a substantially closed system. As a result, rather than utilizing a pump that can generate both a suction and a driving force for a closed system, an independent vacuum device 76 may be employed to generate the necessary suction force, from the top of the reservoir where a volume of air exists, for removal of the undesirable material, while independent pump 73 may be employed to generate the necessary driving force, from the bottom of the reservoir where a volume of aspirated fluid exists, for reinfusion.

[00082] The method of the present invention may also utilize a suction cannula 71 with a deployable funnel tip, similar to funnel 20 in Fig. 2 or in Fig. 3. In such an embodiment, the funnel may be deployed after suction cannula 71 has been positioned adjacent the site of interest. Thereafter, once the suction force has been activated, the funnel may be advanced to engage the undesirable material for removal. The funnel may remain deployed while the suction force is activated, and through multiple cycles, if necessary, until the undesirable material can be removed. Subsequently, the funnel may be retracted in order to reposition or remove suction cannula 71.

[00083] The method of the present invention may further utilize reinfusion cannula 75 that has been incorporated into an introducer sheath, such as sheath 43 as a multi-lumen cannula (Fig. 4C) or as one which concentrically aligns the suction cannula and reinfusion cannula (Fig. 4D). In this embodiment, the sheath/reinfusion cannula 75 may initially be inserted into a first blood vessel. Suction cannula 71 may then be inserted into the introducer lumen of the sheath/reinfusion cannula 75, and the assembly advanced together to a site of interest in a second blood vessel or heart chamber.

[00084] The method of the present invention may also further utilize a combined multi-lumen suction/reinfusion cannula, similar to cannula 46 shown in Fig. 4E. In such an embodiment, the combined suction/reinfusion cannula may initially be inserted into a first blood vessel to a location where its distal suction lumen can be placed adjacent the site of interest within a second blood vessel, while its proximal

located reinfusion lumen can be positioned at an appropriately spaced location from the suction lumen.

[00085] The method of the present invention may, in an embodiment, be employed to remove a plurality of undesirable materials, for instance, within the same vessel or its branches, from multiple vessels within the same vascular bed (e.g. left and right pulmonary arteries), from different vascular beds (e.g. pulmonary artery and iliofemoral veins), or a combination thereof. In such an embodiment, after the first undesirable material has been removed, the suction force may be deactivated. The next undesirable material to be removed may then be located, for example, using an appropriate imaging modality. Suction cannula 71 may thereafter be advanced to the location of this second undesirable material, and the suction force reactivated as above until this second undesirable material may be removed. The cycle may be repeated until each undesirable material at the various identified locations has been removed. Once all undesirable material has been removed, an appropriate procedure to prevent the development of or migration of new material, such as placement of an inferior vena cava filter, may be performed.

[00086] The method of the present invention may also be employed in combination with a balloon embolectomy catheter or other devices suitable for dislodging clots or other undesirable material from a cannula or a vessel. For example, should an undesirable material be lodged within suction cannula 71, a balloon catheter can be inserted through, for instance, a side port, similar to port 51 in Fig. 5, of suction cannula 71 and advanced past the lodged undesirable material. The balloon catheter may subsequently be inflated distal to the undesirable material. Once inflated, the suction force may be activated and the inflated catheter withdrawn along the suction cannula 71 to dislodge the undesirable material its location of obstruction. In a situation where the undesirable material may be adherent to a vessel wall, or for some other reason cannot be dislodged by simply applying suction to the site of interest, the balloon catheter can be inserted through the side port of suction cannula 71, advanced past a distal end of cannula 71, and past the adherent undesirable material. The balloon catheter may then be inflated distal to the undesirable material. Once inflated, the suction force may be activated and the inflated catheter withdrawn along the

suction cannula 71. As it is withdrawn, the balloon catheter can act to drag the undesirable material into suction cannula 71.

[00087] The method of the present invention may further be employed in combination with a distal protection device (not shown), such as a netting device, designed to be positioned downstream of the undesirable material, when removal may be performed within a vessel having arterial flow. In particular, with suction cannula 71 positioned upstream of the undesirable material, the netting device may be inserted through a side port in suction cannula 71, advanced past the undesirable material to a downstream location. The netting device may then be deployed to an open position approximating the diameter of the vessel. The deployed netting device may then act to entrap any material that may be dislodged from the site of interest and pushed downstream by the fluid flow. In the absence of the netting device, a dislodged material may be pushed downstream and may be lodged in a more life threatening location.

[00088] It is evident from the above description that the systems, including the various components, and methods of the present invention can act to remove clots and other types of undesirable material from the circulation, particularly from medium to larger vessels and heart chambers. Important to achieving this includes the ability of the operator to perform substantially *en bloc* removal of the undesirable material without significant fragmentation from the site of interest. Such a protocol may only be achieved previously with invasive, open surgery. In addition, by providing a system with components to permit aspirated fluid from the site of interest to be reinfused back to the patient, the system of the present invention allows a sufficiently and relatively large suction cannula to be employed for the removal of a relatively large undesirable material 15 in substantially one piece, without fragmentation. Furthermore, by providing a definitive mechanical treatment to the problem, the systems and methods of the present invention provide an attractive alternative to treatments, such as thrombolysis, which may not be an option or may be ineffective for many patients, and which may carry a significant risk of major complications. As such, the systems and methods of the *p*resent invention now provide a significant contribution to the field of cardiovascular medicine and surgery, particularly thromboembolic disease.

[00089] Although references have been made in connection with surgical protocols, it should be appreciated that the systems and methods of the present invention may be adapted for use in connection with non-surgical protocols, and in connection with any vessel capable of permitting fluid flow therethrough and capable of being obstructed. For instance, the system of the present invention may be adapted for use in connection with clearing obstructed oil pipelines, water pipes, and air ducts, among others.

[00090] While the present invention has been described with reference to certain embodiments thereof, it should be understood by those skilled in the art that various changes may be made and equivalents may be substituted without departing from the true spirit and scope of the invention. In addition, many modifications may be made to adapt to a particular situation, indication, material and composition of matter, process step or steps, without departing from the spirit and scope of the present invention. All such modifications are intended to be within the scope of the claims appended hereto.

What is claimed is:

1. A system for removing an undesirable material from within a vessel, the system comprising:

a first cannula having a distal end and an opposing proximal end, the first cannula designed for maneuvering within a vessel to a site of interest, such that the undesirable material can be captured substantially *en bloc* through the distal end and removed along the first cannula away from the site;

a pump, in fluid communication with the proximal end of the first cannula, to provide a sufficient suction force for removing the undesirable material from the site of interest; and

a second cannula in fluid communication with the pump and being designed to have its distal end situated in spaced relation to the distal end of the first cannula, such that fluid removed from the site of interest by the first cannula can be directed along the second cannula and reinfused through the distal end of the second cannula.

2. A system as set forth in claim 1, wherein the first cannula is designed to remove the undesirable material from one of a medium size blood vessel, a large size blood vessel, or a heart chamber.

3. A system as set forth in claim 1, wherein the first cannula is designed to remove the undesirable material without substantial fragmentation.

4. A system as set forth in claim 1, wherein the distal end of the first cannula includes a diameter that is relatively larger than that of the proximal end of the first cannula.

5. A system as set forth in claim 4, wherein the distal end of the first cannula can occlude fluid flow adjacent the site of interest in order to enhance the suction force applied to the undesirable material.

6. A system as set forth in claim 1, wherein the distal end of the first cannula is deployable to expand from a first diameter to a relatively larger second diameter.

7. A system as set forth in claim 6, wherein the distal end of the first cannula is funnel shape.

8. A system as set forth in claim 6, wherein the distal end of the first cannula includes a mechanism for substantially occluding fluid flow adjacent the site of interest, in order to enhance suction force being applied to the undesirable material.

9. A system as set forth in claim 1, wherein the first cannula is made from a radioopaque material to permit visualization of the cannula for image guidance purposes.

10. A system as set forth in claim 1, wherein the first cannula is made from a material sufficiently pliable to permit maneuvering of the cannula within the vessel.

11. A system as set forth in claim 1, wherein the first cannula is made from a material sufficiently strong, so as to not collapse under suction.

12. A system as set forth in claim 1, wherein the first cannula is reinforced with to prevent kinking.

13. A system as set forth in claim 1, wherein the first cannula is constructed of a material including one of polyvinyl chloride, polyethylene, polypropylene, polyurethane, Pebax®, silicone, or a combination thereof.

14. A system as set forth in claim 1, wherein the first cannula includes a side port to permit introduction of other instruments or devices into the first cannula.

15. A system as set forth in claim 1, wherein the first cannula includes multiple lumens.

16. A system as set forth in claim 1, wherein the pump can simultaneously generate a negative pressure to create a suction force necessary to pull the undesirable material into the first cannula and a positive pressure to create a driving force necessary to reinfuse fluid through the second cannula.

17. A system as set forth in claim 1, wherein the pump can intermittently generate one of a negative pressure to create a suction force necessary to pull the undesirable material into the first cannula and a positive pressure to create a driving force necessary to reinfuse fluid through the second cannula.

18. A system as set forth in claim 1, wherein the second cannula is made from a material sufficiently pliable to permit maneuvering of the cannula within a vessel.

19. A system as set forth in claim 1, wherein the second cannula includes a side port to permit introduction of other instruments or devices into the second cannula.

20. A system as set forth in claim 1, wherein the second cannula includes multiple lumens.

21. A system as set forth in claim 1, wherein the second cannula and the first cannula are integral in an assembly and include respective distal ends that are in spaced relation relative to one another.

22. A system as set forth in claim 1, wherein the second cannula is integrated as part of an introducer sheath through which the first cannula can be advanced such that the respective distal ends of the second cannula and the first cannula are in spaced relation relative to one another.

23. A system as set forth in claim 1, further including a filter device in fluid communication with the first cannula for entrapping the undesirable material as it exits from the first cannula and removing it from the fluid flow.

24. A system as set forth in claim 23, wherein the filter device includes a permeable sheet capable of permitting fluid directed from the first cannula to flow therethrough, while impeding the undesirable material from flowing downstream within the system.

25. A system as set forth in claim 1, further including a reservoir in fluid communication with the filter device for collecting fluid being directed from the filter device and providing a source of fluid for reinfusion by the second cannula.

26. A system as set forth in claim 1, further including a reservoir and a filter device as an integral unit.

27. A system as set forth in claim 1, further including a second filter positioned in fluid communication between the pump and the second cannula for removing undesirable debris from the fluid flow prior to reinfusion by the second cannula.

28. A system as set forth in claim 1, wherein the undesirable material captured from the site of interest includes one of a clot, a thrombus, an embolus, a tumor, an infective vegetation, and a foreign body.

29. A system as set forth in claim 1, wherein the fluid removed from the site of interest includes blood.

30. A method for removing an undesirable material from within a vessel, the method comprising:

maneuvering a first cannula having a distal end and an opposing proximal end to a site of interest within a vessel in a patient, such that the distal end of the first cannula is positioned adjacent the undesirable material;

positioning a second cannula, in fluid communication with the first cannula, such that its distal end is situated in spaced relation to the distal end of the first cannula;

providing a suction force, through the distal end of the first cannula, to the site of interest, so as to remove the undesirable material *en bloc* from the site of interest through the distal end of the first cannula; and

reinfusing, through the distal end of the second cannula, any fluid removed along with the undesirable material to a location in spaced relation from the distal end of the first cannula.

31. A method as set forth in claim 30, wherein, in the step of maneuvering, the vessel includes one of a medium size blood vessel, a large size blood vessel, or a heart chamber.

32. A method as set forth in claim 30, wherein, in the step of maneuvering, the distal end of the first cannula includes a diameter that is relatively larger than that of the proximal end of the first cannula.

33. A method as set forth in claim 30, wherein the step of maneuvering includes substantially occluding fluid flow within the vessel adjacent the distal end of the first cannula, so as to enhance the suction force applied to the undesirable material.

34. A method as set forth in claim 33, wherein the step of occluding occurs within a vessel exhibiting venous circulation.

35. A method as set forth in claim 33, wherein the step of occluding occurs within a vessel exhibiting arterial circulation.

36. A method as set forth in claim 30, wherein the step of maneuvering includes expanding, at the site of interest, the distal end of the first cannula from a first diameter to a relatively larger second diameter.

37. A method as set forth in claim 30, wherein the step of positioning includes one of placing the distal end of the second cannula within the same vessel as that of the distal end of the first cannula, placing the distal end of the second cannula within a different vessel as that of the distal end of the first cannula, or placing the distal end of the second cannula in spaced relation to the distal end of the first cannula.

38. A method as set forth in claim 30, wherein the step of providing includes generating the suction force and a driving force for reinfusion from one source.

39. A method as set forth in claim 30, wherein the step of providing includes generating the suction force and a driving force for reinfusion from different sources.

40. A method as set forth in claim 30, wherein the step of providing includes removing the undesirable material without substantial fragmentation.

41. A method as set forth in claim 30, wherein the step of providing includes removing at least 10 cm^3 of the undesirable material without substantial fragmentation.

42. A method as set forth in claim 30, wherein the step of providing includes entrapping, downstream of the proximal end of the first cannula and towards a source for the suction force, the undesirable material so as to remove it from the fluid flow.

43. A method as set forth in claim 42, wherein in the step of entrapping includes permitting fluid flow to continue into the second cannula, while impeding movement of the undesirable material toward the second cannula.

44. A method as set forth in claim 42, further including capturing undesirable debris downstream of the entrapped undesirable material but before to the second cannula, so as to remove the debris from the fluid flow prior to reinfusing.

45. A method as set forth in claim 30, wherein the step of reinfusing includes collecting fluid directed from the proximal end of the first cannula and using the collected fluid as a source of fluid for reinfusion.

46. A method as set forth in claim 30, wherein prior to providing a suction force, the method includes priming the circuit with fluid to minimize presence unwanted air being introduced into the patient.

47. A method as set forth in claim 30, wherein the undesirable material being removed from the site of interest includes one of a clot, a thrombus, an embolus, a tumor, an infective vegetation, and a foreign body.

48. A method as set forth in claim 30, wherein, in the step of reinfusing, the fluid removed from the site of interest includes blood.

49. A method as set forth in claim 30, wherein the step of reinfusing includes introducing a sufficient amount of fluid back into the patient, so as to minimize fluid loss in the patient.

50. A method for removing an undesirable material from within a vessel, the method comprising:

identifying in a patient a site of interest within a vessel having an undesirable material to be removed therefrom;

maneuvering to the site of interest a pathway along which the undesirable material can be directed away from the site of interest;

applying a suction force through the pathway to the site of interest, such that a fluid flow is created into the pathway and that the undesirable material is pulled into the pathway and away from the site of interest;

entrapping the undesirable material after it has exited the pathway, so as to remove the material from the fluid flow; and

introducing the fluid flow back into the patient at a location in spaced relation to the site of interest, so as to minimize fluid loss in the patient.

51. An apparatus for removing an undesirable material from within a vessel, the apparatus comprising:

an elongated tube having a distal end through which an undesirable material can be captured, a pathway extending along the tube to provide a passage for transporting the undesirable material from the distal end, and a proximal end in opposing relations to the distal end through which the undesirable material can exit;

a funnel situated at the distal end of the tube, and designed for deployment between a collapsed closed position and an flared open position, so as to better engage and capture the undesirable material; and

a mechanism positioned about a distal portion of the tube, the mechanism, upon actuation, can deploy the funnel between the closed position and the open position.

52. An apparatus as set forth in claim 51, wherein the tube is made from a material sufficiently pliable to permit maneuvering of the cannula within the vessel.

53. An apparatus as set forth in claim 51, wherein the tube is made from a material sufficiently strong, so as to not collapse under suction.

54. An apparatus as set forth in claim 1, wherein the tube includes a side port to permit introduction of other instruments or devices into the first cannula.

55. An apparatus as set forth in claim 51, wherein the tube includes multiple lumens.

56. An apparatus as set forth in claim 51, wherein the funnel includes a plurality of strips, each pivotally coupled at one end to the distal end of the tube.

57. An apparatus as set forth in claim 56, wherein the funnel includes a substantially impermeable membrane extending across a space between adjacent strips.

58. An apparatus as set forth in claim 51, wherein the mechanism comprises:

a balloon positioned circumferentially about the tube at a location proximal to the funnel; and

an attachment mechanism attached at one end to the funnel and at an opposite end to the balloon, so that upon expansion of the balloon, the mechanism can pull on the funnel to deploy it into a flared open position.

59. An apparatus as set forth in claim 58, wherein the balloon is designed to also occlude the vessel within which the apparatus is situated upon expansion of the balloon.

60. An apparatus as set forth in claim 58, wherein the attachment mechanism includes one of a string, a rod, a chain, or other similar mechanisms.

61. An apparatus as set forth in claim 58, further including a jacket provided circumferentially about the distal end of the tube, and extending from the funnel to the balloon.

62. An apparatus as set forth in claim 61, wherein the jacket acts as the mechanism for deploying the funnel into a flared open position upon expansion of the balloon.

63. An apparatus as set forth in claim 61, wherein the jacket extends into the funnel and is attached to a base of the funnel, so as to act as a membrane defining the funnel.

64. An apparatus as set forth in claim 51, wherein the mechanism includes a sheath designed to slide toward and away from the distal end of the tube.

65. An apparatus as set forth in claim 64, wherein the sheath, when actuated to slide away from the distal end tube, exposes the funnel to permit the funnel to be deployed into the flared open position.

66. An apparatus as set forth in claim 64, wherein the sheath, when actuated to slide toward the distal end of the tube, covers up the funnel to permit the funnel to be deployed into a collapsed closed position.

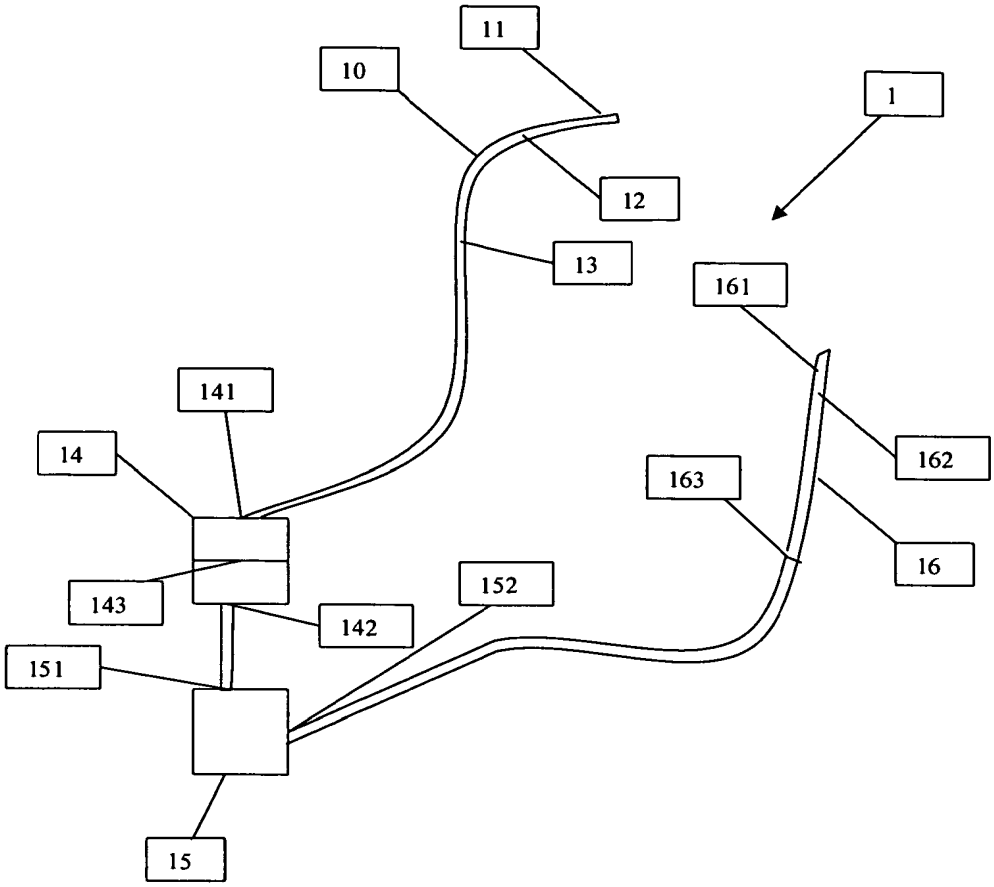


Fig. 1

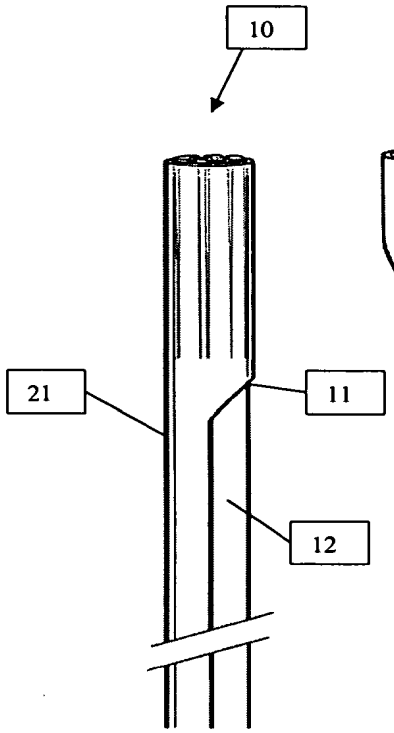


Fig. 2A

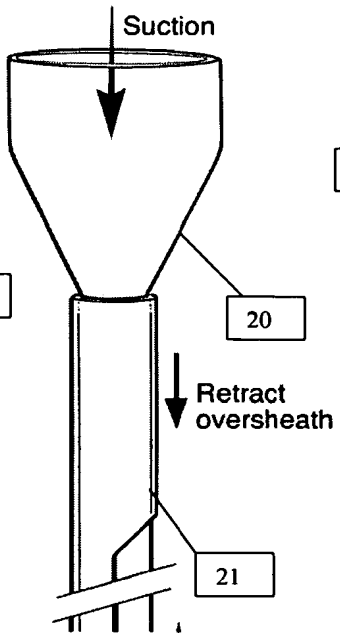


Fig. 2B

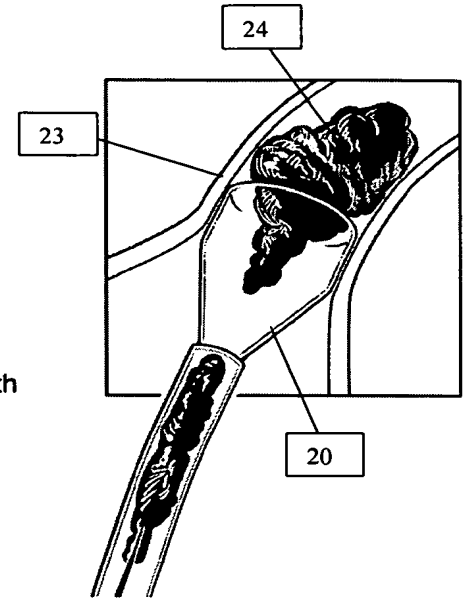


Fig. 2C

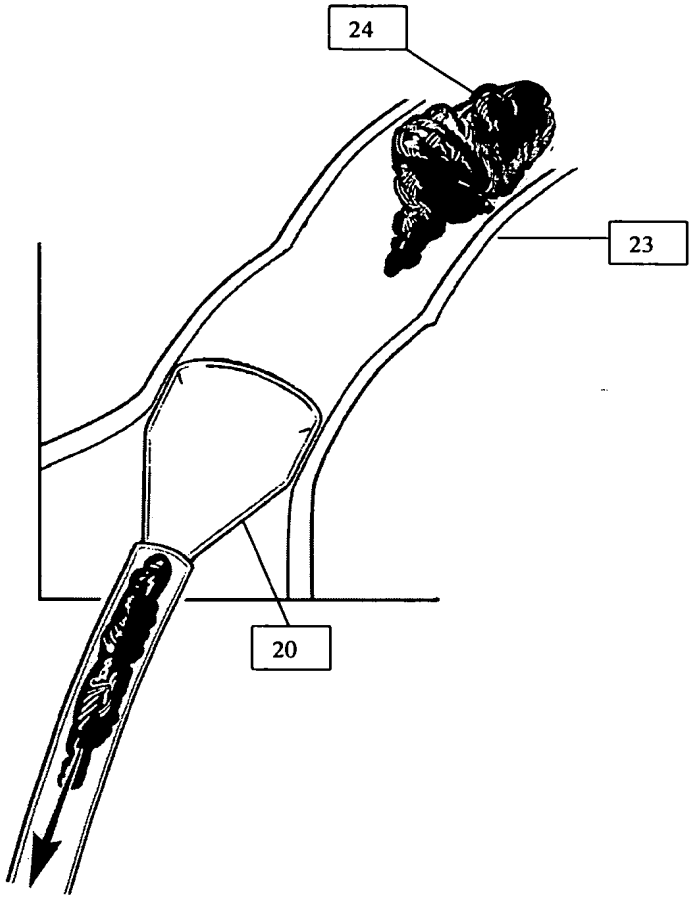


Fig. 2D

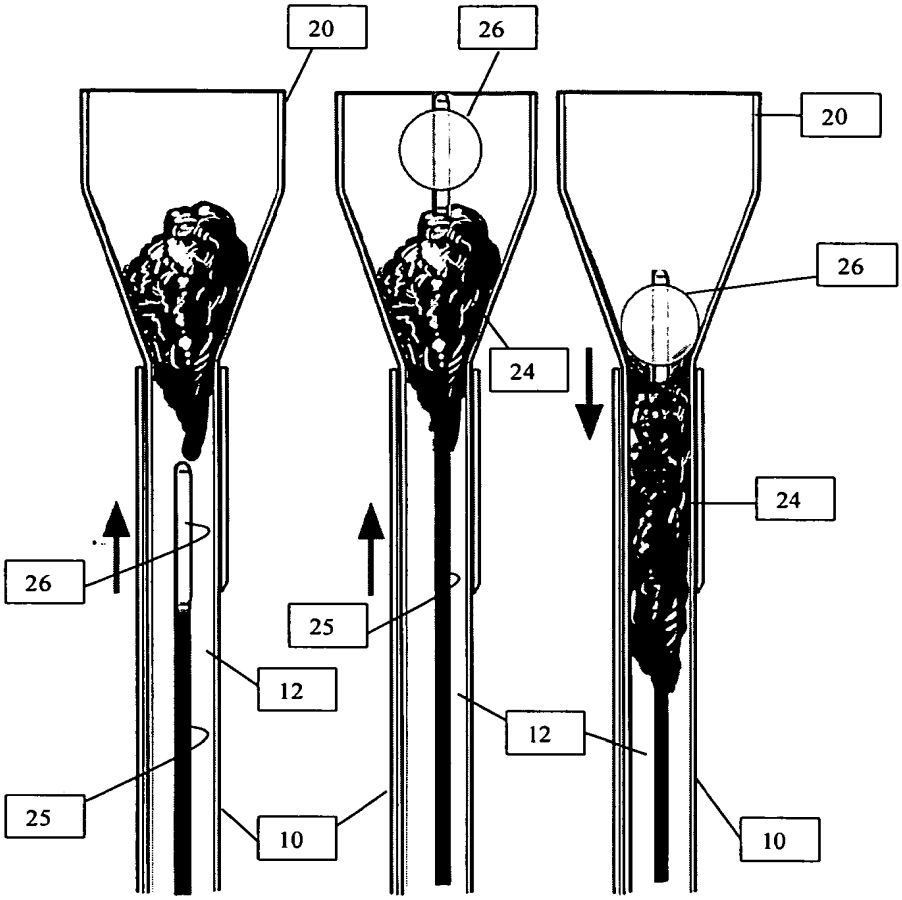


Fig. 2E Fig. 2F Fig. 2G

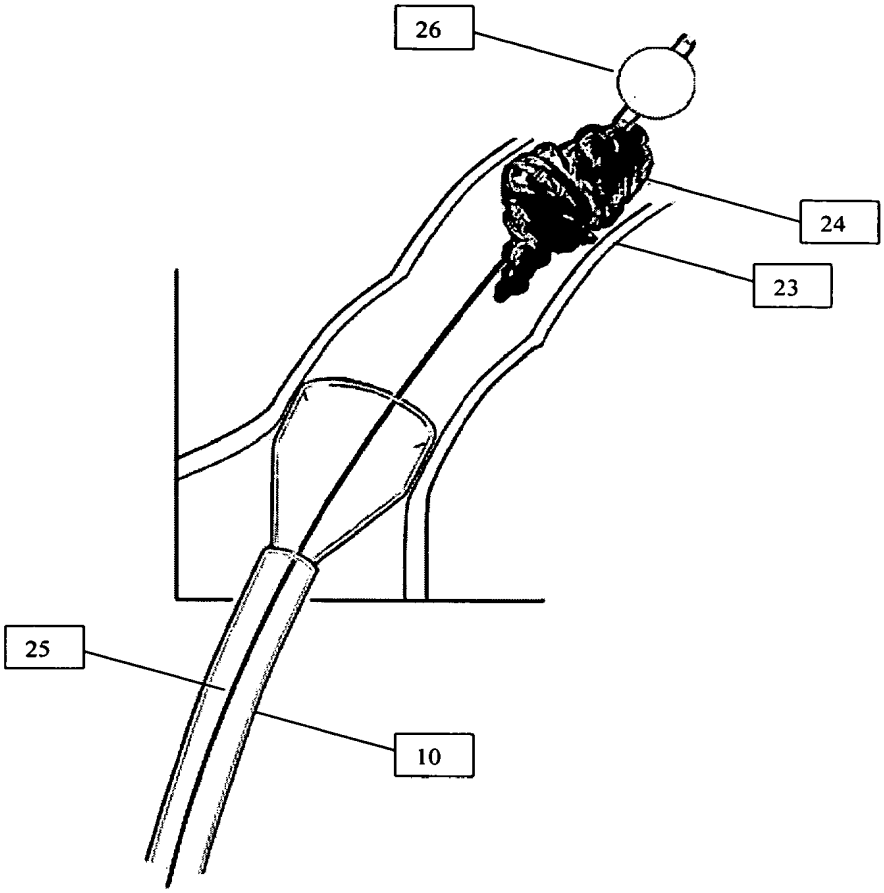


Fig. 2H

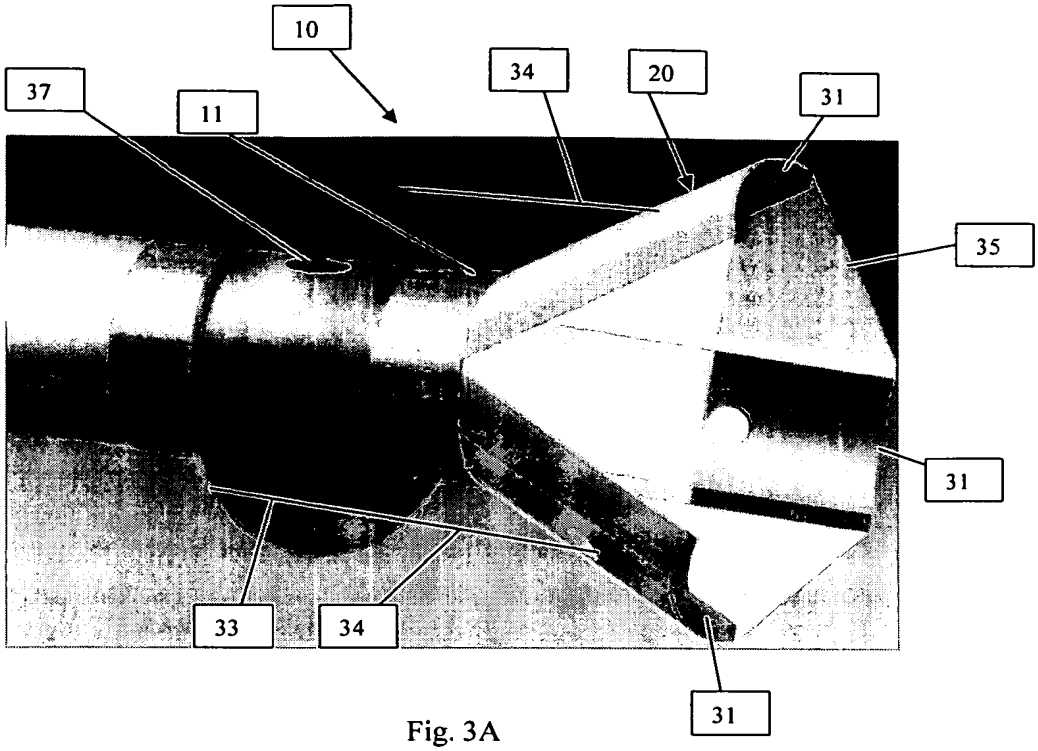


Fig. 3A

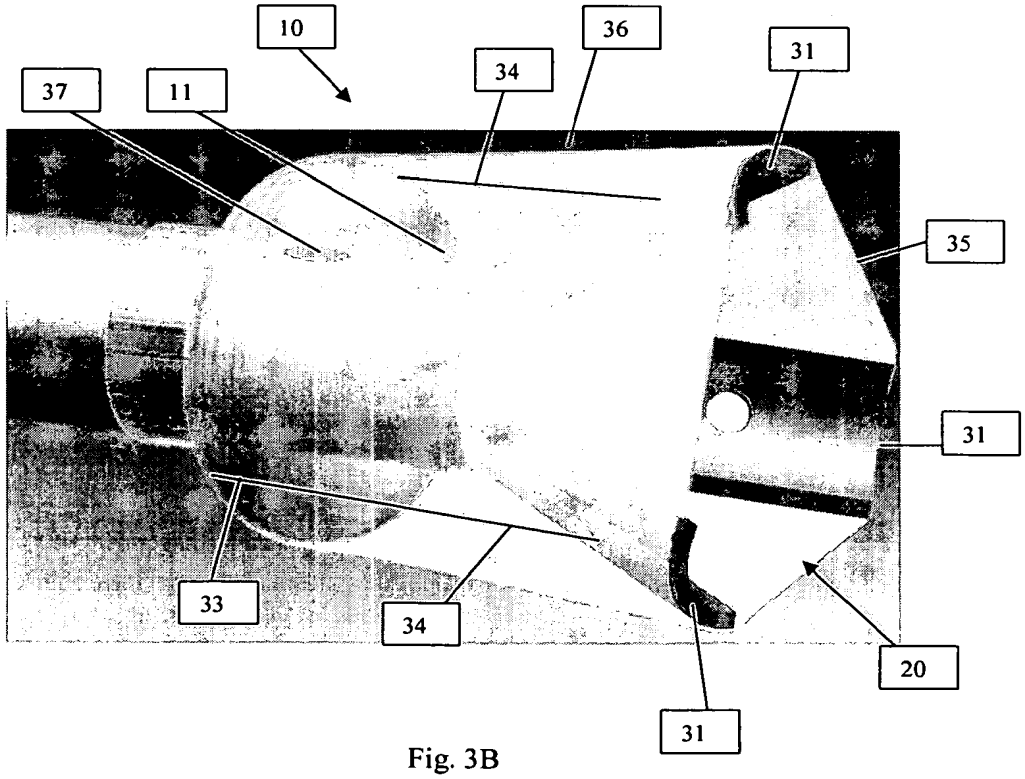


Fig. 3B

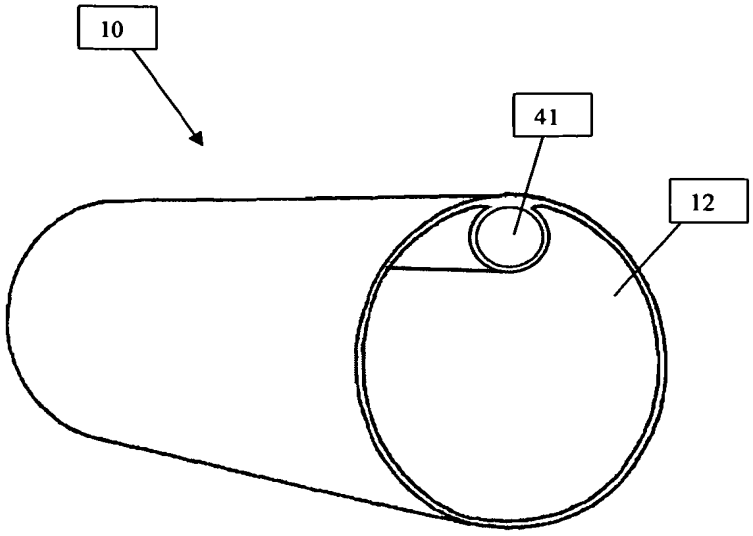


Fig. 4A

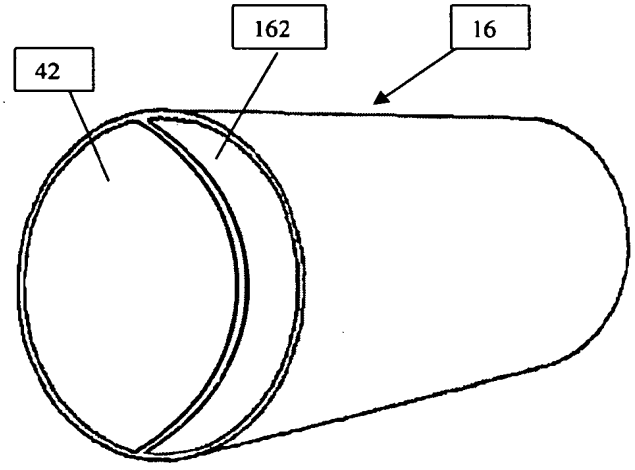


Fig. 4B

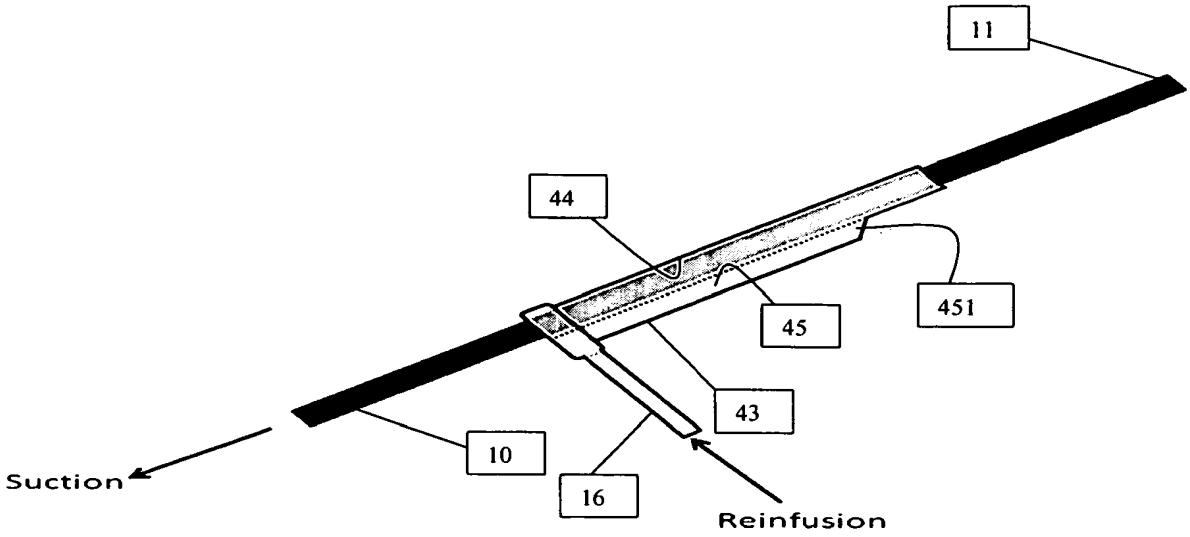

11
44
45
451
43
10
16
Suction
Reinfusion

Fig. 4C

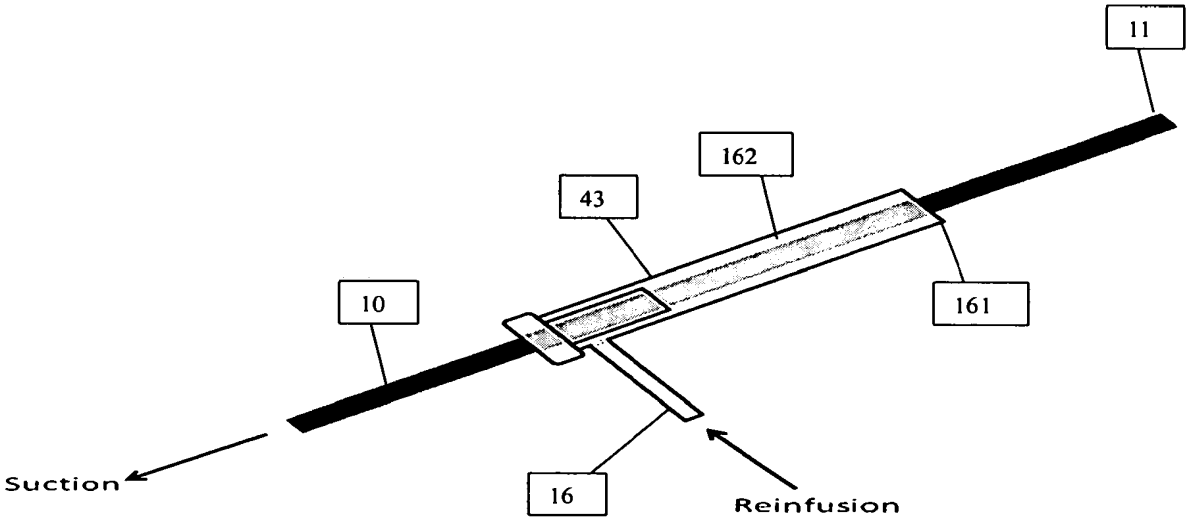

11
162
43
10
161
16
Suction
Reinfusion

Fig. 4D

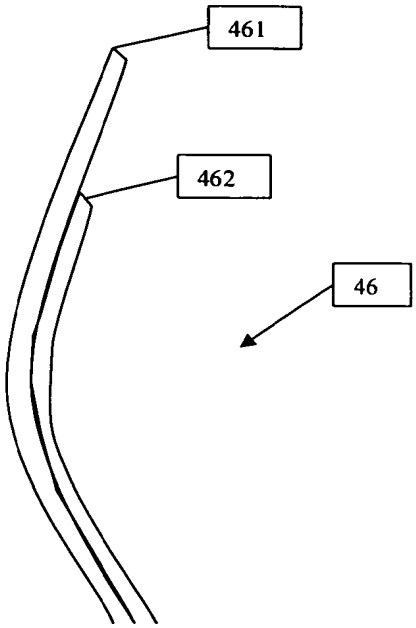


Fig. 4E

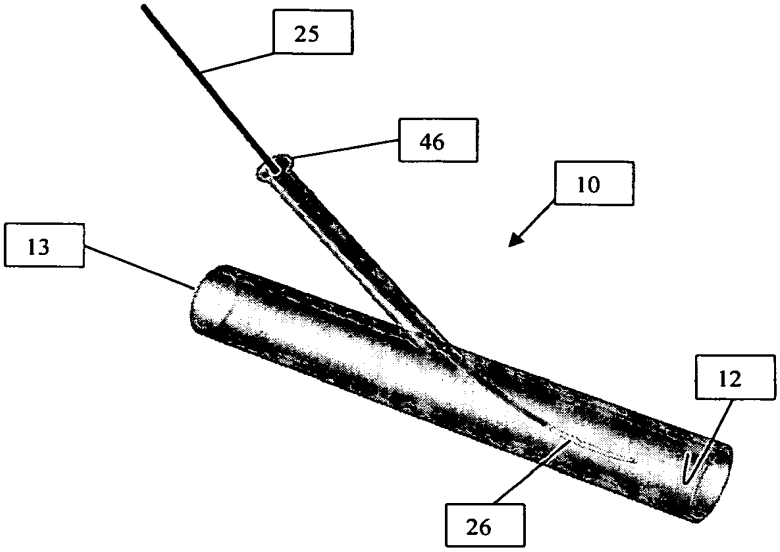


Fig. 5

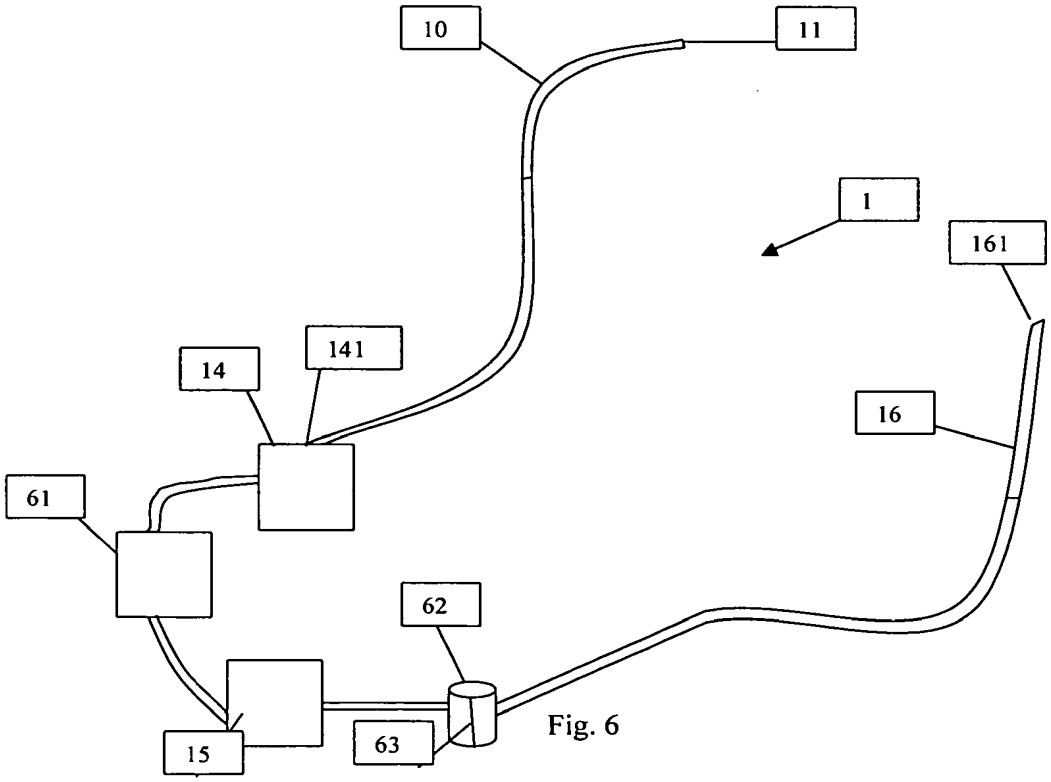


Fig. 6

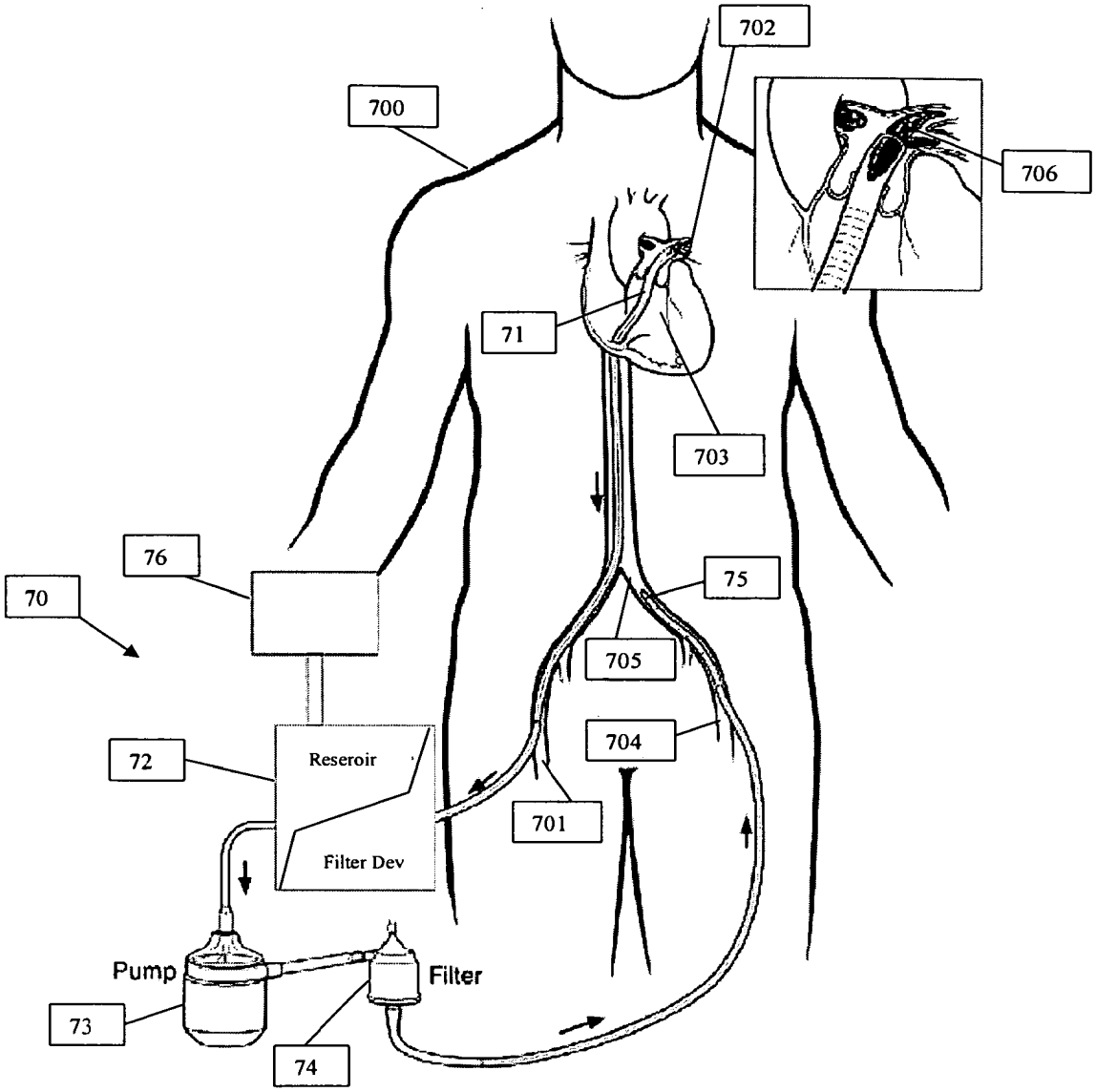

702
700
706
71
703
76
70
75
705
72
Reseroir
704
701
Filter Dev
Pump
Filter
73
74

Fig. 7

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 08/72352

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61M 37/00 (2008.04)
USPC - 604/5.01
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
USPC: 604/5.01

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
USPC: 604/5.01, 5.04, 6.09, 6.11, 6.16

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
PubWEST (PGPB,USPT,USOC,EPAB,JPAB), Freepatentsonline, Google Scholar
Search Terms: clot removal, suction, reinfusion, filter, balloon, occlude, reservoir, pump, vein, artery, heart, vacuum

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 6,719,717 B1 (Johnson et al.) 13 April 2004 (13.04.2004), entire document especially FIG. 2F, col. 1, line 51-54, 57 and 65-67; col. 2, line 6-7,19-34, 36-38, 43-45 and 48-54; col. 3, line 23-39, 42-45, 48-56, 61-64 and 66-67; col. 4, line 8-10 and 57-59; col. 5, line 10-18, 30-36, 48-52, 56-58 and 63-67; col. 6, line 2-5, 18-20 and 59-67 and col. 7, line 1-3	1-4, 6-7, 10-11, 14-21, 23-26, 28-32, 36-45, 47-55 and 64-66 --- 5, 8-9, 12-13, 22, 27, 33-35, 46 and 56-63
Y	US 5,188,618 A (Thomas) 23 February 1993 (23.02.1993), especially col. 3, line 22-25	5, 8 and 33-35
Y	US 5,158,533 A (Strauss et al.) 27 October 1992 (27.10.1992), especially col. 3, line 24-26, col. 4, line 23-25 and col. 8, line 53-66	12 and 46
Y	US 2001/0049486 A1 (Evans et al.) 06 December 2001 (06.12.2001), especially para [0012], [0031] and [0035]	22, 27 and 37
Y	US 2002/0165574 A1 (Reesemann et al.) 07 November 2002 (07.11.2007), especially para [0106], [0114], [0133], [0152] and [0156]	9, 13, 56-57
Y	US 2003/0093112 A1 (Addis) 15 May 2003 (15.05.2003), especially Fig. 4, para [0012], [0028] and [0029]	58-63
Y	US 6,905490 B2 (Parodi) 14 June 2005 (14.06.2005), especially Fig. 3C and col. 7, line 30-42	62-63

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

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
20 October 2008 (20.10.2008)	04 NOV 2008
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: Lee W. Young PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

Form PCT/ISA/210 (second sheet) (April 2007)

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
9 July 2009 (09.07.2009)

PCT

(10) International Publication Number
WO 2009/086482 A1

(51) International Patent Classification:
A61B 17/22 (2006.01)

(21) International Application Number:
PCT/US2008/088371

(22) International Filing Date:
26 December 2008 (26.12.2008)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
61/016,651 26 December 2007 (26.12.2007) US

(71) Applicant *(for all designated States except US)*: **LAZARUS EFFECT, INC.** [US/US]; 767 El Solyo Heights Drive, Felton, CA 95018 (US).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **MARTIN, Brian, B.** [US/US]; 767 El Solyo Heights Drive, Felton, CA 95018 (US). **FOLLMER, Brett** [US/US]; 3408 Creighton Place, Santa Clara, CA 95051 (US). **AGUILAR, Julio** [US/US]; 13055 Clayton Road, San Jose, CA 95127 (US). **DIECK, Martin, S.** [US/US]; 235 Cherry Lane, Campbell, CA 95008 (US).

(74) Agent: **BAGADE, Sanjay, S.**; Levine Bagade Han LLP, 2400 Geng Road, Suite 120, Palo Alto, CA 94303 (US).

(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, BR, BW, BY, BZ, CA, CH, 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, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, 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, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MT, NL, NO, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:
— *with international search report*

(54) **Title:** RETRIEVAL SYSTEMS AND METHODS FOR USE THEREOF

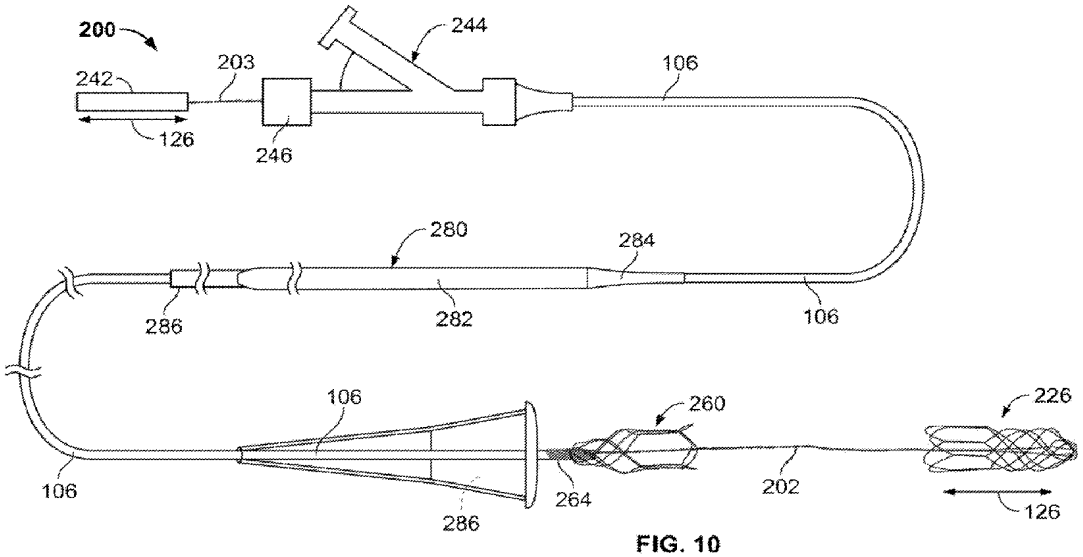


FIG. 10

(57) **Abstract:** The devices and methods described herein relate to improved structures for removing obstructions from body lumens. Such devices have applicability in through-out the body, including clearing of blockages within the vasculature, by addressing the factional resistance on the obstruction prior to attempting to translate and/or mobilize the obstruction within the body lumen.

WO 2009/086482 A1

RETRIEVAL SYSTEMS AND METHODS FOR USE THEREOF

RELATED APPLICATIONS

[0001] This application is a non-provisional application of U.S. Provisional Application No. 61/016,651 filed on December 26, 2007, the entirety of which is incorporated by reference herein.

FIELD OF THE INVENTION

[0002] The devices described herein are intended to retrieve obstructions from the body. In a first variation, the devices are constructed in wire form where the wires diverge from a main bundle to form a variety of shapes that form a composite device. The benefit of such a diverging wire construction is that the composite complex device can be of a "joint-less" construction. Such devices have applicability through out the body, including clearing of blockages within body lumens, such as the vasculature, by providing a capturing portion that can envelop the obstruction to address the frictional resistance between the obstruction and body lumen prior to attempting to translate and/or mobilize the obstruction within the body lumen. In addition, the devices described below include features that prevent unwanted and premature mobilization of the obstruction when removing the obstruction through tortuous anatomy.

BACKGROUND OF THE INVENTION

[0003] Many medical device applications require advancement of device in a reduced profile to a remote site within the body, where on reaching a target site the device assumes or is deployed into a relatively larger profile. Applications in the cerebral vasculature are one such example of medical procedures where a catheter advances from a remote part of the body (typically a leg) through the vasculature and into the cerebral region of the vasculature to deploy a device. Accordingly, the deployed devices must be capable of achieving a larger profile while being able to fit within a small catheter or microcatheter. In addition, the degree to which a physician is limited in accessing remote regions of the cerebral vasculature is directly related to the limited ability of the device to constrain into a reduced profile for delivery.

[0004] Treatment of ischemic stroke is one such area where a need remains to deliver a device in a reduced profile and deploy the device to ultimately remove a blockage in an artery leading to the brain. Left untreated, the blockage causes a lack of supply of oxygen and nutrients to the brain tissue. The brain relies on its arteries to supply oxygenated blood from the heart and lungs. The blood returning from the brain carries carbon dioxide and cellular waste. Blockages that interfere with this supply eventually cause the brain tissue to stop functioning. If the disruption in supply occurs for a sufficient amount of time, the continued lack of nutrients and oxygen causes irreversible cell death (infarction). Accordingly, immediate medical treatment of an ischemic stroke is critical for the recovery of a patient.

[0005] Naturally, areas outside of ischemic stroke applications can also benefit from improved devices. Such improved devices can assume a profile for ultimate delivery to remote regions of the body and can remove obstructions. There also remains a need for devices and systems that can safely remove the obstruction from the body once they are secured within the device at the target site. Furthermore, there remains a need for such devices that are able to safely removed once deployed distally to the obstructions in the even that the obstructions is unable to be retrieved.

[0006] Accordingly, a need remains for devices that can assume deployed configurations and are fabricated to eliminate or reduce the number of joints and/or connection points in the device.

SUMMARY OF THE INVENTION

[0007] The examples discussed herein show the inventive device in a form that is suitable to retrieve obstructions or clots within the vasculature. The term obstructions may include blood clot, plaque, cholesterol, thrombus, naturally occurring foreign bodies (i.e., a part of the body that is lodged within the lumen), a non-naturally occurring foreign body (i.e., a portion of a medical device or other non-naturally occurring substance lodged within the lumen.) However, the devices are not limited to such applications and can apply to any number of medical applications where elimination or reduction of the number of connection points is desired.

[0008] One variation of the device includes a medical device for removing an obstruction from a blood vessel, the medical device comprises a main bundle comprising a group of wires having a first end and a second end, a capturing portion formed by the group of wires and having a translating surface adjacent to a capturing surface, the translating surface having an open proximal end and the capturing surface having a permeable distal end, where the capturing portion is formed from the group of wires such that the group of wires diverges from the second end of the main bundle to form the permeable distal end, the group of wires extend back in a proximal direction to form the capturing surface, the translating surface, and open proximal end about the main bundle; and where the translating surface and capturing surface are configured so that a translating surface axial strength is greater than a capturing surface axial strength, wherein application of a tensile force on the main bundle causes axial compression of the capturing surface without causing axial compression and deformation of the translating surface sufficient to deform the translating surface as the capturing portion engages the obstruction.

[0009] The medical device can include a capturing surface that is configured to generate a spring force against the translating surface when a proximal force applied by the main bundle of wires compresses the capturing surface against the translating surface when encountering resistance from the obstruction, where the capturing surface is configured to have a sufficient axial stiffness to direct the spring force and proximal force to the open proximal end as the open proximal end engages the obstruction where the capturing surface is also sufficiently flexible to conform to a shape of the vessel.

[0010] In another variation, the capturing section is configured so that when the open proximal end of the translating section engages resistance equal to or greater than a threshold force, proximal movement of the leading wire inverts the capturing section within the translating section and reduces a size of the capturing section to enable the capturing section to re-enter a catheter.

[0011] In those variation of the device that are navigated in tortuous anatomy (such as the cerebral vasculature), the device can include a main bundle joined to a proximal bundle, where the proximal bundle comprises a stiffness greater than the main bundle and where the main bundle extends for at least a predetermined range

from the permeable distal end to allow navigation of a distal portion of the medical device within the cerebral vasculature.

[0012] Another variation of the device includes a retrieval device for removing an obstruction from a body lumen, the system comprising at least one leading wire; a retrieval body comprising a translating section adjacent to a capturing section, the translating section having an open proximal end and the capturing section having a permeable distal end, where the leading wire is extends to a portion of the capturing section to permit articulation of the open proximal end relative to the leading wire; and where the translating section and capturing section are configured so that a translating section axial strength is greater than a capturing section axial strength, wherein application of a tensile force on the leading wire causes axial compression of the capturing surface without causing axial deformation of the translating surface when the retrieval body engages the obstruction.

[0013] Variations of the retrieval system can also include a sheath having a hub located at a proximal end, a proximal capture portion affixed to a distal end of the sheath, at least one leading wire extending through the sheath, where a distal section of the leading wire comprises a distal stiffness and where a proximal section of the leading wire comprises a proximal stiffness, where the proximal stiffness is greater than the distal stiffness, a distal capturing portion at the distal end of the leading wire, the distal capturing portion being axially moveable relative to the proximal capture portion, and an insertion tool slidably located over the sheath, the insertion tool comprising a gripping region affixed to a rigid section, where compression of the gripping portion creates a frictional fit between the insertion tool such that when the insertion tool is coupled to the catheter, compression of the gripping portion and axial movement of the insertion tool advances the sheath within the catheter.

[0014] In one variation of the devices described herein, the device comprises a main bundle or group of wires that diverge to form a device having various shapes but few or no connections points or joints (where fabrication of such a construction is referred to as "jointless"). Clearly, the inventive devices described herein are not limited to such a jointless construction. Additional variation includes one or more leading wires that are attached to a capturing portion as described below.

[0015] In another variation, the device includes a main bundle comprising one or a group of wires. The device also includes a capturing portion formed by the wires or wire of the main bundle. The capturing portion includes a cavity or space that is able to surround the obstruction. Accordingly, the capturing portion includes an open proximal end, a permeable distal end, and a capturing surface extending therebetween. The permeable distal end should be sufficiently permeable to allow blood to flow but have sufficient surface area to prevent escape of the obstruction or to prevent particles such as pieces of clot or emboli that would otherwise cause a complication if such pieces migrate through the body. In some variations of the device, the capturing portion is formed from the group of wires such that the group of wires diverges from the second end of the main bundle to form the permeable distal end, the group of wires extend back in a proximal direction to form the capturing surface and open proximal end about the main bundle. Although some closing of the open proximal end can occur, it will not be sufficient to interfere with the obstruction as the capturing portion moves over the obstruction. In some variations, the permeable end may be the distal end or be towards the distal end (meaning anywhere past a proximal end). The terms distal and proximal are relative to the physician (e.g., the distal end is the farthest end from the catheter/physician).

[0016] The devices of the present invention typically include a main bundle from which the wires extend. In most case, the main bundle extends for a length sufficient to withdraw the device from a body of a patient. Accordingly, in such cases, the main bundle shall extend through the length of a catheter. In alternate constructions, the main bundle may be affixed to a single wire or member. In such cases, a main bundle does not extend from the capturing portion to the exterior of the patient. Instead, a single wire extends to the operator interface of the device where the wire is affixed to a main bundle.

[0017] Devices of the present invention can incorporate any number of wires of different characteristics including, but not limited to, materials, shapes, sizes and/or diameters. Clearly, the number of permutations of device configurations is significant. Providing devices with such a composite construction allows for the manipulation of the device's properties to suite the intended application.

[0018] In an additional variation, the surface of the capturing portion can include a wire frame structure, a mesh, a single wound wire, a film, a membrane, a polymer

covering, and a plurality of crossing wires or a heterogeneous mixing of these. In additional variations, a section of the capturing portion can include wires, while another section of the capturing portion can include a film. Clearly, any number of permutations is within the scope of this disclosure. In any case, the capturing surface should prevent the obstruction from escaping as the device is removed from the body. Clearly, the capturing surface can comprise any number of shapes or configurations.

[0019] As noted herein, the joint-less construction improves the flexibility and strength of the device by eliminating joints, connection points, or other attachment points. In addition, the joint-less construction improves the ability of the device to be delivered through a small microcatheter. As a result, the device and microcatheter are able to access remote regions of the vasculature.

[0020] The devices may be fabricated to be self-expanding upon deployment from a catheter. Alternatively, the devices can be constructed from shape-memory alloys such that they automatically deploy upon reaching a pre-determined transition temperature.

[0021] The devices of the present invention may also include features to prevent migration of the obstruction as the capturing portion encapsulates the obstruction. For example, a proximal foot (such as region of increased surface area) can be located on or in the catheter. In another variation, an additional capture portion is located on the catheter where the proximal end of this capture is a mesh, a single wound wire, a film, a membrane, a polymer covering, or a plurality of crossing wires affixed to or in the catheter. Accordingly, the capturing portions both envelope or surround the obstruction as they are moved together. As noted below, additional variations may allow for temporarily locking of the two capturing portions together for increase effectiveness in removing the obstruction from the body.

[0022] The capturing portions disclosed herein can include mechanical features that assist in removal of the obstruction. These features can be hooks, fibers, barb, or any such structure. Any portion of the capturing portion or even the device can have such hooks, fibers, or barbs that grip into the obstruction as the device surrounds the obstruction. It will be important that such features prevent the obstruction from sliding proximally but do not hinder the ability of the practitioner to remove the device from the body.

[0023] The operation of the devices and method described herein secure the obstruction, overcome the friction forces acting on the obstruction, and then remove the obstruction from the anatomy without losing or fractionating the obstruction. In a first variation, the inventive method includes advancing a catheter distal to the obstruction, deploying a first capturing portion distal of the obstruction, where the first capturing portion comprises a translating surface and a capturing surface, the translating surface having an open proximal end and the capturing surface having a permeable distal end, and at least one leading wire affixed to the capturing surface and extending through the capturing portion and through the catheter, where the translating surface and capturing surface are configured so that a translating surface axial strength is greater than that of a capturing surface axial strength, proximally moving the leading wire to compress the capturing surface without compressing the translating surface such that the translating surface gradually advances over the obstruction, and removing the obstruction and first capturing portion from the blood vessel

[0024] Additional variations of the method include (1) passing a catheter distally to the obstruction by passing either through the obstruction and/or between the obstruction and the vascular wall; (2) deploying a first capturing portion distally to the obstruction and the catheter is withdrawn proximal to the obstruction; (3) the capturing portion is then translated over the obstruction by withdrawing the main bundle. Since the main bundle is affixed to a distal end of the capturing portion, misalignment between the bundle and the capturing portion does not cause distortion of the open proximal end. Since the open proximal end remains expanded against the lumen wall, the capturing portion can then be advanced over the obstruction.

[0025] The method and systems may also include the use of an additional capturing portion having an open distal end. This configuration allows the first capturing portion and second capturing portion to envelop or ensnare the obstruction from both the proximal and distal sides. Additional variations even allow for temporarily locking the two capturing portions together. Such a feature increases the ability to remove the obstruction from the body

[0026] It should be noted that reference to surrounding, capturing or securing the obstruction includes partially and/or fully surrounding, engulfing, encapsulating,

and/or securing the obstruction. In any case, a portion of the device engages the obstruction prior to translation of the obstruction within the lumen.

[0027] It should be noted that in some variations of the invention, all or some of the device can be designed to increase their ability to adhere to the obstruction. For example, the wires may be coupled to an energy source (e.g., RF, ultrasonic, or thermal energy) to "weld" to the obstruction. Application of energy to the device can allow the surrounding portion to deform into the obstruction and "embed" within the obstruction. Alternatively, the device can impart a positive charge to the obstruction to partially liquefy the obstruction sufficiently to allow for easier removal. In another variation, a negative charge could be applied to further build thrombus and nest the device for better pulling force. The wires can be made stickier by use of a hydrophilic substance(s), or by chemicals that would generate a chemical bond to the surface of the obstruction. Alternatively, the filaments may reduce the temperature of the obstruction to congeal or adhere to the obstruction.

[0028] Additional variations of the invention include a reentry device for withdrawing an object into a distal end of a sheath, the reentry device comprising a elongate member having a distal portion and a lumen extending therethrough, a plurality of first tines arranged circumferentially at the distal portion, the plurality of first tines each having a distal end forming a first discontinuous funnel where the distal end of each first tine is spaced from the distal end of an adjacent first tine, wherein the first discontinuous funnel is collapsible upon withdrawal into the distal end of the sheath, a second funnel spaced proximal to the first funnel, where the second funnel is collapsible upon withdrawal into the distal end of the sheath, and wherein a distal perimeter of the first discontinuous funnel shape is distal to a distal perimeter of the second funnel.

[0029] In an additional variation, the second funnel comprises a plurality of second tines arranged circumferentially at the distal portion, the plurality of second tines each having a distal end forming a second discontinuous funnel shape where the distal end of each second tine is spaced from the distal end of an adjacent second tine.

[0030] Another example of a reentry device includes an elongate member having a distal portion and a lumen extending therethrough, the elongate member sized to slidably fit within the sheath, a first slotted funnel comprising a plurality of first tines each having free ends discontinuous with free ends of adjacent first tines, where the first

slotted funnel is collapsible upon withdrawal into the distal end of the sheath; and a second funnel located proximal to the free ends of the first tines.

[0031] The reentry device can also comprises a retrieval system for withdrawing an object into a distal end of a sheath. The term sheath, when used with a reentry device, is intended to include any tube, introducer, sheath, or access device. Typically, when the retrieval device is used with neurovascular retrieval devices, the sheath will be a femoral access sheath or device. Regardless, the reentry device includes a first elongate member having a distal portion and a lumen extending therethrough, a second elongate shaft extending through the first elongate member, a flexible layer having a first end inverted on a distal end of the second elongate shaft and a second end affixed to an exterior of the first elongated shaft, where decreasing a distance between the distal end of the second elongate shaft and the exterior of the first elongated member causes the flexible material to form a funnel when the flexible layer further inverts about the second elongate shaft.

[0032] Additional devices and methods for treating ischemic stroke are discussed in commonly assigned U.S. Patent application nos.: 11/671,450 filed February 5, 2007; 11/684,521 filed March 9, 2007; 11/684,535 filed March 9, 2007; 11/684,541 filed March 9, 2007; 11/684,546 filed March 9, 2007; 11/684,982 filed March 12, 2007, 11/736,526 filed April 17, 2007, 11/736,537 filed April 17, 2007, and 11/825,975 filed September 10, 2007; the entirety of each of which is incorporated by reference. The principles of the invention as discussed herein may be applied to the above referenced cases to produce devices useful in treating ischemic stroke. In other words, the wire-shaped construction of devices according to present invention may assume the shapes disclosed in the above-referenced cases when such a combination is not inconsistent with the features described herein.

BRIEF DESCRIPTION OF THE DRAWINGS

[0033] Each of the following figures diagrammatically illustrates aspects of the invention. Variation of the invention from the aspects shown in the figures is contemplated.

[0034] Fig. 1A illustrates an example of a device according to the present invention when used in a system for removing obstructions from body lumens.

[0035] Fig. 1B illustrates a first example of an obstruction removal medical device.

[0036] Fig. 1C illustrates the obstruction removal device articulating relative to leading wires (or a main bundle) without deforming an open end of the capturing portion.

[0037] Figs. 2A to 2E show a capturing portion for use with systems described herein where the capturing portion has sections of varying axial strengths. Such features can optionally be designed to provide a spring force when a section of the capturing portion is compressed and/or staged inversion of the capturing portion so that it can be removed through an immovable obstruction.

[0038] Fig. 3A illustrates a first variation of the device having a joint-less construction of a capturing portion that articulates about a main bundle of wires.

[0039] Figs. 3B to 3H illustrate various constructions of capturing portions for use in the present invention.

[0040] Fig. 4A illustrates a variation of a capturing portion having a main bundle that extends beyond a certain distance to provide a device having an extremely flexible distal region and a relatively stiff proximal region with a strong joint region that will be sufficiently spaced from tortuous anatomy during use of the device.

[0041] Fig. 4B illustrates a main bundle having a curved or shaped portion.

[0042] Figs. 4C to 4E illustrate wires of different constructions within a main bundle.

[0043] Fig. 5A illustrates am example of a proximal foot located on a catheter of the present system.

[0044] Fig. 5B illustrates a distal and a proximal capturing portion located on a system under the present invention.

[0045] Figs. 5C to 5E illustrate an overview of a variation of a delivery system employing a proximal and distal capturing portion.

[0046] Figs. 5F illustrates compression or collapsing of a proximal capturing portion about an obstruction prior to translation of the obstruction in the vessel.

[0047] Figs. 6A to 6B illustrate an example of traversing an obstruction with a sheath to deploy a distal capturing portion.

[0048] Figs. 7A to 7C illustrates a condition where a section of the capturing portion deflects to provide a spring force that gradually drives a traversing section along the obstruction.

[0049] Figs. 7D to 7G illustrate staged inversion of the distal capturing portion to allow removal of the device from an immovable clot.

[0050] Fig. 8A illustrates closure of the proximal opening of a capturing portion without the benefit of articulation of the capturing portion about a leading wire.

[0051] Fig. 8B illustrates, conceptually, one benefit of articulation of a capturing portion about a leading wire or main bundle of wires.

[0052] Figs. 8C to 8D illustrate a proximal capturing portion and a distal capturing portion approaching an obstruction.

[0053] 8F illustrates a device after securing an obstruction between proximal and distal capturing sections.

[0054] Fig. 9 illustrates a main bundle as including an increased surface area or medial foot that is used to dislodge or loosen the obstruction from a wall of the body passage.

[0055] Fig. 10 illustrates a variation of a proximal and distal end of a retrieval device.

[0056] Figs. 11A to 11C illustrate a variation of a funnel catheter useful for retrieving objects from vessels or body lumens.

[0057] Fig. 12A shows an example of a retrieval device getting caught on a guide sheath.

[0058] Figs. 12B to 12C provide illustrative examples of funnel catheter used for removal of an obstruction.

[0059] Fig. 13A to 13G illustrates another variation of a funnel catheter using a mesh or layer of material to form a funnel.

[0060] Figs. 14A to 14D illustrate additional concepts to prevent or minimize flaring of the distal capture portion so that it may be withdrawn into a guide sheath.

DETAILED DESCRIPTION

[0061] It is understood that the examples below discuss uses in the cerebral vasculature (namely the arteries). However, unless specifically noted, variations of the device and method are not limited to use in the cerebral vasculature. Instead, the invention may have applicability in various parts of the body. Moreover, the invention may be used in various procedures where the benefits of the method and/or device are desired.

[0062] Fig. 1A illustrates a system **10** for removing obstructions from body lumens as described herein. In the illustrated example, this variation of the system **10** is suited for removal of an obstruction in the cerebral vasculature. Typically, the system **10** includes a catheter **12** microcatheter, sheath, guide-catheter, or simple tube/sheath configuration for delivery of the obstruction removal device to the target anatomy. The catheter should be sufficient to deliver the device as discussed below. The catheter **12** may optionally include an inflatable balloon **18** for temporarily blocking blood flow or for expanding the vessel to release the obstruction.

[0063] It is noted that any number of catheters or microcatheters maybe used to locate the catheter/microcatheter **12** carrying the obstruction removal device **200** at the desired target site. Such techniques are well understood standard interventional catheterization techniques. Furthermore, the catheter **12** may be coupled to auxiliary or support components **14**, **16** (e.g., energy controllers, power supplies, actuators for movement of the device(s), vacuum sources, inflation sources, sources for therapeutic substances, pressure monitoring, flow monitoring, various bio-chemical sensors, bio-chemical substance, etc.) Again, such components are within the scope of the system **10** described herein.

[0064] In addition, devices of the present invention may be packaged in kits including the components discussed above along with guiding catheters, various devices that assist in the stabilization or removal of the obstruction (e.g., proximal-assist devices that holds the proximal end of the obstruction in place preventing it from straying during removal or assisting in the removal of the obstruction), balloon-tipped guide catheters, dilators, etc.

[0065] Fig. 1B illustrates a first example of an obstruction removal medical device according to the features described herein. As shown, the device **200** generally includes capturing portion **226** comprising a translating section/surface **222** and a capturing section/surface **224**. In the illustrated variation, the translating section **222** shown comprises a wire framework. However, any number of configurations is within the scope of this disclosure. In many variations of the device, the translating section **222** provides a low friction surface so that it translates over the obstruction without significantly moving the obstruction. This permits the capturing portion **226** to envelop or surround the obstruction prior to attempting to move the obstruction within the body lumen. As noted herein, the translating

section **222** attempts to reduce the outward radial force applied by the obstruction against the wall of the lumen during movement of the obstruction within the lumen.

[0066] Fig. 1B illustrates a distal section of the capturing portion **226** that serves as a capturing section/surface **232**. The capturing section **232** has an increased frictional surface (in this variation illustrated by the crossing **204** wires) so that it can capture and ultimately remove the obstruction. The frictional surface of the capturing section **232** can also be described as an increased coverage density. In essence, as the frictional surface of capturing section **232** coverage density increases, there is a greater "device" surface area to interact with the obstruction. In some variations the capturing section **232** increases in frictional surface between the translating section **234** and the end of the device **200**.

[0067] As shown, the device **200** includes a main bundle **202** comprising a group of individual leading wires **204**. In this variation, the bundle of leading wires **204** is surrounded by a coil or coiled wire **205**. The coiled wire **205** can comprise a single leading wire that joins the device **202**. Alternatively, the coiled wire **205** can extend terminate or wrap back prior to forming the capture portion **226**. Moreover, the coiled wire **205** can extend throughout a length the main bundle **202**, or along one or more segments of the main bundle **202**.

[0068] While the example shows the group consisting of four individual leading wires **204**, the bundle **202** can have any number of leading wires. In various examples 2, 4, or 8 wires were used to construct the device. In certain variations, the number of wires in the main bundle loop around from the capturing portion. For example, if 2 leading wires are used to construct the device, then when constructing the main bundle **202** 2 wires are set to extend distally towards the capturing portion, where the 2 wires are then shaped to form the capturing portion. Eventually, the wires then loop back to extend proximally away from the capturing portion. Therefore, the 2 wires are doubled in the main bundle to create 4 separate wires in the main bundle.

[0069] The individual wires **204** themselves may be comprised of a number of different "micro" filaments, wires, or a single type of wire. Variations of the wires **204** are discussed in detail below; however, the wires **204** can be strands, filaments, or any similar structure that is able to be joined to form the device. The bundle **202** may be braided, wrapped, twisted, or joined in any manner such that

they do not separate or become unbundled except where desired. For example, wires in any section of the device **200** can be bonded together (e.g., with epoxy, a polymeric coating, weld, solder, and/or adhesive, etc.) to prevent the wires from separating during deformation of the device as it deploys or removes the obstruction. In addition, the main bundle **202** can incorporate any number of features to assist in orienting the device **200** within the body passage. For example, the main bundle **202** can include a pre-set bend that would bias the capturing portion **226** in a desired orientation upon deployment as discussed below.

[0070] As also discussed below, variations of the present device **200** include capturing portions **226** where the translating section **234** provides a greater axial strength than an axial strength of the capturing section **232**. The axial strength (e.g., column strength) determines whether the respective section of the capturing portion **226** compresses when the device **200** encounters resistance from an object and as a proximal or pulling force is applied through the main bundle or leading wire **202**. In use, the translating section **234** resists axial compression and deformation so that it can locate about the obstruction. While the nature of moving the translating section will place the structure in a state of compression, there will be no visible deformation or deflection that prevents the translating section from advancing across an obstruction.

[0071] There are a number of approaches to adjust the axial strength of a capturing section **232** as well as the entire structure. In a first example, the manner in which the leading wire is wound to form the respective surface **232**, **234** impact the respective axial strength. As shown, the traversing section **234** comprises a series of wrapped wires extending in an axial direction. This axial alignment causes the wires to oppose axial forces and thus increases the axial strength of the traversing section **234** relative to the capturing section **232**. In the latter section, the wires **232** extend in a helical direction about the section **232**. Thus there is less resistance to an axial load when compared to the traversing section **234**.

[0072] Alternatively, or in combination, additional techniques can produce a device **200** with a capturing portion **226** that has sections of varying axial strength. In one example, the wire diameter can be adjusted to produce the desired column strength. Generally, for a given construction, a larger diameter wire increases the column strength of the section. In addition, larger diameter leading wires can

terminate at the translating section **234** to permit smaller diameter wires to form the capturing section **232**. In another example, the leading wire **204** composition can be selected to produce the desired axial strength. For example, drawn filled tube (DFT) wire has 30% platinum 70% nitenol. Decreasing the amount of platinum and increasing the nitenol increases the wire strength and results in higher column strength. In yet another example, the respective section, or the entire capturing portion **226**, can be processed to produce the desired axial strength. For example, changing the annealing profile (e.g., temp, time) affects the wire strength, and therefore the axial strength.

[0073] Variations of devices **200** described herein can have capturing portions with alternate configurations than those shown in above. The capturing portion **226** can include constructional designs such as a basket, a filter, a bag, a coil, a helical wire structure, a mesh, a single wound wire, a film, a membrane, a polymer covering, , or a plurality of crossing wires. In variations of the device, the capturing portion **226** is sufficiently permeable to allow blood or other fluid flow therethrough. As noted above, capturing portion **226** may be any structure that covers, encapsulates, engulfs, and/or ensnares the obstruction either fully or partially. Accordingly, although the capturing portion **226** is illustrated as a filter/bag, the wires may diverge to form a coil, helical shape, other mesh structure, or any other structure that defines a space that can be translated over the obstruction to ultimately remove the obstruction **2**.

[0074] The capturing portion **226** can include an open proximal end **228**, a permeable distal end **230** and a capturing surface **232** located therebetween. The capturing surface **232** of the capturing portion **226** defines a volume, cavity, or space that is able to cover, encapsulate, envelop, engulf, ensnare and/or surround the obstruction. Generally, the term traversing wire or filament refers to the section of leading wire **204** that forms the traversing surface **238**. Generally, the traversing wires form the capturing surface **238** and then form the open proximal end **228**. As discussed herein and illustrated below, the open proximal end **228** expands within the lumen, typically to the lumen walls, so that the obstruction enters the open proximal end **228** as the bundle **202** (or leading wire) translates the device **200** proximally.

[0075] The permeable distal end **230** is typically sufficiently porous so that fluid or blood may flow through. However, the end **230** is sufficiently closed (or has an

increased surface area) so that the obstruction should not escape through the distal end **230** of the device **200**. This construction typically causes the the obstruction to become ensnared within the capturing portion **226** and prevented from passing through by the permeable distal end **230**.

[0076] As shown in Fig. 1C, an important feature of the present devices **200** is that the main bundle **202** and capturing portion **226** can articulate relative to one another without interfering with the size or profile of the open proximal end **228**. This feature is described more fully below. As shown, the main bundle **202** extends through the open proximal end **228** and through at least a the traversing section **234**capturing portion **226**.

[0077] Fig. 1C illustrates a condition where the main bundle **202** and capturing portion **226** articulate relative to one-another. Because the main bundle **202** joins the capturing section **232** at a distance from the open proximal end **228** movement of the main bundle **202** relative to an axis **236** of the capturing portion **226** does not reduce a profile of the open proximal end **228**. If the main bundle **202** were affixed or connected to the open proximal end **228**, then any movement of the bundle **202** away from the capturing portion's axis **236** would exert a force on the open end. This force, in turn, would cause the open end to narrow or deform. By doing so, the open end would not be able to uniformly expand against the lumen wall to capture the obstruction.

[0078] Turning now to the construction of the device **200**, as shown above, the main bundle or a leading wire **202** extends beyond the open proximal end **228** and forms the capturing portion. In one variation, the construction of the device relies on converging/diverging wires to form continuous shapes so that the device is completely joint or connection free. However, as noted herein, the leading wire or main bundle **202** can be affixed to a structure that forms the capturing portion via an attachment point, joint, or junction. In addition, the structures forming the capturing portion can be fabricated from such processes as laser cutting of tubes, etching, metal injection molding, or any other such process.

[0079] The devices of the present invention can also include additional features to aid in removal of obstructions. For example, as shown in Figs. 1B to 1C, the open proximal end **228** can include one or more petals or flanges **238** extending radially outward. The flanges **238** allow device **200** to have a flared structure at the open proximal end **228**. In one example, the capturing portion **226** can be slightly

oversized relative to the body passage containing the obstruction or slightly larger than the capturing portion. The flanges **238** provide an additional force against the wall of the passage to ensure that the device **200** is able to surround or encapsulate the obstruction. In yet another feature, in variations of a system having a proximal and distal capturing portion, the flanges can serve to lock the proximal and distal capturing portions together once they encapsulate or surround an obstruction. This feature minimizes the chance that the obstruction escapes from the capturing portions as the device and obstruction are removed from the body lumen.

[0080] In additional variations, the main bundle can diverge to form the capturing portion in multiple locations so long as the capturing portion's ability to articulate is not sacrificed. For example, the main bundle can diverge in several locations along the capturing surface (not shown).

[0081] Figs. 1B to 1C also shows an integrally formed reinforcement ring **240** located along the length of the capturing surface **232** (i.e., on the traversing wires). The reinforcement ring **240** can be a separate or discrete ring located on or in the capturing surface **232**. Alternatively, or in combination, the reinforcement ring **240** can be a ring shape that is integrally formed through arrangement of the wires **204** (as show in Figs. 1B to 1C). The reinforcement ring **240** assists in expanding the device when deployed in the body lumen and/or prevents the device (e.g., the open proximal end) from collapsing as the device moves within the lumen to secure the obstruction. The reinforcement ring **240** can comprise a single wire, or a twisted pair of wires. Alternatively, the rings do not need to extend entirely circumferentially around the capturing surface. Instead, a reinforcement portion may extend between adjacent traversing wires but does not necessarily extend around the circumference of the capturing section. As noted herein, reinforcement portions may extend between adjacent traversing wires in multiple locations.

[0082] Figs. 2A to 2E show several benefits of varying axial strengths of the different sections of a capture portion **226**. As shown in Fig. 2A, when the physician retrieves the capturing portion **226** by pulling on the leading wire or main bundle **202** (as shown by arrow **120**), the entire capturing portion **226** translates as shown by arrow **122**. However, when the device **200** encounters resistance (as schematically shown by force arrows **124**) the lesser axial strength of the capturing section **232** causes axial deformation or compression of the capturing section **232** (as shown by Fig. 2B). In certain variations, the capturing section **232**

can be constructed to function as spring such that deformation of the capturing section **232** stores energy. Accordingly, the physician can pull the main bundle **202** to build energy in the capturing section **232**, then relax the force on the main bundle **202**. The stored energy in the capturing section **232** gradually drives the open proximal end of the translating section **234** over or along the obstruction. The physician can apply this "pull and relax" technique repeatedly until the obstruction is sufficiently captured by the capturing portion **226**.

[0083] Fig. 2C shows an additional safety benefit given the varying axial strengths of the different sections of a capture portion **226**. In the event the capturing portion **226** encounters an excessive degree or threshold of force (as denoted by arrows **124**), the reduced axial strength of the capturing section **232** can invert within the translating section **234**. As shown, the permeable distal end **230** of the capturing section **232** inverts and is pulled by the main bundle **202** within the translating section **234** and reduces in size. As shown in Fig. 2D, continued pulling on the main bundle **202** causes eventual inversion of the translating section **234** so that the capturing section **232** extends through the translating section **234** and the permeable distal end **230** is now proximal to the translating section **234**. Continuing to apply move the main bundle **202** in a proximal direction **120** inverts the capturing portion **226** as shown in Fig. 2E. As shown, the translating section **234** is now distal to the capturing section **232**. This causes a reduction in the size of the capturing portion through inversion of the capturing portion **226**. This feature permits withdrawal of the capturing portion **226** within a delivery sheath **106** or through an immobile obstruction (as discussed below). As shown below, the ability to sequentially invert the capturing portion **226** and reduce its diameter enables retrieval of the device if deployed distal to atherosclerotic plaque or an immobile object where continued pulling against the object could cause damage or tearing of the body passage or vessel wall. It was found that retrieval devices that are not constructed with regions of varying axial strength, spring function, or staged inversion can often flatten or expand in diameter when attempting to retrieve the device though an immobile or stubborn obstruction.

[0084] Fig. 3A illustrates an additional variation of a capturing portions **226** according to the present disclosure. In Fig. 3A, the main bundle **202** and the group of wires **204** branch or diverge at the permeable distal end **230** to form the capturing portion **226**. In additional variations, the main bundle **202** can branch or

diverge within a mid-portion of the capturing surface **232** rather than at the permeable distal end **230**. In such a case, the wires **204** form the capturing surface **232** first and ultimately branch to form the remainder of the capturing portion. In any case, by extending through the open proximal end **228**, the main bundle **202** is able to articulate relative to the capturing portion **226** without significantly reducing a profile of the open distal end **228**. As discussed above, the capturing surface **232** of these variations is fabricated (either through processing or wire construction) to have an axial strength that is lower than that of the traversing section **234**.

[0085] Fig. 3B illustrates a variation having an integrated reinforcement ring **240**. Typically, the reinforcement ring **240** provides radial strength to the capturing portion **226** to prevent collapse or deformation that would otherwise interfere with enveloping the obstruction. A reinforcement ring **240** may allow for use of wires that would otherwise provide unacceptable radial strength. For example, the reinforcement ring **240** may permit use of smaller diameter wires thereby allowing the device **200** to compress to a smaller diameter during delivery via a catheter.

[0086] In addition to the reinforcement ring **240**, Fig. 3B includes an open proximal end **228** having a number of petals/flanges **238**. In this variation, although the flanges **238** intersect one another, they are independently moveable.

[0087] Fig. 3C shows a variation of a device **200** where the capturing portion **226** includes flanges **238** that are interwoven or connected with adjacent flanges **238**. (Variations include bonding or otherwise joining the adjacent flanges together.) This feature provides the flanges **238** with a higher radial strength that reduces the likelihood that the flanges **238** bend or distort when moving in the body lumen or removing the obstruction.

[0088] Figs. 3D to 3E illustrate additional variations of devices having capturing portions **226** that have a basket type configuration. As shown, the capturing portions **226** and surface **232** comprise a denser mesh of traversing wires that ultimately lead to the traversing section **234** that terminates in flanges **238** at the open proximal end **228**. In such variations, a first portion of the traversing surface **232**that is adjacent to the open proximal end has a low coverage density relative to the remaining portion of the capturing surface having a higher coverage density that eventually forms the permeable distal end **230**. This construction lowers the lowering frictional resistance of the first portion of the capturing surface when

moving over or against the obstruction but allows the remaining portion of the capturing surface to encapsulate and secure the obstruction.

[0089] As shown in Fig. 3E, the wires diverge from the main bundle towards the distal end of the capturing portion **226** to form the permeable distal end **230**. The permeable distal end **230** can actually have the same configuration as the capturing surface **232**. In other words, the permeable distal end can simply be an extension of the capturing surface that extends over the distal end of the capturing portion.

[0090] Naturally, the divergence of the wires can occur over a length of the capturing portion **226** rather than immediately at the distal end. For example, as show in Fig. 3D, the wires diverge towards a mid-section of the capturing portion and ultimately form the permeable distal end **230**.

[0091] Fig. 3F illustrates a variation of a device **200** having multiple reinforcement rings **240**. As noted above, the reinforcement rings provide additional radial strength to the capturing portion **226** as the device **200** moves within the body lumen and prevents distortion of the capturing portion **226**. However, as noted above, the device will be fabricated to provide varying regions of axial strength to allow for either the spring effect or the staged inversion discussed above. In any case, the rings **240** do not need to extend around an entire circumference of a device, variations include any number of supports that extend between adjacent traversing wires.

[0092] Fig. 3G illustrates another variation of a device **200** having a leading wire **202** extending to a distal end **230** of a capturing portion **226**. In this variation the capturing portion **226** is fabricated from a stent-type structure. As noted above, it is within the scope of this disclosure to use any type of similar structure such as a laser cut tube, a chemically etched or photo etched tube, a polymer or metal injection molded structure, a basket, a filter, a bag, a coil, a helical wire structure, a mesh, a single wound wire, a film, a membrane, a polymer covering, or a plurality of crossing wires as the capturing portion **226** so long as the device can be compressed to a small size for delivery and expand after traversing the obstruction. The illustrated variation also shows a covering **270** located on the distal end **230** of the capturing portion **226**. The length of the polymeric covering **270** can vary across the capturing portion **226** to prevent the obstruction from escaping as the device is translated over the obstruction. Furthermore, the covering **270** can be polymeric or a wire mesh. However, typically the covering has sufficient porosity

to allow blood to flow through the device **200**. In this variation, the flanges **238** form the translating surface.

[0093] Fig. 3H illustrates another feature for use with system described herein. In this variation, the system includes a proximal capturing portion **260** located on an exterior of a delivery sheath **106**. The main bundle **202** extends through the sheath **106** to a distal capturing portion (not shown). As discussed below, the proximal capturing portion **260** can be similar to the distal capturing portions **226** described herein with the exception that the distal end **262** of the proximal capturing portion is open while the proximal end **264** of the proximal capturing portion is closed. Furthermore, the proximal capturing portion **260** articulates with respect to the sheath **106** much in the same manner as the distal capturing portion **226** articulates relative to the main bundle **202**. In this variation, the proximal end **264** of the proximal capturing portion **260** is tapered or has a smaller profile than the remaining proximal capturing portion **260**. Such a feature may be useful to improve the deliverability of the device to the intended site as well as to maneuver around any obstructions within the body passage. In addition, as noted below, the proximal capturing portion **260** can be compressed about the obstruction to improve the ability of the system to remove the obstruction. The construction of the proximal capturing portion **260** can optionally include variations having regions of differing axial strength, or sections capable of generating spring force. Typically, since the proximal capturing portion **260** is not advanced distal to the obstruction, the need for staged inversion is not necessary. Accordingly, any number of capturing designs can be incorporated for the proximal capturing portion.

[0094] In some variations, the leading wire can extend to the proximal end of the system for manipulation by the physician. However, it is often the case that the characteristics of the device must vary along its length. For example, when the device is intended for use in remote tortuous anatomy, the proximal section of the device is desirably stiffer (to advance the distal portion of the device to the target anatomy). However, the distal section of the device must have properties that make it suitable for the tortuous anatomy. In the case where devices are used in the cerebral vasculature, the distal section must be extremely flexible, while the proximal section should be stiff. In many cases, different material properties are

required. A problem then arises in attempting to join different materials especially in the joining region.

[0095] Conventional joining methods include soldering, welding, gluing, thermal junctions, etc. These joining methods produce an area having an increase in the stiffness of the device. For example, if two wires are to be laser welded together, then the section where they are joined has an overlap which yields greater stiffness than the rest of the wire. This increased area of stiffness is often balanced against the strength of the joined segment. If the joined region is too long, the strength will be sufficient but the increase in stiffness often prevents navigation through the tortuous anatomy. IF the joined region is too short, then the device can navigate through the anatomy but the bond is weaker and a risk of failure increases.

[0096] Fig. 4A illustrates another variation of an improvement for use with the devices described herein especially for use in tortuous anatomy such as the cerebral vasculature. In this example, the capturing portion **226** is show with a number of leading wires **204** extending proximally. To provide the desired characteristics, the leading wires **204** are joined in region **196** to wires **198** having a structure that is suitable for the proximal anatomy (e.g., the wires are larger in diameter or stiffer). To enable use of the device **200** in the cerebral anatomy without compromising bond strength characteristics or flexibility of the device **200**, the leading wires extend a pre-determined region so that the bond region **196** is placed out of the tortuous anatomy. Since the cerebral vasculature is approximately 30 centimeters in length, the leading wires **204** can extend for a length **195** of at least a predetermined length so that it remains very flexible when navigating the cerebral vasculature or other tortuous anatomy. In one example the length was 20 centimeters (but can be 30 or more centimeters). By deliberately extending the leading wires **204** by length **194**, the length of the bond region **196** can be chosen to accommodate the proximal anatomy (where a greater stiffness of the bond region **196** can be accommodated). The length of the bond region **196** can vary depending on the application (e.g., from 2 to20 cm for a device intended for cerebral the cerebral vasculature). However, the bond can extend along the entire proximal section of leading wire.

[0097] Fig. 4B illustrates an addition aspect of for use with devices described herein where the main bundle **202** has a curved or bend portion **252**. This pre-set

shape assists in orienting the capturing portion **226** within the body passage since the bend will cause the device to bias against a wall of the body passage.

[0098] Fig. 4C and 4D show cross sectional views taken along the line A-A in Fig. 4B. As shown, the wire form construction described herein allows for a number of configurations depending on the particular application. For example, the individual wires **204** (as discussed herein) may themselves comprise a bundle of smaller wires or filaments. In addition, the wires can be selected from materials such as stainless steel, titanium, platinum, gold, iridium, tantalum, Nitinol, alloys, and/or polymeric strands. In addition, the wires used in a device may comprise a heterogeneous structure by using combinations of wires of different materials to produce a device having the particular desired properties. For example, one or more wires in the device may comprise a shape memory or superelastic alloy to impart predetermined shapes or resiliency to the device. In some variations, the mechanical properties of select wires can be altered. In such a case, the select wires can be treated to alter properties including: brittleness, ductility, elasticity, hardness, malleability, plasticity, strength, and toughness.

[0099] The device may include a number of radiopaque wires, such as gold and platinum for improved visibility under fluoroscopic imaging. In other words, any combination of materials may be incorporated into the device. In addition to the materials, the size of the wires may vary as needed. For example, the diameters of the wires may be the same or may vary as needed.

[0100] In addition, the individual wires may have cross-sectional shapes ranging from circular, oval, d-shaped, rectangular shape, etc. Fig. 4C illustrates one possible variation in which a number of circular wires **204** are included with a d-shaped wire 205. Moreover, the device is not limited to having wires having the same cross-sectional shape or size. Instead, the device can have wires having different cross-sectional shapes. For example, as shown in Fig. 4D, one or more wires **205** can have a different cross-sectional shape or size than a reminder of the wires **204**. Clearly, any number of variations is within the scope of this disclosure.

[0101] To illustrate one such example, a device can have 8-12 wires made of .003" round superelastic material (e.g., nitinol). The device may additionally have 2-4 wires made from .002" platinum for fluoroscopy. Of the 8-12 nitinol wires, 1-4 of these wires can be made of a larger diameter or different cross-section to increase the overall strength of the device. Finally, a couple of polymer fibers can

be added where the fibers have a desired surface property for clot adherence, etc. Such a combination of wires provides a composite device with properties not conventionally possible in view of other formation means (such as laser cutting or etching the shape from a tube or joining materials with welds, etc.). Clearly, any number of permutations is possible given the principles of the invention.

[0102] In another example, the device may be fabricated from wires formed from a polymeric material or composite blend of polymeric materials. The polymeric composite can be selected such that it is very floppy until it is exposed to either the body fluids and or some other delivered activator that causes the polymer to further polymerize or stiffen for strength. Various coatings could protect the polymer from further polymerizing before the device is properly placed. The coatings could provide a specific duration for placement (e.g., 5 minutes) after which the covering degrades or is activated with an agent (that doesn't affect the surrounding tissues) allowing the device to increase in stiffness so that it doesn't stretch as the thrombus is pulled out. For example, shape memory polymers would allow the device to increase in stiffness.

[0103] In another variation, one or more of the wires used in the device may comprise a Drawn Filled Tube (DFT) such as those provided by Fort Wayne Metals, Fort Wayne, Indiana. As shown in Fig. 4E, such a DFT wire 252 comprises a first material or shell 208 over a second material 210 having properties different from the outer shell. While a variety of materials can be used, one variation under the present devices includes a DFT wire having a superelastic (e.g., Nitinol) outer tube with a radiopaque material within the super-elastic outer shell. For example, the radiopaque material can include any commercially used radiopaque material, including but not limited to platinum, iridium, gold, tantalum, or similar alloy. One benefit of making a capturing portion from the DFT wire noted above, is that rather than having one or more markers over the capturing portion, the entire capturing portion can be fabricated from a super-elastic material while, at the same time, the super-elastic capturing portion is made radiopaque given the core of radiopaque material within the super-elastic shell. Clearly, any composite DFT wire 252 can be incorporated into the system and capturing portions described herein.

[0104] Fig. 5A shows a working end of a variation of a system **10** for removing an obstruction from a body lumen. In this variation, the system **10** includes a main

bundle **202** and capturing portion **226** extending out of a micro-catheter or catheter **102**. The micro-catheter **102** can optionally include a proximal foot **256** that can slide axially over main bundle **202** and can be variably positioned in relation to the capturing portion **226**. The proximal foot **256** can include any number of configurations apart from the petal/flange **258** configuration (i.e., the foot can be a balloon, coil, shoulder, etc. where such structures simply replace the petals in Fig. 5A). In any case, the proximal foot **256** provides an increased surface area that provides an opposing force to the capturing portion **226**, where the opposing force aids the movement of the obstruction within the capturing portion **226**. Alternatively, the proximal foot stabilizes the obstruction and keeps the obstruction from moving with the capturing portion until the capturing portion envelops the obstruction.

[0105] The size of the proximal foot **256** can be adjusted depending on the target site anatomy. For example, a larger surface area can be employed if the target site is within a bifurcation of the body passage. The size of the proximal foot **256** can also be adjustable during the procedure. For example, in the case of a petal/flange **258** configuration, the petals **258** can assume a larger size to initially stabilize the obstruction and then reduce in size to allow the obstruction to be completely engulfed by capturing section **226**.

[0106] The proximal foot **256** can extend from an interior of the catheter **102**, such as from within the internal lumen of the catheter, or from an additional lumen within a wall of the catheter. Alternatively, the proximal foot **256** can be permanently affixed to the catheter **102**. In such a case, a separate catheter (without a proximal foot) can be employed to traverse the obstruction for deployment of the device distally to the obstruction. Once the device is deployed, the catheters can be exchanged to provide the proximal foot. In an additional variation, the proximal foot **256** can be affixed to a delivery sheath (as described below) and be collapsed within the catheter, where advancement out of the catheter expands the proximal foot **256** so that it may function as described above.

[0107] In an additional variation, a proximal capturing portion (as shown in Fig. 3H) can be used with a foot **256** that is located about the main bundle **202**. Such a variation may or may not include a distal capturing portion. Accordingly, the construction of the proximal capturing portion (as described herein to include

sections of varying axial strength) can be used to perform a push and relax technique (similar to that of the pull and relax technique described herein).

[0108] Fig. 5B illustrates another variation of the system **10** where the system includes a proximal capturing portion **260** located on an exterior of a delivery sheath **106**. Naturally, the proximal capturing portion **260** could also be affixed to an exterior of a micro-catheter. The proximal capturing portion **260** is similar to the capturing portions **226** described herein with the exception that the distal end **262** of the proximal capturing portion is open while the proximal end **264** of the proximal capturing portion is closed. The proximal capturing portion can also optionally be configured to have regions of varying axial strength, spring rate, and various other features associated with the distal capturing portion **226**. In the illustrated variation, the capturing portion **226** and main bundle **202** move relative to the proximal capturing portion **260** to capture an obstruction. Furthermore, the proximal capturing portion **260** articulates with respect to the sheath **106** much in the same manner as the distal capturing portion **226** articulates relative to the main bundle **202**. As shown, the petals **238** on the open ends **228** and **262** can interact to nest once the capturing portions **226** and **260** are moved sufficiently close to one another. The outward force caused by the retained obstruction provides a frictional interaction between adjacent petals/flanges **238** to maintain the nesting.

[0109] Variations of the device include additional structures, such as springs, hooks, barbs, etc, to cause the open ends 228 and 262 to interlock. As noted above, a separate catheter can be used to initially deploy the capturing portion **226** beyond the obstruction. Although the capturing portions shown have the same configuration, the capturing portions **226** and **260** used in any given system do not have to match in size, shape, and configuration. For example, the proximal capturing portion can be impermeable to flow while the distal capturing portion allows flow. In another example, one basket may be undersized relative to the other to improve nesting.

[0110] In any case, the construction of the system **10** shown in Fig. 5B includes open ends **228** and **262** of capturing portions **226** and **260** that are unconnected. Accordingly, as the capturing portions **226** and **260** move towards one another as a result of the main bundle **202** translating relative to the delivery sheath **106** the open ends are free to articulate around the main bundle **202** and delivery sheath **106** respectively to remain expanded against the lumen wall.

[0111] Figs. 5C to 5E illustrate a variation of a system for delivery of the capturing portions **226** and **260**. Fig. 5C shows the proximal **260** capturing portion affixed to a delivery sheath **106**. In alternate variations, the proximal capturing portion **260** can be replaced with a proximal foot (not shown). As noted above, the main bundle or leading wires **202** extends through the delivery sheath **106** and connects to the distal capturing portion **226** beyond the opening **228** of the distal capturing portion **200**. The main bundle or leading wire **202** extends through the proximal capturing portion **260**. This allows the free ends of the capturing portions **228** and **262** to remain relatively unattached so that they can articulate and conform to the curvature of the vessels (as discussed below). The capturing portions **226** and **260**, main bundle **202** and delivery sheath **106** extend through a microcatheter **102**.

[0112] Fig. 5D illustrates a state of deployment after the microcatheter **102** traverses the obstruction (not shown). Once the microcatheter **102** is distal to the obstruction, the distal capturing portion **226** deploys from the end of the microcatheter **102**. As noted herein, the capturing portions can self-expand or can expand upon actuation by the physician. In any case, the distal capturing portion **226** should be sufficiently collapsible to remain within the microcatheter **102** for deployment distal to an obstruction. To deploy the distal capturing portion **200** from the catheter **102**, the main bundle **202** can translate to push the distal capturing portion **226** to eject it from the catheter **102**. Alternatively, the microcatheter **102** can be withdrawn from the distal capturing portion **226**.

[0113] Fig. 5E illustrates the deployment state after the catheter **102** is withdrawn proximal to the obstruction (not shown) and after the proximal capture portion **260** is delivered from the microcatheter **102**. As noted above, the proximal capture portion **260** can be affixed to an exterior of the catheter, in which case the catheter may be either de-sheathed or exchanged. Alternatively, and as shown, the proximal capturing portion **260** is affixed to a delivery sheath **106** and is fabricated to collapse within the microcatheter for ultimate deployment, whereby translating the sheath **106** delivers the proximal portion **260** from the microcatheter.

[0114] Fig. 5F shows another aspect of the system **10** where the proximal end **264** of the proximal capturing portion **260** is collapsed or compressed about an obstruction **2** prior to translation of the obstruction **2** within the vessel. In this illustration, the proximal capturing portion **260** is compressible by advancing the catheter **102** over the closed proximal end **264** of the capturing portion **260**. In

such a case, the proximal capturing portion **260** is slidable within and relative to the catheter **102.** Naturally, variations may include compressing the proximal end **264** during translation of the obstruction **2**. In either case, the proximal capturing portion **260** can be compressed in a number of different ways. For instance, the proximal basket can be compressed using a catheter **102**(as shown), or the delivery sheath **106**, or any other number of mechanisms (not illustrated).

[0115] As shown, the proximal end **264** can be compressed using a sheath **106** and/or catheter **102** However, other means of compressing may be employed (e.g., a loop structure, a tube over the sheath, a draw-string configuration, etc.) In use, once the distal capturing portion **226** is deployed distally to the obstruction **2** and the catheter **102** is withdrawn proximal to the obstruction **2**, the proximal capturing portion **260** is deployed. As the proximal capturing portion **260** partially (or totally) engulfs the obstruction **2**, the physician can collapse or compress the proximal capturing portion **260** to better secure the obstruction within the system **10**.

[0116] It is noted that any number of shapes, configurations, as well as any number of joined wires may be contemplated to form devices under the present disclosure. However, variations of the invention include selecting a number of wires to produce specific structural properties to the device. For example, the devices can have any number of wires where the limit is determined by the ability to produce a device of a sufficiently small size to access the area containing the obstruction. However, in some cases, it may be desired that wires are chosen to impart specified characteristics. For example, in the illustrated variation, the main bundle may comprise any number of wires that do not diverge to form subsequent shapes in the device. In other words, not all of the wires forming a section are required to diverge to form an adjacent section. Instead, these non-diverging wires may simply "loop" back away from the device. In an additional variation, one or more wires may diverge to form a particular portion of the capturing portion (e.g., the closed end, traversing wires, etc.). Then the wires can loop back to converge again with the main bundle.

[0117] Figs. 6A to 6E show one example of the deployment of a variation of a device according to the present invention about an obstruction in a vessel. The figures are intended to demonstrate the initial placement of the device immediately prior to removal of the obstruction.

[0118] Fig. 6A illustrates an obstruction **2** lodged within a body lumen or vessel **6**. In the case where the vessel is a cerebral artery, the obstruction may result in an ischemic stroke. Using standard interventional catheterization techniques, a microcatheter **102** and guidewire **104** traverse the obstruction. The microcatheter **102** may be advanced through the obstruction **2**. Alternatively, the microcatheter **102** may "push" aside the obstruction and is advanced around the obstruction. In any case, the microcatheter **102** travels from the near end **3** (or proximal side) of the obstruction **2** to the far end **4** (or distal side) of the obstruction **2**. It is noted that the catheter **102** may be centered or off-center with respect to the obstruction **2**. Furthermore, the device may or may not be used with a guidewire to navigate to the site and traverse the obstruction.

[0119] Some variations of the device may be placed without an accompanying guidewire. Moreover, the structures discussed herein may be directly incorporated into a guidewire assembly where deployment may require a sheath or other covering to release the components from constraint.

[0120] Fig. 6B illustrates deployment of a capturing portion **226** and main bundle **202** of the device **200** from within the microcatheter **102** distal to the obstruction **2**. Accordingly, in most variations, the capturing portion **226** is designed to fit within the catheter **102** for delivery and expand upon deployment. Alternatively, the device may be actuated to assume the desired shape (e.g., upon reaching a transition temperature where one or more wires comprise a shape memory alloy). As shown, the capturing portion **226** includes a traversing section **234** and a capturing section **232**. In some procedures the traversing section **234** engulfs the obstruction **2** with little or no complication as the main bundle **202**, catheter **102**, or sheath **106** pulls the capturing portion **226** in a proximal direction.

[0121] However, as discussed above, there may be some procedures where the distal capturing portion **226** is deployed distal to an obstruction **2** that is deposited within the vessel or lumen such that a steady translation of the capturing portion **226** will not engulf the obstruction **2**. Figs. 7A to 7G illustrate some examples of such a situation. As shown in Fig. 7A, a sheath **106** might be able to traverse the obstruction **2** to deploy the distal capturing portion **226** in preparation for engulfing the obstruction **2**. Fig. 7B illustrates a condition where the traversing section **234** engages the obstruction **2** but is unable to easily or fully engulf the obstruction **2**. However, in those variations where the capturing portion **226** includes regions

having different axial strength (as discussed above), continued pulling of the main bundle **202** in a proximal direction **120** causes the capturing section **234** to compress. When the capturing section **234** is constructed to function as spring, the deformation of the capturing section **232** stores energy from the proximal movement of the main bundle **202**. This storing of energy allows the physician to relax the pulling force **120** on the main bundle **202**. Fig. 7C shows a compressed capturing section **234**. The energy stored in the capturing section **232** gradually drives the open proximal end **228** of the translating section **234** over or along the obstruction **2**. The physician can apply this "pull and relax" technique repeatedly until the obstruction is sufficiently captured by the capturing portion **226**. In some variations, the capturing section **234** remains compressed as the obstruction **2** finally breaks loose and removed.

[0122] Fig. 7D represents the situation where a distal capturing portion distal to an object **2** that is significantly embedded within a vessel or body lumen. In such cases, the force required to remove the obstruction **2** may damage the vessel or lumen. Such obstructions include atherosclerotic plaque or other immobile objects. As shown, when the distal capturing portion **226** is pulled once the proximal force **120** reaches a threshold value (as determined by the construction of the capturing portion **226**) the capturing portion **226** undergoes a staged inversion as the permeable end **230** enters the traversing section **232**. In this variation, the permeable end **230** actually enters the obstruction **2**. The construction of the capturing portion **226** prevents flattening or expanding in diameter, where such movements would prevent removal of the capturing portion. Again, if the force applied by the capturing portion **226** breaks the obstruction **2** free. The obstruction **2** can be removed even though a part of the capturing portion **226** is within the obstruction **2** as shown in Fig. 2D.

[0123] Fig. 7E shows advanced inversion of the capturing portion **226** as the capturing section **234** is now proximal to the traversing section **232**. The traversing section **232** may be deformed upon inversion but will taper towards the capturing section **234** as the capturing section **234** passes through the obstruction **2** (typically via an opening that was previously created by advancement of a sheath **106** through or around the obstruction **2**).

[0124] Fig. 7F shows the capturing portion **226** nearly passing through the obstruction **2** so that it may be removed from the body. As shown in Fig. 7G, the

capturing portion **226** is now fully inverted and is in a state where it can re-enter a catheter for removal from the patient.

[0125] The construction described herein that allows for staged inversion of the capturing portion **2** provides a significant safety feature. A physician must undertake additional surgical intervention to remove any retrieval device that has become lodged distally to an immobile obstruction. The ability of staged inversion allows the physician to invert and remove the capturing portion **226** if application of a predetermined or threshold force is exceeded by proximal displacement of the device. This feature reduces the need for additional surgical intervention to remove a retrieval device that would otherwise become lodged or separated as a result of excessive forces being applied.

[0126] Figs. 8A to 8B illustrate an additional benefit of affixing a leading wire or bundle of wires **202** beyond a proximal opening **228** of a capturing portion **226**. Fig. 5A illustrates a basket type structure **90** where a wire **202** is affixed to a proximal end **92**. As shown, as the leading wire **202** pulls the basket **90** through tortuous anatomy **6**, the force component pulling away from an axis of the device **90** causes the proximal open end **92** to constrict or reduce in size. As shown, as the proximal end **92** approaches the obstruction **2** the perimeter of the end is not placed against the walls of the body passage **6**. As a result, the constricted opening **92** places an increased axial force on the obstruction **2** as the basket **90** translates over the obstruction **2** (because the proximal end **92** pushes against the obstruction rather than sliding around it), making encapsulation of the obstruction more difficult and possible leading to vascular damage.

[0127] Fig. 8B shows a device **200** according to the principles disclosed herein. The leading wire **202** is affixed to the distal end **230** of the capturing portion **226**. As the main bundle 202 is pulled through the curved vascular path, the capturing portion **226** pivots or articulates about the bundle 202 and remains aligned with the axis of the vessel. As a result any misalignment between the leading wire **202** and an axis of the capturing portion **226** does not affect the open proximal end **228**. As noted above, some closing of the open proximal end may occur, though it will not be sufficient to interfere with the obstruction as the capturing portion moves over the obstruction. Such a configuration allows the perimeter of the open proximal end **228** to remain against the wall of the passage **6**. As shown, because the open

proximal end **228** is not constricted, the open proximal end **228** is better suited to slide around the obstruction for eventual removal.

[0128] Fig. 8C shows withdrawal of the microcatheter **102** to the proximal side **3** of the obstruction **2** and deployment of a proximal capturing portion **260** (in alternate variations, a proximal foot can be used or the capturing portion **226** alone can be used). Again, the catheter **102** can be exchanged for a catheter **102** having a proximal capturing portion **260**. Alternatively, and as shown in the accompanying figures, the proximal capturing portion **260** can be affixed to a delivery sheath **106** that is fed through the microcatheter **102**.

[0129] As also shown in the figure, the main bundle **202** and capturing portions become misaligned due to the tortuousity of the anatomy. However, because the capturing portions **226** and **260** are able to pivot or articulate relative to the main bundle **202** and catheter **102** or sheath **106**, the open ends are able to remain against the lumen wall. In conventional devices where the open end is attached to either a wire or catheter, when the wire or catheter bends in the anatomy, the forces exerted on the open ends deform or distort the end to assume a reduced profile. Accordingly, the physician may have difficulty in removing an obstruction if the profile of the open end becomes reduced in size. Closing of the open end can also result in vascular damage if the physician applies too much force in translating the device.

[0130] Fig. 8D shows movement of the capturing portions **226** and **260** adjacent to the obstruction **2**. The proximal capturing portion **260** can remain stationary or may be advanced relative to the distal capturing portion **226**. Regardless, the physician is able to ensnare the obstruction **2** within the cavities defined by the capturing portions **226** and **260**. Fig. 8E illustrates the system as the two capturing portions are drawn together. For purposes of clarity, the obstruction is not shown. Upon sufficient advancement of the capturing portion **226** and proximal capturing portion **260** relative to one-another, flanges **238** on the respective open ends can interlock. This feature provides added safety in removing the device as the obstruction is encapsulated between the two nested portions.

[0131] Fig. 8F illustrates a device **200** after securing an obstruction between a proximal **260** and distal **226** capturing sections. As shown, the captured obstruction **2** is held between capturing portions **226** and **260** where the flanges **238** nest within one-another to "lock" the capturing portions together. In some

variations of the device, one of the capturing portions can be undersized relative to the other. This configuration allows for the undersized capturing portion to become further compressed as the devices are pulled together. The compression of the capturing surface then serves to further compress the obstruction **2** captured within the device.

[0132] The capturing portions described herein can include coverings or wrappings so long as the other features of the device are not impaired. Such coverings can be located on both capturing portions **226** and **260**, only one or more capturing portions. The covering can include a strand or fiber wrapped or woven about the section, a polymer film, or a dipped polymer coating such as silicone, urethane, etc. The coating on either capturing portion can be solid or porous. In the latter case, blood can continue to flow through the coating. In one variation, the proximal capturing portion **260** could employ a solid covering while the distal capturing portion **200** could include a porous covering. In such a case, blood or other fluid flow could be temporarily halted by the presence of the solid covering to assist in removal of the obstruction.

[0133] Fig. 9 illustrates a variation of the system where the main bundle **202** includes a medial foot **274**. The construction of the medial foot **274** can be similar to that of the proximal foot discussed above (e.g., wires looped into a petal configuration.) However, the medial foot includes a surface area or diameter larger than a diameter of the main bundle. In any case, the increased surface area of the medial foot **274** provides an increased resistance to the obstruction **2** as the distal capturing portion **200** and main bundle **202** are pulled in a proximal direction towards an obstruction **2**. The medial foot **274** engages the obstruction **2** to partially displace or loosen the obstruction from the walls of the body passage. The medial foot **274** can be slidably located on the main bundle such that after a threshold force, the medial foot moves within the distal capturing portion **200**. The main bundle **202** can include any number of medial feet **274**.

[0134] Although the illustrated variation shown above comprise open-ended, circular, looped or partial loop shape cross sectional areas, variations of the capturing portions can include any number of shapes. For example, such a shape can include a circle, an arcuate shape, a partial circular shape, a loop, an oval, a square, a rectangle, a polygon, an overlapping loop, a pair of semi-circles, etc.) The various shapes may be heat set to be either self-expanding (i.e., superelastic)

or the use of shape memory alloys can allow for the device to assume the particular shape upon reaching a desired transition temperature.

[0135] The exemplary shapes discussed above permit the shaped section to adjust in diameter in response to placement in varying diameters of body lumens. It is noted that a device may have different shaped sections on different ends of the device.

[0136] While many different shapes are contemplated to be within the scope of this disclosure, the shapes will depend upon the ultimate application of the device. As noted herein, the illustrated examples have particular applicability in retrieving obstructions from the vasculature. Accordingly, for these applications the shaped sections should form a shape so that they can expand against a vessel wall without causing trauma to the vessel. For example, upon release from the catheter, the shaped section can assume their resting shape and expand within the vessel. The resting shape can be constructed to have a size slightly greater than that of the vessel. Sizing the device relative to the target vessel may assist in placing the parts of the device against a vessel.

[0137] In an additional aspect, the shaped sections may be designed to have an unconstrained shape that is larger than the intended target vessel or simply different than a cross sectional profile of the intended vessel (i.e., not circular or tubular, but e.g., linear or other different shape). In such an example, as the shaped section is released from the delivery catheter, the shape section attempts to return to the unconstrained shape. In those variations where the unconstrained shape is different from the circular profile of the vessel, the leading wire assumes a shape that accommodates the vessel but is more rigid and stable since its unconstrained shape is entirely different from that of the vessel. In other words, the shaped section continually exerts an outward force on the vessel.

[0138] In yet another aspect, the shaped sections shown herein may not necessarily lie in the same plane. Instead, they can be axially spaced by an offset. One benefit of constructing the device to have non-planar shaped section is that the configuration might allow for delivery of the device through a smaller microcatheter because the shaped sections do not interfere with one another when collapsed to fit within the microcatheter.

[0139] Another aspect applicable to all variations of the devices is to configure the devices (whether the traversing filament or the surrounding portion) for better

adherence to the obstruction. One such mode includes the use of coatings that bond to certain clots (or other materials causing the obstruction.) For example, the wires may be coated with a hydrogel or adhesive that bonds to a thrombus. Accordingly, as the device secures about a clot, the combination of the additive and the mechanical structure of the device may improve the effectiveness of the device in removing the obstruction. Coatings may also be combined with the capturing portions or catheter to improve the ability of the device to encapsulate and remove the obstruction (e.g., a hydrophilic coating).

[0140] Such improvements may also be mechanical or structural. Any portion of the capturing portion can have hooks, fibers, or barbs that grip into the obstruction as the device surrounds the obstruction. The hooks, fibers, or barbs **154** can be incorporated into any portion of the device. However, it will be important that such features do not hinder the ability of the practitioner to remove the device from the body.

[0141] In addition to additives, the device can be coupled to an RF or other power source (such as **14** or **16** in Fig. 1A), to allow current, ultrasound or RF energy to transmit through the device and induce clotting or cause additional coagulation of a clot or other the obstruction.

[0142] The methods described herein may also include treating the obstruction prior to attempting to remove the obstruction. Such a treatment can include applying a chemical or pharmaceutical agent with the goal of making the occlusion shrink or to make it more rigid for easier removal. Such agents include, but are not limited to chemotherapy drugs, or solutions, a mild formalin, or aldehyde solution.

[0143] As for other details of the present invention, materials and manufacturing techniques may be employed as within the level of those with skill in the relevant art. The same may hold true with respect to method-based aspects of the invention in terms of additional acts that are commonly or logically employed. In addition, though the invention has been described in reference to several examples, optionally incorporating various features, the invention is not to be limited to that which is described or indicated as contemplated with respect to each variation of the invention.

[0144] Fig. 10 illustrates one variation of a retrieval device **200** including a distal capture portion **226** coupled to one or more leading wires in the form of a main bundle **202**. The main bundle extends through a sheath **106** that includes a

proximal capture portion **260**. The configuration of the retrieval device **200** can incorporate the proximal and distal capture portions discussed herein as well as various other configurations discussed in the commonly assigned patent applications noted above. In addition, the relative sizes of the various components shown in Fig. 10 and discussed below are for illustrative purposes only.

[0145] An end **264** of the proximal capture portion **260** is affixed to a distal end of the sheath **106**. However, as noted above, other variations are within the scope of the disclosure. The main bundle **202** can optionally terminate at a handle **242**. As noted above, in certain variations, the main bundle is joined to a stiffer wire or stiffer bundle of wires. This allows the device **200** to have a very flexible distal section with a relatively stiffer proximal section. Fig. 4A above, discusses placement of a joint at a location spaced from the distal section of the device so as to increase a bond strength but not impair the distal section's flexibility. In any case, the device **200** can have a proximal bundle **203** that comprises either the exposed wires or a covering/tube over the wires. In certain variations, the bundle or wire **202**, **203** can be encapsulated with a coating.

[0146] The proximal end of the sheath **106** includes a sheath handle **244**. As discussed herein, axial movement of the bundle **202** or proximal bundle **203** (typically at the handle **242**) results in movement **126**, or translation of the bundle within the sheath **106**. This action moves the distal capture portion **226** (as shown by arrows **126**). In certain variations, the device **200** is loaded into a microcatheter (not shown but discussed above) that is delivered to the site of the obstruction and crosses the obstruction.

[0147] In some variations, the sheath hub **244** includes one or more locking hubs **246**. Where actuation (either axial or rotational) of the locking hub **246** locks the main bundle **202** relative to the sheath handle **244** and sheath **106**. It follows that such locking action also locks the distal capture portion **226** relative to the proximal capture portion **260**. A variety of methods can be employed to increase a frictional interference between the locking hub **246** and the proximal bundle **203**. As a result, when a physician determines a length of an obstruction, the physician can set a spacing between the capturing portions **226** **260** by locking the proximal bundle **203** relative to the sheath hub **244**. Accordingly, the proximal bundle **203** can include any type of incremental markings to allow the physician to readily determine a spacing of the capturing portions. As illustrated, the sheath hub **244**

can include additional injection ports to deliver fluid or other substances through the sheath **106**.

[0148] As noted above, the device **200** can be used with micro-catheter. In those variations it is important that the device **200** is loaded without damaging the distal bundle **202**, capture portions **226 260**, and/or sheath **106**. As a result, the device **200** can include an optional funnel **286** that reduces the proximal capture portion **260** (and /or the distal capture portion **226**) for loading within the microcatheter and/or sheath **106**.

[0149] Another variation of the device **200** includes an insertion tool **280** slidably affixed to the sheath **280**. Because variations of the device **200** can be extremely flexible, the insertion tool **280** can be used to provide column strength to the sheath **106**, bundle **202** or other components as the device **200** is pushed into the microcatheter. The insertion tool comprises a rigid section **282** and a frictional coupler **284**. The rigid section **282** has a column strength that supports the device **200** to prevent buckling. The frictional coupler **284** can be a flexible material that allows an operator to squeeze or grip the coupler **284** to create a temporary frictional interface between the loading tool **280** and the device **200** (typically the sheath **106**). Such an action allows axial advancement of the device **200** as the loading tool **280** is advanced into the microcatheter. Once the rigid section **282** is fully inserted into the microcatheter, the operator releases the frictional coupler **284** and can withdraw the loading tool **280** from the catheter without withdrawing the device **200**. The insertion tool **280** can also include an optional loading tube **286** slidably coupled to the rigid section **282**. When used, the funnel **286** can withdraw the proximal and distal capturing portion **226 260** within the loading tube **286**. The loading tube **286** then couples to a microcatheter allowing the capturing portions to advance therein as the rigid section **282** and frictional coupler **284** advance the device **200** relative to the loading tube **286**.

[0150] Fig. 11A illustrates a funnel catheter **300** useful for retrieving objects from vessels or body lumens. Typically, when a physician captures an obstruction in various retrieval devices, the device and the obstruction are easily removed from the body by withdrawing the device and obstruction into a sheath, guide catheter or introducer ("guide catheter"). However, in some circumstances, a physician has difficulty withdrawing the obstruction loaded device within a sheath, guide catheter or introducer. Specifically, one or more components of the retrieval

device might become caught on an edge of the guide catheter. The concern may still remain even when using a guide catheter having an increased diameter (such as when the retrieval device catches on one edge of the guide catheter tip). Moreover, large guide catheters are difficult to advance within various parts of the anatomy. As a result, the obstruction loaded device must travel further. Movement of the obstruction loaded device within the body creates the risk that the obstruction will detach or break apart and cause additional adverse consequences.

[0151] The funnel catheter **300** includes a first and second slotted funnels **330**, **340** located at the distal end of an inner shaft **302.** Each funnel **330 340** comprises a number of extensions or tines **332 342**. The inner shaft **302** can be cut to produce the first tines **332**. Alternatively, the first tines **332** can be affixed to a portion of the inner shaft **302**. The second slotted funnel **340** is offset in both a proximal and rotational position relative to the first slotted funnel **330**. The purpose of this dual offset is discussed in detail below. As shown, the second funnel **340** can be a slotted tube that is affixed over the inner shaft **302**. In an alternate variation, a plurality of second tines **342** can be located about the inner shaft **302** to form a second slotted funnel **340**. As shown in Fig. 11B, the tines **332 342** can be configured to expand outward (if not restrained) via use of a coil or other spring-type means. Alternatively, they can be actuated to expand outward. However, in most cases, the tines **332 342** can expand passively upon entry of the retrieval device **200**. The expansion of one or both funnels assists in receiving the retrieval device. In additional configurations, one or more funnels can be designed so that they remain in a cylindrical shape rather than expand outwards (as shown in Fig. 11C). Variations of the funnel catheter **300** can include configurations having one or more funnels, or configurations where the tines spaced or adjacent (or a combination thereof).

[0152] Fig. 11C also illustrates the dual offset nature of the dual funnel catheter **300**. The first offset is a linear offset **316** such that the distal ends of the first tines **332** or funnel **330** extends beyond a distal end of the second tines **342** or second funnel **340**. The second offset comprises a rotational offset (denoted by rotational angle **A**). For example, the illustrated rotational offset **A** is 45 degrees. However, the rotational offset can vary depending on the particular application. In most variations, the rotational offset **A** will place the second tines **342** over the gaps or spaces between the first tines **332**. The number of tines can vary depending on the

application. Variations of the funnel catheter can include discontinuous funnels with two or more tines.

[0153] Turning back to Fig. 11A, the funnel catheter **300** can optionally include any number of medical fittings or components. As shown, the catheter **300** includes a hemostasis valve or hub **306** at the proximal end. The hemostasis valve **306** can include a fluid side port **308** for delivery of fluid through the catheter **300**. The catheter **300** can also include one or more radiopaque markers **310** so that the location of the funnel or funnels **330 340** can be identified via non-invasive imaging (e.g., under fluoroscopy). The funnel catheter **300** can also optionally include one or more markers **312**. Such markers are useful to inform a physician (who is only able to view the proximal end of the device **300**) of the distance to the first or second funnel. As a result, the physician will be able to determine whether the funnels are advanced out of the guide catheter. Fig. 11A also shows the funnel catheter **300** as including a loading tool **314**. The loading tool **314** can be advanced over the funnels **330 340** to compress the funnel when loading into a guide catheter or other sheath.

[0154] Figs. 12A to 12C provide an illustrative example where use of a funnel catheter **300** aids in removal of an obstruction **2** loaded within a retrieval device **200**.

[0155] As shown in Fig. 12A, attempting to remove the obstruction **2** when engulfed in the retrieval device **200** creates a risk that one or more portions of the device **200** become caught on the guide sheath or access catheter **108**. In some cases, the physician can simply engage the device **200** against the distal end of the guide sheath **108** and withdraw until the obstruction **6** and device **200** are located in an acceptable area of the body or withdrawn entirely from the body. For example, in certain situations, the obstruction **6** and device **200** can be withdrawn with the guide sheath **108** until all components reach a high flow, non-critical locations (e.g., the groin area). In the case of a clot, a clot dissolving substance (TPA) can then be applied to dissolve and remove the clot. Alternatively, the physician can attempt to aspirate through the guide sheath **108** in an attempt to draw the entire retrieval device **200** and obstruction **2** within the guide sheath **108**. In yet another variation, the physician can advance fibers or guide wires out through the guide sheath **108**, then withdraw the obstruction **2**/retrieval device **200** and attempt to use the fibers or guide wires as a moveable surface to capture the

device **200**. Furthermore, the physician can attempt to use a variety of existing devices (e.g., the FastCath provided by Genesis Medical Inc., the Merci Retriever provided by Concentric Medical Inc., or any commercially available snare or distal protection device) to remove the engulfed obstruction **2** from the body.

[0156] In some variations, the capturing portions discussed above can be constructed to improve their ability to be withdrawn into a guide sheath. For example, increasing the number of petals or flanges on the traversing sections increases the probability that the distal flanges nest within the proximal capturing portion. Alternatively, or in combination, the petals **238** on the distal capturing portion can be staggered in length or position to ease insertion into the proximal capturing portion. In another variation, the petals **238** shape or curvature can be adjusted so that they do not flare outward.

[0157] Fig. 12B shows a distal end of a funnel catheter **300** as it receives an obstruction **2** loaded retrieval device **200**. As shown, the tines **332** of the first funnel **330** receive the device **200**. The tines **332** minimize the likelihood that the device **200** becomes caught. The limited surface area of the tine **332** (combined with the rounded tines **332 342**) produces a tendency for the device **200** to deflect away from the tines as it is withdrawn into the funnels. The second funnel **340**(being rotationally offset from the first funnel **330** provides coverage over the spaces between the first tines **332** thereby assisting in nesting of the device **200** within the funnels. Ultimately, the device **200** and obstruction **2** are withdrawn into a guide sheath **108** and removed from the body.

[0158] Figs. 12 C to 12D show additional variations of funnel catheter **300**. Fig. 12C shows a single funnel **330** having a plurality of tines **332**. Fig. 12D illustrates a dual funnel catheter **300** having a discontinuous first funnel **230** and a second funnel **346**. The second funnel **346** can be a continuous funnel so long as it is able to retract within the guide sheath **108**. As shown, the second funnel **346** can include a single slit **348** that allows the funnel to compress within the guide sheath **108**. In addition, the variation of Fig. 12D can be used without the first discontinuous funnel **330**. Accordingly, as the retrieval device **200** and clot **2** approach the funnel **346** and enters the funnel, further withdrawing the retrieval device **200** causes squeezing of the retrieval device **200** and obstruction **2**. In yet another variation, the funnel **346** can incorporate a drawstring to compress the funnel **346** once the retrieval device **200** and obstruction are located therein.

[0159] Fig. 13A to 13B illustrates another variation of a funnel catheter **350** suited to remove a retrieval device **200** from the body. As shown in Fig. 13A, the funnel catheter **350** includes a first shaft **352** and a second shaft **354** slidably located therein. A mesh **370** is fused to each shaft **352 354** at a distal location **362 364**. Accordingly, relative movement of the shafts **352 354** (either the first shaft **352** can be pushed or the second shaft **354** can be pulled) creates a funnel shape **372** as the mesh portion affixed to the second shaft **354** is inverted within the remainder of the mesh **370**. It is noted that in some variations of the system, the mesh funnel funnels are combined with the tine based funnels described above. Such that one funnel comprises the tines while the other comprises the mesh structure described herein.

[0160] In another variation, a third distally located capture portion (similar to a distal capture portion) can be used to draw the retrieval device within a guide sheath. In such a variation, the third capture portion can be a larger distal capture portion and when the retrieval device engulfs an obstruction, the third basket portion can be proximally withdrawn to capture the retrieval device and obstruction.

[0161] As illustrated in Fig. 13B, as the retrieval device **200** and obstruction **2** approach the funnel catheter **350**, the distal attachment points **362 364** of the shafts **352 354** are moved together to invert the mesh **370** and form a funnel **372**. The retrieval device **200** can then be withdrawn into the funnel. This design allows for the retrieval device **200** to be fully withdrawn into the catheter **350** while the funnel **372** is expanded. Alternatively, the funnel **372** can be used to compress the retrieval device **200** and obstruction **2** prior to withdrawal into the catheter **350**.

[0162] The mesh **370** can include any medically acceptable material such as a nitenol braid. Furthermore, the mesh allows for flow through the vessel or lumen while expanded. However, additional variations of the device can include a solid layer of material substituted for the mesh.

[0163] Figs. 13C to 13E illustrate another variation of a funnel catheter **350** suited to remove a retrieval device **200** from the body. As shown in Fig. 13C, the funnel catheter **350** includes a first shaft **352** and a second shaft **354** slidably located therein. A mesh **370** is joined only the rear shaft **354** at a distal location **362**. The end of the mesh **370** is free at the distal end of the device **350**. The mesh **370** is sized at a distal end **371** to neck down. Accordingly, as the distal shaft moves

rearward, the mesh **370** is unsupported. The necked section **371** of the mesh allows for distal advancement of the device **200** through the neck portion **371**. However, as shown by Fig. 13D, rearward movement of the device **200** causes engagement with the neck portion **371**. Further rearward movement of the device **200** causes the unsupported mesh **370** to form a funnel shape **372** as shown in Fig. 13E. The funnel shape allows for the retrieval device **200** to be fully withdrawn into the catheter **350** while the funnel **372** is expanded. Alternatively, the funnel **372** can be used to compress the retrieval device **200** and obstruction **2** prior to withdrawal into the catheter **350**. To compress the funnel, the device **200** can be advanced out of the funnel and away from the mesh **370**. Next, the distal shaft **352** can be advanced through the neck portion **371** of the mesh **370** to receive the device **200**. In another variation, the device **350** can include a single shaft **354** where the mesh **370** can extend beyond the shaft **354**. The mesh can be heat set to assume a funnel shape upon the application of a current or as it reaches body temperature. In another variation, the mesh **370** can comprise a super-elastic material that assumes the shape shown in Fig. 13E when released from a constraining member.

[0164] Figs. 13F to 13G illustrate yet another variation a funnel catheter **350** suited to remove a retrieval device **200** from the body. In this variation, the funnel catheter **350** includes a single shaft **354** having a mesh **370** is fused to a distal location **364**. The mesh **370** is free at a proximal side. The mesh is also pre-formed to assume a funnel shape as shown in Fig. 13G. Accordingly, upon delivery the mesh **370** can be constrained (e.g., via a sheath, or other removable restraint). Once the restraint is removed, the mesh **370** expands to form a funnel **372**.

[0165] Figs. 14A to 14D illustrate additional concepts for use with various retrieval devices **200**. Fig. 14A illustrates a distal capturing portion **226** and a proximal capturing portion **260** where the proximal capturing portion includes a covering **212** (e.g., a polymeric covering or a wire or fiber wound about the flanges **238**). The covering **212** prevents the flanges **238** of the distal capturing portion **226** from flaring outside of the proximal capturing portion **260**.

[0166] Fig. 14B illustrates a variation of a reentry sleeve where tines **332** of the reentry sleeve **302** include protrusions **214** on an inner surface. The protrusions **214** cause the tines **332** to splay out as the retrieval device **200** is withdrawn within

the tines **332**. As the reentry sleeve **302** is withdrawn in a guide catheter (as discussed above) the protrusions serve to compress the retrieval device **200** even further.

[0167] Fig. 14C and 14D illustrate variations of a wire or fiber **218** affixed to the flanges **238** of a distal capturing portion **226** to assist in compressing the flanges **238** prior to entry within a guide sheath. As shown in Fig. 14C the fiber **218** can be affixed to a suture ring **216**. As the fiber **218** is pulled, the suture ring **216** compresses the flanges **238** to prevent outward flaring. In Fig. 14D, one or more fibers **218** are affixed to one or more flanges **238**. Once the obstruction is captured, the fibers can be pulled to draw the flanges **238** closed.

[0168] Various changes may be made to the invention described and equivalents (whether recited herein or not included for the sake of some brevity) may be substituted without departing from the true spirit and scope of the invention. Also, any optional feature of the inventive variations may be set forth and claimed independently, or in combination with any one or more of the features described herein. Accordingly, the invention contemplates combinations of various aspects of the embodiments or combinations of the embodiments themselves, where possible. Reference to a singular item, includes the possibility that there are plural of the same items present. More specifically, as used herein and in the appended claims, the singular forms "a," "and," "said," and "the" include plural references unless the context clearly dictates otherwise.

[0169] It is important to note that where possible, aspects of the various described embodiments, or the embodiments themselves can be combined. Where such combinations are intended to be within the scope of this disclosure.

CLAIMS

We claim:

1. A medical device for removing an obstruction from a blood vessel, the medical device comprising:

a main bundle comprising a group of wires having a first end and a second end;

a capturing portion formed by the group of wires and having a translating surface adjacent to a capturing surface, the translating surface having an open proximal end and the capturing surface having a permeable distal end;

where the capturing portion is formed from the group of wires such that the group of wires diverges from the second end of the main bundle to form the permeable distal end, the group of wires extend back in a proximal direction to form the capturing surface, the translating surface, and open proximal end about the main bundle; and

where the translating surface and capturing surface are configured so that a translating surface axial strength is greater than a capturing surface axial strength, wherein application of a tensile force on the main bundle causes axial compression of the capturing surface without causing axial compression and deformation of the translating surface sufficient to deform the translating surface as the capturing portion engages the obstruction.

2. The medical device of claim 1, where the capturing portion is formed such that articulation of the capturing portion relative to the main bundle does not cause the open proximal end to reduce in size.

3. The medical device of claim 1, where the capturing surface is configured to generate a spring force against the translating surface when a proximal force applied by the main bundle of wires compresses the capturing surface against the translating surface when encountering resistance from the obstruction, where the capturing surface is configured to have a sufficient axial stiffness to direct the spring force and proximal force to the open proximal end as the open proximal end engages the obstruction where the capturing surface is also sufficiently flexible to conform to a shape of the vessel.

4. The medical device of claim 1, where the capturing section is configured so that when the open proximal end of the translating section engages resistance equal to or greater than a threshold force, proximal movement of the main bundle inverts the capturing section within the translating section and reduces a size of the capturing section.

5. The medical device of claim 4, where the capturing section and traversing section are configured to invert upon continued proximal movement of the main bundle such that the traversing surface moves distally to the capturing surface.

6. The medical device of claim 1, where the main bundle is joined to a proximal bundle, where the proximal bundle comprises a stiffness greater than the main bundle and where the main bundle extends for a pre-determined distance from the permeable distal end to allow navigation of a distal portion of the medical device within the cerebral vasculature.

7. The medical device of claim 6, where the pre-determined distance is at least 20 cm.

8. The medical device of claim 1, where the capturing surface has an increased frictional resistance as compared to the translating surface, such that the capturing surface engages the obstruction for removal of the obstruction.

9. The medical device of claim 1, where the open proximal end further comprises a plurality of flanges extending from the translating surface.

10. The medical device of claim 9, where the flanges extend radially away from an axis of the capturing portion.

11. The medical device of claim 1, where the capturing portion is self-expandable.

12. The medical device of claim 1, where at least a portion of the capturing surface comprises a structure selected from the group consisting of a basket, a filter, a bag, a coil, a helical wire structure, a mesh, a single wound wire, and a plurality of crossing wires or a combination thereof.

13. The medical device of claim 1, where the main bundle of wires includes at least a first wire and a second wire where the first and second wire each have different characteristics.

14. The medical device of claim 13, where the characteristics are selected from a group consisting of material, cross-sectional shape, and cross-sectional size.

15. The medical device of claim 1, where the main bundle of wires includes at least one shape memory alloy wire.

16. The medical device of claim 1, where the main bundle of wires includes at least one wire selected from the group consisting of a superelastic wire, a polymeric wire, or a metal alloy.

17. The medical device of claim 16, where the metal alloy comprises an alloy selected from the group consisting of stainless steel, titanium, platinum, gold, iridium, tantalum, nitinol, and combinations thereof.

18. The medical device of claim 1, further comprising at least one radiopaque material located on the capturing portion.

19. The medical device of claim 1, where the individual wires in the group of wires each comprise a bundle of smaller wires.

20. The medical device of claim 1, where the individual wire comprises a super-elastic outer shell and an inner core of a radiopaque material.

21. The medical device of claim 20, where the inner core comprises a material selected from a group consisting of platinum, iridium, gold, and tantalum.

22. The medical device of claim 1, where the capturing portion is jointless.

23. The medical device of claim 1, where at least one of the wires from the main bundle returns to the main bundle after forming at least a part of the capturing portion.

24. The medical device of claim 1, where each of the wires from the main bundle returns to the main bundle after forming a part of the capturing portion.

25. The medical device of claim 1, where the main bundle is surrounded by a coil or coiled wire.

26. A retrieval device for removing an obstruction from a body lumen, the retrieval device comprising:

at least one leading wire;

a retrieval body comprising a translating section adjacent to a capturing section, the translating section having an open proximal end and the capturing section having a permeable distal end, where the leading wire extends to a portion of the capturing section to permit articulation of the open proximal end relative to the leading wire; and

where the translating section and capturing section are configured so that a translating section axial strength is greater than a capturing section axial strength, wherein application of a tensile force on the leading wire causes axial compression of the capturing surface without causing axial deformation of the translating surface when the retrieval body engages the obstruction.

27. The retrieval device of claim 26, where the retrieval body is formed such that articulation of the retrieval body relative to the leading wire occurs without narrowing of the open proximal end during articulation.

28. The retrieval device of claim 26, where the capturing section is configured to generate a spring force against the translating section when a proximal force applied by the leading wire compresses the capturing section against the translating section when encountering resistance from the obstruction, where the capturing section is configured to have a sufficient axial stiffness to direct the spring force and proximal force to the open proximal end as the open proximal end engages the obstruction, where the capturing section is also sufficiently flexible to conform to a shape of the body lumen.

29. The retrieval device of claim 26, where the capturing section is configured so that when the open proximal end of the translating section engages resistance equal to or greater than a threshold force, proximal movement of the leading wire inverts the capturing section within the translating section and reduces a size of the capturing section.

30. The retrieval device of claim 29, where the capturing section and traversing section are configured to invert upon continued proximal movement of the leading wire such that the traversing section moves distally to the capturing section.

31. The retrieval device of claim 26, where the at least one leading wire is joined to at least one proximal leading wire, where the proximal leading wire comprises a stiffness greater than the leading wire and where the leading wire extends for a pre-determined distance from the permeable distal end to allow navigation of a distal portion of the retrieval device within the cerebral vasculature.

32. The retrieval device of claim 31, where the pre-determined distance is at least 20 cm.

33. The retrieval device of claim 26, where the leading wire is surrounded by a coil or coiled wire.

34. The retrieval device of claim 26, where the leading wire extends to the permeable distal end.

35. The retrieval device of claim 26, where the capturing portion comprises a structure selected from a group consisting of a laser cut tube, an etched tube, an injection molded structure.

36. The retrieval device of claim 36, where the at least one leading wire is attached to the capturing portion via a joint or junction.

37. The retrieval device of claim 26, where the translating section has a low coverage density relative to the capturing section, thereby lowering frictional resistance of the first portion of the capturing surface when moving over the obstruction.

38. The retrieval device of claim 37, where the at least one leading wire comprises a super-elastic outer shell and an inner core of a radiopaque material.

39. The retrieval device of claim 38, where the inner core comprises a material selected from a group consisting of platinum, iridium, gold, tantalum, alloys or mixtures thereof.

40. The retrieval device of claim 38, where leading wire is continuous with and forms the capturing portion.

41. The retrieval device of claim 26, where the at least one leading wire comprises a group of wires forming a main bundle and where the group of wires forms the capturing portion such that the group of wires diverges from a second end of the main bundle to form the permeable distal end, the group of wires continue to extend to form both the capturing surface and open end.

42. The retrieval device of claim 26, where the at least one leading wire comprises a group of wires forming a main bundle and where the group of wires forms, the capturing portion such that the group of wires diverges from a second end of the main bundle to form the capturing surface, the group of wires continues to extend to form both the permeable distal end and open proximal end.

43. The retrieval device of claim 26, where the at least one leading wire comprises a group of wires forming a main bundle and where at least one individual wire has a cross-sectional shape selected from the group consisting of a circle, an oval, a rectangular shape, a polygon, and a D-shape.

44. The retrieval device of claim 26, where the retrieval body is jointless.

45. The retrieval device of claim 26, where at least a portion of the capturing section comprises a structure selected from the group consisting of a basket, a filter, a bag, a coil, a helical wire structure, a mesh, a single wound wire, a plurality of crossing wires, and a combination thereof.

46. The retrieval device of claim 26, where the open proximal end of the translating section further comprises a plurality of flanges extending from the capturing portion

47. The retrieval device of claim 26, where the retrieval body is self-expandable and compresses to fit within a lumen of a catheter.

48. The retrieval device of claim 26, further comprising at least one radiopaque material located on the capturing section.

49. The retrieval device of claim 26, where the leading wire comprise a bundle of smaller wires.

50. The retrieval device of claim 26, where the leading wire comprises a group of wires that diverges towards the permeable distal end of the capturing section.

51. The retrieval device of claim 26, further comprising a proximal capturing portion where the retrieval body is moveable relative to the proximal capturing portion, where the proximal capturing portion comprises an open distal end and a proximal end, where the leading wire extends through the open distal end of the proximal capturing portion, and is moveable relative to the proximal capturing portion such that a distance between the distal open end of the proximal capturing portion and the proximal open end of the retrieval body can be changed.

52. The retrieval device of claim 51, where the proximal end of the proximal capturing portion is permeable.

53. The retrieval device of claim 51, where the proximal end of the proximal capturing portion is non-permeable.

54. The retrieval device of claim 51, further comprising a first plurality of flanges located on the proximal open end of the distal capturing portion and a second plurality of flanges located on the distal open end of the proximal capturing portion, where the first and second plurality of flanges can removably engage each other.

55. The retrieval device of claim 51, where the proximal capturing portion and retrieval body are rotatable relative to each other.

56. The retrieval device of claim 51, where the proximal end of the proximal capturing portion is connected about the leading wire such that the leading wire is moveable therethrough.

57. The retrieval device of claim 51, further comprising a sheath extending over the leading wire, where the proximal end of the proximal capturing portion is affixed to the sheath.

58. The retrieval device of claim 51, where the proximal capturing portion comprises a structure selected from a group consisting of a laser cut tube, an etched tube, an injection molded structure.

59. The retrieval device of claim 58, where the at least one leading wire is attached to the proximal capturing portion via a joint or junction

60. The retrieval device of claim 51, where the proximal capturing portion has a coverage density that increases from the open distal end to the proximal end.

61. The retrieval device of claim 51, where the proximal capturing portion is formed from a wire comprising super-elastic outer shell and an inner core of a radiopaque material.

62. The retrieval device of claim 61, where the inner core comprises a material selected from a group consisting of platinum, iridium, gold, and tantalum or combination thereof.

63. The retrieval device of claim 51, where the proximal capturing portion is jointless.

64. The retrieval device of claim 51, where at least a portion of a surface of the proximal capturing portion comprises a structure selected from the group consisting of a basket, a filter, a bag, a coil, a helical wire structure, a mesh, a single wound wire, a plurality of crossing wires, and a combination thereof.

65. A method of removing an obstruction from a blood vessel, the method comprising:

advancing a catheter distal to the obstruction;

deploying a first capturing portion distal of the obstruction, where the first capturing portion comprises a translating surface and a capturing surface, the translating surface having an open proximal end and the capturing surface having a permeable distal end, and at least one leading wire affixed to the capturing surface and extending through the capturing portion and through the catheter, where the translating surface and capturing surface are configured so that a translating surface axial strength is greater than that of a capturing surface axial strength;

proximally moving the leading wire to compress the capturing surface without compressing the translating surface sufficient to cause axial deformation of the translating surface such that the translating surface gradually advances over the obstruction; and

removing the obstruction and first capturing portion from the blood vessel.

66. The method of claim 65, where pulling on the leading wire causes the capturing surface to apply a spring force against the translating surface such that the open proximal end advances along the obstruction.

67. The method of claim 65, where applying a threshold force on the leading wire while the open proximal end engages the obstruction causes the capturing surface to invert within the capturing portion.

68. The method of claim 67, where applying the threshold force comprises continuing to apply the threshold force to withdraw the capturing surface into the catheter distal end.

69. The method of claim 67, where applying the threshold force comprises continuing to apply the threshold force to invert the capturing portion such that the capturing surface is proximal to the translating surface.

70. The method of claim 65, where pulling on the leading wire to apply the force to the capturing surface comprises applying the force to the permeable distal end.

71. The method of claim 65, where pulling on the leading wire to apply the force to the capturing surface comprises applying the force to the capture surface.

72. The method of claim 65, further comprising a second capturing portion having an open distal end and a proximal end attached axially moveable relative to the first capturing portion, such that moving the first capturing portion over the obstruction causes the open proximal end of the first capturing portion to move towards the open distal end of the second capturing portion to surround the obstruction.

73. The method of claim 72, where the proximal end of the second capturing portion is non-permeable and temporarily occludes or interrupts flow.

74. The method of claim 72, where the proximal end of the second capturing portion is permeable and permits flow during removal of the obstruction.

75. The method of claim 72, further comprising continuing to move the first capturing portion towards the second capturing portion such that the open proximal end and the open distal end can removably engage each other.

76. The method of claim 72, further comprising compressing the second capturing portion about the obstruction to further secure the obstruction.

77. A reentry device for withdrawing an object into a distal end of a sheath, the reentry device comprising:

a elongate member having a distal portion and a lumen extending therethrough; and

a plurality of first tines arranged circumferentially at the distal portion, the plurality of first tines each having a distal end forming a first discontinuous funnel where the distal end of each first tine is spaced from the distal end of an adjacent first tine, wherein the first discontinuous funnel is collapsible upon withdrawal into the distal end of the sheath..

78. The reentry device of claim 77, further comprising:

a second funnel spaced proximal to the first funnel, where the second funnel is collapsible upon withdrawal into the distal end of the sheath; and

wherein a distal perimeter of the first discontinuous funnel shape is distal to a distal perimeter of the second funnel.

79. The reentry device of claim 78, where the second funnel comprises a plurality of second tines arranged circumferentially at the distal portion, the plurality of second tines each having a distal end forming a second discontinuous funnel shape where the distal end of each second tine is spaced from the distal end of an adjacent second tine.

80. The reentry device of claim 79, further comprising at least one protrusion on an inner surface of at least the first or second tine.

81. The reentry device of claim 78, where the second funnel comprises a continuous funnel.

82. The reentry device of claim 77, further comprising a second funnel, where the second funnel comprises a flexible layer.

83. The reentry device of claim 82, where the flexible layer comprises a mesh braid.

84. The reentry device of claim 83, where the mesh braid comprises a Nitinol braid.

85. The reentry device of claim 77, where the second funnel comprises a tapered split tube.

86. A reentry device for withdrawing an object into a distal end of a sheath, the reentry device comprising:

an elongate member having a distal portion and a lumen extending therethrough, the elongate member sized to slidably fit within the sheath;

a first slotted funnel comprising a plurality of first tines each having free ends discontinuous with free ends of adjacent first tines, where the first slotted funnel is collapsible upon withdrawal into the distal end of the sheath; and

a second funnel located proximal to the free ends of the first tines.

87. The reentry device of claim 86, where the second funnel comprises a second slotted funnel comprising a plurality of second tines each having free ends discontinuous with free ends of adjacent second tines, where the first slotted funnel is collapsible upon withdrawal into the distal end of the sheath.

88. The reentry device of claim 87, where the free ends of the second tines are located proximally to the free ends of the first tines relative to the elongate member and where the first and second tines are rotationally offset.

89. The reentry device of claim 86, where the second funnel comprises a second continous funnel, where the second continuous funnel is collapsible upon withdrawal into the distal end of the sheath.

90. The reentry device of claim 86, where the second funnel comprises a tapered split tube.

91. The reentry device of claim 86, where the second funnel comprises a flexible layer.

92. The reentry device of claim 91 where the flexible layer comprises a mesh braid.

93. The reentry device of claim 92, where the mesh braid comprises a Nitinol braid.

94. A retrieval system for withdrawing an object into a distal end of a sheath, the retrieval system comprising:

an elongate member having a distal portion and a lumen extending therethrough; a flexible layer having a portion affixed to the elongate member, where a first end of the flexible layer is configured to form a funnel at the distal portion of the elongate member;

a retrieval device advanceable through the elongate member for engaging the object, where proximal movement of the retrieval device into the flexible causes the flexible layer to engage the retrieval device to assist the retrieval device securing the object to the sheath.

95. The retrieval system of claim 94, where the elongate member comprises a first shaft and a second shaft, where the first and shaft are in telescoping engagement, where a first end of the flexible layer is affixed to the first shaft and a second end of the flexible member is affixed to the second shaft, where moving the first and second shaft to decrease a distance between ends of the flexible member causes the flexible material to form a funnel when the flexible layer further inverts about the second elongate shaft.

96. The retrieval system of claim 94, where the flexible layer is affixed to the elongate member at a single location.

97. The retrieval system of claim 96, where the flexible member is affixed to the elongate member at a distal location, and where the flexible member has a pre-determined funnel shape such that when unrestrained the flexible member forms the funnel shape about the distal end of the elongate member.

98. The retrieval system of claim 96, where the flexible member is affixed to the elongate member at a proximal location, and where the flexible member extends beyond the distal end of the elongate member.

99. The retrieval system of claim 98, where proximal movement of the retrieval device engages he flexible member causing the flexible member to form a funnel shape.

100. The retrieval system of claim 98, where the flexible member has a pre-determined funnel shape such that the flexible member assumes a funnel shape when un-restrained.

101. The retrieval system of claim 94, where the flexible layer comprises a mesh braid.

102. The retrieval system of claim 101, where the mesh braid comprises a Nitinol braid.

103. The retrieval system of claim 94, where the flexible layer comprises a flexible layer of material.

104. The retrieval system of claim 94, further comprising:

a retrieval sheath extending through the second elongate member having a proximal capture portion affixed to a distal end;

at least one leading wire extending through the retrieval sheath, where a distal section of the leading wire comprises a distal stiffness and where a proximal section of the leading wire comprises a proximal stiffness, where the proximal stiffness is greater than the distal stiffness; and

a distal capturing portion at the distal end of the leading wire, the distal capturing portion being axially moveable relative to the proximal capture portion.

105. The retrieval system of claim 104, where the distal section of the leading wire extends proximally for a pre-determined distance from the distal capturing portion to allow navigation of a distal section of the leading wire within the cerebral vasculature.

106. The retrieval system of claim 105, where the pre-determined distance is at least 20 cm.

107. A system for removing a object within a body, the system device comprising:

a sheath having a sheath distal end and a sheath lumen extending therethrough; a reentry device slidably located in the sheath lumen and being advanceable out of the sheath distal end, the reentry device comprising an elongate member having a first slotted funnel and a second slotted funnel, the elongate member having a distal portion and a lumen extending therethrough and being sized to slidably fit within the sheath,

the first slotted funnel and the second slotted funnel each respectively comprising a plurality of first and second tines, each of the tines having a free end discontinuous with the free ends of an adjacent tines, where a distal end of the second slotted funnel is proximal to a distal end of the first slotted funnel and where the first and second tines are rotationally offset such that upon withdrawal into the sheath, the second tines cover a portion off a space between adjacent first tines.

108. The system of claim 107, further comprising a capturing section slidably advanceable through the elongate member.

109. A retrieval system for use with a catheter, the system comprising:

a retrieval sheath;

a proximal capture portion affixed to a distal end of the retrieval sheath;

at least one leading wire extending through the retrieval sheath, where a distal section of the leading wire comprises a distal stiffness and where a proximal section of the leading wire comprises a proximal stiffness, where the proximal stiffness is greater than the distal stiffness; and

a distal capturing portion at the distal end of the leading wire, the distal capturing portion being axially moveable relative to the proximal capture portion.

110. The retrieval system of claim 109, an insertion tool slidably located over the retrieval sheath, the insertion tool comprising a gripping region affixed to a rigid section, where compression of the gripping portion creates a frictional fit between the insertion tool such that when the insertion tool is coupled to the retrieval sheath, compression of the gripping portion and axial movement of the insertion tool advances the retrieval sheath within the catheter.

111. The retrieval system of claim 109, where distal section of the leading wire is joined to the proximal section of the leading wire at a bond region, where the bond region is located a pre-determined distance from distal capture portion to allow navigation of a distal section of the system within the cerebral vasculature.

112. The retrieval system of claim 111, where the pre-determined distance is at least 20 cm.

113. The retrieval system of claim 109, further comprising a funnel slidably located on the sheath, where movement of the proximal capture portion and distal capture portion within the funnel causes the proximal and distal capture portions to compress.

114. The retrieval system of claim 109, where the insertion tool comprises a loading tube such that the proximal capture portion and distal capture portion can compress within the loading tube.

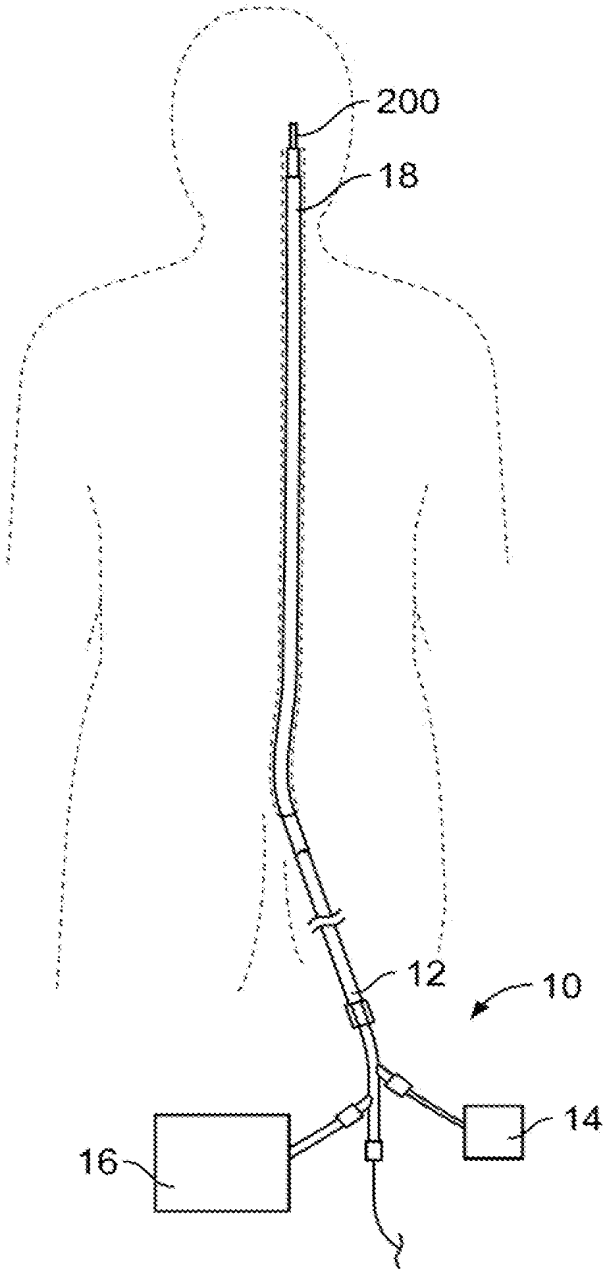


FIG. 1A

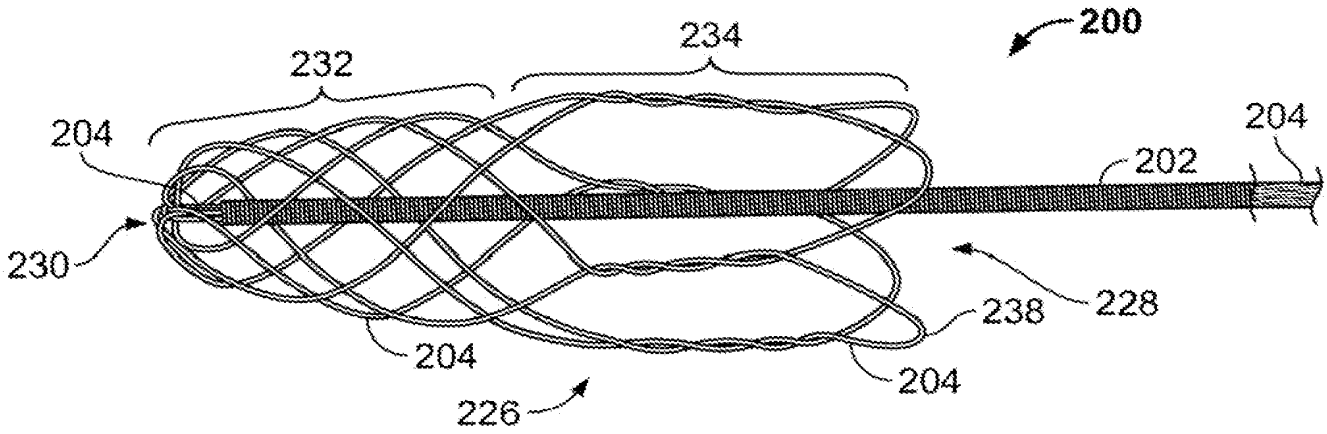

200
234
232
204
204
202
230
238
228
204
204
226

FIG. 1B

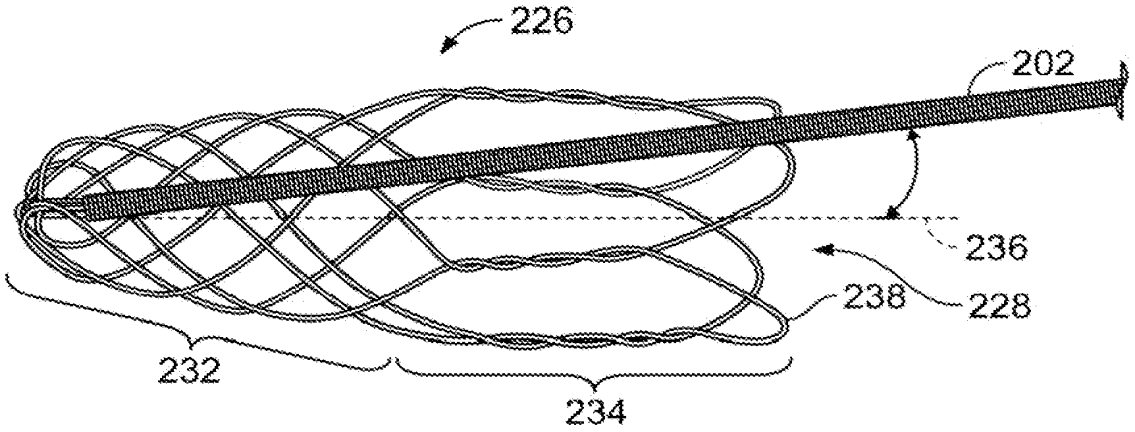

226
202
236
238
228
232
234

FIG. 1C

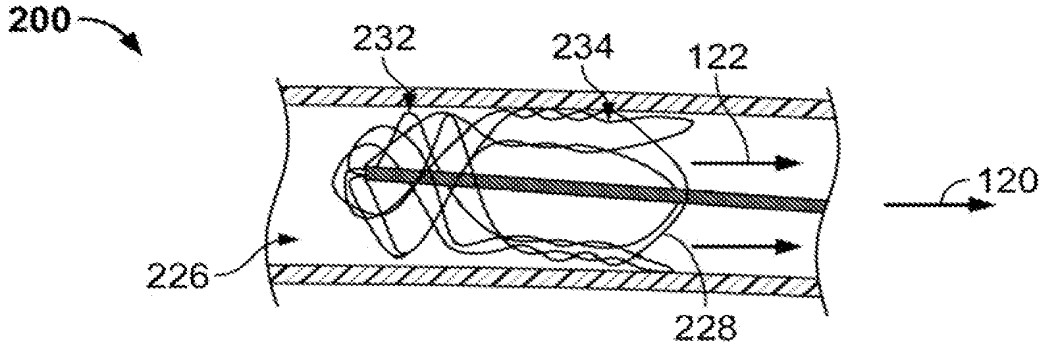


FIG. 2A

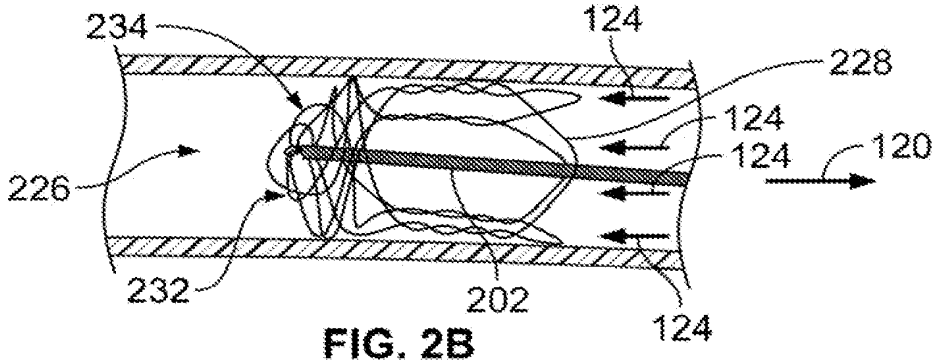


FIG. 2B

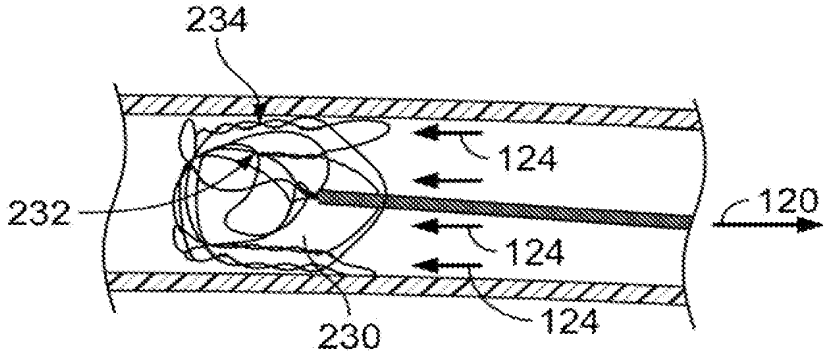


FIG. 2C

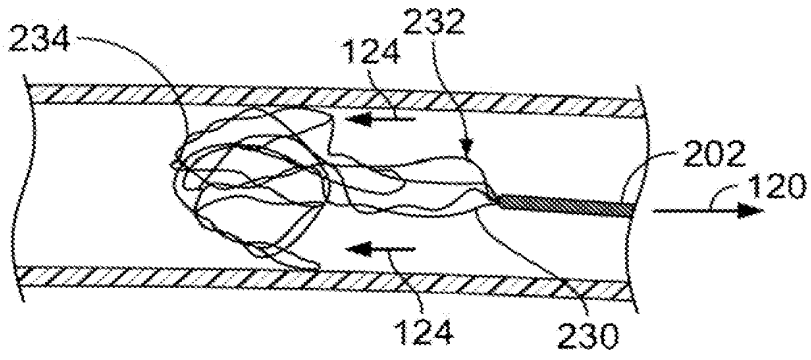


FIG. 2D

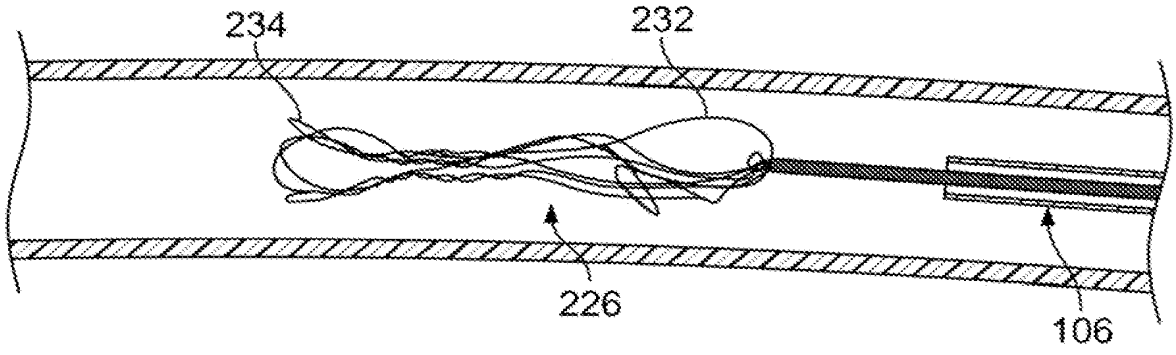


FIG. 2E

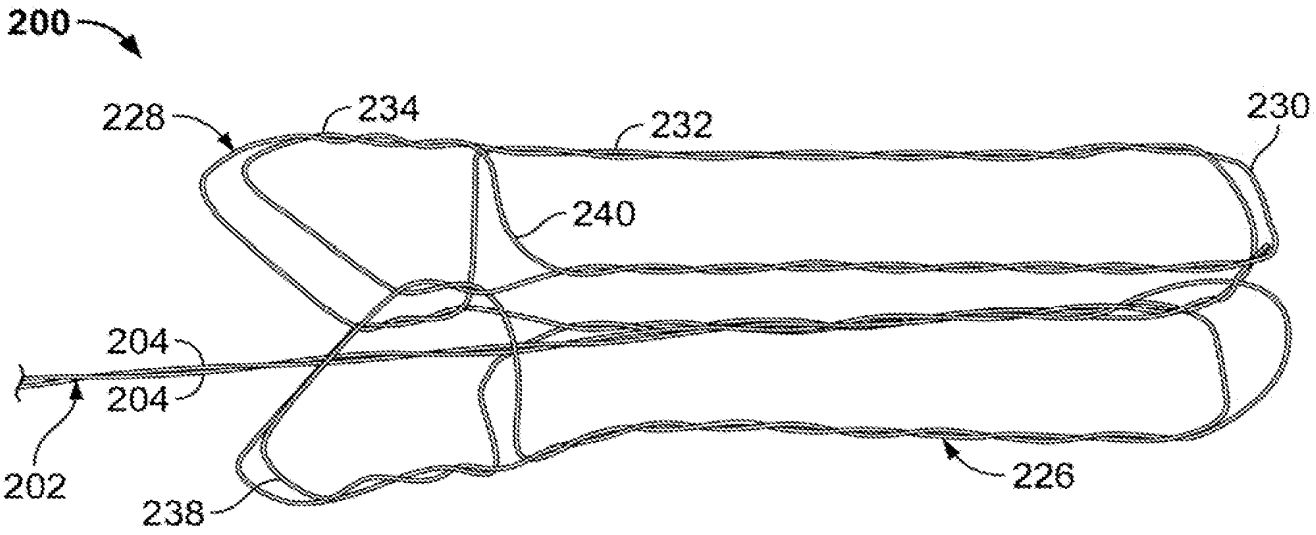

200
228
234
232
230
240
204
204
202
238
226

FIG. 3A

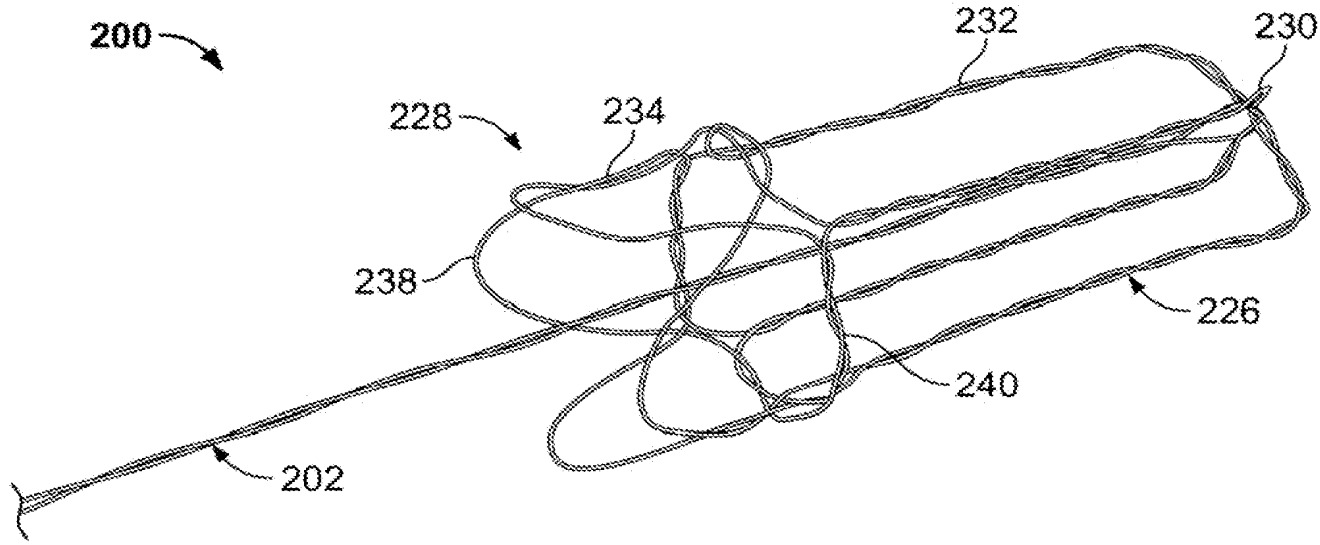

200
232
230
228
234
238
226
240
202

FIG. 3B

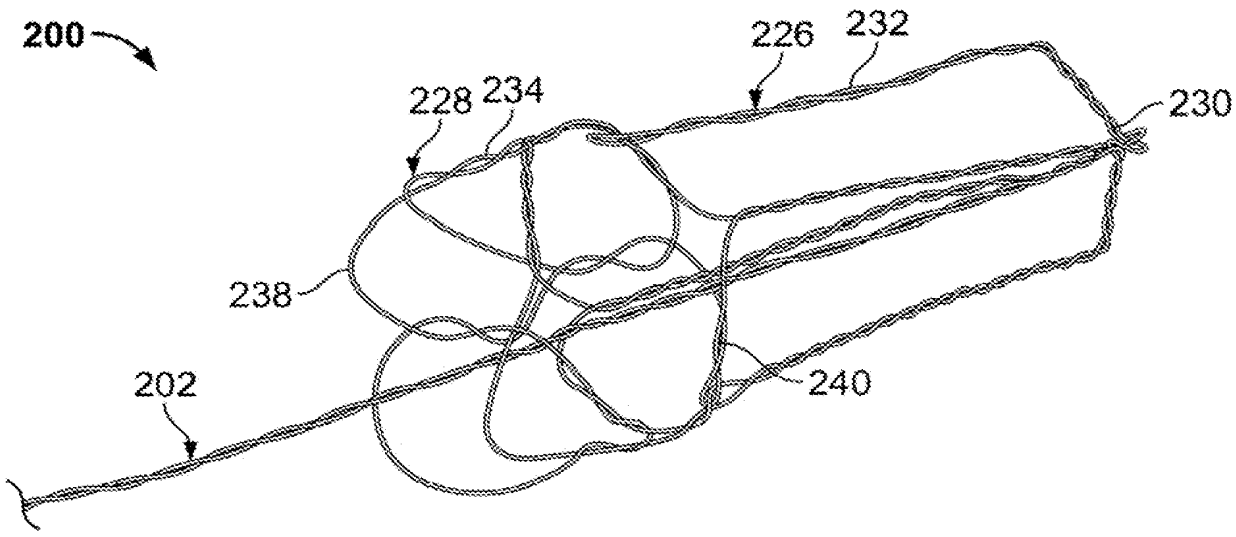


FIG. 3C

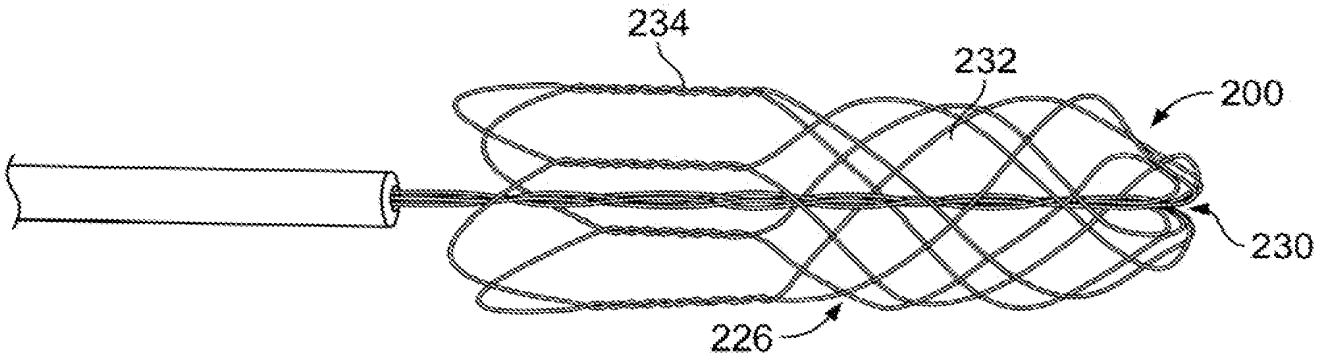


FIG. 3D

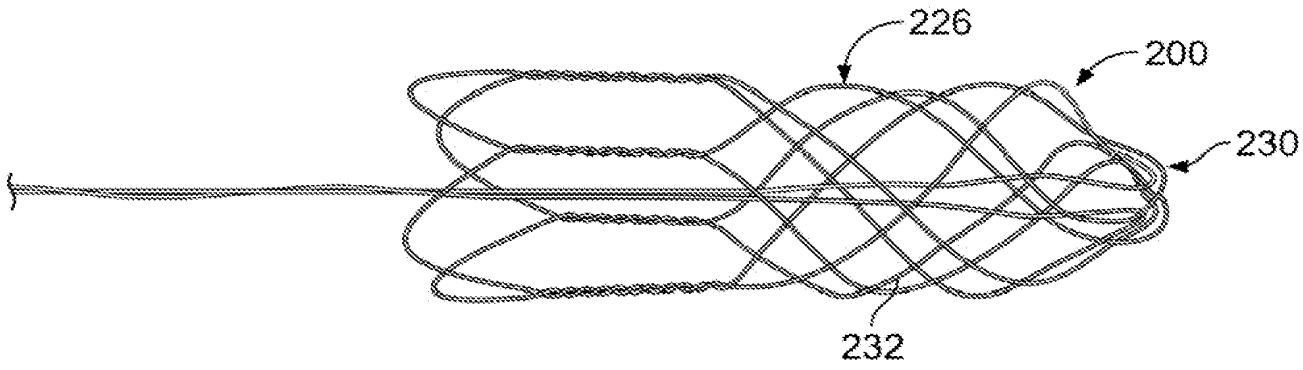


FIG. 3E

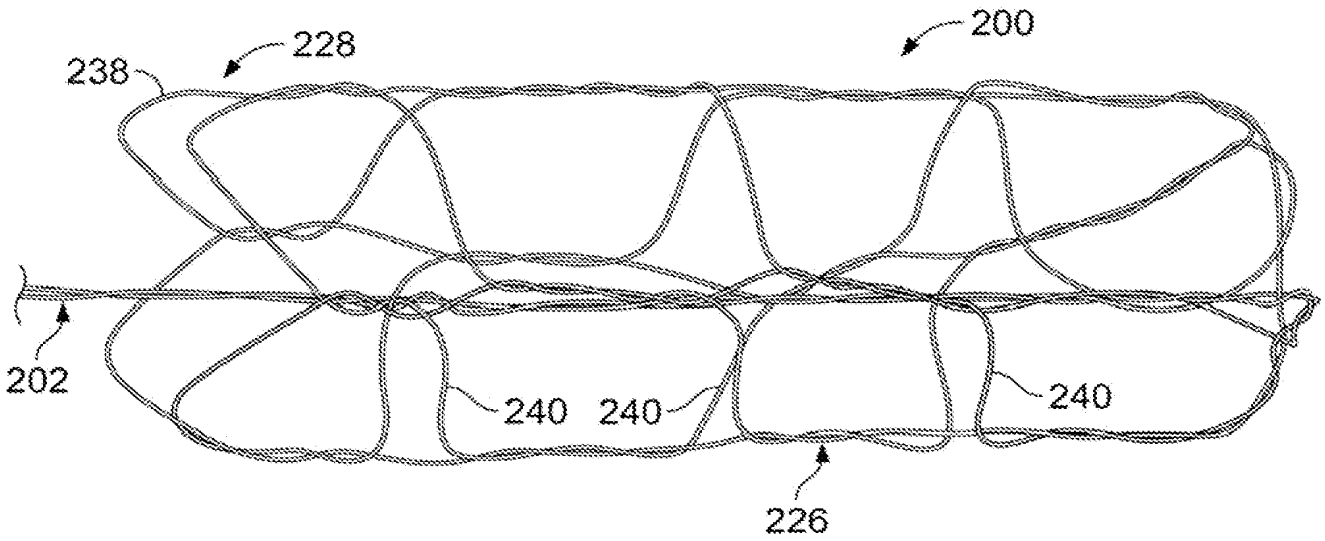


FIG. 3F

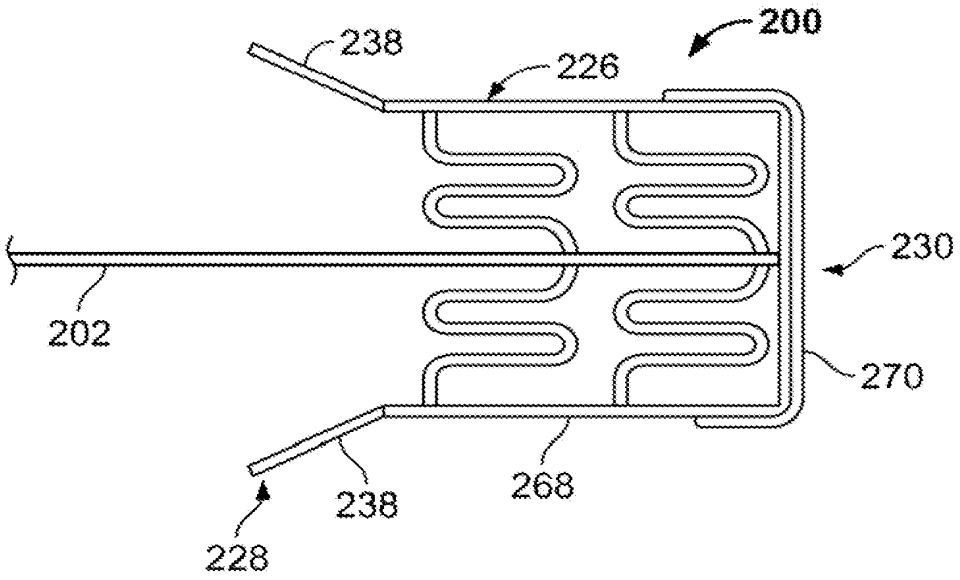


FIG. 3G

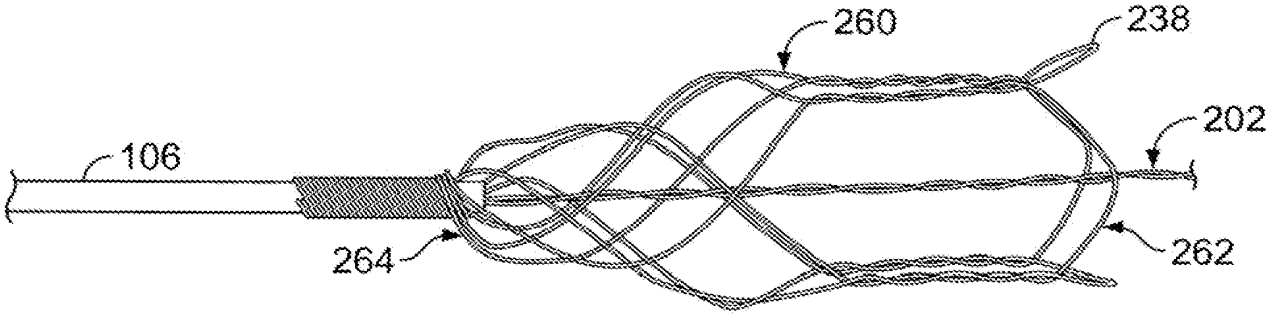


FIG. 3H

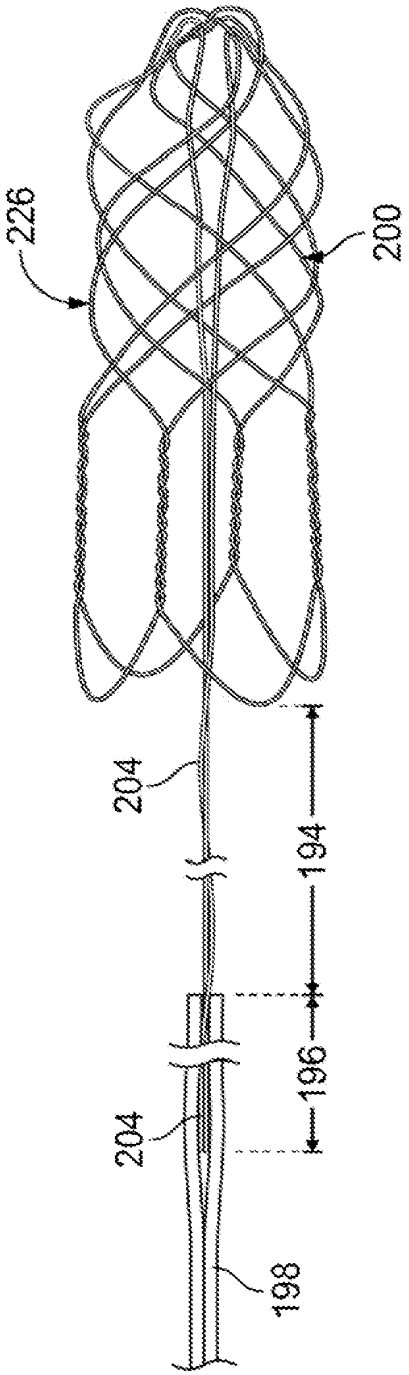


FIG. 4A

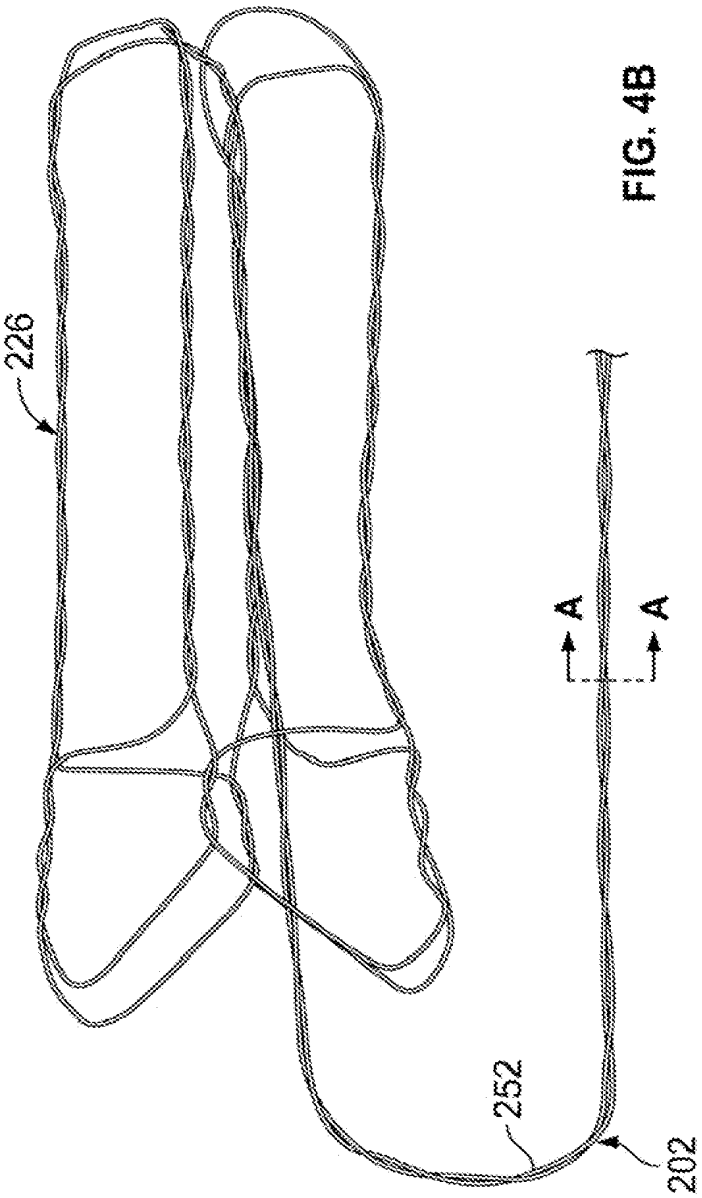


FIG. 4B

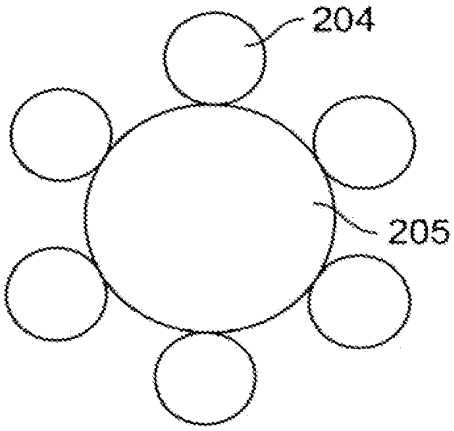


FIG. 4C

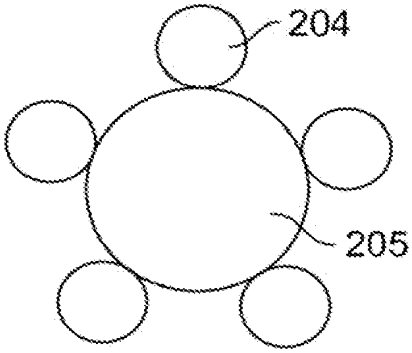


FIG. 4D

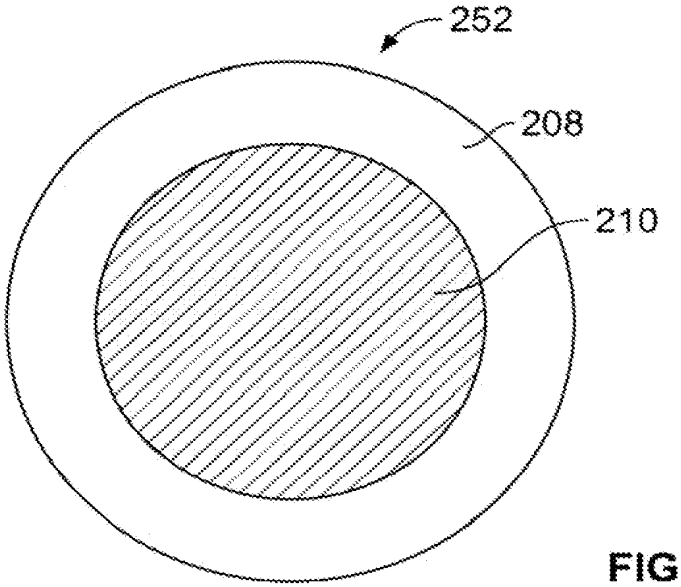


FIG. 4E

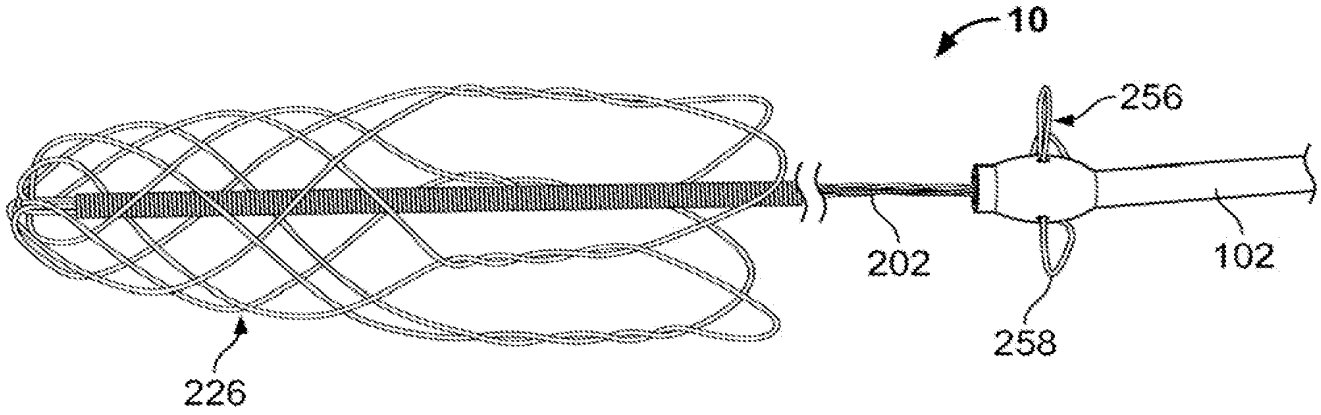


FIG. 5A

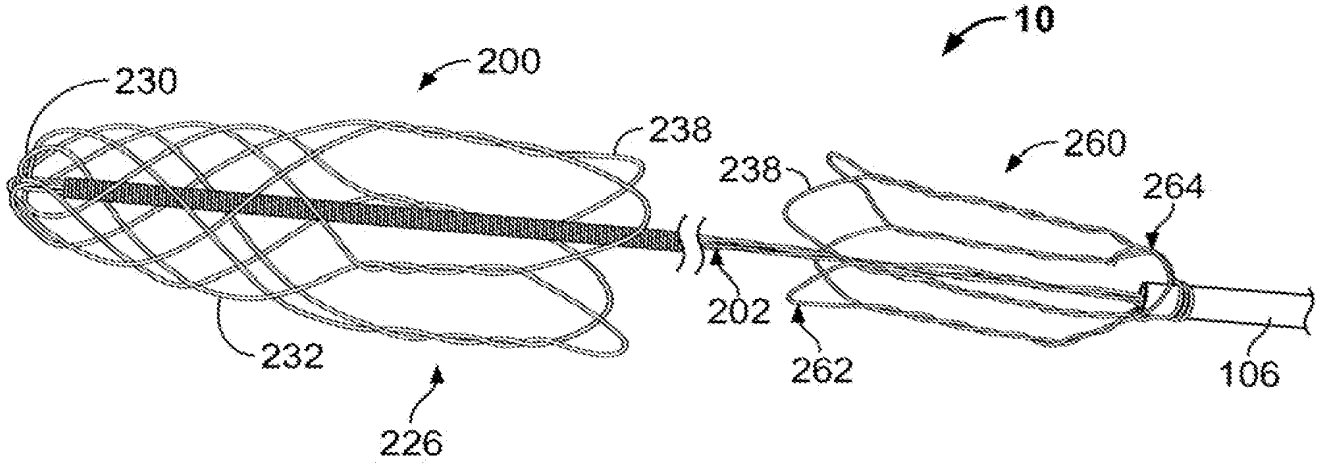


FIG. 5B

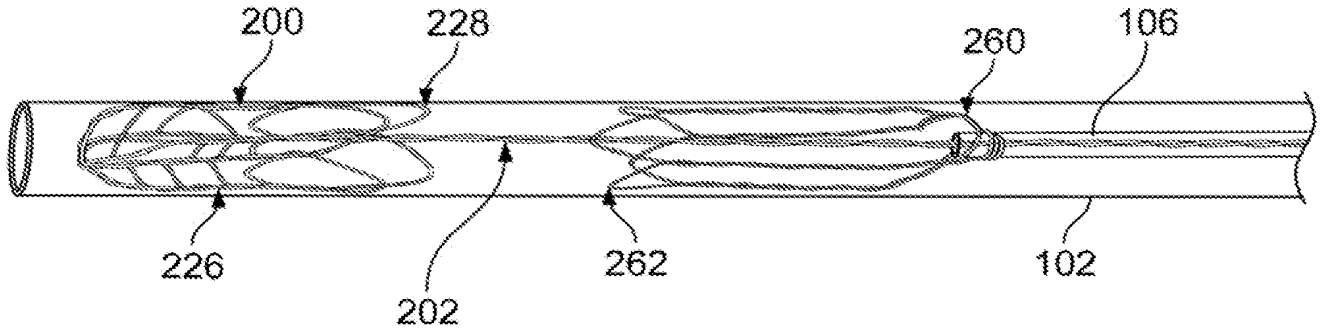


FIG. 5C

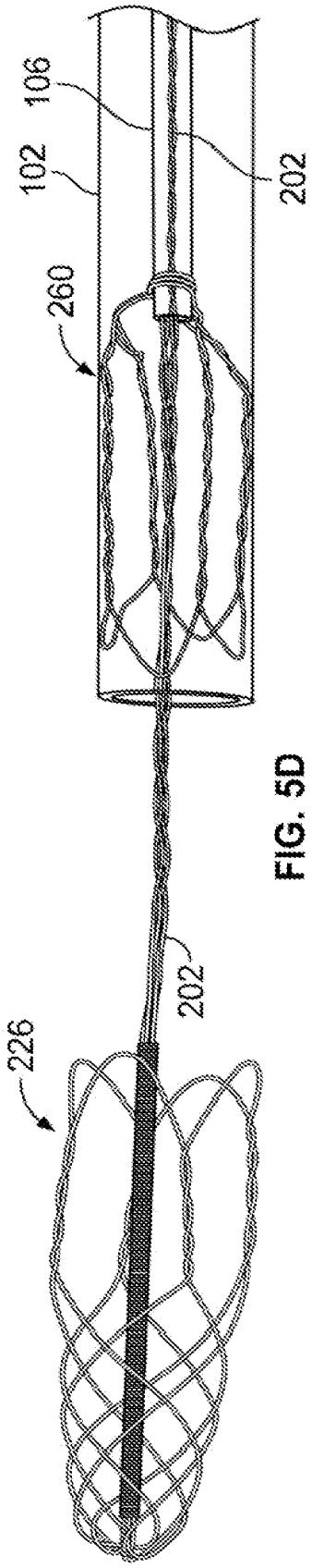


FIG. 5D

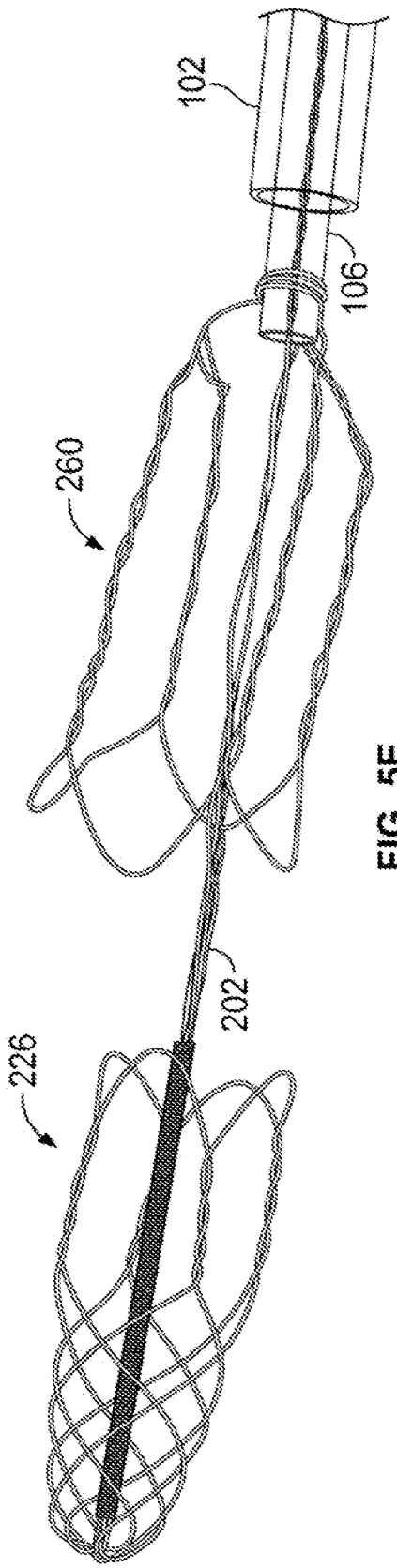


FIG. 5E

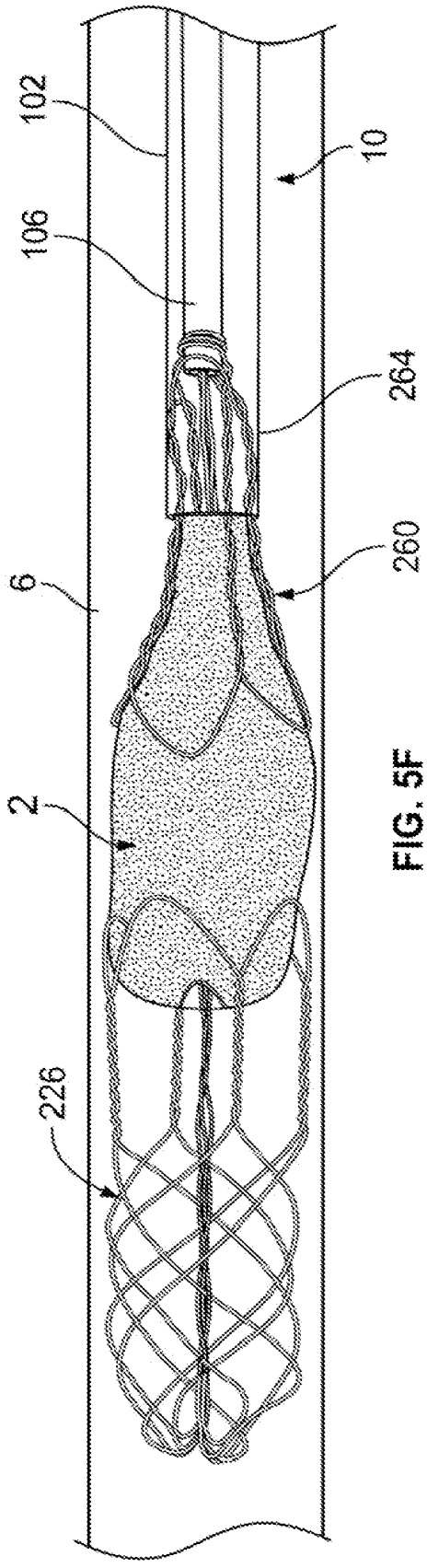


FIG. 5F

SUBSTITUTE SHEET (RULE 26)

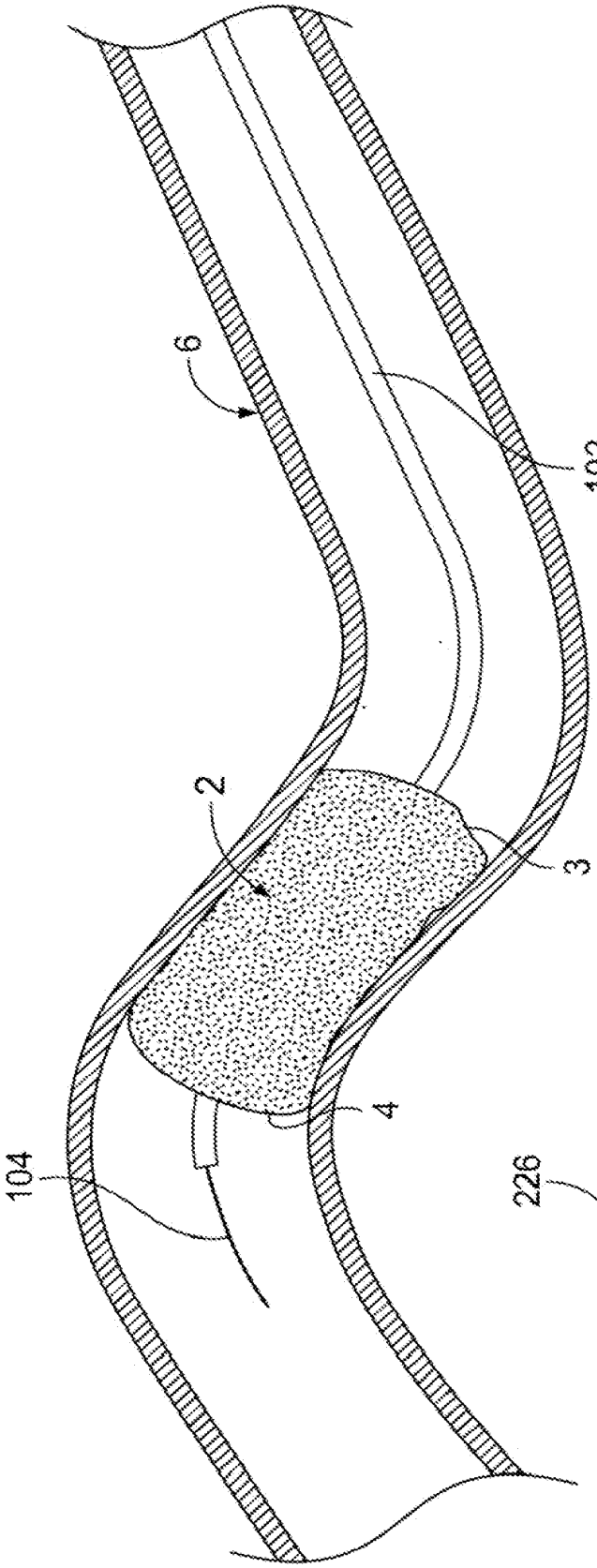


FIG. 6A

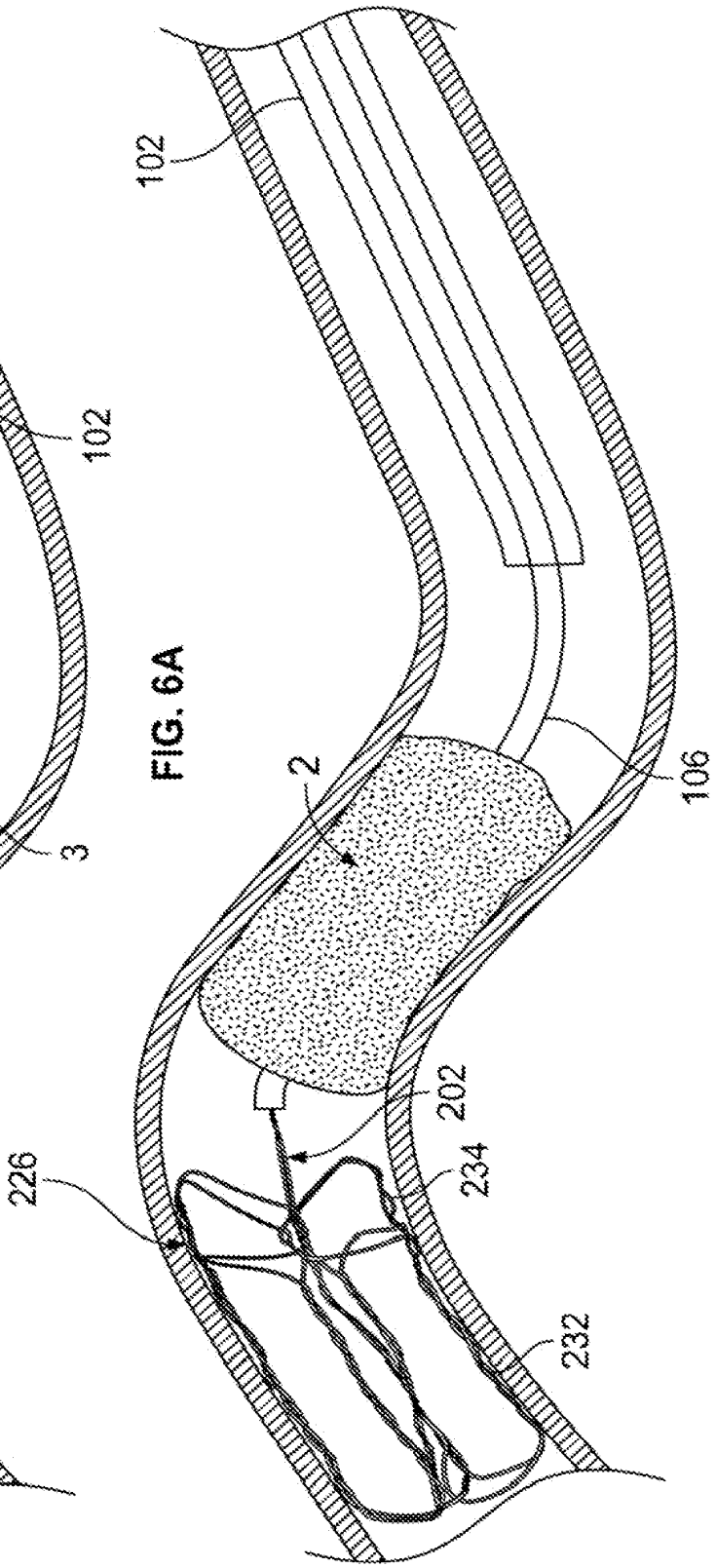


FIG. 6B

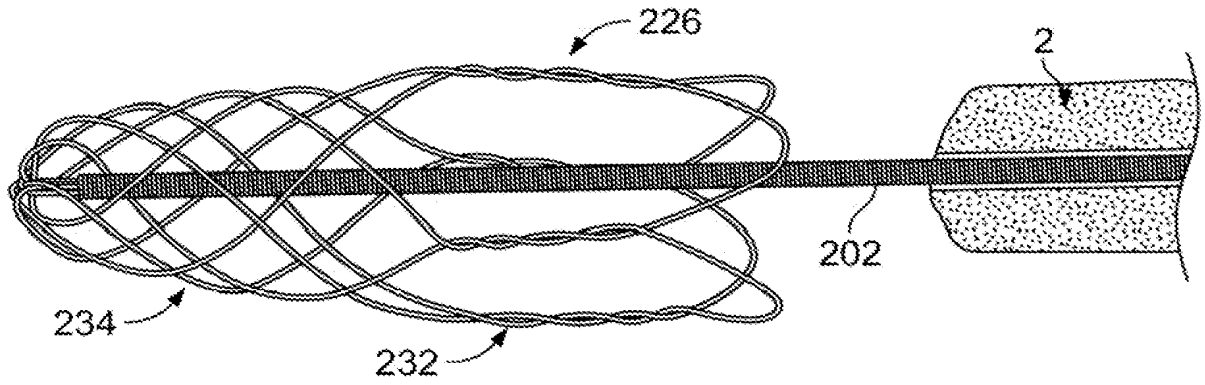


FIG. 7A

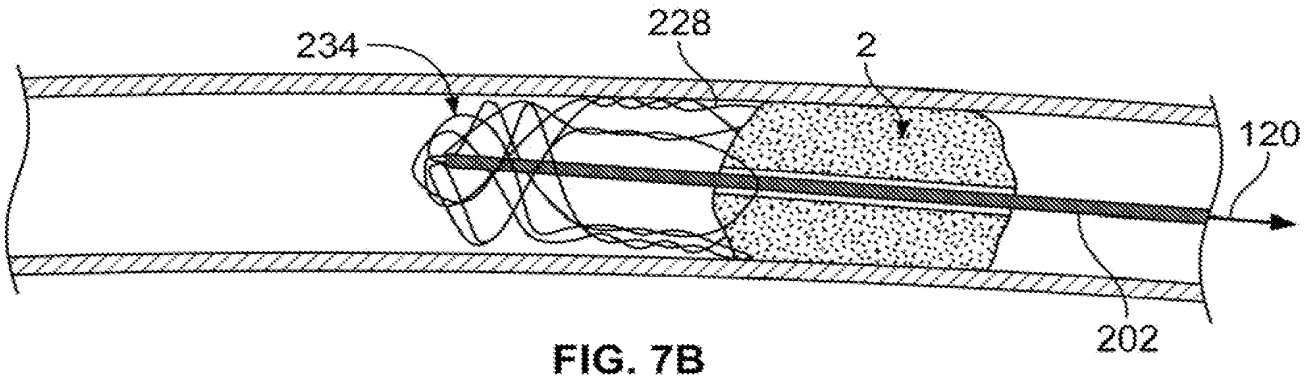


FIG. 7B

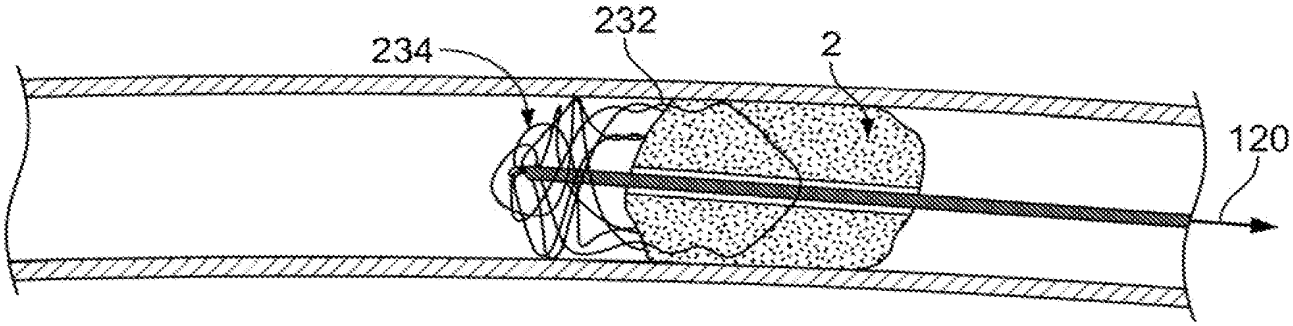


FIG. 7C

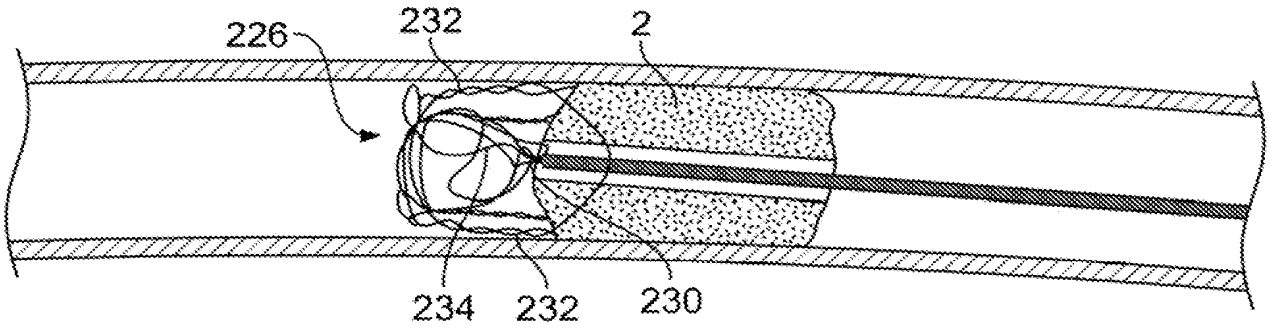


FIG. 7D

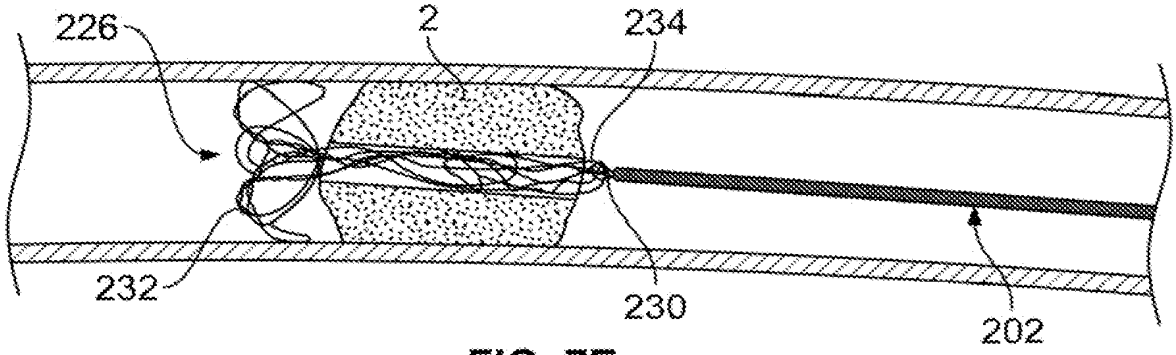


FIG. 7E

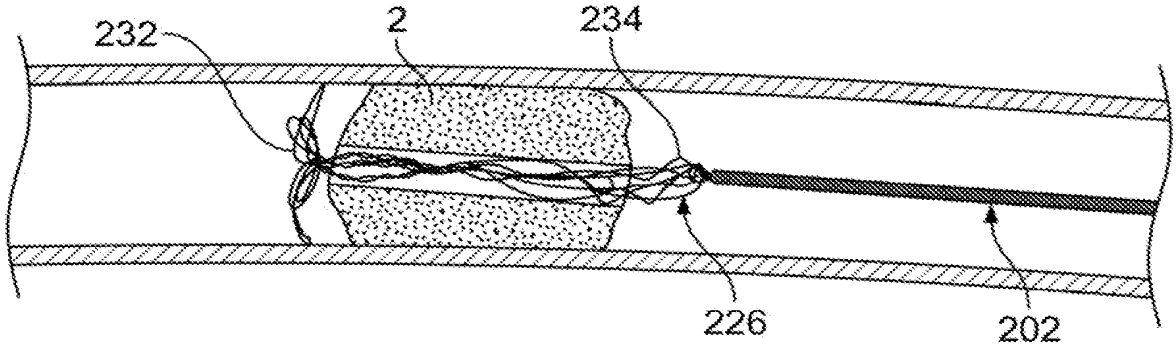


FIG. 7F

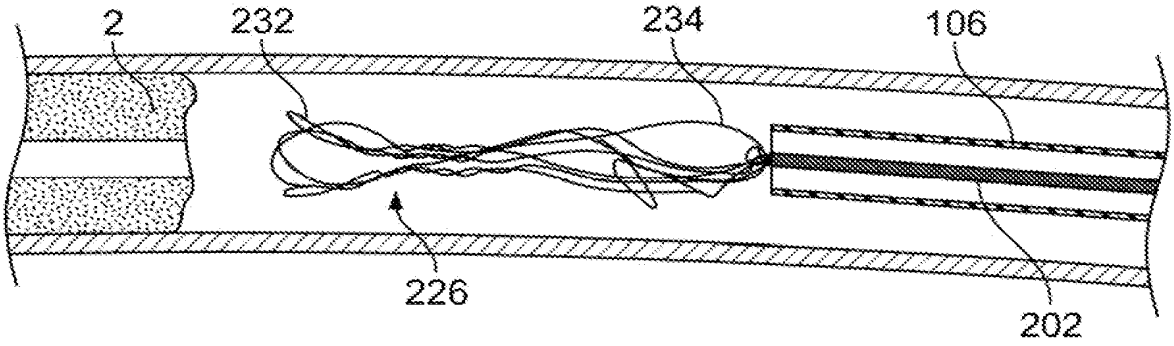


FIG. 7G

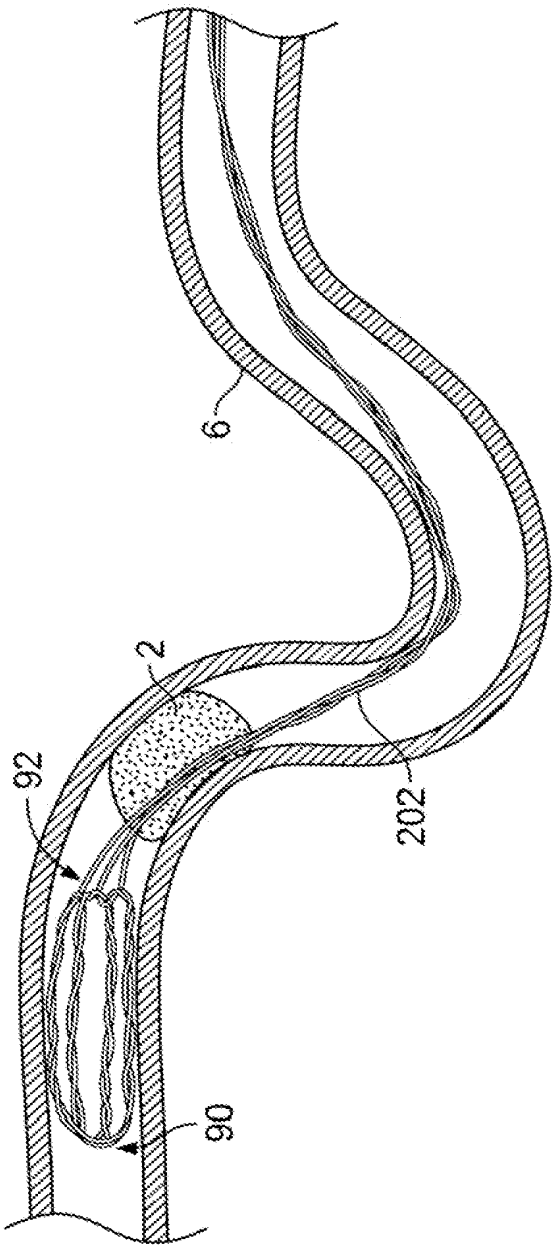


FIG. 8A

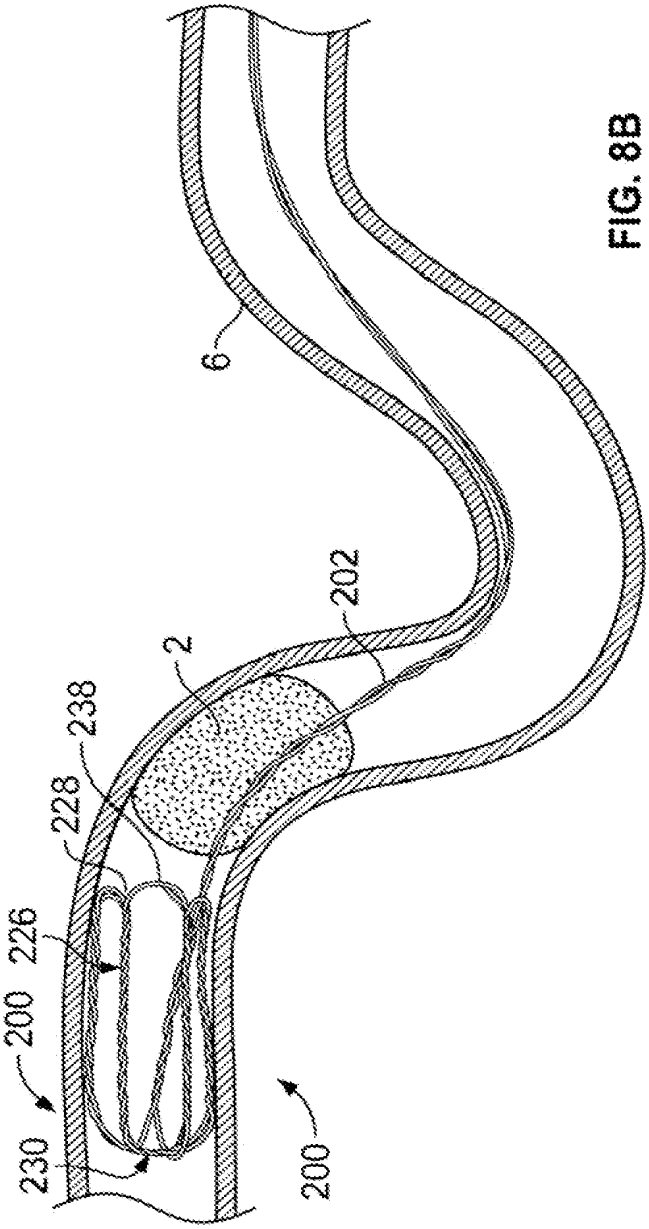


FIG. 8B

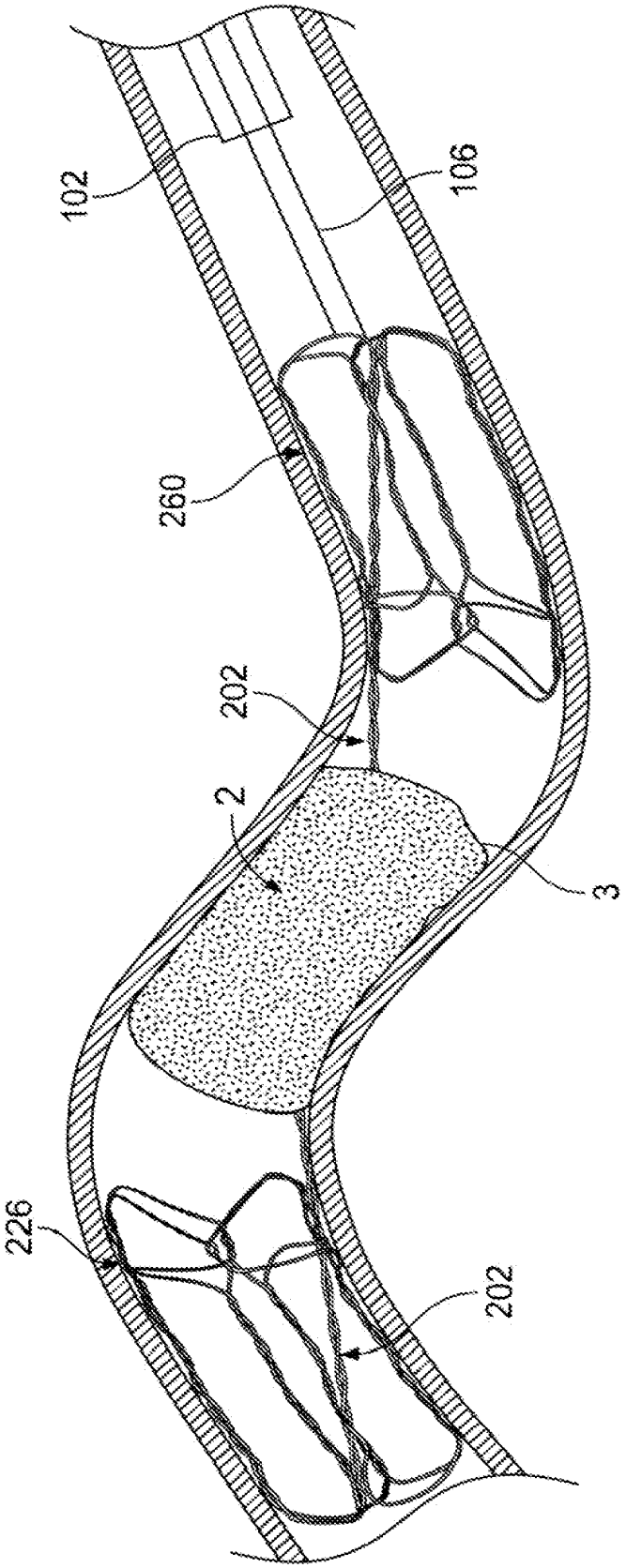


FIG. 8C

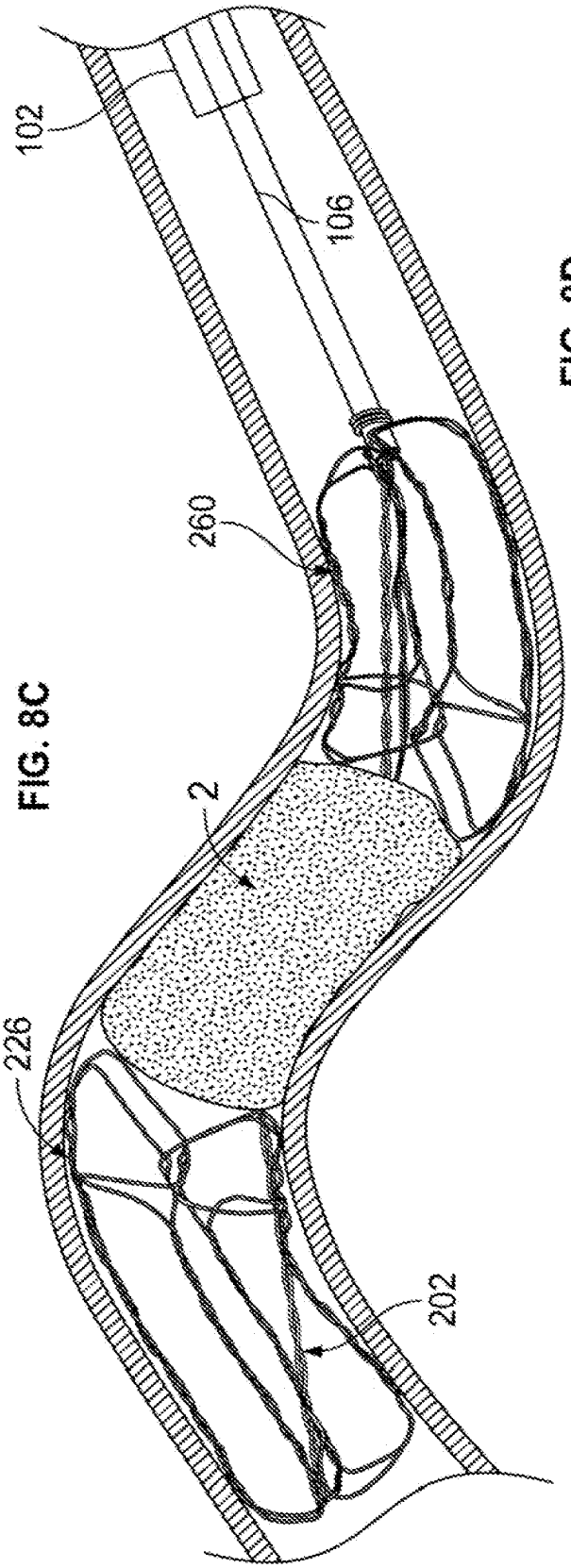


FIG. 8D

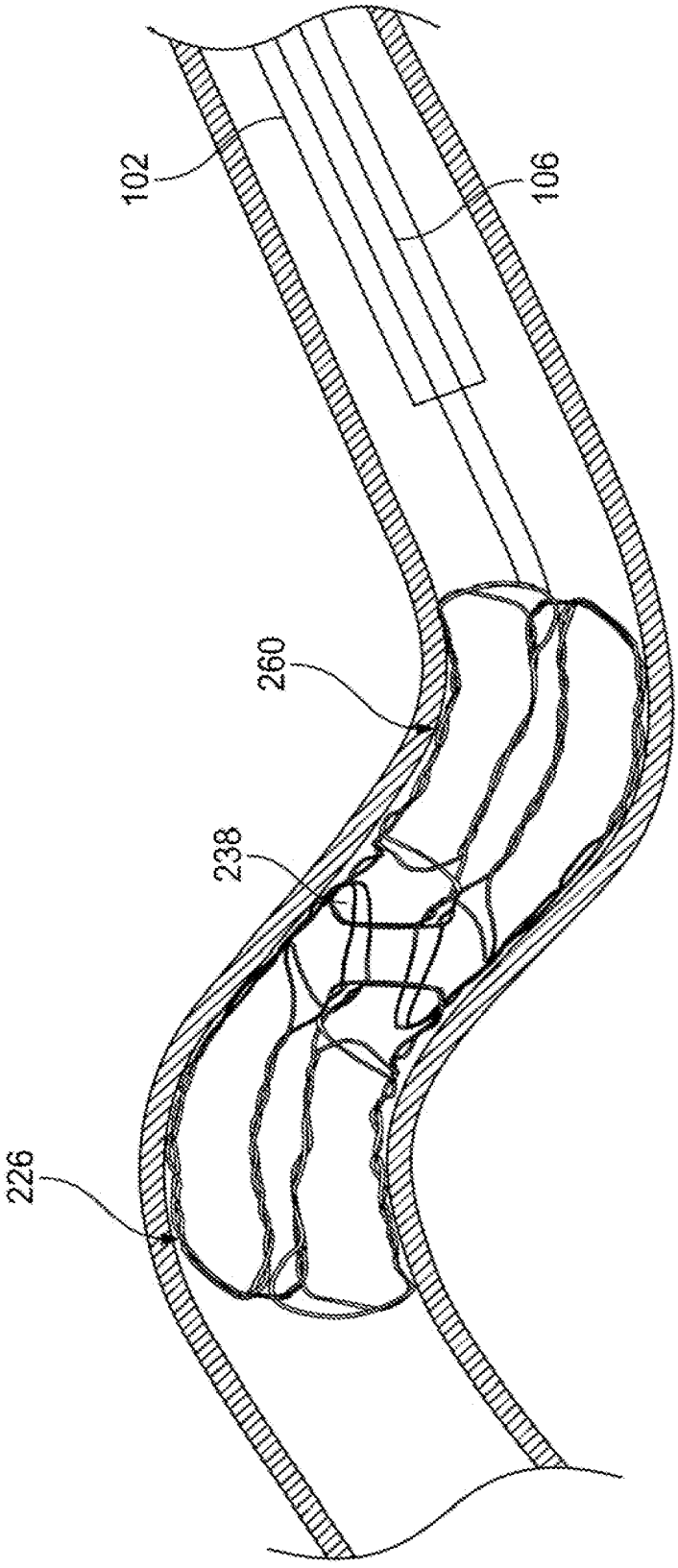


FIG. 8E

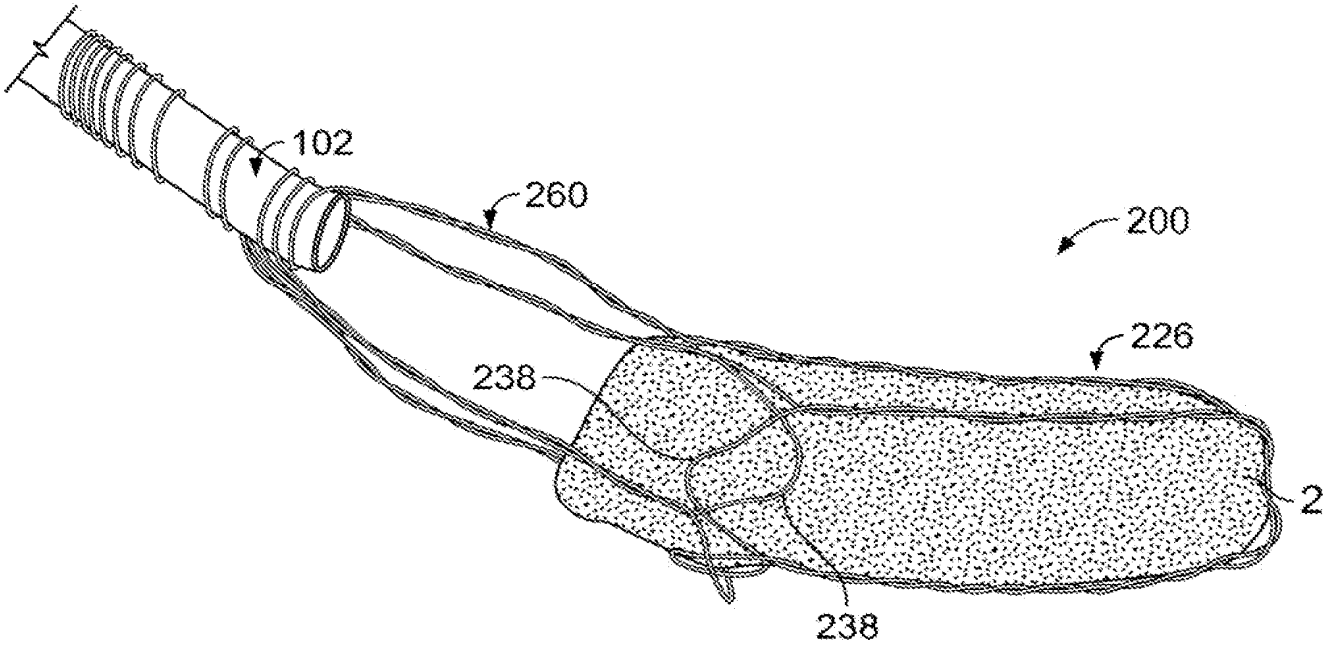


FIG. 8F

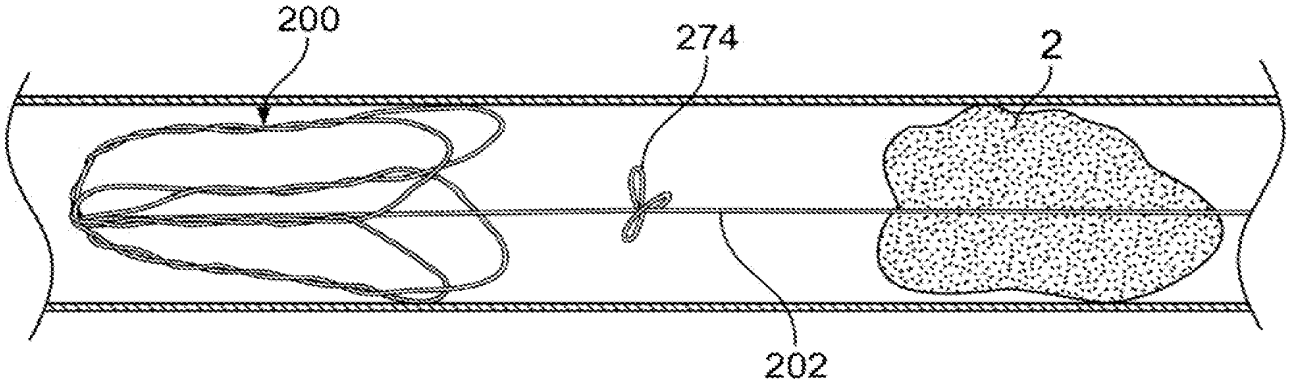


FIG. 9

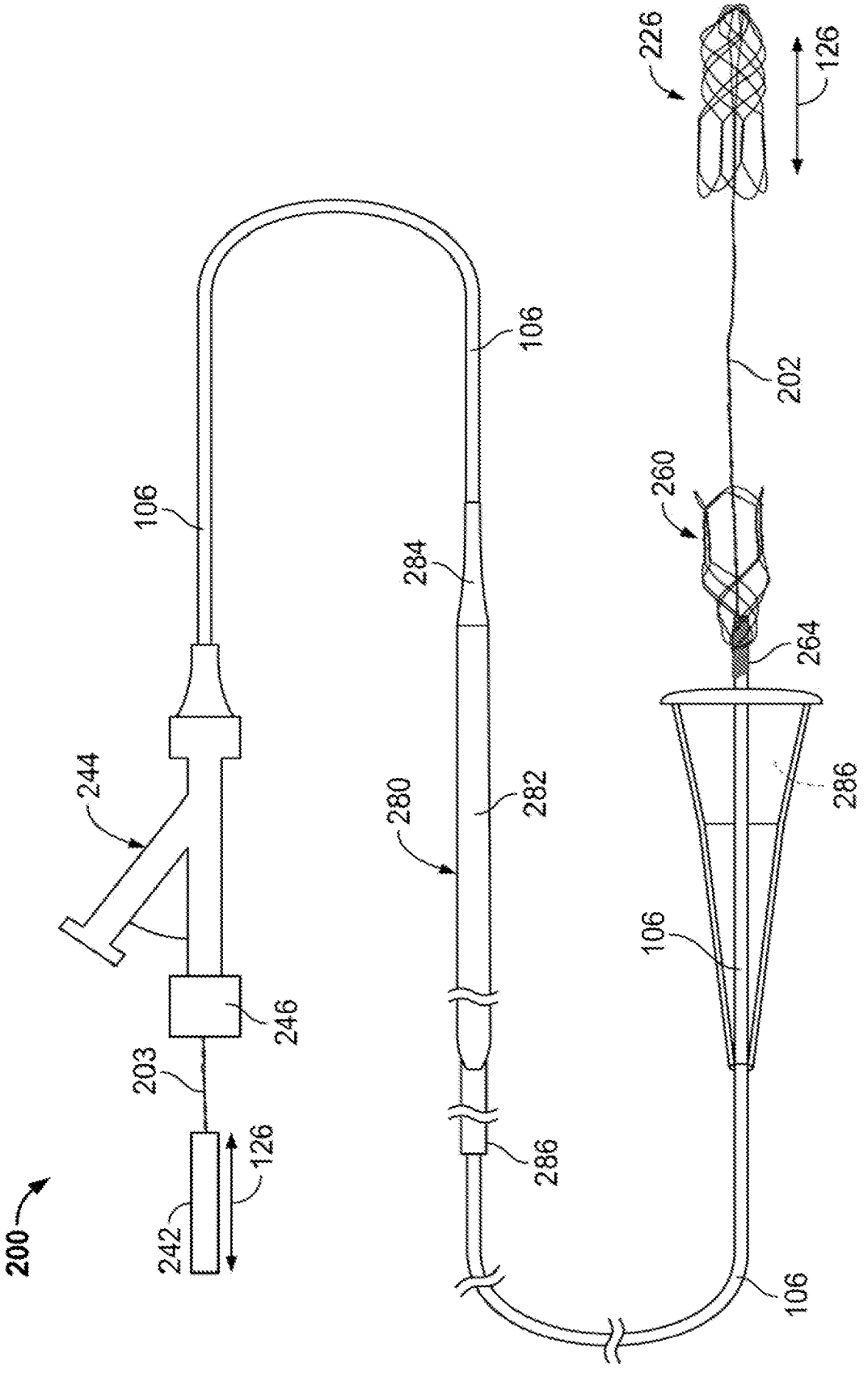

200
242
126
203
246
244
106
106
284
280
282
286
286
106
106
260
264
226
126
202

FIG. 10

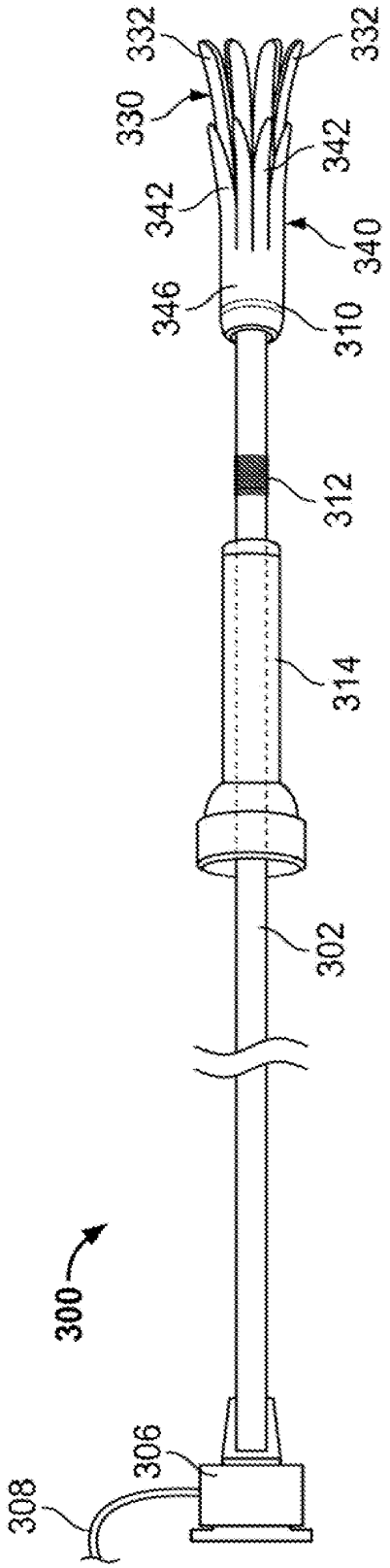


FIG. 11A

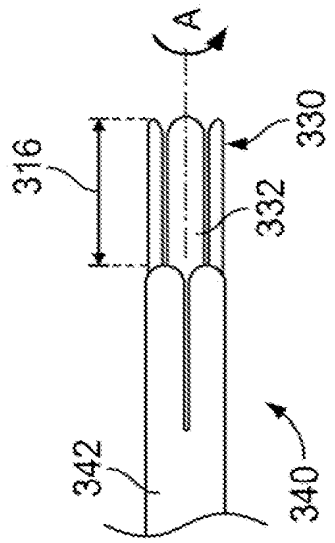


FIG. 11C

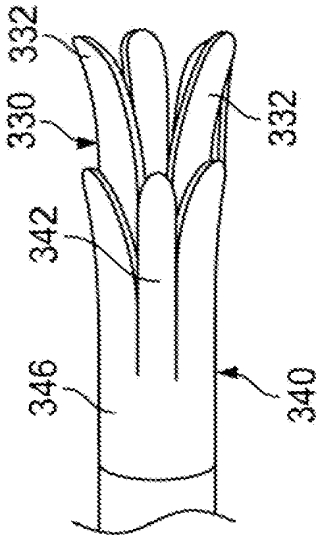


FIG. 11B

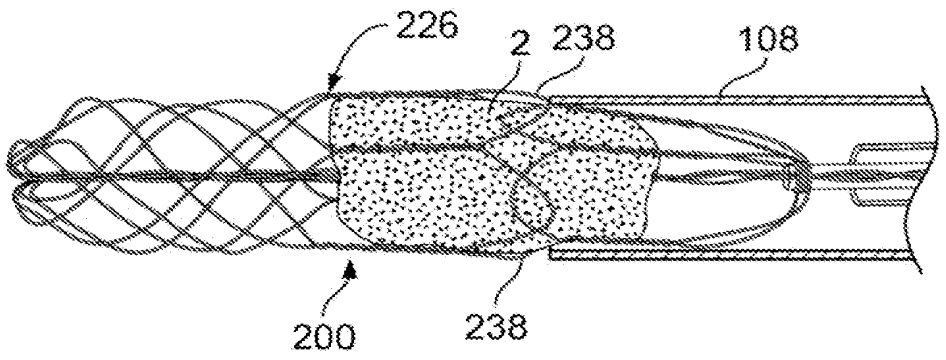


FIG. 12A

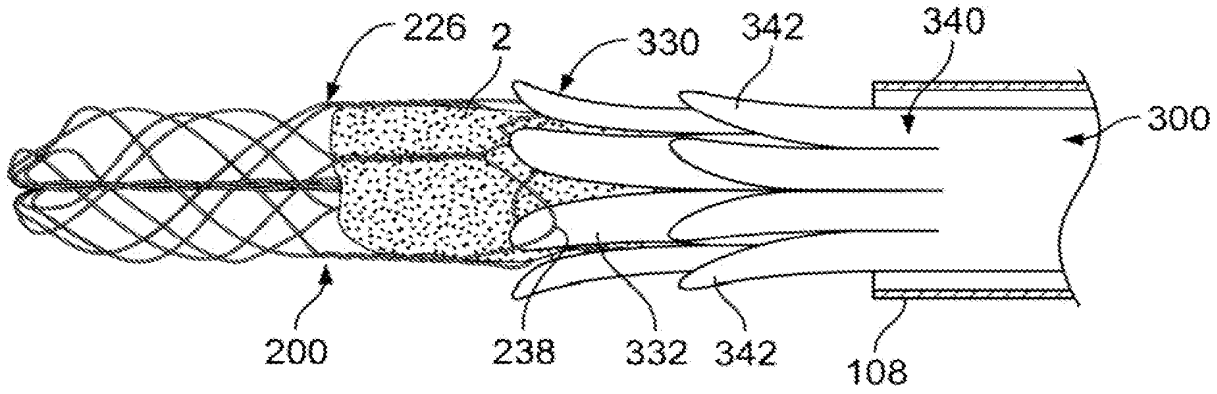


FIG. 12B

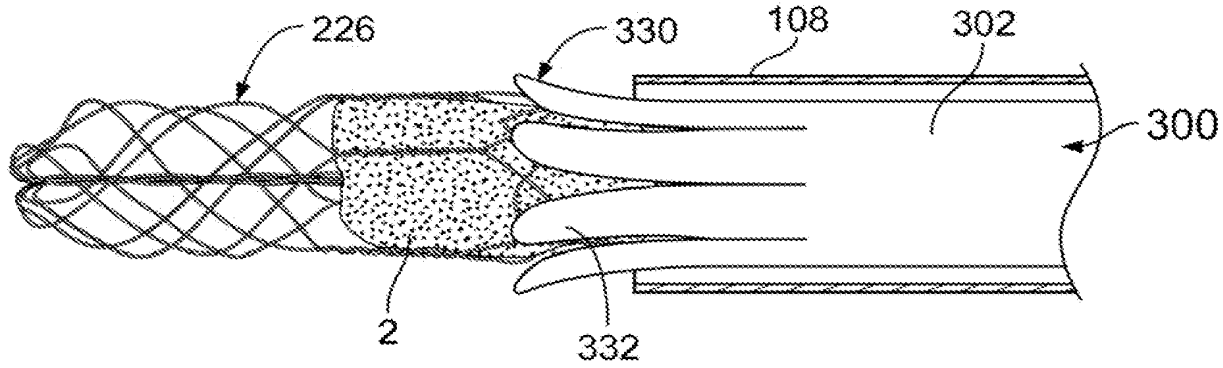


FIG. 12C

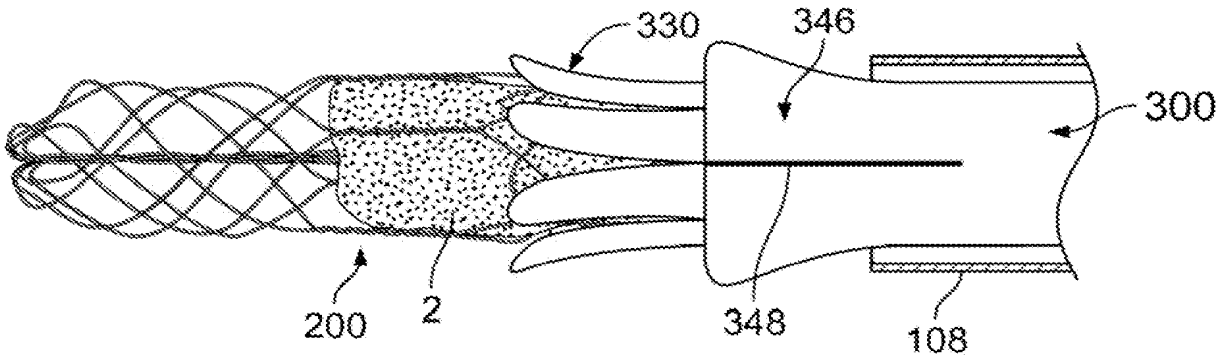


FIG. 12D

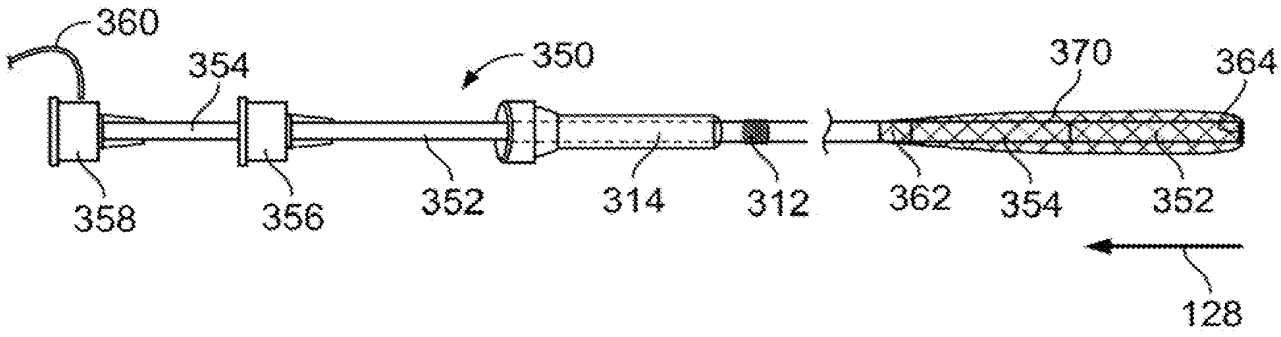


FIG. 13A

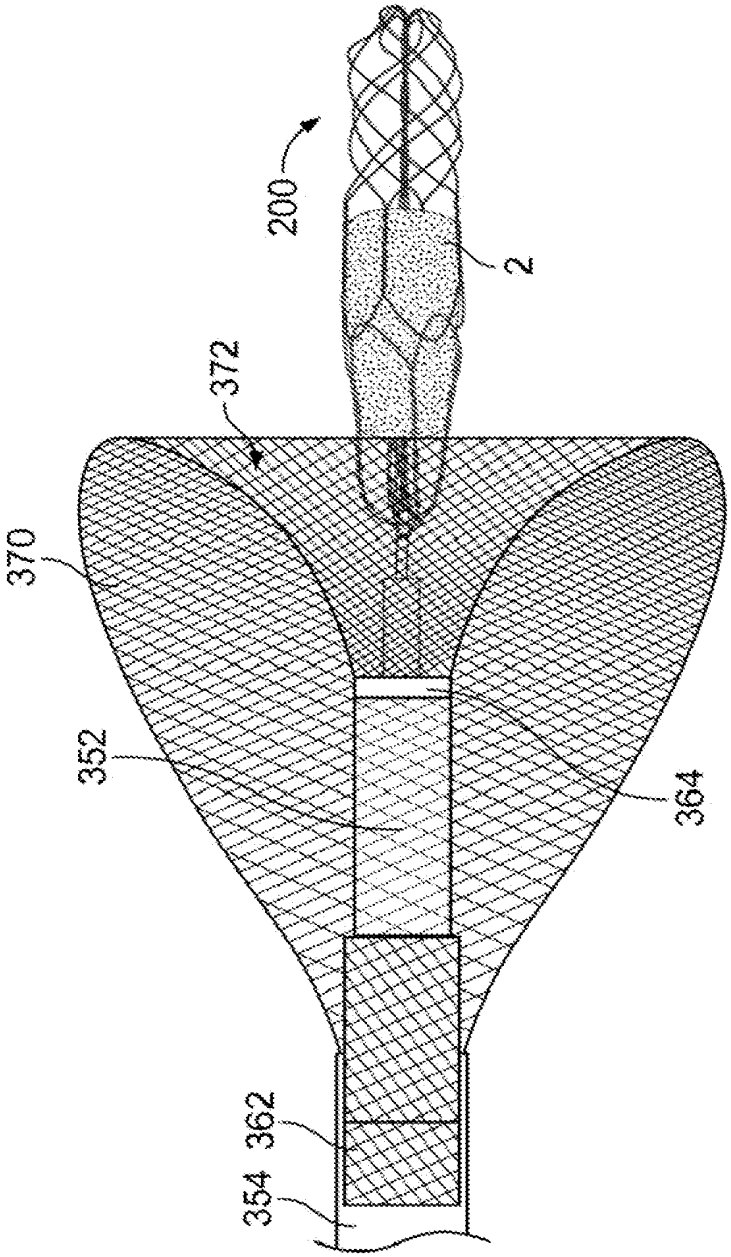


FIG. 13B

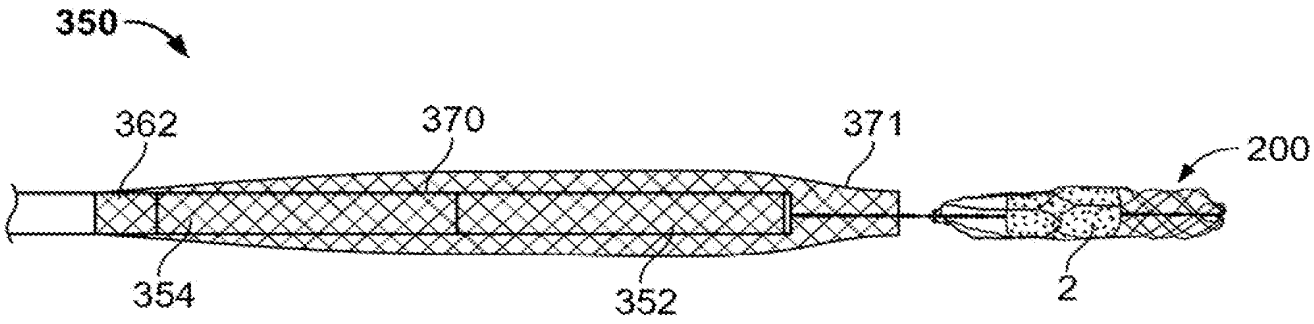


FIG. 13C

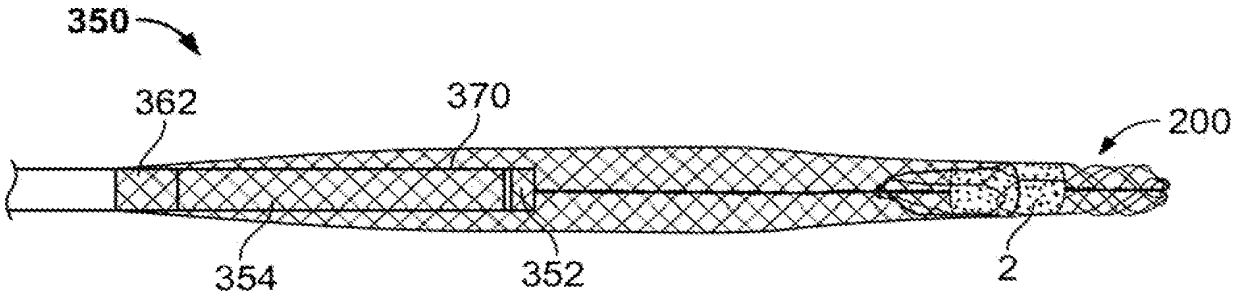


FIG. 13D

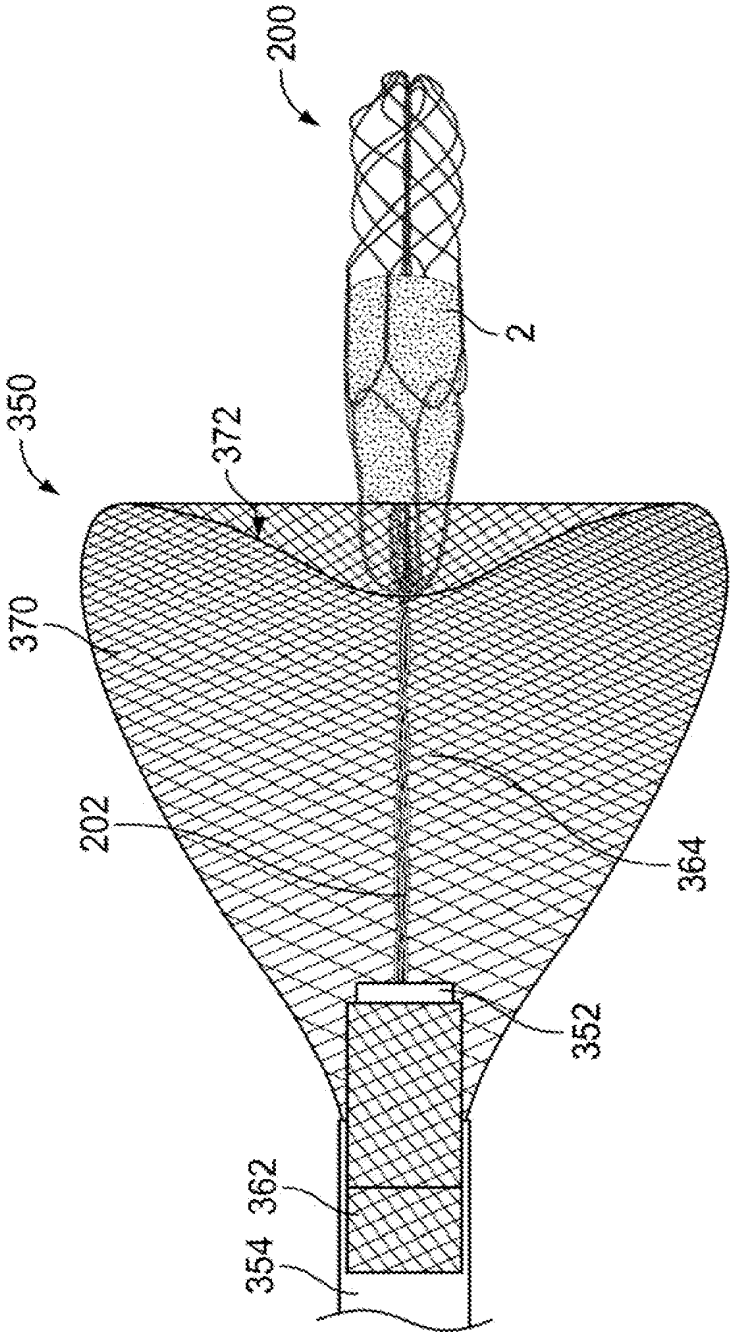


FIG. 13E

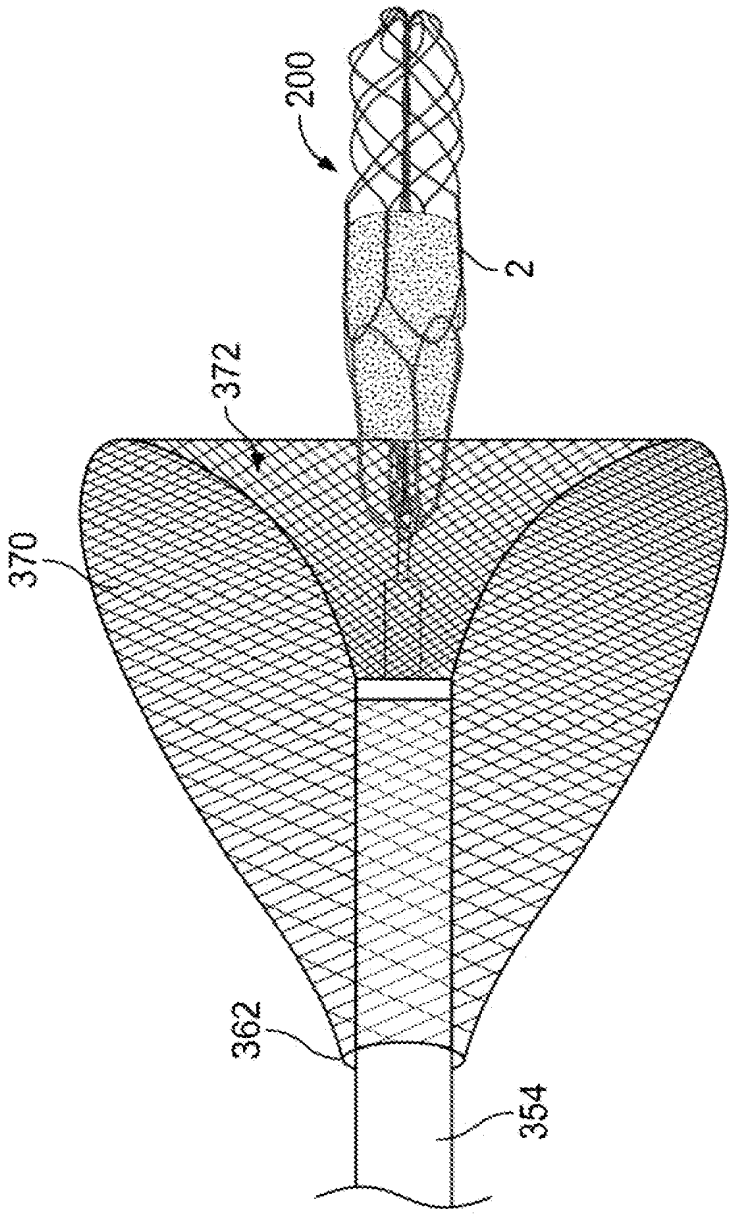


FIG. 13G

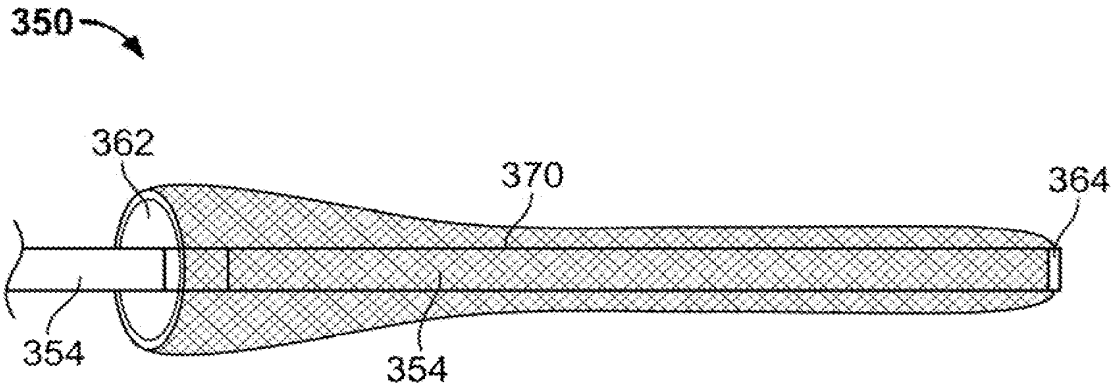


FIG. 13F

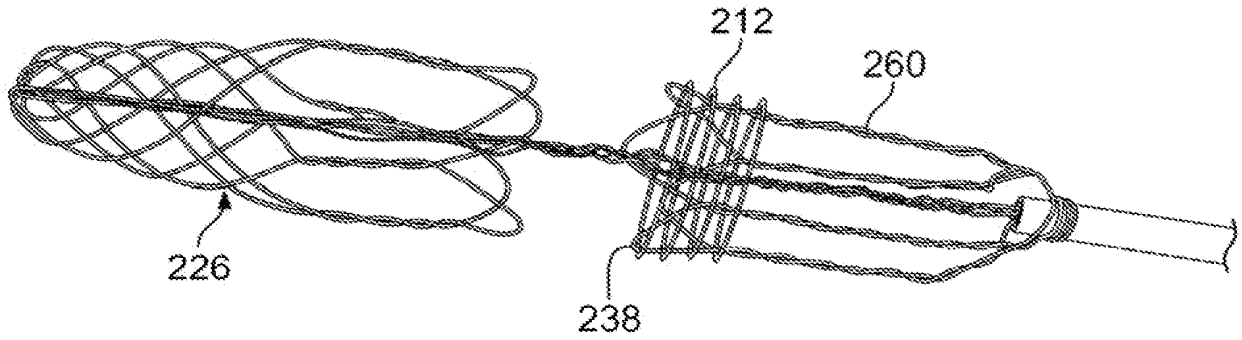


FIG. 14A

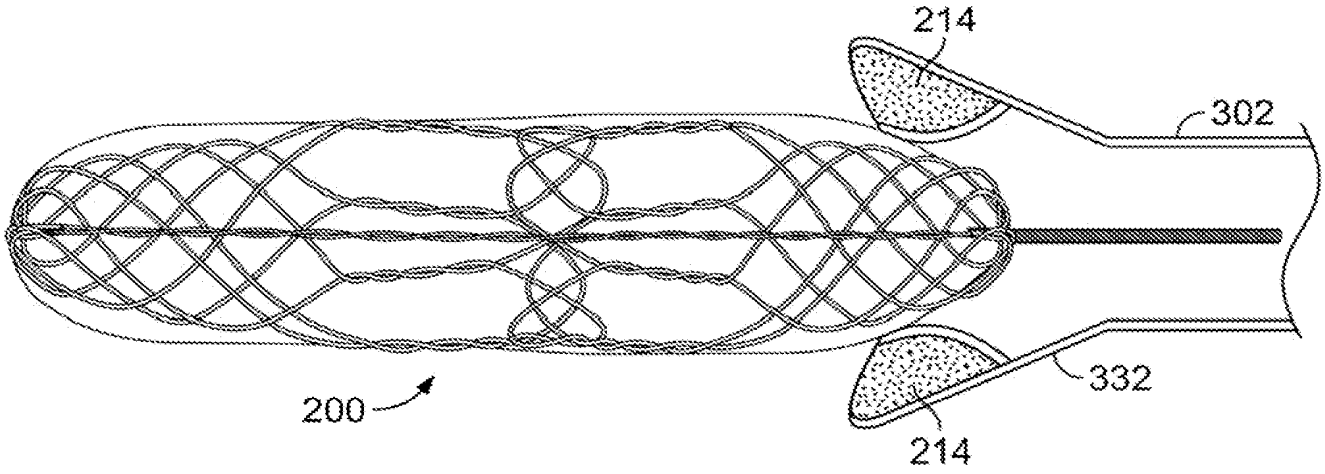


FIG. 14B

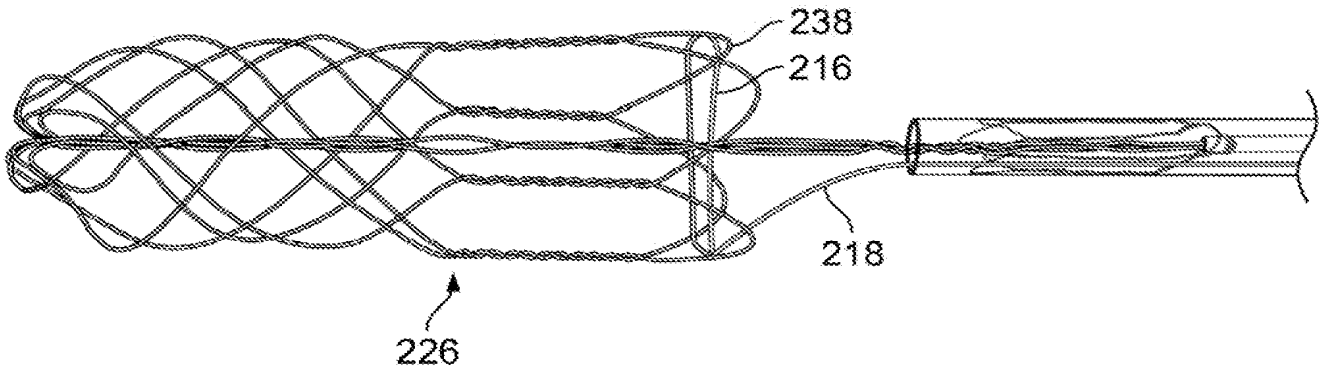


FIG. 14C

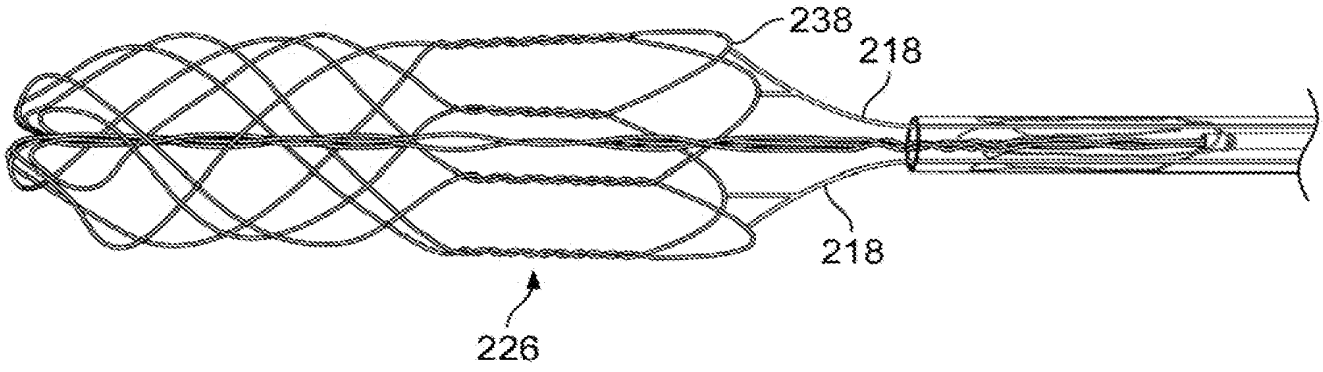


FIG. 14D

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 08/88371

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61B 17/22 (2009.01)
USPC - 606/200
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)
606/200

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
A61B 17/221 (2009.01)
606/127, 159

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
PubWest, Google
Search Terms Used: obstruction, blood vessel,lumen, wire, capture, removal, catheter, retrieval device, friction,

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2006/0009784 A1 (Behl et al.) 12 January 2006 (12.01.2006), abstract, para [0009], [0013]-[0014], [0029]-[0030]	1-76, 109-114
Y	US 2007/0225749 A1 (MARTIN et al.) 27 September 2007 (27.09.2007), para [0014]-[0017], [0044], [0082], [0096]-[0098]	1-76, 109-114
Y	US 2005/0090857 A1 (Kusleika et al.) 28 April 2005 (28.04.2005), para [0035] .Fig.4B, para [0066], [0073], [0089]. Fig 8.	18, 20-21, 38-40, 48, 51-64, 66-69, 72-76, 109-114
Y	US 2005/0004594 A1 (Nool et al.) 6 January 2005 (6.01.2005), para [0042], [0077]	53, 73
Y	US 6,221,006 B1 (Dubrul et al.) 24 April 2001 (24.04.2001), Col 16, ln 41-42.	7, 32, 111-112

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

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
5 April 2009 (05. 04. 2009)	16 APR 2009
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: Lee W. Young PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

Form PCT/ISA/210 (second sheet) (April 2007)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 08/88371

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:
In order for more that one invention to be examined, the appropriate examination fees must be paid.
There are considered to be 2 inventions as follows:

Group I: claims 1-76 and 109-114 characterized by the axial strength of the capture wire
Group II: claims 77-108 characterized by a funnel

Groups I and II share the technical feature of a retrieval sheath. This generic feature does not avoid the prior art, as evinced by US 2005/0090857 A1 to KUSLEIKA et al which teaches a common example of such a sheath (para [0046]).

The inventions listed above do not relate to a single general inventive concept under PCT rule 13.1 because, under PCT Rule 13.2 the inventions lack the same or corresponding special technical features. Neither of these technical features is common to the other group nor do they correspond to a special technical feature in the other groups.

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.:
claims 1-76 and 109-114

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.

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

To: MATTHEW S. WILLIAMS
PERKINS COIE LLP
P.O. BOX 1247
SEATTLE, WA 98111-1247

RECEIVED
PATENT DOCKETING
MAR 25 2022
PERKINS COIE LLP

PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL SEARCH REPORT AND THE WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY, OR THE DECLARATION

(PCT Rule 44.1)

Applicant's or agent's file reference: 111552-8029WO00	Date of mailing (day/month/year): MAR 22 2022
International application No.: PCT/US 21/59735	FOR FURTHER ACTION: See paragraphs 1 and 4 below
Applicant: INARI MEDICAL, INC.	International filing date (day/month/year): 17 November 2021 (17.11.2021)

1. ☒ The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

Filing of amendments and statement under Article 19:
The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46).

When? The time limit for filing such amendments is normally two months from the date of transmittal of the international search report.

How? Directly to the International Bureau preferably through ePCT, or on paper to:
The International Bureau of WIPO, 34, chemin des Colombettes, 1211 Geneva 20, Switzerland

For more detailed instructions, see the *PCT Applicant's Guide*, International Phase, paragraphs 9.004 – 9.011.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.

3. ☐ **With regard to any protest** against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:
   ☐ the protest together with the decision thereon has been transmitted to the International Bureau together with any request to forward the texts of both the protest and the decision thereon to the designated Offices.
   ☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. **Reminders**

The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the International Bureau. These comments will be made available to the public after international publication. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established.

Shortly after the expiration of 18 months from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau before the completion of the technical preparations for international publication (Rules 90*bis*.1 and 90*bis*.3).

Within 19 months from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase **until 30 months** from the priority date (in some Offices even later); otherwise, the applicant must, **within 20 months** from the priority date, perform the prescribed acts for **entry into the national phase** before those designated Offices. In respect of other designated Offices, the time limit of **30 months** (or later) will apply even if no demand is filed within 19 months. For details about the applicable time limits, Office by Office, see www.wipo.int/pct/en/texts/time_limits.html and the *PCT Applicant's Guide*, National Chapters.

Within 22 months from the priority date, the applicant may request that a supplementary international search be carried out by a different International Searching Authority that offers this service (Rule 45*bis*.1). The procedure for requesting supplementary international search is described in the *PCT Applicant's Guide*, International Phase, paragraphs 8.006–8.032.

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	Authorized officer: Kari Rodriquez
Facsimile No. 571-273-8300	Telephone No. PCT Helpdesk: 571-272-4300

Form PCT/ISA/220 (revised January 2020)

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
111552-8029WO00		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 21/59735	17 November 2021 (17.11.2021)	18 November 2020 (18.11.2020)
Applicant INARI MEDICAL, 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.

☐ 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. 18

☒ as suggested by the applicant.

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

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

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

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 21/58735

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:
This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I: Claims 1-7 directed to a proximal ring, a distal ring and a tube portion.

Group II: Claims 8-20 directed to a handle and an actuator.

Continued in Supplemental Box

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
1-7

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 21/60735

A. CLASSIFICATION OF SUBJECT MATTER
IPC - A61M 25/00 (2022.01)
CPC - A61M 25/0147; A61M 25/0138

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	WO 2019/246240 A1 (INTUITIVE SURGICAL OPERATIONS, INC.) 26 December 2019 (26.12.2019), entire document, especially Fig 4A, 4C; para [0071]-[0084]	1-3, 5-7
Y		4-5
Y	US2010/0016837 A1 (Howat) 21 January 2010 (21.01.2010), entire document, especially Fig 1-5; para [0034]-[0042]	4-5
A	US 2004/0138625 A1 (Saadat et al.) 15 July 2004 (15.07.2004), entire document	1-7
A	US 2020/0113413 A1 (AMBU A/S) 16 April 2020 (16.04.2020), entire document	1-7
A	US 2009/0192498 A1 (Ostrovsky et al.) 30 July 2009 (30.07.2009), entire document	1-7

☐ 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
20 February 2022	MAR 29 2022
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 Kari Rodriquez Telephone No. PCT Helpdesk: 571-272-4300

Form PCT/ISA/210 (second sheet) (July 2019)

/* Box No. III - Observations where unity of invention is lacking */

The inventions listed as Groups I-II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

SPECIAL TECHNICAL FEATURES

The invention of Group I includes the special technical feature of a proximal ring; a distal ring configured to be fixedly attached to a pull wire; and a tube portion extending between the proximal and distal rings, wherein the tube portion includes a plurality of openings extending therethrough to define a plurality of ribs, and wherein the ribs are configured to flex away from each other when the pull wire is pulled proximally, not required by Group II.

The invention of Group II includes the special technical feature of a handle coupled to the proximal region of the aspiration catheter, wherein the handle includes an actuator; and pull wire extending between the actuator and the deflectable member, wherein actuation of the actuator is configured to pull the pull wire, not required by the claims of Group I.

COMMON TECHNICAL FEATURES

Groups I-II share the common technical features of an aspiration catheter including a proximal region and a distal region, wherein the distal region includes a deflectable member; and a pull wire configured to deflect the deflectable member to deflect the distal region of the aspiration catheter relative to the proximal region. However, this shared technical feature does not represent a contribution over prior art as being anticipated by US 2004/0138525 A1 to Saadat et al. (hereinafter "Saadat"), which discloses an aspiration catheter (30; Fig 21A-21B; para [0097]; see analogous Fig 41, para [0125] describing tool arm 30 used for aspiration, wherein the tool arm 30 is interpreted as an aspiration catheter) including a proximal region (proximal half of 30; Fig 21A-21B; para [0097]; the proximal half of 30 being the bottom-most half of the entire tool arm 30 in the orientation shown in Fig 21A) and a distal region (distal half of 30; Fig 21A-21B; para [0097]; the distal half of 30 being the top-most half of the entire tool arm 30 in the orientation shown in Fig 21A), wherein the distal region includes a deflectable member (portion of 30 from bottom slot 132 to the distal-most end of 30; Fig 21A-21B; para [0097]); and a pull wire configured to deflect the deflectable member to deflect the distal region of the aspiration catheter relative to the proximal region (96; Fig 21A-21B; para [0097]; pullwire 96 is shown to be attached to the portion of 30 extending distally from distal-most slot 132 via fixation point 104 wherein pulling the pullwire 96 causes the distal tip of tool arm 30 to deflect relative to the proximal region of tool arm 30).

As the common technical features were known in the art at the time of the invention, these cannot be considered special technical feature that would otherwise unify the groups.

Therefore, Groups I-II lack unity under PCT Rule 13 because they do not share a same or corresponding special technical feature.

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To: MATTHEW S. WILLIAMS
PERKINS COIE LLP
P.O. BOX 1247
SEATTLE, WA 98111-1247

RECEIVED
PATENT DOCKETING

MAR 25 2022

PERKINS COIE LLP

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis* 1)

Applicant's or agent's file reference 111552-8029WO00	Date of mailing *(day/month/year)* MAR 22 2022 FOR FURTHER ACTION See paragraph 2 below

International application No.	International filing date *(day month year)*	Priority date *(day month year)*
PCT/US 21/59735	17 November 2021 (17.11.2021)	18 November 2020 (18.11.2020)

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

IPC - A61M 25/00 (2022.01)

CPC - A61M 25/0147; A61M 25/0138

Applicant INARI MEDICAL, INC.

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

- [X] Box No. I Basis of the opinion
- [ ] Box No. II Priority
- [ ] Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- [X] Box No. IV Lack of unity of invention
- [X] Box No. V Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement
- [ ] Box No. VI Certain documents cited
- [ ] Box No. VII Certain defects in the international application
- [X] 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	20 February 2022	Kari Rodriquez PCT Help Desk Telephone No. 571-272-4300

Form PCT/ISA/237 (cover sheet) (revised January 2019)

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 21/59738

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:

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 21/59735

Box No. IV Lack of unity of invention

1. [X] In response to the invitation (Form PCT/ISA/206) to pay additional fees the applicant has, within the applicable time limit:

- [ ] paid additional fees.
- [ ] paid additional fees under protest and, where applicable, the protest fee.
- [ ] paid additional fees under protest but the applicable protest fee was not paid.
- [X] not paid additional fees.

2. [ ] This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is

- [ ] complied with.
- [X] not complied with for the following reasons:

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I: Claims 1-7 directed to a proximal ring; a distal ring and a tube portion.

Group II: Claims 8-20 directed to a handle and an actuator.

The inventions listed as Groups I-II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

SPECIAL TECHNICAL FEATURES

The invention of Group I includes the special technical feature of a proximal ring; a distal ring configured to be fixedly attached to a pull wire; and a tube portion extending between the proximal and distal rings, wherein the tube portion includes a plurality of openings extending therethrough to define a plurality of ribs, and wherein the ribs are configured to flex away from each other when the pull wire is pulled proximally, not required by Group II.

The invention of Group II includes the special technical feature of a handle coupled to the proximal region of the aspiration catheter, wherein the handle includes an actuator; and pull wire extending between the actuator and the deflectable member, wherein actuation of the actuator is configured to pull the pull wire, not required by the claims of Group I.

COMMON TECHNICAL FEATURES

Groups I-II share the common technical features of an aspiration catheter including a proximal region and a distal region, wherein the distal region includes a deflectable member; and a pull wire configured to deflect the deflectable member to deflect the distal region of the aspiration catheter relative to the proximal region. However, this shared technical feature does not represent a contribution over prior art as being anticipated by US 2004/0138525 A1 to Saadat et al. (hereinafter "Saadat"), which discloses an aspiration catheter (30; Fig 21A-21B; para [0097]; see analogous Fig 41, para [0128] describing tool arm 30 used for aspiration, wherein the tool arm 30 is interpreted as an aspiration catheter) including a proximal region (proximal half of 30; Fig 21A-21B; para [0097]; the proximal half of 30 being the bottom-most half of the entire tool arm 30 in the orientation shown in Fig 21A) and a distal region (distal half of 30; Fig 21A-21B; para [0097]; the distal half of 30 being the top-most half of the entire tool arm 30 in the orientation shown in Fig 21A), wherein the distal region includes a deflectable member (portion of 30 from bottom slot 132 to the distal-most end of 30; Fig 21A-21B; para [0097]); and a pull wire configured to deflect the deflectable member to deflect the distal region of the aspiration catheter relative to the proximal region (98; Fig 21A-21B; para [0097]; pullwire 98 is shown to be attached to the portion of 30 extending distally from distal-most slot 132 via fixation point 104 wherein pulling the pullwire 98 causes the distal tip of tool arm 30 to deflect relative to the proximal region of tool arm 30).

As the common technical features were known in the art at the time of the invention, these cannot be considered special technical feature that would otherwise unify the groups.

Therefore, Groups I-II lack unity under PCT Rule 13 because they do not share a same or corresponding special technical feature.

4. Consequently, this opinion has been established in respect of the following parts of the international application:

- [ ] all parts.
- [X] the parts relating to claims Nos. 1-7

Form PCT/ISA/237 (Box No. IV) (revised January 2015)

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 21/58735

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

1. Statement

Novelty (N)	Claims	3-6, 7	YES
	Claims	1-2, 8	NO
Inventive step (IS)	Claims	None	YES
	Claims	1-7	NO
Industrial applicability (IA)	Claims	1-7	YES
	Claims	None	NO

2. Citations and explanations:

Claims 1-2 and 8 lack novelty under PCT Article 33(2) as being anticipated by WO 2019/246240 A1 to INTUITIVE SURGICAL OPERATIONS, INC. (hereinafter "Intuitive").

As per claim 1, Intuitive teaches an aspiration catheter (Fig 4A, 4C; para [0071]-[0084]; the flexible elongate device 400 is taught to correspond to elongate device 202, which is taught in para [0064] to be used for suction - further, para [0072] teaches wherein flexible elongate device 400 comprises a main lumen 411, which receives medical tools and is considered to be capable of receiving a suction tool or having suction applied therethrough), comprising:
a proximal region (402; Fig 4A; para [0072]); and
a distal region (404, portion of 408 extending distally from 425 collectively; Fig 4A; para [0072]) including a deflectable member (422, 424, 425 collectively; Fig 4A, 4C; para [0072]-[0076]), wherein the deflectable member includes:
a proximal ring (425; Fig 4A; para [0078]);
a distal ring configured to be fixedly attached to a pull wire (422; Fig 4A; para [0073]; control elements 421, taught to be pull wires, are taught to attach to distal mount 422); and
a tube portion extending between between the proximal and distal rings (424; Fig 4A; para [0076]-[0076]; axial support structure 424 is shown to extend between stopper 425 and distal mount 422), wherein the tube portion includes a plurality of openings extending therethrough (openings extending through left portions of 424; Fig 4A; para [0076]-[0078]; the axial support structure 424 is shown to comprise openings extending through every other circular portion of 424 on the left side) to define a plurality of ribs (left sides of 424; Fig 4A; para [0076]-[0078]; the left half of axial support structure 424 includes portions extending between the left openings), and wherein the ribs are configured to flex away from each other when the pull wire is pulled proximally (Fig 4A; para [0076]-[0078]; Intuitive teaches wherein when unequal forces are applied to control elements, the distal section 404, with axial support structure 424, bends in the direction defined by the net actuation forces, such that inherently when a right control element 421 is pulled, the support structure 424 bends right, which causes the left portions of 424 extending between the left openings to flex away from each other).

As per claim 2, Intuitive teaches the aspiration catheter of claim 1 wherein the tube portion includes a spine extending in a direction between the proximal and distal rings (right-most edge of 424; Fig 4A; para [0076]-[0078]; the axial support structure comprises a right most edge extending between the distal mount 422 and stopper 425), wherein the ribs extend away from the spine (Fig 4A; para [0076]-[0078]; the left portions of 424 extend away from the right-most edge of 424), and wherein the spine is configured to extend generally parallel to and over the pull wire (Fig 4A, para [0076]-[0078]; the control elements 421 are taught to extend through control element lumens 412, wherein Fig 4C shows the edges of axial support 424 to extend over the control element lumens 412, wherein the right-most edge of the axial support inherently extends over the right control elements 421 within the control element lumens 412).

As per claim 8, Intuitive teaches the aspiration catheter of claim 1 wherein the tube portion extends along a longitudinal axis in a relaxed state (Fig 4A; para [0072]-[0078]; the control elements 421 are taught to be used to bend the distal section 404 when force is applied to control elements 421, para [0077], wherein Fig 4A is reasonably considered to be a relaxed state such that control elements 421 are not actuated, wherein the axial support structure 424 is shown to extend along the longitudinal axis of the flexible elongate device 400, shown to be the horizontal axis extending through the main lumen 411 in Fig 4A), and wherein the plurality of openings (Box VIII) extend circumferentially about the longitudinal axis and generally parallel to one another in the relaxed state (Fig 4A, para [0072]-[0076]; the left openings of axial support structure 424 are shown to extend circumferentially about the longitudinal axis of the flexible elongate device 400 and further shown to be substantially parallel to one another in Fig 4A).

Claims 3 and 7 lack an inventive step under PCT Article 33(3) as being obvious over Intuitive.

As per claim 3, Intuitive teaches the aspiration catheter of claim 1, wherein the proximal region and the distal region define a lumen [having a diameter of 20 French or greater] (411; Fig 4A, 4C; para [0072]) While Intuitive teaches a similar catheter used to be positioned within an esophagus of a patient (Fig 3A-3B; para [0068]; the medical instrument shown in Fig 3A-3B is shown to be relatively large and inserted into the esophagus of the patient), Intuitive is silent as to the diameter of the lumen. However, it is well known in the art that optimizing size, shape and angle is of the ordinary skill in the art. Accordingly, it would have been obvious to one of ordinary skill in the art to have optimized the size of the lumen to have arrived at the lumen having a diameter of 20 French or greater, in order to allow for the lumen to receive more instrument (para [0072]).

-*-Continued in Supplemental Box-*-

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 21/58735

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:

Claim 8: The term "the openings" is confusing and lacks proper antecedent basis. The term "the openings" appears to be referring to the plurality of openings previously referred to. For purposes of this opinion, the term "the openings" has been interpreted to be "the plurality of openings."

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.
Continuation of:
-*-Box V.2 - Citations and explanations-*-

As per claim 7, Intuitive teaches the aspiration catheter of claim 1. While Intuitive teaches wherein the proximal ring includes an annular lumen configured to slidably receive the pull wire therethrough (Fig 4A; para [0072]; the control element lumen 412, shown to be annular in Fig 4C, is shown to extend through stopper 425) and an annular member extending through the lumen (423; Fig 4A-4B; para [0073]-[0076]; coil pipe 423 is taught to extend through the control element lumens 412 and terminate at the transition section 406 proximal to the distal section 404); Intuitive does not specifically teach wherein the proximal ring includes an annular member configured to slidably receive the pull wire therethrough. However, it is well known that routine experimentation and various engineering design choices could have been made to have arrived at wherein the proximal ring includes an annular member configured to slidably receive the pull wire therethrough (Note: providing the coil pipe 423 to extend through the control element lumen 412 within stopper 425, allows for the coil pipe 423 to still terminate proximal to distal section 404, as taught in para [0073]). Accordingly, it would have been obvious to one of ordinary skill in the art to have arrived at wherein the proximal ring includes an annular member configured to slidably receive the pull wire therethrough, in order to improve the structural integrity of the lumen within the proximal ring.

Claims 4-5 lack an inventive step under PCT Article 33(3) as being obvious over Intuitive in view of US 2010/0016837 A1 to Howat.

As per claim 4, Intuitive teaches the aspiration catheter of claim 1, further comprising an intermediate region between the proximal and distal regions (portion of 408 extending proximally from 425; Fig 4A; para [0072]). While Intuitive teaches wherein select portions of the aspiration catheter can be stiffened (para [0105]), Intuitive does not specifically teach wherein the proximal region and the intermediate region include a braid of wires extending therethrough. However, Howat teaches a similar catheter (Fig 5-8; para [0034]-[0042]) wherein a proximal region and an intermediate region include a braid of wires extending therethrough (Fig 8; para [0034]-[0037]; Howat teaches wherein an introducer sheath 20 is assembled, in which a braided member 40 is shown to extend along the entire length of the inner tube of the introducer sheath such that the braided member 40 extends through a proximal and intermediate region of the introducer sheath 20). Accordingly, it would have been obvious to one of ordinary skill in the art to have employed the braid of wires taught by Howat with the aspiration catheter taught by Intuitive, in order to improve the structural integrity of the aspiration catheter.

As per claim 5, Intuitive in view of Howat teach the aspiration catheter of claim 4, and Howat further teaches wherein the intermediate region includes a wire coiled around the braid (Fig 7; para [0038]; a coiled member 50, wherein para [0022] further teaches wherein coiled member is a flat wire coil, wherein the coiled member 50 extends along the length of the inner tube 30, such that the coiled member 50 is considered to be included in the intermediate region with the modification as combined).

Claims 1-7 have industrial applicability as defined by PCT Article 33(4) because the subject matter can be made or used by industry.

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

To: MATTHEW S. WILLIAMS
PERKINS COIE LLP
P.O. BOX 1247
SEATTLE, WA 98111-1247

RECEIVED
PATENT DOCKETING

MAR 2 2 2022

PERKINS COIE LLP

PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL SEARCH REPORT AND THE WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY, OR THE DECLARATION

(PCT Rule 44.1)

Date of mailing *(day/month/year)*	MAR 16 2022
Applicant's or agent's file reference: 111552-8027WO00	**FOR FURTHER ACTION** See paragraphs 1 and 4 below
International application No.: PCT/US 21/58793	International filing date *(day/month/year)*: 10 November 2021 (10.11.2021)
Applicant: INARI MEDICAL, INC.	

1. ☒ The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

   Filing of amendments and statement under Article 19:
   The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46):

   When? The time limit for filing such amendments is normally two months from the date of transmittal of the international search report.

   How? Directly to the International Bureau preferably through ePCT, or on paper to:
   The International Bureau of WIPO, 34, chemin des Colombettes, 1211 Geneva 20, Switzerland

   For more detailed instructions, see the *PCT Applicant's Guide*, International Phase, paragraphs 9.004 – 9.011.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.

3. ☐ **With regard to any protest** against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:
   - ☐ the protest together with the decision thereon has been transmitted to the International Bureau together with any request to forward the texts of both the protest and the decision thereon to the designated Offices.
   - ☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. **Reminders**

   The applicant may **submit comments on an informal basis on the written opinion of the International Searching Authority** to the International Bureau. These comments will be made available to the public after international publication. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established.

   Shortly after the expiration of **18 months from the priority date, the international application will be published** by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau before the completion of the technical preparations for international publication (Rules 90*bis*.1 and 90*bis*.3).

   Within **19 months** from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase **until 30 months** from the priority date (in some Offices even later); otherwise, the applicant must, **within 20 months** from the priority date, perform the prescribed acts for **entry into the national phase** before those designated Offices. In respect of other designated Offices, the time limit of **30 months** (or later) will apply even if no demand is filed within 19 months. For details about the applicable time limits, Office by Office, see www.wipo.int/pct/en/texts/time_limits.html and the *PCT Applicant's Guide*, National Chapters.

   Within **22 months from the priority date, the applicant may request that a supplementary international search be carried out** by a different International Searching Authority that offers this service (Rule 45*bis*.1). The procedure for requesting supplementary international search is described in the *PCT Applicant's Guide*, International Phase, paragraphs 8.006-8.032.

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 Kari Rodriquez Telephone No. PCT Helpdesk: 571-272-4300

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
111552-8027WO00		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 21/58793	10 November 2021 (10.11.2021)	10 November 2020 (10.11.2020)
Applicant INARI MEDICAL, 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 3 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. 1C

☒ as suggested by the applicant.

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

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

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

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 21/58793

A. CLASSIFICATION OF SUBJECT MATTER

IPC - A61B 17/03; A61B 17/04 (2022.01)

CPC - A61B 17/04; A61B 2017/0496; A61B 17/03; A61B 17/56; A61B 17/0467; A61B 17/8869; A61B 17/0482; A61B 17/0469

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 5,376,101 A (GREEN et al.) 27 December 1994 (27.12.1994); entire document, especially col 6 ln 56 to col 7 ln 17, and Fig. 15-18.	1, 5-7 -- 2-4
Y	US 5,192,274 A (BIERMAN) 9 March 1993 (09.03.1993); especially col 2 ln 21-54, and Fig. 1-2.	2-3
Y	US 2013/0116708 A1 (ZINITI et al.) 9 May 2013 (09.05.2013); especially para [0090], and Fig. 18A-B.	4
A	US 2004/0260344 A1 (LYONS et al.) 23 December 2004 (23.12.2004); entire document.	1-7

☐ 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
2 March 2022	MAR 16 2022
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 Kari Rodriquez Telephone No. PCT Helpdesk: 571-272-4300

-*- Box III.0 - Explanations where unity of invention is lacking -*-

SPECIAL TECHNICAL FEATURES

The invention of Group I includes the special technical feature of when the first through-hole and the second through-hole receive the suture and the actuator is in the second position, the actuator and the housing cooperate to permit the suture to move relative to the housing, not required by the claims of Group II-III.

The invention of Group II includes the special technical feature of a biasing member operably coupled between the actuator and the housing, not required by the claims of Group I or II.

The invention of Group III includes the special technical feature of adjusting a tension of the suture to a desired tension, not required by the claims of Group I-II.

COMMON TECHNICAL FEATURES

Groups I-III share the common technical feature of a suture tensioning device.
However, this shared technical feature does not represent a contribution over prior art as being anticipated by US 8,888,791 B2 (JARAMILLO et al.) (hereinafter Jaramillo), which discloses a suture tensioning device (100; Fig. 1; col 5 ln 40-62).

Groups I-II share the common technical feature of a device for tensioning a suture, comprising:
a housing having a first through-hole; and
an actuator coupled to the housing and having a second through-hole,
wherein the actuator is movable relative to the housing from a first position to a second position.
However, this shared technical feature does not represent a contribution over prior art as being anticipated by Jaramillo, which discloses a device for tensioning a suture (Fig. 9; col 7 ln 41-51), comprising:
a housing (upper housing of 900; Fig. 9; col 7 ln 41-51) having a first through-hole (902; Fig. 9; col 7 ln 41-51); and
an actuator (903, unlabeled semicircular half adjacent 903; Fig. 9; col 7 ln 41-51) coupled to the housing and having a second through-hole (901; Fig. 9; col 7 ln 41-51),
wherein the actuator is movable relative to the housing from a first position (903 adjacent and flush with housing of 900; Fig. 9; col 7 ln 41-51) to a second position (position of Fig. 9 with 903 deployed rotated outward; Fig. 9; col 7 ln 41-51).

As the common technical features were known in the art at the time of the invention, these cannot be considered special technical features that would otherwise unify the groups.

Therefore, Groups I-III lack unity under PCT Rule 13 because they do not share a same or corresponding special technical feature.

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To: MATTHEW S. WILLIAMS
PERKINS COIE LLP
P.O. BOX 1247
SEATTLE, WA 98111-1247

RECEIVED
PATENT DOCKETING

MAR 2 2 2022

PERKINS COIE LLP

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing *(day/month/year)*	MAR 16 2022
Applicant's or agent's file reference 111552-8027WO00	FOR FURTHER ACTION See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/US 21/58793	10 November 2021 (10.11.2021)	10 November 2020 (10.11.2020)

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

IPC - A61B 17/03; A61B 17/04 (2022.01)

CPC - A61B 17/04; A61B 2017/0496; A61B 17/03; A61B 17/56; A61B 17/0467; A61B 17/8869; A61B 17/0482; A61B 17/0469

Applicant INARI MEDICAL, INC.

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

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

2. **FURTHER ACTION**

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

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

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

Name and mailing address of the ISA/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	2 March 2022	Kari Rodriquez PCT Help Desk Telephone No. 571-272-4300

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

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 21/58793

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:

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 21/58793

Box No. IV Lack of unity of invention

1. ☒ In response to the invitation (Form PCT/ISA/206) to pay additional fees the applicant has, within the applicable time limit:

   ☐ paid additional fees.

   ☐ paid additional fees under protest and, where applicable, the protest fee.

   ☐ paid additional fees under protest but the applicable protest fee was not paid.

   ☒ not paid additional fees.

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is

   ☐ complied with.

   ☒ not complied with for the following reasons:

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be searched, the appropriate additional search fees must be paid.

Group I: Claims 1-7 directed to a device for tensioning a suture, having a housing with a first through-hole and an actuator with a second through-hole.

Group II: Claims 8-14 directed to a suture tensioning device, having a housing, an actutator, and a biasing member.

Group III: Claims 15-20 directed to a method of tensioning a suture.

The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

SPECIAL TECHNICAL FEATURES

The invention of Group I includes the special technical feature of when the first through-hole and the second through-hole receive the suture and the actuator is in the second position, the actuator and the housing cooperate to permit the suture to move relative to the housing, not required by the claims of Group II-III.

The invention of Group II includes the special technical feature of a biasing member operably coupled between the actuator and the housing, not required by the claims of Group I or II.

The invention of Group III includes the special technical feature of adjusting a tension of the suture to a desired tension, not required by the claims of Group I-II.

COMMON TECHNICAL FEATURES

Groups I-III share the common technical feature of a suture tensioning device.
However, this shared technical feature does not represent a contribution over prior art as being anticipated by US 8,888,791 B2 (JARAMILLO et al.) (hereinafter Jaramillo), which discloses a suture tensioning device (100; Fig. 1; col 5 ln 40-62).

Groups I-II share the common technical feature of a device for tensioning a suture, comprising:
a housing having a first through-hole; and
an actuator coupled to the housing and having a second through-hole,
wherein the actuator is movable relative to the housing from a first position to a second position.
However, this shared technical feature does not represent a contribution over prior art as being anticipated by Jaramillo, which discloses a device for tensioning a suture (Fig. 9; col 7 ln 41-51), comprising:
a housing (upper housing of 900; Fig. 9; col 7 ln 41-51) having a first through-hole (902; Fig. 9; col 7 ln 41-51); and
an actuator (903, unlabeled semicircular half adjacent 903; Fig. 9; col 7 ln 41-51) coupled to the housing and having a second through-hole (901; Fig. 9; col 7 ln 41-51),
wherein the actuator is movable relative to the housing from a first position (903 adjacent and flush with housing of 900; Fig. 9; col 7 ln 41-51) to a second position (position of Fig. 9 with 903 deployed rotated outward; Fig. 9; col 7 ln 41-51).

-*- See Supplemental Box -*-

4. Consequently, this opinion has been established in respect of the following parts of the international application:

   ☐ all parts.

   ☒ the parts relating to claims Nos. 1-7

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 21/58793

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	2-4	YES
	Claims	1, 5-7	NO
Inventive step (IS)	Claims	None	YES
	Claims	1-7	NO
Industrial applicability (IA)	Claims	1-7	YES
	Claims	None	NO

2. Citations and explanations:

Claims 1 and 5-7 lack novelty under PCT Article 33(2) as being anticipated by US 5,376,101 A (GREEN et al.) (hereinafter Green).

As pertaining to claim 1, Green teaches a device for tensioning a suture (Fig. 15-18; col 6 ln 56 to col 7 ln 17), comprising:
a housing (510; Fig. 15-18; col 6 ln 56-62) having a first through-hole (511; Fig. 15-18; col 6 ln 56-62); and
an actuator (520; Fig. 15-18; col 6 ln 56-62) coupled to the housing and having a second through-hole (passageway 526; Fig. 15-18; col 6 ln 63 to col 7 ln 13),
wherein the actuator is movable relative to the housing from a first position (position of 520 relative to 510 in Fig. 17; col 7 ln 4-12) to a second position (position of 520 relative to 510 in Fig. 16; col 6 ln 63 to col 7 ln 3),
wherein the first through-hole and the second through-hole are configured to receive a suture therethrough (10; Fig. 15-18; col 7 ln 1-3), and wherein-
when the first through-hole and the second through-hole receive the suture and the actuator is in the first position, the actuator and the housing cooperate to inhibit the suture from moving relative to the housing (receipt of 10 through 511, hole through 520, secured in Fig. 17; col 7 ln 4-17); and
when the first through-hole and the second through-hole receive the suture and the actuator is in the second position, the actuator and the housing cooperate to permit the suture to move relative to the housing (receipt of 10 through 511, hole through 520, adjustable in Fig. 16, col 6 ln 63 to col 7 ln 3).

As pertaining to claim 5, Green teaches the device of claim 1 wherein the first through-hole and the second through-hole are axially offset in the first position (position of 520 and 526 offset relative to 510 and 511 in Fig. 17; col 7 ln 4-12), and wherein the first through-hole and the second through-hole are axially aligned in the second position (position of 520 and 526 aligned relative to 510 and 511 in Fig. 16; col 6 ln 63 to col 7 ln 3).

As pertaining to claim 6, Green teaches the device of claim 5 wherein the housing and actuator engage the suture in the first position to clamp the suture relative to the housing (clamping of 10 with respect to 510 by 520 action; Fig. 16-17; col 6 ln 63 to col 7 ln 17).

As pertaining to claim 7, Green teaches the device of claim 1 wherein the first through-hole and the second through-hole are aligned along an axis in the second position (position of 520 and 526 aligned relative to 510 and 511 in Fig. 16; col 6 ln 63 to col 7 ln 3), and wherein the actuator is movable from the first position to the second position in a direction generally orthogonal to the axis (movement of 520 orthogonal to axis of 511; Fig. 16-17; col 6 ln 63 to col 7 ln 3).

Claims 2-3 lack an inventive step under PCT Article 33(3) as being obvious over Green in view of US 5,192,274 A to BIERMAN (hereinafter Bierman).

As pertaining to claim 2, Green teaches the device of claim 1, but is silent wherein further comprising a flexible pad coupled to the housing.
However, Bierman teaches a device (Fig. 1-2; col 2 ln 21-54), comprising:
a housing (12; Fig. 1-2; 2 ln 29-42); and
a flexible pad coupled to the housing (22; Fig. 1-2; col 2 ln 50-53, col 1 ln 22-24).
Accordingly, it would have been obvious to a person having ordinary skill in the art to have employed the pad of Bierman upon the device of Green, in order to safely and removably secure the device to a patient's skin.

As pertaining to claim 3, Green in view of Bierman teaches the device of claim 2 and Bierman further discloses wherein the flexible pad is configured to be placed against skin of a patient and to conform to the skin of the patient (flexible pad 22 applied upon skin of patient; Fig. 1-2; col 2 ln 50-53, col 1 ln 22-24).

-*- See Supplemental Box -*-

Supplemental Box

In case **the space in any of the preceding boxes is not sufficient.**
Continuation of:
-*- Box IV.2 - Explanations where unity of invention is lacking -*-

As the common technical features were known in the art at the time of the invention, these cannot be considered special technical features that would otherwise unify the groups.

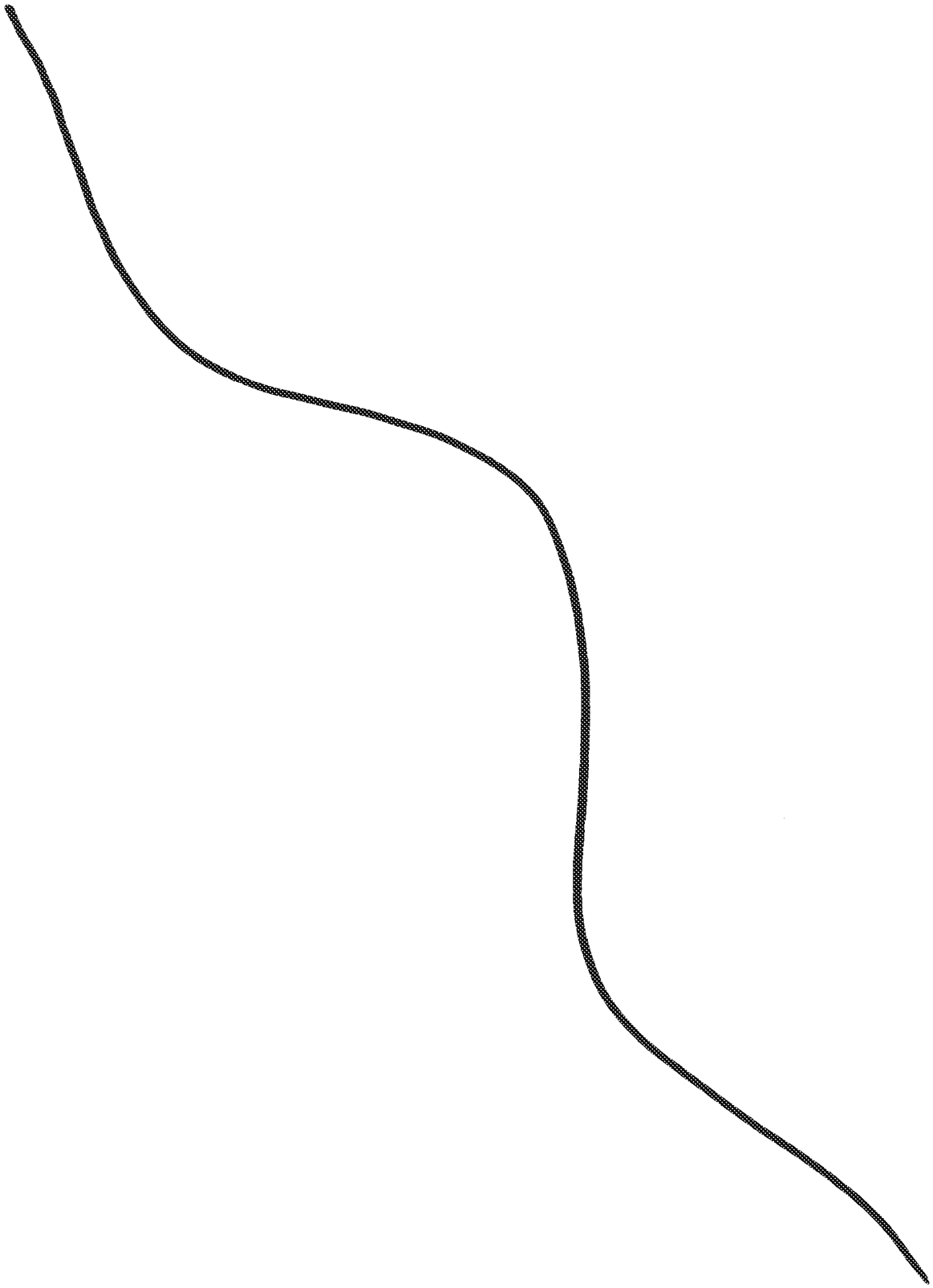
Therefore, Groups I-III lack unity under PCT Rule 13 because they do not share a same or corresponding special technical feature.

-*- Box V.2 - Citations and explanations -*-

Claim 4 lacks an inventive step under PCT Article 33(3) as being obvious over Green in view of US 2013/0116708 A1 to ZINITI et al. (hereinafter Ziniti).

As pertaining to claim 4, Green teaches the device of claim 1 but is silent wherein further comprising a biasing member operably coupled between the actuator and the housing, wherein the biasing member is configured to bias the actuator to the first position.
However, Ziniti further discloses a device (Fig. 18A-B; para [0090]), comprising:
a biasing member operably coupled between the actuator and the housing (spring 612; Fig. 18A-B; para [0093]),
wherein the biasing member is configured to bias the actuator to the first position (spring 612 capable of being disposed to bias actuator; Fig. 18A-B; para [0093]).
Accordingly, it would have been obvious to a person having ordinary skill in the art to have employed the biasing member of Ziniti upon the device of Green, in order to aid in user deployment of the device.

Claims 1-7 have industrial applicability as defined by PCT Article 33(4) because the subject matter can be made or used by industry.



Application Number	PCT/US 21/58793
Search Conducted By	SBF
Search Approved By	SCL

CPC/IPC Classifications Searched	IPC(8) A61B 17/03; A61B 17/04 (2022.01) CPC A61B 17/04; A61B 2017/0496; A61B 17/03; A61B 17/56; A61B 17/0467; A61B 17/8869; A61B 17/0482; A61B 17/0469
Date Conducted	25 February-2 March 2022 (25.02.-02.03.2022)

Documentation Searched	IPC(8) A61B 17/03; A61B 17/04 (2022.01) CPC A61B 17/04; A61B 2017/0496; A61B 17/03; A61B 17/56; A61B 17/0467; A61B 17/8869; A61B 17/0482; A61B 17/0469 (keyword limited; terms below)
Search Terms Used	Suture tensioner inari medical flowstasis retention large bore through holes lock retainer misalign tighten adjust gap aperture align line up slot friction clamp clutch thread cable cord increment ratchet button actuator spring load stop restrain
Date Conducted	25 February-2 March 2022 (25.02.-02.03.2022)

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	25 February-2 March 2022 (25.02.-02.03.2022)
Search Logic:	

25 February-
Search 1: pa=(inari medical*) (Results 12)
Search 2: inv=(macias jacqueline* or enright paige* or tu thomas*) (Results 16)
Search 3: 1 or 2 (Results 26)
Search 4: pn=(US8888791) (Results 1)
Search 5: 3 and ft=(suture* near tension*) (Results 0)
Search 6: ctf 4 or ctb 4 (Results 165)
Search 7: 6 and ft=(suture* near (tension* or tighten* or adjust*)) (Results 100)
Search 8: 7 not (4 or 3) (Results 99)
Search 9: cpc=(A61B2017/0496*) (Results 1269)
Search 10: 9 and ft=((hole* or gap* or aperture*) near (align* or (line up*))) (Results 176)
Search 11: 10 not (7 or 4 or 3) (Results 173)

28 February-
Search 12: pn=(US20040260344A1) (Results 1)
Search 13: ctf 12 or ctb 12 (Results 193)
Search 14: 13 and ft=(suture* near (tension* or tighten* or adjust*)) (Results 105)
Search 15: 14 not (12 or 10 or 7 or 4 or 3) (Results 99)
Search 16: pn=(jp2018000843) (Results 1)
Search 17: ctf 16 or ctb 16 (Results 4)
Search 18: cpc=(A61B17/8869*) (Results 409)
Search 19: 18 and ft=((hole* or gap* or aperture* or slot*) near (align* or (line up*) or misalign* or friction*)) (Results 89)
Search 20: 19 not (17 or 16 or 14 or 12 or 10 or 7 or 4 or 3) (Results 79)
Search 21: 13 and ft=((hole* or gap* or aperture*) near (align* or (line up*))) (Results 25)
Search 22: pn=(us5376101) (Results 1)
Search 23: ctf 22 or ctb 22 (Results 308)
Search 24: 23 and ft=((hole* or gap* or aperture* or slot*) near (align* or (line up*) or misalign* or friction*)) (Results 78)
Search 25: 24 not (22 or 21 or 19 or 17 or 16 or 14 or 12 or 10 or 7 or 4 or 3) (Results 57)

2 March-
Search 26: ic=(A61B17/03* OR A61B17/04*) (Results 44372)
Search 27: cpc=(A61B17/03* OR A61B17/04* OR A61B17/56* OR A61B17/0467* OR A61B17/8869* OR A61B17/0482* OR A61B17/0469* OR A61B2017/0496*) (Results 45941)
Search 28: 26 or 27 (Results 76570)
Search 29: 28 and ft=((hole* or gap* or aperture* or slot*) near (align* or (line up*) or misalign* or friction* or clamp* or clutch*)) (Results 9859)
Search 30: 29 and ft=((suture* or thread* or cable* or cord*) near (tension* or tighten* or increment* or ratchet*)) (Results 1998)
Search 31: 30 and ft=(button* or actuator* or (spring* near load*)) (Results 1019)
Search 32: 31 and ft=(spring*) (Results 873)
Search 33: 32 and ft=(suture* near (lock* or stop* or restrain*)) (Results 238)
Search 34: 33 not (24 or 22 or 21 or 19 or 17 or 16 or 14 or 12 or 10 or 7 or 4 or 3) (Results 156)
Search 35: ft=(suture* near (tension* or tighten*)) (Results 6198)
Search 36: 35 and ft=((hole* or gap* or aperture* or slot* or groove*) near (align* or (line up*) or misalign* or friction*)) (Results 1081)
Search 37: 36 and ft=(suture* near (lock* or stop* or restrain*)) (Results 452)
Search 38: 37 and ft=(spring*) (Results 317)
Search 39: 38 and ft=(spring* near (load* or actuat*)) (Results 154)
Search 40: 39 not (33 or 24 or 22 or 21 or 19 or 17 or 16 or 14 or 12 or 10 or 7 or 4 or 3) (Results 20)

Electronic Database Searched	Google
Files Searched	Google Patents
Date Conducted	25 February-2 March 2022 (25.02.-02.03.2022)
Search Logic:	

Suture tensioning through holes
About 12,200 results

Suture tensioning through holes ratchet
About 4,700 results

Suture tensioning through holes lock
About 12,000 results

Suture retainer lock hole misalign
About 6,350 results

Electronic Database Searched	Google
Files Searched	Google Web
Date Conducted	25 February-2 March 2022 (25.02.-02.03.2022)
Search Logic:	

Suture tensioner
About results

Suture tensioner inari medical
About results

Flowstasis suture retention
About results

Large bore suture retention

(19)中华人民共和国国家知识产权局

(12)发明专利申请

(10)申请公布号 CN 103764049 A
(43)申请公布日 2014.04.30

(21)申请号 201280036998.X
(22)申请日 2012.07.25
(30)优先权数据
13/191,306 2011.07.26 US
13/543,657 2012.07.06 US
(85)PCT国际申请进入国家阶段日
2014.01.24
(86)PCT国际申请的申请数据
PCT/US2012/048158 2012.07.25
(87)PCT国际申请的公布数据
WO2013/016435 EN 2013.01.31
(71)申请人 迈克尔·P·马克思
地址 美国加利福尼亚州
申请人 莱克·奎
(72)发明人 迈克尔·P·马克思 莱克·奎
(74)专利代理机构 上海专利商标事务所有限公司 31100
代理人 张兰英
(51)Int.Cl.
A61B 17/22(2006.01)
A61M 25/00(2006.01)

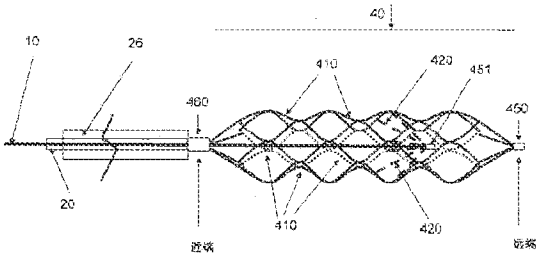
权利要求书4页 说明书29页 附图58页

(54)发明名称

血管内血栓切除装置及其使用方法

(57)摘要

提供一种用于加大或恢复体腔内流量的装置和方法。该装置和方法可通过从血管内去除凝块和/或重新打开血管来治疗像中风的病症。该装置可具有可扩张隔室，该可扩张隔室包括可重构元件和支承元件。支承元件可调节可重构元件的径向力和构造，由此允许从血管有效地去除凝块和/或重新打开血管，而对血管的损伤最少或没有损伤。或者，该装置可具有接合隔室，该接合隔室包括远侧接合元件和近侧接合元件。血管内的凝块可接合到远侧接合元件和近侧接合元件内和/或之间。可调节接合元件中的一个或两个的位置以及接合元件之间的间距以确保与凝块或闭塞物的接合。



CN 103764049 A

1. 一种用于体腔的装置，所述装置包括：

推送管件和可扩张隔室；

其中，所述可扩张隔室包括：

控制元件，所述控制元件包括近端和远端；

可重构元件，所述可重构元件与支承元件和所述控制元件相关联；以及

支承元件，所述支承元件与所述控制元件和所述可重构元件相关联，其中，所述支承元件构造成调节所述可重构元件的径向力和构造。

2. 如权利要求 1 所述的装置，其特征在于，所述控制元件包括线材、线缆或编织物。

3. 如权利要求 1 所述的装置，其特征在于，所述可重构元件和 / 或所述支承元件包括多个线材。

4. 如权利要求 3 所述的装置，其特征在于，所述可重构元件能自扩张到松弛的可扩张状态，以形成隔室或筐状物。

5. 如权利要求 4 所述的装置，其特征在于，所述可重构元件包括多个单元，且单元的尺寸和形成所述单元的线材的厚度在所述可重构元件内变化。

6. 如权利要求 1 所述的装置，其特征在于，所述支承元件呈支杆的形式，所述支杆由与所述可重构元件相同的材料制成，并且自动连接到所述可重构元件。

7. 如权利要求 1 所述的装置，其特征在于，所述支承元件呈丝网或编织物的形式。

8. 如权利要求 1 所述的装置，其特征在于，所述推送管件连接到所述可扩张隔室。

9. 如权利要求 1 所述的装置，其特征在于，所述控制元件被所述推送管件围绕，并能在所述推送管件内自由运动。

10. 如权利要求 1 所述的装置，其特征在于，所述支承元件包括第一构造和第二构造，所述支承元件和所述控制元件之间的角度在所述第一构造下比在所述第二构造下小。

11. 如权利要求 1 所述的装置，其特征在于，所述支承元件包括第一构造和第二构造，所述第一构造具有比所述第二构造的外直径小的外直径。

12. 如权利要求 10 和 11 所述的装置，其特征在于，所述控制元件向远侧方向突出使所述支承元件过渡到所述第一构造，因而，所述可重构元件的径向力减小。

13. 如权利要求 10 和 11 所述的装置，其特征在于，所述控制元件向近侧方向突出使所述支承元件过渡到所述第二构造，因而，所述可重构元件的径向力增大。

14. 如权利要求 1 所述的装置，其特征在于，所述装置构造成去除阻塞血管的闭塞物 / 凝块、打开血管的阻塞部段和 / 或增大血管内的流量。

15. 如权利要求 1 所述的装置，其特征在于，所述可重构元件的远端连结从而形成端部闭合的可重构元件，或者不连结从而形成端部敞开的可重构元件。

16. 如权利要求 1 所述的装置，其特征在于，所述可重构元件的各侧连结从而形成各侧闭合的可重构元件，或者不连结从而形成各侧敞开的可重构元件。

17. 如权利要求 1 所述的装置，其特征在于，所述支承元件包括多个线材，且所述线材能在所述近端和远端之间延伸，并且基本上被所述可重构元件围绕。

18. 如权利要求 1 所述的装置，其特征在于，所述可重构元件和所述支承元件呈丝网的形式，所述丝网能在所述近端和远端之间延伸，且所述支承元件基本上被所述可重构元件围绕，由此形成双层的可重构元件或可扩张隔室。

19. 如权利要求 1 所述的装置，其特征在于，所述可重构元件包括大致平行对准的多个直线形线材和呈大致圆形的多个线材，且所述支承元件包括与所述可重构元件和所述控制元件相关联的至少两个线材，由此形成伞形的可扩张隔室。

20. 如权利要求 1 所述的装置，其特征在于，所述可重构元件的远端和所述支承元件的远端不连接，并且独立运动。

21. 如权利要求 1 所述的装置，其特征在于，非创伤性柔性线圈附连到所述可重构元件的所述远侧末端。

22. 如权利要求 1 所述的装置，其特征在于，所述装置包括远侧可扩张结构和近侧可扩张结构。

23. 如权利要求 22 所述的装置，其特征在于，所述第一可扩张结构包括可重构元件、控制元件以及可选地支承元件。

24. 如权利要求 22 所述的装置，其特征在于，所述第二可扩张结构包括可重构元件和可选地封闭元件。

25. 如权利要求 22 所述的装置，其特征在于，所述远侧可扩张结构和所述近侧可扩张结构之间的间距可调。

26. 一种去除存在于血管的第一位置的闭塞物 / 凝块的方法，所述方法包括 ：

将如权利要求 1 所述的装置引入所述血管 ；

将所述装置定位在所述血管的所述第一位置 ；

通过调节所述装置的可重构元件的径向力和 / 或构造而与所述闭塞物 / 凝块接合 ；以及

从所述第一位置去除所述闭塞物 / 凝块。

27. 如权利要求 26 所述的方法，其特征在于，去除所述闭塞物 / 凝块还包括选自如下组中的一个或多个 ：

使所述闭塞物 / 凝块至少部分地与所述装置接合 ；

将所述闭塞物 / 凝块拆解成小尺寸碎屑，并收集所述碎屑中的至少一部分 ；以及

使所述血管的区域扩张。

28. 如权利要求 26 所述的方法，其特征在于，所述方法构造成应用于治疗中风。

29. 一种增大血管内流量的方法，所述方法包括 ：

将如权利要求 1 所述的装置引入所述血管 ；

将所述装置定位在大约所述血管的需要增大流量的第一位置 ；以及

调节所述装置的可重构元件的径向力和 / 或构造以使所述第一位置的区域扩张。

30. 一种去除存在于血管的第一位置的闭塞物 / 凝块的方法，所述方法包括 ：

将如权利要求 1 所述的装置引入所述血管 ；

将所述装置定位在大约所述血管的所述第一位置 ；

通过所述控制元件的近侧运动使与所述可重构元件相关联的支承元件延伸来支持所述可重构元件的扩张状态 ；

通过所述控制元件的近侧运动使与所述可重构元件相关联的支承元件延伸来进一步支持所述可重构元件的更扩张状态 ；

用于处于扩张状态的所述可重构元件 / 可扩张隔室来抓取所述闭塞物 / 凝块 ；

通过使所述控制元件向远侧运动来使所述可重构元件的构造向更松弛状态变化；以及

从所述第一位置去除所述闭塞物 / 凝块。

31. 一种去除存在于血管的第一位置的闭塞物 / 凝块的方法，所述方法包括：

将如权利要求 22 所述的装置引入所述血管；

将所述装置定位在所述血管的位置远侧；

向近侧拉动推送管件，以抓取处于扩张状态的两个可扩张结构之间的闭塞物 / 凝块；

通过所述控制元件的近侧运动使与所述可重构元件相关联的支承元件延伸来支持所述可重构元件的扩张状态；

用近侧可扩张结构来抓取所述闭塞物 / 凝块；

用远侧可扩张结构来捕获闭塞物 / 凝块碎屑；

在拉动所述控制元件时可选地收回所述装置以增大所述可扩张结构的径向力，并进一步支持所述可扩张结构的扩张状态；以及

从所述第一位置去除所述闭塞物 / 凝块。

32. 一种用于体腔的装置，所述装置包括：

微型导管，所述微型导管包括近端和远端；

管件隔室；

中心线；以及

接合隔室，

其中，所述接合隔室包括：

近侧接合元件；以及

远侧接合元件，

其中，所述远侧接合元件是与所述中心线相关联的可扩张元件，且所述近侧接合元件和所述远侧接合元件之间的间距可调。

33. 如权利要求 32 所述的装置，其特征在于，所述远侧接合元件包括形成支架的多个线材或支杆。

34. 如权利要求 32 所述的装置，其特征在于，所述远侧接合元件与延伸到所述装置的近端的中心线固定，由此，所述远侧接合元件在体腔内的位置由所述中心线的运动来控制。

35. 如权利要求 32 所述的装置，其特征在于，所述近侧接合元件是包括多个线材或支杆的可扩张元件，并能扩张成漏斗状或锥形结构。

36. 如权利要求 32 所述的装置，其特征在于，所述近侧接合元件与所述中心线相关联，并沿所述中心线运动。

37. 如权利要求 36 所述的装置，其特征在于，所述近侧接合元件与延伸到所述装置的近端的管件隔室固定，由此，所述近侧接合元件在体腔内的位置由所述管件隔室的运动来控制。

38. 如权利要求 36 所述的装置，其特征在于，所述近侧接合元件不与所述管件隔室固定，并构造成沿所述中心线自由运动。

39. 如权利要求 32 所述的装置，其特征在于，所述近侧接合元件位于所述微型导管的远端处。

40. 如权利要求 39 所述的装置，其特征在于，所述近侧接合元件不是所述微型导管的

一体部分，而是固定在所述微型导管的所述远端处。

41. 如权利要求 39 所述的装置，其特征在于，所述近侧接合元件是可膨胀或接合元件。

42. 如权利要求 39 所述的装置，其特征在于，所述近侧接合元件是微型导管的一体部分。

43. 如权利要求 42 所述的装置，其特征在于，所述近侧接合元件包括所述微型导管的所述远端的构造成根据施加于所述微型导管的所述远端的压力来改变形状的部分。

44. 如权利要求 42 所述的装置，其特征在于，所述近侧接合元件包括所述微型导管的所述远端的包括微型导管末端的部分和覆盖所述微型导管末端的薄管件层，其中，所述近侧接合元件的至少一部分构造成在移除所述薄管件层时改变形状。

45. 如权利要求 32 所述的装置，其特征在于，所述管件隔室包括推送管件和连接管件。

46. 如权利要求 32 所述的装置，其特征在于，所述管件隔室由一件具有可变刚度的管件制成，因而，所述管件隔室的远端是软的和柔性的，因此，所述装置能通过曲折的解剖体，同时所述管件隔室的近端刚硬到加强所述装置的可推送性。

47. 如权利要求 32 所述的装置，其特征在于，所述中心线包括线材、线缆或编织物。

48. 如权利要求 32 所述的装置，其特征在于，所述近侧接合元件和所述远侧接合元件之间的间距约在 0 到 50 毫米的范围内可调。

49. 如权利要求 32 所述的装置，其特征在于，所述近侧接合元件包括面向所述远侧接合元件的远端，所述近侧接合元件的所述远端被弯曲、倒圆或弄成圆滑。

50. 如权利要求 32 所述的装置，其特征在于，所述近侧接合元件包括面向所述远侧接合元件的远端，所述近侧接合元件的所述远端构造成不与所述体腔的表面直接接触。

51. 一种从体腔内的第一位置去除闭塞物的至少一部分的方法，所述方法包括：

将如权利要求 32 所述的装置引入所述体腔内；

将所述装置定位在大约所述第一位置；

使所述闭塞物的至少一部分与所述接合元件接合；以及

从所述第一位置去除接合的闭塞物。

52. 如权利要求 51 所述的方法，其特征在于，所述接合包括：

调节所述近侧接合元件和所述远侧接合元件中的一个或两个的位置以使所述闭塞物的至少一部分与所述近侧接合元件和 / 或所述远侧接合元件接合。

53. 如权利要求 51 所述的方法，其特征在于，所述接合包括：

调节所述近侧接合元件和所述远侧接合元件之间的间距以使所述闭塞物的至少一部分接合到所述近侧接合元件和所述远侧接合元件之间。

54. 如权利要求 51 所述的方法，其特征在于，所述方法还包括：

在接合之后，锁定所述近侧接合元件和所述远侧接合元件中的一个或两个的位置。

55. 如权利要求 51 所述的方法，其特征在于，在所述接合时，所述闭塞物的至少一部分与选自如下组的任何部件接合：所述体腔的表面、所述微型导管、所述管件隔室、所述近侧接合元件、所述远侧接合元件及其任何组合。

血管内血栓切除装置及其使用方法

[0001] 发明背景

技术领域

[0002] 本发明总地涉及用于诸如人体血管之类的体腔内的装置及其使用方法。

[0003] 相关技术的说明

[0004] 会至少部分地由于血管的阻塞或闭塞或凝块而造成多种病症。这种病症的熟知示例包括但不限于是中风。其它这种病症包括心肌梗塞、下肢缺血、血管移植物和旁路的闭塞或凝块以及静脉血栓。

[0005] 中风经常被称为“脑部侵袭”。这由于脑部供血紊乱经常会造成脑部功能的快速和明显丧失。由此，运动无力、语言的使用、视觉和许多其它生物功能会暂时地或不可逆地受到影响。中风是出血性的(由于出血)或者缺血性的(由于供血不足)。大部分中风是缺血性的。估计每年在美国发生约 700000 起缺血性中风。缺血性中风的大多数起因包括在供给脑部的血管中形成血栓(结块)或者从诸如心脏的另一源至供给脑部的血管的栓塞物。有时，在脑部中有预先存在的血管狭窄之处形成血栓，通常形成动脉粥样硬化疾病。

[0006] 急性缺血性中风的治疗集中于尽可能快地重新建立至脑部的血流。治疗包括使用诸如组织纤溶酶原激活剂(tPA)、血栓溶解剂(降凝块药)之类的药物。最近，食品与药品管理局已许可诸如 Merci 血栓切除装置(加利福尼亚州山景城的集中医药公司(Concentric Medical)) 以及 Penumbra 吸入血栓切除导管(加利福尼亚州阿拉米达的派母巴公司(Penumbra, Inc.)) 以及 Solitaire 血栓切除装置(加利福尼亚州欧文的 ev3 神经血管公司(Neurovascular))的装置用于急性中风的血栓切除。这些装置不总是能实现完全再通。有时，它们根本不能打开血管或者仅可部分地打开血管。它们工作起来还耗时，在重新打开血管之前需要装置多次进入颅内循环。此外，它们会弄碎凝块，并使得凝块的某些部分会在脑循环中运动到更远侧。需要具有以更快速方式执行的具有高完全再通率以及完全或部分凝块捕获功能的装置。

发明内容

[0007] 根据本发明的一方面，提供用于体腔内的装置。该装置可包括推送管件和可扩张隔室。根据一些实施例，可扩张隔室可包括包含近端和远端的控制元件、可重构元件和支承元件，该可重构元件可与支承元件和控制元件相关联，支承元件可与控制元件和可重构元件相关联。根据一些其它实施例，支承元件可构造成调节可重构元件的径向力和构造。

[0008] 在前述装置中，控制元件在至少一些实施例中可包括线材、线缆、或编织物。在一些其它实施例中，可重构元件和 / 或所述支承元件可包括多个线材。在又一些其它实施例中，可重构元件能自扩张到松弛的可扩张状态，以形成隔室或筐状物。在另一些其它实施例中，可重构元件包括多个单元，且单元的尺寸和形成所述单元的线材或支杆的尺寸可在可重构元件内变化。

[0009] 在一些实施例中，前述装置的支承元件呈支杆的形式，该支杆由与可重构元件相

同的材料制成，并且自动连接到可重构元件。在一些其它实施例下，支承元件可以呈丝网或编织物的形式。在一些替代实施例中，推送管件可连接到可扩张隔室。在又一些其它实施例下，控制元件可被推送管件围绕，并能在推送管件内自由运动。

[0010] 在一些其它实施例中，前述装置的支承元件可包括第一构造和第二构造，支承元件和控制元件之间的角度在所述第一构造比在第二构造下小。在某些实施例中，支承元件可包括第一构造和第二构造，所述第一构造的外直径比第二构造的外直径小。

[0011] 根据又一些其它实施例，控制元件向远侧方向突出使支承元件过渡到第一构造，因而，可重构元件的径向力或构造可减小。在一些替代实施例中，控制元件向近侧方向突出可使支承元件过渡到第二构造，因而，可重构元件的径向力或构造可增大。在某些方面，该装置可构造成去除阻塞血管的闭塞物 / 凝块、打开血管的阻塞部段和 / 或增大血管内的流量。

[0012] 根据某些方面，可重构元件的远端可连结从而形成端部闭合的可重构元件，或者不连结从而形成端部敞开的可重构元件。在一些实施例中，可重构元件的各侧可连结从而形成各侧闭合的可重构元件，或者不连结从而形成各侧敞开的可重构元件。在某些实施例中，支承元件包括多个线材，且这些线材能在所述近端和远端之间延伸，并且基本上被可重构元件围绕。

[0013] 在一些其它方面，前述装置的可重构元件和支承元件呈丝网的形式，该丝网能在近端和远端之间延伸，且支承元件基本上被可重构元件围绕，由此形成双层的可重构元件或可扩张隔室。在一些实施例中，可重构元件可包括大致平行对准的多个直线形线材和呈大致圆形的多个线材，且支承元件包括与可重构元件和控制元件相关联的至少两个线材，由此形成伞形的可扩张隔室。

[0014] 根据又一些其它方面，可重构元件的远端和支承元件的远端不连接，并且能独立运动。在某些实施例中，非创伤性线圈可附连到可重构元件的远侧末端。

[0015] 根据又一些其它方面，该装置包括远侧可扩张结构和近侧可扩张结构。在一些实施例中，第一可扩张结构包括可重构元件、控制元件和可选地支承元件。在一些其它实施例中，第二可扩张结构包括可重构元件和可选地封闭元件。在某些实施例中，远侧和近侧可扩张结构之间的间距可调。

[0016] 根据又一些其它方面，提供了一种在血管的第一位置去除闭塞物 / 凝块的方法。该方法可包括将根据至少一些实施例的前述装置引入血管内，将装置定位在血管的第一位置，通过调节装置的可重构元件的径向力和 / 或构造而与闭塞物 / 凝块接合；以及从第一位置去除闭塞物 / 凝块。在一些实施例中，去除闭塞物 / 凝块还包括选择如下的一个或多个：使闭塞物 / 凝块至少部分地与装置接合，将闭塞物 / 凝块拆解成小尺寸碎屑，并收集碎屑中的至少一部分；以及使血管的区域扩张。在一些其它实施例中，该方法可构造成应用于治疗中风。

[0017] 根据又一些其它方面，提供一种增大血管内流量的方法。该方法可包括将根据至少一些实施例的前述装置引入血管内，将装置定位在血管的需要增大流量的第一位置附近；以及调节装置的可重构元件的径向力和 / 或构造以使第一位置的区域扩张。

[0018] 根据又一些其它方面，提供了一种在血管的第一位置去除闭塞物 / 凝块的方法。该方法可包括将根据至少一些实施例的前述装置引入血管内，将装置定位在血管的第一位

置附近，通过控制元件的近侧运动使与可重构元件相关联的支承元件延伸来支持可重构元件的扩张状态，通过控制元件的近侧运动使与可重构元件相关联的支承元件延伸来进一步支持可重构元件的更扩张状态，用处于扩张状态的可重构元件 / 可扩张隔室来抓取闭塞物 / 凝块，通过使控制元件向远侧运动来使可重构元件的构造向松弛状态变化，以及从第一位置去除闭塞物 / 凝块。

[0019] 根据又一些其它方面，提供了一种在血管的第一位置去除闭塞物 / 凝块的方法。该方法可包括将根据至少一些实施例的前述装置引入血管内，将装置定位在血管的位置远侧；向近侧拉动推送管件，以抓取处于扩张状态的两个可扩张结构之间的闭塞物 / 凝块，通过控制元件的近侧运动使与可重构元件相关联的支承元件延伸来支持可重构元件的扩张状态，用近侧可扩张结构来抓取闭塞物 / 凝块，用远侧可扩张结构来捕获闭塞物 / 凝块碎屑；在拉动控制元件时可选地收回装置以增大可扩张结构的径向力，并进一步支持可扩张结构的扩张状态，以及从第一位置去除闭塞物 / 凝块。

[0020] 根据本发明的又一方面，提供用于体腔内的装置。该装置可包括微型导管，该微型导管包括近端和远端、管件隔室、中心线以及接合隔室。接合隔室可包括近侧接合元件和远侧接合元件。远侧接合元件是与中心线相关联的可扩张元件，且近侧接合元件和远侧接合元件之间的间距可调。

[0021] 在一些实施例中，前述装置的远侧接合元件可包括形成支架的多个线材或支杆。远侧接合元件可相对于延伸到装置近端的中心线固定，由此，远侧接合元件在体腔内的位置由中心线的运动来控制。

[0022] 在一些其它实施例中，前述装置的近侧接合元件可以是包括多个线材或支杆的可扩张元件，并能扩张成漏斗状或锥形结构。近侧接合元件可与中心线相关联，并沿中心线运动。在一些替代实施例中，近侧接合元件相对于延伸到装置近端的管件隔室固定，由此，近侧接合元件在体腔内的位置由管件隔室的运动来控制。在又一些替代实施例中，近侧接合元件可以相对于管件隔室不固定，并构造成沿中心线自由运动。

[0023] 在又一些替代实施例中，近侧接合元件可位于微型导管的远端处。在某些实施例中，近侧接合元件不是微型导管的一体部分，而是固定在微型导管的远端处。

[0024] 在又一些其它实施例中，近侧接合元件可以是可膨胀或接合元件。在某些实施例中，近侧接合元件可以是微型导管的一体部分。

[0025] 在又一些其它实施例中，前述装置的近侧接合元件可包括微型导管的远端的构造成根据施加于微型导管远端的压力来改变形状的部分。在某些实施例中，近侧接合元件包括微型导管的远端的包括微型导管末端的部分和覆盖微型导管末端的薄管件层，其中，近侧接合元件的至少一部分构造成在移除薄管件层时改变形状。

[0026] 在又一些其它实施例中，任何前述装置的管件隔室可包括推送管件和连接管件。

[0027] 在又一些其它实施例中，装置的管件隔室可由一件具有可变刚度的管件制成，因而，管件隔室的远端是软和柔性的，因此，装置能通过曲折的解剖体，同时管件隔室的近端刚硬到加强装置的可推送性。

[0028] 在又一些其它实施例中，任何装置的中心线可包括线材、线缆或编织物。近侧接合元件和远侧接合元件之间的间距在约 0 到 50 毫米的范围内可调。

[0029] 在又一些其它实施例中，近侧接合元件可包括面向所述远侧接合元件的远端，近

侧接合元件的所述远端被弯曲、倒圆或弄成圆滑。在替代实施例中，装置的近侧接合元件包括面向远侧接合元件的远端，近侧接合元件的远端构造成不与体腔的表面直接接触。

[0030] 根据本发明的另一方面，提供一种从体腔内的第一位置去除闭塞物的至少一部分的方法。该方法可包括将前述装置引入体腔内，将装置定位在第一位置附近；使闭塞物的至少一部分与接合元件接合；以及从第一位置去除接合的闭塞物。

[0031] 在一些实施例中，该方法的接合步骤可包括调节近侧接合元件和所述远侧接合元件中的一个或两个的位置，以使闭塞物的至少一部分与近侧接合元件和/或远侧接合元件接合。在一些其它实施例中，该方法的接合步骤可包括调节近侧接合元件和远侧接合元件中的一个或两个的位置，以使闭塞物的至少一部分接合到近侧接合元件和远侧接合元件之间。

[0032] 在一些其它实施例中，该方法还可包括在接合之后锁定近侧接合元件和远侧接合元件中的一个或两个的位置。在某些实施例中，在前述方法的接合步骤中，闭塞物的至少一部分与选择如下组的任何部件接合：体腔的表面、微型导管、管件隔室、近侧接合元件、远侧接合元件及其任何组合。

附图说明

[0033] 图 1 示出根据本发明的一些实施例的装置的非限制性说明性示例。

[0034] 图 2A-F 示出根据本发明的一些实施例的装置的特别是当该装置位于体腔内时的另一非限制性说明性示例，并示出根据本发明的一些实施例的用于从血管去除闭塞物/凝块和/或使血管扩张的机构的一些非限制性示例。

[0035] 图 3A-D 示出根据本发明的一些实施例的装置的又一非限制性说明性示例。

[0036] 图 4A-C 示出根据本发明的一些实施例的装置的另一非限制性说明性示例。

[0037] 图 5A-C 示出根据本发明的一些实施例的又一非限制性说明性装置。

[0038] 图 6A-C 示出根据本发明的一些实施例的装置的另一非限制性说明性示例。

[0039] 图 7A-D 示出根据本发明的一些实施例的装置的又一非限制性说明性示例。

[0040] 图 8A-D 示出根据本发明的一些实施例的装置的又一非限制性说明性示例。

[0041] 图 9A-E 示出根据本发明的一些实施例的装置的又一非限制性说明性示例。

[0042] 图 10A-D 示出根据本发明的一些实施例的装置的又一非限制性说明性示例。

[0043] 图 11 示出根据本发明的一些实施例的装置的另一非限制性说明性示例。

[0044] 图 12A-D 示出根据本发明的一些实施例的装置的又一非限制性说明性示例。

[0045] 图 13 示出根据本发明的一些实施例的装置的另一非限制性说明性示例。

[0046] 图 14A-D 示出根据本发明的一些实施例的制成装置的过程的非限制性说明性示例。

[0047] 图 15 示出根据本发明的一些实施例的包括装置的设备的非限制性说明性示例。

[0048] 图 16 示出根据本发明的一些实施例的装置的另一非限制性说明性示例。

[0049] 图 17A-B 示出根据本发明的一些实施例的装置的另一非限制性说明性示例。

[0050] 图 18 示出根据本发明的一些实施例的包括装置的设备的非限制性说明性示例。

[0051] 图 19A-H 示出根据本发明的一些实施例的去除血闭塞物/血凝块或者使血管扩张的方式的一些非限制性说明性示例。

[0052] 图 20A, A', B 和 C 示出根据本发明的装置的非限制性说明性示例。图 20A 示出装置的打开状态，图 20B 示出装置的闭合状态(远侧接合元件和近侧接合元件之间)，而图 20C 示出具有远侧接合元件的端部闭合的远侧末端的装置。图 20A' 示出近侧接合元件由管件构成的实施例。

[0053] 图 21A-C 示出根据本发明的用于从体腔去除闭塞物或一部分闭塞物的方法的非限制性说明性示例。

[0054] 图 22A-D 示出根据本发明的用于从体腔去除闭塞物或一部分闭塞物的方法的又一非限制性说明性示例。

[0055] 图 23A-F 示出根据本发明的用于从体腔去除闭塞物的方法的一些其它非限制性说明性实施例。

[0056] 图 24 示出根据本发明的系统的非限制性说明性实施例。

[0057] 图 25 示出根据本发明的系统的又一非限制性说明性实施例。

[0058] 图 26A-B 示出根据本发明的装置的另一非限制性说明性实施例。图 26A 示出装置的打开状态，而图 26B 示出装置的闭合状态。

[0059] 图 27A-C 示出根据本发明的用于从体腔去除闭塞物或一部分闭塞物的方法的非限制性说明性示例。

[0060] 图 28 示出根据本发明的系统的另一非限制性说明性实施例。

[0061] 图 29 示出根据本发明的系统的另一非限制性说明性实施例。

[0062] 图 30A-B 示出根据本发明的装置的又一非限制性说明性实施例。图 30A 示出装置的打开状态，而图 30B 示出装置的闭合状态。

[0063] 图 31A-C 示出根据本发明的用于从体腔去除闭塞物的方法的又一非限制性说明性实施例。

[0064] 图 32A-B 示出根据本发明的装置的又一非限制性说明性实施例。图 32A 示出装置的打开状态，而图 32B 示出装置的闭合状态，在该闭合状态下，闭塞物与装置接合。

[0065] 图 33A-B 示出根据本发明的装置的又一非限制性说明性实施例。图 33A 示出装置的打开状态，而图 33B 示出装置的闭合状态，在该闭合状态下，闭塞物与装置接合。

[0066] 图 34A-B 示出根据本发明的装置的又一非限制性说明性实施例。图 34A 示出装置的打开状态，而图 34B 示出装置的闭合状态，在该闭合状态下，闭塞物与装置接合。

[0067] 图 35 示出根据本发明的装置的又一非限制性说明性实施例。特别是，附图示出装置的近侧部的替代实施例。

[0068] 图 36A-C 示出根据本发明的装置的又一非限制性说明性实施例。特别是，附图示出微型导管包括可转变成不同形状的末端的实施例。

[0069] 图 37A-D 示出根据本发明的特别是使用图 36 中所示的装置从体腔去除闭塞物的方法的非限制性说明性实施例。

[0070] 图 38A-D 示出根据本发明的装置的又一非限制性说明性实施例，在该实施例中，微型导管在其大约远端处包括可转变末端。

[0071] 图 39A-B 示出根据本发明的装置的另一非限制性说明性实施例，在该实施例中，微型导管在其大约远端处包括可转变末端。

[0072] 图 40A-B 示出根据本发明的装置的另一非限制性说明性实施例，在该实施例中，

微型导管在其大约远端处包括可转变末端。

[0073] 图 41A-C 示出根据本发明的装置的又一非限制性说明性实施例，在该实施例中，微型导管在其大约远端处包括可转变末端。

[0074] 图 42A-B 示出根据本发明的装置的又一非限制性说明性实施例，在该实施例中，微型导管在其大约远端处包括可转变末端。

[0075] 图 43A-B 示出根据本发明的装置的又一非限制性说明性实施例，在该实施例中，微型导管在其大约远端处包括可转变末端。

[0076] 图 44A-B 示出根据本发明的装置的又一非限制性说明性实施例，在该实施例中，微型导管在其大约远端处包括可转变末端。

[0077] 图 45A-B 示出根据本发明的装置的又一非限制性说明性实施例，在该实施例中，微型导管在其大约远端处包括可转变末端。

[0078] < 用于在附图中标示主要部件的附图标记 >

[0079] 1: 体腔表面

[0080] 5: 引导线

[0081] 10: 控制元件 / 中心线

[0082] 20: 推送管件

[0083] 21: 内推送管件

[0084] 22: 中间推送管件

[0085] 23: 外推送管件

[0086] 24: 远侧推送管件

[0087] 25: 近侧推送管件

[0088] 26: 引导器套管

[0089] 30: 微型导管

[0090] 31: 连接管件

[0091] 35: 微型导管毂

[0092] 40: 可扩张隔室

[0093] 41: 近侧元件连接件

[0094] 42: 近侧元件连结介质

[0095] 43: 外部近侧元件连接件

[0096] 50: 腔体表面

[0097] 60: 闭塞物 / 凝块

[0098] 65: 近侧接合元件

[0099] 70: 近侧元件标记

[0100] 80: 远侧元件连接件

[0101] 81: 远侧元件连结介质

[0102] 82: 外部远侧元件连接件

[0103] 90: 远侧接合元件

[0104] 100: 远侧元件标记

[0105] 120: 远侧部件控制手柄

[0106] 130：接头

[0107] 140：近侧部件的远侧连接件

[0108] 150：近侧部件的连接线

[0109] 160：近侧部件的段连接件

[0110] 170：可膨胀或可扩张元件

[0111] 180：注射通道

[0112] 190：注射器

[0113] 195：注射液体

[0114] 200：可转变的微型导管远侧末端

[0115] 210：外套管

[0116] 220：线材

[0117] 230：通道

[0118] 410：可重构元件

[0119] 420：支承元件

[0120] 425：封闭元件

[0121] 430：连接件

[0122] 431：外部连接件

[0123] 432：内部连接件

[0124] 440：标记

[0125] 450：远端连接件

[0126] 451：支承元件远侧连接件

[0127] 452：支承元件外部远侧连接件

[0128] 453：支承元件内部远侧连接件

[0129] 455：近侧可扩张结构的连接件

[0130] 460：近端连接件

[0131] 461：外部近端连接件

[0132] 462：内部近端连接件

[0133] 463：连接件连结介质(粘合剂、焊料等)

[0134] 470：调节管

[0135] 471：滑动管

[0136] 475：长内管

[0137] 480：高峰位置

[0138] 490：控制元件手柄管件

[0139] 520：连接线 / 抗拉伸线

[0140] 540：线圈

[0141] 550：远侧可扩张结构 / 远侧结构

[0142] 560：近侧可扩张结构 / 近侧结构

[0143] 570：连结介质

[0144] 580：推送管件连接点

[0145] 495：远侧柔性线圈

具体实施方式

[0146] 本发明总地涉及用于诸如血管的体腔内的装置及其使用方法。在一些实施例中，装置可定位在体腔内，以使内腔扩开和/或从内腔去除闭塞物/凝块。尽管装置位于体腔需要治疗的部分内，但操作者可操纵该装置以使内腔扩张和/或与闭塞物/凝块接合。

[0147] 本发明的一些方面提供构造成治疗血管内病症、包括但不限于是中风的装置和方法。在一些实施例中，装置和方法构造成通过从血管去除闭塞物/凝块和/或使具有一定潜在狭窄的血管重新打开以在血管内恢复血流来治疗与缺血性中风相关的病症。

[0148] 血管的非限制性示例可包括动脉、静脉和起到循环系统的部件作用的手术植入的移植物和旁路。

[0149] 术语“闭塞物”或“凝块”一般包括部分或完全阻碍血管内腔的任何物质。闭塞物/凝块减缓或阻碍了流经内腔的流动(例如，血流或任何其它生物流体)。闭塞物/凝块的示例可包括存在于血管以及脂肪或外来物体内的血闭塞物/血凝块和动脉粥样硬化斑块。

[0150] 术语“中风”一般包括部分地由于扰乱对脑部供血而引起的病症。扰乱可由血液的阻塞(例如，缺血性中风)和/或出血(例如，出血性中风)引起。特别是，缺血性中风会由于血管的部分或基本上闭塞/结块而引起。缺血性病症的治疗可应用于在脑部以及诸如心脏的其它组织内存在的血管。由此，本申请中公开的装置和方法不限于用于任何特定器官，而是可应用于需要使内腔扩开或去除闭塞物/凝块以恢复血流的任何人体血管。此外，根据本发明的装置和方法可用于治疗会造成除了局部缺血外的其它病症的静脉闭塞物/凝块。

[0151] 通过导管将该装置引入血管内。“导管”一般包括能插入体腔内的管状结构，由此允许将装置和/或化学物质给送到需要进行治疗的人体区域。术语“微型导管”可指构造成在诸如血管的相对较小的体腔内给送的导管。

[0152] 术语“管件”一般是指可包括用于保持和/或传导被包含的物体的中空空间(例如，圆筒形)的诸如导管的管状物体。管件可由各种材料制成，诸如金属、塑料、玻璃或其任何组合。

[0153] 术语“线材”一般是指拉成柔性细线或细杆的金属或非金属物体。线材的长度和厚度可从纳米级大幅变化到米级。

[0154] 术语“支架”一般是指暂时或永久地放置于例如血管、通道或管道的体腔内以治愈或解除障碍物的管状支承件。支架可由一个或多个线材构成。在一些情况下，支架可以呈支杆的形式，支杆一般是指形成框架的一部分并设计成抗压缩的杆或条。在一些其它情况下，支架可以呈线网或丝网的形式。

[0155] 此外，可以在不影响本发明范围的情况下进行对于本领域技术人员来说显然的许多不同变化和改型，以适当地用于特定治疗病症。因此，不仅在本申请中公开的示例、而且这种显然的变化和改型也应包含在本发明的范围内。

[0156] 本发明的一个方面与用于血管的装置有关，该装置包括可重构元件、支承元件、控制元件、推送管件等。控制元件、可重构元件和支承元件形成可扩张隔室。

[0157] 血管的尺寸可从较小动脉和静脉中的约 0.03 英寸(约 1 毫米)的直径大幅变化到主动脉中的约 1.0 英寸(约 25 毫米)的直径。由此，在一些实施例中，装置的直径可从塌缩

状态下的约 0.01 英寸(约 0.25 毫米)到扩张状态下的 1.0 英寸(约 25 毫米)。

[0158] 在一些实施例中,控制元件可包括线材、编织物或线缆,并构造成控制可扩张隔室的构造。各种材料可用于制造控制元件,控制元件包括金属和非金属材料。用于控制元件的金属材料的一些非限制性示例可包括镍、钛、不锈钢、钴、铬和前述的任何合金,诸如是镍钛诺(NiTi)、不锈钢或钴铬合金。此外,具有控制元件的期望特性的任何聚合物或塑料可用于生产该控制元件。聚合物包括但不限于聚酰亚胺、PEEK (聚醚醚酮)、尼龙、PTFE (聚四氟乙烯)、PET (聚对苯二甲酸乙二醇酯)、聚丙烯等。包括但不限于 PTFE 涂覆的不锈钢或 PTFE 涂覆的 NiTi 的聚合物涂覆的金属也可用作控制元件;控制元件还可由复合材料制成,诸如,NiTi 或不锈钢上的 PTFE 或 FEP (氟化乙烯丙烯)管件等。

[0159] 控制元件的直径可从约 0.001 英寸到约 0.10 英寸。

[0160] 术语"可扩张隔室"一般包括能插入体腔内的结构,以通过打开血管或去除闭塞物/凝块使阻塞的血管再通或者消除局部流动收缩。可重构元件是形成可扩张隔室的一个部件。在一些实施例中,可重构元件可包括由管件或板材构成的支杆(参见图 3 中示例)。在一些其它实施例中,可重构元件可包括能形成为网的多个线材(参见图 4 中示例)。在一些其它实施例中,可重构元件的多个线材可对准在一起并形成管状形状(参见图 11 中示例)。可重构元件可由金属材料制成。用于可重构元件的这种金属材料的一些非限制性示例包括镍钛 (NiTi) 合金、不锈钢、钛及其合金、以及钴铬 (CoCr) 合金等。或者,具有可重构元件的期望特性的任何聚合物或塑料可用作生产该可重构元件的材料。在其它替代示例中,可使用两种或更多种不同材料来构造可重构元件。

[0161] 在一些实施例中,用于可重构元件的支杆的直径可从约 0.0005 英寸变化到 0.1 英寸(12.5μm 到 2500μm)。在一些其它实施例中,用于可重构元件的线材的直径可从约 0.0005 英寸变化到 0.1 英寸(12.5μm 到 2500μm)。可重构元件大致柔性并具有弹性或超弹性特性。因此,可重构元件的构造可重构。可重构元件通常包括至少三种不同的构造,它们被称为"塌缩(即,轴向延伸、折叠或闭合)"构造、"松弛(即,未折叠或打开)"构造以及"扩张(即,径向延伸或径向扩张)"构造。可重构元件的完全塌缩构造一般表示可重构元件的外半径变为最小而其轴向长度最大的状态。当装置位于其引导器套管或微型导管内时,可重构元件处于其塌缩构造。当将可重构元件从微型导管或引导器套管推出时,并且如果没有压缩力,即没有任何约束,可重构元件处于其松弛状态。可重构元件的扩张构造一般表示可重构元件的外半径进一步扩张的状态。可重构元件的构造可通过控制元件或支承元件控制从其塌缩状态或松弛状态到扩张状态。外直径可随可重构元件的构造变化而变化,并且在塌缩构造下可从约 0.01 英寸变化到 0.5 英寸(0.25mm 到 12.5mm)。扩张构造直径的范围从约 0.04 英寸到 1.0 英寸(1.0mm 到 25mm)。可重构元件的轴向长度还可随其构造变化而变化。在某些实施例中,可重构元件的轴向长度可在其变得塌缩时增大。相反,可重构元件的轴向长度可在其变得扩张时缩短。可重构元件的轴向长度的范围可从约 0.1 英寸到 3 英寸(2.5mm 到 75mm)。

[0162] 根据本发明的一些实施例,支承元件包括多个线材或支杆。支承元件的多个线材或支杆可呈大致直线形状或大致非直线形状。在某些实施例中,支承元件呈丝网形式。在其它实施例中,支承元件呈编织物形式。在其它实施例中,支承元件呈通过激光切割由管制成的有孔管状形式。在其它实施例中,支承元件连同可重构元件呈通过激光切割或光蚀刻

工艺制成的有孔板形式。支承元件一般构造成调节可重构元件的构造，由此提供对可重构元件的径向扩张程度的精密控制。装置的这种精密控制机构在许多方面是有益的。在将装置递送并释放到选定的治疗部位之后，看起来似乎自扩张可重构元件的半径和／或径向力可小于对于该应用所期望的半径和／或径向力。在这种情况下，支承元件可向内腔进一步提供径向力／压力。可期望有时增加或减少装置施加于周围组织或闭塞物／凝块的径向力大小。在这种情况下，可动态控制可重构元件的构造，以提供根据本发明的装置的较大范围的径向力。该装置还可在递送、移除和／或操作该装置的同时减少对血管造成不必要的冲击或损伤或将其减到最少。在一些实施例中，当递送该装置时，在装置在血管内释放并可扩张到大于内腔直径时，它会向内腔提供不期望的压力和／或冲击。在这种情况下，可通过在必要时控制元件和支承元件的运动来减小可重构元件的直径和径向力。在其它情况下，当移除装置时，径向力会太大，并且在拉回通过血管时可能会引起损伤。相似地，可通过控制元件和支承元件的运动来减小可重构元件的直径和径向力。

[0163] 本发明的又一方面与用于血管的装置有关，该装置包括微型导管、中心线、管件部件和接合部件／隔室。接合部件／隔室可包括近侧接合元件和远侧接合元件。在一些实施例中，远侧接合元件可与中心线相关联。近侧和远侧接合元件中的一个或两个可以是接合元件。在某些实施例中，远侧和近侧接合元件之间的间距可调。远侧和近侧接合元件之间的间距可在至少一些实施例中约从 0mm 调节到 50mm。在某些实施例中，远侧和近侧接合元件之间的间距可调节为约 0mm, 5mm, 10mm, 15mm, 20mm, 25mm, 30mm, 35mm, 40mm, 45mm 和 50mm 以及它们之间的任何范围。在替代实施例中，远侧和近侧接合元件之间的间距可调节到大于 50 毫米。

[0164] 在一些实施例中，可将装置引入血管。血管的尺寸可从较小的动脉和静脉中的约 0.03 英寸(约 1 毫米)的直径大幅变化到较大动脉中的约 1.0 英寸(约 25 毫米)。由此，在一些实施例中，装置的直径可从约 0.01 英寸(约 0.25 毫米)到 1.0 英寸(约 25 毫米)。同样，当接合隔室打开(或扩张)或闭合(或塌缩)时，在操作过程中单个装置的直径可以改变。

[0165] 在一些实施例中，装置还包括中心线。中心线可穿过管件部件，并自由地运动通过管件部件。在某些实施例中，中心线与接合隔室相关联。更具体地，中心线可与远侧接合元件和近侧接合元件相关联。相关联一般是指两个物体之间的任何类型的连接。相关联包括固定，因此，当两个物体相关联时，一个物体的运动将受到另一物体的阻碍。换言之，一旦两个物体以固定方式相关联，则两个物体的运动将同步。然而，相关联不一定表示一个物体固定到另一个。由此，当两个物体相关联但不在固定状态下时，一个物体相对于另一物体的运动不受到阻碍。因此，在至少一些实施例中，均与中心线相关联的远侧接合元件和近侧接合元件可沿中心线自由运动。

[0166] 根据某些实施例，中心线与远侧接合元件固定或连结。在一些情况下，远侧接合元件的近端可连结到中心线的远端。中心线和远侧接合元件之间的关联(即，连接)可通过诸如焊接、胶粘或夹住之类的各种方式完成。在一些实施例中，中心线和远侧接合元件之间的接头被远侧元件连接件所覆盖。或者，将不提供覆盖物来围绕连接的控制线和远侧接合元件。

[0167] 在一些实施例中，中心线可包括线材、编织物或绳缆或呈线材、编织物或线缆的形式。各种材料可用于制造中心线，这些材料包括金属和非金属材料。用于中心线的金属材

料的一些非限制性示例可包括镍、钛、不锈钢、钴、铬以及前述任何合金，诸如镍钛诺(NiTi)或钴铬合金。此外，具有呈中心线的期望特性的任何聚合物或塑料可用于生产中心线。聚合物包括但不限于是聚酰亚胺、PEEK（聚醚醚酮）、尼龙、PTFE（聚四氟乙烯）、PET（聚对苯二甲酸乙二酯）、聚丙烯等。包括但不限于 PTFE 涂覆的不锈钢或 PTFE 涂覆的 NiTi 的聚合物涂覆的金属也可用作中心线。还可施加亲水涂层。可部分地施加这种涂层，以减小中心线和管件隔室之间的摩擦。中心线也可由复合材料制成，诸如 NiTi 线上的 PTFE 或 FEP(氟化乙烯丙烯)管件或者不锈钢上的 PTFE 或 FEP 管件等。中心线的直径范围可从约 0.001 英寸到 0.25 英寸。在某些实施例中，中心线的直径可以约为 0.001, 0.002, 0.003, 0.004, 0.005, 0.006, 0.007, 0.008, 0.009, 0.011, 0.012, 0.013, 0.014, 0.015, 0.016, 0.017, 0.018, 0.019, 0.020, 0.021, 0.022, 0.023, 0.024 和 0.025 英寸。或者，中心线的直径可大于 0.025 英寸。

[0168] 术语“接合隔室”一般包括这样的结构，即，该结构可压缩成小直径并插入体腔内，并且在释放压缩时扩张到较大直径，以通过打开血管或去除闭塞物的至少一部分来使阻塞的血管再通或者消除局部流动收缩。接合隔室可包括远侧接合元件和近侧接合元件。远侧接合元件和近侧接合元件在至少一些实施例中可以是编织结构。它们还可通过激光切割的海波管或者光蚀刻的板材来制成。会需要热处理使它们处于期望形状，例如锥形或圆柱形形状。

[0169] 在一些实施例中，接合元件可包括由管件或板材制成的支架。在一些其它实施例中，接合元件可包括能形成为网的多个线材。在一些情形下，远侧接合元件的远端可如图 20C 中可见那样是闭合的。或者，远侧接合元件的远端可保持打开，如图 20A 中可见那样。

[0170] 远侧接合元件可由金属材料制成。用于远侧接合元件的这种金属材料的一些非限制性示例包括镍钛(NiTi)合金、不锈钢、钛及其合金以及钴铬(CoCr)合金。或者，可使用具有针对远侧接合元件的期望特性的任何聚合物或塑料。在一些实施例中，远侧接合元件由柔性材料制成。在其它替代示例中，远侧接合元件能使用诸如聚合物涂覆的金属材料的两种或更多种不同材料来制成。

[0171] 在一些实施例中，远侧接合元件的直径可从约 1 毫米变化到其扩张状态下的约 8 毫米。在某些实施例中，处于其扩张状态的远侧接合元件的直径可以约为 1mm, 2mm, 3mm, 4mm, 5mm, 6mm, 7mm 和 8mm 或它们之间任何范围。在一些其它实施例中，远侧接合元件的长度可从约 10mm 变化到 40mm。在某些实施例中，远侧接合元件的长度可约为 10mm, 15mm, 20mm, 25mm, 30mm, 35mm 和 40mm 或者任何它们之间的范围。此外，在替代实施例中，远侧接合元件的长度可大于 40mm。

[0172] 远侧接合元件一般是柔性的，并且具有弹性或超弹性特性。由此，远侧接合元件的形状可变化。远侧接合元件通常包括至少两种不同的构造，这些构造被称为“塌缩(即，折叠或闭合)”构造以及“松弛(即，未折叠或打开)”构造。远侧接合元件的塌缩构造一般表示远侧接合元件的外半径变为最小的状态。当远侧接合元件位于微型导管内时，远侧接合元件处于其塌缩构造。当将远侧接合元件推出微型导管时且如果没有约束远侧接合元件的压缩力，远侧接合元件处于其松弛状态。在一些实施例中，远侧接合元件可包括可自扩张的支架。由此，一旦将支架推出微型导管或者撤回微型导管从而使支架留在微型导管远侧，则支架不受约束，并且它将自行扩张。由于远侧接合元件的柔性特性，可通过向微型导管轻轻拉

动或者推动远侧接合元件而将远侧接合元件容易地放置于微型导管内。

[0173] 根据本发明的一些实施例，近侧接合元件可包括由管件或板材制成的一个或多个线材。在一些其它实施例中，近侧接合元件可包括能如图 20 中所示形成为筐状形状的一个或多个线材。或者，近侧接合元件能制造成许多形状或形式。例如，近侧接合元件的可面向体腔表面的远端可进行修改，以减少对体腔表面的任何损伤。由此，使近侧接合元件的远端基本上平滑，以使得即使与近侧接合元件直接接触，体腔也保持很大程度上不受损。同样，近侧接合元件的远端将例如如图 30 中所示那样弯曲，因而，尖锐的端部将不与体表面直接接触。此外，近侧接合元件的形状或形式可在操作过程中变化。因此，在某些实施例中，近侧接合元件的远端、更具体来说是远侧末端可构造成在操作过程中移除。例如，如图 32-34 中所示，近侧接合元件的远侧末端直接(例如，图 33 和 34)或间接地(例如经由如图 32 中所示的连接线)连接到连接件。借助这些构造，近侧接合元件的远侧末端将通过连接件的运动而移动离开体腔。更具体来说，当远侧元件的近侧连接件连同凝块向近侧运动时，它可向近侧拉动近侧接合元件的远侧末端，并将近侧元件折叠成期望的筐形，其中末端为圆形或非创伤性的。因此，至少在一些实施例中，由于与体腔表面(例如，血管)直接接触而产生的损伤体腔的风险将大幅降低。这些末端特征还在需要时在内腔中向前推动近侧接合元件，并且不损伤体腔表面。

[0174] 在一些实施例中，近侧接合元件构造成大幅改善凝块接合和收回效率。例如，如图 3 中所示那样，当使用根据一些实施例的装置时，闭塞物可设置在近侧和远侧接合元件之间。该设计具有通过用两个独立的接合元件保持闭塞物或凝块来牢固接合闭塞物或凝块的改善的能力。

[0175] 近侧接合元件可由金属材料制成。用于近侧接合元件的这种金属材料的一些非限制性示例包括镍钛(NiTi)合金、不锈钢、钛及其合金以及钴铬(CoCr)合金。或者，可使用具有针对近侧接合元件的期望特性的任何聚合物或塑料。在一些实施例中，近侧接合元件由柔性材料制成。在其它替代示例中，近侧接合元件能使用两种或更多种不同材料来制成，如图 34 中所示。

[0176] 在一些实施例中，近侧接合元件的直径可从约 1 毫米变化到其扩张状态下的约 8 毫米。在某些实施例中，处于其扩张状态的近侧接合元件的直径可以约为 1mm, 2mm, 3mm, 4mm, 5mm, 6mm, 7mm 和 8mm 或任何它们之间的范围。在一些其它实施例中，近侧接合元件的长度可从约 2mm 变化到 40mm。在某些实施例中，近侧接合元件的长度可约为 2mm, 5mm, 7mm, 10mm, 12mm, 15mm, 17mm, 20mm, 22mm, 25mm, 27mm, 30mm, 32mm35mm, 37mm, 40mm 或任何它们之间的范围。此外，在替代实施例中，近侧接合元件的长度可大于 40mm。

[0177] 近侧接合元件一般是柔性的，并且具有弹性或超弹性特性。由此，近侧接合元件的形状可变化。近侧接合元件通常包括至少两种不同的构造，这些构造被称为“塌缩(即，折叠或闭合)”构造以及“松弛(即，未折叠或打开)”构造。近侧接合元件的塌缩构造一般表示近侧接合元件的外半径变为最小的状态。当近侧接合元件位于微型导管内时，近侧接合元件处于其塌缩构造。

[0178] 当近侧接合元件不在微型导管内并且不受约束时，近侧接合元件处于其松弛构造。

[0179] 在一些实施例中，近侧接合元件由弹性或超弹性材料制成，并由此自扩张。由于其

柔性特性，可通过向微型导管轻轻拉动会推动近侧接合元件而将近侧接合元件容易地放置于微型导管内。在其它替代实施例中，近侧接合元件可具有多于两种的不同状态。例如，如图 32-34 中所示那样，近侧接合元可构造成在操作过程中改变其形状，并且由此将呈完全塌缩和完全松弛状态之间的许多不同状态。

[0180] 在一些实施例中，可将一种或多种标记加到装置。这种标记可包括不透辐射材料，这些材料有助于监测装置在体内的位置和 / 或运动。不透辐射标记的一些非限制性示例可包括金、金合金、CoCr 合金、铂或铂合金。标记也可呈不透辐射涂层的形式。标记可加到装置中的任何位置。在一些实施例中，可将一种或多种标记加到远侧接合元件处，因此，将确定远侧接合元件在体内的位置。在一些其它实施例中，可将一种或多种标记加到近侧接合元件处，因而将确定近侧接合元件在体内的位置。在又一些其它实施例中，远侧和近侧接合元件均包含标记。远侧和近侧接合元件中的每个内的标记可以是相同或不同材料。或者，可将一种或多种标记加到中心线和 / 或管件隔室。在一些实施例中，标记可以约为 0.10 到 4mm 长，而直径约为 0.001 到 0.030 英寸。然而，任何尺度（例如，长度、直径、尺寸和质量）和标记的形状方面的任何变型是合适的。

[0181] 在一些实施例中，装置可包括管件隔室。管件隔室可包括多个管件元件。这种管件元件可包括推送管件和连接管件。推送管件还可在至少一些实施例中包括内推送管件、中间推送管件、外推送管件。同样在替代实施例中，推送管件可包括远侧推送管件和近侧推送管件。各种材料可用于制造管件元件，它们包括金属和非金属材料。在一些实施例中，远侧推送管件和 / 或外推送管件可由诸如 PTFE 或 PET 的光滑和柔性聚合物制成。中间和近侧推送管件可由镍钛诺超弹性材料、不锈钢、CoCr 合金、钛合金或聚合物（诸如，聚酰亚胺、PEEL 等）制成。管件元件中的一个或多个也可涂覆有诸如 PTFE 涂层、亲水涂层等的润滑材料。管件元件也可由复合材料制成，诸如镍钛诺线材上的 PTFE 或 FEP（氟化乙烯丙烯）管件或者不锈钢上的 PTFE 或 FEP 管件等。

[0182] 中心线可呈线材、编织物或管件的形式。用于中心线的金属材料的一些非限制性示例可包括镍、钛、不锈钢、钴、铬以及前述任何合金，诸如镍钛诺（NiTi）或钴铬合金。此外，具有呈中心线的期望特性的任何聚合物或塑料可用于生产中心线。聚合物包括但不限于是聚酰亚胺、PEEK（聚醚醚酮）、尼龙、PTFE（聚四氟乙烯）、PET（聚对苯二甲酸乙二酯）、聚丙烯等。包括但不限于 PTFE 涂覆的不锈钢或 PTFE 涂覆的 NiTi 的聚合物涂覆的金属也可用作中心线。还可施加亲水涂层。

[0183] 在一些实施例中，推送管件和连接管件的直径可约为 0.001 到 0.050 英寸。在其它实施例中，推送管件和连接管件的直径可小于 0.001 英寸或者超过 0.050 英寸。在又一些其他实施例中，装置可包括推送管件，而没有连接管件。

[0184] 为了说明的目的，在以下附图中提供根据本发明的装置的一些非限制性和说明性示例。尽管为了说明的目的文中仅描述了少数示例性应用，但也可进行对于本领域普通技术人员来说显然的许多不同改型和修改，而不影响本发明的范围。因此，不仅在本申请中公开的示例、而且明显的改型和修改也应包含在本发明的范围内。

[0185] 参见图 1，示出包括可重构元件（410）、支承元件（420）、控制元件（10）和推送管件（20）的装置。可扩张隔室（40）可存在于引导器套管（26）内。

[0186] 在临床手术过程中，可将该装置经由引导器套管（26）推入微型导管（30）内，并且

进一步推到损伤部位，如图 2 中所示。可重构元件（410）可连接到推送管件（20），在此情况下是中空薄管。支承元件可与控制元件相关联。控制元件（10）的至少一部分可由推送管件（20）围绕，并且控制元件（10）可自由地滑动通过推送管件（20）。由此，控制元件（10）和推送管件（20）的运动可不受彼此的限制，并且分别可沿装置的轴向轴线自由滑动，如图 3B 和 4B 中所示。可借助引导线将微型导管放置于闭塞物 / 凝块位置处。推送管件可用于将装置推入微型导管。然后，在治疗过程中可将该装置的可扩张隔室推出微型导管。可通过向近侧或远侧拉动或推动控制元件来调节可重构元件的径向力和直径。

[0187] 图 2 示出从血管去除闭塞物 / 凝块所需步骤。由此，内腔表面（50）可代表血管壁。在一些实施例中，可将该装置递送到存在有闭塞物 / 凝块（60）的内腔区域（50）。在递送过程中，借助引导线（5），微型导管的远侧末端可行进到阻塞部位，并穿过闭塞物 / 凝块（60），如图 2A 中所示。血管造影导引可用于确定微型导管相对于血管和闭塞物 / 凝块的位置。

[0188] 在移除引导线（5）之后，可将收回装置引入微型导管（30）内。可将可扩张隔室（40）推过微型导管（30）直到可扩张隔室（40）的远端到达微型导管的远端为止（图 2B）。如图 2C 中所示，当推送管件（20）保持稳定时，可通过向近侧拉动微型导管（30）来略撤回微型导管（30）。可扩张隔室（40）暴露于闭塞物 / 凝块（60），并部分地打开，如图 2D 中所示。操作者可调节可重构元件（410）的构造，即可重构元件的径向力、直径和轴向长度，以允许可重构元件（410）使闭塞物 / 凝块（60）裂开或与闭塞物 / 凝块（60）接合、破坏闭塞物 / 凝块（60）的至少一部分和 / 或使血管内腔扩张。可重构元件构造的这种调节可至少通过向远侧或近侧拉动或推动控制元件（10）来实现，如图 2E 中所示。在闭塞物 / 凝块（60）与可扩张隔室（40）接合之后，可从血管收回装置连同微型导管（30），如图 2F 中所示。

[0189] 或者，可先将微型导管放置到超出闭塞物 / 凝块，可扩张部件可在闭塞物 / 凝块远侧打开。在操纵并调节可重构元件的直径和径向力之后，可向近侧拉动该装置，而闭塞物 / 凝块可被可扩张隔室捕获并被拉出血管。

[0190] 尽管图 2 的实施例示出从内腔的阻塞部位基本上去除闭塞物 / 凝块，但可使用诸如破坏闭塞物 / 凝块的至少一部分的替代治疗。闭塞物 / 凝块经常是基本上软的，并且能以相对微小的冲击来使其断开。在这种情况下，可重构元件可将闭塞物 / 凝块部分地分裂成更小的部分。用装置收集并从主体去除各片阻塞材料。如果在可重构元件在血管内径向扩张时可重构元件的线材或支杆切过闭塞物 / 凝块（例如，血凝块），则当它扩张到血管的全直径时，闭塞物 / 凝块的各部分变得包含到可扩张隔室内或与可扩张隔室接合。通过将可重构元件部分地拉到微型导管末端内来使可重构元件略塌缩，可重构元件各单元的线材 / 支杆之间的开口将变得更小。这会将闭塞物 / 凝块保持在可扩张隔室内。支承元件还可有助于将闭塞物 / 凝块保持在可扩张隔室内。然后，可从血管拉出包含闭塞物 / 凝块的各部分的整个装置。在其它替代实施例中，该装置可使内腔扩开 / 扩张成在内腔的阻塞部位处重新形成流动。闭塞物 / 凝块也可以不用软到足以允许装置与闭塞物 / 凝块基本上接合。在这种情况下，可重构元件的构造可控制成与闭塞物 / 凝块的至少一部分接合，并使其运动。当可重构元件的直径进一步打开时，它的线材或支杆将推抵于闭塞物 / 凝块。当向近侧拉动时，可重构元件和闭塞物 / 凝块之间的摩擦会引起闭塞物 / 凝块从血管壁脱开并被去除。

[0191] 图 3 和 4 示出根据本发明的一些实施例的装置。该装置包括推送管件（20），该推送管件（20）与可重构元件（410）的近端连接件（460）连接。推送管件以及控制元件基本上

是长的。在一些实施例中，推送管件以及控制元件可长到足以使操作者经由推送管件以及控制元件从体外控制收回装置。在一些实施例中，推送管件以及控制元件可延伸约 100cm, 110cm, 120cm, 130cm, 140cm, 150cm, 160cm, 170cm, 175cm, 180cm, 185cm, 190cm 或 200cm。如果必要，这些线材可延伸超过 200 厘米。

[0192] 可重构元件（410）可包括至少两个端部，即远端和近端。可重构元件（410）的远端一般是指在近端之前进入人体的端部。可重构元件（410）的近端一般是指使可重构元件（410）与推送管件（20）相关联的端部。

[0193] 在一些实施例中，可重构元件（410）的远端闭合，这意味着可重构元件的线材或支杆（410）的远端借助例如熔化焊接、焊料焊接或胶粘、在使用或不使用连接件（430 或 450）的情况下保持在一起。在一些实施例中，控制元件（10）的远端和支承元件（420）的远端可借助例如熔化焊接、焊料焊接或胶粘等、在使用或不使用连接件（451）的情况下保持在一起。或者，远端连接件（451）可用于联接控制元件（10）的远端和支承元件（420）的远端。在可重构元件（410）的近端处有外侧近端连接件（461）和内侧近端连接件（462），这两个近端连接件都是如图 3B-8B 中所示的管状结构。可重构元件（410）的近侧线材或支杆端部可置于外侧近端连接件（461）和内侧近端连接件（462）之间，并且通过上述手段固定在位。控制元件（10）可通过内侧近端连接件（462）的内腔，以使它能在内侧近端连接件（462）内自由滑动。

[0194] 该装置还包括支承元件（420），该支承元件（420）可与可重构元件的线材 / 支杆（410）以及控制元件（10）相关联。支承元件（420）可经由连接件（430 和 / 或 451）与控制元件（10）相关联，例如如图 7 中所示。在一些实施例中，支承元件（420）以基本上固定不动的方式与控制元件（10）的远端相关联。由此，当向近侧拉动控制元件（10）时，可向近侧拉动支承元件（420）的远端。支承元件（420）可如图 3 和 4 中所示附连到可重构元件（410）。在该实施例中，附连到可重构元件（410）的支承元件端部可向外运动，从而使可重构元件（410）扩大（如图 3C 和 4C 中所示）。这将增大可重构元件的径向力。在其它实施例中，支承元件（420）由与如图 3 和 14 中所示的可重构元件（410）相同的材料制成。由此，无须连结这两个部件。在此实施例中，向近侧拉动控制元件（10）将使支承元件（420）与控制元件（10）之间的角度 α （图 3C）扩大，从而使可重构元件（410）变大（如图 3D 中所示）。这将增大可重构元件的径向力。

[0195] 如图 3B 和 4B 中所示，控制元件（10）可存在于近侧内连接件（462）的内腔内，并自由地滑动通过连接件（460）。在一些实施例中，可将标记（440）加到装置，例如，支承元件（420）在标记处与线材 / 支杆（410）相关联。这种标记可包括不透辐射材料，该材料有助于看到 / 监测装置在人体内的位置和 / 或运动。不透辐射标记的一些非限制性示例可包括金和 / 或铂。如果期望，可在支承元件（420）和可重构元件（410）的线材 / 支杆、控制元件或支承元件（420）的任何部分之间的一些附连点处加入标记。例如，可将标记施加于可重构元件的大约远端和 / 或近端处，或者涂覆到线材和 / 或连接件的任何部分上。还可通过使用 CoCr 合金作为可重构元件、控制元件和 / 或支承元件来实现装置的不透辐射特性。

[0196] 能以多种形式来构造支承元件。图 3、13 和 14 中所示的具体示例是内在结构，即，支承元件和可重构元件由管件或平板的一件材料制成。由此，不需要它们之间的附加连结 / 粘合。

[0197] 图 4 包括呈大致线性线材形式的多个支承元件。用于制造支承元件的材料是金属或非金属材料。用于支承元件的一些非限制性材料包括但不限于是镍、钛、NiTi、不锈钢、钴铬和前述任何合金。通过控制元件和支承元件的运动可控制可重构元件的构造。在使微型导管穿过闭塞物 / 凝块之后，可将该装置递送到微型导管内。当该装置从微型导管脱开时(参见例如图 2)，它可露出并与闭塞物 / 凝块接合。

[0198] 在一些实施例中，可重构元件一旦离开微型导管，则可以自扩张，并且可通过向远侧或近侧拉动或推动控制元件还可进一步改变可重构元件的构造。通过控制元件和支承元件可进一步控制可重构元件的径向力。如果自扩张隔室构造成扩张到大于血管直径，该自扩张过程会向壁施加过大的力。这会造成对血管伤害，从而造成撕裂或穿孔。由此，有益的是能以精密的方式控制可重构元件的构造(包括可重构元件的径向力、尺寸和形状)以实现安全和有效的治疗。此外，在可重构元件实现其标称自扩张直径之后，可重构元件需要进一步扩张，或可重构元件的径向力需要进一步增大。例如，会需要加强可重构元件的径向力以与闭塞物 / 凝块基本上接合、切过闭塞物 / 凝块和 / 或移动闭塞物 / 凝块。因此，所期待的是，需要在治疗过程中动态改变可重构元件的构造。根据本发明的至少一些实施例的装置设计成提供可重构元件的这种动态控制。

[0199] 或者，可重构元件可以不是自扩张的，并由此需要控制可重构元件的完全打开和闭合。在这种情况下，当可扩张隔室从微型导管脱开以治疗内腔中的病症时，可以向近侧略拉动控制元件，以使可重构元件可轴向扩张。类似于自扩张的可重构元件，该非自扩张的可重构元件的进一步扩张或塌缩将通过附连到支承元件的控制元件的运动来控制。

[0200] 在一些实施例中，装置包括至少两个机构来控制可重构元件的构造。首先，由支承元件提供控制。支承元件一般由控制元件控制。在控制元件进行远侧运动时，支承元件也变得沿轴向轴线延伸。当控制元件向近侧缩回时，支承元件将径向扩张，这将向可重构元件提供进一步支承压力。当控制元件更向近侧运动时，支承元件将变得更扩张，由此控制元件和支承元件之间的角度(图 3 和 4 中的 α)将增大。角度 α 的范围可以在约 0 度到 90 度之间。此外，将通过控制元件的运动来控制可重构元件的构造(例如，可重构元件的总体形状、轴向长度和外直径)。控制元件的向远侧运动将使可重构元件转换到其塌缩状态，即，可重构元件轴向延伸且其外直径缩小，同时轴向长度增加。控制元件的向近侧运动将使可重构元件的构造向其扩张状态转换，即，可重构元件变得径向扩张。由此，可重构元件的轴向长度可缩小，而外直径增加。可重构元件向其扩张状态的这种转换将加强可重构元件的径向力。

[0201] 连接件可以是诸如不锈钢(SS)、铂、金、镍钛诺管件的金属海波管件，诸如聚酰亚胺管件的塑料管件，或者可以是由不锈钢、铂合金、金或 CoCr 合金线材等构成的一段线圈。当使用诸如金、铂等的透辐射材料时，连接件也可用作标记。

[0202] 在一些实施例中，将在血管内控制可重构元件的构造，以从内腔去除闭塞物 / 凝块和 / 或使内腔扩张。一旦闭塞物 / 凝块与可重构元件接合，则该装置从内腔撤回并最终从人体撤出。当从内腔撤回装置时，与闭塞物 / 凝块接合的可扩张隔室可部分地撤回到微型导管内或留在微型导管远侧。具有闭塞物 / 凝块的可扩张隔室和微型导管可同时拉回到具有较大内直径的引导导管内。可使用荧光检查法来确定微型导管、引导导管和可扩张隔室之间的相对位置。

[0203] 图 5 和 6 中提供该装置的替代实施例。在该特定实施例中，支承元件（420）包括如图 5 中所示的多个线材或如图 6 中所示的编织结构。支承元件（420）从可重构元件或线材 / 支杆（410）的近端延伸，并止于可重构元件（410）的远端（在图 5-7 中标记为“*”）之前，由此形成双层可扩张隔室。支承元件（420）的远端可与控制元件（10）的远侧末端固定。

[0204] 如图 5B 和 6B 中所示，可通过近侧连接件（460）来使可重构元件（410）与支承元件（420）相关联。近侧连接件可包括至少两个隔室，即，外近侧连接件（461）和内近侧连接件（462）。可重构元件线材的近端和支承元件的近端用粘合剂、熔化焊接、焊料焊接来固定（463），或通过近侧外部连接件和内部连接件之间的机械连接来固定。在一些其它实施例中，这些内近侧连接件和外近侧连接件可以是管状或线圈结构，并且控制元件可自由地滑动通过内部连接件。

[0205] 在上述装置中，当控制元件（10）向近侧撤回时，它会引起支承元件（420）扩张，从而向可重构元件线材 / 支杆提供支承，这导致可重构元件（410）的直径的扩大和径向力的扩大。

[0206] 图 7 中提供该装置的又一替代实施例。在该特定示例中，支承元件（420）构造成包括两个高峰（plateau）位置（480），在这两个位置，支承元件（420）可向可重构元件线材 / 支杆（410）提供最大的支承强度。支承元件（420）可形成为如图 7 中可见的正弦形状。支承元件的远端固定到控制元件（10）。可重构元件和支承元件的近端都如图 7B 中所示固定到近侧连接件。如图 7C 中所示，支承元件的中间（薄）部段经由中间外部和内部管件连接件连接，而控制元件在近侧和中间连接件（430）内自由运动。

[0207] 在支承元件内具有两个或更多个高峰的一个优点是能在较佳位置选择性地加强径向力。如图 7 中容易可见，可重构元件（410）在两个高峰位置（480）处从支承元件（420）获得最大的支承强度，并且当它远离高峰时支承强度将减小。由此，如果期望，装置可向内腔区域提供较大范围的径向力。此外，支承元件的数目也可从两个变化到更多个，这些支承元件可周向分布在控制元件（10）周围，以使装置的径向力和 / 或外部形状和密度变化。

[0208] 图 8 中提供该装置的又一替代实施例。在该特定示例中，控制元件（10）延伸通过支承元件（420）的远端，并到达可重构元件（410）的远端。如图 8C 中可见，支承元件的远端可沿控制元件自由地滑动。支承元件（420）可在支承元件（420）的远端处例如经由连接件（451）与控制元件（10）相关联。连接件 450 由支承性远侧内部连接件（453）和支承性远侧外部连接件（452）构成，从而在它们之间连结支承元件的远端。控制元件（10）可在内部连接件的内腔中滑动。当向近侧拉动控制元件（10）时，可重构元件的连接件（450）和支承元件的远端（451）之间的距离变短。当两个连接件彼此接触时，支承元件将扩张，从而压抵于可重构元件，并且产生附加的径向力，如图 8D 中可见那样。图 8 的该特定实施例的一个益处是支承元件的远端（451）和可重构元件的远端（450）轴向对准，从而在向近侧拉动控制元件时避免支承元件末端倾斜。当该装置缩回到微型导管内时，还可避免对可重构元件（410）和支承元件（420）之间的线材轴向长度的限制。

[0209] 图 9 中提供该装置的又一替代实施例。在该特定示例中，支承元件（420）包括至少两个高峰位置（480）。此外，支承元件（420）的远端可以不是在装置的远端附近基本上固定不动的。因此，支承元件（420）可在支承元件的远端处例如经由连接件（430）与控制元件（10）相关联。这些连接件（430）可构造成沿控制元件自由滑动。连接件（430）的结构还由

内部连接件和外部连接件构成，以确保控制元件能自由地运动通过连接件。由此，当向近侧拉动控制元件时，可重构元件的远端连接件（450）可运动到更靠近于支承元件的远端。当两个连接件彼此接触时，支承元件将扩张，并且将推抵于可重构元件（410），从而如图 9E 中可见那样产生附加的径向力。

[0210] 图 9 的该特定装置可提供至少三个益处。支承元件包括多于一个高峰位置，高峰位置可允许在较佳位置处选择性地加强径向力。由此，如果期望，装置可向内腔区域提供较大范围的径向力。此外，类似于图 8 的装置，支承元件的远端和支承元件的远端通过控制元件轴向对准，从而在向近侧拉动控制元件时避免末端倾斜。当装置缩回到微型导管内时，还可避免对可重构元件（410）和支承元件（420）之间的线材轴向长度的约束。

[0211] 根据本发明的一些实施例，可将调节管用于所有所述设计中的装置。如图 10 中可见，调节管（470）可在支承元件的近端和远端之间放置于控制元件上。调节管可选择性地沿控制元件自由滑动。当在装置中存在调节管时，调节管可防止连接件（451 或 430）太接近于可扩张隔室的近端。由此，具有调节管（470）的装置可防止可重构元件的过度轴向扩张。当将装置拉回到引导器套管或微型导管内时，管件还可防止或减少控制元件与支承元件的支杆 / 线材之间的摩擦。

[0212] 图 11 中提供该装置的又一替代实施例。在该特定伞形装置中，可重构元件（410）可包括多个线材，并如图中可见那样形成管状结构。也可包括多个线材的支承元件可用于改变可重构元件的构造。支承元件（420）可与控制元件（10）以及可重构元件（410）相关联，且关联位置中的至少一些可联接有标记（440）。支承元件（420）以及可重构元件（410）能以基本上固定不动的方式与控制元件（10）相关联。支承元件（420）的所有线材可经由连接件（430）与控制元件（10）相关联。连接件（430）固定到控制元件。因此，向近侧拉动控制元件（10）或向远侧推动控制元件（10）还可相应地作用于其它线材（即，可重构元件和支承元件）。

[0213] 图 12 中示出前述装置的一些非限制性和说明性改型。在图 12A 和 12B 中所示的装置中，可重构元件（410）包括沿装置的轴向轴线对准的八个大致直线形线材。该装置还包括分布在装置的近端和远端之间的两组支承元件（420）。每组支承元件（420）可包括四个线材以操纵装置的径向力。或者，图 12C 的装置包括可重构元件（410）和支承元件（420），可重构元件（410）包括轴向对准的六个大致直线形线材，而支承元件（420）包括在同一组内的三个线材。此外，诸如使用一组或两组支承元件以及使用多于二组支承元件的任何进一步和其它改型可应用于该装置。此外，如果期望，可重构元件和支承元件可呈类似于图 7 中可见的丝网（编织物）的形式。

[0214] 在图 13 中示出根据本发明的另一实施例。在该特定示例中，可重构元件单元的尺寸和支杆的尺寸或线材的直径可在单个装置内变化。从可重构元件的近端到远端，该单元可从大尺寸变为小尺寸，或者反之，且支杆尺寸可从厚支杆变成薄支杆，或反之。在该图中所示的装置中，可重构元件（410）在区域 A 中比在区域 B 中具有一般更大的单元，或者反之。此外，支杆尺寸或线材直径可在区域 A 中比区域 B 更厚，或者反之。这些实施例的优点可包括如下中的至少一个或多个：

[0215] 1）较大近侧单元尺寸可具有较小的线材密度，这在增加径向力时会增加每个支杆施加的力和压力。这会使可重构元件（线材或支杆）能更容易地切过闭塞物 / 凝块或使其裂

开。闭塞物/凝块也可由于较宽的开口更容易地落入可扩张隔室内。小尺寸的远侧单元用于捕获和保持从可扩张隔室的近端裂开的闭塞物/凝块碎屑，因此碎屑将不会从装置逸出而行进到下游。

[0216] 2) 可重构元件的支杆尺寸也可从近端变化到远端，其中，近端处的支杆较宽/厚，而远端处支杆较薄。大又牢固的近端支杆将具有较大刚度，并可更容易地切割闭塞物/凝块。由于远端处加大数目的单元，远端处的支杆尺寸需要薄，以使装置能在其压缩状态下保持较小轮廓，从而能装入微型导管内。

[0217] 由此，应用中所示的示例不应认为限制本发明的范围，而是可以在不影响本发明范围的情况下进行对于本领域技术人员来说显然的许多不同修改和改型。因此，不仅在本申请中公开的示例、而且明显的修改和变型也应包含在本发明的范围内。

[0218] 可通过本领域中已知的多种技术来制造根据本发明的一些实施例的装置。例如，可重构元件和支承元件可由某件材料通过激光切割海波管制成。通过激光器切割之后的海波管可热固成可重构元件和支承元件的期望的形状和尺寸，这些可重构元件和支承元件能如图 13 中所示进一步组装到装置内。

[0219] 或者，可重构元件/支杆和支承元件/支杆可由相同薄型板通过激光切割或光蚀刻制成，如图 14A 中可见。该部件可热固成可重构部件和支承部件的期望形状和尺寸。这些部件可进一步组装到装置内。可重构元件的各侧可使用粘合剂、熔化焊接、焊料焊接和机械连结等方式来连结以形成各侧闭合的可扩张隔室(参见图 14B)或者简单地敞开作为各侧敞开的可扩张隔室(图 14C)。

[0220] 可重构元件的远端可以是闭合端部(线材或支杆端部连结，图 14B 和 14C 中所示)或者可以是开口端部(即，线材或支杆端部未连结，如图 14D 中所示)。

[0221] 海波管和金属板可由选自以下的一种或多种制成：镍钛(NiTi)合金、不锈钢、钛(及其合金)和钴铬(CoCr)合金等。

[0222] 加工海波管或薄板的上述技术的许多实施例的一个优点是可避免多个线材(例如，可重构元件和支承元件之间)的相关联(或连结)，因此，装置轮廓(尺寸)可较小。这些实施例与编织线材结构相比有利，因为可重构元件的支杆均连接到每个单元或窗的角部处。在不增加装置的轮廓的情况下，可通过单元形状和结构设计来控制径向力。

[0223] 本发明的一些实施例涉及设计成将可扩张隔室放置于对象的血管结构内的装置。对象可以是需要治疗、诸如去除血液堵塞物/血凝块和/或恢复体内的血流的患者。在图 15 和 18 中示出装置的示例性非限制性实施例。根据一些方面，在推送管件(20)和可扩张隔室(40)之间有线圈部段(540)。该线圈部段可被认为是推送管件的一部分。线圈(540)的功能可使装置的远侧部段柔性，因此，装置可通过曲折的血管。为了进一步改善装置的可推送性，可将诸如 PTFE、PET 等的塑料管件加到线圈周围，或者在推送管件的远端处简单地替换线圈作为柔性推送部件。如果使用线圈，一个或多于两个的薄线材(520)可用于连接推送管件(20)和可扩张隔室(40)的连接件，以防止线圈(540)伸展。根据另一些方面，推送管件(20)可连接到线圈(540)。此外，控制元件(10)可在推送管件(20)的内腔以及可重构元件的近侧连接件(460)和线圈或柔性管部段内自由滑动。根据又一些其它方面，在装置的近端处，控制元件手柄管件(490)可加到并固定到控制元件(10)的近端。借助该特征，操作者可容易地抓取控制元件手柄管件(490)，以控制可重构元件的打开或闭合。部件之间的

所有连接可通过胶粘(粘合剂)、熔化焊接、焊料焊接等连结。参见图 15,柔性线圈(495)可加到可扩张隔室的远端,以使装置末端为非创伤性,从而避免戳到管腔。

[0224] 在图 16 和图 17 中示出其它替代实施例。在这些实施例中,该装置可包括两个结构,即远侧可扩张结构(550)和近侧可扩张结构(560)。对于图 16 中所示的装置,两个可扩张结构之间的距离可改变 / 调节,即,例如通过推动或拉动控制元件(10),远侧结构可向近侧结构拉动 / 滑动或者远离近侧结构推动 / 滑动。

[0225] 参照图 16,远侧结构(550)呈包括可重构元件(410)、支承元件(420)和控制元件在内的筐状物或可扩张隔室的形式。控制元件(10)的远侧末端可连接到支承元件(420),并可在滑动管(471)和推送管件(20)内自由移动。通过经由控制元件来调节支承元件,可调节远侧结构的半径和径向力。如本申请中其它地方所示,支承元件的调节可通过推动或拉动中心元件来实现。在一些其它实施例中,滑动管(471)的近端可固定到推送管件的远端。远侧结构(550)的远端可通过连接件(460)固定到滑动管的中间点。近侧结构可以是伞形部件(560)。近侧结构的近端可与包括外部连接件和内部连接件在内的连接件(455)相关联。连接件的内直径一般大于滑动管的外直径,以使滑动管能在连接件内自由地滑动。在闭塞物 / 凝块收回过程中,当使微型导管脱开时,近侧结构由于摩擦而由微型导管的末端保持。近侧结构可与远侧结构分开。当拉动推送管件时,远侧结构向近侧结构运动。可接合 / 抓取两个结构之间的闭塞物 / 凝块(图 19 中将进一步示出装置如何捕获闭塞物 / 凝块的详细机构)。如果向近侧拉动控制元件,则远侧结构可进一步扩张。滑动管(在连接件 460 和滑动管的末端之间)的段具有与图 10 中的调节管(470)相同的功能,即,阻止远侧结构如之前部分中所述那样过度扩张。标记(440)也可如需要地加到远侧和近侧结构的远侧末端。

[0226] 参见图 17A,近侧结构(560)是可扩张隔室,它由可重构元件(410)、支承元件(420)和控制元件(10)构成。该结构的近端可连结到外管(460)和内管(475)之间。控制元件(10)的远侧末端能连接到支承元件(450),并在近侧结构的远端处在内管(475)内以及在推送管件(20)内自由运动。通过经由控制元件来调节支承元件,可调节近侧结构的构造和径向力。远侧结构(550)呈包括可重构元件(410)和封闭元件(425)在内的筐状物或自扩张隔室的形式。在远侧结构的中间,封闭元件的末端可通过连接件(451)来连结,以形成闭合的隔室 / 结构。封闭元件的结构可以与前述支承元件的一样,但其功能仅仅是使隔室闭合。由于封闭元件的末端不连接到控制元件,所以不能调节结构(550)的构造和径向力。或者,也可在没有封闭元件的情况下形成远侧结构。远端可通过如图 17B 中所示使可重构元件(410)的远侧线材 / 支杆连结来闭合(451)。远侧结构(550)的近端可固定到控制元件的远侧末端。在收回过程中,远侧结构可捕获不能由近侧结构保持 / 包含的闭塞物 / 凝块碎屑。两个结构之间的空间还可用作在收回过程中包含闭塞物 / 凝块或闭塞物 / 凝块碎屑的室。

[0227] 从推送管件末端 / 近侧连接件延伸到近侧结构(560)的中间部分内的内管件(475)具有与图 10 中的调节管 470 相同的功能,即,如之前部分中所述那样防止远侧可扩张结构的过度扩张。

[0228] 在包括两个隔室的实施例中,可如申请中其它地方公开那样通过激光切割、光蚀刻或线材编织形成远侧部件和近侧部件。其它地方所述的各种材料可用于形成可重构元

件。在这种实施例中，近侧结构的强度 / 刚度或线材 / 支杆尺寸可与远侧结构不同。此外，远侧结构的尺寸（当它完全扩张时）可与近侧结构不同。

[0229] 在图 18 中示出使用图 16 中所示设计作为示例的构造成应用包括两个可扩张结构的实施例的装置。在此特定实施例中，在装置中采用远侧结构（550）和近侧结构（560）。在图 19 中示出使用根据图 18 的装置来收回闭塞物 / 凝块。图 19 中所示的机构仅仅示出各种应用，并表示为某些实施例的说明。如申请中其它地方所述，根据本申请的装置可用于收回或去除例如血管内的闭塞物 / 凝块。此外，装置可用于使内腔区域扩张和 / 或恢复血流，这可以需要或不需要收回闭塞物 / 凝块。

[0230] 在闭塞物 / 凝块（60）如图 19A 可见定位在血管（50）内的假设条件下，包括收回装置的微型导管（30）可行进和定位在闭塞物 / 凝块近侧或远侧附近。然后，使微型导管（30）脱开，以使收回装置暴露于闭塞物 / 凝块。在图 19 中所示的一些实施例中，闭塞物 / 凝块可通过如下机构接合和收回：

[0231] 闭塞物 / 凝块（60）可保持在近侧结构（560）与微型导管（30）的末端之间，并从原位置被去除（图 19B）。

[0232] 闭塞物 / 凝块（60）可保持在近侧结构（560）与远侧结构（550）之间，并从原位置被去除（图 19C）。

[0233] 闭塞物 / 凝块（60）可由近侧结构（560）保持 / 接合，并从原位置被去除（图 19D）。在一些情况下，闭塞物 / 凝块可接合到近侧结构和动脉壁之间，并借助闭塞物 / 凝块与装置之间的摩擦去除。

[0234] 闭塞物 / 凝块（60）可由远侧结构（550）保持 / 接合，并从原位置被去除（图 19E）。在一些情况下，闭塞物 / 凝块可接合到远侧结构和动脉壁之间，并借助摩擦去除。

[0235] 闭塞物 / 凝块（60）可由于近侧结构而裂开成碎屑。碎屑会落入远侧结构（550）或被远侧结构（550）捕获和 / 或留在近侧结构（560）和远侧结构（550）之间（图 19F），并从原位置被去除。

[0236] 闭塞物 / 凝块（60）可接合在各种位置 / 位点，并通过任何上述机构（图 19G）的组合去除，并且从原位置被去除。

[0237] 根据一些实施例，在闭塞物 / 凝块接合和 / 或收回过程中，能在任何时间拉回控制元件（10），以操纵收回装置的径向力和半径（即，尺寸），以确保闭塞物 / 凝块与装置接合，并且不滑离装置（图 19H）。

[0238] 图 20 示出根据本发明的一方面的装置。该装置可包括管件部件和接合隔室。管件部件可包括诸如推送管件（20）和连接管件（31）的多个管件元件。接合隔室可包括远侧接合元件（90）和近侧接合元件（65）。该装置还可包括中心线（10）。

[0239] 如图 20 中可见，在某些实施例中，远侧接合元件（90）和近侧接合元件 65 与中心线（10）相关联。在某些实施例中，远侧接合元件 90 可连接到（或固定到）中心线（10），且近侧接合元件（65）可连接到连接管件（31），该连接管件还可连接到推送管件（20）。中心线（10）可放置于连接管件 31 和推送管件（20）内，并自由运动通过连接管件以及推送管件。在一些实施例中，中心线（10）和推送管件（20）可延伸到装置的近端。

[0240] 在一些实施例中，可独立操纵中心线（10）和连接管件（31），由此允许单独控制远侧接合元件和近侧接合元件。更具体来说，远侧接合元件将通过连接到远侧接合元件的中

心线的运动来控制；而近侧接合元件将通过与近侧接合元件连接的连接管件或推送管件的运动来控制。在诸如图 20 中可见那样的某些实施例中，推送管件和连接管件彼此连接，由此，推送管件的运动可最终控制近侧接合元件。

[0241] 在某些实施例中，远侧接合元件可在其远端处具有开口端部（例如，参见图 20A）。或者，在某些其它实施例中，远侧元件可在其远端处具有闭合端部（例如，参见图 20C）。远侧接合元件（90）可连接到中心线（10）。远侧接合元件可通过例如焊接、胶粘或夹紧的各种手段在其大约近端处连接到中心线。

[0242] 在某些实施例中，中心线（10）和远侧接合元件（90）之间的连接置于远侧元件连接件（80）内。远侧元件连接件可呈较短管或线圈的形式，并放置于中心线（10）上。在一些实施例中，远侧元件连接件可包括外部远侧元件连接件（82）和 / 或远侧元件连结介质（81）。在这种实施例中，远侧接合元件的近端可放置于外部连接件和中心线之间。在一些情况下，远侧接合元件、连接件和中心线可通过诸如夹子、扣钩或紧固件之类的连结介质来连接，这些连结介质将远侧接合元件和中心线紧固或保持在一起。

[0243] 根据一些实施例，近侧接合元件可包括多个线材。或者，近侧接合元件可由管件例如通过激光切割技术来制成。因此，在某些实施例中，在近端处省去了一小段管件，并且在远端处切割或形成支承件，如图 20A' 中可见。在这种实施例中，是近侧接合元件的一体部分的位于近端处的管件段可用作近侧元件连接件。在替代实施例中，可将单独的近侧元件连接件加到装置，如图 20A 中可见。在一些实施例中，近侧元件连接件（41）可包括诸如连结介质（42）和外部近侧元件连接件（43）的多个元件。在这种实施例中，近侧接合元件的近端可置于内部近侧元件连接件处、外部近侧元件连接件处或外部近侧元件连接件和连接管件的末端之间。在一些实施例中，将近侧接合元件的近端置于内部近侧元件连接件内。在一些情况下，近侧接合元件的近端与连接件可使用诸如夹子、扣钩或紧固件之类的连结介质来连结，这些连结介质紧固或保持远侧接合元件、更具体是其近端。或者，近侧元件连接件可包括其内放置有近侧接合隔室的单层管件。

[0244] 当存在单独的近侧元件连接件（例如，图 20）时，近侧接合元件到近侧连接件的连接可通过诸如焊接或胶粘的各种手段来进行。或者，如上讨论的那样，近侧连接件可包括能紧固或保持近侧接合元件的连结介质。在任何情况下，近侧元件连接件围绕中心线，并且允许中心线在近侧元件连接件内作自由运动。

[0245] 在某些实施例中，装置包含连接到近侧接合元件的连接管件。在一些实施例中，连接管件可进一步连接到推送管件，例如如图 20 中所示。借助该构造，近侧接合元件永久地连接到推送管件。然而，或者，将近侧接合元件固定到推送管件是暂时的或者可逆的，因此，如果期望，则近侧接合元件、可选地连同近侧连接件能从推送管件脱开。作为另一替代方式，近侧接合元件和与其相关联的近侧元件连接件可以不固定到管件隔室处（参见，例如图 26）。替代地，它们能沿中心线自由滑动。

[0246] 根据本发明的一方面，远侧接合元件的位置可通过控制中心线来确定。例如，在图 20 中所示的实施例中，远侧接合元件与中心线连接。操作者能控制中心线的运动（例如，推入和推出），以将远侧接合元件定位在期望的位置。在某些实施例中，近侧接合元件可通过例如推送管件、连接管件或两者的管件元件的运动来定位。如图 20 中所示，在一些实施例中，近侧接合元件固定到管件元件的远端附近。由此，操作者可通过控制管件元件、即推送

管件和连接管件将近侧接合元件定位在期望位置。借助这些构造，能独立操纵两个接合元件。此外，这允许使两个接合元件之间的间距能变化。当用该装置来治疗患者时，装置的两个接合元件之间的间距能变化的这方面是有益的。该设计能通过将闭塞物或凝块保持在两个独立的接合元件之间来牢固地接合闭塞物或凝块。此外，通过调节每个接合元件的位置以及两者之间的距离，它可使保持的效率和精度最大化。

[0247] 在图 20B 中，示出图 20A 中所示的装置的不同状态。在该闭合位置，向近侧拉动中心线，由此向近侧接合元件拉动远侧接合元件，从而缩短两个接合元件之间的距离。

[0248] 图 21 示出从体腔(例如，血管)去除凝块或闭塞物的示例性实施例。在某些实施例中，装置可如下所述用于与凝块或闭塞物接合并从体腔去除凝块或闭塞物：

[0249] (A) 首先借助引导线的引导将微型导管(30)设置到在体腔内发生闭塞的区域。根据凝块或闭塞物的硬度、长度、位置和形状，微型导管可部分地穿过凝块(或闭塞物)或者到达凝块远侧。之后，管件隔室和接合部件可通过微型导管递送到闭塞物。在该技术中，近侧可扩张元件与远侧可扩张元件分离。当放置于装置内时，将近侧接合元件的末端放置于凝块或闭塞物后面 / 近侧。

[0250] (B) 将微型导管拉回以使接合部件和管件隔室的一部分脱开。理想地，近侧接合元件位于凝块近侧，而远侧接合元件位于凝块远侧，或者如果凝块相当长的话，位于凝块的近侧部的远侧。在一些实施例中，如图 21B 中可见那样，在此阶段，凝块将至少部分地由远侧接合元件保持或与其接合。

[0251] (C) 如果期望，操作者还可调节接合元件中的一个或两个的位置。例如，在保持推送管件以固定近侧接合元件时，操作者可向近侧拉动与远侧接合元件连接的中心线。然后，由于远侧接合元件与凝块之间的摩擦，凝块将向近侧运动。当这发生时，两个接合元件之间的距离缩短了，而凝块被抓取或接合在两个接合元件内和 / 或之间。如果操作者在拉动中心线和远侧接合元件时感觉到阻力，这表示凝块被接合在两个接合元件内和 / 或之间。然后，他或她能锁定远侧和近侧接合元件的位置，并从体腔(例如，动脉)拉出装置和被接合的凝块连同微型导管。在一些实施例中，通过置于装置上的标记(70)和 / 或(100)来识别装置的位置。

[0252] 在图 22 中，示出从体腔去除凝块或闭塞物的技术的替代实施例。该装置可如下所述用于与凝块或闭塞物接合并从体腔去除凝块或闭塞物：

[0253] (A) 微型导管(30)行进到在体腔内发生闭塞的区域。微型导管可在凝块或闭塞物的远端上前进。根据凝块或闭塞物的硬度、长度、位置和形状，微型导管可穿过凝块(或闭塞物)或者在基本上不干扰凝块的情况下经过凝块。在一些实施例中，一旦微型导管位于闭塞区域附近的位置，就将管件隔室和接合元件引入到微型导管内。在某些情况下，操作者可将微型导管和可扩张隔室放置于一旦脱开近侧接合元件就位于凝块近端的远侧的位置。如申请中其它地方阐释的，例如能使用装置中存在的标记来监测装置的位置。

[0254] (B) 使微型导管脱开，且接合隔室和管件隔室的一部分露出。

[0255] (C) 操作者还可进一步调节接合元件中的一个或两个的位置。例如，当保持中心线以及因此保持远侧接合元件稳定时，拉回近侧接合元件直至其远端刚经过凝块的近端。这可通过观察近侧接合元件的远端内的标记(70)来指示。近侧接合元件的远端在此位置打开。或者，如果期望，在保持近侧接合元件时，可调节远侧接合元件。此外，如果期望，可一

起调节近侧和远侧接合元件以确保与凝块的接合。

[0256] (D) 当通过固定推送管件来保持近侧接合元件稳定时，操作者可拉动连接到远侧接合元件的中心线。然后，由于远侧接合元件与凝块之间的摩擦，凝块可向近侧运动。两个接合元件之间的距离缩短了，且凝块被抓取或接合在两个接合元件内和 / 或之间。如果操作者在拉动中心线和远侧接合元件时感觉到阻力，这表示凝块被接合在两个部件内和 / 或之间。然后，他或她能锁定远侧和近侧接合元件的位置，并从体腔（例如，动脉）拉出装置和接合的凝块连同微型导管。在一些实施例中，通过置于装置上的标记（70）和 / 或（100）来识别装置和微型导管的位置。

[0257] 图 22 中所示的实施例的一些优点包括近侧接合元件能在脱开之后定位到凝块近侧，以在相对于凝块或闭塞物放置接合部件时确保相对较高的精度。由于可将近侧接合元件直接放置于凝块或闭塞物后面，当拉动远侧接合元件以使凝块向近侧运动时，凝块在接合到两个接合元件之间之前仅须行进非常短的距离。因此，与图 21 中所示的技术相比，凝块丢失的可能性降低。

[0258] 在图 23 中，表示出使用装置接合凝块的一些附加机构。如图 23 中所示，凝块可接合到管件元件和体腔表面（例如，动脉壁）之间（23A）、微型导管和近侧接合元件之间（23B）、近侧接合元件和动脉壁之间（23C）、远侧接合元件和动脉壁之间（23D）、近侧和远侧接合元件之间（23E）以及近侧接合元件和导管末端之间并且同时在两个接合元件之间（23F）。因此，显然可以在不脱离本发明的范围和精神的情况下对本申请中公开的装置和方法进行各种修改和应用。由此，当然本发明的范围包含这种变型和修改中的任一种。

[0259] 图 24 示出包括前述装置的系统的说明性实施例。在一些实施例中，中心线（10）可延伸到装置的近端，并连结到远侧部件手柄（120）。系统从远端到近端的长度可以约为 100 到 200 厘米。在一些实施例中，系统从远端到近端的长度可约为 100cm, 110cm, 120cm, 130cm, 140cm, 150cm, 160cm, 170cm, 180cm, 190cm 和 200cm。在一些其它实施例中，系统从远端到近端的长度可比 100 厘米短或者比 200 厘米长。在一些实施例中，系统可包括多个推送管件，诸如近侧推送管件（25）、中间推送管件（22）和远侧推送管件（24）。在一些其它实施例中，连接管件可连接到中间和近侧推送管件。可在系统的远端处，即如图 24 中所示借助远侧部件控制手柄和近侧推送管件由操作者来操作远侧和近侧接合元件。

[0260] 图 25 示出存在有远侧推送管件和近侧推送管件的系统的替代实施例。在连接管件顶上有远侧推送管件。在一些实施例中，推送管件中的至少一些部分是柔性的以确保装置能行进通过曲折路径。在其它实施例中，远侧推送管件中的至少一些部分可以是光滑和柔性的，因此，它还加强装置的可推送性。在某些实施例中，推送管件的近端可由刚硬 / 牢固的管件制成，以加强装置的可推送性。

[0261] 在装置需要拉回到微型导管内的情况下，每个接合元件可独立操作。例如，可先将近侧接合元件拉回到微型导管内，然后可通过拉动中心线将远侧部件拉入微型导管内，以避免两个元件（及其支杆）交叠。这将避免两个可扩张元件彼此交叠以及不能拉到微型导管内。在某些实施例中，一旦凝块被接合，两个接合元件的位置可锁定。在这种实施例中，两个接合元件的运动将同步，且将它们相继引入微型导管内。

[0262] 图 26 示出装置的替代实施例。特别是，近侧接合元件可以不与管件隔室连接。而是，与近侧元件连接件（41）相关联的近侧接合元件（65）可如图 26A 中可见那样沿中心线

10 自由滑动。在一些实施例中，近侧元件连接件（41）的内直径大于中心线（10）的外直径，因此，与近侧元件连接件（41）相关联的近侧接合元件（65）可在中心线（10）上自由滑动。此外，在至少一些实施例中连接管件是不需要的。图 26B 示出图 26A 中所示的实施例的闭合状态，其中，向近侧拉动中心线（10），由此，远侧接合元件 90 向近侧接合元件（65）运动。这将缩短两个接合元件之间的空间（或距离）。该特征将装使装置能如下图中所示与凝块接合。

[0263] 图 27 示出特别是使用图 26 中所示的装置从体腔（例如，血管）去除凝块或闭塞物的示例性实施例。在某些实施例中，装置可如下所述用于与凝块或闭塞物接合并从体腔去除凝块或闭塞物：

[0264] (A) 先借助引导线的引导使微型导管（30）行进到在体腔内发生闭塞的区域。微型导管可定位到在凝块或闭塞物近端的远侧。根据凝块或闭塞物的硬度、尺寸、位置和形状，微型导管可穿过凝块（或闭塞物）或者在基本上不干扰凝块的情况下经过凝块。之后，管件隔室和接合隔室可通过微型导管递送到闭塞物。近侧可扩张元件与远侧可扩张元件分开。当放置装置时，近侧接合元件的末端放置于凝块或闭塞物的近侧。

[0265] (B) 使微型导管脱开，且接合隔室和管件隔室的一部分露出。操作者可将装置调节成使近侧接合元件可位于凝块近侧，而远侧接合元件可位于凝块远侧，或者如果凝块相当长，则至少经过凝块的一部分。在一些实施例中，如图中可见，在此阶段，凝块将至少部分地由远侧接合元件保持。

[0266] (C) 操作者可进一步调节远侧接合元件的位置。例如，操作者可向近侧拉动与远侧接合元件连接的中心线。然后，由于远侧接合元件与凝块之间的摩擦，凝块将向近侧运动。两个接合元件之间的间距缩短。当凝块与近侧接合元件接触时，凝块可被抓取或接合到两个接合元件内和 / 或之间。同时，接合隔室和凝块进一步拉动到微型导管末端附近。为了确保接合，操作者可锁定远侧接合元件的位置并拉动装置。

[0267] 在某些实施例中，图 27 中所示的过程可如下进行：当进行图 26 中所示过程时，当装置脱开时，在微型导管内腔和近侧接合元件之间会有摩擦，并且近侧接合元件被拉离远侧接合元件。一旦两个元件离开微型导管，两个接合元件之间的间距可最大化或者基本上延长。操作者无须在展开之后调节两个接合元件的位置。操作者可通过与中心线连接的推送管件向近侧拉动远侧接合元件。因此，两个部件之间的距离将缩短以与凝块接合。在某些情形下，微型导管的末端可用于防止近侧接合元件向后运动。当操作者在向近侧拉动推送管件 / 中心线时感到阻力时，这可表示凝块被接合到两个接合元件内和 / 或之间，且近侧接合元件还被微型导管的末端止挡。此时，可锁定该装置并将其从体腔移除。因此，能容易地并以高效率去除凝块或闭塞物。

[0268] 图 28 示出包括图 26 中所示装置的系统的又一示例性实施例。或者，图 20 中所示的装置可用于图 28 的该系统中。在一些实施例中，近侧接合元件（65）位于中心线（10）周围，由此，它能在远侧接合元件 90 和推送管件（140）的远侧末端之间自由地滑动。此外，远侧接合元件 90 可连接到中心线（10）。中心线（10）可向近侧延伸。中心线 10 可与推送管件（例如，近侧推送管件 25、中间推送管件 22、内推送管件 21 和外推送管件 23）中的至少一个连结。因此，与图 24 中所示的实施例不同，中心线 10 不必延伸到装置的近端。而是，它可与管件元件中的任一个连接，并且与连接的管件一起被控制。在一些实施例中，外推送管

件(23)可以是柔性的且光滑的，并放置到接近于系统的远端，因而，它可允许装置通过体腔内的曲折路径。此外，在一些其它实施例中，薄内推送管件(21)可存在于系统中，而该内推送管件(21)可以是柔性的，但又能增加系统的可推送性。在又一些其它实施例中，具有一定柔性的中间推送管件(22)可存在于系统中。在又一些其它实施例中，相对刚硬的远侧推送管件(24)和/或近侧推送管件(25)可存在于该系统内，以使该系统的可推送性进一步提高。一个或多个推送管件可用粘合剂彼此连接，并还可与包括中心线(10)在内的其它部件连接。在又一些其它实施例中，具有可变刚度的单个推送管件可用于该装置中，以替代多个推送管件和连结部。该管件可通过将管件磨成不同壁厚或通过螺旋形切割来形成，以确保远端更柔性，而近端更刚硬。

[0269] 图 29 示出存在远侧推送管件和近侧推送管件的系统的替代实施例。在该实施例中，中心线(10)可以不延伸到系统的近端。类似于图 28 中所示的示例，中心线连接到管件元件中的一个或多个，并且通过连接的管件元件来控制。在连接管件顶上有远侧推送管件。在一些实施例中，远侧推送管件中的至少一些部分是柔性的，以确保装置能行进通过曲折路径。在其它实施例中，远侧推送管件中的至少一些部分可以是光滑和柔性的，因此，它还加强装置的可推送性。在某些实施例中，推送管件的近端可由刚硬/牢固的管件制成，以加强装置的可推送性。

[0270] 图 30A 示出装置的替代实施例。与图 20 中所示的实施例不同，该装置包括可推动和可拉动的近侧接合元件。然而，在该设计中修改了近侧接合元件的远侧末端。近侧接合元件的远端可如图 30 中所示向内弯曲或弄成圆滑，这可进一步确保末端对于动脉的内壁是无创伤性的。由此，可在动脉内腔中拉动和推动近侧接合元件，而损伤动脉壁的风险低得多。图 30B 示出图 30A 中所示的装置的靠拢状态，其中，近侧和远侧接合元件之间的距离最小化。

[0271] 图 31 示出特别是使用图 30 中所示的装置从体腔(例如，血管)去除凝块或闭塞物的示例性实施例。该图中所示的凝块收回机构很大程度上类似于图 21 和 22 中的收回机构。

[0272] 根据本发明的一些实施例的装置具有明显优点。例如，在操作过程中，如果凝块不位于两个接合元件内和/或之间，或者一个或两个接合元件位于凝块太远侧或太近侧，操作者可将接合元件中的一个或两个定位成确保接合。特别是，在图 31 中所示的实施例中，通过经由连接管件拉动或推动来将近侧接合元件调节到期望位置。由于近侧元件具有非创伤性圆形末端且能被向前推动以使凝块与远侧元件接合，该手术/技术可避免需要仅用远侧接合元件来拉动凝块一段距离，这可进一步降低在手术过程中丢失凝块的可能性。因此，这种装置可使用两个接合元件与凝块接合，并稳定凝块直至从体腔去除凝块。两个接合元件的这种独立控制允许在手术过程中非常精细地调节装置，因此，特别是在治疗中的精确定位是必要的情形下(例如，脑内中风治疗)十分有用。

[0273] 图 32A 示出装置的替代实施例。在该特定实施例中，近侧接合元件具有筐状特征。在该近侧接合元件(65)上没有相对尖锐的端部，因为近侧接合元件的远端通过近侧接合元件的连接线(150)连接到近侧接合元件的远侧连接件(140)。因此，当近侧接合元件被压缩时，其远端将向后运动并形成如图 32B 中所示的光滑远端。该光滑端部对于动脉内腔是无创伤性的。在至少一些实施例中，该近侧接合元件可在体腔内拉动和推动。在某些实施例中，近侧接合元件的远端比近侧接合元件的其它部分薄。因此，当凝块在两个接合元件内和

/ 或之间被拉动或推动时，近侧接合元件的远侧部会弯折或者翻转，如图 32B 中所示，因而，凝块被近侧接合元件接合将不会被近侧接合元件 65 和近侧接合元件的远侧连接件（140）之间的附加关联所阻碍。

[0274] 图 33A 示出装置的另一替代实施例。在该特定实施例中，近侧接合元件具有筐状特征。然而，与图 32 中所示的实施例不同，近侧接合元件 65 的远端与近侧部件的远侧连接件（140）直接连结。该装置还在近侧接合元件上具有不尖锐的端部，且由此还减少损伤体腔的任何风险。在该设计中，用于近侧接合元件的近侧部的材料可以与近侧接合元件的其它部分的材料相同或者不同。在某些实施例中，近侧接合元件的远侧部可由比近侧接合元件的其它部分相对柔性的元件构成。由此，当凝块抵靠于近侧接合元件被拉动时，近侧接合元件的远侧部会弯折或翻转，以使近侧接合元件可如图 33B 中所示与凝块更好接合。

[0275] 图 34A 示出装置的另一替代实施例。该装置还包括用于进一步确定装置的安全性的附加特征。该设计可包括具有筐状特征的近侧接合元件。将近侧元件的远侧部通过软的 / 柔性连接件（例如，段连接件 160）连结到近侧元件的近侧部，这些软的 / 柔性连接件允许弯折，而远侧部向后压缩。可例如通过控制与近侧接合元件相关联的管件隔室而拉动或推动近侧接合元件。在近侧接合元件中没有尖锐端部，因此，它对于动脉壁来说无创伤性。此外，在该设计中，近侧接合元件可由多于一种材料制成，材料中的一种比另一种软。因此，在与凝块接合时易于使近侧接合元件的至少远侧部弯折或翻转（参见图 34B）。

[0276] 图 35 示出装置的近侧部的又一替代实施例。该装置还包括用于进一步确定装置的安全性的附加特征。该设计包括具有圆形远侧端部的近侧接合元件，以形成对于血管更无创伤的末端。因此，可例如通过控制与近侧接合元件相关联的管件隔室而拉动或推动近侧接合元件。

[0277] 下图 36-45 提供用于接合（和去除）凝块的近侧元件位于微型导管的远侧末端或端部处的进一步的替代实施例。在一些实施例中，该接合元件可附连到微型导管的远侧末端处。在一些其它实施例中，微型导管本身的远侧末端或端部成形为并构造成起到近侧接合元件的作用。换言之，近侧接合元件是微型导管的一体部分。

[0278] 在一些实施例中，可单独地附连到微型导管或者是微型导管的一体部分的近侧接合元件可在收回过程中或需要时改变形状和 / 或尺寸。例如，在收回装置放置于期望位置，即完全或部分经过凝块之后，可将收回装置插入微型导管内。然后，可向近侧拉动微型导管以使装置脱开。当微型导管的远侧末端到达凝块的大约近端处时，将微型导管的远侧末端操纵成改变成打开 / 漏斗形状。当保持微型导管稳定时，收回装置可连同与收回装置的接合元件部分接合的凝块一起拉回，直至凝块基本上或完全接合（或捕获）在微型导管的远侧末端（即，近侧接合元件）与收回装置的接合元件（即，远侧接合元件）之间。通过将收回装置和微型导管锁定到装置的近端处，可从例如动脉的内腔拉出装置和微型导管连同被接合的凝块。

[0279] 在微型导管的远侧末端提供近侧接合元件的某些实施例中，它可简化收回装置的设计以及由此其制造过程。代替两个单独的接合元件，例如如图 20 的实施例中所示，收回装置可仅需一个接合元件，即远侧接合元件，而起到近侧接合元件作用的另一元件可由微型导管来提供。

[0280] 图 36 示出诸如囊体的可膨胀或接合元件附连到微型导管的远端 / 远侧末端处的

装置的实施例。可扩张或接合元件(170)的形状和尺寸可通过其膨胀和收缩来控制。根据一些实施例,可扩张或接合元件(170)可例如通过用注射器 190 将液体(195)(例如,盐水溶液)注入可扩张或接合元件(170)内来膨胀,以形成期望的形状。在某些实施例中,将注入的液体通过注射通道 180 传递到可扩张或接合元件(170)。可扩张或接合元件(170)在膨胀后的形状和尺寸可变化。例如,当将预形成的囊体附连到微型导管的远侧末端时,它在膨胀时可成形为任何预形成的形状,例如漏斗状形状,如图 36B 中可见那样。或者,如图 36C 中可见,当膨胀时可仅增加可扩张或接合元件(170)的表面面积。由微型导管提供的可变形的近侧接合元件可单独地或者与其它元件(例如,体腔表面、微型导管、管件隔室、近侧接合元件、远侧接合元件及其任何组合)组合并以高效率与凝块接合(例如,参见图 33 和 37)。

[0281] 图 37 示出使用图 36 的装置来接合和去除凝块的机构。在收回过程中,操作者可将微型导管(30)插入体腔(例如,动脉)内直至远侧末端进入或通过凝块(60)。收回装置可与微型导管一起或者一旦微型导管在位则通过微型导管递送到闭塞物位置。在某些实施例中,可推动收回装置直至其接合元件 90 可如图 37A 中可见那样通过凝块的至少一部分。当保持收回装置稳定时,操作者可向后(即,向近侧)拉动微型导管,直至微型导管的远侧末端位于凝块的大约近端处,并且使收回装置的接合元件 90 露出,并扩张到其松弛或打开状态(图 37B)。因此,凝块可位于远侧接合元件 90 和微型导管的远侧末端(即,近侧接合元件 170)之间。然后,操作者可使微型导管 170 的可变形的远侧末端扩张,以将末端在凝块的近端处变形为漏斗形状(图 37C)。当保持微型导管稳定时,操作者可向后拉动远侧接合元件 90,因而,凝块可向后运动,并且接合到远侧接合元件 90 与微型导管的远侧末端(170)之间。然后,操作者可固定微型导管和收回装置,并且将它们拉出动脉,这使得能去除凝块。

[0282] 图 38 示出微型导管的远侧末端形成接合元件、更具体是近侧接合元件的装置的另一实施例。在该特定实施例中,例如通过激光切割来切割微型导管(200)的远侧末端,因而,在收回过程中,它能在被凝块(60)和 / 或远侧接合元件 90 压缩时转变成漏斗形状。在某些实施例中,在到达微型导管远侧末端的到底端之前结束切割过程,因而,微型导管的远侧末端仍是闭合的。

[0283] 图 39 示出微型导管的远侧末端(200)经受螺旋形切割的实施例的又一替代方案。类似于图 38 的装置,在收回过程中,当被压缩时,微型导管的远侧末端将成形为例如漏斗形状(图 39B)。在某些实施例中,在到达微型导管远侧末端的到底端之前结束切割过程,因而,微型导管的远侧末端仍是闭合的。

[0284] 图 40 示出微型导管的远侧末端形成为编织结构的又一实施例。或者,如申请中其它地方所述,单独的编织结构可附连到微型导管的远侧末端处。附连到微型导管处或形成于微型导管内的编织结构(200)可以是具有或不具有塑料涂层的金属编织物。在与远侧接合元件 90 一起与凝块接合时,编织结构(200)将被压缩和成形为例如漏斗形状,因而,凝块保持在远侧接合元件 90 和编织结构(200)之间。

[0285] 图 41 示出微型导管的远侧末端切割到到底端的又一实施例。因此,如图中可见,微型导管的远侧末端的该到底端并不闭合。在用远侧接合部件 90 向后拉动凝块时,微型导管的末端压缩成例如漏斗形状(沙嘴),并且凝块保持在收回装置的远侧接合部件 90 和微型导管(200)的远侧末端之间。图 41B 和 C 示出微型导管的开口末端的两个不同形状。

[0286] 在某些实施例中,近侧接合元件可包括微型导管的远端的包括微型导管末端的一

部分和覆盖微型导管末端的一层薄管件。在一些实施例中，近侧接合元件的至少一部分构造成在移除一层薄管件时改变形状。在图 42 中示出这种实施例的示例。图 42 示出一装置，在该装置中，外套管层施加于微型导管。在某些实施例中，用作接合元件的微型导管的远侧末端可包括预成形结构或形状记忆结构。外套管（210）可保持微型导管的远侧末端（200），因此，它能在接合之前通过凝块。当将微型导管向近侧拉到凝块时，通过向近侧拉动外套管而使末端打开到其预成形，例如漏斗形状。或者，形状记忆材料可用于微型导管的远侧末端（200），因而，它能在从外套管露出时形成一定形状。

[0287] 图 43 示出线材用于在微型导管的远侧末端处提供一定形状的装置的又一实施例。图 43B 中所示的该设计示出具有嵌入到末端内的例如弹性线材的线材（220）的微型导管的远侧末端（200），以确保末端将在被拉出外套管（210）之后扩张到其预设定的形状。

[0288] 图 44 示出装置的另一实施例。在该特定实施例中，预成形漏斗末端结构（切片的）放置于微型导管的末端处，且微型导管的末端通过线材（220）保持，这些线材延伸通过微型导管壁的内通道（230）内的内腔。线材可保持微型导管的末端平直或未折叠，直到在接合之前该末端通过凝块。当通过向近侧拉动线材而将微型导管向近侧拉到凝块时，末端打开到其预成形、例如漏斗形状。

[0289] 图 45 示出编织结构和外套管被一起采用的装置的又一实施例。将预成形编织结构放置于微型导管的远侧末端，一层外套管保持末端平直，因此，能在接合之前循环前进到达或通过凝块。当通过向近侧拉动外套管而将微型导管定位到凝块近侧时，编织物末端打开到其预成形、例如漏斗形状。

[0290] 尽管文中描述了各种方面和实施例，但其它方面和实施例将对于本领域技术人员来说是显然的。文中公开的各种方面和实施例是出于说明的目的，并且不意在限制，由下述权利要求书表示实际范围和精神。

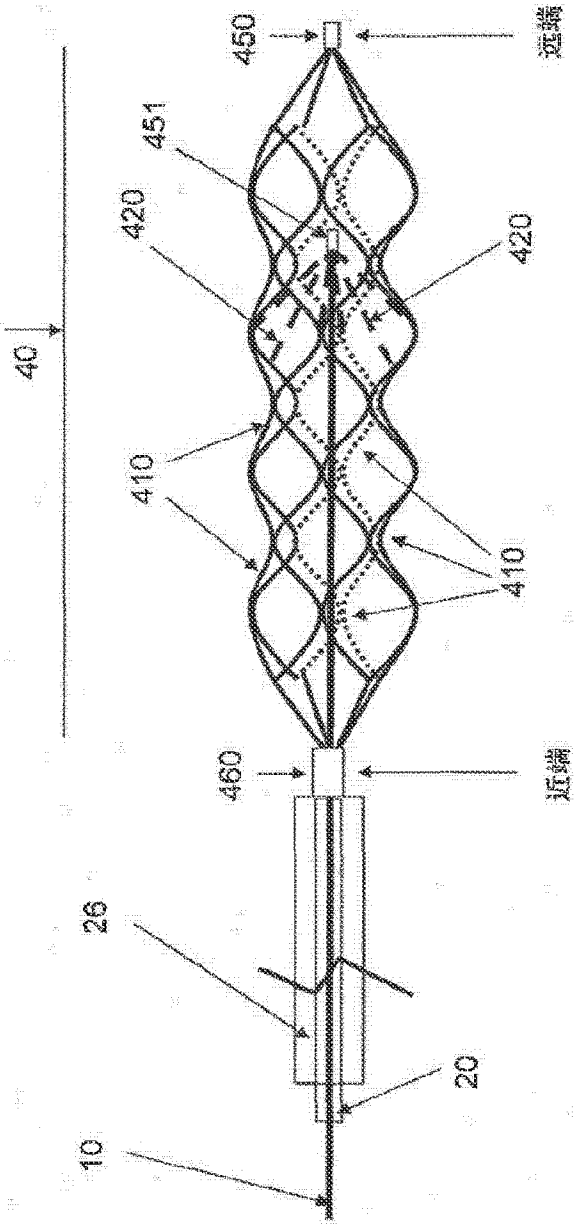


图 1

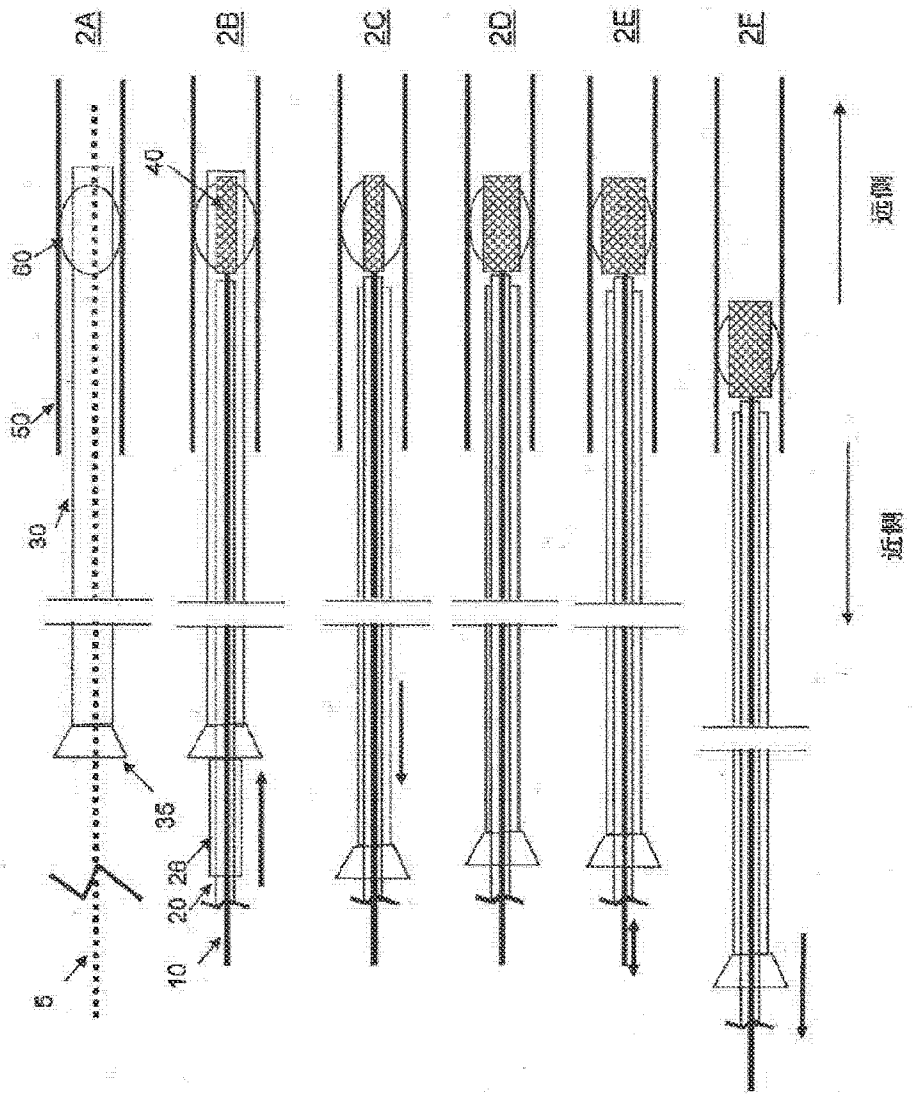


图 2A-F

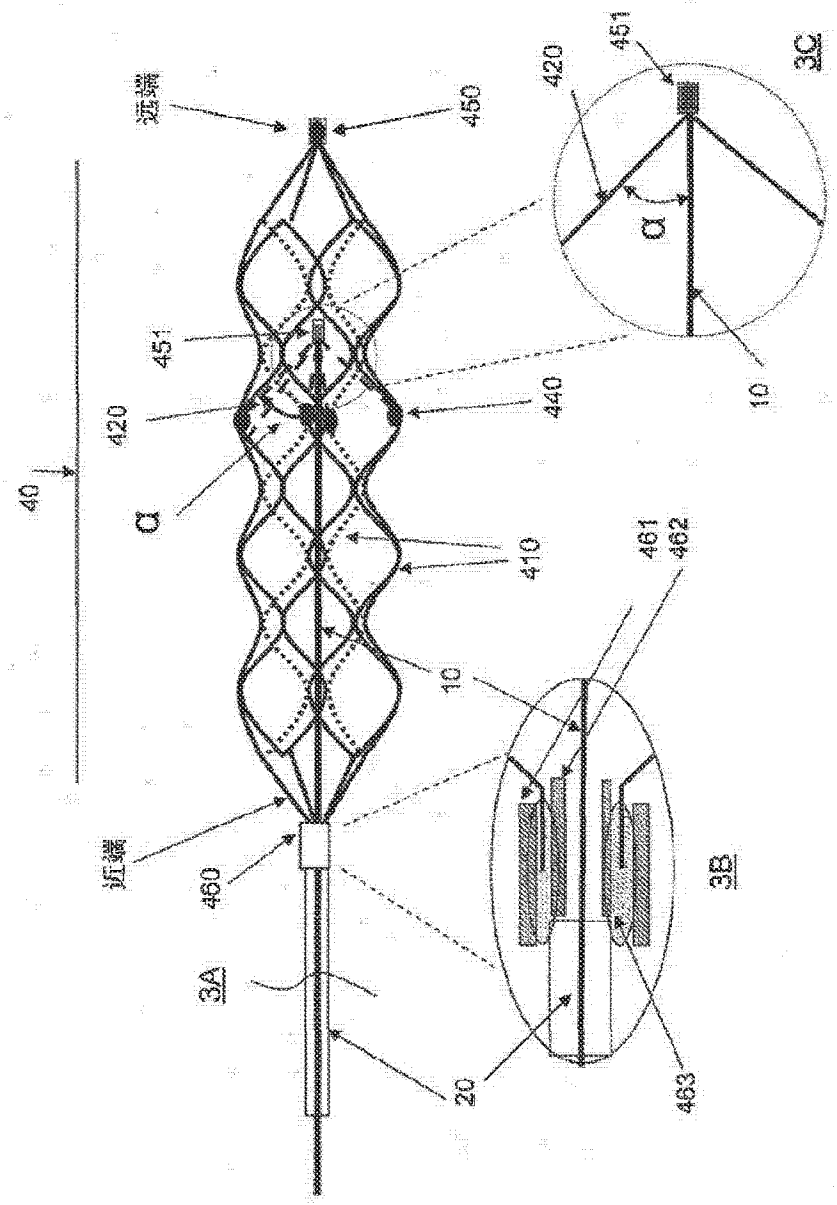

远端
450
420
451
3C
α
10
451
420
440
40
α
410
461
462
10
近端
460
3B
3A
20
463

图 3A-C

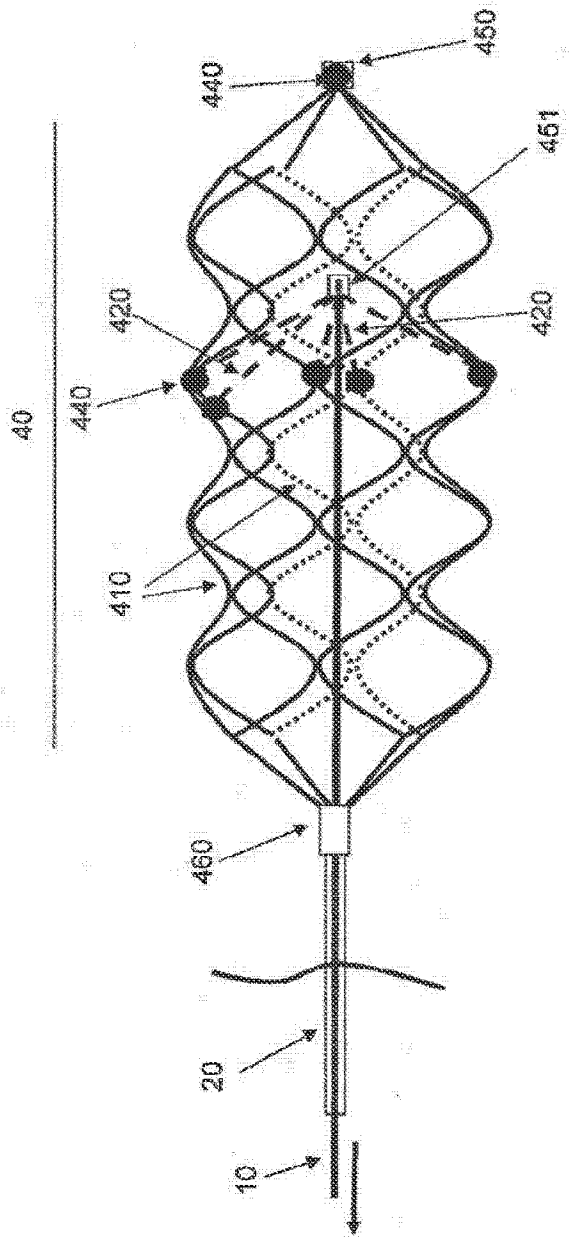


图 3D

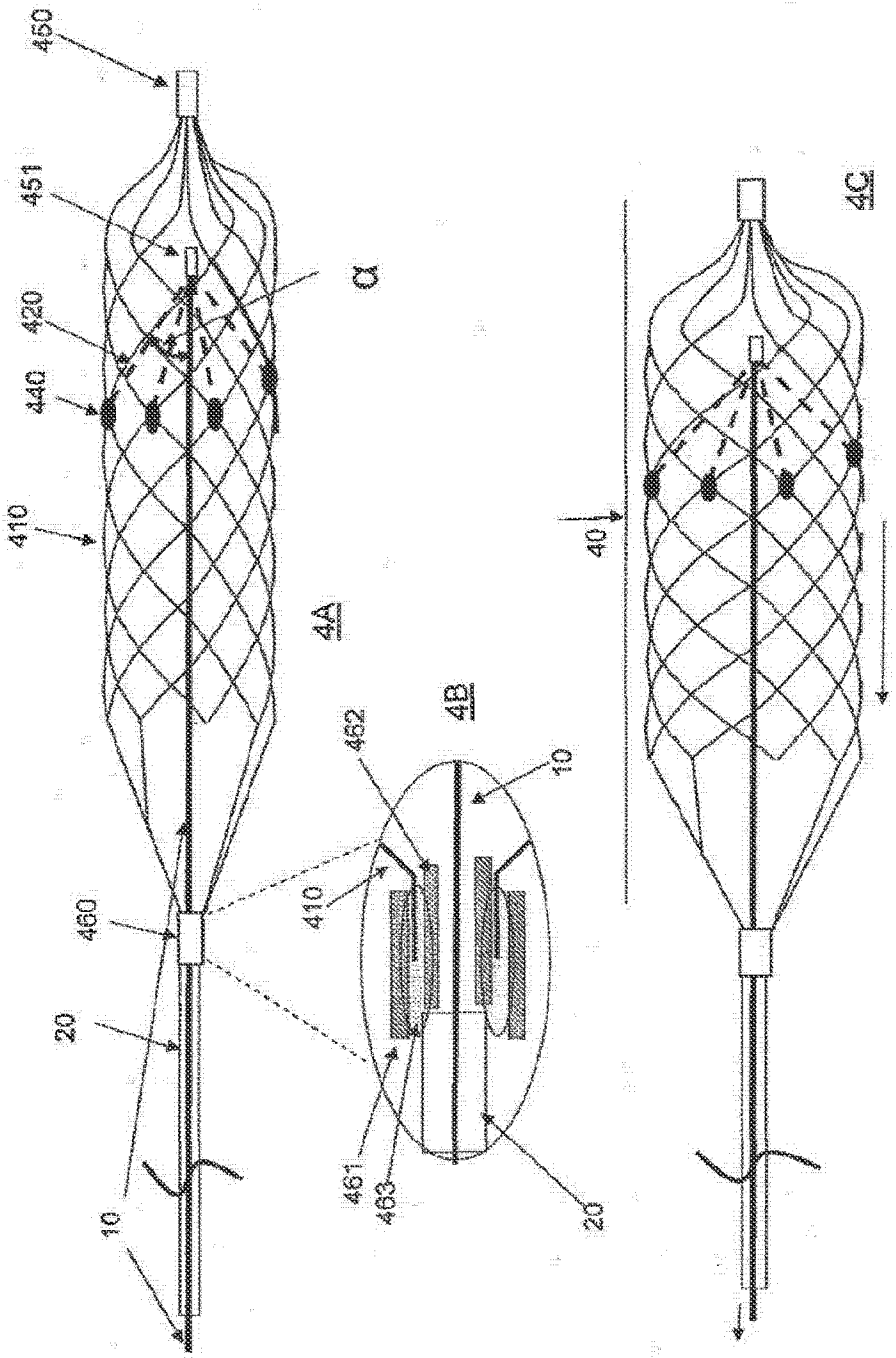


图 4A-C

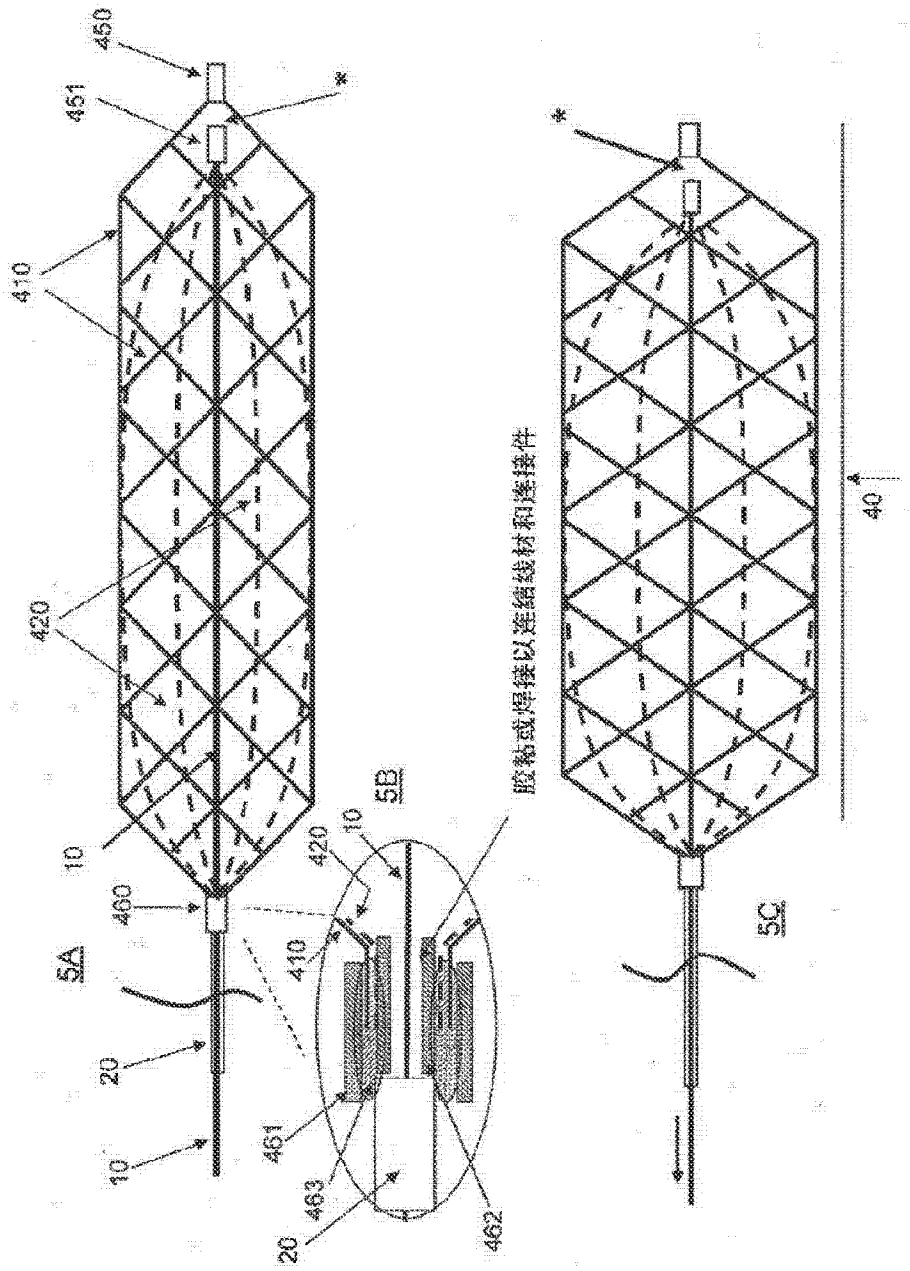

450
451
*
410
420
10
460
5A
20
10
461
463
20
462
5B
420
10
410
胶粘或焊接以连结线材和连接件
*
40
5C

图 5A-C

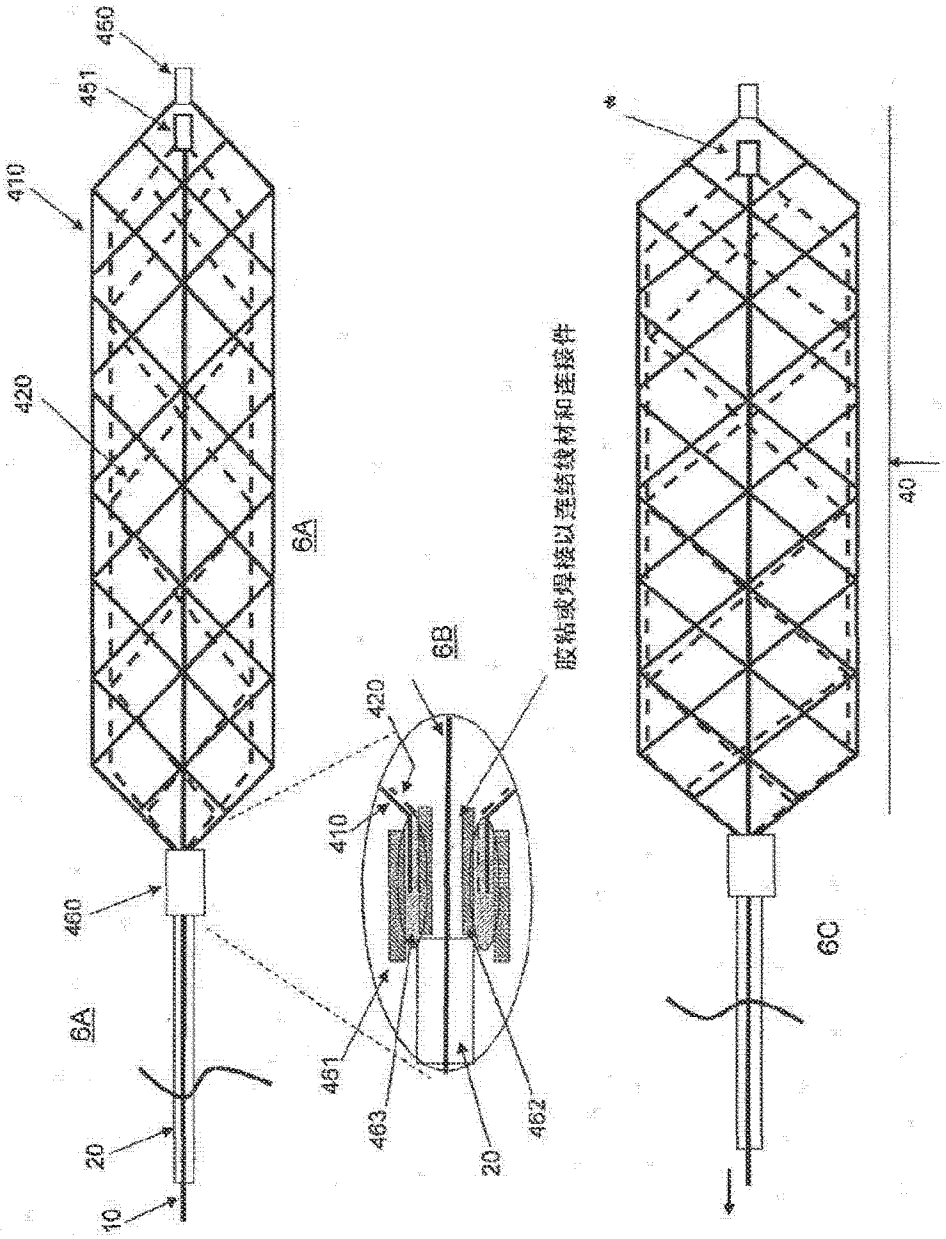

460
451
410
420
6A
460
6A
20
10
6B
420
410
461
463
462
20
胶粘或焊接以连结线材和连接件
40
6C

图 6A-C

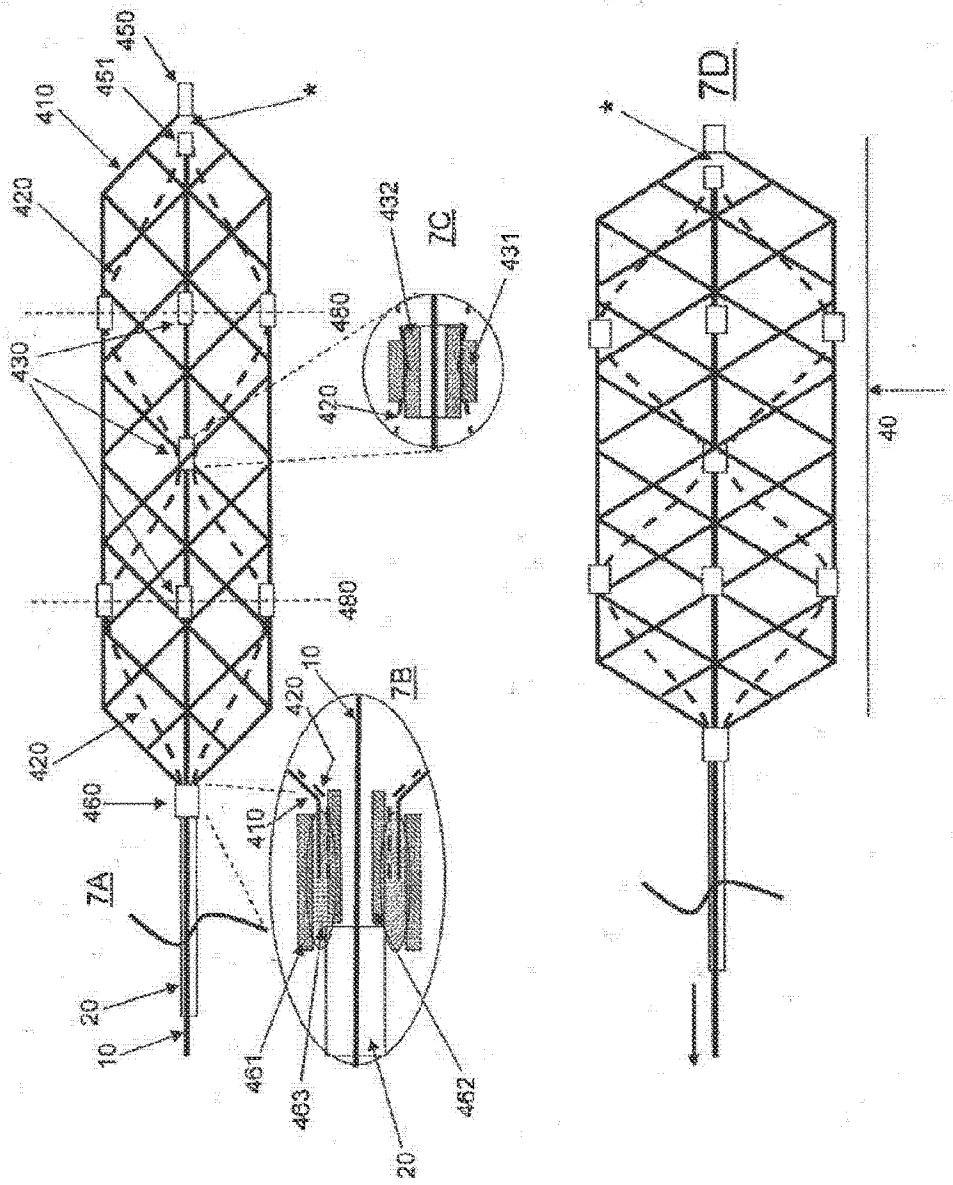

450
451
410
420
430
480
460
ZA
20
10
ZB
461
463
462
ZC
432
431
7D
40

图 7A-D

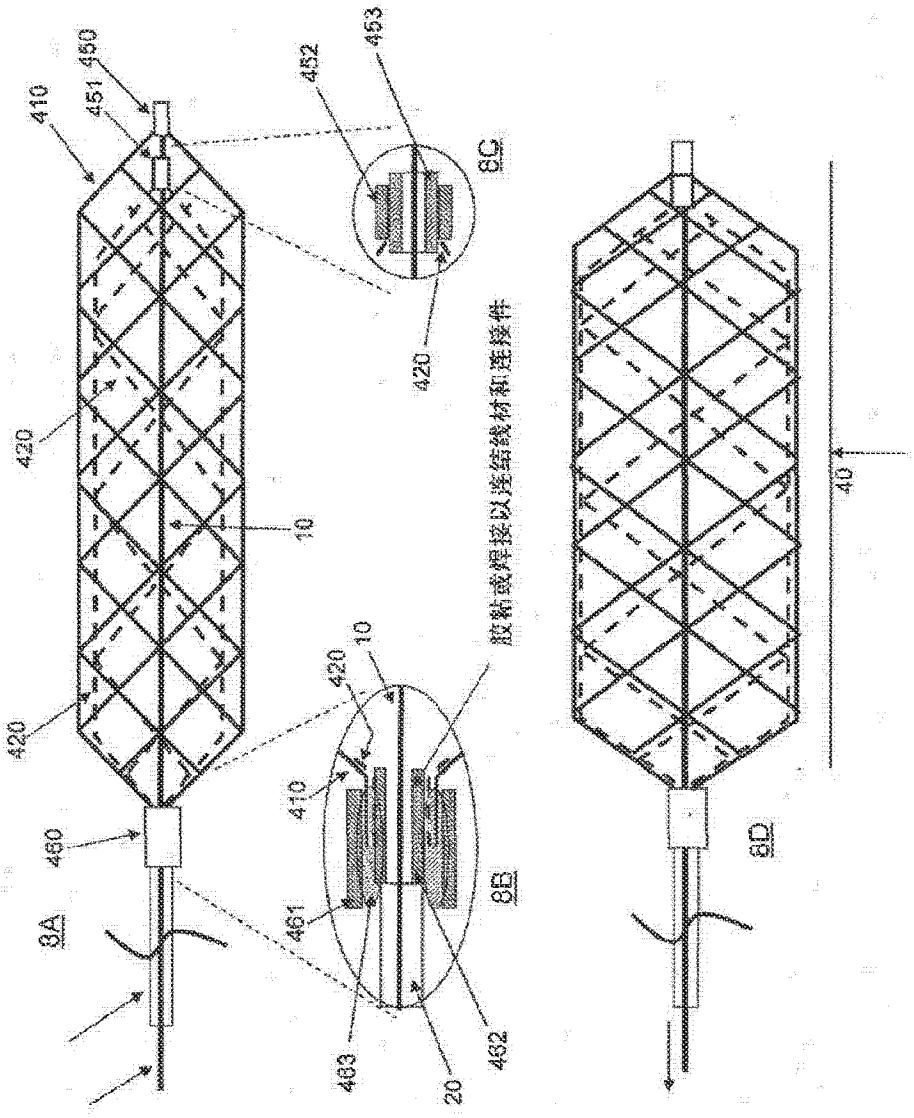

410
451
450
452
453
8C
420
420
10
420
420
10
410
460
461
8A
8B
463
20
462
胶粘或焊接以连结线材和连接件
8D
40

图 8A-D

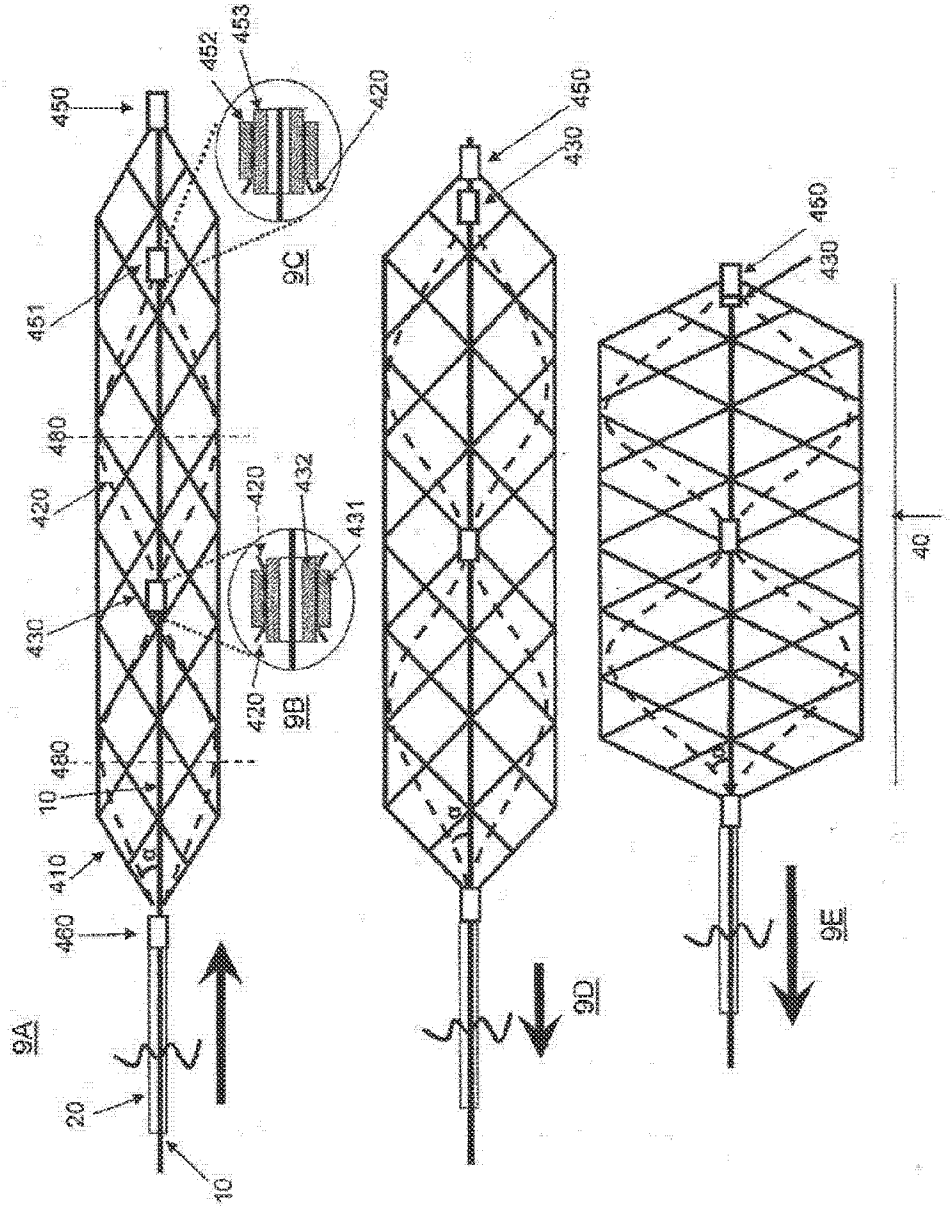

450
452
453
420
9C
451
460
420
432
431
420
430
9B
480
10
410
460
9A
20
10
450
430
9D
460
430
40
9E

图 9A-E

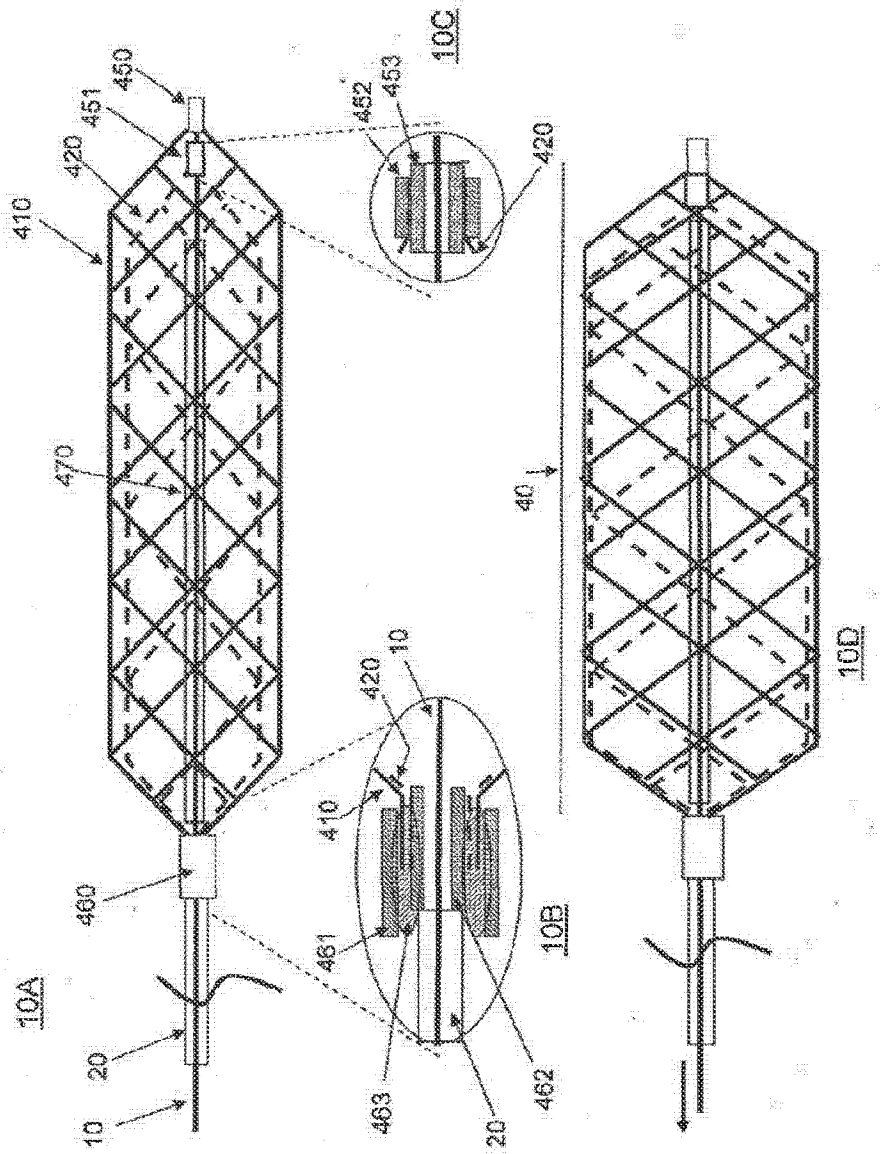

10C
450
451
420
410
452
453
420
470
40
10D
420
10
410
460
461
10B
10A
20
10
463
462
20

图 10A-D

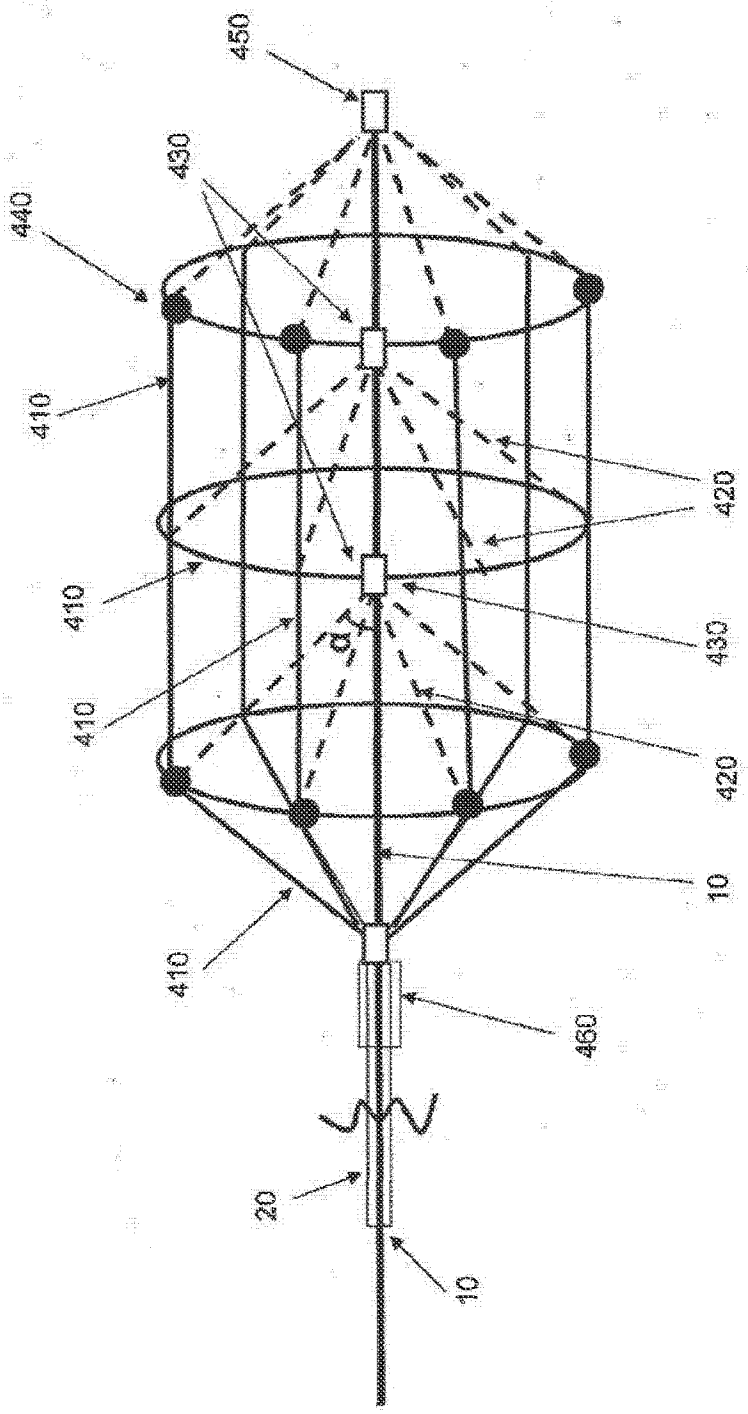


图 11

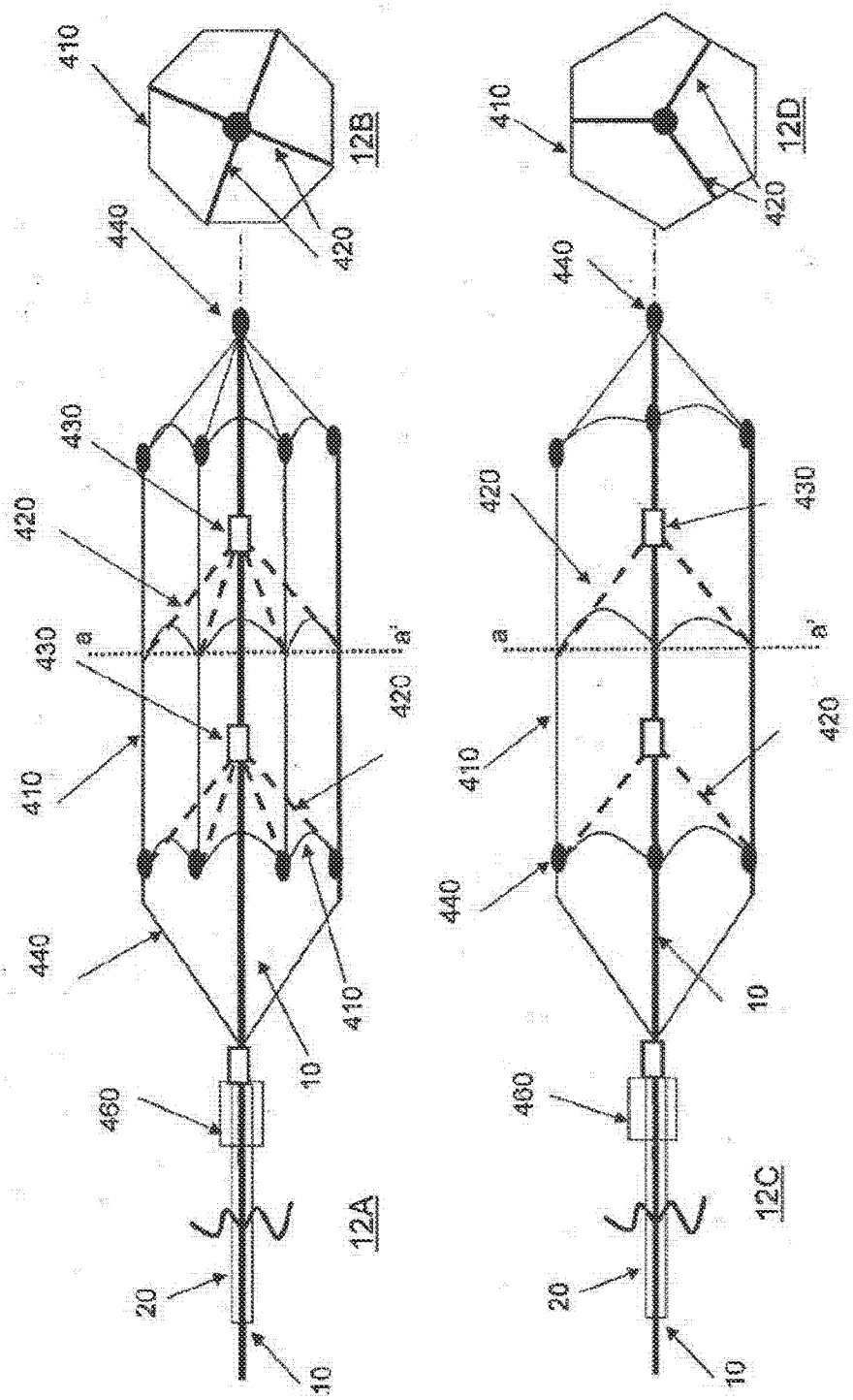

410
420
12B
440
430
420
a
a'
430
420
410
440
410
10
460
12A
20
10
410
420
12D
440
420
430
a
a'
420
410
440
10
460
12C
20
10

图 12A-D

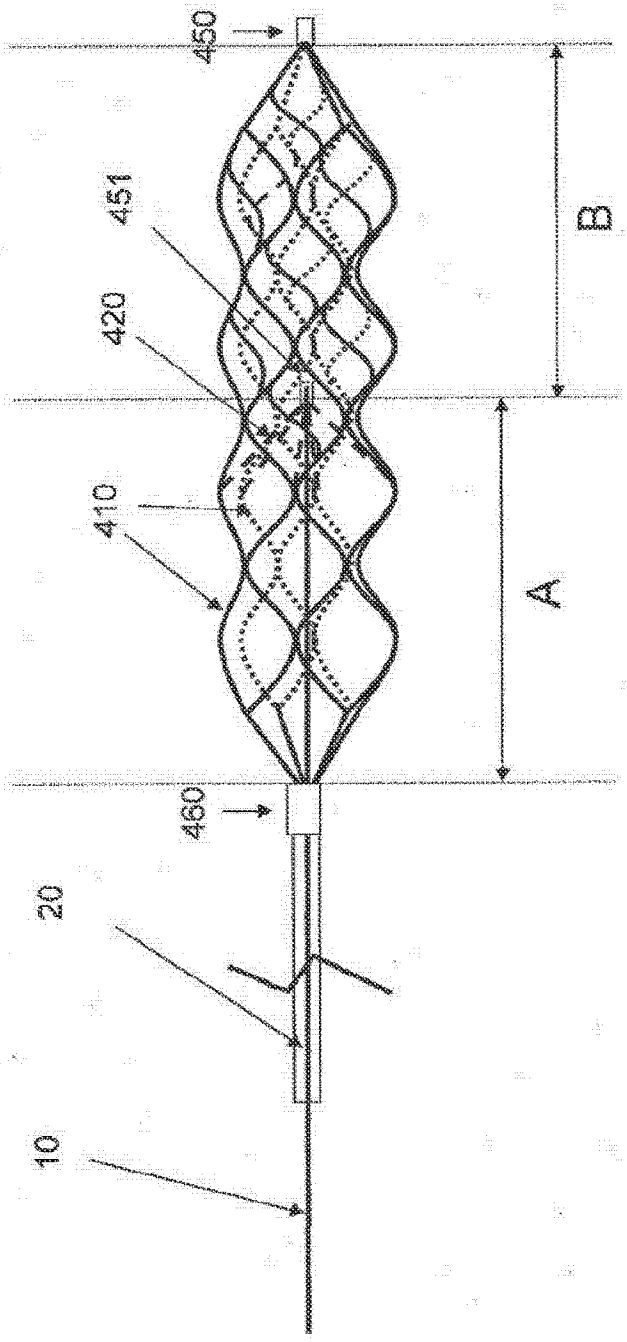
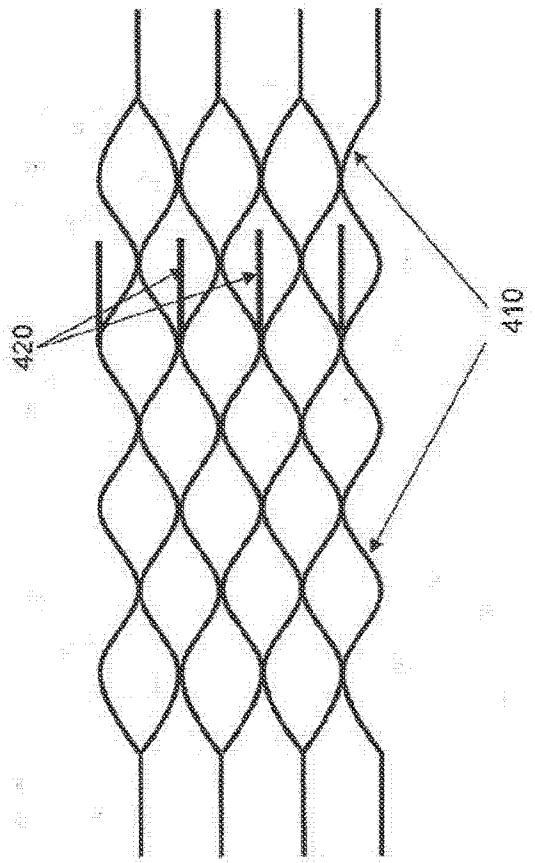


图 13



14A

图 14A

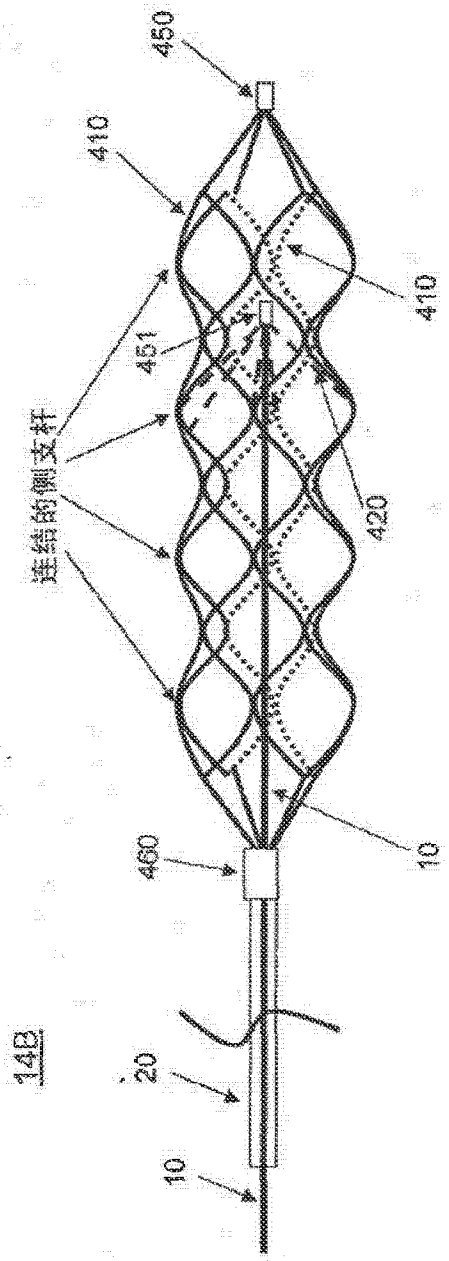


图 14B

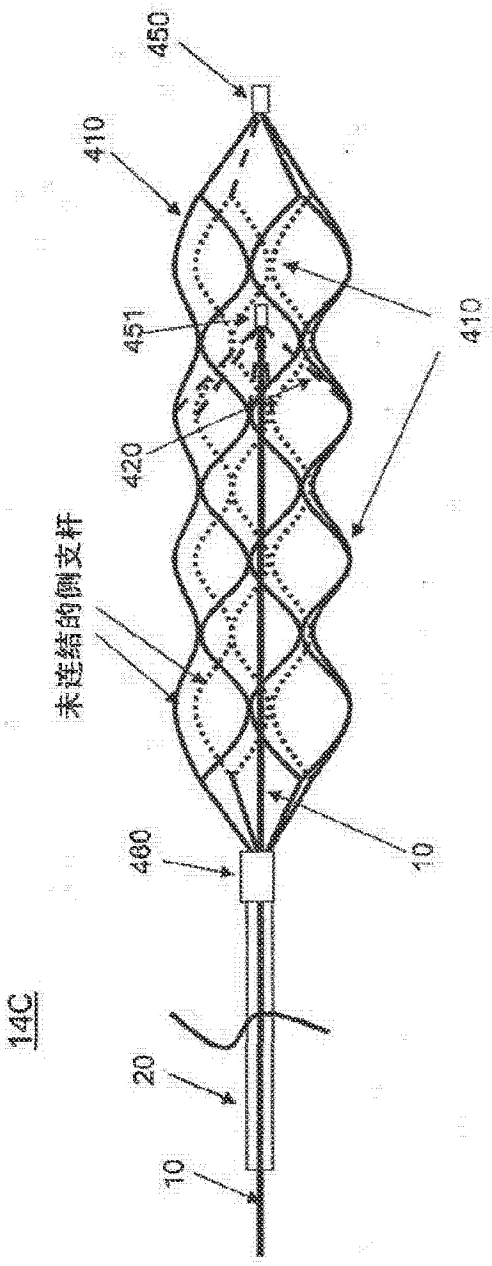
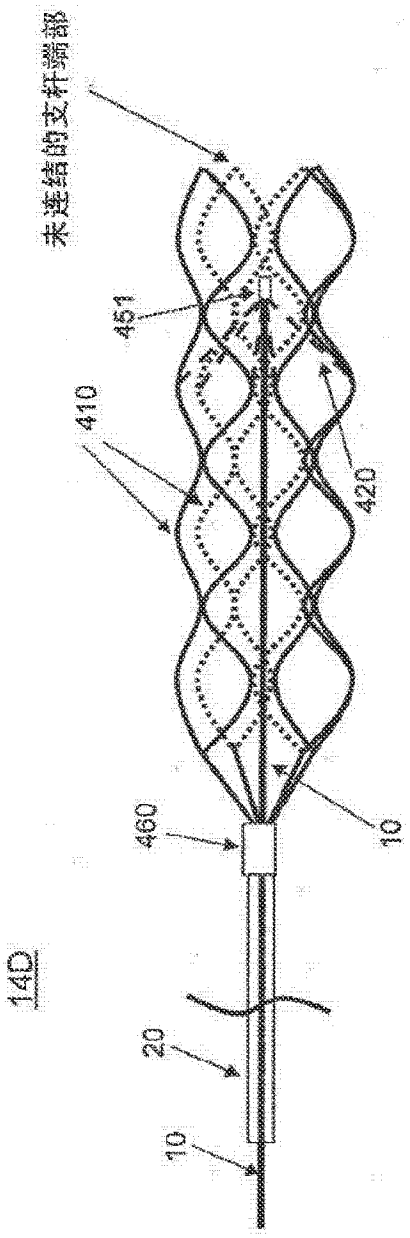


图 14C



14D

图 14D

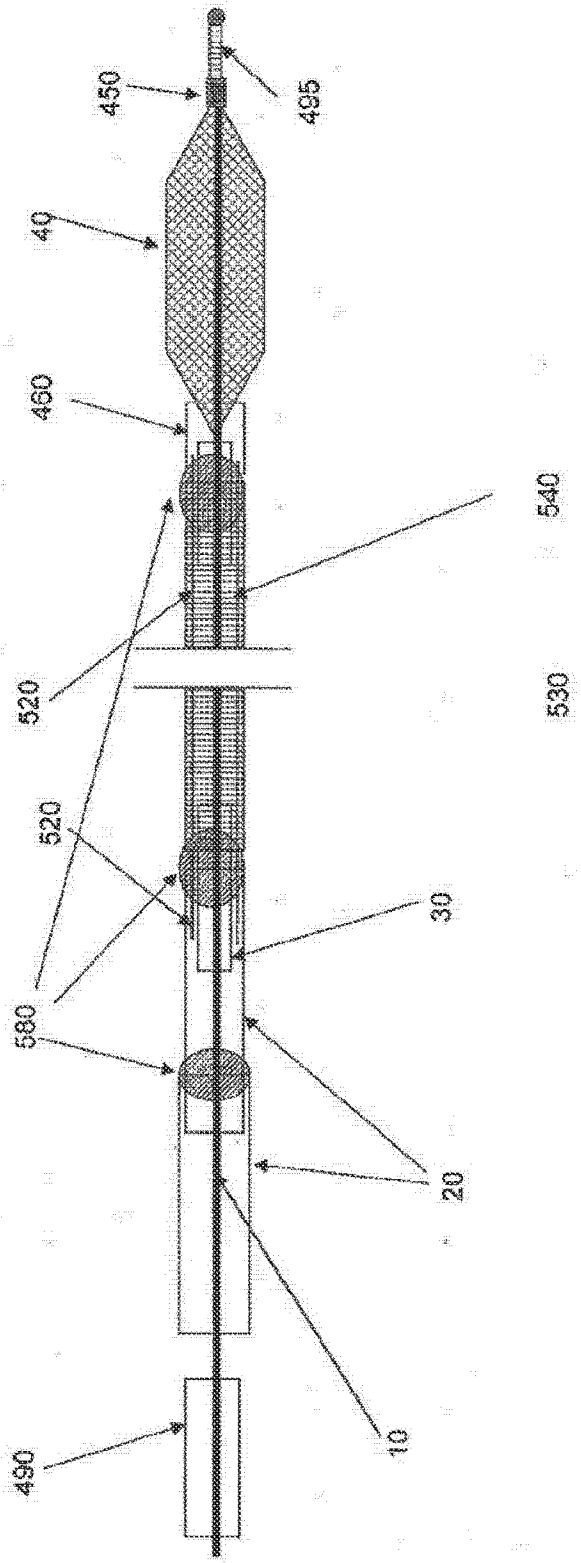


图 15

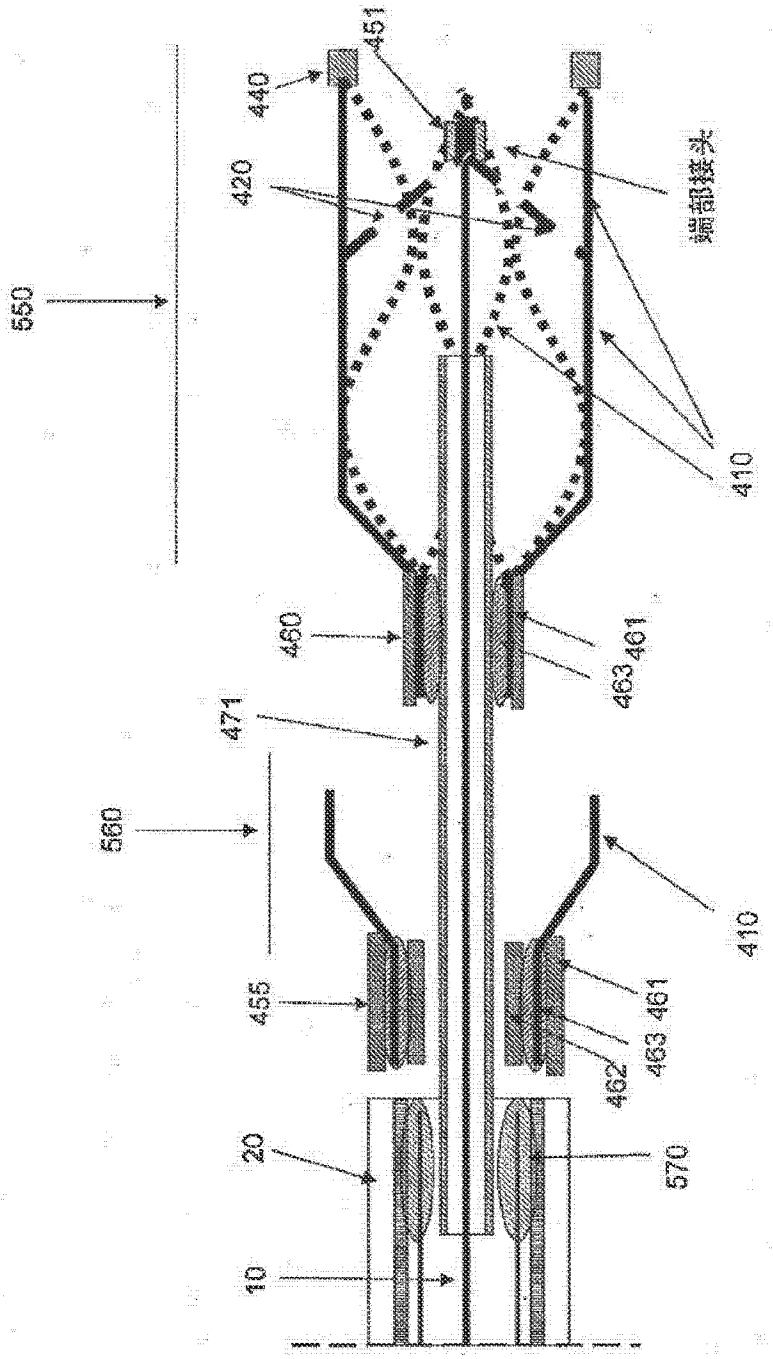

451
440
420
端部接头
550
410
460
461
463
471
560
410
455
461
463
462
20
570
10

图 16

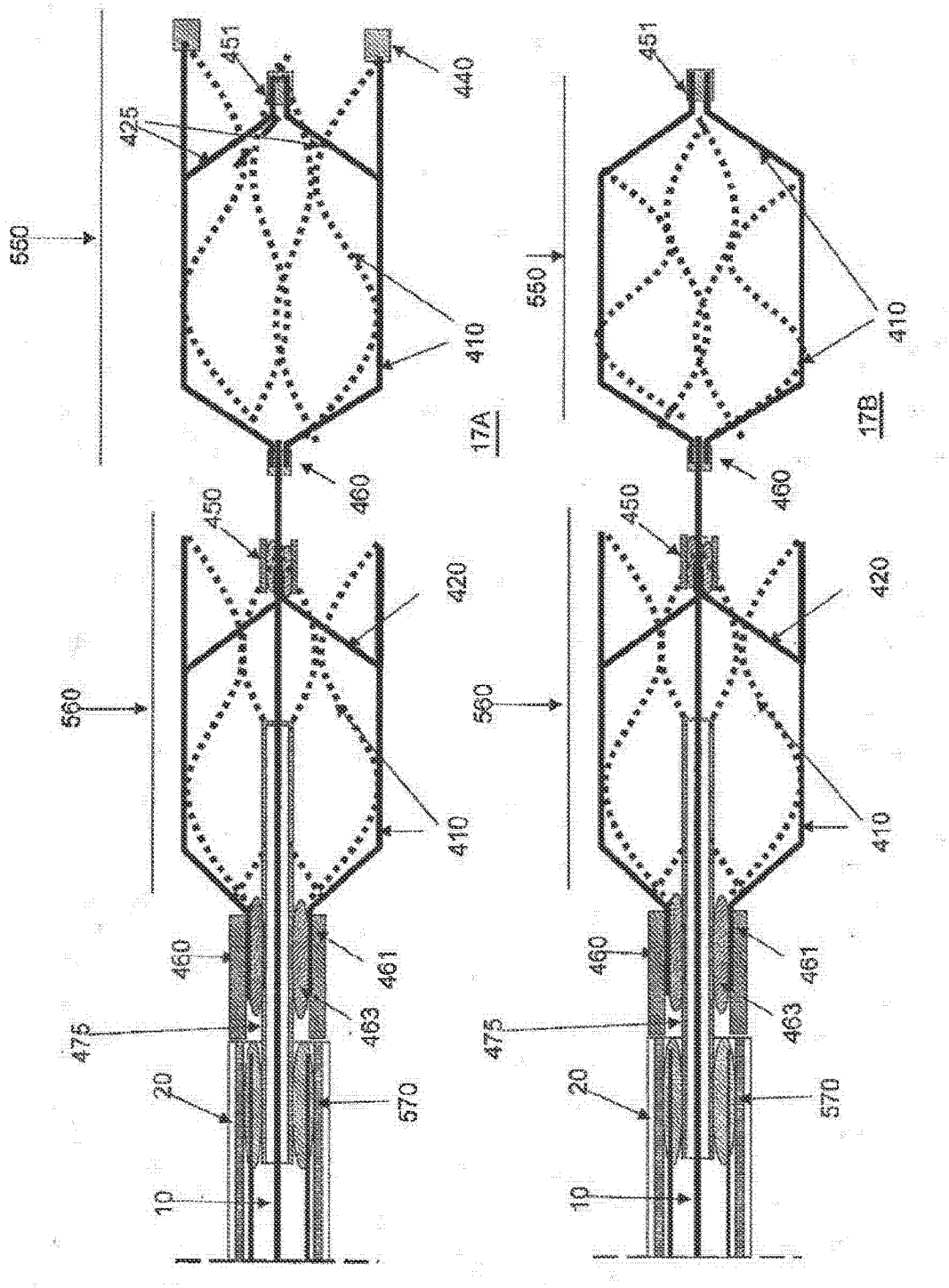

451
425
440
550
410
17A
460
450
420
560
410
460
461
463
475
20
570
10
451
550
410
17B
460
450
420
560
410
460
461
463
475
20
570
10

图 17A-B

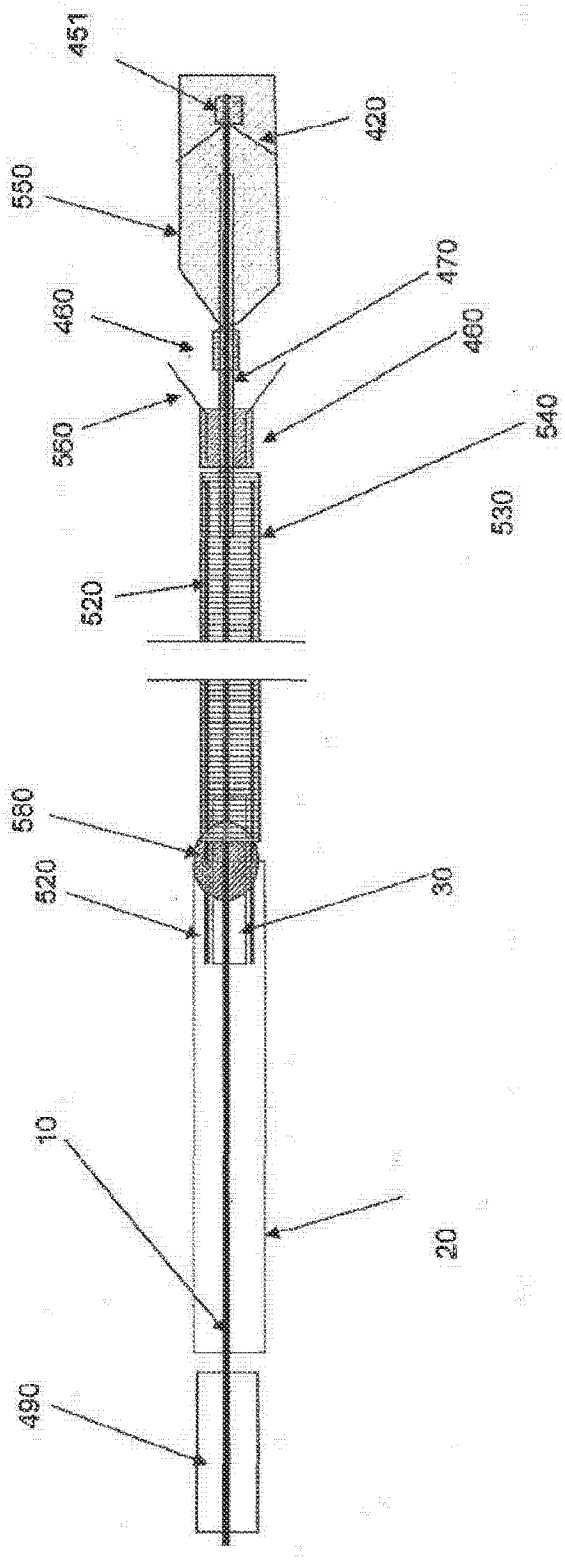


图 18

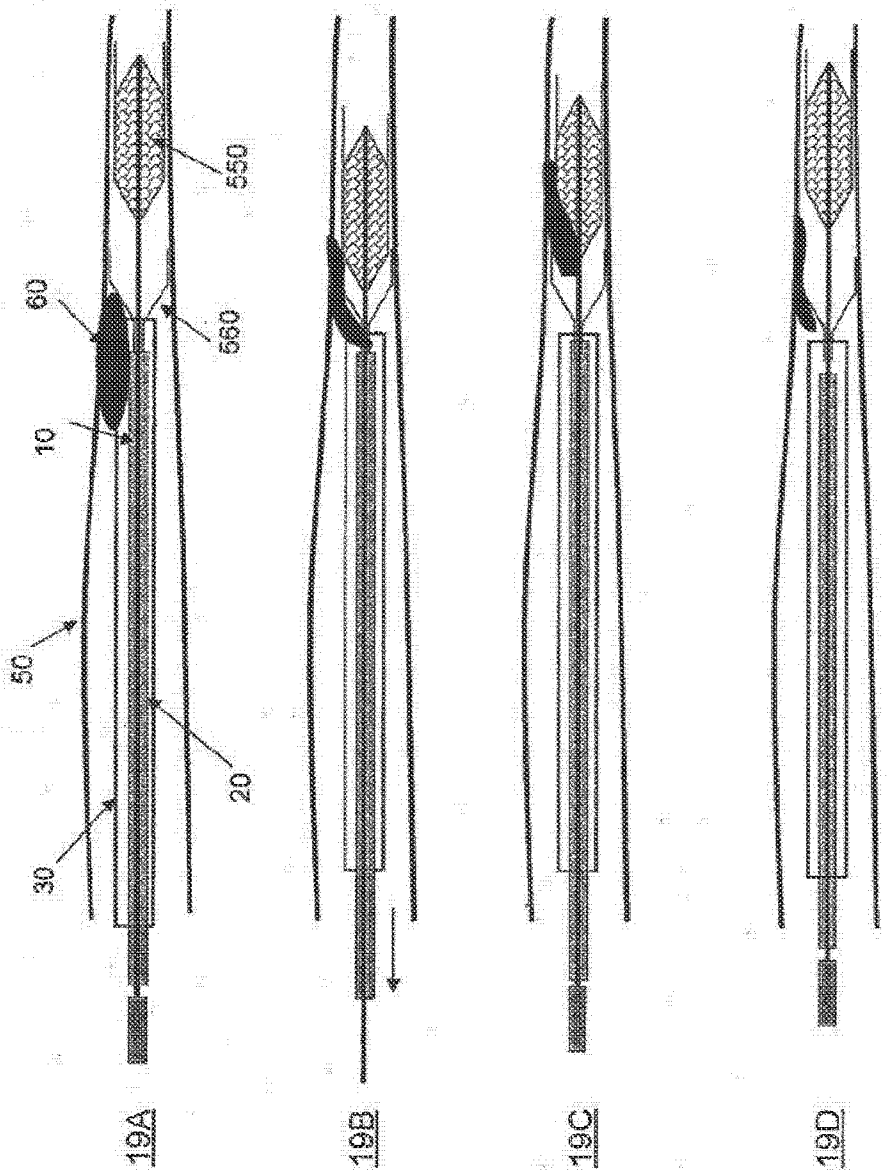


图 19A-D

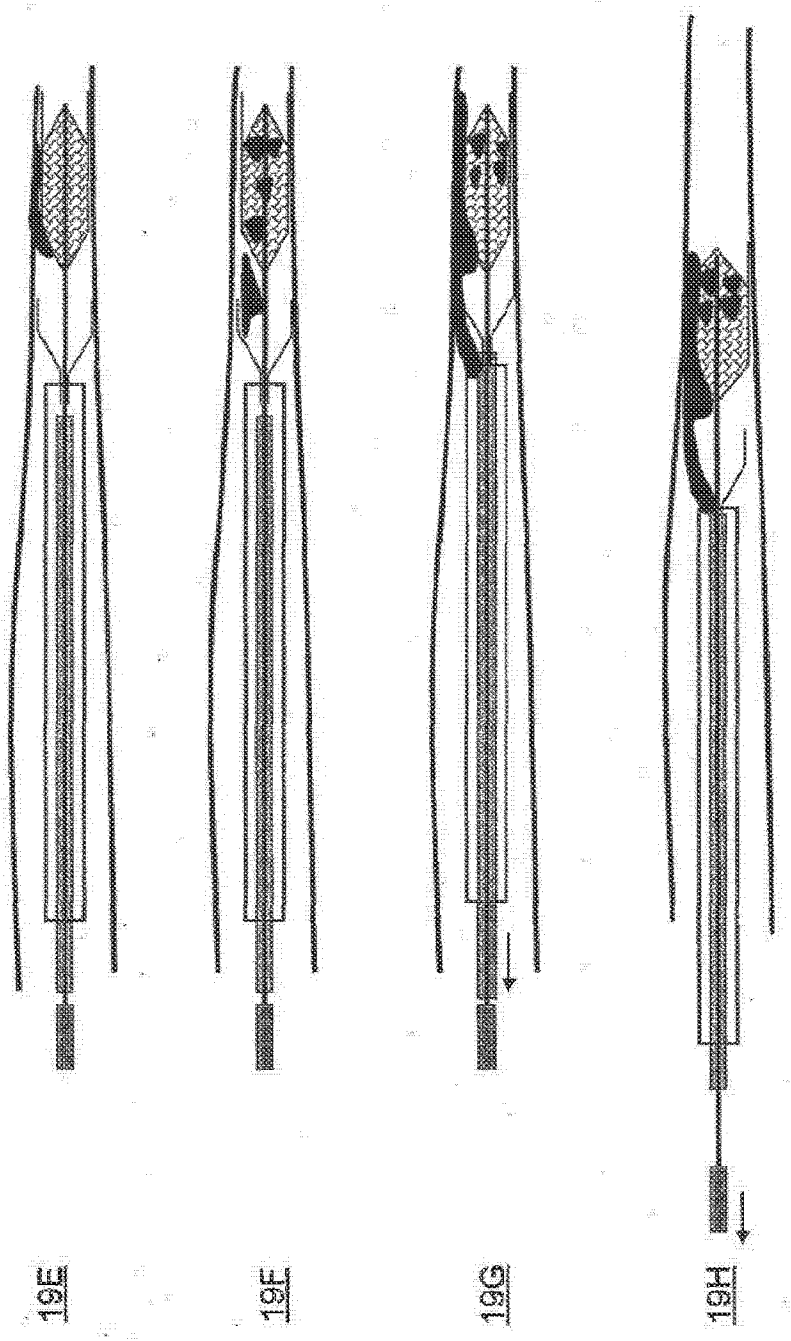


图 19E-H

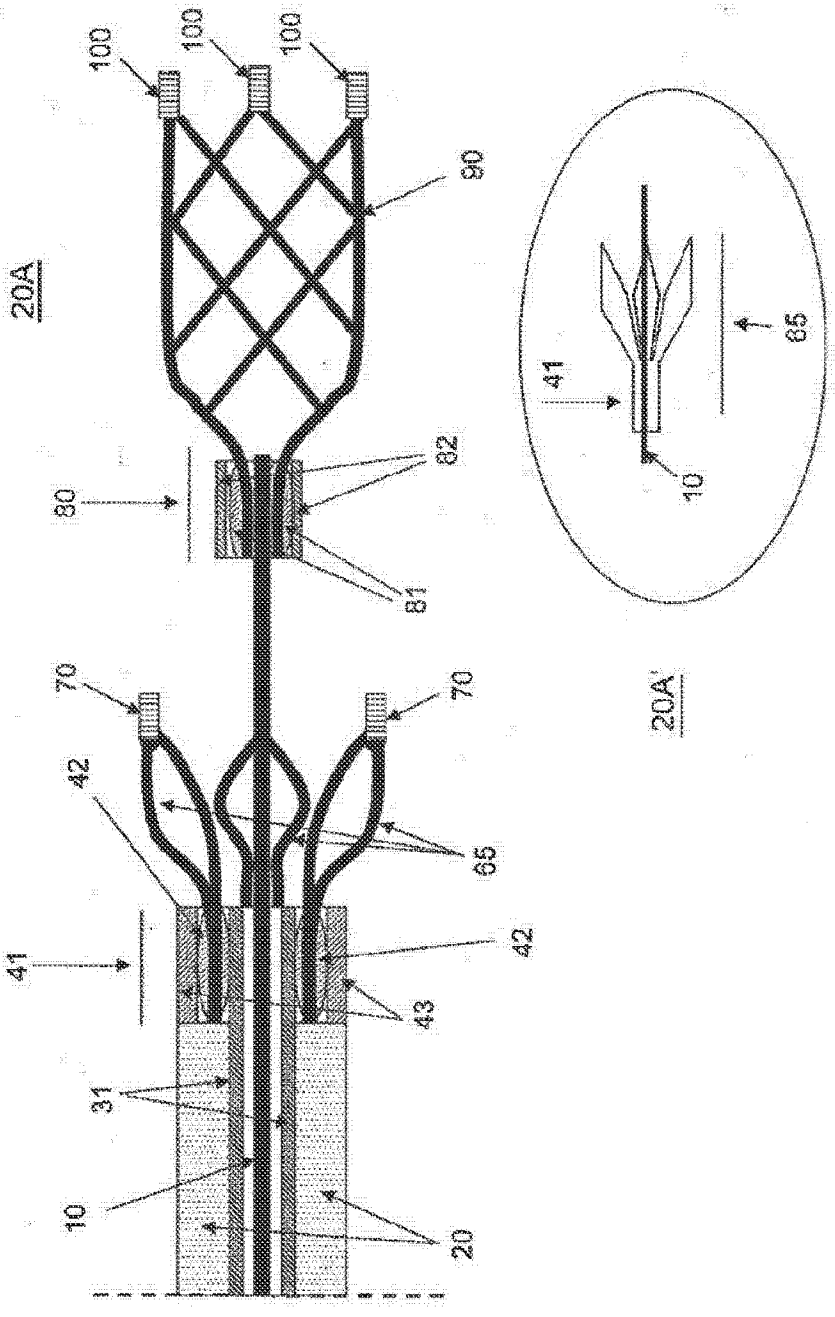


图 20A-A'

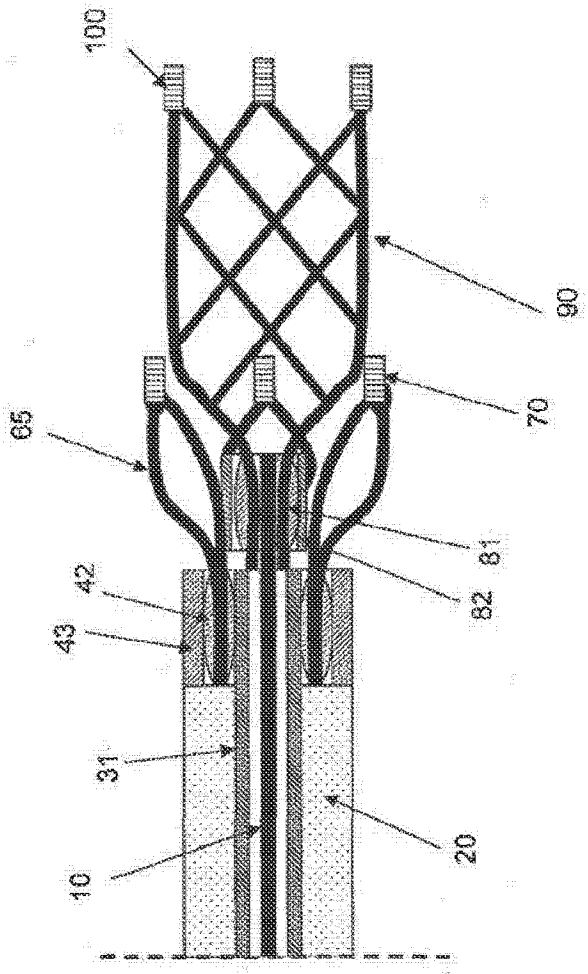


图 20B

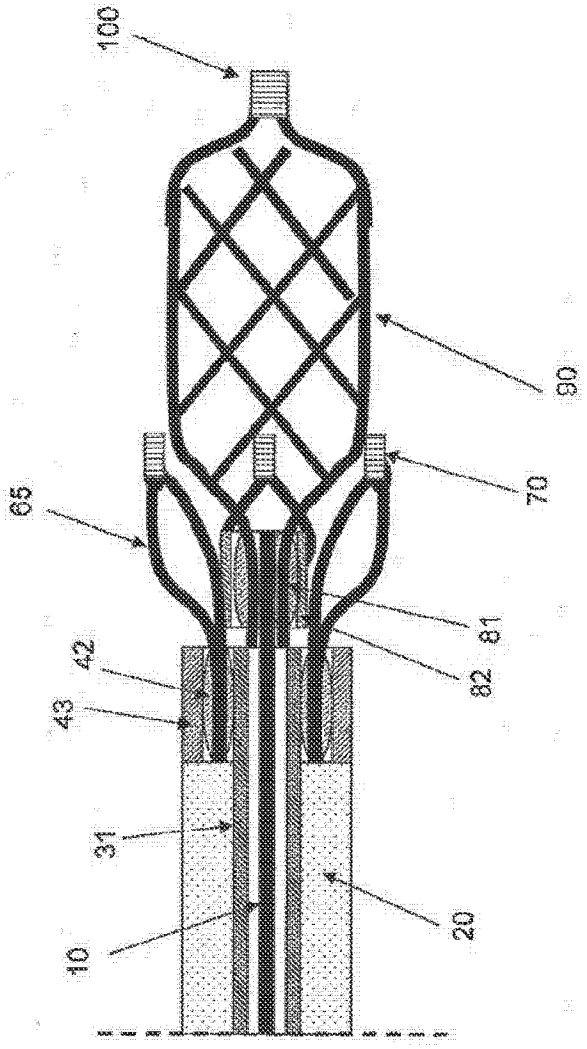


图 20C

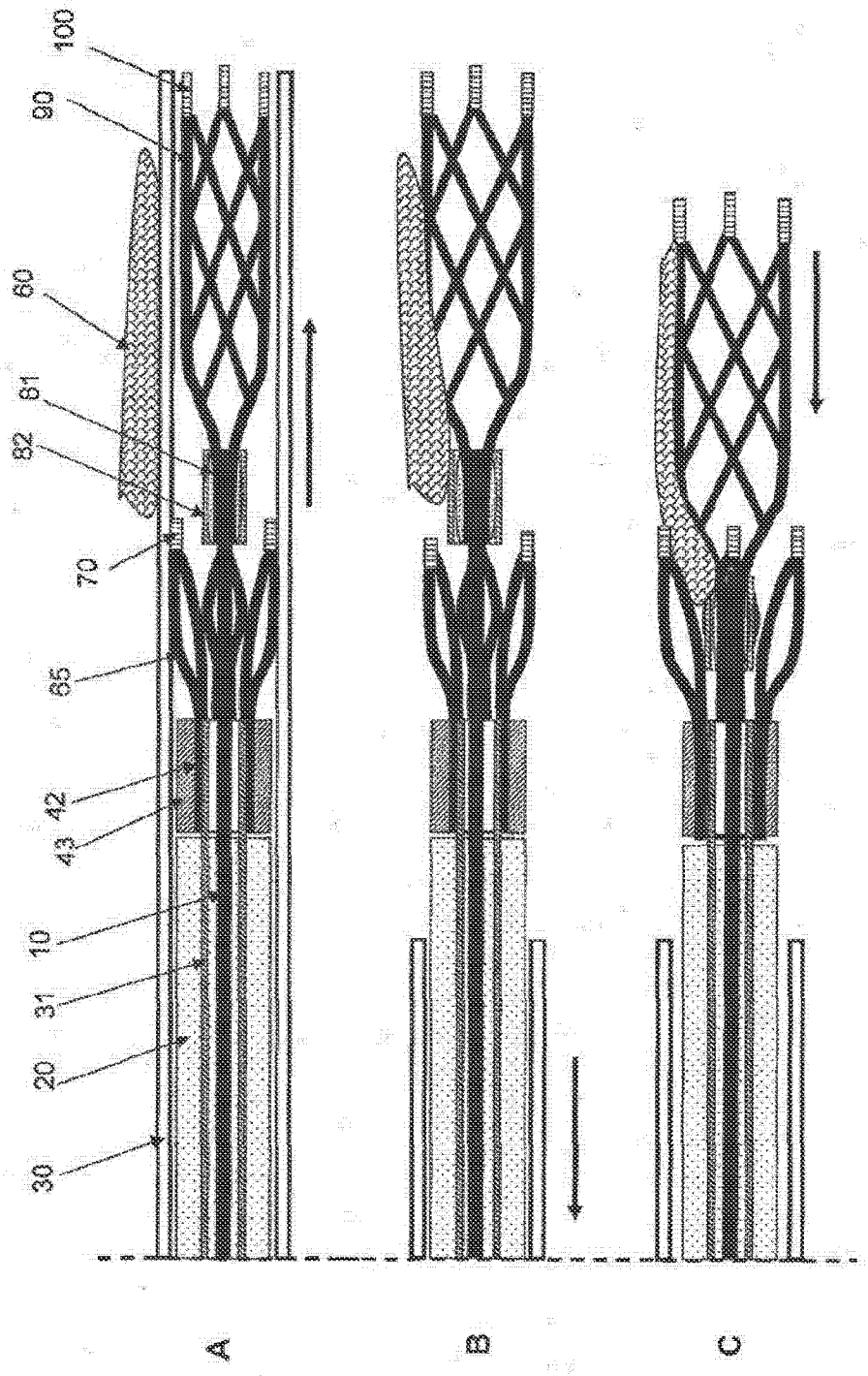


图 21A-C

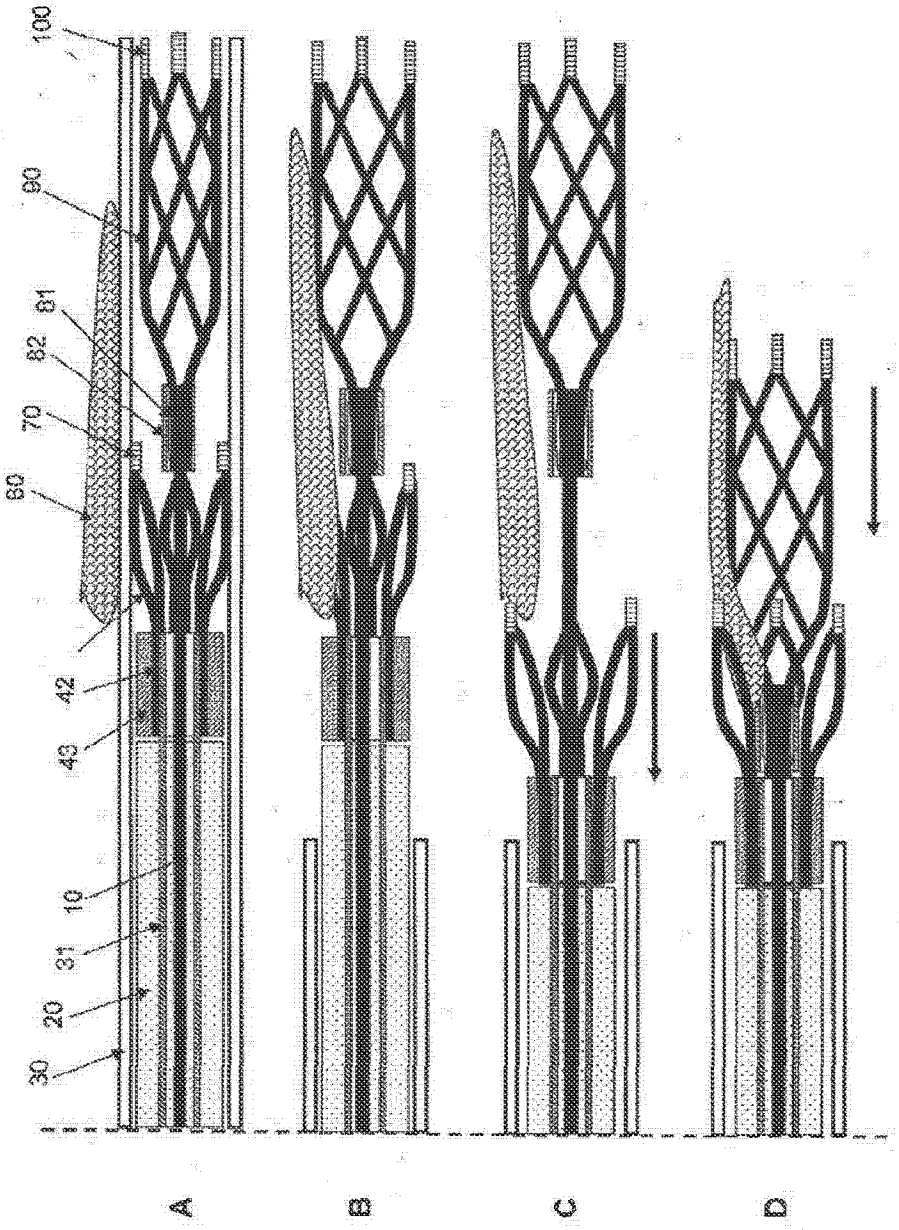


图 22A-D

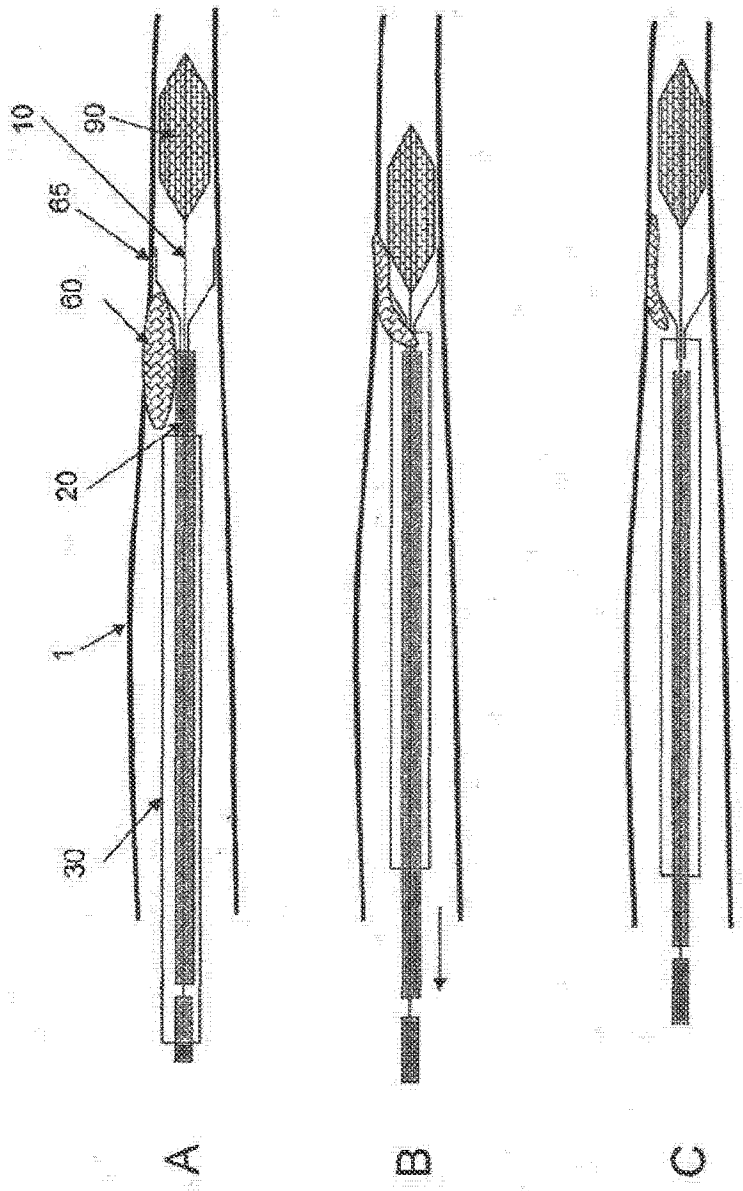


图 23A-C

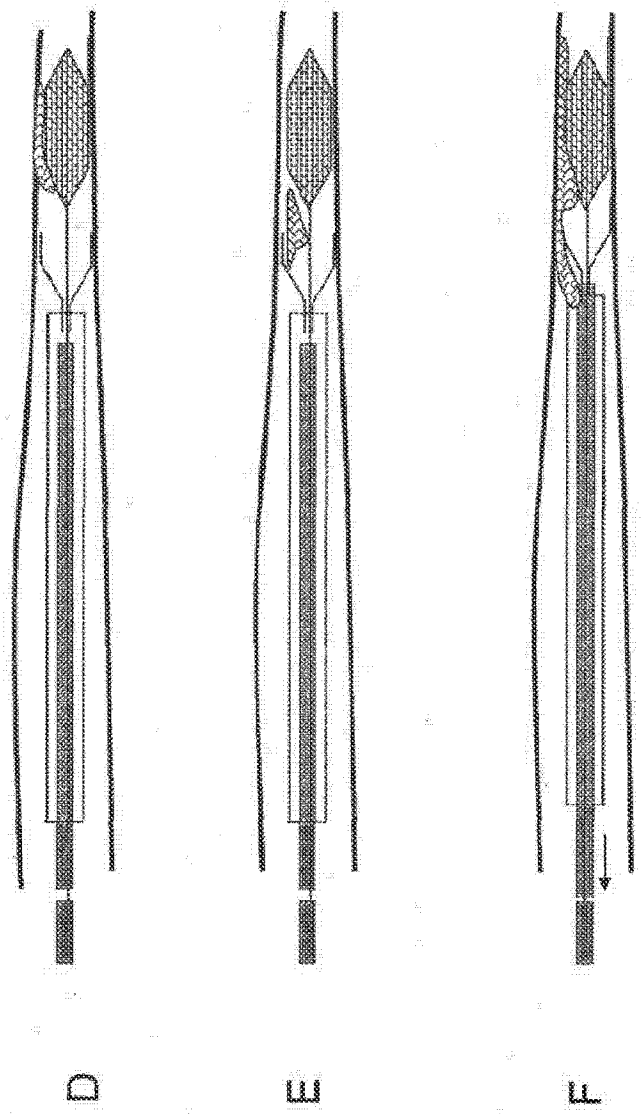


图 23D-F

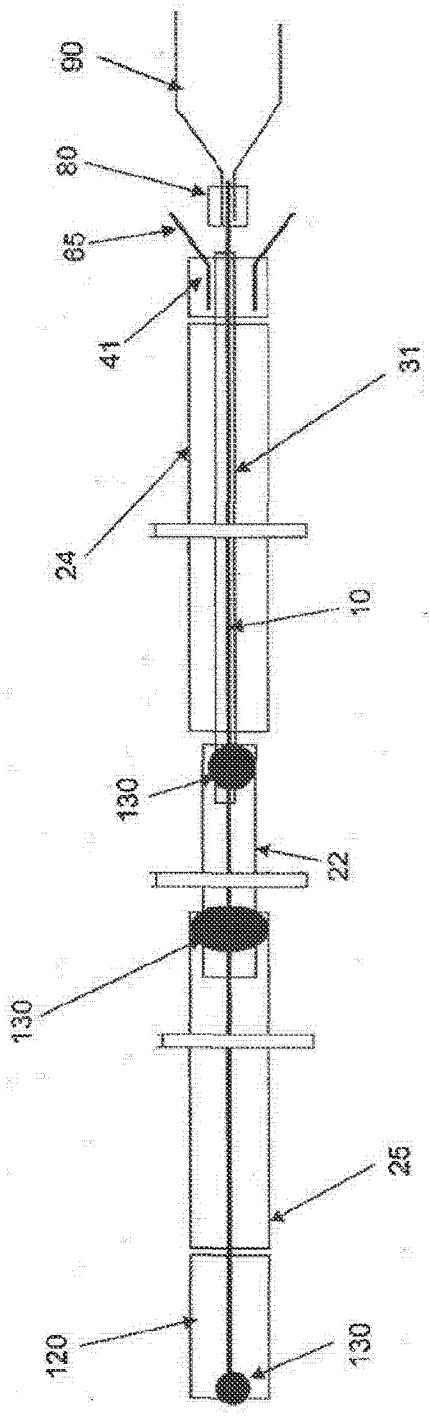


图 24

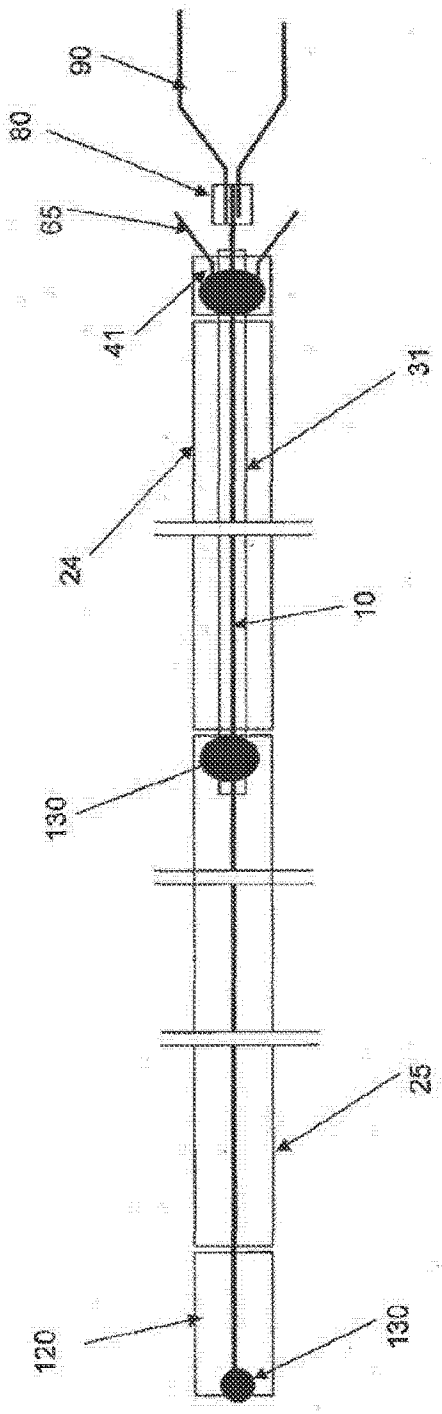


图 25

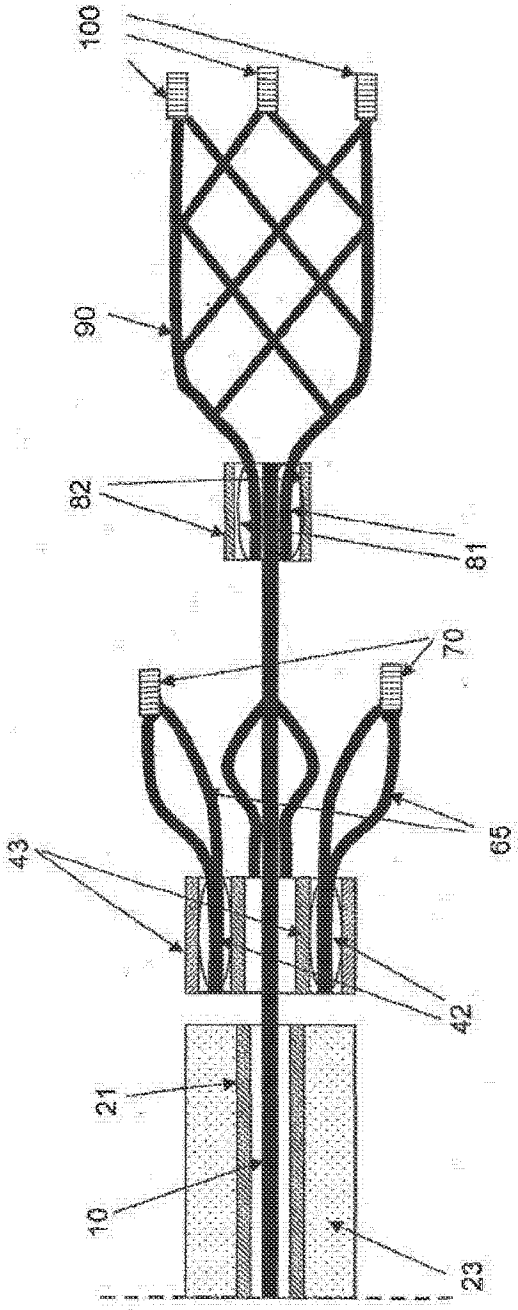


图 26A

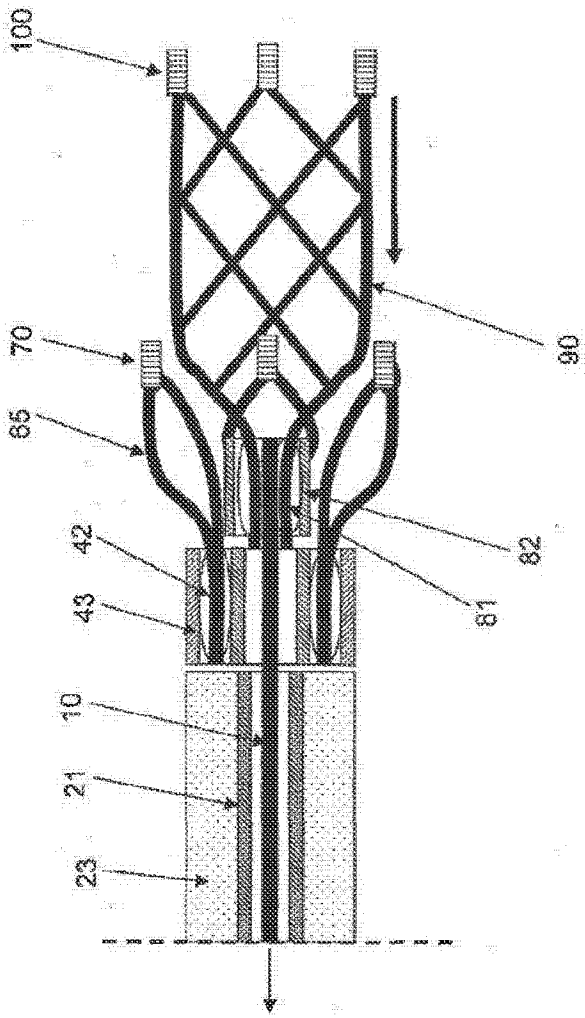


图 26B

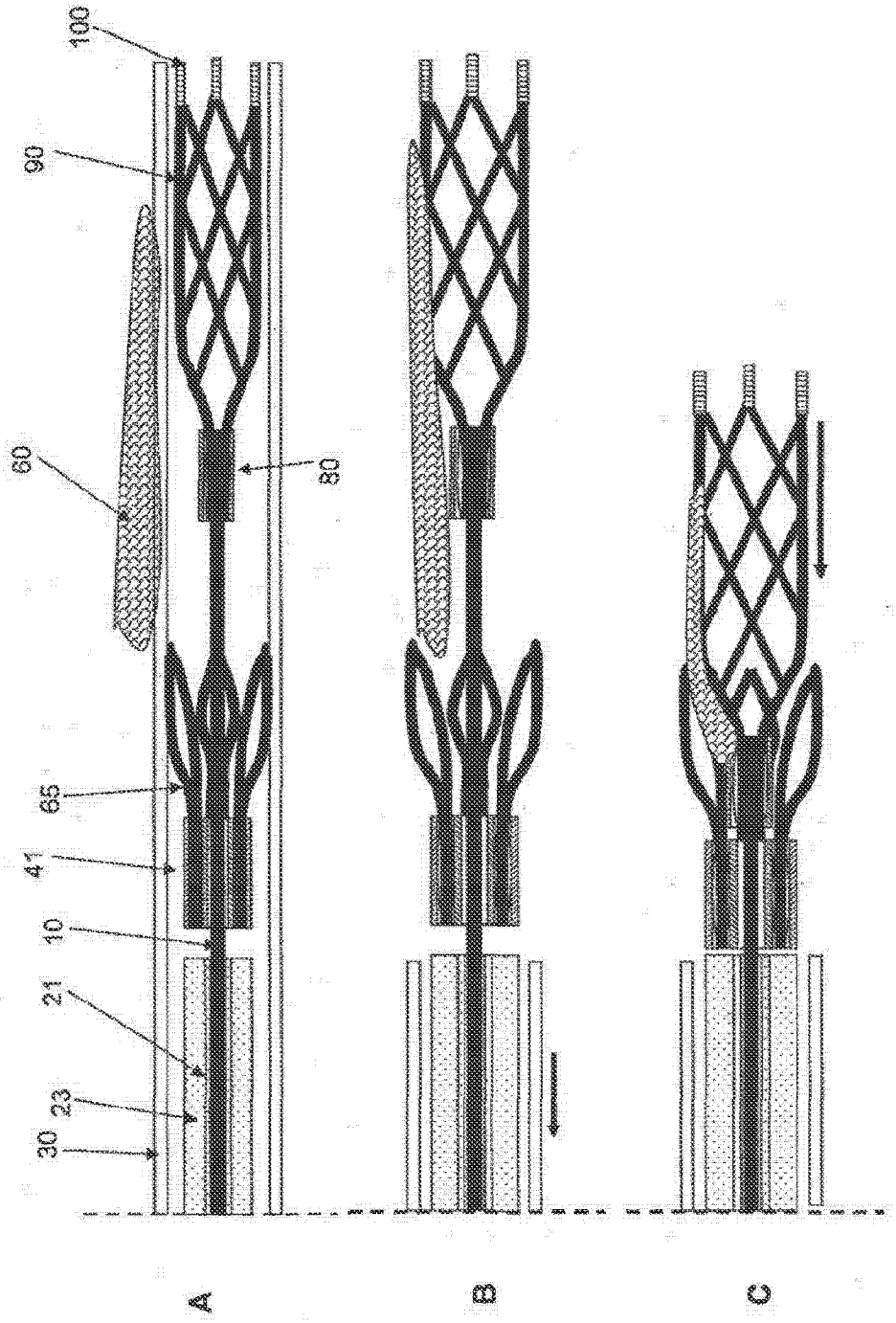


图 27A-C

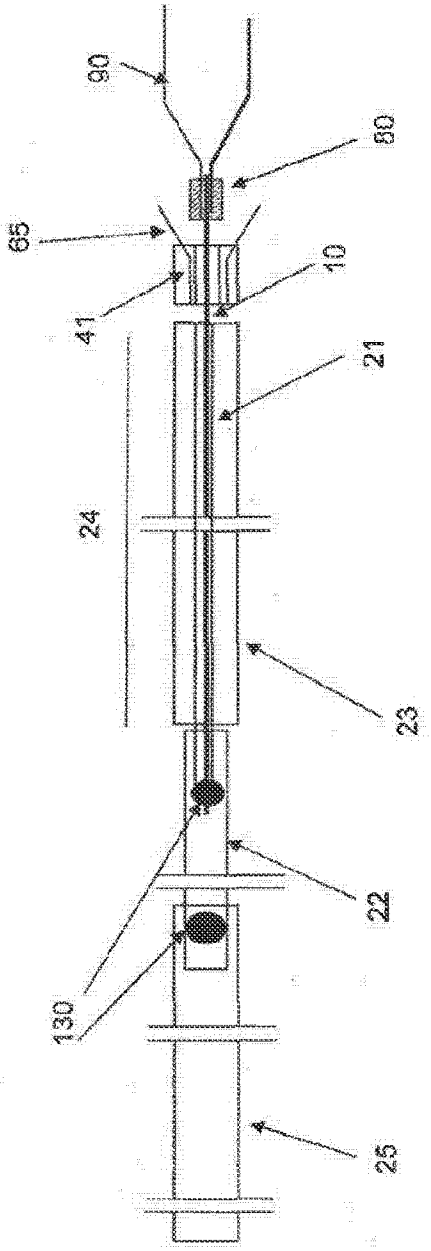


图 28

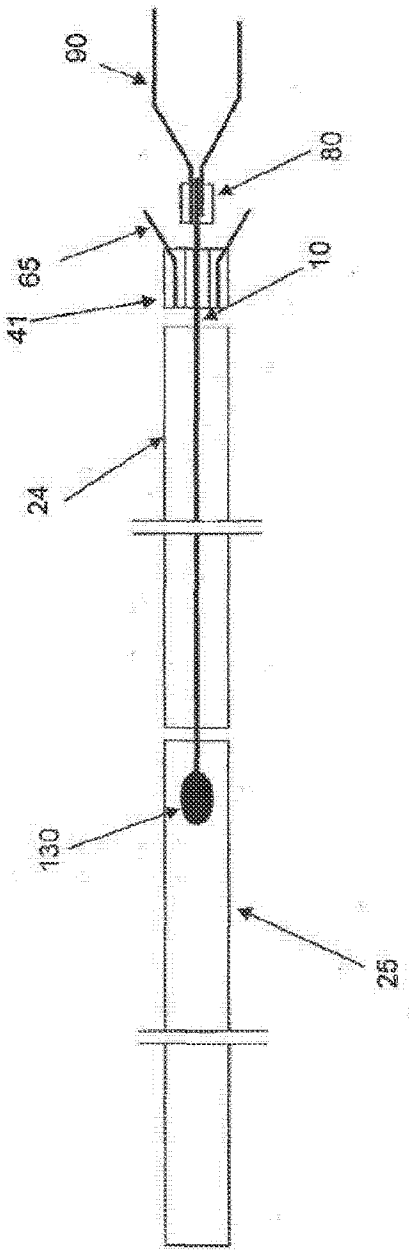


图 29

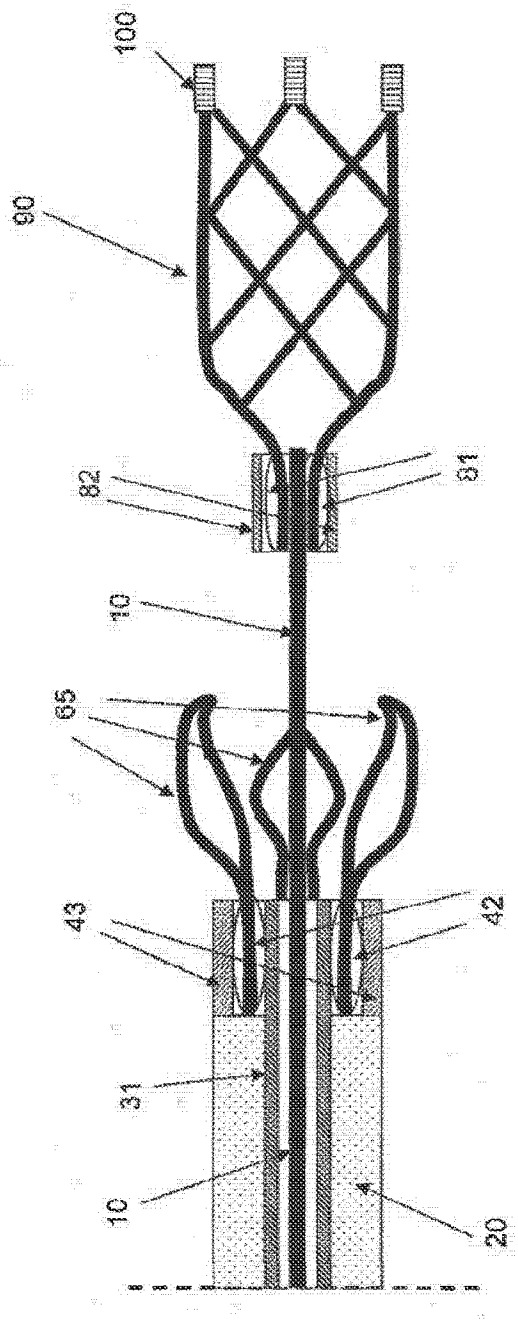


图 30A

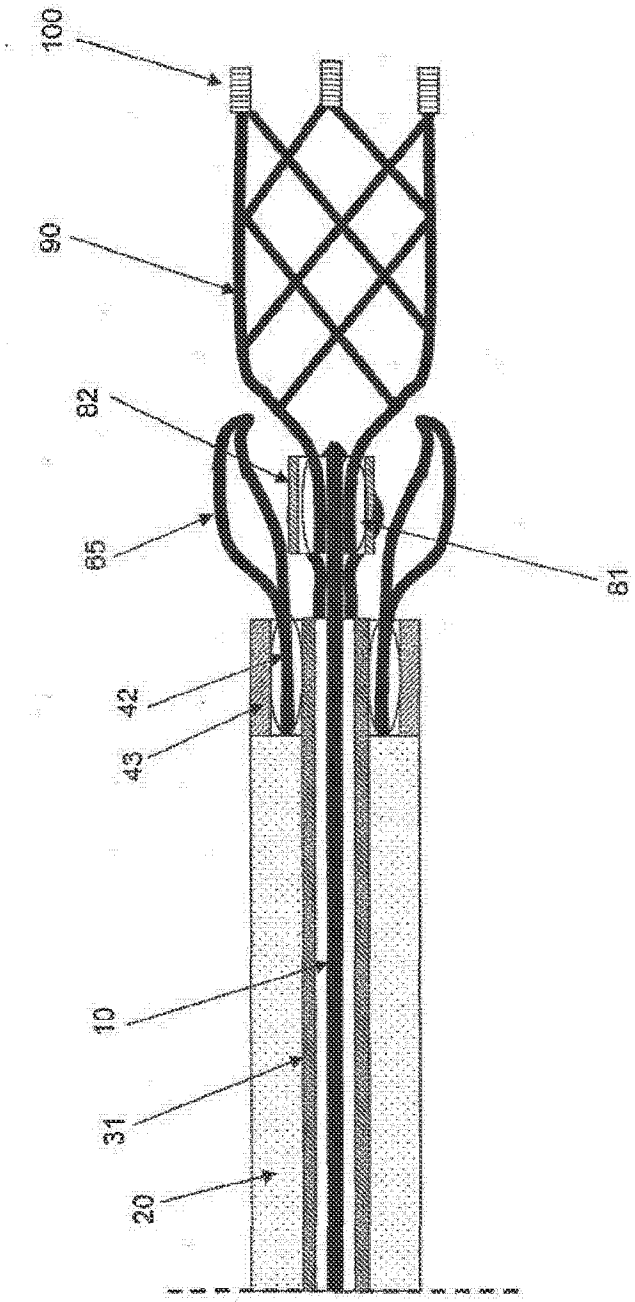


图 30B

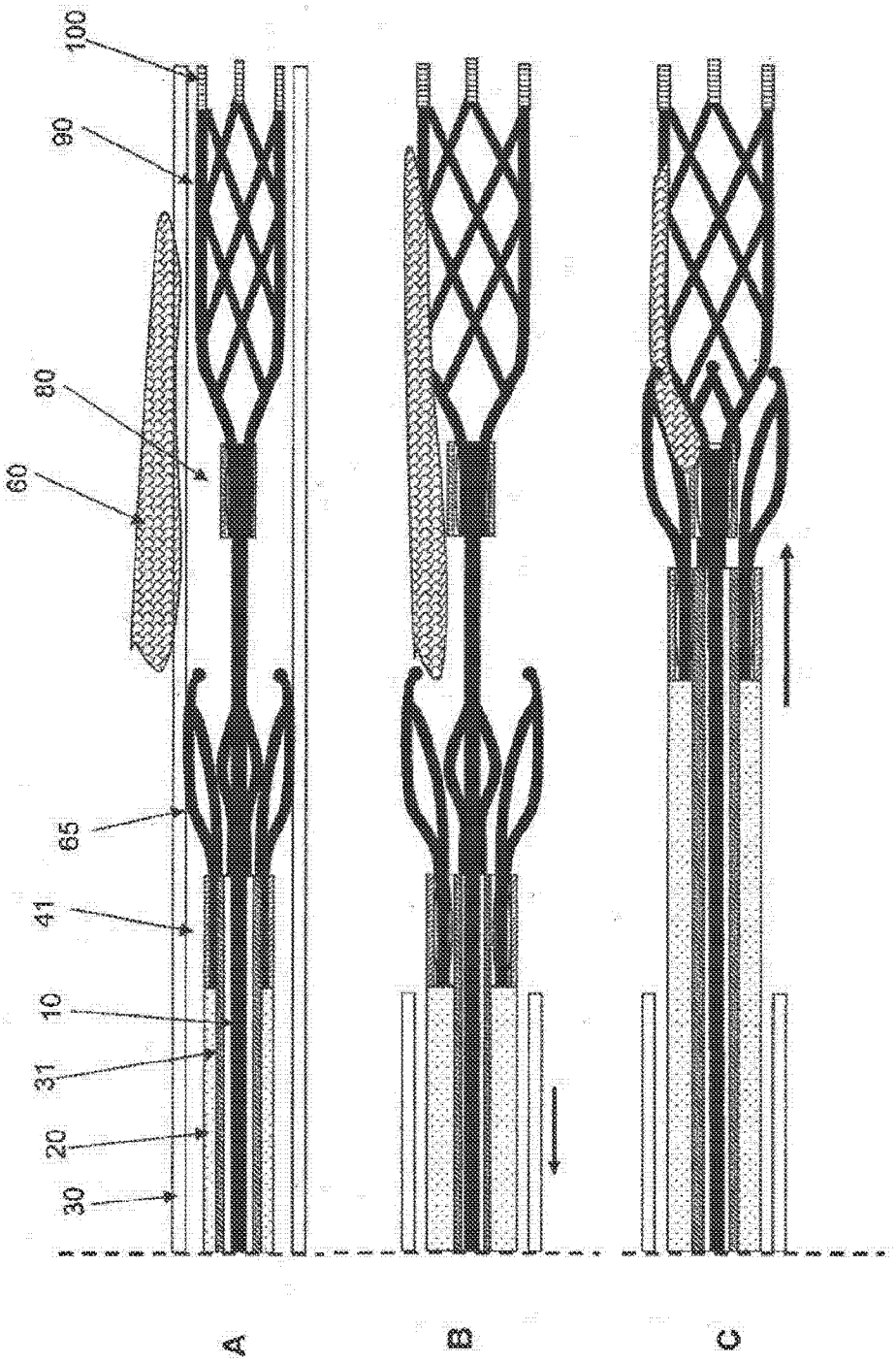


图 31A-C

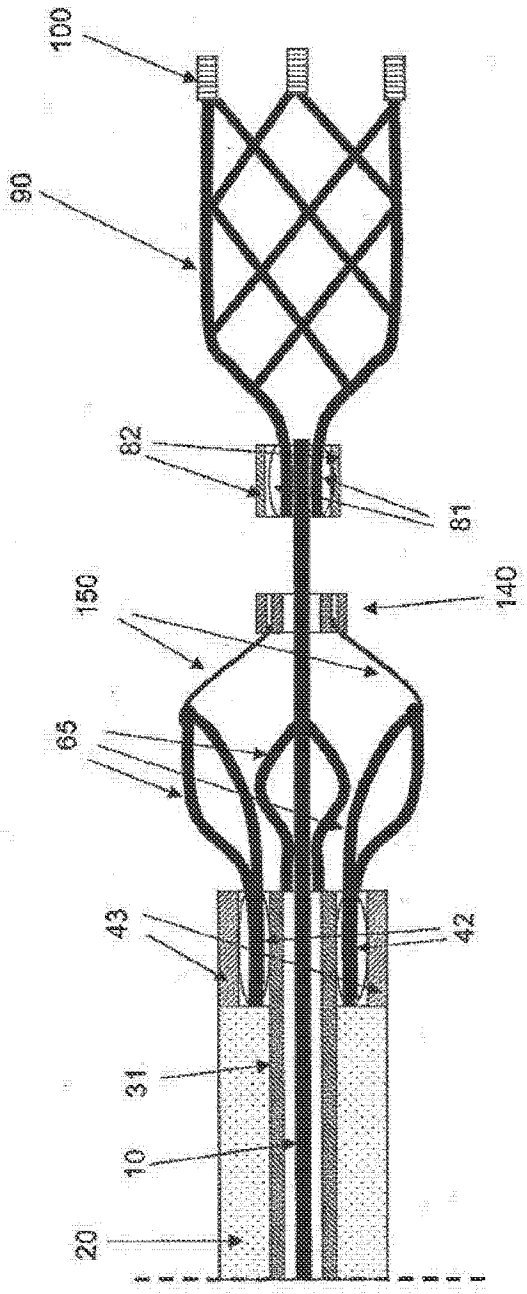


图 32A

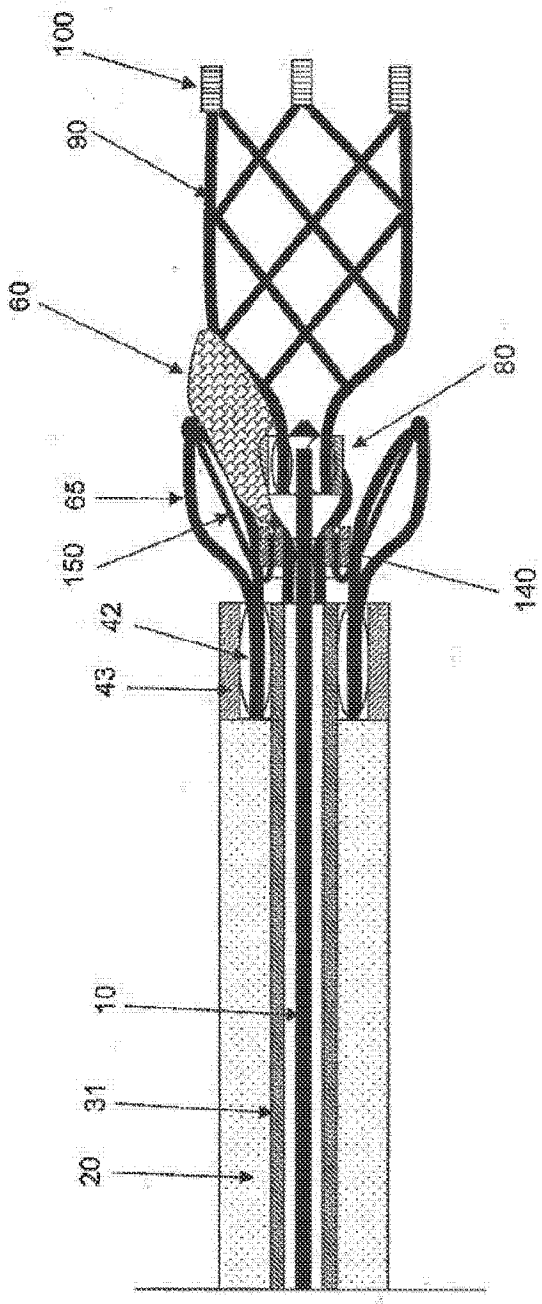


图 32B

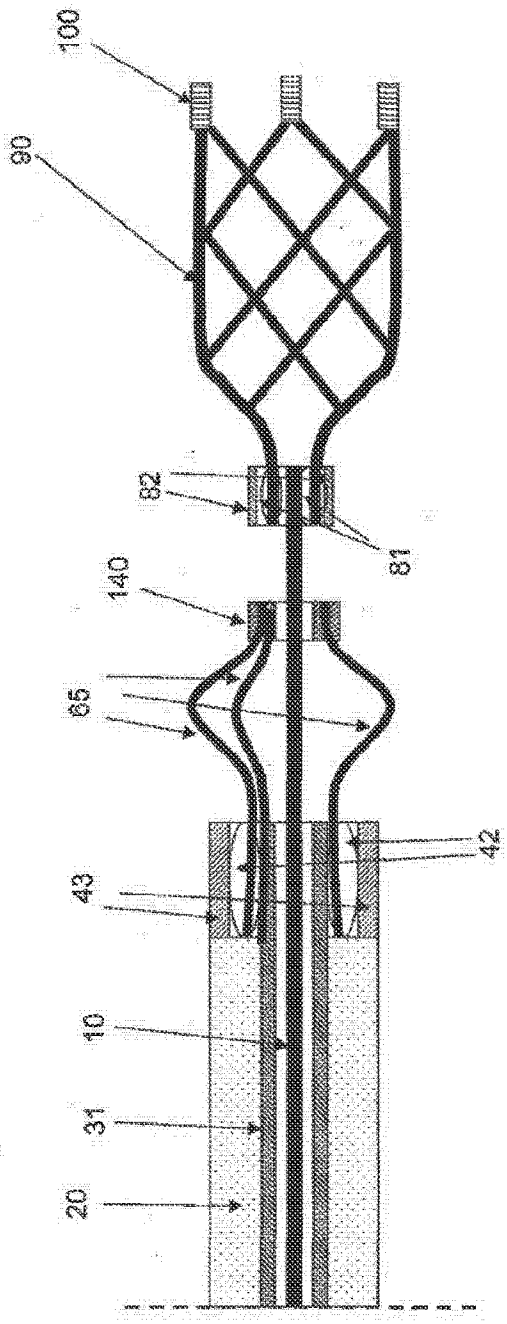


图 33A

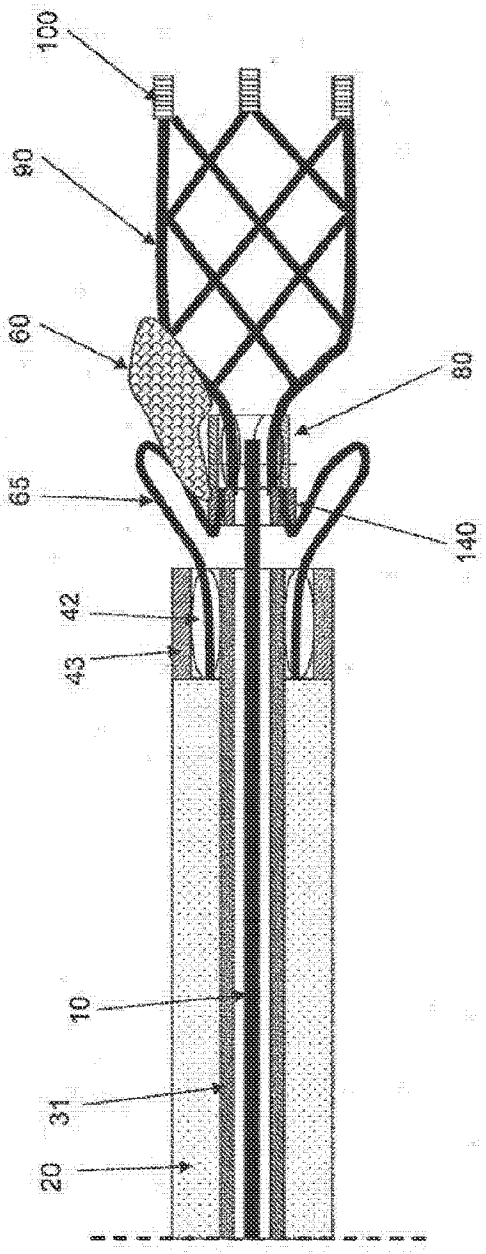


图 33B

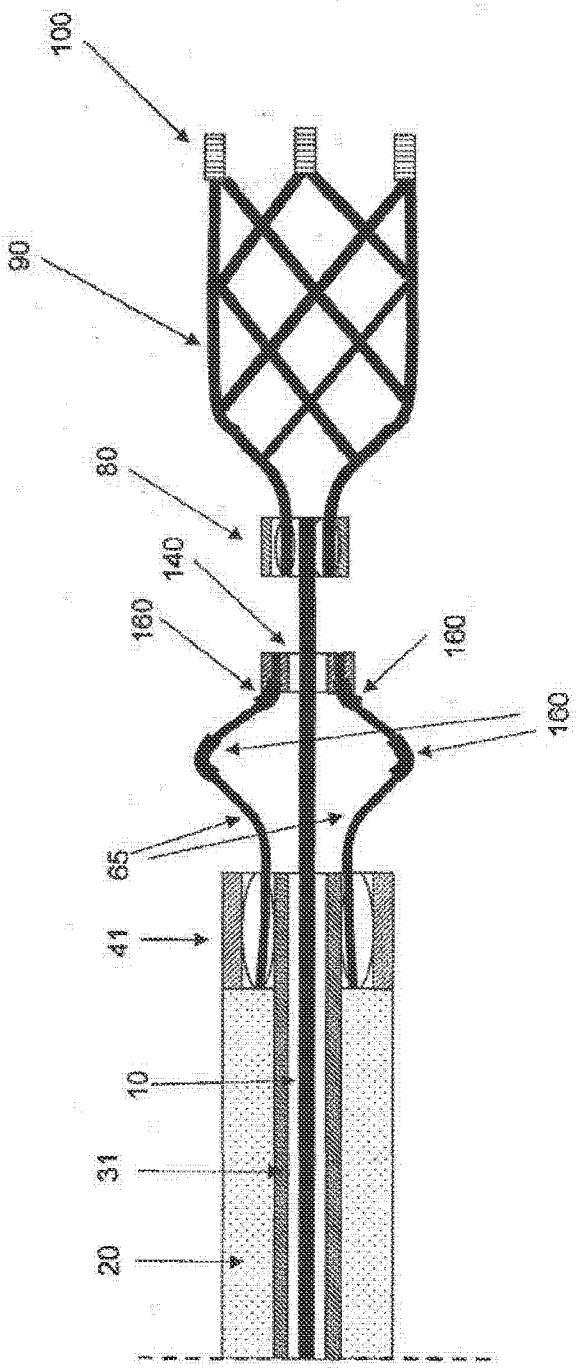


图 34A

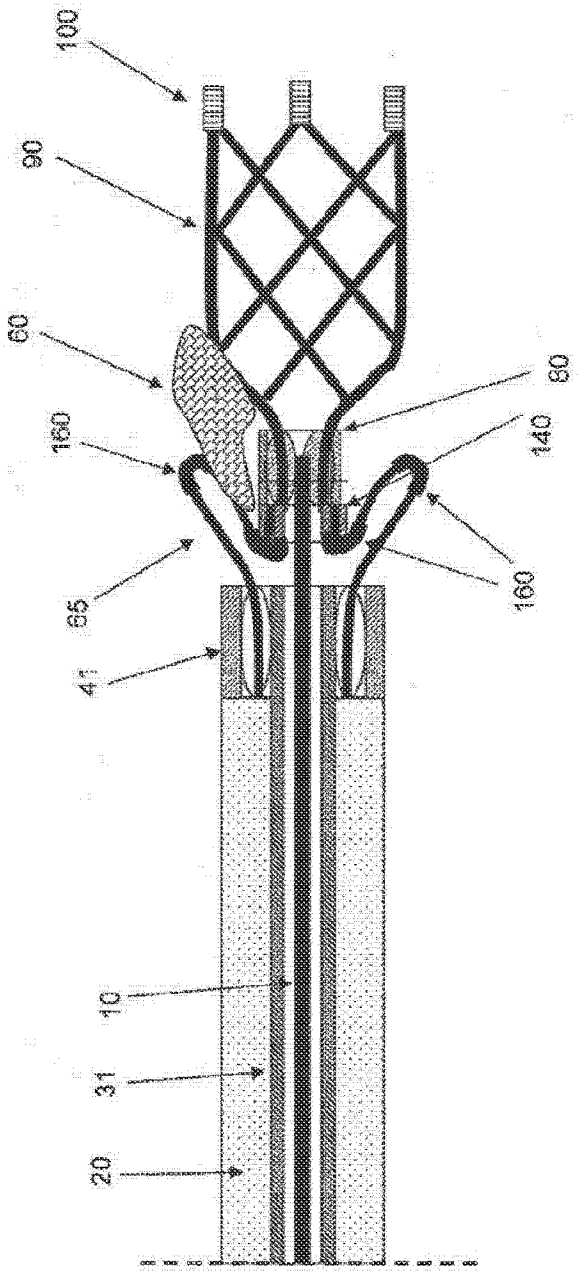


图 34B

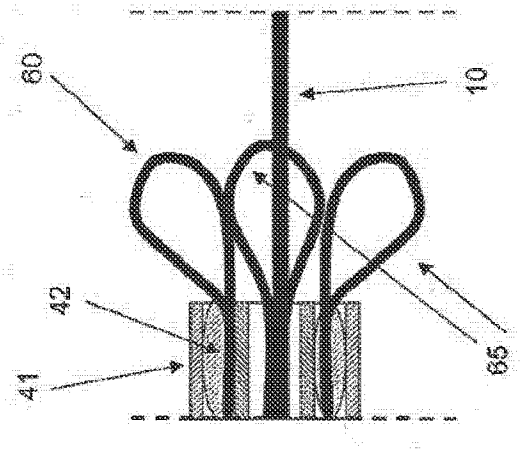


图 35

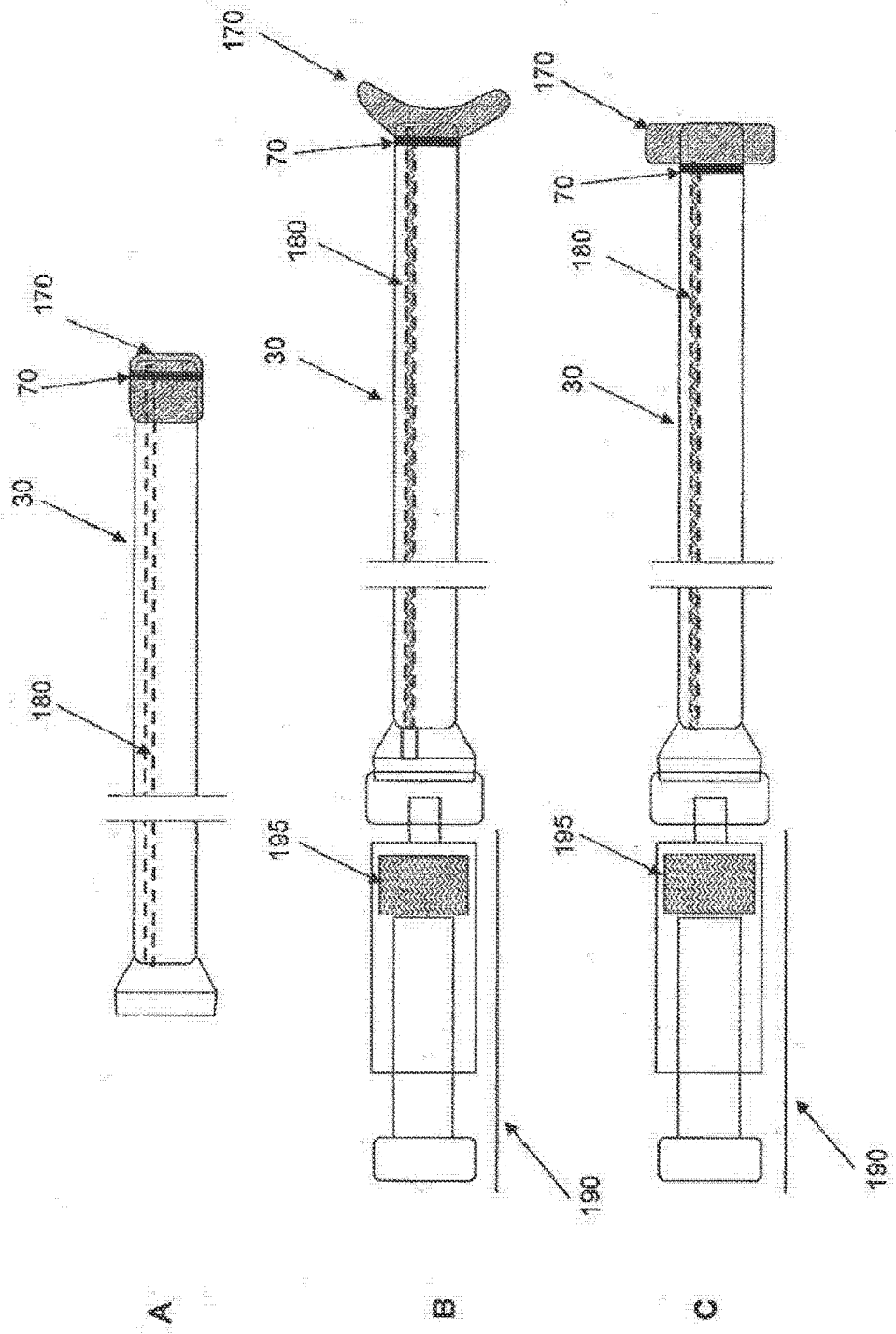


图 36A-C

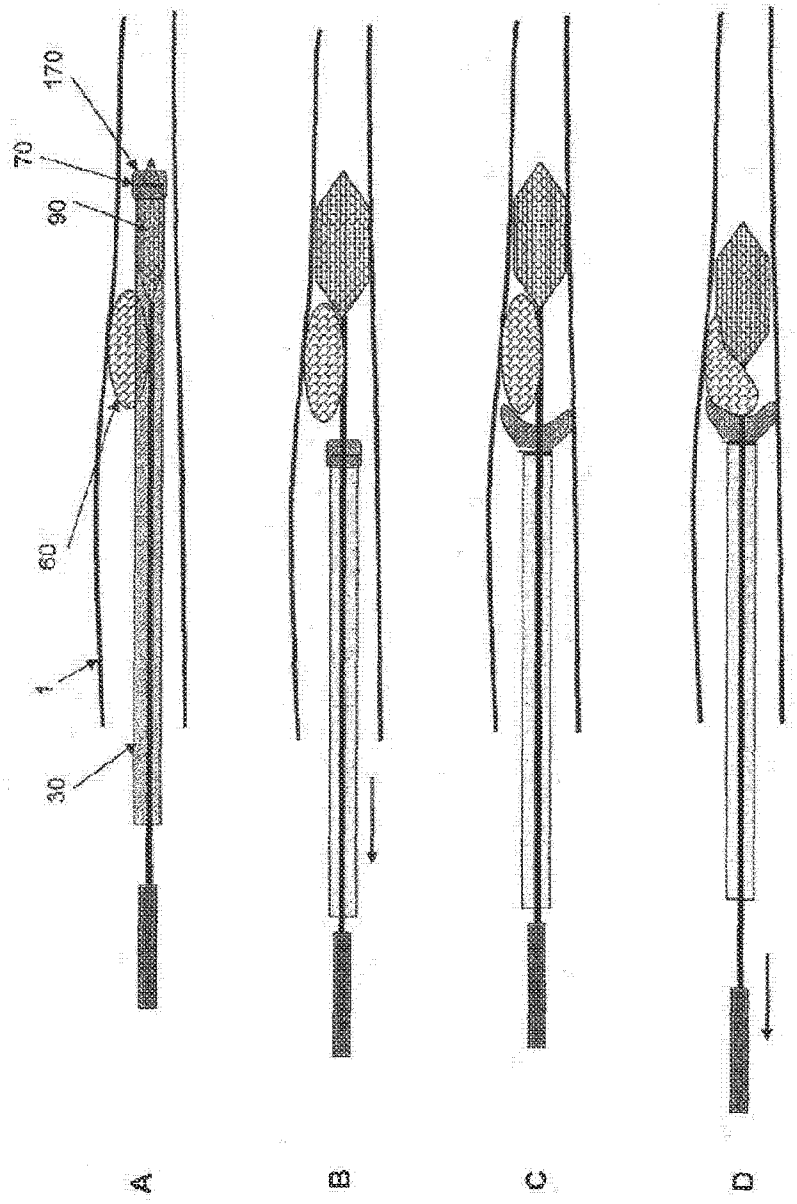


图 37A-D

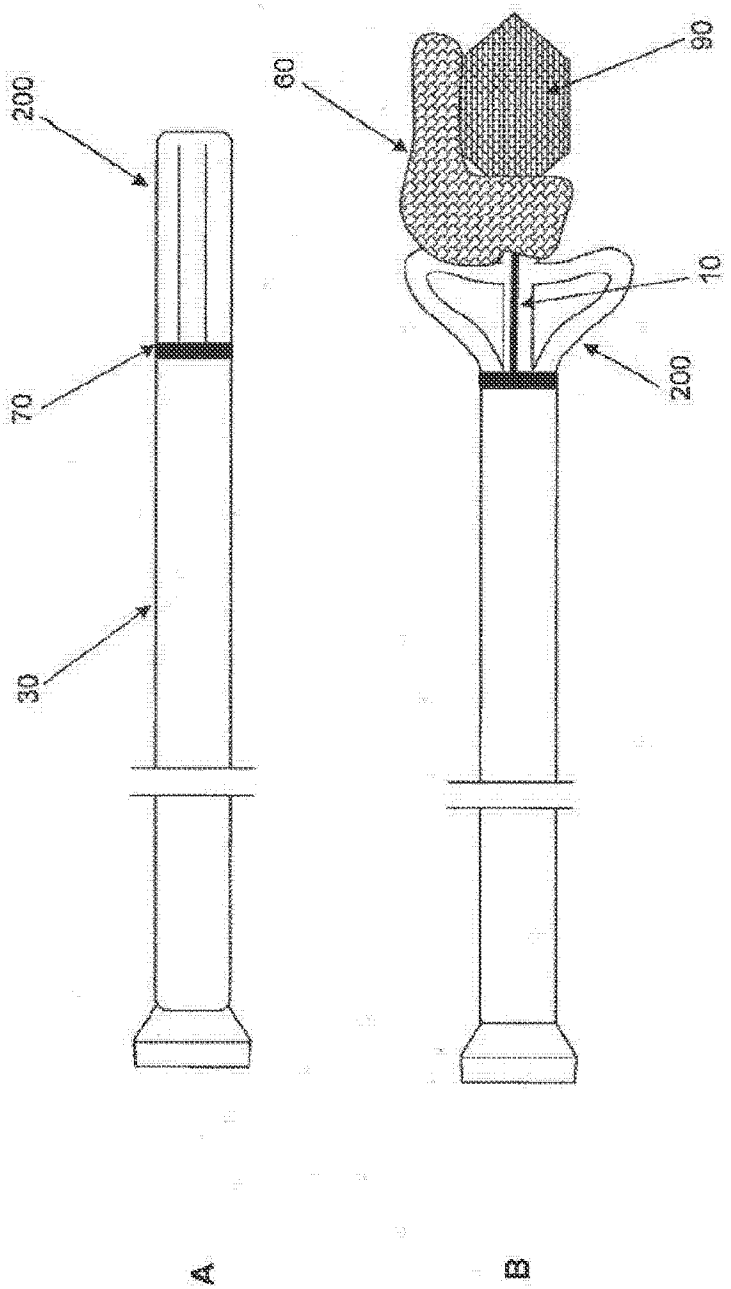


图 38A-B

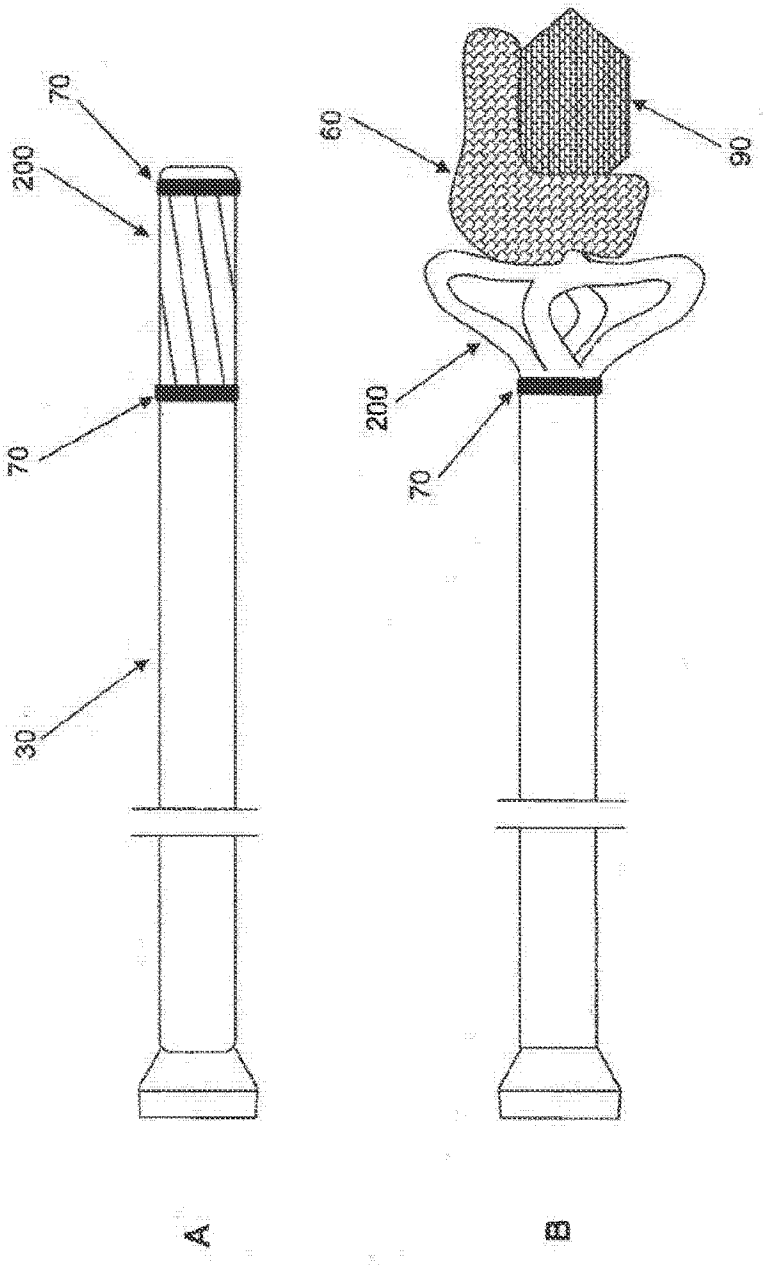


图 39A-B

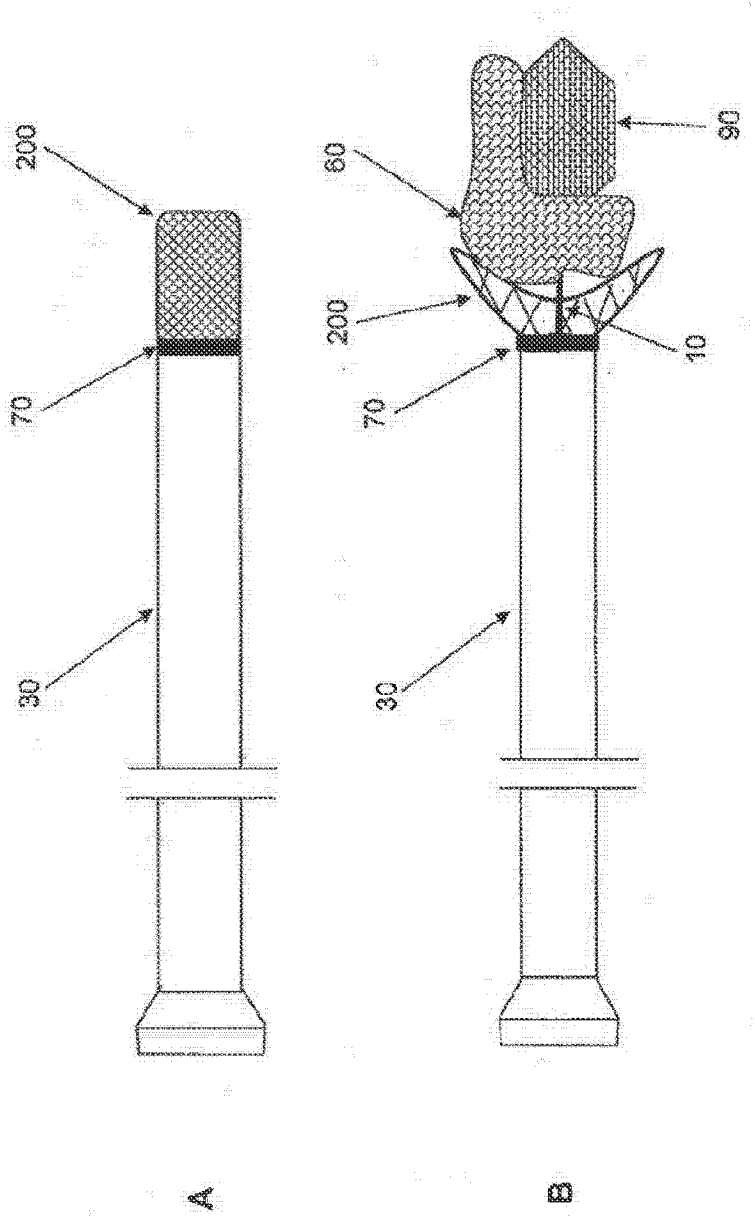


图 40A-B

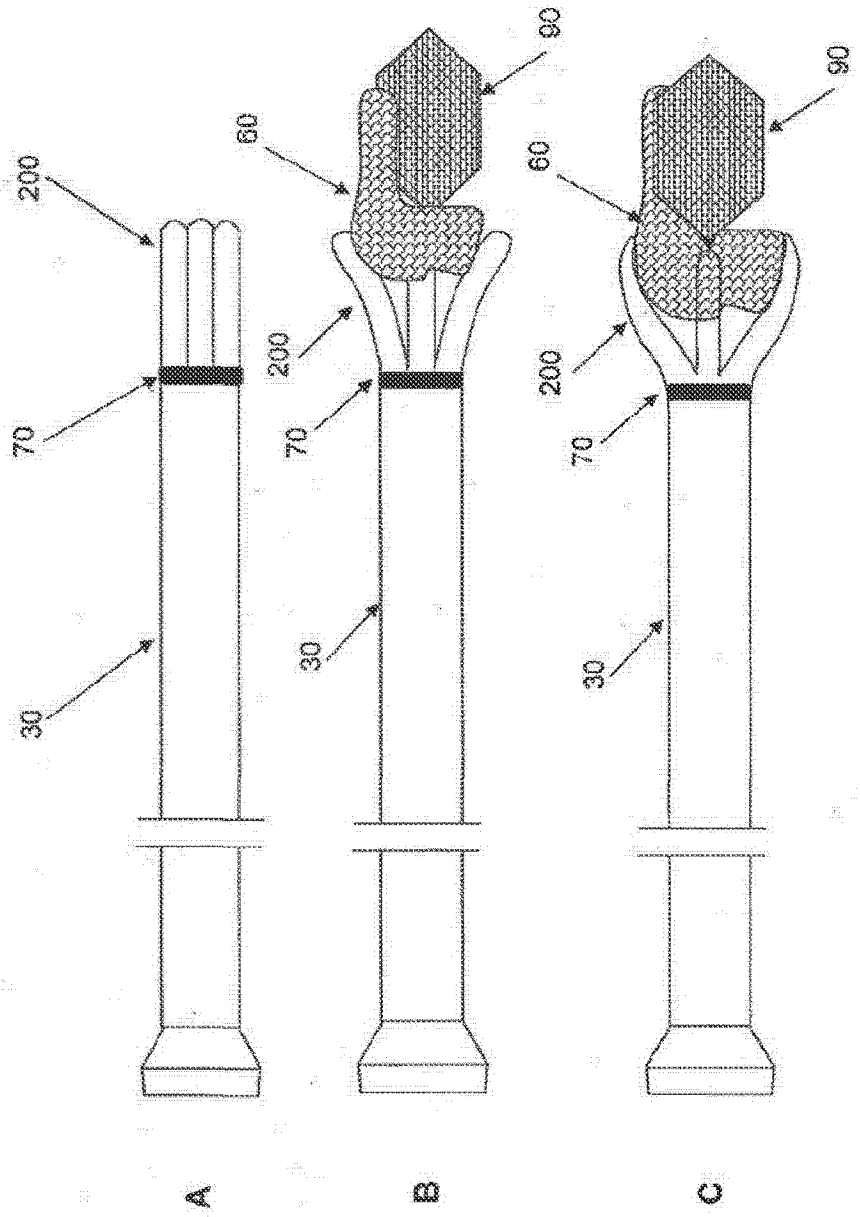


图 41A-C

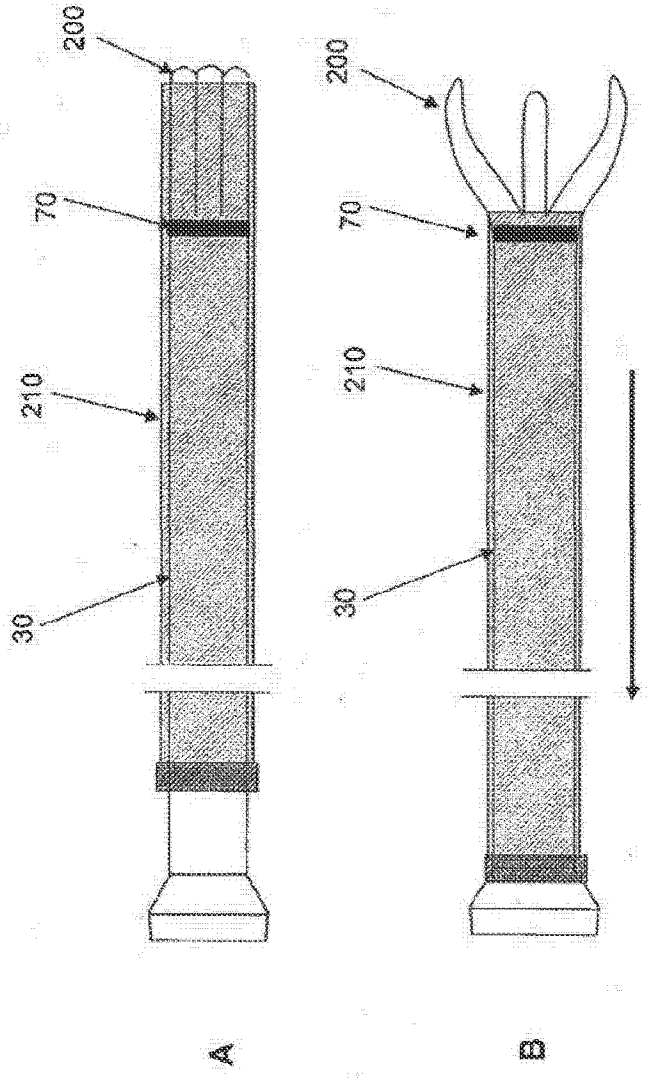


图 42A-B

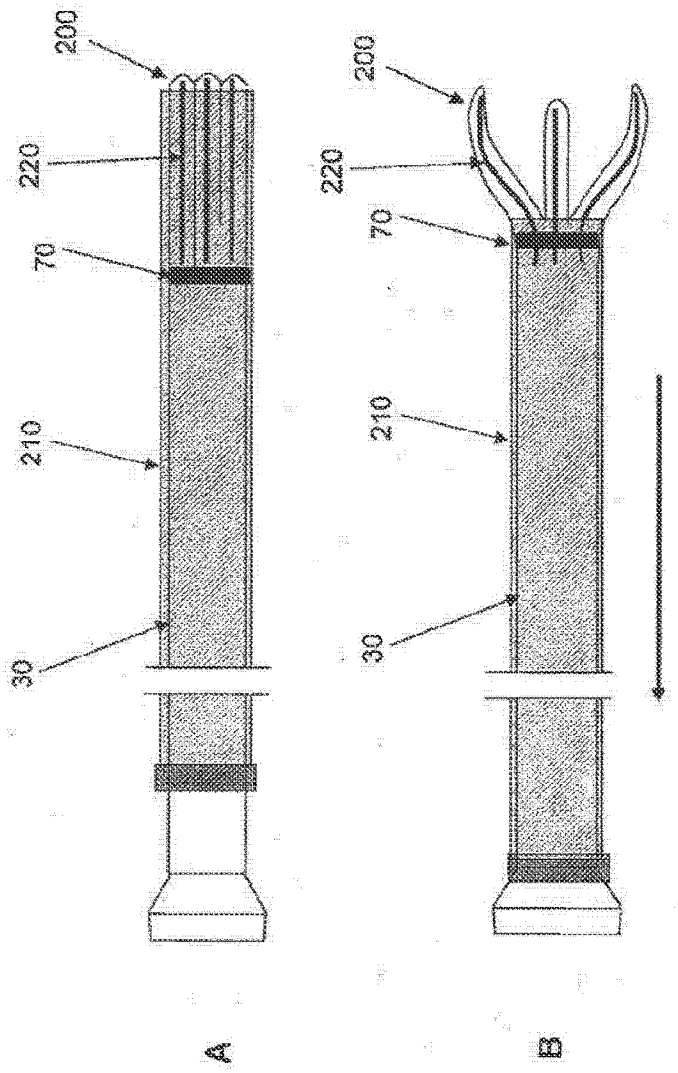


图 43A-B

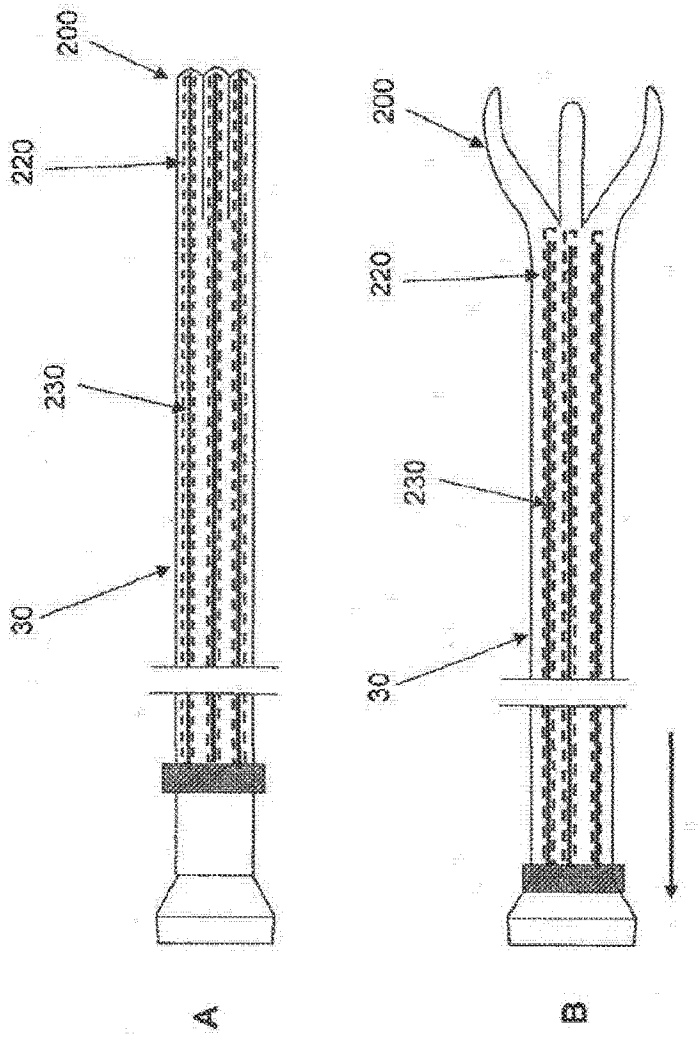


图 44A-B

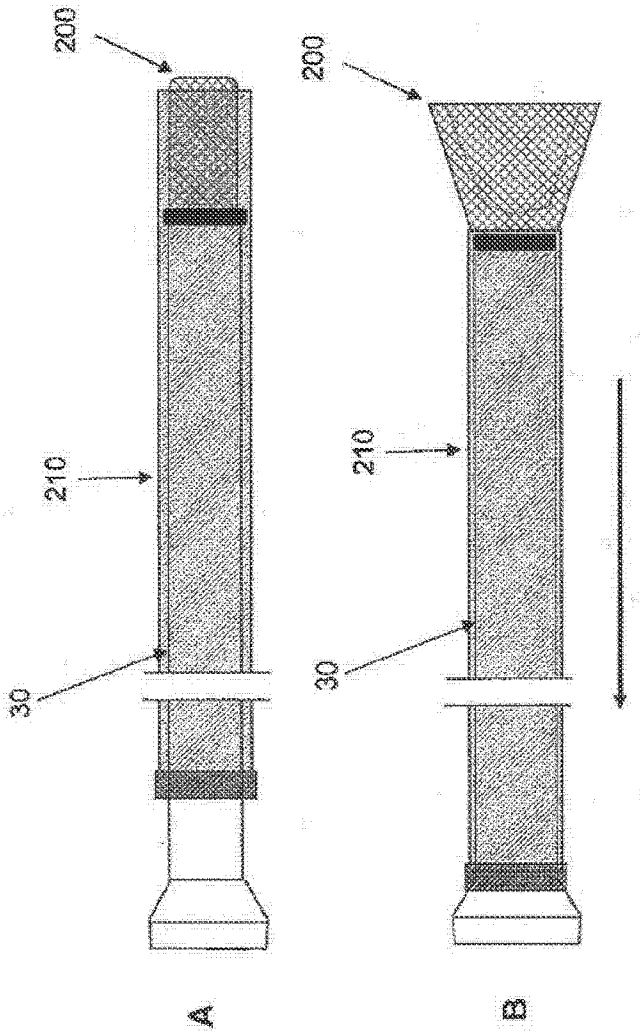


图 45A-B

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
22 April 2021 (22.04.2021)

WIPO | PCT

(10) International Publication Number
WO 2021/076954 A1

(51) International Patent Classification:
A61B 17/14 (2006.01) *A61F 2/01* (2006.01)
A61B 17/22 (2006.01) *A61M 25/01* (2006.01)
A61B 17/32 (2006.01) *A61M 25/08* (2006.01)

(21) International Application Number:
PCT/US2020/056067

(22) International Filing Date:
16 October 2020 (16.10.2020)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
62/916,044 16 October 2019 (16.10.2019) US

(71) Applicant: **INARI MEDICAL, INC.** [US/US]; 9 Parker, Suite #100, Irvine, California 92618 (US).

(72) Inventor: **DINH, James Quang**; 9 Parker, Suite #100, Irvine, California 92618 (US).

(74) Agent: **WILLIAMS, Matthew S.** et al.; PERKINS COIE LLP, P.O. Box 1247, Seattle, Washington 98111-1247 (US).

(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, DJ, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, IT, JO, JP, KE, KG, KH, KN, KP, KR, KW, 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, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, WS, 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,

(54) Title: SYSTEMS, DEVICES, AND METHODS FOR TREATING VASCULAR OCCLUSIONS

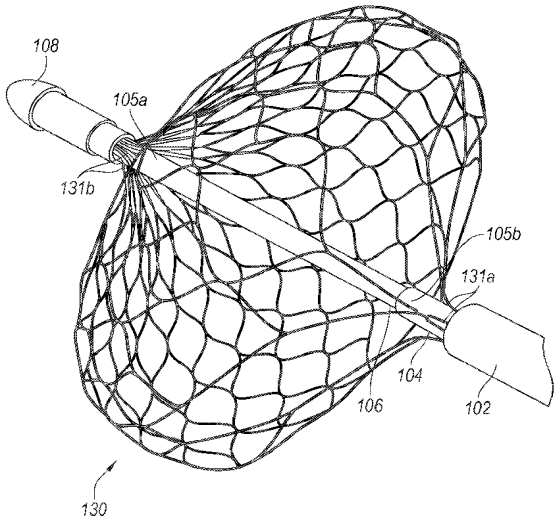


Fig. 1C

(57) Abstract: Systems and methods for the intravascular treatment of clot material within a blood vessel of a human patient are disclosed herein. A device in accordance with embodiments of the present technology can include, for example, a plurality of interconnected struts forming a unitary structure having a proximal portion and a distal portion. The struts can form a plurality of first cells in the proximal portion and a plurality of second cells, smaller than the first cells, in the distal portion. The device can be pulled against clot material within a blood vessel to engage, disrupt, and/or capture the clot material.

WO 2021/076954 A1

[Continued on next page]

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).

Published:
— *with international search report (Art. 21(3))*

SYSTEMS, DEVICES, AND METHODS FOR TREATING VASCULAR OCCLUSIONS

CROSS-REFERENCE TO RELATED APPLICATION

[0001] This application claims the benefit of U.S. Provisional Patent Application No. 62/916,044, filed October 16, 2019, and titled "SYSTEMS, DEVICES, AND METHODS FOR TREATING VASCULAR OCCLUSIONS," which is incorporated herein by reference in its entirety.

TECHNICAL FIELD

[0002] The present technology relates generally to systems, devices, and methods for the intravascular treatment of colt material (e.g., emboli and/or thrombi) within a blood vessel of a human patient. In particular, some embodiments of the present technology relate to expandable devices for engaging and removing clot material.

BACKGROUND

[0003] Thromboembolic events are characterized by an occlusion of a blood vessel. Thromboembolic disorders, such as stroke, pulmonary embolism, heart attack, peripheral thrombosis, atherosclerosis, and the like, affect many people. These disorders are a major cause of morbidity and mortality.

[0004] When an artery is occluded by a clot, tissue ischemia develops. The ischemia will progress to tissue infarction if the occlusion persists. However, infarction does not develop or is greatly limited if the flow of blood is reestablished rapidly. Failure to reestablish blood flow can accordingly lead to the loss of limb, angina pectoris, myocardial infarction, stroke, or even death.

[0005] In the venous circulation, occlusive material can also cause serious harm. Blood clots can develop in the large veins of the legs and pelvis, a common condition known as deep venous thrombosis (DVT). DVT commonly occurs where there is a propensity for stagnated blood (e.g., long distance air travel, immobility, etc.) and clotting (e.g., cancer, recent surgery, such as orthopedic surgery, etc.). DVT can obstruct drainage of venous blood from the legs leading to swelling, ulcers, pain and infection. DVT can also create a reservoir in which blood

clots can collect and then travel to other parts of the body including the heart, lungs, brain (stroke), abdominal organs, and/or extremities.

[0006] In the pulmonary circulation, the undesirable material can cause harm by obstructing pulmonary arteries—a condition known as pulmonary embolism. If the obstruction is upstream, in the main or large branch pulmonary arteries, it can severely compromise total blood flow within the lungs, and therefore the entire body. This can result in low blood pressure and shock. If the obstruction is downstream, in large to medium pulmonary artery branches, it can prevent a significant portion of the lung from participating in the exchange of gases to the blood resulting in low blood oxygen and buildup of blood carbon dioxide.

[0007] There are many existing techniques to reestablish blood flow through an occluded vessel. Embolectomies, for example, are a surgical technique involving incising a blood vessel and placing a balloon-tipped device (such as the Fogarty catheter) at the location of the occlusion. The balloon is then inflated at a point beyond the clot and used to withdraw the obstructing material back to the point of incision. The obstructing material is then removed by the surgeon. Although such surgical techniques have been useful, exposing a patient to surgery may be traumatic and best avoided when possible. Additionally, the use of a Fogarty catheter may be problematic due to the possible risk of damaging the interior lining of the vessel as the catheter is being withdrawn.

[0008] Percutaneous methods are also utilized for reestablishing blood flow. A common percutaneous technique is referred to as balloon angioplasty where a balloon-tipped catheter is introduced to a blood vessel (e.g., typically through an introducing catheter). The balloon-tipped catheter is then advanced to the point of the occlusion and inflated to dilate the stenosis. Balloon angioplasty is appropriate for treating vessel stenosis, but it is generally not effective for treating acute thromboembolisms as none of the occlusive material is removed and restenosis regularly occurs after dilation. Another percutaneous technique involves placing a catheter near the clot and infusing streptokinase, urokinase, or other thrombolytic agents to dissolve the clot. Unfortunately, thrombolysis typically takes hours to days to be successful. Additionally, thrombolytic agents can cause hemorrhage, and in many patients the thrombolytic agents cannot be used at all.

[0009] Various devices exist for performing a thrombectomy or removing other foreign material. However, such devices have been found to have structures which are either highly complex, cause trauma to the treatment vessel, or lack the ability to be appropriately fixed against

the vessel. Furthermore, many of the devices have highly complex structures that lead to manufacturing and quality control difficulties as well as delivery issues when passing through tortuous or small diameter catheters. Less complex devices may allow the user to pull through the clot, particularly with inexperienced users, and such devices may not completely capture and/or collect all of the clot material.

[0010] Thus, there exists a need for improved systems and methods for embolic extraction.

BRIEF DESCRIPTION OF THE DRAWINGS

[0011] Many aspects of the present technology can be better understood with reference to the following drawings. The components in the drawings are not necessarily to scale. Instead, emphasis is placed on illustrating clearly the principles of the present disclosure.

[0012] Figures 1A and 1B are side views of a clot treatment system in a pre-deployed configuration and a deployed configuration, respectively, configured in accordance with embodiments of the present technology.

[0013] Figure 1C is an enlarged perspective view of a distal portion of the clot treatment system shown in Figure 1B configured in accordance with an embodiment of the present technology.

[0014] Figures 2A–2C are a side view, a proximally-facing perspective view, and a distally-facing perspective view, respectively, of a clot treatment device of the clot treatment system of Figures 1A–1C configured in accordance with embodiments of the present technology.

[0015] Figure 3 is a flow diagram of a process or method for operating the clot treatment system to remove clot material from within a blood vessel of a human patient in accordance with an embodiment of the present technology.

[0016] Figures 4A–4F are schematic illustrations of a distal portion of the clot treatment system during a procedure to remove clot material from a blood vessel of a human patient in accordance with embodiments of the present technology.

DETAILED DESCRIPTION

[0017] The present technology is generally directed to systems, devices, and methods for removing clot material from a blood vessel of a human patient. In some embodiments, a clot removal system can include a delivery catheter and a clot treatment device. The clot treatment device can include a plurality of interconnected struts forming a unitary structure that is movable

between a compressed configuration and an expanded configuration. In the expanded configuration, the unitary structure can include (i) a proximal connection region, (ii) a proximal conical region extending from the proximal connection region, (iii) a cylindrical region extending from the proximal conical region, (iv) a distal conical region extending from the cylindrical region, and (v) a distal connection region extending from the distal conical region. In some embodiments, a first portion of the struts form first cells in the proximal conical region, and a second portion of the struts form second cells in the distal conical region that are smaller than the first cells.

[0018] In some embodiments, the system further includes a handle configured to be gripped by an operator, and a first shaft coupled between the handle and the proximal connection region of the clot treatment device. The clot treatment device can be maintained in the compressed configuration within a lumen of the delivery catheter and near a distal terminus of the delivery catheter. To move the clot treatment device to the expanded configuration, the operator can move the handle to advance the first shaft to thereby advance the clot treatment device past the distal terminus and out of the lumen of the delivery catheter. When the clot treatment device is no longer constrained by the delivery catheter, the clot treatment device can expand (e.g., self-expand) to the expanded configuration. In some embodiments, the system further includes a second shaft extending at least partially through the first shaft and coupled to the distal connection region of the clot treatment device. Relative movement between the first and second shafts can allow the clot treatment device to lengthen/shorten and to correspondingly radially expand/compress.

[0019] During a procedure to remove clot material from a blood vessel of a human patient, the clot treatment device can be expanded distal of the clot material within the blood vessel, and then retracted proximally into the clot material to capture/disrupt the clot material. In one aspect of the present technology, the larger first cells of the clot treatment device are configured to receive the clot material therethrough as the clot treatment device is pulled against the clot material, and the smaller second cells of the clot treatment device are configured to retain the clot material within the clot treatment device. In another aspect of the present technology, the clot treatment device has sufficient radial stiffness (e.g., at the cylindrical region) to inhibit the clot treatment device from slipping (e.g., not engaging) the clot material when the clot treatment device is pulled against the clot material. Accordingly, the clot treatment device can be used to capture/disrupt adhered, organized, and/or chronic clots that would otherwise be difficult to remove.

[0020] Although many of the embodiments are described below with respect to systems, devices, and methods for treating a pulmonary embolism, other applications and other embodiments in addition to those described herein are within the scope of the technology (e.g., intravascular procedures other than the treatment of emboli, intravascular procedures for treating cerebral embolism, intravascular procedures for treating deep vein thrombosis (DVT), etc.). Additionally, several other embodiments of the technology can have different configurations, states, components, or procedures than those described herein. Moreover, it will be appreciated that specific elements, substructures, advantages, uses, and/or other features of the embodiments described with reference to Figures 1–4F can be suitably interchanged, substituted or otherwise configured with one another in accordance with additional embodiments of the present technology. Furthermore, suitable elements of the embodiments described with reference to Figures 1–4F can be used as standalone and/or self-contained devices. A person of ordinary skill in the art, therefore, will accordingly understand that the technology can have other embodiments with additional elements, or the technology can have other embodiments without several of the features shown and described below with reference to Figures 1–4F.

[0021] With regard to the terms "distal" and "proximal" within this description, unless otherwise specified, the terms can reference a relative position of the portions of a catheter subsystem with reference to an operator and/or a location in the vasculature. Also, as used herein, the designations "rearward," "forward," "upward," "downward," etc. are not meant to limit the referenced component to use in a specific orientation. It will be appreciated that such designations refer to the orientation of the referenced component as illustrated in the Figures; the systems and devices of the present technology can be used in any orientation suitable to the user.

[0022] Figures 1A and 1B are side views of a clot treatment or clot removal system 100 ("system 100") configured in accordance with embodiments of the present technology. The system 100 is in a constrained/pre-deployment configuration in Figure 1A, and the system 100 is in an expanded/deployed configuration in Figure 1B. Referring to Figures 1A and 1B together, in the illustrated embodiment the system 100 includes a delivery catheter 102 (e.g., a tube, a shaft, etc.; which can also be referred to herein as an outer shaft) defining a lumen and having a proximal end portion 103a and a distal end portion 103b. The proximal end portion 103a of the delivery catheter 102 is coupled to a hub 110, such as a sealable hub, valve, etc. The lumen of the delivery catheter 102 can be fluidly coupled to a port assembly 112 via the hub 110.

[0023] In the illustrated embodiment, the port assembly 112 includes a fluid control device 114 fluidly coupled between (i) a port connector 116 (e.g., a Luer connector/fitting) and (ii) a tubing section 118 coupled to the hub 110 (e.g., to a branch or side port of the hub 110). The fluid control device 114 is actuatable to fluidly connect the lumen of the delivery catheter 102 to the port connector 116. In the illustrated embodiment, the fluid control device 114 is a stopcock while, in other embodiments, the fluid control device 114 can be a clamp, valve, and/or other suitable fluid control device. During a clot removal procedure using the system 100, various components (e.g., syringes, vacuum sources, etc.) can be coupled to the port connector 116 to remove fluid from and/or inject fluid into the lumen of the delivery catheter 102. For example, in some embodiments a syringe or other pressure source can be coupled to the port connector 116 and used to draw a vacuum while the fluid control device 114 is closed, and the fluid control device 114 can then be opened to instantaneously or nearly instantaneously apply the vacuum to the lumen of the delivery catheter 102 (e.g., to generate suction at the distal portion 103b for removing clot material). In other embodiments, a constant vacuum source (e.g., a pump) can be coupled to the port assembly 112 to provide constant aspiration of the lumen of the delivery catheter 102. In some embodiments, flushing fluid (e.g., saline) can be injected through the port assembly 112 to flush the lumen of the delivery catheter 102.

[0024] In the illustrated embodiment, the system 100 further includes an intermediate shaft 104 (e.g., a catheter, tube, etc.) extending at least partially through the lumen of the delivery catheter 102 and defining a lumen, and an inner shaft 106 (e.g., a catheter, tube, etc.) extending at least partially through the lumen of the intermediate shaft 104. Accordingly, in some embodiments the delivery catheter 102, the intermediate shaft 104, and the inner shaft 106 are coaxially aligned/arranged. The system 100 further includes a clot treatment device 130 coupled to the intermediate shaft 104 and the inner shaft 106. The delivery catheter 102, the intermediate shaft 104, the inner shaft 106, and the clot treatment device 130 can collectively be referred to as a treatment portion 111 (e.g., an insertion portion) of the system 100. As described in greater detail below with reference to Figures 3–4F, the treatment portion 111 is configured to be inserted through a guide catheter to position the clot treatment device 130 at a treatment site during a clot removal procedure.

[0025] As described in greater detail below with reference to Figures 2A–2C, the clot treatment device 130 can be a self-expanding unitary structure comprising a plurality of interconnected struts. In the pre-deployment configuration shown in Figure 1A, the clot treatment device 130 is constrained within the delivery catheter 102 and thus obscured. In the

deployed configuration shown in Figure 1B, the clot treatment device 130 extends past the distal end portion 103b of the delivery catheter 102 (e.g., a distal terminus of the delivery catheter 102) and is radially expanded.

[0026] Figure 1C is an enlarged perspective view of a distal portion of the system 100 shown in Figure 1B configured in accordance with an embodiment of the present technology. In the illustrated embodiment, the intermediate shaft 104 includes a distal end portion 105b coupled to a proximal portion 131a of the clot treatment device 130. In some embodiments, the proximal portion 131a of the clot treatment device 130 includes a plurality of struts that are gathered together and secured to the distal end portion 105b of the intermediate shaft 104. For example, the struts at the proximal portion 131a of the clot treatment device 130 can be secured to the outer surface of the intermediate shaft 104 via adhesives, fasteners, a hub or other device, etc. The inner shaft 106 includes a distal end portion 107 coupled to a distal portion 131b of the clot treatment device 130. In some embodiments, the distal portion 131b of the clot treatment device 130 includes a plurality of struts that are gathered together and secured to the distal end portion 107 of the inner shaft 106 via a friction fit, pressure fit, etc., between the inner shaft 106 and a distal tip 108 (e.g., an atraumatic tip). In other embodiments, the struts at the distal portion 131b of the clot treatment device 130 can be secured to the outer surface of the inner shaft 106 via adhesives, fasteners, a hub or other device, etc.

[0027] Referring again to Figures 1A and 1B together, the intermediate shaft 104 includes a proximal end portion 105a coupled to the handle 120 (e.g., to a distal portion of the handle 120) to operably couple the handle 120 to the clot treatment device 130. Accordingly, the intermediate shaft 104 extends between and operably couples the handle 120 and the clot treatment device 130. In some embodiments, a proximal end portion of the inner shaft 106 (obscured in Figures 1A and 1B) is not coupled to any portion of the system 100 and floats within the lumen of the intermediate shaft 104. In one aspect of the present technology, this arrangement allows the inner shaft 106 to move relative to the intermediate shaft 104 in response to external forces on the clot treatment device 130, thereby allowing the clot treatment device 130 to elongate/shorten longitudinally and to correspondingly radially compress/expand. In other embodiments, the proximal end portion of the inner shaft 106 can be coupled to an actuation mechanism 122 (shown in dashed lines in Figures 1A and 1B) of the handle 120. The actuation mechanism 122 can be configured to drive the inner shaft 106 proximally and/or distally to shorten and/or elongate, respectively, the clot treatment device 130. More specifically, in some embodiments distal movement of the actuation mechanism 122 relative to

the handle 120 can move the inner shaft 106 distally relative to the intermediate shaft 104 to lengthen and radially compress the clot treatment device 130, while proximal movement of the actuation mechanism 122 relative to the handle 120 can move the inner shaft 106 proximally relative to the intermediate shaft 104 to shorten and radially expand the clot treatment device 130.

[0028] In the illustrated embodiment, the handle 120 further includes a proximal hub 124, such as a Luer hub, configured to receive a guidewire (not shown) therethrough. The handle 120, the inner shaft 106, and the tip 108 can together define a lumen for receiving the guidewire therethrough. In some embodiments, the guidewire can have a diameter of about 0.035 inch, about 0.018 inch, less than about 0.1 inch, less than about 0.05 inch, etc. In some embodiments, the handle 120 further includes a lock feature 126 such as, for example, a spinlock or a push-in-and-turn lock. The lock feature 126 is configured to selectively engage (e.g., lockingly engage) with a mating feature 115 of the hub 110. Locking the handle 120 to the hub 110 via the lock feature 126 and the mating feature 115 secures the position of the intermediate shaft 104 relative to the delivery catheter 102. In the illustrated embodiment, the intermediate shaft 104 is longer than the delivery catheter 102 such that a portion of the intermediate shaft 104 and the clot treatment device 130 extend distally from the distal end portion 103b of the delivery catheter 102 when the handle 120 is lockingly engaged with the hub 110.

[0029] To deploy the clot treatment device 130 from the pre-deployment configuration (Figure 1A) to the deployed configuration (Figure 1B), an operator can move the handle 120 distally toward the hub 110 and/or can move the hub 110 toward the handle 120. This movement advances the intermediate shaft 104 distally through the delivery catheter 102 and pushes the clot treatment device 130 distally out of the delivery catheter 102. The clot treatment device 130 can self-expand as it is released from the lumen of the delivery catheter 102. When the handle 120 abuts the hub 110, the operator can actuate the lock feature 126 to secure the position of the intermediate shaft 104 relative to the delivery catheter 102 to, for example, maintain the clot treatment device 130 in the deployed configuration.

[0030] In some embodiments, proximal movement of the handle 120 and/or distal movement of the hub 110 (e.g., from the position shown in Figure 1B to the position shown in Figure 1A) can retract the clot treatment device 130 back into the delivery catheter 102. That is, in some embodiments the clot treatment device 130 can be resheathed within the delivery catheter 102. In such embodiments, the clot treatment device 130 can be repeatedly expanded

and then retracted and compressed into the delivery catheter 102. In some embodiments, the tip 108 is configured (e.g., sized and shaped) to abut the distal end portion 103b of the delivery catheter 102 in the pre-deployment configuration (Figure 1A). This can inhibit or even prevent the clot treatment device 130 from being pulled fully through the delivery catheter 102 and, in some embodiments, can substantially seal the lumen of the delivery catheter 102. In other embodiments, the tip 108 is sized and shaped to allow the tip 108—and thus the entire clot treatment device 130—to be retracted through the delivery catheter 102.

[0031] Figures 2A–2C are a side view, a proximally-facing perspective view, and a distally-facing perspective view, respectively, of the clot treatment device 130 in the expanded configuration in accordance with embodiments of the present technology. Referring to Figures 2A–2C together, the clot treatment device 130 comprises a plurality of struts 240 that together define a plurality of first cells 250 (e.g., interstices, pores, openings, etc.) and a plurality of second cells 252. The struts 240 can have a variety of shapes and sizes and, in some embodiments, the struts 240 can have a thickness and/or diameter between about 0.0125–0.150 inch, between about 0.075–0.125 inch, between about 0.090–0.150 inch, and/or other dimensions. In general, the struts 240 together form a unitary structure that is configured to engage, capture, disrupt, and/or separate a portion of a thrombus (e.g., a vascular thrombus) from a blood vessel containing the thrombus.

[0032] In the illustrated embodiment, (i) the first cells 250 generally face proximally while the second cells 252 generally face distally, and (ii) the first cells 250 are larger than the second cells 252. As best seen in Figure 2A, the clot treatment device 130 includes (i) a first region 242 including the proximal portion 131a, (ii) a second region 243 distal of the first region 242, (iii) a third (e.g., central) region 244 distal of the second region 243, (iv) a fourth region 245 distal of the third region 244, and (v) a fifth region 246 distal of the fourth region 245 and including the distal portion 131b. In the illustrated embodiment, the struts 240 are gathered together (e.g. positioned proximate one another) at the first and fifth regions 242, 246 to facilitate their connection to the intermediate and inner shafts 104, 106, respectively, as shown in Figure 1C. The second region 243 can have a generally conical shape that tapers (e.g., radially narrows) in the proximal direction. Similarly, the fourth region 245 can have a generally conical shape that tapers in the distal direction. The third region 244 can have a generally tubular/cylindrical shape including, for example a generally flat outer strut surface/boundary 248. Moreover, in the illustrated embodiment the first and second regions 242, 243 have fewer of the struts 240 than the fourth and fifth regions 245, 246 to thereby define the larger first cells 250. Conversely, the

fourth and fifth regions 245, 246 have more of the struts 240 than the first and second regions 242, 243 to thereby define the smaller second cells 252. The third region 244 can be a transition region in which the number of the struts 240 increases in the proximal direction (e.g., toward the fourth region 245) such that some of the first cells 250 abut some of the second cells 252 in the third region 244. In other embodiments, the first cells 250 can be formed only in the second region 243, can occupy the entire third region 244, can extend into the fourth region 245, etc.

[0033] In some embodiments, the clot treatment device 130 is made from a shape memory material such as a shape memory alloy and/or a shape memory polymer. For example, the clot treatment device 130 can comprise nitinol and/or a nitinol alloy. Similarly, the clot treatment device 130 can be made using a variety of techniques including welding, laser welding, cutting, laser cutting, expanding, etc. For example, in some embodiments the clot treatment device 130 can first be laser cut from a piece of nitinol (e.g., a nitinol tube), and then further shaped using a heat setting process such that the clot treatment device 130 has the illustrated shape in the expanded configuration. For example, as is known in the art of heat setting nitinol structures, a fixture, mandrel, or mold may be used to hold the clot treatment device 130 in its desired configuration, and then the clot treatment device 130 can be subjected to an appropriate heat treatment such that the struts 240 of the clot treatment device 130 assume or are otherwise shape-set to the outer contour of the mandrel or mold. The heat setting process may be performed in an oven or fluidized bed, as is well-known. Therefore, the heat setting process can impart a desired shape, geometry, bend, curve, serration, scallop, void, hole, etc., in the super-elastic and/or shape memory material or materials used to form the clot treatment device 130. Accordingly, the clot treatment device 130 may be radially constrained without plastic deformation and will self-expand on release of the radial constraint.

[0034] In general, the size of the clot treatment device 130 can be selected based on the size (e.g., diameter) of the blood vessel from which thrombus is to be extracted. In some embodiments, in a fully-expanded configuration unconstrained within a vessel, the clot treatment device 130 can have a length L (Figure 2A) of between about 0.025–1.50 inches, between about 0.70–1.15 inches, etc. In some embodiments, in the fully-expanded position unconstrained within a vessel, the clot treatment device 130 can have a maximum diameter D (Figure 2A; e.g., at the third region 244) of between about 0.025–1.5 inches, between about 0.71–1.34 inches, etc.

[0035] The clot treatment device 130 is configured (e.g., shaped, sized, angled, formed, etc.) to engage, disrupt, and/or capture clot material from within a blood vessel when the clot

treatment device 130 is retracted through/against the clot material in the expanded configuration. For example, as described in greater detail below with reference to Figures 3–4F, the clot treatment device 130 can be withdrawn proximally through/against the clot material. In one aspect of the present technology, the larger first cells 250 are configured to receive the clot material therethrough as the clot treatment device 130 is pulled against the clot material, and the smaller second cells 252 (and associated struts 240) are configured to retain the clot material within the clot treatment device 130. In another aspect of the present technology, the clot treatment device 130 has sufficient radial stiffness (e.g., at the third region 244) to inhibit the clot treatment device 130 from slipping (e.g., not engaging) the clot material when the clot treatment device 130 is pulled against the clot material. Accordingly, the clot treatment device 130 can be used to capture/disrupt adhered, organized, and/or chronic clots. In some embodiments, portions of the struts 240 (e.g., at the second region 243) can be sharpened and/or can include a cutting element (e.g., a knife or knife edge) attached thereto or otherwise integrated with to further facilitate disruption/cutting of the clot material.

[0036] Figure 3 is a flow diagram of a process or method 360 for operating the system 100 to remove clot material from within a blood vessel (e.g., a pulmonary blood vessel) of a patient (e.g., a human patient) in accordance with an embodiment the present technology. Figures 4A–4F are schematic illustrations of a distal portion of the system 100 inserted through a guide catheter 470 during a procedure to remove clot material PE from a blood vessel BV of a patient in accordance with embodiments of the present technology. Although some features of the method 360 are described in the context of the embodiments shown in Figures 4A–4F for the sake of illustration, one skilled in the art will readily understand that the method 360 can be carried out using other suitable systems and/or devices described herein.

[0037] With reference to Figures 3 and 4A, at block 361, the method 360 can include positioning a distal portion 471 of the guide catheter 470 proximate to the clot material PE within the blood vessel BV (e.g., at a treatment site). In the illustrated embodiment, a distal terminus of the guide catheter 470 is positioned proximate to a proximal portion of the clot material PE. However, in other embodiments the distal terminus of the guide catheter 470 can be positioned at least partially within the clot material PE, or the distal terminus of the guide catheter 470 can be positioned distal of the clot material PE. Access to the blood vessel BV can be achieved through the patient's vasculature, for example, via the femoral vein. In some embodiments, such as when the blood vessel BV is a pulmonary blood vessel, an introducer (e.g., a Y-connector with a hemostasis valve; not shown) is connected to the guide catheter 470 and can be partially

inserted into the femoral vein. A guidewire 472 can be guided into the femoral vein through the introducer and navigated through the right atrium, the tricuspid valve, the right ventricle, the pulmonary valve, and into the main pulmonary artery. Depending on the location of the clot material PE, the guidewire 472 can be guided to one or more of the branches of the right pulmonary artery and/or the left pulmonary artery. In some embodiments, the guidewire 472 can be extended entirely or partially through the clot material PE. In other embodiments, the guidewire 472 can be extended to a location just proximal of the clot material PE. After positioning the guidewire 472, the guide catheter 470 can be placed over the guidewire 472 and advanced to the position proximate to the clot material PE as illustrated in Figure 4A.

[0038] In some embodiments, a pressure source can be coupled to the guide catheter 470 and used to aspirate the lumen of the guide catheter 470 to, for example, generate suction (e.g., as indicated by arrows A) to suck/draw all or a portion of the clot material PE into the guide catheter 470. For example, in some embodiments a vacuum can be pre-charged (e.g., in a syringe fluidly coupled to the lumen of the guide catheter 470) and the vacuum can be applied to the lumen of the guide catheter 470 to instantaneously or nearly instantaneously generate suction at the distal portion 471 of the guide catheter 470 (e.g., to generate a suction pulse at the distal portion 471 of the guide catheter 470). Specific details of such methods and associated devices are disclosed in U.S. Patent Application No. 16/536,185, filed August 8, 2019, and titled "SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED DEVICES AND METHODS," which is incorporated herein by reference in its entirety.

[0039] However, even where suction is applied to remove/dislodge the clot material PE from the blood vessel BV, the suction may not be enough to dislodge/disrupt all the clot material PE. For example, many chronic (e.g., organized) clots can strongly adhere to the walls of the blood vessel BV—making it difficult to remove them. In one aspect of the present technology, the system 100 can be inserted through the guide catheter 470 before, during, and/or after suction is applied via the guide catheter 470 to engage, disrupt, and/or capture the clot material PE—even where the clot material PE is strongly adhered within the blood vessel BV.

[0040] For example, with reference to Figures 3 and 4B, at block 362, the method 360 can include advancing the clot treatment device 130 (compressed within the delivery catheter 102 and thus obscured in Figure 4B) through the guide catheter 470 to proximate the clot material PE. More specifically, the treatment portion 111 of the system 100 can be advanced through the guide catheter 470 in the compressed pre-deployment configuration until the tip 108 is positioned

(i) distal of the distal portion 471 of the guide catheter 470 and (ii) distal of the clot material PE within the blood vessel BV. In other embodiments, the tip 108 can be positioned within the clot material PE. In some embodiments, the treatment portion 111 can be advanced over the guidewire 472 while, in other embodiments, the guidewire 472 can be omitted.

[0041] With reference to Figures 3 and 4C, at block 363, the method 360 can include moving the clot treatment device 130 from the compressed pre-deployment configuration to the expanded deployed configuration such that the clot treatment device 130 is expanded distal and/or partially within the clot material PE. For example, as described in detail above with reference to Figures 1A and 1B, an operator of the system 100 can advance the handle 120 distally toward the hub 110 and/or retract the hub 110 toward the handle 120 to move the intermediate shaft 104 relative to the delivery catheter 102 to advance the clot treatment device 130 out of the delivery catheter 102, thereby allowing the clot treatment device 130 to expand (e.g., self-expand) within the blood vessel BV. In the illustrated embodiment, the clot treatment device 130 (e.g., the outer strut surface 248 of the third region 244) contacts (e.g., engages, apposes, etc.) the wall of the blood vessel BV. In some embodiments, the clot treatment device 130 is oversized relative to the blood vessel BV such that the clot treatment device 130 exerts a radially outward force on the wall of the blood vessel BV. In other embodiments, the clot treatment device 130 can be sized such that it does not contact the walls of the blood vessel BV.

[0042] With reference to Figures 3 and 4D, at block 364, the method 360 can include retracting the clot treatment device 130 proximally (e.g., in the direction of arrow B) into/toward the clot material PE. More specifically, with reference to Figures 1A and 1B, the operator can pull the entire system 100 proximally (e.g., by gripping the hub 110) to retract the treatment portion 111 through the lumen of the guide catheter 470. As the clot treatment device 130 is retracted, the clot treatment device 130 engages the clot material PE to capture/disrupt the clot material PE. For example, the clot material PE can enter through the first cells 250 (Figures 2A–2C) and be retained within the clot treatment device 130 by the smaller second cells 252 (Figures 2A–2C). In one aspect of the present technology, the clot treatment device 130 can shear the clot material PE from the wall of the blood vessel BV even where the clot material PE is strongly adhered to the wall of the blood vessel BV.

[0043] In some embodiments, where the inner shaft 106 floats within the lumen of the intermediate shaft 104, the length L (Figure 2A) of the clot treatment device 130 can increase as the clot treatment device 130 is pulled into/against the clot material PE and the intermediate shaft

104 moves proximally relative to the inner shaft 106. In other embodiments, where the system 100 includes the actuation mechanism 122, the operator can actuate the actuation mechanism 122 to increase the longitudinal and/or radial stiffness of the clot treatment device 130 by locking or substantially locking the relative position of the intermediate and inner shafts 104, 106.

[0044] With reference to Figures 3 and 4E, at block 365, the method 360 can include retracting the clot treatment device 130 and the captured clot material PE into the lumen of the guide catheter 470. In some embodiments, the clot treatment device 130 can be fully removed from the guide catheter 470. In some embodiments, if any of the clot material PE remains in the blood vessel BV, the clot treatment device 130 can be cleaned and blocks 362–365 can be repeated to capture the remaining clot material PE. Alternatively, a new clot treatment device 130 can be reinserted through the guide catheter 470 to capture the remaining clot material PE. In some embodiments, the clot treatment device 130 can break apart the clot material PE without necessarily capturing the clot material PE and, after or during retraction of the clot treatment device 130, aspiration can be applied to the guide catheter 470 to suck the remaining clot material PE into the guide catheter 470. Finally, with reference to Figures 3 and 4F, at block 366, the method 360 can include removing the guide catheter 470 from the blood vessel BV and from the patient after a sufficient portion of the clot material is removed from the patient.

[0045] Several aspects of the present technology are set forth in the following additional examples:

1. A clot treatment system, comprising:

an outer catheter defining a lumen;

an inner catheter positioned at least partially in the lumen of the outer catheter; and

a clot treatment device including a plurality of interconnected struts forming a unitary structure movable between a compressed configuration and an expanded configuration, wherein in the expanded configuration the unitary structure includes—

a proximal connection region coupled to the outer catheter;

a proximal conical region extending from the proximal connection region, wherein a first portion of the struts form first cells in the proximal conical region;

a cylindrical region extending from the proximal conical region;

a distal conical region extending from the cylindrical region, wherein a second portion of the struts from second cells in the distal conical region, and wherein the second cells are smaller than the first cells; and

a distal connection region extending from the distal conical region and coupled to the inner catheter.

2. The clot treatment system of example 1 wherein the inner catheter has (a) a distal end portion coupled to the distal connection region of the clot treatment device and (b) a proximal end portion configured to float within the lumen of the outer catheter.

3. The clot treatment system of example 1 or example 2 wherein the inner and outer catheters are configured to receive a guidewire therethrough.

4. The clot treatment system of any one of examples 1–3, further comprising a handle coupled to a proximal end portion of the outer catheter, wherein the handle includes an actuation mechanism coupled to a proximal end portion of the inner catheter, and wherein actuation of the actuation mechanism is configured to translate the inner catheter relative to the outer catheter to longitudinally compress or longitudinally elongate the clot treatment device.

5. The clot treatment system of any one of examples 1–4, further comprising:

a delivery catheter defining a lumen; and

a handle coupled to a proximal end portion of the outer catheter and movable between a first position and a second position relative to the delivery catheter, wherein—

in the first position, the clot treatment device is constrained within the lumen of the delivery catheter in the compressed configuration, and

in the second position, the clot treatment device is positioned distal of the lumen in the expanded configuration.

6. The clot treatment system of example 5, further comprising a hub coupled to a proximal end portion of the delivery catheter, wherein the handle includes a lock feature configured to secure the handle to the hub in the second position.

7. The clot treatment system of example 5 or example 6 wherein the handle, the delivery catheter, the outer catheter, and the inner catheter are configured to receive a guidewire therethrough.

8. The clot treatment system of any one of examples 1–7 wherein, in the expanded configuration, the cylindrical region has a diameter of between about 0.71 inch to about 1.34 inches.

9. The clot treatment system of any one of examples 1–8 wherein the struts of the clot treatment device are configured to self-expand from the compressed configuration to the expanded configuration when unconstrained.

10. The clot treatment system of any one of examples 1–9 wherein the struts of the clot treatment device include a shape memory material.

11. The clot treatment system of any one of examples 1–10 wherein the unitary structure includes (a) a first number of the struts in the proximal conical region and (b) a second number of the struts in the distal conical region that is greater than the first number of struts.

12. A method of clot removal, the method comprising:

positioning a distal portion of a guide catheter proximate to clot material within a blood vessel of a human patient;

advancing a clot treatment device through the guide catheter to proximate the clot material;

expanding the clot treatment within the blood vessel distal of the clot material, wherein the clot treatment device includes a plurality of interconnected struts forming a unitary structure having a proximal portion and a distal portion, wherein the struts form a plurality of first cells in the proximal portion and a plurality of second cells in the distal portion, and wherein the first cells are larger than the second cells;

generating suction at the distal portion of the guide catheter; and

proximally retracting the clot treatment device through the clot material.

13. The method of example 12 wherein advancing the clot treatment device through the guide catheter includes advancing the clot treatment device over a guidewire.

14. The method of example 12 or example 13 wherein the proximal portion of the unitary structure is coupled to an outer catheter extending at least partially through the guide catheter, and wherein the distal portion of the unitary structure is coupled to an inner catheter extending at least partially through the outer catheter.

15. The method of example 14 wherein advancing the clot treatment device through the guide catheter includes advancing the clot treatment device over a guidewire extending through the guide, outer, and inner catheters.

16. The method of any one of examples 12–15 wherein generating suction at the distal portion of the guide catheter includes generating suction, before proximally retracting the clot treatment device, to aspirate a first portion of the clot material into the guide catheter.

17. The method of example 16 wherein proximally retracting the clot treatment device includes proximally retracting the clot treatment device through a second portion of the clot material remaining in the blood vessel to capture the second portion of the clot material.

18. The method of any one of examples 12–17 wherein proximally retracting the clot treatment device through the clot material includes capturing at least a portion of the clot material, and wherein the method further comprises retracting the clot treatment device and the captured clot material into the guide catheter.

19. A clot treatment system, comprising:

an outer shaft defining a lumen;

an inner shaft positioned at least partially in the lumen of the outer shaft; and

a plurality of interconnected struts forming a unitary structure having a proximal portion and a distal portion, wherein the proximal portion is coupled to the outer shaft, wherein the distal portion is coupled to the inner shaft, and wherein the struts form a plurality of first cells in the proximal portion and a plurality of second

cells in the distal portion, and wherein the first cells are larger than the second cells.

20. The clot treatment system of example 12 wherein the outer shaft and the inner shaft are configured to receive a guidewire therethrough.

21. A clot treatment device, comprising:

a plurality of interconnected struts forming a unitary structure movable between a compressed configuration and an expanded configuration, wherein in the expanded configuration the unitary structure includes—

a proximal connection region;

a proximal conical region extending from the proximal connection region, wherein a first portion of the struts form first cells in the proximal conical region;

a cylindrical region extending from the proximal conical region;

a distal conical region extending from the cylindrical region, wherein a second portion of the struts from second cells in the distal conical region, and wherein the second cells are smaller than the first cells; and

a distal connection region extending from the distal conical region.

22. The clot treatment device of example 21, further comprising:

a first shaft coupled to the proximal connection region and defining a lumen; and

a second shaft coupled to the distal connection region and extending at least partially through the lumen of the first shaft.

23. The clot treatment device of example 21 or example 22 wherein the second shaft has (a) a distal end portion coupled to the distal connection region and (b) a proximal end portion configured to float within the lumen of the first shaft.

24. The clot treatment device of any one of examples 21–23 wherein the struts are configured to self-expand from the compressed configuration to the expanded configuration when unconstrained.

25. The clot treatment device of any one of examples 21–24 wherein the struts are made from a shape memory material.

26. A clot treatment device, comprising:

a plurality of interconnected struts forming a unitary structure having a proximal portion and a distal portion, wherein the struts form a plurality of first cells in the proximal portion and a plurality of second cells in the distal portion, and wherein the first cells are larger than the second cells.

[0046] The above detailed descriptions of embodiments of the technology are not intended to be exhaustive or to limit the technology to the precise form disclosed above. Although specific embodiments of, and examples for, the technology are described above for illustrative purposes, various equivalent modifications are possible within the scope of the technology as those skilled in the relevant art will recognize. For example, although steps are presented in a given order, alternative embodiments may perform steps in a different order. The various embodiments described herein may also be combined to provide further embodiments.

[0047] From the foregoing, it will be appreciated that specific embodiments of the technology have been described herein for purposes of illustration, but well-known structures and functions have not been shown or described in detail to avoid unnecessarily obscuring the description of the embodiments of the technology. Where the context permits, singular or plural terms may also include the plural or singular term, respectively.

[0048] Moreover, unless the word "or" is expressly limited to mean only a single item exclusive from the other items in reference to a list of two or more items, then the use of "or" in such a list is to be interpreted as including (a) any single item in the list, (b) all of the items in the list, or (c) any combination of the items in the list. Additionally, the term "comprising" is used throughout to mean including at least the recited feature(s) such that any greater number of the same feature and/or additional types of other features are not precluded. It will also be appreciated that specific embodiments have been described herein for purposes of illustration, but that various modifications may be made without deviating from the technology. Further, while advantages associated with some embodiments of the technology have been described in the context of those embodiments, other embodiments may also exhibit such advantages, and not all embodiments need necessarily exhibit such advantages to fall within the scope of the

technology. Accordingly, the disclosure and associated technology can encompass other embodiments not expressly shown or described herein.

CLAIMS

I/We claim:

1. A clot treatment system, comprising:

an outer catheter defining a lumen;

an inner catheter positioned at least partially in the lumen of the outer catheter; and

a clot treatment device including a plurality of interconnected struts forming a unitary structure movable between a compressed configuration and an expanded configuration, wherein in the expanded configuration the unitary structure includes—

a proximal connection region coupled to the outer catheter;

a proximal conical region extending from the proximal connection region, wherein a first portion of the struts form first cells in the proximal conical region;

a cylindrical region extending from the proximal conical region;

a distal conical region extending from the cylindrical region, wherein a second portion of the struts from second cells in the distal conical region, and wherein the second cells are smaller than the first cells; and

a distal connection region extending from the distal conical region and coupled to the inner catheter.

2. The clot treatment system of claim 1 wherein the inner catheter has (a) a distal end portion coupled to the distal connection region of the clot treatment device and (b) a proximal end portion configured to float within the lumen of the outer catheter.

3. The clot treatment system of claim 1 wherein the inner and outer catheters are configured to receive a guidewire therethrough.

4. The clot treatment system of claim 1, further comprising a handle coupled to a proximal end portion of the outer catheter, wherein the handle includes an actuation mechanism coupled to a proximal end portion of the inner catheter, and wherein actuation of the actuation

mechanism is configured to translate the inner catheter relative to the outer catheter to longitudinally compress or longitudinally elongate the clot treatment device.

5. The clot treatment system of claim 1, further comprising:

a delivery catheter defining a lumen; and

a handle coupled to a proximal end portion of the outer catheter and movable between a first position and a second position relative to the delivery catheter, wherein—

in the first position, the clot treatment device is constrained within the lumen of the delivery catheter in the compressed configuration, and

in the second position, the clot treatment device is positioned distal of the lumen in the expanded configuration.

6. The clot treatment system of claim 5, further comprising a hub coupled to a proximal end portion of the delivery catheter, wherein the handle includes a lock feature configured to secure the handle to the hub in the second position.

7. The clot treatment system of claim 5 wherein the handle, the delivery catheter, the outer catheter, and the inner catheter are configured to receive a guidewire therethrough.

8. The clot treatment system of claim 1 wherein, in the expanded configuration, the cylindrical region has a diameter of between about 0.71 inch to about 1.34 inches.

9. The clot treatment system of claim 1 wherein the struts of the clot treatment device are configured to self-expand from the compressed configuration to the expanded configuration when unconstrained.

10. The clot treatment system of claim 1 wherein the struts of the clot treatment device include a shape memory material.

11. The clot treatment system of claim 1 wherein the unitary structure includes (a) a first number of the struts in the proximal conical region and (b) a second number of the struts in the distal conical region that is greater than the first number of struts.

12. A method of clot removal, the method comprising:

positioning a distal portion of a guide catheter proximate to clot material within a blood vessel of a human patient;

advancing a clot treatment device through the guide catheter to proximate the clot material;

expanding the clot treatment within the blood vessel distal of the clot material, wherein the clot treatment device includes a plurality of interconnected struts forming a unitary structure having a proximal portion and a distal portion, wherein the struts form a plurality of first cells in the proximal portion and a plurality of second cells in the distal portion, and wherein the first cells are larger than the second cells;

generating suction at the distal portion of the guide catheter; and

proximally retracting the clot treatment device through the clot material.

13. The method of claim 12 wherein advancing the clot treatment device through the guide catheter includes advancing the clot treatment device over a guidewire.

14. The method of claim 12 wherein the proximal portion of the unitary structure is coupled to an outer catheter extending at least partially through the guide catheter, and wherein the distal portion of the unitary structure is coupled to an inner catheter extending at least partially through the outer catheter.

15. The method of claim 14 wherein advancing the clot treatment device through the guide catheter includes advancing the clot treatment device over a guidewire extending through the guide, outer, and inner catheters.

16. The method of claim 12 wherein generating suction at the distal portion of the guide catheter includes generating suction, before proximally retracting the clot treatment device, to aspirate a first portion of the clot material into the guide catheter.

17. The method of claim 16 wherein proximally retracting the clot treatment device includes proximally retracting the clot treatment device through a second portion of the clot material remaining in the blood vessel to capture the second portion of the clot material.

18. The method of claim 12 wherein proximally retracting the clot treatment device through the clot material includes capturing at least a portion of the clot material, and wherein the method further comprises retracting the clot treatment device and the captured clot material into the guide catheter.

19. A clot treatment system, comprising:

an outer shaft defining a lumen;

an inner shaft positioned at least partially in the lumen of the outer shaft; and

a plurality of interconnected struts forming a unitary structure having a proximal portion and a distal portion, wherein the proximal portion is coupled to the outer shaft, wherein the distal portion is coupled to the inner shaft, and wherein the struts form a plurality of first cells in the proximal portion and a plurality of second cells in the distal portion, and wherein the first cells are larger than the second cells.

20. The clot treatment system of claim 12 wherein the outer shaft and the inner shaft are configured to receive a guidewire therethrough.

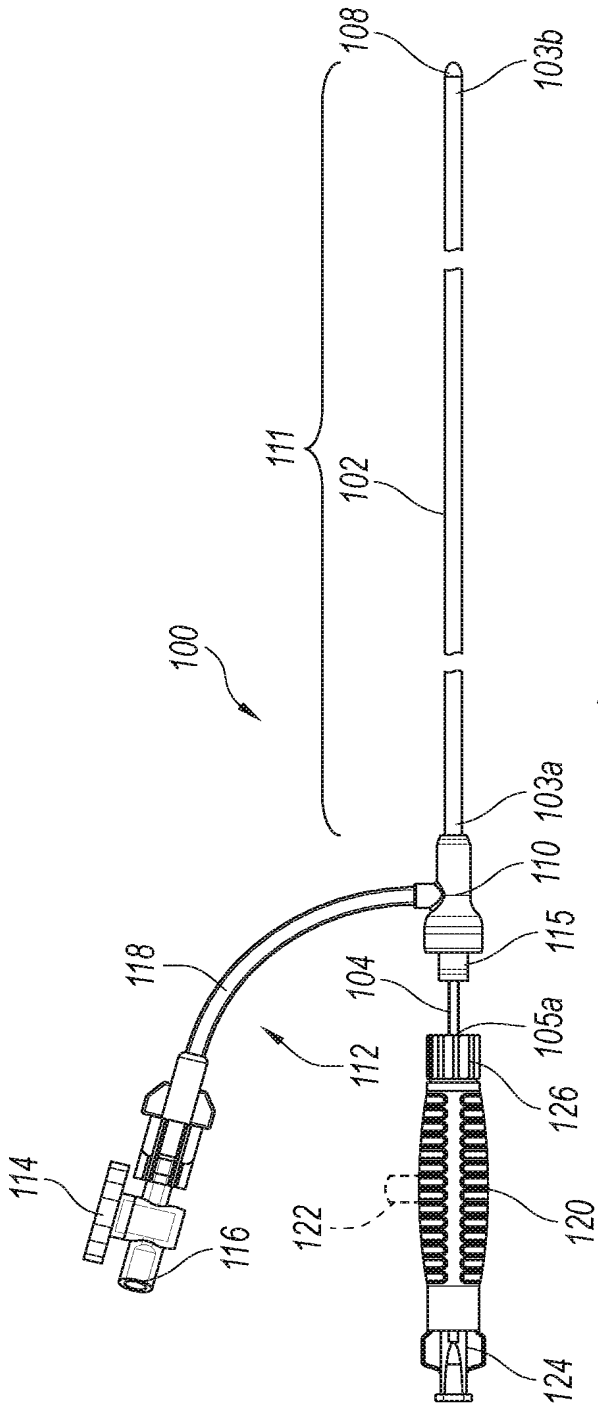


Fig. 1A

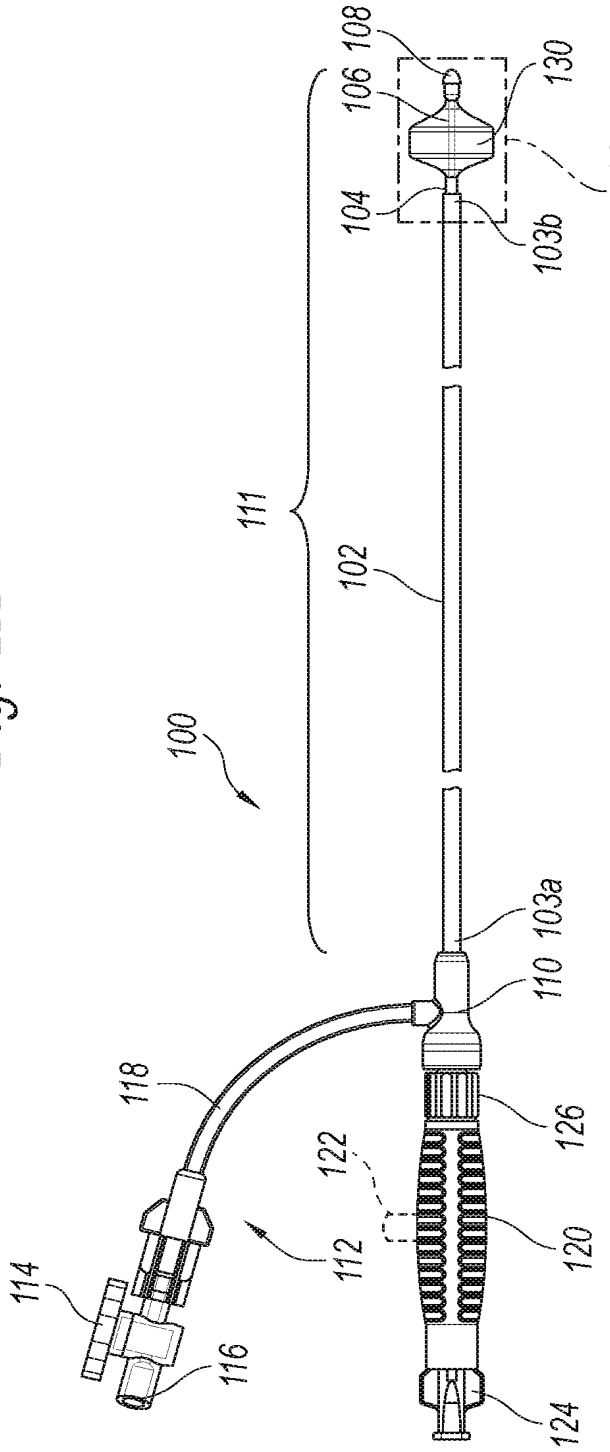


Fig. 1B

Fig. 1C

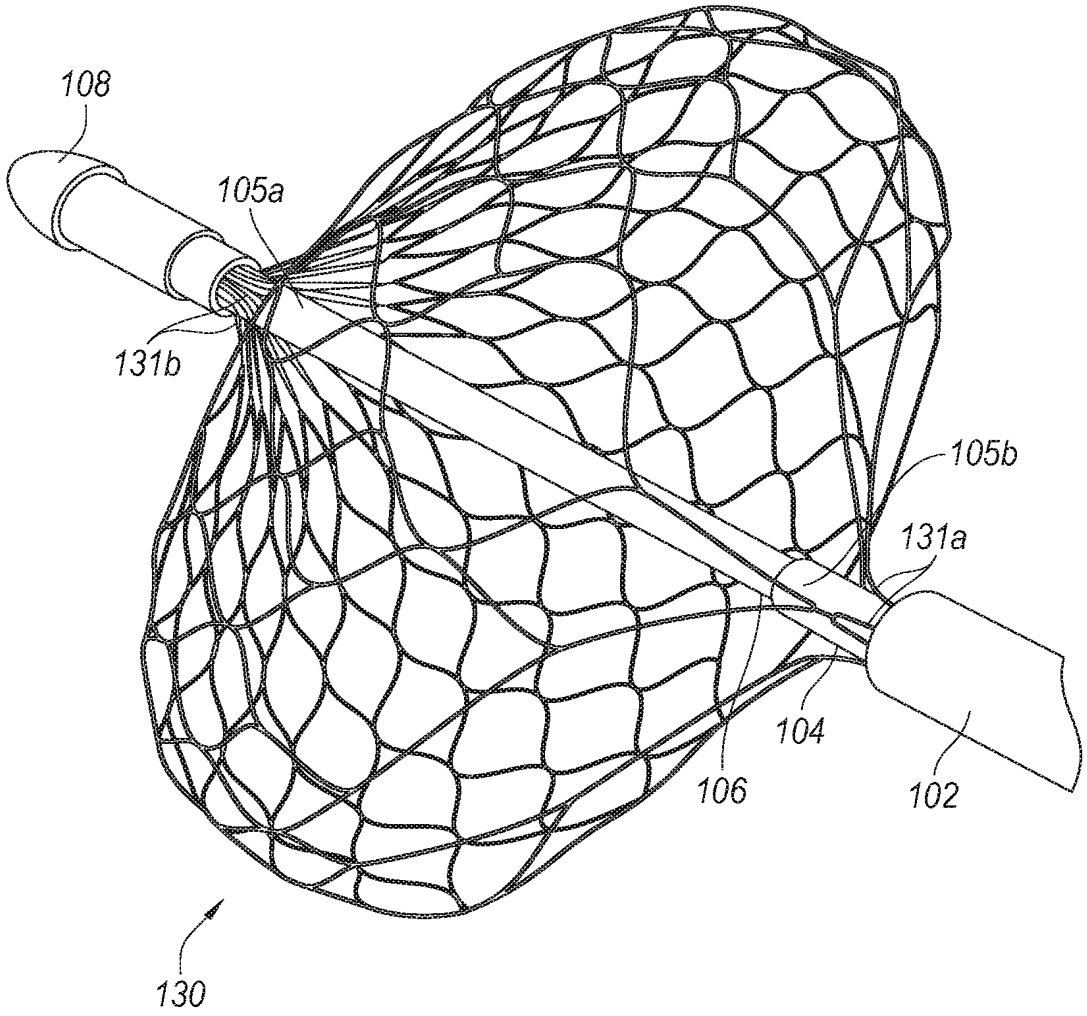


Fig. 1C

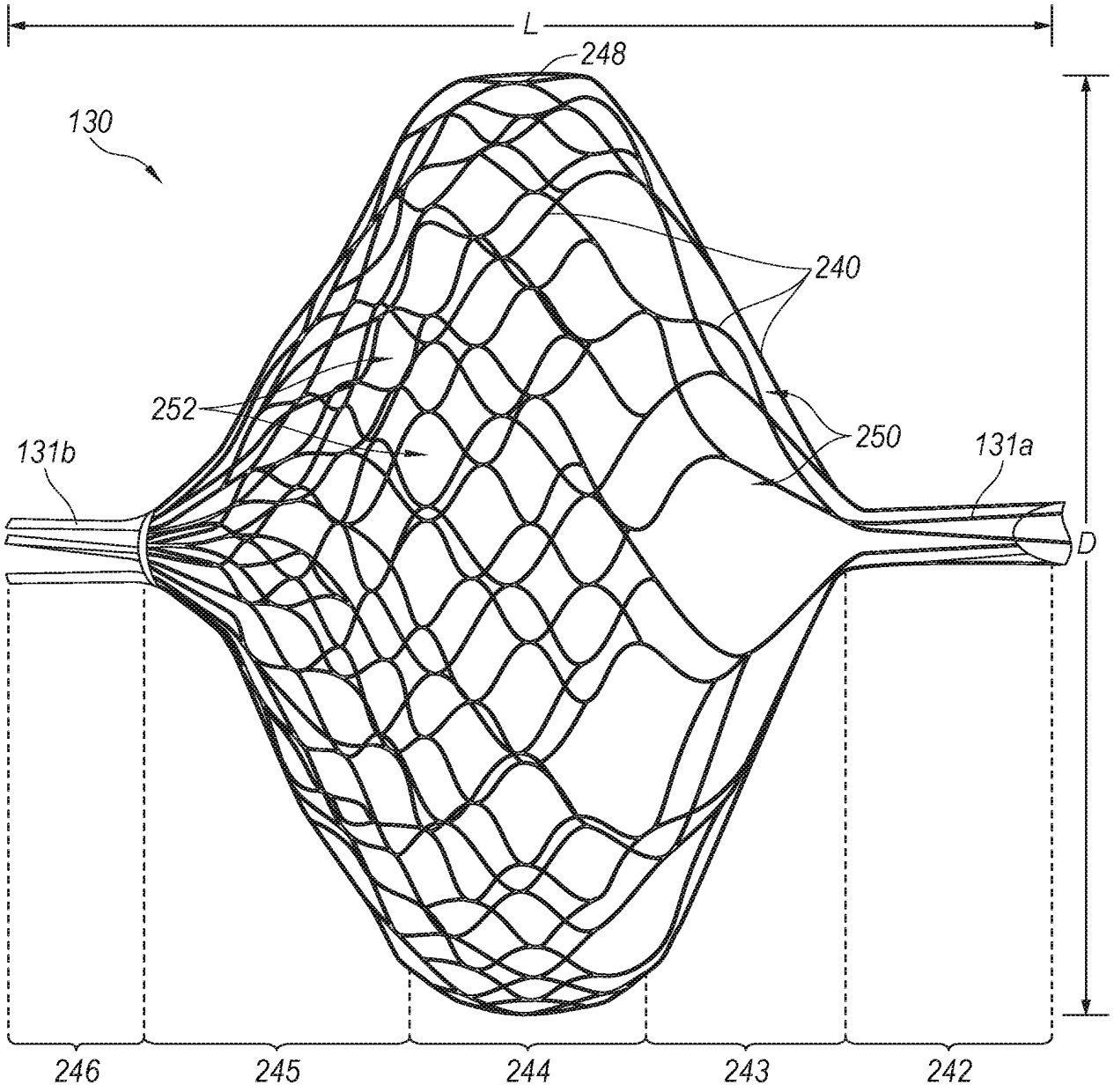


Fig. 2A

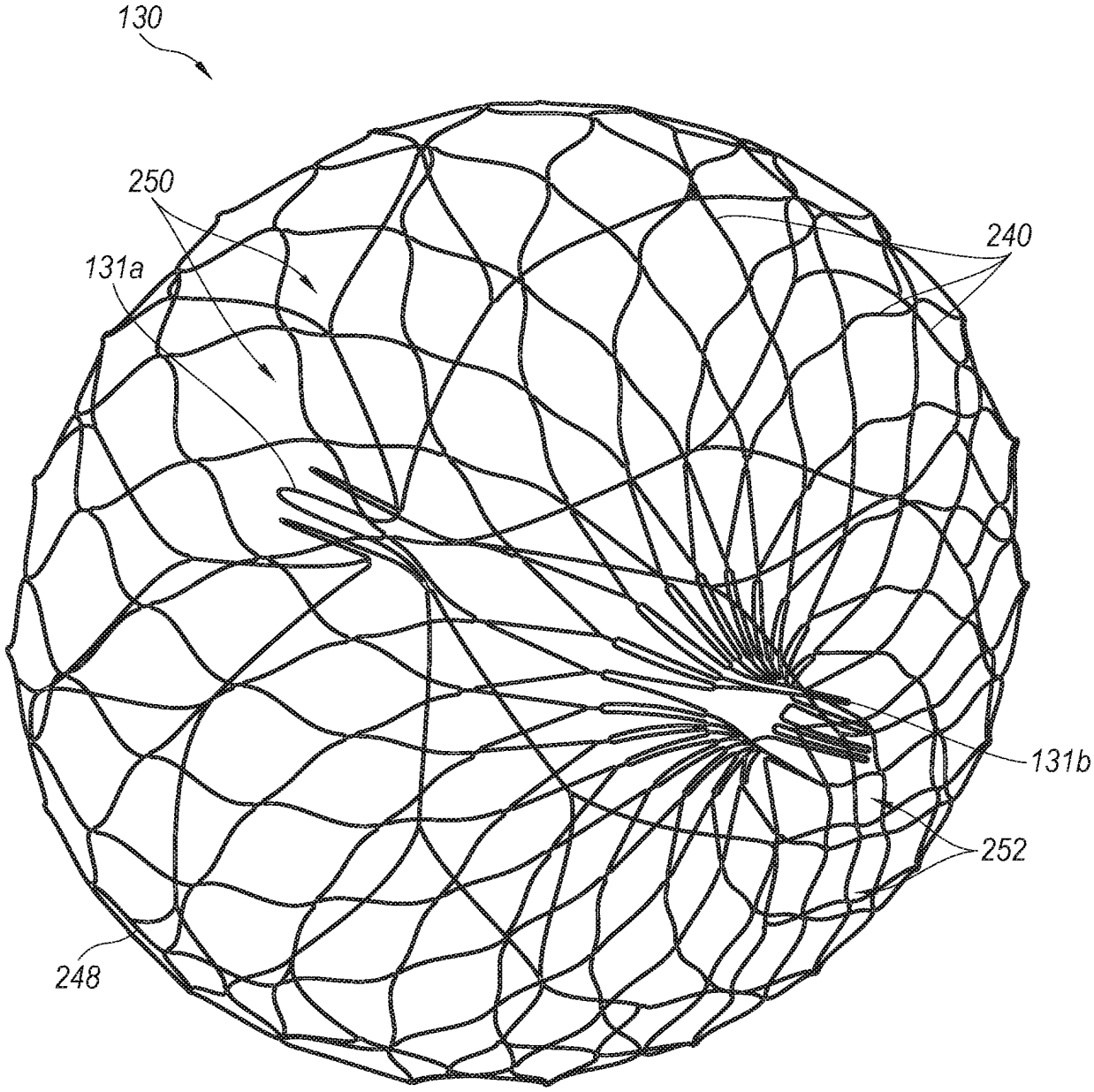


Fig. 2B

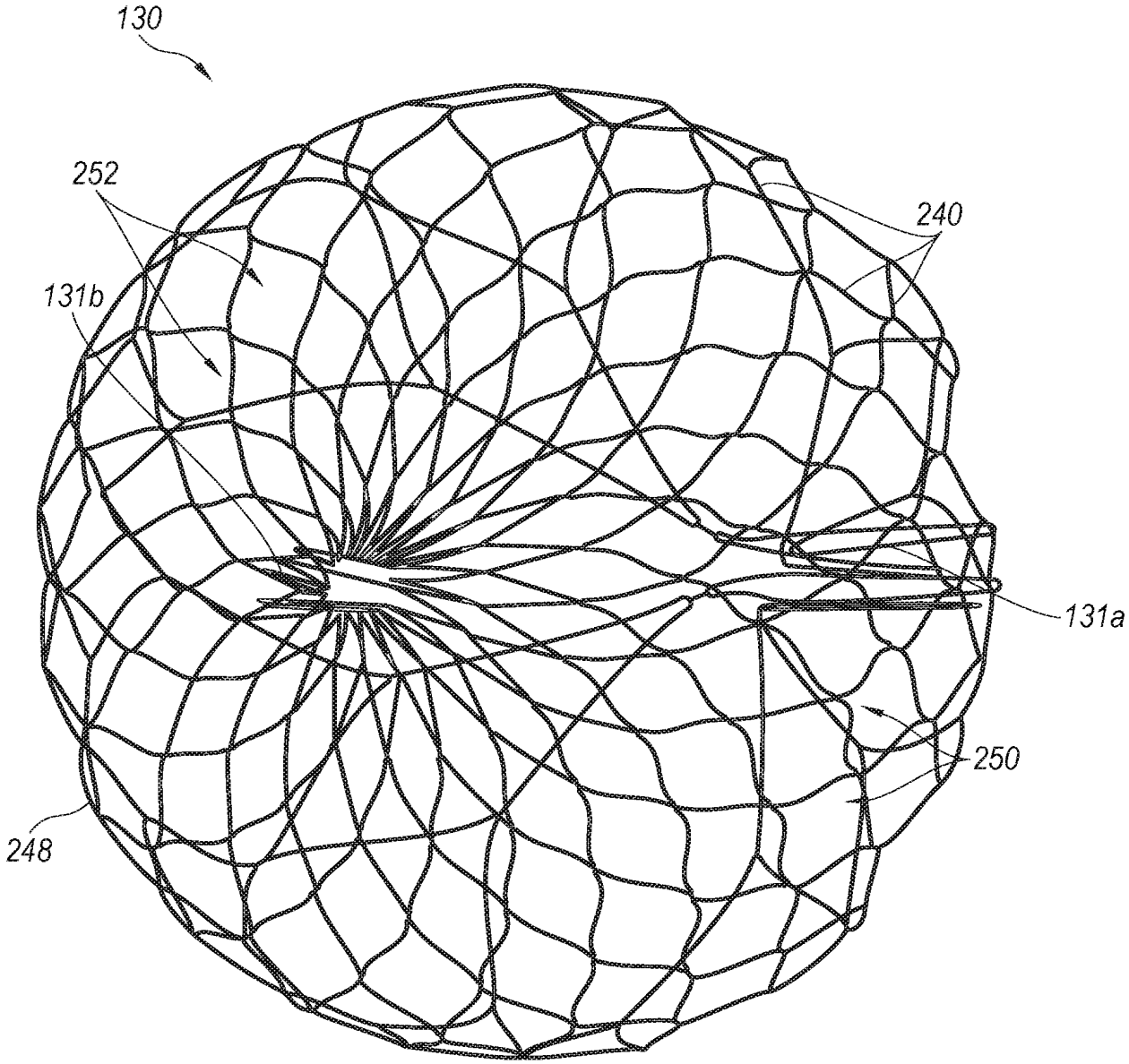


Fig. 2C

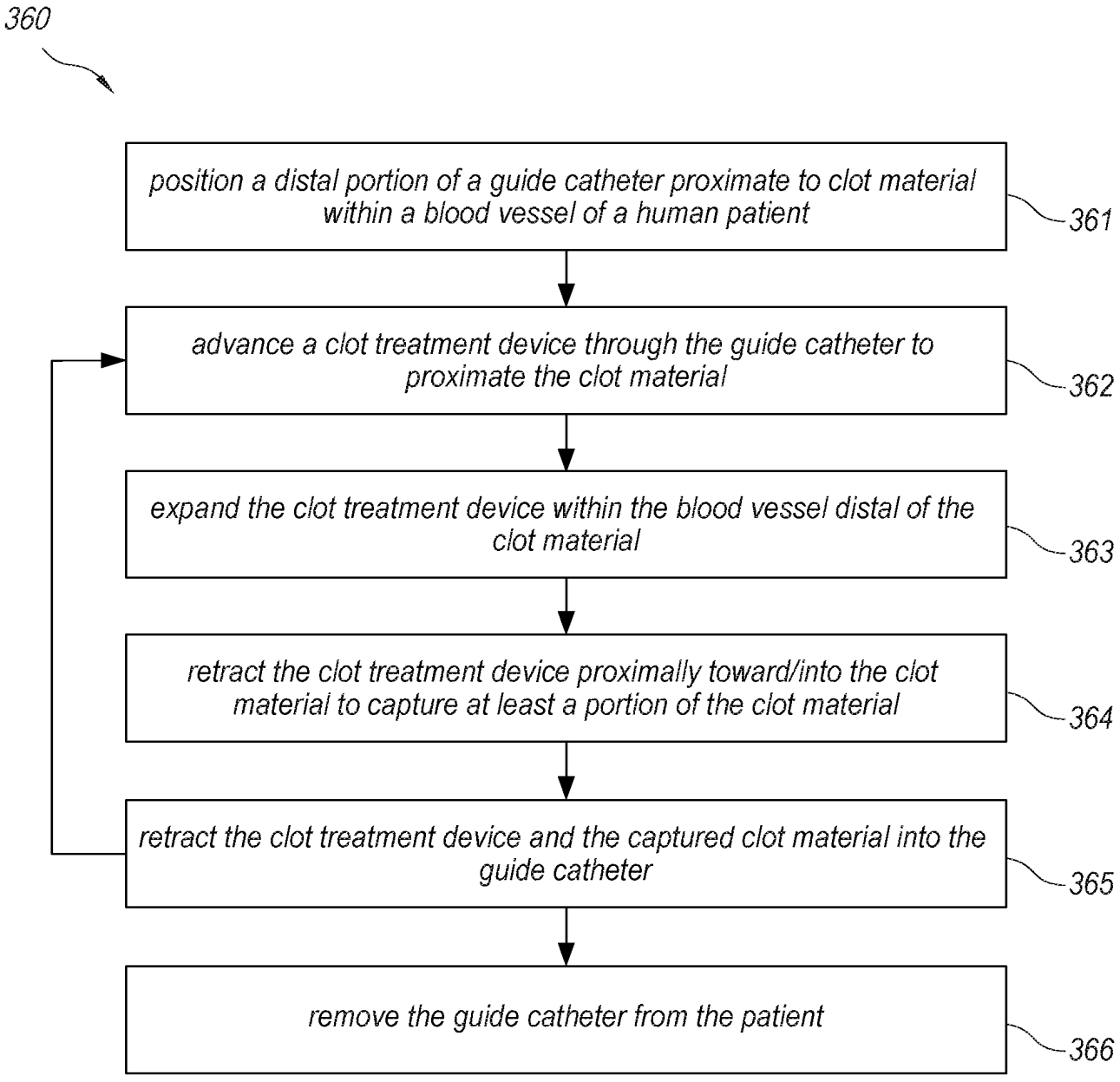

360
position a distal portion of a guide catheter proximate to clot material within a blood vessel of a human patient
361
advance a clot treatment device through the guide catheter to proximate the clot material
362
expand the clot treatment device within the blood vessel distal of the clot material
363
retract the clot treatment device proximally toward/into the clot material to capture at least a portion of the clot material
364
retract the clot treatment device and the captured clot material into the guide catheter
365
remove the guide catheter from the patient
366

Fig. 3

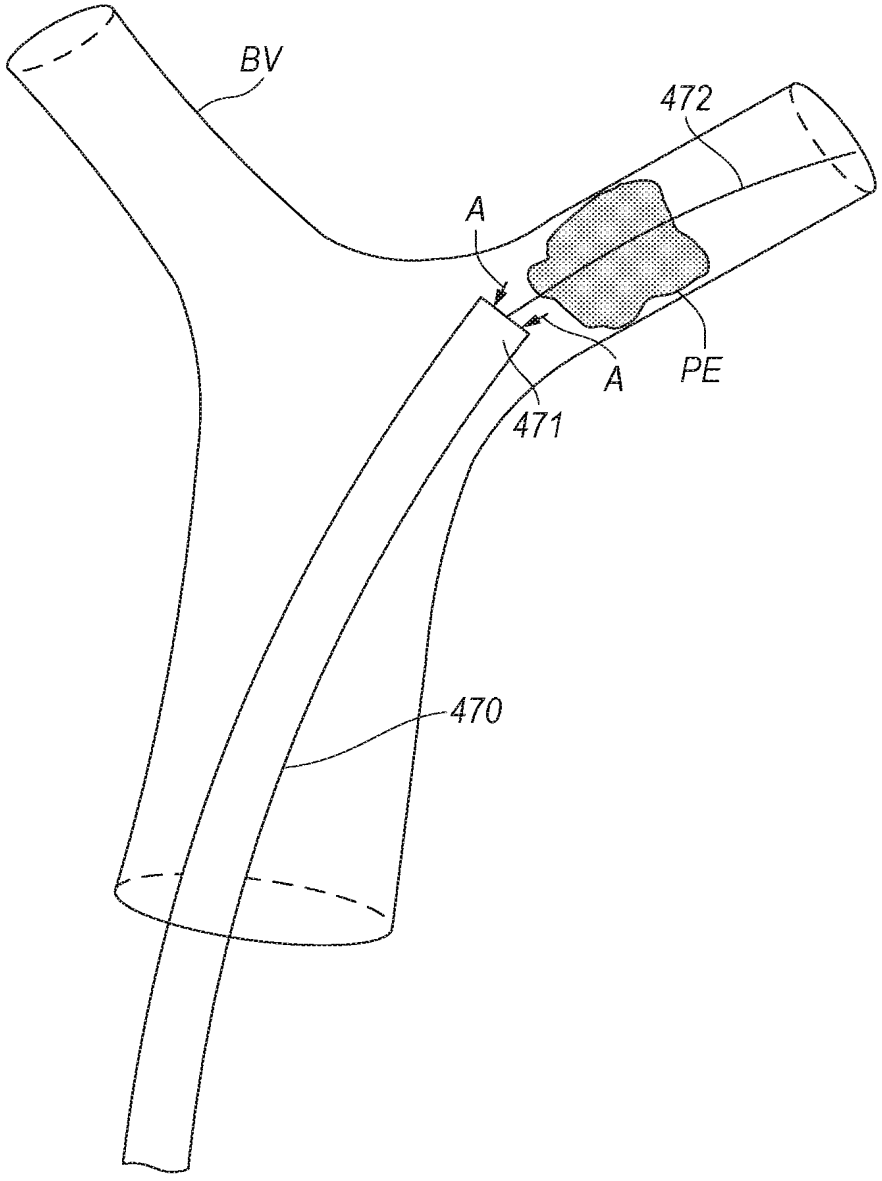


Fig. 4A

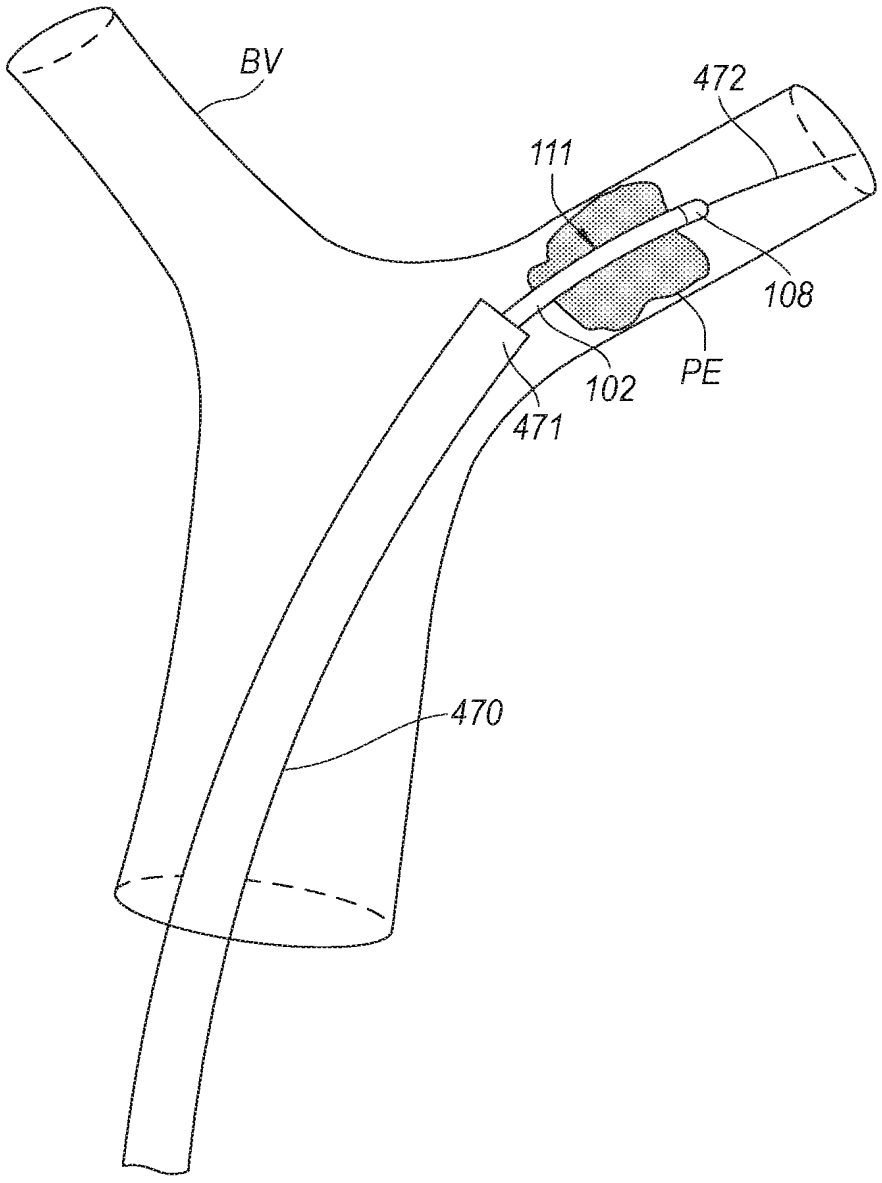


Fig. 4B

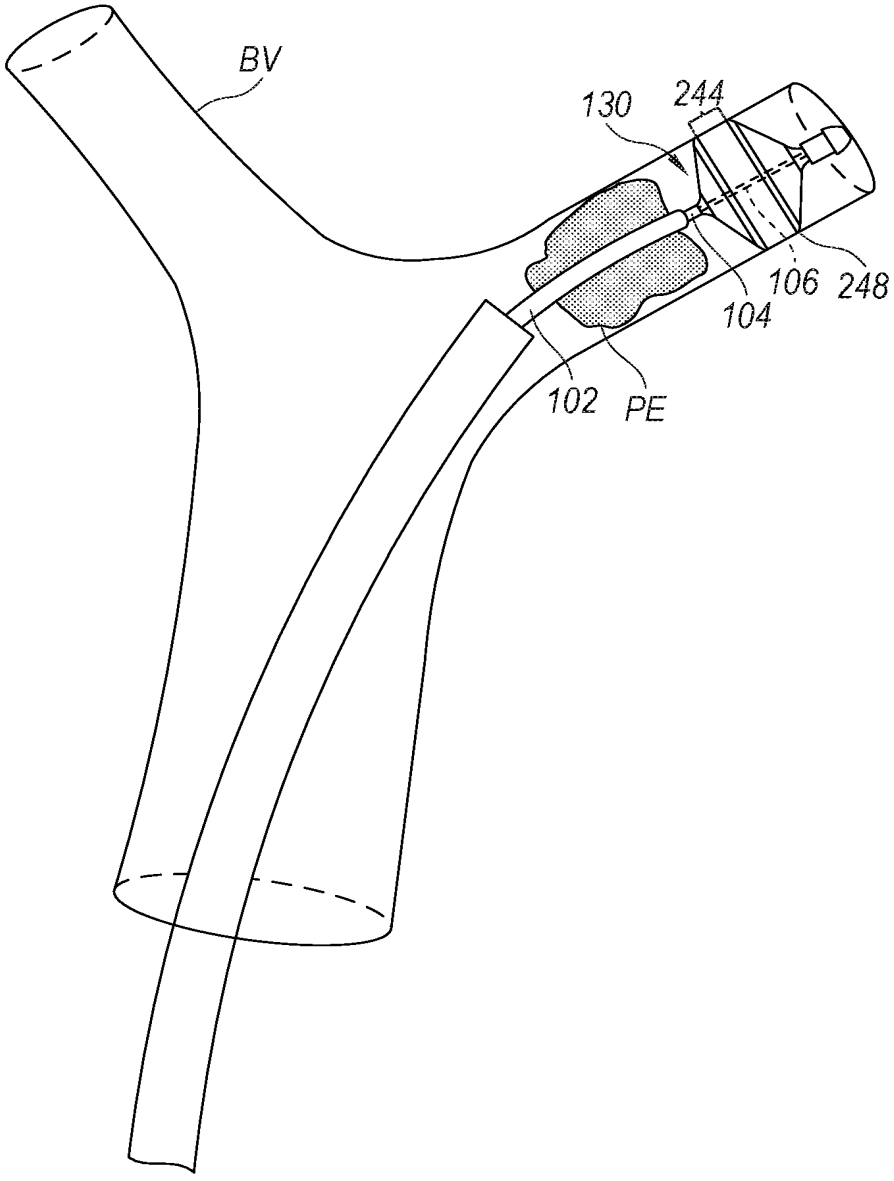


Fig. 4C

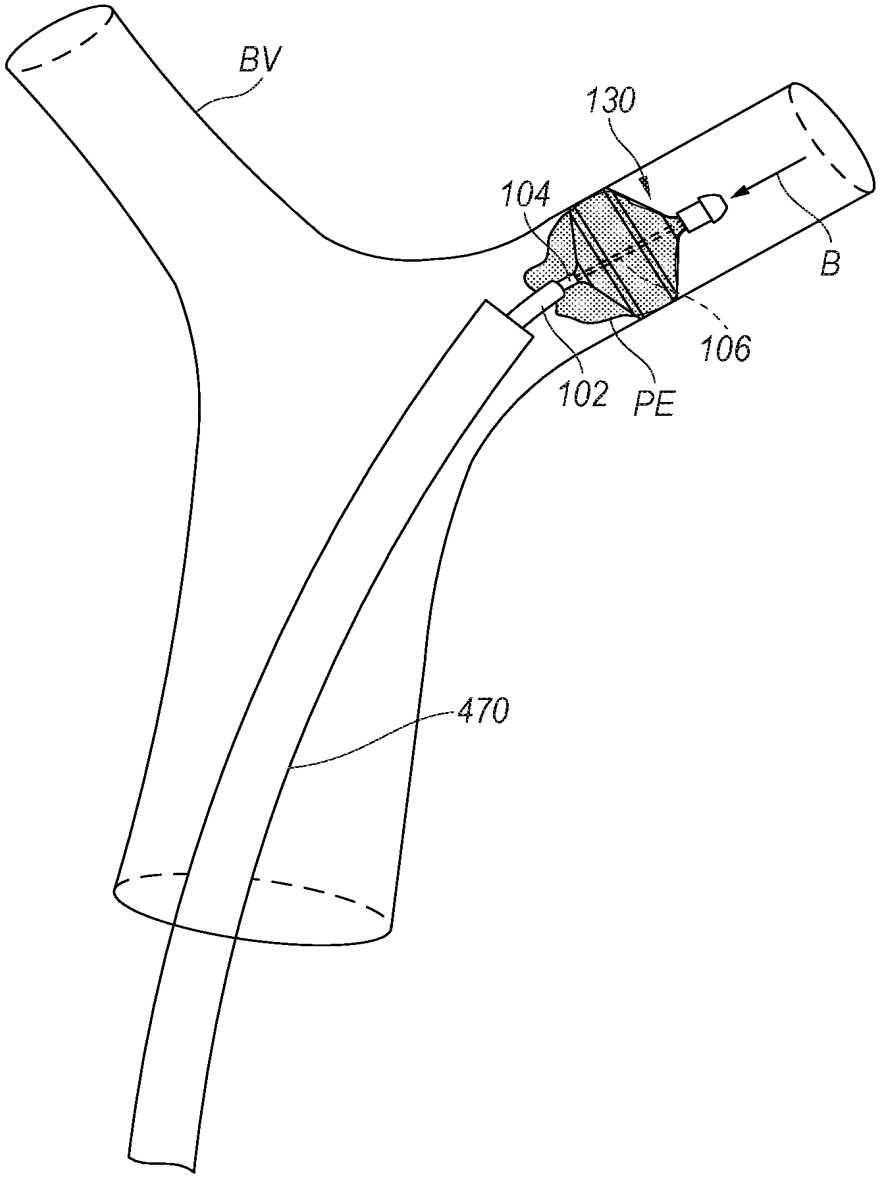


Fig. 4D

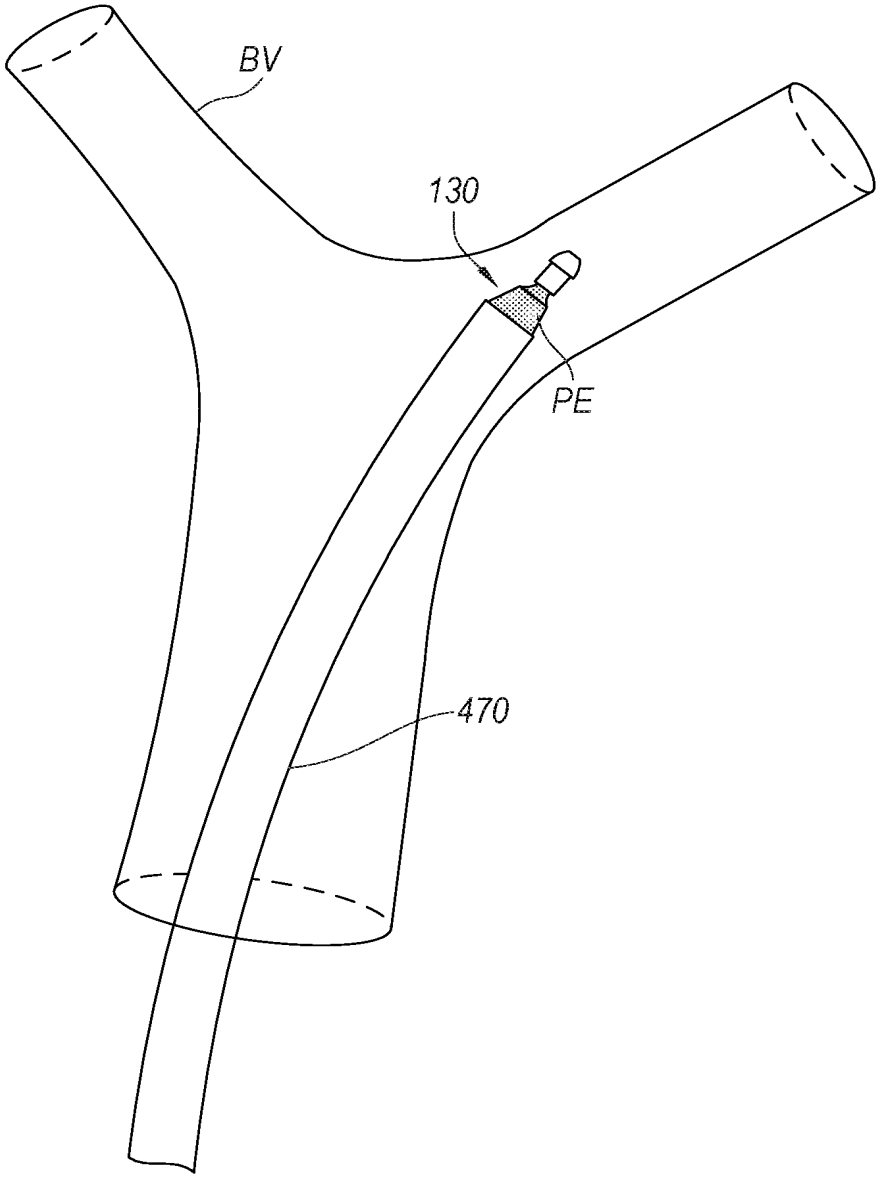


Fig. 4E

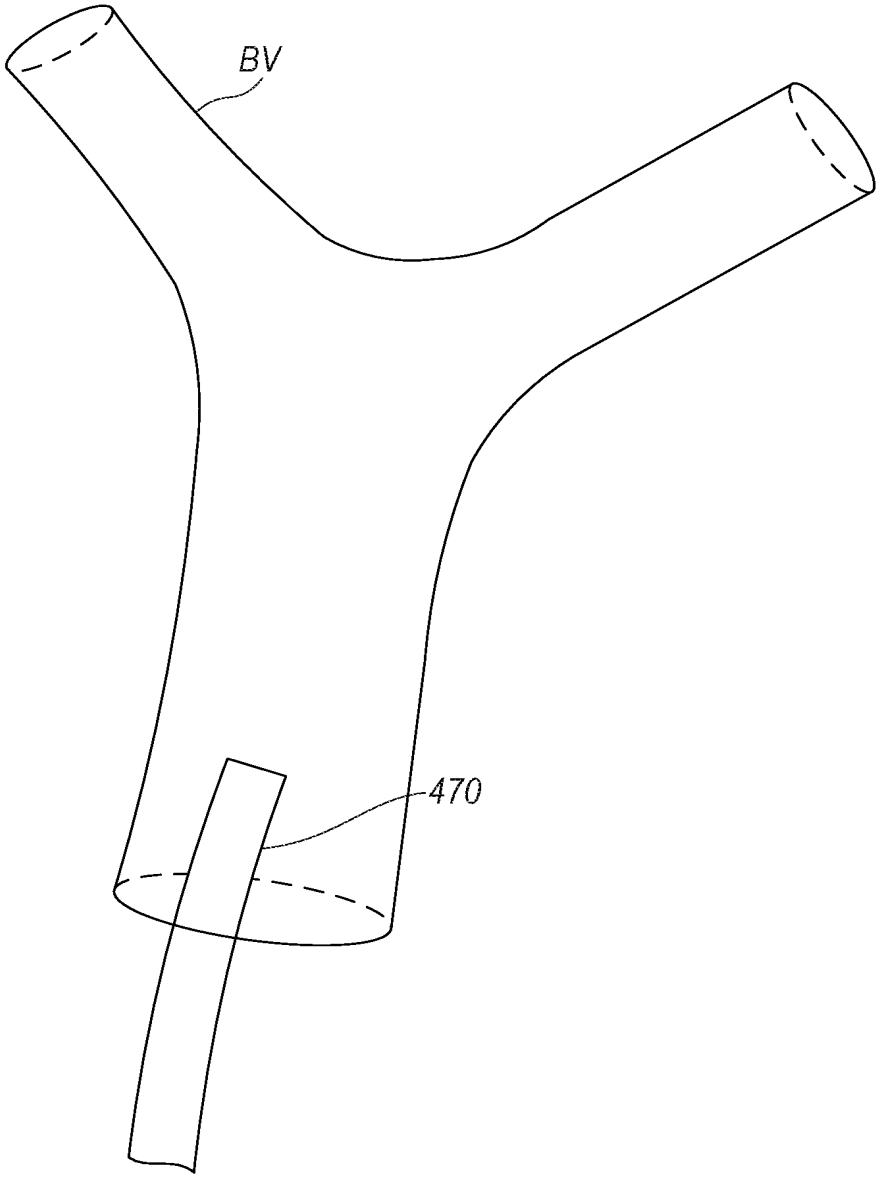


Fig. 4F

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 20/56067

A. CLASSIFICATION OF SUBJECT MATTER

IPC - A61B 17/14; A61B 17/22; A61B 17/32; A61F 2/01; A61M 25/01; A61M 25/08 (2020.01)

CPC - A61B 17/14; A61B 17/22; A61B 17/32; A61F 2/01; A61M 25/01; A61M 25/08; A61M 25/09; A61B 17/221; A61B 17/3205; A61B 17/3207

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	US 2019/0046219 A1 (INARI MEDICAL, INC.) 14 February 2019 (14.02.2019); entire document, especially para [0196]-[0201], and Fig. 29-34D.	1-20
A	US 2019/0000492 A1 (NEURAVI LIMITED) 3 January 2019 (03.01.2019); entire document.	1-20
A	US 2014/0371779 A1 (NEURAVI LIMITED) 18 December 2014 (18.12.2014); entire document.	1-20
A	US 2018/0064454 A1 (NEUROVASC TECHNOLOGIES, INC.) 8 March 2018 (08.03.2018); entire document.	1-20

☐ 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
18 December 2020	22 JAN 2021
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)

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
08 April 2021 (08.04.2021)

WIPO | PCT

(10) International Publication Number
WO 2021/067134 A1

(51) International Patent Classification:
A61M 5/31 (2006.01) *A61M 3/00* (2006.01)
A61M 5/32 (2006.01) *A61M 5/00* (2006.01)

(21) International Application Number:
PCT/US2020/052760

(22) International Filing Date:
25 September 2020 (25.09.2020)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
62/908,377 30 September 2019 (30.09.2019) US

(71) Applicant: **BECTON, DICKINSON AND COMPANY** [US/US]; 1 Becton Drive, Franklin Lakes, New Jersey 07417-1880 (US).

(72) Inventors: **YU, Bo Yang**; 62 Irving Street, Winchester, Massachusetts 01890 (US). **WILKINSON, Bradley**; 39 Hillside Drive, North Haledon, New Jersey 07508 (US). **PETERSON, Bart**; 1988 West Silver Spur Way, Farmington, Utah 84025 (US). **NEWBY, Mark**; 1038 W. Abigail Drive, UT, Kamas 84036 (US).

(74) Agent: **METHIPARA, Jomy** et al.; DICKINSON WRIGHT PLLC, 1825 Eye Street, NW, Suite 900, Washington, District of Columbia 20006 (US).

(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, DJ, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, IT, JO, JP, KE, KG, KH, KN, KP, KR, KW, 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, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, WS, 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,

(54) Title: MEDICAMENT FILLING SYSTEM

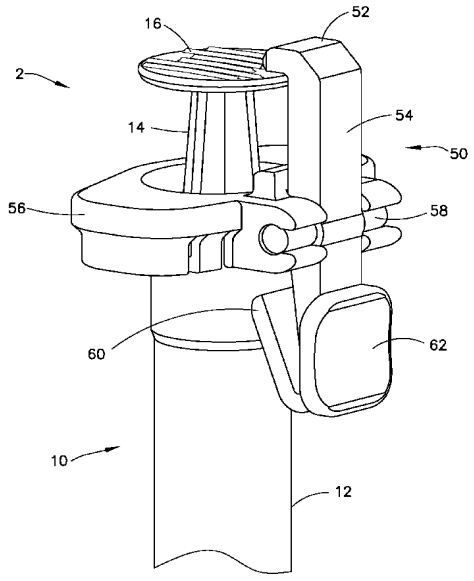


FIG. 1

(57) Abstract: A syringe assembly (2) that locks a syringe (10) to prevent backflow of medicament, the syringe assembly (2) comprising a syringe (10) including a barrel (12) configured to carry the medicament, a plunger (14) that communicates with the barrel (12), and a plunger head (16) disposed on a proximal end of the plunger (14), and a locking assembly (50) disposed around the barrel (12), wherein the locking assembly (50) prevents the plunger (14) from moving away from the barrel (12) to draw the medicament into the barrel (12).

WO 2021/067134 A1

[Continued on next page]

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).

Published:

— *with international search report (Art. 21(3))*

— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))*

MEDICAMENT FILLING SYSTEM

RELATED APPLICATION

[0001] This application claims the benefit under 35 U.S.C. § 119(e) of U.S. Provisional Patent Application Serial 62/908,377, filed on September 30, 2019, which is hereby incorporated by reference in its entirety.

FIELD OF THE INVENTION

[0002] Various exemplary embodiments of the invention relate to devices that fill a delivery device with medicament.

BACKGROUND OF THE INVENTION

[0003] Systems such as delivery devices and syringe assemblies are typically used to inject medication, such as insulin, into a patient. However, inefficiencies and inconveniences can arise. These challenges include providing dosage feedback, minimizing air entering into the delivery device, preventing medicament backflow from exiting the delivery device during and after the filling step, and improving safety, handling and stability.

SUMMARY OF THE INVENTION

[0004] It is an aspect of the present invention to provide a syringe assembly that locks a syringe to prevent backflow of medicament. After the delivery device is filled with the medicament, a plunger of the syringe is configured to prevent medicament backflow from the delivery device into the syringe. Such an assembly provides efficient and improved accuracy of the medicament transferred to the delivery device.

[0005] Another aspect of the present invention provides a syringe assembly that provides haptic feedback during dose setting. Such a configuration gives a user confirmation of a specified dose setting, prevents unintended locking and minimizes user confusion.

[0006] In another aspect of the present invention, a fluid transfer device engages a syringe to provide different fluid paths for drawing medicament and injecting the medicament. Such a configuration prevents medicament backflow from the delivery device into the syringe, avoids the use of a locking mechanism and provides efficient and improved accuracy of the medicament transferred to the delivery device while not modifying the syringe.

[0007] The foregoing and/or other aspects of the present invention can be achieved by providing a syringe assembly that locks the syringe to prevent backflow of medicament, the syringe assembly comprising a syringe including a barrel configured to carry the medicament, a plunger that communicates with the barrel, and a plunger head disposed on a proximal end of the plunger, and a locking assembly disposed around the barrel, wherein the locking assembly prevents the plunger from moving away from the barrel to draw the medicament into the barrel.

[0008] The foregoing and/or other aspects of the present invention can further be achieved by providing a syringe assembly that provides haptic feedback during dose setting, the syringe assembly comprising a syringe including a barrel configured to carry a medicament, a plunger having a plunger head disposed on a proximal end of the plunger, the plunger communicating with the barrel, the plunger including a plurality of axial ribs extending along a length of the plunger, and a notch disposed in each axial rib, and a dose selector disposed around the barrel, wherein the dose selector passes through one of the notches to set a dose.

[0009] The foregoing and/or other aspects of the present invention can also be achieved by providing a fluid transfer device that prevents backflow of medicament, the fluid transfer device comprising a barrel configured to carry the medicament, a plunger connected to the barrel, and a vial adapter comprising a first needle cannula that allows the medicament to exit the fluid transfer device, a second needle cannula that allows the medicament to enter the fluid transfer device, the second needle cannula being shorter in length than the first needle cannula, a first one-way valve connected to the first needle cannula, and a second one-way valve connected to the second needle cannula.

[0010] The foregoing and/or other aspects of the present invention can additionally be achieved by providing a fluid transfer device that prevents backflow of medicament, the fluid transfer device comprising a first needle cannula that allows the medicament to exit the fluid transfer device, a second needle cannula that allows the medicament to enter the fluid transfer device, the second needle cannula being shorter in length than the first needle cannula, the second needle cannula being disposed within the first needle cannula, and a two-way valve connected to the first needle cannula and the second needle cannula, wherein the second needle cannula is configured to draw the medicament from a vial, and when the fluid transfer

device is engaged to a delivery device, the first needle cannula transfers medicament to the delivery device.

[0011] Additional and/or other aspects and advantages of the present invention will be set forth in the description that follows, or will be apparent from the description, or may be learned by practice of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

[0012] The above aspects and features of the present invention will be more apparent from the description for the exemplary embodiments of the present invention taken with reference to the accompanying drawings, in which:

[0013] Figure 1 illustrates a first exemplary embodiment of a left perspective view of a syringe assembly;

[0014] Figure 2 illustrates a second exemplary embodiment of a right perspective view of a syringe assembly with a plunger head platform;

[0015] Figure 3 illustrates a third exemplary embodiment of a side elevation view of a syringe assembly with a dial dose and a position indicator;

[0016] Figure 4 is a perspective view of the syringe assembly of Figure 3 in an unlocked position;

[0017] Figure 5 is a perspective view of the syringe assembly of Figure 3 in a locked position;

[0018] Figure 6 illustrates a fourth exemplary embodiment of a right perspective view of a syringe assembly providing haptic feedback;

[0019] Figure 7 is a cross-sectional view of the syringe assembly along line A-A of Figure 6;

[0020] Figure 8 illustrates a fifth exemplary embodiment of a side elevation view of a syringe assembly engaging the plunger head platform;

[0021] Figure 9 illustrates a sixth exemplary embodiment of a cross-sectional view of a fluid transfer device engaged to a syringe;

[0022] Figure 10 is a cross-sectional view of the fluid transfer device of Figure 9 engaged to a vial;

[0023] Figure 11 is a cross-sectional view of the fluid transfer device of Figure 9 engaged to an insulin delivery device;

[0024] Figure 12 illustrates a seventh exemplary embodiment of a cross-sectional view of a fluid transfer device drawing medicament;

[0025] Figure 13 is a cross-sectional view of the fluid transfer device of Figure 12 shown expelling the medicament;

[0026] Figure 14 is a cross-sectional view of the fluid transfer device of Figure 12 shown drawing the medicament and providing an air vent passage; and

[0027] Figure 15 is a cross-sectional view of the fluid transfer device of Figure 12 shown expelling the medicament and providing an air vent passage.

DETAILED DESCRIPTION OF EXEMPLARY EMBODIMENTS

[0028] Figure 1 illustrates a syringe assembly 2 according to one embodiment. The syringe assembly 2 includes a syringe 10 having a barrel 12, a plunger 14, a plunger head 16 and a needle (not shown) as conventionally understood by one skilled in the art. Specifically, the barrel 12 carries medicament and the plunger 14 is disposed in the barrel 12 to move the medicament into and out of the barrel 12. The plunger head 16 is connected to a proximal end of the plunger 14 and allows a user to move the plunger 14 to perform the medicament filling and dispensing operations. The needle receives the medicament from a vial and dispenses the medicament to an insulin delivery device.

[0029] The syringe assembly 2 further includes a locking assembly 50 that locks the plunger 14 of the syringe 10 after the medicament is dispensed to advantageously prevent backflow of medicament into the barrel 12. The locking assembly 50 includes a hook 52, an arm 54, a base 56, a pivot shaft 58, a spring member 60 and a button 62.

[0030] The hook 52 is disposed on a proximal end of the arm 54 and includes a cantilevered surface that is configured to engage a top surface of the plunger head 16 when the medicament is dispensed from the barrel 12 of the syringe 10. The base 56 is fixed to the barrel 12 and surrounds the barrel 12. The pivot shaft 58 is disposed on a side surface of the base 56 and is rotatable. The pivot shaft 58 engages a central portion of the arm 54 to allow the hook 52 to rotate.

[0031] A distal end of the arm 54 includes the spring member 60 and the button 62. The spring member 60 contacts the barrel 12 at one side of the arm 54 and the button 62 is disposed on an opposing side of the arm 54 to provide the user with a depressible surface. The hook 52 is configured to rotate about the pivot shaft 58 disposed between the button 62

and the hook 52. The pivot shaft 58 allows the arm 54 to rotate between an engaged and a disengaged position based on user activation of the button 62.

[0032] Specifically, when the medicament from the syringe 10 is dispensed, the plunger 14 is at a distal position. A natural state of the locking assembly 50 positions the hook 52 above the plunger head 16 to lock the plunger 14 from movement. In this state, the button 62 is in a free or released state and the spring member 60 pushes the button 62 (a first compression force) to provide maximum engagement of the hook 52 to the plunger head 16.

[0033] To unlock the syringe 10 from the locking assembly 50, the user depresses the button 62 against the springe force of the spring member 60 (a second compression force). This causes the arm 54 to rotate about the pivot shaft 58 and disengage the hook 52 from the plunger head 16. The second compression force is greater than the first compression force.

[0034] When a syringe conventionally fills an insulin delivery device, the user must simultaneously hold down the plunger head and remove the syringe from the insulin delivery device to avoid backflow of medicament into the syringe 10. The locking assembly 50 disclosed herein advantageously locks the plunger head 16 after the medication is dispensed into the insulin delivery device. In this manner, no medicament will backflow into the syringe 10 and the user can comfortably remove the syringe 10 from the insulin delivery device. The locking assembly 50 also advantageously allows the user to unlock the syringe 10 for use if the syringe 10 was accidentally locked.

[0035] Figure 2 illustrates a syringe assembly 4 according to a second embodiment. This embodiment discloses the syringe 10 and the locking assembly 50 as similarly described above with the following modifications. The plunger head 16 of the syringe 10 includes a plunger head platform 20. The platform 20 is disposed below the plunger head 16 such that a gap is present between the two features. The platform 20 is preferably molded as part of the plunger 14 but alternately can be a separate part attached to the plunger 14. The hook 52 of the locking assembly 50 is advantageously configured to engage the gap to lock the plunger 14 after the medicament is dispensed from the barrel 12 of the syringe 10.

[0036] Additionally, the hook 52 includes a plurality of protrusions 66 that provide a depressible surface. Accordingly, the user can advantageously apply a force to the hook 52 where the plurality of protrusions 66 are located or apply a force to the button 62 to move the hook 52 from an engaged, locked position to a disengaged, unlocked position. The configuration in this embodiment advantageously provides a complete surface at the plunger

head 16 available for the user to manipulate when engaging and disengaging the locking assembly 50.

[0037] Figures 3-5 illustrate a syringe assembly 6 according to a third embodiment. This embodiment discloses the syringe 10 and the locking assembly 50 as similarly described above with the following modifications. The plunger head 16 includes a dial dose 18. The dial dose 18 indicates a dosage unit amount. Specifically, the plunger head 16 is rotated to set a desired dose identified by the dial dose 18.

[0038] In addition, the locking assembly 50 includes a position indicator 64 shaped as an arrowhead. The position indicator 64 advantageously cooperates with the dial dose 18 to identify a dose position of the plunger head 16. As illustrated in Figure 5, the position indicator 64 points to a specific dosage amount expressed by the dial dose 18 that is set by the user via rotation of the plunger head 16. The button 62 on the locking assembly 50 also includes protrusions 66 that provide a friction surface for the user to depress the button 62.

[0039] In operation, Figures 3 and 4 illustrate an unlocked position of the locking assembly 50 whereas Figure 5 illustrates a locked position. In the unlocked position, the plunger 14 is free to move in the barrel. In the locked positon, the plunger 14 is unable to move since the hook 52 engages the platform 20 to prevent movement.

[0040] Figures 6 and 7 illustrate a syringe assembly 8 according to a fourth embodiment. This embodiment discloses the syringe 10 as similarly described above with the following modifications. This embodiment incorporates a dose selector 70 with the syringe 10 to advantageously provide haptic feedback to the user when setting a dose.

[0041] The plunger 14 of the syringe 10 is modified to cooperate with the dose selector 70. Specifically, the plunger 14 includes a plurality of axial ribs 24 extending along a length of the plunger 14. The axial ribs 24 provide stability and stiffness to the plunger 14. A curved indent 28 is disposed between each of the adjacent axial ribs 24.

[0042] Figure 6 illustrates that a vertical portion of the plurality of axial ribs 24 includes a notch 26. A cross section of the plunger 14 at the notch 26 is illustrated in Figure 7. The notch 26 advantageously provides a smooth raised surface around the plunger 14. The notch 26 also advantageously provides a continuous surface between the adjacent curved indents 28.

[0043] Figure 6 further illustrates the dose selector 70 including an arm 72, a position indicator 74, a base 76 and a tab 78. The base 76 is fixed to and surrounds the barrel 12 of

the syringe 10. The arm 72 extends upwardly from the base 76 and includes the position indicator 74 such as an arrowhead, for example, that indicates a set dose. The base 76 and the position indicator 74 are also similarly described above for various embodiments of the locking assembly.

[0044] The tab 78 is an inwardly extending member disposed on an inner surface of the base 76. The tab 78 cooperates with the plunger 14 and the notch 26. Specifically, the plunger 14 can only move vertically when the tab 78 is disposed between the axial ribs 24, in the curved indent 28 and outside of the notch 26 of the plunger 14. The user places the tab 78 at a vertical position of the plunger 14 where the notch 26 is located to rotate the plunger 14 and adjust the dosage.

[0045] When the user rotates the plunger 14 to set the dose, every time the tab 78 encounters the notch 26 of one of the axial ribs 24, a detent or force is advantageously provided. As illustrated in Figure 7, this force or detent occurs because there is contact between the axial rib 24 and the tab 78 in the notch 26. This detent or force is the haptic feedback the user receives to indicate that the dosage is being changed. In this position, the plunger 14 is also locked to prevent vertical movement.

[0046] When the tab 78 is disposed between two of the axial ribs 24 as illustrated in Figure 7, no detent or force is provided because there is no contact. That is, the tab 78 does not contact the curved indent 28. Accordingly, the user advantageously experiences alternate pressures (haptic feedback) when rotating between dose setting positions.

[0047] Figure 8 illustrates a syringe assembly 9 according to a fifth embodiment. This embodiment also discloses the syringe 10 and the locking assembly 50 as similarly described above with the following modifications. Specifically, the plunger head platform 20 includes a rounded circumferential surface that the hook 52 engages. More specifically, the hook 52 includes a hook indent 53 that is contoured to engage and receive the rounded circumferential surface of the plunger head platform 20. Such a configuration advantageously provides a more secure and smooth engagement of the hook 52 to the platform 20 when the locking assembly 50 is in the locked position.

[0048] Figures 9-11 illustrate a cross-sectional view of a fluid transfer device 120 attached to a syringe 121 according to a fifth embodiment. Figure 10 illustrates the fluid transfer device 120 engaged to a vial 100 to receive medicament. Figure 11 illustrates the

fluid transfer device 120 engaged to an insulin delivery device (IDD) 110 to transfer medicament. Further details of the fluid transfer device 120 are provided below.

[0049] The syringe 121 is commonly understood by one skilled in the art and includes, for example, a barrel 122 that carries the medicament and a plunger 124 disposed in the barrel 122 to draw and dispense the medicament. The syringe 121 is configured to engage a vial adapter 130 of the fluid transfer device 120 to establish fluid communication. In an alternate embodiment, the fluid transfer device 120 includes the barrel 122 and the plunger 124 that are in fluid communication with the vial adapter 130.

[0050] The vial adapter 130 includes a first needle cannula 132, a second needle cannula 134, a first one-way valve 136 and a second one-way valve 138. The first needle cannula 132 is used for transferring the medicament from the barrel 122 into the insulin delivery device 110 as illustrated in Figure 11. The second needle cannula 134 is used to receive the medicament from the vial 100 as illustrated in Figure 10.

[0051] The first needle cannula 132 is advantageously longer than the second needle cannula 134 so that only the first needle cannula 132 engages the insulin delivery device 110. As illustrated in Figure 11, the second needle cannula 132 is too short to engage the insulin delivery device 110.

[0052] On the other hand, the second needle cannula 134 is advantageously shorter than the first needle cannula 132 to receive more of the medicament from the vial 100. Figure 10 illustrates that both the first and second needle cannulas 132, 134 are disposed in the vial 100. However, a distal end of the second needle cannula 134 is closer to a bottom portion of the vial 100. As the medicament exits the vial 100, the associated fluid level decreases in the vial 100. Having a short needle cannula 134 advantageously optimizes the amount of medicament that can be removed from the vial 100.

[0053] The first one-way valve 136 controls medicament flow through the first needle cannula 132 such that the medicament in the barrel 122 can only exit through the first needle cannula 132. That is, the first one-way valve 136 does not allow the first needle cannula 132 to receive the medicament into the barrel 122.

[0054] On the other hand, the second one-way valve 138 controls medicament flow through the second needle cannula 134 such that the medicament can only enter through the second needle cannula 134 to fill the barrel 122. Conversely, the second one-way valve 138

does not allow the second needle cannula 134 to dispense the medicament from the barrel 122.

[0055] The fluid transfer device 120 of this embodiment provides an alternate means to prevent backflow of the medicament from the insulin delivery device 110 into the syringe 121. To achieve this benefit, the fluid transfer device 120 advantageously provides separate fluid paths without the use of a plunger locking mechanism and without the need to manually hold down a syringe plunger after fluid delivery.

[0056] Figures 12-15 illustrate a cross-sectional view of a fluid transfer device 220 according to a sixth embodiment. The fluid transfer device 220 includes a vial adapter 230, a first needle cannula 232, a second needle cannula 234, a two-way valve 236, a vent membrane 239 and a syringe adapter 242. Figure 14 illustrates that the vial adapter 230 is engaged to a vial 200, preferably via a snap lock engagement, although other means are contemplated herein. The syringe adapter 242 is configured to engage a syringe (not shown), preferably via a luer lock, although other means are contemplated herein.

[0057] As similarly described above, the first needle cannula 232 is used for transferring the medicament from the syringe into the insulin delivery device 210 as illustrated in Figure 15. The second needle cannula 234 is used to receive the medicament from the vial 200 as illustrated in Figure 14.

[0058] The first needle cannula 232 is advantageously longer than the second needle cannula 234 so that only the first needle cannula 232 engages the insulin delivery device 210. A bottom surface of the vial adapter 230 advantageously controls the insertion depth of the first needle cannula 232 in the insulin delivery device 210. As illustrated in Figure 15, the second needle cannula 232 is too short to engage the insulin delivery device 210. Specifically, the second needle cannula 232 does not extend beyond the bottom surface of the vial adapter 230 to advantageously ensure that no fluid communication to the insulin delivery device 210 takes place.

[0059] On the other hand, the second needle cannula 234 is advantageously shorter than the first needle cannula 232 to receive more of the medicament from the vial 200. Figure 14 illustrates that a distal end of the second needle cannula 234 is closer to a bottom portion of the vial 200. As the medicament exits the vial 200, the associated fluid level decreases in the vial 200. Having a short second needle cannula 234 optimizes the amount of medicament

that is removed from the vial 200. A depth of a cavity in the vial adapter 230 that engages the vial 200 advantageously controls the insertion depth of the second needle cannula 234.

[0060] Further, the first needle cannula 232 is advantageously disposed within the second needle cannula 234. Such a configuration optimizes space, provides a simple design and continues to provide different fluid paths as described in more detail below.

[0061] The two-way valve 236 is preferably a combination duckbill and umbrella valve. However, other combination of valves can be used to achieve the functional benefits described herein. The two-way valve 236 controls medicament flow through the first needle cannula 232 such that the medicament in the syringe can only exit through the first needle cannula 232. That is, the two-way valve 236 does not allow the first needle cannula 232 to receive the medicament into the syringe.

[0062] The two-way valve 236 also controls medicament flow through the second needle cannula 234 such that the medicament can only enter through the second needle cannula 234 to fill the syringe. Similarly, the two-way valve 236 does not allow the second needle cannula 234 to dispense the medicament from the syringe.

[0063] In view of the above, the two-way valve 236 advantageously controls the transfer of the medicament. However, the two-way valve 236 does not control the exchange of air. Further explanation of an airflow path 254 in the fluid transfer device 220 is described below.

[0064] Figures 12-15 also illustrate a vent membrane 239 connecting to the airflow path 254, as well as a medicament entrance path 250 and a medicament exit path 252. Figure 12 illustrates the syringe being filled with the medicament. Specifically, the medicament entrance path 250 is described in a manner where the medicament enters a distal end of the second needle cannula 234, routed in a path offset from the centerline of the vial adapter 230 to the two-way valve 236 and ultimately enters into the syringe adapter 242 to fill the syringe.

[0065] Figure 14 illustrates the medicament entrance path 250 when the vial adapter 230 is engaged to the vial 200. The vent membrane 239 cooperates with the transfer of the medicament from the vial 200 to the syringe and is located upstream from the two-way valve 236.

[0066] Specifically, when the medicament exits the vial 200, air advantageously enters into the vial 200 via the airflow path 254 and the vent membrane 239. The airflow path 254 includes a path upstream from the two-way valve 236 and through the first needle cannula

232. In this manner, there is no vacuum created in the vial 200 and the pressure in the vial 200 is equalized with the environmental pressure.

[0067] Figures 13 and 15 illustrate the medicament exit path 252 that allows the medicament to exit the syringe and enter the insulin delivery device 210. The medicament exit path 252 travels through the two-way valve 236, through a centerline of the fluid transfer device 220, and through the first needle cannula 232 before ultimately entering into the insulin delivery device 210.

[0068] Meanwhile, the same airflow path 254 through the first needle cannula 232 and the vent membrane 239 as described above is used to remove air from the insulin delivery device 220. Advantageously, there is no vacuum created in the insulin delivery device 220 and the pressure in the insulin delivery device 220 is equalized with the environmental pressure.

[0069] The fluid transfer device 220 of this embodiment provides an alternate means to prevent backflow of the medicament from the insulin delivery device 210 into the syringe. To achieve this benefit, the fluid transfer device 220 advantageously provides separate fluid and air paths without the use of a plunger locking mechanism and without the need to manually hold down a syringe plunger after fluid delivery.

[0070] The foregoing detailed description of the certain exemplary embodiments has been provided for explaining the principles of the invention and its practical application, thereby enabling others skilled in the art to understand the invention for various embodiments and with various modifications as are suited to the particular use contemplated. This description is not necessarily intended to be exhaustive or to limit the invention to the precise embodiments disclosed. In addition, any of the embodiments, features and/or elements disclosed herein may be combined with one another to form various additional combinations not specifically disclosed, as long as the embodiments, features and/or elements being combined do not contradict each other. Accordingly, additional embodiments are possible and are intended to be encompassed within this specification and the scope of the invention. The specification describes specific examples to accomplish a more general goal that may be accomplished in another way.

[0071] As used in this application, the terms "front," "rear," "upper," "lower," "upwardly," "downwardly," and other orientational descriptors are intended to facilitate the description of the exemplary embodiments of the present invention, and are not intended to

limit the structure of the exemplary embodiments of the present invention to any particular position or orientation. Terms of degree, such as "substantially" or "approximately" are understood by those of ordinary skill to refer to reasonable ranges around and including the given value, for example, general tolerances associated with manufacturing, assembly, and use of the described embodiments.

CLAIMS

1. A syringe assembly that locks a syringe to prevent backflow of medicament, the syringe assembly comprising:

a syringe, including:

a barrel configured to carry the medicament;

a plunger that communicates with the barrel; and

a plunger head disposed on a proximal end of the plunger; and

a locking assembly disposed around the barrel;

wherein the locking assembly prevents the plunger from moving away from the barrel to draw the medicament into the barrel.

2. The syringe assembly of claim 1, wherein the plunger head includes a dial dose to indicate a dose setting.

3. The syringe assembly of claim 1, wherein:

the locking assembly includes:

a hook configured to engage the plunger head; and

a depressible button and spring member connected to the hook,

wherein the depressible button controls engagement and disengagement between the hook and the plunger head.

4. The syringe assembly of claim 3, wherein:

the locking assembly further includes:

a base engaged to the barrel;

an arm that connects the hook to the depressible button and the spring member; and

a shaft that connects the arm to the base.

5. The syringe assembly of claim 4, wherein the shaft allows the arm to rotate to control engagement and disengagement between the hook and the plunger head.

6. The syringe assembly of claim 4, wherein:

the spring member contacts the barrel and is disposed on one side surface of the arm while the button is disposed on an opposing side surface of the arm;

when the button is in a free state, the spring is compressed at a first compression force and the hook is engaged to the plunger head;

when the button is depressed, the spring member is compressed at a second compression force and the hook is disengaged from the plunger head; and

the second compression force is greater than the first compression force.

7. The syringe assembly of claim 3, wherein:

the plunger head further includes a platform disposed distally from a top surface of the plunger head; and

the hook is configured to engage the plunger between the top surface of the plunger head and the platform to lock the plunger.

8. The syringe assembly of claim 7, wherein the hook includes an indent feature that engages and disengages the platform to secure engagement.

9. The syringe assembly of claim 3, wherein the hook includes one of protrusions and a position indicator to aid in handling and dose setting.

10. A syringe assembly that provides haptic feedback during dose setting, the syringe assembly comprising:

a syringe, including:

a barrel configured to carry a medicament; and

a plunger having a plunger head disposed on a proximal end of the plunger, the plunger communicating with the barrel, the plunger includes:

a plurality of axial ribs extending along a length of the plunger; and

a notch disposed in each axial rib; and

a dose selector disposed around the barrel wherein the dose selector passes through one of the notches to set a dose.

11. The syringe assembly of claim 10, wherein:

the plunger includes a curved indent between each of the notches, the curved indents are disposed between adjacent axial ribs of the plurality of axial ribs; and

the dose selector engages and disengages the notches to provide haptic feedback regarding the dose setting.

12. The syringe assembly of claim 11, wherein:

the plunger head includes a dial dose to indicate a dose setting; and

the dose selector includes an arm having a position indicator that cooperates with the dial dose to identify and set a desired dose.

13. The syringe assembly of claim 12, wherein:

the dose selector having a base that is fixed to the barrel;

the arm extends upward from the base; and

a tab is disposed on an inner surface of the base to engage and disengage the notches.

14. A fluid transfer device engagable to a syringe having a barrel configured to carry a medicament and a plunger connected to the barrel, the fluid transfer device preventing backflow of medicament into the syringe, the fluid transfer device comprising:

a vial adapter comprising:

a first needle cannula that allows the medicament to exit the fluid transfer device;

a second needle cannula that allows the medicament to enter the fluid transfer device, the second needle cannula being shorter in length than the first needle cannula; and

a first one-way valve connected to the first needle cannula and a second one-way valve connected to the second needle cannula.

15. The fluid transfer device of claim 14, wherein:

the medicament is drawn from a vial through the second needle cannula; and

when the fluid transfer device is engaged to a delivery device, the first needle cannula is in fluid communication with the delivery device to transfer the medicament.

16. The fluid transfer device of claim 14, wherein the first one-way valve prevents pressure in a delivery device from pushing the medicament back into the fluid transfer device.

17. The fluid transfer device of claim 14, wherein when the fluid transfer device is engaged to a delivery device, the second needle cannula is disengaged from the delivery device.

18. A fluid transfer device that prevents backflow of medicament, the fluid transfer device comprising:

a first needle cannula that allows the medicament to exit the fluid transfer device;

a second needle cannula that allows the medicament to enter the fluid transfer device, the second needle cannula being shorter in length than the first needle cannula, the second needle cannula being disposed within the first needle cannula; and

a two-way valve connected to the first needle cannula and the second needle cannula;

wherein the second needle cannula is configured to draw the medicament from a vial; and

wherein when the fluid transfer device is engaged to a delivery device, the first needle cannula transfers medicament to the delivery device.

19. The fluid transfer device of claim 18, wherein the two-way valve comprises a combination duckbill and umbrella valve.

20. The fluid transfer device of claim 18, further comprising a vent membrane that provides air to the vial when the medicament is drawn and releases air from the delivery device when the medicament is delivered to the delivery device.

21. The fluid transfer device of claim 18, wherein the two-way valve prevents backflow of the medicament when the medicament is delivered to the delivery device.

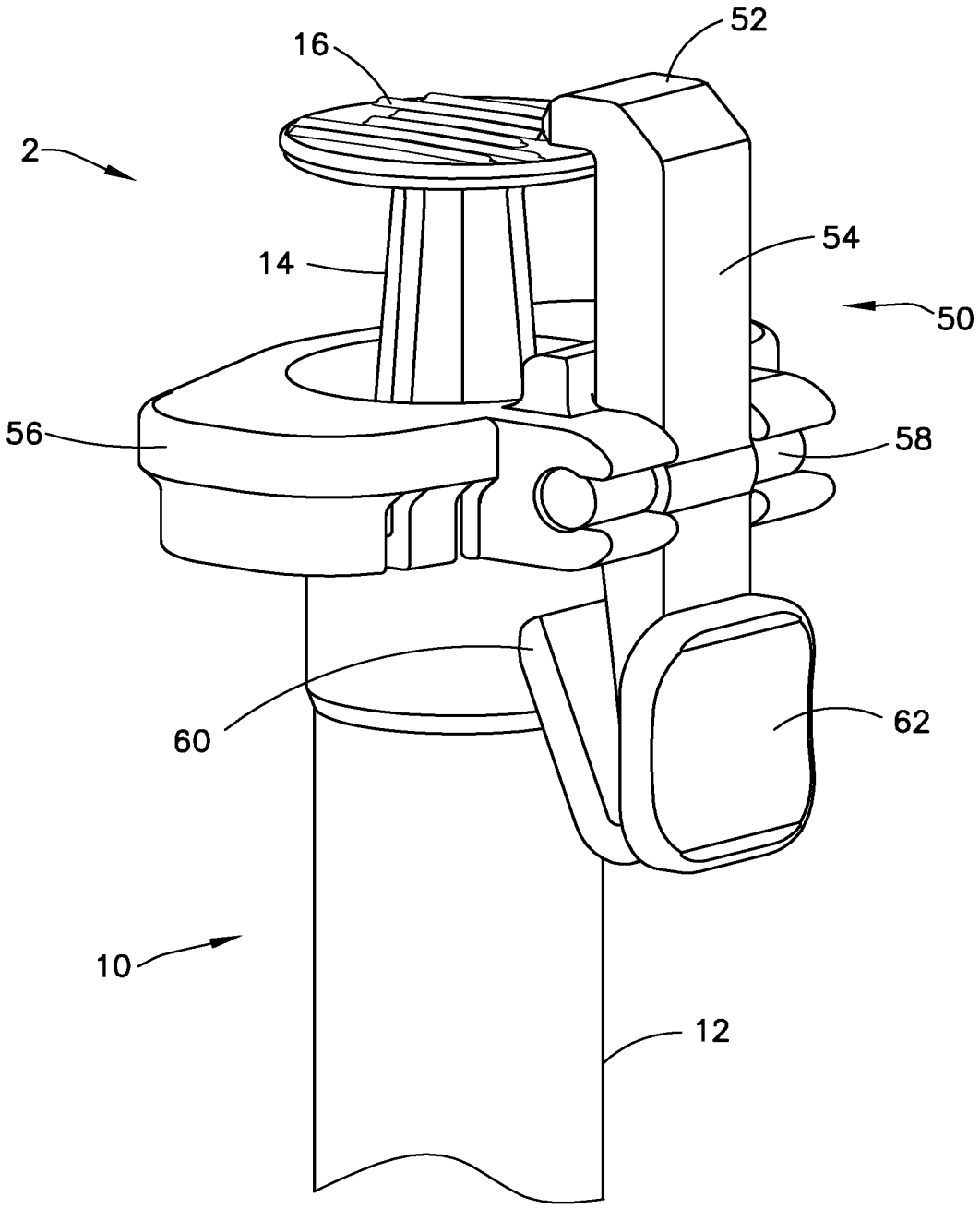


FIG. 1

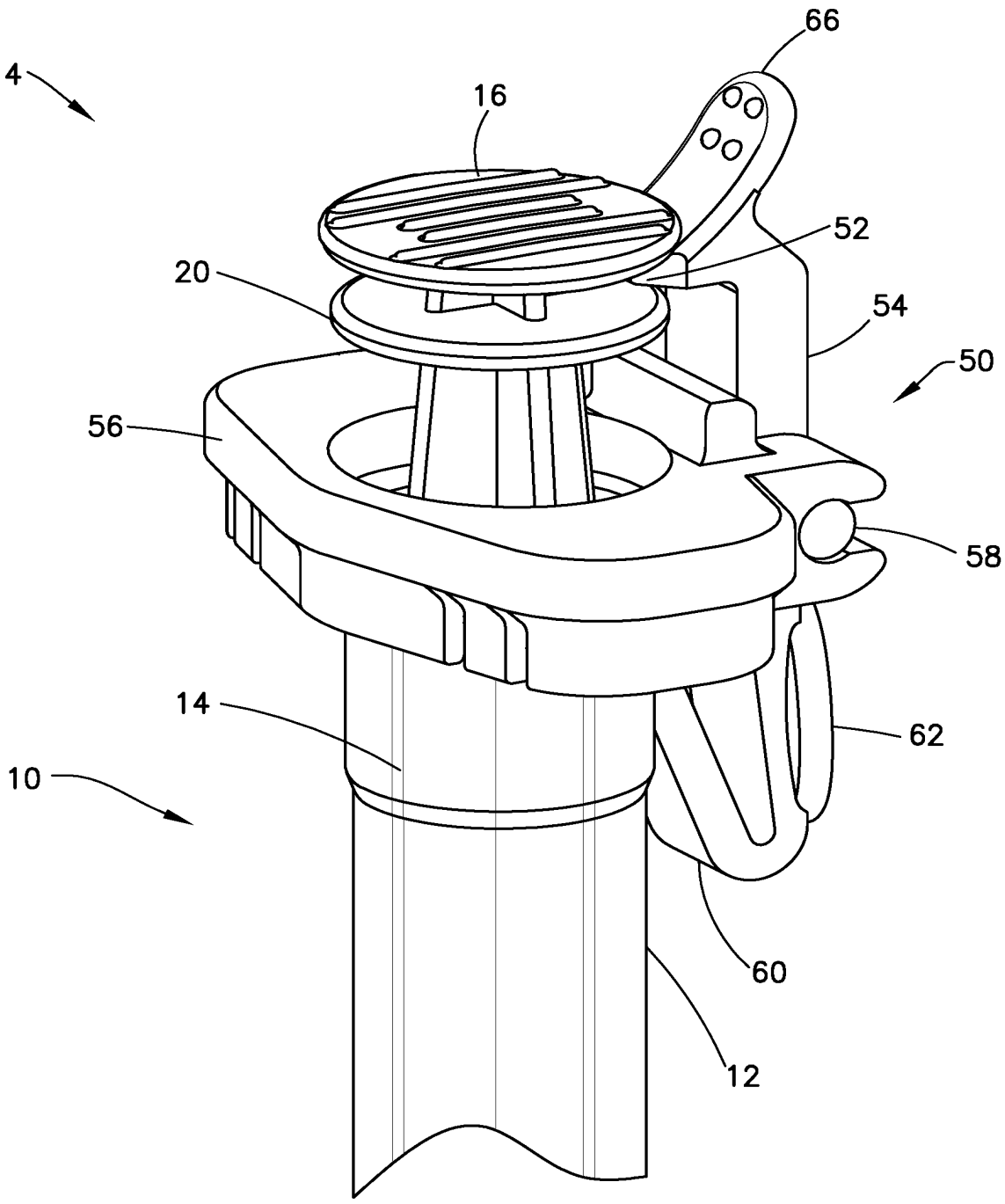


FIG.2

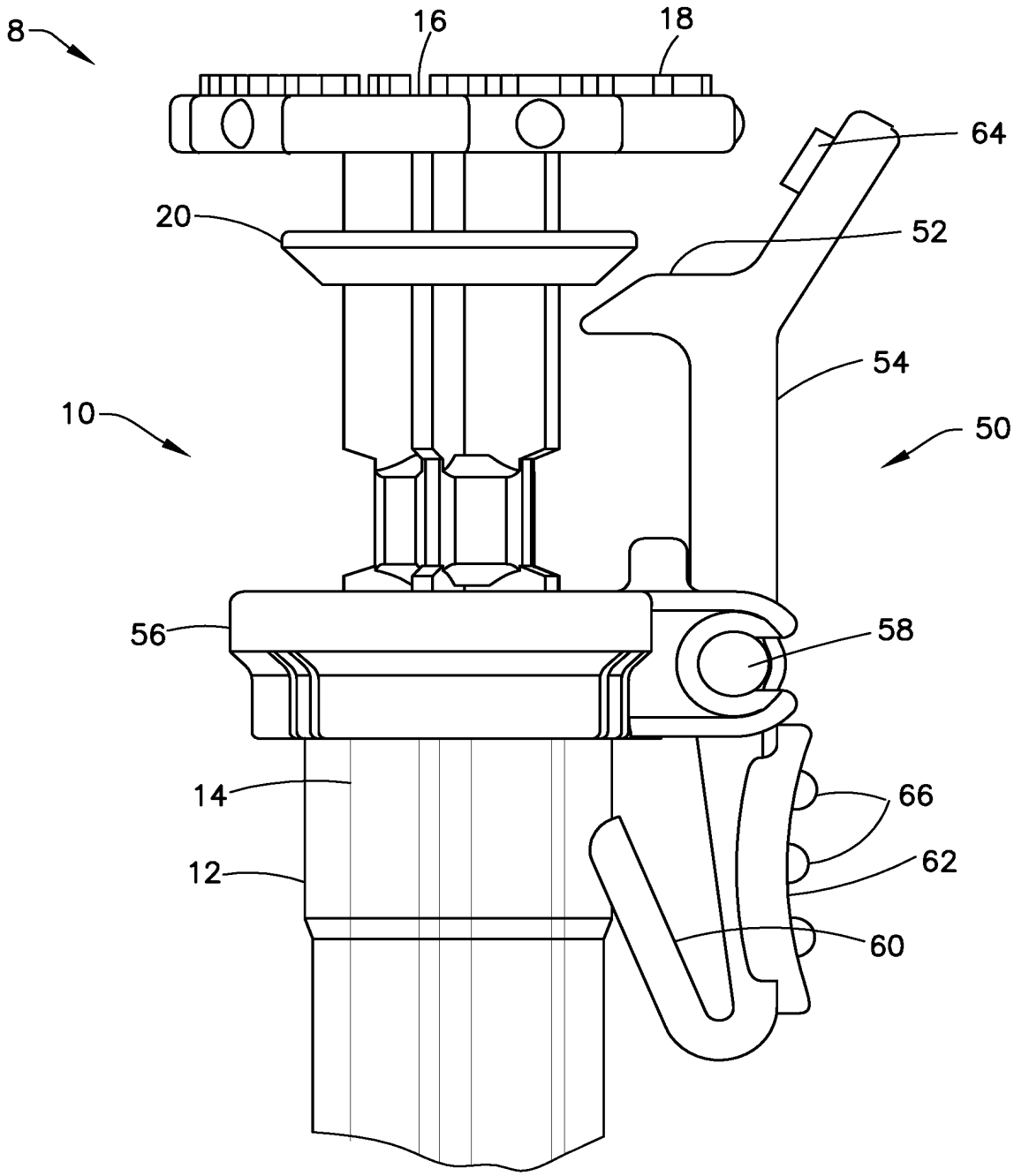


FIG.3

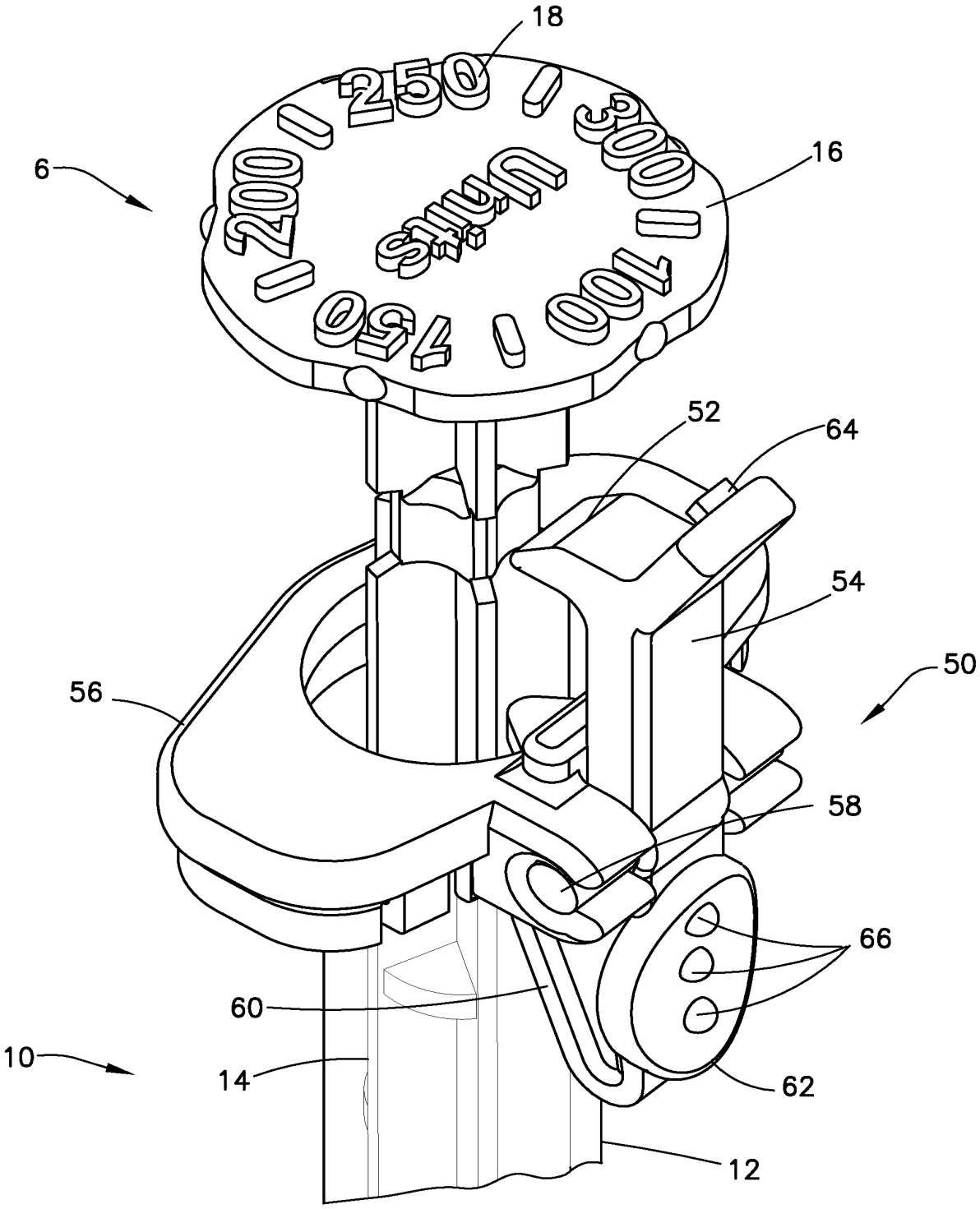


FIG.4

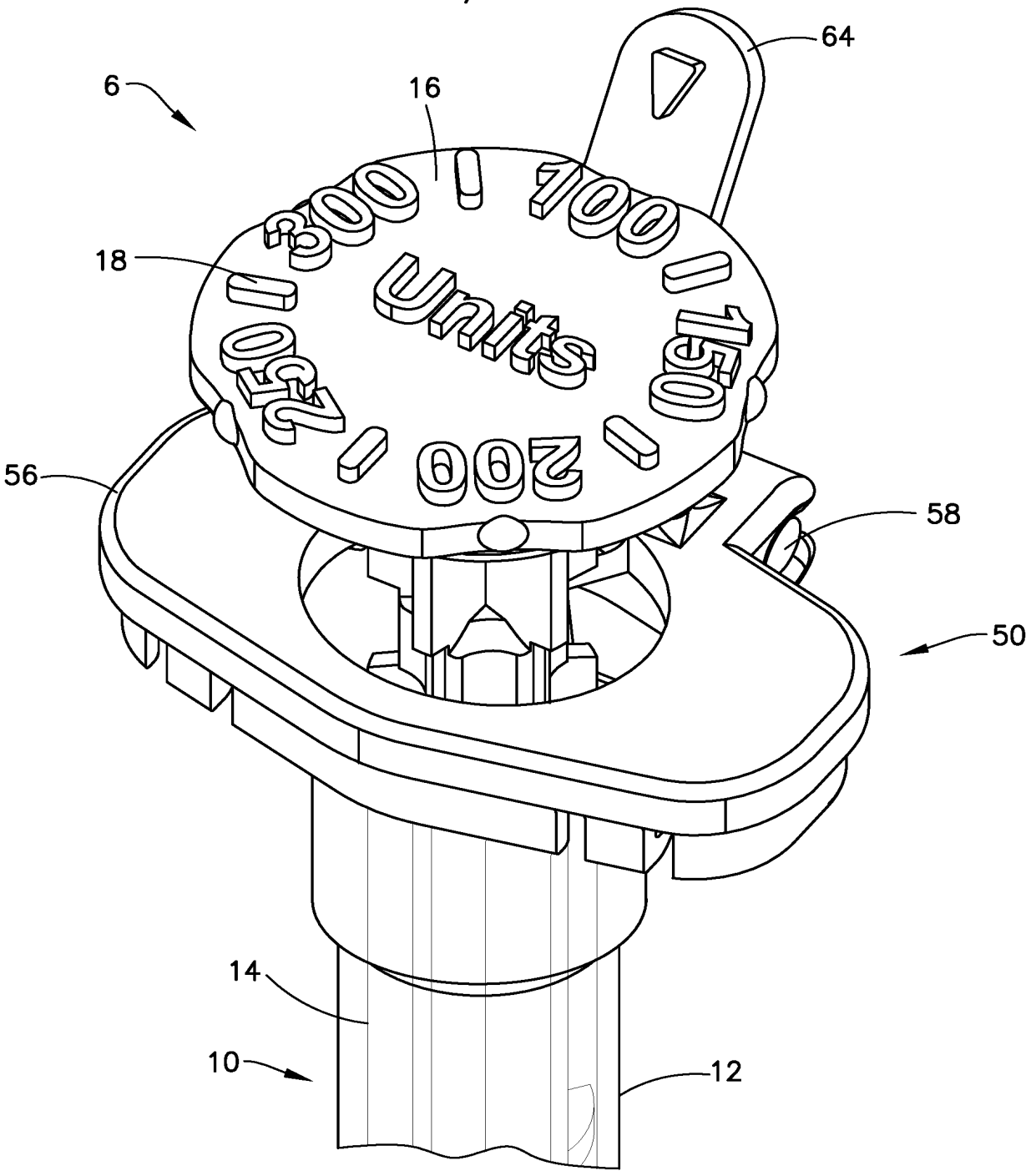


FIG.5

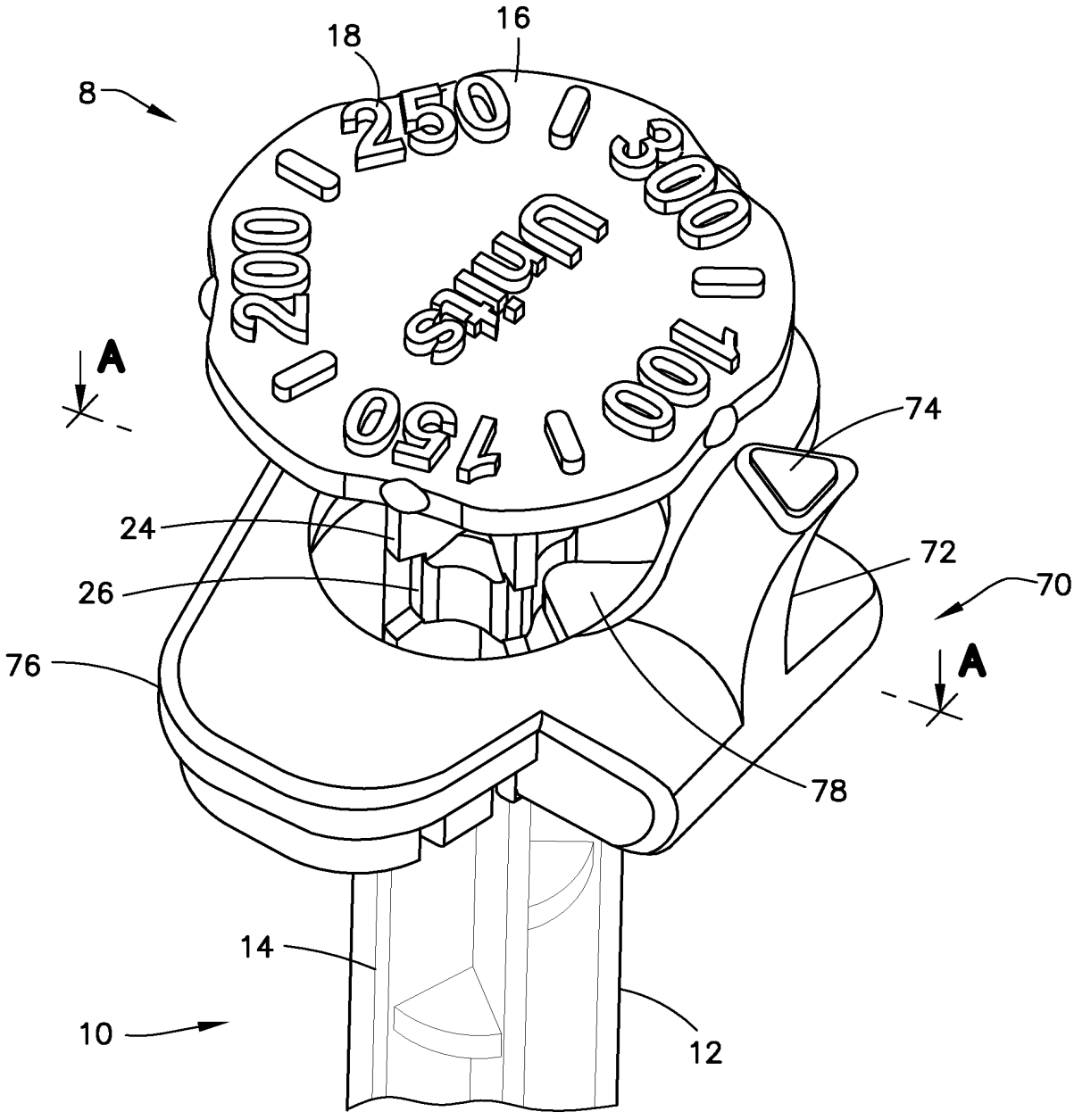


FIG.6

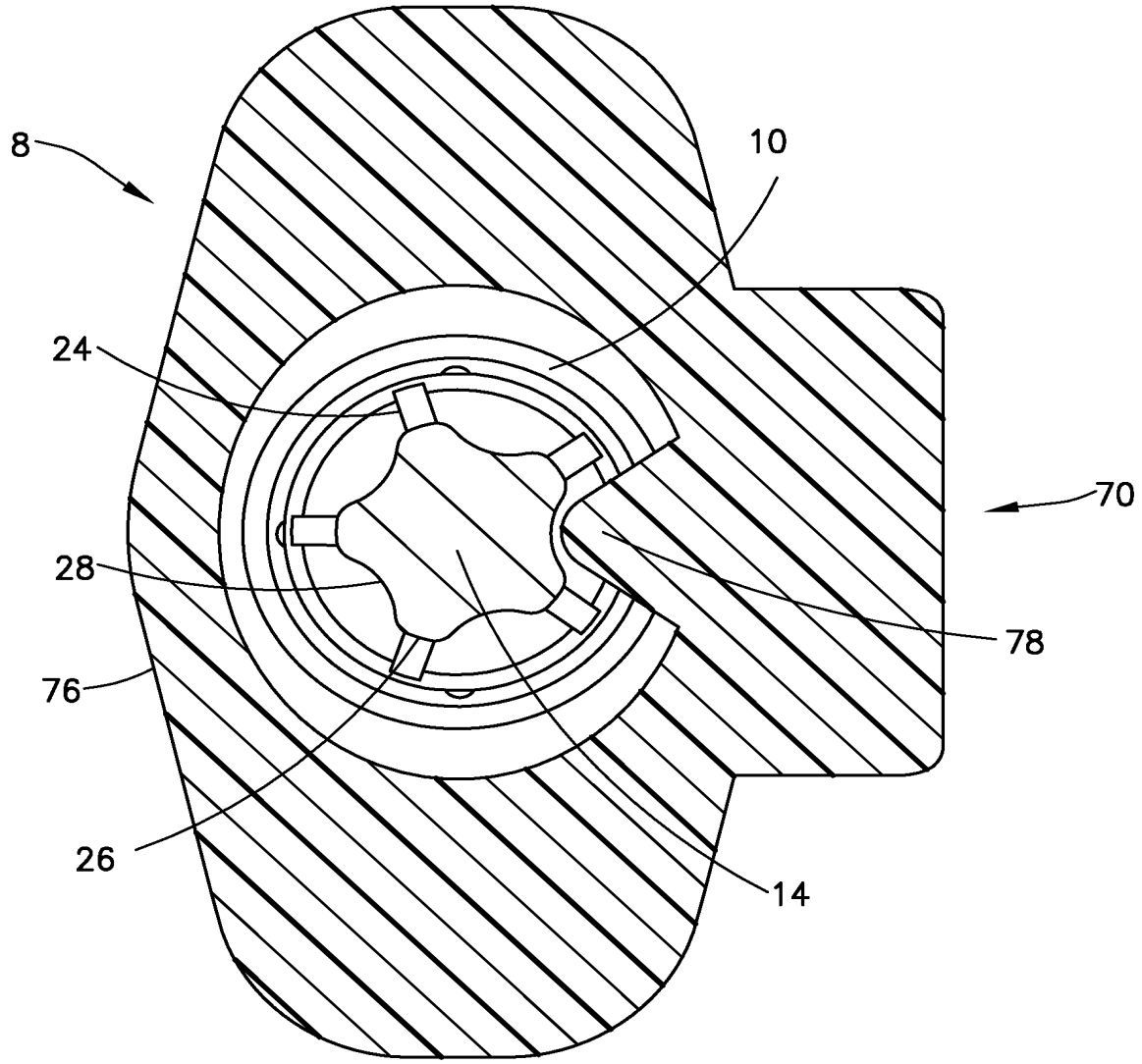


FIG.7

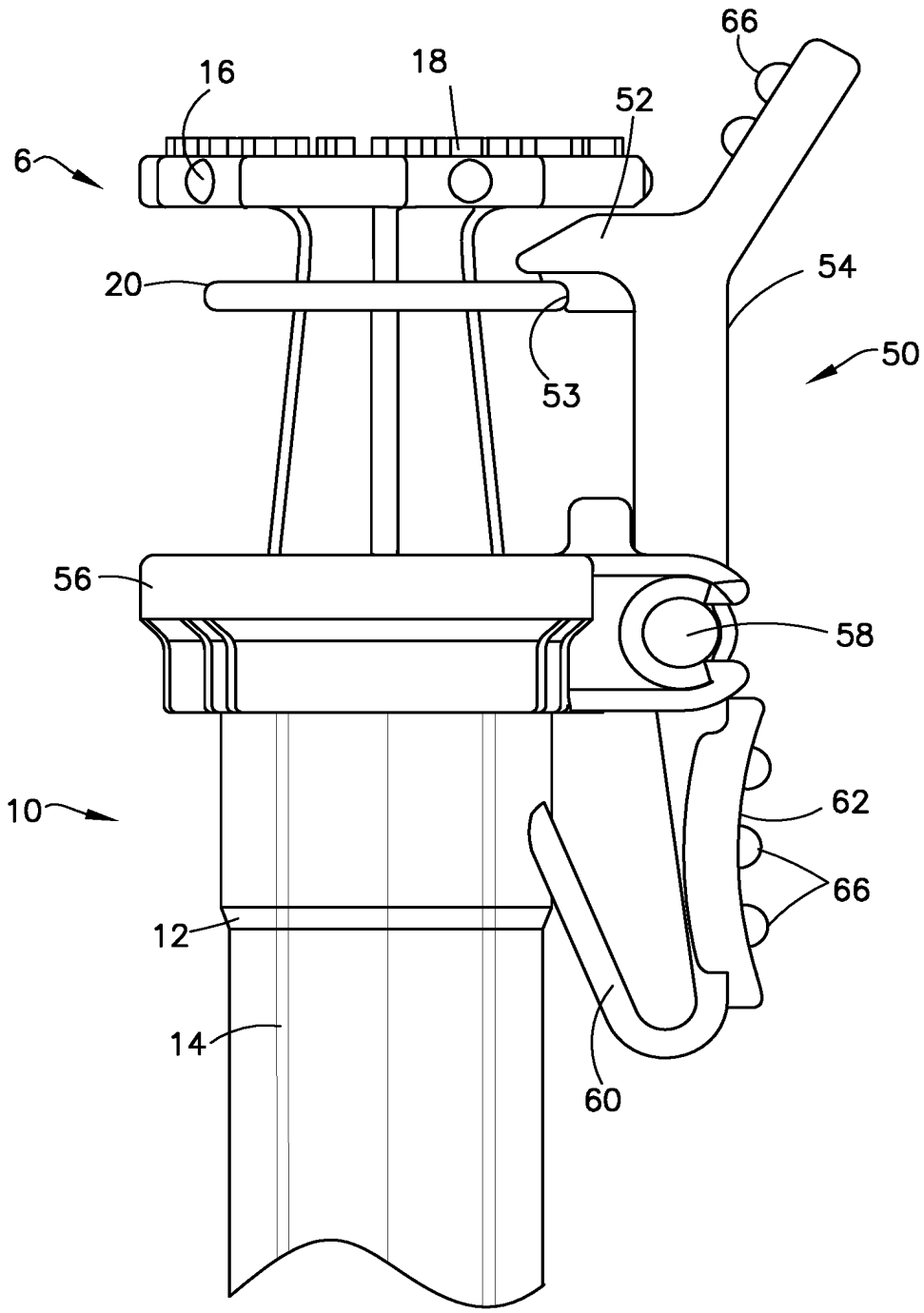


FIG.8

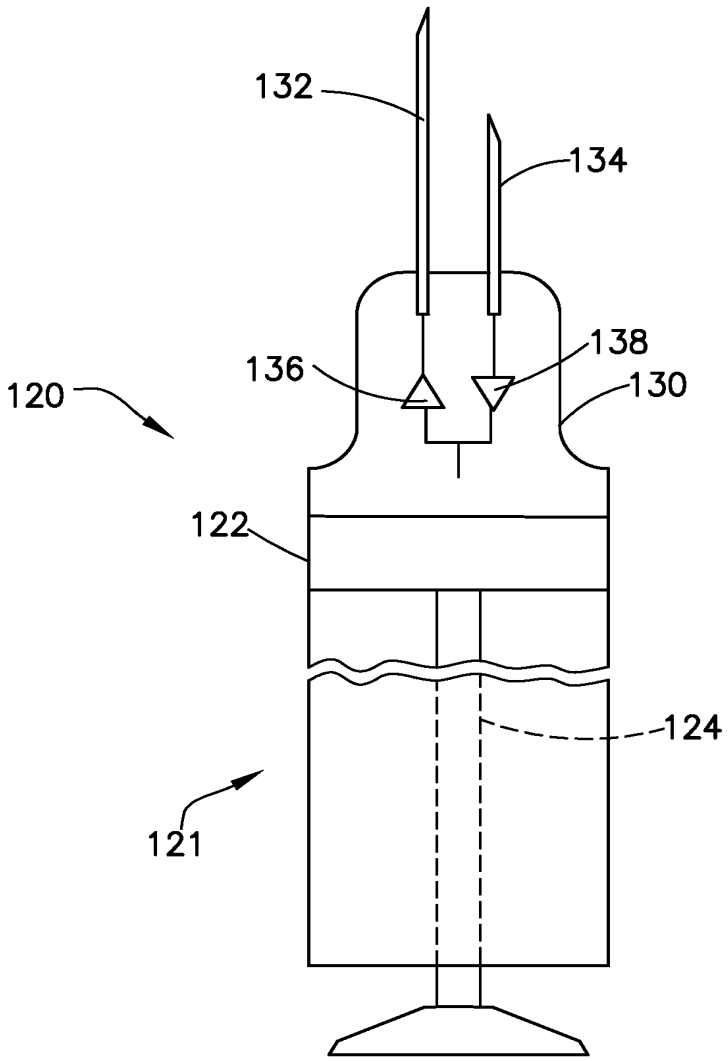


FIG.9

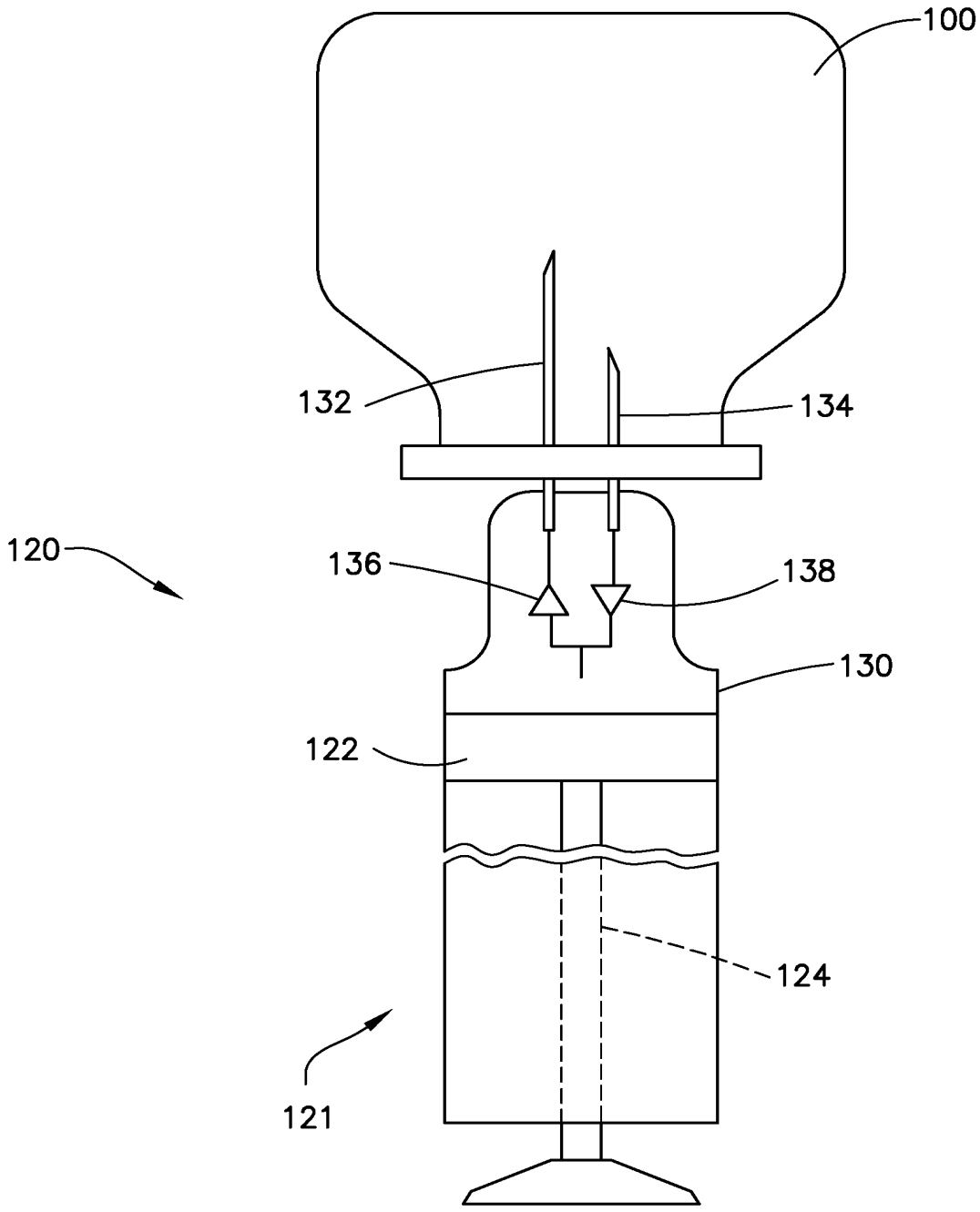


FIG.10

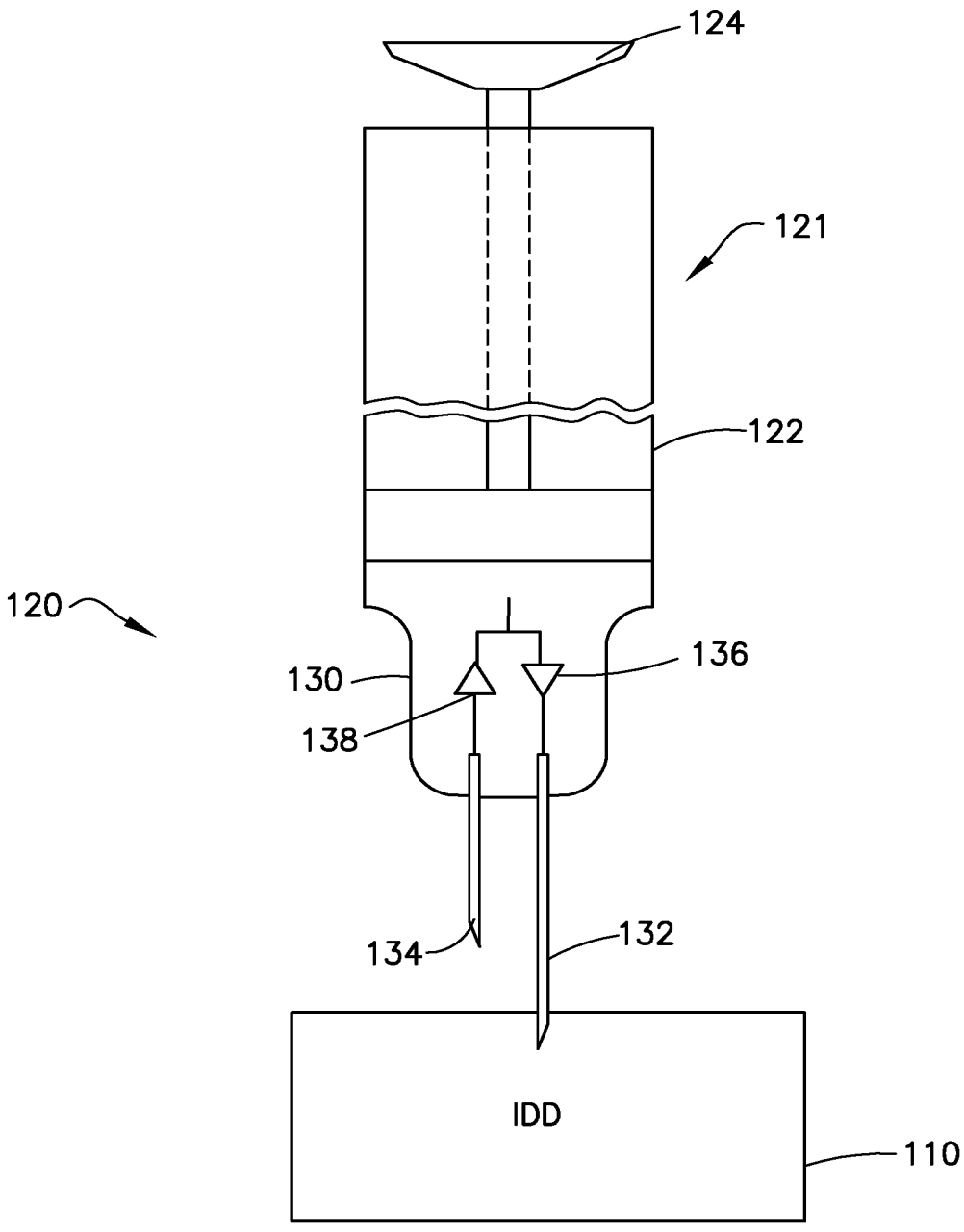


FIG.11

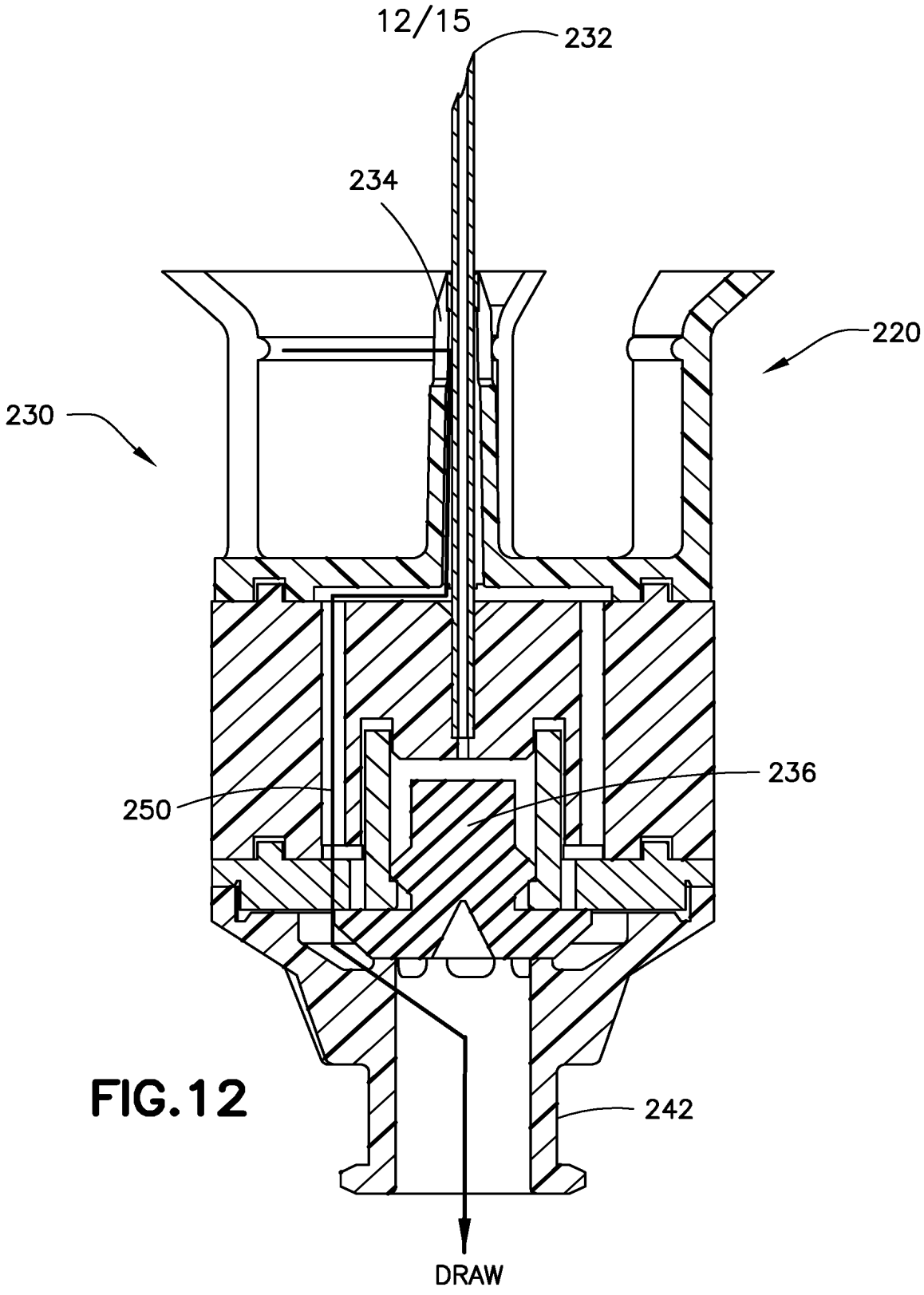


FIG. 12

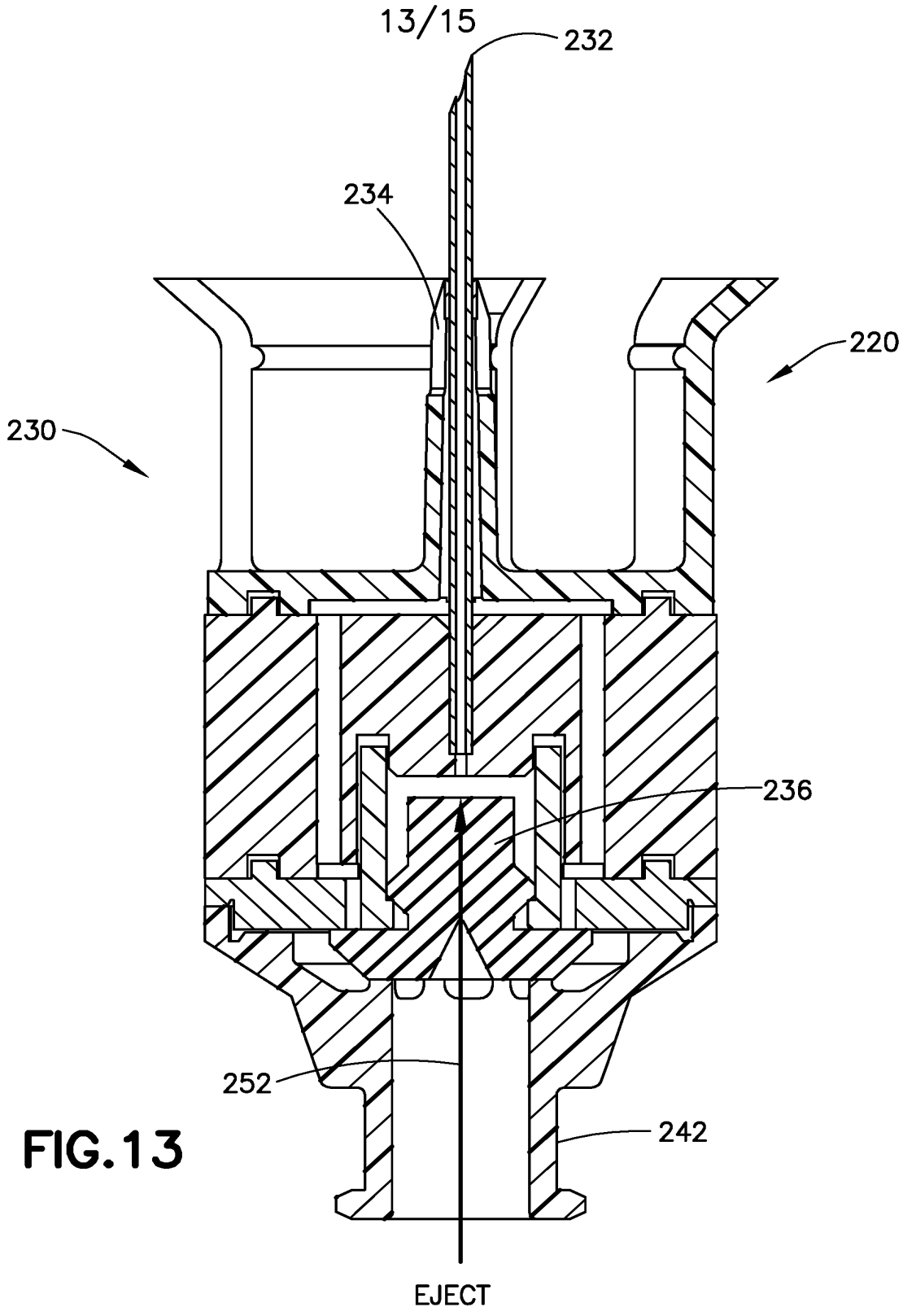


FIG.13

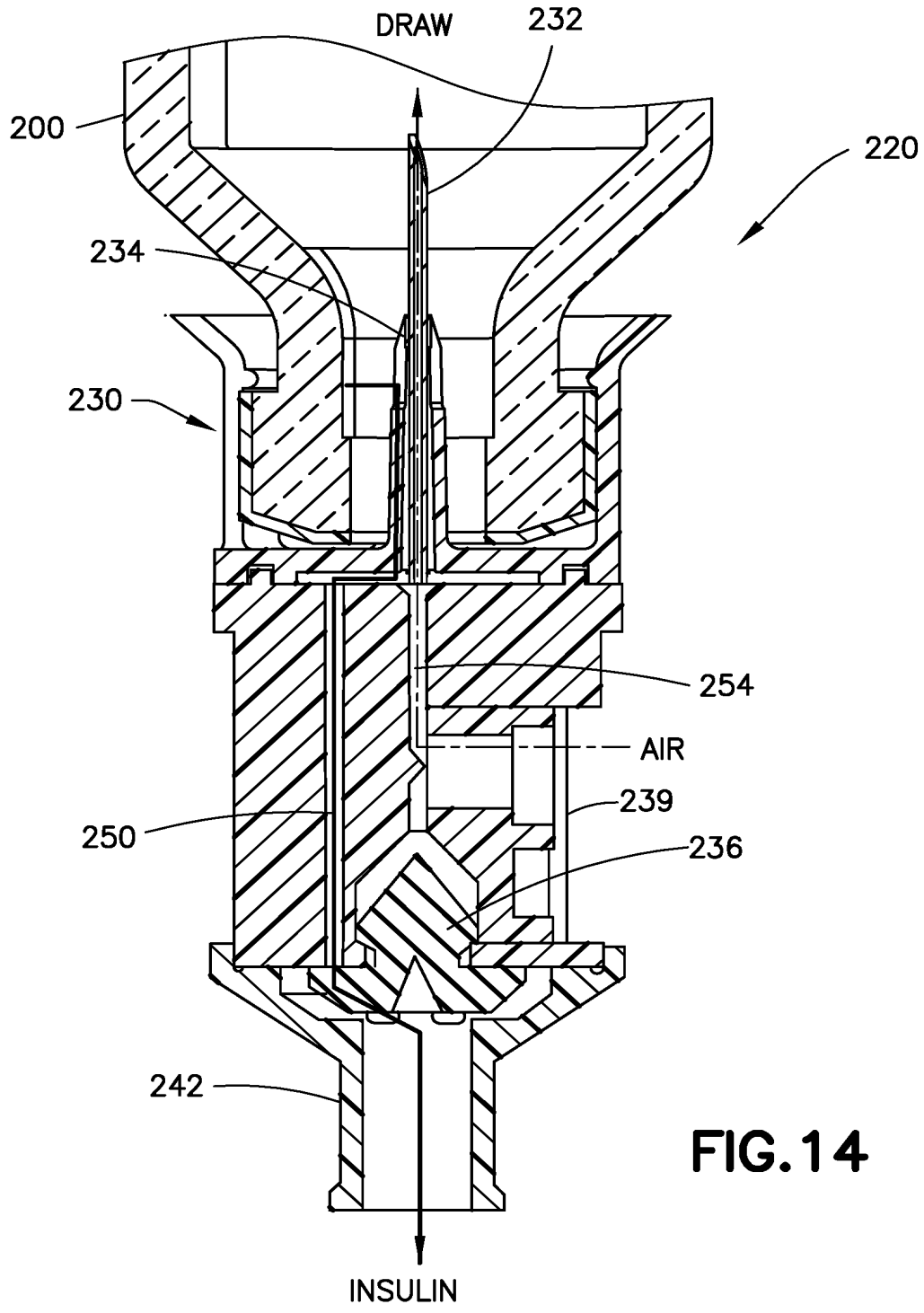


FIG.14

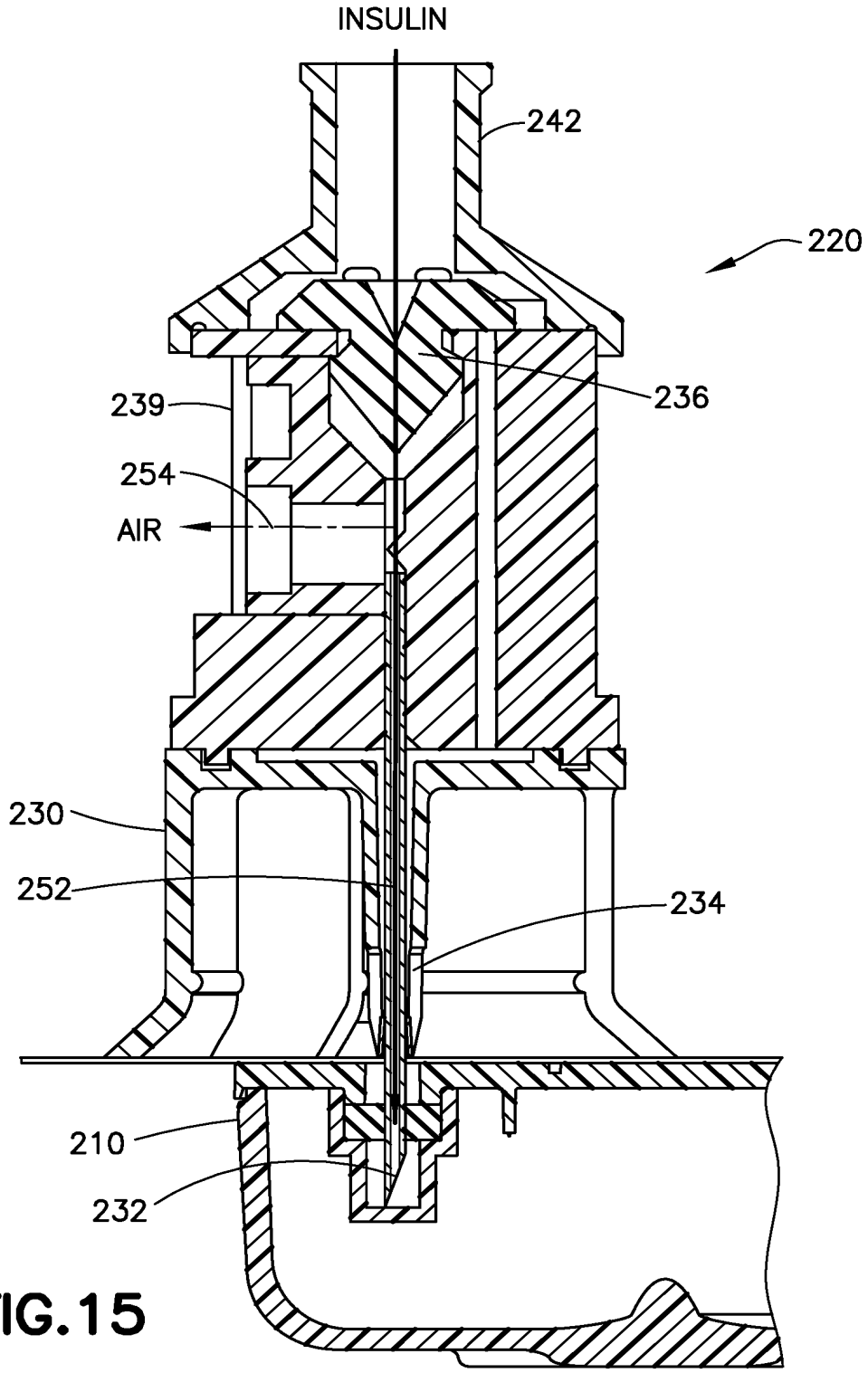


FIG.15

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 20/52760

A. CLASSIFICATION OF SUBJECT MATTER

IPC - A61M 5/31; A61M 5/32; A61M 3/00; A61M 5/00 (2021.01)

CPC - A61M 5/31563; A61M 5/31536; A61M 5/32; A61M 2005/31508; A61M 2205/60; A61M 5/31591; A61M 5/31501; A61M 5/5013; A61M 5/3125; A61M 5/3126; A61M 2005/3139; A61M 5/3146; A61M 5/315; A61M 5/31525; A61M 5/31528; A61M 5/3153; A61M 5/31533; A61M 5/31536; A61M 5/3155; A61M 3/00; A61M 5/00

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 -- A	US 5,830,152 A (TAO) 3 November 1998 (03.11.1998); entire document, especially col 6 ln 14-51, and Fig. 1-2.	1 -- 2 -- 3-9
X -- A	WO 99/07421 A1 (GENESIS INDUSTRIES INCORPORATED) 18 February 1999 (18.02.1999); entire document, especially pg 6 ln 19 to pg 7 ln 12, and Fig. 1-2.	10 -- 11-13
X -- A	US 2010/0276034 A1 (GONNELLI et al.) 4 November 2010 (04.11.2010); entire document, especially para [0063], and Fig. 17.	14-17 -- 18-21
Y	US 4,498,904 A (TURNER et al.) 12 February 1985 (12.02.1985); especially col 3 ln 45-65, and Fig. 1-4.	2
A	US 2010/0084041 A1 (FEHR et al.) 8 April 2010 (08.04.2010); entire document.	1-21
A	US 2014/0018770 A1 (SUTKIN) 16 January 2014 (16.01.2014); entire document.	1-21

☐ 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
13 January 2021	17 FEB 2021
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)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 20/52760

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:
This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be searched, the appropriate additional search fees must be paid.

Group I: Claims 1-9 directed to a syringe assembly that locks a syringe to prevent backflow of medicament, having a locking assembly.

Group II: Claims 10-13 directed to a syringe assembly that provides haptic feedback during dose setting, having a plurality of axial ribs extending along a length of the plunger, a notch disposed in each axial rib, and a dose selector.

Group III: Claims 14-21 directed to a fluid transfer device, having a first needle cannula and a second needle cannula.

-*- See Supplemental Box -*-

1. ☒ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☒ No protest accompanied the payment of additional search fees.

International application No.
PCT/US 20/52760

-*- Box III.0 - Explanations where unity of invention is lacking -*-

The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

SPECIAL TECHNICAL FEATURES

The invention of Group I includes the special technical feature of a locking assembly disposed around the barrel, not required by the claims of Groups II-III.

The invention of Group II includes the special technical feature of a dose selector disposed around the barrel wherein the dose selector passes through one of the notches to set a dose, not required by the claims of Groups I or III.

The invention of Group III includes the special technical feature of a first needle cannula that allows the medicament to exit the fluid transfer device, not required by the claims of Groups I-II.

COMMON TECHNICAL FEATURES

Groups I-III share the common technical feature of a syringe having a barrel configured to carry a medicament and a plunger connected to the barrel.
However, this shared technical feature does not represent a contribution over prior art as being anticipated by US 5,735,825 A (STEVENS et al.) (hereinafter Stevens), which teaches a syringe (10; Fig. 1; col 5 ln 11-25) having a barrel (14; Fig. 1) configured to carry a medicament (fluid within 14; Fig. 1; col 5 ln 11-25) and a plunger connected to the barrel (12; Fig. 1).

Groups I-II share the common technical feature of a plunger head disposed on a proximal end of the plunger.
However, this shared technical feature does not represent a contribution over prior art as being anticipated by Stevens, which teaches a plunger head (32; Fig. 1) disposed on a proximal end of the plunger (12; Fig. 1).

As the common technical features were known in the art at the time of the invention, these cannot be considered special technical features that would otherwise unify the groups.

Therefore, Groups I-III lack unity under PCT Rule 13 because they do not share a same or corresponding special technical feature.

(12) STANDARD PATENT (11) Application No. **AU 2015210338 B2**
(19) AUSTRALIAN PATENT OFFICE

(54) Title
STEERABLE MEDICAL DELIVERY DEVICES AND METHODS OF USE

(51) International Patent Classification(s)
A61M 25/01 (2006.01) ***A61M 25/16*** (2006.01)
A61M 25/09 (2006.01)

(21) Application No: **2015210338** (22) Date of Filing: **2015.08.04**

(43) Publication Date: **2015.08.27**
(43) Publication Journal Date: **2015.08.27**
(44) Accepted Journal Date: **2018.02.01**

(62) Divisional of:
2010266027

(71) Applicant(s)
Shifamed Holdings, LLC

(72) Inventor(s)
Salahieh, Amr;Lepak, Jonah;Leung, Emma;Saul, Tom;Dueri, Jean-Pierre

(74) Agent / Attorney
Pizzeys Patent and Trade Mark Attorneys Pty Ltd, GPO Box 1374, BRISBANE, QLD, 4001, AU

(56) Related Art
US 5454787 A
WO 2006/122155 A1
US 6048339 A
US 2006/0241564 A1
EP 1927375 A2
WO 2006/012668 A1
US 2005/0131343 A1
US 7402151 B2

ABSTRACT

A steerable medical device, comprising a steerable portion; a first tubular member comprising a first flexible polymeric tubular member; and a second tubular member comprising a second flexible polymeric tubular member, wherein the first tubular member is disposed within the second tubular member and permanently axially fixed to the second tubular member at a fixation location distal to the steerable portion; and an external controller that is adapted to be actuated to put one of the first tubular member and the second tubular member in tension and the other of the first tubular member and the second tubular member in compression, and wherein the first and second tubular members are adapted such that the steerable portion is steered in a first direction when the external controller is actuated.

2015210338 04 Aug 2015

STEERABLE MEDICAL DELIVERY DEVICES AND METHODS OF USE

CROSS-REFERENCE

[0001] This application claims the benefit of U.S. Provisional Application No. 61/220,160, filed June 24, 2009; U.S. Provisional Application No. 61/220,163, filed June 24, 2009; and U.S. Provisional Application No. 61/232,362, filed August 7, 2009, all of which are incorporated by reference herein.

BACKGROUND OF THE INVENTION

[0002] Delivery devices are used to deliver, or guide, medical devices or instruments to a target location within a subject. The delivery devices provide access to target locations within the body where, for example, diagnostic, therapeutic, and interventional procedures are required. Access via these devices is generally minimally invasive, and can be either percutaneous, or through natural body orifices. The access can require providing a guiding path through a body lumen, such as, for example without limitation, a blood vessel, an esophagus, a trachea and adjoining bronchia, ducts, any portion of the gastro intestinal tract, and the lymphatics. Once the delivery device has provided access to the target location, the delivery device is then used to guide the medical device or instrument to perform the diagnostic, therapeutic, or interventional procedure. An example of such a delivery device is a guide catheter, which may be delivered by steering it to its required destination, tracking it along a previously delivered guide wire, or both. The list of components being delivered for use percutaneously is large and rapidly growing.

[0003] Minimal outer dimensions of these delivery devices are important for minimizing the injury associated with delivery. Minimizing the wall thickness of the delivery device provides additional space for the medical device to be guided, while minimizing the injury associated with entry into the subject and the closure needed. Flexibility of the delivery device is important in allowing the guiding device to track or be steered to its target destination along tortuous paths while minimizing injury to the intervening tissues. The delivery device also needs to have compressive and tensile properties sufficient to support its delivery to the target site. When tracking around bends in the body, any kinks created in the guiding device can create an obstruction to the delivery of the medical device. When used as a steerable device, the distal end of the delivery device is preferably deflectable over a range of bend radii and responsive to the steering controls. The delivery device also should support torque transmitted from the handle to the distal region.

[0004] Once the delivery device is in place the delivery device preferably also supports torque around a distal bend such that the medical device may be rotated into position while sustaining some contact loads. Additionally, once in place the guiding device preferably is sufficiently stiff to support and guide the medical device to its target destination. The guiding device should also remain stable and not shift from one state of equilibrium to another either spontaneously or under the influence of forces being imparted to it from the delivery of the medical device or its own control mechanisms. As the delivery

2015210338 04 Aug 2015

device often travels down fluid-filled lumens such as, for example without limitation, blood vessels, it should additionally incorporate a seal against fluids impinging upon its periphery and another at its distal end which interfaces with the medical device to maintain a seal around the delivery device.

[0005] There exists a need for improved steerable delivery devices and guiding medical devices.

SUMMARY OF THE INVENTION

[0006] One aspect of the disclosure is a steerable medical delivery device. The device includes a steerable portion comprising a first tubular member and a second tubular member, wherein one of the first and second tubular members is disposed within the other, wherein the first and second tubular elements are axially fixed relative to one another at a fixation location distal to the steerable portion, and wherein the first and second tubular members are axially movable relative to one another along the steerable portion to steer the steerable portion in a first direction, and wherein the first tubular member is adapted to preferentially bend in a first direction.

[0007] In some embodiments the second tubular member is substantially uniform and is not adapted to preferentially bend.

[0008] In some embodiments the first tubular member comprises at least one slot therein to define a first spine. The second tubular member can also include at least one slot therein to define a second spine.

[0009] In some embodiments the first tubular member comprises a braided material.

[0010] In some embodiments the first tubular member is disposed within the second elongate tubular member.

[0011] In some embodiments the first tubular member is adapted to be moved axially relative to the second tubular member to apply one of a compressive force and a tensile force to the first tubular member and the other of the compressive force and the tensile force to the second tubular member to steer the steerable portion in a first direction.

[0012] In some embodiments the second tubular member is adapted to preferentially bend in a second direction, which can be substantially opposite the first direction.

[0013] In some embodiments the second elongate tubular element is a floating tubular member.

[0014] One aspect of the disclosure is a steerable medical delivery device. The device includes a steerable portion comprising an outer tubular member and an inner tubular member, wherein the inner tubular member is disposed radially within the outer tubular member, wherein the outer tubular member includes at least one outer slot therein to define an outer spine, wherein the inner tubular member includes at least one inner slot therein to define an inner spine, the inner and outer spines being offset relative to one another, and wherein the outer tubular member and the inner tubular member are axially movable relative to one another along the steerable portion and are axially fixed relative to one another at a location distal to the steerable portion.

[0015] In some embodiments the outer tubular member comprises a plurality of discontinuous slots to define the outer spine.

[0016] In some embodiments the inner tubular member comprises a plurality of discontinuous slots to define the inner spine.

2015210338 04 Aug 2015

[0017] In some embodiments the inner and outer spines are offset substantially 180 degrees from one another.

[0018] In some embodiments the inner and outer spines are adapted to receive one of a compressive force and a tensile force to steer the steerable portion of the delivery device. The inner spine can be adapted to receive a compressive force thereto and the outer spine can be adapted to receive a tensile force thereto to steer the steerable portion of the delivery device in a first direction. Alternatively, the inner spine is adapted to receive a tensile force thereto and the inner spine is adapted to receive a compressive force thereto to steer the steerable portion of the delivery device in a first direction.

[0019] In some embodiments the inner and outer slots are in substantial alignment relative to a longitudinal axis of the steerable portion when the steerable portion is in a straightened configuration. The inner and outer slots can be substantially perpendicular to the longitudinal axis of the steerable portion when the steerable portion is in a straightened configuration.

[0020] In some embodiments the inner and outer slots are not in alignment relative to a longitudinal axis of the steerable portion when the steerable portion is in a straightened configuration.

[0021] In some embodiments at least one of the outer slot and the inner slot includes a first interlocking element and a second interlocking element each adapted to allow relative movement therebetween when in a first configuration and each further adapted to prevent movement therebetween when in a second configuration.

[0022] In some embodiments the delivery device further comprises a fixation element distal to the steerable portion adapted to prevent axial movement between the outer tubular element and the inner tubular element.

[0023] In some embodiments the inner tubular member has an inner surface, and wherein the inner surface is sized to allow a medical device to be advanced therethrough.

[0024] One aspect of the disclosure is a method of steering a medical delivery device. The method includes a steerable medical delivery device comprising a steerable portion with an outer tubular member and an inner tubular member, wherein the outer tubular member includes at least one outer slot therein to define an outer spine, and wherein the inner tubular members includes at least one inner slot therein to define an inner spine, the inner and outer spines being offset relative to one another. The method includes applying a compressive force to one of the inner and outer spines and a tensile force to the other of the inner and outer spines to steer the steerable portion from a first configuration to a second configuration. The method also includes preventing relative axial movement of the inner tubular member and outer tubular member at a location distal to the steerable portion while the steerable portion is being steered.

[0025] In some embodiments the applying step comprises applying the compressive force to the inner spine, and wherein applying the compressive force to the inner spine causes the tensile force to be applied to the outer spine to steer the steerable portion. Applying the compressive force to inner spine can include moving the inner tubular member distally relative to the outer tubular member.

[0026] In some embodiments the applying step comprises applying the tensile force to the inner spine, and wherein applying the tensile force to the inner spine causes the compressive force to be applied

2015210338 04 Aug 2015

to the outer spine to steer the steerable portion. Applying the tensile force to the inner spine can include moving the inner tubular member proximally relative to the outer tubular member.

[0027] In some embodiments the applying step comprises applying the compressive force to the outer spine, and wherein applying the compressive force to the outer spine causes the tensile force to be applied to the inner spine to steer the steerable portion. Applying the compressive force to the outer spine can include moving the outer spine distally relative to the inner tubular member.

[0028] In some embodiments the applying step comprises applying the tensile force to the outer spine, and wherein applying the tensile force to the outer spine causes the compressive force to be applied to the inner spine to steer the steerable portion. Applying the tensile force to the outer spine can include moving the outer tubular element proximally relative to the inner tubular member.

[0029] One aspect of the disclosure is a steerable medical delivery device. The medical device includes an elongate member comprising a steerable portion adapted to be steered in a first direction, and a floating element disposed within the steerable portion, wherein the floating element is axially fixed relative to the elongate member at a location proximal to the steerable portion, and is not axially fixed relative to the elongate member along the steerable portion.

[0030] In some embodiments the elongate member is a catheter.

[0031] In some embodiments the elongate member comprises an inner tubular member with an inner slot therein to define a first spine, and an outer tubular member with an outer slot therein to define an outer spine, wherein the spines are offset from one another.

INCORPORATION BY REFERENCE

[0032] All publications and patent applications mentioned in this specification are herein incorporated by reference to the same extent as if each individual publication or patent application was specifically and individually indicated to be incorporated by reference.

BRIEF DESCRIPTION OF THE DRAWINGS

[0033] The novel features of the invention are set forth with particularity in the disclosure herein. A better understanding of the features and advantages of the present invention will be obtained by reference to the following detailed description that sets forth illustrative embodiments, in which the principles of the disclosure are utilized, and the accompanying drawings of which:

[0034] FIG. 1 is a perspective view of a steerable portion of a steerable medical delivery device.

[0035] FIGS. 2a, 2b, and 2c illustrate steering of exemplary steerable portions of steerable medical delivery devices

[0036] FIG. 3 illustrates a flattened view showing an exemplary slot pattern for use in a steerable portion of a delivery device.

[0037] FIG. 4 illustrates a flattened view showing an exemplary slot pattern for use in a steerable portion of a delivery device.

[0038] FIG. 5 illustrates a flattened view showing an exemplary slot pattern for use in a steerable portion of a delivery device.

2015210338 04 Aug 2015

[0039] FIG. 6 illustrates a flattened view showing an exemplary slot pattern for use in a steerable portion of a delivery device.

[0040] FIGS. 7a and 7b illustrate flattened views showing exemplary slot patterns for use in a steerable portion of a delivery device.

[0041] FIG. 8 illustrates an exemplary steerable portion including an outer slotted tubular member and an inner slotted tubular member, with an intermediate tubular element therebetween.

[0042] FIG. 9 illustrates an exemplary steerable portion including an outer slotted tubular member and an inner non-slotted tubular member.

[0043] FIG. 10 illustrates an exemplary steerable portion including an inner slotted tubular member and outer non-slotted tubular member.

[0044] FIG. 11a is a representation of a pattern for use in a steerable portion capable of being cut from a tube or created by winding a ribbon into a tube.

[0045] FIG. 11b illustrates a section of a ribbon for use in the tube of FIG. 11a.

[0046] FIGS. 12a and 12b are different views of a groove pattern for use in a steerable portion.

[0047] FIGS. 13a, 13b, and 13c are various views of a cut pattern for use in a guide catheter

[0048] FIG. 14 illustrates an outer guide member and a delivery device therein.

[0049] FIG. 15 illustrates a discontinuous cut pattern for use on a tubular member that is most steerable in compression.

[0050] FIGS. 16a and 16b illustrate a portion of a tubular member formed with the cut pattern from FIG. 15, while FIG. 16c illustrates compressive and tensile forces acting thereon.

[0051] FIG. 17 is a graph illustrating Force v. Displacement behavior associated with the application of loads or displacements at various points around the tubular member shown in FIGS. 15-16c.

[0052] FIG. 18 illustrates a continuous cut pattern for use on a tubular member that is most steerable in tension.

[0053] FIG. 19 illustrates a discontinuous cut pattern for use on a tubular member most steerable in tension.

[0054] FIG. 20 illustrates a continuous cut pattern for use on a tubular member most deflectable in tension.

[0055] FIG. 21 illustrates a discontinuous cut pattern for use on a tubular member with a substantially straight, continuous spine.

[0056] FIG. 22 illustrates a discontinuous cut pattern for use on a tubular member with a helical, continuous spine.

[0057] FIG. 23 is a flattened view of an exemplary tubular member with more than one spines.

[0058] FIG. 24 is a flattened view of an exemplary member with a single substantially straight spine.

[0059] FIG. 25 illustrates a flattened portion of an exemplary tubular member. The slots create a relatively neutral pattern.

[0060] FIG. 26 illustrates a flattened portion of an exemplary tubular member including interlocking features with complimentary curved surfaces that are adapted to support rotation of the tubular member.

2015210338 04 Aug 2015

[0061] FIG. 27 illustrates an exemplary steerable delivery device including a floating tubular member disposed therein.

[0062] FIG. 28 illustrates an exemplary steerable medical delivery system.

[0063] FIGS. 29A and 29B illustrate an exemplary embodiment of a lockable portion of a guiding device.

[0064] FIGS. 30A-30H illustrate exemplary beads that can be used in a lockable guiding device.

DETAILED DESCRIPTION OF THE INVENTION

[0065] The disclosure relates generally to steerable delivery devices, which may be considered steerable guide devices, and their methods of use. The steerable delivery devices can be used to deliver, or guide, any type of suitable medical device or instrument therethrough to a location within a patient's body. For example, the steerable delivery devices can be used to deliver, or guide, a medical device into bodily lumens such as, for example without limitation, a blood vessel, an esophagus, a trachea and possibly adjoining bronchia, any portion of the gastrointestinal tract, an abdominal cavity, a thoracic cavity, various other ducts within the body, and the lymphatics. Once the steerable delivery device has gained access to a target location within the subject, the medical device or instrument is delivered, or guided, to the target location to carry out the medical intervention. Steerable delivery devices described herein can be tracked along a previously delivered guide wire.

[0066] Figure 1 is a perspective view of a distal portion of an exemplary steerable delivery device. Steerable device 10 includes steerable portion 12 and has distal end 15. Steerable portion 12 includes an outer tubular member 14 and inner tubular member 16. Outer tubular member 14 has an inner surface defining a lumen therein, and inner tubular member 14 is sized to be disposed within the inner lumen of outer tubular member 14. Outer tubular member 14 and inner tubular member 16 are axially fixed relative to one another at fixation location 18 along the length of steerable device 10. That is, at fixation location 18, the inner and outer tubular members are not adapted to move distally or proximally relative to one another. Fixation location 18 is located distal to steerable portion 12. At locations proximal to fixation location 18, inner tubular member 16 and outer tubular member 14 are axially movable relative to one another. That is, along steerable portion 12, inner tubular member 16 and outer tubular member 14 are adapted to move axially relative to another. Outer tubular member 14 has slots 22 formed therein to define spine 20. Spine 20 extends along a length of steerable portion 12. Slots 22 are shown substantially perpendicular to the longitudinal axis "L" of steerable portion 12, when steerable portion 12 is in a straightened configuration as shown in Figure 1. Inner tubular member 16 also has slots formed therein (not shown) in the steerable portion to define a spine (not shown).

[0067] Figures 2a and 2b illustrate an exemplary embodiment of a steerable delivery device. Steerable device 30 has a distal end 37 and includes outer tubular element 34 and inner tubular element 36 which are axially immovable relative to one another at fixation location 38, but are axially movable proximal to fixation location 38. Outer tubular element 34 includes a plurality of slots 42 formed therein to define spine 40. Inner tubular element 36 also includes a plurality of slots formed therein (not shown) to define a spine (not shown). In Figures 2a and 2b, the spines are disposed substantially 180 degrees

2015210338 04 Aug 2015

apart from one another. Figure 2a illustrates steerable portion 32 deflected, or steered, into a first bent configuration, while Figure 2b illustrates steerable portion 32 steered into a second bent configuration different than the first bent configuration. To steer the steerable portion into the configuration shown in Figure 2a, a proximal portion of outer tubular member 34 is moved axially, and specifically proximally, relative to inner tubular member 36, while the tubular elements 34 and 36 are axially fixed relative to one another at fixation location 38. This can be accomplished by pulling outer tubular member 23 in a proximal "P" direction while maintaining the position of inner tubular member 36, by pushing inner tubular member 36 in a distal "D" direction while maintaining the position of outer tubular member, or by a combination thereof. The relative axial movement of the inner and outer tubular members as shown in Figure 2a applies substantially opposing compressive and tensile forces to the spines of the tubular members, thus deflecting, or steering, the device in the direction of spine 40 of outer tubular member 34, as is shown in Figure 2a. Figure 2b illustrates a step of steering device 30 in the substantially opposite direction from that shown in Figure 2a. To steer device 30 into the configuration shown in Figure 2b, inner tubular member is moved proximally relative to outer tubular member 34. This can be performed by moving the outer tubular member distally, moving the inner tubular member proximally, or a combination thereof. This relative axial movement applies substantially opposing compressive and tensile forces to the spines in steerable portion 32 of device 30, thereby deflecting the device in a direction substantially opposite that of spine 40 of outer tubular member 34.

[0068] Figure 2c shows a sectional view of the steerable portion from Figure 2b, including optional floating tubular member 505 disposed within inner tubular member 504. Steerable portion 500 includes inner tubular member 504 and outer tubular member 502. Inner tubular member 504 has interrupted slots 512 formed therein to define spine 506. Outer tubular member 502 has interrupted slots 510 formed therein to define spine 508. The steerable portion is bent along the axis of spine 506. Spine 508 and spine 506 are substantially 180 degrees apart from one another (i.e., they are on substantially opposite sides of steerable portion 500).

[0069] To steer steerable portion 500 into the configuration shown in Figure 2c (also shown in Figure 2b), inner tubular member 504 is pulled in the proximal direction relative to outer tubular member 502, as is illustrated in Figure 2b. Pulling on the inner member 504 applies a tensile force to inner spine 506. Because inner and outer tubular members 504 and 502 are axially fixed relative to one another at a location distal to the steerable portion, pulling on inner member 504 relative to outer tubular member 502 results in a compressive force applied to the distal end of the steerable portion of outer tubular member 502. The compressive force begins to compress slots 510 on outer tubular member 502. Compression of outer slots 510 causes outer tubular member to bend in the direction shown in Figure 2c, and the bending stops when inner slots 510 are closed. Thus, outer slots 510 limit the degree of the bend of steerable portion 500. The same type of bending that is shown in Figures 2b and 2c would occur if outer tubular element 502 were pushed distally relative to inner tubular member 504.

[0070] If outer tubular member 502 were pulled proximally relative to inner tubular member 504 (or if inner tubular member 504 were pushed distally relative to outer tubular member 502), steerable portion

2015210338 04 Aug 2015

500 would bend in the manner shown in Figure 2a. The degree of the bend would be limited by inner slots 512.

[0071] Figure 2c illustrates an embodiment of a medical device including a floating tubular member, which may be referred to herein as a floating liner. In general, a floating liner is disposed within an outer structure. In the exemplary embodiment in Figure 2c, the outer structure includes the inner and outer tubular members. The outer structure generally provides structural and mechanical properties for the delivery device, and the floating liner provides lubricity for a medical device or instrument to be advanced therethrough. A floating liner is generally impermeable as well. A floating liner "floats" with a portion of the outer structure. That is, the floating liner is not fixed to a portion of the outer structure in which it floats. In the exemplary embodiment in Figures 2c, the floating liner floats within the steerable portion (i.e., is not attached to the steerable portion). In general, a floating liner is attached to the outer structure at a location proximal to the steerable or bendable portion of the device. For example, in the embodiment in Figure 2C, the floating liner is attached to the outer structure at a location proximal to the steerable portion. A floating liner doesn't impede the ability of the outer structure to move as it is steered, bent, actuated, receives forces applied thereto, etc.

[0072] In some embodiments the floating liner is a lubricious polymer tube. In some embodiments the floating liner includes wire windings and/or axially laid wires.

[0073] The outer structure in which the floating liner floats can be any suitable tubular member. For example, the outer structure can be a catheter, guiding device, a steerable device, etc. In some embodiments the outer structure has a neutral bending preference but is not intended to be steered. In this embodiment the outer structure provides axial and radial stiffness thereby limiting the likelihood of kinks while the floating liner provides lubricity and is additionally restrained from kinking by the outer structure.

[0074] Figures 2a and 2b also show proximal portion 35 of device 30, which is proximal to steerable portion 32, having a substantially neutral portion designed to have no preferential bending axis while at the same time transmitting axial force and torque applied at a proximal end of the device (not shown).

[0075] In some embodiments, the inner and outer tubular members are adapted to have opposing compressive and tensile loads applied thereto to steer the steerable portion. In some embodiments at least one of the tubular members has a neutral bending axis. A neutral bending axis, as used herein, generally refers to an axis of the tubular member along which there is substantially no axial displacement in response to a compressive and/or tensile force applied thereto. Axial displacement along the neutral bending axis, in response to a compressive and/or tensile force applied thereto, is less than axial displacement of structures elsewhere in the tubular member. In particular, axial displacement along the neutral bending axis is minimal relative to axial displacement of structures elsewhere in the tubular member. Examples of a neutral bending axis include spine 382 in Figure 21 and spines 412 and 414 in Figure 23.

[0076] In some embodiments at least one of the tubular members is adapted to offset the neutral bending axis relative to the opposite tubular member. The neutral bending axes of the tubular members

2015210338 04 Aug 2015

can be offset to be approximately tangent to opposite sides of the opposing members, making the neutral bending axis offset equal to the diameter of the device, thus providing the highest possible bending leverage ratio for a given device diameter.

[0077] The tubular members described herein may exhibit preferential or neutral bending behavior. Neutral bending behavior implies that the displacement for a given radially applied load (from the edge of the tubular member through the longitudinal axis of the tubular member) will be independent of the radial angle from which the load was applied. In contrast, in a non-neutral structure the displacement associated with a radial load will change as a function of the radial angle. An exemplary tubular member tending towards neutral bending behavior is shown in Figure 25 or the uninterrupted spiral pattern of Figure 25 which is essentially a spring.

[0078] In some embodiments the inner and outer tubular elements are adapted to be rotated relative to one another to enhance the steerability of the steerable portion. The tubular elements can rotate relative to one another yet remain axially fixed relative to one another at a location distal to the steerable portion. In these embodiments, in addition to axial forces being applied to one or more tubes, one or more tubular members are also rotated with respect to each other to steer the steerable portion.

[0079] In some embodiments only one of the inner and outer tubular members has at least one slot defining a spine along the steerable portion, while the other does not have any slots along the steerable portion. For example, in Figures 2a and 2b, outer tubular member 34 can have a slot and a spine while inner tubular member 36 does not have a slot formed therein. Alternatively, inner tubular member 36 can have at least one slot and a spine while outer tubular member 34 does not have a slot formed therein. The steerable portion can be steered as described herein if at least one of the inner and outer tubular members is adapted to preferentially bend in a first direction.

[0080] In the embodiment in Figures 1 and 2 the slots in both tubular members are substantially perpendicular to the longitudinal axis of the steerable portion. The slots in one or both of the tubular members can be, however, at an angle relative to the longitudinal axis that is other than substantially 90 degrees.

[0081] In some embodiments the steerable device also includes a tubular element disposed between the inner and outer tubular members. The intermediate member can be, for example without limitation, a flexible polymeric material. The intermediate member can be encasing one or both of the tubular members, or comprising one or both of the members. The intermediate member can be adapted to provide a fluid barrier and/or a low friction surface.

[0082] Slots as described herein can be formed in a tubular member by laser machining or other machining processes. Forming the slots creates at least one spine in a tubular member. A spine as used herein can be considered a region of the steerable portion that imparts axial stiffness in compression or tension, or both, and may additionally include features that provide torsional stiffness. When a single spine is created in a tubular member, the neutral bending axis of the tubular member is moved to the spine of the tubular member.

2015210338 04 Aug 2015

[0083] In some embodiments, a tubular member includes at least two spines, the combination of which moves the neutral bending axis of the tubular member to an axis parallel to, or tangent to when bent, the longitudinal axis of the tubular device and passing through the spines.

[0084] In some embodiments a liner, such as a flexible polymer liner, is bonded on the inner surface of the inner tubular member. In some embodiments a flexible polymer is bonded or otherwise disposed over the outer surface of the outer tubular member. A liner can also be disposed such that it is encasing the inner tubular member.

[0085] In some embodiments the steerable portion is comprised of a first tubular member that is adapted to bend preferentially in a first direction and a second tubular member that is not adapted to bend preferentially in one direction. In some instances of these embodiments, the second tubular member is a flexible polymer material with or without a braided or wire support. In some instances, a wire or other structural support is included in the first tubular member in the deflectable area to increase compressive and tensile stiffness along one side of the tubular member, thus moving the neutral bending axis from the longitudinal axis of the tubular member to the side of the tubular member that includes the structural support. In some instances wires are laid longitudinally and distributed evenly to increase axial stiffness in tension without creating a preferential bending.

[0086] In some embodiments the device includes three tubular members, having three offset neutral bending axes approximately 120 degrees radially spaced apart, thus providing the steerable device with universal steering in any direction.

[0087] Figure 3 illustrates, for ease of description, a flattened, or unrolled, portion of exemplary tubular member 50, which can be an inner or an outer tubular member. Tubular member 50 includes fixation region 52, steerable portion 54, and a proximal neutral portion 58. Steerable portion 54 includes a plurality of slots 56 formed therein to define spine 55 extending along the steerable portion. Slots 56 are sinuous-shaped slots, and spine 55 has a generally straight configuration along the length of steerable portion 54. That is, spine 55 is substantially parallel with the longitudinal axis of the tubular member. Fixation region 52 includes a plurality of holes 57 to facilitate bonding to provide for axial fixation relative to a second tubular member (not shown). Proximal portion 58 includes a plurality of multiple overlapping slots 60 to provide the desired flexibility, axial force transmission, and torque transmission characteristics.

[0088] Figure 4 illustrates a flattened, or unrolled, portion of exemplary tubular member 61, which can be an inner or an outer tubular member of a steerable portion. Tubular member 61 includes fixation region 62, steerable portion 64, and proximal neutral bending portion 68. Neutral bending portion 68 will exhibit minimal bending preference upon a compressive or tensile force applied thereto. Tubular member 61 is similar to tubular member 50 shown in Figure 3, but includes linking elements 72, which can be flexible. Each linking element extends from one side of a slot to the other side. Each linking element includes two arm portions extending from one side of the slot to the other side of the slot. The two arms meet at the point at which they are connected to one side of the slot. The linking elements extend along steerable portion 64 on substantially the opposite side as spine 65. Linking elements 72 enhance and/or

2015210338 04 Aug 2015

control torque response and bending of steerable portion 64. As steerable portion 64 is bent about spine 65, linking elements 72 bend and stretch under tension. As steerable portion 64 is twisted, or put in torque, linking elements 72 are put in compression. In torque, the gap between a given linking element and the section of the tubular member proximally adjacent to the given linking element collapses, effectively increasing the torsional stiffness of steerable portion 64.

[0089] Figure 5 illustrates a flattened portion of exemplary tubular member 80, including fixation portion 82, steerable portion 84, and proximal neutral portion 86. The embodiment in Figure 5 is similar to the outer tubular member as shown in Figures 2a and 2b. Steerable portion 84 includes substantially straight slots 90 that are substantially perpendicular to the longitudinal axis of tubular member 80. Spine 88 is substantially straight in configuration, extending along the length of steerable portion 84 substantially parallel to the longitudinal axis of the tubular member 80. Fixation portion 82 includes holes 92 therethrough (four shown) to facilitate bonding. Proximal portion 86 has multiple overlapping slots 94 to give the desired flexibility, axial force and torque transmission.

[0090] Figure 6 illustrates a flattened portion of exemplary tubular member 96, including fixation portion 98, steerable portion 100, and proximal neutral portion 102. Steerable portion 100 includes substantially straight slots 108 that are substantially perpendicular to the longitudinal axis of tubular member 96, but each is offset relative to the adjacent slot so that spine 106 has a sinuous shape extending along the length of steerable portion 100. Fixation portion 98 includes holes 104 therethrough (four shown) to facilitate bonding. Proximal portion 102 includes multiple overlapping slots 110 to give the desired flexibility, axial force and torque transmission characteristics.

[0091] Figures 7a and 7b illustrate exemplary portions of flattened first and second tubular members 112 and 128. First tubular member 112 can be an inner tubular member and second tubular member 128 can be an outer tubular member, or first tubular member 112 can be an outer tubular member and second tubular member 128 can be an inner tubular member. Tubular members 112 and 128 can be assembled as part of a steerable delivery device. That is, one of the first and second tubular members can be disposed within the other. First tubular member 112 includes fixation portion 114, steerable portion 116, and proximal neutral portion 118. Fixation portion 114 includes holes 120. Steerable portion 116 has slots 124 formed therein to define spine 122. Spine 122 has a generally sinuous shape. Proximal portion 118 includes a plurality of overlapping slots 126. Second tubular member 128 includes fixation portion 130, steerable portion 132, and proximal neutral portion 134. Fixation portion 130 includes holes 136. Steerable portion 132 has slots 140 formed therein to define spine 138. Spine 138 has a generally sinuous shape. Proximal portion 134 includes a plurality of overlapping slots 142.

[0092] In Figures 7a and 7b, the slots in each of tubular members 112 and 128 are offset relative to the adjacent slot, interrupted, and have a general helical configuration. Spines 122 and 138 have generally sinuous configurations. The slots in the tubular members are at the same angle relative to the longitudinal axis of the tubular member, but are formed in opposite helical patterns. A advantage of having inner and outer tubular members with slots that are not in alignment (as opposed to inner and outer tubular members that have slots perpendicular to the longitudinal axis of the tubular member) is that the

2015210338 04 Aug 2015

slots are less likely to get caught up on one another as the steerable portion is steered. The angled slots shown in Figures 7a and 7b also provide for an increased torque response based on a torque applied at the proximal end of the device.

[0093] Figure 8 illustrates a portion of an exemplary steerable delivery device. Steerable device 150 includes outer tubular member 152, inner tubular member 154, and intermediate tubular member 156. A portion of outer tubular member 152 and intermediate member 156 are cut away to show inner tubular member 154. Intermediate tubular member 156 can be a flexible polymeric tube. Inner and outer tubes 152 and 154 have slots 160, 164 formed therein to define spines 158 and 162. The spines are substantially 180 degrees apart, as shown. The slots formed in the respective tubular members are at an angle relative to the longitudinal axis of the steerable portion and are formed in opposite helical patterns.

[0094] Figure 9 illustrates a portion of an exemplary steerable delivery device. Steerable device 166 includes outer tubular member 168 and inner tubular member 170. Inner tubular member 170 can be a flexible polymeric tubular element. Outer tubular member 168 has a plurality of slots 174 formed therein to define spine 172. Inner tubular member 170 has no preferential bending axis. Inner tubular member 170 could alternatively have a modified bending axis offset by having, for example, a stiffening element incorporated into the wall of inner tubular member 170 approximately 180 degrees from spine 172. In some embodiments inner tubular member 170 may incorporate wire braids and or axially-laid wires which reduce kinkability and increase axial stiffness as is common in braided catheters or other similar known tubular medical devices.

[0095] Figure 10 illustrates a portion of an exemplary steerable delivery device. Steerable delivery device 178 includes outer tubular member 180 and inner tubular member 182. Outer tubular member 180 can be, for example, a flexible polymeric tubular member. Inner tubular member 182 has a plurality of slots 186 formed therein to define spine 184, which is substantially parallel to the longitudinal axis of the steerable portion. Outer tubular member 180 has no preferential bending axis. Alternatively, outer tubular member 180 can have a preferential bending axis. For example, a structural support element can be incorporated into the wall of outer tubular member 180 approximately 180 degrees from spine 184. Outer tubular member 180 can be substantially the same as inner tubular element 170 in Figure 9, but for any lubricity enhancing feature. In some embodiments inner tubular member 170 may incorporate wire braids and or axially laid wires which reduce kinkability and increase axial stiffness as is common in braided catheter or other similar known tubular medical device.

[0096] In an alternative embodiment, the device includes inner and outer slotted tubes, and additionally includes an outermost tubular member similar to 180 shown in Figure 10. The outermost tubular member can be, for example without limitation, a polymeric tubular member.

[0097] Figure 11a illustrates a portion of an exemplary embodiment of a first tubular member that can be included in a steerable delivery device. Tubular member 190 is a tubular member formed from a ribbon wire. Tubular member 190 has spine 192 formed by coiling a ribbon shaped with interlocking elements 194 and 196, which together form an interlocking feature along spine 192. Interlocking elements 194 and 196 may be press-fit to interlock the two. The interlocking elements can be encased

2015210338 04 Aug 2015

with a tubular member, such as a polymer tubular member, to secure them in place. The interlocking elements can also, or alternatively, have a polymer tubular member disposed therein to help secure them in place. In addition to the interlocking features, the ribbon wire has sections of decreased width 198 which once wound into a tubular structure create the steerable portion for flexibility. A second tubular member of the steerable delivery device can be created in a similar manner to the tubular member in Figure 11a. Figure 11b illustrates an embodiment of the ribbon with interlocking elements 196 and decreased width regions 200 between elements 196. The angle of interlocking elements 196 relative to the longitudinal axis of the tubular element can be varied based on the pitch of the coil. Such a pattern can additionally be fabricated by laser machining.

[0098] Figures 12a and 12b illustrate an exemplary embodiment of a tubular member. Tubular member 210 comprises a tube 214 with grooves 212 formed therein on the outer surface of tube 214. Grooves 212 do not extend all the way through tube 214. Tubular member can be, for example, a stiff polymeric tubular member. Figure 12a shows a sectional view of a portion of tubular 210 showing the depth of grooves 212 in the steerable portion. Figure 12b illustrates a flattened view of tubular member 210 showing grooves 212 formed in tube 214. Grooves 212 define a single substantially straight spine 216. Grooves 212 cut into tube 214 increase flexibility of the steerable portion to allow the steerable portion to be steered. Spine 216 provides for the application of compressive and tensile forces to steer the device. Because the cut does not go all the way through the wall of the tube, it inherently creates a fluid tight barrier and a lubricious liner. In some embodiments tubular member 210 can an inner or outer tubular member of a steerable device, and the other of the inner and outer tubular elements can also includes a tubular element with grooves formed thereon. In some embodiments the steerable device can also have a polymeric sleeve to encapsulate the outer tube to create a smooth outer surface.

[0099] Figure 13a illustrates a portion of an exemplary introducer sheath reinforcement member 220. Member 220 is formed by laser cutting a tubular member to slots or gaps therein. A helical slot 222 defines interlocking T-shaped patterns 224 formed in reinforcement member 220. The helical path is shown generally in helical path 226. Flexibility slots 228 are formed in member 220 to provide flexibility to member 220. Member 220 also includes bonding slots 230 formed therein to allow for bonding to one or more components of the device. Figure 13b illustrates member 220 from Figure 13a in a flattened pattern showing the interlocking T-shaped pattern along helical path 226, flexibility slots 228, and bonding slots 230. Figure 13c shows a close-up of the section shown in Figure 13b.

[00100] In some embodiments a guide catheter includes a relatively rigid metal or polymer reinforcement member (an example of which is shown in Figure 13a-13c) layered between an inner and an outer flexible polymer tube. The rigid reinforcement member can be laser machined or otherwise cut in a pattern in order to enhance flexibility along the longitudinal axis of the tube, to allow some limited radial compliance, and to allow bonding of the inner and outer flexible polymers. The slot pattern can include an interlocking T-shaped pattern arranged helically around the tube for flexibility and radial compliance, a slot pattern where the slots are substantially perpendicular to the tube longitudinal axis, and are patterned along the tube longitudinal axis to further enhance flexibility and bonding of said layers.

2015210338 04 Aug 2015

[00101] Figure 14 illustrates an exemplary embodiment of a guide system adapted to guide and deliver a therapeutic, diagnostic, interventional, or any other type of medical device 260 intraluminaly to a target location within a body. Guide system 250 includes outer guide member 252 and steerable delivery device 256, a portion of which is disposed within outer guide member 250. Steerable delivery device 256 can be, for example, any of the steerable delivery devices described herein. Outer guide member 252 has a preset bend 254 that can be formed by, for example, heat setting. Steerable delivery device 256 includes steerable portion 258, which can be formed as, for example, any of the steerable portions described herein. For example, steerable delivery device can include outer and inner tubular members, wherein at least one of the tubular members is adapted to preferentially bend in a first direction. In the embodiment shown in Figure 14, steerable portion 258 is comprised of a single steerable tubular member steered into the configuration shown in Figure 14 by actuating pull wire 264. Alternatively, steerable delivery device 256 can be comprised of the embodiment described in Figure 2, and steered by relative axial movement of inner and outer tubular members, as described herein.

[00102] Alternatively, outer guide member 252 can be adapted to be bent using optional pull wire 262, shown in Figure 14. In such an embodiment bend 254 may or may not preset. Guide member 250 comprises a tubular member incorporating a pattern of slots as described for steering portions herein. When located in position pull wire 262 is tensioned and the axial and torsional stiffness of bend 254 is thereby increased. A steerable outer guide member 252 in its delivery configuration (non-bent) is generally loose and compliant, but is tensioned or compressed to reconfigure it into a pre-set shape. Its stiffness in the bent configuration is a function of the amount of tension or compression applied and the particular slot pattern chosen.

[00103] Bend 254 in outer guide member 252 is compliant enough to be straightened for delivery, for example advanced on a guide wire, but rigid enough to be able to guide steerable delivery device 256 around bend 254. Steerable delivery device 256 is steerable and transmits torque.

[00104] The structural properties of the inner and outer tubular members of the steerable delivery device will determine the manner in which they respond to force applied thereon. The structural properties of the inner and/or outer tubes will depend on the tubing material and the design, or characteristics, of the slots created in the tubular members (unless one of the inner and outer tubular members does not have any slots therein). The design of the slot pattern is therefore a function of the required structural properties of the tubular member. For example, structural properties of the tubular member that can be modified by changing the design of the slots or slot patterns include flexural stiffness, torque transmission, steerability, radius of curvature, and allowable wall thickness of the steerable assembly.

[00105] Figure 15 is a flattened view and illustrates a portion of an exemplary steerable portion of a tubular member. Tubular member 290 can be an inner or an outer tubular member as described herein. Steerable portion 290 is typically a laser-cut tubular member, but may in fact be fabricated by any technique capable of creating the appropriate widths of cuts required (e.g., water jet, wire EDM, etc.) wherein first cut, or slot, 292 is made, defined by first surface 294 and second surface 296. Slot 292

2015210338 04 Aug 2015

extends almost all the way around tubular member 290, and defines spine 308. Slots 282 are thickest, along the tubular longitudinal axis, along compression axis C which allows tubular member to be compressed along compression axis C, which changes the configuration of tubular member 290. Tubular member 290 also includes interlocking features 298 (only one of which is labeled), which include first interlocking element 300 and second interlocking element 302. Slot 292 includes slot portion 304, which is defined by the first and second interlocking elements 300 and 302 and allows for movement between the two interlocking elements 300 and 302 in the axial direction. Tubular member 290 also includes stress relief slots 306, which extend across spine 308 and provide stress relief for spine 308. Stress relief slots 306 can be considered to be axially in-between slots 292. Slots 292 are not connected with slots 306. Slots 306 are substantially thinner than slots 292. As will be described in detail below, tubular member 290 is adapted to be compressed along compression axis C, which is substantially 180 degree from spine 308.

[00106] Figures 16a and 16b illustrate a portion of tubular member 290 shown in Figure 15. Figure 16b illustrates tubular member 290 with slot 292, with a greatest thickness along compression axis C. Slot 292 includes slot 304, which is defined by interlocking elements 300 and 303. Slot 292 and slot 304 allow for compression of tubular member 290, shown in Figure 16a. When a compressive force A is applied along compressive axis C surfaces 294 and 296 are brought closer towards another, as are surfaces 300 and 302. Slots 292 and 304 therefore allow for axial compression of tubular member 290, until surfaces 294 and 296 engage one another, or until surfaces 300 and 302 engage one another, whichever happens first. Slots 292 and 304 can be designed such that the slots close at the same time. Once the surfaces engage, they behave substantially like a solid tube and can no longer be compressed along the engagement points. Upon a compressive force to tubular member 290, tubular member will therefore be steered into the configuration shown in Figure 16a. Similarly, when a tensile force is applied to tubular member 290 shown in Figure 16a, tubular member 290 will straighten to the configuration shown in Figure 16b. Particularly, tubular member 290 will straighten until the interlocking features engage one another and prevent further movement. Figure 16c illustrates the tubular member from Figures 16a and 16b and indicates points of load application including those illustrated in Figures 16b and 16c. Torsional force T indicates a torsional force acting on tubular member 290 upon the application of torque at a proximal end of the device. Tensile and compressive forces are listed as "a" or "b" depending on the behavior exhibited by the tubular member as described below.

[00107] Figure 17 is a graph illustrating Force v. Displacement behavior associated with the application of loads or displacements at various points around tubular member 290 shown in Figures 15-16c. The Force/Displacement behavior of tubular member 290 for loads applied in planes passing through the longitudinal axis of the tubular member, ranges between the lines A and B in Figure 17. Curve A illustrates the behavior along a compliant axis on the surface of the tubular member and parallel to the longitudinal axis of the tubular member where the slots are widest, while curve B illustrates the behavior where the slots are vary narrow. As the tubular member is bent about spine 308 in a fashion which closes slots 292, the forces required to bend the tubular member are low and the

2015210338 04 Aug 2015

Force/Displacement curve has a small slope. The tubular member is compliant in this region. When the width of the slots decreases to zero the structure becomes much stiffer as indicated by the second much higher slope region of curve A. The amount of displacement associated with closing the slots is essentially indicated by point D where the slope of the Force/Displacement curve changes. Curve A indicates the behavior expected from forces applied at a point along compressive axis C, illustrating that a large amount of axial displacement follows from minimal compressive force on tubular member 290. Upon closing slots, the compressive axis becomes stiff (indicated by the large increase in Force at point D in the curve). Curve B in the graph indicates compression along the axis running through spine 308. Due to stress relief slots 306, a small amount of compressive displacement occurs before spine 308 stiffens and begins to act substantially like a solid tube, as indicated by point E in the graph. The structure will exhibit the behavior of curve B for tensional loads applied to the top of the structure on the compressive axis C as the gaps closed under this loading are very narrow. Curve B also represents the behavior of the structure to torsional loads, as the gaps impacted most by these loads are narrow.

[00108] Figure 18 illustrates a flattened view of exemplary tubular member 320. Slot 330, or cut, formed therein has a spiral (also referred to herein as helical) pattern and is un-interrupted. Tubular member 320 is shown in an as-cut compressed configuration, and is adapted to be expanded the greatest amount along expansion axis EA upon the application of a tensile force thereto. Tubular member 320 includes interlocking features 332, which include surfaces 322 and 324, and surfaces 326 and 328. Slot 330 includes the slot defined by surfaces 326 and 328, and by surfaces 322 and 324. In this embodiment the slot, or gap, defined by surfaces 326 and 328 is larger than the gap defined by surfaces 322 and 324. That is, the gap that is closer to expansion axis EA is larger than the gap that is further from expansion axis EA. Tubular member 334 also includes spine 334, which is interrupted by small slots 336. As illustrated in Figure 16c, tubular member 320, upon the application of axial loads applied thereto, will exhibit Force/Displacement curves as follows: a compressive force (downwards) applied at EA will exhibit curve B, while a tensile load at EA (upwards) will exhibit curve A. A torsional load will exhibit curve B.

[00109] Figure 19 is a flattened view and illustrates a portion of a tubular member. Tubular member 270 can be an inner or an outer tubular member as described herein. Steerable portion 270 is a laser-cut tubular member wherein first cut, or slot, 274 is made to define spine 276. Cut 274 is made almost all the way around tubular member 270. Cut 274 also defines interlocking features 278 (only one of them is labeled), which are comprised of a first interlocking element 280 and a second interlocking element 282. Cut 274 includes cut 284, which creates the interlocking features and allows for movement between the two interlocking elements. Tubular member 270 also includes stress relief 272, which extend across spine 276 and provide stress relief for spine 276. Stress relief slots 272 can be considered to be axially in-between slots 274. Slots 274 are not connected with slots 272. Tubular member 270 is adapted to be expanded along expansion axis EA, and is adapted to be minimally compressible upon the application of compressive forces thereto. Spine 276 is substantially static. Upon the application of tensile forces to

2015210338 04 Aug 2015

tubular member 270 along expansion axis EA, tubular member 270 will deflect from a straightened configuration into a bent configuration.

[00110] Figure 20 illustrates an embodiment similar to that shown in Figure 18 and only differences in the structure between the two will be described. All other features can be considered the same. Tubular member 350 includes interlocking features including interlocking elements 354 and 356. Slot 360 created in tubular member 350 includes the gap defined by surfaces of interlocking elements 354 and 356.

[00111] Figure 21 illustrates a flattened portion of an exemplary tubular member 380 including interrupted cuts 390 that define spine 382. Tubular member 380 includes interlocking features 384, which include interlocking elements 386 and 388. Interlocking features 384 allow for expansion along expansion axis EA upon the application of a tensile force thereto. Tubular member 380, like all tubular members described herein unless specifically stated otherwise, can be incorporated into a steerable portion as an inner or an outer tubular member.

[00112] Figure 22 illustrates a flattened portion of an exemplary tubular member 400. Interrupted slots 404 define spine 402, which has a spiral shape. Tubular member 400 does not have static axis.

[00113] Figure 23 illustrates a flattened portion of an exemplary tubular member 410. Tubular member 410 includes interrupted helical slots 418, which define spines 412 and 414. Tubular member 410 has two spines, 180 degrees around the periphery of the device from one other. The helical cut pattern repeats itself every 180 degrees to define substantially straight spines. Tubular member 410 also includes a plurality of interlocking features 420 which provide torsional stiffness. The maximal expansion/compression is at axis 416.

[00114] Figure 24 illustrates a flattened portion of an exemplary tubular member 430, which is similar to the embodiment in Figure 23 but rather than repeating every 180 degrees, the cut pattern repeats every 360 degrees. Slots 434 have an interrupted helical design, and tubular member 430 has a single spine 432. Feature 436 provides additional torsional stiffness. Tubular member 430 exhibits maximal expansion/compression along axis 438.

[00115] Figure 25 illustrates a flattened portion of an exemplary tubular member 440. Tubular member 440 includes slots 448, which repeat every 190 degrees to define spines 442 and 446. The slots have an interrupted helical pattern, and create a relatively neutral pattern.

[00116] Figure 26 illustrates a flattened portion of an exemplary tubular member 450. Tubular member 450 has uninterrupted slot 456 formed therein, which repeats every 360 degrees. Tubular member 450 also includes interlocking features 454 comprised of at least two interlocking elements as described herein. In this embodiment, the interlocking elements have complimentary curved surfaces and are adapted to support rotation. Slot 456 defines spines 452, while slot 456 allows compression and/or expansion along axes A.

[00117] Figure 27 illustrates an exemplary steerable delivery device including steerable portion 520. Steerable delivery device includes outer tubular member 522, inner tubular member 524, and floating inner member 534. Inner tubular member 524 is disposed within and coaxial to outer tubular member

2015210338 04 Aug 2015

522, and floating inner member 534 is disposed within and coaxial with inner tubular member 524. Floating inner member 534 is axially fixed relative to inner tubular member 524 at a location proximal to steerable portion 520. The device shown in Figure 27 can also include a liner member disposed between the outer and inner tubular members.

[00118] Figure 28 illustrates an exemplary steerable delivery system 600. System 600 includes control device 602 that is adapted to steer steerable portion 610 of a steerable delivery device. The steerable delivery device includes outer tubular member 606 and inner tubular member 608 disposed within outer tubular member 606. Control device 602 includes housing 612 with a slot therein adapted to allow for movement of actuator 604. Actuator 604 is coupled to inner tubular member 608, and is adapted to be moved axially, either distally D or proximally P to control the axial movement of inner tubular member 608. Any other suitable type of actuator can also be used including actuators incorporating mechanical advantage. Actuation of actuator 604 causes inner tubular member 608 to move axially relative to outer tubular member, which causes steerable portion 610 to bend. The control device is therefore adapted to steer steerable portion 610 inside of a subject. System 600 also includes a floating liner member 616 and hemostatic valve 614.

[00119] One aspect of the disclosure is a guide device that is adapted to be maintained, or locked, in a specific configuration to provide access for a medical device or instrument to be passed therethrough, but may or may not be steerable. In Figures 2A-2C, steerable portion 32 is adapted to be steered or deflected into any configuration between those shown in Figures 2A and 2B. Steerable portion is adapted to be steered to, for example, navigate bends or turns within a bodily lumen. In that specific embodiment, compressive and/or tensile forces are applied to the inner and/or outer tubular members to steer the steerable portion. In some embodiments, once steerable portion 32 is steered into a curved configuration, the forces applied thereto (e.g., compressive, tensile, torsional) can be released, and yet a medical device or instrument can be passed through the tubular members. In some embodiments, however, the bent configuration of the steerable portion can be maintained by maintaining the application of the forces thereto. For example, in Figures 2A-2C, steerable portion 32 can be maintained, or locked, in the bent configurations shown by maintaining the application of the compressive and/or tensile forces. By maintaining the application of the forces to the steerable portion or locking the relative displacements of the inner and outer tubes, the inner and outer tubes are substantially axially fixed relative to one another along the length of the steerable portion.

[00120] In an exemplary method of use, multiple bend portions may be incorporated and adapted to have a locked configuration that closely mimics, or resembles, a portion of the subject's anatomy. The bend portion can be advanced through the subject (e.g., over a guide wire) to a desired location, and can then be actuated into a curved configuration, such as by the application of compressive and/or tensile forces thereto. The curved configuration can be adapted to resemble the path of the anatomical lumen in which the device is positioned. Application of the actuation force maintains, or stiffens, the bend portions in the desired curved configuration. A medical device or instrument can then be advanced through the curved portion to a target location within the subject.

2015210338 04 Aug 2015

[00121] The device shown in Figure 14 can alternatively be configured to be operated in this manner. For example, steerable delivery device 256 in Figure 14 can be actuated to have a first bend or curved region 254 and a second bend or curved region 258. The curves, or bends, form a general S-shaped portion of the device. The delivery device 256 can be maintained, or locked, in the general S-shape to guide a medical device or instrument therethrough. The S-shape of the delivery device 256 can be used if it resembles a portion of the anatomy into which it is placed, but any other type of preformed configuration can be used, depending on the anatomical requirements. In the alternative to Figure 14, the delivery device can be actuated into the configuration shown by the application of compressive and/or tensile forces to inner and outer tubular members, as is described herein.

[00122] Figures 29A and 29B illustrate an exemplary embodiment of a portion of a lockable device adapted to be locked, or maintained, in a specific configuration that mimics that of a portion of the subject's anatomy. In the unlocked form the structure is compliant and easily guidable whereas in the locked form the device is rigid in its predetermined form. The device can then be used to provide access for a medical device or instrument to be passed therethrough to a target location within the subject. Bend portion 700 of the device includes a plurality of beads, 702, 704, and 706. Bead 702 is the distal-most bead, bead 706 is the proximal-most bead and beads 704 are disposed between the two end beads 702 and 706. The beads are separate and distinct structural features, not mechanically coupled to one another. Each bead has two bores 715 therethrough, each adapted to receive one of the two control wires 708. Control wires 708 are secured only to distal bead 702, using any suitable technique (e.g., adhesive). Wires 708 therefore are adapted to be axially moveable relative to beads 704 and 706. Proximal bead 706 has a substantially constant height H around the periphery of the bead, while beads 702 and 704 do not have a constant height. Specifically, the height of the beads 702 and 704 decreases around a portion of each of the beads. The gap between adjacent beads is therefore relatively large between bead 702 and 704, and between beads 704, while the gap between bead 706 and the adjacent bead 704 is relatively small compared to the other gaps.

[00123] To adjust the lockable portion into its predetermined form, an axially directed (i.e., distally directed) compressive force C is applied to proximal bead 706 while maintaining wires 208 is position. Maintaining wires 208 in position can occur based on a proximally directed tensile force applied to wires 208, or wires 208 may be secured to a portion of the delivery system that is not actuated. This causes the distance between surfaces 711 and 713 to decrease, until they engage one another as shown in Figure 29B. The actuation force is continued until all of the beads' adjacent surfaces are engaged, as shown in the configuration in Figure 29B. In Figure 29B, lockable portion 700 is in a bent configuration adapted to mimic a portion of the patient's anatomy in which it is to be positioned. Figure 29B also shows a section portion of one side of the beads through which one of wires 708 passes. Lockable portion is maintained in the locked configuration in Figure 29B by maintaining the distally directed compressive force to proximal bead 706 or the relative displacements between distal bead 702 and proximal bead 706. Lockable portion 208 can also be bent into the configuration shown in Figure 29B upon the application of a proximally directed tensile force applied to wires 708, while applying a distally directed compressive

2015210338 04 Aug 2015

force to proximal bead 706. While six beads are shown in Figures 29A and 29B, the lockable portion can have two or more beads.

[00124] Figures 30A-30H show exemplary beads that can be incorporated into a lockable portion as described herein. Figure 30A illustrates bead 716 with wire bores 717 therethrough. The height H of bead 716 is substantially constant. When the height is substantially constant, the planes through the proximal and distal ends of the beads are substantially parallel. When the height is not constant, the planes are not parallel. Bead 716 is the same as proximal bead 706 in Figure 29A. In an embodiment with a lockable portion comprised entirely of beads that have a constant height, the lockable portion would have a straight configuration under compression. Figure 30B shows bead 718 with bores therethrough, wherein the height at portion 720 is less than at portion 721. Bead 718 has the same general shape as beads 702 and 704 in Figure 29A. The height of portion 720 can be adjusted to modify the curvature of the lockable portion. Generally, as height 720 decreases, the degree of the bend increases (i.e., the radius of curvature decreases). Similarly, the height of portion 721 can be modified to modify the curvature. Figure 30C illustrates bead 722 that can be injection molded. Bead 722 includes two outer wire features 724 and two inner wire features 726 formed in bead 722. Each outer wire feature has a portion that overlaps with a portion the corresponding inner wire feature to define an opening through which a control wire can pass. Molding the bead with the wire features to create the wire bore can be easier than forming a hole the entire way through the bead. Bead 722 is formed to have 2 control wires pass therethrough. Figure 30D illustrates bead 730 that can be injection molded. Bead 730 includes two indentations 732 and two indentations 734. The indentations in bead 730 allow for the height of wire bore 736 to be less than it would be without the indentations. The indentations can make the wire bores easier to mold. Figure 30E illustrates bead 740 including tabs 742 stamped therein. The tabs are stamped in the body of bead 740 to form wire openings 744, through which a control wire is passed. Bead 740 can be, for example, a hypotube, sheet metal rolled into an annular shape, etc. Figure 30F is similar to Figure 30E and includes interlocking features including interlocking elements 754 (male) and 756 (female). The interlocking features generally enhance torque transmission. The interlocking feature could be comprised of any interlocking elements described herein or any other suitable interlocking elements. Figure 30G illustrates bead 760 including an inner corrugated member 764 and outer member 762. The spaces between inner member 764 and outer member 762 define control wire bores 768, which are adapted to receive control wires therethrough. In Figure 30G, twelve control wires can be passed through bead 760. Figure 30H shows a plurality of beads 760 (from Figure 30G) and 770, each with inner member 764 and outer member 762. In adjacent beads 760 and 770, the control wire bores are defined by peaks and valleys formed in the inner members on adjacent beads.

[00125] While the embodiments have been shown with control wires being secured relative to a single bead, all of the control wires in a lockable portion need not be secured to the same bead. For example, a control wire can be secured to any bead in the lockable portion.

[00126] The locked configuration of the lockable portion can be modified by modifying characteristics of the beads. For example, the number of beads in the lockable portion can be modified to

2015210338 04 Aug 2015

change the radius of curvature. The height of portion of the beads can be modified, as shown in the comparison between Figure 30A and 30B. The lockable portion additionally need not include beads of the same type. For example, a lockable portion could alternate the beads shown in Figures 30A and 30B, creating a curve with a degree of bend less than that shown in Figure 29A. Beads of similar design can be rotationally offset from one another along the length of the lockable portion. For example, in the embodiment in Figure 29A, every other bead could be rotated 90 degrees in the same direction relative to the adjacent beads. Additionally, the relative angle between the control wire bore axis and the plane of a bead end can be adjusted. For example, in Figure 30B, the axes of control wire bores 719 can be substantially 90 degrees relative to the plane of the distal end of bead 718. The axes of bores 719, can, however, be offset such that they are not substantially 90 degrees relative to the plane of the distal end of bead 718.

[00127] The beads as described herein can have almost any length. In some embodiments a bead is a section of straight tubing. Any bead can also incorporate any of the slotted cut patterns described herein

[00128] While the lockable portions have been shown to include curved, or bent sections, the lockable device can have a locked configuration in which the device is substantially straight. For example, if the lockable device included 2 or more beads as shown in Figure 30A, the lockable device would have a substantially straight locked configuration.

[00129] In some embodiments the lockable device could have a floating liner (as described herein) disposed therein. The floating liner could, in some embodiments, secured to the distal-most bead. The lockable device could alternatively or additionally have an outer liner disposed on the outside of the lockable device. The outer liner could also be secured to the distal-most bead or the outer liner could be affixed to the inner liner and the beads left to float inside.

[00130] In some embodiments the lockable device (e.g., the device shown in Figures 29A and 29B) is adapted to be advanced over a steerable device within the subject. For example, a traditional guidewire or the steerable device shown in Figures 2A-2C can be steered to a desired location within the subject. A lockable device, such as a beaded lockable device described herein, can then be tracked over the steered device. The lockable device comprising at least two beads is flexible to allow it to follow the curvature of the steered device. Once the lockable device has been advanced over the steered device to the desired position, the beads of the lockable device are locked in place as described herein, and the lockable device assumes its preset configuration.

[00131] In alternative embodiments, the lockable portion (e.g., the beaded structure in Figures 29A and 29B) includes a floating liner therein.

[00132] In an exemplary embodiment of use, a guiding element (e.g., a guidewire) is advanced to a desired location within the subject. The device comprising the lockable portion is then tracked over the guiding element until it reaches a desired position. The lockable portion is then actuated to change the configuration of the lockable portion to the desired configuration. The lockable portion is then maintained, or locked, in the desired configuration. A medical device, medical instrument, or other device is then advanced therethrough to a target location within the subject.

2015210338 04 Aug 2015

[00133] While preferred embodiments of the present disclosure have been shown and described herein, it will be obvious to those skilled in the art that such embodiments are provided by way of example only. Numerous variations, changes, and substitutions will now occur to those skilled in the art without departing from the disclosure. It should be understood that various alternatives to the embodiments of the disclosure described herein may be employed in practicing the disclosure. The following claims define the scope of the disclosure and that methods and structures within the scope of these claims and their equivalents are covered thereby.

Claims

1. A steerable medical device, comprising:

a steerable portion;

a first tubular member comprising a first flexible polymeric tubular member; and

a second tubular member comprising a second flexible polymeric tubular member, wherein the first tubular member is disposed within the second tubular member and permanently axially fixed to the second tubular member at a fixation location distal to the steerable portion; and

an external controller that is adapted to be actuated to put one of the first tubular member and the second tubular member in tension and the other of the first tubular member and the second tubular member in compression, and wherein the first and second tubular members are adapted such that the steerable portion is steered in a first direction when the external controller is actuated.

2. The steerable medical delivery device of claim 1 wherein the first and second flexible polymeric tubular members each comprise a wall of solid material along the steerable portion.

3. The steerable medical delivery device of claim 2 wherein the first and second tubular members each further comprise a structural support embedded in the respective first and second flexible polymeric tubular members.

4. The steerable medical delivery device of claim 2 wherein the first and second flexible polymeric tubular members each comprise a variable structure in the steerable portion, and the variable structures impart the respective preferential bending.

5. The steerable medical delivery device of claim 4 wherein the variable structures for each is a variable thickness in the steerable portion, and the variable thicknesses impart the preferential bending in the respective first and second tubular members.

6. The steerable medical device of claim 1 wherein the first and second tubular members are configured to preferentially bend in opposite directions.

7. The steerable medical device of claim 1 wherein the external controller is adapted so that when the actuator is actuated, the first tubular member and the second tubular member are axially moved relative to one another within the external controller.

20152103338 04 Aug 2015

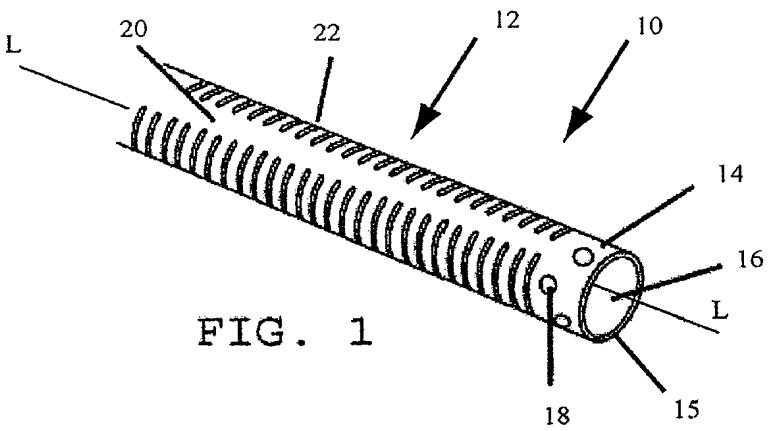


FIG. 1

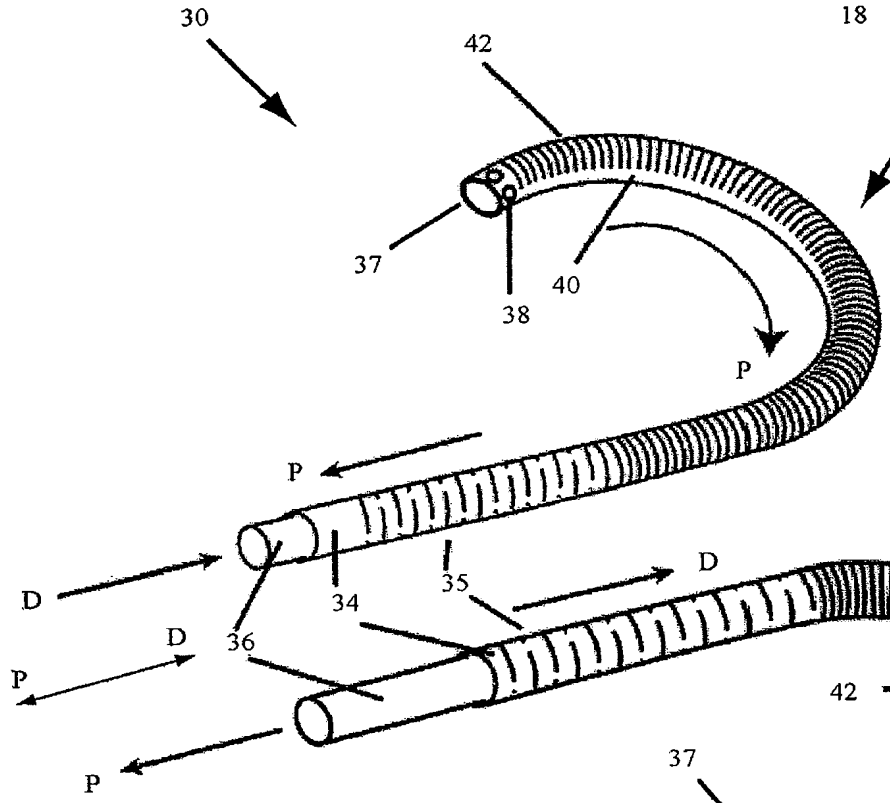


FIG. 2a

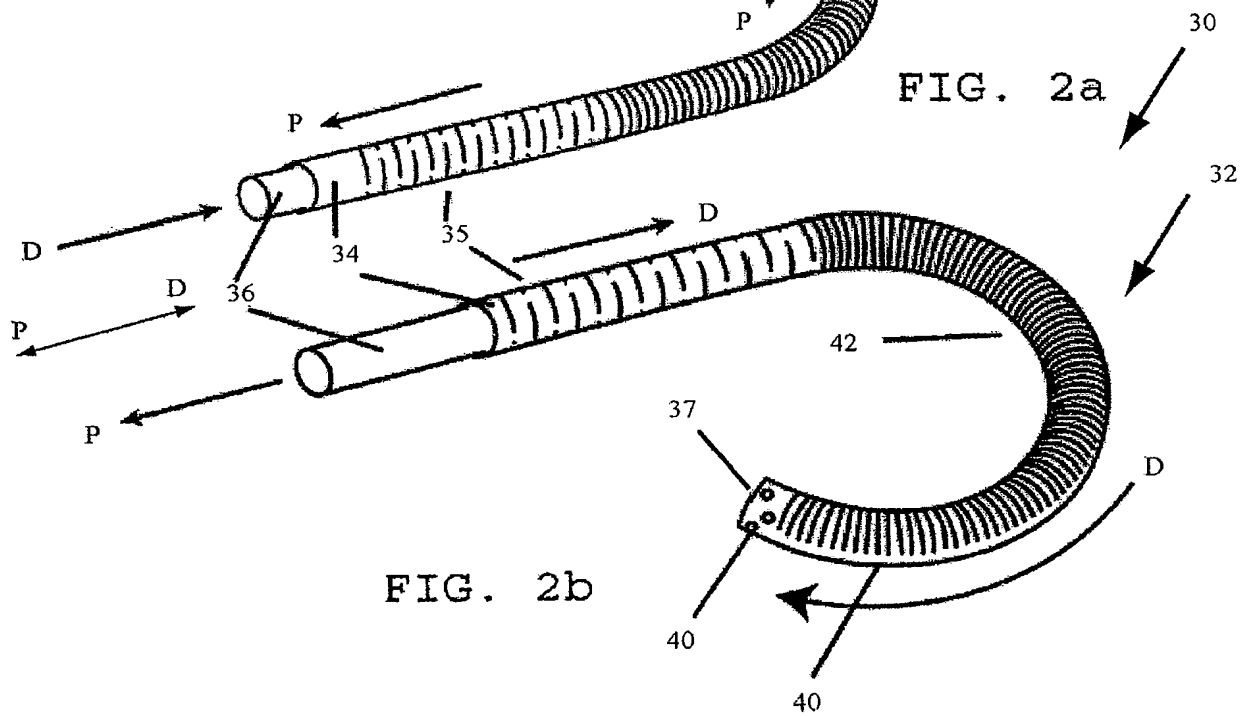


FIG. 2b

2015210338 04 Aug 2015

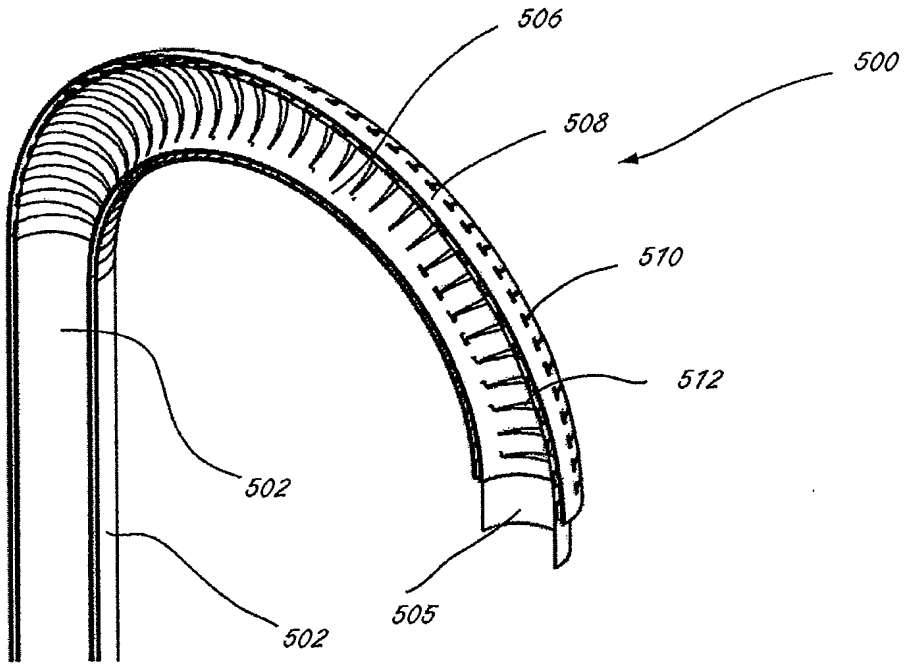


Fig 2c

20152103338 04 Aug 2015

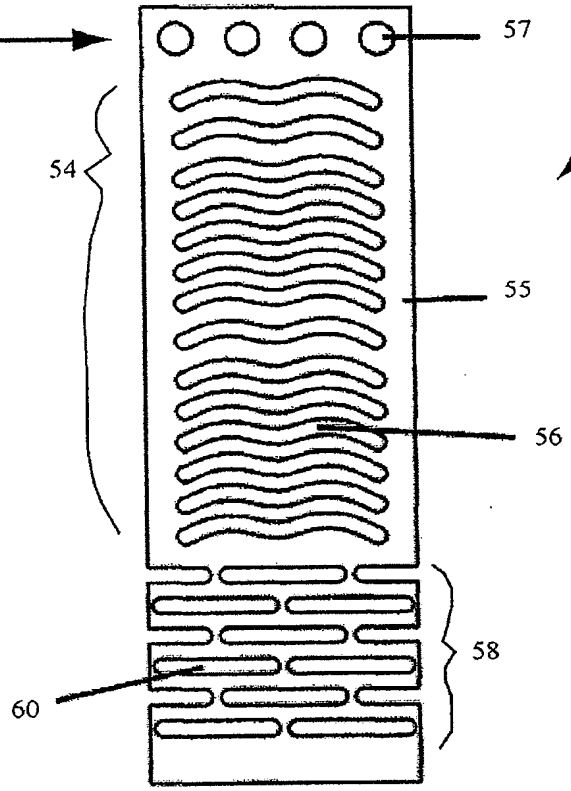


FIG. 3

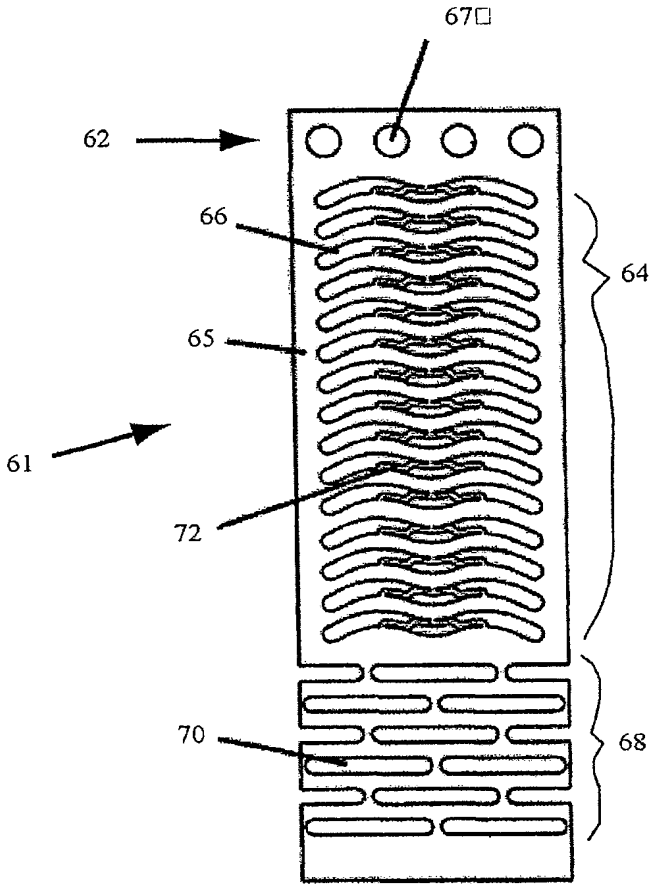


FIG. 4

2015210338 04 Aug 2015

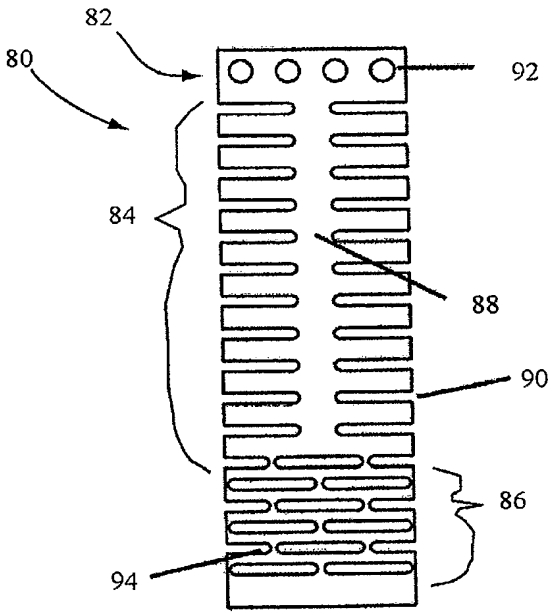


FIG. 5

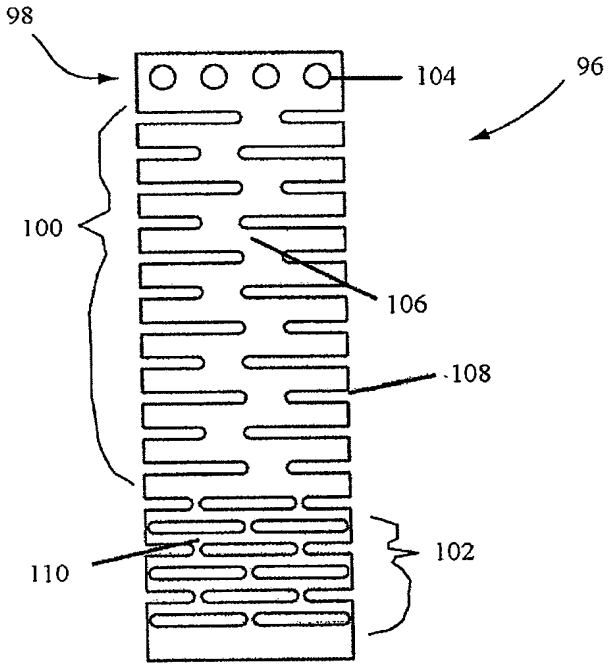


FIG. 6

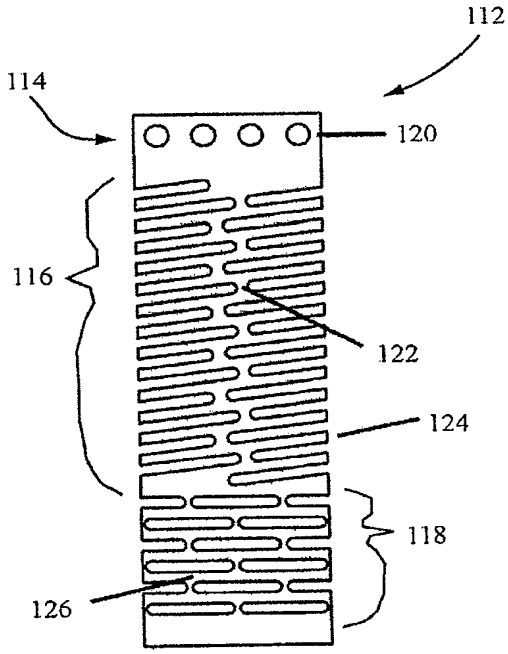


FIG. 7a

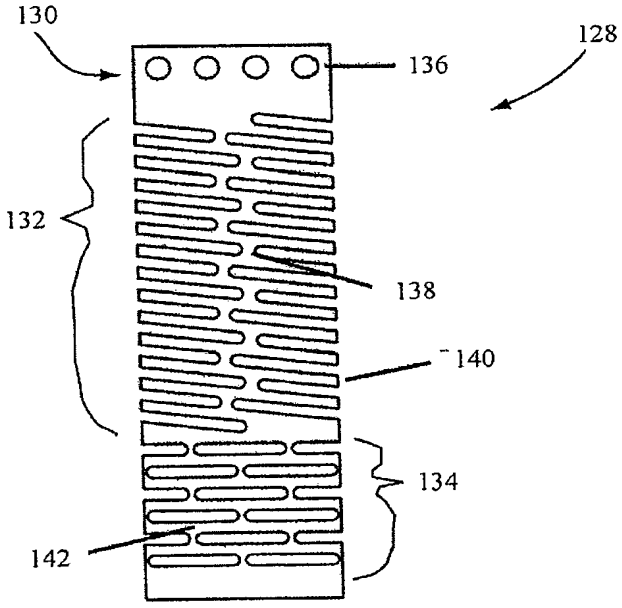


FIG. 7b

2015210338 04 Aug 2015

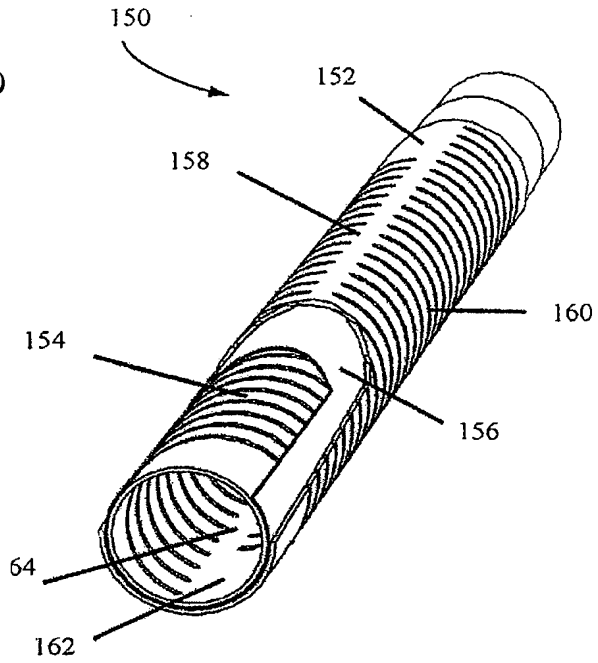


FIG. 8

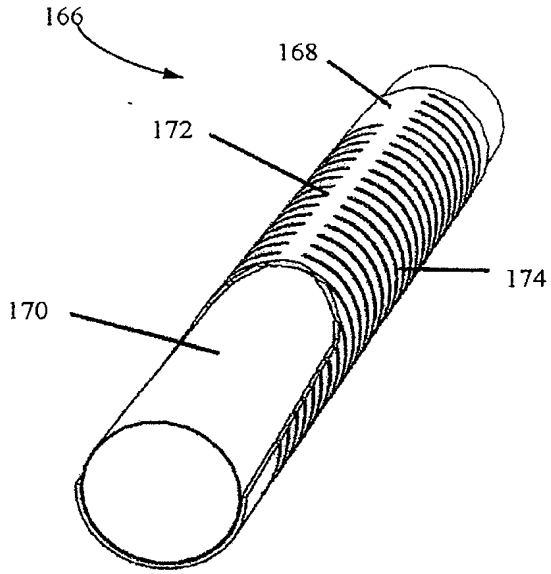


FIG. 9

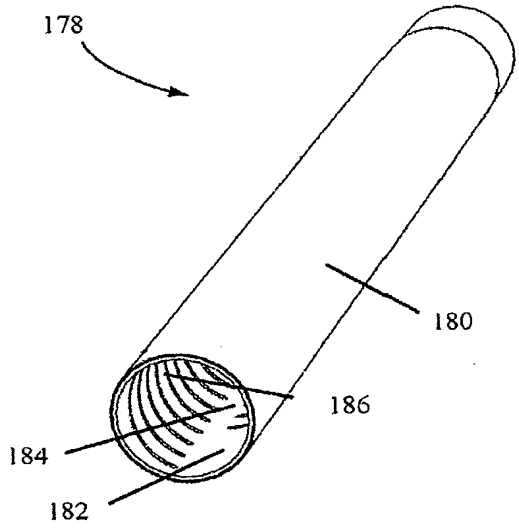


FIG. 10

2015210338 04 Aug 2015

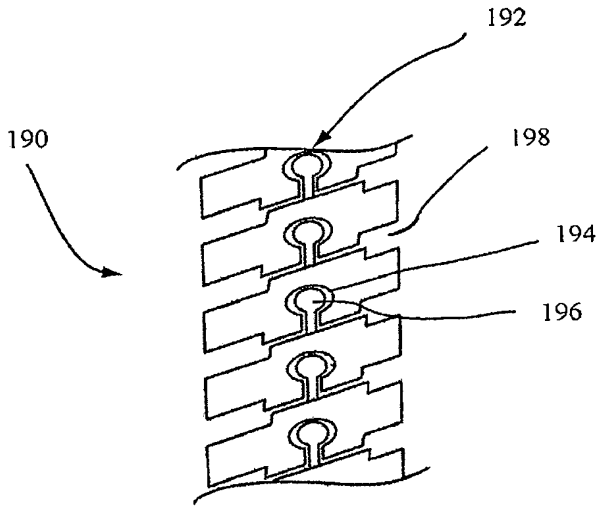


Fig 11A

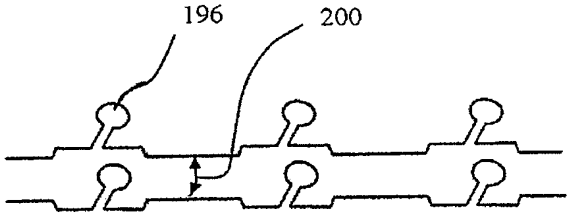


Fig 11B

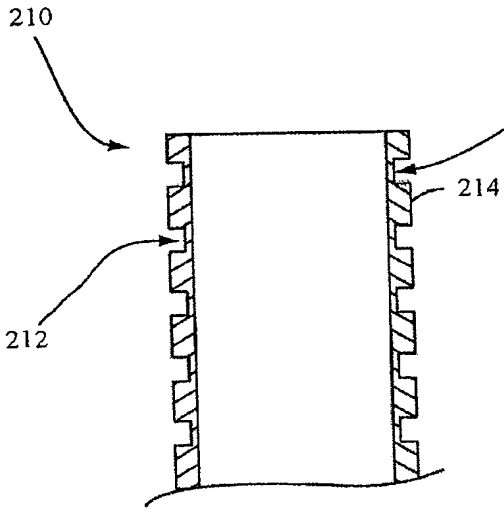


Fig 12A

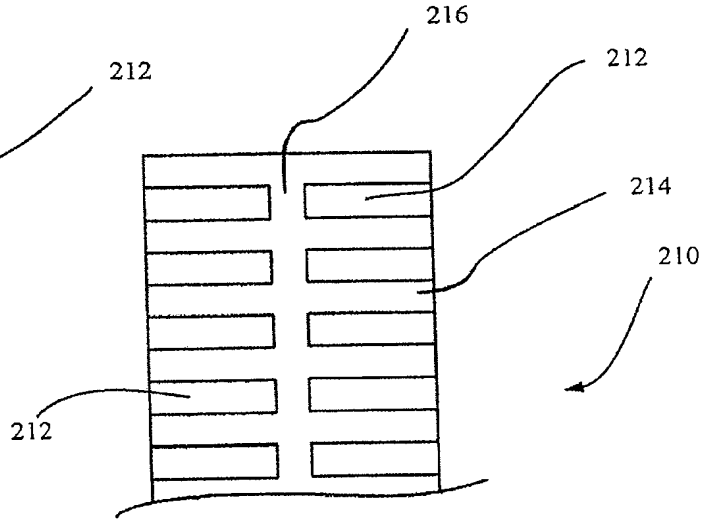


Fig 12B

20152103338 04 Aug 2015

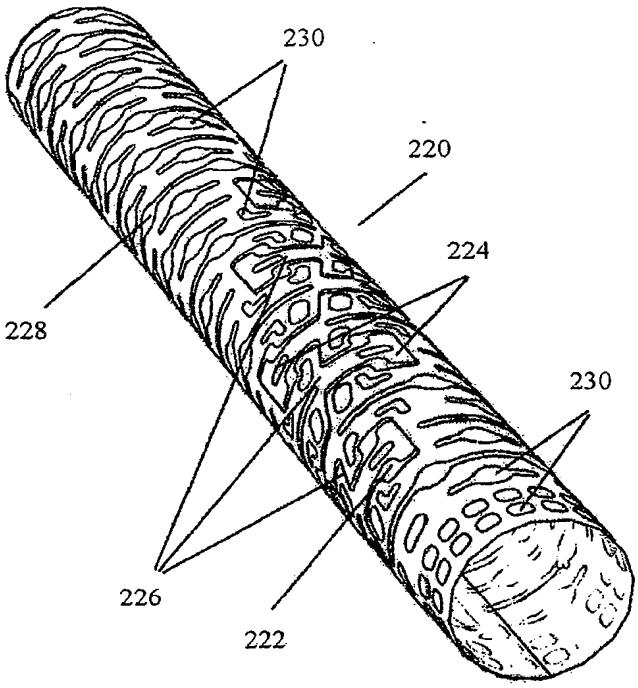


Fig 13a

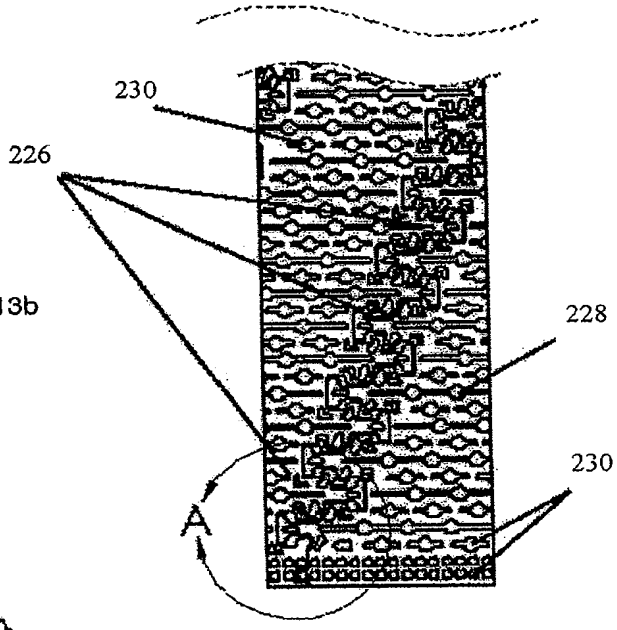


Fig 13b

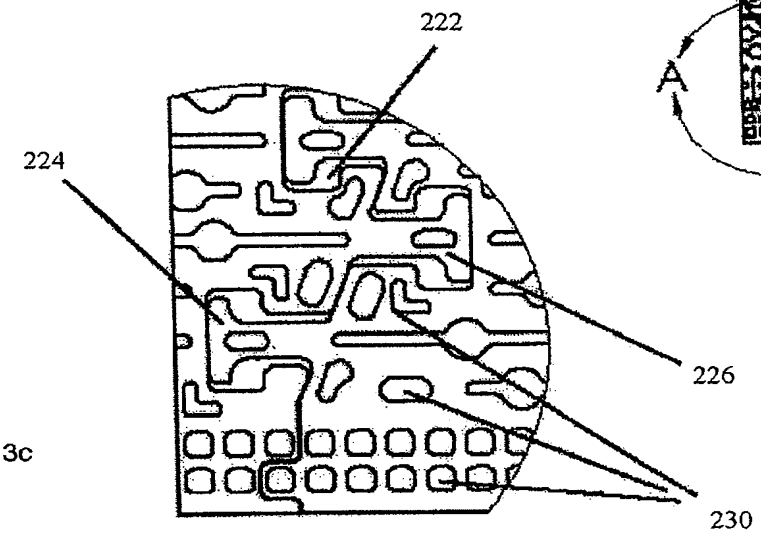


Fig 13c

2015210338 04 Aug 2015

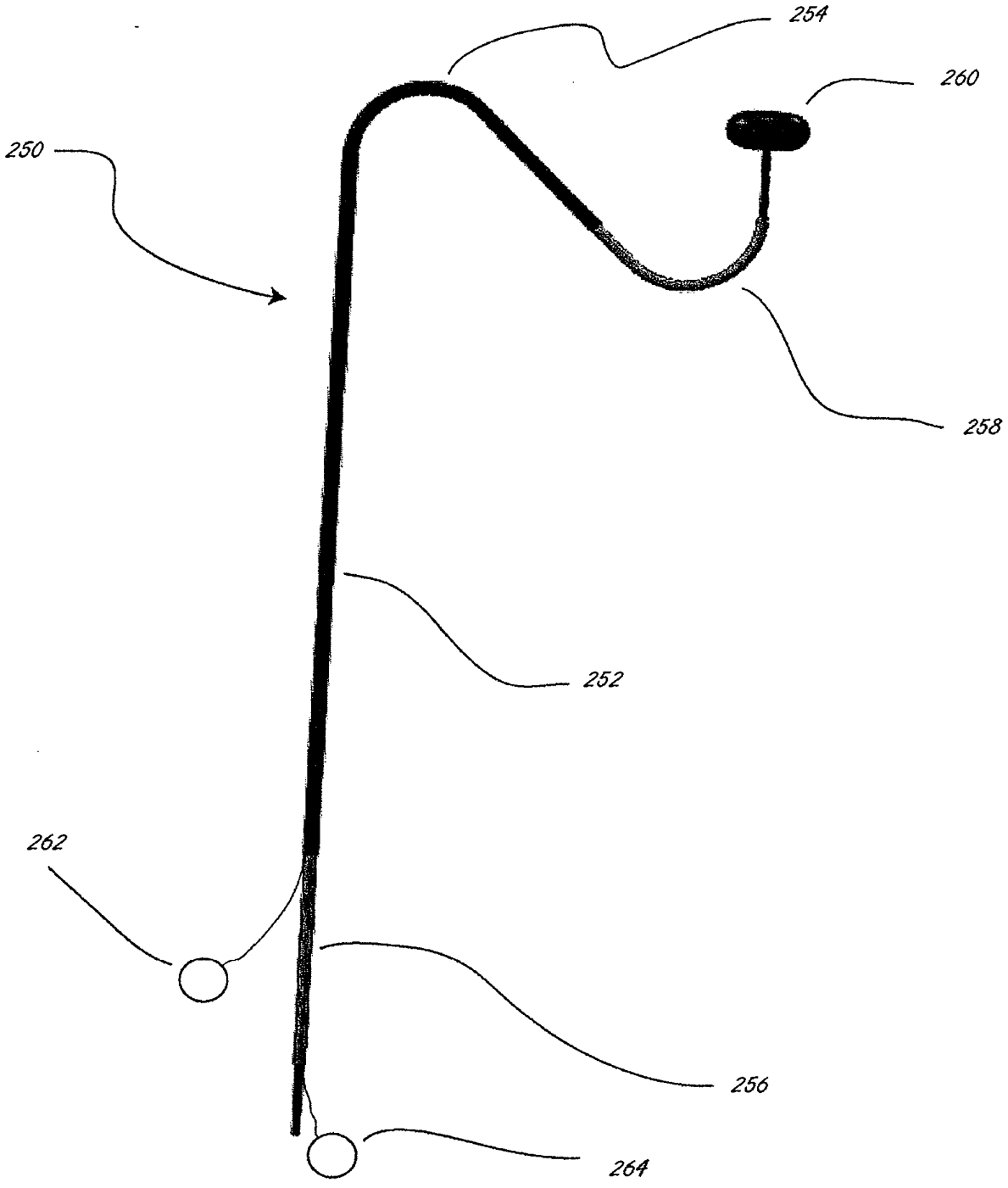


Fig 14

2015210338 04 Aug 2015

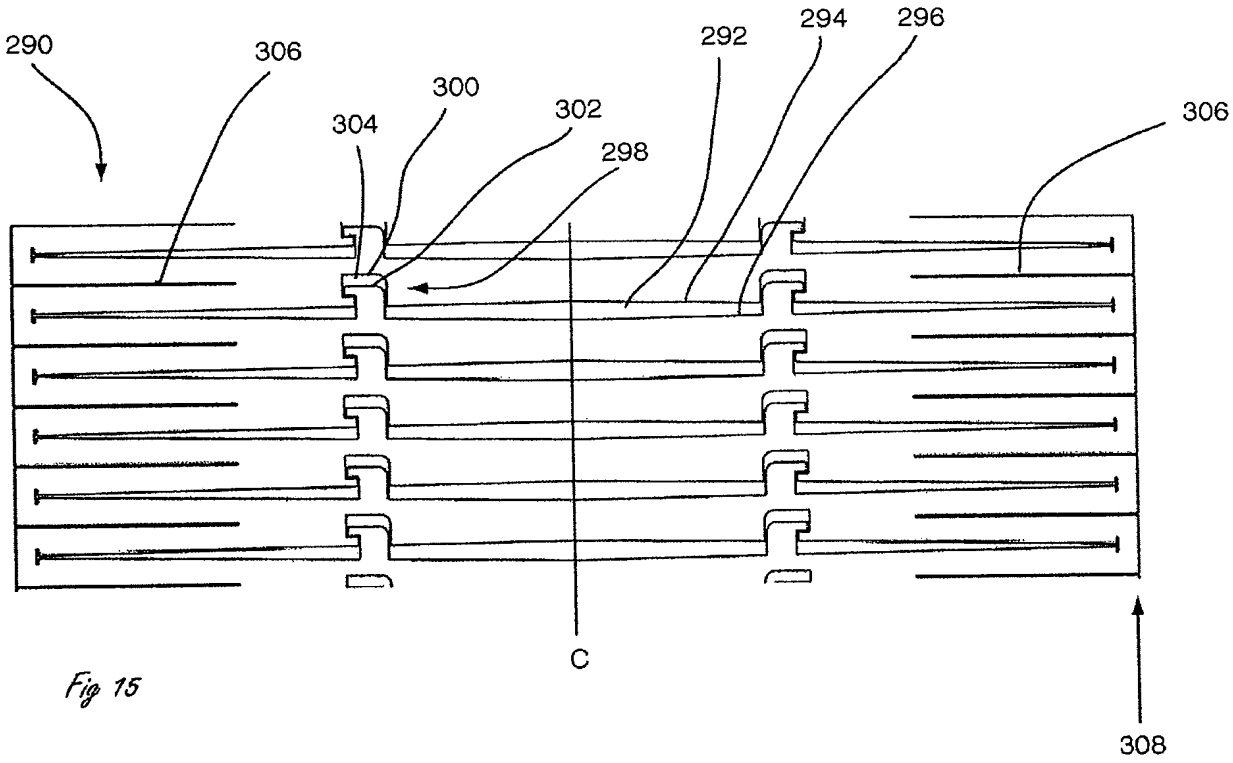


Fig 15

20152103338 04 Aug 2015

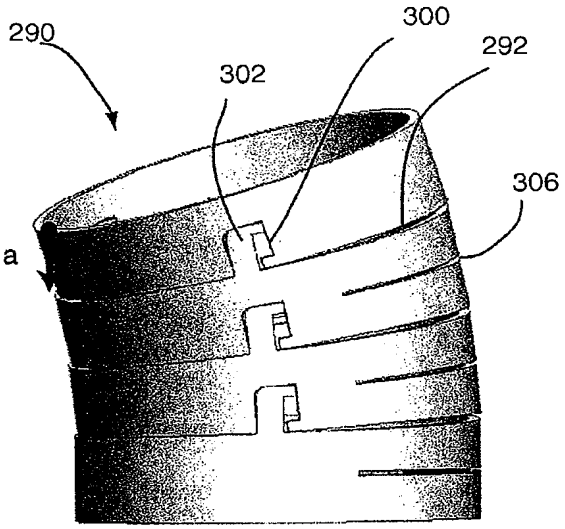


Fig 16a

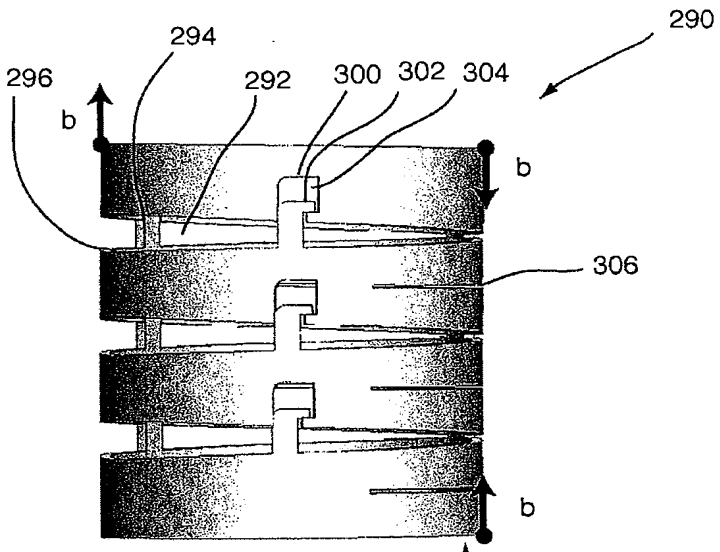


Fig 16b

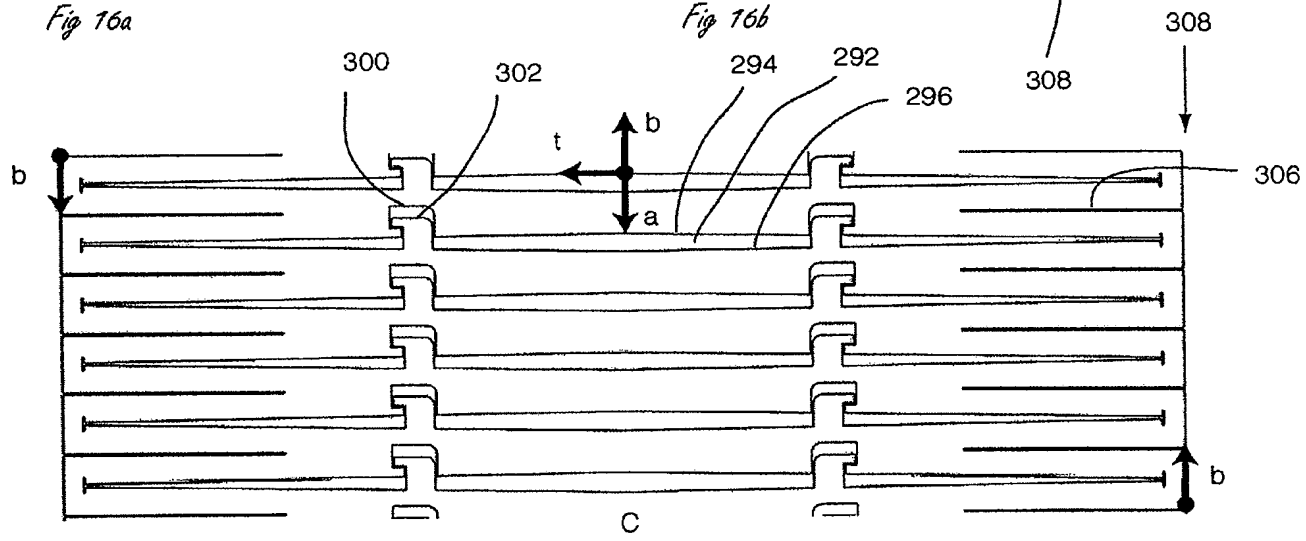


Fig 16c

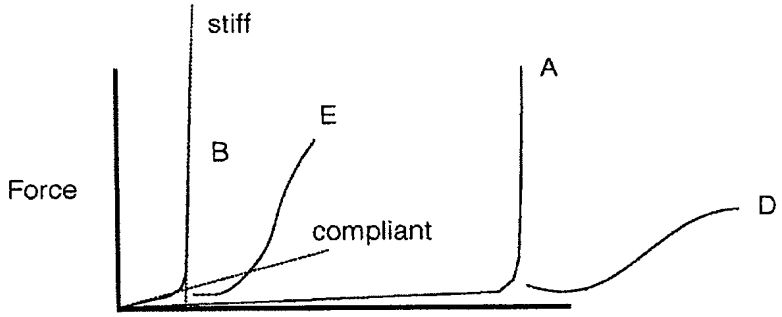


Fig 17

2015210338 04 Aug 2015

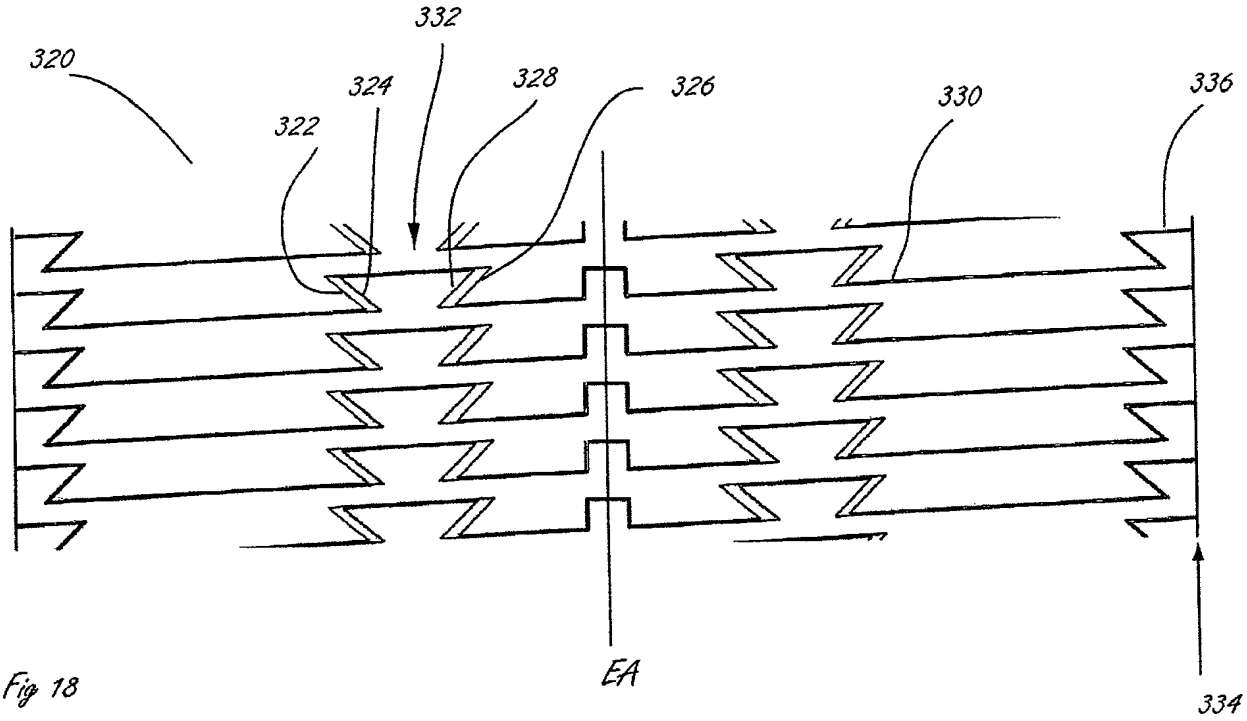


Fig 18

2015210338 04 Aug 2015

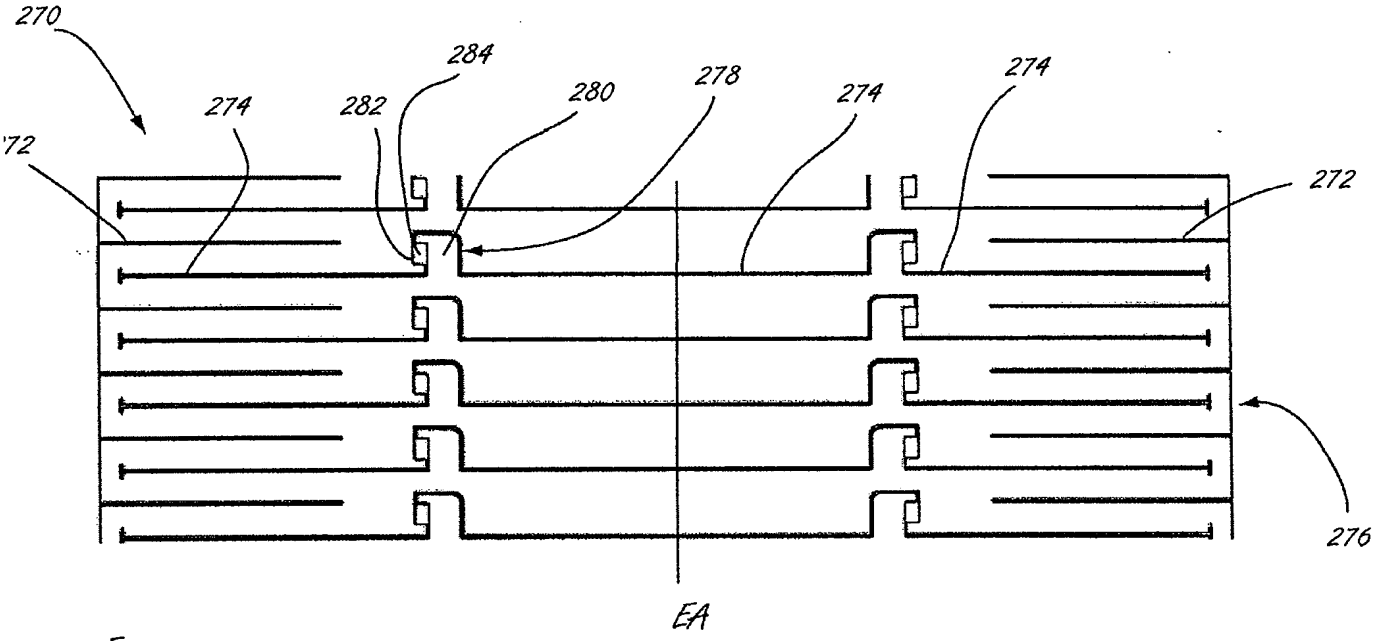


Fig 19

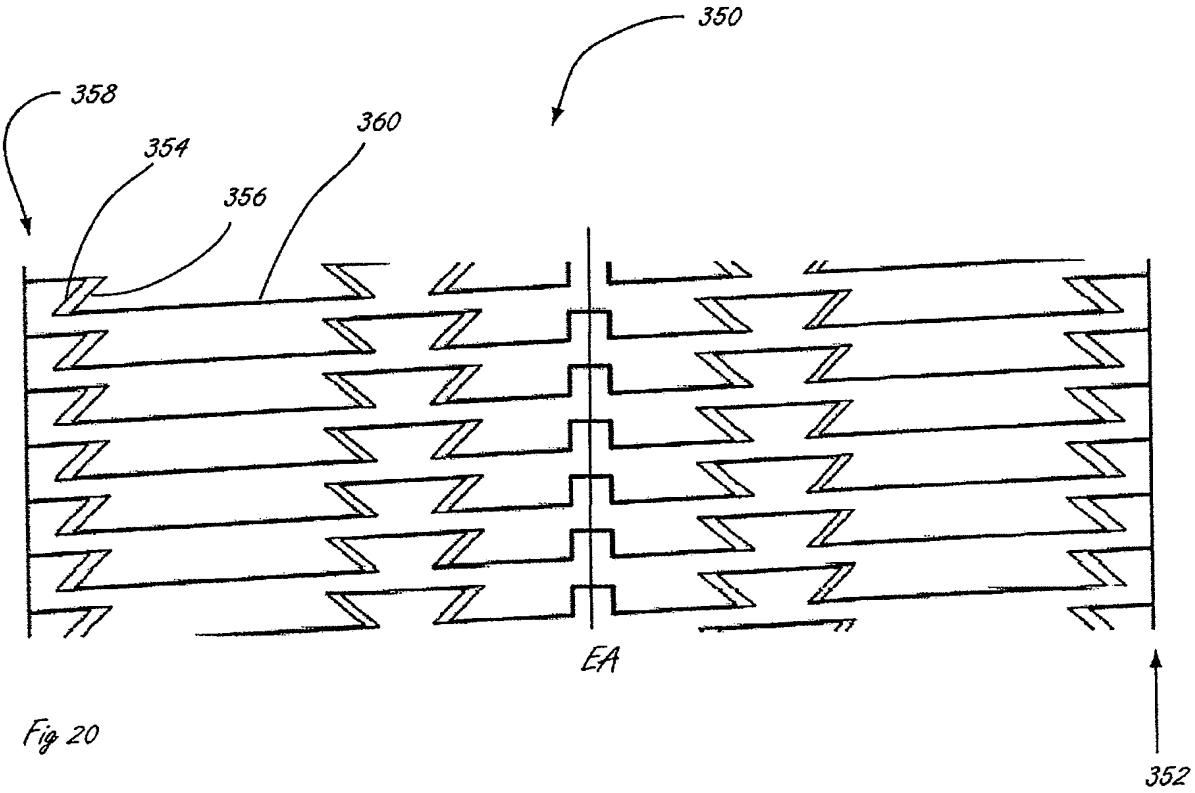


Fig 20

04 Aug 2015 2015210338

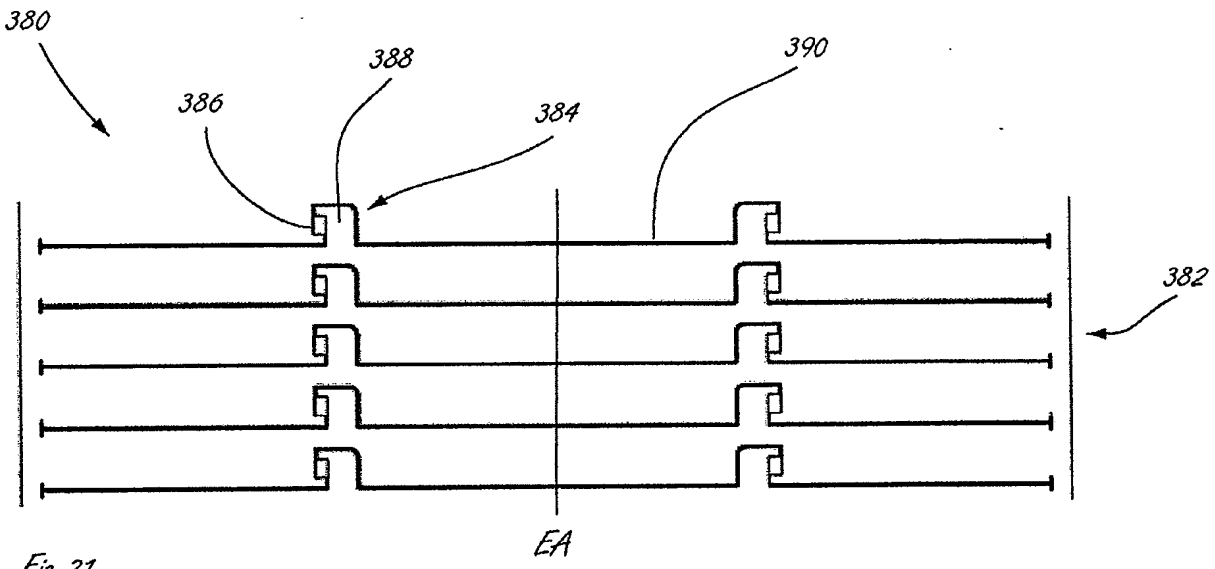


Fig 21

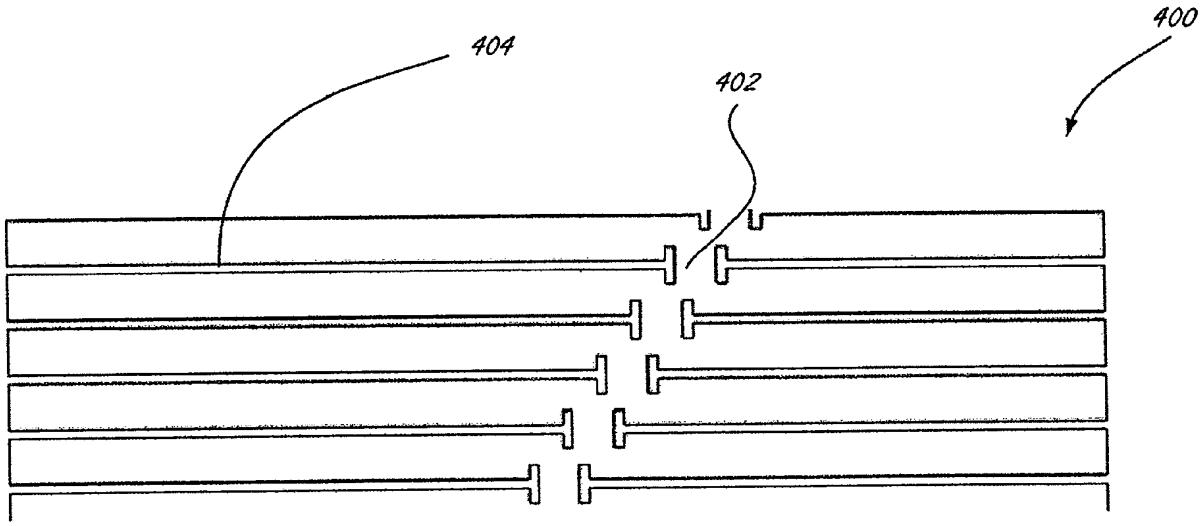


Fig 22

20152103338 04 Aug 2015

Fig 23

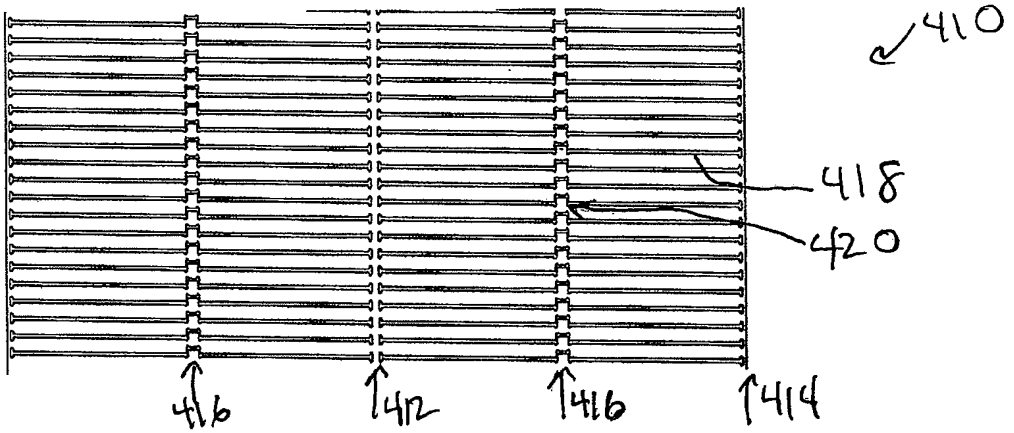


Fig 24

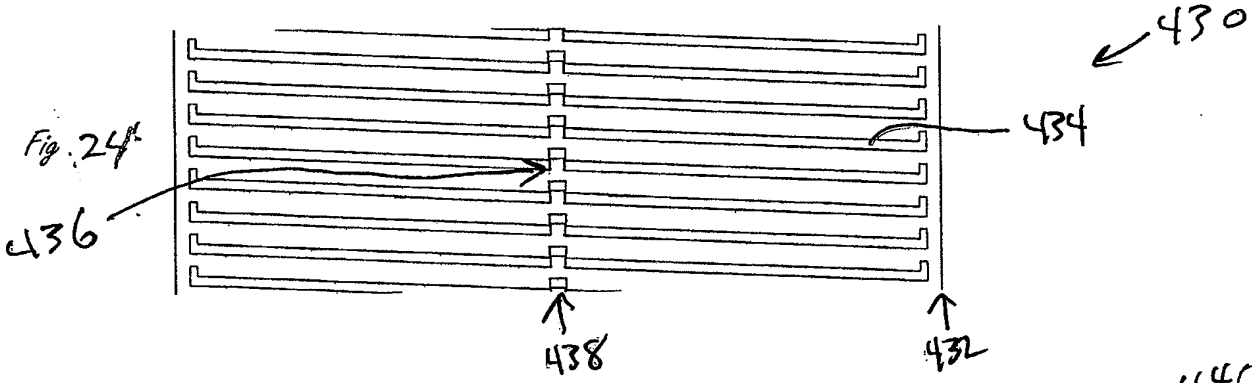


Fig 25

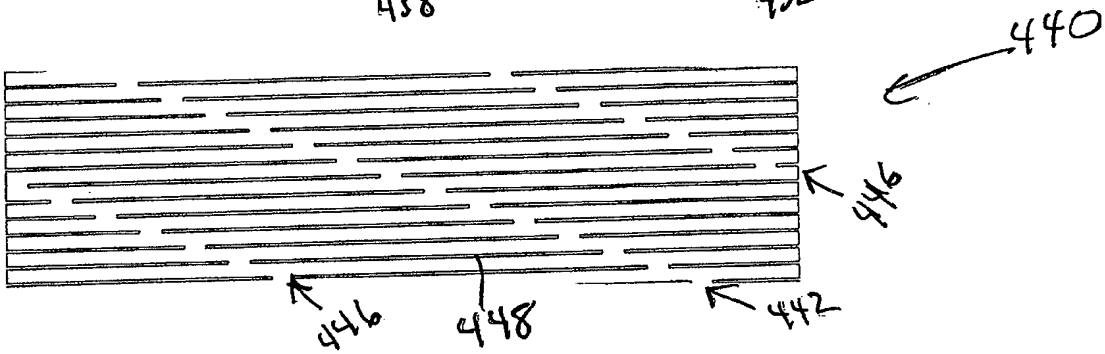
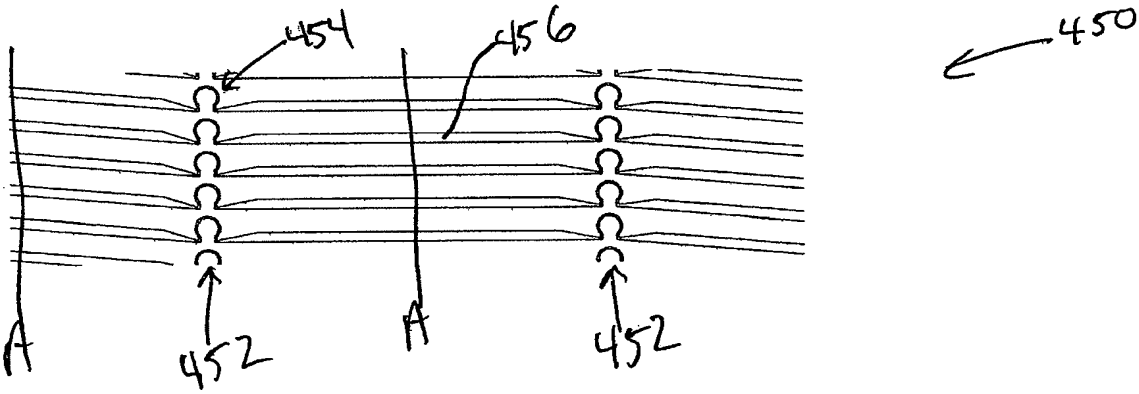


Fig 26



20152103338 04 Aug 2015

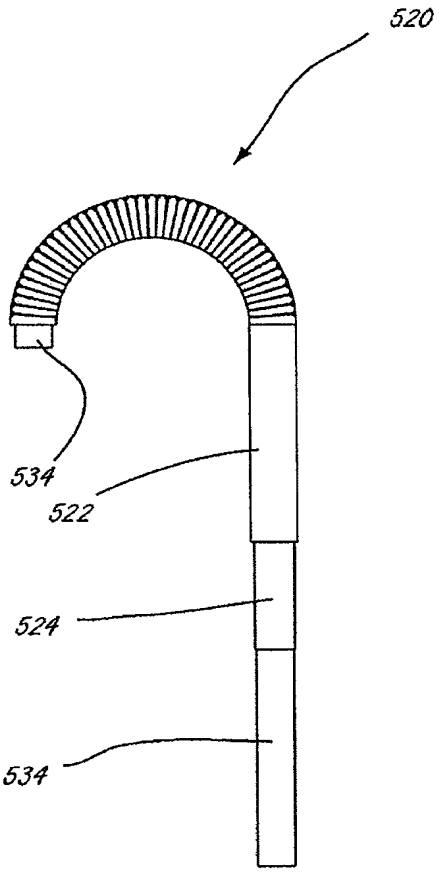


Fig 27

2015210338 04 Aug 2015

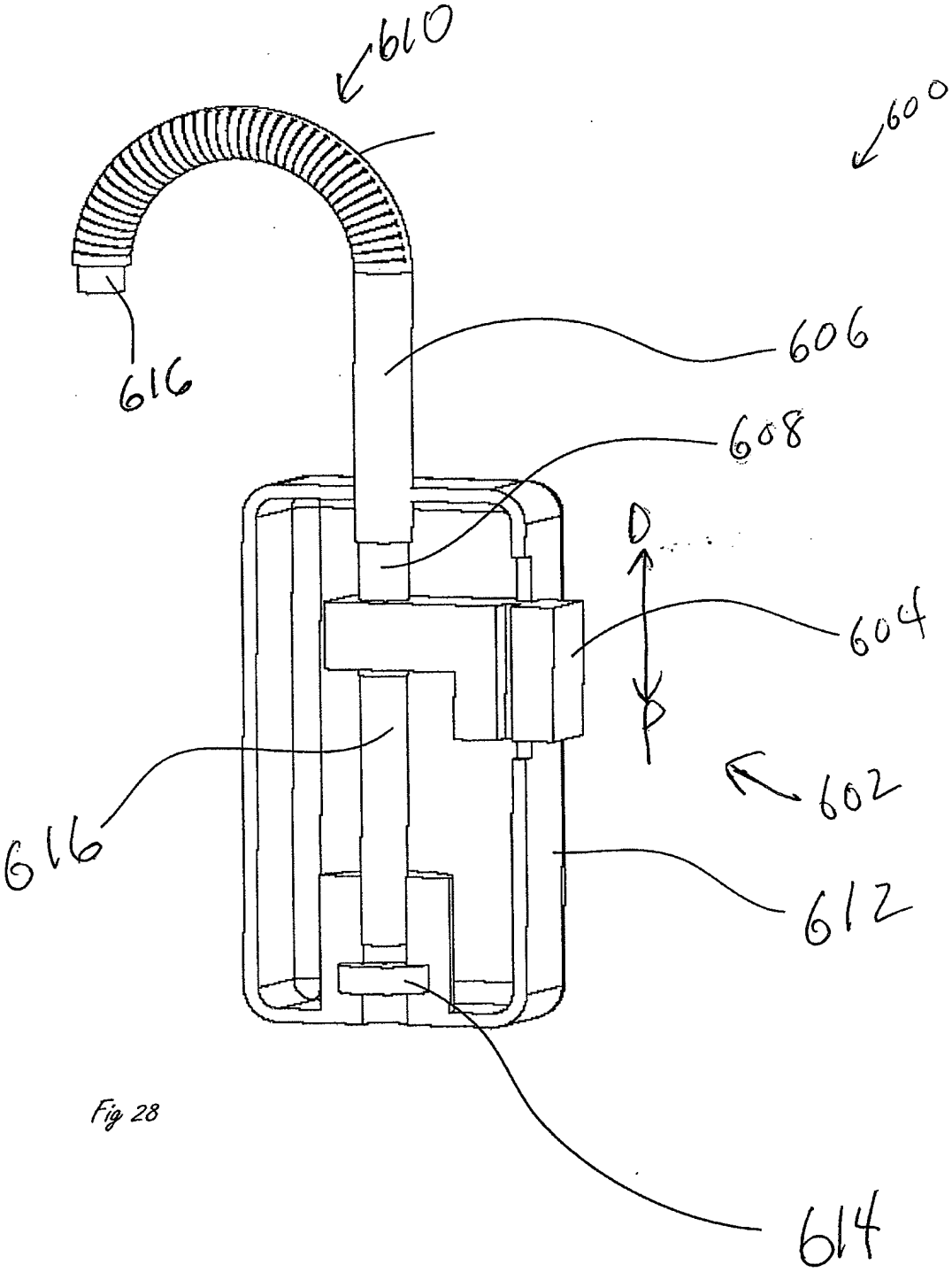


Fig 28

20152103338 04 Aug 2015

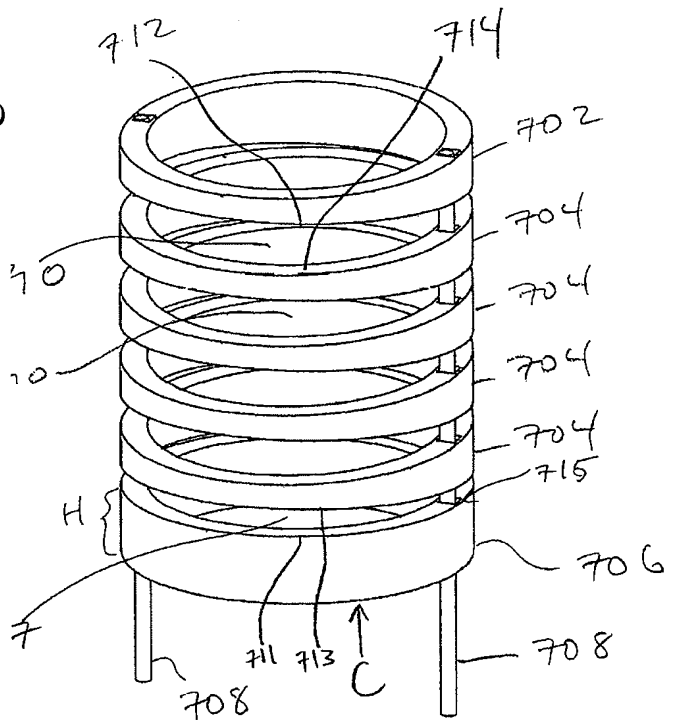


FIG. 29A

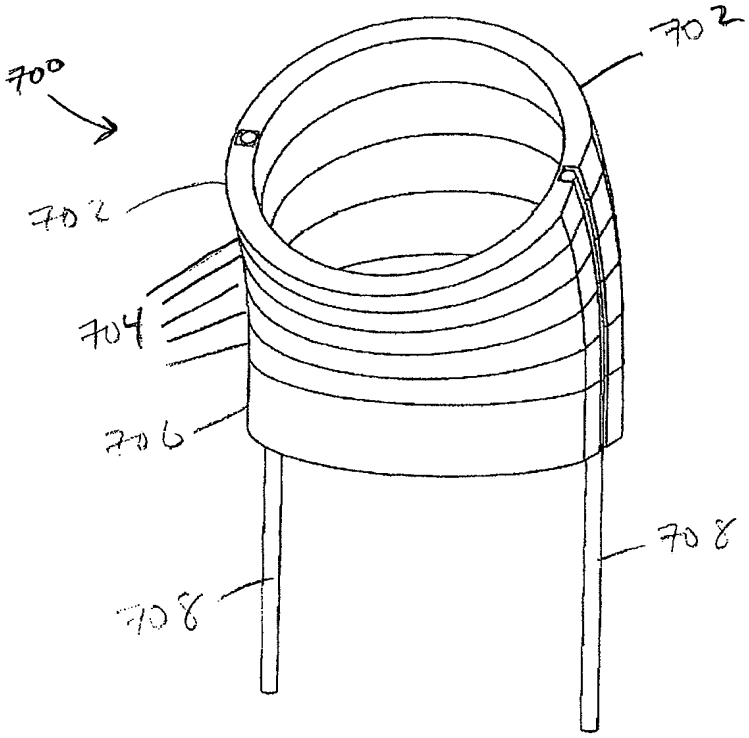


FIG. 29B

20152103338 04 Aug 2015

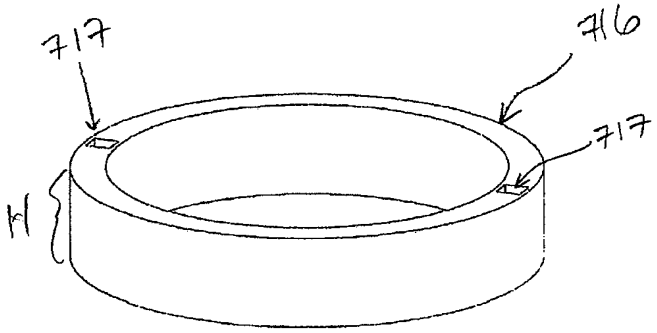


FIG. 30A

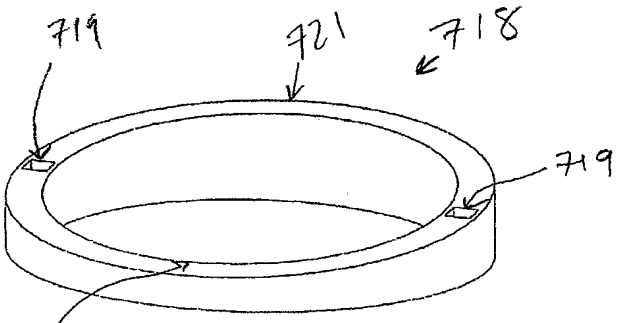


FIG. 30B

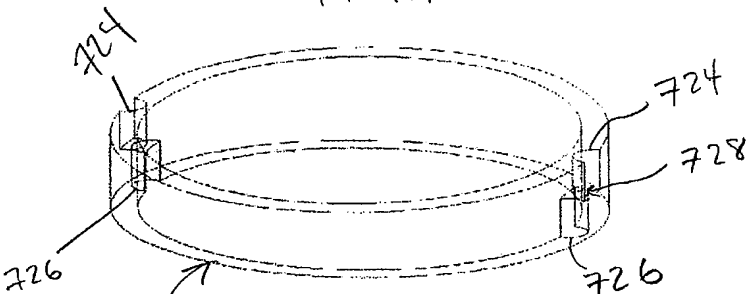


FIG. 30C

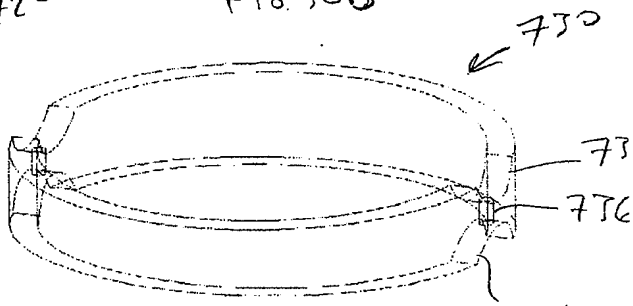


FIG. 30D

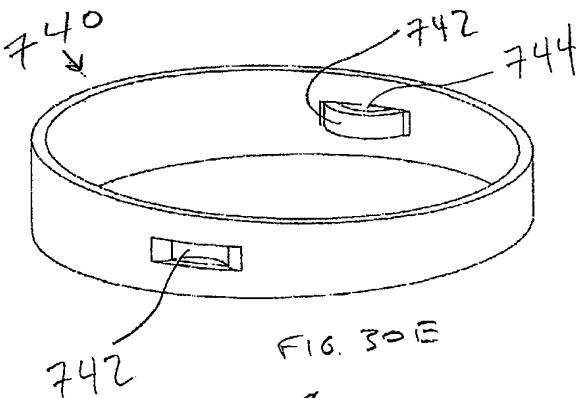


FIG. 30E

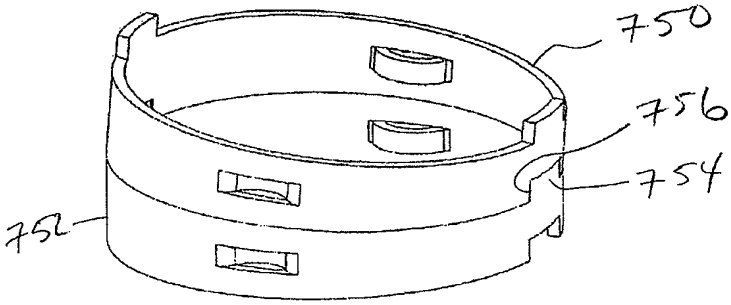


FIG. 30F

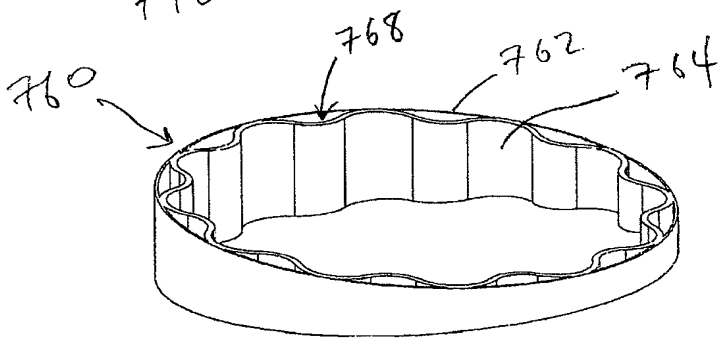


FIG. 30G

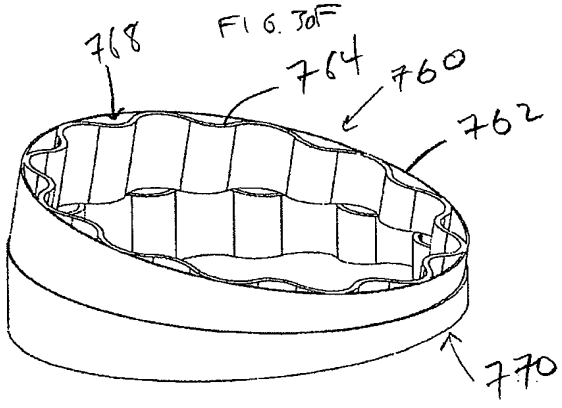


FIG. 30H

1588072

PATENT SPECIFICATION (11) 1588072

(21) Application No. 3838/78 (22) Filed 31 Jan. 1978 (19)
(31) Convention Application No. 767696 (32) Filed 11 Feb. 1977 in
(33) United States of America (US)
(44) Complete Specification published 15 April 1981
(51) INT. CL.³ A61B 17/50
(52) Index at acceptance
A5R CX

(54) EXTRACTING DEVICE FOR REMOVING OBJECTS FROM HUMAN BODY PASSAGES

(71) I, WILLIAM HOWARD BEECHER, a citizen of the United States of America of 292 Boyd Avenue, Elmhurst, Illinois 60126, United States of America, do hereby declare the invention, for which I pray that a patent may be granted to me, and the method by which it is to be performed, to be particularly described in and by the following statement:—

This invention relates to an extracting device for removing kidney stones or other objects from the urinary tract or other passages of the human body, some of which, such as blood vessels, may be reached through incisions.

An object of the present invention is to provide a new and improved extracting device which can easily be inserted into the ureters or other narrow passages of the human body, and will be capable of removing kidney stones and other objects in a highly effective and efficient manner.

A further object is to provide such a new and improved extracting device which will be capable of removing kidney stones and other similar objects from narrow passages of the human body, without scratching or otherwise injuring the walls of the passages.

According to the present invention there is provided an extracting device comprising an outer flexible tube the distal end of which is insertable into a body passage, an inner flexible tube slideably received within the outer tube for free longitudinal sliding movement with the distal end of the inner tube normally projecting beyond the distal end of the outer tube, the inner and outer tubes having clearance space therebetween for carrying fluid under pressure, a thin, tubular, highly distendable and limp sleeve having its proximal end portion connected to the distal end of the outer tube, the sleeve having a distal end portion which is inverted and is connected to the distal end of the inner tube for insertion into the body passage, the sleeve being otherwise free to expand upon inflation, the tubular sleeve having first and second tubular surfaces on opposite sides of the sleeve,the first surface facing inwardly at the proximal end portion of the sleeve, the inverted distal end portion of the sleeve being turned inside out with the second surface facing inwardly, the sleeve being inflatable by fluid transmitted along said clearance space to dilate the body passage, the sleeve when inflated having an annular flaring portion bulging beyond the distal end of the inner tube and curved convexly in longitudinal section for sealing engagement with a foreign object in the body passage, the annular flaring curved portion being soft, pliable and capable of conforming to the shape of the foreign object to effect a seal therewith, the inner tube being operative to transmit suction for capturing and holding the foreign object in sealing engagement with the annular flaring portion of the sleeve, and means for retracting the inner tube relative to the outer tube while the suction pulls the foreign object within the confines of the sleeve and the sleeve is progressively turned inside out around the foreign object to envelop the foreign object for removal with the tubes.

The sleeve may be inflatable by compressed air or some other fluid transmitted along the clearance space between the outer and inner tubes. The inflation of the sleeve dilates the body passage, so as to loosen any kidney stone or the like which may be lodged in the passage. A pressure source and a control valve are preferably connected to the free end of the outer tube, for selectively supplying fluid pressure thereto so as to inflate the sleeve.

A vacuum source and a vacuum control valve are preferably connected to the free end of the inner tube, for selectively providing a vacuum or suction within the inner tube, to suck the kidney stone against the end of the inflated sleeve, so as to capture the kidney stone. The inner tube is then retracted relative to the outer tube, so that the kidney stone will be pulled into the confines of the sleeve. Simultaneously, the sleeve is preferably deflated so that the sleeve will enfold the kidney stone. The outer and inner tubes may then be withdrawn from the body passage, so as to remove the kidney stone or other object. The sleeve surrounds the kidney stone and

prevents it from scratching or otherwise injuring the inner walls of the body passage.

The flexible inner and outer tubes are preferably made of a resinous plastics material, such as polyethylene, for example. An X-ray contrast medium is preferably incorporated into or coated upon the material of the outer or inner tube, so that an X-ray fluoroscope may be used to assist in inserting the outer tube into the ureter or other body passage. Alternatively, the probe formed by the outer and inner tubes can be rendered visible on an X-ray fluoroscope by inserting a flexible metal wire within the inner tube. Alternatively, a fiber optic device can be used for observing and guiding the probe during insertion.

The inflatable sleeve is preferably made of a thin elastic latex rubber material or the like.

A manipulator is preferably connected to the free ends of the outer and inner tubes, so that the operator can easily advance and retract the inner tube, relative to the outer tube, with the thumb and fingers of one hand. The other hand may then be employed to operate the control valves which regulate the air pressure and the suction.

The inflatable sleeve preferably has first and second reduced end portions which are stretched around and secured to the outer and inner tubes. The second end portion is reentrant in that it extends into the sleeve, so that the inflated sleeve will project endwise beyond the end of the inner tube. In this way, the inflated sleeve will be capable of forming a seal with the kidney stone or other object to be removed.

One or more auxiliary tubes may be inserted through the inner tube to provide auxiliary communication with the body passage. The auxiliary tubes may be employed to supply various medications. The auxiliary tubes may also be employed to withdraw mucus or other fluids from the body passage. An auxiliary tube having a plurality of tube elements or bores may be employed if desired.

Alternately, one or more auxiliary tubes may be inserted into the body passage along with the outer tube.

While the extracting device is particularly well adapted for removing kidney stone from the urinary tract, the extracting device may also be employed for removing gallstones, by inserting the extracting device through a drainage tube which has been installed during gallbladder surgery. The extracting device may also be employed to remove foreign objects from the respiratory tract or the esophagus. In addition, the extracting device may be employed to remove blood clots, foreign materials or foreign bodies from blood vessels, by inserting the extracting device through an incision into the blood vessel.

The invention will now be described by way of example with reference to the accompanying drawings, in which:

Fig. 1 is an elevational view of an extracting device to be described as an illustrative embodiment of the present invention, the view being partly in longitudinal section.

Fig. 2 is a fragmentary longitudinal section of the extracting device, showing the inflatable sleeve in a changed position.

Fig. 3 is a fragmentary elevation of the manipulator for the extracting device, the view being taken generally as indicated by the line 3—3 in Fig. 1.

Fig. 4 is a fragmentary perspective view showing the inflatable sleeve on the insertable end of the extracting device.

Fig. 5 is a fragmentary perspective view, showing the manipulator for the extracting device.

Fig. 6(a) is a fragmentary enlarged longitudinal section of the extracting device, the view being partly diagrammatic.

Fig. 6(b) is a fragmentary section corresponding to a portion of Fig. 6(a) and showing a modified construction.

Fig. 6(c) is a fragmentary section corresponding to a portion of Fig. 6(a) and showing a modified construction with a sliding seal used with a snare, wire or one or more auxiliary tubes, to permit full use of the device with the snare, wire or one or more auxiliary tubes in place.

Figs. 7(a)—(g) are a series of fragmentary sections showing successive steps in a procedure whereby the extracting device may be used to capture and enfold a kidney stone or some other object in a human body passage.

Figs. 8(a)—(e) are a series of fragmentary sections showing successive steps in a procedure for advancing the insertable portion of the extracting device through a narrow body passage.

Fig. 9(a) is a fragmentary section showing the insertable portion of the extracting device, as employed in conjunction with an auxiliary tube adapted to be inserted into the body passage along with the extracting device.

Fig. 9(b) is a view similar to Fig. 9(a), but showing the extracting device in conjunction with two auxiliary tubes.

Fig. 9(c) is a view similar to Fig. 9(a), but showing the extracting device in conjunction with an auxiliary tube having three tube elements affording three individual passages.

Figs. 10(a)—(f) are a series of diagramatic sections showing several alternative constructions of the inflatable sleeve.

Figs. 11(a)—(f) are fragmentary longitudinal sections showing the insertable portion of the extracting device in conjunction with a snare to assist in capturing a kidney stone or other object, the views showing successive

steps of a procedure for capturing and enfolding the object.

Fig. 12 is an enlarged fragmentary section showing the insertable portion of the extracting device in conjunction with a stiffening wire or auxiliary tube, inserted through the inner tube of the extracting device.

Fig. 13 is a fragmentary enlarged longitudinal section showing the extracting device in conjunction with a plurality of auxiliary tubes, inserted through the inner tube of the extracting device.

Fig. 14(a) is a fragmentary enlarged section of the insertable portion of the extracting device in conjunction with an auxiliary tube having a plurality of tube elements to afford a plurality of individual passages, the tube being inserted through the inner tube of the extracting device.

Fig. 14(b) is a fragmentary cross section of the auxiliary tube shown in Fig. 14(a).

As just indicated, Figs. 1—6 illustrate an extracting device 20 comprising an outer flexible tube or sheath 22 capable of being inserted into a narrow passage of the human body, such as one of the ureters. The outer tube 22 is sufficiently long to be inserted through the urethra and the bladder into one of the ureters, and along such ureter as far as possible toward the corresponding kidney. The diameter of the outer tube 22 is such as to fit snugly but comfortably into one of the ureters. The inflatable sleeve 28 can be made in various sizes to accommodate various sized objects to be removed. The inner tube 24 and the outer tube 22 can be sized accordingly. The outer tube 22 may be made of a resinous plastics material, such as polyethylene, for example. The tube 22 is sufficiently flexible to conform to the shape of the body passage, while being sufficiently stiff to provide for insertion of the tube without causing it to collapse.

The outer tube 22 may be inserted into one of the ureters with the aid of an auxiliary device such as a cystoscope and an X-ray system having a fluoroscope. Thus, the insertable portion of the extracting device 20 should preferably incorporate a material which is sufficiently opaque to X-rays to be visible on the fluoroscope. For this purpose, an X-ray contrast medium may be incorporated into the plastics material of the outer tube 22 or may be coated thereon. Alternately, a flexible metal wire may be inserted within the extracting device 20, as will be discussed below in greater detail. The wire is visible on the X-ray fluoroscope and also may serve to stiffen the insertable portion of the extracting device 20, so that it will be easier to insert. Alternately, a fiber optic device can be used for observing and guiding the probe during insertion.

As shown in Fig. 6, an inner flexible tube 24 is telescopically received within the outer tube 22, with an annular clearance space 26 therebetween for transmitting air or some other fluid under pressure. The inner tube 24 is freely slidable within the outer tube 22. As in the case of the outer tube 22, the inner tube 24 is preferably made of a resinous plastics material, such as polyethylene, for example. If desired, an X-ray contrast material may be incorporated into the material of the inner tube 24, or may be coated thereon so that the inner tube will be visible on an X-ray fluoroscope. Alternately, a fiber optic device can be used for observing and guiding the probe during insertion. In addition to serving as a conduit for air or some other fluid, the inner tube may be inserted more easily into the body passage by the operator, without causing the outer tube 22 to collapse.

An inflatable sleeve or dilator 28 is connected between the insertable end of the outer tube 22 and the corresponding end of the inner tube 24. The sleeve 28 is thin, highly flexible and limp, and also is preferably elastic so as to be capable of stretching when inflated with compressed air or some other fluid. The sleeve 28 is preferably made of thin latex rubber or some other similar material. The thin rubber material may be similar to that employed for surgical rubber gloves and other thin rubber objects. A thin resinous plastics film material can also be used.

The thin flexible sleeve 28 has one end portion 28*a* which is stretched around and secured to the insertable end of the outer tube 22, as by means of a suitable cement or adhesive. The sleeve 28 has a second end portion 28*b* which is stretched around the insertable end of the inner tube 24 and is secured thereto, as by means of a suitable cement or adhesive. Any other suitable means, such as a tieing ring or collar, may be employed to secure the ends of the sleeve 28 to the ends of the tubes 22 and 24.

As shown in Figs. 6(a) and 10(a), the end portion 28*b* of the flexible sleeve 28 is reentrant, in that end portion 28*b* extends into the sleeve 28. With this construction, the sleeve 28 projects beyond the end of the inner tube 22, particularly when the sleeve 28 is inflated, as shown, for example, in Fig. 7(b).

As shown in Fig. 6(a), the extracting device 20 preferably includes a system or means 30 for supplying air or some other fluid under pressure to the clearance space 26 between the outer and inner tubes 22 and 24, so as to inflate the thin flexible sleeve 28. The system 30 also preferably includes means for producing suction or a vacuum in the inner tube 24 to assist in capturing the kidney stone or other object which is to be removed from the body passage.

As shown in Fig. 6, the free end of the outer tube 22 is provided with a connector or fitting 32 to which a flexible hose 32*a* or the

like may be connected, the hose being represented diagramatically by a solid line. Similarly, the inner tube 24 is provided with a connector or fitting 34 to which a hose 34*a* or the like may be connected. As shown, the hoses 32*a* and 34*a* extend radially or at right angles to the outer and inner tubes 22 and 24. The inner tube 24 extends through an annular seal 36 mounted in an opening 38 in the fitting 32, such opening being coaxial with the outer tube 22.

The illustrated system 30 of Fig. 6 for selectively producing air pressure incorporates an air compressor 40 which supplies compressed air to a pressure line 42 to which a pressure gauge 44 may be connected. A pressure regulator 46 and a combination flow control valve and meter 46*a* are preferably connected between the high pressure line 42 and a low pressure line 48 to which another pressure gauge 50 may be connected. A storage tank 52 may also be connected to the low pressure line 48, if desired.

In this embodiment, a filter 54 and a control valve 56 are connected between the low pressure line 48 and the hose or conduit 32*a* which is connected to the end fitting 32 on the outer tube 22. The illustrated control valve 56 is of a three-way type, adapted to connect the interior of the outer tube 22 to either the pressure line 48 or a vent line 58 leading to the atmosphere. In the position of the valve 56 shown in Fig. 6(a), the outer tube 22 is connected to the vent line 58 by an internal passage 60 within the valve 56. It will be apparent that the valve 56 may be shifted to a position in which the internal passage 60 establishes a connection between the pressure line 48 and the interior of the tube 22. The pressure regulator 46 and the flow control valve and meter 46*a* may be adjustable so that the air pressure in the low pressure line 48 may be varied, as desired.

In the system 30*a* of Fig. 6(a), a combined compressor and vacuum pump 40*a* supplies vacuum to an output vacuum line 62, to which a vacuum gauge 64 may be connected. It will be realized that the compressor and the vacuum pump may be provided as two separate units, if desired. In this embodiment, a vacuum regulator 66 and a combustion flow control valve and meter 66*a* are connected between the vacuum line 62 and a regulated vacuum line 68 to which another vacuum gauge 70 may be connected. A storage tank 72 may also be connected to the vacuum line 68 if desired.

A filter 74 and a vacuum control valve 76 are preferably connected between the regulated vacuum line 68 and the hose 34*a* which leads to the fitting 34 on the end of the inner tube 24. The control valve 76 may be of the three-way type and is shown in a position in which the interior of the inner tube 24 is connected to a vent line 78 by an internal passage 80 within the valve 76. It will be evident that the valve 76 can be shifted into a position in which the regulated vacuum line 68 is connected to the interior of the inner tube 24. The vacuum regulator 66 and flow control valve 66*a* may be adjustable so that the vacuum in the line 68 may be varied, as desired.

In the system 30*a* of Fig. 6(a), the combined compressor and vacuum pump 40*a* supplies pressure to an auxiliary pressure supply system 81, illustrated as comprising a compressor output pressure line 81*a* to which a control valve 81*b* may be connected. It will be realized that the compressor and the vacuum pump may be provided as two separate units if desired. The illustrated control valve 81*b* is of a three-way type, adapted to connect the compressor output pressure line 81*a* to either a high pressure input line 81*c* or a vent line 81*d*, leading to the atmosphere. In the position of the valve 81*b* shown in Fig. 6(a), the compressor output pressure line 81*a* is connected to the high pressure input line 81*c*. It will be apparent that the valve 81*b* may be shifted to a position in which the compressor output pressure line 81*a* is connected to the vent 81*d*. A gauge 81*e* may be connected to the high pressure input line 81*c*. A pressure regulator 81*f* and a combination flow control valve and meter 81*g* are preferably connected between the high pressure input line 81*c* and a low pressure line 81*h* to which another pressure gauge 81*i* may be connected. A storage tank 81*j* may also be connected to the low pressure line 81*h* if desired. In this embodiment, a filter 81*k* is connected between the low pressure line 81*h* and a hose or conduit 81*m* which is connected to the auxiliary tube or tubes 130 and 132, to be described in connection with Figs. 9(a)—(d) and Figs. 12 to 14.

Fig. 6(b) shows a modified construction of the fitting 34 having an axial opening 82 through which an auxiliary tube, a snare or a stiffening wire may be inserted into the inner tube 24. A plug 84 may be provided to close the opening 82 when not in use.

Fig. 6(c) shows another modified construction in which the plug 84 of Fig. 6(b) is replaced by a sliding seal or bushing 85 through which the auxiliary tube, snare or stiffening wire 130 may be inserted into the inner tube 24. The seal is inserted into the opening 82 in the fitting 32. The plug 84 may be used to close the opening 82 when the seal 85 is not in use.

As shown in Figs. 1 to 5, a manipulator 90 is preferably connected to the free ends of the outer and inner tubes 22 and 24, to make it easy to advance and retract the inner tube 24 relative to the outer tube 22. By using the manipulator 90, the operator can advance and retract the inner tube 24 with the thumb

and fingers of one hand, so that the other hand can be used to operate the pressure and vacuum control valves 56 and 76 of Fig. 6.

As illustrated in Figs. 1 to 5, the manipulator 90 comprises a first member 92 which is telescopically slidable within a second member 94. The members 92 and 94 are connected to the outer and inner tubes 22 and 24, respectively. More specifically, the fitting or connector 32 on the free end of the outer tube 22 is mounted in the member 92, while the end fitting or connector 34 on the free end of the inner tube 24 is mounted in the member 94.

Finger and thumb rings are preferably provided on the telescopically slidable members 92 and 94. As shown, a thumb ring 96 is connected to the member 92 by means of a plunger rod 98. A swivel joint 100 is provided between the thumb ring 96 and the plunger rod 98, so that the thumb ring can be turned to an angle which is comfortable and convenient. The illustrated thumb ring 96 is made from a strip of sheet metal and can be bent to adjust the size of the thumb ring, as desired by the operator.

As shown, the member 94 is fitted with a pair of finger rings 102 which are also bent from a strip of sheet metal, so that the size of the rings 102 can easily be adjusted to suit the needs of the operator. The finger rings 102 are swingably mounted on the body member 94. For this purpose, the finger rings 102 are provided with a mounting member 104 having a pair of arms 106 which are swingably connected to the body member 94 by diametrically opposite pivots 108.

In the illustrated manipulator 90, two stop nuts 110 are mounted on the plunger rod 98, which is threaded to receive the stop nuts. It will be seen that the stop nuts 110 may be adjusted to limit the extent to which the plunger rod 98 may be depressed through the mounting member 104, which is apertured to provide a passage for the rod 98. In effect, the stop nuts 110 thereby provide an adjustment of the extent to which the inner tube 24 may be retracted relative to the outer tube 22.

The operation of the extracting device 10 is illustrated in Figs. 7 and 8, which should be taken in conjunction with Figs. 1—6. The unit comprising the outer flexible tube 22, the inner flexible tube 24 and the inflatable sleeve 28 constitutes a probe 120 which can readily be inserted into the urinary tract of the human body for removing kidney stones. The diameter of the outer tube 22 is such as to fit snugly but easily into the urethra and either of the ureters. Specifically, the probe 120 is properly lubricated and is inserted through the urethra into the bladder, and then through the bladder into one of the ureters. An X-ray fluoroscope and a cystoscope may be employed advantageously to assist in inserting the probe 120 into either urethra. In order that the probe 120 may be clearly visible on the X-ray fluoroscope, the probe preferably incorporates an X-ray contrast material which is relatively opaque to X-rays. Such material may be incorporated into the plastics material of either the outer tube 22 or the inner tube 24, or both. Alternatively, the X-ray contrast material may comprise a thin coating of a metal, such as gold, silver or aluminium. Another alternative is to insert a thin flexible metal wire into the inner tube 24, while the probe 120 is being inserted. The wire has the additional advantage of stiffening the probe 120. After the probe has been inserted, the wire can be removed. Alternately, a fiber optic device can be used for observing and guiding the probe during insertion.

Figs. 7(a)—(g) show steps 1—7 of a procedure for capturing and removing a kidney stone 122 or some other similar object, which may be lodged in one of the ureters. As shown in Fig. 7(a), the probe 120 is inserted until it is close to the kidney stone 122. The sleeve 28 is then inflated, as shown in Fig. 7(b), by supplying compressed air through the clearance space 26 between the tubes 22 and 24. The compressed air is supplied by operating the compressed air control valve 56 to the position in which it transmits compressed air from the pressure line 48 to the fitting 32 on the free end of the outer tube 22.

The inflation of the sleeve 28 dilates the ureter to some extent, so as to dislodge or loosen the kidney stone 122. Suction is then applied to the inner tube 24, so as to suck the kidney stone 122 toward the end of the inner tube 24 and into engagement with the projecting end of the inflated sleeve 28, as shown in Fig. 7(c). The end of the thin rubber sleeve 28 forms a seal with the kidney stone 122, so that it is securely held against the end of the probe by the suction.

The inner tube 24 is then gradually retracted, while the sleeve 28 is simultaneously and gradually deflated, as shown in Figs. 7(c)—(g), so that the kidney stone 122 is pulled within the confines of the sleeve 28. It will be seen that the deflated sleeve 28 enfolds the kidney stone 122, as shown to best advantage in Fig. 7(g), so that the sleeve 28 is interposed between the kidney stone 122 and the inner walls of the ureter.

The suction is applied to the inner tube 24 by operating the suction control valve 76 of Fig. 6, so that it establishes communication between the vacuum line 68 and the end fitting 34 on the inner tube 24. The suction is maintained while the probe 120 is withdrawn from the urinary tract. The kidney stone 122 remains a captive within the confines of the sleeve 28, so that the kidney stone is removed from the urinary tract. During the removal of the probe 120, the sleeve 28 prevents the

kidney stone 122 from scratching or otherwise injuring the inner walls of the urinary tract.

Fig. 8 illustrates a procedure for using the inflatable sleeve 28 to assist in the insertion of the probe 120 into a narrow passage such as a ureter. In Fig. 8(a), the probe 120 has been inserted as far as possible with the sleeve 28 deflated. The sleeve 28 is then inflated, as shown in Fig. 8(b), so as to dilate the passage. Next, the sleeve 28 is again deflated, as shown in Fig. 8(c), and the outer tube 22 is immediately advanced, as shown in Fig. 8(d), while some of the dilation persists. The advancing movement of the outer tube 22 causes the sleeve 28 to collapse.

The inner tube 24 is then advanced within the outer tube 22, as shown in Fig. 8(e), so that the sleeve 28 is no longer collapsed. It will be seen that Fig. 8(e) is the same as Fig. 8(a), except that the probe 120 has been advanced. If further advancing movement is needed, the successive steps of Figs. 8(a)—(e) are repeated. This may be done several times until the probe 120 has been fully inserted to the desired position in the ureter or other body passage.

In some cases, it may be desirable to insert an auxiliary tube 130, along with the probe 120, as shown in Fig. 9(a). The auxiliary tube 130 provides auxiliary communication with the ureter or other body passage and may be employed to convey various fluids to or from the body passage. For example, the auxiliary tube may be emplyed to carry air into the body passage, beyond the probe 120, so as to obviate or lessen the tendency of the suction, applied by the probe 120, to cause partial collapse of the walls of the body passage. When the auxiliary tube 130 is supplied with compressed air from the combination vacuum pump-compressor 40*a* of Fig.6(a), the throughput of the closed system will provide the same amount of compressed air (volume measured as free air at atmospheric pressure) as the amount of air evacuated by the vacuum side of the pump (volume measured as free air at atmospheric pressure). The auxiliary tube 130 may also be employed to introduce a lubricating fluid into the body passage. A fluid medication can also be introduced into the body passage through the auxiliary tube 130. It is also possible to use the auxiliary tube 130 to withdraw mucus or other body fluids from the body passage.

As shown in Fig. 9(b), two or more auxiliary tubes 130 may be inserted into the body passage along with the probe 120, two such auxiliary tubes being shown in this view.

Fig. 9(c) shows a modified auxiliary tube 132 having a plurality of tube elements forming a plurality of individual auxiliary passages. As shown to best advantage in the cross section of Fig. 9(d), the auxiliary tube 132 has three tube elements 132*a*, *b* and *c*, which may be employed for simultaneously handling different fluids.

The auxiliary tubes 130 and 132 are preferably made of a flexible resinous plastics material, such as polyethylene, for example. The triple tube 132 may be formed by extrusion of the plastics material.

Fig. 12 shows a modified arrangement in which the auxiliary tube 130 is inserted through the inner tube 24 of the probe 120. The auxiliary tube 130 may be inserted into the tube 24 through the sliding seal 85 of Fig. 6(c). As shown in Fig. 13, two or more of the auxiliary tubes 130 may be inserted through the inner tube 24, after being inserted into the tube through a suitable sliding seal.

Figs. 14(a) and (b) show that the triple auxiliary tube 132 may be inserted through the inner tube 24 after being inserted through a suitable sliding seal. In all cases, the auxiliary tubes 130 and 132 may be inserted along the inner tube 124 either before or after the probe 120 is inserted into the body passage. The auxiliary tubes 130 and 132 may be removed from the inner tube 24 without removing the probe 120 from the body passage. The plug 84 may then be inserted in the connector.

It may also be considered that Fig. 12 illustrated insertion of a flexible metal wire within the inner tube 24. The element 130 may be regarded as the wire. As previously indicated, the flexible wire may be employed to stiffen the tubes 22 and 24 of the probe 120, or to absorb X-rays so that the probe 120 will be clearly visible on an X-ray fluoroscope. Alternately, a fiber optic device can be used for observing and guiding the probe during insertion.

Fig. 10 illustrates various alternative shapes for the inflatable sleeve 28. In Fig. 10(a), the sleeve 28 has a cylindrical sidewall 138 and radial endwalls 140 and 142. In Fig. 10(b) the sleeve has a tapered or frusto-conical sidewall 138(a).

In Figs. 10(c), (d) and (e), the cylindrical sidewall 138 is employed, but the endwall 142 is modified. Thus, the sleeve of Fig. 10(c) has a re-entrant, tapered, frusto-conical endwall 142(a) which may be advantageous in some instances to assist in the enfolding of the kidney stone by the sleeve. In Fig. 10(d), the sleeve has a stepped endwall 142(b). In Fig. 10(e), the sleeve has a re-entrant endwall 142(c) which is concavely curved. This construction may be advantageous in some cases for capturing and enfolding kidney stones.

In Fig. 10(f), the inflatable seal or sleeve 28 has one or more holes 143 which may be either molded in or pierced. Air or fluid from the inflator supply will pass through the holes 143 so as to obviate or lessen the tendency of the suction applied by the probe 120 to cause partial collapse of the walls of

the body passage. The various alternative shapes shown in Figs. 10(b), (c), (d) and (e) may also be provided with one or more holes 143.

Figs. 11(a)—(f) illustrate the successive steps of a procedure for using the probe 120 in conjunction with a snare 150 to assist in capturing and removing a foreign object, such as the illustrated kidney stone 122. The illustrated snare 150 comprises a capturing head or portion 154 and an operating portion or member 156, here shown as a flexible wire which is inserted through the inner tube 24, so as to be accessible to the operator at the free end of the probe 120. The wire 156 is freely slidable within the inner tube 24.

The capturing head 154 of the snare 150 may comprise a multitude of strands or filaments 158, made of a material such as tinsel, capable of entwining the kidney stone 122. The filaments 158 are in a form resembling a ball and are secured to the front end of the operating wire 156. The filaments 158 may be made of metal, a resinous plastics material, or any other suitable material.

In the procedure of Figs. 11(a)—(f), the probe 120 is inserted into the ureter, or some other body passage, until the capturing head 154 of the snare 150 is as close as possible to the kidney stone 122, as shown in Fig. 11(a). The sleeve 28 is then inflated, as shown in Fig. 11(b), by supplying air or some other fluid under pressure to the interior of the outer tube 22. The inflation of the sleeve 28 tends to dislodge or loosen the kidney stone 122 from the walls of the ureter.

As shown in Fig. 11(c), the snare 150 is then advanced by moving the operating wire 156 through the inner tube 24. As the capturing head 154 is advanced, the filaments 158 become entwined around the kidney stone 122, as will be evident from Fig. 11(c). As the snare 150 is advanced, suction is preferably applied to the interior of the inner tube, so that the suction assists in the capture of the kidney stone 122.

The snare 150 is then retracted by moving the operating wire 156 within the inner tube 24, so as to bring the capturing head 154 and the kidney stone 122 as close as possible to the end of the inner tube. Meanwhile, suction within the inner tube 22 is maintained. Then, the inner tube 22 is gradually retracted, as shown in Figs. 11(d)—(f), to draw the kidney stone 122 and the capturing head 154 of the snare 150 into the confines of the sleeve 28. Simultaneously, the sleeve 28 is gradually deflated, so that it will enfold the kidney stone 122 and the capturing head 154. The thin rubber sleeve 28 forms a seal with the kidney stone 122 and the capturing head 154, so that the suction effectively retains the kidney stone within the folds of the sleeve 28.

With the suction still maintained, the probe 120 may then be withdrawn from the body passage, to remove the kidney stone 122 or other object. The sleeve 28 is interposed between the kidney stone 122 and the walls of the body passage, so that neither the kidney stone nor the head 154 of the snare 150 will scratch or otherwise injure the walls of the body passage.

WHAT I CLAIM IS:—

1. An extracting device for insertion into a human body passage for removing foreign objects therefrom, said device comprising an outer flexible tube the distal end of which is insertable into a body passage, an inner flexible tube slideably received within the outer tube for free longitudinal sliding movement with the distal end of the inner tube normally projecting beyond the distal end of the outer tube, the inner and outer tubes having clearance space therebetween for carrying fluid under pressure, a thin, tubular, highly distendable and limp sleeve having its proximal end portion connected to the distal end of the outer tube, the sleeve having a distal end portion which is inverted and is connected to the distal end of the inner tube for insertion into the body passage, the sleeve being otherwise free to expand upon inflation, the tubular sleeve having first and second tubular surfaces on opposite sides of the sleeve, the first surface facing inwardly at the proximal end portion of the sleeve, the inverted distal end portion of the sleeve being turned inside out with the second surface facing inwardly, the sleeve being inflatable by fluid transmitted along said clearance space to dilate the body passage, the sleeve when inflated having an annular flaring portion bulging beyond the distal end of the inner tube and curved convexly in longitudinal section for sealing engagement with a foreign object in the body passage, the annular flaring curved portion being soft, pliable and capable of conforming to the shape of the foreign object to effect a seal therewith, the inner tube being operative to transmit suction for capturing and holding the foreign object in sealing engagement with the annular flaring portion of the sleeve, and means for retracting the inner tube relative to the outer tube while the suction pulls the foreign object within the confines of the sleeve and the sleeve is progressively turned inside out around the foreign object to envelop the foreign object for removal with the tubes.

2. A device according to Claim 1, in which the inner and outer tubes are made of a resinous plastics material.

3. A device according to Claim 1, in which the sleeve is made of rubber.

4. A device according to Claim 1, including manipulating means connected to the proximal ends of the tubes for advancing and retracting the inner tube relative to the outer

tube.

5. A device according to Claim 4, wherein said manipulating means includes first and second telescopically movable members connected to the respective inner and outer tubes, the first and second members having finger receiving rings for use in manually moving the members.

6. A device according to Claim 1, including first means for selectively supplying fluid under pressure to the proximal end of the clearance space to inflate the sleeve.

7. A device according to Claim 1 or 6, including second means for selectively supplying suction to the proximal end of the inner tube.

8. A device according to Claim 1, in which the proximal and distal end portions of the sleeve are of reduced diameters relative to the intermediate portion of the sleeve and are secured to the distal ends of the inner and outer tubes.

9. A device according to Claim 8, wherein the reduced distal end portion of the sleeve extends within the sleeve for receiving the distal end of the inner tube whereby the sleeve projects beyond the distal end of the inner tube.

10. A device according to Claim 1, including at least one auxiliary tube slideable within the inner tube to afford auxiliary communication with the body passage.

11. A device according to Claim 10, wherein the auxiliary tube includes a plurality of individual tube elements.

12. A device according to Claim 1, including at least one auxiliary tube extending along the outside of the outer tube and insertable in said body passage along with the outer and inner tubes to afford auxiliary communication with the body passage.

13. A device according to Claim 12, in which the auxiliary tube has a plurality of individual tube elements.

14. A device according to Claim 1, including a stiffening member slideably receivable in the inner tube for stiffening the inner and outer tubes to facilitate the insertion of the outer tube into the body passage.

15. A device according to Claim 1, including a snare having an operating member slideable within the inner tube, said snare being operative to assist in capturing a foreign object in the body passage.

16. A device according to Claim 1, including a snare having a thin flexible wire-like operating member slideably received in the inner tube, said snare having a capturing portion secured to the operating member and including a plurality of filamemts disposed adjacent the sleeve to assist in capturing a foreign object.

17. An extracting device for insertion into a human body passage, substantially as hereinbefore described with reference to the accompanying drawings.

WITHERS & ROGERS,
Chartered Patent Agents,
4 Dyer's Buildings,
Holborn,
London, EC1N 2JT.
Agents for the Applicant.

Printed for Her Majesty's Stationery Office by Burgess & Son (Abingdon) Ltd.—1981. Published at The Patent Office, 25 Southampton Buildings, London, WC2A 1AY, from which copies may be obtained.

1588072 COMPLETE SPECIFICATION
6 SHEETS This drawing is a reproduction of the Original on a reduced scale
Sheet 1

FIG. 1

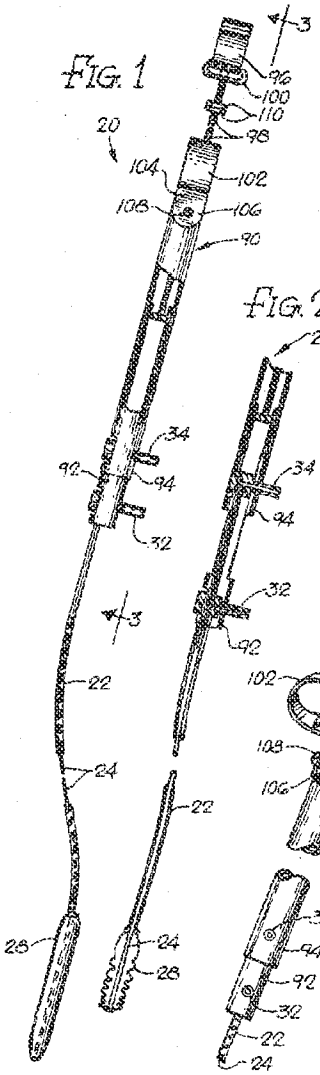


FIG. 2

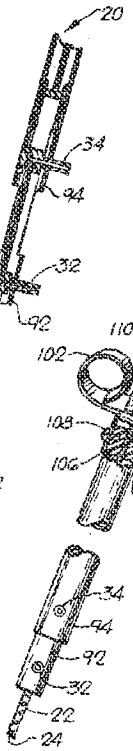


FIG. 3

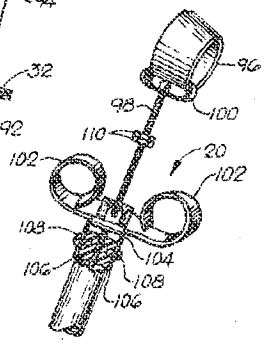


FIG. 5

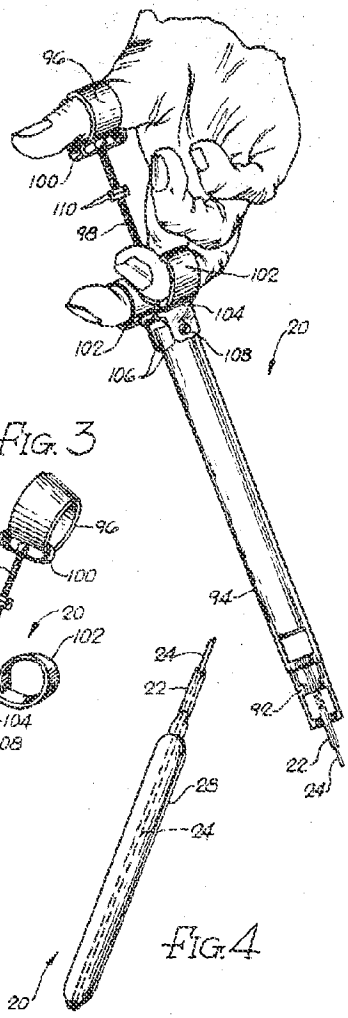
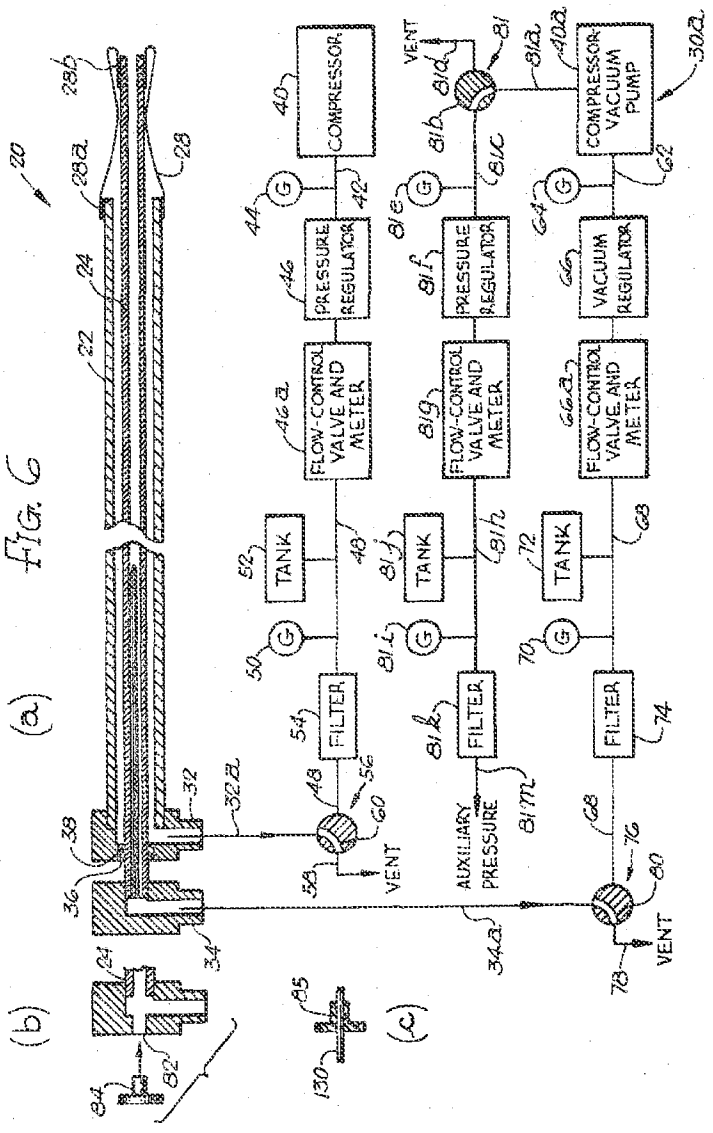


FIG. 4

1588072 COMPLETE SPECIFICATION
6 SHEETS This drawing is a reproduction of the Original on a reduced scale
Sheet 2



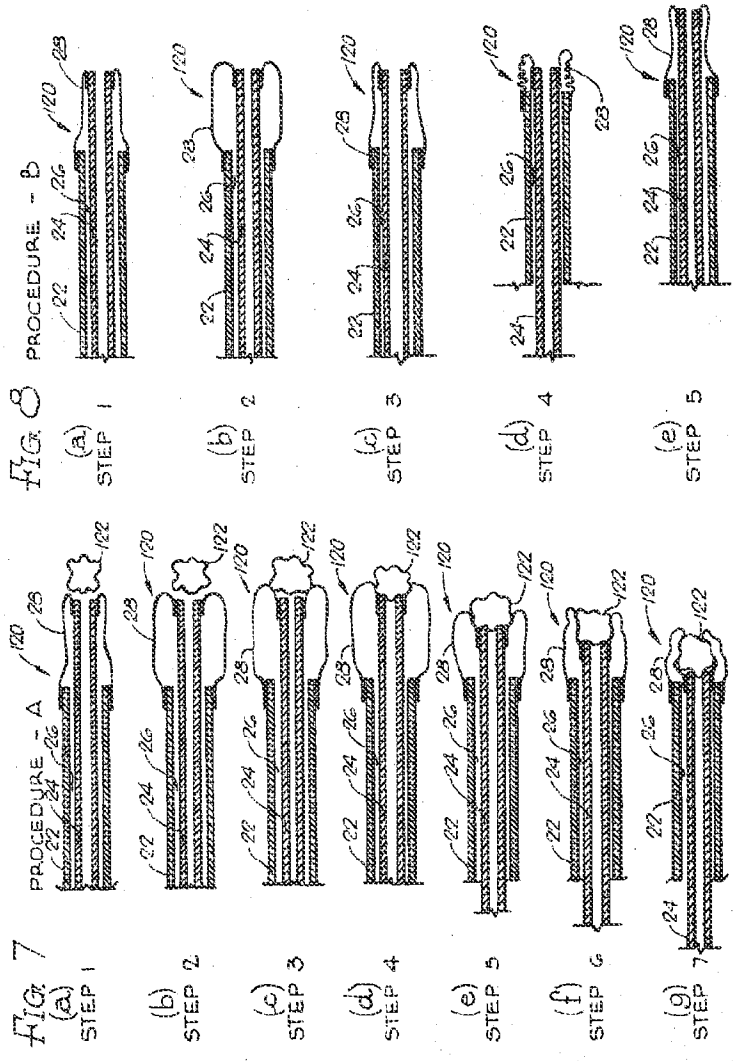

FIG. 7
PROCEDURE - A
(a) STEP 1
(b) STEP 2
(c) STEP 3
(d) STEP 4
(e) STEP 5
(f) STEP 6
(g) STEP 7
FIG. 8
PROCEDURE - B
(a) STEP 1
(b) STEP 2
(c) STEP 3
(d) STEP 4
(e) STEP 5

FIG. 9

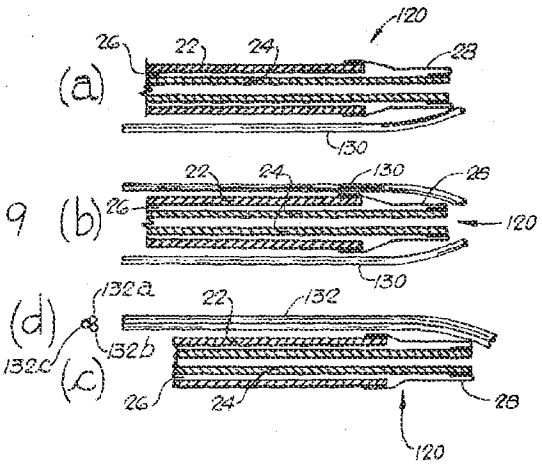

(a)
120
26
22
24
28
130
(b)
22
24
130
26
26
120
130
(d)
132a
22
132
132b
132c
(c)
26
24
28
120

FIG. 10

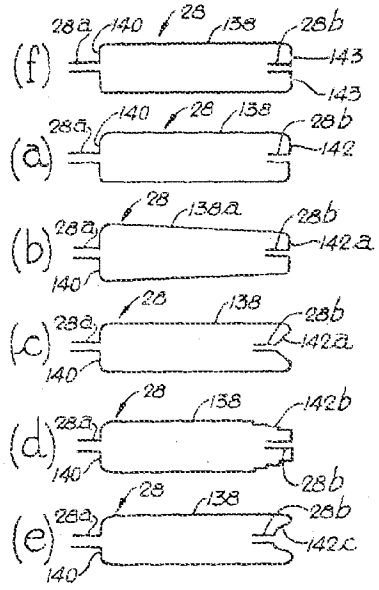

(f)
28a
140
28
138
28b
143
143
(a)
28a
140
28
138
28b
142
(b)
28
138a
28b
142a
28a
140
(c)
28
138
28b
142a
28a
140
(d)
28
138
142b
28a
140
28b
(e)
28
138
28b
142c
28a
140

FIG. 11

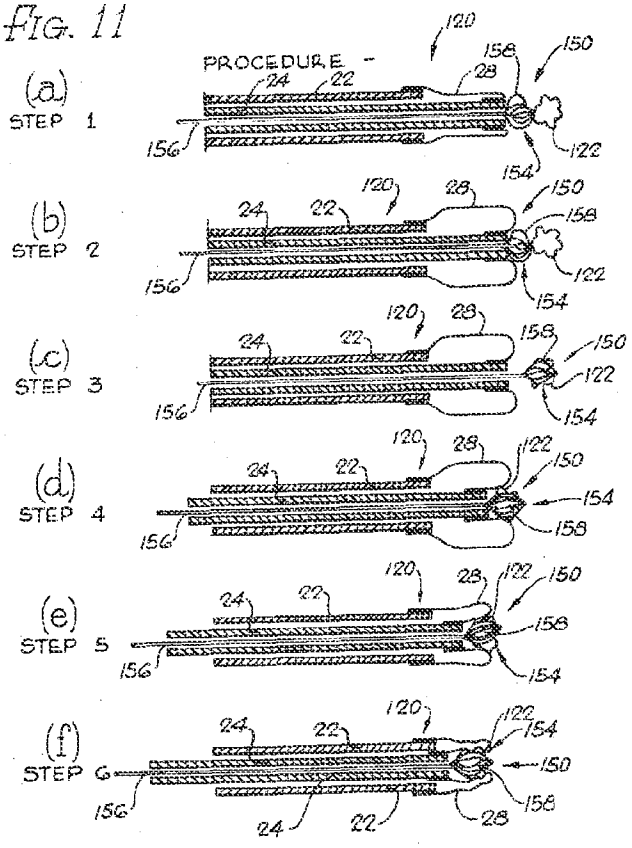

PROCEDURE
(a) STEP 1
(b) STEP 2
(c) STEP 3
(d) STEP 4
(e) STEP 5
(f) STEP 6
120
150
156
28
24
22
122
154
158

FIG. 12

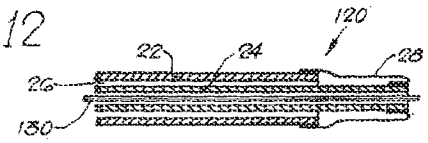


FIG. 13

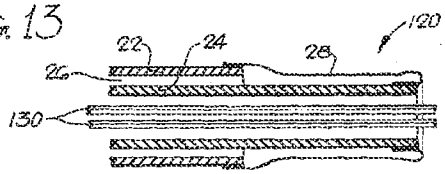
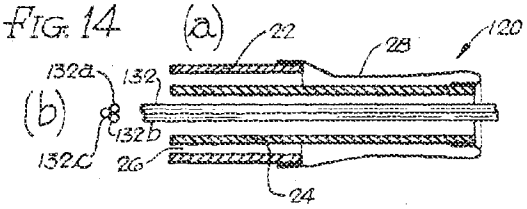


FIG. 14



(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
27 May 2022 (27.05.2022)

WIPO | PCT

(10) International Publication Number
WO 2022/109034 A1

(51) International Patent Classification:
A61M 25/00 (2006.01)

(21) International Application Number:
PCT/US2021/059735

(22) International Filing Date:
17 November 2021 (17.11.2021)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
63/115,515 18 November 2020 (18.11.2020) US

(71) Applicant: **INARI MEDICAL, INC.** [US/US]; 9 Parker, Suite #100, Irvine, California 92618 (US).

(72) Inventors: **DOLENDO, Edward Enriquez**; 9 Parker, Suite #100, Irvine, California 92618 (US). **BRODT, Thomas Robert**; 9 Parker, Suite #100, Irvine, California 92618 (US). **TU, Thomas M.**; 9 Parker, Suite #100, Irvine, California 92618 (US).

(74) Agent: **WILLIAMS, Matthew S.** et al.; PERKINS COIE LLP, P.O. Box 1247, Seattle, Washington 98111-1247 (US).

(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, DJ, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, IT, JO, JP, KE, KG, KH, KN, KP, KR, KW, 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, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, WS, 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,

(54) Title: CATHETERS HAVING STEERABLE DISTAL PORTIONS, AND ASSOCIATED SYSTEMS AND METHODS

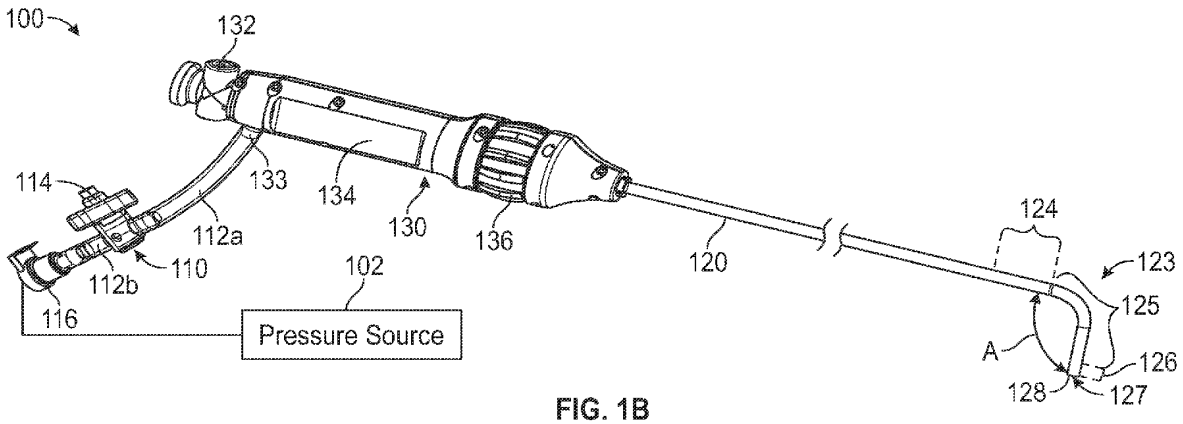


FIG. 1B

(57) Abstract: Disclosed herein are clot removal systems including steerable catheters, and associated systems and methods. In some embodiments, a clot removal system includes (i) an aspiration catheter having a proximal region and a distal region and (ii) a handle coupled to the proximal region of the catheter and having an actuator. The distal region of the catheter can include a deflectable member, and the clot removal system can include a pull wire extending between the actuator and the deflectable member. Actuation of the actuator is configured to pull the pull wire to deflect the deflectable member to deflect the distal region relative to the proximal region. The deflection can facilitate steering of the catheter to hard-to-reach (e.g., tortuous) portions of the anatomy of a patient.

WO 2022/109034 A1

[Continued on next page]

TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Published:

— *with international search report (Art. 21(3))*
— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))*

CATHETERS HAVING STEERABLE DISTAL PORTIONS, AND ASSOCIATED SYSTEMS AND METHODS

CROSS-REFERENCE TO RELATED APPLICATION

[0001] This application claims the benefit of U.S. Provisional Patent Application No. 63/115,515, filed November 18, 2020, and titled "CATHETERS HAVING STEERABLE DISTAL PORTIONS, AND ASSOCIATED SYSTEMS AND METHODS," which is incorporated herein by reference in its entirety.

TECHNICAL FIELD

[0002] The present technology generally relates to clot removal systems including catheters (e.g., large bore aspiration catheters) having a steerable distal portion to, for example, facilitate positioning of the catheter in hard-to-reach regions of the vasculature of a patient.

BACKGROUND

[0003] Thromboembolic events are characterized by an occlusion of a blood vessel. Thromboembolic disorders, such as stroke, pulmonary embolism, heart attack, peripheral thrombosis, atherosclerosis, and the like, affect many people. These disorders are a major cause of morbidity and mortality.

[0004] When an artery is occluded by a clot, tissue ischemia develops. The ischemia will progress to tissue infarction if the occlusion persists. Infarction does not develop or is greatly limited if the flow of blood is reestablished rapidly. Failure to reestablish blood flow can lead to the loss of limb, angina pectoris, myocardial infarction, stroke, or even death.

[0005] In the venous circulation, occlusive material can also cause serious harm. Blood clots can develop in the large veins of the legs and pelvis, a common condition known as deep venous thrombosis (DVT). DVT arises most commonly when there is a propensity for stagnated blood (e.g., long distance air travel, immobility, etc.) and clotting (e.g., cancer, recent surgery, such as orthopedic surgery, etc.). DVT causes harm by: (1) obstructing drainage of venous blood from the legs leading to swelling, ulcers, pain, and infection, and (2) serving as a reservoir for blood clots to travel to other parts of the body including the heart, lungs, brain (stroke), abdominal organs, and/or extremities.

[0006] In the pulmonary circulation, the undesirable material can cause harm by obstructing pulmonary arteries—a condition known as pulmonary embolism. If the obstruction is upstream, in the main or large branch pulmonary arteries, it can severely compromise total blood flow within the lungs, and therefore the entire body, and result in low blood pressure and shock. If the obstruction is downstream, in large to medium pulmonary artery branches, it can prevent a significant portion of the lung from participating in the exchange of gases to the blood resulting in low blood oxygen and buildup of blood carbon dioxide.

[0007] There are many existing techniques to reestablish blood flow through an occluded vessel. One common surgical technique, an embolectomy, involves incising a blood vessel and introducing a balloon-tipped device (such as the Fogarty catheter) to the location of the occlusion. The balloon is then inflated at a point beyond the clot and used to translate the obstructing material back to the point of incision. The obstructing material is then removed by the surgeon. Although such surgical techniques have been useful, exposing a patient to surgery may be traumatic and best avoided when possible. Additionally, the use of a Fogarty catheter may be problematic due to the possible risk of damaging the inner lining of the vessel as the catheter is being withdrawn.

[0008] Percutaneous methods are also utilized for reestablishing blood flow. A common percutaneous technique is referred to as balloon angioplasty where a balloon-tipped catheter is introduced to a blood vessel (e.g., typically through an introducing catheter). The balloon-tipped catheter is then advanced to the point of the occlusion and inflated to dilate the stenosis. Balloon angioplasty is appropriate for treating vessel stenosis, but it is generally not effective for treating acute thromboembolisms as none of the occlusive material is removed and the vessel will re-stenos after dilation. Another percutaneous technique involves placing a catheter near the clot and infusing streptokinase, urokinase, or other thrombolytic agents to dissolve the clot. Unfortunately, thrombolysis typically takes hours to days to be successful. Additionally, thrombolytic agents can cause hemorrhage and in many patients the agents cannot be used at all.

[0009] Various devices exist for performing a thrombectomy or removing other foreign material. However, such devices have been found to have structures which are either highly complex, cause trauma to the treatment vessel, or lack sufficient retaining structure and thus cannot be appropriately fixed against the vessel to perform adequately. Furthermore, many of the devices have highly complex structures that lead to manufacturing and quality control difficulties as well as delivery issues when passing through tortuous or small diameter catheters.

Less complex devices may allow the user to pull through the clot, particularly with inexperienced users, and such devices may not completely capture and/or collect all the clot material.

BRIEF DESCRIPTION OF THE DRAWINGS

[0010] Many aspects of the present technology can be better understood with reference to the following drawings. The components in the drawings are not necessarily to scale. Instead, emphasis is placed on illustrating clearly the principles of the present disclosure.

[0011] Figures 1A and 1B are partially schematic side and isometric views, respectively, of a clot removal system in accordance with embodiments of the present technology.

[0012] Figure 2 is an enlarged, partially cut-away side view of a portion of a proximal region of a catheter of the clot removal system of Figures 1A and 1B in accordance with embodiments of the present technology.

[0013] Figure 3A is an enlarged, partially cut-away side view, and Figure 3B is an enlarged, partially cut-away isometric view, of a portion of an intermediate region of the catheter of Figures 1A and 1B in accordance with embodiments of the present technology.

[0014] Figures 4A and 4B are a distally-facing isometric view and an enlarged proximally-facing isometric view, respectively, of a deflectable member of a deflectable region of the catheter of Figures 1A and 1B in accordance with embodiments of the present technology.

[0015] Figures 4C and 4D are isometric views of a proximal ring and a distal ring, respectively, of the deflectable member of Figures 4A and 4B in accordance with embodiments of the present technology.

[0016] Figure 5A is a partially cross-sectional side view of a handle and a portion of the proximal region of the catheter of the clot removal system of Figures 1A and 1B in accordance with embodiments of the present technology; and Figure 5B is an enlarged cross-sectional isometric view of a portion of the handle shown in Figure 5A.

[0017] Figures 6A and 6B are a distally-facing isometric view and a side view, respectively, of a deflectable member in accordance with additional embodiments of the present technology.

[0018] Figure 6C is top view of a flat pattern that can be cut to integrally form a proximal ring and a tube portion of the deflectable member of Figures 6A and 6B in accordance with

embodiments of the present technology; and Figure 6D is an enlarged top view of a portion of the pattern shown in Figure 6C.

[0019] Figures 7A–7C are side views of a portion of the catheter of the clot removal system of Figures 1A and 1B during a procedure for removing clot material from within a blood vessel of a patient in accordance with embodiments of the present technology.

DETAILED DESCRIPTION

[0020] The present technology is generally directed to clot removal systems including aspiration catheters having a deflectable/steerable distal portion for improved flexibility through hard-to-reach (e.g., tortuous) vascular anatomy of a patient, and associated systems and methods. In some embodiments, a clot removal system in accordance with embodiments of the present technology includes (i) an aspiration catheter having a proximal region and a distal region and (ii) a handle coupled to the proximal region of the catheter and having an actuator. The distal region of the catheter can include a deflectable member, and the clot removal system can include a pull wire extending between the actuator and the deflectable member. Actuation of the actuator is configured to pull the pull wire to deflect the deflectable member to deflect the distal region relative to the proximal region. The deflection can facilitate steering of the catheter to the hard-to-reach portions of the anatomy of the patient.

[0021] In some embodiments, the deflectable member includes a proximal ring, a distal ring, and a tube portion extending between the proximal and distal rings. The proximal ring can include an annular member coupled (e.g., welded) thereto and configured to slidably receive the pull wire. The distal ring can be configured to be fixedly attached (e.g., welded) to the pull wire. The tube portion can include a plurality of openings (e.g., circumferentially extending openings) that define a plurality of ribs. The ribs can flex away from each other when the actuator is actuated to pull the pull wire. In some embodiments, the tube portion further includes a spine extending between the proximal and distal rings and generally aligned with the pull wire.

[0022] In some embodiments, the catheter further includes an intermediate region between the proximal and distal regions. The catheter can include a braid of wires extending along the proximal and distal regions, and a coil extending over the braid along the intermediate region.

[0023] In some aspects of the present technology, the catheter is configured to be steered to and positioned in difficult-to-reach regions of the anatomy of a patient while still having a relatively large size (e.g., 20 French, 24 French, greater than 24 French). More particularly, the

catheter can have an improved torque response and flexibility compared to conventional catheters having the same size. For example, the braid can provide good torque response along the proximal and intermediate regions of the catheter. Additionally, the deflectable region can be configured (e.g., shaped, sized) to be positioned within and steered/flexed into the difficult-to-reach regions of the anatomy. Further, the coil can provide increased hoop strength at the intermediate region while still allowing the catheter to flex. For example, the coil can inhibit or even prevent kinking or other unwanted movement of the catheter when the catheter is aspirated during a clot removal procedure.

[0024] Certain details are set forth in the following description and in Figures 1–7C to provide a thorough understanding of various embodiments of the present technology. In other instances, well-known structures, materials, operations, and/or systems often associated with intravascular procedures, clot removal procedures, catheters, and the like are not shown or described in detail in the following disclosure to avoid unnecessarily obscuring the description of the various embodiments of the technology. Those of ordinary skill in the art will recognize, however, that the present technology can be practiced without one or more of the details set forth herein, and/or with other structures, methods, components, and so forth.

[0025] The terminology used below is to be interpreted in its broadest reasonable manner, even though it is being used in conjunction with a detailed description of certain examples of embodiments of the technology. Indeed, certain terms may even be emphasized below; however, any terminology intended to be interpreted in any restricted manner will be overtly and specifically defined as such in this Detailed Description section.

[0026] The accompanying Figures depict embodiments of the present technology and are not intended to be limiting of its scope unless expressly indicated. The sizes of various depicted elements are not necessarily drawn to scale, and these various elements may be enlarged to improve legibility. Component details may be abstracted in the Figures to exclude details such as position of components and certain precise connections between such components when such details are unnecessary for a complete understanding of how to make and use the present technology. Many of the details, dimensions, angles and other features shown in the Figures are merely illustrative of particular embodiments of the disclosure. Accordingly, other embodiments can have other details, dimensions, angles and features without departing from the present technology. In addition, those of ordinary skill in the art will appreciate that further

embodiments of the present technology can be practiced without several of the details described below.

[0027] With regard to the terms "distal" and "proximal" within this description, unless otherwise specified, the terms can reference a relative position of the portions of a catheter subsystem with reference to an operator and/or a location in the vasculature. Also, as used herein, the designations "rearward," "forward," "upward," "downward," and the like are not meant to limit the referenced component to a specific orientation. It will be appreciated that such designations refer to the orientation of the referenced component as illustrated in the Figures. The systems of the present technology can be used in any orientation suitable to the user.

[0028] Figures 1A and 1B are partially schematic side and isometric views, respectively, of a clot removal system 100 in accordance with embodiments of the present technology. The clot removal system 100 can also be referred to as an aspiration assembly, a clot treatment system, and/or a thrombectomy system. Referring to Figures 1A and 1B together, the clot removal system 100 includes a tubing assembly 110 coupled to a catheter 120 via a handle 130. In general, the clot removal system 100 (i) can include features generally similar or identical to those of the clot removal systems described in detail in U.S. Patent Application No. 16/536,185, filed August 8, 2019, and titled "SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED DEVICES AND METHODS," which is incorporated herein by reference in its entirety, and/or (ii) can be used to treat/remove clot material from a patient (e.g., a human patient) using any of the methods described in detail therein.

[0029] Referring to Figure 1A, the catheter 120 can include (i) a proximal region or portion 121, (ii) an intermediate region 122 adjacent to and distal of the proximal region 121, and (iii) a distal region 123 adjacent to and distal of the intermediate region 122. Referring to Figure 1B, the distal region 123 can further include a transition region 124, a deflectable region 125 (e.g., a flexible region, steerable region, deformable region) distal of the transition region 124, and a tip region 126 distal of the deflectable region 125. Referring again to Figures 1A and 1B together, the catheter 120 further defines a lumen 127 extending therethrough from the proximal region 121 to the tip region 126. The proximal region 121 defines a proximal terminus (obscured by the handle 130 in Figures 1A and 1B; e.g., a proximal terminus 529 shown in Figure 5A) of the catheter 120 that can be positioned within the handle 130, and the tip region 126 defines a distal terminus 128 of the catheter 120.

[0030] In some embodiments, the proximal region 121 has a first length, the intermediate region 122 has a second length less than the first length, and the distal region 123 has a third length less than the first and second lengths. For example, the first length can be between about 50–100 millimeters (e.g., about 80 millimeters), the second length can be between about 10–50 millimeters (e.g., about 25 millimeters), and the third length can be between about 1.0–10 millimeters (e.g., about 4.2 millimeters). In some embodiments, the transition region 124 can have a length of between about 0.1–5.0 millimeters (e.g., about 0.6 millimeters), the deflectable region 125 can have a length of between about 1.0–10 millimeters (e.g., about 3.0 millimeters), and the tip region 126 can have a length of between about 0.1–5.0 millimeters (e.g., about 0.6 millimeters). In other embodiments, the lengths of one or more of the regions 121–126 can be different. In some embodiments, the catheter 120 can have varying flexibilities, shapes, thicknesses, and/or other properties in/along the various regions 121–126.

[0031] In the illustrated embodiment, the handle 130 includes and/or is coupled to a valve 132. The valve 132 can include a branch or side port 133 configured to fluidly couple the lumen 127 of the catheter 120 to the tubing assembly 110, and can be integral with or coupled to the proximal region 121 of the catheter 120. In some embodiments, the valve 132 is a hemostasis valve that is configured to maintain hemostasis during a clot removal procedure by inhibiting or even preventing fluid flow in the proximal direction through the valve 132 as various components such as delivery sheaths, pull members, guidewires, interventional devices, other aspiration catheters, and so on are inserted through the valve 132 to be delivered through the catheter 120 to a treatment site in a blood vessel. In some embodiments, the valve 132 can be a valve of the type disclosed in U.S. Patent Application No. 16/117,519, filed August 30, 2018, and titled "HEMOSTASIS VALVES AND METHODS OF USE," which is incorporated herein by reference in its entirety.

[0032] In the illustrated embodiment, the tubing assembly 110 fluidly couples the catheter 120 to a pressure source 102, such as a syringe. The tubing assembly 110 can include one or more tubing sections 112 (individually labeled as a first tubing section 112a and a second tubing section 112b), at least one fluid control device 114 (e.g., a valve), and at least one connector 116 (e.g., a Toomey tip connector) for fluidly coupling the tubing assembly 110 to the pressure source 102 and/or other suitable components. In some embodiments, the fluid control device 114 is a stopcock that is fluidly coupled to (i) the side port 133 of the valve 132 via the first tubing section 112a and (ii) the connector 116 via the second tubing section 112b. The fluid control device 114 is externally operable by a user to regulate the flow of fluid therethrough and,

specifically, from the lumen 127 of the catheter 120 to the pressure source 102. In some embodiments, the connector 116 is a quick-release connector (e.g., a quick disconnect fitting) that enables rapid coupling/decoupling of the catheter 120 and the fluid control device 114 to/from the pressure source 102.

[0033] In the illustrated embodiment, the handle 130 includes a housing 134 and an actuator 136. The actuator 136 can be operably coupled to the catheter 120 and movable (e.g., rotatable) relative to the housing 134 to deflect (e.g., steer, flex) the deflectable region 125 from (i) a first position (e.g., an unflexed position, an aligned position) shown in Figure 1A in which the deflectable region 125 is generally aligned with the intermediate region 122 and/or the proximal region 121 to (ii) a second position (e.g., a flexed position) shown in Figure 1B in which the deflectable region 125 is deflected relative to the intermediate region 122 and/or the proximal region 121. That is, the actuator 136 can be configured to deflect the deflectable region 125 away from a longitudinal axis generally aligned with the proximal region 121 and/or the intermediate region 122. In some embodiments, the deflectable region 125 can have a bend angle A in the second position (Figure 1B) of greater than about 30 degrees, greater than about 50 degrees, greater than about 70 degrees, greater than about 90 degrees, or greater. In some embodiments, the bend angle A is about 90 degrees.

[0034] Figure 2 is an enlarged, partially cut-away side view of a portion of the proximal region 121 of the catheter 120 in accordance with embodiments of the present technology. Figure 3A is an enlarged, partially cut-away side view, and Figure 3B is an enlarged, partially cut-away isometric view, of a portion of the intermediate region 122 of the catheter 120 in accordance with embodiments of the present technology. Referring to Figures 1–3B together, the catheter 120 includes an outer sheath 240 and an inner liner 242 extending through/defining each of the regions 121–126. The outer sheath 240 is positioned over (e.g., radially outside of) the inner liner 242. The outer sheath 240 can also be referred to as an outer jacket, an outer shaft, or an outer layer, and the inner liner 242 can also be referred to as an inner layer, an inner sheath, or an inner shaft.

[0035] In some embodiments, the outer sheath 240 can be formed from a plastic material, elastomeric material, and/or thermoplastic elastomer (TPE) material. In some embodiments, the outer sheath 240 can be formed from a TPE manufactured by Arkema S.A., of Colombes, France, such as the TPEs manufactured under the trademark "Pebax." In some embodiments, the outer sheath 240 can have a varying hardness (e.g., durometer), thickness, flexibility, rigidity, and/or

other property in one or more of the different regions 121–126. For example, the outer sheath 240 can have (i) a first hardness along the proximal region 121 of between about 65D–75D (e.g., about 72D), (ii) a second hardness along the intermediate region 122 of between about 30D–40D (e.g., about 35D), (iii) a third hardness along the transition region 124 of between about 50D–60D (e.g., about 55D), (iv) a fourth hardness along the deflectable region of between about 20D–30D (e.g., about 25D), and (v) a fifth hardness along the tip region 126 of between about 50D–60D (e.g., about 55D). In other embodiments, the outer sheath 240 can have a different hardness or other property along one or more of the regions 121–126.

[0036] The inner liner 242 can be formed of a lubricious material that facilitates the movement (e.g., distal advancement, proximal retraction) of various components through the lumen 127, such as delivery sheaths, pull members, guidewires, interventional devices, other aspiration catheters, and the like. In some embodiments, the inner liner 242 can be formed from a polymer material, a fluoropolymer material (e.g., polytetrafluoroethylene (PTFE)), and/or another material having a high degree of lubricity. In some embodiments, the inner liner 242 can define a diameter D (Figure 2) of the lumen 127, and the diameter D can be greater than about 6 French, greater than about 10 French, greater than about 16 French, greater than about 20 French, greater than about 24 French, or greater. In some embodiments, the diameter D is about 8 French, about 16 French, about 20 French, or about 24 French. In certain embodiments, the diameter D of the inner liner 242 is the same in each of the regions 121–126 while, in other embodiments, the diameter D can vary along one or more of the regions 121–126.

[0037] The catheter 120 can further include a braid 244 extending along the proximal region 121 and the intermediate region 122 between the outer sheath 240 and the inner liner 242. In some embodiments, the braid 244 terminates at or before the distal region 123 such that the braid 244 does not extend along the transition region 124, the deflectable region 125, or the tip region 126. In the illustrated embodiment, the catheter 120 further includes a coil 346 (Figures 3A and 3B) extending at least partially along the intermediate region 122 between the braid 244 and the outer sheath 240. In some embodiments, the coil 346 extends only along the intermediate region 122 and does not extend into the proximal region 121 or the distal region 123.

[0038] The braid 244 can include wires, filaments, threads, sutures, fibers, or the like (collectively "wires 248") that have been woven or otherwise coupled, attached, formed, and/or joined together at a plurality of interstices 249. Accordingly, the braid 244 can also be referred to as a braided structure, a braided filament structure, a braided filament mesh structure, a mesh

structure, a mesh filament structure, and the like. In some embodiments, the wires 248 can comprise metals, polymers, and/or composite materials. In some embodiments, individual ones of the wires 248 can be rolled flat wires having a cross-sectional dimension of between about 0.0005–0.005 inch (e.g., about 0.002 inch) by about 0.002–0.005 inch (e.g., about 0.0033 inch).

[0039] In the illustrated embodiment, the coil 346 is a single wire wound around the braid 244 and the inner liner 242 along the intermediate region 122. In other embodiments, the coil 346 can include more than one wire wound about the braid 244. For example, the coil 346 can include multiple wires wound over one another and/or multiple wires wound to at least partially overlap one another to form a braided or overlapping coil structure on the braid 244. In other embodiments, the coil 346 can be formed directly over the inner liner 242, and the braid 244 can be formed over the coil 346. The coil 346 can be formed from a metallic or other suitably strong material, such as nickel-titanium alloys (e.g. nitinol), platinum, cobalt-chrome alloys, stainless steel, tungsten, and/or titanium.

[0040] Figures 4A and 4B are a distally-facing isometric view and an enlarged proximally-facing isometric view, respectively, of a deflectable member 450 of the deflectable region 125 of the catheter 120 in accordance with embodiments of the present technology. The deflectable member 450 can be positioned between the outer sheath 240 and the inner liner 242 (Figures 2–3B), which are both omitted in Figures 4A and 4B for clarity. In the illustrated embodiment, the deflectable member 450 includes a proximal ring 452, a distal ring 454, and a tube portion 456 extending between the proximal ring 452 and the distal ring 454. The deflectable member 450 can be formed from a flexible metallic material—such as nickel-titanium alloys (e.g. nitinol), platinum, cobalt-chrome alloys, stainless steel, tungsten, and/or titanium—or another suitably strong and flexible material. Similarly, the deflectable member 450 can be manufactured (e.g., laser cut) as a single integral piece, or one or more of the proximal ring 452, the distal ring 454, and the tube portion 456 can be separately manufactured and then coupled (e.g., welded, tack welded, adhered, fastened) together.

[0041] Figures 4C and 4D are isometric views of the proximal ring 452 and the distal ring 454, respectively, in accordance with embodiments of the present technology. Referring to Figures 4A–4C together, the proximal ring 452 can include an annular body 462 having an outer surface 461 and an inner surface 463. An annular member 464 can be coupled (e.g., welded, tack welded, adhered, fastened) to the inner surface 463 of the annular member 464 and can define/include a lumen 465. Referring to Figures 4A and 4D together, the distal ring 454 can

include an annular body 468 having an outer surface 467 and an inner surface 469. Referring to Figures 4A–4D together, the lumen 465 of the annular body 462 is configured to slidably receive a pull wire 458 (Figure 4D). The pull wire 458 can be coupled (e.g., welded, tack welded, adhered, fastened) to the inner surface 469 of the distal ring 454 and can extend from the distal ring 454 to the handle 130 (Figure 1), as described in greater detail below with reference to Figures 5A and 5B.

[0042] Referring again to Figures 4A and 4B together, the tube portion 456 can include a plurality of openings 451 extending partially about a circumference of the tube portion 456 to define a spine 453 and a plurality of ribs 455. In the illustrated embodiment, the spine 453 extends generally parallel to a longitudinal axis L (Figure 4A) of the deflectable member 450 and is generally aligned with the annular member 464 and the pull wire 458 (Figure 4D). That is, the pull wire 458 can extend through the tube portion 456 generally parallel to the spine 453. In some embodiments, the openings 451 are generally elongate openings that extend (i) generally parallel to one another and (ii) circumferentially about the longitudinal axis L such that, for example, the ribs 455 have a generally similar or identical shape. The openings 451 and/or the ribs 455 can all have the same dimensions as shown in Figures 4A and 4B while, in other embodiments, some or all of the openings 451 and/or the ribs 455 can have different dimensions and/or arrangements about the tube portion 456. In some embodiments, the tube portion 456 can be a laser-cut hypo tube.

[0043] Referring to Figures 2–4D together, in some embodiments the deflectable member 450 can be positioned between the outer sheath 240 and the inner liner 242 such that (i) the outer sheath 240 extends over/along the outer surface 461 of the proximal ring 452, an outer surface of the tube portion 456, and the outer surface 467 of the distal ring 454 and (ii) the inner liner 242 extends over/along the inner surface 463 of the proximal ring 452, an inner surface of the tube portion 456, and the inner surface 469 of the distal ring 454. In some embodiments, some or all of the pull wire 458 can be coated with PTFE or another suitable material (e.g., a fluoropolymer material). For example, the PTFE material can be omitted where the pull wire 458 is attached to the distal ring 454. The PTFE or other coating material can help inhibit the outer sheath 240 from adhering to the pull wire 458—thereby allowing the pull wire 458 to be moved relative to the deflectable member 450 after the outer sheath 240 is applied thereover.

[0044] Referring to Figures 1–3B together, in some embodiments the transition region 124 and the tip region 126 can include only the outer sheath 240 and the inner liner 242. In some

embodiments, the transition region 124 and/or the tip region 126 can include a marker band (not shown), such as a radiopaque marker configured to facilitate visualization of the position of the catheter 120 during a medical procedure (e.g., a clot removal procedure) using the catheter 120. For example, the transition region 124 and the tip region 126 can each include a radiopaque marker to facilitate visualization of the deflectable region 125 of the catheter 120.

[0045] Referring to Figures 1–4D together, in some embodiments, the catheter 120 can be formed about a mandrel or other elongate member. For example, the inner liner 232 can first be positioned about the mandrel. Then, the braid 244 can be formed (e.g., wound, braided) about the inner liner 242 around the mandrel (e.g., along the proximal and intermediate regions 121, 122) and/or the deflectable member 450 can be positioned about the inner liner 242 around the mandrel (e.g., along the deflectable region 125). Next, the coil 346 can be wound around the mandrel about the braid 244 over the intermediate region 122. Next, the outer sheath 240 can be positioned over the inner liner 242, the braid 244, the coil 346, and the deflectable member 450, and then heat shrunk or otherwise secured thereto. In some embodiments, the outer sheath 240 can be fused to the inner liner 242, the braid 244, the coil 346, and/or the deflectable member 450 to secure these components of the catheter 120 together.

[0046] Figure 5A is a partially cross-sectional side view of the handle 130 and a portion of the proximal region 121 of the catheter 120 in accordance with embodiments of the present technology. Figure 5B is an enlarged cross-sectional isometric view of a portion of the handle 130 shown in Figure 5A. Referring to Figures 5A and 5B, together, the housing 134 defines a proximal chamber 570 (e.g., a volume, lumen, compartment) and a distal chamber 572 that can be separated by the actuator 136. The valve 132 can be coupled to the housing 134 (e.g., a proximal portion of the housing 134) and positioned at least partially within the proximal chamber 570.

[0047] In the illustrated embodiment, the handle 130 includes a hollow tube member 574 positioned at least partially within the proximal chamber 570. The tube member 574 can include a proximal end portion 571a and a distal end portion 571b coupled to (e.g., secured to) the actuator 136. The tube member 574 can define a lumen 573 extending between the proximal and distal end portions 571a-b, and the tube member 574 can have a threaded inner surface 575 extending at least partially along the lumen 573. The actuator 136 can be a rotatable member, such as a wheel, grip wheel, or dial that is rotatable relative to the housing 134 to rotate the tube member 574 within the proximal chamber 570.

[0048] In the illustrated embodiment, the handle 130 further includes a catheter support or guide 576 extending at least partially through (i) the distal chamber 572, (ii) the actuator 136 (e.g., through a lumen in the actuator), (iii) the lumen 573 of the tube member 574, and (iv) the proximal chamber 570. In some embodiments, the catheter guide 576 defines a lumen 577 extending therethrough and includes a proximal flange portion 578 that can be secured to the housing 134. In some embodiments, the catheter guide 576 is fixed to the housing 134 such that the catheter guide 576 does not rotate when the actuator 136 is actuated to move the tube member 574. The proximal region 121 of the catheter 120 can extend into the handle 130, through the lumen 577 in the catheter guide 576, and to the valve 132. The proximal terminus 529 of the catheter 120 can be fluidly coupled to the valve 132. Accordingly, the catheter 120, the catheter guide 576, and the tube member 574 can be coaxially aligned. In other embodiments, the catheter guide 576 can be omitted.

[0049] The handle 130 can further include a shuttle member 580 positioned at least partially in the lumen 573 of the tube member 574 over the catheter guide 576 (e.g., over an outer surface thereof). In some embodiments, the shuttle member 580 is a hollow member slidably positioned over the catheter guide 576 and movable relative to the catheter 120. In the illustrated embodiment, the shuttle member 580 includes a threaded portion 582 having a threaded outer surface 583 and an anchor portion 584 extending from the threaded portion 582. The threaded outer surface 583 is configured to engage the threaded inner surface 575 of the tube member 574 such that, for example, movement of the tube member 574 drives the shuttle member 580 to move through the lumen 573 over the catheter guide 576 and relative to the catheter 120.

[0050] In the illustrated embodiment, the pull wire 458 extends along the catheter 120 into the handle 130 where it secured to the anchor portion 584 of the shuttle member 580. More specifically, the pull wire 458 can extend from the distal ring 454 of the deflectable member 450 (Figure 4D) and through/along the transition, intermediate, and proximal regions 124, 122, 121 of the catheter 120 (Figures 1A and 1B) to the handle 130. For example, the pull wire 458 can be routed (i) through a lumen formed in the wall of the catheter 120 or (ii) simply between the outer sheath 240 and inner liner 242 (Figures 2–3B). In the illustrated embodiment, the pull wire 458 exits the catheter 120 and the catheter guide 476 (e.g., via openings therein) and enters the distal chamber 572. From the distal chamber 572, the pull wire 458 can extend through the actuator 136 and through the lumen 573 of the tube member 574 to the anchor portion 584. As best seen in Figure 5B, in some embodiments the pull wire 458 can be secured to anchor portion

584 via a screw 581 or other fastener. In some embodiments, the handle 130 can further include a biasing member 585, such as a coil spring, coupled to and/or over the pull wire 458. The biasing member 585 can be configured to smooth/distribute tension loads on the pull wire 458 during operation that might otherwise damage the pull wire 458 and/or various components of the handle 130.

[0051] Referring to Figures 1A, 1B, and 4A–5B together, the deflectable region 125 (and correspondingly the deflectable member 450) is in the first position and the handle 130 is in a corresponding first position in which the shuttle member 580 is positioned distally within the lumen 473 of the tube member 574 proximate to the actuator 136 and/or the distal end portion 571b of the tube member 574. To move the deflectable region 125 to the second (e.g., bent) position, a user can rotate the actuator 136 in a first direction to rotate the tube member 574. The rotation of the tube member 574 can drive the shuttle member 580 to move proximally through the lumen 573 in a direction toward the proximal end portion 571a of the tube member 574 via the engagement of the threaded outer surface 583 with the threaded inner surface 575. That is, the handle 130 is configured to translate the rotational movement of the actuator 136 into linear movement of the shuttle member 580. As the shuttle member 580 moves proximally, the shuttle member 580 pulls the pull wire 458 proximally and increases the tension therein. The pull wire 458 thus moves (e.g., slides) proximally through the lumen 465 in the annular member 464 of the deflectable member 450 and, because the pull wire 458 is fixedly attached to the distal ring 454 of the deflectable member 450, the pull wire 458 urges the distal ring 454 proximally relative to the proximal ring 452. This differential force causes the tube portion 456 of the deflectable member 450 to bend toward the second position shown in Figure 1B. More specifically, because the pull wire 458 is aligned with the spine 453 of the deflectable member 450, the spine 453 can define an inner radius of the bend while the ribs 455 flex away from one another, thereby increasing a size of the openings 451. To return the deflectable region 125 from the second position to the first position, the user can rotate the actuator 136 in a second direction opposite the first direction to translate the shuttle member 580 distally through the lumen 573 to decrease the tension in the pull wire 458, thereby allowing the deflectable member 450 to return to the relaxed position shown in Figures 4A and 4B.

[0052] In other embodiments, the handle 130 can include other features for moving/driving the shuttle member 580 through the housing 134 to tension the pull wire 458. For example, the actuator 136 can be a slider, clip, or other actuator movable relative to the housing 134.

[0053] Referring to Figures 1A–5B together, in some aspects of the present technology, the catheter 120 is configured to be steered to and positioned in difficult-to-reach regions of the anatomy of a patient while still having a relatively large size (e.g., 20 French, 24 French, greater than 24 French). More particularly, the catheter 120 can have an improved torque response and flexibility compared to conventional catheters having the same size. For example, the braid 234 can provide good torque response along the proximal and intermediate regions 121, 122 of the catheter 120. Moreover, the varying hardness (e.g., distally decreasing hardness) of the outer sheath 240 can provide (i) good torque response and/or pushability at the proximal region 121 and (ii) increased flexibility at the intermediate and distal regions 122, 123. Additionally, the deflectable region 125 is configured (e.g., shaped, sized) to be positioned within and steered/flexed into the difficult-to-reach regions of the anatomy. Further, the coil 346 can provide increased hoop strength at the intermediate region 122 while still allowing the catheter 120 to flex. For example, the coil 346 can inhibit or even prevent kinking or other unwanted movement of the catheter 120 when the lumen 127 is aspirated during a clot removal procedure.

[0054] Figures 6A and 6B are a distally-facing isometric view and a side view, respectively, of a deflectable member 650 in accordance with additional embodiments of the present technology. The deflectable member 650 is configured to be positioned in the deflectable region 125 of the catheter 120 (Figure 1) and can include some features generally similar or identical to the deflectable member 450 described in detail above with reference to Figures 4A–4D. For example, in the illustrated embodiment the deflectable member 650 includes a proximal ring 652, a distal ring 654, and a tube portion 656 extending between the proximal ring 652 and the distal ring 654. The proximal ring 652 includes an annular member 664 coupled thereto and configured to slidably receive the pull wire 458. The pull wire 458 can extend through the tube portion 656 and be fixedly secured (e.g., welded) to the distal ring 654.

[0055] In the illustrated embodiment, the tube portion 656 includes a plurality of openings 651 (identified individually as first openings 651a and second openings 651b) extending partially about a circumference of the tube portion 656 to define a plurality of ribs 655 (identified individually as first ribs 655a and second ribs 655b). In some embodiments, the first openings 651a are generally elongate openings that extend (i) generally parallel to one another and (ii) circumferentially about a longitudinal axis M of the deflectable member 650 such that, for example, the first ribs 655a have a generally similar or identical shape. Similarly, the second openings 651b can each have an elongate tapered shape and can extend (i) generally parallel to one another and (ii) circumferentially about the longitudinal axis M of the deflectable member

650 such that, for example, the second ribs 655b have a generally similar or identical shape. In the illustrated embodiment, the second ribs 655b have a smaller dimension (e.g. width) in a direction along the longitudinal axis M than the first ribs 655a. Accordingly, the second ribs 655b can be relatively more flexible than the first ribs 655a.

[0056] In some embodiments, the pull wire 458 can extend over/adjacent to the first ribs 655a. Accordingly, referring to Figures 5–6B together, actuation of the actuator can 136 pull the pull wire 458 to urge the distal ring 654 proximally relative to the proximal ring 652. This differential force causes the tube portion 656 of the deflectable member 650 to bend such that, for example, a portion of the first ribs 655a define an inner radius of the bend while the second ribs 655b flex away from one another, thereby increasing a size of the second openings 651b (e.g., and conversely decreasing a size of the first openings 651a).

[0057] In some embodiments, all or a portion of the deflectable member 650 can be manufactured as a single integral piece. For example, Figure 6C is top view of flat pattern that can be cut to integrally form the proximal ring 652 and the tube portion 656 of the deflectable member 650 in accordance with embodiments of the present technology. Figure 6D is an enlarged top view of a portion of the pattern shown in Figure 6C. Referring to Figures 6C and 6D together, the pattern can be laser cut from a single piece of material (e.g., stainless steel), formed to have the three-dimensional tubular shape shown in Figures 6A and 6B, and then welded or otherwise adhered together to form the deflectable member 650.

[0058] Figures 7A–7C are side views of a portion of the catheter 120 of the clot removal system 100 during a procedure for removing clot material PE (e.g., a pulmonary embolism) from within a blood vessel BV (e.g., a pulmonary blood vessel) of a patient (e.g., a human patient) in accordance with embodiments of the present technology. As noted above, in some embodiments the clot removal procedure illustrated in Figures 7A–7C can be generally similar or identical to any of the clot removal procedures disclosed in U.S. Patent Application No. 16/536,185, filed August 8, 2019, and titled "SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED DEVICES AND METHODS," which is incorporated herein by reference in its entirety.

[0059] With reference to Figures 1A–7A together, the catheter 120 can be advanced through the patient toward and/or proximate to the clot material PE within the blood vessel BV (e.g., advanced to a treatment site within the blood vessel BV). In some embodiments, however, the blood vessel BV can include a hard-to-reach (e.g., tortuous) region, such as a region beyond a bend 790 in the blood vessel BV that can have a relatively small radius of curvature. The

region of the blood vessel BV distal of the bend 790 can be difficult to reach due to the required approach angle, varying anatomy of the blood vessel BV, and/or irregularities due to illness of the patient.

[0060] Accordingly, with reference to Figures 1A–5B and 7B together, the deflectable region 125 can be moved fully or partially from the first position (Figure 1A) to the second position (Figure 1B) before and/or during further advancement of the catheter 120 toward the clot material PE. More specifically, the user can actuate (e.g., rotate) the actuator 136 of the handle to pull the pull wire 458 to deflect the deflectable member 450 to deflect the deflectable region 125, as described in detail above. In some embodiments, the catheter 120 can be advanced through the blood vessel BV until the distal terminus 128 of the catheter 120 is positioned proximate to a proximal portion of the clot material PE. In some embodiments, the position of the distal terminus 128 can be confirmed or located via visualization of a marker band (not shown; e.g., in/along the tip region 126) using fluoroscopy or another imaging procedure (e.g., a radiographic procedure). In other embodiments, the distal terminus 128 can be positioned at least partially within the clot material PE or distal of the clot material PE.

[0061] In some aspects of the present technology, moving the deflectable region 125 to the second position helps the catheter 120 flex/bend around the bend 790 and into the hard-to-reach region of the blood vessel BV distal thereof. In some embodiments, before advancing the catheter 120 to the position shown in Figure 7B, the catheter 120 can be rotated to align the deflectable region 125 with the bend 790. In contrast, conventional catheters of the same size may be too stiff to easily position proximate the clot material PE. For example, such conventional catheters may "rainbow" over the clot material PE by following or tracking along the wall of the blood vessel BV at the outside of the bend 790. In addition to the deflectable region 125, both (i) the varying hardness of the outer sheath 240 (Figures 2–3B) and (ii) the flexibility of the braid 244 (Figures 2–3B) and the coil 346 (Figures 3B and 3C) can help the catheter 120 flex through the anatomy of the blood vessel BV to the desired position proximate the clot material PE.

[0062] Access to the pulmonary vessels can be achieved through the patient's vasculature, for example, via the femoral vein. In some embodiments, the clot removal system 100 can include an introducer (e.g., a Y-connector with a hemostasis valve; not shown) that can be partially inserted into the femoral vein. A guidewire (not shown) can be guided into the femoral vein through the introducer and navigated through the right atrium, the tricuspid valve, the right

ventricle, the pulmonary valve, and into the main pulmonary artery. Depending on the location of the clot material PE, the guidewire can be guided to one or more of the branches of the right pulmonary artery and/or the left pulmonary artery. In some embodiments, the guidewire can be extended entirely or partially through the clot material PE. In other embodiments, the guidewire can be extended to a location just proximal of the clot material PE. After positioning the guidewire, the catheter 120 can be placed over the guidewire and advanced to the position proximate to the clot material PE as illustrated in Figure 7B. In some embodiments, the guidewire can then be withdrawn while, in other embodiments, the guidewire can remain and can be used to guide other catheters (e.g., delivery catheters, additional aspiration guide catheters, etc.), interventional devices, etc., to the treatment site. It will be understood, however, that other access locations into the venous circulatory system of a patient are possible and consistent with the present technology. For example, the user can gain access through the jugular vein, the subclavian vein, the brachial vein, or any other vein that connects or eventually leads to the superior vena cava. Use of other vessels that are closer to the right atrium of the patient's heart can also be advantageous as it reduces the length of the instruments needed to reach the clot material PE.

[0063] With reference to Figures 1A, 1B, and 7C together, the pressure source 102 is configured to generate (e.g., form, create, charge, build-up) a vacuum (e.g., negative pressure) and store the vacuum for subsequent application to the catheter 120. For example, after positioning the catheter 120 proximate the clot material PE, a user can first close the fluid control device 114 before generating the vacuum in the pressure source 102 by, for example, withdrawing the plunger of a syringe coupled to the connector 116. In this manner, a vacuum is charged within the pressure source 102 (e.g., a negative pressure is maintained) before the pressure source 102 is fluidly connected to the lumen 127 of the catheter 120. To aspirate the lumen 127 of the catheter 120, the user can open the fluid control device 114 to fluidly connect the pressure source 102 to the catheter 120 and thereby apply or release the vacuum stored in the pressure source 102 to the lumen 127 of the catheter 120.

[0064] Opening of the fluid control device 114 instantaneously or nearly instantaneously applies the stored vacuum pressure to the tubing assembly 110 and the catheter 120, thereby generating a suction pulse throughout the catheter 120. In particular, the suction is applied at the tip region 126 of the catheter 120 to suck/aspirate at least a portion of the clot material PE into the lumen 127 of the catheter 120, as shown in Figure 7C. In one aspect of the present technology, pre-charging or storing the vacuum in the pressure source 102 before applying the

vacuum to the lumen 127 of the catheter 120 is expected to generate greater suction forces and corresponding fluid flow velocities at and/or near the tip region 126 of the catheter 120 compared to simply activating the pressure source 102 while it is fluidly connected to the catheter 120.

[0065] Sometimes, as shown in Figure 7C, discharging the vacuum stored in the pressure source to aspirate the lumen 127 of the catheter 120 may remove substantially all (e.g., a desired amount) of the clot material PE from the blood vessel BV. That is, a single aspiration pulse may adequately remove the clot material PE from the blood vessel BV. In other embodiments, a portion of the clot material PE may remain in the blood vessel BV. In such instances, the user may wish to again apply vacuum pressure (conduct an "aspiration pass") to remove all or a portion of the remaining clot material PE in the blood vessel BV. In such instances, the pressure source 102 can be disconnected from the tubing assembly 110 and drained (e.g., aspirated clot removal removed) before the pressure source 102 is reconnected to the tubing assembly 110 and activated once again. After removing a desired amount of the clot material PE, the catheter 120 can be withdrawn from the patient.

[0066] In some aspects of the present technology, the relatively great flexibility and torquability of the catheter 120 allow the catheter 120 to be positioned in difficult-to-reach areas of the blood vessel BV (or elsewhere in the vasculature of the patient) without decreasing the size of the lumen 127 and while keeping the lumen 127 of constant diameter throughout. It is expected that the increased size of the lumen 127 will provide greater suction forces over a smaller period of time (e.g., will provide a larger vacuum impulse). In some embodiments, the greater suction forces can facilitate the removal of clot material from a blood vessel of a patient even where the clot material is strongly lodged or attached within the blood vessel (e.g., a chronic clot). Accordingly, in contrast to conventional catheters, the catheter 120 can be used to generate greater aspirational forces for improved clot removal in hard-to-reach places of the vasculature. In additional aspects of the present technology, the coil 336 (Figures 3B and 3C) can provide a high hoop strength that inhibits or even prevents kinking or other unwanted movement of the catheter 120 when the pressure source 102 is used to generate a suction pulse at the distal region 123 of the catheter 120.

[0067] Although described in the context of removing clot material from pulmonary blood vessels, in other embodiments the clot removal system 100 can be used to remove clot from other locations in the body of the patient. For example, the clot removal system 100 can used to aspirate or otherwise remove clot material (e.g., stationary or in transit) and/or vegetation from

the heart (e.g., the right atrium, tricuspid valve, pulmonary valve), the vena cava, the renal arteries, and so on.

[0068] Several aspects of the present technology are set forth in the following examples:

1. An aspiration catheter, comprising:

a proximal region; and

a distal region including a deflectable member, wherein the deflectable member includes—

a proximal ring;

a distal ring configured to be fixedly attached to a pull wire; and

a tube portion extending between the proximal and distal rings, wherein the tube portion includes a plurality of openings extending therethrough to define a plurality of ribs, and wherein the ribs are configured to flex away from each other when the pull wire is pulled proximally.

2. The aspiration guide catheter of example 1 wherein the tube portion includes a spine extending in a direction between the proximal and distal rings, wherein the ribs extend away from the spine, and wherein the spine is configured to extend generally parallel to and over the pull wire.

3. The aspiration catheter of example 1 or example 2 wherein the proximal region and the distal region define a lumen having a diameter of 20 French or greater.

4. The aspiration catheter of any one of examples 1–3, further comprising an intermediate region between the proximal and distal regions, wherein the proximal region and the intermediate region include a braid of wires extending therethrough.

5. The aspiration catheter of example 4 wherein the intermediate region includes a wire coiled around the braid.

6. The aspiration catheter of any one of examples 1–5 wherein the tube portion extends along a longitudinal axis in a relaxed state, and wherein the openings extend

circumferentially about the longitudinal axis and generally parallel to one another in the relaxed state.

7. The aspiration catheter of any one of examples 1–6 wherein the proximal ring includes an annular member configured to slidably receive the pull wire therethrough.

8. A clot removal system, comprising:

an aspiration catheter including a proximal region and a distal region, wherein the distal region includes a deflectable member;

a handle coupled to the proximal region of the aspiration catheter, wherein the handle includes an actuator; and

a pull wire extending between the actuator and the deflectable member, wherein actuation of the actuator is configured to pull the pull wire to deflect the deflectable member to deflect the distal region of the aspiration catheter relative to the proximal region.

9. The clot removal system of example 8 wherein the aspiration catheter extends along an axis, and wherein the actuation of the actuator is configured to deflect the distal region of the aspiration catheter away from the axis by about 90 degrees or greater.

10. The clot removal system of example 8 or example 9 wherein the aspiration guide catheter has a size of 20 French or greater.

11. The clot removal system of any one of examples 8–10 wherein the deflectable member has a tubular shape that extends along a longitudinal axis, and wherein the deflectable member includes (a) a spine extending parallel to the longitudinal axis and (b) a plurality of ribs extending from the spine and circumferentially about the longitudinal axis.

12. The clot removal system of example 11 wherein the deflectable member has a distal portion and a proximal portion, and wherein the pull wire is attached to the distal portion of the deflectable member.

13. The clot removal system of example 12 wherein the actuation of the actuator is configured pull the distal portion proximally relative to the proximal portion.

14. The clot removal system of example 12 or example 13 wherein the ribs define a plurality of openings therebetween, and wherein the actuation of the actuator is configured pull the distal portion of the deflectable member proximally relative to the proximal portion to bend the spine and increase a size of the openings.

15. The clot removal system of any one of examples 8–14 wherein the aspiration catheter further includes—

an intermediate region between the proximal and distal regions;

an inner liner extending through the proximal, intermediate, and distal regions;

a braid of wires extending through the proximal and intermediate regions over the inner liner;

a wire extending through the intermediate region and coiled around the braid; and

an outer liner extending through the proximal, intermediate, and distal regions over the inner liner, the braid, and the wire, wherein the deflectable member is positioned between the inner and outer liners in the distal region.

16. The clot removal system of example 15 wherein—

the distal region further includes a proximal transition region, a distal tip region, and a deflectable region between the proximal transition region and the distal tip region;

the deflectable member is positioned in the deflectable region;

the outer liner has a first hardness in the proximal transition region, a second hardness in the deflectable region, and a third hardness in the distal tip region; and

the second hardness is less than the first hardness and less than the third hardness.

17. A method of removing clot material from a blood vessel, the method comprising:

advancing an aspiration catheter through the blood vessel, wherein the aspiration catheter includes a distal portion and a proximal portion;

actuating a handle coupled to the aspiration catheter to deflect the distal portion of the aspiration catheter away from a longitudinal axis of the proximal portion;

positioning a distal tip of the aspiration catheter proximate to the clot material;

activating a pressure source coupled to the aspiration catheter via a fluid control device, while the fluid control device is closed, to generate a vacuum in the pressure source; and

opening the fluid control device to apply the vacuum to the aspiration catheter to thereby aspirate at least a portion of the clot material into the aspiration catheter.

18. The method of example 17 wherein actuating the handle to deflect the distal portion of the aspiration catheter includes deflecting the distal portion of the aspiration catheter away from the longitudinal axis in a deflection direction, and wherein the method further comprises rotating the aspiration catheter such that the deflection direction is at least partially aligned with a bend in the blood vessel.

19. The method of example 17 or example 18 wherein the aspiration catheter has a size of 20 French or greater.

20. The method of any one of examples 17–19 wherein the aspiration catheter includes a deflectable member positioned in the distal portion, and wherein actuating the handle includes rotating an actuator of the handle to pull a pull wire coupled to the deflectable portion proximally to deflect the deflectable member to deflect the distal portion of the aspiration catheter.

[0069] The above detailed descriptions of embodiments of the technology are not intended to be exhaustive or to limit the technology to the precise form disclosed above. Although specific embodiments of, and examples for, the technology are described above for illustrative purposes, various equivalent modifications are possible within the scope of the technology as those skilled in the relevant art will recognize. For example, although steps are presented in a given order, alternative embodiments may perform steps in a different order. The various embodiments described herein may also be combined to provide further embodiments.

[0070] From the foregoing, it will be appreciated that specific embodiments of the technology have been described herein for purposes of illustration, but well-known structures and functions have not been shown or described in detail to avoid unnecessarily obscuring the

description of the embodiments of the technology. Where the context permits, singular or plural terms may also include the plural or singular term, respectively.

[0071] Moreover, unless the word "or" is expressly limited to mean only a single item exclusive from the other items in reference to a list of two or more items, then the use of "or" in such a list is to be interpreted as including (a) any single item in the list, (b) all of the items in the list, or (c) any combination of the items in the list. Additionally, the term "comprising" is used throughout to mean including at least the recited feature(s) such that any greater number of the same feature and/or additional types of other features are not precluded. It will also be appreciated that specific embodiments have been described herein for purposes of illustration, but that various modifications may be made without deviating from the technology. Further, while advantages associated with some embodiments of the technology have been described in the context of those embodiments, other embodiments may also exhibit such advantages, and not all embodiments need necessarily exhibit such advantages to fall within the scope of the technology. Accordingly, the disclosure and associated technology can encompass other embodiments not expressly shown or described herein.

CLAIMS

I/We claim:

1. An aspiration catheter, comprising:

a proximal region; and

a distal region including a deflectable member, wherein the deflectable member includes—

a proximal ring;

a distal ring configured to be fixedly attached to a pull wire; and

a tube portion extending between the proximal and distal rings, wherein the tube portion includes a plurality of openings extending therethrough to define a plurality of ribs, and wherein the ribs are configured to flex away from each other when the pull wire is pulled proximally.

2. The aspiration guide catheter of claim 1 wherein the tube portion includes a spine extending in a direction between the proximal and distal rings, wherein the ribs extend away from the spine, and wherein the spine is configured to extend generally parallel to and over the pull wire.

3. The aspiration catheter of claim 1 wherein the proximal region and the distal region define a lumen having a diameter of 20 French or greater.

4. The aspiration catheter of claim 1, further comprising an intermediate region between the proximal and distal regions, wherein the proximal region and the intermediate region include a braid of wires extending therethrough.

5. The aspiration catheter of claim 4 wherein the intermediate region includes a wire coiled around the braid.

6. The aspiration catheter of claim 1 wherein the tube portion extends along a longitudinal axis in a relaxed state, and wherein the openings extend circumferentially about the longitudinal axis and generally parallel to one another in the relaxed state.

7. The aspiration catheter of claim 1 wherein the proximal ring includes an annular member configured to slidably receive the pull wire therethrough.

8. A clot removal system, comprising:

an aspiration catheter including a proximal region and a distal region, wherein the distal region includes a deflectable member;

a handle coupled to the proximal region of the aspiration catheter, wherein the handle includes an actuator; and

a pull wire extending between the actuator and the deflectable member, wherein actuation of the actuator is configured to pull the pull wire to deflect the deflectable member to deflect the distal region of the aspiration catheter relative to the proximal region.

9. The clot removal system of claim 8 wherein the aspiration catheter extends along an axis, and wherein the actuation of the actuator is configured to deflect the distal region of the aspiration catheter away from the axis by about 90 degrees or greater.

10. The clot removal system of claim 8 wherein the aspiration guide catheter has a size of 20 French or greater.

11. The clot removal system of claim 8 wherein the deflectable member has a tubular shape that extends along a longitudinal axis, and wherein the deflectable member includes (a) a spine extending parallel to the longitudinal axis and (b) a plurality of ribs extending from the spine and circumferentially about the longitudinal axis.

12. The clot removal system of claim 11 wherein the deflectable member has a distal portion and a proximal portion, and wherein the pull wire is attached to the distal portion of the deflectable member.

13. The clot removal system of claim 12 wherein the actuation of the actuator is configured pull the distal portion proximally relative to the proximal portion.

14. The clot removal system of claim 12 wherein the ribs define a plurality of openings therebetween, and wherein the actuation of the actuator is configured pull the distal portion of the deflectable member proximally relative to the proximal portion to bend the spine and increase a size of the openings.

15. The clot removal system of claim 8 wherein the aspiration catheter further includes—

an intermediate region between the proximal and distal regions;

an inner liner extending through the proximal, intermediate, and distal regions;

a braid of wires extending through the proximal and intermediate regions over the inner liner;

a wire extending through the intermediate region and coiled around the braid; and

an outer liner extending through the proximal, intermediate, and distal regions over the inner liner, the braid, and the wire, wherein the deflectable member is positioned between the inner and outer liners in the distal region.

16. The clot removal system of claim 15 wherein—

the distal region further includes a proximal transition region, a distal tip region, and a deflectable region between the proximal transition region and the distal tip region;

the deflectable member is positioned in the deflectable region;

the outer liner has a first hardness in the proximal transition region, a second hardness in the deflectable region, and a third hardness in the distal tip region; and

the second hardness is less than the first hardness and less than the third hardness.

17. A method of removing clot material from a blood vessel, the method comprising:

advancing an aspiration catheter through the blood vessel, wherein the aspiration catheter includes a distal portion and a proximal portion;

actuating a handle coupled to the aspiration catheter to deflect the distal portion of the aspiration catheter away from a longitudinal axis of the proximal portion;

positioning a distal tip of the aspiration catheter proximate to the clot material;

activating a pressure source coupled to the aspiration catheter via a fluid control device, while the fluid control device is closed, to generate a vacuum in the pressure source; and

opening the fluid control device to apply the vacuum to the aspiration catheter to thereby aspirate at least a portion of the clot material into the aspiration catheter.

18. The method of claim 17 wherein actuating the handle to deflect the distal portion of the aspiration catheter includes deflecting the distal portion of the aspiration catheter away from the longitudinal axis in a deflection direction, and wherein the method further comprises rotating the aspiration catheter such that the deflection direction is at least partially aligned with a bend in the blood vessel.

19. The method of claim 17 wherein the aspiration catheter has a size of 20 French or greater.

20. The method of claim 17 wherein the aspiration catheter includes a deflectable member positioned in the distal portion, and wherein actuating the handle includes rotating an actuator of the handle to pull a pull wire coupled to the deflectable portion proximally to deflect the deflectable member to deflect the distal portion of the aspiration catheter.

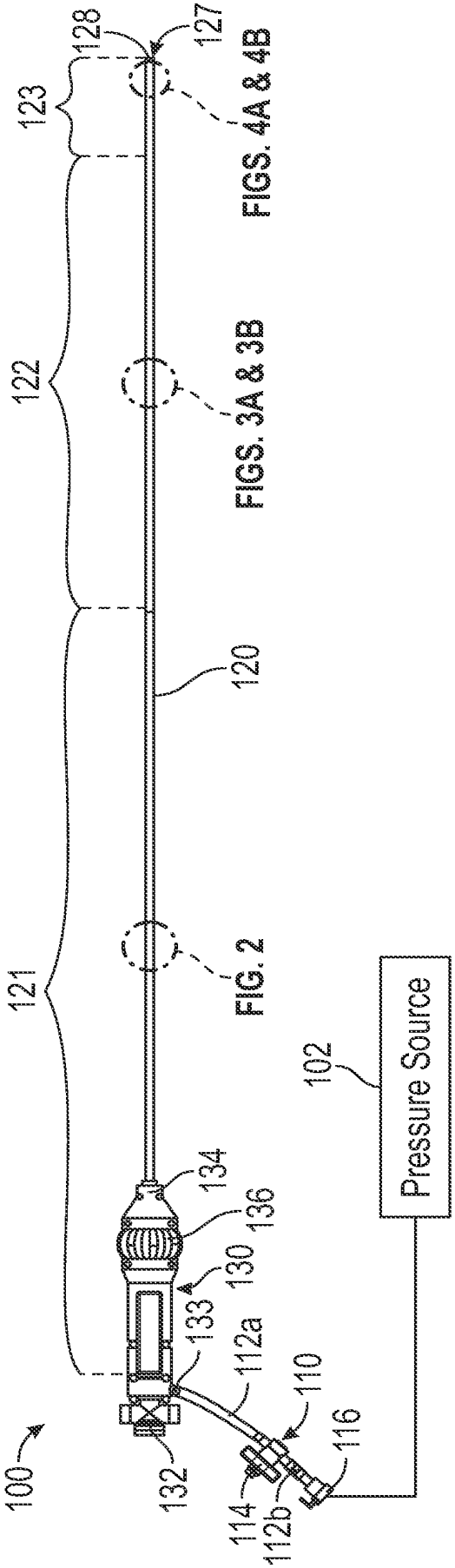

100
132
114
112b
116
110
112a
133
130
136
134
121
122
123
128
127
120
102
Pressure Source
FIG. 2
FIGS. 3A & 3B
FIGS. 4A & 4B

FIG. 1A

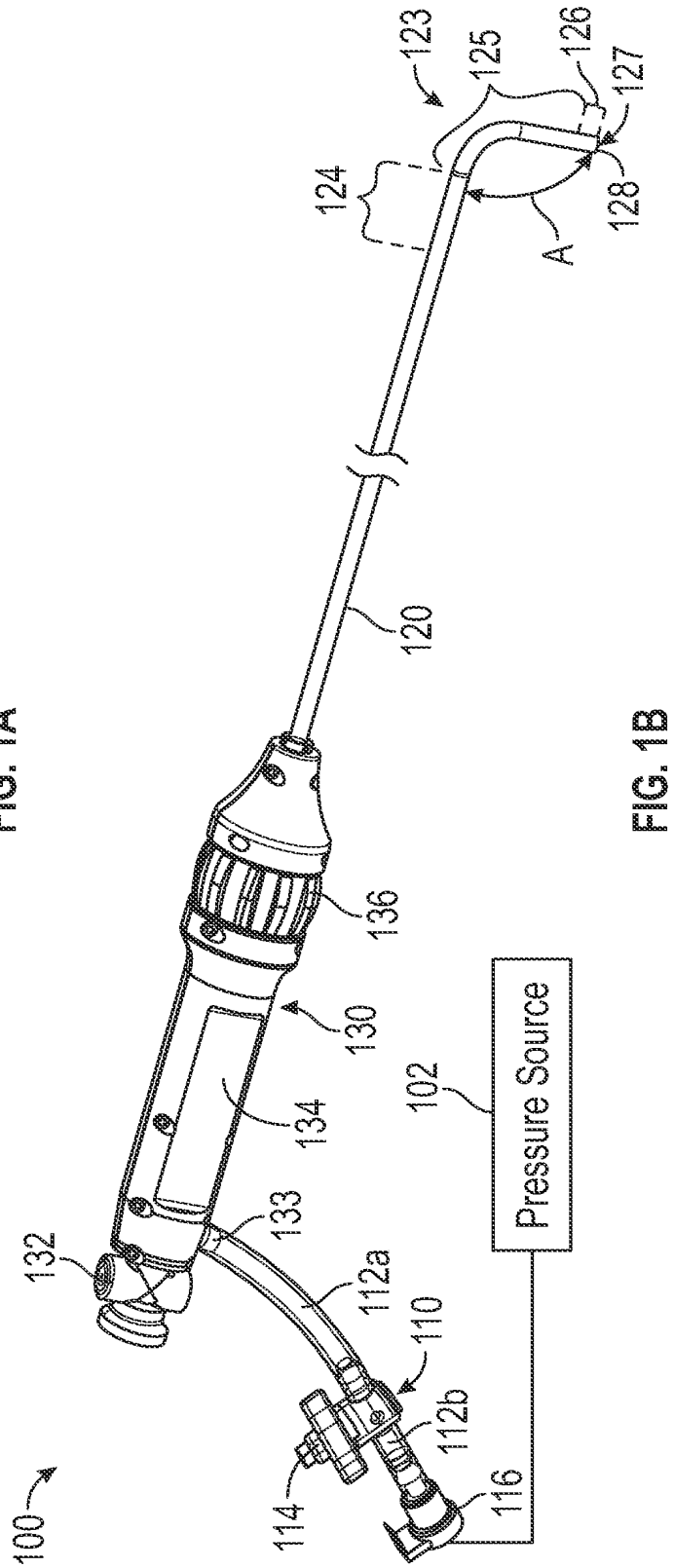

100
132
114
112b
116
110
112a
133
130
136
134
123
124
125
126
127
128
A
120
102
Pressure Source

FIG. 1B

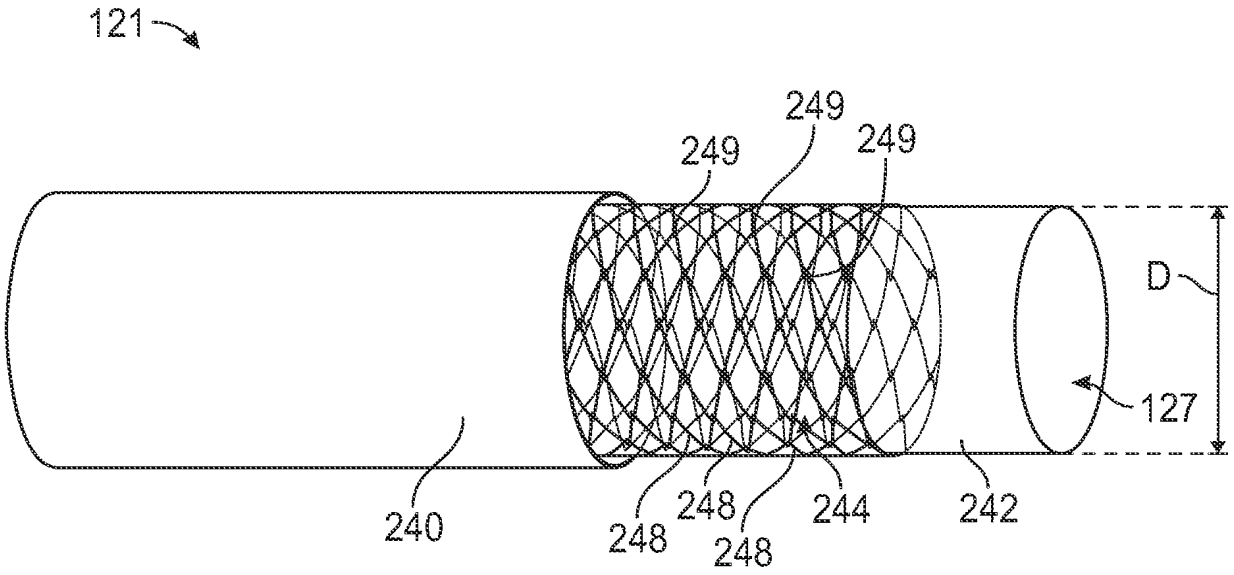

121
249
249
249
D
127
240
248
248
248
244
242

FIG. 2

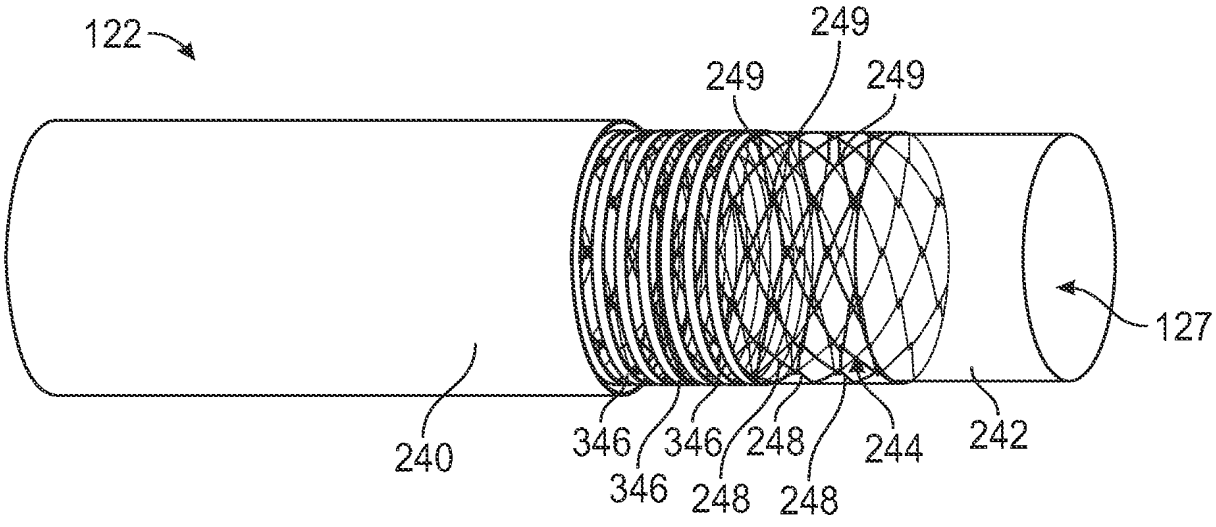

122
249
249
249
127
240
346
346
346
248
248
248
244
242

FIG. 3A

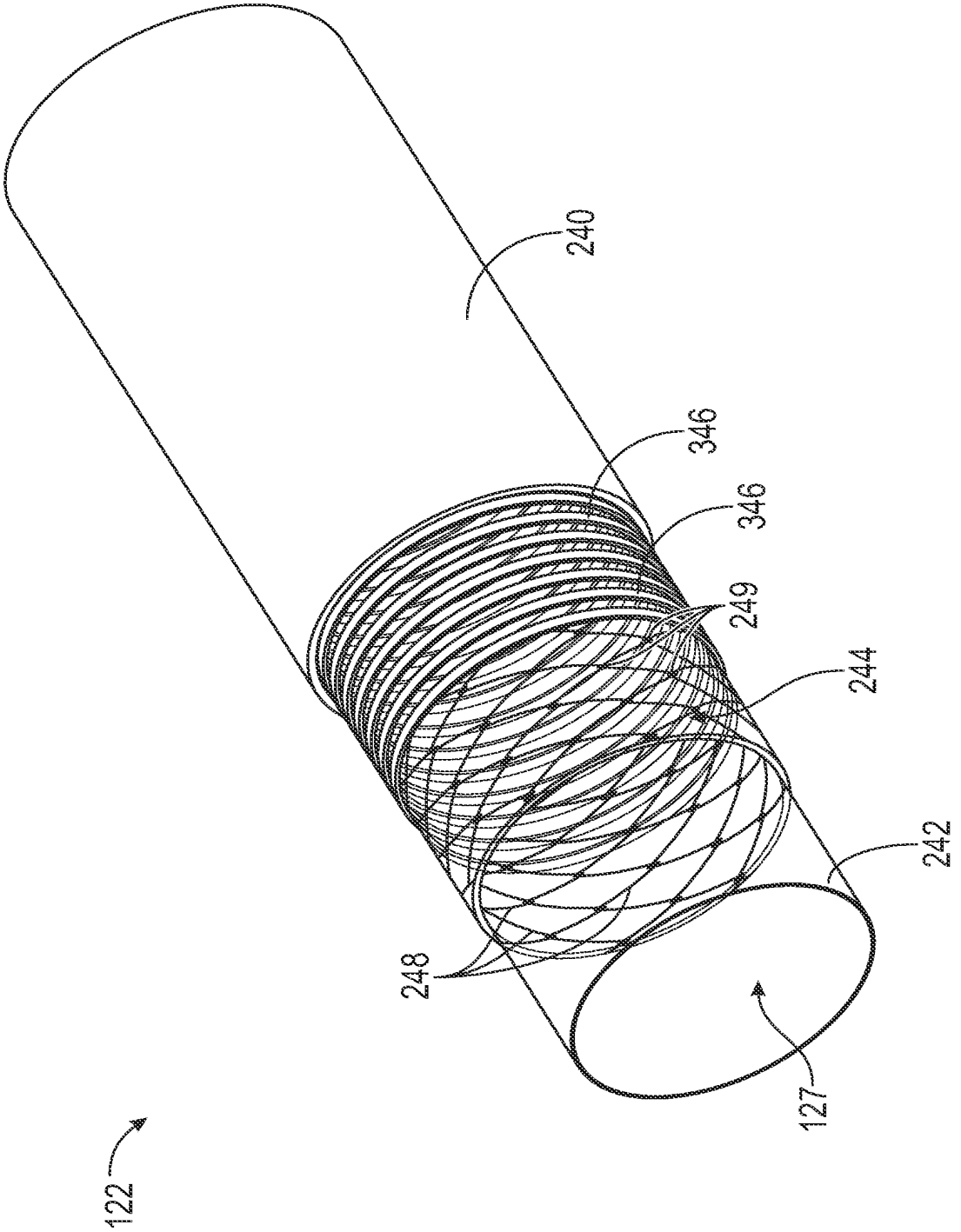


FIG. 3B

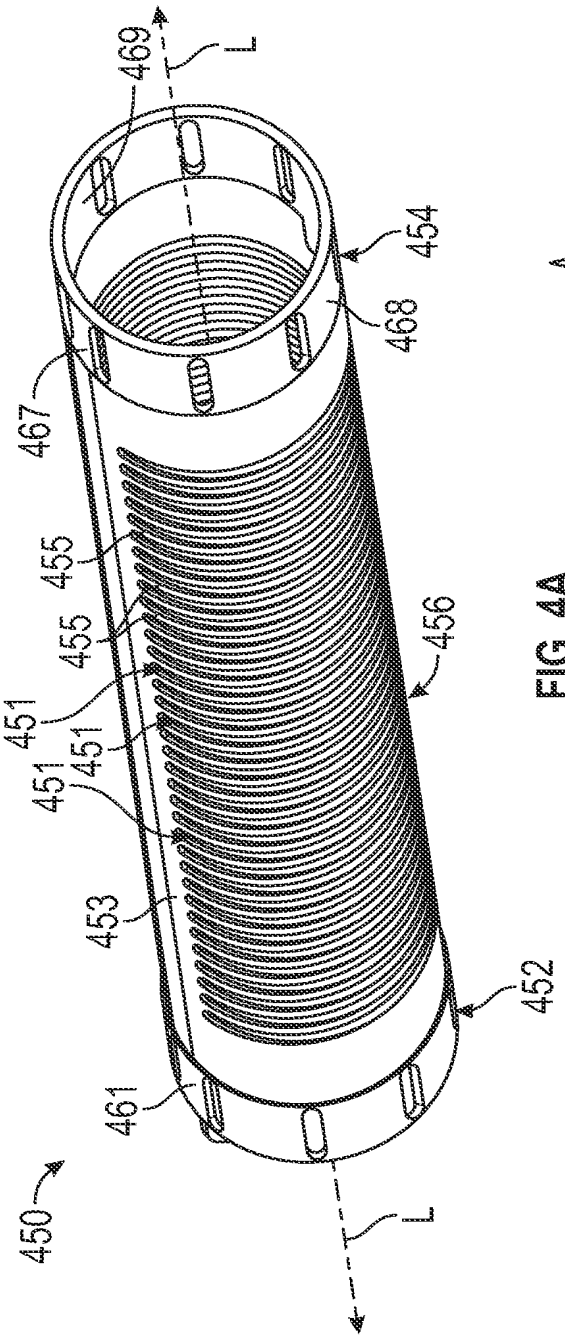

469
L
454
468
467
455
455
451
451
451
453
456
452
461
450
L

FIG. 4A

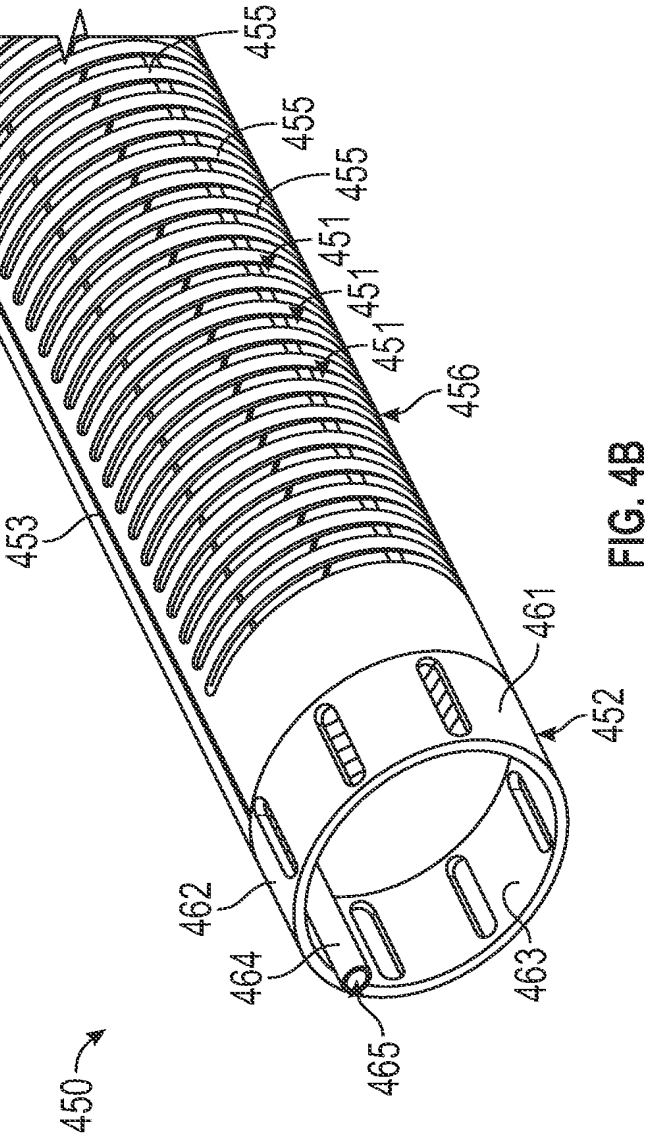

455
455
455
451
451
451
456
453
461
452
462
464
463
465
450

FIG. 4B

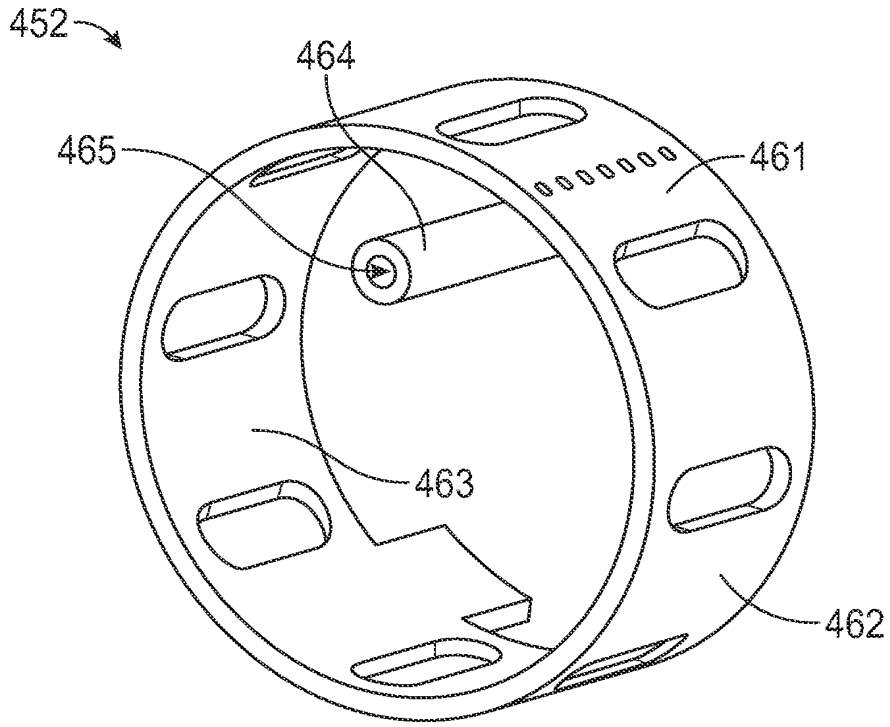


FIG. 4C

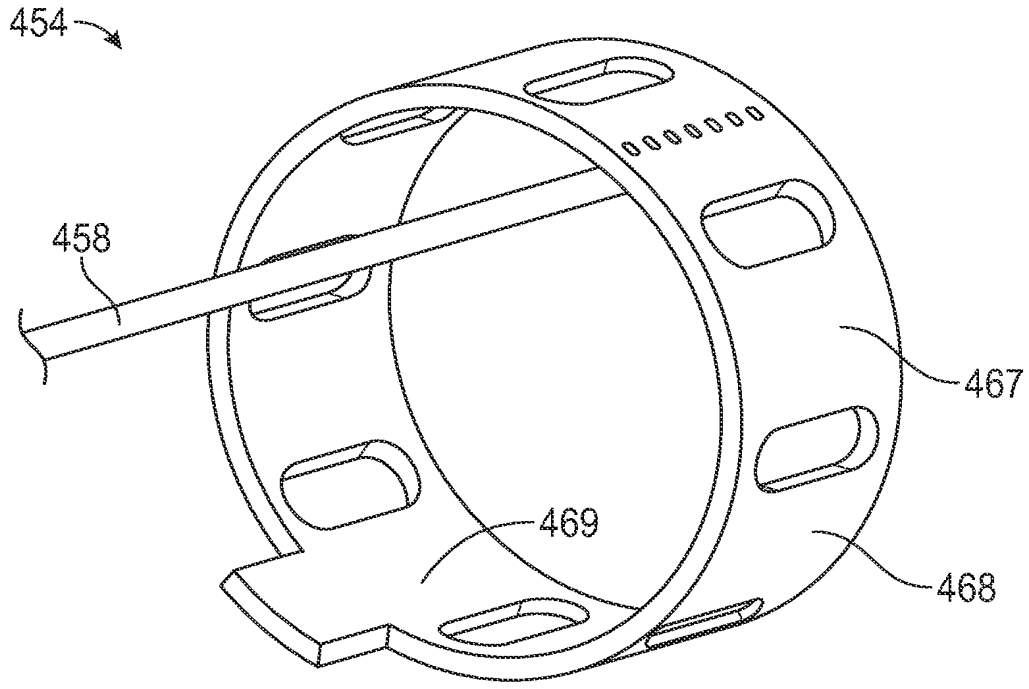


FIG. 4D

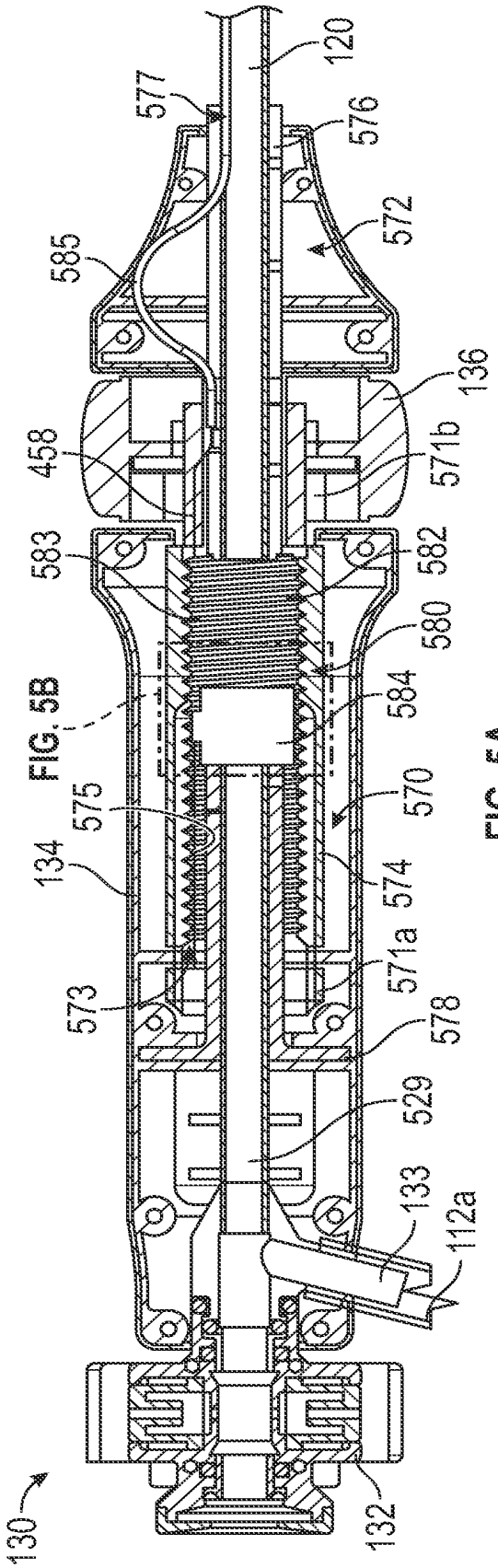


FIG. 5B

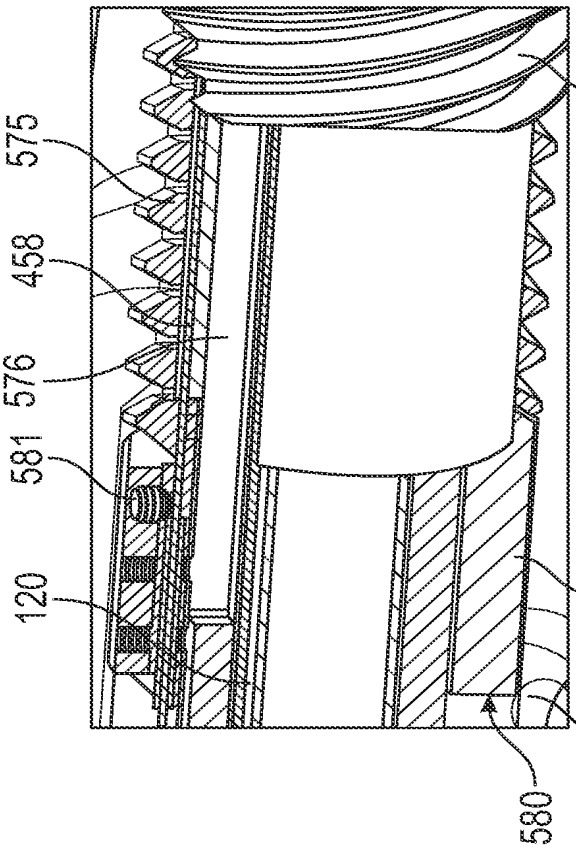


FIG. 5A

FIG. 5B

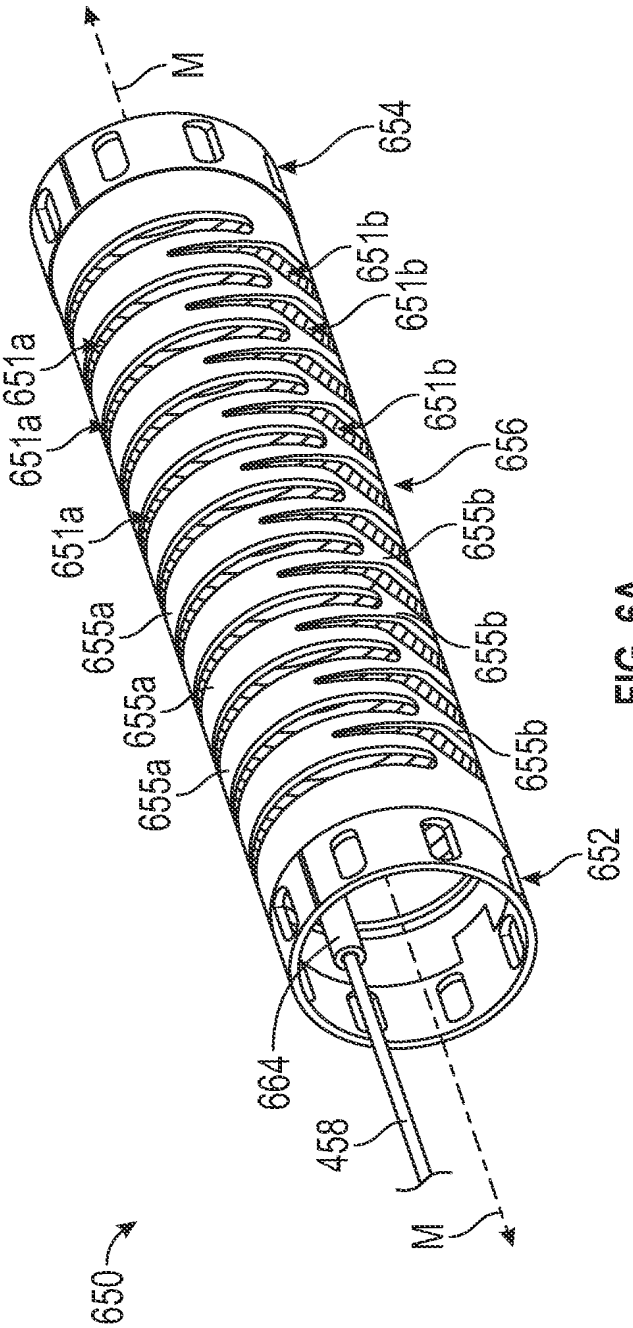

M
654
651b
651b
651a
651a
651b
656
651a
655b
655a
655b
655a
655b
652
664
458
M
650

FIG. 6A

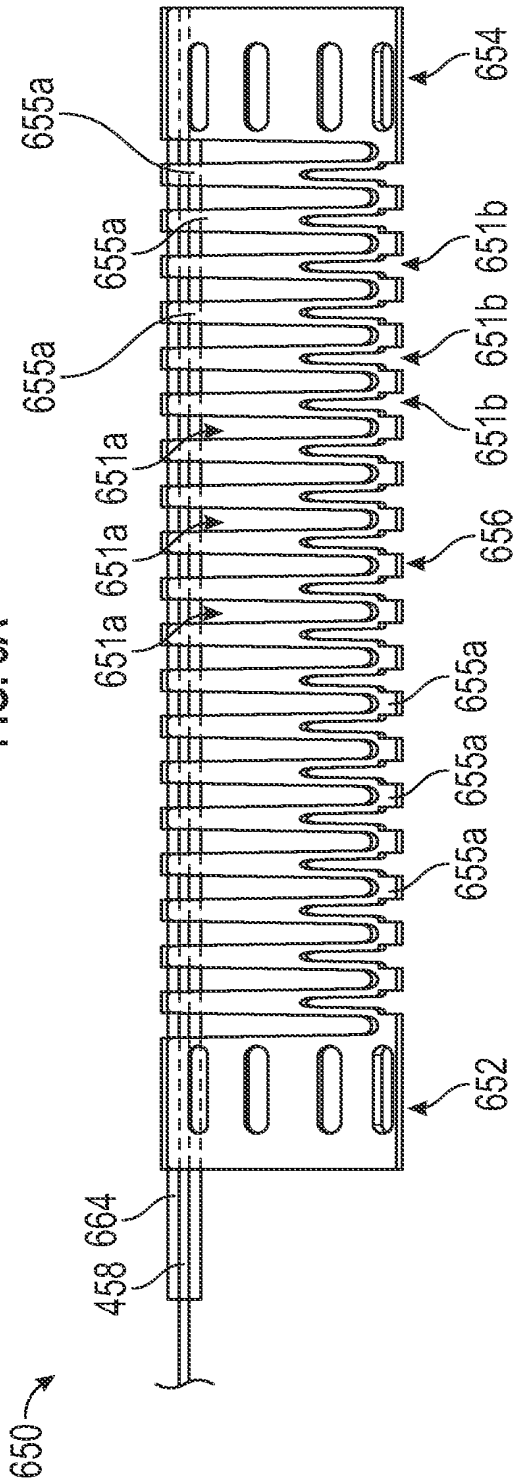

654
655a
655a
651b
651b
655a
651b
651b
651a
651a
656
651a
655a
655a
655a
652
664
458
650

FIG. 6B

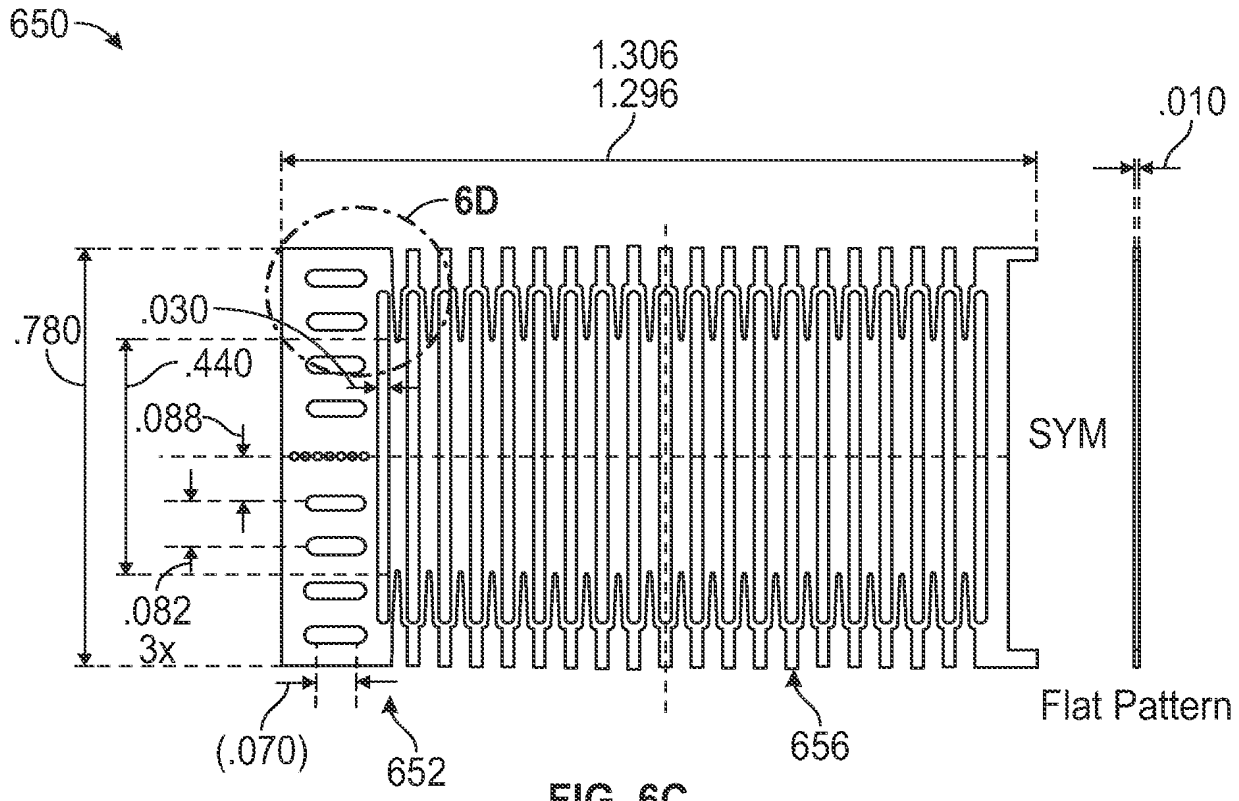

650
1.306
1.296
.010
6D
.780
.030
.440
.088
.082
3x
SYM
(.070)
652
656
Flat Pattern

FIG. 6C

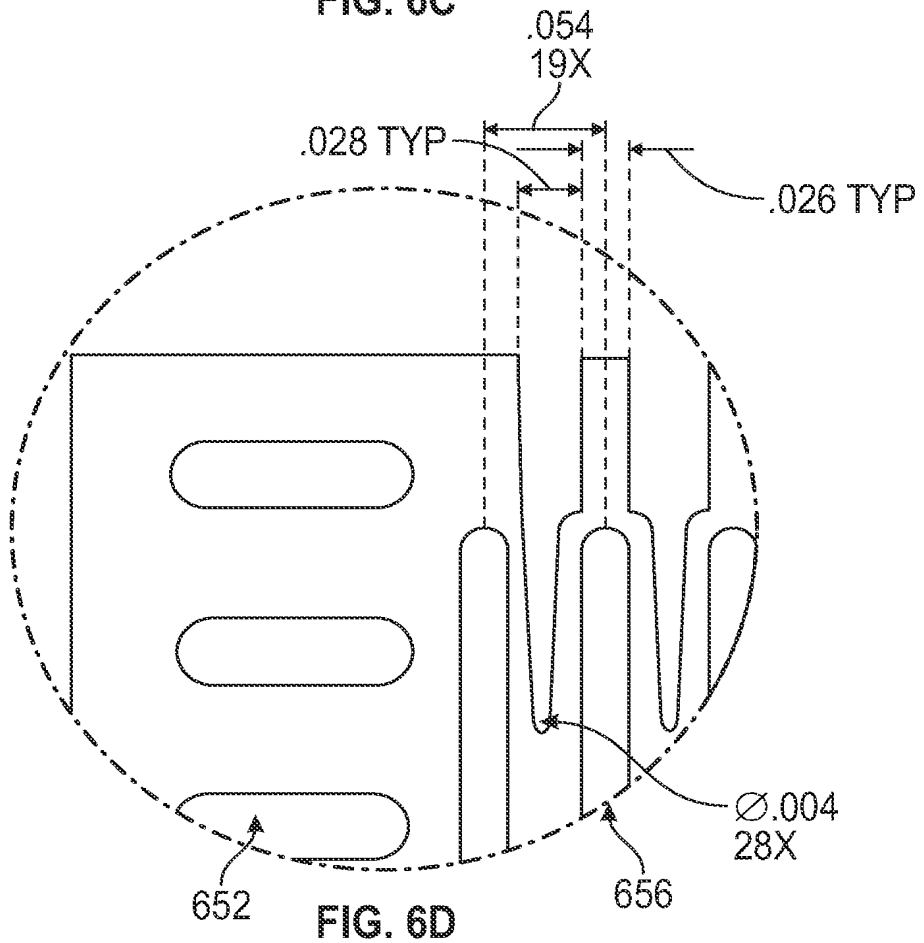

.054
19X
.028 TYP
.026 TYP
∅.004
28X
652
656

FIG. 6D

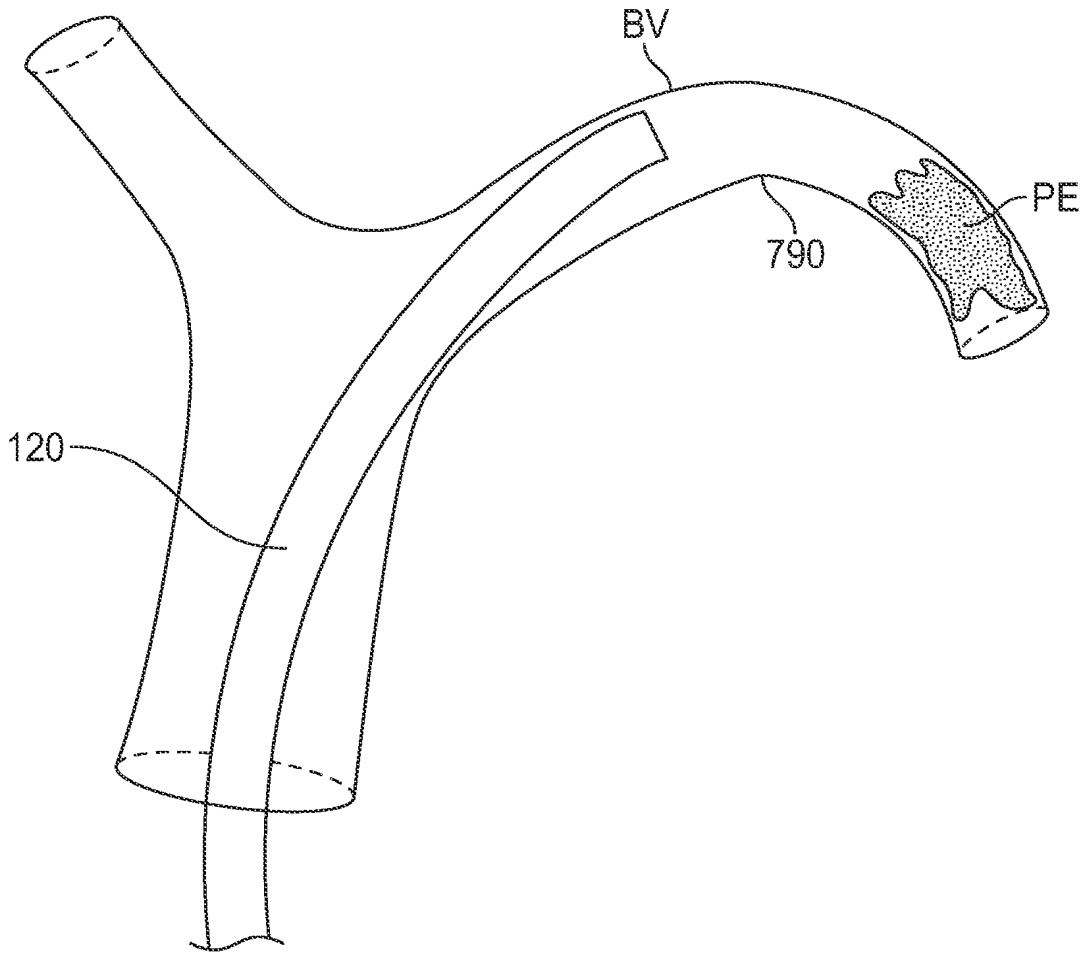


FIG. 7A

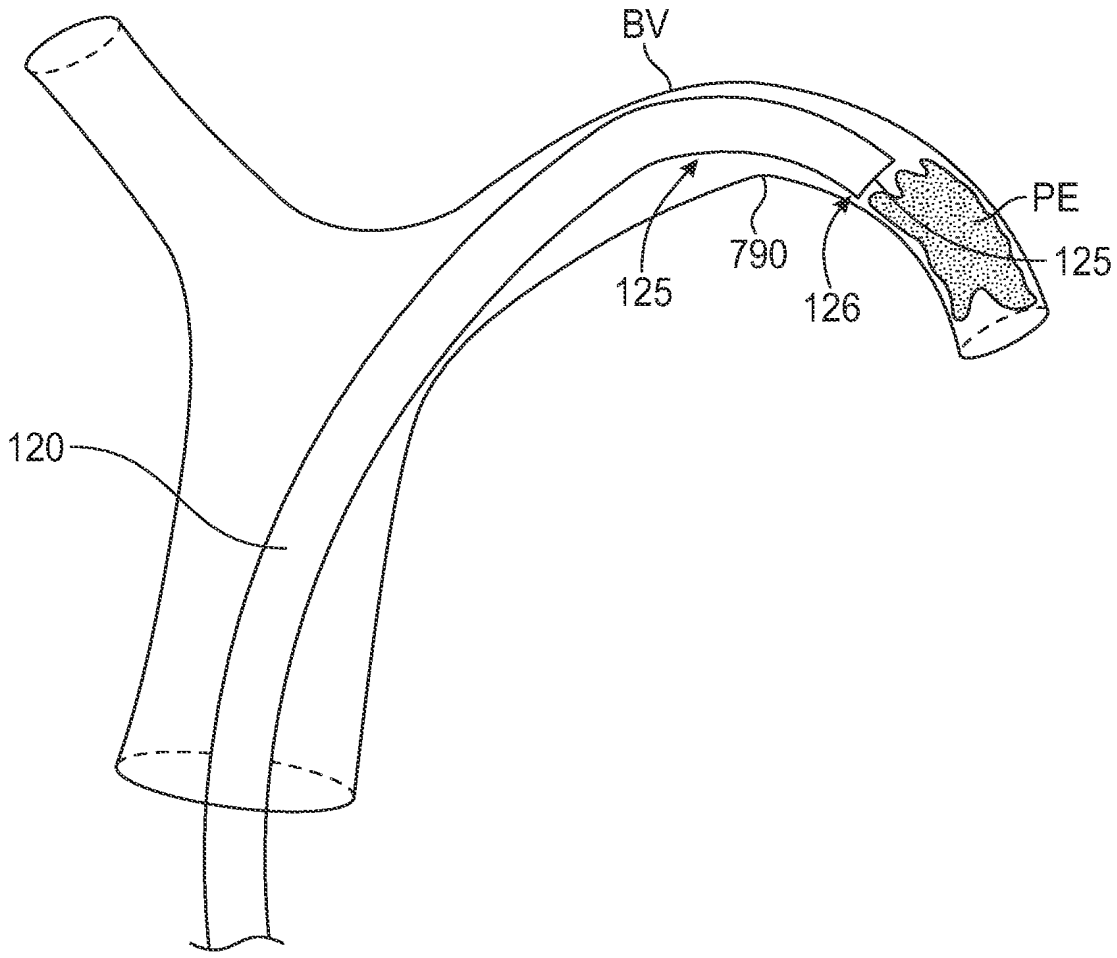


FIG. 7B

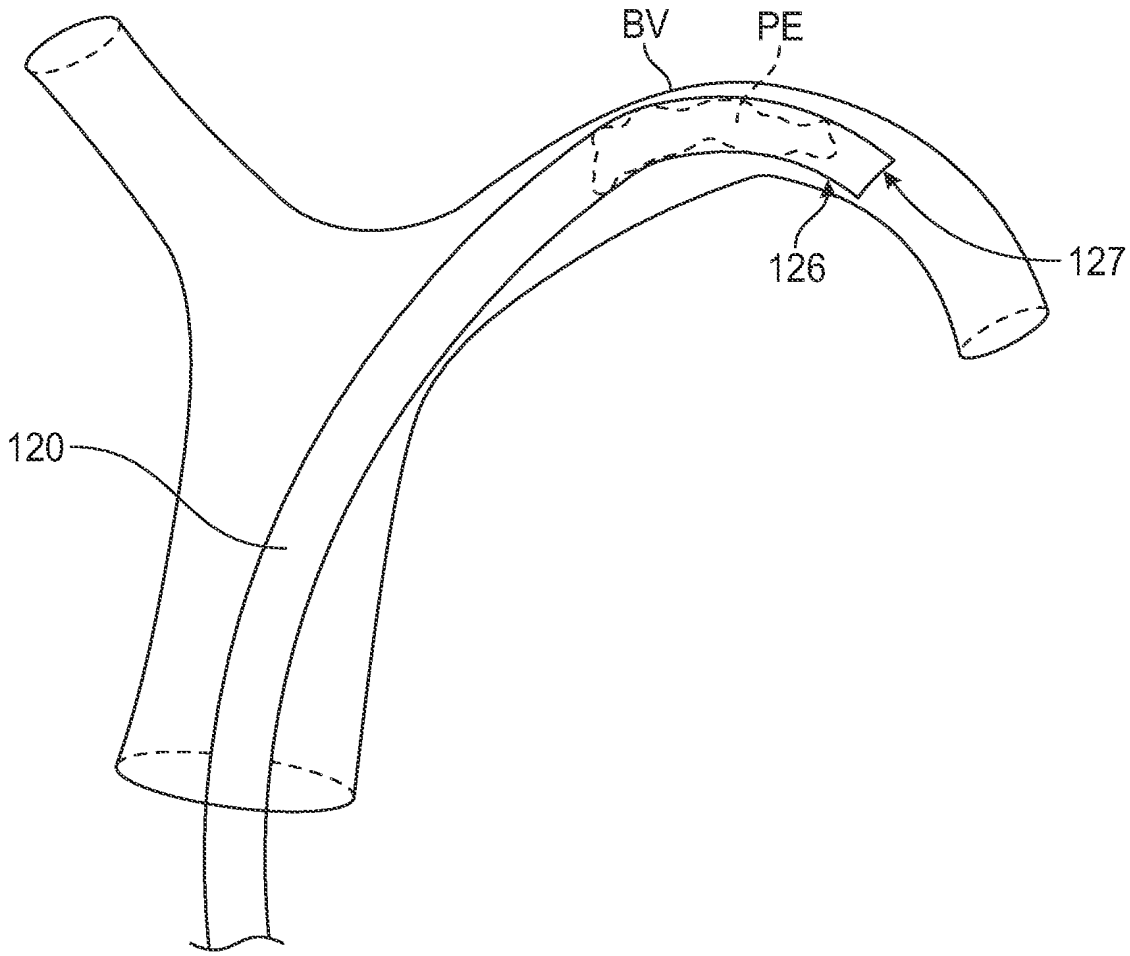


FIG. 7C

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 21/59735

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:
This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I: Claims 1-7 directed to a proximal ring; a distal ring and a tube portion.

Group II: Claims 8-20 directed to a handle and an actuator.

-*-Continued in Supplemental Box-*-

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
1-7

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 21/59735

A. CLASSIFICATION OF SUBJECT MATTER
IPC - A61M 25/00 (2022.01)
CPC - A61M 25/0147; A61M 25/0138

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	WO 2019/246240 A1 (INTUITIVE SURGICAL OPERATIONS, INC.) 26 December 2019 (26.12.2019), entire document, especially Fig 4A, 4C; para [0071]-[0084]	1-3, 6-7
Y		4-5
Y	US2010/0016837 A1 (Howat) 21 January 2010 (21.01.2010), entire document, especially Fig 1-8; para [0034]-[0042]	4-5
A	US 2004/0138525 A1 (Saadat et al.) 15 July 2004 (15.07.2004), entire document	1-7
A	US 2020/0113412 A1 (AMBU A/S) 16 April 2020 (16.04.2020), entire document	1-7
A	US 2009/0192495 A1 (Ostrovsky et al.) 30 July 2009 (30.07.2009), entire document	1-7

☐ 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
20 February 2022	MAR 22 2022
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 Kari Rodriquez Telephone No. PCT Helpdesk: 571-272-4300

Form PCT/ISA/210 (second sheet) (July 2019)

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 21/59735

-*-Box No. III - Observations where unity of invention is lacking-*-

The inventions listed as Groups I-II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

SPECIAL TECHNICAL FEATURES

The Invention of Group I includes the special technical feature of a proximal ring; a distal ring configured to be fixedly attached to a pull wire; and a tube portion extending between the proximal and distal rings, wherein the tube portion includes a plurality of openings extending therethrough to define a plurality of ribs, and wherein the ribs are configured to flex away from each other when the pull wire is pulled proximally, not required by Group II.

The invention of Group II includes the special technical feature of a handle coupled to the proximal region of the aspiration catheter, wherein the handle includes an actuator; and pull wire extending between the actuator and the deflectable member, wherein actuation of the actuator is configured to pull the pull wire, not required by the claims of Group I.

COMMON TECHNICAL FEATURES

Groups I-II share the common technical features of an aspiration catheter including a proximal region and a distal region, wherein the distal region includes a deflectable member; and a pull wire configured to deflect the deflectable member to deflect the distal region of the aspiration catheter relative to the proximal region. However, this shared technical feature does not represent a contribution over prior art as being anticipated by US 2004/0138525 A1 to Saadat et al. (hereinafter "Saadat"), which discloses an aspiration catheter (30; Fig 21A-21B; para [0097]; see analogous Fig 41, para [0125] describing tool arm 30 used for aspiration, wherein the tool arm 30 is interpreted as an aspiration catheter) including a proximal region (proximal half of 30; Fig 21A-21B; para [0097]; the proximal half of 30 being the bottom-most half of the entire tool arm 30 in the orientation shown in Fig 21A) and a distal region (distal half of 30; Fig 21A-21B; para [0097]; the distal half of 30 being the top-most half of the entire tool arm 30 in the orientation shown in Fig 21A), wherein the distal region includes a deflectable member (portion of 30 from bottom slot 132 to the distal-most end of 30; Fig 21A-21B; para [0097]); and a pull wire configured to deflect the deflectable member to deflect the distal region of the aspiration catheter relative to the proximal region (96; Fig 21A-21B; para [0097]; pullwire 96 is shown to be attached to the portion of 30 extending distally from distal-most slot 132 via fixation point 104 wherein pulling the pullwire 96 causes the distal tip of tool arm 30 to deflect relative to the proximal region of tool arm 30).

As the common technical features were known in the art at the time of the invention, these cannot be considered special technical feature that would otherwise unify the groups.

Therefore, Groups I-II lack unity under PCT Rule 13 because they do not share a same or corresponding special technical feature.

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
09 December 2021 (09.12.2021)

WIPO | PCT

(10) International Publication Number
WO 2021/248042 A1

(51) International Patent Classification:
A61B 17/00 (2006.01) *A61M 25/10* (2013.01)
A61B 17/22 (2006.01) *A61M 1/00* (2006.01)
A61B 17/3207 (2006.01)

(21) International Application Number:
PCT/US2021/035965

(22) International Filing Date:
04 June 2021 (04.06.2021)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
63/035,605 05 June 2020 (05.06.2020) US

(71) Applicant: **INARI MEDICAL, INC.** [US/US]; 9 Parker, Suite #100, Irvine, California 92618 (US).

(72) Inventors: **THRESS, John Coleman**; 9 Parker, Suite #100, Irvine, California 92618 (US). **MERRITT, Benjamin Edward**; 9 Parker, Suite #100, Irvine, California 92618 (US). **LOUW, Jacob F.**; 9 Parker, Suite #100, Irvine, California 92618 (US). **MACIAS, Jacqueline**; 9 Parker, Suite #100, Irvine, California 92618 (US). **STRAUSS, Brian Michael**; 9 Parker, Suite #100, Irvine, California 92618 (US). **ZOZULENKO, Marcus Ian Tambongco**; 9 Parker, Suite #100, Irvine, California 92618 (US). **ZIKRY, Christopher Andrew**; 9 Parker, Suite #100, Irvine, California 92618 (US). **IAN, Cheng Lance**; 9 Parker, Suite #100, Irvine, California 92618 (US).

(74) Agent: **WILLIAMS, Matthew S.** et al.; PERKINS COIE LLP, P.O. Box 1247, Seattle, Washington 98111-1247 (US).

(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, DJ, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, IT, JO, JP, KE, KG, KH, KN, KP, KR, KW, 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, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, WS, 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).

Published:
— *with international search report (Art. 21(3))*
— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))*

(54) Title: RECAPTURABLE FUNNEL CATHETERS, AND ASSOCIATED SYSTEMS AND METHODS



Fig. 10C

(57) Abstract: Systems and methods for the intravascular treatment of clot material within a blood vessel of a human patient are disclosed herein. In one embodiment, a funnel catheter assembly includes an outer shaft and an inner shaft extending through and coaxial with the outer shaft. An expandable funnel can be coupled to a distal portion of the inner shaft. The funnel catheter assembly further includes a control assembly operably coupled to the proximal portion of the outer shaft and configured to move the outer shaft between a first position and a second position. In the first position, the outer shaft is positioned at least partially over the funnel to constrain the funnel in a compressed state. In the second position, the outer shaft is retracted proximally relative to the funnel such that the funnel can expand to an expanded state.

WO 2021/248042 A1

RECAPTURABLE FUNNEL CATHETERS, AND ASSOCIATED SYSTEMS AND METHODS

CROSS-REFERENCE TO RELATED APPLICATION

[0001] This application claims the benefit of U.S. Provisional Patent Application No. 63/035,605, filed June 5, 2020, and titled "RECAPTURABLE FUNNEL CATHETERS, AND ASSOCIATED SYSTEMS AND METHODS," which is incorporated herein by reference in its entirety.

TECHNICAL FIELD

[0002] The present technology generally relates to systems, methods, and devices for embolic protection during procedures for extracting thrombi from blood vessels of human patients.

BACKGROUND

[0003] Thrombosis is the local coagulation or clotting of the blood in a part of the circulatory system, and a thrombus is a blood clot formed in situ within the vascular system. A venous thrombus is a blood clot that forms within a vein. A common type of venous thrombosis is a deep vein thrombosis (DVT), which is the formation of a blood clot within a deep vein (e.g., predominantly in the legs). Nonspecific signs of a thrombosis may include pain, swelling, redness, warmness, and engorged superficial veins.

[0004] If the thrombus breaks off (embolizes) and flows towards the lungs, it can become a life-threatening pulmonary embolism (PE) (e.g., a blood clot in the lungs). In addition to the loss of life that can arise from PE, DVT can cause significant health issues such as post thrombotic syndrome, which can cause chronic swelling, pressure, pain, and ulcers due to valve and vessel damage. Further, DVT can result in significant health-care costs either directly or indirectly through the treatment of related complications and inability of patients to work.

[0005] Three processes are believed to result in venous thrombosis. First is a decreased blood flow rate (venous stasis), second is an increased tendency to clot (hypercoagulability), and the third is changes to the blood vessel wall. DVT formation typically begins inside the valves of the calf veins where the blood is relatively oxygen deprived, which activates certain biochemical pathways. Several medical conditions increase the risk for DVT, including

diabetes, cancer, trauma, and antiphospholipid syndrome. Other risk factors include older age, surgery, immobilization (as with bed rest, orthopedic casts, and sitting on long flights), combined oral contraceptives, pregnancy, the postnatal period, and genetic factors. The rate of DVT increases dramatically from childhood to old age and, in adulthood, about 1 in 1,000 adults develop DVT annually.

[0006] Although current devices and methods of prevention and/or treatment of DVT exist, there are a number of shortcomings that have yet to be resolved, such as high incidence of DVT re-occurrence, use of devices not designed to remove large clot volumes, and/or complicated treatments involving multiple treatment devices and/or pharmaceuticals. Accordingly, new devices, systems, and methods of treating thrombus, and particularly DVT are desired.

BRIEF DESCRIPTION OF THE DRAWINGS

[0007] Many aspects of the present technology can be better understood with reference to the following drawings. The components in the drawings are not necessarily to scale. Instead, emphasis is placed on illustrating clearly the principles of the present disclosure.

[0008] Figure 1 is a partially transparent and partially cross-sectional side view of a funnel catheter assembly in accordance with embodiments of the present technology.

[0009] Figures 2A and 2B are side views of the funnel catheter assembly in a first position and a second position, respectively, in accordance with embodiments of the present technology.

[0010] Figure 3 is a side view of the funnel catheter assembly in the first position with a dilator inserted therethrough in accordance with embodiments of the present technology.

[0011] Figure 4 is a side view of the funnel catheter assembly including a non-self-expanding funnel in accordance with embodiments of the present technology.

[0012] Figures 5–8 are schematic views illustrating various thrombectomy techniques for removing a thrombus from a blood vessel of a human patient utilizing the funnel catheter assembly in accordance with embodiments of the present technology.

[0013] Figures 9A and 9B are enlarged, partially transparent side and side cross-sectional views, respectively, of a portion of a funnel catheter assembly in accordance with additional embodiments of the present technology.

[0014] Figures 10A–10C are side views of the funnel catheter assembly of Figures 9A and 9B in a sheathed position, a partially-unsheathed or intermediate position, and an unsheathed position, respectively, in accordance with embodiments of the present technology

[0015] Figure 11 is a flow diagram of a process or method for operating the funnel catheter assembly during an intravascular procedure in accordance with embodiments of the present technology.

DETAILED DESCRIPTION

[0016] The present technology is generally directed to methods and systems for removing clot material (e.g., a thrombus) from a blood vessel of a human patient. More particularly, the present technology is directed to funnel catheter assemblies configured to provide embolic protection during a clot removal or other intravascular procedure. In some embodiments, a funnel catheter assembly includes an outer shaft and an inner shaft extending through and coaxial with the outer shaft. An expandable funnel, such as a self-expanding funnel, can be coupled to a distal portion of the inner shaft. The funnel catheter assembly further includes a control assembly operably coupled to the proximal portion of the outer shaft. The funnel catheter assembly can be actuated by an operator (e.g., a physician) to move the outer shaft between a first position and a second position. In the first position, the outer shaft is positioned at least partially over the funnel to constrain the funnel in a compressed state. In the second position, the outer shaft is retracted proximally relative to the funnel such that the funnel can expand to an expanded state. Accordingly, the funnel catheter assembly enables the funnel to be unsheathed and sheathed during an intravascular procedure via the movement of the outer shaft between the first and second positions.

[0017] In one aspect of the present technology, the control assembly is operable to compress the funnel after it has been expanded within a blood vessel of a patient. This can permit the funnel catheter assembly to be repositioned within the blood vessel without fully withdrawing the funnel catheter assembly from the patient. Similarly, the funnel catheter assembly can be fully withdrawn from the patient (e.g., at the conclusion of a thrombectomy procedure) in the first position with the funnel compressed inside the outer shaft. Thus, the funnel catheter assembly is configured to inhibit or even prevent the funnel from contacting the wall of the blood vessel during movement of the funnel catheter assembly within the blood vessel. This can help inhibit injury/damage to the patient that could otherwise be caused by the moving the funnel through a blood vessel or an associated organ in the expanded state.

[0018] Although many of the embodiments are described below with respect to devices, systems, and methods for treating vascular thrombi (e.g., deep vein thrombosis (DVT)), other applications and other embodiments in addition to those described herein are within the scope of the technology (e.g., intravascular procedures other than the treatment of emboli, intravascular procedures for treating cerebral embolism, intravascular procedures for treating pulmonary embolism, etc.). In general, for example, the devices, systems, and methods of the present technology can be used to extract any formation of material in a vessel (e.g., a venous or arterial vessel), such as cancerous growths, vegetation, etc. Additionally, several other embodiments of the technology can have different configurations, states, components, or procedures than those described herein. Moreover, it will be appreciated that specific elements, substructures, advantages, uses, and/or other features of the embodiments described with reference to Figures 1–11 can be suitably interchanged, substituted or otherwise configured with one another in accordance with additional embodiments of the present technology. Furthermore, suitable elements of the embodiments described with reference to Figures 1–11 can be used as standalone and/or self-contained devices. A person of ordinary skill in the art, therefore, will accordingly understand that the technology can have other embodiments with additional elements, or the technology can have other embodiments without several of the features shown and described below with reference to Figures 1–11.

[0019] With regard to the terms "distal" and "proximal" within this description, unless otherwise specified, the terms can reference a relative position of the portions of a catheter subsystem with reference to an operator and/or a location in the vasculature. Also, as used herein, the designations "rearward," "forward," "upward," "downward," etc. are not meant to limit the referenced component to use in a specific orientation. It will be appreciated that such designations refer to the orientation of the referenced component as illustrated in the Figures; the systems of the present technology can be used in any orientation suitable to the user.

[0020] The headings provided herein are for convenience only and should not be construed as limiting the subject matter disclosed.

I. Selected Embodiments of Funnel Catheter Assemblies

[0021] Figure 1 is a partially transparent and partially cross-sectional side view of a funnel catheter assembly 100 in accordance with embodiments of the present technology. In the illustrated embodiment, the funnel catheter assembly 100 includes an elongate outer shaft 102 and an elongate inner shaft 104 coaxial with the outer shaft 102. The outer and inner shafts 102,

104 ("shafts 102, 104") can also be referred to as sheaths, catheters, hollow members, and so on. The outer shaft 102 defines a lumen 106 and includes a proximal portion 107a and a distal portion 107b. The inner shaft 104 extends through the lumen 106 of the outer shaft 102 and similarly defines a lumen 108 and includes a proximal portion 109a and a distal portion 109b. The proximal portions 107a and 109a can each terminate at a proximal end/terminus, and the distal portions 107b and 109b can each terminate at a distal end/terminus. The shafts 102, 104 can be elastic and/or flexible and can have any suitable length and diameter.

[0022] In the illustrated embodiment, the funnel catheter assembly 100 further includes a sealable hub 110 coupled to the proximal portion 109a of the inner shaft 104. In some embodiments, as described in greater detail below with reference to Figures 9A–9C, the sealable hub 110 can be rotatable coupled to the inner shaft 104 such that the sealable hub 110 can rotate independently of the inner shaft 104. The sealable hub 110 is configured to allow access to the lumen 108 of the inner shaft 104 and can be self-sealing and/or can comprise a self-sealing seal. For example, in the illustrated embodiment the sealable hub 110 is a hemostasis valve that is configured to maintain hemostasis (e.g., during a thrombus extraction procedure) by inhibiting or even preventing fluid flow in the proximal direction through the sealable hub 110 as, for example, various components (e.g., dilator assemblies, thrombus extraction devices, etc.) are inserted through the sealable hub 110 to be delivered through the inner shaft 104 to a treatment site in a blood vessel. More specifically, the sealable hub 110 can be a valve of the type disclosed in U.S. Patent Application No. 16/117,519, filed August 30, 2018, and titled "HEMOSTASIS VALVES AND METHODS OF USE," which is incorporated herein by reference in its entirety. The sealable hub 110 can include one or more buttons or actuators that enable an operator to selectively seal/unseal the sealable hub 110.

[0023] The funnel catheter assembly 100 can further include an aspiration port 112 connected to the sealable hub 110 (e.g., to a side port of the sealable hub 110) and/or the inner shaft 104 (e.g., to the proximal portion 109a of the inner shaft 104) via, for example, a connecting tube 114. The aspiration port 112 can be connected to a syringe connector 116 that can be selectively coupled to a syringe or other aspiration device, or the aspiration port 112 can be connected to other suitable elements. In some embodiments, the funnel catheter assembly 100 includes a fluid control device 118 configured to selectively fluidly connect the aspiration port 112 to the lumen 108 of the inner shaft 104. In the illustrated embodiment, the fluid control device 118 is a stopcock operably coupled to the connecting tube 114 between the lumen 108 of the inner shaft 104 and the aspiration port 112. In other embodiments, the fluid control device

118 can be a clamp or another suitable valve. In some embodiments, a vacuum source (not shown; e.g., a syringe) can be coupled to the syringe connector 116 and used to aspirate the lumen 108 of the inner shaft 104. In some embodiments, as described in greater detail below with reference to Figures 9A–9C, the aspiration port 112 and the connecting tube 114 can be rotatable relative to the sealable hub 110 and/or the inner shaft 104.

[0024] In the illustrated embodiment, a funnel 120 is coupled to the distal portion 109b of the inner shaft 104. As described in greater detail below, in operation of the funnel catheter assembly 100 during an intravascular procedure, the funnel 120 is configured to expand (e.g., radially expand) into apposition with a blood vessel and/or other bodily lumen (e.g., of an organ) and act as a proximal or distal thrombus/embolic protection device that inhibits any thrombus from moving past the funnel 120 and embolizing in an unwanted location (e.g., the right heart, the pulmonary arteries, another arterial space, etc.). The funnel 120 can be fused to the distal portion 109b of the inner shaft 104, and/or attached to the inner shaft 104 via welding, adhesives, fasteners, etc. In Figure 1, the funnel catheter assembly 100 is in a first position/state/configuration in which the distal portion 107b of the outer shaft 102 extends beyond the distal portion 109b of the inner shaft 104 such that the funnel 120 is at least partially (e.g., entirely) positioned within the lumen 106 of the outer shaft 102. The funnel 120 can be configured to expand (e.g., self-expand) and, accordingly, the funnel 120 can be in a first, constrained position/state/configuration when the funnel catheter assembly 100 is in the first position. In some embodiments, the funnel 120 can be formed from at least one of a castellated nitinol braid, a nitinol braided stent, a laser cut nitinol, a laser cut polymer tube, an injection molded polymeric structure, or an inflatable balloon. In some embodiments, the funnel 120 can comprise a mesh having a pore size sufficiently small to prevent the passage of thrombus through the pores of the mesh. In some embodiments, the funnel 120 can be permeable to blood. In some embodiments, the funnel 120 can include a covering over at least a portion thereof that is permeable or non-permeable to blood.

[0025] In the illustrated embodiment, the proximal portion 107a of the outer shaft 102 is operably coupled to a control assembly 130. The control assembly 130 is operable to move the outer shaft 102 distally and proximally relative to the inner shaft 104 to constrain and release the funnel 120 from within the lumen 106 of the outer shaft 102. More specifically, in the illustrated embodiment the control assembly 130 includes (i) a housing 132 having a proximal portion 133a and a distal portion 133b, and (ii) an actuation member 134 operably/movably coupled to the housing 132. The housing 132 defines a lumen 135 extending between the proximal and distal

portions 133a, b thereof. The proximal portion 133a of the housing 132 can be coupled to the sealable hub 110. In some embodiments, the proximal portion 133a of the housing 132 is integrally formed with the sealable hub 110.

[0026] In the illustrated embodiment, the actuation member 134 includes a body portion 136 positioned within the lumen 135 of the housing 132 and coupled to the proximal portion 107a of the outer shaft 102 via, for example, adhesive, fasteners, welding, etc. The actuation member 134 further includes one or more grip members 138 extending from the body portion 136 to outside of the lumen 135. More specifically, the grip members 138 can extend through corresponding slots 140 formed in/along the housing 132. The housing 132 can define a proximal terminus 142a and a distal terminus 142b for each of the slots 140. In some embodiments, the control assembly 130 can include one, or more than the illustrated two of the grip members 138 and corresponding slots 140.

[0027] In operation, an operator (e.g., a physician) can slide the actuation member 134 along the housing 132 to distally advance and proximally retract the outer shaft 102 relative to the inner shaft 104 to constrain and release the funnel 120, respectively. More specifically, Figures 2A and 2B are side views of the funnel catheter assembly 100 in the first position and in a second position, respectively, in accordance with embodiments of the present technology. Referring to Figures 1–2B together, to move the funnel catheter assembly 100 from the first position (Figures 1 and 2A) to the second position (Figure 2B), the operator can grip the grip members 138 of the actuation member 134 and slide the grip members 138 proximally (e.g., in the direction of arrow P in Figure 2A) relative to the housing 132 to drive the body portion 136 through the lumen 135 to thereby drive the outer shaft 102 proximally relative to the inner shaft 104. The funnel 120 is released/unsheathed from within the lumen 106 of the outer shaft 102 as the distal portion 107b of the outer shaft 102 moves proximally past the funnel 120, thereby allowing the funnel 120 to expand. In some embodiments, the actuation member 134 can abut the proximal termini 142a of the slots 140 in the second position such that the housing 132 inhibits further proximal movement of the outer shaft 102.

[0028] In some embodiments, the distal terminus of the outer shaft 102 is positioned at or proximal of the distal terminus of the inner shaft 104 in the second position such that the funnel 120 is fully released from (e.g., positioned fully outside of) the lumen 106 of the outer shaft 102. In other embodiments, the distal terminus of the outer shaft 102 can be positioned distal of the distal terminus of the inner shaft 104 in the second position such that the funnel 120 is only

partially released from the lumen 106 of the outer shaft 102. Moreover, as shown in Figure 2B, the funnel 120 can have a conically shaped portion 222 (e.g., a truncated-conically shaped portion) and a cylindrical portion 224 once expanded. In other embodiments, the funnel 120 can have other suitable shapes. For example, in some embodiments the funnel 120 can be inverted relative to the embodiment shown in Figure 2B. That is, the cylindrical portion 224 of the funnel 120 can be coupled to the distal portion 109b of the inner shaft 104 while the conically shaped portion 222 extends distally from the cylindrical portion 224.

[0029] To move the funnel catheter assembly 100 from the second position (Figure 2B) to the first position (Figures 1 and 2A), the operator can grip the grip members 138 of the actuation member 134 and slide the grip members 138 distally (e.g., in the direction of arrow D in Figure 2B) relative to the housing 132 to drive the body portion 136 through the lumen 135 to thereby drive the outer shaft 102 distally relative to the inner shaft 104. The funnel 120 is captured/sheathed in the lumen 106 of the outer shaft 102 as the distal portion 107b of the outer shaft 102 moves distally over the funnel 120, thereby collapsing/compressing the funnel 120 within the lumen 106. In some embodiments, the actuation member 134 can abut the distal termini 142b of the slots 140 in the first position such that the housing 132 inhibits further distal movement of the outer shaft 102.

[0030] In some embodiments the actuation member 134 is configured to be releasably secured/locked to the housing 132 in the first and second positions to inhibit or even prevent unintended movement of the actuation member 134. For example, referring again to Figure 1, the housing 132 of the control assembly 130 can include (i) proximal engagement members 144a (e.g., tabs, protrusions, etc.) configured to engage the actuation member 134 in the first position and (ii) distal engagement members 144b configured to engage the actuation member 134 in the second position. More specifically, in some embodiments the proximal and distal engagement members 144a, b can mate with corresponding slots/grooves in the actuation member 134 (e.g., formed in/on the grip members 138) to releasably secure the actuation member 134 in the first or second positions via a snap fit arrangement.

[0031] In some embodiments, the inner shaft 104 is sized to slidably receive one or more medical instruments inserted through the sealable hub 110 during an intravascular procedure using the funnel catheter assembly 100, such as a thrombectomy procedure. Figure 3, for example, is a side view of the funnel catheter assembly 100 in the first position with a dilator 350 inserted through the sealable hub 110 and the lumen 108 of the inner shaft 104 (Figure 1) in

accordance with embodiments of the present technology. The dilator 350 can extend entirely through the inner shaft 104 and past the distal terminus of the distal portion 107b of the outer shaft 102 such that a distal tip 352 (e.g., an atraumatic tip) is positioned beyond the distal terminus of the outer shaft 102.

[0032] In some embodiments, the dilator 350 and the funnel catheter assembly 100 together define an introducer assembly that can be inserted into a patient (e.g., a human patient) and subsequently used to introduce intravascular medical devices into the patient. For example, the dilator 350 and the funnel catheter assembly 100 can be inserted into and advanced together through a blood vessel of the patient to a target location in the blood vessel. The dilator 350 can then be retracted proximally through the funnel catheter assembly 100, and the funnel catheter assembly 100 can be moved to the second position to expand the funnel 120 at the target location.

[0033] Referring to Figures 1–3 together, in one aspect of the present technology the inner shaft 104 is the "working" shaft of the funnel catheter assembly 100 that can be aspirated and/or receive various medical components (e.g., the dilator 350). In contrast, the outer shaft 102 is used to compress/expand the funnel 120. Accordingly, the shafts 102, 104 can be sized to maximize the size of the inner shaft 104 to permit larger-sized components to be inserted therethrough, or to provide greater aspiration force/power. For example, the outer shaft 102 can have an inner diameter that is only slightly greater than an outer diameter of the inner shaft 104. In some embodiments, the inner shaft 104 can have an outer diameter of at least 10 French, at least 12 French, at least 14 French, at least 18 French, at least 20 French, at least 22 French, at least 26 French, greater than 26 French, between 10 French and 26 French, between 14 French and 24 French, between 15 French and 21 French, between 16 French and 22 French, and/or any other or intermediate size. In some embodiments, the lumen 108 of the inner shaft 104 can have an internal diameter of at least 2 French, at least 10 French, at least 14 French, at least 18 French, at least 20 French, at least 22 French, between 11 French and 12 French, between 10 French and 22 French, between 14 French and 21 French, between 16 French and 20 French, and/or any other or intermediate size.

[0034] In another aspect of the present technology, the control assembly 130 is operable, via the movement of the actuation member 134 from the second position to the first position, to compress the funnel 120 after it has been expanded within a blood vessel. This can permit the funnel catheter assembly 100 to be repositioned within the blood vessel without fully withdrawing the funnel catheter assembly 100 from the patient. For example, after (i)

introducing the funnel catheter assembly 100 into the blood vessel with the dilator 350 and (ii) removing the dilator 350, the funnel catheter assembly 100 can be repositioned proximally simply by moving the funnel catheter assembly 100 back to the first position to collapse the funnel 120 and then retracting the funnel catheter assembly 100 proximally. To reposition the funnel catheter assembly 100 distally, the dilator 350 can be reinserted and the funnel catheter assembly 100 pushed proximally in the first position with the funnel 120 compressed. Similarly, the funnel catheter assembly 100 can be fully withdrawn from the patient (e.g., at the conclusion of a thrombectomy procedure) in the first position with the funnel 120 compressed in the lumen 106 of outer shaft 102. Thus, the funnel catheter assembly 100 is configured to inhibit or even prevent the funnel 120 from contacting the wall of the blood vessel during advancement/withdrawal. This can help inhibit injury/damage to the patient that could otherwise be caused by the moving the funnel 120 through the blood vessel or an associated organ in the expanded state.

[0035] In some embodiments, the funnel catheter assembly 100 and/or methods of operating the funnel catheter assembly 100 can include some features the same as or similar to the thrombectomy systems (e.g., the introducer assemblies) described in detail in (i) U.S. Patent No. 9,700,332, filed September 16, 2016, and titled "INTRAVASCULAR TREATMENT OF VASCULAR OCCLUSION AND ASSOCIATED DEVICES, SYSTEMS, AND METHODS," and/or (ii) U.S. Patent No. 10,098,651, filed April 26, 2017, and titled "DEVICES AND METHODS FOR TREATING VASCULAR OCCLUSION," both of which are incorporated herein by reference in their entirety.

[0036] In other embodiments, the control assembly 130 can be configured to drive the distal and proximal movement of the outer shaft 102 in other manners. For example, the actuation member 134 can comprise a rotatable member (e.g., a ring gear, corkscrew, rotatable handle, etc.) coupled to the outer shaft 102. In some embodiments, the rotatable member can be a ratcheting member that is rotatable to a plurality of discreet positions between the first and second positions.

[0037] Similarly, in other embodiments the control assembly 130 can be operably coupled to the inner shaft 104 rather than the outer shaft 102. Accordingly, operation of the control assembly 130 can move the inner shaft 104 and the sealable hub 110 relative to the outer shaft 102 to move the funnel catheter assembly 100 between the first and second positions to constrain/compress and release/expand the funnel 120, respectively.

[0038] In yet other embodiments, the funnel 120 can be operably coupled to the outer shaft 102 such that movement of the outer shaft 102 between the first and second positions expands the funnel 120. More specifically, for example, Figure 4 is a side view of the funnel catheter assembly 100 including a non-self-expanding funnel 420 in accordance with embodiments of the present technology. In some embodiments, the funnel 420 can have a similar shape as the funnel 120 described in detail above with reference to Figures 1–3, but can be formed of one or more non-self-expanding materials such as metal (e.g., a non-heat-activated metal), plastic, fiber, polymer, etc. In the illustrated embodiment, the funnel 420 is coupled to (i) the distal portion 109b of the inner shaft 104 (Figure 1) and (ii) the distal portion 107b of the outer shaft 102 via a plurality of flexible tethers 426. The tethers 426 are configured (e.g., shaped, sized, and/or positioned) such that movement of the control assembly 130 from the first position to the second position pulls the tethers 426 to thereby pull and expand the funnel 420 as it is unsheathed from within the outer shaft 102.

[0039] In some embodiments, the funnel catheter assembly 100 can include one or more features for actuating/manipulating the funnel 420 (or the funnel 120 described in detail with reference to Figures 1–3). For example, the control assembly 130 can include an actuation member 454 (shown schematically) operably coupled to the funnel 420 via one or more control lines 462 (e.g., wires, tethers, rigid members etc.). The actuation member 454 can be a slider, rotatable member, or other component configured to exert a force on the funnel 420 via the control lines 462. In some embodiments, the control lines 462 can be asymmetrically/eccentrically coupled to the funnel 420 such that actuation of the actuation member 454 bends the funnel 420 away from a longitudinal axis of the shafts 102, 104. In one aspect of the present technology, this arrangement can be used to help steer the funnel 420 into a tortuous region of a patient (e.g., a tortuous vessel, the left atrial appendage (LAA), etc.) that may otherwise be difficult to position the funnel 420 in. Additionally or alternatively, the funnel catheter assembly 100 can include one or more components (e.g., pull wires) for steering (e.g., bending, deflecting, etc.) the outer shaft 102 and/or the inner shaft 104 to facilitate positioning of the funnel 420.

II. Selected Embodiments of Procedures Utilizing Funnel Catheter Assemblies for Embolic Protection

[0040] Referring to Figures 1–4 together, the funnel catheter assembly 100 can be used in a myriad of procedures to capture thrombi and inhibit the thrombi from embolizing in portions

of a patient's vasculature. For example, Figures 5–8 are schematic views illustrating various thrombectomy techniques for removing a thrombus T from a blood vessel BV of a human patient utilizing the funnel catheter assembly 100 in accordance with various embodiments of the present technology.

[0041] Referring first to Figure 5, in some embodiments the thrombus T (e.g., clot material) can be accessed through a popliteal access site 560. The funnel catheter assembly 100 can extend from the popliteal access site 560 to a deployment position 562 in the blood vessel BV at which the funnel 120 (or the funnel 420) can be deployed. The deployment position 562 can be proximate to and proximal of the thrombus T. The funnel 120 can at least partially appose a wall of the blood vessel BV after the funnel catheter assembly 100 is moved from the first position to the second position to expand the funnel 120, as described in detail above with reference to Figures 1–4.

[0042] In the illustrated embodiment, a thrombus extraction device 564 has been (i) inserted through the funnel catheter assembly 100, (ii) passed through the thrombus T in the direction of blood flow, and (iii) expanded distal of the thrombus T. The thrombus extraction device 564 can include a coring element 565 (e.g., a stent-like device) and a capture element 566 (e.g., a braided mesh bag). In some embodiments, some or all of the thrombus extraction device 564 can extend into one of the iliac veins and/or the inferior vena cava. After expansion distal of the thrombus T, the thrombus extraction device 564 can be retracted through the thrombus T and into the lumen 108 of the inner shaft 104 (Figure 1) through the funnel 120. During retraction, the coring element 565 can core/separate the thrombus T and the capture element 566 can capture all or a portion of the thrombus T. In some embodiments, the thrombus extraction device 564 and the associated thrombectomy procedure can be generally similar or identical to the thrombus extraction devices and associated methods described in detail in (i) U.S. Patent No. 9,700,332, filed September 16, 2016, and titled "INTRAVASCULAR TREATMENT OF VASCULAR OCCLUSION AND ASSOCIATED DEVICES, SYSTEMS, AND METHODS," and/or (ii) U.S. Patent No. 10,098,651, filed April 26, 2017, and titled "DEVICES AND METHODS FOR TREATING VASCULAR OCCLUSION," both of which are incorporated herein by reference in their entirety.

[0043] In one aspect of the present technology, as the thrombus extraction device 564 and the captured thrombus T are retracted through the funnel 120, the funnel 120 can capture/retain any of the thrombus T that breaks free of the thrombus extraction device 564 as the thrombus

extraction device 564 is compressed into the inner shaft 104. Accordingly, the funnel 120 can inhibit portions of the thrombus T from traveling upstream where they could potentially embolize. In some embodiments, a vacuum (e.g., a pre-charged vacuum) can be applied to the inner shaft 104 (e.g., via a syringe coupled to the syringe connector 116 shown in Figure 1) at any point during retraction of the thrombus extraction device 564. In some embodiments, application of the vacuum can generate instantaneous or nearly instantaneous suction at the distal portion 109b of the inner shaft 104 that can aspirate any remaining portions of the thrombus T into and/or through the inner shaft 104.

[0044] Referring next to Figure 6, in some embodiments the thrombus T (not shown in Figure 6; e.g., positioned lower in the iliac or femoral veins) can be accessed through an internal jugular access site 670, and the funnel catheter assembly 100 can be inserted into the patient's body via the internal jugular access site 670. The funnel catheter assembly 100 can extend from the internal jugular access site 670 to a deployment position 672 at which the funnel 120 (or the funnel 420) can be deployed proximal to the thrombus T. In the illustrated embodiment, the outer shaft 102 and the inner shaft 104 (obscured in Figure 6) extend from the internal jugular access site 670 through the superior vena cava and the inferior vena cava to the deployment position 672 in one of the common iliac veins. In some embodiments, the deployment position 672 can be located in, for example, the inferior vena cava, one of the iliac veins, the femoral vein, the popliteal vein, before or beyond the iliac arch, or any other location proximate to and/or proximal to the thrombus T. In some embodiments, the thrombus extraction device 564 can be inserted through the funnel catheter assembly 100 and withdrawn through the thrombus T to capture the thrombus T, as described in detail above with reference to Figure 5.

[0045] In one aspect of the present technology, accessing the thrombus T via the internal jugular access site 670 allows the funnel 120 to be positioned downstream of the thrombus T. Accordingly, the funnel 120 can capture any of the thrombus T that may break off and be carried downstream toward the heart during operation of the thrombus extraction device 564. In another aspect of the present technology, the funnel 120 can be compressed—for example, by moving the actuation member 134 from the second position to the first position as described in detail above with reference to Figures 1–4—before withdrawing the funnel catheter assembly 100 at the conclusion of the thrombectomy procedure. This prevents the funnel 120 from being withdrawn in the expanded configuration through the heart of the patient (e.g., through the right atrium) which could potentially damage the heart.

[0046] Referring next to Figure 7, in some embodiments the thrombus T can be accessed by the thrombus extraction device 564 through the popliteal access site 560 using a separate introducer assembly 774, while the funnel catheter assembly 100 can be inserted into the patient's body via the internal jugular access site 670 (Figure 6). The funnel 120 can be expanded at the deployment position 672 during a thrombectomy procedure using the thrombus extraction device 564. The funnel 120 can therefore capture any of the thrombus material T that may break away and flow downstream during the procedure. In the illustrated embodiment, the thrombus extraction device 564 is inserted through an outer shaft 776 of the introducer assembly 774. In one aspect of the present technology, in comparison to using the funnel catheter assembly 100 as the introducer for the thrombus extraction device 564, the outer shaft 776 can be made relatively larger than the inner shaft 104 because the outer shaft 102 need not be positioned thereabout for constraining the funnel 120. This can permit the thrombus extraction device 564 to be made larger and/or enable greater aspiration forces to be generated through the outer shaft 776.

[0047] Referring next to Figure 8, in some embodiments the thrombus T can be accessed by the thrombus extraction device 564 through the popliteal access site 560 using the introducer assembly 774, while the funnel catheter assembly 100 can be inserted into the patient's body via a femoral access site 880. The funnel catheter assembly 100 can traverse the common iliac veins to the deployment position 672, or another suitable deployment position.

[0048] In other embodiments, the funnel catheter assembly 100 can be inserted into a patient's body via other venous or arterial access sites, and can be used in a myriad of different procedures. For example, additional applications of the funnel catheter assembly 100 include but are not limited to:

[0049] Internal jugular vein (IJ) access for deployment in the inferior vena cava (IVC) for treatment of lower extremity deep vein thrombsis (DVT);

[0050] IJ access for deployment in the IVC for removal of IVC filters and/or treatment of thrombus located in the IVC;

[0051] IJ access for deployment in the deep veins of the lower extremity veins (iliac, femoral, popliteal veins, etc.) for treatment of lower extremity DVT;

[0052] Common femoral vein (CFV) access for deployment in the superior vena cava (SVC) for treatment of upper extremity DVT and/or SVC thrombus;

[0053] CFV access for deployment in the upper extremity veins (brachiocephalic, subclavian, axillary veins, etc.) for treatment of upper extremity DVT and/or SVC thrombus;

[0054] CFV access for deployment in the pulmonary arteries (PAs) for treatment of pulmonary embolism;

[0055] CFV access with transseptal access for deployment in the left atrium ostium and the left atrial appendage (LAA) for thrombus removal;

[0056] Internal Carotid Artery (ICA) accesss for deployment in the common carotid artery (CCA) for carotid endarterectomy (CEA);

[0057] ICA accesss for deployment in descending thoracic aorta for treatment of thoraco-abdominal and/or abdominal aortic (AA) thrombus and/or aorto-arterial thrombosis;

[0058] ICA accesss for deployment in the descending/thoracic aorta for treatment of renal thrombosis;

[0059] ICA accesss for intra-atrterial placement for treament of superior mesenteric artery (SMA) thrombosis (MAT);

[0060] Common Femoral Artery (CFA) access for treatment of atherosclerosis in the brachial artery, radial artery, popiteal artery, or dorsalis pedis artery;

[0061] CFA access for deployment in the common iliac artery for treatment of aorto-arterial thrombosis and/or occlusions;

[0062] CFA access for deployment in the abdominal aorta for treatment of renal artery thrombosis; and/or

[0063] CFA access for deployment in the aorta for treatment of thoraco-abdominal and/or AA thrombus and/or aorto-arterial thrombosis.

[0064] Figures 9A and 9B are enlarged, partially transparent side and side cross-sectional views, respectively, of a portion of a funnel catheter assembly 900 in accordance with additional embodiments of the present technology. Referring to Figures 9A and 9B together, the funnel catheter assembly 900 can include some features that are at least generally similar in structure and function, or identical in structure and function, to the corresponding features of the funnel catheter assembly 100 described in detail above with reference to Figures 1–8, and can operate

in a generally similar or identical manner to the funnel catheter assembly 100. In the illustrated embodiment, for example, the funnel catheter assembly 900 includes the sealable hub 110, the connecting tube 114, the aspiration port 112, the outer shaft 102, and the inner shaft 104 (obscured in Figure 9A). The funnel catheter assembly 900 further includes a control assembly 930 including a housing 932 and an actuation member 934 having a pair of grip member 938. As shown in Figure 9B, the actuation member 934 includes a hub 936 positioned within the housing 932 and coupled to the outer shaft 102 (e.g., the proximal portion 107a of the outer shaft 102). The actuation member 934 is movable (e.g., slidable) relative to the housing 932 to advance/retract the outer shaft 102 relative to the inner shaft 104 and a funnel (e.g., the funnel 120 shown in Figures 10B and 10C) attached to a distal portion thereof.

[0065] The funnel catheter assembly 900 is in a first, sheathed position in Figure 9A in which the funnel is constrained by the outer shaft 102 and in a second, unsheathed position in Figure 9B in which the funnel is not constrained by the outer shaft 102. Referring to Figure 9A, in some embodiments the housing 932 can include a marking 931 indicating a position of the actuation member 934 in which the funnel is in the unsheathed position. In some embodiments, a proximal portion 933a of the housing 932 can include gripping features, such as a groove 935, a cross-hatched pattern 937, and/or other features for increasing the grip-ability of the housing 932. In some embodiments, an operator can grip the housing 932 (e.g., via the groove 935 and/or the pattern 937) while moving (i) the actuation member 934 relative to the housing 932 and/or (ii) the housing 932 relative to the actuation member 934. In some embodiments, the funnel catheter assembly 900 can further include a lock mechanism 911 that can be attached to the sealable hub 110 (e.g., to buttons thereof) to lock the sealable hub 110 in the open/unsealed position.

[0066] In the illustrated embodiment, the funnel catheter assembly 900 further includes a rotatable side port 950 fluidly connecting the sealable hub 110, the connecting tube 114, and the inner shaft 104. Figure 9C is an enlarged isometric cross-sectional view of a portion of the sealable hub 110, the rotatable side port 950, and the control assembly 930 in accordance with embodiments of the present technology. Referring to Figure 9C, the side port 950 defines a lumen 952 that provides a fluid path from the inner shaft 104 to the sealable hub 110. In the illustrated embodiment, the side port 950 includes a first groove 954 and a second groove 956 that each extend circumferentially about an outer surface of the side port 950. The sealable hub 110 includes a first projection 964 positioned in the first groove 954 and the housing 932 includes a second projection 966 positioned in the second groove 956. The engagement of the first and

second projections 964, 966 in the first and second grooves 954, 956 couples the housing 932 to the sealable hub 110. Moreover, the first and second projections 964, 966 are rotatable within the first and second grooves 954, 956 such that the sealable hub 110, the side port 114, and the housing 932 can each rotate independently of one another while remaining coupled together.

[0067] In some embodiments, the control assembly 930 can further include a connector 958 coupled to the proximal portion 109a of the inner shaft 104 and positioned at least partially between the side port 950 and the housing 932. The connector 958 can be rotatable within the housing 932 such that the housing 932 can rotate independently of the connector 958 and the inner shaft 104. Accordingly, in some aspects of the present technology rotation of the sealable hub 110, the side port 950 (e.g., the aspiration port 112 shown in Figures 9B and 9C), and/or the housing 932 will not substantially rotate the inner shaft 104. This can help inhibit the funnel attached to the inner shaft 104 from rotating within a vessel during a procedure using the funnel catheter assembly 900—while still allowing for movement of the sealable hub 110, the side port 950, and/or other components of the funnel catheter assembly 900.

[0068] Figures 10A–10C are side views of the funnel catheter assembly 900 in the sheathed position, a partially-unsheathed or intermediate position, and the unsheathed position, respectively, in accordance with embodiments of the present technology. Referring to Figures 10A–10C together, the funnel catheter assembly 900 can be moved between the sheathed and unsheathed positions by moving the actuation member 934 relative to the housing 932 and/or by moving the housing 932 (and the coupled sealable hub 110) relative to the actuation member 934. In some embodiments, for example, the operator can slide the actuation member 134 relative to the housing 932 in the direction indicated by the arrow P in Figure 10B to retract the outer shaft 102 to unsheathe the funnel 120. In some aspects of the present technology, moving the actuation member 934 rather than the housing 932 moves only the outer shaft 102 such that the funnel 120 remains in a constant or generally constant position (e.g., stationary position). In other embodiments, the operator can advance the housing 932 relative to the actuation member 934 in the direction indicated by the arrow D in Figure 10A to unsheathe the funnel 120. In some aspects of the present technology, moving the housing 932 relative to the actuation member 934 advances the inner shaft 104 and the funnel 120 distally relative to the outer shaft 102.

[0069] In the unsheathed position shown in Figure 10C, the actuation member 934 can be positioned adjacent or near the marking 931 to indicate to the operator that the funnel 120 is deployed. In some embodiments, to re-sheathe the funnel 120 (e.g., from the unsheathed position

shown in Figure 10C to the sheathed position shown in Figure 10A), the operator can retract the housing 932 relative to the actuation member 934 (e.g., in the direction of the arrow P) to pull the funnel 120 into the outer shaft 102. In some aspects of the present technology, such a retracting motion can be intuitive to the user as the motion of the housing 932 is in the same direction as the removal/collapse of the funnel 120. Nevertheless, in other embodiments the operator can advance the actuation member 934 relative to the housing 932 to sheathe the funnel 120 within the outer shaft 102.

[0070] Figure 11 is a flow diagram of a process or method 1110 for operating the funnel catheter assembly 100 and/or the funnel catheter assembly 900 (collectively referred to as "the funnel catheter assembly") during an intravascular procedure in accordance with embodiments of the present technology. Although some features of the method 1110 are described in the context of the embodiments shown in Figures 1–10C for the sake of illustration, one skilled in the art will readily understand that the method 1110 can be carried out using other suitable systems and/or devices described herein.

[0071] At block 1111, the method 1110 includes inserting the funnel catheter assembly into a patient's body via a vascular site. For example, the dilator 350, the outer shaft 102, and inner shaft 104 can be inserted together through a venous or arterial access site.

[0072] At block 1112, the method 1110 includes advancing the funnel catheter assembly to a deployment position within the vasculature of the patient. For example, the dilator 350, the outer shaft 102, and inner shaft 104 can be advanced together through the vasculature to the selected deployment position. The funnel catheter assembly can be advanced in the first position such that the funnel 120 is constrained/compressed within the outer shaft 102. The deployment position can be a portion of a blood vessel, a portion of the heart, or another suitable location.

[0073] At block 1113, the method 1110 includes expanding the funnel 120 at the deployment position. For example, the control assembly 130 of the funnel catheter assembly 100 can be moved from the first position to the second position to release/unsheathe the funnel 120 from within the outer shaft 102, thereby allowing the funnel 120 to expand at the deployment position. Likewise, the actuation member 934 can be slid relative to the housing 932 to unsheathe the funnel 120. After expansion, the funnel 120 can appose/contact the anatomy surrounding the deployment position, such as a wall of a blood vessel. In some embodiments, the dilator 350 can be removed from the funnel catheter assembly before expanding the funnel 120.

[0074] At block 1114, the method 1110 optionally includes compressing and repositioning the funnel 120. For example, the control assembly 130 can be moved from the second position to the first position to constrain/sheathe the funnel 120 within the outer shaft 102. Likewise, the housing 932 of the funnel catheter assembly 900 can be retracted proximally relative to the actuation member (and/or the actuation member 934 can be advanced distally relative to the housing) to sheathe the funnel 120. Then, the funnel catheter assembly can be repositioned to a different deployment position (block 1112) and expanded once again (block 1113). In some embodiments, the dilator 350 can be reinserted into the funnel catheter assembly 100 before repositioning the funnel catheter assembly 100.

[0075] At block 1115, the method 1110 includes maintaining the funnel 120 in the expanded position during an intravascular procedure. As described in detail above, the funnel 120 can capture thrombi that break free during the intravascular procedure to inhibit their embolization elsewhere in the vasculature of the patient.

[0076] At block 1116, the method 1110 includes compressing the funnel 120 and withdrawing the funnel catheter assembly 100 from the patient. For example, the control assembly 130 of the funnel catheter assembly 100 can be moved from the second position to the first position to constrain/sheathe the funnel 120 within the outer shaft 102, and the funnel catheter assembly 100 can then be withdrawn proximally to and from the vascular access site. Likewise, the housing 932 of the funnel catheter assembly 900 can be retracted proximally relative to the actuation member (and/or the actuation member 934 can be advanced distally relative to the housing) to sheathe the funnel 120.

III. Examples

[0077] Several aspects of the present technology are set forth in the following examples:

1. A funnel catheter assembly, comprising:

an outer shaft defining a lumen;

an inner shaft extending through the lumen and having a proximal portion and a distal portion;

an expandable funnel coupled to the distal portion of the inner shaft; and

a control assembly configured to move the funnel between a first position and a second position, wherein—

in the first position, the funnel is constrained within the lumen of the outer shaft, and

in the second position, the funnel is positioned at least partially outside the lumen of the outer shaft such that the funnel can expand.

2. The funnel catheter assembly of example 1 wherein the control assembly is coupled to the outer shaft and configured to move the outer shaft relative to the inner shaft.

3. The funnel catheter assembly of example 1 or example 2 wherein the control assembly includes an actuator movable to move the funnel between the first and second positions.

4. The funnel catheter assembly of example 3 wherein the actuator is a slider.

5. The funnel catheter assembly of any one of examples 2–4 wherein the funnel includes a proximal portion and a distal portion, and wherein the proximal portion of the funnel is coupled to the distal portion of the inner shaft.

6. The funnel catheter of example 5 wherein the distal portion of the funnel is coupled to the outer shaft.

7. The funnel catheter assembly of any one of examples 1–6, further comprising a sealable hub and a side port, wherein the side port is rotatably coupled between the control assembly and the sealable hub.

8. A funnel catheter assembly, comprising:

an outer shaft defining an outer lumen;

an inner shaft extending through the outer lumen and having a proximal portion and a distal portion;

an expandable funnel coupled to the distal portion of the inner shaft; and

a control assembly operably coupled to the proximal portion of the outer shaft and configured to move the outer shaft between a first position and a second position, wherein—

in the first position, the outer shaft is positioned at least partially over the funnel to radially constrain the funnel, and

in the second position, the outer shaft is retracted proximally relative to the funnel such that the funnel can radially expand.

9. The funnel catheter assembly of example 8 wherein the control assembly includes a housing and an actuation member, wherein the actuation member is coupled to a proximal portion of the outer shaft, and wherein the actuation member is slidable along the housing to move the outer shaft between the first and second positions.

10. The funnel catheter assembly of example 8 or example 9 wherein the funnel is configured to self-expand.

11. The funnel catheter assembly of example 8 or example 9 wherein the funnel is non-self-expanding, wherein the funnel is further coupled to a distal portion of the outer shaft, and wherein movement of the outer shaft from the first position to the second position is configured to expand the funnel.

12. The funnel catheter assembly of example 11 wherein a distal portion of the funnel is coupled to the distal portion of the outer shaft via one or more tethers.

13. The funnel catheter assembly of any one of examples 8–12 wherein the inner shaft defines an inner lumen sized to receive a dilator.

14. A method of operating a funnel catheter assembly during an intravascular procedure on a patient, the method comprising:

at least partially inserting an inner shaft, an outer shaft, and a funnel of the funnel catheter assembly into the vasculature of the patient;

advancing the inner shaft, the outer shaft, and the funnel together to a deployment position within the vasculature of the patient, wherein the funnel is sheathed within a lumen of the outer shaft during the advancement;

moving the outer shaft relative to the inner shaft to unsheathe the funnel and permit the funnel to expand to an expanded position;

maintaining the funnel in the expanded position during at least a portion of the intravascular procedure;

moving the outer shaft relative to the inner shaft and/or moving the inner shaft relative to the outer shaft to sheath the funnel within the lumen of the outer shaft; and

withdrawing the funnel catheter assembly from the patient.

15. The method of example 14 wherein the funnel is self-expandable, and wherein moving the outer shaft relative to the inner shaft to unsheathe the funnel includes permitting the funnel to self-expand to the expanded position.

16. The method of example 14 or example 15 wherein moving the outer shaft relative to the inner shaft to unsheathe the funnel includes moving a slider of a control assembly of the funnel catheter assembly from a first position to a second position, and wherein the slider is coupled to a proximal portion of the outer shaft.

17. The method of any one of examples 14–16 wherein moving the outer shaft relative to the inner shaft to unsheathe the funnel includes rotating a rotatable element of a control assembly of the funnel catheter assembly from a first position to a second position.

18. The method of any one of examples 14, 16, and 17 wherein the funnel is non-self-expanding, and wherein the method further comprises actuating the funnel to expand to the expanded position.

19. The method of any one of examples 14–18 wherein—

inserting the inner shaft, the outer shaft, and the funnel into the vasculature of the patient further includes at least partially inserting a dilator positioned within the inner shaft into the vasculature of the patient; and

advancing the inner shaft, the outer shaft, and the funnel further includes advancing the inner shaft, the outer shaft, the funnel, and the dilator together to the deployment position.

20. The method of any one of examples 14–19 wherein moving the outer shaft relative to the inner shaft to unsheathe the funnel includes moving the outer shaft in a first

direction, and wherein the method further comprises moving the outer shaft relative to the inner shaft to sheath the funnel by moving the outer shaft in a second direction opposite to the first direction.

IV. Conclusion

[0078] The above detailed descriptions of embodiments of the technology are not intended to be exhaustive or to limit the technology to the precise form disclosed above. Although specific embodiments of, and examples for, the technology are described above for illustrative purposes, various equivalent modifications are possible within the scope of the technology as those skilled in the relevant art will recognize. For example, although steps are presented in a given order, alternative embodiments may perform steps in a different order. The various embodiments described herein may also be combined to provide further embodiments.

[0079] From the foregoing, it will be appreciated that specific embodiments of the technology have been described herein for purposes of illustration, but well-known structures and functions have not been shown or described in detail to avoid unnecessarily obscuring the description of the embodiments of the technology. Where the context permits, singular or plural terms may also include the plural or singular term, respectively.

[0080] Moreover, unless the word "or" is expressly limited to mean only a single item exclusive from the other items in reference to a list of two or more items, then the use of "or" in such a list is to be interpreted as including (a) any single item in the list, (b) all of the items in the list, or (c) any combination of the items in the list. Additionally, the term "comprising" is used throughout to mean including at least the recited feature(s) such that any greater number of the same feature and/or additional types of other features are not precluded. It will also be appreciated that specific embodiments have been described herein for purposes of illustration, but that various modifications may be made without deviating from the technology. Further, while advantages associated with some embodiments of the technology have been described in the context of those embodiments, other embodiments may also exhibit such advantages, and not all embodiments need necessarily exhibit such advantages to fall within the scope of the technology. Accordingly, the disclosure and associated technology can encompass other embodiments not expressly shown or described herein.

CLAIMS

I/We claim:

1. A funnel catheter assembly, comprising:

an outer shaft defining a lumen;

an inner shaft extending through the lumen and having a proximal portion and a distal portion;

an expandable funnel coupled to the distal portion of the inner shaft; and

a control assembly configured to move the funnel between a first position and a second position, wherein—

in the first position, the funnel is constrained within the lumen of the outer shaft, and

in the second position, the funnel is positioned at least partially outside the lumen of the outer shaft such that the funnel can expand.

2. The funnel catheter assembly of claim 1 wherein the control assembly is coupled to the outer shaft and configured to move the outer shaft relative to the inner shaft.

3. The funnel catheter assembly of claim 1 wherein the control assembly includes an actuator movable to move the funnel between the first and second positions.

4. The funnel catheter assembly of claim 3 wherein the actuator is a slider.

5. The funnel catheter assembly of claim 1 wherein the funnel includes a proximal portion and a distal portion, and wherein the proximal portion of the funnel is coupled to the distal portion of the inner shaft.

6. The funnel catheter of claim 5 wherein the distal portion of the funnel is coupled to the outer shaft.

7. The funnel catheter assembly of claim 1, further comprising a sealable hub and a side port, wherein the side port is rotatably coupled between the control assembly and the sealable hub.

8. A funnel catheter assembly, comprising:

an outer shaft defining an outer lumen;

an inner shaft extending through the outer lumen and having a proximal portion and a distal portion;

an expandable funnel coupled to the distal portion of the inner shaft; and

a control assembly operably coupled to the proximal portion of the outer shaft and configured to move the outer shaft between a first position and a second position, wherein—

in the first position, the outer shaft is positioned at least partially over the funnel to radially constrain the funnel, and

in the second position, the outer shaft is retracted proximally relative to the funnel such that the funnel can radially expand.

9. The funnel catheter assembly of claim 8 wherein the control assembly includes a housing and an actuation member, wherein the actuation member is coupled to a proximal portion of the outer shaft, and wherein the actuation member is slidable along the housing to move the outer shaft between the first and second positions.

10. The funnel catheter assembly of claim 8 wherein the funnel is configured to self-expand.

11. The funnel catheter assembly of claim 8 wherein the funnel is non-self-expanding, wherein the funnel is further coupled to a distal portion of the outer shaft, and wherein movement of the outer shaft from the first position to the second position is configured to expand the funnel.

12. The funnel catheter assembly of claim 11 wherein a distal portion of the funnel is coupled to the distal portion of the outer shaft via one or more tethers.

13. The funnel catheter assembly of claim 8 wherein the inner shaft defines an inner lumen sized to receive a dilator.

14. A method of operating a funnel catheter assembly during an intravascular procedure on a patient, the method comprising:

at least partially inserting an inner shaft, an outer shaft, and a funnel of the funnel catheter assembly into the vasculature of the patient;

advancing the inner shaft, the outer shaft, and the funnel together to a deployment position within the vasculature of the patient, wherein the funnel is sheathed within a lumen of the outer shaft during the advancement;

moving the outer shaft relative to the inner shaft to unsheathe the funnel and permit the funnel to expand to an expanded position;

maintaining the funnel in the expanded position during at least a portion of the intravascular procedure;

moving the outer shaft relative to the inner shaft and/or moving the inner shaft relative to the outer shaft to sheath the funnel within the lumen of the outer shaft; and

withdrawing the funnel catheter assembly from the patient.

15. The method of claim 14 wherein the funnel is self-expandable, and wherein moving the outer shaft relative to the inner shaft to unsheathe the funnel includes permitting the funnel to self-expand to the expanded position.

16. The method of claim 14 wherein moving the outer shaft relative to the inner shaft to unsheathe the funnel includes moving a slider of a control assembly of the funnel catheter assembly from a first position to a second position, and wherein the slider is coupled to a proximal portion of the outer shaft.

17. The method of claim 14 wherein moving the outer shaft relative to the inner shaft to unsheathe the funnel includes rotating a rotatable element of a control assembly of the funnel catheter assembly from a first position to a second position.

18. The method of claim 14 wherein the funnel is non-self-expanding, and wherein the method further comprises actuating the funnel to expand to the expanded position.

19. The method of claim 14 wherein—

inserting the inner shaft, the outer shaft, and the funnel into the vasculature of the patient further includes at least partially inserting a dilator positioned within the inner shaft into the vasculature of the patient; and

advancing the inner shaft, the outer shaft, and the funnel further includes advancing the inner shaft, the outer shaft, the funnel, and the dilator together to the deployment position.

20. The method of claim 14 wherein moving the outer shaft relative to the inner shaft to unsheathe the funnel includes moving the outer shaft in a first direction, and wherein the method further comprises moving the outer shaft relative to the inner shaft to sheath the funnel by moving the outer shaft in a second direction opposite to the first direction.

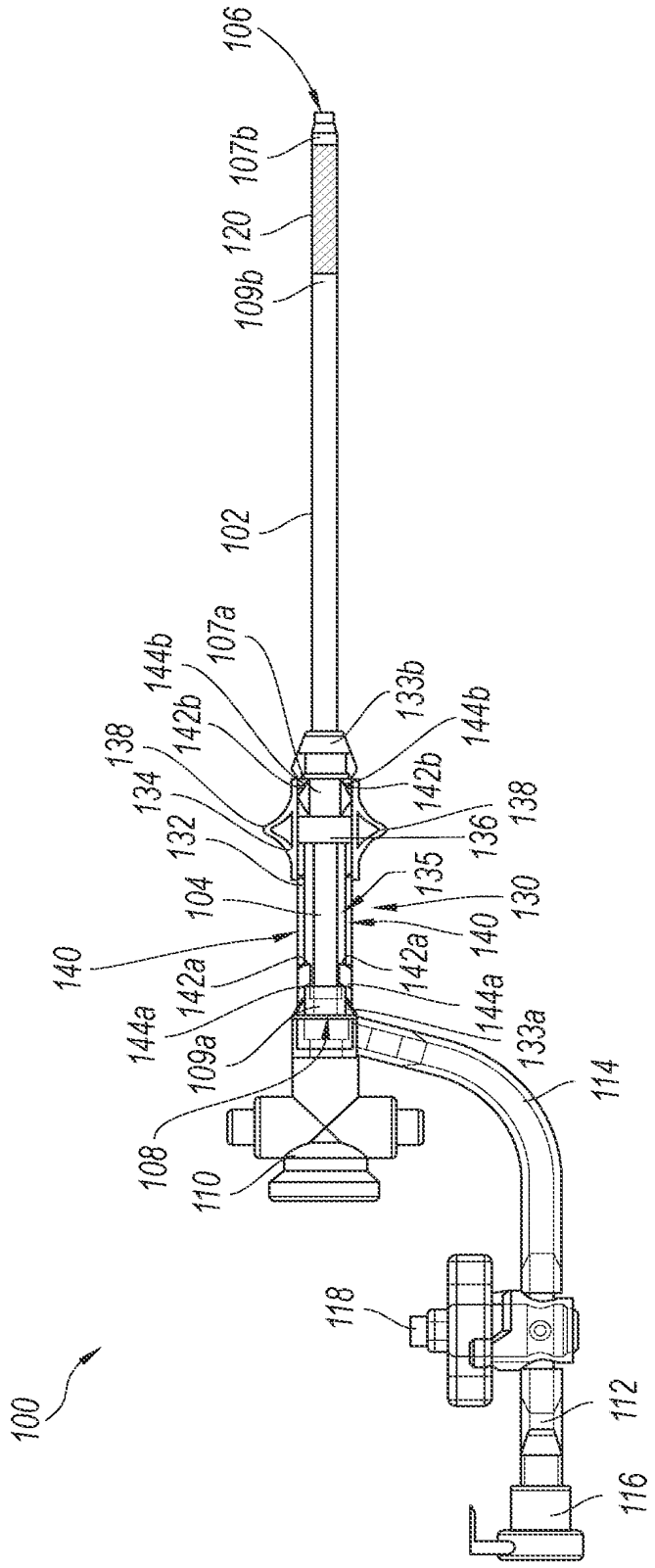

106
107b
120
109b
102
107a
144b
142b
138
134
132
104
140
142a
144a
109a
108
110
133b
144b
142b
138
136
135
130
140
142a
144a
133a
114
118
112
116
100

Fig. 1

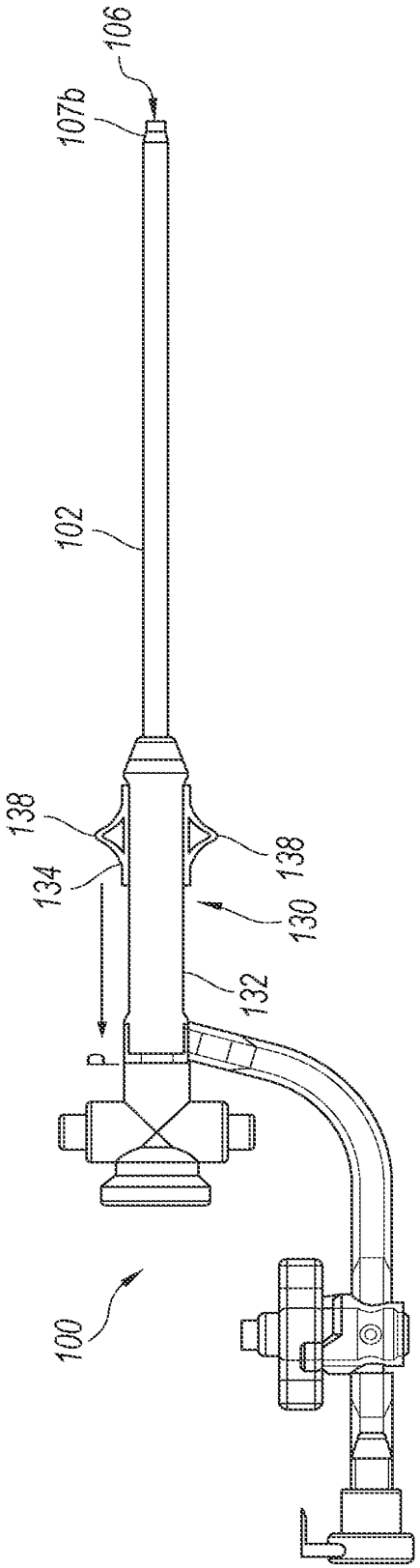

106
107b
102
138
134
138
130
132
P
100

Fig. 2A

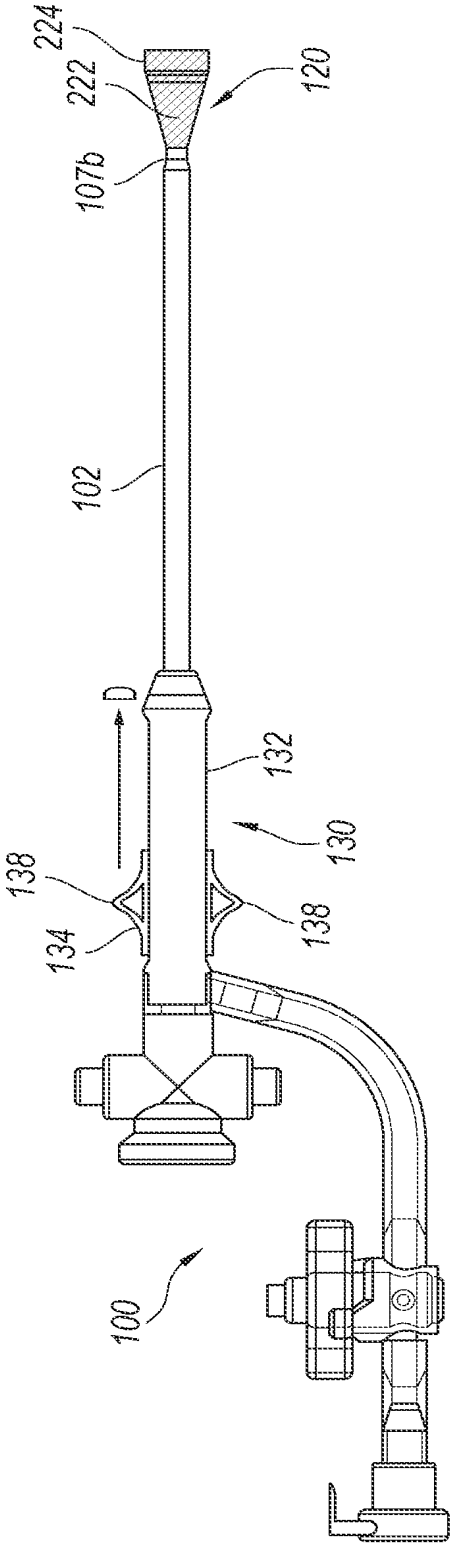

224
222
120
107b
102
D
132
130
138
134
138
100

Fig. 2B

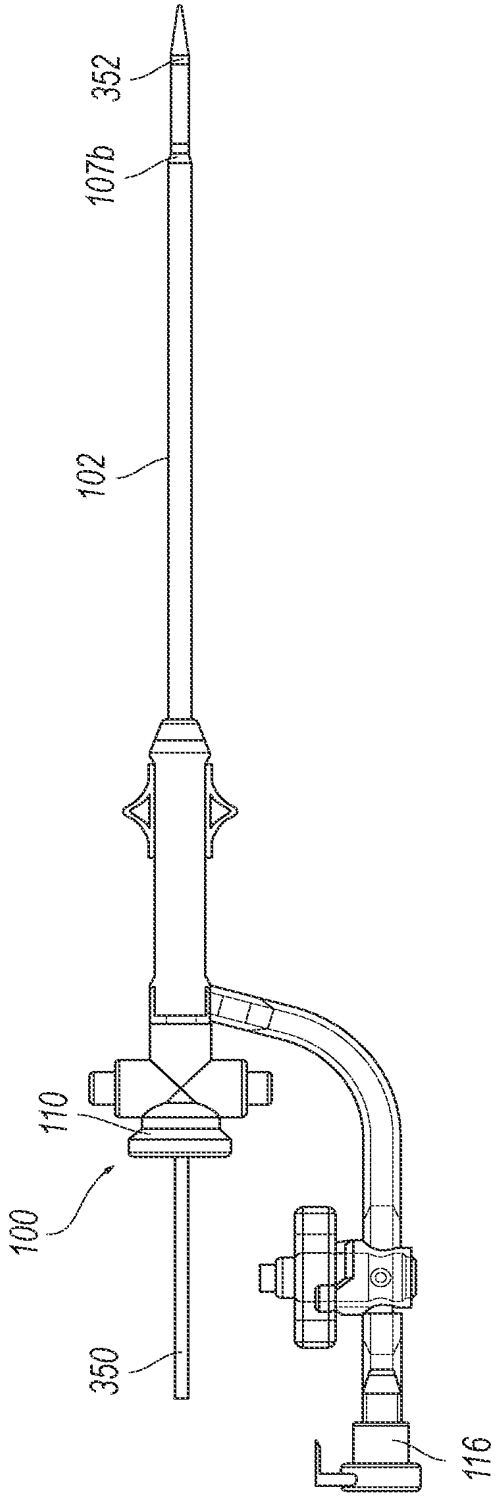


Fig. 3

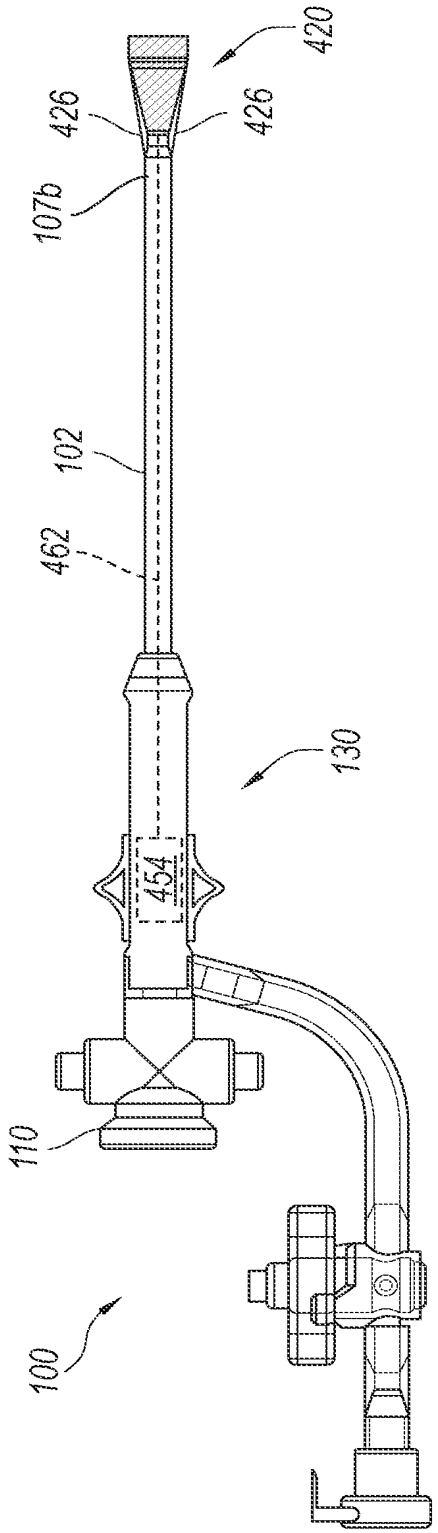


Fig. 4

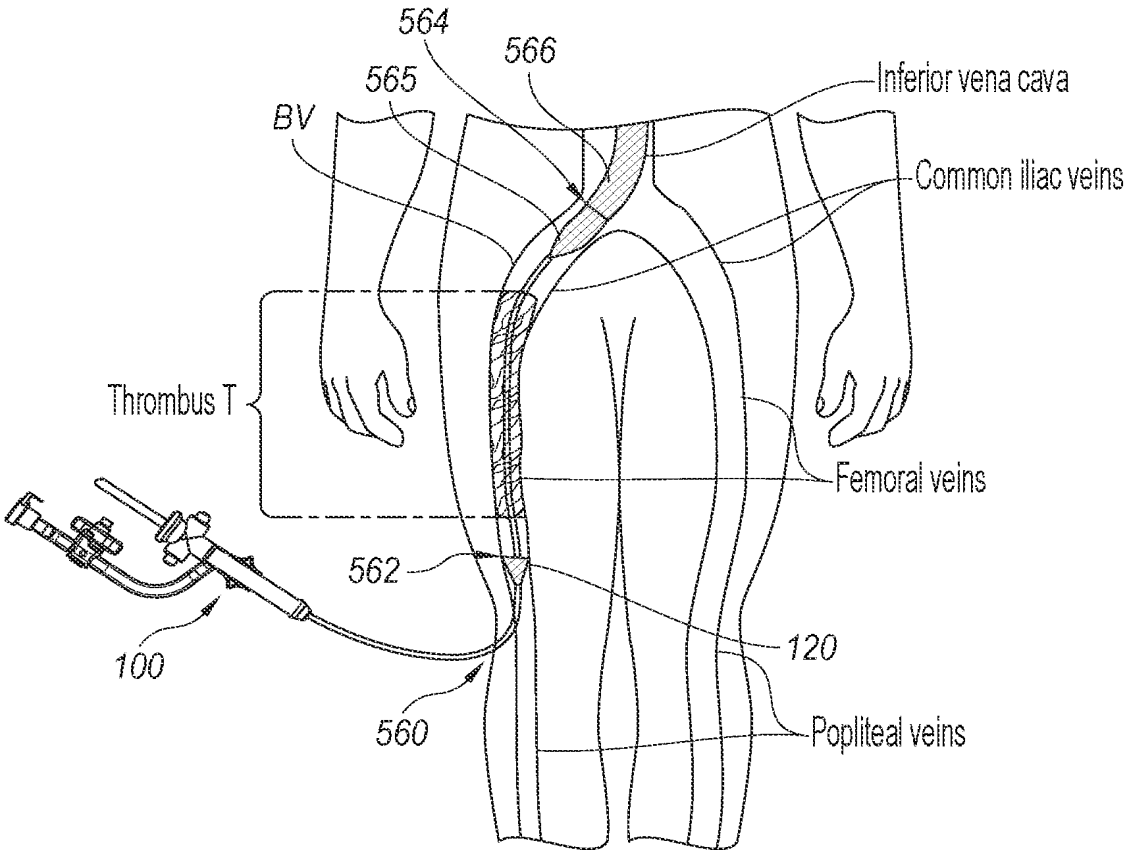

564
566
565
BV
Inferior vena cava
Common iliac veins
Thrombus T
Femoral veins
562
120
100
560
Popliteal veins

Fig. 5

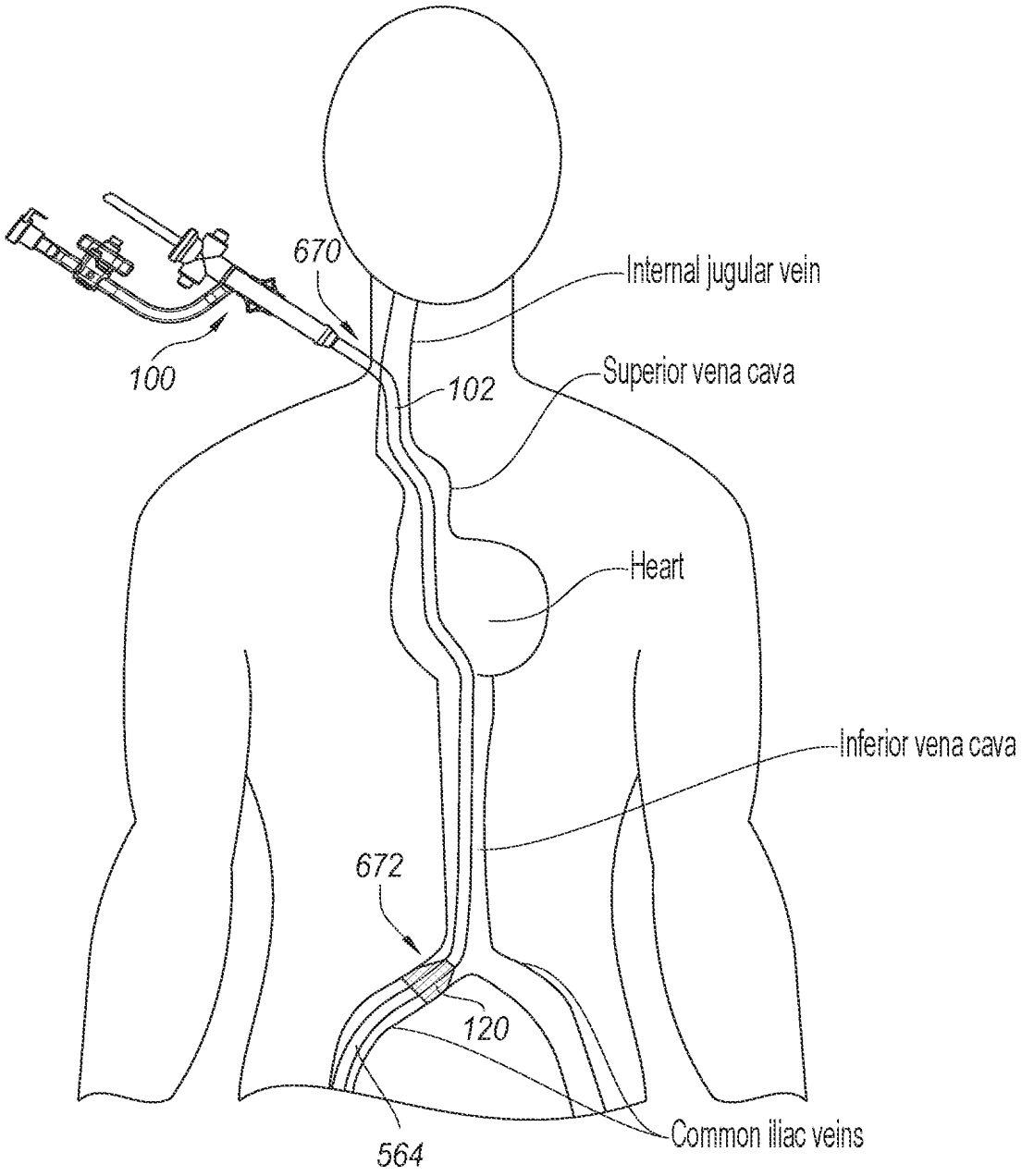

670
Internal jugular vein
100
102
Superior vena cava
Heart
Inferior vena cava
672
120
564
Common iliac veins

Fig. 6

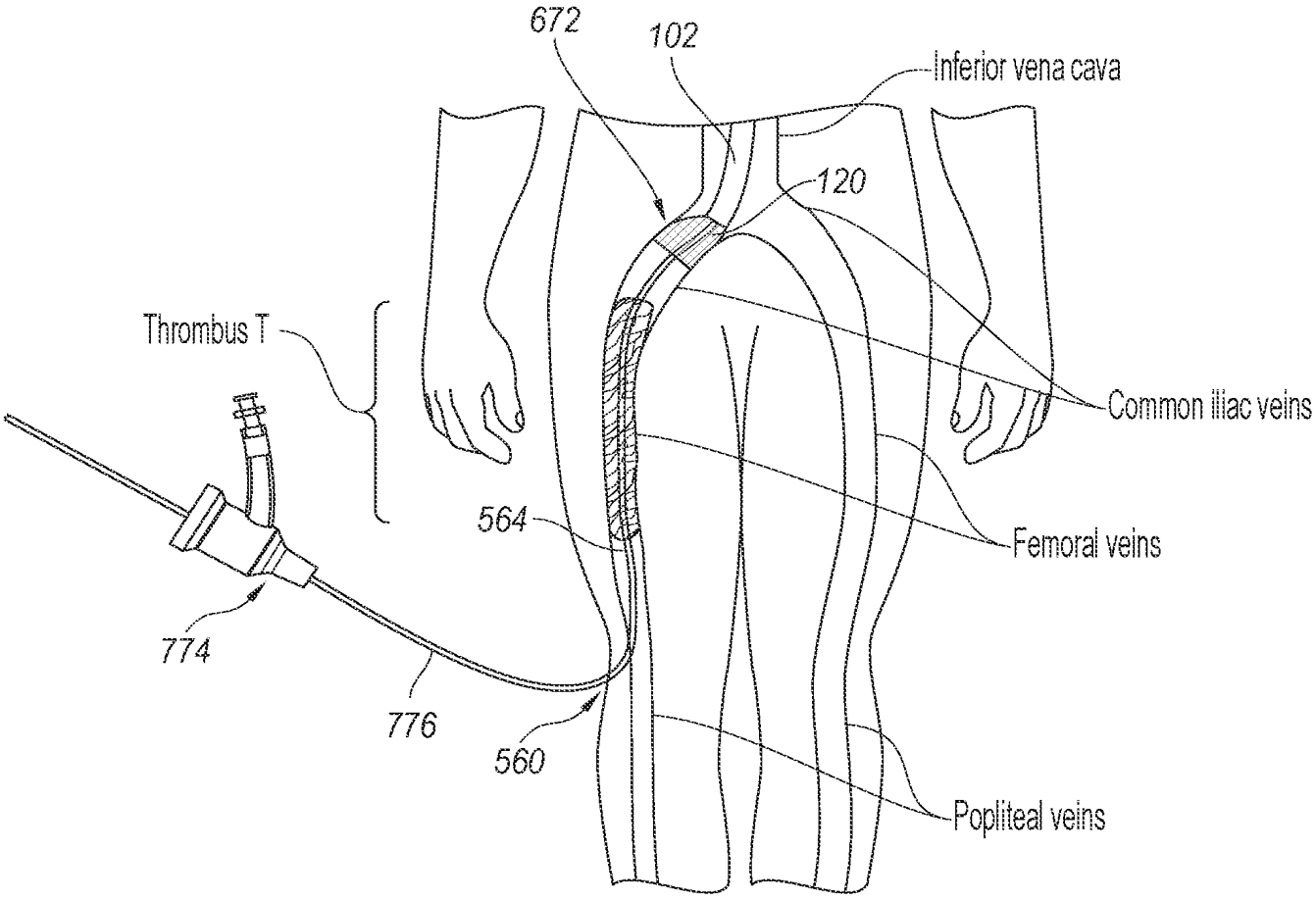

672
102
Inferior vena cava
120
Thrombus T
Common iliac veins
564
Femoral veins
774
776
560
Popliteal veins

Fig. 7

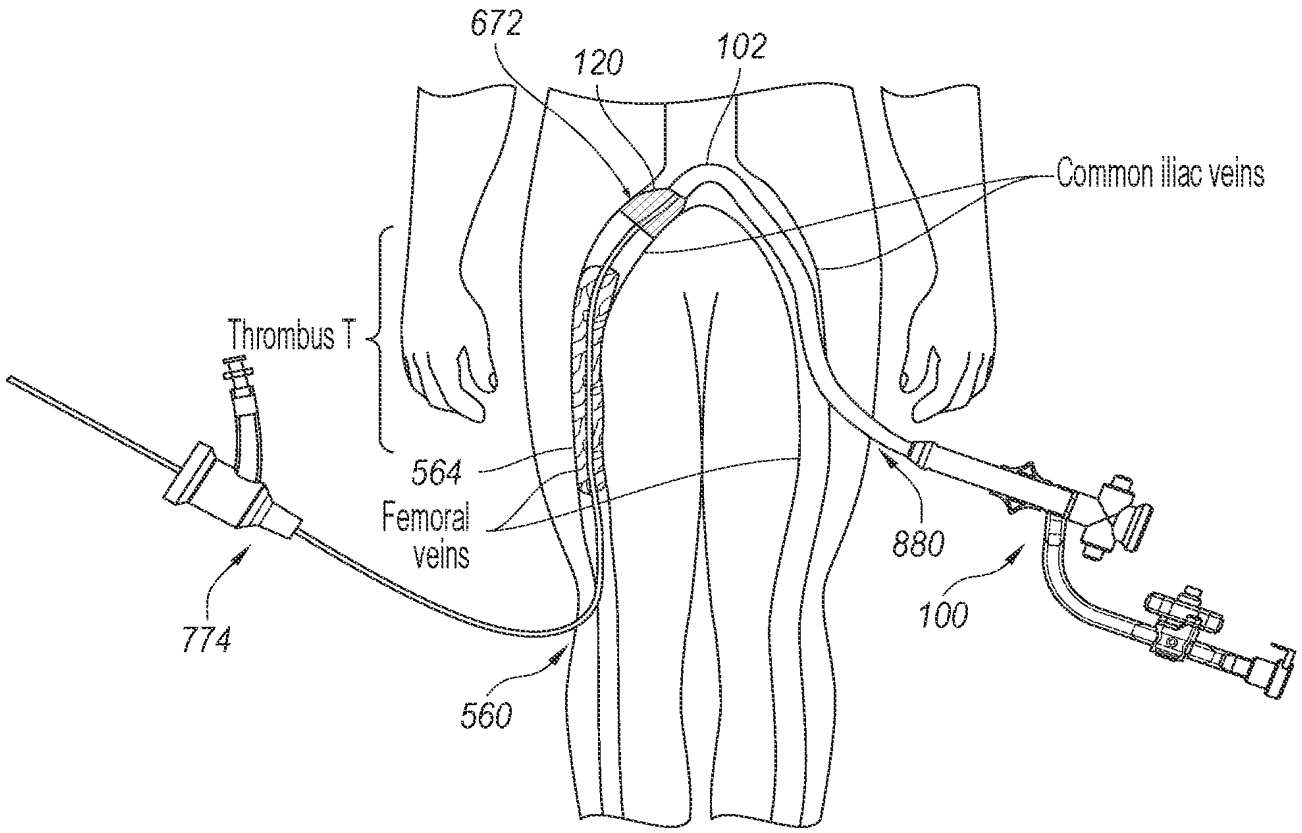

672
120
102
Common iliac veins
Thrombus T
564
Femoral veins
880
100
774
560

Fig. 8

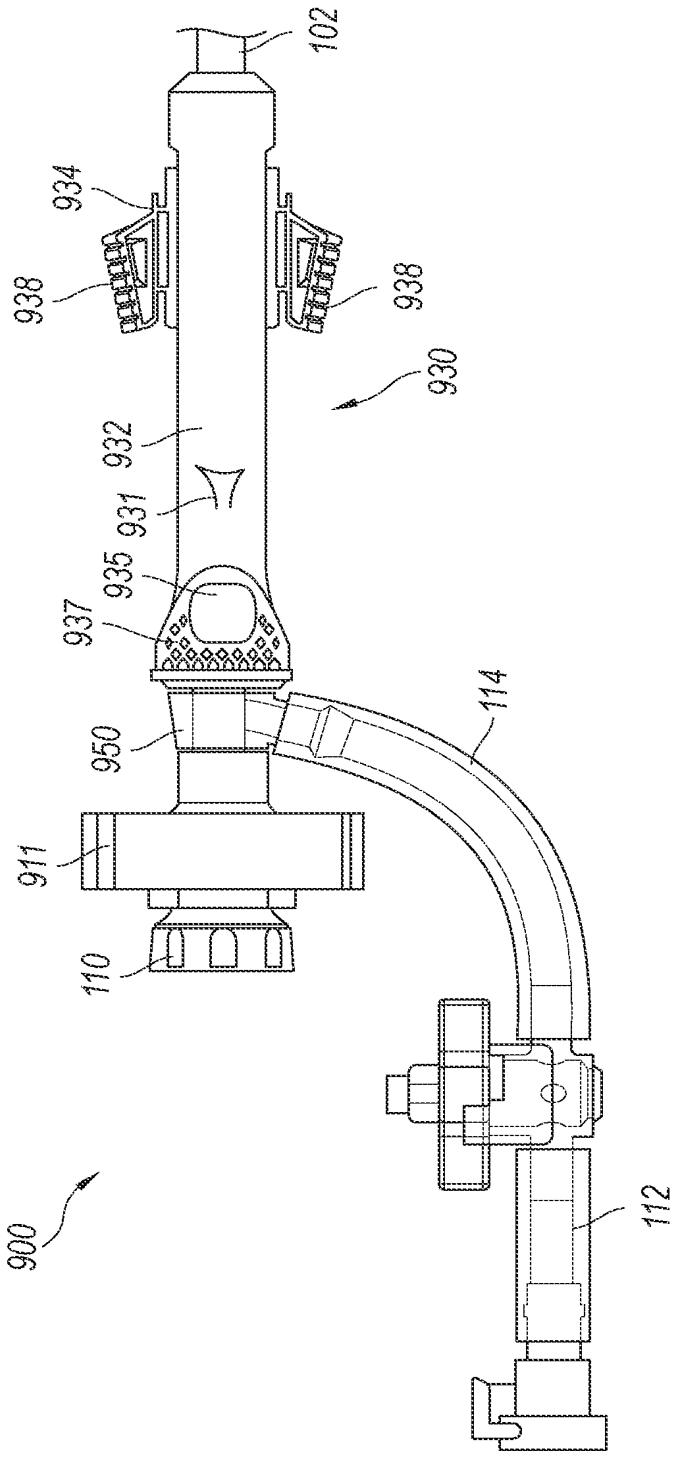


Fig. 9A

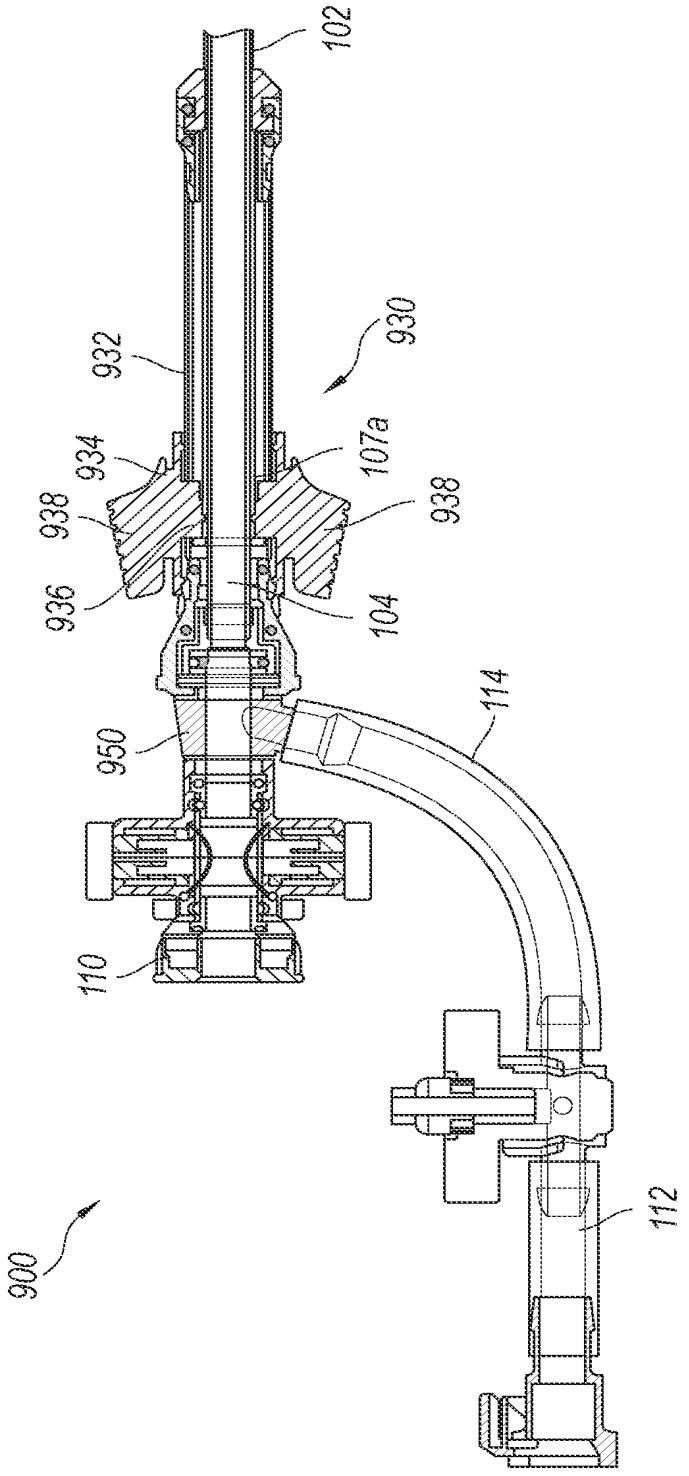


Fig. 9B

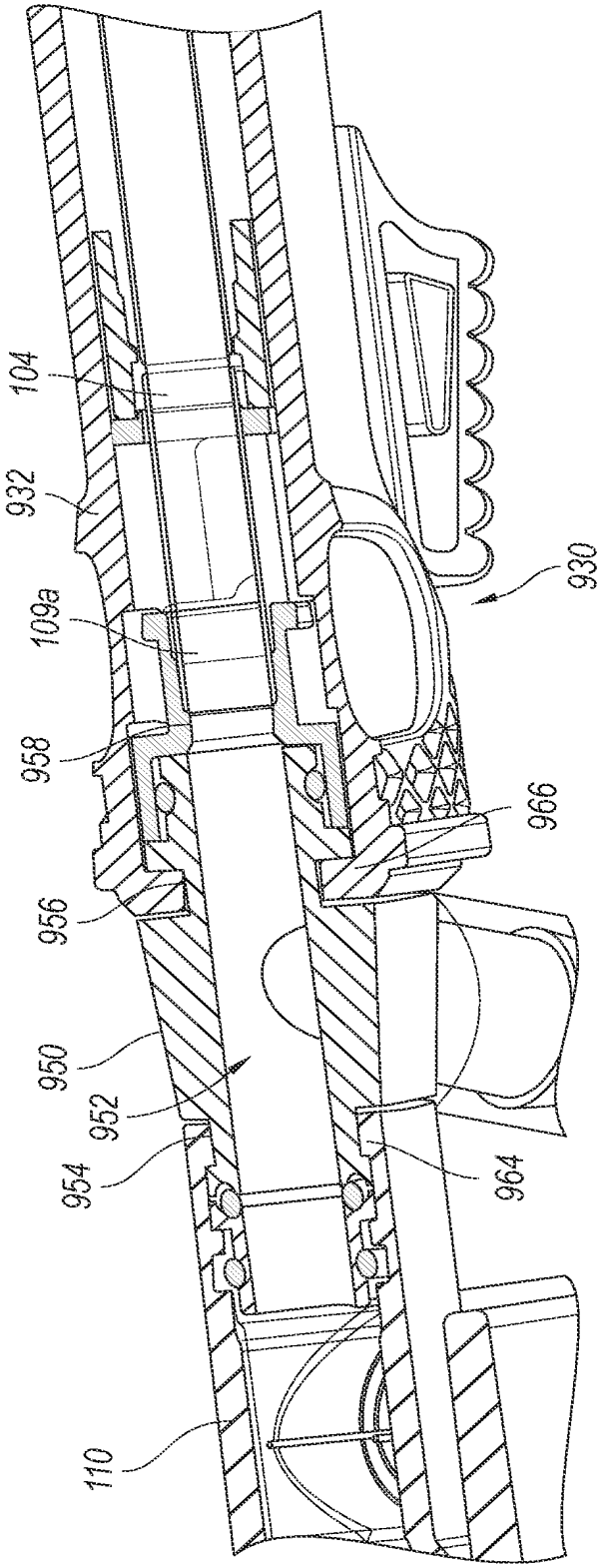


Fig. 9C

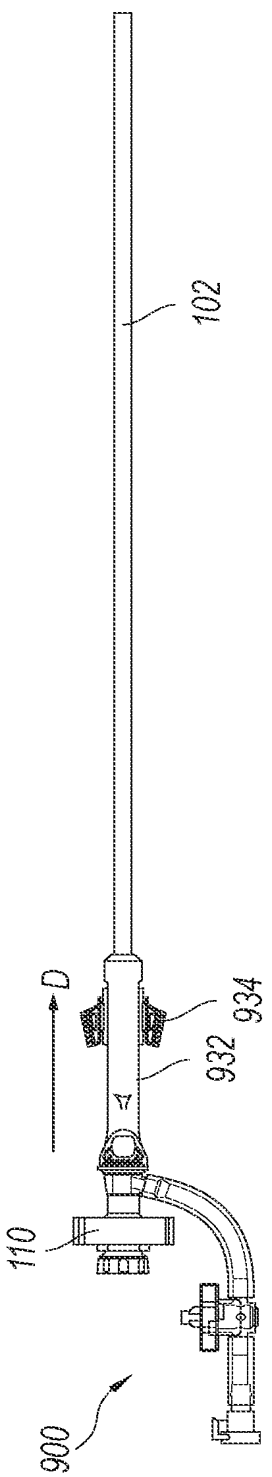


Fig. 10A



Fig. 10B

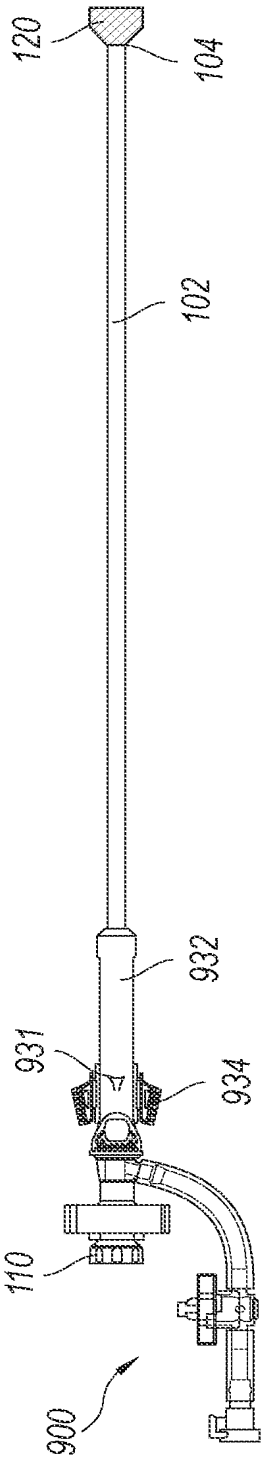


Fig. 10C

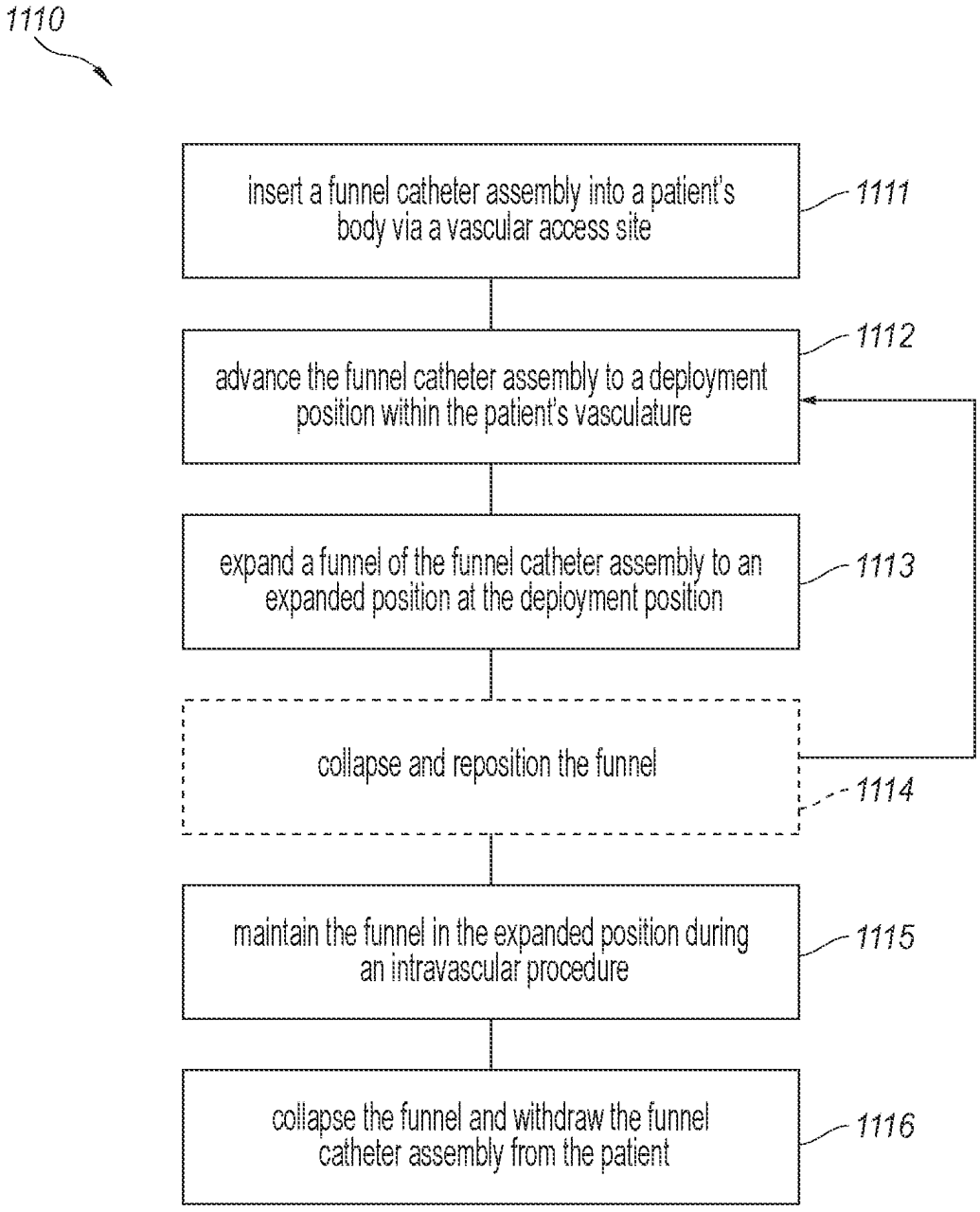

1110
insert a funnel catheter assembly into a patient's body via a vascular access site
1111
advance the funnel catheter assembly to a deployment position within the patient's vasculature
1112
expand a funnel of the funnel catheter assembly to an expanded position at the deployment position
1113
collapse and reposition the funnel
1114
maintain the funnel in the expanded position during an intravascular procedure
1115
collapse the funnel and withdraw the funnel catheter assembly from the patient
1116

Fig. 11

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 21/35965

A. CLASSIFICATION OF SUBJECT MATTER

IPC - A61B 17/00, A61B 17/22, A61B 17/3207, A61M 25/10, A61M 1/00 (2021.01)

CPC - A61M 2025/1045, A61B 17/22, A61B 17/221, A61B 2217/005, A61M 2025/109

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 5,011,488 A (Ginsburg) 30 April 1991 (30.04.1991), entire document	1-10, 13-17, 19-20 ---------- 18
X	US 5,800,457 (Gelbfish) 1 Septemebr 1998 (01.09.1998), entire document	8, 11-12
Y	WO 2009/082513 A1 (Tex Medical) 2 July 2009 (02.07.2009), entire document	18
A	US 2002/0161392 A1 (Dubrul) 31 October 2002 (31.10.2002), entire document	1-20
A	WO 2018/148174 A1 (KP Medcure, Inc) 16 August 2018 (16.08.2018), entire document	1-20

☐ 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
6 August 2021	SEP 28 2021
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 Kari Rodriquez Telephone No. PCT Helpdesk: 571-272-4300

Form PCT/ISA/210 (second sheet) (July 2019)

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
23 June 2011 (23.06.2011)

PCT

(10) International Publication Number
WO 2011/073176 A1

(51) International Patent Classification:
A61M 5/315 (2006.01)

(21) International Application Number:
PCT/EP2010/069597

(22) International Filing Date:
14 December 2010 (14.12.2010)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
09179229.1 15 December 2009 (15.12.2009) EP

(71) Applicant *(for all designated States except US)*: **NOVARTIS AG** [CH/CH]; Lichtstrasse 35, CH-4056 Basel (CH).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **BEDFORD, Tony** [GB/GB]; Cambridge Consultants, Science Park, Milton Road, Cambridge Cambridgeshire CB4 0DW (GB). **BISHOP, Duncan** [GB/GB]; Cambridge Consultants, Science Park, Milton Road, Cambridge Cambridgeshire CB4 0DW (GB). **GOW, Andrew** [GB/GB]; Cambridge Consultants, Science Park, Milton Road, Cambridge Cambridgeshire CB5 0DW (GB). **HARRIS, Dave** [GB/GB]; Cambridge Consultants, Science Park, Milton Road, Cambridge Cambridgeshire CB4 0DW (GB). **HAWSON, Nick** [GB/GB]; Cambridge Consultants, Science Park, Milton Road, Cambridge Cambridgeshire CB4 0DW (GB). **LLOYD-LUCAS, Dominic** [GB/GB]; Cambridge Consultants, Science Park, Milton Road, Cambridge Cambridgeshire CB4 0DW (GB). **MURPHY, Martin** [GB/GB]; Cambridge Consultants, Science Park, Milton Road, Cambridge Cambridgeshire CB4 0DW (GB). **ROYER, Christophe** [FR/CH]; Novartis Pharma AG, Postfach, CH-4002 Basel (CH).

(74) Agent: **MCLEAN, Craig**; Novartis Pharma AG, Patent Department, CH-4002 Basel (CH).

(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, 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, IS, JP, KE, KG, KM, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PE, PG, PH, PL, PT, RO, RS, RU, 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, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, 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, ML, MR, NE, SN, TD, TG).

Declarations under Rule 4.17:

[Continued on next page]

(54) **Title**: SYRINGE

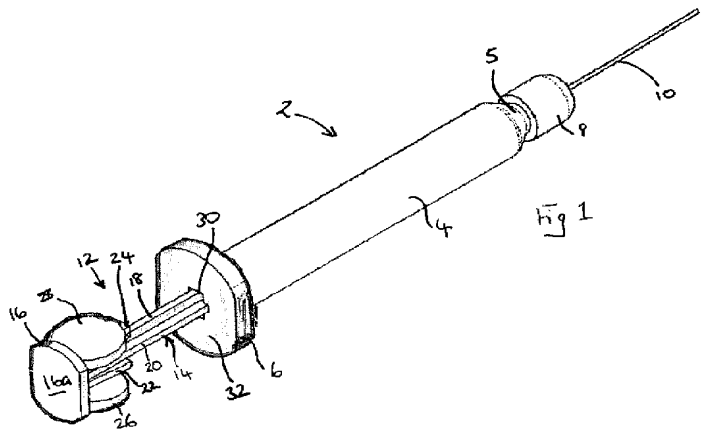


Fig 1

(57) **Abstract**: A syringe (2) including a barrel (4) with discharge end (5) defining a discharge passage, plunger (12) being adapted to move axially within the barrel and capable of displacing fluid from the chamber through the discharge end; the plunger includes a control arm (22, 24) including a first releasable stop element and a second non-releasable stop element, the first and second stops are both axially spaced from the rear end of the plunger, the control arm has a first configuration in which the first stop element is axially aligned with a stop surface (32) defined by a part of the barrel (4), the first stop element is adapted to limit the axial movement of the plunger; and a second configuration in which the first stop element is disposed out of alignment with the stop surface and the second stop element is axially aligned with the stop surface, the second stop element is adapted to limit the plunger movement from the first stop element to the second stop element.

WO 2011/073176 A1

— *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))*

Published:

— *with international search report (Art. 21(3))*

— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))*

Syringe

The present invention relates to a syringe and, in particular, to a syringe adapted to permit priming, followed by dosing of a pre-determined dose.

It is often desirable to deliver a relatively small volume of fluid from a syringe in a method that is both accurate and reproducible. Typically, syringes containing fluids are first primed, to ensure that no air or other gas is present in the syringe and then a second, delivery (dosage) step is performed to deliver the required volume of fluid. However, it is difficult to deliver accurately a relatively small volume of fluid during the delivery step using a conventional syringe.

WO01/62319, US3,934,586 and WO03/004080 all describe dual stage syringes, but none of them addresses the issue of delivering accurately and reproducibly a relatively small volume of a fluid.

According to a first aspect of the present invention, there is provided a syringe for dispensing a fluid, the syringe including a barrel including a discharge end defining a discharge passage, and a plunger disposed within the barrel, the plunger being adapted to move axially within the barrel such that the plunger and discharge end define a variable volume chamber within the barrel and the plunger is capable of displacing fluid from the chamber through the discharge end; wherein the plunger includes a control arm which includes a first releasable stop element and a second non-releasable stop element, wherein the first and second stops are both axially spaced from the rear end of the plunger and wherein the control arm has a first configuration in which the first stop element is axially aligned with a stop surface defined by a part of the barrel, whereby the first stop element is adapted to limit the axial movement of the plunger, and a second configuration in which the first stop element is disposed out of alignment with the stop surface and the second stop element is axially aligned with the stop surface, whereby the second stop element is adapted to limit the plunger movement from the first stop element to the second stop element.

By having a first, releasable stop, a priming stroke can be defined in which the plunger is moved from a start position to the first stop. The first stop can then be removed or by-passed by moving the control arm from the first configuration to the second configuration. When the first stop is removed, by disposing it out of alignment with the stop surface, the syringe may

be used to deliver a dose of fluid contained therein by further movement of the plunger from the first to the second stop. The spacing between the first and second stops corresponds to a fixed dose for a given internal diameter of the barrel. Thus, the second stop element is disposed rearwardly from the first stop element and the spacing between the first and second stop elements defines the dosing stroke of the plunger.

Locating the first and second stops on a control arm and spacing both of the stops from the end of the plunger means that it is possible to achieve accurate and reproducible dosing of relatively small doses of the fluid by controlling the spacing between the stops. This is because the second stop is well defined. In the art, the second stop is often defined by a plunger button engaging or contacting the barrel body. However, this opens up the possibility that the user does not fully displace the plunger, resulting in an underdose being delivered. Additionally or alternatively, there is the possibility of foreign material becoming lodged at the rear of the barrel, which would prevent complete displacement of the plunger to the second stop. This would also result in an underdose being delivered. For doses having relatively small volumes, it is important that the dosing stroke is well defined.

In an embodiment of the invention as defined anywhere herein, the control arm is resiliently deformable, wherein the first configuration represents a rest or non-deflected position, and the second configuration represents a deflected position. In such an arrangement, the control arm must be urged from the first configuration to the second configuration in order to remove or release the first stop.

The plunger may include a retaining element to retain the control arm in the second configuration. For example, this might include an axially slidable collar or sleeve carried by the plunger or a two-part clip, wherein one part of the clip is carried by the control arm and the other part of the clip is carried by the plunger. In this arrangement, the syringe may be used one-handed, as the control arm does not need to be manually retained in the second configuration and the retaining element prevents the accidental return of the control arm to the first configuration from the second configuration and the consequent re-engagement of the first stop.

In a further embodiment of the invention as defined anywhere herein, the plunger includes a shaft connected at one end to a piston disposed in use within the barrel and connected at the other end to a push button, and the control arm is hingedly coupled to the shaft. This

arrangement provides a control arm which is relatively straightforward to engineer and is intuitive for a user to operate.

The barrel may include a collar comprising a collar body which defines therethrough a shaft guide channel, wherein the shaft of the plunger is slidably retained within the guide channel. The collar body may further define the stop surface.

The guide channel may be adapted to receive therein the first stop element when the control arm is in the second configuration.

In order to maintain the first stop element aligned with the stop surface, for example during the priming step, the shaft of the plunger may include an orientation controlling element which is adapted to maintain the axial orientation of the plunger shaft relative to the guide channel. This ensures that the plunger remains in the desired axial orientation until the priming step is complete and the first stop element of the plunger has engaged the stop surface.

In an embodiment of the invention as defined anywhere herein, the orientation controlling element includes a spline (a longitudinally extending rib) carried by the plunger shaft which is located in use within a spline channel defined through the collar.

The interaction of the spline carried by the plunger shaft with the spline channel prevents unwanted movement, e.g. rotation, of the plunger relative to the barrel.

The skilled person will appreciate that the plunger may include more than one spline, wherein the splines are circumferentially offset from each other.

In such an embodiment, the barrel and/or collar typically includes corresponding spline channels for each spline.

A common arrangement for plungers is to include a cruciform-shaped shaft. Thus, in an embodiment of the invention as defined anywhere herein, the plunger shaft has a cruciform cross sectional configuration. In such an embodiment, the collar body may define a guide channel having complimentary cruciform shape.

In embodiments where the spline channel is adapted to receive therein the first stop element when the control arm is in the second configuration, one or more of the splines may include a longitudinal notch which is capable of receiving therein at least a part of the control arm. Thus, the first stop element of the control arm may have a cross-section which is smaller than or congruent with the cross section of the notch formed within the respective spline, wherein the first stop element extends laterally outwards from the spline in the first configuration of the control arm and is axially aligned with the spline in the second configuration of the control arm. In other words, the first stop element may be contained within the notch in the second configuration of the control arm.

Of course, the first stop element may extend beyond the notch defined by the spline in embodiments where the spline channel is adapted to receive therein the first stop element, i.e. in addition to the spline itself.

The first stop element may be a forward facing end wall of the control arm.

The second stop element may extend outwardly from the first stop element. In such embodiments, the second stop element may be carried by the control arm and is spaced rearwardly from the first stop element to define a dosing stroke which is the spacing between the first and second stop elements.

The second stop element may be defined by an edge portion of a control button which defines a substantially planar button surface. In such an embodiment, it is clear to a user how to operate the syringe: the syringe is primed by urging the plunger forwards until the first stop engages or contacts the stop surface. The control button is then pressed, which moves the control arm from the first to the second configuration, whereupon the first stop element is disengaged from (moved out of alignment with) the stop surface. The plunger is then again urged forwards until the second, non-releasable, stop element engages or contacts the stop surface, at which point the dose stroke is complete.

In an embodiment of the invention as defined anywhere herein, the plunger includes a pair of opposed control arms. By having two or more control arms, the possibility of the first stop element accidentally and/or unintentionally being disposed out of axial alignment with the stop surface is significantly reduced.

According to a second aspect of the invention, there is provided a plunger assembly for use with a syringe barrel, the assembly including a collar adapted to engage one end of the barrel; and a plunger including a piston adapted to be located within the barrel, an elongate shaft extending from the piston and a push button at the end of the shaft opposite to the piston, wherein the elongate shaft is slidably retained within the collar, and wherein the plunger shaft includes a control arm which includes a first releasable stop element and a second non-releasable stop element, wherein the first and second stops are both axially spaced from the push button and wherein the control arm has a first configuration in which the first stop element is axially aligned with a stop surface defined by the collar, whereby the first stop element is adapted to limit the axial movement of the plunger, and a second configuration in which the first stop element is disposed out of alignment with the stop surface and the second stop element is axially aligned with the stop surface, whereby the second stop element is adapted to limit the plunger movement from the first stop element to the second stop element.

The additional features described and defined herein in connection with the first aspect of the invention may apply equally to the second aspect of the invention. Thus, the second aspect of the invention may include any, some or all of the additional features described hereinabove.

According to a third aspect of the invention, there is provided a syringe kit including a syringe barrel and a plunger assembly according to the second aspect of the invention.

According to a fourth aspect of the invention, there is provided a pre-filled syringe for dispensing a fluid, the syringe including a barrel including a discharge end defining a discharge passage, the barrel containing therein a medicament in fluid form; and a plunger disposed within the barrel, the plunger being adapted to move axially within the barrel such that the plunger and discharge end define a variable volume chamber within the barrel and the plunger is capable of displacing fluid from the chamber through the discharge end; wherein the plunger includes a control arm which includes a first releasable stop element and a second non-releasable stop element, wherein the first and second stops are both axially spaced from the rear end of the plunger and wherein the control arm has a first configuration in which the first stop element is axially aligned with a stop surface defined by a part of the barrel, whereby the first stop element is adapted to limit the axial movement of the plunger, and a second configuration in which the first stop element is disposed out of alignment with

the stop surface and the second stop element is axially aligned with the stop surface, whereby the second stop element is adapted to limit the plunger movement from the first stop element to the second stop element.

The additional features described and defined herein in connection with the first aspect of the invention may apply equally to the fourth aspect of the invention. Thus, the fourth aspect of the invention may include any, some or all of the additional features described hereinabove.

As used herein, the term “forward” means towards the discharge end of the syringe and the term “rearward” means away from the discharge end of the syringe.

The skilled person will appreciate that the features specified above in connection with embodiments of the invention may be combined with each other and any of the aspects of the invention as defined. Thus, the present invention includes within its scope an aspect of the invention combined with two or more of the features described anywhere herein as optional features. All such combinations of features described herein are considered to be made available to the skilled person.

Embodiments of the invention will now be described in detail, by way of example only, with reference to the accompanying drawings in which:

Figure 1 is a perspective view of a syringe according to a first embodiment of the invention;
Figure 2 is side elevational view of the syringe shown in Figure 1;
Figure 3 is a plan view from above of the plunger assembly of the syringe shown in Figure 1;
Figure 4 is a perspective view of a syringe according to a second embodiment of the invention; and
Figure 5 is a side elevational view of the syringe shown in Figure 4.

For the avoidance of doubt, the skilled person will appreciate that in this specification, the terms “up”, “down”, “front”, “rear”, “upper”, “lower”, “width”, etc. refer to the orientation of the components as found in the syringe when installed for normal use as shown in the Figures.

A syringe 2 according to a first embodiment of the invention is shown in Figures 1, 2 and 3. The syringe 2 includes a barrel 4 defining a cylinder therein. Located at the rear of the barrel 4 is a collar 6 and at the opposite end, i.e. the front, of the barrel 4 is a discharge end 5

which defines therein a discharge passage. Secured to the discharge end 5 is a connecting collar 8 of a hypodermic needle 10.

The skilled person will appreciate that the hypodermic needle connecting collar 8 may be a simple friction fit with the discharge end 5 of the barrel 4 or it may be a locking collar, such as a Luer-Lok collar. The connection of hypodermic needles to syringe barrels is well known in the art and will not be described in detail herein.

The syringe 2 further includes a plunger assembly 12. The plunger assembly 12 consists of a plunger shaft 14 which terminates at its rearward end in a push button 16 and terminates at its forward end in a piston (not shown) located within the cylinder defined by the barrel 4. The plunger shaft 14 is slidably retained within the collar 6.

The push button 16 defines a rearward facing push button surface 16a which is substantially planar.

The plunger shaft 14 is cruciform in cross-section and defines a pair of opposed vertical splines 18 and a pair of opposed horizontal splines 20.

Included in the plunger assembly 12 is a pair of opposed control arms 22, 24 hingedly connected to the plunger shaft 14 adjacent to the push button 16. Figure 2 shows the control arms 22, 24 in a first configuration in which the distal ends of the control arms 22, 24 are laterally spaced from the plunger shaft 14. The forward facing end surfaces of the control arms 22, 24 define the first stop elements.

The width of each of the control arms 22, 24 is slightly greater than the width of the corresponding vertical spline 18, and the height of each of the control arms 22, 24 is slightly less than the corresponding vertical spline 18.

The collar 6 includes a body which defines therein a plunger shaft guide channel in the form of a cruciform aperture 30 substantially about the longitudinal axis of the barrel 4. Each of the four arms of the cruciform-shaped aperture 30 has a height which is slightly greater than the height of the corresponding spline 18, 20. The width of the horizontal arms is similarly slightly greater than the width of the corresponding horizontal splines 20. However, the width of the

vertical arms of the cruciform aperture 30 is such that they are slightly wider than the width of the corresponding control arms 22, 24.

The body of the collar 6 about the cruciform aperture 30 defines a stop surface.

The vertical splines 18 each define a notch 40 which is sized to accommodate the corresponding control arm 22, 24 in their second configuration in which the control arms 22, 24 are arranged axially within the corresponding vertical spline 18. Thus, each notch 40 is substantially equal in length to the corresponding control arm 22, 24 and the depth of each notch 40 is substantially identical to the height of the corresponding control arm 22, 24.

The front facing wall of each of the control arms 22, 24 includes a recess (not shown) which is configured to receive therein a corresponding protrusion (not shown) which extends outwards from the rear facing wall of each of the vertical splines 18.

Extending outwardly from the control arms 22, 24 are respective control buttons 26, 28 in the form of short cylindrical bodies. The forward facing side wall portion of each control button 26, 28 defines a respective second stop element.

In use, the barrel 4 includes a medicament in fluid form and the plunger is disposed in a start position in which the first stop elements defined by the forward facing walls of the control arms 22, 24 are spaced from the stop surface defined by the body of the collar 6. The control arms 22, 24 are in their rest position, as shown in Figure 2.

A user initiates a priming step to remove any gas or dead volume from within the barrel by urging the plunger forward via the rearward facing push button surface 16a. This causes the piston within the barrel 4 to move forward, expelling the unwanted gas and priming the syringe. The priming stroke is continued until the forward facing end walls of the control arms 22, 24 engage the stop surface defined by the body of the collar 6.

Once the priming step is complete, the user exerts a force on each of the two control buttons 26, 28 which urges them towards each other. This causes the control arms 22, 24 to be located within the corresponding notch 40 of the respective vertical spline 18 and for the forward facing end walls of the control arms 22, 24 to become axially aligned with the vertical arms of the cruciform aperture 30. Thus, in this second configuration of the control arms 22,

24, the forward facing end walls of the control arms 22, 24 are no longer axially aligned with the stop surface defined by the body of the collar 6 and are capable of being received into the vertical arms of the cruciform aperture 30.

When the control arms 22, 24 are fully located within the corresponding notch 40, the protrusions extending from the rearward facing end wall portions of the vertical splines 18 engage with the respective recesses formed in the forward facing end walls of the control arms 22, 24 such that the control arms 22, 24 are releasably retained in the second configuration.

Once the control arms 22, 24 are in their second configuration, the hypodermic needle 10 is inserted into or through the skin of a patient and the dose stroke is commenced. The dose stroke is defined by the short distance between the forward facing end walls of the control arms 22, 24 and the forward facing side walls of the cylindrical-shaped control buttons 26, 28. At the end of the dose stroke, the forward facing side walls of the cylindrical-shaped control buttons 26, 28 engage the stop surface defined by the body of the collar 6.

The skilled person will appreciate that the actual dose delivered by the syringe during the dose stroke is a function of the internal diameter of the barrel 4 and the spacing between the first stop elements (the forward facing end walls of the control arms 22, 24) and the second stops (the forward facing side walls of the cylindrical-shaped control buttons 26, 28). The delivery dose can be varied by varying one or both of these physical properties.

A second embodiment of the invention is shown in Figures 4 and 5.

A syringe 102 according to the second embodiment of the invention includes a barrel 104 defining a cylinder therein. Located at the rear of the barrel 104 is a collar 106 and at the opposite end, i.e. the front, of the barrel 104 is a discharge end 105 which defines therein a discharge passage. Secured to the discharge end 105 is a connecting collar 108 of a hypodermic needle 110.

The syringe 102 further includes a plunger assembly 112. The plunger assembly 112 consists of a plunger shaft 114 which terminates at its forward end in a piston (not shown) located within the cylinder defined by the barrel 4. The plunger shaft 114 is slidably retained within the collar 106.

A push button 116 is slidably coupled to a rear end portion of the plunger shaft 114 and defines a rearward facing push button surface 116a which is substantially planar. A cylindrical sleeve 150 extends forward from the push button 116 and overlies a portion of the plunger shaft 114. The push button 116 and associated sleeve 150 can move axially relative to the plunger shaft 114 within fixed limits.

The plunger shaft 114 is cruciform in cross-section and defines a pair of opposed vertical splines 118 and a pair of opposed horizontal splines 120.

Included in the plunger assembly 112 is a pair of opposed control arms 122, 124 hingedly connected to the plunger shaft 114 adjacent to the push button 116. A proximal portion of the control arms 122, 124 adjacent to the push button 116 is disposed within the sleeve 150.

Figure 5 shows the control arms 122, 124 in a first configuration in which the distal ends of the control arms 122, 124 are spaced from the plunger shaft 114. The hinged arrangement of the control arms 122, 124 is such that they are biased towards this first configuration and they provide a resistive force against movement towards each other.

The forward facing end surfaces of the control arms 122, 124 define the first stop elements.

The width of each of the control arms 122, 124 is substantially the same as the width of the corresponding vertical spline 118, and the height of each of the control arms 122, 124 is slightly less than the corresponding vertical spline 118.

The collar 106 includes a body which defines therein a plunger shaft guide channel in the form of a cruciform aperture 130 substantially about the longitudinal axis of the barrel 104. Each of the four arms of the cruciform-shaped aperture 130 has a height which is slightly greater than the height of the corresponding spline 118, 120 and a width which is similarly slightly greater than the width of the corresponding splines 118, 120.

The body of the collar 106 about the cruciform aperture 130 defines a stop surface.

The vertical splines 118 each define a notch 140 which is sized to accommodate the corresponding control arm 122, 124 in their second configuration in which the control arms

122, 124 are arranged axially within the corresponding vertical spline 118. Thus, each notch 140 is substantially equal in length to the corresponding control arm 122, 124 and the depth of each notch 140 is substantially identical to the height of the corresponding control arm 122, 124.

Extending outwardly from the control arms 122, 124 are respective lugs 126, 128 in the form of triangular-shaped wedges. The forward facing wall of each of the lugs 126, 128 defines a respective second stop element.

In use, the barrel 4 includes a medicament in fluid form and the plunger is disposed in a start position in which the first stop elements defined by the forward facing walls of the control arms 22, 24 are spaced from the stop surface defined by the body of the collar 6. The control arms 22, 24 are in their rest position, as shown in Figure 2.

A user initiates a priming step to remove any gas or dead volume from within the barrel by urging the plunger forward via the rearward facing push button surface 116a. As the frictional forces between the piston and the cylinder defined within the barrel 104 and between the plunger shaft 114 and the cruciform aperture 130 are less than the resistive forces exerted by the control arms 122, 124, the force exerted by the user on the push button 116 causes the piston within the barrel 104 to move forward, expelling the unwanted gas and priming the syringe 102. The priming stroke is continued until the forward facing end walls of the control arms 122, 124 engage the stop surface defined by the body of the collar 106.

When the forward facing end walls of the control arms 122, 124 engage the stop surface defined by the body of the collar 106, further movement of the plunger shaft forward is prevented.

At this point, the hypodermic needle 110 is inserted into or through the skin of a patient and the dose stroke initiated.

To initiate the dose stroke, the user continues to apply force to rearward facing surface 116a of the push button 116. As the plunger shaft 114 is prevented from moving forward by the forward facing end walls of the control arms 122, 124 contacting the stop surface, the force is directed through the sleeve 150 to the control arms 122, 124. This force overcomes the resistive force of the control arms 122, 124 and urges them towards each other until they

become axially aligned with the vertical splines 118 and contained within the respective notches 140. At this point the forward facing end walls of the control arms 122, 124 no longer contact the stop surface defined by the body of the collar 106 and the control arms 122, 124 are capable of entering the respective arms of the cruciform aperture 130.

When the forward facing end walls of the control arms 122, 124 disengage from the stop surface, the plunger shaft and the attached piston can continue to move forward for the dose stroke until the outwardly extending lugs 126, 128 contact the stop surface, at which point the dose step is complete.

Example 1

Tests of the first embodiment syringe described above were carried out as follows:

Test Apparatus

The syringe plunger and collar were assembled to a sample 1ml syringe barrel. A needle was fitted to the discharge end of the syringe barrel.

Preparation and Measurement

The syringe was filled with a nominal volume of RO/DI water, held vertically and tapped to release air bubbles, and primed to the first stop. A clean Eppendorf Tube was tared on an analytical balance. The control buttons were urged towards each other to release the first stops and to permit dosing, and the plunger depressed to the second stop, discharging the dose into the vial.

The vial was then closed and weighed.

The test was repeated, re-using the syringe, but taking a clean vial each time.

Calculation

Dose mass was calculated from the difference in weight of the vial.
Dose volume was calculated from the mass by dividing by density.
Density = 998.022kg/m^3 at lab conditions of 21°C and 42%RH

Apparatus

Sartorius ME235S-OCE analytical balance (5 decimal places / 1g)

300 µl Eppendorf Tubes

Syringe Device as described above

Results

Table 1

	mean	Standard deviation	lowest	highest
Mass (g)	0.0520	0.0032	0.0474	0.0584
Volume (µl)	52.11	3.21	47.52	58.52

The results from N = 10 measurements

The dose delivered by the prototype in the tests is in the range 53.02 ± 5.5µl i.e. 47.52 to 58.52µl.

The syringe delivered a well controlled dose, within a tolerance of ± 5.5µl, which is within the tolerance of ± 7.5µl associated with the acceptance limits.

Claims

1. A syringe for dispensing a fluid, the syringe including a barrel including a discharge end defining a discharge passage, and a plunger disposed within the barrel, the plunger being adapted to move axially within the barrel such that the plunger and discharge end define a variable volume chamber within the barrel and the plunger is capable of displacing fluid from the chamber through the discharge end; wherein the plunger includes a control arm including a first releasable stop element and a second non-releasable stop element, wherein the first and second stops are both axially spaced from the rear end of the plunger and wherein the control arm has a first configuration in which the first stop element is axially aligned with a stop surface defined by a part of the barrel, whereby the first stop element is adapted to limit the axial movement of the plunger; and a second configuration in which the first stop element is disposed out of alignment with the stop surface and the second stop element is axially aligned with the stop surface, whereby the second stop element is adapted to limit the plunger movement from the first stop element to the second stop element, the control arm is resiliently deformable and the first configuration represents a rest or non-deflected position, and the second configuration represents a deflected position.

2. A syringe according to Claim 1, wherein the plunger includes a retaining element to retain the control arm in the second configuration.

3. A syringe according to Claim 2, wherein the retaining element is selected from an axially slidable sleeve and a two-part clip, wherein one part of the clip is carried by the control arm and the other part of the clip is carried by the plunger.

4. A syringe according to any preceding claim, wherein the plunger includes a shaft connected at one end to a piston disposed in use within the barrel and connected at the other end to a push button, and the control arm is hingedly coupled to the shaft.

5. A syringe according to Claim 4, wherein the barrel includes a collar comprising a collar body which defines therethrough a shaft guide channel, wherein the shaft of the plunger is slidably retained within the guide channel, and wherein the collar body defines the stop surface.

6. A syringe according to Claim 5, wherein the guide channel is adapted to receive therein the first stop element when the control arm is in the second configuration.

7. A syringe according to Claim 5 or 6, wherein the shaft of the plunger includes an orientation controlling element which is adapted to maintain substantially fixed the axial orientation of the plunger shaft relative to the guide channel.

8. A syringe according to Claim 7, wherein the plunger shaft has a cruciform cross-sectional configuration and the collar body defines a guide channel having a complimentary cruciform shape.

9. A syringe according to any preceding claim, wherein the first stop element includes a forward facing end wall of the control arm.

10. A syringe according to any preceding claim, where the second stop element is a projection from the control arm which extends outwardly from the first stop element and is spaced rearwardly from the first stop element.

11. A syringe according to Claim 10, wherein the second stop element is defined by a forward facing wall portion of a cylindrical control button carried by the control arm.

12. A syringe according to any preceding claim, which includes a pair of opposed control arms.

13. A plunger assembly for use with a syringe barrel, the assembly including a collar adapted to engage one end of the barrel; and a plunger including a piston adapted to be located within the barrel, an elongate shaft extending from the piston and a push button at the end of the shaft opposite to the piston, wherein the elongate shaft is slidably retained within the collar, and wherein the plunger shaft includes a control arm including a first releasable stop element and a second non-releasable stop element, wherein the first and second stops are both axially spaced from the push button and wherein the control arm has a first configuration in which the first stop element is axially aligned with a stop surface defined by the collar, whereby the first stop element is adapted to limit the axial movement of the plunger, and a second

configuration in which the first stop element is disposed out of alignment with the stop surface and the second stop element is axially aligned with the stop surface, whereby the second stop element is adapted to limit the plunger movement from the first stop element to the second stop element.

14. A pre-filled syringe for dispensing a fluid, the syringe including a barrel including a discharge end defining a discharge passage, the barrel containing therein a medicament in fluid form; and a plunger disposed within the barrel, the plunger being adapted to move axially within the barrel such that the plunger and discharge end define a variable volume chamber within the barrel and the plunger is capable of displacing fluid from the chamber through the discharge end; wherein the plunger includes a control arm including a first releasable stop element and a second non-releasable stop element, wherein the first and second stops are both axially spaced from the rear end of the plunger and wherein the control arm has a first configuration in which the first stop element is axially aligned with a stop surface defined by a part of the barrel, whereby the first stop element is adapted to limit the axial movement of the plunger, and a second configuration in which the first stop element is disposed out of alignment with the stop surface and the second stop element is axially aligned with the stop surface, whereby the second stop element is adapted to limit the plunger movement from the first stop element to the second stop element.

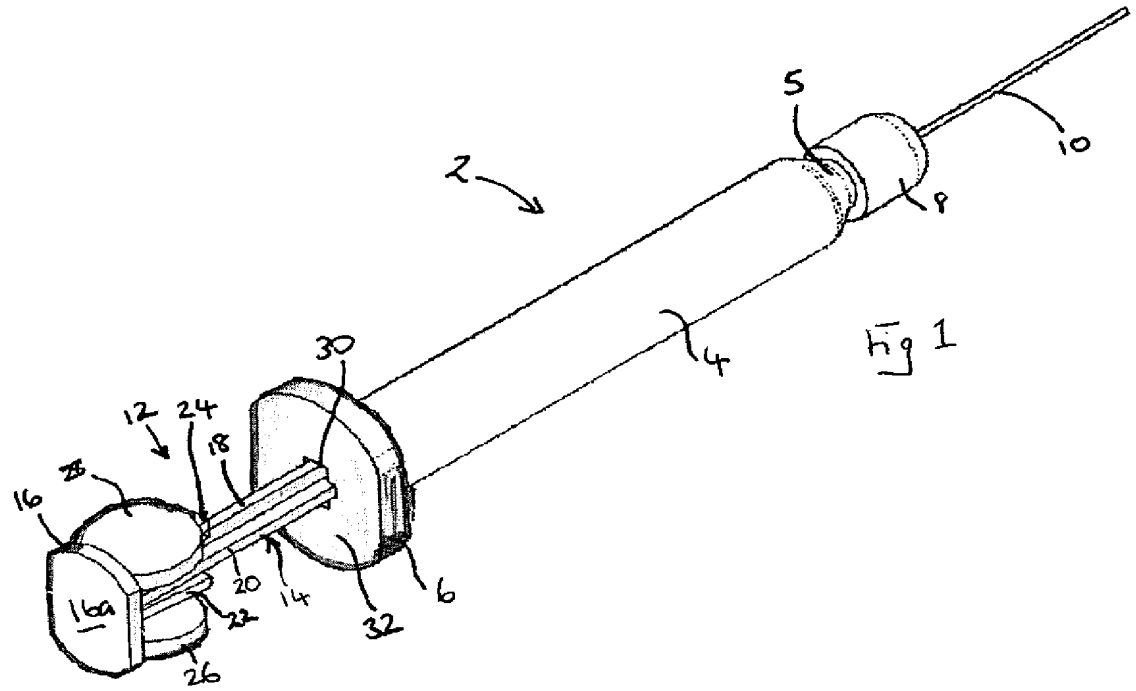


Fig 1

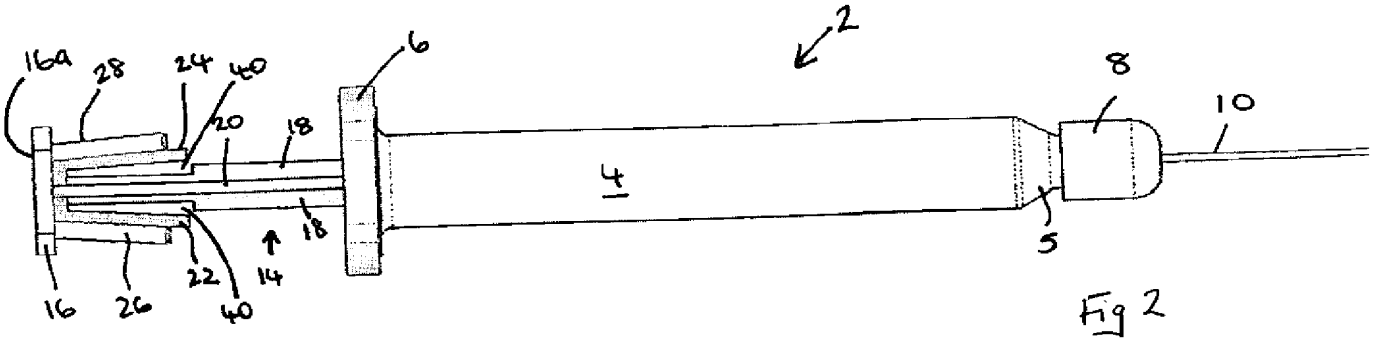


Fig 2

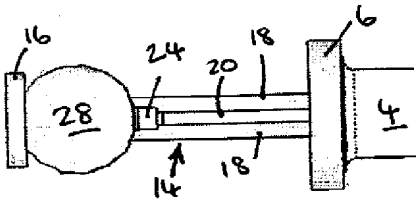


Fig 3

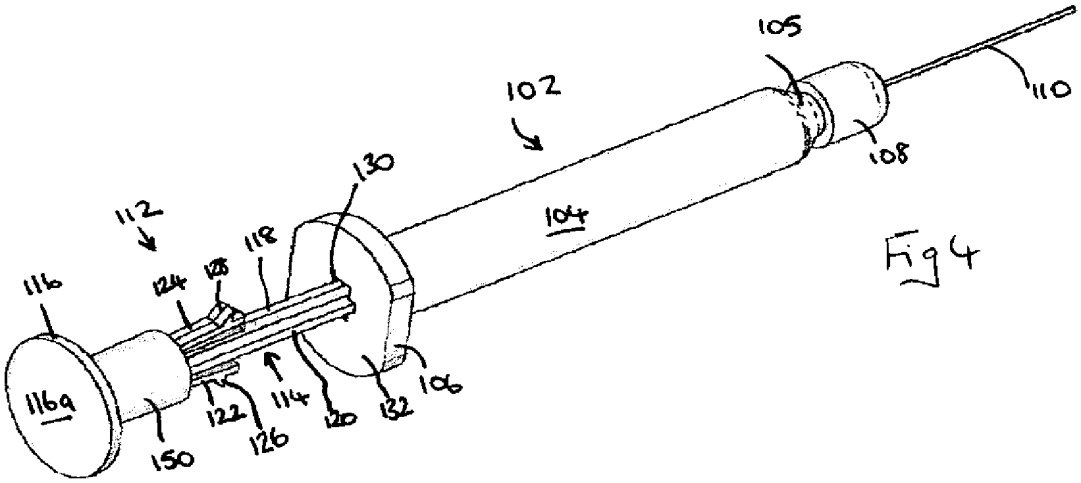

105
102
110
108
130
112
104
118
116
124
128
116a
114
122
120
132
106
126
150

Fig 4

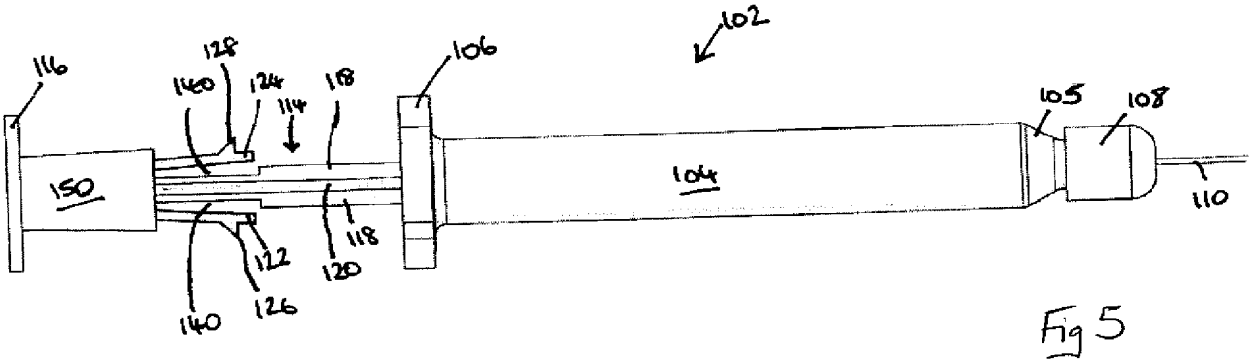

102
116
128
106
160
124
118
114
105
108
150
104
110
122
118
120
140
126

Fig 5

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2010/069597

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61M5/315
ADD.

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61M

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

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 03/004080 A1 (AKZO NOBEL NV [NL]; RIKKEN JOHANNES MATHIAS GERARD [NL]; NICKOLSON VIC) 16 January 2003 (2003-01-16) cited in the application	14
Y	page 4, line 5 - page 6, line 9	1,9,13
A	figures 1, 2A-2D	2-4

A	WO 01/62319 A2 (ABBOTT LAB [US]) 30 August 2001 (2001-08-30) page 12, line 12 - line 16 page 17, line 7 - line 27 figures 1B,1C,7A,7B	1,4-8

	-/--	

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

[X] See patent family annex.

* Special categories of cited documents :

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

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

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

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

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

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

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

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

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
24 May 2011	31/05/2011

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

2

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

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	FR 2 627 087 A1 (PLANCON J [FR]; SEBBIN LABORATOIRES [FR]) 18 August 1989 (1989-08-18) page 3, line 28 - page 4, line 2 page 5, line 9 - line 13 figures 1, 4	1,9
A	EP 0 911 046 A2 (TAKEDA CHEMICAL INDUSTRIES LTD [JP]) 28 April 1999 (1999-04-28) paragraph [0006]; figure 19	2,4
Y	GB 1 230 522 A (TASMAN VACCINE LAB LTD) 5 May 1971 (1971-05-05)	13
A	page 2, line 21 - line 27 figures 1, 4	5,7,8

2

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/EP2010/069597

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 03004080 A1	16-01-2003	NONE	
WO 0162319 A2	30-08-2001	AT 297769 T	15-07-2005
		AU 4158401 A	03-09-2001
		AU 2001241584 B2	14-04-2005
		CA 2400937 A1	30-08-2001
		DE 60111501 D1	21-07-2005
		DE 60111501 T2	18-05-2006
		EP 1257310 A2	20-11-2002
		ES 2243459 T3	01-12-2005
		JP 2004500201 T	08-01-2004
		US 2005004530 A1	06-01-2005
FR 2627087 A1	18-08-1989	NONE	
EP 0911046 A2	28-04-1999	AT 284723 T	15-01-2005
		CA 2246985 A1	16-03-1999
		DE 69828135 D1	20-01-2005
		DE 69828135 T2	03-11-2005
		JP 3968445 B2	29-08-2007
		JP 11076405 A	23-03-1999
		US 6371941 B1	16-04-2002
GB 1230522 A	05-05-1971	AU 455834 A	
		FR 2024089 A5	21-08-1970
		NL 6908371 A	04-12-1970

Patent Translate
Powered by EPO and Google

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.

DESCRIPTION JPH07323090A

[0001]

13 INDUSTRIAL APPLICABILITY The present invention relates to a medical tube suitably used for manufacturing a catheter such as a catheter for vasodilation and a catheter for endovascular treatment diagnosis.

[0002]

19 BACKGROUND ART The catheter has been an instrument used for draining and injecting body fluids and drugs from body cavities or tubular organs.

21 In recent years, catheters have become more sophisticated, and for example, angioplasty catheters used for percutaneous transluminal angioplasty (PTA) that dilates narrowed parts of blood vessels, urinary conduction and bladder temperature measurement. A urine-guided balloon catheter with a temperature sensor that can be performed at the same time, a thermodilution catheter that is placed inside the heart and used to measure heart rate output, and a drug used in intraarterial infusion therapy, etc., is injected into the target site for treatment. Catheter for drug injection treatment, catheter for angioplasty for injecting contrast agent for angioplasty, cyanoacrylate, ethylene-vinyl alcohol copolymer for aneurysms and arteriovenous malformations found in cerebral blood vessels, etc. Applications include liquid embolization substances such as dimethylsulfoxide solutions, granular embolization substances such as polyvinyl alcohol resin granules, and embolization catheters used for embolization in which an embolization member such as a coil is injected. Various applications other than the above have been attempted for these catheters.

[0003]

37 Until now, heart and brain surgery required large-scale surgery that required thoracotomy,

craniotomy, etc., and the key to success or failure of surgery was whether or not the postoperative recovery was good rather than the surgery itself. ..

40 The above-mentioned procedure using a catheter enables diagnosis and treatment with low physical aggression without incising the human body such as thoracotomy, laparotomy, and craniotomy. In addition, since it does not require major surgery, for example, the patient's intraoperative and postoperative pain is reduced, postoperative early recovery / early rehabilitation, less physical damage, less mental burden, and financial burden. It has advantages such as mitigation. In the future, diagnosis and treatment methods using catheters are expected to develop further.

[0004]

50 The medical tube, which is the main body of the high-performance catheter as described above, is required to have high flexibility and a wall thickness as thin as possible.

52 That is, it is desired that the outer diameter of the tube is as small as possible and the inner hole through which the fluid flows is made as large as possible in order to improve the insertability into the body. However, reducing the wall thickness conflicts with making it difficult to easily collapse. Generally, a tube with a thin wall is easy to break (poor kink resistance), easy to crush (weak to external pressure applied from the outside of the tube, that is, insufficient pressure resistance on the outside), and easy to burst (inside the tube). It is known that it is vulnerable to external pressure applied from, that is, its inner pressure resistance is insufficient).

[0005]

63 On the other hand, catheters used by inserting into body cavities or tubular organs are required to have operability so that they can be inserted quickly and reliably even when applied to a vasculature with a thin and complicated pattern. To.

66 In order to have high operability, it is necessary to satisfy the following points. The first is that the pushing force of the operator for inserting into the blood vessel can be reliably transmitted from the proximal end side to the distal end side of the catheter, that is, it has a so-called pushing property. The second is that the rotational force applied on the proximal end side of the catheter can be reliably transmitted to the distal end side, that is, it has so-called torque transmissibility. Third, it is possible to proceed smoothly in a curved blood vessel along a pre-inserted guide wire without damaging the inner wall of the blood vessel, so-called followability (hereinafter, "following to the guide wire" or simply "following"). "). Fourth, as mentioned above, the catheter tip reaches the target location, and even after the guide wire is pulled out, the catheter does not bend at the curved or bent part of the blood vessel, so-called kink resistance. To have.

[0006]

80 From such a demand, a medical tube using a reinforcing material has been proposed.

81 For example, Japanese Patent Application Laid-Open No. 58-38565 and Japanese Patent Application Laid-Open No. 60-126170 disclose a so-called "enhanced type" medical tube having a blade or a coil and a method for manufacturing the same. In these tubes, a reinforcing body is embedded in the resin in order to impart rigidity to the tubes. As a result, these tubes are very hard and have excellent pressure resistance, but thin-walled ones have the disadvantage of being easily broken. Examples of applications of reinforced tubes to catheters include US Pat. No. 4,516,972, International Application WO88 / 06465, Epoxy 3-54592, Epoxy 4-670, and Epoxy 4-44553. There are Japanese Patent Laid-Open No. 4-44554, Japanese Patent Application Laid-Open No. 2-191465, etc., but the main purpose is to give the catheter rigidity. Is manufactured by impregnating with a resin, and has the above-mentioned problems.

[0007]

95 For the purpose of improving the torque transmission, pushability and flexibility of the catheter, a catheter in which a flexible coating is placed on a vine winding spring body or a coil is available in US Pat. No. 4,351,341 and Special Table 3-50189. It is described in Japanese Patent Publication No. 4-792272, Japanese Patent Publication No. 2-172474, International Application No. WO 93/05842, etc., because these are merely a single coil coated with an outer sheath. In addition, although it has excellent kink resistance, it has the disadvantage that the wall surface must be thickened in order to have pressure resistance from the inside.

103 Further, in this tube, since the coil is exposed in the lumen of the catheter, the guide wire is easily caught by the coil. Further, in the catheter for embolization, there is a possibility that a granular embolic substance or an expansion member such as a coil may be caught in the gap of the coil and clogged due to the opening of the gap between the strands, especially when the tube is bent. It requires careful operation.

[0008]

111 Japanese Patent Publication No. 3-29669 has an example in which a torque cable composed of multi-layer coils wound in opposite directions is applied to a catheter, but this also does not have an inner sheath and has the above-mentioned problem. Have.

114 Japanese Patent Application Laid-Open No. 53-21910 and JP-A-5-15585 propose a spirally curved core material in which the inner and outer surfaces are covered with flexible inner and outer pipes by forming gaps. ing. These are structures that only cover the inside and outside of a single spiral tubular coil with a large gap, and although they are excellent in flexibility, they have insufficient inner and outer pressure resistance, torque transmission, and pushability, so they have a large diameter. Although it is sufficient as a guide tube and a flexible tube for a heart-lung machine, it has been virtually impossible to use it as a main body tube of a small-diameter catheter that is used by inserting it into the body cavity or the

central side of a tubular organ.

[0009]

126 INDUSTRIAL APPLICABILITY The present invention has been made in view of the above problems, and satisfies the properties required for a tube constituting a catheter applicable to various body cavities, that is, flexibility and flexibility. It is an object of the present invention to provide an unprecedented medical tube having excellent kink resistance, thin wall thickness, excellent torque transmission and pushability, and excellent inner and outer pressure resistance.

132 Another object of the present invention is to provide a medical tube through which a guide wire can be satisfactorily inserted without being caught on the inner surface of the catheter. Furthermore, it is an object of the present invention to obtain a medical tube particularly suitable for constructing a small-diameter catheter applied in a fine body cavity, such as a catheter for vasodilation and a catheter for cerebrovascular embolization.

[0010]

140 SOLUTION: Such an object is solved by the present invention of the following (1) to (13).

141 (1) A medical tube having a flexible tubular body having an open tip and a proximal end and a reinforcing body arranged inside the tubular body, the reinforcing body having at least a part thereof. , A coil layer composed of a first coil and a second coil provided substantially coaxially with the first coil and wound in the direction opposite to the first coil. Is arranged so that the width of the gap between the pitches of the first and second coils can be freely displaced over a predetermined length from the tip end to the base end, and the curvature of the tubular body is formed. A medical tube characterized by being configured to be flexibly curved without being restricted by the tubular body.

[0011]

152 (2) The medical tube according to (1) above, wherein the coil layer is substantially in close contact with the tubular body.

[0012]

157 (3) The medical tube according to (1) or (2) above, wherein the first and second coils are provided in close contact with each other.

[0013]

162 (4) The medical tube according to any one of (1) to (3) above, wherein the first and second coils are each wound in close contact winding.

[0014]

(5) The medical tube according to any one of (1) to (4) above, wherein the first and second coils are flat plate coils.

[0015]

(6) The coil layer further has one or more coils provided substantially coaxially with the first and second coils, and all the coils of the coil layer have a free width of the gap between pitches. The medical tube according to any one of (1) to (5), which is provided so as to be displaced to.

[0016]

(7) The medical tube according to (6), wherein all the coils in the coil layer are configured by winding adjacent coils in opposite directions.

[0017]

(8) A medical tube having a flexible inner layer, a reinforcing layer adhered to the outside of the inner layer, and a flexible outer layer adhered to the outside of the reinforcing layer, wherein the reinforcement is provided. The body, at least in part thereof, is provided substantially coaxially with the first coil and the first coil, wound in the direction opposite to the first coil, and substantially around the first coil. It is composed of a coil layer composed of a second coil that is not fixed, and the coil layer extends from the tip thereof toward the proximal end for a predetermined length, and is a gap between the pitches of the first and second coils. Almost all of the widths of the inner layer are arranged so as to be freely displaceable, and are configured to be flexibly curved with the curvature of the inner layer and the outer layer without being restricted by the inner layer and the outer layer. A medical tube featuring.

[0018]

(9) The above-mentioned (1) to (8), wherein the vicinity of the tip of the medical tube is made of a flexible material and has the most flexible tip portion on which the coil layer is not arranged. Medical tube.

[0019]

(10) A catheter for cerebrovascular embolization, comprising a tube body inserted into a body cavity, wherein the tube body is composed of the medical tube according to any one of

(1) to (9) above.

[0020]

210 (11) It has a tube body inserted into a body cavity, at least one lumen formed in the tube body, and an extension body provided at the tip of the tube body and having an internal space communicating with the lumen. A catheter for vasodilation, wherein the tube body is composed of the medical tube according to any one of (1) to (9).

[0021]

217 (12) An inner tube having a first lumen with an open tip, and an inner tube provided coaxially with the inner tube and having a tip at a position recessed by a predetermined length from the tip of the inner tube, and an outer surface of the inner tube. It has an outer tube forming a second lumen between them, a tip portion and a proximal end portion, the proximal end portion is attached to the outer tube, the distal end portion is attached to the inner tube, and the proximal end portion is attached. A contractionable or foldable extension that communicates with the second lumen in the vicinity, a first opening that communicates with the first lumen provided at the base end of the inner tube, and the outer tube. A balloon catheter having a second opening that communicates with the second lumen provided at the proximal end, wherein at least one of the inner tube and the outer tube is any of the above (1) to (9). A vasodilator catheter characterized by being composed of the medical tubing described in the above.

[0022]

232 (13) It is composed of the catheter for cerebrovascular embolization described in (10) above, a guide wire composed of a metal elastic core material, a plastic coating material coated on the surface thereof, and a hydrophilic lubricating layer fixed to the surface of the coating material. Catheter device.

[0023]

239 (14) It is composed of the catheter for vasodilation according to the above (11) or (12), a metal elastic core material, a plastic coating material coated on the surface thereof, and a hydrophilic lubricating layer fixed to the surface of the coating material. A catheter instrument consisting of a guide wire that can be inserted into a tube.

[0024]

246 In the medical tube of the present invention, at least a part of the reinforcing body is composed of the coil layer described above, and due to the configuration, at least the tip

portion is flexible, can be freely bent in all directions, and has kink resistance. ..

249 The coil body or the vine winding body having a spring property is rich in flexibility because the gap between the pitches can be freely widened and narrowed (freely displaceable).

251 It is preferable that the flexible tubular body or the flexible inner and outer layers are in close contact with the coil layer, but the coil layer may be adhered to the tubular body or the inner layer and the outer layer, or the gap may be formed. Embedding so as to be buried impairs the flexibility of the coil layer.

255 Therefore, it is preferable that the coil layer does not substantially adhere and is not embedded over a predetermined length from the tip end to the base end.

[0025]

260 The medical tube of the present invention has a structure in which the coil layer is arranged inside a flexible tubular body, that is, a structure in which the coil layer is arranged between the flexible inner layer and the outer layer, so that the wall of the tube is formed. It can be made thin and has high pressure resistance.

264 It is not possible to flow a liquid or the like only with a coil layer having a gap between winding pitches, but by providing a tubular body or an inner layer and an outer layer that cover the inside and outside of the coil layer, a fluid, a guide wire, or the above-mentioned embolic substance can be provided. Etc. to facilitate passage.

268 The pressure resistance of these tubular bodies or the inner and outer layers to the pressure applied from the opposite side to the coil is improved because they are supported from the back side by the coil.

271 This pressure resistance increases as the gap between pitches becomes smaller, that is, the coil winding becomes denser, and it does not depend on the wall thickness or material of the tubular body or the inner layer and the outer layer.

274 Therefore, even if the entire medical tube is thinned, the pressure resistance is not affected.

[0026]

278 Hereinafter, the configuration of the present invention will be described in detail with reference to the drawings.

280 1 is a plan view showing a configuration example of the medical tube of the present invention, FIG. 2 is a partially broken enlarged perspective view of the vicinity of the tip of the medical tube shown in FIG. 1, and FIG. 3 is a medical tube shown in FIG. A partially enlarged cross-sectional view showing the configuration of the tube, FIG. 4 is an enlarged cross-sectional view taken along the line I-I of FIG.

285 Hereinafter, the right side in FIGS. 1 to 3 is referred to as a "tip" and the left side is referred to as a "base end".

[0027]

290 The medical tube 1 shown in FIG. 1 is composed of a flexible tubular body 2.

291 The tubular body 2 is composed of a base portion 11 or a main body portion 11 and a tip portion 12 in order from the base end, and a lumen 14 is formed inside from the base end to the tip end.

294 In the illustrated example, the tip end side of the base portion 11 is formed with a tapered portion 13 whose inner diameter and outer diameter gradually decrease in a tapered shape from the base end side toward the tip end, whereby the tip end portion 12 is larger than the base portion 11. It has a small diameter.

298 In this way, by making the diameter of the medical tube 1 smaller at the tip portion 12 than at the base portion 11, the tip end side can be made relatively flexible and the base end side can be made relatively hard, and the pushability and the guide wire can be obtained. Followability can be improved.

302 Further, by making the inner diameter of the base portion 11 wider than that of the tip portion 12, the guide wire inserted in the tube 1 becomes easy to move smoothly, and the operability of the guide wire is improved.

305 In the present invention, the inner diameter and the outer diameter of the medical tube 1 are not limited to the above configurations, and may be substantially constant over the entire length of the tube 1, for example.

[0028]

311 As shown in FIG. 2, the tubular body 2 is composed of an inner layer 21 and an outer layer 22.

313 The inner layer 21 and the outer layer 22 are made of a thin-walled tube made of a flexible synthetic resin, are arranged substantially coaxially, extend from the base end to the tip end of the medical tube 1, and extend from the tip end and the base end. They are joined over a predetermined length by, for example, bonding or fusion.

317 Then, the space inside the inner layer 21 forms the lumen 14.

318 Further, the inner layer 21 and the outer layer 22 form the tapered portion 13 by gradually reducing the inner diameter and the outer diameter from the base end to the tip end in a predetermined length between the tip end and the base end. ..

321 Further, on the tip side of the tapered portion, the inner layer 21 and the outer layer 22 have substantially constant inner and outer diameters, respectively, and constitute the tip portion 12. Further, even on the proximal end side of this portion, the inner layer 21 and the outer layer 22 have substantially constant inner and outer diameters, respectively, and the tapered portion is also included to form the base portion 11.

[0029]

329 The constituent material of the tubular body 2, in other words, the constituent materials of the inner layer 21 and the outer layer 22 may be any material having a certain degree of flexibility, for example, polyethylene, polypropylene, polybutene, polymethylpentene,

polybutadiene, polyisoprene, and the like. Elastomers such as propylene-butene copolymers and ethylene-propylene copolymers, modified polyethylenes, modified polyolefins such as modified polypropylenes, fluororesins such as soft polyvinyl chloride and polytetrafluoroethylene, ethylene-vinyl acetate copolymers, polyesters. , Polyamite, polyacetal, polyurethane and other flexible resins, olefin-based elastomers, urethane-based elastomers, ester-based elastomers, polyvinyl chloride-based elastomers, polyamide-based elastomers, styrene-based elastomers and other elastomers, silicone rubber, Examples thereof include elastomers such as latex rubbers and natural rubbers, and blends of these materials.

341 Further, the resin and the elastomer are preferably thermoplastic, and if it is thermoplastic, the medical tube 1 can be easily manufactured.

[0030]

346 The inner layer 21 and the outer layer 22 do not necessarily have to be made of the same material, and further, an X-ray impermeable substance, a plasticizer, a pigment, or the like may be mixed with these materials.

349 In particular, as the constituent material of the inner layer 21, polyethylene, polypropylene, and fluororesin are particularly preferable from the viewpoints of ease of molding, ease of insertion into the coil layer 4, which will be described later, and chemical resistance.

[0031]

355 Further, since the outer layer 22 can easily coat the coil layer 4 described later, it is preferable to form the outer layer 22 with a solvent-swellable resin tube or a heat-shrinkable resin tube.

358 Examples of the solvent-swellable resin include the modified polyolefin, ethylene-vinyl acetate copolymer, polyamide elastomer, polyester elastomer, polyurethane and the like. In particular, from the viewpoint of adhesion and fusion with the inner layer 21, modified polyolefin is preferable, and among the modified polyolefin, modified polyethylene containing polyethylene as a main component is preferable. As the modified polyethylene, an adhesive resin made of ethylene and a copolymer made of, for example, acrylate, maleic anhydride, or the like as a raw material has a particularly preferable property. The tube made of this resin quickly swells with a solvent such as THF, the inner and outer diameters of the tube expands, and the outer layer 22 is surely restored to its original shape by removing the solvent by air drying or the like. If it is configured, it can be easily and surely coated and adhered to the coil layer 3 described later. Further, as the heat-shrinkable resin, a resin tube such as an electron beam-crosslinked polyolefin, crosslinked silicon, or a shape memory resin can be preferably used. Since these tubes can be contracted by heat, by forming the outer layer 22 with these tubes, the coil layer 3 described later can be easily inserted and adhered.

[0032]

375 As shown in FIGS. 2 to 4, a coil layer 3 having a role as a reinforcing body for reinforcing the strength of the medical tube 1 is arranged inside the tubular body 2, that is, between the inner layer 21 and the outer layer 22. Has been done.

378 In other words, the coil layer 3 which has a role as a reinforcing body for reinforcing the strength of the medical tube 1 is adhered to the outside of the inner layer 21, and the outer layer 22 is adhered to the outside of the coil layer 3. ing. The coil layer 3 shown in FIG. 2 is provided substantially coaxially with the first coil 31 wound on the outer peripheral surface of the inner layer 21 and the first coil 31, and is in close contact with the first coil 31. It is composed of a coil 31 of 1 and a second coil 32 that is wound in the opposite direction. The coil layer 3 has a long tube-like shape, and its outer peripheral surface and inner peripheral surface are arranged in the tube 1 in a state of being in contact with the tubular body 2, in other words, the inner layer 21 and the outer layer 22.

[0033]

390 A cutting-edge portion 16 in which the coil layer 3 is not arranged is formed near the tip of the tube 1.

392 The coil layer 3 extends in the proximal direction from a position slightly retracted from the tips of the tubular body 2, that is, the inner layer 21 and the outer layer 22, and the tip side of the coil layer 3 is the most composed of the inner layer 21 and the outer layer 22. It is a tip portion 16. Since the coil layer 3 is not arranged, the cutting edge portion 16 is more flexible than the portion on the proximal end side of the cutting edge portion 16. Therefore, when the tube 1 is inserted into a blood vessel, the irritation given to the blood vessel can be reduced. Further, since the coil layer 3 does not protrude from the tubular body 2, that is, the tips of the inner layer 21 and the outer layer 22, there is no possibility that the protruding portion will damage the body cavity or the tubular organ when inserted into the body cavity or the tubular organ. preferable. The length of the cutting edge portion 16, that is, the distance from the tip of the coil layer 3 to the tips of the tubular body 2 or the inner layer 21 and the outer layer 22 is preferably about 10 mm or less, more preferably 0.5 to 5 mm. Degree.

[0034]

408 The position of the coil layer 3 in the medical tube 1 is not particularly limited, but it is preferable that the coil layer 3 extends from the base end of the medical tube 1 to the vicinity of the tip end of the tube 1.

411 By arranging the coil layer 3 over the entire length of the tube 1 in this way, the torque and the pushing force applied to the base 11 can be satisfactorily transmitted to the vicinity of the tip of the tube 1 via the coil layer 3. In the illustrated example, in the vicinity of the base end of the tube 1, the coil layer 3 has a base end at a position slightly separated from the base ends of the tubular body 2, that is, the inner layer 21 and the outer layer 22, and the

medical tube 1 has a base end. The structure is such that the coil layer 3 is provided over almost the entire length.

[0035]

421 Then, in the medical tube 1, even if a pressure higher than that of the inner layer 21, that is, the lumen 14, is applied to the inner layer 21, the inner layer 21 is supported from the opposite side by the first coil 31, and is related to the thickness of the inner layer 21. However, it exhibits higher pressure resistance than the case of the inner layer 21 alone.

425 Further, even if a higher pressure is applied to the outer layer 22 than the outside of the outer layer 22, the outer layer 22 is supported from the opposite side by the second coil 32, and the outer layer 22 is supported from the opposite side regardless of the thickness of the outer layer 22 as compared with the case of the outer layer 22 alone. Demonstrates high pressure resistance. Therefore, the medical tube 1 has excellent pressure resistance inside and outside, and even if a pressure higher than the inside or the outside of the tube 1 is applied to the tube 1, the tube 1 is unlikely to be crushed or burst.

[0036]

435 In order to exert such an action satisfactorily, it is preferable that the coil layer 3 is in close contact with the tubular body 2 or the inner layer 21 and the outer layer 22.

437 In other words, the first coil 31 is preferably in close contact with the tubular body 2 or the inner layer 21, and the second coil 32 is preferably in close contact with the tubular body 2 or the outer layer 22. The first coil layer 31 and the second coil layer 32 may be in close contact with the inner layer 21 or the outer layer 22 over the entire length thereof, but at least a part thereof, for example, the tip portion 12 is predetermined. It may be in close contact over the length. Further, by bringing the first coil layer 31 and the second coil layer 32 into close contact with the inner layer 21 or the outer layer 22, the wall thickness of the medical tube 1 can be reduced, so that the diameter of the tube 1 can be reduced satisfactorily. be able to. Further, due to the close contact, the torque and the pushing force at the base 11 of the medical tube 1 can be reliably transmitted to the vicinity of the tip of the tube 1.

[0037]

451 In the illustrated example, the first coil 31 and the second coil 32 have an inner diameter and an outer diameter gradually decreasing from the proximal end to the distal end over a predetermined length between the tip and the proximal end, and the tapered portion. It constitutes 13.

455 Further, on the tip side of the tapered portion, the inner and outer diameters of the coils 31 and 32 are substantially constant, respectively, and constitute the tip portion 12. Further, even on the proximal end side of this portion, the inner diameter and the outer diameter of

the coils 31 and 32 are substantially constant, respectively, and the base portion 11 includes the tapered portion.

[0038]

463 As shown in FIG. 3, the first coil 31 is a medical tube in which a bundle 31A in which five flat wire wires 31a, 31b, 31c, 31d to 31e having a rectangular cross-sectional shape are bundled together. It is configured by winding right-handed toward the tip of 1.

466 Further, the second coil 32 is a bundle 32A in which five flat wire wires 32a, 32b, 32c, 32d to 32e having a rectangular cross-sectional shape as described above are bundled into a medical tube 1 The coil is wound in the direction opposite to that of the first coil 31, that is, left-handed, toward the tip of the coil.

[0039]

473 For these strands 31a to e and strands 32a to e, it is preferable that the width x of the gap between the strands in the bundles 31A and 32A described above is close to zero, respectively.

476 The closer the width x is to zero, the more the strands 31a to e or the strands 32a to e are in close contact with each other, which is advantageous for supporting the inner layer 21 and the outer layer 22. In other words, the larger the width x, the higher the possibility that the inner layer 21 and the outer layer 22 will fall into the gap between the strands 31a to e and the strands 32a to e, resulting in minute tearing.

[0040]

484 Further, in the first coil 31 and the second coil 32, the width of the gap between the pitches (in the illustrated example, the width of the gap between the pitches of the bundles 31A and 32A) y is the strands 31a to e and, respectively. It is preferably smaller than the width z of the strands 32a to e, more preferably about 30% or less of the width z, and more preferably closer to zero, that is, the coils 31 and 32 are tightly wound. ..

489 By doing so, it is possible to prevent the wires 31a to e of the coil 31 from jumping out of the gap of the coil 32, and it is possible to prevent the wires 32a to e of the coil 32 from falling into the gap of the coil 31. The thickness t of the first coil 31 and the second coil 32 is preferably about 0.005 to 0.1 mm, more preferably about 0.005 to 0.05 mm, respectively.

[0041]

496 The cross-sectional shapes of the first coil 31 and the second coil 32 are not limited to the rectangle shown in the figure, and may be, for example, a circle, an ellipse, a triangle, a square, a parallelogram, a polygon of a pentagon or more, and the like. May be good.

499 However, it is preferable that the coils 31 and 32 are flat plate coils in which the strands 31a

to 31a to 32a to e form a flat plate. By using a flat plate coil, the thickness of the coil layer 3 can be effectively reduced, and the coils 31 and 32 can be easily wound in close contact with each other. Further, it is preferable that the first coil 31 and the second coil 32 are in close contact with each other. By bringing the medical tube 1 into close contact, the wall thickness of the medical tube 1 can be reduced, so that the diameter of the tube can be reduced, and the torque and pushing force applied to the base 11 of the medical tube 1 are applied to the tube via the coils 31 and 32. It is possible to reliably convey to the vicinity of the tip of 1.

[0042]

510 Then, the coil layer 3 has a predetermined length from its tip toward the proximal end (in other words, in the distal end side portion of the coil layer 3) between the pitches of the first coil 31 and the second coil 32. Almost all of the width y of the gap is arranged so as to be freely displaceable, and is configured to be able to flexibly bend without being restricted by the tubular body 2 (inner layer 21 and outer layer 22).

515 As a result, the coil layer 3 can freely widen or narrow the width y of almost the entire gap between the pitches, and can be bent very flexibly without hindering the bending of the tubular body 2.

[0043]

521 Specifically, the first coil 31 is embedded so as to extend at least a predetermined length from its tip toward the proximal end, not to be fixed to the inner layer 21, and to fill almost all the gaps between the pitches. It has not been.

524 Almost all of the gaps between the pitches are voids because the material such as resin and the adhesive constituting the inner layer 21 do not substantially flow into the gaps. Similarly, the second coil 32 is also embedded so that it is not fixed to the outer layer 22 and fills almost all the gaps between the pitches, at least for a predetermined length from the tip end toward the base end. No material such as resin or an adhesive constituting the outer layer 22 has substantially flowed into almost all of the gaps between the pitches, resulting in voids. In the first and second coils 31 and 32 configured in this way, almost the entire width y of the gap between the pitches can be freely widened or narrowed due to the curvature of the inner layer 21 and the outer layer 22, which is extremely high. Can be flexibly curved.

[0044]

536 In the present invention, "the width of the gap between the pitches of the coil can be freely displaced" means that the width y of the gap between the pitches freely widens and narrows without substantially impairing the original flexibility of the coil. It is possible (displaceable).

[0045]

542 In the coil layer 3, it is preferable that the entire gap between pitches can be freely displaced in the tip side portion, but if the flexible curvature of this portion is not substantially hindered, the coil layer 3 may be part of the coil layer 3. For example, an adhesive, a resin material, or the like may flow into the gap to form a region that cannot be freely displaced.

546 Such a region has a length sufficiently shorter than the total length of the distal end side portion of the coil layer 3 (for example, 10% or less of the total length of the distal end side portion).

549 It should be noted that this region may be dispersedly provided at two or more locations on the tip end side portion of the coil layer 3, but it is preferably provided at one location, and in the case of two or more locations, the regions are as close as possible. Is preferable.

[0046]

555 Further, as shown in the figure, when the coil layer 3 is provided up to the vicinity of the base end of the tubular body 2, the adhesive is impregnated over a certain length on the base side of the coil layer 3 in order to improve the pushability of the catheter. , May be hard.

558 In this case, if the entire coil layer 3 is impregnated with the adhesive, the flexibility of the coil layer 3 is lost. Therefore, it is decided to impregnate only the base side of the medical tube 1, specifically, the medical tube 1. From the base end, it is preferable to impregnate the total length of the medical tube 1 over a length of about 5 to 50%, more preferably about 10 to 40%, still more preferably about 20 to 30%.

[0047]

566 The medical tube 1 configured in this way is highly flexible and has appropriate rigidity.

567 Further, a lubricant such as silicone oil may be applied between the coil layer 3 and the inner layer 21 and the outer layer 22 in order to improve the sliding of the coil layer 3. By doing so, the coil layer 3 can be bent more flexibly without being caught by the inner layer 21 and the outer layer 22.

[0048]

574 Examples of the constituent materials of the strands 31a to e and the strands 32a to e constituting the first coil 31 and the second coil 32 include metal materials such as stainless steel, tungsten, aluminum, Ni—Ti alloy, and brass. Highly rigid resins such as polytetrafluoroethylene (Teflon), polyvinyl chloride, polyamide, polyethylene terephthalate, polysulfone, polycarbonate, polyarylate, polyacetal, polyphenylene sulfide, polyetherketone, polyetheretherketone, polyimide, polyamideimide, etc. Materials, PAN-based, pitch-based, naphthalene-based, carbon fibers and carbon fibers such as their prepregs, ceramics, etc. can be used, but materials with high safety for medical use are preferable, and in particular, shaping and quenching is possible. Stainless steel such as SUS304 is preferable.

[0049]

586 From such a constituent material, the strands 31a to 32a to 32a to e are formed by appropriately selecting dimensions such as wall thickness and width, and these are wound at a predetermined pitch to form the coil shown in FIG. 2. Layer 3 is obtained.

589 In the production of the coil layer 3, for example, the strands 31a to e are spirally wound (in the illustrated example, in the right-handed direction toward the tip) along the rod-shaped core material, and then the strands 32a to e are wound. Is wound in the direction opposite to the strands 31a to e (in the illustrated example, in the left-handed direction toward the tip), and then the core material is removed.

[0050]

597 The dimensions of the medical tube 1 vary depending on the application, but the length is 200 to 2000 mm, preferably 1000 to 2000 mm, and the outer diameter is 0.35 to 4.3 mm, preferably 0.40 to 2.00 mm. The inner diameter is 0.25 to 4.00 mm, preferably 0.30 to 1.80 mm.

601 Further, the thickness (thickness) of the tube wall of the medical tube 1 is preferably thin, but when the wall thickness of the tube 1 is T and the inner diameter of the tube 1 is S, this wall thickness T is the inner diameter S. The value divided by (thickness inner diameter ratio) is preferably in the range of T / S = 0.05 to 0.50, and more preferably 0.07 to 0.326.

605 When this value is less than 0.05, the wall thickness T becomes too thin with respect to the inner diameter S, and the strength of the medical tube 1 is significantly reduced. On the other hand, if it exceeds 0.50, the wall thickness T and the outer diameter of the tube accompanying it increase too much, which is not preferable.

[0051]

612 In the illustrated example, the first coil 31 is right-handed and the second coil 32 is left-handed, each of which is configured as a set of five strands, but in the present invention, the coils 31 and 32 are right-handed. The order of left-handed winding and the number of strands to be bundled are free, and the above-mentioned width x and width y may differ depending on the part of the medical tube 1.

617 For example, by increasing the width x or the width y toward the tip, in other words, reducing the width x or the width y toward the base end, the closer the coils 31 and 32 are to the tip, the more flexible the bending becomes. Moreover, the closer it is to the base end, the more difficult it is to bend, and it is possible to obtain a medical tube having good flexibility near the tip end and excellent torque transmission and pushability. Further, the width z of the first coil 31 and the second coil 32 may be constant over the entire length of the medical tube 1 or may differ depending on the site. For example, by making the width z smaller toward the tip, in other words, increasing the width z toward the base end, the closer the coils 31 and 32 are to the tip, the easier it is to bend, and the closer it is to the base end, the more difficult it

is to bend. It is possible to obtain a medical tube having good flexibility near the tip and excellent torque transmission and pushing property.

[0052]

631 FIG. 5 is a partially broken enlarged perspective view showing the vicinity of the tip portion of another configuration example of the medical tube of the present invention.

633 The same configurations as those shown in FIGS. 1 to 4 are designated by the same reference numerals and the description thereof will be omitted.

[0053]

638 The medical tube 10 shown in FIG. 5 has almost the same configuration as the medical tube 1, but has a tip soft tip 15 made of a highly flexible material, and the tip 15 and the coil layer 3 are formed. It differs in that the tip 160 is configured from the portion near the tip of the unarranged tubular body 2 (inner layer 21 and outer layer 22).

642 The tip 15 is formed in a short tubular shape, and is bonded to the tubular body 2, in other words, the tips of the inner layer 21 and the outer layer 22 by adhesion or the like so that the lumen thereof communicates with the lumen 14. With this configuration, the cutting-edge portion 160 of the medical tube 10 has higher flexibility than the portion in which the coil layer 3 is arranged, so that a stimulus given to the blood vessel or the like when inserted into the blood vessel or the like is given. Can be reduced.

[0054]

651 As the constituent material of the advanced soft chip 15, it suffices to have flexibility, and for example, polyurethane, vinyl chloride-urethane copolymer, silicone RTV rubber and the like can be used.

654 The length of the chip 15 is 0.5 to 30 mm, preferably about 2 to 15 mm.

[0055]

658 Although the configuration example in which the coil layers form a two-layer structure has been described above, in the present invention, the coil layer may have a structure of three or more layers in which three or more coils are arranged substantially coaxially.

661 In this case, it is preferable that the adjacent coils are wound in opposite directions in each coil. Further, the coil layers in the present invention do not have to have the same number of layers over the entire length thereof. It may be provided in some places.

[0056]

667 Further, in the illustrated example, the coil layer 3 is arranged over almost the entire area of

the medical tube 1 and is formed so as to reinforce the medical tube 1 over almost the entire area. However, in the medical tube of the present invention, a part thereof. In the above, a reinforcing body other than the coil layer, for example, a tube or a tube body made of a member having high rigidity may be arranged, and such a body and the coil layer may be combined to form a reinforcing body.

673 However, by forming the reinforcing body only with the coil layer and forming the medical tube with a material having relatively high flexibility (flexibility) except for this coil layer, appropriate flexibility and rigidity (hardness) are obtained. With), good kink resistance, excellent torque transmission and push-in performance, and by using a guide wire, it can be inserted into the body cavity well following this guide wire, and it also has excellent pressure resistance. You can get a medical tube.

[0057]

682 Further, in the present invention, the coil layer is not limited to the one arranged over the entire length of the medical tube, for example, a configuration in which the coil layer 3 is not arranged in the middle of the medical tube 1 or the tip portion of the tube 1. The coil layer 3 may be arranged only on the twelve.

686 However, if the coil layer is arranged over almost the entire length of the medical tube, the torque and pushing force applied at the base 11 can be satisfactorily transmitted to the vicinity of the tip of the medical tube via the coil layer.

[0058]

692 Further, in the present invention, it is preferable that the outer surface of the tubular body 2 or the outer layer 22 is covered with a hydrophilic (or water-soluble) polymer substance (not shown).

695 As a result, when the outer surface of the tubular body 2 or the outer layer 22 comes into contact with blood, physiological saline, or the like, the coefficient of friction is reduced to impart lubricity, and the slidability of the medical tube 1 is further improved. As a result, pushability, followability, and kink resistance are further improved. Further, when the inner surface of the inner layer 21 is also lubricated with the hydrophilic polymer substance, silicone oil, oil or fat, etc., the guide wire inserted in the tube 1 becomes easy to move in the tube 1, and the guide wire can be operated. Sex improves.

[0059]

705 Examples of the hydrophilic polymer substance include the following natural or synthetic polymer substances or derivatives thereof.

707 <Natural polymer substance> 1) Starch-based examples: carboxymethyl starch, dialdehyde starch 2) Cellulose-based examples: CMC (carboxymethyl cellulose), MC (methyl cellulose), HEC (hydroxyethyl cellulose), HPC (hydroxypropyl cellulose) 3) Tannin, starch-based

examples: tannin, nignin Examples: alginic acid, gum arabic, guar gum, tragant gum, tamarint species 5) Protein examples: gelatin, casein, glue, collagen

[0060]

715 <Synthetic water-soluble polymer> Example: Polyvinyl alcohol 2) Polyethylene oxide-based Example: Polyethylene oxide, Polyethylene glycol 3) Acrylic acid-based Example: Polyacrylic acid sodium 4) Anhydrous maleic acid-based Example: Methyl vinyl ether Anhydrous maleic acid copolymer 5) phthalic acid-based example: polyhydroxyethyl phthalic acid ester 6) water-soluble polyester example: polydimethyllol propionic acid ester 7) ketone aldehyde resin example: methylisopropylketoneformaldehyde resin 8) acrylamide-based example: polyacrylamide, polydimethylacrylamide 9) Polyvinylpyrrolidone-based 10) Polyamine-based Example: Polyethyleneimine 11) Polyelectron Example: Polystyrenesulfonate Example: Water-soluble nylon, P (GMA-DMAA) block copolymer (poly (glycidyl methacrylate-dimethylacrylamide) block copolymer)

[0061]

728 Among these, in particular, a cellulose-based polymer substance (for example, hydroxypropyl cellulose), a polyethylene oxide-based polymer substance (polyethylene glycol), and a maleic anhydride-based polymer substance (for example, a methylvinyl ether anhydrous maleic acid copolymer). Such as maleic anhydride copolymers), acrylamide-based polymer substances (eg, polyacrylamide), water-soluble nylons (eg, AQ-nylon P-70 manufactured by Toray Co., Ltd.), polyglycidyl methacrylate-dimethylacrylamide copolymers. , It is preferable because a low friction coefficient can be stably obtained.

735 Among them, in particular, the polyglycidyl methacrylate-dimethylacrylamide copolymer, which is a block copolymer composed of a hydrophilic compound block and a hydrophobic compound block, is lubricated because the hydrophilic compound (polydimethylacrylamide) is a water-swellable compound. Since it has excellent properties and has a hydrophilic / hydrophobic microdomain structure, antithrombotic properties can also be expected.

[0062]

743 Further, the derivative of the polymer substance is not limited to a water-soluble substance, and as long as the water-soluble polymer substance has the basic composition, there is no particular limitation, and even an insolubilized polymer substance can be used as a molecular chain. It suffices as long as it has a degree of freedom and contains water.

747 For example, esterified products, salts, amidated products, anhydrides, halides, etherified products, hydrolysates, acetal products, formal products, and alkylols obtained by condensation, addition, substitution, oxidation, reduction reaction, etc. of the above polymer substances. Diazonium group, azide group, isocyanate group, acid chloride group, acid anhydride group, iminocarbonate ester group, amino group, carboxyl group, Cross-linked

products with substances having two or more epoxy groups, hydroxyl groups, aldehyde groups, reactive functional groups; copolymers with vinyl compounds, acrylic acids, methacrylic acid, diene compounds, maleic anhydride and the like can be mentioned.

[0063]

758 In order to fix the coating layer of such a hydrophilic polymer substance to the outer surface of the tubular body 2 or the outer layer 22, it is preferable to covalently bond with the reactive functional group present or introduced on the surface. ..

761 This makes it possible to obtain a long-lasting lubricious surface.

762 The reactive functional group existing or introduced in or on the surface of the tubular body 2 or the outer layer 22 may be any group as long as it reacts with the polymer substance and is bonded or crosslinked to fix it. , Azido group, isocyanate group, acid chloride group, acid anhydride group, iminocarbonate ester group, amino group, carboxyl group, epoxy group, hydroxyl group, aldehyde group and the like, and in particular, isocyanate group, amino group, epoxy group and aldehyde. Groups are suitable.

[0064]

771 The average molecular weight of the hydrophilic polymer substance is not particularly limited, but is preferably about 3 to 5 million.

773 As a result, a lubricating layer having high lubricity, an appropriate thickness, and an appropriate degree of swelling when water is contained can be obtained. The thickness of the lubricating layer made of such a hydrophilic polymer is not particularly limited, but is preferably about 0.1 to 100 μm, particularly preferably about 1 to 30 μm. The composition and coating method of the hydrophilic polymer substance are described in, for example, JP-A-53-106778, US Pat. No. 4,300,309, JP-A-60-259269, and Japanese Patent Application Laid-Open No. 1-33181. You can apply something like that.

[0065]

783 Further, in the present invention, it is preferable to apply a treatment for imparting higher biocompatibility to the outer surface of the tubular body 2 or the outer layer 22.

785 As biocompatibility, antithrombotic property is required, and various known methods can be mentioned for imparting antithrombotic property. However, it is preferable to fix heparin on the outer surface by coating with a heparin solution or heparin bonding. Further, if a thrombolytic agent is mixed with the constituent material of the tubular body 2 or the outer layer 22 and extruded to form a tube, the thrombolytic agent is gradually released when inserted into a blood vessel and used, which is preferable. ..

[0066]

794 FIG. 6 is a plan view showing a configuration example of the catheter for cerebrovascular embolization of the present invention.

796 Hereinafter, the catheter for cerebrovascular treatment of the present invention will be described with reference to the drawings. The same components as those of the configuration examples shown in FIGS. 1 to 4 are designated by the same reference numerals and the description thereof will be omitted. The cerebrovascular treatment catheter 4 of the present invention includes the medical tube 1 shown in FIGS. 1 to 4, the reinforcing tube 41 mounted around the outer periphery of the vicinity of the base end of the tube 1, the medical tube 1 and the reinforcing tube. It is composed of a hub 42 mounted near the base end of 41, a tip soft tip 43 joined to the tip of a medical tube 1, and a contrast marker 44.

[0067]

807 The reinforcing tube 41 is, for example, a heat-shrinkable tube 51 having a heat-shrinkable inner diameter slightly smaller than the outer diameter near the base end of the tube 1. It can be easily attached by fitting it in the vicinity of the base end of No. 1 and heating (for example, applying hot air) to shrink it.

811 Further, the hub 42 has a lumen communicating with the lumen 14 of the tube 1 and an opening communicating the lumen 14 with the outside, and has an injection port for a chemical solution, an embolic substance, etc. into the lumen 14 and a guide wire. It functions as an insertion port and also functions as a grip when operating the cerebrovascular treatment catheter 4.

[0068]

819 The tip soft chip 43 is made of a highly flexible material similar to the chip 15 described above.

821 The tip 43 is formed in the shape of a short cylinder, and is fixed and joined to the tip of the tube 1 by adhesion or the like so that the lumen thereof communicates with the lumen 14 of the tube 1. Further, the contrast marker 44 is configured by winding a platinum wire rod around the outer surface of the chip 53 in a coil shape. The marker 44 may be embedded in the tubular body 2, between the inner layer 21 and the outer layer 22, or in the tip soft tip 43. With such a structure, the tip 44 does not protrude to the outer surface of the catheter, so that a step is formed. Is not formed and irritation to blood vessels is reduced. The length of the chip 43 is about 0.5 to 30 mm, preferably about 2 to 15 mm.

[0069]

832 Since the cerebrovascular embolization catheter 4 is composed of the medical tube 1 as a tube body to be inserted into the cerebrovascular vessel, it is flexible and rich in kink resistance.

835 In addition, the pressure resistance on the inside and the pressure resistance on the outside

are also very excellent, it is hard to be crushed even if the wall thickness is thin, and it can be inserted well along the guide wire even in a blood vessel that branches and bends finely and complicatedly. It is difficult to rupture even if a high pressure is applied to the inside of the catheter 4 by pouring a large amount of a highly viscous contrast medium or embolic substance.

[0070]

844 The dimensions of the cerebral vascular embolization catheter 4 are about 1000 to 2000 mm in length, preferably about 1300 to 1700 mm, and the outer diameter is about 0.3 to 3 mm, preferably about 0.4 to 1.0 mm. The inner diameter is about 0.20 to 0.70 mm, preferably about 0.3 to 0.7 mm, and the wall thickness is about 0.04 to 0.15 mm, preferably about 0.06 to 0.1 mm.

[0071]

852 Further, in the cerebrovascular embolization catheter 4, the outer surface of the portion to be inserted into the blood vessel, that is, the outer surface of the tip soft tip 44 and the medical tube 1, is coated with a lubricating polymer substance and biocompatibility treatment is performed. Is preferable.

856 The coating of the lubricating polymer substance and the biocompatibility treatment can be performed in the same manner as described above.

858 The coating of the lubricating polymer substance and the biocompatibility treatment may be performed at the stage of manufacturing the medical tube 1 or after assembling the cerebrovascular embolization catheter 4.

[0072]

864 Further, in the cerebrovascular embolization catheter 4, in a part of the medical tube 1, an adhesive, a resin material or the like may be allowed to flow into the gap between the pitches of the coil layer 3 to regulate the displacement of the gap. ..

867 In particular, when the portion extending from the base end of the tube 1 to the predetermined length is made in this way, the hardness from the base end of the tube 1 to the predetermined length is increased, and the torque transmissibility and the pushing property of the catheter 4 can be further improved. In order to obtain the catheter 4 having such a configuration, for example, the gap may be impregnated with an adhesive or the like at the stage where the coil layer 3 is formed, or after the medical tube 1 is manufactured, the hub 42 is tubed. It is also possible to impregnate the base end of the tube 1 with an adhesive by utilizing the capillary phenomenon before attaching to 1.

[0073]

878 Next, the method and operation of the above-mentioned cerebrovascular embolization catheter 4 will be described.

880 First, a guiding catheter (not shown) having a lumen through which the catheter 4 can be inserted is inserted and indwelled from the femoral artery to the internal carotid artery, the external carotid artery, or the vertebral artery via the aorta. The inner surface of the guiding catheter has a hydrophilic coating. Next, a guide wire composed of a metal elastic core material, a plastic coating material coated on the surface thereof, and a hydrophilic lubricating layer fixed to the surface of the coating material, or a metal elastic core material and the tip of the core material are provided. A catheter 4 in which a guide wire composed of a obtained X-ray contrast-enhanced coil and a fluorine-based coating material coated on the surface of the core material is inserted and set is placed along the lumen of the guiding catheter of the guiding catheter. It protrudes from the tip and is inserted to the target blood vessel together with the above guide wire. When the blood vessel branches on the way, the guide wire is preceded so that it can be selectively inserted into the target blood vessel, and then the catheter is pushed in. If it is difficult to insert along the guide wire, rotate the hand of the catheter and push it in while transmitting the rotation to the tip of the catheter to advance to the target blood vessel. The cerebral aneurysm existing in the target blood vessel is confirmed from the upstream side under fluoroscopy with a contrast medium of a catheter. When the target site is reached, the tip 11 of the catheter 4 is inserted into the cerebral aneurysm, the guide wire is removed, and then an embolic substance such as a liquid, granular, or microcoil is introduced. When the introduction is completed, the guiding catheter and the catheter 4 are removed from the body, hemostasis is performed, and the procedure is completed.

[0074]

904 Since the catheter 4 of the present invention is configured with the medical tube 1 of the present invention as a member, it is highly flexible and kink-resistant, and even a fine and complicated blood vessel of a cerebral aneurysm can be satisfactorily used. It can be inserted and has good followability to the guide wire, and even complicatedly curved and bent blood vessels can easily proceed along the guide wire without kinking.

909 In addition, it has excellent torque transmission and pushability, making it a catheter with good operability, and also has excellent pressure resistance on the inside and outside, so it is hard to collapse even without a guide wire in a fine and complicated blood vessel. There is little risk of bursting even if liquid or granular embolic material is poured.

[0075]

916 The catheter for cerebrovascular embolization of the present invention is not limited to the configuration shown in the figure. A cutting-edge portion that is more flexible than the portion in which the coil layer 3 that serves as a reinforcing body is arranged may be formed.

919 Even in such a configuration, since the cutting edge portion is composed of a flexible inner

layer 21 and an outer layer 22, it is very flexible, and therefore, when it is inserted into a body cavity such as a blood vessel, there is little irritation to the body cavity. It is also possible to prevent damage to the inner wall of the body cavity, and obtain a catheter that can be inserted quickly and with certain selectivity even in a body cavity having a fine and complicated pattern such as a cerebral blood vessel. Further, in this case, the contrast marker may be embedded and arranged between the inner layer 21 and the outer layer 22 at the most advanced portion.

[0076]

930 7 is a plan view showing a configuration example of the vasodilator catheter of the present invention, and FIG. 8 is a vertical cross-sectional view showing the tip of the vasodilator catheter shown in FIG. 7.

933 Hereinafter, the vasodilator catheter of the present invention will be described with reference to the drawings. The same components as those of the configuration examples shown in FIGS. 1 to 4 are designated by the same reference numerals and the description thereof will be omitted. The vasodilator catheter 5 shown in FIGS. 7 and 8 is provided at the tube body 50 inserted into the body cavity, at least one lumen 511 formed in the tube body 50, and the tip of the tube body 50. It has an expansion body 53 having an internal space communicating with the lumen 511, and the tube body 50 is composed of the medical tube 1 shown in FIGS. 1 to 4.

[0077]

944 Specifically, the catheter 5 is a so-called double lumen coaxial type guide wire movable (over the wire type) vasodilator catheter, and the tube body 50 is composed of an inner tube 51 and an outer tube 52. Has been done.

947 An inner pipe 51 having a first lumen 511 having an open tip and an inner pipe 51 provided coaxially with the inner pipe 51 and having a tip at a position retracted by a predetermined length from the tip of the inner pipe 51. It has an outer pipe 52 forming a second lumen 521, a tip portion 531 and a base end portion 532, the base end portion 532 is attached to the outer pipe 52, and the tip portion 531 is an inner pipe 51. A contractionable or foldable expansion body 53 that is attached to and communicates with the second lumen 521 near the proximal end portion 532, and a first that communicates with the first lumen 511 provided at the proximal end portion of the inner tube 51. Has an opening 581 and a second opening 591 communicating with a second lumen 521 provided at the base end of the outer tube 52. At least one of the inner tube 51 and the outer tube 52 is composed of the above-mentioned medical tube of the present invention.

[0078]

961 In the illustrated example, the inner tube 51 is configured using the medical tube 1 shown in

FIGS. 1 to 4, and as shown in FIG. 8, the flexible tubular body 2 and the tubular body 2 It has a coil layer 3 which has a role as a reinforcing body arranged inside.

964 The tubular body 2 is composed of a flexible inner layer 21 and a flexible outer layer 22, in other words, the inner tube 51 is adhered to the flexible inner layer 21 and the outer side of the inner layer 21. It has a structure having a coil layer 3 having a role as a reinforcing layer and a flexible outer layer 22 adhered to the outside of the coil layer 3. The coil layer 3 is composed of a first coil 31 and a second coil that is wound in the direction opposite to that of the first coil 31. The coil layer 3 is arranged so that the gap between the pitches of the first and second coils 31 and 32 can be freely displaced over a predetermined length from the tip end to the base end, and the tubular body 2 is curved. As a result, it can be flexibly curved without being restricted by the tubular body 2.

[0079]

976 The inner tube 51 has a first lumen 511 with an open tip.

977 The first lumen 511 is a lumen for inserting a guide wire, and communicates with a first opening 581 forming a guide wire port provided in the branch hub 57 described later. The inner pipe 51 has an outer diameter of 0.40 to 2.50 mm, preferably 0.55 to 2.40 mm, and an inner diameter of 0.25 to 2.35 mm, preferably 0.30 to 1.80 mm. ..

[0080]

984 The outer pipe 52 has an inner pipe 51 inserted therein and is provided coaxially with the inner pipe 51, and the tip thereof is provided at a position slightly retracted from the tip of the inner pipe 51.

987 A second lumen 521 is formed by the inner surface of the outer pipe 52 and the outer surface of the inner pipe 51. By forming in this way, the cross-sectional area of the second lumen 521 can be made large, and the lumen having a sufficient volume can be obtained. The second lumen 521 communicates with the extension 53 at its tip and at its proximal end, and the proximal end of the second lumen 521 is a fluid (eg, angiographic agent) for expanding the extension 53. Communicates with a second opening 591 of the branch hub 57 forming an injection port for injecting the fluid. The outer tube 52 has an outer diameter of 0.70 to 4.30 mm, preferably 0.75 to 4.00 mm, and an inner diameter of 0.70 to 3.80 mm, preferably 0.80 to 3.00 mm. ..

[0081]

999 The constituent material of the outer tube 52 may be any material having a certain degree of flexibility, for example, polyolefins such as polyethylene, polypropylene, polybutene, and ethylene-propylene copolymer, polyvinyl chloride, and ethylene-vinyl acetate copolymer weight. Thermoplastic resins such as coalesced, polyurethane and polyester, polyamide elastomers, polyester elastomers, silicone rubbers, polytetrafluoroethylene and the like can

be used, preferably the above-mentioned thermoplastic resins, and more preferably polyolefins.

[0082]

1009 The expansion body 53 is contractable, and in a non-expandable state, it can be folded around the outer periphery of the inner tube 51.

1011 The dilated body 53 is foldable and has a substantially cylindrical portion 533 having at least a substantially cylindrical shape and having substantially the same diameter so that the narrowed portion of the blood vessel can be easily dilated.

1014 The above-mentioned substantially cylindrical portion does not have to be a perfect cylinder, and may be a polygonal columnar portion. The base end portion 532 of the extended body 53 is liquid-tightly fixed to the tip end portion of the outer tube 52 by adhesion or heat fusion, and the tip end portion 531 is the tip end of the inner tube 51 as shown in FIG. It is directly adhered to the part in a liquid-tight manner. The extended body 53 forms an internal space 534 between the inner surface of the extended body 53 and the outer surface of the inner tube 51. The internal space 534 communicates with the second lumen 521 at the base end portion 532 on the entire circumference thereof. In this way, since the second lumen 521 having a relatively large volume is communicated with the base end of the expansion body 53, the expansion fluid can be injected from the second lumen 521 into the internal space 534 of the expansion body 53. It's easy. The constituent material of the extended body 53 is preferably one having a certain degree of flexibility, for example, polyolefins such as polyethylene, polypropylene and ethylene-propylene copolymer, polyvinyl chloride, ethylene-vinyl acetate copolymer, polyurethane and the like. Thermoplastic resin, polyamide elastomer, silicone rubber, latex rubber, polyethylene terephthalate, polyester, polyamide, polyphenylene sulfide and the like can be used. Preferred is polyphenylene sulfide.

[0083]

1034 Further, the extended body 53 has a tapered portion from the distal end side and the proximal end side of the substantially cylindrical portion 533 to the distal end portion 531 and the proximal end portion 532 fixed to the inner pipe 51 and the outer pipe 52. There is.

1038 As for the size of the extended body 53, the outer diameter of the substantially cylindrical portion 533 when expanded is 1.00 to 35.00 mm, preferably 1.50 to 30.00 mm, and the length is 10.00 to 80. It is 0.00 mm, preferably 15.00 to 75.00 mm, and the total length of the extension 53 is 15.00 to 120.00 mm, preferably 20.00 to 100.00 mm.

[0084]

1045 Further, a marker 54 made of an X-ray opaque material (for example, gold, platinum or an

alloy thereof) is provided on the outer surface of the inner tube 51 at a position between the tip end portion 531 and the base end portion 532. Has been done.

1048 This marker 54 makes it possible to easily confirm the position of the extended body 53 under fluoroscopy. As the form of the marker 54, it is preferable to crimp the ring formed of the above metal to the outer surface of the inner tube 51. This makes it possible to obtain a clear X-ray contrast image.

[0085]

1055 Further, a tip soft tip 55 is fixed and joined to the tip of the inner tube 52 as the most advanced portion of the inner tube 52.

1057 The tip soft tip 55 is formed in the shape of a short cylinder, and is fixed and joined to the tip of the inner tube 51 by adhesion or fusion so that its lumen communicates with the first lumen 511. By providing the tip 55, the possibility of damaging the blood vessel at the tip of the catheter 5 can be reduced. As the constituent material of the chip 55, it suffices to have flexibility, and for example, polyurethane, silicone RTV rubber, vinyl chloride-urethane copolymer, styrene-based elastomer and the like can be used. The length of the chip 55 is 0.5 to 5 mm, preferably about 0.5 to 3 mm.

[0086]

1067 Further, the catheter 5 shown in FIGS. 7 and 8 has a reinforcing tube 56 and a branch hub 57.

1069 In the illustrated example, the reinforcing tube 56 is attached around the outer periphery of the outer tube 52 near the base end. The reinforcing tube 56 is, for example, a tube 56 having heat shrinkage, formed so that the inner diameter after heat shrinkage is slightly smaller than the outer diameter near the base end of the outer pipe 52, and has heat shrinkage. Can be easily attached by fitting the outer tube 52 in the vicinity of the base end and heating (for example, applying hot air) to shrink the outer tube 52. The reinforcing tube is not limited to the above, and for example, the inner tube 51 may be provided with the same tube as the reinforcing tube 56.

[0087]

1080 The branch hub 57 has a first opening 581 that communicates with the first lumen 511 to form a guide wire port, and communicates with the inner tube hub 58 fixed to the inner tube 51 and the second lumen 521. It has a second opening 591 forming an injection port, and is composed of an outer pipe hub 59 fixed to the outer pipe 52.

1084 The inner tube hub 58 and the outer tube hub 59 are fixed to each other. As a constituent material of the branch hub 574, a thermoplastic resin such as polycarbonate, polyamide, polysulfone, polyarylate, and a methacrylate-butylene-styrene copolymer can be preferably used. Further, the branch hub 57 may not be provided, and a tube having a port member

forming an opening at the base end may be attached to each of the first lumen 511 and the second lumen 521 in a liquid-tight manner.

[0088]

1093 Next, the method and operation of the vasodilator catheter 5 will be described by taking as an example the case of treating a stenosis generated in a coronary artery blood vessel.

1095 First, before inserting the catheter 5 into the blood vessel, the air in the dilator 53 and the second lumen 521 is removed as much as possible and replaced with a liquid such as a contrast medium. At this time, the extended body 53 is kept in a contracted or folded state. Next, a sheath is placed in the patient's blood vessel by, for example, the Seldinger method, and then a guiding catheter is inserted into the blood vessel through the lumen of the sheath and placed at the entrance of the coronary artery. It is preferable that the inner surface of the guiding catheter has a hydrophilic coating. Next, a guide wire composed of a metal elastic core material, a plastic coating material coated on the surface thereof, and a hydrophilic lubricating layer fixed to the surface of the coating material, or a metal elastic core material and the tip of the core material. A guide wire composed of the provided X-ray contrast-enhanced coil and the fluorine-based coating material coated on the surface of the core material is inserted into the first lumen 511, and the catheter 5 is inserted from the lumen of the guiding catheter. Insert into a blood vessel. Subsequently, the position of the marker 54 is visually recognized under fluoroscopy, and while confirming the positions of the catheter 5 and the tip of the guide wire, the guide wire is advanced to advance the catheter 5, and the catheter 5 is inserted to the stenosis and expanded. The body 53 is positioned within the stenosis.

[0089]

1115 After that, an injector with a pressure gauge is connected to the second opening 581 forming the injection port of the catheter 5, an angiographic agent is injected so as to be about several to ten and several atmospheres, and the dilator 63 is inflated. The lesion, the atheroma, is compressed and the stenosis is dilated.

1119 Then, the contrast medium is injected from the contrast medium injection port provided in the connector of the guiding catheter, and the peripheral blood flow is confirmed by X-ray imaging. When the blood flow is improved, the catheter 5 and the guide wire are removed, and then the guiding catheter is removed to complete the procedure.

[0090]

1126 Since the catheter 5 of the present invention is configured with the medical tube 1 of the present invention as a member, it is highly flexible and resistant to kink, and can be satisfactorily inserted into a relatively thin blood vessel such as a coronary artery. The followability to the guide wire is also good, and even a complicatedly curved or bent blood

vessel can easily proceed along the guide wire without kinking.

1131 In addition, it has excellent torque transmission and pushability, making it a catheter with good operability. Furthermore, it has excellent pressure resistance on the inside and outside, and even if an expansion fluid is poured into the internal space 534 of the expansion body 53 at high pressure. It is unlikely to collapse or burst. Further, even if a contrast medium is poured into the first lumen 511 during the operation, it is unlikely to be crushed or ruptured and can be safely handled.

[0091]

1140 In the illustrated example, the inner tube 51 is made of the medical tube 1, but the present invention is not limited to this, and the outer tube 52 may be made of the medical tube 1 or the inner tube. Both the 51 and the outer tube 52 may be composed of the medical tube 1.

1143 Further, the medical tube of the present invention constituting the inner tube 51 and the outer tube 52 is not limited to the illustrated medical tube 1, and is shown in FIG. 5, for example, in place of the medical tube 1 described above. A medical tube 10 may be used.

[0092]

1149 Further, in the illustrated example, a double lumen coaxial type guide wire movable (over-the-wire type) vasodilator catheter has been described, but the present invention is not limited to this, and the US patent 4,771,778 is not limited thereto. The so-called on-the-wire type vasodilator catheter in which the dilator is directly fixed to the guide wire described in the specification, etc., and the catheter described in the US patents 4,748,982, etc. are used for the blood vessel. It can also be applied to a so-called monorail type vasodilator catheter in which the guide wire can be replaced while it is inserted, and the medical tube of the present invention may be used for such a type of catheter tube.

[0093]

1160 The medical tube, the cerebral vascular treatment catheter, and the vasodilator catheter in the present invention have been described above, but the present invention is not limited to this, and for example, a vascular catheter such as a contrast catheter, a guiding catheter, and a drug injection are used. It may be applied to a catheter, a devascularization catheter for open heart surgery, an endoscopic catheter, a laparoscopic catheter, a thoracic laparoscopic catheter and the like.

[0094]

1169 Hereinafter, the present invention will be described in more detail based on specific examples.

1171 [Example 1] Using linear low-density polyethylene (manufactured by Mitsui Nisseki Polymer

Co., Ltd., trade name: Ultozex, grade 4570) as a raw material, an inner diameter of 0.47 mm and an outer diameter of 0.52 mm are obtained by ordinary extrusion molding. I got a tube.

1174 By pulling down the die from this tube, a molded body of the inner layer 21 was manufactured as a two-stage different diameter tube having an inner diameter of 0.41 mm and an outer diameter of 0.45 mm.

1177 The obtained inner layer 21 had a total length of 1700 mm, a small diameter tip portion of 800 mm, and a base length of 900 mm.

[0095]

1182 On the other hand, using a modified polyethylene resin (manufactured by Atchem, trade name Bondine, grade TX-8030) as a raw material, the take-up speed is changed in the middle of extrusion molding to manufacture a molded body of an outer layer 22 having a different diameter between the tip portion and the base portion. bottom.

1186 The total length of the outer layer 22 is 1700 mm, and the length of the tip portion having a small diameter is 750 mm. The length of the tapered portion was 50 mm, and the length of the base including the tapered portion was 950 mm. The inner diameter of the tip portion was 0.50 mm and the outer diameter was 0.56 mm, the tapered portion was smoothly changed, and the inner diameter of the base portion was 0.56 mm and the outer diameter was 0.63 mm.

[0096]

1195 Further, strands 31a to e made of stainless steel (SUS304), having a plate thickness t of 0.010 mm and a plate width z of 0.120 mm were prepared, and the strands 31a to e were combined into a bundle 31A. The first coil 31 was manufactured by winding the strands 31a to e right-handed on core materials having different diameters at the tip and the base in a state where the strands 31a to e were in close contact with each other without any gap.

1200 The gap y between the pitches of the coils 31 was 0.02 mm.

[0097]

1204 Subsequently, the strands 32a to e configured in the same manner as the strands 31a to e are prepared, the strands 32a to e are made into a bundle 32A as a set of five, and the strands 32a to e are brought into close contact with each other without a gap. In this state, the core material and the first coil 31 were overlapped and wound counterclockwise to produce a second coil 32.

1209 The gap y between the pitches of the coil 32 was set to 0.02 mm as in the coil 31.

[0098]

1213 Then, the core material was extracted to manufacture a coil layer 3 having a different

diameter between the tip portion and the base portion.

1215 The obtained coil layer 3 has an inner diameter of 0.47 mm, an outer diameter of 0.51 mm, a length of 730 mm, and a tapered portion having a length of 50 mm, and has a smooth diameter. It was changing. The inner diameter of the base was 0.53 mm, the outer diameter was 0.57 mm, and the length was 820 mm including the tapered portion.

[0099]

1222 The coil layer 32 was inserted into the outer layer 22 swollen in a THF solvent, the outer layer 22 was air-dried, and then the inner layer 21 was inserted into the coil layer 3.

1224 Then, these coil layers 3, the inner layer 21 and the outer layer 22 were heat-treated in an oven at 60 ° C. for 16 hours. By this heat treatment, the residual stress of the inner layer 21 was removed, the inner diameter and the outer diameter of the inner layer 21 were increased, and the inner layer 21 and the coil layer 3 were in close contact with each other. Further, both end portions of the inner layer 21 and the outer layer 22 were fused and fused at a position 1 mm ahead of the tip end and the base end of the coil layer 3 to obtain the medical tube 1 of the present invention shown in FIGS. 1 to 4. The obtained medical tube 1 has a total length of 1500 mm, an inner diameter of the tip portion 12 of 0.43 mm, an outer diameter of 0.57 mm, and a length of 730 mm, and the tapered portion 13 has a length of 50 mm and a smooth diameter. It had changed to. The inner diameter of the base 11 was 0.48 mm, the outer diameter was 0.64 mm, and the length was 770 mm.

[0100]

1238 [Comparative Example 1] High-density polyethylene (manufactured by Mitsubishi Yuka Co., Ltd., trade name Mitsubishi Polyeth-HD, grade EY40H) is molded by ordinary extrusion molding and has an inner diameter of 0.43 mm and an outer diameter of 0.57 mm. A tube of Comparative Example 1 having the same dimensions as the tip portion 12 of Example 1 was manufactured.

[0101]

1246 [Comparative Example 2] A reinforced tube having an inner diameter of 0.43 mm and an outer diameter of 0.57 mm reinforced with a metal braid and having the same dimensions as the tip portion 12 of the embodiment according to the method described in Japanese Patent Publication No. 4-670. Manufactured.

1250 Specifically, high-density polyethylene (manufactured by Mitsubishi Yuka Co., Ltd., trade name Mitsubishi Polyeth-HD, grade JY20) was coated on a copper wire having an outer diameter of 0.43 mm to a thickness of 15 μm using a cross molding machine. ..

1253 A 20 μm stainless steel (SUS304) blade wire is wound around a copper wire in a mesh pattern using a braider device (manufactured by Nagata Seiki Co., Ltd., model number STM-II), and then the same resin is melt-coated using a coating die. , The above blade wire was

buried. Then, the copper wire used for the core was stretched, stretched, and removed to prepare a tube of Comparative Example 3.

[0102]

1261 [Comparative Example 3] A tube of Comparative Example 2 composed of a coil layer 3 and an outer layer 22 was produced in the same manner as in Example 1 except that the inner layer 21 of Example 1 was not provided.

1264 Experiments 1 to 4 shown below were carried out for Examples 1 and Comparative Examples 1 to 3 to compare the mechanical strengths.

[0103]

1269 [Experiment 1] The flexural modulus and bending stress of the tips 12 of Example 1 and the tubes of Comparative Examples 1 to 3 were measured by a three-point bending test.

1271 The flexural modulus was used as a comparison of tube hardness, and the bending stress was used as a comparison of tube flexibility. The three-point bending test was performed by cutting the tip portion 21 of Example 1 and the tubes of Comparative Examples 1 and 2 to 20 mm each, using the jig 20 shown in FIG. 9, and referring to the bending test of JIS K7203. .. The test was carried out using an AUTOGRAPH AGS-100A manufactured by Shimadzu Corporation at a test speed of 1 mm / min at room temperature.

[0104]

1280 Two support rods 62 having a diameter of 2 mm were placed on the sample table 61 of the jig 6 shown in FIG. 9, and the tip portion 21 of Example 1 cut to a fixed size was placed and supported on the support rod 62.

1283 The distance between the support rods 62 (distance between fulcrums) was 10 mm. In this state, a pusher 64 having a fulcrum ball 63 having a diameter of 2 mm is connected to a load cell (not shown) of the testing machine, and the pusher 64 is moved in the direction of the arrow in the figure to perform a three-point bending test. rice field. The same test as above was performed on the tubes of Comparative Examples 1 to 3.

[0105]

1291 By the above bending test, the stress strain curve shown in FIG. 10 was obtained.

1292 The initial slope in this stress-strain curve is defined as the bending stress W, and this bending stress W represents the force required to simply bend each sample by 1 mm. bottom. The results are shown in Table 1 below.

[0106]

1298 [Experiment 2] The inner pressure resistance test shown below was performed on the tip portion 12 of Example 1 and the tubes of Comparative Examples 1 to 3 to evaluate the pressure resistance to pressure from the inside.

1301 As shown in FIG. 11, the tip of the tip portion 12 of Example 1 was sealed with an epoxy resin 71, and the connector 72 was connected to the base end. These were placed in a hot water bath at 37 ° C., and nitrogen gas was sent from the injection port 73 of the connector 72 to the inside of the tip portion 12 using a nitrogen gas cylinder, and the pressure was applied at a rate of 1.0 kg / cm2 per minute. By visually observing the bubbles generated in the water, the pressure value at which the leak or rupture occurred was measured. In addition, the same measurements as above were performed for the tubes of Comparative Examples 1 to 3. The results are shown in Table 1 below.

[0107]

1312 [Experiment 3] The outer pressure resistance test shown below was performed on the tip portion 12 of Example 1 and the tubes of Comparative Examples 1 to 3 to evaluate the pressure resistance against crushing from the outside.

1315 As shown in FIG. 12, the tip portion 12 of Example 1 was covered with a metallic sheath 82 having an injection port 81, and the tip 83 and the base end 84 of the sheath 82 were sealed with epoxy resin, respectively. At this time, the tip portion 12 was made longer than the total length of the sheath 82 and protruded from the tip end 83 and the base end 84. In this state, the whole was placed in a hot water bath at 37 ° C. The lumen 85 composed of the tip portion 12 and the sheath 82 was pressurized with nitrogen gas, and the outside of the tip portion 12 was pressurized by 1.0 kg / cm2.

[0108]

1325 At the time when the pressurization was started, a straight core rod 86 made of stainless steel (SUS304) was passed through the inner lumen 14 of the tip portion 12, and the passability of the core rod 86 was confirmed.

1328 The outer diameter of the core rod 86 was set to 0.38 mm, which is 0.05 mm smaller than the inner diameter of the tip portion 12. The pressure value when the lumen 14 was crushed by the deformation of the tip portion 12 due to pressurization and the core rod became immobile was obtained, and the crush resistance due to the pressure from the outside was evaluated. In addition, the pressure value at the time of leakage or rupture was also obtained by visually observing the bubbles generated in the water, but in most cases, the occurrence of crushing occurred earlier. In addition, the same measurements as above were performed for the tubes of Comparative Examples 1 to 3. The results are shown in Table 1 below.

[0109]

1340 [Experiment 4] The kinkability test shown below was performed on the tips 12 of Example 1 and the tubes of Comparative Examples 1 to 3 using the device 9 shown in FIG.

1342 The kink resistance test was performed using an autograph (AUTOGRAPH AGS-100A manufactured by Shimadzu Corporation) at a test speed of 10 mm / min. At room temperature. As shown in FIG. 13, core rods 91 are inserted into both ends of the tip portion 12 of the first embodiment cut to 65 mm, the space between the two core rods 91 is set to 25 mm, and the gap between the core rod 91 and the tip portion 12 is set. Was filled with epoxy resin. Both ends of the tip portion 12 into which the core rod 91 is inserted are sandwiched between chucks 92, and the chuck 92 on the upper side is lowered at a constant speed to narrow the interval. The moving distance of the chuck 92 on the upper side at this time was measured. It can be said that the smaller this measured value is, the worse the kink resistance is. In addition, the same measurements as above were performed for the tubes of Comparative Examples 1 to 3. The results are shown in Table 1 below.

[0110]

1357 [Experiment 5] The tip portion 12 of Example 1 and the tubes of Comparative Examples 1 to 3 were subjected to the tensile test shown below, the breaking strength and the breaking elongation were measured, and the strength of the tubes was compared.

1360 The tensile test was performed using an autograph (AUTOGRAPH AGS-100A manufactured by Shimadzu Corporation) at a test speed of 100 mm / min. At room temperature, and the breaking strength and breaking elongation were determined. In this test, using the same equipment as in Experiment 4, the chuck 92 was widened between the two chucks 92 at a constant speed, contrary to Experiment 4, and the chuck 92 when the tip portion 12 of Example 1 was broken. The distance traveled was measured. The same measurement was performed on the tubes of Comparative Examples 1 to 3. The results are shown in Table 1 below.

[0112]

1371 As shown in Table 1 above, from the measured values of flexural modulus, the hardness of the tube is the hardest in the reinforced tube of Comparative Example 2, and it is composed only of a flexible resin material, and has the same dimensions. It can be said that the tube of Example 1 is more flexible than the tube of Comparative Example 1.

1375 Further, it can be seen from the measured values of bending stress that the tube of Example 1 is more flexible than that of Comparative Examples 1 and 2. Furthermore, it is clear from the measured values of kink resistance that the tube of Example 1 is less likely to cause kink and is excellent in flexibility. From the above, it is understood that the medical tube of the present invention is excellent in flexibility and kink resistance.

[0113]

1383 Regarding the inner and outer pressure resistance, from the measured values shown in Table 1, the tube of Example 1 is superior to the tube of Comparative Example 1 in both inner pressure resistance and outer pressure resistance. Understand.

1386 Further, the tube of Comparative Example 2 is excellent in pressure resistance, but is a hard tube as described above. Further, comparing Example 1 and Comparative Example 3, Example 1 in which the inner layer 21 is provided inside the coil layer 3 has an inner pressure resistance as compared with Comparative Example 3 in which the inner layer 21 is not provided inside the coil layer 3. It has been shown that the sex is significantly improved. That is, it can be seen that the pressure resistance is remarkably improved by forming the structure in which the flexible layer is covered with the coil layer. Conventionally, for tubes of the same inner and outer diameters, the pressure resistance depends on the hardness of the material of the tube. Therefore, it was conventionally thought that the pressure resistance would be lost if the tube was softened. It is understood that the medical tube of the present invention satisfies both the flexibility and pressure resistance of the tube.

[0114]

1401 Further, from the results of the tensile test of the tube, it is shown that the tube of Example 1 is superior in strength to the tube of Comparative Examples 1 and 2.

1403 Further, the tube of Comparative Example 2 has a remarkably low breaking elongation, and such a tube tends to break suddenly, so that it is not preferable for safety as a tube used by inserting it into a body cavity. From the above, it is understood that the medical tube of the present invention has both satisfactory flexibility, pressure resistance and strength.

[0115]

1410 When the tubes of Example 1 and Comparative Examples 1 and 2 were bent at right angles and the presence or absence of kink was observed, the tubes of Example 1 maintained the inner holes and did not break, but Comparative Examples 1 to 2. The tube 2 was broken and the inner hole was crushed.

[0116]

1417 [Example 2] The medical tube 10 shown in FIG. 5 was manufactured.

1418 The chip 15 was manufactured using polyurethane.

1419 When the same test as above was performed on this tube 10, the flexibility, pressure resistance and strength were all excellent as in Example 1. Further, the tip of this tube 10 was very flexible as compared with Example 1.

[0117]

1425 [Example 3] Using the medical tube 1 of Example 1 as a member, a catheter 4 for cerebrovascular embolization shown in FIG. 6 was manufactured.

1427 Specifically, after cutting the medical tube 1 of Example 1 to a fixed size with an excimer laser, the tube 1 is provided with a reinforcing tube 41 (material: polyethylene resin) and a hub 42 (material: nylon 12 resin).), The tip soft tip 43 (material; polyurethane), and the contrast marker 44 made of a platinum coil were attached using a urethane adhesive. The marker 44 was wrapped around the outer surface of the chip 43, and a urethane adhesive was applied on the marker 44 so that the outer surface of the catheter 4 was smooth.

[0118]

1436 The catheter 4 is a catheter having a taper of 1.7 Fr at the tip and 1.9 Fr at the base, the total length of the catheter is 1500 mm, and the effective length of the catheter (length excluding the hub and the reinforcing tube) is 1400 mm.

1439 At the time of assembly, a cyanoacrylate-based instant adhesive was impregnated into the gap between the first and second coils 31 and 32 on the proximal end side of the medical tube 1 by utilizing the capillary phenomenon. The instant adhesive penetrated to about 1/3 of the base 11 of the medical tube 1, and the portion became hard. Further, the tip portion 12 having a small diameter was coated with a P (GMA-DMAA) block copolymer which is a hydrophilic polymer substance, and a surface treatment having lubricity when wet was performed.

[0119]

1449 When cerebral vascular treatment (cerebral artery embolization) for embolizing a cerebral aneurysm was performed using this catheter 4, the bending followability and torque controllability for a winding blood vessel were very good, and the catheter operability was improved. It was excellent.

[0120]

1456 [Example 4] The vasodilator catheter 5 shown in FIG. 7 was manufactured using the multilayer medical tube 1 of Example 1 as a member.

1458 Specifically, the medical tube 1 of Example 1 is cut to a fixed size, and this is used as an inner tube 51, which is made of an outer tube 52 (material: polypropylene resin), an expansion body 53 (material: polycarbonate sulfide resin), and platinum. The contrast marker 54, the tip soft tip 55 made of polyurethane, the reinforcing tube 56 (material: polyethylene resin), the inner tube hub 58 (material: polycarbonate resin), and the outer tube hub 59 (material: polycarbonate resin) were attached.

1464 The entire obtained catheter 5 was a tapered catheter with an outer diameter of 2.7 Fr (outer diameter of about 0.9 mm), and the total length of the catheter was 1550 mm and the

effective length of the catheter was 1350 mm.

[0121]

1470 When the PTCA procedure was performed using this catheter 5, the catheter was excellent in flexion followability, stenosis passage, pushability, and guide wire mobility, and the catheter was easy to operate.

1473 In addition, during the PTCA procedure, a contrast medium with high viscosity was used as the expansion fluid of the expansion body 53, and the pressurizing pressure of the expansion body 53 was increased to 16 kg / cm2, but the inner tube 51 was not crushed or ruptured at all. I couldn't.

[0122]

1480 INDUSTRIAL APPLICABILITY As described above, the medical tube of the present invention is rich in flexibility and kink resistance, has good torque transmissibility and push-in property, and is also excellent in pressure resistance on the inside and outside. ..

1483 Therefore, it can be suitably used as a member of a catheter having excellent operability, and is particularly effective as a member of a small-diameter catheter used by inserting it into a body cavity having a small diameter. Therefore, it is possible to provide a catheter useful for, for example, angioplasty, drug infusion therapy, angiography, and embolization therapy.

[0123]

1491 In addition, the catheter for cerebrovascular embolization of the present invention composed of the above-mentioned medical tube is rich in flexibility and kink resistance, has good torque transmissibility and push-in property, and has inner and outer pressure resistance. Are better.

1495 Therefore, it has excellent operability, can reach the target site of the fine and complicated cerebral blood vessels along the guide wire well, minimizes damage to the tubular tissue and organs of the human body, and is safe. Very expensive.

[0124]

1501 Further, the vasodilator catheter of the present invention composed of the above-mentioned medical tube is rich in flexibility and kink resistance, has good torque transmissibility and push-in property, and has excellent inner and outer pressure resistance. There is.

1504 Therefore, it has excellent operability, can reach the target member well along the guide wire, and can minimize damage to the tubular tissue and organs of the human body. In addition, there is very little risk of explosion even if a high pressure is applied when expanding the expanded body, and the safety is very high.

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
27 May 2022 (27.05.2022)

WIPO | PCT

(10) International Publication Number
WO 2022/109021 A1

(51) International Patent Classification:
A61M 25/00 (2006.01) *A61B 17/22* (2006.01)

(21) International Application Number:
PCT/US2021/059718

(22) International Filing Date:
17 November 2021 (17.11.2021)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
63/115,512 18 November 2020 (18.11.2020) US

(71) Applicant: **INARI MEDICAL, INC.** [US/US]; 9 Parker, Suite #100, Irvine, California 92618 (US).

(72) Inventors: **DOLENDO, Edward Enriquez**; 9 Parker, Suite #100, Irvine, California 92618 (US). **BRODT, Thomas Robert**; 9 Parker, Suite #100, Irvine, California 92618 (US). **TU, Thomas M.**; 9 Parker, Suite #100, Irvine, California 92618 (US).

(74) Agent: **WILLIAMS, Matthew S.** et al.; PERKINS COIE LLP, P.O. Box 1247, Seattle, Washington 98111-1247 (US).

(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, DJ, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, IT, JO, JP, KE, KG, KH, KN, KP, KR, KW, 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, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, WS, 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).

Published:
— *with international search report (Art. 21(3))*
— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))*

(54) Title: CATHETERS HAVING SHAPED DISTAL PORTIONS, AND ASSOCIATED SYSTEMS AND METHODS

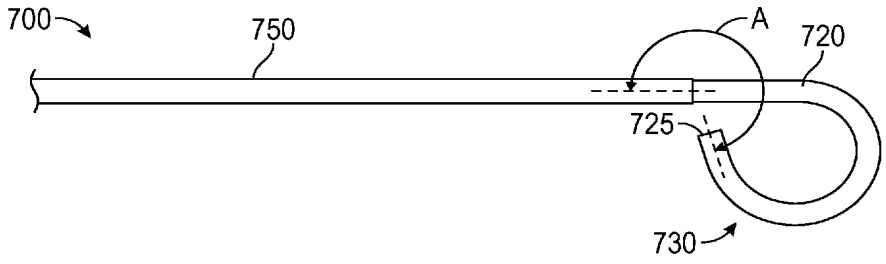


FIG. 7C

(57) Abstract: Disclosed herein are aspiration guide catheters having a pre-shaped distal portion configured to deflect away from a longitudinal axis of the catheter, and associated systems and methods. In some embodiments, an aspiration guide catheter includes an inner liner defining a lumen and having a proximal region and a distal region. The catheter further includes a braid of wires over the inner liner, and a wire coiled around the braid over at least a portion of the distal region of the inner liner. At least a portion of the braid over the distal region of the inner liner is configured to deflect away from a longitudinal axis of the proximal region. The catheter can further include an outer sheath over the braid, the wire, and the inner liner.

WO 2022/109021 A1

CATHETERS HAVING SHAPED DISTAL PORTIONS, AND ASSOCIATED SYSTEMS AND METHODS

CROSS-REFERENCE TO RELATED APPLICATION

[0001] This application claims the benefit of U.S. Provisional Patent Application No. 63/115,512, filed November 18, 2020, and titled "CATHETERS HAVING SHAPED DISTAL PORTIONS, AND ASSOCIATED SYSTEMS AND METHODS," which is incorporated herein by reference in its entirety.

TECHNICAL FIELD

[0002] The present technology generally relates to catheters having shaped (e.g., pre-shaped) distal potions, such as a distal curved portion, to facilitate positioning of the catheter in hard-to-reach regions of the vasculature of a patient.

BACKGROUND

[0003] Thromboembolic events are characterized by an occlusion of a blood vessel. Thromboembolic disorders, such as stroke, pulmonary embolism, heart attack, peripheral thrombosis, atherosclerosis, and the like, affect many people. These disorders are a major cause of morbidity and mortality.

[0004] When an artery is occluded by a clot, tissue ischemia develops. The ischemia will progress to tissue infarction if the occlusion persists. Infarction does not develop or is greatly limited if the flow of blood is reestablished rapidly. Failure to reestablish blood flow can lead to the loss of limb, angina pectoris, myocardial infarction, stroke, or even death.

[0005] In the venous circulation, occlusive material can also cause serious harm. Blood clots can develop in the large veins of the legs and pelvis, a common condition known as deep venous thrombosis (DVT). DVT arises most commonly when there is a propensity for stagnated blood (e.g., long distance air travel, immobility, etc.) and clotting (e.g., cancer, recent surgery, such as orthopedic surgery, etc.). DVT causes harm by: (1) obstructing drainage of venous blood from the legs leading to swelling, ulcers, pain, and infection, and (2) serving as a reservoir for blood clots to travel to other parts of the body including the heart, lungs, brain (stroke), abdominal organs, and/or extremities.

[0006] In the pulmonary circulation, the undesirable material can cause harm by obstructing pulmonary arteries—a condition known as pulmonary embolism. If the obstruction is upstream, in the main or large branch pulmonary arteries, it can severely compromise total blood flow within the lungs, and therefore the entire body, and result in low blood pressure and shock. If the obstruction is downstream, in large to medium pulmonary artery branches, it can prevent a significant portion of the lung from participating in the exchange of gases to the blood resulting in low blood oxygen and buildup of blood carbon dioxide.

[0007] There are many existing techniques to reestablish blood flow through an occluded vessel. One common surgical technique, an embolectomy, involves incising a blood vessel and introducing a balloon-tipped device (such as the Fogarty catheter) to the location of the occlusion. The balloon is then inflated at a point beyond the clot and used to translate the obstructing material back to the point of incision. The obstructing material is then removed by the surgeon. Although such surgical techniques have been useful, exposing a patient to surgery may be traumatic and best avoided when possible. Additionally, the use of a Fogarty catheter may be problematic due to the possible risk of damaging the interior lining of the vessel as the catheter is being withdrawn.

[0008] Percutaneous methods are also utilized for reestablishing blood flow. A common percutaneous technique is referred to as balloon angioplasty where a balloon-tipped catheter is introduced to a blood vessel (e.g., typically through an introducing catheter). The balloon-tipped catheter is then advanced to the point of the occlusion and inflated to dilate the stenosis. Balloon angioplasty is appropriate for treating vessel stenosis, but it is generally not effective for treating acute thromboembolisms as none of the occlusive material is removed and the vessel will re-stenos after dilation. Another percutaneous technique involves placing a catheter near the clot and infusing streptokinase, urokinase, or other thrombolytic agents to dissolve the clot. Unfortunately, thrombolysis typically takes hours to days to be successful. Additionally, thrombolytic agents can cause hemorrhage and in many patients the agents cannot be used at all.

[0009] Various devices exist for performing a thrombectomy or removing other foreign material. However, such devices have been found to have structures which are either highly complex, cause trauma to the treatment vessel, or lack sufficient retaining structure and thus cannot be appropriately fixed against the vessel to perform adequately. Furthermore, many of the devices have highly complex structures that lead to manufacturing and quality control difficulties as well as delivery issues when passing through tortuous or small diameter catheters.

Less complex devices may allow the user to pull through the clot, particularly with inexperienced users, and such devices may not completely capture and/or collect all the clot material.

BRIEF DESCRIPTION OF THE DRAWINGS

[0010] Many aspects of the present technology can be better understood with reference to the following drawings. The components in the drawings are not necessarily to scale. Instead, emphasis is placed on illustrating clearly the principles of the present disclosure.

[0011] Figure 1 is a partially schematic side view of a clot treatment system including a catheter in accordance with embodiments of the present technology.

[0012] Figure 2 is an enlarged, partial cut-away side view of a portion of a proximal region of the catheter of Figure 1 in accordance with embodiments of the present technology.

[0013] Figure 3A is an enlarged, partial cut-away side view, and Figure 3B is an enlarged, partial cut-away perspective view, of a portion of a distal region of the catheter of Figure 1 in accordance with embodiments of the present technology.

[0014] Figure 3C is an enlarged cross-sectional view of the distal region of the catheter of Figure 1 taken along the line 3C-3C in Figure 3B in accordance with embodiments of the present technology.

[0015] Figures 4A and 4B are side views of the distal portion of the catheter of Figure 1 during a procedure for removing clot material from within a blood vessel of a patient in accordance with embodiments of the present technology.

[0016] Figures 5A and 5B are side views of the distal portion of the catheter of Figure 1 during a procedure for removing clot material from within a blood vessel of a patient in accordance with additional embodiments of the present technology.

[0017] Figure 6 illustrates various shapes for the distal portion of the catheter of Figure 1 in accordance with additional embodiments of the present technology.

[0018] Figures 7A–7C are side views of a distal portion of a clot treatment system in accordance with additional embodiments of the present technology.

DETAILED DESCRIPTION

[0019] The present technology is generally directed to aspiration guide catheters having a pre-shaped distal portion for improved flexibility through tortuous/hard-to-reach vascular

anatomy, and associated systems and methods. In some embodiments, an aspiration guide catheter includes an inner liner defining a lumen and having a proximal region and a distal region. The catheter can further include a braid of wires over the inner liner, and a wire coiled around the braid over at least a portion of the distal region of the inner liner. At least a portion of the braid over the distal region of the inner liner is configured to deflect away from a longitudinal axis of the proximal region to define a distal shaped portion of the catheter. In some embodiments, the distal shaped portion of the catheter can comprise a curved portion. The catheter can further include an outer sheath over the braid, the wire, and the inner liner and securing these components together.

[0020] In some aspects of the present technology, the catheter is configured to be steered to and positioned in difficult-to-reach regions of the anatomy (e.g., the venous anatomy) of a patient while still having a relatively large lumen (e.g., 20 French, 24 French, greater than 24 French). More particularly, the catheter can have an improved torque response and flexibility compared to conventional catheters having the same lumen size. For example, the braid can provide good torque response along the entire length of the catheter, while the shaped portion is configured to flex into and be positioned within the difficult-to-reach regions of the anatomy. In some embodiments, the outer sheath can have a hardness that decreases in the distal direction to provide (i) good pushability/torquability at the proximal region and (ii) good flexibility at the distal region. Further, the coil can be configured to provide a selected hoop strength at the distal region while still allowing the catheter to flex. For example, the coil can inhibit or even prevent kinking or other unwanted movement of the catheter when the lumen is aspirated during a clot removal procedure.

[0021] Certain details are set forth in the following description and in Figures 1–7C to provide a thorough understanding of various embodiments of the present technology. In other instances, well-known structures, materials, operations, and/or systems often associated with intravascular procedures, clot removal procedures, catheters, and the like are not shown or described in detail in the following disclosure to avoid unnecessarily obscuring the description of the various embodiments of the technology. Those of ordinary skill in the art will recognize, however, that the present technology can be practiced without one or more of the details set forth herein, and/or with other structures, methods, components, and so forth.

[0022] The terminology used below is to be interpreted in its broadest reasonable manner, even though it is being used in conjunction with a detailed description of certain examples of

embodiments of the technology. Indeed, certain terms may even be emphasized below; however, any terminology intended to be interpreted in any restricted manner will be overtly and specifically defined as such in this Detailed Description section.

[0023] The accompanying Figures depict embodiments of the present technology and are not intended to be limiting of its scope unless expressly indicated. The sizes of various depicted elements are not necessarily drawn to scale, and these various elements may be enlarged to improve legibility. Component details may be abstracted in the Figures to exclude details such as position of components and certain precise connections between such components when such details are unnecessary for a complete understanding of how to make and use the present technology. Many of the details, dimensions, angles and other features shown in the Figures are merely illustrative of particular embodiments of the disclosure. Accordingly, other embodiments can have other details, dimensions, angles and features without departing from the present technology. In addition, those of ordinary skill in the art will appreciate that further embodiments of the present technology can be practiced without several of the details described below.

[0024] With regard to the terms "distal" and "proximal" within this description, unless otherwise specified, the terms can reference a relative position of the portions of a catheter subsystem with reference to an operator and/or a location in the vasculature. Also, as used herein, the designations "rearward," "forward," "upward," "downward," and the like are not meant to limit the referenced component to a specific orientation. It will be appreciated that such designations refer to the orientation of the referenced component as illustrated in the Figures; the systems of the present technology can be used in any orientation suitable to the user.

[0025] Figure 1 is a partially schematic side view of a clot treatment system 100 in accordance with embodiments of the present technology. The clot treatment system 100 can also be referred to as an aspiration assembly, a clot removal system, and/or a thrombectomy system. In the illustrated embodiment, the clot treatment system 100 includes a tubing assembly 110 fluidly coupled to a catheter 120 via a valve 102. In general, the clot treatment system 100 (i) can include features generally similar or identical to those of the clot treatment systems described in detail in U.S. Patent Application No. 16/536,185, filed August 8, 2019, and titled "SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED DEVICES AND METHODS," which is incorporated herein by reference in its entirety, and/or (ii) can be used to

treat/remove clot material from a patient (e.g., a human patient) using any of the methods described in detail therein.

[0026] In the illustrated embodiment, the catheter 120 includes (i) a proximal region or portion 122, (ii) an intermediate region 124 adjacent to and distal of the proximal region 122, (iii) a distal region 126 adjacent to and distal of the intermediate region 124, and (iv) a distal tip region 128 adjacent to and distal of the distal region 126 (collectively "regions 122–128"). The catheter 120 further defines a lumen 121 extending entirely therethrough from the proximal region 122 to the distal tip region 128. The proximal region 122 defines a proximal terminus 123 of the catheter 120, and the distal tip region 128 defines a distal terminus 125 of the catheter 120. In the illustrated embodiment, the distal tip region 128 includes a marker band 129, such as a radiopaque marker configured to facilitate visualization of the position of the catheter 120 during a medical procedure (e.g., a clot removal procedure) using the catheter 120.

[0027] In some embodiments, the proximal region 122 has a first length, the intermediate region 124 has a second length less than the first length, the distal region 126 has a third length greater than the second length but less than the first length, and the distal tip region 128 has a fourth length less than the first, second, and third lengths. For example, the first length can be between about 20.0–28.0 inches (e.g., about 24.0 inches), the second length can be between about 2.0–3.0 inches (e.g., about 2.50 inches), the third length can be between about 11.00–15.00 inches (e.g., about 13.25 inches), and the fourth length can be between about 0.10–0.50 inch (e.g., about 0.25 inch). In other embodiments, the lengths of one or more of the regions 122–128 can be different.

[0028] In some embodiments, the catheter 120 can have varying flexibilities, shapes, thicknesses, and/or other properties in/along the various regions 122–128. For example, the distal region 126 can include a shaped portion 130 configured (e.g., heat set) to deflect away from a longitudinal axis Z of the catheter 120 relative to the rest of the distal region 126, the intermediate region 124, and the proximal region 122. That is, the shaped portion 130 can be configured to deflect away from the longitudinal axis Z that is aligned with the proximal region 122, the intermediate region 124, and/or the unshaped portion of the distal region 126 proximal to the shaped portion 130. In the illustrated embodiment, the shaped portion 130 has a generally curved shape. In some embodiments, the shaped portion 130 can move between (i) a relaxed position in which the shaped portion 130 has the curved shape illustrated in Figure 1 and (ii) a constrained position in which the shaped portion 130 is more closely aligned with the

longitudinal axis Z, as shown in phantom lines in Figure 1. In some embodiments, the shaped portion 130 has (i) a length L that can be between about 1.0–5.0 inches (e.g., about 2.35 inches), (ii) a bend radius R of between about 0.5–1.0 inch (e.g., about 0.8 inch, less than about 0.8 inch), and/or (iii) a bend angle A of between about 165–195 degrees (e.g., about 180 degrees) or greater than 195 degrees (e.g., between about 250–290 degrees, about 270 degrees). In other embodiments, the bend angle A can be less than 165 degrees.

[0029] In other embodiments, the shaped portion 130 can have other dimensions and/or shapes. For example, Figure 6 illustrates various shapes for the shaped portion 130 of the catheter 120 in accordance with additional embodiments of the present technology. The shaped portion 130 can have any of the shapes illustrated in Figure 6, such as a Tiger curve shape, a Jacky curve shape, an Amplatz left shape, an LCB shape, an RCB shape, a Judkins left shape, a Judkins right shape, a Multipurpose A2 shape, an IM shape, a 3D LIMA shape, a IM VB-1 shape, and so on.

[0030] The valve 102 is fluidly coupled to the lumen 121 of the catheter 120 and can be integral with or coupled to the proximal region 122 of the catheter 120. In some embodiments, the valve 102 is a hemostasis valve that is configured to maintain hemostasis during a clot removal procedure by preventing fluid flow in the proximal direction through the valve 102 as various components such as delivery sheaths, pull members, guidewires, interventional devices, other aspiration catheters, and so on are inserted through the valve 102 to be delivered through the catheter 120 to a treatment site in a blood vessel. The valve 102 includes a branch or side port 104 configured to fluidly couple the lumen 121 of the catheter 120 to the tubing assembly 110. In some embodiments, the valve 102 can be a valve of the type disclosed in U.S. Patent Application No. 16/117,519, filed August 30, 2018, and titled "HEMOSTASIS VALVES AND METHODS OF USE," which is incorporated herein by reference in its entirety.

[0031] In the illustrated embodiment, the tubing assembly 110 fluidly couples the catheter 120 to a pressure source 106, such as a syringe. The tubing assembly 110 can include one or more tubing sections 112 (individually labeled as a first tubing section 112a and a second tubing section 112b), at least one fluid control device 114 (e.g., a valve), and at least one connector 116 (e.g., a Toomey tip connector) for fluidly coupling the tubing assembly 110 to the pressure source 106 and/or other suitable components. In some embodiments, the fluid control device 114 is a stopcock that is fluidly coupled to (i) the side port 104 of the valve 102 via the first tubing section 112a and (ii) the connector 116 via the second tubing section 112b. The fluid

control device 114 is externally operable by a user to regulate the flow of fluid therethrough and, specifically, from the lumen 121 of the catheter 120 to the pressure source 106. In some embodiments, the connector 116 is a quick-release connector (e.g., a quick disconnect fitting) that enables rapid coupling/decoupling of the catheter 120 and the fluid control device 114 to/from the pressure source 106.

[0032] Figure 2 is an enlarged, partial cut-away side view of a portion of the proximal region 122 of the catheter 120 in accordance with embodiments of the present technology. Figure 3A is an enlarged, partial cut-away side view, and Figure 3B is an enlarged, partial cut-away perspective view, of a portion of the distal region 126 of the catheter 120 in accordance with embodiments of the present technology. Referring to Figures 1–3B together, the catheter 120 includes an outer sheath 230 and an inner liner 232 extending through/defining each of the regions 122–128. The outer sheath 230 is positioned over (e.g., radially outside of) the inner liner 232. The outer sheath 230 can also be referred to as an outer jacket, an outer shaft, or an outer layer, and the inner liner 232 can also be referred to as an inner layer, an inner sheath, or an inner shaft.

[0033] The catheter 120 further includes (i) a braid 234 extending along each of the regions 122–128 between the outer sheath 230 and the inner liner 232 and (ii) a coil 336 (Figures 3A–3C) extending at least partially along the distal region 126 between the braid 234 and the outer sheath 230. In some embodiments, the coil 336 can extend from the distal region 126 at least partially (e.g., entirely) along the intermediate region 124 and/or the proximal region 122. In certain embodiments, the coil 336 is omitted in the proximal region 122 but extends substantially entirely along the intermediate region 124 and the distal region 126.

[0034] In some embodiments, the outer sheath 230 can be formed from a plastic material, elastomeric material, and/or thermoplastic elastomer (TPE) material. In some embodiments, the outer sheath 230 can be formed from a TPE manufactured by Arkema S.A., of Colombes, France, such as the TPEs manufactured under the trademark "Pebax." In some embodiments, the outer sheath 230 can have a varying hardness (e.g., durometer), thickness, flexibility, rigidity, and/or other property in one or more of the different regions 122–128. For example, the outer sheath 230 can have a first hardness along the proximal region 122, a second hardness along the intermediate region 124 that is less than the first hardness, a third hardness along the distal region 126 that is less than the first hardness and the second hardness, and a fourth hardness in the distal tip region 128 that is greater than third hardness. In some embodiments, the first hardness and

the fourth hardness can each be between about 65D–75D (e.g., about 72D), the second hardness can be between about 50D–60D (e.g., about 55D), and the third hardness can be between about 30D–40D (e.g., about 35D). In other embodiments, one or more of the regions 122–128 can have a different hardness.

[0035] The inner liner 232 defines the lumen 121 and, in some embodiments, can be formed of a lubricious material that facilitates the movement (e.g., distal advancement, proximal retraction) of various components through the lumen 121, such as delivery sheaths, pull members, guidewires, interventional devices, other aspiration catheters, and the like. In some embodiments, the inner liner 232 can be formed from a polymer material, a fluoropolymer material (e.g., polytetrafluoroethylene (PTFE)), and/or another material having a high degree of lubricity. In some embodiments, the inner liner 232 can have a diameter D (Figure 2) of greater than about 6 French, greater than about 10 French, greater than about 16 French, greater than about 20 French, greater than about 24 French, or greater. In some embodiments, the diameter D is about 8 French, about 16 French, about 20 French, or about 24 French. In certain embodiments, the diameter D of the inner liner 232 is the same in each of the regions 122–128 while, in other embodiments, the diameter D can vary along one or more of the regions 122–128.

[0036] The braid 234 can include wires, filaments, threads, sutures, fibers, or the like (collectively "wires 238") that have been woven or otherwise coupled, attached, formed, and/or joined together at a plurality of interstices 239. Accordingly, the braid 234 can also be referred to as a braided structure, a braided filament structure, a braided filament mesh structure, a mesh structure, a mesh filament structure, and the like. In some embodiments, the wires 238 can comprise metals, polymers, and/or composite materials. At least a portion of the wires 238 at the shaped portion 130 of the catheter 120 can be formed from a shape memory material, a shape memory alloy, and/or a shape memory polymer, such as nickel-titanium alloys (e.g., nitinol). In some embodiments, individual ones of the wires 238 can be rolled flat wires having a cross-sectional dimension of between about 0.001–0.005 inch (e.g., about 0.002 inch) by about 0.002–0.005 inch (e.g., about 0.0033 inch).

[0037] In the illustrated embodiment, the coil 336 is a single wire wound around the braid 234 and the inner liner 232. In other embodiments, the coil 336 can include more than one wire wound about the braid 234. For example, the coil 336 can include multiple wires wound over one another and/or multiple wires wound to at least partially overlap one another to form a

braided or overlapping coil structure on the braid 234. In other embodiments, the coil 336 can be formed directly over the inner liner 232, and the braid 234 can be formed over the coil 336. The coil 336 can be formed from a metallic or other suitably strong material, such as nickel-titanium alloys (e.g. nitinol), platinum, cobalt-chrome alloys, stainless steel, tungsten, and/or titanium. In some embodiments, the coil 336 can include a shape memory material at least at the shaped portion 130 of the catheter 120.

[0038] Figure 3C is an enlarged cross-sectional view of a portion of the distal region 126 of the catheter 120 taken along the line 3C-3C in Figure 3B in accordance with embodiments of the present technology. In the illustrated embodiment, the outer sheath 230 has a first thickness T_1, the coil 336 has a second thickness T_2 less than the first thickness T_1, the braid 234 has a third thickness T_3 less than the first thickness T_1 but greater than the second thickness T_2, and the inner liner 232 has a fourth thickness T_4 less than the first, second, and third thicknesses T_{1-3}. For example, the first thickness T_1 can be between about 0.005–0.010 inch (e.g., between about 0.006–0.007 inch, about 0.006 inch, about 0.007 inch), the second thickness T_2 can be between about 0.001–0.005 inch (e.g., about 0.003 inch), the third thickness T_3 can be between about 0.002–0.006 inch (e.g., about 0.004 inch), and the fourth thickness T_4 can be between about 0.001–0.004 inch (e.g., about 0.002 inch). In other embodiments, one or more of the first through fourth thicknesses T_{1-4} can be different.

[0039] In some embodiments, the catheter 120 can be formed about a mandrel or other elongate member. For example, the inner liner 232 can first be positioned about the mandrel. Then, the braid 234 can be formed (e.g., wound, braided) about the inner liner 232 around the mandrel. Next, the coil 336 can be wound around the mandrel about the braid 234 over the intermediate region 124 and the distal region 126 (e.g., of the inner liner 232 and the braid 234). In some embodiments, the marker band 129 can be positioned about the mandrel at the distal tip region 128. Next, the outer sheath 230 can be positioned over the inner liner 232, the braid 234, and the coil 336, and then heat shrunk or otherwise secured thereto. In some embodiments, the outer sheath 230 can be fused to the coil 336, the braid 234, and/or the inner liner 232 to secure these components of the catheter 120 together.

[0040] Finally, the shaped portion 130 of the catheter 120 can be shaped using a heat setting or other suitable process to have the curved shape illustrated in Figure 1, or another shape (e.g., any of the shapes shown in Figure 6). For example, as is known in the art of heat setting shape memory structures, a fixture, mandrel, or mold may be used to hold the shaped portion

130 in its desired shape, and then the shaped portion 130 can be subjected to an appropriate heat treatment such that the wires 238 of the braid 234 and/or the coil 336 assume or are otherwise shape-set to the outer contour of the mandrel or mold. In some embodiments, only the wires 238 of the braid 234 include a shape memory material that is shaped via the heat setting process. In other embodiments, the coil 336 can alternatively or additionally include a shape memory material that is shaped via the heat setting process. The heat setting process may be performed in an oven or fluidized bed, as is well-known. Therefore, the heat setting process can impart a desired shape, geometry, bend, and/or curve in the super-elastic and/or shape memory material or materials used to form the braid 234 and/or the coil 336. Accordingly, the shaped portion 130 may be radially constrained without plastic deformation (e.g., as shown in phantom in Figure 1) and will self-expand on release of the radial constraint to the position illustrated in Figure 1.

[0041] In some aspects of the present technology, the catheter 120 is configured to be steered to and positioned in difficult-to-reach regions of the anatomy (e.g., venous anatomy) of a patient while still having a relatively large size (e.g., 20 French, 24 French, greater than 24 French). More particularly, the catheter 120 can have an improved torque response and flexibility compared to conventional catheters having the same size. For example, the braid 234 can provide good torque response along the entire length of the catheter 120 because the braid 234 extends entirely through each of the regions 122–128 of the catheter 120. Moreover, the varying hardness (e.g., distally decreasing hardness) of the outer sheath 230 can provide (i) good torque response and/or pushability at the proximal region 122 and (ii) increased flexibility at the intermediate and distal regions 124, 126. Additionally, the shaped portion 130 is configured (e.g., shaped, sized, positioned) to flex into and be positioned within the difficult-to-reach regions of the anatomy. Further, the coil 336 can provide increased hoop strength at the distal region 126 while still allowing the catheter 120 to flex. For example, the coil 336 can inhibit or even prevent kinking or other unwanted movement of the catheter 120 when the lumen 121 is aspirated during a clot removal procedure.

[0042] Figures 4A and 4B are side views of the distal region 126 of the catheter 120 of the clot treatment system 100 during a procedure for removing clot material PE (e.g., a pulmonary embolism) from within a blood vessel BV (e.g., a pulmonary blood vessel) of a patient (e.g., a human patient) in accordance with embodiments of the present technology. As noted above, in some embodiments the clot removal procedure illustrated in Figures 4A and 4B can be generally similar or identical to any of the clot removal procedures disclosed in U.S. Patent Application No. 16/536,185, filed August 8, 2019, and titled "SYSTEM FOR TREATING EMBOLISM

AND ASSOCIATED DEVICES AND METHODS," which is incorporated herein by reference in its entirety.

[0043] With reference to Figures 1 and 4A together, the catheter 120 can be advanced through the patient to proximate the clot material PE with the blood vessel BV (e.g., advanced to a treatment site within the blood vessel BV). In some embodiments, the catheter 120 can be advanced through the blood vessel BV until the distal terminus 125 of the catheter 120 is positioned proximate to a proximal portion of the clot material PE. In some embodiments, the position of the distal terminus 125 can be confirmed or located via visualization of the marker band 129 using fluoroscopy or another imaging procedure (e.g., a radiographic procedure). In other embodiments, the distal terminus 125 can be positioned at least partially within the clot material PE or distal of the clot material PE.

[0044] In some aspects of the present technology, the shaped portion 130 helps the catheter 120 flex/bend into tortuous (e.g., hard-to-reach) regions of the blood vessel BV. For example, in the illustrated embodiment the shaped portion 130 has flexed around a bend 440 in the blood vessel BV that can have a relatively small radius of curvature. The portion of the blood vessel BV distal of the bend 440 can be difficult to reach due to the required approach angle, varying anatomy of the blood vessel BV, and/or irregularities due to illness of the patient. In some embodiments, the blood vessel BV can be a portion of left pulmonary artery, the temporal arteries, the inferior vena cava, or the right atrium. In some embodiments, the clot material PE can be a clot in transit (CIT) within the right atrium.

[0045] In some embodiments, before advancing the catheter 120 to the position shown in Figure 4A, the catheter 120 can be rotated to align the shaped portion 130 with the bend 440 (e.g., to at least generally align a deflection direction of the shaped portion 130 with the bend 440). In contrast to the catheter 120 of the present technology, conventional catheters of the same size may be too stiff to easily position proximate the clot material PE. For example, such conventional catheters may "rainbow" over the clot material PE by following or tracking along the wall of the blood vessel BV at the outside of the bend 400. In addition to the shaped portion 130, both (i) the varying hardness of the outer sheath 230 (Figures 2–3C) and (ii) the flexibility of the braid 234 (Figures 2–3C) and the coil 446 (Figures 3A–3C) can help the catheter 120 flex through the anatomy of the blood vessel BV to the desired position proximate the clot material PE.

[0046] Access to the pulmonary vessels can be achieved through the patient's vasculature, for example, via the femoral vein. In some embodiments, the clot treatment system 100 can include an introducer (e.g., a Y-connector with a hemostasis valve; not shown) that can be partially inserted into the femoral vein. A guidewire (not shown) can be guided into the femoral vein through the introducer and navigated through the right atrium, the tricuspid valve, the right ventricle, the pulmonary valve, and into the main pulmonary artery. Depending on the location of the clot material PE, the guidewire can be guided to one or more of the branches of the right pulmonary artery and/or the left pulmonary artery. In some embodiments, the guidewire can be extended entirely or partially through the clot material PE. In other embodiments, the guidewire can be extended to a location just proximal of the clot material PE. After positioning the guidewire, the catheter 120 can be placed over the guidewire and advanced to the position proximate to the clot material PE as illustrated in Figure 4A. In some embodiments, the guidewire can then be withdrawn while, in other embodiments, the guidewire can remain and can be used to guide other catheters (e.g., delivery catheters, additional aspiration guide catheters), interventional devices, etc., to the treatment site. It will be understood, however, that other access locations into the venous circulatory system of a patient are possible and consistent with the present technology. For example, the user can gain access through the jugular vein, the subclavian vein, the brachial vein, or any other vein that connects or eventually leads to the superior vena cava. Use of other vessels that are closer to the right atrium of the patient's heart can also be advantageous as it reduces the length of the instruments needed to reach the clot material PE.

[0047] With reference to Figures 1 and 4B together, the pressure source 106 is configured to generate (e.g., form, create, charge, build-up) a vacuum (e.g., negative relative pressure) and store the vacuum for subsequent application to the catheter 120. For example, after positioning the catheter 120 proximate the clot material PE, a user can first close the fluid control device 114 before generating the vacuum in the pressure source 106 by, for example, withdrawing the plunger of a syringe coupled to the connector 116. In this manner, a vacuum is charged within the pressure source 106 (e.g., a negative pressure is maintained) before the pressure source 106 is fluidly connected to the lumen 121 of the catheter 120. To aspirate the lumen 121 of the catheter 120, the user can open the fluid control device 114 to fluidly connect the pressure source 106 to the catheter 120 and thereby apply or release the vacuum stored in the pressure source 106 to the lumen 121 of the catheter 120.

[0048] Opening of the fluid control device 114 instantaneously or nearly instantaneously applies the stored vacuum pressure to the tubing assembly 110 and the catheter 120, thereby generating a suction pulse throughout the catheter 120. In particular, the suction is applied at the distal tip region 128 of the catheter 120 to suck/aspirate at least a portion of the clot material PE into the lumen 121 of the catheter 120, as shown in Figure 4B. In one aspect of the present technology, pre-charging or storing the vacuum in the pressure source 106 before applying the vacuum to the lumen 121 of the catheter 120 is expected to generate greater suction forces and corresponding fluid flow velocities at and/or near the distal tip region 128 of the catheter 120 compared to simply activating the pressure source 106 while it is fluidly connected to the catheter 120.

[0049] Sometimes, as shown in Figure 4B, discharging the vacuum stored in the pressure source to aspirate the lumen 121 of the catheter 120 may remove substantially all (e.g., a desired amount) of the clot material PE from the blood vessel BV. That is, a single aspiration pulse may adequately remove the clot material PE from the blood vessel BV. In other embodiments, a portion of the clot material PE may remain in the blood vessel BV. In such instances, the user may wish to again apply vacuum pressure (conduct an "aspiration pass") to remove all or a portion of the remaining clot material PE in the blood vessel BV. In such instances, the pressure source 106 can be disconnected from the tubing assembly 110 and drained (e.g., aspirated clot removal removed) before the pressure source 106 is reconnected to the tubing assembly 110 and activated once again. After removing a desired amount of the clot material PE, the catheter 120 can be withdrawn from the patient.

[0050] In some aspects of the present technology, the relatively great flexibility and torquability of the catheter 120 allow the catheter 120 to be positioned in difficult-to-reach areas of the blood vessel BV (or elsewhere in the vasculature of the patient) without reducing the size of the lumen 121. It is expected that the increased size of the lumen 121 will provide greater suction forces over a smaller period of time (e.g., will provide a larger vacuum impulse). In some embodiments, the greater suction forces can facilitate the removal of clot material from a blood vessel of a patient even where the clot material is strongly lodged or attached within the blood vessel (e.g., a chronic clot). Accordingly, in contrast to conventional catheters, the catheter 120 can be used to generate greater aspirational forces for improved clot removal in hard-to-reach places of the vasculature. In additional aspects of the present technology, the coil 336 (Figures 3A–3C) can provide a high hoop strength along the distal region 126 of the catheter 120 that inhibits or even prevents kinking or other unwanted movement of the catheter 120 when

the pressure source 106 is used to generate a suction pulse at the distal region 126 of the catheter 120.

[0051] Figures 5A and 5B are side views of the distal region 126 of the catheter 120 of the clot treatment system 100 during another procedure for removing the clot material PE from within the blood vessel BV in accordance with additional embodiments of the present technology. As noted above, in some embodiments the clot removal procedure illustrated in Figures 5A and 5B can be generally similar or identical to any of the clot removal procedures disclosed in U.S. Patent Application No. 16/536,185, filed August 8, 2019, and titled "SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED DEVICES AND METHODS," which is incorporated herein by reference in its entirety.

[0052] Referring first to Figure 5A, the catheter 120 ("first catheter 120") can be advanced through the patient to proximate the clot material PE with the blood vessel BV as described in detail above with reference to Figure 4A. As shown in Figure 5A, in some embodiments a second catheter 550 can then be advanced over the first catheter 120 to proximate the clot material PE. The second catheter 550 can define a lumen 552 having a larger size (e.g., 20 French or greater, 24 French or greater) than the lumen 121 of the first catheter 120. In some embodiments, the second catheter 550 has a greater stiffness than the first catheter 120. In other embodiments, the second catheter 550 can be larger than but generally similar or identical to the first catheter 120 (e.g., having a distal heat-set shaped portion).

[0053] Accordingly, the first catheter 120 can act as a guide or rail for guiding the advancement of the second catheter 550 to proximate the clot material PE. In some aspects of the present technology, the larger size and/or stiffness of the second catheter 550 could make the second catheter 550 difficult to navigate to proximate the clot material PE (e.g., across the bend 440) without the first catheter 120 acting as a guide. That is, the first catheter 120 can be flexibly positioned proximate the clot material PE and used to guide the larger and/or stiffer second catheter 550 into a position it would otherwise be difficult or impossible to do so.

[0054] The second catheter 550 can be part of a clot treatment system (not shown) having features generally similar or identical to that of the clot treatment system 100 of Figure 1 including, for example, a fluid control device and a pressure source. Accordingly, with reference to Figure 5B, the pressure source can be used to generate a vacuum in the lumen 552 of the second catheter, and the fluid control device can be opened to fluidly connect the pressure source to the second catheter 550 and thereby apply or release the vacuum stored in the pressure source

to the lumen 552 of the second catheter 550. Opening of the fluid control device instantaneously or nearly instantaneously applies the stored vacuum pressure to the second catheter 550, thereby generating a suction pulse throughout the second catheter 550 that can suck at least a portion of the clot material PE into the lumen 552 of the second catheter 550. In some embodiments, the clot treatment system 100 (Figure 1) can also be operated to aspirate the clot material PE into the lumen 121 of the lumen 121 of the first catheter 120, as described in detail above with reference to Figures 4A and 4B. In some aspects of the present technology, the larger size of the lumen 552 of the second catheter 550 can be used to generate greater suction forces than the smaller lumen 121 of the first catheter 120. After removing a desired amount of the clot material PE, the first and second catheters 120, 550 can be withdrawn from the patient.

[0055] Referring to Figures 4A–5B together, in some embodiments one or more additional devices can be advanced through the catheter 120. For example, one or more aspiration catheters, mechanical thrombectomy devices, and/or the like can be advanced through the catheter 120 to proximate the clot material PE to aid in the clot removal process. In some such embodiments, the shaped portion 130 can facilitate the advancement of the one or more additional devices through the catheter 120. For example, the one or more additional devices can track through the shaped portion 130 of the catheter 120 to at and/or proximate the clot material PE.

[0056] Figures 7A–7C are side views of a distal portion of a clot treatment system 700 in accordance with embodiments of the present technology. Referring to Figures 7A–7C together, the clot treatment system 700 can include some features that are least at generally similar in structure and function, or identical in structure and function, to the corresponding features of the clot treatment system 100 described in detail above with reference to Figures 1–6, and can operate in a generally similar or identical manner to the clot treatment system 100. In the illustrated embodiment, for example, the clot treatment system 700 includes a first catheter 720 (e.g., a pre-shaped catheter) that can be advanced through a larger second catheter 750. The first catheter 720 can have a shaped distal portion 730 (obscured in Figure 7A) including a distal tip or terminus 725. In some embodiments the first catheter 720 has a size of about 20 French or greater than 20 French, and the second catheter 750 has a size of about 24 French or greater than 24 French.

[0057] Figures 7A–7C illustrate the sequential deployment of the shaped distal portion 730 from within the second catheter 750. More specifically, the shaped distal portion 730 is (i)

positioned substantially within and constrained by the second catheter 750 in Figure 7A, (ii) positioned partially within and partially outside the second catheter 750 in Figure 7B, and (iii) positioned substantially outside of (e.g., distal of) and constrained by the second catheter 750 in Figure 7C. In the illustrated embodiment, the shaped distal portion 730 is configured (e.g., heat set) to deflect away from a longitudinal axis Z (Figures 7A) of the first and second catheters 720, 750 to have a generally curved shape. In some embodiments, the shaped distal portion 730 can deflect by an angle A of between about between about 250–290 degrees (e.g., about 255 degrees, about 260 degrees, about 270 degrees) when fully unconstrained by the second catheter 750 as shown in Figure 7C. The shaped distal portion 730 can be deployed from the second catheter 750 via advancement of the first catheter 720 relative to the second catheter 750 and/or retraction of the second catheter 750 relative to the first catheter 720. That is, for example, the second catheter 750 can be retracted off of the shaped distal portion 730 such that the shaped distal portion 730 is no longer constrained by the second catheter 750 and thereby able to deflect away from the longitudinal axis Z as shown in Figure 7C.

[0058] Several aspects of the present technology are set forth in the following examples:

1. An aspiration catheter, comprising:

an inner liner defining a lumen and having a proximal region and a distal region;

a braid of wires over the inner liner, wherein a deflectable portion of the braid over at least a portion of the distal region of the inner liner is configured to deflect away from a longitudinal axis of the proximal region when the aspiration catheter is unconstrained;

a wire coiled over at least a portion of the distal region of the inner liner; and

an outer sheath over the braid, the wire, and the inner liner.

2. The aspiration catheter of example 1 wherein the wires in the deflectable portion of the braid is pre-shaped to deflect away from the longitudinal axis.

3. The aspiration catheter of example 1 or example 2 wherein the deflectable portion of the braid is configured to deflect away from the longitudinal axis to have a bend angle of between about between about 165–195 degrees when the aspiration catheter is unconstrained.

4. The aspiration catheter of example 1 or example 2 wherein the deflectable portion of the braid is configured to deflect away from the longitudinal axis to have a bend angle of between about 270 degrees when the aspiration catheter is unconstrained.

5. The aspiration catheter of any one of examples 1–4 wherein the lumen has a diameter of 20 French or greater.

6. The aspiration catheter of any one of examples 1–5 wherein the lumen has a diameter of 24 French or greater.

7. The aspiration catheter of any one of examples 1–6 wherein the inner liner is formed from polytetrafluoroethylene material, and wherein the outer sheath is formed from a thermoplastic elastomer material.

8. The aspiration catheter of any one of examples 1–7 wherein the outer sheath has a first hardness over the proximal region of the inner liner, and wherein the outer sheath has a second hardness over the distal region of the inner liner that is less than the first hardness.

9. An aspiration catheter, comprising:

a proximal region defining a longitudinal axis;

an intermediate region extending from the proximal region;

a distal region extending from the intermediate region;

an inner lining defining a lumen and extending through the proximal region, the intermediate region, and the distal region;

a braid of wires extending over the inner liner and through the proximal region, the intermediate region, and the distal region, wherein a deflectable portion of the braid in the distal region is configured to deflect away from the longitudinal axis when the aspiration catheter is unconstrained;

a wire coiled in the distal region; and

an outer sheath extending over the braid, the wire, and the inner liner and through the proximal region, the intermediate region, and the distal region.

10. The aspiration catheter of example 9 wherein the deflectable portion of the braid is configured to deflect away from the longitudinal axis to have a bend angle of between about between about 165–195 degrees when the aspiration catheter is unconstrained.

11. The aspiration catheter of example 9 or example 10 wherein the outer sheath has (a) a first hardness in the proximal region of between about 65D–75D, (b) a second hardness in the intermediate region of between about 50D–60D, and (c) a third hardness in the distal region of between about 30D–40D.

12. The aspiration catheter of any one of examples 9–11 wherein the outer sheath has (a) a first hardness in the proximal region, (b) a second hardness in the intermediate region less than the first hardness, and (c) a third hardness in the distal region less than the second hardness.

13. The aspiration catheter of example 12 wherein (a) the proximal region has a first length, (b) the intermediate region has a second length less than the first length, and (c) the distal region has a third length greater than the second length and less than the first length.

14. The aspiration catheter of example 13 wherein the first length is between about 20.0–28.0 inches, the second length is between about 2.0–3.0 inches, and the third length is between about 11.00–15.00 inches.

15. A method of removing clot material from a blood vessel, the method comprising:

advancing an aspiration catheter through the blood vessel, wherein the aspiration catheter includes a distal portion and a proximal portion, wherein the distal portion is configured to deflect away from a longitudinal axis of the proximal portion;

positioning a distal tip of the aspiration catheter proximate the clot material;

activating a pressure source coupled to the aspiration catheter via a fluid control device, while the fluid control device is closed, to generate a vacuum in the pressure source; and

opening the fluid control device to apply the vacuum to the aspiration catheter to thereby aspirate at least a portion of the clot material into the aspiration catheter.

16. The method of example 15 wherein the distal portion of the aspiration catheter is configured to deflect away from the longitudinal axis in a deflection direction, and wherein the method further comprises rotating the aspiration catheter such that the deflection direction is at least partially aligned with a bend in the blood vessel.

17. The method of example 15 or example 16 wherein the aspiration catheter has a size of 20 French or greater.

18. The method of any one of examples 15–17 wherein the distal portion of the aspiration catheter is configured to deflect away from the longitudinal axis to have a bend angle of between about between about 165–195 degrees when the aspiration catheter is unconstrained.

19. The method of any one of examples 15–17 wherein the distal portion of the aspiration catheter is configured to deflect away from the longitudinal axis to have a bend angle of about 270 degrees when the aspiration catheter is unconstrained.

20. The method of any one of examples 15–19 wherein the distal portion of the aspiration catheter includes—

an inner liner defining a lumen;

a braid of wires extending over the inner liner;

a wire coiled around the braid; and

an outer sheath extending over the braid.

[0059] The above detailed descriptions of embodiments of the technology are not intended to be exhaustive or to limit the technology to the precise form disclosed above. Although specific embodiments of, and examples for, the technology are described above for illustrative purposes, various equivalent modifications are possible within the scope of the technology as those skilled in the relevant art will recognize. For example, although steps are presented in a given order, alternative embodiments may perform steps in a different order. The various embodiments described herein may also be combined to provide further embodiments.

[0060] From the foregoing, it will be appreciated that specific embodiments of the technology have been described herein for purposes of illustration, but well-known structures and functions have not been shown or described in detail to avoid unnecessarily obscuring the

description of the embodiments of the technology. Where the context permits, singular or plural terms may also include the plural or singular term, respectively.

[0061] Moreover, unless the word "or" is expressly limited to mean only a single item exclusive from the other items in reference to a list of two or more items, then the use of "or" in such a list is to be interpreted as including (a) any single item in the list, (b) all of the items in the list, or (c) any combination of the items in the list. Additionally, the term "comprising" is used throughout to mean including at least the recited feature(s) such that any greater number of the same feature and/or additional types of other features are not precluded. It will also be appreciated that specific embodiments have been described herein for purposes of illustration, but that various modifications may be made without deviating from the technology. Further, while advantages associated with some embodiments of the technology have been described in the context of those embodiments, other embodiments may also exhibit such advantages, and not all embodiments need necessarily exhibit such advantages to fall within the scope of the technology. Accordingly, the disclosure and associated technology can encompass other embodiments not expressly shown or described herein.

CLAIMS

I/We claim:

1. An aspiration catheter, comprising:

an inner liner defining a lumen and having a proximal region and a distal region;

a braid of wires over the inner liner, wherein a deflectable portion of the braid over at least a portion of the distal region of the inner liner is configured to deflect away from a longitudinal axis of the proximal region when the aspiration catheter is unconstrained;

a wire coiled over at least a portion of the distal region of the inner liner; and

an outer sheath over the braid, the wire, and the inner liner.

2. The aspiration catheter of claim 1 wherein the wires in the deflectable portion of the braid is pre-shaped to deflect away from the longitudinal axis.

3. The aspiration catheter of claim 1 wherein the deflectable portion of the braid is configured to deflect away from the longitudinal axis to have a bend angle of between about between about 165–195 degrees when the aspiration catheter is unconstrained.

4. The aspiration catheter of claim 1 wherein the deflectable portion of the braid is configured to deflect away from the longitudinal axis to have a bend angle of between about 270 degrees when the aspiration catheter is unconstrained.

5. The aspiration catheter of claim 1 wherein the lumen has a diameter of 20 French or greater.

6. The aspiration catheter of claim 1 wherein the lumen has a diameter of 24 French or greater.

7. The aspiration catheter of claim 1 wherein the inner liner is formed from polytetrafluoroethylene material, and wherein the outer sheath is formed from a thermoplastic elastomer material.

8. The aspiration catheter of claim 1 wherein the outer sheath has a first hardness over the proximal region of the inner liner, and wherein the outer sheath has a second hardness over the distal region of the inner liner that is less than the first hardness.

9. An aspiration catheter, comprising:

a proximal region defining a longitudinal axis;

an intermediate region extending from the proximal region;

a distal region extending from the intermediate region;

an inner lining defining a lumen and extending through the proximal region, the intermediate region, and the distal region;

a braid of wires extending over the inner liner and through the proximal region, the intermediate region, and the distal region, wherein a deflectable portion of the braid in the distal region is configured to deflect away from the longitudinal axis when the aspiration catheter is unconstrained;

a wire coiled in the distal region; and

an outer sheath extending over the braid, the wire, and the inner liner and through the proximal region, the intermediate region, and the distal region.

10. The aspiration catheter of claim 9 wherein the deflectable portion of the braid is configured to deflect away from the longitudinal axis to have a bend angle of between about between about 165–195 degrees when the aspiration catheter is unconstrained.

11. The aspiration catheter of claim 9 wherein the outer sheath has (a) a first hardness in the proximal region of between about 65D–75D, (b) a second hardness in the intermediate region of between about 50D–60D, and (c) a third hardness in the distal region of between about 30D–40D.

12. The aspiration catheter of claim 9 wherein the outer sheath has (a) a first hardness in the proximal region, (b) a second hardness in the intermediate region less than the first hardness, and (c) a third hardness in the distal region less than the second hardness.

13. The aspiration catheter of claim 12 wherein (a) the proximal region has a first length, (b) the intermediate region has a second length less than the first length, and (c) the distal region has a third length greater than the second length and less than the first length.

14. The aspiration catheter of claim 13 wherein the first length is between about 20.0–28.0 inches, the second length is between about 2.0–3.0 inches, and the third length is between about 11.00–15.00 inches.

15. A method of removing clot material from a blood vessel, the method comprising:

advancing an aspiration catheter through the blood vessel, wherein the aspiration catheter includes a distal portion and a proximal portion, wherein the distal portion is configured to deflect away from a longitudinal axis of the proximal portion;

positioning a distal tip of the aspiration catheter proximate the clot material;

activating a pressure source coupled to the aspiration catheter via a fluid control device, while the fluid control device is closed, to generate a vacuum in the pressure source; and

opening the fluid control device to apply the vacuum to the aspiration catheter to thereby aspirate at least a portion of the clot material into the aspiration catheter.

16. The method of claim 15 wherein the distal portion of the aspiration catheter is configured to deflect away from the longitudinal axis in a deflection direction, and wherein the method further comprises rotating the aspiration catheter such that the deflection direction is at least partially aligned with a bend in the blood vessel.

17. The method of claim 15 wherein the aspiration catheter has a size of 20 French or greater.

18. The method of claim 15 wherein the distal portion of the aspiration catheter is configured to deflect away from the longitudinal axis to have a bend angle of between about between about 165–195 degrees when the aspiration catheter is unconstrained.

19. The method of claim 15 wherein the distal portion of the aspiration catheter is configured to deflect away from the longitudinal axis to have a bend angle of about 270 degrees when the aspiration catheter is unconstrained.

20. The method of claim 15 wherein the distal portion of the aspiration catheter includes—

an inner liner defining a lumen;

a braid of wires extending over the inner liner;

a wire coiled around the braid; and

an outer sheath extending over the braid.

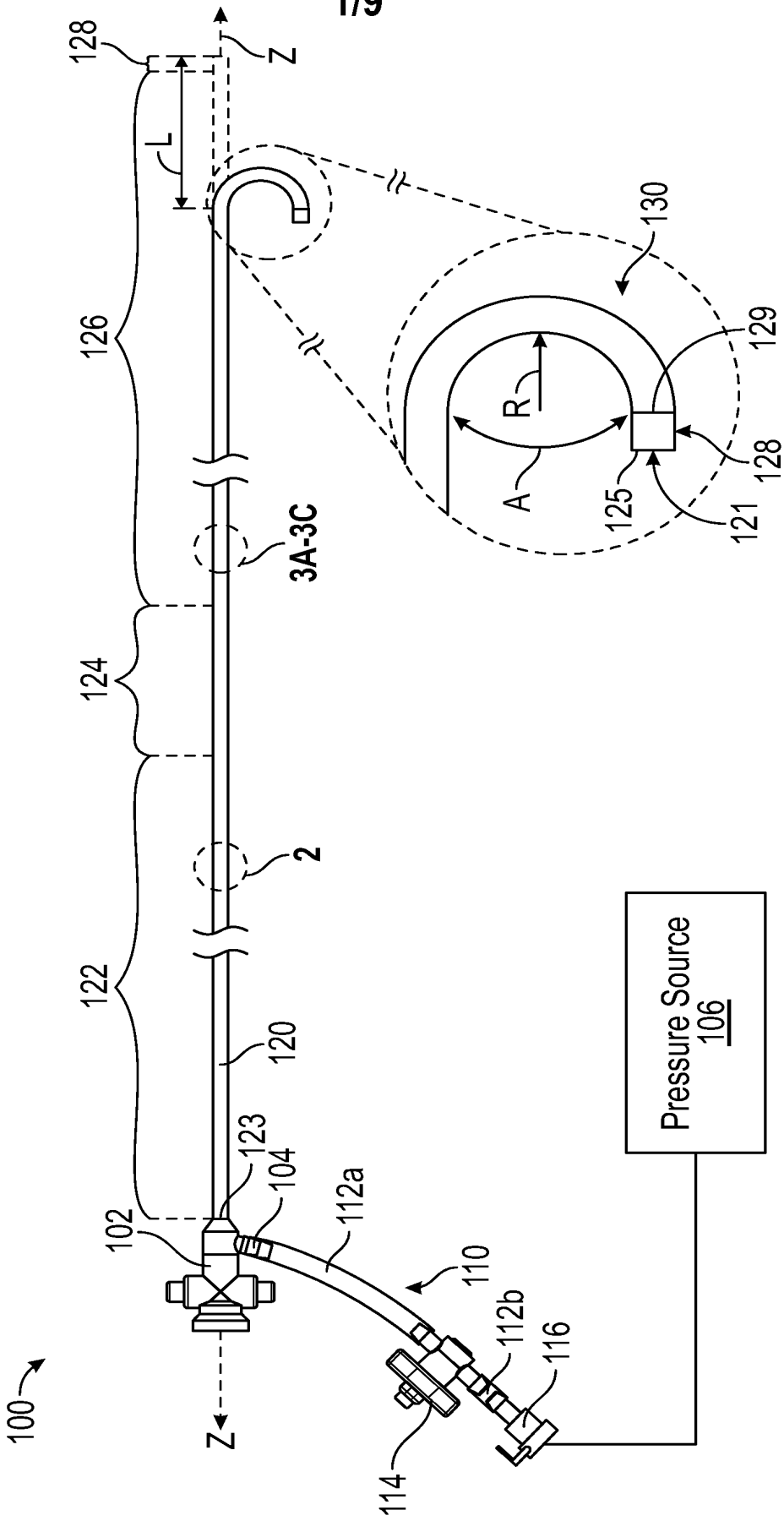

128
Z
L
126
130
129
R
A
125
121
128
3A-3C
124
2
122
120
123
104
112a
102
110
112b
116
114
100
Z
Pressure Source
106

FIG. 1

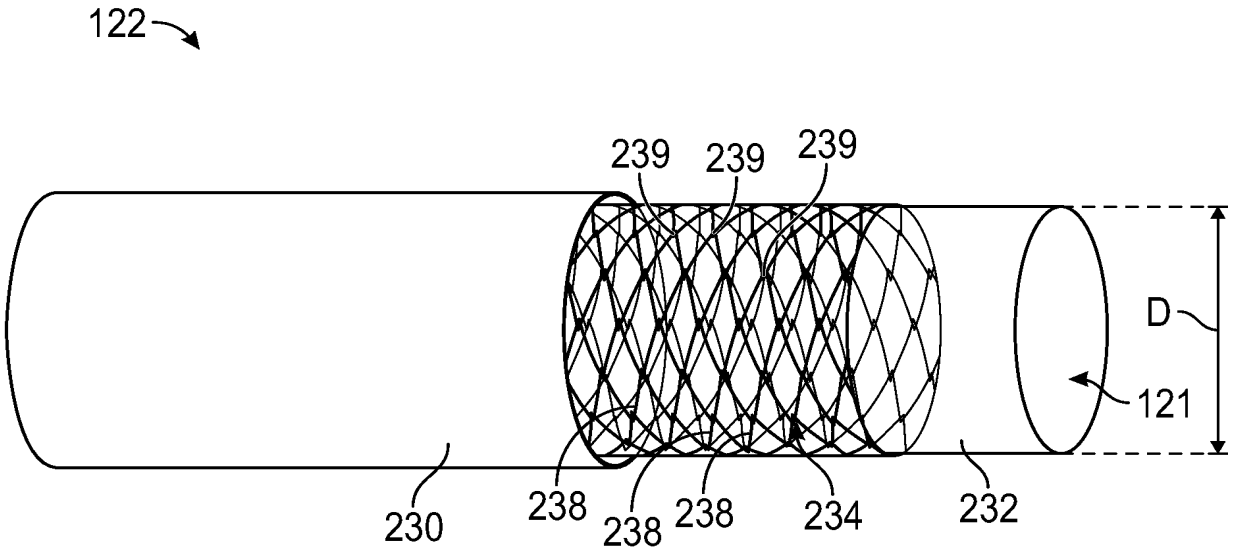

122
239
239
239
D
121
230
238
238
238
234
232

FIG. 2

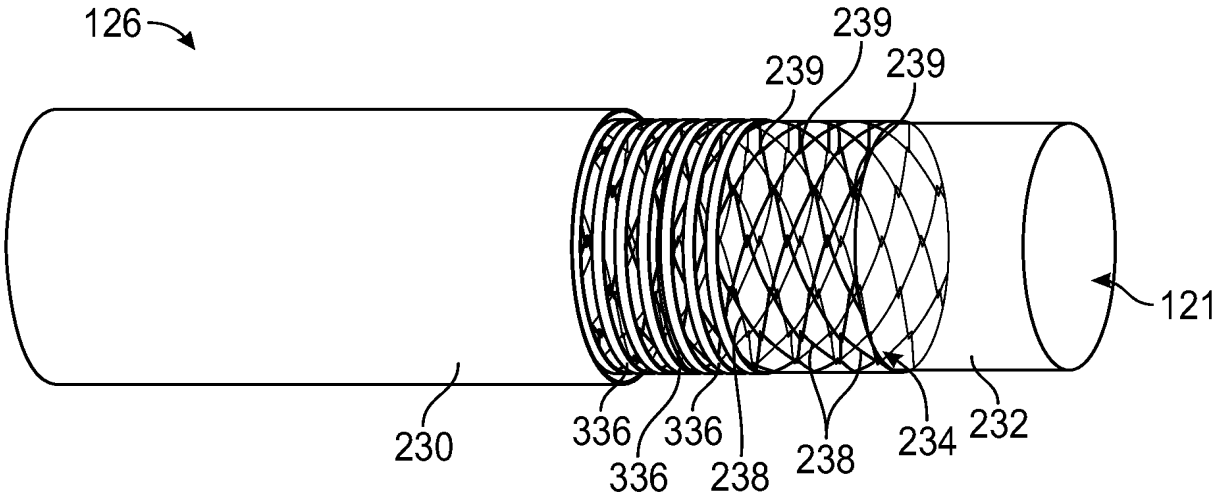

126
239
239
239
121
230
336
336
336
238
238
234
232

FIG. 3A

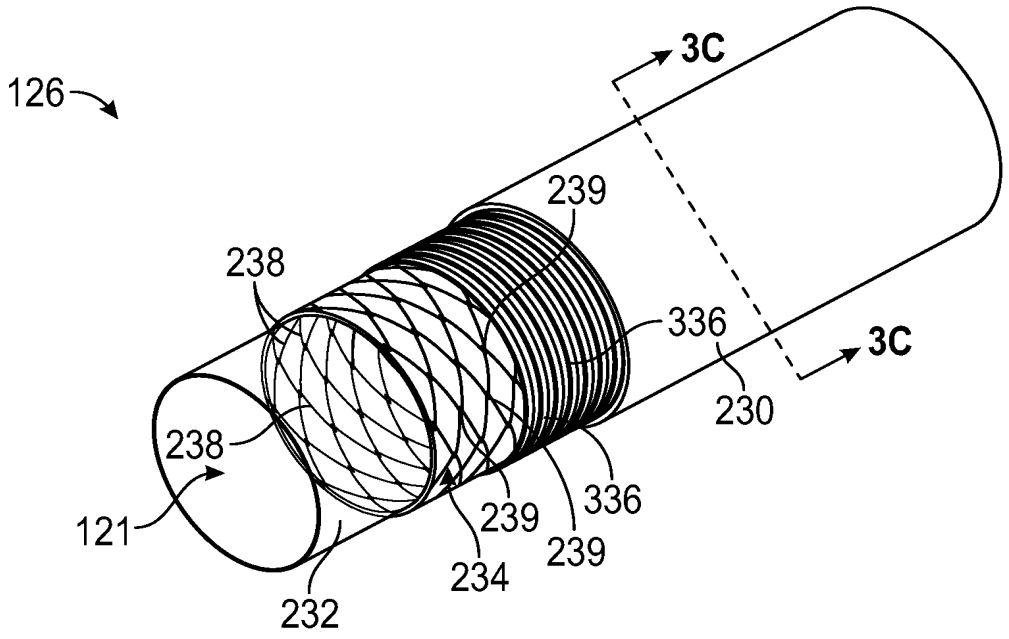

126
3C
239
238
336
3C
230
238
121
239
336
239
234
232

FIG. 3B

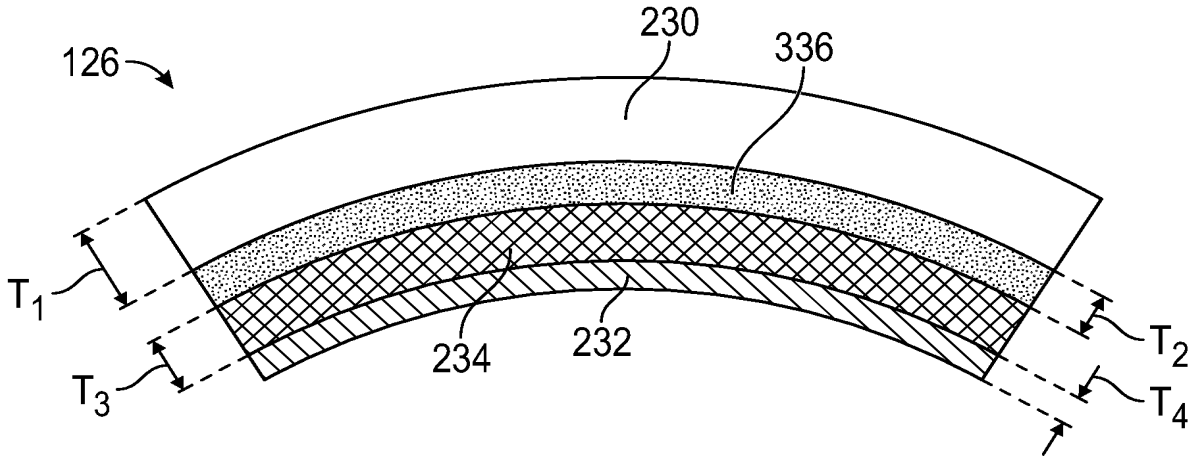

126
230
336
T_1
T_3
234
232
T_2
T_4

FIG. 3C

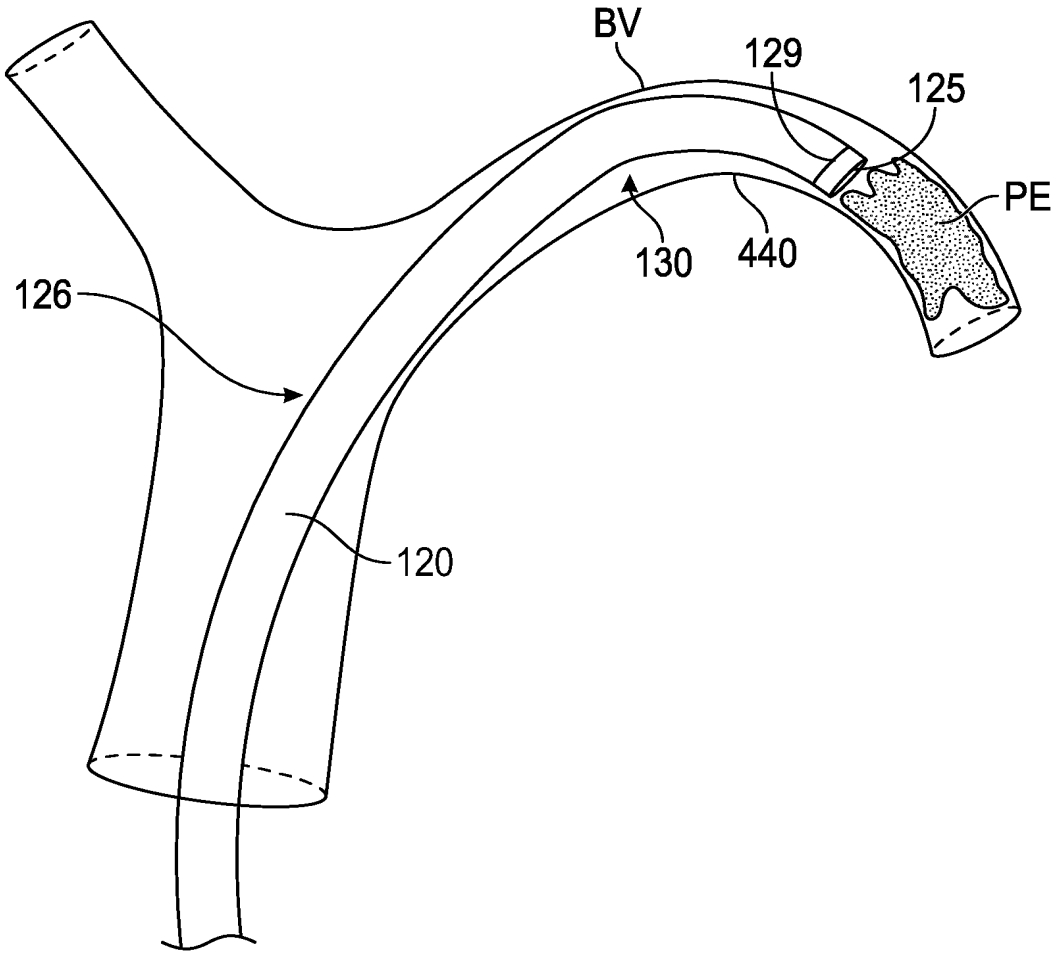


FIG. 4A

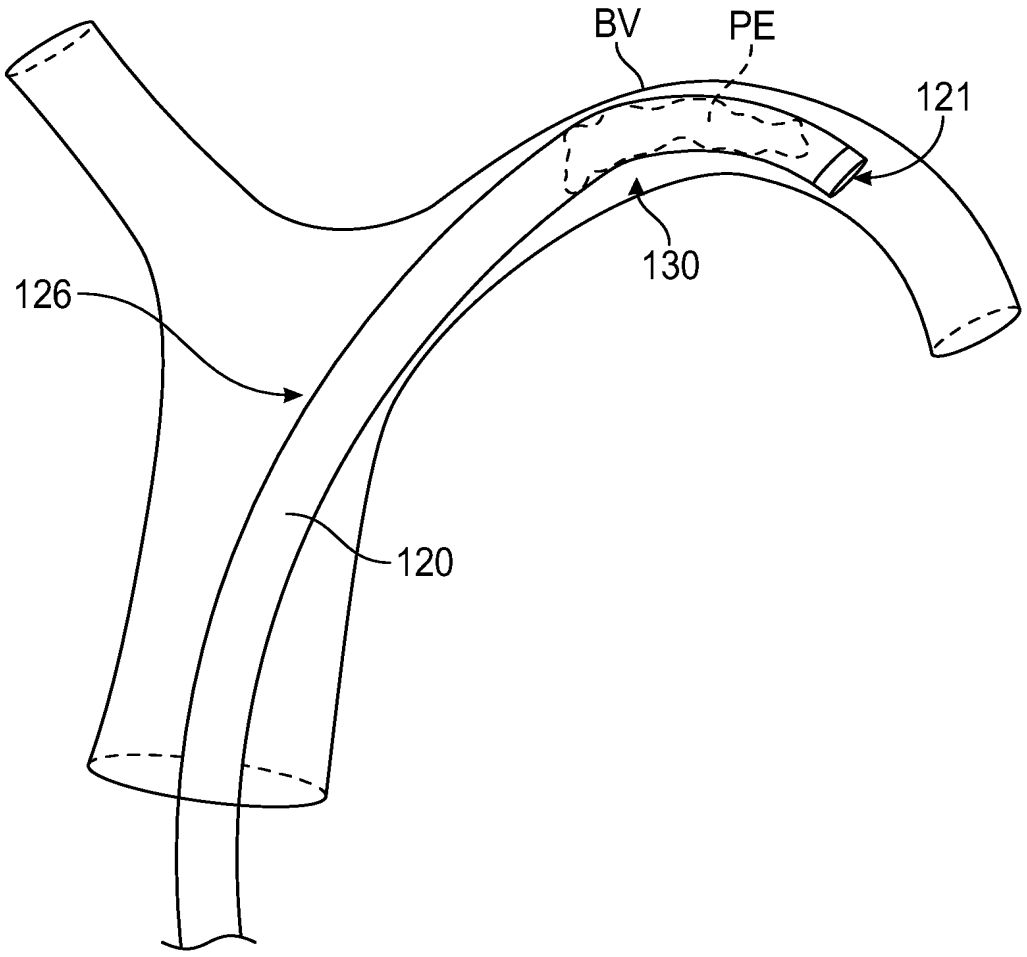


FIG. 4B

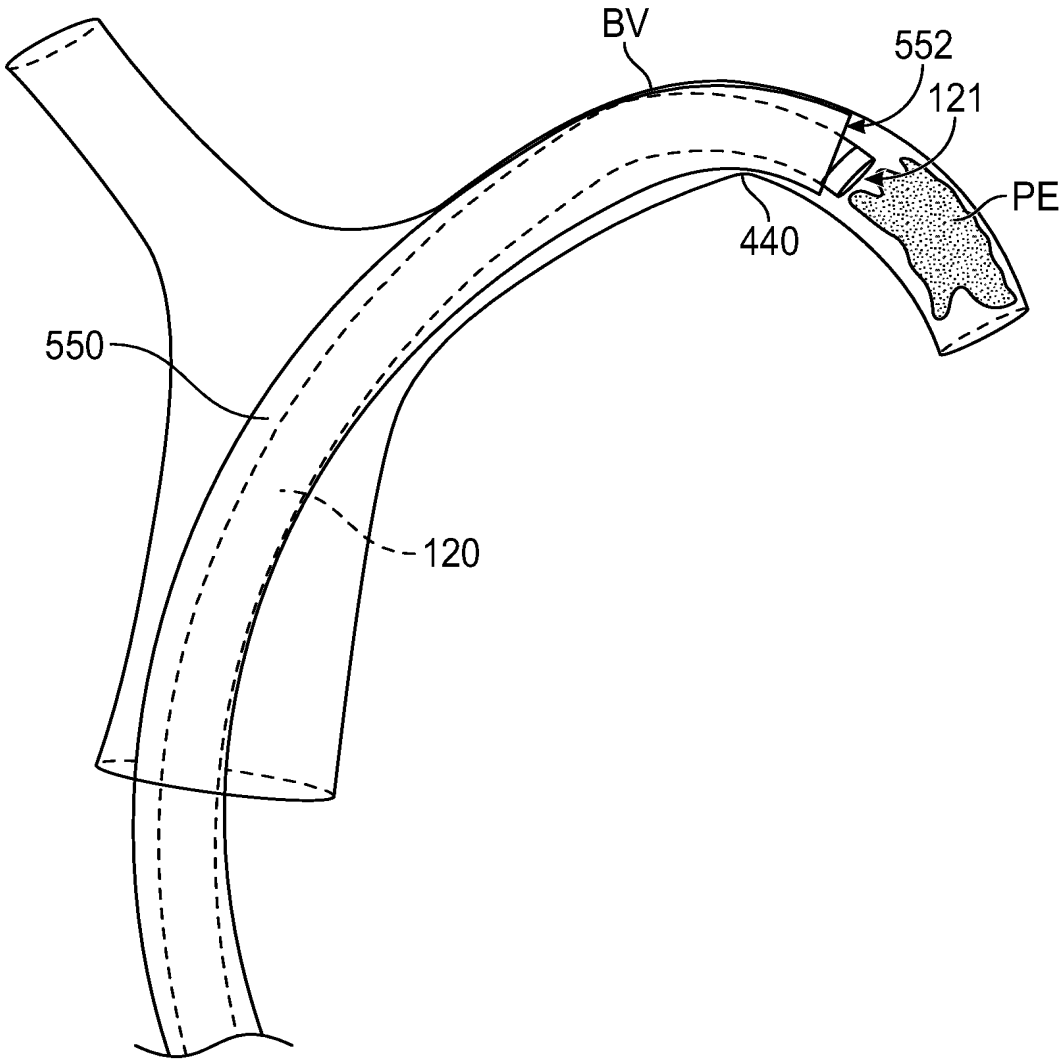


FIG. 5A

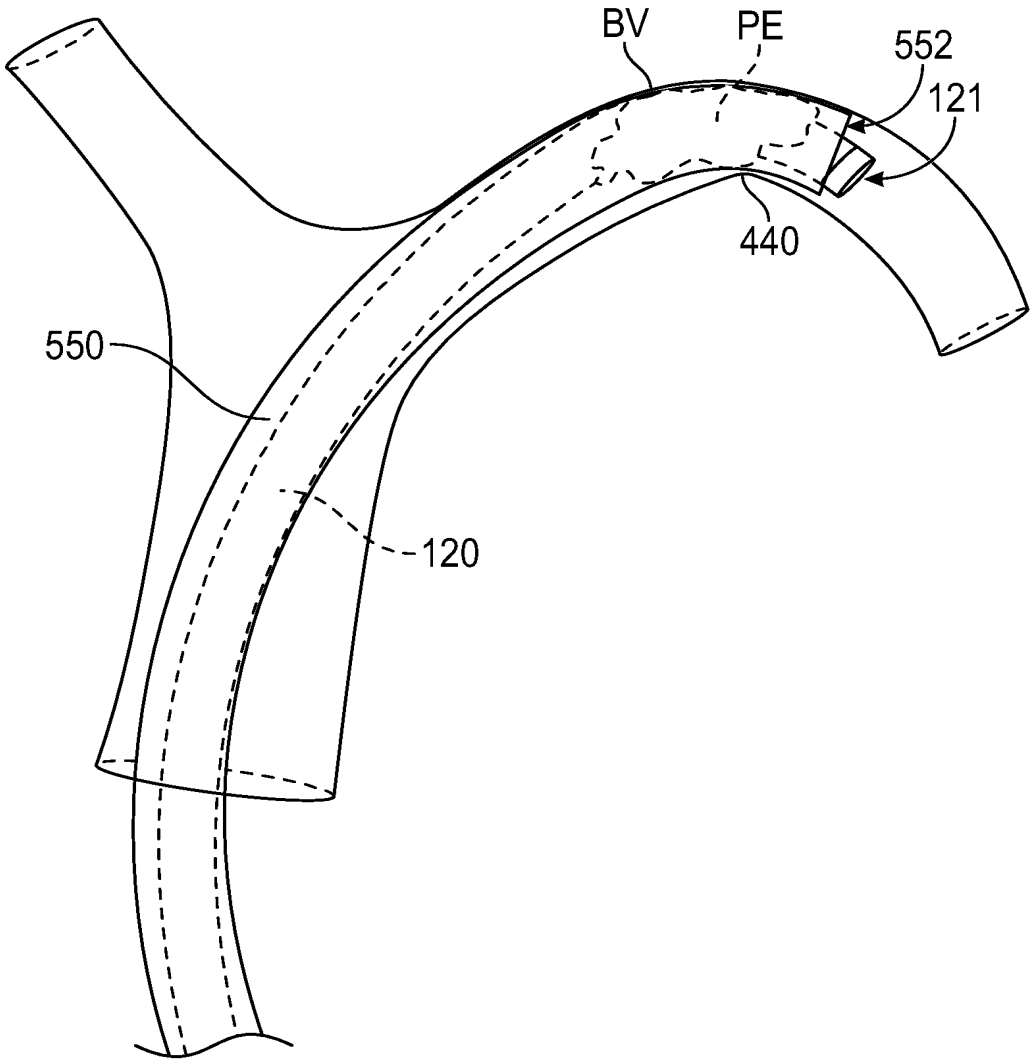


FIG. 5B

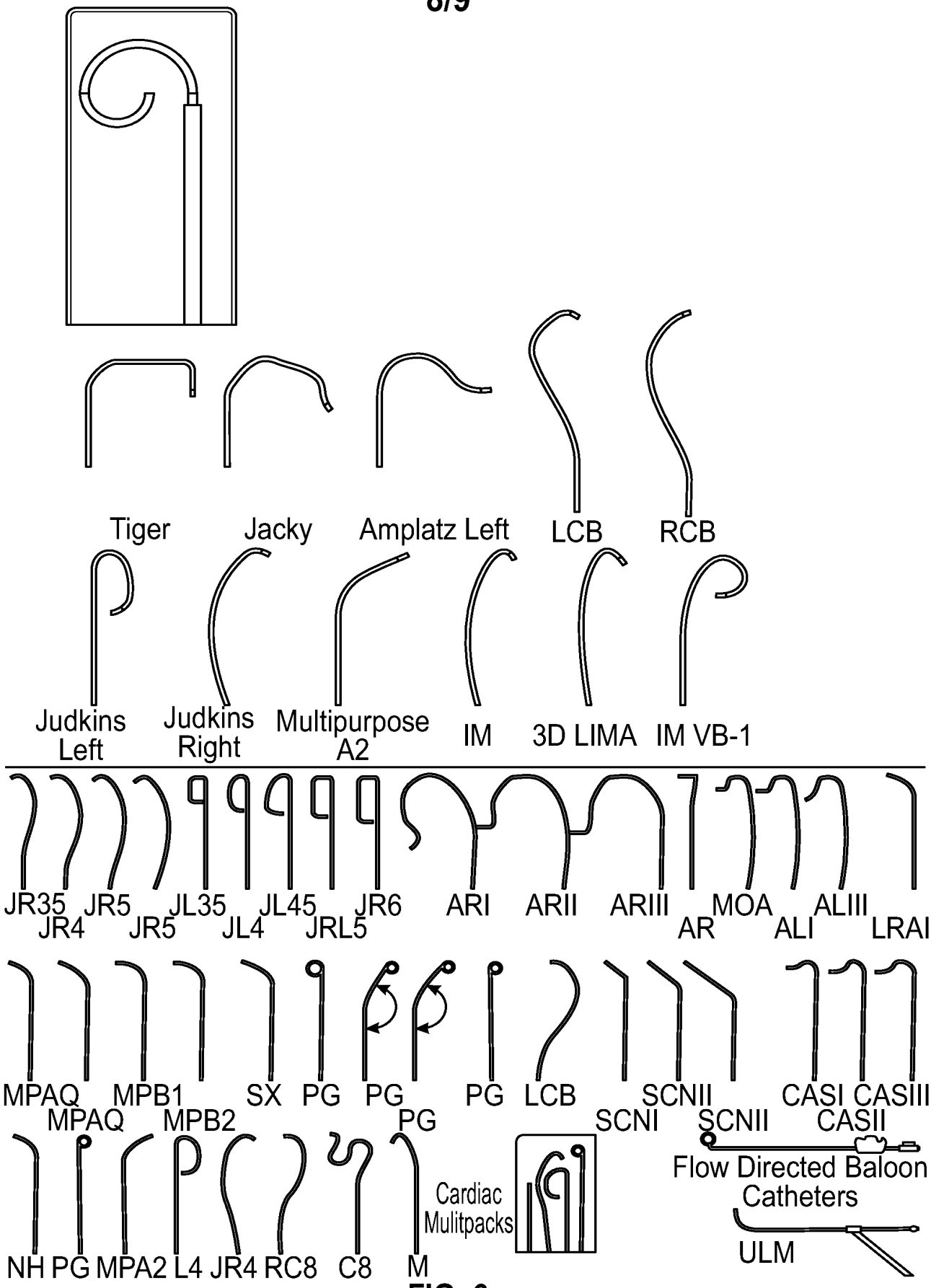

Tiger
Jacky
Amplatz Left
LCB
RCB
Judkins Left
Judkins Right
Multipurpose A2
IM
3D LIMA
IM VB-1
JR35
JR4
JR5
JR5
JL35
JL4
JL45
JRL5
JR6
ARI
ARII
ARIII
AR
MOA
ALI
ALIII
LRAI
MPAQ
MPAQ
MPB1
MPB2
SX
PG
PG
PG
PG
LCB
SCNI
SCNII
SCNII
CASI
CASII
CASIII
NH
PG
MPA2
L4
JR4
RC8
C8
M
Cardiac Mulitpacks
Flow Directed Baloon Catheters
ULM

FIG. 6

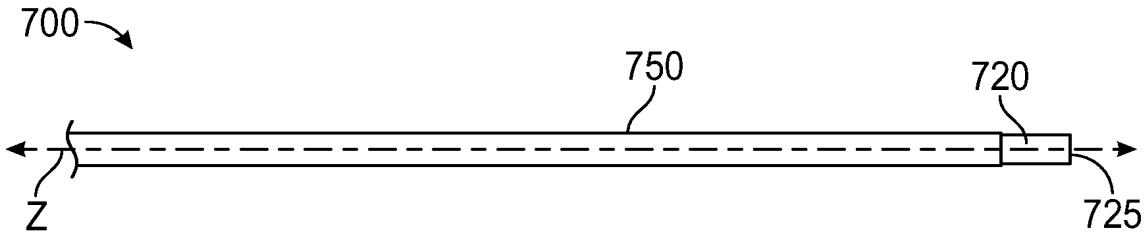


FIG. 7A

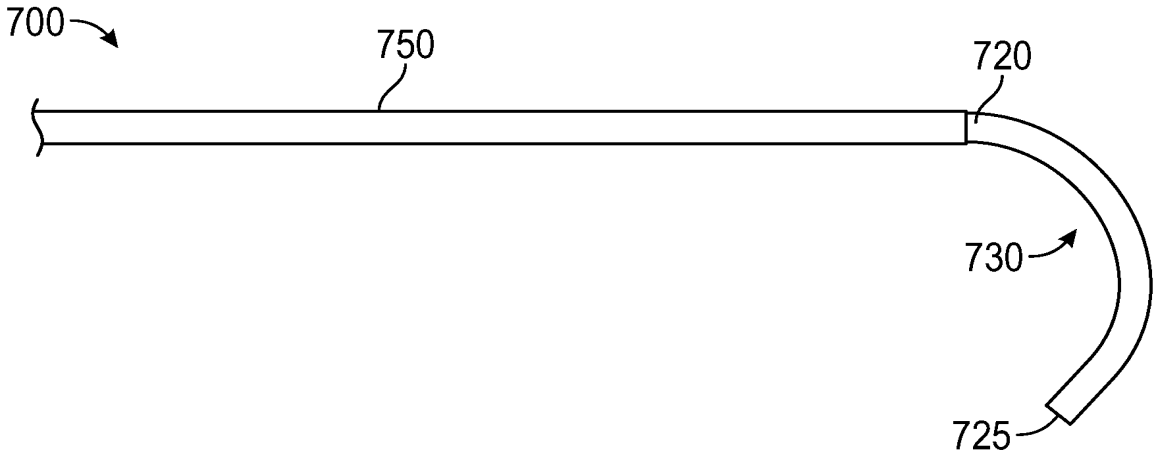


FIG. 7B



FIG. 7C

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 21/59718

A. CLASSIFICATION OF SUBJECT MATTER
IPC - A61M 25/00; A61B 17/22 (2022.01)
CPC - A61M 25/0041; A61M 25/0045

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.
Y	CN 110652645 A (Shanghai Warbey Medical Technology Co Ltd) 07 January 2020 (07.01.2020), entire document, especially	1-14
Y	US 2006/0074401 A1 (Ross) 06 April 2006 (06.04.2006), entire document, especially	1-14
A	US 2016/0151605 A1 (GMEDIX, INC.) 02 June 2016 (02.06.2016), entire document	1-14
A	US 2013/0197454 A1 (Terumo Kabushiki Kaisha) 01 August 2013 (01.08.2013), entire document	1-14

☐ 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
03 March 2022	MAR 22 2022
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 Kari Rodriquez Telephone No. PCT Helpdesk: 571-272-4300

Form PCT/ISA/210 (second sheet) (July 2019)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 21/59718

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:
This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I: Claims 1-14 directed to an aspiration catheter.

Group II: Claims 15-20 directed to a method of removing clot material from a blood vessel.

-*-Continued in Supplemental Box-*-

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
1-14

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.

The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The invention of Group II includes the special technical feature of positioning a distal tip of the aspiration catheter proximate the clot material; activating a pressure source coupled to the aspiration catheter via a fluid control device, while the fluid control device is closed, to generate a vacuum in the pressure source; and opening the fluid control device to apply the vacuum to the aspiration catheter to thereby aspirate at least a portion of the clot material into the aspiration catheter, not required in Group I.

The inventions of Groups I-II share the technical features of an aspiration catheter, comprising: a distal portion and a proximal portion, wherein the distal portion is configured to deflect away from a longitudinal axis of the proximal portion. Specifically, Groups I and II are related as an apparatus (Group I) and methods for using the apparatus (Group II). The apparatus is known in prior art as shown in CN 110652645 A to Shanghai Warbey Medical Technology Co Ltd (hereinafter "Shanghai"). Therefore, Groups I and II lack unity since the shared technical features do not represent a contribution over Shanghai:

Shanghai discloses of an aspiration catheter (Fig 1A-1B; para [0093]-[0099]; para [0115] further teaches wherein the catheter can be used for aspiration), comprising: a distal portion (left half of 10; Fig 1A-1B; para [0093]) and a proximal portion (right half of 10; Fig 1A-1B; para [0093]), wherein the distal portion is configured to deflect away from a longitudinal axis of the proximal portion (Fig 1A-1B; para [0076]; Shanghai teaches wherein the distal region of the aspiration catheter has good flexibility wherein the flexibility of the distal end of the catheter allows for a distal end of the braid of wires within the distal end of the catheter taught by Shanghai to be flexible and deflectable with respect to the longitudinal axis of the proximal portion taught by Shanghai).

As the common features were known in the art at the time of the invention, they cannot be considered special technical features that would otherwise unify the groups.

Therefore, Groups I-II lack unity under PCT Rule 13 because they do not share a same or corresponding special technical feature.

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
26 December 2019 (26.12.2019)

WIPO | PCT

(10) International Publication Number
WO 2019/246240 A1

(51) International Patent Classification:
A61B 1/00 (2006.01) *A61M 25/01* (2006.01)
A61B 1/005 (2006.01) *A61B 17/00* (2006.01)
A61B 1/018 (2006.01) *A61B 34/20* (2016.01)
A61B 1/267 (2006.01) *G02B 23/24* (2006.01)

(21) International Application Number:
PCT/US2019/037954

(22) International Filing Date:
19 June 2019 (19.06.2019)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
62/687,120 19 June 2018 (19.06.2018) US

(71) Applicant: **INTUITIVE SURGICAL OPERATIONS, INC.** [US/US]; 1020 Kifer Road, Sunnyvale, California 94086 (US).

(72) Inventors: **BOGUSKY, Joseph D.**; c/o Intuitive Surgical Operations, Inc., 1020 Kifer Road, Sunnyvale, California 94086 (US). **SCHLESINGER, Randall L.**; c/o Intuitive Surgical Operations, Inc., 1020 Kifer Road, Sunnyvale, California 94086 (US).

(74) Agent: **GENCO, Brian C.** et al.; Meunier Carlin & Curfman LLC, 999 Peachtree St. NE, Suite 1300, Atlanta, Georgia 30309 (US).

(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, DJ, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JO, JP, KE, KG, KH, KN, KP, KR, KW, 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).

Published:
— *with international search report (Art. 21(3))*

(54) **Title:** SYSTEMS AND METHODS FOR HOLDING A FLEXIBLE ELONGATE DEVICE IN A POSE

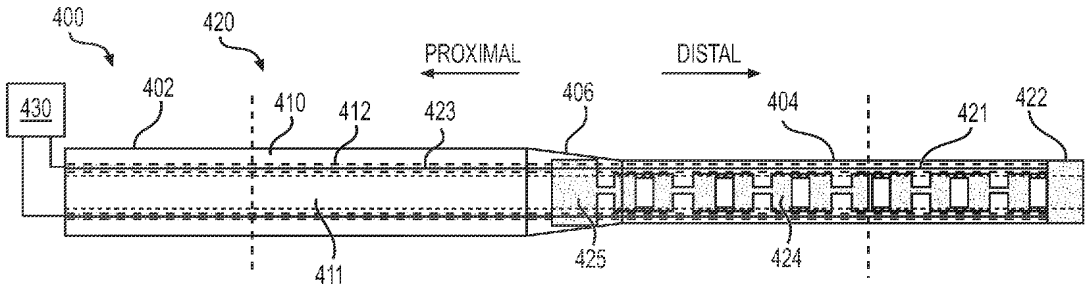


FIG. 4A

(57) **Abstract:** Disclosed herein are a range of stiffening mechanisms or systems that assist or enable holding a pose or shape of a flexible body (1010, 216, 410, 420, 801). These stiffening mechanisms may be part of the steering mechanism (500, 800), may be separately actuated and/or may themselves also enable steering of the flexible elongate device (400). Further, the stiffening mechanisms may use information from sensor (826) systems, such as a shape sensor (222, 314, 426) in the form of an optical fiber, a plurality of EM sensors (426, 826) distributed along the length of a flexible device, and/or navigation systems, such as a sensor system (108) that computes the approximate location of medical instruments (such as a flexible body) within the anatomy of the patient and/or medical tools that are delivered through a main lumen (411, 811) of the flexible body (1010, 216, 410, 420, 801), to inform a control system (112, 116) which then controls formation and holding of a shape of the flexible body (1010, 216, 410, 420, 801).

WO 2019/246240 A1

SYSTEMS AND METHODS FOR HOLDING A FLEXIBLE ELONGATE DEVICE IN A POSE

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit of U.S. Provisional Patent Application Serial No. 62/687,120 filed June 19, 2018, the disclosure of which is expressly incorporated herein by reference.

TECHNICAL FIELD

[0002] The present disclosure is directed to teleoperated systems and in particular teleoperated systems involving use of flexible elongate devices.

BACKGROUND

[0003] Flexible elongate devices can be employed in range of fields needing access to restricted openings such as for the exploration of pipes or in medical procedures, especially minimally invasive medical techniques.

[0004] Minimally invasive medical techniques are intended to reduce the amount of tissue that is damaged during medical procedures, thereby reducing patient recovery time, discomfort, and harmful side effects. Such minimally invasive techniques may be performed through natural orifices in a patient anatomy or through one or more surgical incisions. Through these natural orifices or incisions physician may insert minimally invasive medical instruments (including surgical, diagnostic, therapeutic, or biopsy instruments) to reach a target tissue location.

[0005] One such minimally invasive technique is to use a flexible and/or steerable elongate device, such as a flexible catheter, that can be inserted into anatomic passageways and navigated toward a region of interest within the patient anatomy. In some applications, the flexible and/or steerable elongate device needs to be held in a particular shape to enable or improve the safety of a procedure. It would be advantageous to provide improvements to systems and methods for holding a flexible elongate device in a desired pose.

SUMMARY OF THE INVENTION

[0006] Disclosed herein are a range of stiffening mechanisms or systems that assist or enable holding a pose or shape of a flexible body. These stiffening mechanisms may be part of the steering mechanism, may be separately actuated and/or may themselves also enable steering of the flexible elongate device. Further, the stiffening mechanisms may use information from sensor systems, such as a shape sensor in the form of an optical fiber, a plurality of EM sensors distributed

along the length of a flexible device, and/or navigation systems, such as a sensor system that computes the approximate location of medical instruments (such as a flexible body) within the anatomy of the patient and/or medical tools that are delivered through a main lumen of the flexible body, to inform a control system which then controls formation and holding of a shape of the flexible body.

[0007] One embodiment includes a flexible elongate device having a flexible body, a support structure, and a stiffening mechanism. The flexible body has a proximal end, a distal end, and at least one lumen extending between the proximal and distal ends. The flexible body has sufficient flexibility to form a pose. The support structure is coupled with the flexible body. The support structure includes a plurality of sub-elements arranged in series. At least a portion of the sub elements are configured to spread apart when the flexible body flexes into the pose. The stiffening mechanism has at least one stiffening element extending along at least a portion of the flexible body and is configured for actuation independent of the support structure. Actuation of the at least one stiffening element stiffens the support structure to hold at least a portion of the pose of the flexible body. The stiffening element includes a compression feature configured to engage the support structure.

[0008] The support structure includes a coil and the sub-elements include windings of the coil in another embodiment. The support structure includes a spine in another embodiment.

[0009] In various embodiments, the stiffening mechanism includes an inflatable system wherein the inflatable system includes a balloon configured to engage the support structure. The balloon can be configured to extend in between the sub-elements. For example, the balloon can be configured to extend between the sub-elements due to application of a vacuum pressure causing the balloon to collapse into an exterior of the support structure and in between the sub-elements. In yet another embodiment, the balloon is configured to extend in between the sub-elements due to the application of an inflation pressure causing the balloon to expand into an interior defined within the support structure and in between the sub-elements.

[0010] The balloon system, in other embodiments, includes a plurality of balloon portions. For example, the balloon portions can be selectively inflatable to hold the at least the portion of the pose. The balloon portions can be positioned between the sub elements. Further, the balloon portions can spiral between the sub elements.

[0011] In yet another embodiment, the stiffening mechanism can comprise a plurality of control elements extending along the flexible body and configured to exert tension on the flexible body in conjunction with selective inflation of the balloon portions to further hold the at least the portion of the pose.

[0012] Other embodiments can include a shape sensor configured to determine the pose of the flexible body and a controller. The controller can be connected in communication with the shape sensor and the controller is configured to activate the stiffening mechanism to hold at least the portion of the pose of the flexible body.

[0013] In another embodiment, the medical system includes a flexible body, a shape sensor, a stiffening mechanism and a controller. The flexible body has a proximal end, a distal end, and at least one lumen extending between the proximal and distal ends, wherein the flexible body includes a plurality of sub-portions. The shape sensor extends along at least a portion of the flexible body. The stiffening mechanism has a plurality of stiffening elements, each of the stiffening elements positioned within one of the plurality of sub-portions, wherein the sub-portions extend along the flexible body. The controller is connected in communication with the shape sensor, configured to selectively activate the stiffening elements based in part on data received from the shape sensor.

[0014] In another embodiment, the controller is further configured to selectively activate the stiffening elements based in part on a type of instrument for insertion through the flexible body. For example, the controller can be configured to energize selected ones of the stiffening elements to reduce curvature of the flexible body to match a stiff type of instrument.

[0015] In another embodiment, the controller is further configured to selectively activate the stiffening elements based in part on anatomical information. The anatomical information can also information identifying a target area of anatomy and wherein the controller is further configured to actuate selected ones of the stiffening elements to protect the target area of anatomy.

[0016] In another embodiment, the shape sensor includes at least one of a shape sensing fiber extending along the flexible body or a plurality of EM sensors extending along the flexible body.

[0017] In other embodiments, the stiffening mechanism includes a longitudinal balloon array having a plurality of balloon portions and wherein each of the stiffening elements is one of the plurality of balloon portions.

[0018] In another embodiment, the flexible body includes a coil with a plurality of adjacent windings and wherein each of the balloon portions are configured to extend between the adjacent windings with the application of pressure. Further, controller may be configured to selectively apply pressure to each of the balloon portions to urge apart adjacent windings to shape the flexible body.

[0019] Other embodiments further comprise a steering mechanism configured to control the distal end portion of the flexible body. For example, the steering mechanism can include a plurality of pull wires and wherein the controller is further configured to adjust tension in the pull

wires along with selective activation of the stiffening elements to hold the portion of the flexible body in the pose.

[0020] In other embodiments, the plurality of stiffening elements includes a plurality of nitinol actuators. For example, the flexible body can include a wall structure and the plurality of nitinol actuators are embedded in the wall structure. The plurality of nitinol actuators can be distributed circumferentially within the wall structure.

[0021] Other embodiments include a method of holding at least a portion of a pose of a flexible body. The method can include engaging a stiffening element of a stiffening mechanism within a spacing between at least a pair of the plurality of sub-elements, wherein the plurality of sub-elements extend along the flexible body.

[0022] In another embodiment, engaging stiffening element includes urging a portion of the stiffening element into the spacing between the at least the pair of the plurality of sub-elements.

[0023] In another embodiment, urging the portion of the stiffening element includes one of inflating or deflating the stiffening element.

[0024] In another embodiment, actuating a plurality of pull wires extending within a wall structure of the flexible body including adjusting tension in the plurality of pull wires while selectively activating the stiffening elements to hold the pose of the flexible body.

[0025] Other embodiments include a method of holding a pose of a flexible body using a controller. The method includes measuring a current configuration of a flexible body based at least in part on a sensor coupled to the flexible body, determining a desired configuration of the flexible body, and selectively activating a stiffening mechanism to position the flexible body from the current configuration to the desired configuration, wherein the stiffening mechanism includes a plurality of stiffening elements distributed down the length of the flexible body.

[0026] In another embodiment, positioning the flexible body in the desired configuration includes activating each of the plurality of stiffening elements independently.

[0027] In another embodiment, the current configuration includes a measured shape of the flexible body.

[0028] In another embodiment, the method can comprise identifying a small radius in the measured shape, wherein selectively activating the stiffening mechanism includes activating select ones of the plurality of the stiffening elements to increase a bend radius of the flexible body at the identified small radius in the measured shape.

[0029] In another embodiment, the method can comprise receiving information describing stiffness of an instrument to be delivered by the flexible body, wherein the identifying of the small radius in the measured shape includes determining a minimum bend radius corresponding to the

stiffness of the instrument.

[0030] In another embodiment, determining the desired configuration comprises receiving information identifying a target area of anatomy and setting the desired configuration to activate select ones of the plurality of the stiffening elements at the identified target area of anatomy. The information received identifying the target area of anatomy may be based on live imaging.

[0031] In another embodiment, determining the desired configuration comprises receiving a preoperatively recorded surgical image, registering the flexible body to the preoperatively recorded surgical image using sensor data from the sensor coupled to the flexible body, and identifying a portion of the flexible body positioned within the identified target area of anatomy based on the registration. The information received identifying the target area of anatomy is based on the preoperatively recorded surgical image

[0032] In other embodiments, the plurality of the stiffening elements includes a plurality of nitinol actuators extending within a wall structure of the flexible body, and wherein the selectively activating the stiffening mechanism includes energizing at least one of the plurality of nitinol actuators.

[0033] In yet other embodiments, the plurality of the stiffening elements includes a plurality of balloons, and wherein the selectively activating the stiffening mechanisms includes inflating or deflating at least one of the plurality of balloons.

[0034] Embodiments of the present invention have a range of advantages. For example, in the environment of articulating devices that navigate the tortuosity of human anatomy, it is advantageous to securely hold the contorted position of said device while instruments are being delivered through the device. Frequently, devices that pass through an articulating device will exert forces that have a tendency to straighten a contorted and articulated portion of the device. Embodiments of the invention provides various apparatus and methods to hold the pose of a catheter in a contorted position for stable delivery of instruments

BRIEF DESCRIPTIONS OF THE DRAWINGS

[0035] FIG. 1 is a simplified diagram of a teleoperated medical system according to some embodiments.

[0036] FIG. 2A is a simplified diagram of a medical instrument system according to some embodiments.

[0037] FIG. 2B is a simplified diagram of a medical instrument with an extended medical tool according to some embodiments.

[0038] FIGS. 3A and 3B are simplified diagrams of side views of a patient coordinate space

including a medical instrument mounted on an insertion assembly according to some embodiments.

[0039] FIGS. 4A-4C are simplified diagrams of a flexible elongate device according to some embodiments.

[0040] FIG. 5 is a simplified cross-sectional view of a control element conduit according to some embodiments.

[0041] FIGS. 6A-6D are simplified diagrams of a stiffening mechanism or system according to some embodiments.

[0042] FIGS. 7A-7D are simplified diagrams of a stiffening mechanism or system according to some embodiments.

[0043] FIGS. 8A-8E are simplified diagrams of a stiffening mechanism or system according to some embodiments.

[0044] FIGS. 9A-9B are simplified diagrams of methods of using a flexible elongate device with a stiffening mechanism of other embodiments.

[0045] FIGS. 10A-10B are simplified diagrams of a stiffening mechanism or system according to some embodiments.

[0046] FIG. 11 is a simplified flow diagram of a method for identifying target areas of anatomy and activating a stiffening mechanism according to some embodiments.

[0047] FIG. 12 is a simplified flow diagram of a method for identifying an external force and activating a stiffening mechanism according to some embodiments.

DETAILED DESCRIPTION

[0048] In the following description, specific details are set forth describing some embodiments consistent with the present disclosure. Numerous specific details are set forth in order to provide a thorough understanding of the embodiments. It will be apparent, however, to one skilled in the art that some embodiments may be practiced without some or all of these specific details. The specific embodiments disclosed herein are meant to be illustrative but not limiting. One skilled in the art may realize other elements that, although not specifically described here, are within the scope and the spirit of this disclosure. In addition, to avoid unnecessary repetition, one or more features shown and described in association with one embodiment may be incorporated into other embodiments unless specifically described otherwise or if the one or more features would make an embodiment non-functional.

[0049] In some instances well known methods, procedures, components, and circuits have not been described in detail so as not to unnecessarily obscure aspects of the embodiments.

[0050] This disclosure describes various instruments and portions of instruments in terms of their state in three-dimensional space. As used herein, the term "position" refers to the location of an object or a portion of an object in a three-dimensional space (e.g., three degrees of translational freedom along Cartesian x-, y-, and z-coordinates). As used herein, the term "orientation" refers to the rotational placement of an object or a portion of an object (three degrees of rotational freedom – e.g., roll, pitch, and yaw). As used herein, the term "pose" refers to the position of an object or a portion of an object in at least one degree of translational freedom and to the orientation of that object or portion of the object in at least one degree of rotational freedom (up to six total degrees of freedom). As used herein, the term "shape" refers to a set of poses, positions, or orientations measured along an object.

[0051] FIG. 1 is a simplified diagram of a teleoperated medical system 100 according to some embodiments. In some embodiments, teleoperated medical system 100 may be suitable for use in, for example, surgical, diagnostic, therapeutic, or biopsy procedures. While some embodiments are provided herein with respect to such procedures, any reference to medical or surgical instruments and medical or surgical methods is non-limiting. The systems, instruments, and methods described herein may be used for animals, human cadavers, animal cadavers, portions of human or animal anatomy, non-surgical diagnosis, as well as for industrial systems and general robotic or teleoperational systems.

[0052] As shown in FIG. 1, medical system 100 generally includes a manipulator assembly 102 for operating a medical instrument 104 in performing various procedures on a patient P. The manipulator assembly 102 may be teleoperated, non-teleoperated, or a hybrid teleoperated and non-teleoperated assembly with select degrees of freedom of motion that may be motorized and/or teleoperated and select degrees of freedom of motion that may be non-motorized and/or non-teleoperated. Manipulator assembly 102 is mounted to or near an operating table T. A master assembly 106 allows an operator (e.g., a surgeon, a clinician, or a physician as illustrated in FIG. 1) to view the interventional site and to control manipulator assembly 102. Master assembly 106 generally includes one or more control devices for controlling manipulator assembly 102.

[0053] Manipulator assembly 102 supports medical instrument 104 and may optionally include a plurality of actuators or motors that drive inputs on medical instrument 104 in response to commands from the control system (e.g., a control system 112). The actuators may optionally include drive systems that when coupled to medical instrument 104 may advance medical instrument 104 into a naturally or surgically created anatomic orifice. Other drive systems may move the distal end of medical instrument 104 in multiple degrees of freedom, which may include three degrees of linear motion (e.g., linear motion along the X, Y, Z Cartesian axes) and in three

degrees of rotational motion (e.g., rotation about the X, Y, Z Cartesian axes). Additionally, the actuators can be used to actuate an articulable end effector of medical instrument 104 for grasping tissue in the jaws of a biopsy device and/or the like. Actuator position sensors such as resolvers, encoders, potentiometers, and other mechanisms may provide sensor data to medical system 100 describing the rotation and orientation of the motor shafts. This position sensor data may be used to determine motion of the objects manipulated by the actuators.

[0054] Teleoperated medical system 100 may include a sensor system 108 with one or more sub-systems for receiving information about the instruments of manipulator assembly 102. Such sub-systems may include a position/location sensor system (e.g., an electromagnetic (EM) sensor system); a shape sensor system for determining the position, orientation, speed, velocity, pose, and/or shape of a distal end and/or of one or more segments along a flexible body that may make up medical instrument 104; and/or a visualization system for capturing images from the distal end of medical instrument 104.

[0055] Teleoperated medical system 100 also includes a display system 110 for displaying an image or representation of the surgical site and medical instrument 104 generated by sub-systems of sensor system 108. Display system 110 and master assembly 106 may be oriented so operator O can control medical instrument 104 and master assembly 106 with the perception of telepresence. Display system 110 may present images of a surgical site recorded pre-operatively or intra-operatively using image data from imaging technology such as, computed tomography (CT), magnetic resonance imaging (MRI), fluoroscopy, thermography, ultrasound, optical coherence tomography (OCT), thermal imaging, impedance imaging, laser imaging, nanotube X-ray imaging, and/or the like. The pre-operative or intra-operative image data may be presented as two-dimensional, three-dimensional, or four-dimensional (including e.g., time based or velocity-based information) images and/or as images from models created from the pre-operative or intra-operative image data sets. In some embodiments, often for purposes of imaged guided surgical procedures, display system 110 may display a virtual navigational image in which the actual location of medical instrument 104 is registered (i.e., dynamically referenced) with the preoperative or concurrent images/model.

[0056] In some embodiments, display system 110 may display a virtual navigational image in which the actual location of medical instrument 104 is registered with preoperative or concurrent images to present the operator O with a virtual image of medical instrument 104 within the surgical site from an external viewpoint. An image of a portion of medical instrument 104 or other graphical or alphanumeric indicators may be superimposed on the virtual image to assist operator O in the control of medical instrument 104. As described herein, visual representations of data

points may be rendered to display system 110. For example, measured data points, moved data points, registered data points, and other data points described herein may be displayed on display system 110 in a visual representation.

[0057] Teleoperated medical system 100 may also include control system 112. Control system 112 includes at least one memory and at least one computer processor (not shown) for effecting control between medical instrument 104, master assembly 106, sensor system 108, and display system 110. Control system 112 also includes programmed instructions (e.g., a non-transitory machine-readable medium storing the instructions) to implement some or all of the methods described in accordance with aspects disclosed herein, including instructions for providing information to display system 110. While control system 112 is shown as a single block in the simplified schematic of FIG. 1, the system may include two or more data processing circuits with one portion of the processing optionally being performed on or adjacent to manipulator assembly 102, another portion of the processing being performed at master assembly 106, and/or the like. The processors of control system 112 may execute instructions comprising instruction corresponding to processes disclosed herein and described in more detail below. Any of a wide variety of centralized or distributed data processing architectures may be employed. Similarly, the programmed instructions may be implemented as a number of separate programs or subroutines, or they may be integrated into a number of other aspects of the teleoperational systems described herein. In one embodiment, control system 112 supports wireless communication protocols such as Bluetooth, IrDA, HomeRF, IEEE 802.11, DECT, and Wireless Telemetry.

[0058] In some embodiments, control system 112 may receive force and/or torque feedback from medical instrument 104. Responsive to the feedback, control system 112 may transmit signals to master assembly 106. In some examples, control system 112 may transmit signals instructing one or more actuators of manipulator assembly 102 to move medical instrument 104. Control system 112 may optionally further include a virtual visualization system to provide navigation assistance to operator O when controlling medical instrument 104 during an image-guided surgical procedure.

[0059] During a virtual navigation procedure, sensor system 108 may be used to compute an approximate location of medical instrument 104 with respect to the anatomy of patient P. The location can be used to produce both macro-level (external) tracking images of the anatomy of patient P and virtual internal images of the anatomy of patient P. The system may implement one or more electromagnetic (EM) sensor, fiber optic sensors, and/or other sensors to register and display a medical implement together with preoperatively recorded surgical images, such as those from a virtual visualization system. For example, PCT Publication WO 2016/191298 (published

December 1, 2016) (disclosing "Systems and Methods of Registration for Image Guided Surgery"), which is incorporated by reference herein in its entirety, discloses such one system.

[0060] FIG. 2A is a simplified diagram of a medical instrument system 200 according to some embodiments. Medical instrument system 200 includes elongate device 202, such as a flexible catheter, coupled to a drive unit 204. Elongate device 202 includes a flexible body 216 having proximal end 217 and distal end or tip portion 218.

[0061] Medical instrument system 200 further includes a tracking system 230 for determining the position, orientation, speed, velocity, pose, and/or shape of distal end 218 and/or of one or more segments 224 along flexible body 216 using one or more sensors and/or imaging devices as described in further detail below. The entire length of flexible body 216, between distal end 218 and proximal end 217, may be effectively divided into segments 224. Tracking system 230 may optionally be implemented as hardware, firmware, software or a combination thereof which interact with or are otherwise executed by one or more computer processors, which may include the processors of control system 112 in FIG. 1.

[0062] Tracking system 230 may optionally track distal end 218 and/or one or more of the segments 224 using a shape sensor 222. Shape sensor 222 may optionally include an optical fiber aligned with flexible body 216 (e.g., provided within an interior channel (not shown) or mounted externally). In one embodiment, the optical fiber has a diameter of approximately 200 μm. In other embodiments, the dimensions may be larger or smaller. The optical fiber of shape sensor 222 forms a fiber optic bend sensor for determining the shape of flexible body 216. In one alternative, optical fibers including Fiber Bragg Gratings (FBGs) are used to provide strain measurements in structures in one or more dimensions. Various systems and methods for monitoring the shape and relative position of an optical fiber in three dimensions are described in U.S. Patent Application No. 11/180,389 (filed July 13, 2005) (disclosing "Fiber optic position and shape sensing device and method relating thereto"); U.S. Patent Application No. 12/047,056 (filed on Jul. 16, 2004) (disclosing "Fiber-optic shape and relative position sensing"); and U.S. Patent No. 6,389,187 (filed on Jun. 17, 1998) (disclosing "Optical Fibre Bend Sensor"), which are all incorporated by reference herein in their entireties.

[0063] In some embodiments, tracking system 230 may optionally and/or additionally track distal end 218 using a position sensor system 220. Position sensor system 220 may be a component of an EM sensor system with position sensor system 220 including one or more conductive coils that may be subjected to an externally generated electromagnetic field. Each coil of the EM sensor system then produces an induced electrical signal having characteristics that depend on the position and orientation of the coil relative to the externally generated electromagnetic field. In some

embodiments, position sensor system 220 may be configured and positioned to measure six degrees of freedom, e.g., three position coordinates X, Y, Z and three orientation angles indicating pitch, yaw, and roll of a base point or five degrees of freedom, e.g., three position coordinates X, Y, Z and two orientation angles indicating pitch and yaw of a base point. Further description of a position sensor system is provided in U.S. Patent No. 6,380,732 (filed August 11, 1999) (disclosing "Six-Degree of Freedom Tracking System Having a Passive Transponder on the Object Being Tracked"), which is incorporated by reference herein in its entirety. In some examples, a series of positional sensors (not shown), such as electromagnetic (EM) sensors similar to the sensors in position sensor 220 may be positioned along flexible body 216 and then used for shape sensing. Flexible body 216 includes a channel 221 sized and shaped to receive a medical instrument 226.

[0064] FIG. 2B is a simplified diagram of flexible body 216 with medical instrument 226 extended according to some embodiments. In some embodiments, medical instrument 226 may be used for procedures such as surgery, biopsy, ablation, illumination, irrigation, or suction.

[0065] Medical instrument 226 may additionally house cables, linkages, or other actuation controls (not shown) that extend between its proximal and distal ends to controllably bend the distal end of medical instrument 226. Steerable instruments are described in detail in U.S. Patent No. 7,316,681 (filed on Oct. 4, 2005) (disclosing "Articulated Surgical Instrument for Performing Minimally Invasive Surgery with Enhanced Dexterity and Sensitivity") and U.S. Patent Application No. 12/286,644 (filed Sept. 30, 2008) (disclosing "Passive Preload and Capstan Drive for Surgical Instruments"), which are incorporated by reference herein in their entireties.

[0066] Flexible body 216 may also house cables, linkages, or other steering controls (not shown) that extend between drive unit 204 and distal end 218 to controllably bend distal end 218 as shown, for example, by broken dashed line depictions 219 of distal end 218. Steerable elongate devices are described in detail in U.S. Patent Application No. 13/274,208 (filed Oct. 14, 2011) (disclosing "Catheter with Removable Vision Probe"), which is incorporated by reference herein in its entirety. In embodiments in which medical instrument system 200 is actuated by a teleoperational assembly, drive unit 204 may include drive inputs that removably couple to and receive power from drive elements, such as actuators, of the teleoperational assembly. In some embodiments, medical instrument system 200 may include gripping features, manual actuators, or other components for manually controlling the motion of medical instrument system 200. Elongate device 202 may be steerable or, alternatively, the system may be non-steerable with no integrated mechanism for operator control of the bending of distal end 218. In some examples, one or more lumens, through which medical instruments can be deployed and used at a target surgical location, are defined in the walls of flexible body 216.

[0067] The information from tracking system 230 may be sent to a navigation system 232 where it is combined with information from visualization system 231 and/or the preoperatively obtained models (e.g., anatomic models of the patient anatomy) to provide the physician or other operator with real-time position information. In some examples, the real-time position information may be displayed on display system 110 of FIG. 1 for use in the control of medical instrument system 200. In some examples, control system 116 of FIG. 1 may utilize the position information as feedback for positioning medical instrument system 200. Various systems for using fiber optic sensors to register and display a surgical instrument with surgical images are provided in U.S. Patent Application No. 13/107,562, filed May 13, 2011, disclosing, "Medical System Providing Dynamic Registration of a Model of an Anatomic Structure for Image-Guided Surgery," which is incorporated by reference herein in its entirety.

[0068] In some examples, medical instrument system 200 may be teleoperated within medical system 100 of FIG. 1. In some embodiments, manipulator assembly 102 of FIG. 1 may be replaced by direct operator control. In some examples, the direct operator control may include various handles and operator interfaces for hand-held operation of the instrument.

[0069] FIGS. 3A and 3B are simplified diagrams of side views of a patient coordinate space including a medical instrument mounted on an insertion assembly according to some embodiments. As shown in FIGS. 3A and 3B, a surgical environment 300 includes a patient P is positioned on the table T of FIG. 1. Instrument carriage 306 or insertion stage 308 may include actuators, such as servomotors, (not shown) that control motion of instrument carriage 306 along insertion stage 308. Elongate device 310 is coupled to an instrument body 312. Instrument body 312 is coupled and fixed relative to instrument carriage 306. In some embodiments, an optical fiber shape sensor 314 is fixed at a proximal point 316 on instrument body 312. Shape sensor 314 measures a shape from proximal point 316 to another point such as distal end 318 of elongate device 310. Point gathering instrument 304 may be substantially similar to medical instrument system 200. A position measuring device 320 provides information about the position of instrument body 312 as it moves on insertion stage 308 along an insertion axis A. Position measuring device 320 may include resolvers, encoders, potentiometers, and/or other sensors that determine the rotation and/or orientation of the actuators controlling the motion of instrument carriage 306 and consequently the motion of instrument body 312. In some embodiments, insertion stage 308 is linear. In some embodiments, insertion stage 308 may be curved or have a combination of curved and linear sections.

[0070] FIG. 3A shows instrument body 312 and instrument carriage 306 in a retracted position along insertion stage 308. In FIG. 3B, instrument body 312 and instrument carriage 306 have

advanced along the linear track of insertion stage 308 and distal end 318 of elongate device 310 has advanced into patient P.

[0071] FIGS. 4A-4C are simplified diagrams of a flexible elongate device 400 according to some embodiments. According to some embodiments consistent with FIGS. 1-3, flexible elongate device 400 may correspond to elongate device 202 of medical instrument system 200. As depicted in FIG. 4A, flexible elongate device 400 can include a proximal section 402, a distal section 404 and a transition section 406 therebetween.

[0072] Flexible elongate device 400 can include a flexible body 410 with a flexible wall having a thickness extending from an inner surface to an outer surface of the flexible body 410. A main lumen 411 can extend within the flexible body 410, through the proximal section 402, the transition section 406, and the distal section 404. The main lumen 411 can provide a delivery channel for a medical tool, such as an endoscope, biopsy needle, ultrasound (EBUS or IVUS) probe, ablation tool, chemical delivery tool, and/or the like, to be inserted through flexible body 410. According to some embodiments, a plurality of control element lumens 412 extend through the flexible wall of the flexible body 410 arranged circumferentially in the flexible wall around the main lumen 411. According to some embodiments, a sensor lumen 419 extends through the flexible wall of the flexible body 410. The sensor lumen 419 can extend from the proximal end of the flexible elongate device 400, through the proximal section 402, transition section 406, terminating at a distal portion of the distal section 404. In some examples, flexible body 410 may include various other types of lumens for electrical wires, fibers, sensors, small medical instruments, chemical delivery, and/or the like. In alternative embodiments, flexible body 410 may include an all-purpose lumen that can be used for a variety of purposes, including accommodating multiple concurrently inserted instruments, control elements, sensors, and/or the like.

[0073] As depicted in FIGS. 4A-4C, within each of the control element lumens 412, a coil pipe or conduit 423 can extend through the proximal section 402 of the flexible body 410, providing channels through which a plurality of control elements 421 extends. In some examples, control elements 421 can include pull wires, tendons, push rods and/or the like. The conduits 423 terminate at the transition section 406, proximal to the distal section 404. The control elements 421 extend out of the conduits 423 at the transition section 406, entering the distal section 404 through control element lumens 412, and attach to a distal mount 422. The one or more control elements 421 can be used to actuate distal section 404 of flexible elongate device 400. As depicted in FIGS. 4B and 4C, four control elements 421 can be disposed within control element lumens 412 and evenly spaced around the circumference of flexible elongate device 400.

[0074] In the illustrative example provided in FIG. 4B, a pair of lumens that includes sensor lumen 419 and one of control element lumens 412 is approximately centered along a side of the rounded square formed by main lumen 411. Consequently, neither sensor lumen 419 nor control element lumens 412 are individually centered along the side of the rounded square. Moreover, because control elements 421 are equally spaced around the perimeter of the rounded square, none of the control element lumens 412 are centered relative to the rounded square. As a result, the square formed by control elements 421 and the rounded square formed by main lumen 411 are offset by approximately 30 degrees. However, it is to be understood that different numbers and/or arrangements of control elements 421 are possible. For example, control elements 421 may be unevenly spaced around the circumference of flexible elongate device 400 and/or centered relative to the sides of main lumen 411.

[0075] Distal section 404 is actuated by applying actuation forces to control elements 421 (e.g., pulling and/or pushing on control elements 421 in an unequal manner). Applying actuation forces causes distal section 404 to bend in the direction defined by the net actuation forces. In some examples, the actuation forces may be applied manually, robotically, and/or the like. For example, the actuation forces may be applied using an actuator 430 positioned at the proximal end of flexible elongate device 400. Conduits 423 transfer the actuation forces applied to control elements 421 from the proximal end to the distal end of proximal section 402 at transition section 406. Consequently, even when unequal actuation forces are applied to control elements 421, little actuation force appears within proximal section 402. In some examples, conduits 423 may be flexible to retain the flexibility of proximal section 402. Further examples of conduits are provided in P.C.T. Patent Application PCT/US14/62188 entitled "Flexible Instrument with Embedded Actuation Conduits," filed October 24, 2014, which is hereby incorporated by reference in its entirety.

[0076] Any bend along the length of the proximal section 402 of the flexible elongate device 400 results in a change of length of control element lumens 412. For example, with reference to FIG. 4A, if the flexible body bends in a downward motion, the control element lumens 412 on the lower portion of flexible body 410 will decrease in length while the control element lumens 412 on the upper portion of flexible body will increase in length. Thus, it can be necessary for the conduits 423 to axially slide within the control element lumens 412. In some examples, the conduits can be constrained (e.g., fixed and/or prevented from sliding proximally along a conduit longitudinal axis) at a proximal end of the flexible elongate device within the actuator 430 and can terminate at the transition section 406. The conduits may be constrained (e.g., fixed and/or prevented from sliding distally along a conduit longitudinal axis) at the transition section 406. In

this example, within transition section 406, a stopper 425 is coupled between conduits 423 on the stopper proximal side and an axial support structure 424 on the distal stopper side. Stopper 425 prevents conduits 423 from shifting distally along flexible elongate device 400. In alternative examples, the conduits may be fixed to stopper 425.

[0077] Within distal section 404, axial support structure 424 is configured to bend in response to actuation forces applied to control elements 421. Consequently, when unequal actuation forces are applied to control elements 421, distal section 404 bends in the direction defined by the net actuation forces. Axial support structure 424 supports distal section 404 against axial loads generated by the actuation forces applied to control elements 421. In particular, axial support structure 424 may prevent or reduce distortion, compression and/or collapse of distal section 404 under axial loads. Further examples of axial support structures are provided in U.S. Provisional Patent Application 62/378,943 entitled "Axial Support Structure for a Flexible Elongate Device," which is hereby incorporated by reference in its entirety.

[0078] Although axial support structure 424 is depicted as having a spine-like structure in FIG. 4A, other structures are possible. In some examples, axial support structure 424 may be formed as a single large coil that encloses main lumen 411. Additionally, while FIG. 4C illustrates control elements 421 within control element lumens 412, in a similar configuration as shown in FIG 4B for proximal section 402, axial support structure 424 may be include conduits similar to conduits 423. In some embodiments, conduits 423 may continue to run through both proximal and distal sections of flexible body 420. In alternative embodiments, separate conduits 423 may run in the proximal section and distal section. Whereas the conduits of conduits 423 are arranged concentrically around control elements 421 to counteract the actuation forces applied to control elements 421, the conduits of axial support structure 424 may be offset from control elements 421 (e.g., located at different positions around the circumference of flexible body 410) to allow axial support structure 424 to bend in response to actuation forces. Alternately or additionally, the conduits of axial support structure 424 may be more flexible (e.g., smaller diameter and/or constructed using smaller gauge wire) than the conduits of conduits 423.

[0079] In some examples, one or more of lumens 411, 412, 419, and/or sections thereof, may be keyed. That is, a lumen and/or a portion of a lumen may have a non-circular cross-sectional shape that prevents or constrains the rotation of a tool (e.g., a medical instrument, sensor, fiber, electrical wire, actuation element, and/or the like) with a matching non-circular cross-sectional shape when inserted through the lumen. As depicted in FIG. 4B, main lumen 411 of proximal section 402 is keyed. In particular, the main lumen 411 has a rounded square cross-sectional shape that supports four keyed orientations.

[0080] In some examples, a localization sensor 426, such as an optical fiber of shape sensor 222, extends through sensor lumen 419. Like conduits 423, localization sensor may be constrained (e.g., fixedly attached and/or prevented from sliding axially) at each end of flexible elongate device 400. In one example, the localization sensor is fixedly attached to distal mount 422, free-floating within sensor lumen 419, and fixedly attached at actuator 430. In some examples, a service loop can be provided within actuator 430 between a fixed localization attachment and a proximal end of flexible elongate device 400 to accommodate the varying length of sensor lumen 419 due to bending. In alternative examples, the service loop can be provided between actuator 430 and the distal end of flexible elongate device 400 or within the flexible elongate device.

[0081] In some examples, the cross-sectional shape of lumens 411-419 may change between proximal section 402 and distal section 404. For example, main lumen 411 may be keyed within proximal section 402 and unkeyed within distal section 404. As depicted in FIG. 4C, main lumen 411 of distal section 404 is unkeyed, having a circular cross-sectional shape that does not constrain the rotation of a medical instrument inserted therein. Examples of keyed lumens are discussed in greater detail below with reference to FIG. 10.

[0082] In some examples, the diameter of lumens 411-419 may change between proximal section 402 and distal section 404. Accordingly, lumens 411-419 may be tapered within transition section 406 to provide a gradual transition between the different cross-sectional shapes, e.g., a keyed lumen on the proximal side and an unkeyed lumen on the distal side.

[0083] In some examples, the flexible wall of the flexible body 410 may vary between the proximal section 402 and distal section 404. In some examples, a required bending flexibility and/or compressive strength may vary along the length of the catheter based on potential positioning within patient anatomy. Thus, the flexible wall may include a plurality of layers which can vary within a proximal section flexible wall and within a distal section flexible wall.

[0084] Despite the advantages of the above-described construction of the flexible elongate device 400 being able to actuate distal section 404 of flexible elongate device 400 by, for example, operation of the control elements 421 within conduits 423, in certain situations, once the flexible elongated device 400 is positioned in a desired pose, attempting to hold the shape of the flexible body in a desired configuration can be difficult. In addition, instances occur in which it would be advantageous to adapt the shape of the flexible body 410 based on known information about the surrounding anatomy and/or the instruments to be inserted through the main lumen 411, or other lumens. To this end, a range of stiffening mechanisms or systems are described that assist or enable holding a pose or shape of the flexible body 410. These stiffening mechanisms may be part of the steering mechanism, may be separately actuated and/or may themselves also enable steering

of the flexible elongate device 400. Further, the stiffening mechanisms may use information from sensor systems, such as shape sensor 426 in the form of an optical fiber, a plurality of EM sensors distributed along the length of a flexible device, a plurality of force sensors distributed along the length of a flexible device, and/or navigation systems, such as sensor system 108 that computes the approximate location of medical instruments (such as the flexible body 410) within the anatomy of the patient and/or medical tools that are delivered through main lumen 411, to inform the control system 112 which then controls formation and holding of a shape of the flexible body 410.

[0085] In some embodiments, stiffening mechanisms, especially stiffening mechanisms with sub-elements, exhibit behaviors that can be used to stiffen the shape of the flexible body 410. In one embodiment, as shown in FIGS. 6A-6D, for example, a stiffening system or mechanism 500 uses the characteristics of the coil pipe 423 within the control element lumen 412 to stiffen the pose of the flexible body 410.

[0086] FIG. 5 is an enlarged schematic showing an example of the conduit or coil pipe 423 within control element lumen 412 extending around the control element 421, such as a pull wire. Notably, in this example, the coil pipe 423 includes a plurality of windings 504. In this configuration, the windings 504 of the coil pipe 423 extend linearly in a stacked array with very little (or no) distance between them. The windings 504 are shown as rings but the coil pipe 423 can be a helical structure that extends helically along a central axis of the control element lumen 412. The control element lumen 412 and the control element 421 are shown in a straight, or un-bent, configuration.

[0087] The stiffening mechanism 500 shown in FIGS. 6A – 6D, includes a restricting balloon 502 sleeved over the coil pipe 423. During actuation and steering of the flexible elongate device 400, the restricting balloon is in a passive or natural state. Once the flexible elongate device has been positioned at a desired target location, vacuum can be applied using a pump (not shown), deflating balloon 502 to interdigitate within the spaces between a plurality of windings 504 of the coil pipe. This interdigitation stiffens to hold the shape of the coil pipe 423 subsequently holding the shape and pose of the flexible elongate body 400 and providing a more stable platform for delivery of instruments through the flexible body 410.

[0088] FIG. 6A shows a cross-sectional view of the control element lumen 412, and the stiffening mechanism 500 including the balloon 502. The external circle denotes the outline of the control element lumen 412 within which is a balloon layer or internal wall 506a. The balloon wall extends around (e.g., is sleeved over) the coil pipe 423. In the illustrated embodiment of FIGS. 6A-6D, the balloon 502 can be formed as a tubular structure with an open center lumen such that

the balloon 502 can extend between the coil pipe 423 and an inner surface of the control element lumen 412. FIG. 6B shows a cross-sectional view taken along the longitudinal axis of a portion of the flexible body 410.

[0089] FIG. 6C shows a cross-sectional view of the control element lumen 412 bending under tension from the control element 421 (or other forces and manners of application thereof) into a curved pose along with the surrounding wall structure of the flexible body 410. In this bent pose, the windings 504 of the coil pipe 423 spread apart on the outer curvature due to tracing a longer path and compress more together on the inner curvature as they are tracing a shorter path. The balloon 502, not yet under an inflation pressure or deflation vacuum pressure, passively bends along with the control element lumen 412 and the coil pipe 423.

[0090] In FIG. 6D, the stiffening mechanism is activated by using the pump to apply a suction pressure or vacuum within the lumen of the balloon 502. The suction pressure draws the compliant balloon wall 506a inward into conforming contact with the windings 504 of the coil pipe 423. Generally, on an outside curvature where the windings are spread apart, the balloon wall 506a fills the gap between adjacent pairs of the windings. Even on an inner curvature formed in the coil pipe 423, the balloon wall 506a could achieve some interdigitation between the windings 504. In this embodiment, the adherence of the balloon wall 506a tightens the relationship between it and the windings 504 causing friction which interferes with the coil pipe 423 thus holding it in its current configuration or pose. The presence of the balloon wall 506a in between the windings 504 may wedge the adjacent pairs of windings 504 into the spread apart relationship.

[0091] FIGS. 7A-7D show another embodiment using a balloon 502 that is similar to the embodiment of FIGS. 6A-6D, except the balloon 502 is positioned within the coil pipe 423 such that an external balloon wall 506b is positioned along an inner surface of the coil pipe 423. In the illustrated embodiment of FIGS. 7A-7D, the balloon 502 can be formed as a tubular structure with an open center lumen such that the balloon 502 can extend between the control element 421 and the coil pipe 423, as shown in FIG. 7A. In an alternative embodiment, a pull wire is not used to control actuation of the elongate flexible device 400, so the balloon 502 can be positioned within a lumen of the coil pipe 423, filling the entire coil pipe lumen when inflated. In either configuration, the balloon is inflated (FIG. 7C to FIG. 7D) to adhere against and interdigitate between the windings 504 of the coil pipe 423. This embodiment could be combined with, or substituted for, the embodiment of FIGS. 6A-6D (or used with other embodiments within the scope of this disclosure) depending on the desired level of friction or mechanical blocking and strength of the hold.

[0092] While a single coil pipe 423 is shown for FIGS. 6A-6D and 7A-7D, it should be understood that multiple coil pipes may be distributed within a single elongated flexible device 400. For example, as shown in the embodiments above of FIGS. 4A-4C, there are four control element lumens 412 and each of these could include one or more balloons 502 extending over the coil pipes 23 within the lumens 412. Alternatively or additionally, in another example without pull wires, as shown in FIG 10A, a single coil pipe 1023 could surround a lumen 1011 of an elongated flexible device 1000 including flexible body 1010. Regardless, multiple coil pipes 423 with multiple balloons 502 or balloon portions could be used for one, several, or all the control elements 421 used in the flexible elongate device 400. Each of these balloons 502 could be selectively drawn inward with a vacuum to engage the respective windings 504 of the coils or expanded outward with pressure to engage respective windings 504 of the coils, depending on the shape or pose of the flexible body 410. Additionally, separate balloons or balloon portions could be distributed down the length of each coil pipe, such that stiffening or holding of coil pipe positions could vary down the length of the coil pipe. Thus, by controlling the amount and distribution of the applied vacuum and pressure to different balloons or balloon portions, an entire length of a flexible body can be actively controlled depending upon where and how stiff and what shape is required by the particular anatomy or particular medical procedure.

[0093] As noted above, the axial support structure 424 of the flexible body 410 may include a single large coil that encloses the main lumen 411. The structure of this larger coil, like the coil pipe 423, can be used to stiffen the flexible body 410 in a pose or shape in other embodiments. FIGS. 10A-10B show a cross-section of an embodiment including a coil pipe 1023 surrounding a lumen 1011 of an elongated flexible device 1000 including flexible body 1010. In one embodiment, a single balloon 1002 can spiral along between windings of the coil pipe 1023. As shown in FIG. 10A, the balloon is in a deflated configuration showing a cross-section which bows inward. In this embodiment, the balloon can be inflated (not shown) to force the windings of the coil pipe 1023 to expand against adjacent windings, causing the flexible body 1010 to stiffen or hold a current pose. In an alternative embodiment, a set of separate balloons or a single balloon may be partitioned into balloon portions 1002a-1002d, each positioned within different windings of the coil pipe 1023. As illustrated in FIG. 10B, each balloon portion 1002a-1002d are selectively inflated or deflated to stiffen the flexible body 1010 in a bent configuration. In this example, selected inflation of balloon portions 1002a and 1002c, can cause hold an angle between adjacent segments of the coil support structure 1023 and, along with it, the shape of the flexible body 410. On an inner bend of the flexible body 1010, balloon portions 1002b and 1002d, are deflated to allow for compression of adjacent segments along the inner bend.

[0094] The actuator 430 may include actuation for both control of the pump for inflating or drawing vacuum in the balloons and mechanisms for varying the amount of tension in the control elements 421. Thus, the actuator 430 may vary inflation and or vacuum in the balloons and tension of the control elements 421 in a coordinated relationship to achieve the desired amount of stiffness of the shape or pose of the flexible body 410. The control system 112's actuation of the balloons 502 (or other stiffening elements) and control elements 421 can be based on feedback from various sensors (such as localization sensor 426) to accomplish other objectives, such as adapting to instruments or avoiding injury to sensitive anatomy or withstanding different loading profiles. In this case, the shaping function of the control elements 421 can be facilitated by the stiffening mechanism 500, rather than the stiffening mechanism just being used to stiffen and hold a current pose or shape of the flexible body 410.

[0095] The balloon 502 can be generally constructed of similar materials as balloons for other medical applications, such as for deployment of various medical devices, such as cardiovascular devices. Such balloons can have varied beginning and end shapes depending upon the processes and molds employed in their creation. For example, balloons with large inflated diameters can be compressed down to compact configurations due to careful folding or forming. Generally, however, the balloons used in the embodiments of FIGS. 6A-6D and 7A-7D benefit from sufficient toughness to withstand multiple uses and the friction of interaction with the support structure – such as being able to be trapped or pinched between the windings 504 of the coil pipe 423. At the same time, the balloons benefit from sufficient flexibility to conform to the coil pipe 423 where spread apart to achieve a sufficient amount of friction or blocking for higher stiffnesses of holding the pose under a range of loading conditions.

[0096] The stiffening mechanism 500 could also employ other stiffening elements for holding the shape of the flexible body 410. For example, a foam could be expanded between the coil pipe 423 and the control element lumen 412 or MEMS technology employed to drive wedges or blockers between the spread apart windings 504. The balloons 502 could also be deployed in arrays of multiple balloons and the balloons themselves could be shaped to have features – such as wedge shapes configured for urging between the spread apart coils if inflated or vacuumed into contact with the coil pipe 423. Although the illustrated use of a coil pipe 423 works particularly well because of the nature of the windings 504 forming stacked, adjacent elements that spread apart during bending. Balloons could also be employed with other support structures than the coil pipe. For example, an interconnected linkage may be used in association with (or as) the control elements 421 wherein the linkages have a shape or articulation relative to each other that is stiffened upon being adhered to or wedged between by a balloon. The spacing and shape of the

sub-elements could also be configured to work well with the shape and features of the stiffening elements of the stiffening mechanism. For example, wedge-shaped spaces between sub-elements of the support structure could be locked by insertion of conforming wedge-shaped stiffening elements.

[0097] It should be noted that some embodiments of the invention work well with any type of flexible elongate device 400 with the flexible body 410, wherein the flexible body has some changing structural characteristic that can be trapped, blocked, adhered to or otherwise intervened in with the operative elements of the stiffening mechanism 500 to stiffen the pose or shape of the flexible body. In previously described embodiments, the structural characteristics are within coil pipes. However, in alternative or additional examples, a support structure such as axial support structure 424 may be used in conjunction with one or more balloons surrounding the support structure or positioned within a lumen of the support structure. Particularly useful is a support structure that uses a plurality of sub-elements arranged in series, where the sub-elements exhibit differential characteristics (such as spreading apart) when adjusted into various shapes by flexing or shaping of the flexible body 410 in which they are embedded.

[0098] FIGS. 8A-8E show another embodiment of a stiffening mechanism 800 for a flexible elongate device with a flexible body 801 defining a lumen 811 and divided into a plurality of portions or segments 812. In this embodiment, the stiffening mechanism includes a plurality of nitinol wires 810 distributed circumferentially around each of the plurality of segments 812. Generally, selective activation or energizing of the nitinol wires 810 causes them to engage – by changing their length – the portion of the flexible body to hold or change its pose. The controller of the stiffening mechanism 800 can then modulate its energizing of the nitinol wires 810 based on feedback from various sensors, such as the sensor 826, to hold the pose in varying conditions. In another aspect, the nitinol wires 810 could be employed to just hold the pose of the portion of the flexible body 801 rather than be involved in shaping or steering the flexible body 410.

[0099] FIG. 8A shows the nitinol wires 810, in one aspect, can be embedded in a wall structure of the flexible body 801. For example, four of the nitinol wires 810 are distributed circumferentially with about 90 degrees between them. Also, FIG. 8A shows a sensor lumen such as sensor lumen 819, defined within the wall structure of the flexible body 801 about equidistant between two of the nitinol wires 810. This distribution of the nitinol wires 810 and positioning of the sensor lumen 819, with the sensors 826, such as a fiber-based shape sensor, extending therein, facilitates 360-degree bending control of the flexible body 801 by selectively controlling the amount of energization of the four nitinol wires 810 based on feedback from the shape sensor. The sensors 826 within the sensor lumen 819 may include one or more additional sensors instead of or

in addition to the optical fiber shape sensor. For example, the sensors 826 may include a plurality of EM sensors distributed along the length of the flexible body 801, a plurality of force sensors distributed along the length of the flexible body 801, and/or navigation systems, such as sensor system 108 that computes the approximate location of medical instruments (such as the flexible body 801) within the anatomy of the patient and/or medical tools that are delivered through main lumen 811, to inform the control system 112 which then controls formation and holding of a shape of the flexible body 801. Fewer or more embedded nitinol wires 810 are possible with different relative distributions within the wall structure depending on the desired amount and distribution of actuation and holding forces from the stiffening mechanism 800.

[0100] FIGS. 8B-8E show how the flexible body 801 can be formed of a plurality of portions or segments 812. Each of the segments is a short cylindrical portion of the whole flexible body 801. In this embodiment, the nitinol wires 810 are short lengths beginning and ending in the segment. The actuator 430 may be coupled to each of these lengths of nitinol wires 810 and able to energize those wires to be able to hold or adjust the pose of the segment. FIGS. 8D and 8E show how the segments 812 can be arranged end-to-end to form a longitudinal array 814 and a larger portion (or the entire) flexible body 801. In addition, FIG. 8E shows how the cumulative change in pose of each of the segments 812 results in a change in, and/or holding of shape of, the flexible body 801.

[0101] The nitinol wires are comprised of a shape memory material in the form of a nickel-titanium alloy with a transition temperature. The actuator 430 can selectively change the length of the nitinol wires by heating them, such as with electrical power, through the transition temperature to change between shapes. For example, the memorized shape of the nitinol wires may be a shorter length than the starting length. Thus, heating the nitinol wire causes it to shorten and then change the pose of the segment by compressing the segment 812. Memorized shapes could also be various curves or other configurations to help with shaping. Notably, embodiments of the present invention may also include shape memory materials other than nitinol or mechanical devices that are able to expand, retract and/or change shape to cause and hold pose changes.

[0102] In the previously described balloon and nitinol wire embodiments, the flexible body can be driven to a target location with balloon portions or nitinol wires deactivated or otherwise in a natural configuration, using pull wires or other control elements 421 for steering. Once in position, the current shape of the flexible body 410 or 801 can be measured using a shape sensing system such as tracking system 230. Then, the balloon portions 508 or nitinol wires 810 can be selectively inflated, deflated, or actuated in varying amounts to help maintain the measured shape.

[0103] In the case of nitinol wires, using the data from the optical fiber or other shape sensor, the controller system 112 can be configured to energize the appropriate nitinol wires 810 of the longer composite tube (with multiple segments) to hold its shape. Also, using shape data from the optical fiber sensor, such as sensing deviations from a desired pose or shape, forces could be applied in appropriate regions to maintain a measured shape. Additionally, the nitinol wires 810 can be used to apply greater force to increase bending moments when a stiff instrument is inserted through the device.

[0104] In another example, the balloon portions 508 can be inflated/deflated or nitinol wires can be activated, and pull wires can be additionally controllably altered in tension to maintain the measured shape. Both examples include automatic maintenance of a measured shape or the automatic hold of a pose using pull wires to further stiffen the flexible body 410.

[0105] In other embodiments, the flexible body 410/801 can be navigated within tortuous anatomy 516 in a flexible state, parked within anatomy to position a distal end of the flexible body 410/801 at a target location, then select portions of the flexible body may be stiffened or rigidized depending on different conditions. For example, during a pre-procedure planning stage, a user can identify target areas of the anatomy on a pre-operative model or map, about which one or more proximate portions of the flexible body 410/801 may be selectively rigidize. For example, target areas of the anatomy may include anatomy which are particularly sensitive (e.g., a lung airway is near the pleura, or in a different application, the path of a flexible body 410/801 is near an organ). Alternatively or additionally, imaging techniques can be used to automatically identify target areas of the anatomy. Using registration of a flexible elongate device 400 and real time tracking previously described in reference to FIGS. 2A and 2B, and by identifying the target areas of the anatomy, the flexible body 410/801 can be parked at a target, then portions of the flexible body 410/801 which are proximate the target areas of the anatomy (e.g. various discrete portions along the length of flexible body 410/801) can be selectively discretely rigidized, using stiffening mechanisms such as stiffening mechanism 500/800, to provide protection for the target area of the anatomy (e.g., sensitive anatomy) during delivery of devices through the catheter.

[0106] In another embodiment, the flexible body 410/801 is positioned in tortuous anatomy 516 forcing it adapt to and form tight bends, as shown in FIG. 9A. Thus, delivering a stiff device through a working lumen of the flexible body is challenging. Using selective stiffening control of the embodiments above, a tight bend 518 could be identified as a target area of the anatomy manually by a user, automatically by the control system analyzing the pre-operative model using imaging techniques, and/or by the control system 112 using shape sensing data and a threshold setting for a minimum bend radius. Along the length of the catheter positioned around the tight

bend 518, the control system 112 can command the actuator 430 and stiffening mechanism 500/800 to reconfigure the shape of the flexible body 410 into a larger radius to allow for delivery of the stiff device, as shown in FIG. 9B.

[0107] More generally, in some embodiments, the control system 112 measures a current configuration of the flexible body 410/801 and determines a desired configuration of the flexible body 410/801. The current configuration of the flexible body 410/801 may include a current pose, for example, measuring the current configuration includes measuring a shape of the current pose, such as a radius of a curve along the flexible body 410/801. As discussed above, the current pose may be determined using shape sensing data from an optical fiber sensor or other shape sensor (e.g. a plurality of EM or strain sensors) along the length of the flexible body 410/801. Alternatively, shape may be determined using kinematic data describing the flexible body 410/801 and actuator 430 such as which actuators are activated, a tension in actuators, or pressure applied by actuators.

[0108] The control system 112 may determine deviations from the current configuration to a desired configuration of the flexible body 410/801. Responsive to the determined deviations, the control system 112 can command the actuator 430 to selectively stiffen one or more stiffening mechanisms 500/800 along the length of the flexible body 410/801 to apply forces in appropriate regions to position the flexible body from the current configuration to the desired configuration. For example, the stiffening mechanisms may include a plurality of the balloon portions 508/1002 and/or nitinol wires 810 distributed down the length of the flexible body 410/801 to stiffen discrete portions of the flexible body 410/801 down the length of the flexible body 410/801. Each of the stiffening mechanisms (e.g. each of the balloon portions 508/1002 and/ or each of the nitinol wires 810) may be independently activated by the actuator 430.

[0109] Following the examples above, the control system 112 may determine deviations from the measured radius of a curve at a location along the flexible body 410/801 (e.g., current configuration) and the minimum bend radius (e.g., desired configuration). The minimum bend radius may be determined by the control system 112 based on receiving information describing stiffness of an instrument to be delivered by the flexible body 410/801. Accordingly, the control system 112 can command the actuator 430 to selectively stiffen ones of the stiffening mechanisms along the length of the flexible body 410/801 to apply forces in appropriate regions to position the flexible body to increase a bend radius of the curve at the location along the flexible body 410/801.

[0110] Again following the examples above, the control system 112 may determine the desired configuration by identifying target areas of the anatomy. FIG. 11 is a simplified flow diagram of a method 1100 performed by the control system 112 for identifying target areas of the anatomy

and activating a stiffening mechanism according to some embodiments. For example, the target areas of the anatomy may be identified based on the control system 112 receiving live images or preoperatively recorded surgical images and identifying portions of the flexible body 410/801 that are proximate to the target areas of the anatomy. For example, at 1102, live images or pre-operative images are received by the control system 112. The images may be received from imaging technology such as, computed tomography (CT), magnetic resonance imaging (MRI), fluoroscopy, thermography, ultrasound, optical coherence tomography (OCT), thermal imaging, impedance imaging, laser imaging, nanotube X-ray imaging, and/or the like. In one embodiment, a pre-operative model may be generated from pre-operative images.

[0111] At 1104, target areas of the anatomy may be identified within the pre-operative model, by a user, or automatically using imaging techniques. In another embodiment, target areas of the anatomy can be identified (by users or automatically using imaging techniques) within captured live images. The identified target areas of the anatomy include sensitive anatomy or anatomy with tight bends within anatomical passageways (e.g. small radius bends where the radius is less than the minimum bend radius), for example.

[0112] At 1106, the control system 112 may be used to register the flexible body 410/801 to the live images or to the pre-operative model using sensor data from one or more sensors 426 (or 826) positioned along the flexible body 410/801, while the flexible body is being navigated within anatomy. The registration of the flexible body 410/801 to the pre-operative model/live image is based on the relative known positions between position/shape sensors (e.g. fiber optic shape sensors, EM sensors, etc.) and stiffening mechanism components 502/1002/810. Various systems for using fiber optic sensors to register and display a surgical instrument with surgical images are provided in U.S. Patent Application No. 13/107,562, filed May 13, 2011, disclosing, "Medical System Providing Dynamic Registration of a Model of an Anatomic Structure for Image-Guided Surgery," which is incorporated by reference herein in its entirety. Systems for registering live imaging devices to a pre-operative image or imaging system are provided in PCT application PCT/US2017/017433, filed February 2, 2017, disclosing, "Systems and Methods for Using Registered Fluoroscopic Images in Image-Guided Surgery" and PCT application PCT/US17/17391, filed February 2, 2017, disclosing, "Systems and Methods of Pose Estimation and Calibration of Perspective Imaging System in Image Guided Surgery", which are each incorporated by reference herein in their entirety.

[0113] Information from tracking system 230 may be sent to a navigation system 232 where it is combined with information from visualization system 231 and/or the pre-operatively obtained models (e.g., anatomic models of the patient anatomy) to provide the physician or other operator

with real-time position information. At 1108, the real-time position information, including the current configuration of the flexible body 410/801 is received by the control system 112. At 1110, based on the real time position information of the flexible body 410/801, and the identified target areas of the anatomy, the control system 112 can identify portions of the flexible body 410/801 that are positioned at the target areas of the anatomy. At 1112, the control system 112 can command actuators 430, to selectively stiffen one or more stiffening mechanisms 500/800 along the length of the flexible body 410/801 proximate the target areas of the anatomy (the determined portion/s of the flexible body 410/801) to provide protection for sensitive anatomy or to reconfigure the specific length of the flexible body to form a larger radius bend that is greater than or equal to the minimum bend radius.

[0114] In some examples, the real-time position information may be displayed on display system 110 of FIG. 1 for use in the control of medical instrument system 200. In some examples, a virtual image of the flexible body may be overlaid or integrated into the pre-operative model and the identified target areas of the, such as sensitive anatomy and/or tight bends may be displayed. The virtual image of the flexible body may be updated based on the real-time position information obtained from tracking system 230.

[0115] In another embodiment, the flexible body 410/801 is positioned in anatomy which may apply an external force against the flexible body 410/801. For example, anatomy may apply an external force as part of respiration, circulation, or excretion. Using selective discrete stiffening control of the embodiments above, upon detecting an external force at a location at a distal end or along the length of the flexible body 410/801, the control system 112 can command the actuator 430 to selectively stiffen discrete portions along the length of the flexible body 410/801 at the location of the external force.

[0116] FIG. 12 is a simplified flow diagram of a method 1200 performed by the control system 112 for identifying an external force and activating a stiffening mechanism according to some embodiments. At 1202, the control system 112 receives sensor data sensor data from one or more sensors 426 (or 826) positioned along the flexible body 410/801 for detecting application of an external force. At 1204, the control system 112 determines whether any of the received sensor data is out of a predetermined threshold for identifying application of an external force to the flexible body 410/801.

[0117] For example, the external force may be detected based on detecting a change in the shape of the flexible body 410/801 as determined by the shape sensor. In some examples, the external force is detected based on a change in shape determined by the shape sensor or a change in shape viewed by live imaging that is not a result of control of the actuator 430 or movement of

a medical instrument through the main lumen 411/811. In other words, the external force is detected based on a change in shape determined by the shape sensor that is independent of operation of the actuator 430 or movement of a medical instrument through the main lumen 411/811. In another example, a fiber optic shape sensor can be configured to calculate both shape and force along the length of the flexible body 410/810.

[0118] In another example, the external force may be detected based on readings from one or more force sensors positioned along the length of the flexible body 410/801. The force sensors may include one or more of a strain gauge, a load cell, a force sensing resistor, or any other suitable force sensor. Each of the force sensors may correspond to a particular location, region, or segment of the flexible body 410/801.

[0119] At 1208, the control system 112 identifies a corresponding location, region, or segment of the flexible body 410/801 where the sensor data is out of threshold. For example, the control system 112 identifies a corresponding location, region, or segment of the flexible body 410/801 where an external force is being applied to the flexible body 410/801. At 1210, upon one of the force sensors detecting where the external force is being applied to the flexible body 410/801, the control system 112 can command the actuator 430 to selectively stiffen the flexible body 410/801 at the corresponding location of the external force. In some examples, the external force detected based on the force sensors is independent of operation of the actuator 430 or movement of a medical instrument through the main lumen 411/811.

[0120] In one embodiment as described above, the flexible body 410/801 is fully positioned in anatomy such that a distal end of the flexible body 410/801 is positioned at or near an anatomical target to be used as a working channel for delivery of therapeutic and/or diagnostic tools. In order to protect anatomy, the controller may selectively stiffen discrete portions of the flexible body. Shape sensing and or external force measurements can be used to determine a portion (or plurality of portions) of the flexible body 410/801 is/are currently configured in a tight radius bend or experiencing external force. Additionally or alternatively, shape sensing can be used in conjunction with a registered pre-operative model where target areas of anatomy have been previously identified, to determine whether a portion (or plurality of portions) of the flexible body 410/801 is/are currently configured in a tight radius bend (e.g., a radius less than the minimum bend radius) or experiencing external force due to the current positioning of the flexible body 410/801 in anatomy. The controller can then selectively activate discrete stiffening elements 502/1002/810 to selectively stiffen portions of the flexible body 410/801 located at the determined portions of the flexible body 410/810.

[0121] In an alternative embodiment, the flexible body is navigated through anatomy and as a portion of the flexible body is actively inserted through a portion of anatomy that has been identified as a target area of the anatomy (e.g. tight bend, sensitive anatomy, etc.), the controller selectively activates the portion situated within the target area of anatomy. In one example, shape sensing can be used in conjunction with a registered pre-operative model by the controller to determine which portion of the flexible body is currently positioned within a target area of the anatomy. In another example, the controller can use shape sensing and/or force sensing to instantly determine which portion or plurality of portions of the flexible body is/are positioned within a tight bend or experience an excessive external force beyond a threshold. The controller can then selectively active discrete stiffening elements 502/1002/810 to selectively stiffen portions of the flexible body 410/801 located at the determined portions of the flexible body which are positioned within a target area of the anatomy, experience a tight bend, and/or experience excessive external force. The controller can propagate the selective stiffness down the length of the flexible device as the flexible device is inserted in anatomy. Accordingly, the flexible body may be stiffened in a controlled manner into a desired pose that protects anatomy from damage the flexible body as it is inserted into anatomy. For example, as a most distal section of the flexible body is positioned near to a target area of the anatomy, the controller selectively stiffens the most distal section only. Then as the flexible body is further inserted in anatomy, the most distal section is relaxed and a section just proximal the most distal section is selectively stiffened. Thus, as the flexible body is being inserted within anatomy, the flexible body can be positioned in a known and controlled pose to protect anatomy instead of allowing a fully flexible device to potentially rub or press against anatomical walls.

[0122] Embodiments above disclose embodiments of stiffening mechanism 500 that provide for selective stiffening of portions of the elongate body along its length and actuation of discrete balloon, nitinol wire or other stiffening elements for selective stiffening to hold a pose or shape. In other embodiments, selective inflation and deflation of balloon portions 1002a-1002d can be used to additionally or alternatively actuate and control steering of the elongated flexible device 1000 in addition to holding pose of the flexible body 1010 of the elongated flexible device 1000. This same ability to steer the flexible body 410 can be employed to hold the pose or shape of the flexible body 410. For example, feedback from the shape sensor 426 could be used to selectively adjust to pressure in the balloons to hold the pose or shape of the flexible body 410.

ADDITIONAL EXAMPLES

[0123]

1. A method of holding a pose of a flexible body using a controller, the method comprising:

measuring a current configuration of a flexible body based at least in part on a sensor coupled to the flexible body;

determining a desired configuration of the flexible body; and

selectively activating a stiffening mechanism to position the flexible body from the current configuration to the desired configuration, wherein the stiffening mechanism includes a plurality of stiffening elements distributed down the length of the flexible body.

2. The method of example 1, wherein positioning the flexible body in the desired configuration includes activating each of the plurality of stiffening elements independently.

3. The method of examples 1 or 2, wherein the current configuration includes a measured shape of the flexible body.

4. The method of example 3 further comprising identifying a small radius in the measured shape, wherein selectively activating the stiffening mechanism includes activating select ones of the plurality of the stiffening elements to increase a bend radius of the flexible body at the identified small radius in the measured shape.

5. The method of example 4 further comprising receiving information describing stiffness of an instrument to be delivered by the flexible body, wherein the identifying of the small radius in the measured shape includes determining a minimum bend radius corresponding to the stiffness of the instrument.

6. The method of any of examples 1-5, wherein determining the desired configuration comprises:

receiving information identifying a target area of anatomy; and

setting the desired configuration to activate select ones of the plurality of the stiffening elements at the identified target area of anatomy.

7. The method of any of examples 1-5, wherein determining the desired configuration comprises:

receiving information identifying anatomical passageways including small radius bends; and

setting the desired configuration to activate select ones of the plurality of the stiffening elements at the small bends.

8. The method of example 6 or 7, wherein the information received is based on live imaging.

9. The method of example 6 or 7, wherein determining the desired configuration further comprises:

receiving a preoperatively recorded surgical image;

registering the flexible body to the preoperatively recorded surgical image using sensor data from the sensor coupled to the flexible body;

identifying a portion of the flexible body positioned within the identified target area of anatomy or the small bends based on the registration.

10. The method of example 6 or 7, wherein the information received is based on the preoperatively recorded surgical image.

11. The method of any of examples 1-10, wherein the current configuration includes an external force applied to the flexible body.

12. The method of any of examples 1-11, wherein the plurality of the stiffening elements includes a plurality of nitinol actuators extending within a wall structure of the flexible body, and wherein the selectively activating the stiffening mechanism includes energizing at least one of the plurality of nitinol actuators.

13. The method of any of examples 1-11, wherein the plurality of the stiffening elements includes a plurality of balloons, and wherein the selectively activating the stiffening mechanisms includes inflating or deflating at least one of the plurality of balloons.

CLAIMS

What is claimed is:

1. A medical system comprising:

a flexible elongate device including:

a flexible body with a proximal end, a distal end, and at least one lumen extending between the proximal and distal ends, wherein the flexible body includes a plurality of sub-portions;

a shape sensor extending along at least a portion of the flexible body; and

a stiffening mechanism having a plurality of stiffening elements, each of the stiffening elements positioned within one of the plurality of sub-portions, wherein the sub-portions extend along the flexible body; and

a controller connected in communication with the shape sensor, configured to selectively activate the stiffening elements based in part on data received from the shape sensor.

2. The medical system of claim 1, wherein the controller is further configured to selectively activate the stiffening elements based in part on a type of instrument for insertion through the flexible body.

3. The medical system of claim 2, wherein the controller is configured to energize selected ones of the stiffening elements to reduce curvature of the flexible body to match a stiff type of instrument .

4. The medical system of claim 1, wherein the controller is further configured to selectively activate the stiffening elements based in part on anatomical information.

5. The medical system of claim 4, wherein the anatomical information includes information identifying a target area of anatomy and wherein the controller is further configured to actuate selected ones of the stiffening elements to protect the target area of anatomy.

6. The medical system of claim 4, wherein the anatomical information includes identifying a small radius bend within the anatomy and wherein the controller is further configured to actuate selected ones of the stiffening elements to reduce the curvature of the flexible body around the small radius bend.

7. The medical system of any of claims 1-6, wherein the shape sensor includes at least one of a shape sensing fiber extending along the flexible body or a plurality of EM sensors extending along the flexible body.

8. The medical system of any one of claims 1-6, wherein the stiffening mechanism includes a longitudinal balloon array having a plurality of balloon portions and wherein each of the stiffening elements is one of the plurality of balloon portions.

9. The medical system of claim 8, wherein the flexible body includes a coil with a plurality of adjacent windings and wherein each of the balloon portions are configured to extend between the adjacent windings with the application of pressure.

10. The medical system of claim 9, wherein the controller is further configured to selectively apply pressure to each of the balloon portions to urge apart adjacent windings to shape the flexible body.

11. The medical system of any one of claims 1-6, further comprising a steering mechanism configured to control the distal end portion of the flexible body, wherein the steering mechanism includes a plurality of pull wires and wherein the controller is further configured to adjust tension in the pull wires along with selective activation of the stiffening elements to hold the portion of the flexible body in a pose determined from the shape sensor data.

12. The medical system of any one of claims 1-6, wherein the plurality of stiffening elements includes a plurality of nitinol actuators, the flexible body includes a wall structure, and the plurality of nitinol actuators are embedded in the wall structure.

13. The medical system of claim 12, wherein the plurality of nitinol actuators are distributed circumferentially within the wall structure.

14. A flexible elongate device comprising:

a flexible body with a proximal end, a distal end, and at least one lumen extending between the proximal and distal ends, the flexible body having sufficient flexibility to form a pose;

a support structure coupled with the flexible body, the support structure including a plurality of sub-elements arranged in series, wherein at least a portion of the sub-elements are configured to spread apart when the flexible body flexes into the pose; and

a stiffening mechanism having at least one stiffening element extending along at least a portion of the flexible body and configured for actuation independent of the support structure, wherein actuation of the at least one stiffening element stiffens the support structure to hold at least a portion of the pose of the flexible body;

wherein the at least one stiffening element includes a compression feature configured to engage the support structure.

15. The flexible elongate device of claim 14, wherein the support structure includes a coil and the sub-elements include windings of the coil.

16. The flexible elongate device of claim 14, wherein the support structure includes a spine.

17. The flexible elongate device of any one of claims 14-16, wherein the stiffening mechanism includes an inflatable system.

18. The flexible elongate device of claim 17, wherein the inflatable system includes a balloon configured to extend in between the sub-elements.

19. The flexible elongate device of claim 18, wherein the balloon is configured to extend in between the sub-elements due to the application of a vacuum pressure causing the balloon to collapse into an exterior of the support structure and in between the sub-elements.

20. The flexible elongate device of claim 18, wherein the balloon is configured to extend in between the sub-elements due to the application of an inflation pressure causing the balloon to expand into an interior defined within the support structure and in between the sub-elements.

21. The flexible elongate device of claim 17, wherein the inflatable system includes a plurality of balloon portions.

22. The flexible elongate device of claim 21, wherein the plurality of balloon portions are selectively inflatable to hold the at least the portion of the pose.

23. The flexible elongate device of claim 21, wherein the plurality of balloon portions are positioned between the sub elements.

24. The flexible elongate device of claim 21, wherein the plurality of balloon portions spiral between the sub elements.

25. The flexible elongate device of claim 21, further comprising a plurality of control elements extending along the flexible body and configured to exert tension on the flexible body in conjunction with selective inflation of the balloon portions to further hold the at least the portion of the pose.

26. The flexible elongate device of any one of claims 14-16, further comprising:

a shape sensor configured to determine the pose of the flexible body; and

a controller, wherein the controller is connected in communication with the shape sensor and wherein the controller is configured to activate the stiffening mechanism to hold at least the portion of the pose of the flexible body.

27. A method of holding at least a portion of a pose of a flexible body, the method comprising engaging a stiffening element of a stiffening mechanism within a spacing between at least a pair of a plurality of sub-elements, wherein the plurality of sub-elements extend along the flexible body.

28. The method of claim 27, further comprising wherein engaging the stiffening element includes urging a portion of the stiffening element into the spacing between the at least the pair of the plurality of sub-elements.

29. The method of claim 28, wherein the urging of the portion of the stiffening element includes one of inflating or deflating the stiffening element.

30. The method of claim 27-29, further comprising actuating a plurality of pull wires extending within a wall structure of the flexible body including adjusting tension in the plurality of pull wires while selectively activating the stiffening elements to hold the pose of the flexible body.

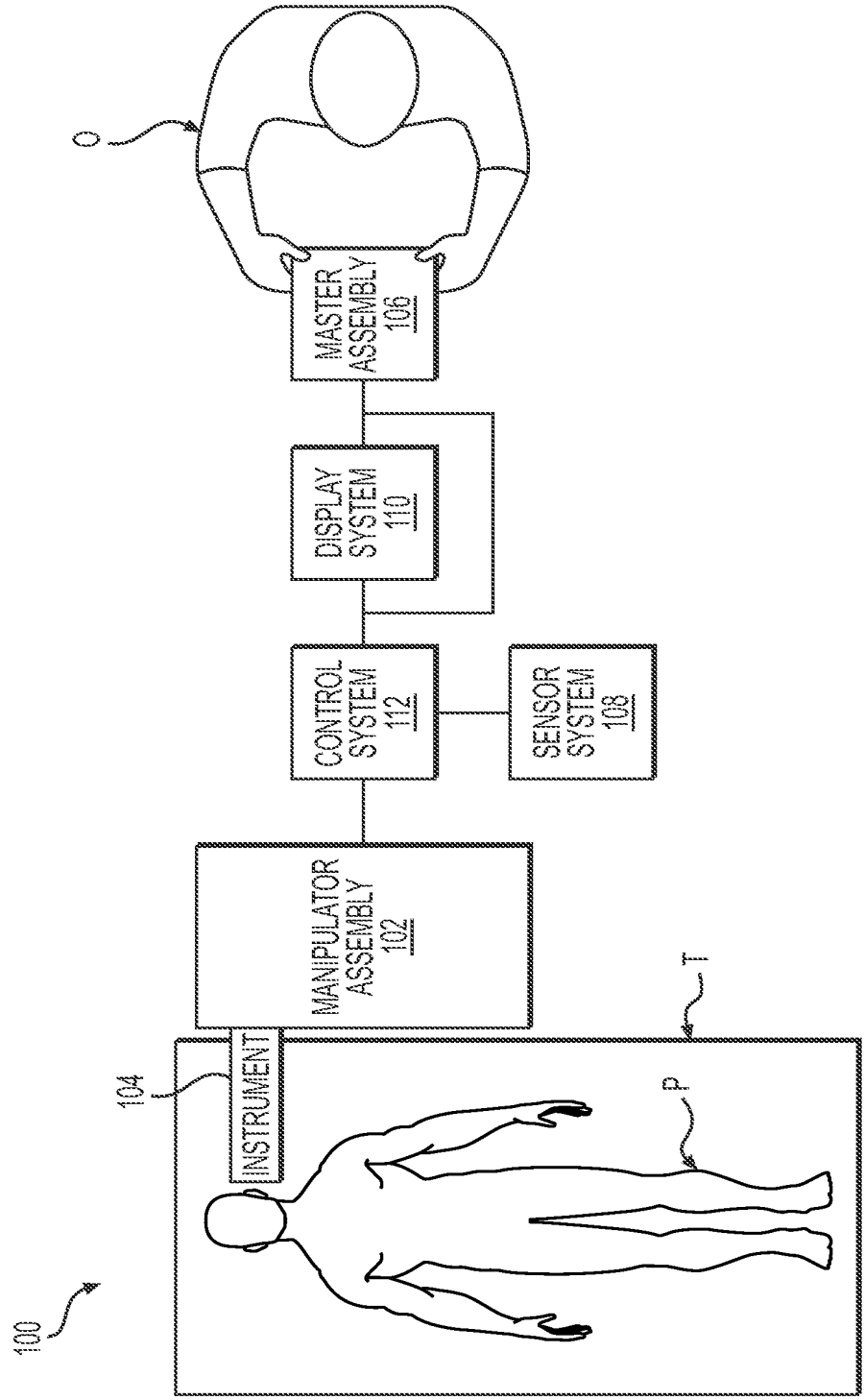

O
MASTER ASSEMBLY 106
DISPLAY SYSTEM 110
CONTROL SYSTEM 112
SENSOR SYSTEM 108
MANIPULATOR ASSEMBLY 102
INSTRUMENT
104
T
P
100

FIG. 1

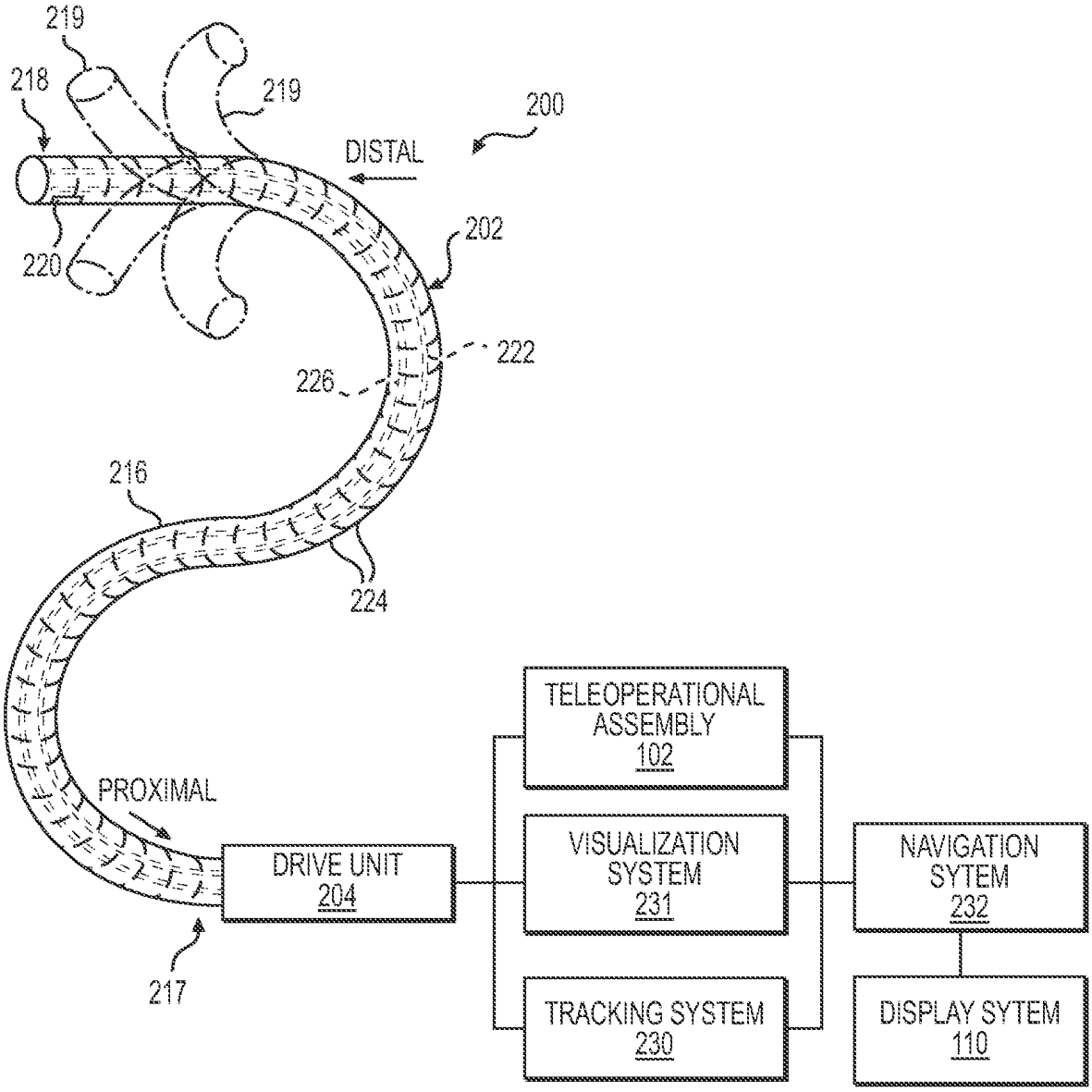

219
218
219
200
DISTAL
202
220
222
226
216
224
PROXIMAL
217
TELEOPERATIONAL ASSEMBLY 102
VISUALIZATION SYSTEM 231
NAVIGATION SYTEM 232
DRIVE UNIT 204
TRACKING SYSTEM 230
DISPLAY SYTEM 110

FIG. 2A

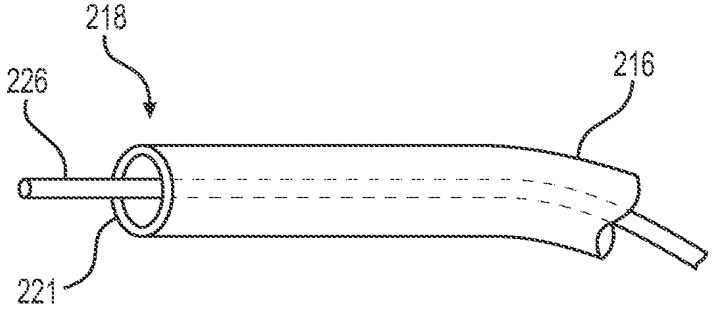

218
226
216
221

FIG. 2B

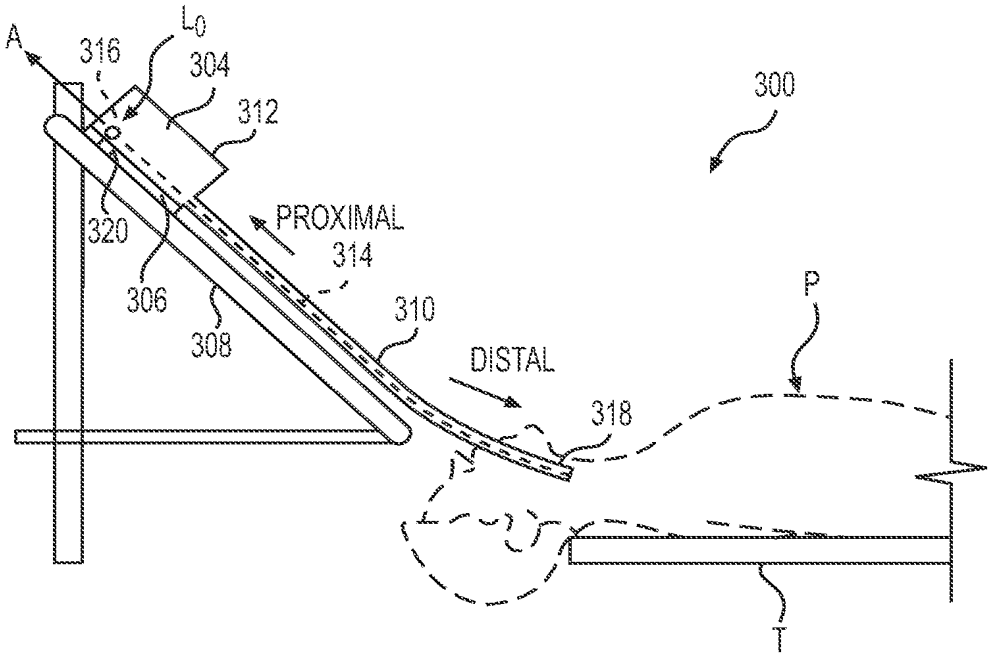

A
316
L_0
304
312
300
PROXIMAL
320
314
306
310
P
308
DISTAL
318
T

FIG. 3A

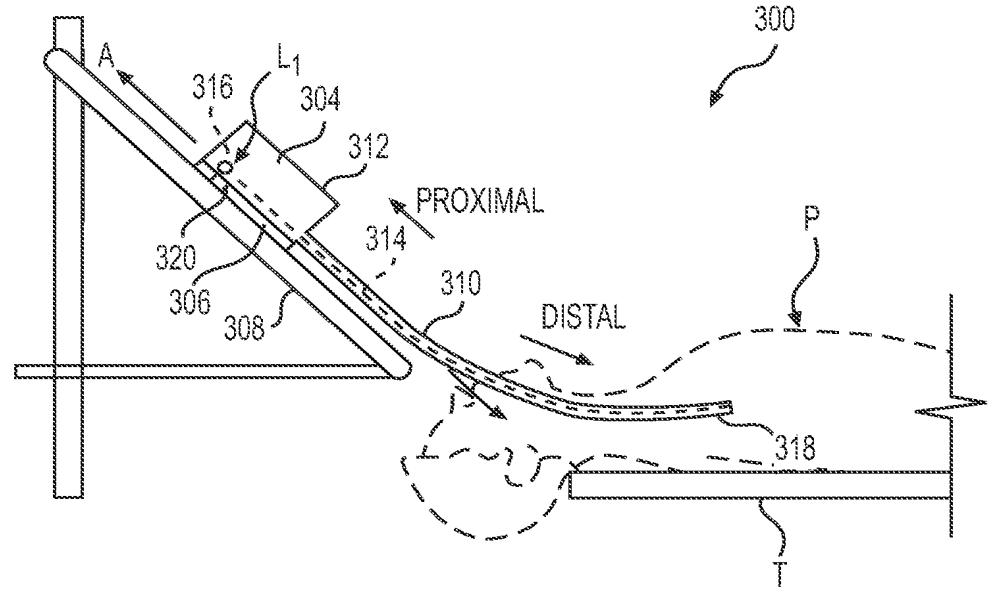

300
A
L_1
316
304
312
PROXIMAL
320
314
P
306
310
308
DISTAL
318
T

FIG. 3B

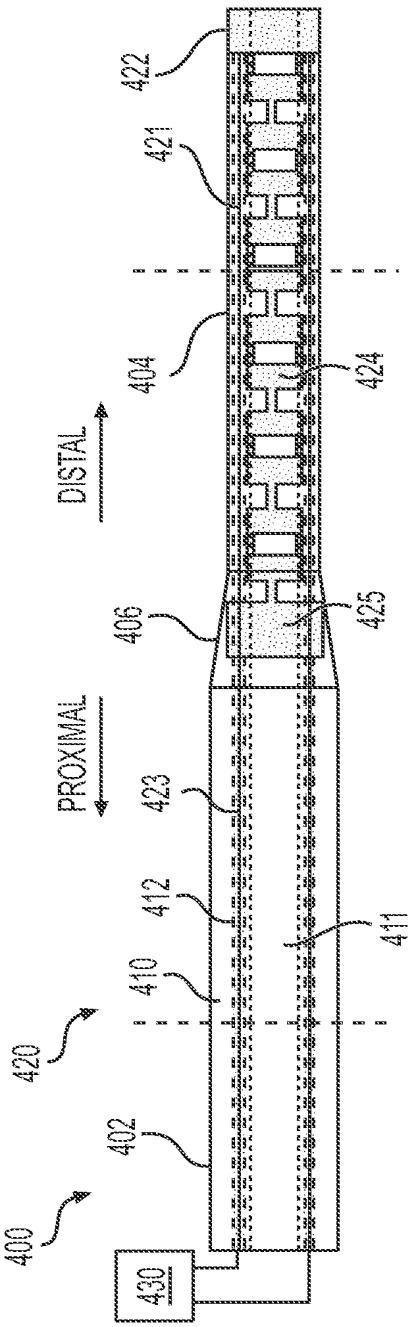


FIG. 4A

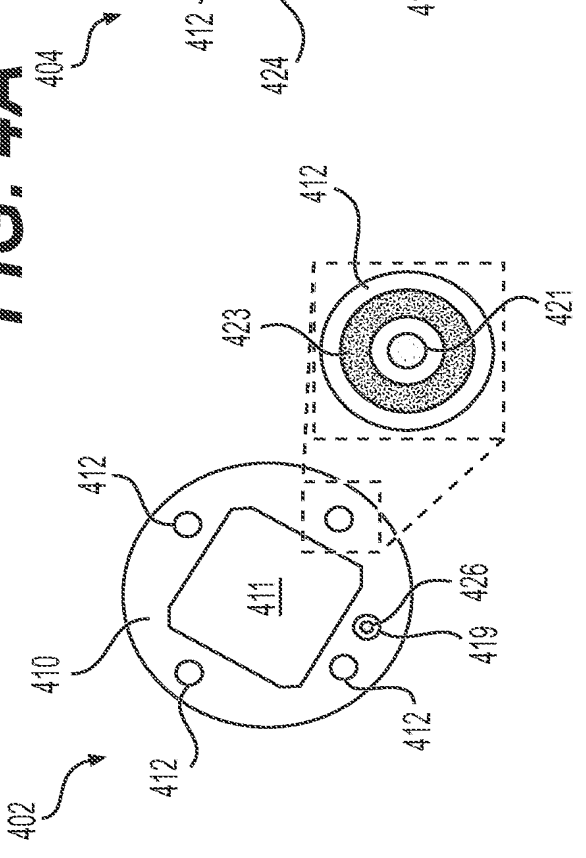


FIG. 4B

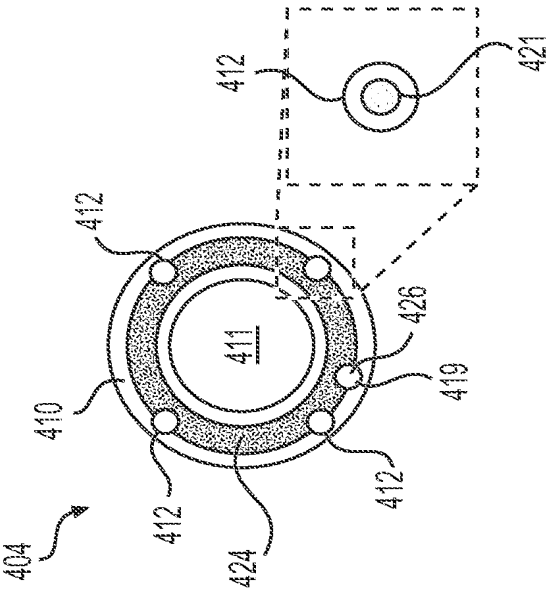


FIG. 4C

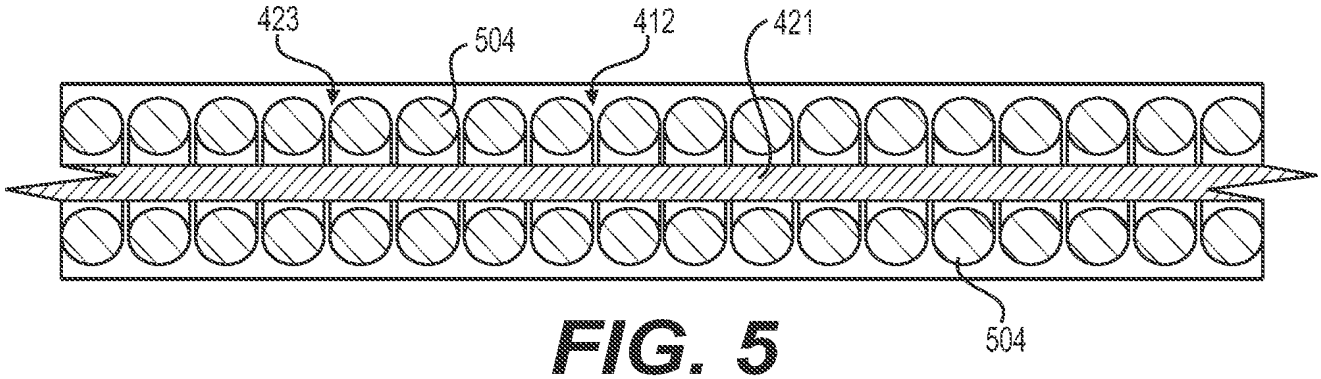


FIG. 5

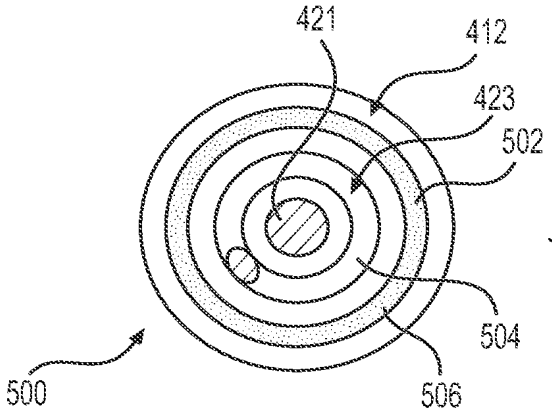


FIG. 6A

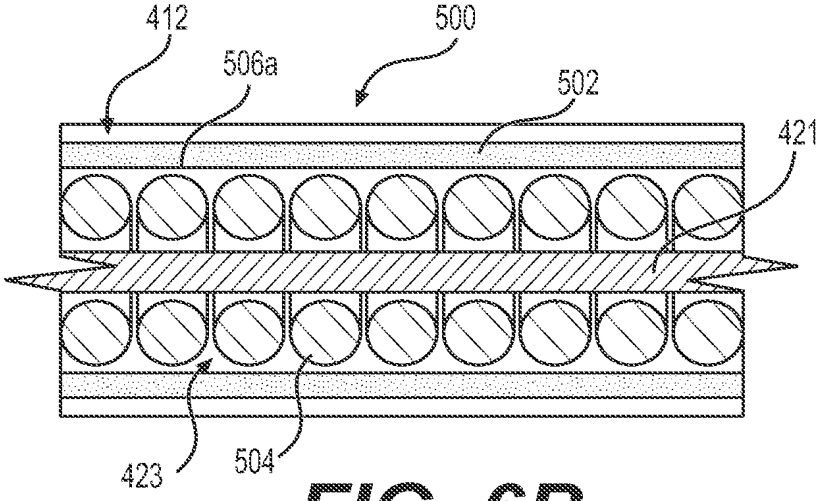


FIG. 6B

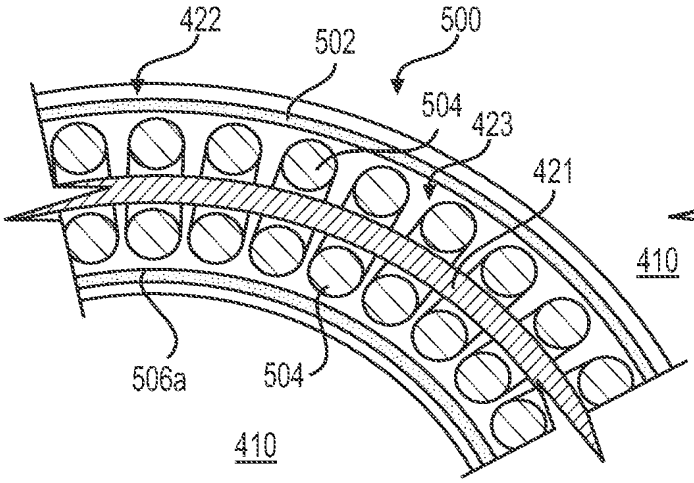


FIG. 6C

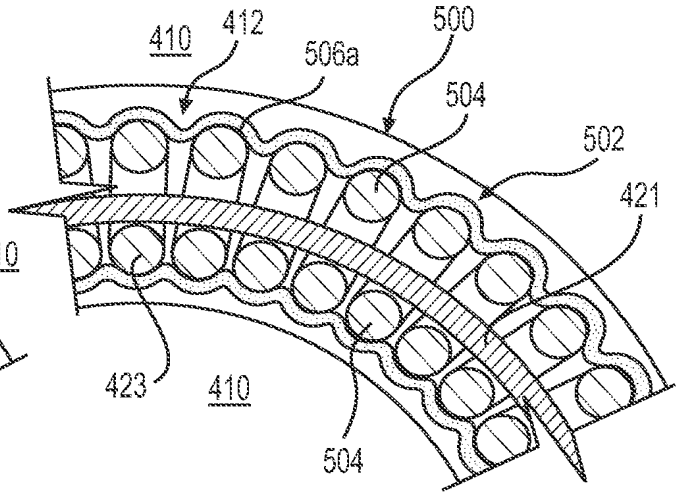


FIG. 6D

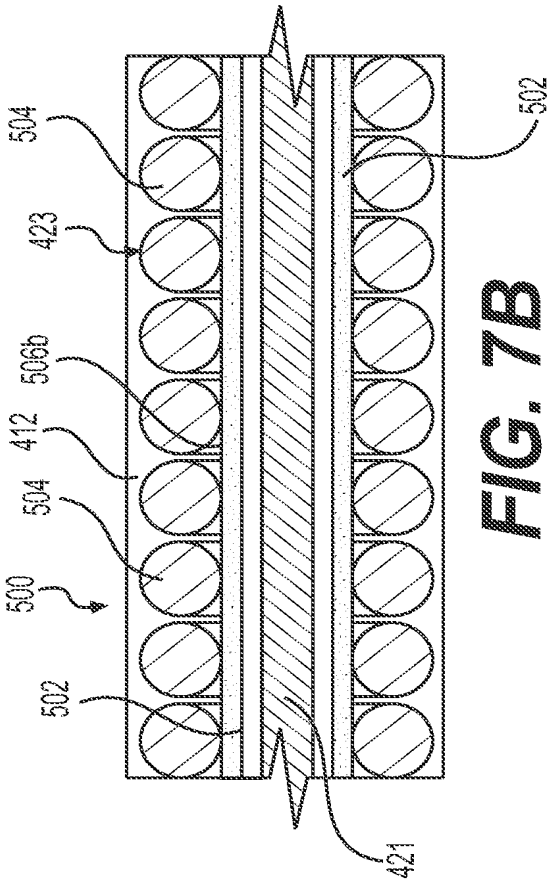


FIG. 7B

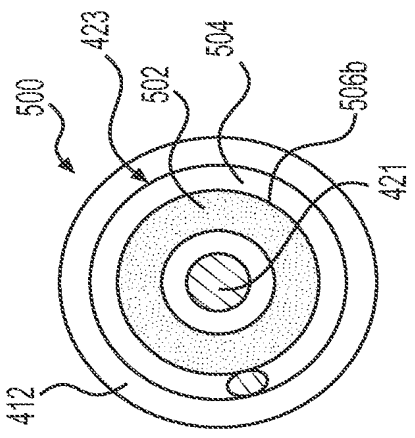


FIG. 7A

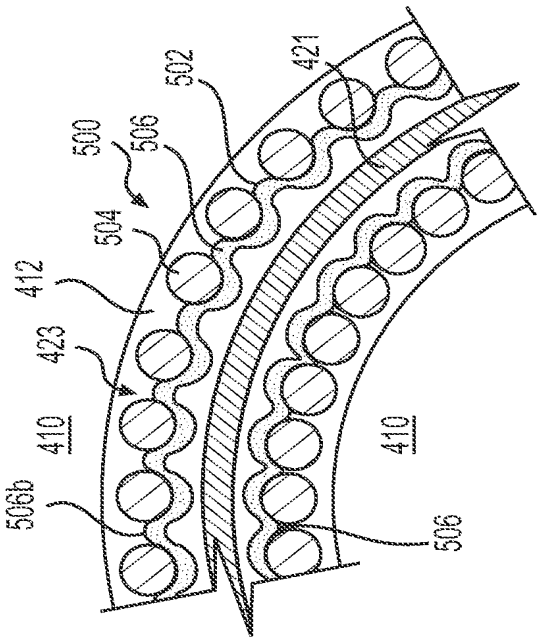


FIG. 7D

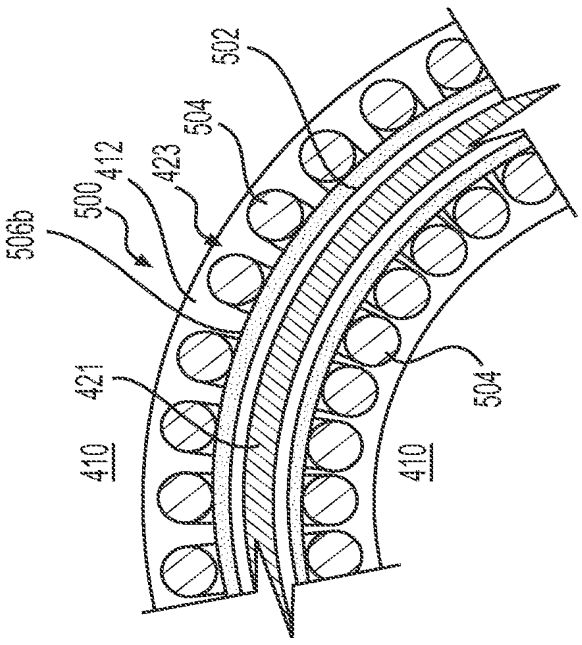


FIG. 7C

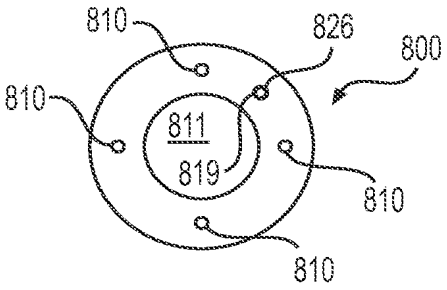


FIG. 8A

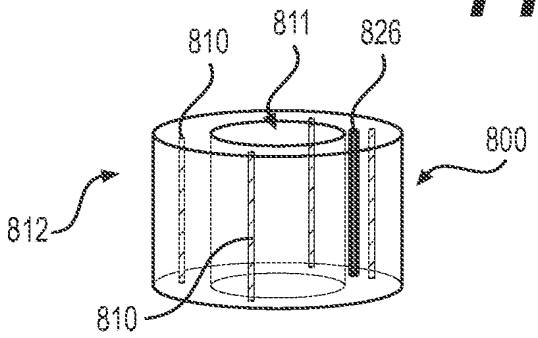


FIG. 8B

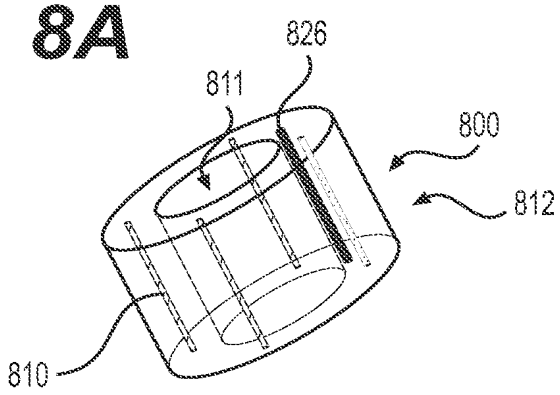


FIG. 8C

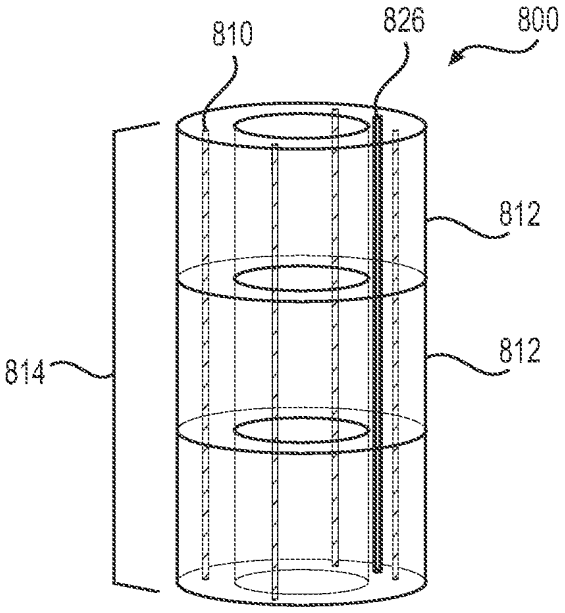


FIG. 8D

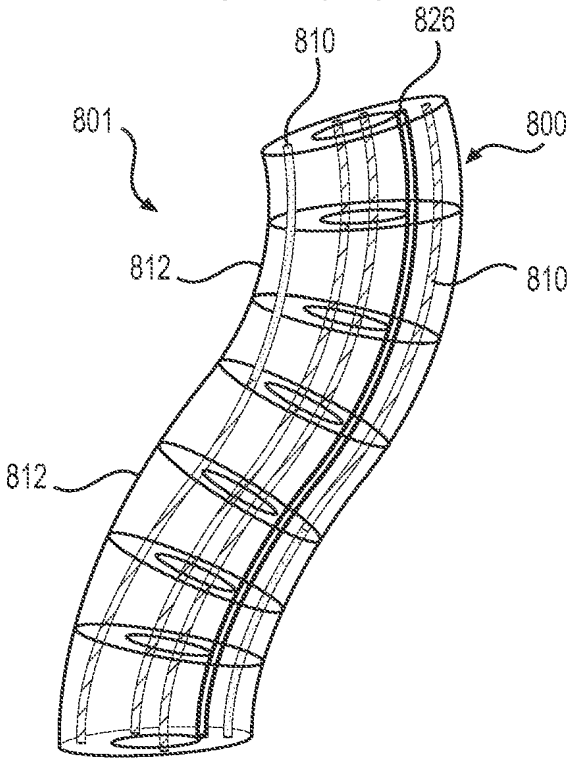


FIG. 8E

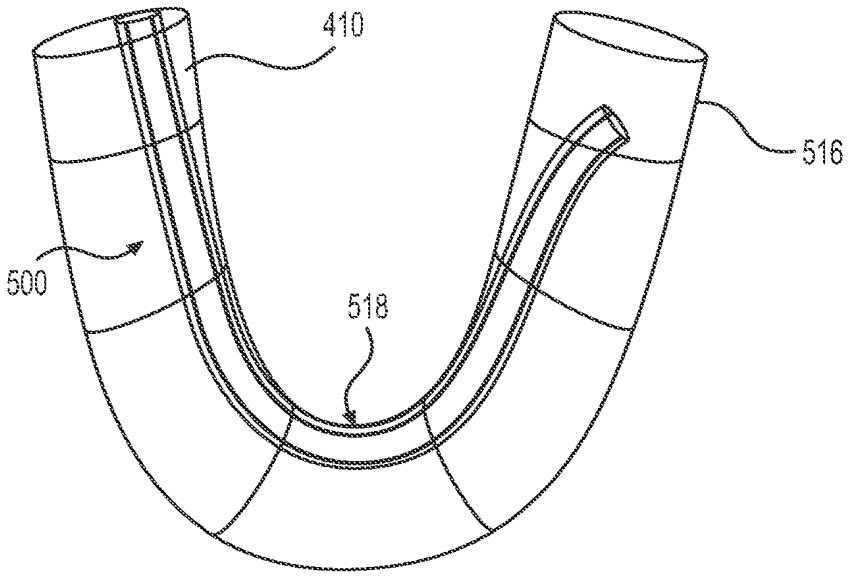


FIG. 9A

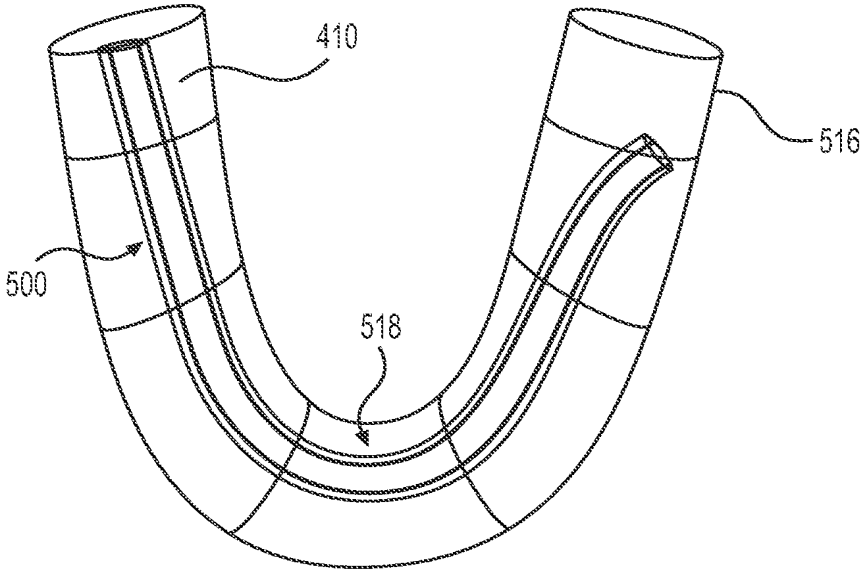


FIG. 9B

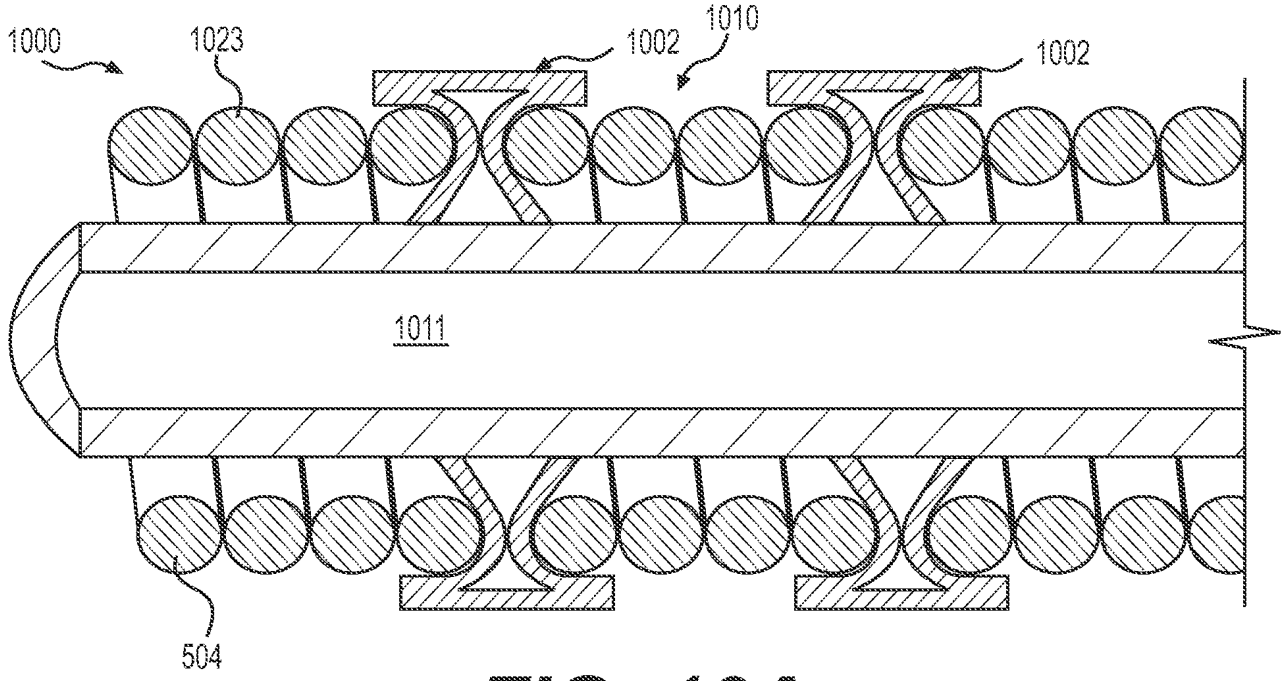


FIG. 10A

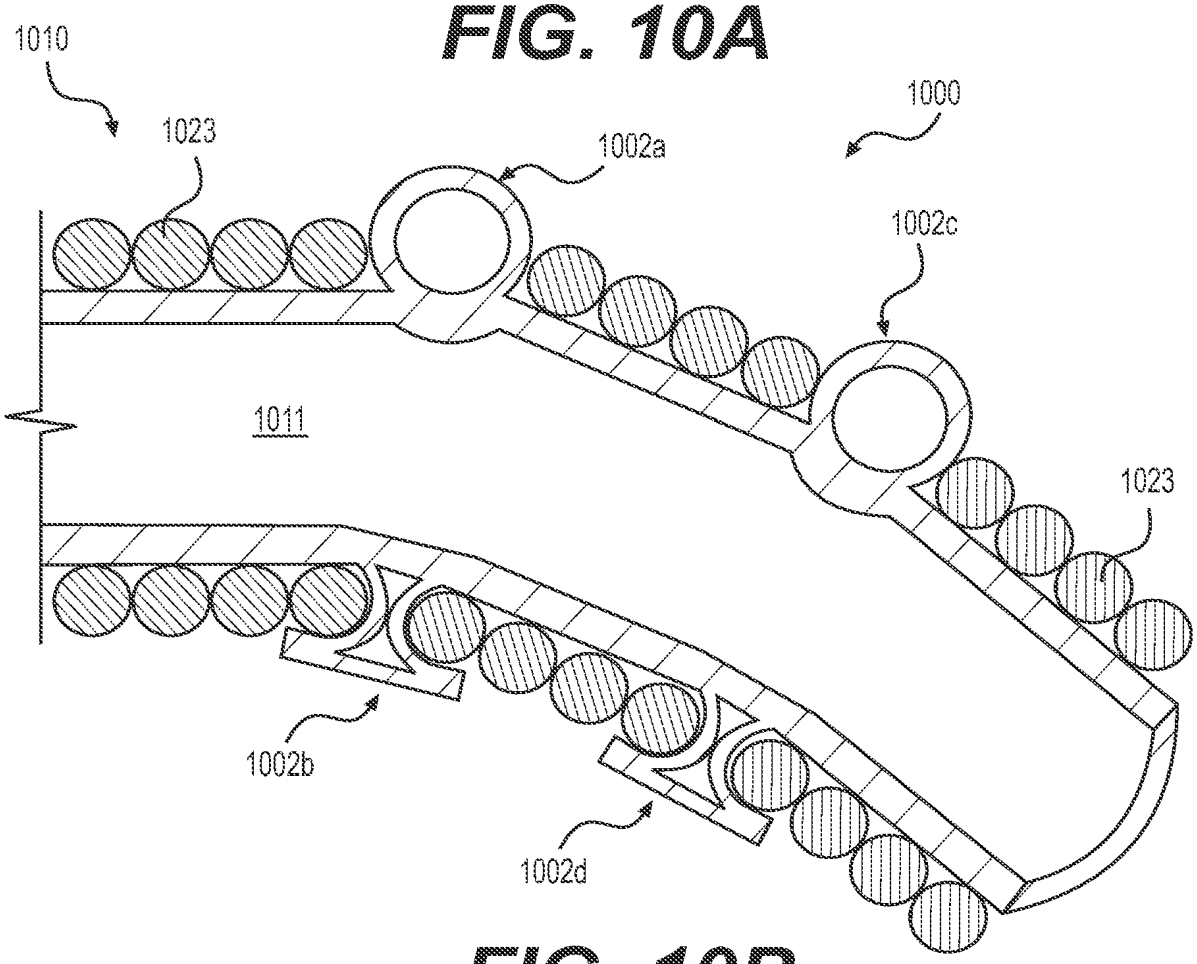


FIG. 10B

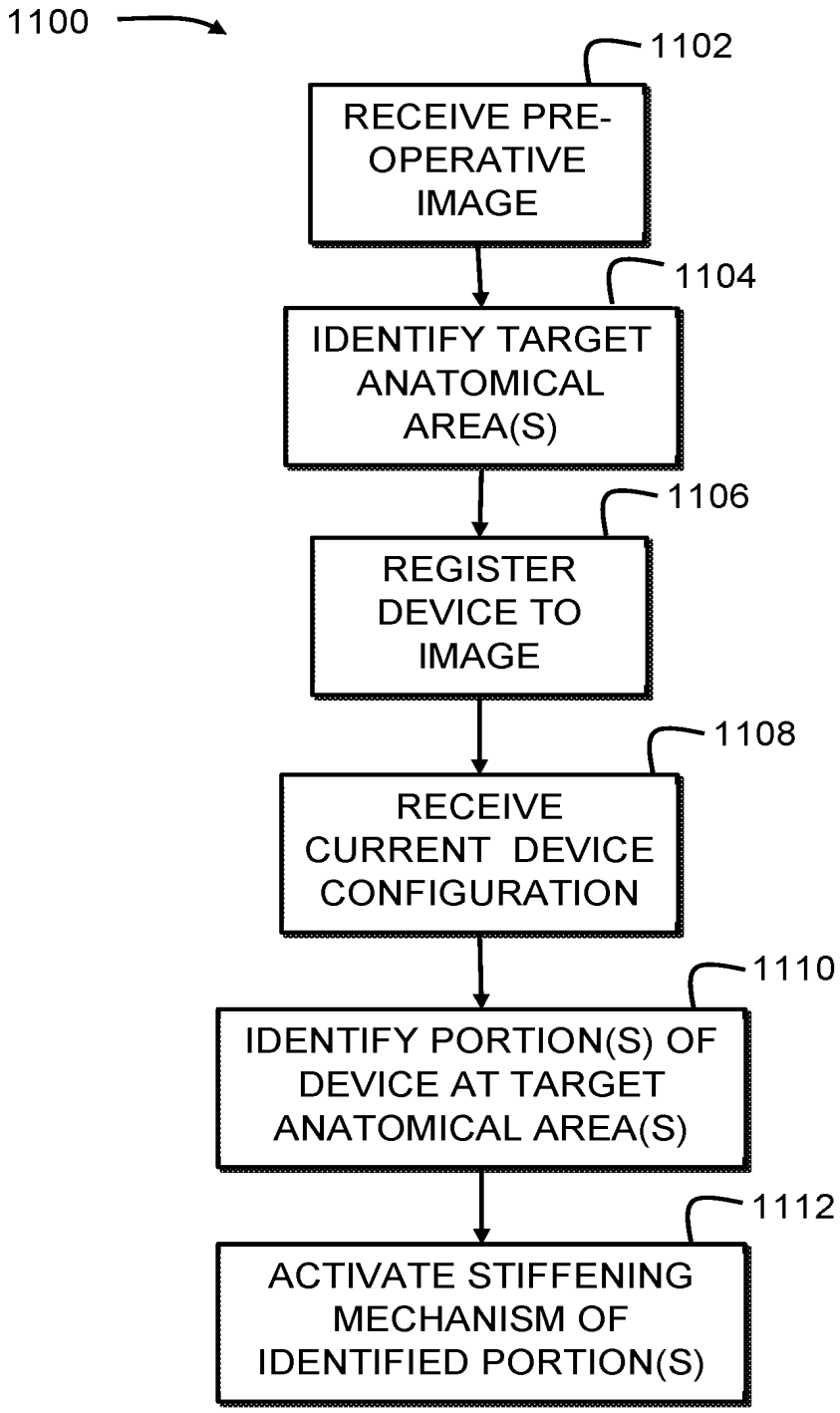

1100
1102
RECEIVE PRE-OPERATIVE IMAGE
1104
IDENTIFY TARGET ANATOMICAL AREA(S)
1106
REGISTER DEVICE TO IMAGE
1108
RECEIVE CURRENT DEVICE CONFIGURATION
1110
IDENTIFY PORTION(S) OF DEVICE AT TARGET ANATOMICAL AREA(S)
1112
ACTIVATE STIFFENING MECHANISM OF IDENTIFIED PORTION(S)

FIG. 11

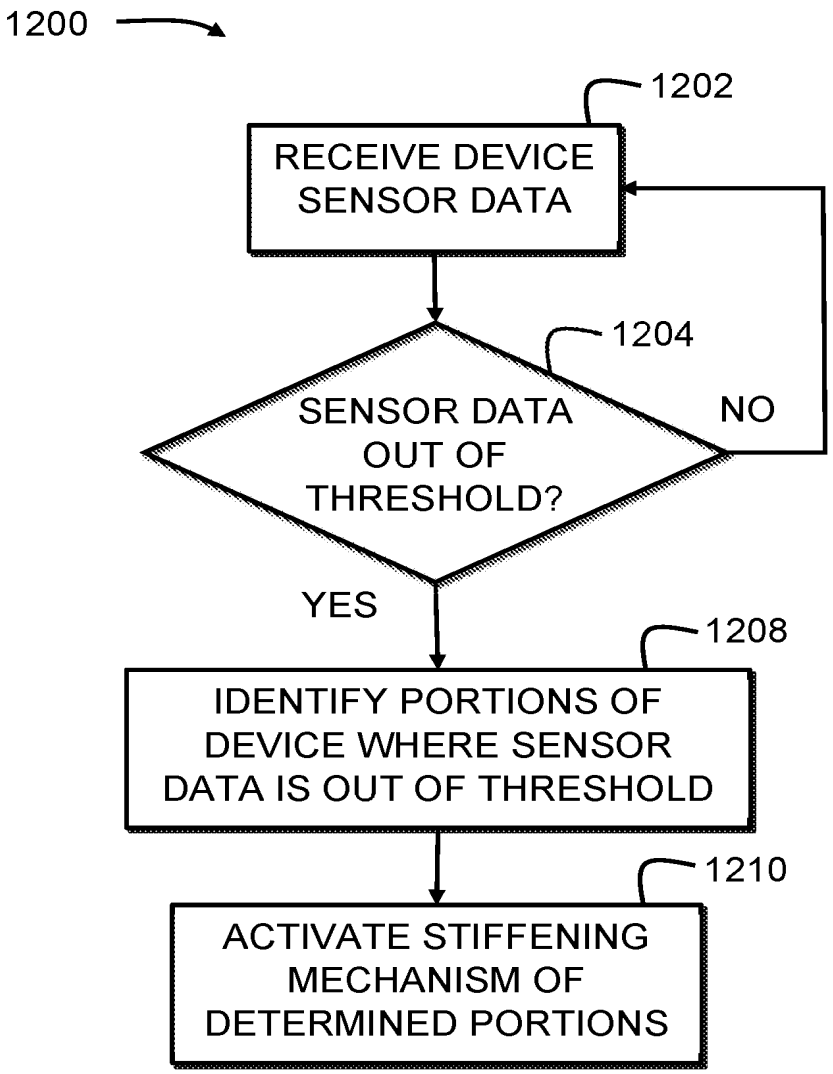

1200
1202
RECEIVE DEVICE SENSOR DATA
1204
SENSOR DATA OUT OF THRESHOLD?
NO
YES
1208
IDENTIFY PORTIONS OF DEVICE WHERE SENSOR DATA IS OUT OF THRESHOLD
1210
ACTIVATE STIFFENING MECHANISM OF DETERMINED PORTIONS

FIG. 12

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2019/037954

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B1/00 A61B1/005 A61B1/018 A61B1/267 A61M25/01
ADD. A61B17/00 A61B34/20 G02B23/24

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 G02B A61M

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 2016/160586 A1 (BARRISH MARK D [US]) 6 October 2016 (2016-10-06) paragraphs [0003], [0007], [0025], [0053], [0055], [0081], [0180], [0185] paragraphs [0194], [0195], [0307] figures 1, 1-1, 3, 4A, 4B	1,7-30
X	US 2013/096385 A1 (FENECH CAROLYN M [US] ET AL) 18 April 2013 (2013-04-18) paragraphs [0024], [0025], [0033], [0036], [0039] figures 1, 3A	1-5,7
X	WO 2018/005928 A1 (INTUITIVE SURGICAL OPERATIONS [US]) 4 January 2018 (2018-01-04) paragraphs [0044], [0063] - [0065], [0078]	1,4,6

☐ 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
17 September 2019	30/09/2019

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	Hemb, Björn

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

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/US2019/037954

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 2016160586 A1	06-10-2016	AU 2016243508 A1	12-10-2017
		CA 2980745 A1	06-10-2016
		CN 107835703 A	23-03-2018
		CN 107835704 A	23-03-2018
		CN 107921236 A	17-04-2018
		EP 3274038 A1	31-01-2018
		EP 3274039 A1	31-01-2018
		EP 3274040 A1	31-01-2018
		JP 2018514350 A	07-06-2018
		US 2016279388 A1	29-09-2016
		US 2017021132 A1	26-01-2017
		US 2017021143 A1	26-01-2017
		WO 2016160586 A1	06-10-2016
		WO 2016160587 A1	06-10-2016
		WO 2016160589 A1	06-10-2016
US 2013096385 A1	18-04-2013	NONE	
WO 2018005928 A1	04-01-2018	CN 109310287 A	05-02-2019
		EP 3478149 A1	08-05-2019
		US 2019231449 A1	01-08-2019
		WO 2018005928 A1	04-01-2018

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/865,315	07/14/2022	Ben Merritt	111552-8018.US03	7298

25096 7590 08/18/2022

PERKINS COIE LLP - SEA General
PATENT-SEA
P.O. BOX 1247
SEATTLE, WA 98111-1247

EXAMINER
CENTRAL, DOCKET

ART UNIT	PAPER NUMBER
3781	

NOTIFICATION DATE	DELIVERY MODE
08/18/2022	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentprocurement@perkinscoie.com

Decision Granting Request for Prioritized Examination (Track I)	**Application No.** 17/865,315	**Applicant(s)** Merritt et al.	
	Examiner CHERYL P GIBSON BAYLOR	**Art Unit** OPET	**AIA (FITF) Status** Yes

1. THE REQUEST FILED 14 July 2022 IS **GRANTED** .

   The above-identified application has met the requirements for prioritized examination
   - A. ☑ for an original nonprovisional application (Track I).
   - B. ☐ for an application undergoing continued examination (RCE).

2. **The above-identified application will undergo prioritized examination**. The application will be accorded special status throughout its entire course of prosecution until one of the following occurs:
   - A. filing a **petition for extension of time** to extend the time period for filing a reply;
   - B. filing an **amendment to amend the application to contain more than four independent claims, more than thirty total claims** , or a multiple dependent claim;
   - C. filing a **request for continued examination** ;
   - D. filing a notice of appeal;
   - E. filing a request for suspension of action;
   - F. mailing of a notice of allowance;
   - G. mailing of a final Office action;
   - H. completion of examination as defined in 37 CFR 41.102; or
   - I. abandonment of the application.

Telephone inquiries with regard to this decision should be directed to CHERYL GIBSON BAYLOR at (571)272-3213. In his/her absence, calls may be directed to Petition Help Desk at (571) 272-3282.

/CHERYL GIBSON BAYLOR/ Paralegal Specialist, OPET	

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
17/865,315	07/14/2022	3783	1820	111552-8018.US03	10	2

CONFIRMATION NO. 7298

FILING RECEIPT

25096
PERKINS COIE LLP - SEA General
PATENT-SEA
P.O. BOX 1247
SEATTLE, WA 98111-1247

OC000000135388833

Date Mailed: 07/26/2022

Receipt is acknowledged of this non-provisional utility 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 FIRST INVENTOR, 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 corrected Filing Receipt, including a properly marked-up ADS showing the changes with strike-through for deletions and underlining for additions. If you received a "Notice to File Missing Parts" or other Notice requiring a response for this application, please submit any request for correction 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 provided that the request is grantable.

Inventor(s)

Ben Merritt, San Clemente, CA;
Jacqueline Macias, Fullerton, CA;
Brian Michael Strauss, San Clemente, CA;
Thomas Tu, Louisville, KY;

Applicant(s)

Inari Medical, Inc., Irvine, CA;

Power of Attorney: The patent practitioners associated with Customer Number 25096

Domestic Priority data as claimed by applicant

This application is a CON of 16/536,185 08/08/2019
which claims benefit of 62/718,269 08/13/2018
and claims benefit of 62/718,248 08/13/2018

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: 07/25/2022

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US 17/865,315**

Projected Publication Date: 11/03/2022

Non-Publication Request: No

Early Publication Request: No

Title

SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED DEVICES AND METHODS

Preliminary Class

604

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.

PATENT APPLICATION FEE DETERMINATION RECORD

Substitute for Form PTO-875

Application or Docket Number: 17/865,315

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			N/A	320
SEARCH FEE (37 CFR 1.16(k), (i), or (m))	N/A	N/A	N/A			N/A	700
EXAMINATION FEE (37 CFR 1.16(o), (p), or (q))	N/A	N/A	N/A			N/A	800
TOTAL CLAIMS (37 CFR 1.16(i))	10 minus 20 =	*			OR	x 100 =	0.00
INDEPENDENT CLAIMS (37 CFR 1.16(h))	2 minus 3 =	*				x 480 =	0.00
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			TOTAL	1820

APPLICATION AS AMENDED - PART II

		(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($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE($)
AMENDMENT A	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	

		(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($)	OTHER THAN SMALL ENTITY ADDITIONAL FEE($)
AMENDMENT B	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.

PTO/AIA/82A (07-13)
Approved for use through 03/31/2021. OMB 0651-0035
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 displays a valid OMB control number.

TRANSMITTAL FOR POWER OF ATTORNEY TO ONE OR MORE REGISTERED PRACTITIONERS

NOTE: This form is to be submitted with the Power of Attorney by Applicant form (PTO/AIA/82B) to identify the application to which the Power of Attorney is directed, in accordance with 37 CFR 1.5, unless the application number and filing date are identified in the Power of Attorney by Applicant form. If neither form PTO/AIA/82A nor form PTO/AIA82B identifies the application to which the Power of Attorney is directed, the Power of Attorney will not be recognized in the application.

Application Number	Not Yet Assigned
Filing Date	Concurrently Herewith
First Named Inventor	Ben Merritt
Title	SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED DEVICES AND METHODS
Art Unit	Not Yet Assigned
Examiner Name	Not Yet Assigned
Attorney Docket Number	111552-8018.US03

SIGNATURE of Applicant or Patent Practitioner

Signature	/Paul T. Parker/	Date (Optional)	2022-07-14
Name	Paul T. Parker	Registration Number	38,264
Title (if Applicant is a juristic entity)	Attorney for Applicant		
Applicant Name (if Applicant is a juristic entity)	Inari Medical, Inc.		

NOTE: This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4(d) for signature requirements and certifications. If more than one applicant, use multiple forms.

☑ *Total of 1 forms are submitted.

This collection of information is required by 37 CFR 1.131, 1.32, and 1.33. 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 3 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.

Doc Code: PA..
Document Description: Power of Attorney

PTO/AIA/82B (07-13)
Approved for use through 03/31/2021. OMB 0651-0035
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 displays a valid OMB control number

POWER OF ATTORNEY BY APPLICANT

I hereby revoke all previous powers of attorney given in the application identified in either the attached transmittal letter or the boxes below.

Application Number	Filing Date

(Note: The boxes above may be left blank if information is provided on form PTO/AIA/82A.)

☑ I hereby appoint the Patent Practitioner(s) associated with the following Customer Number as my/our attorney(s) or agent(s), and to transact all business in the United States Patent and Trademark Office connected therewith for the application referenced in the attached transmittal letter (form PTO/AIA/82A) or identified above: 25096

OR

☐ I hereby appoint Practitioner(s) named in the attached list (form PTO/AIA/82C) as my/our attorney(s) or agent(s), and to transact all business in the United States Patent and Trademark Office connected therewith for the patent application referenced in the attached transmittal letter (form PTO/AIA/82A) or identified above. (Note: Complete form PTO/AIA/82C.)

Please recognize or change the correspondence address for the application identified in the attached transmittal letter or the boxes above to:

☑ The address associated with the above-mentioned Customer Number

OR

☐ The address associated with Customer Number:

OR

☐ Firm or Individual Name					
Address					
City		State		Zip	
Country					
Telephone		Email			

I am the Applicant (if the Applicant is a juristic entity, list the Applicant name in the box):

Inari Medical, Inc.

☐ Inventor or Joint Inventor (title not required below)

☐ Legal Representative of a Deceased or Legally Incapacitated Inventor (title not required below)

☑ Assignee or Person to Whom the Inventor is Under an Obligation to Assign (provide signer's title if applicant is a juristic entity)

☐ Person Who Otherwise Shows Sufficient Proprietary Interest (e.g., a petition under 37 CFR 1.46(b)(2) was granted in the application or is concurrently being filed with this document) (provide signer's title if applicant is a juristic entity)

SIGNATURE of Applicant for Patent

The undersigned (whose title is supplied below) is authorized to act on behalf of the applicant (e.g., where the applicant is a juristic entity).

Signature		Date (Optional)	10 Dec 2021
Name	Brian Strauss		
Title	Vice President, Inari Medical, Inc.		

NOTE: Signature - This form must be signed by the applicant in accordance with 37 CFR 1.33. See 37 CFR 1.4 for signature requirements and certifications. If more than one applicant, use multiple forms.

☑ Total of 1 forms are submitted.

This collection of information is required by 37 CFR 1.131, 1.32, and 1.33. 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 3 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.

SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED DEVICES AND METHODS

CROSS-REFERENCES TO RELATED APPLICATIONS

[0001] This application is a continuation of U.S. Patent Application No. 16/536,185, filed August 8, 2019, which claims the benefit of U.S. Provisional Patent Application No. 62/718,269, filed on August 13, 2018, and U.S. Provisional Patent Application No. 62/718,248, filed on August 13, 2018, each of which is herein incorporated by reference in its entirety.

TECHNICAL FIELD

[0002] The present technology relates generally to systems, methods, and devices for the intravascular treatment of emboli and/or thrombi within a blood vessel of a human patient. In particular, some embodiments of the present technology relate to systems for releasing stored vacuum pressure to aspirate clot material from a blood vessel.

BACKGROUND

[0003] Thromboembolic events are characterized by an occlusion of a blood vessel. Thromboembolic disorders, such as stroke, pulmonary embolism, heart attack, peripheral thrombosis, atherosclerosis, and the like, affect many people. These disorders are a major cause of morbidity and mortality.

[0004] When an artery is occluded by a clot, tissue ischemia develops. The ischemia will progress to tissue infarction if the occlusion persists. However, infarction does not develop or is greatly limited if the flow of blood is reestablished rapidly. Failure to reestablish blood flow can accordingly lead to the loss of limb, angina pectoris, myocardial infarction, stroke, or even death.

[0005] In the venous circulation, occlusive material can also cause serious harm. Blood clots can develop in the large veins of the legs and pelvis, a common condition known as deep venous thrombosis (DVT). DVT commonly occurs where there is a propensity for stagnated blood (e.g., long distance air travel, immobility, etc.) and clotting (e.g., cancer, recent surgery, such as orthopedic

surgery, etc.). DVT can obstruct drainage of venous blood from the legs leading to swelling, ulcers, pain and infection. DVT can also create a reservoir in which blood clots can collect and then travel to other parts of the body including the heart, lungs, brain (stroke), abdominal organs, and/or extremities.

[0006] In the pulmonary circulation, the undesirable material can cause harm by obstructing pulmonary arteries—a condition known as pulmonary embolism. If the obstruction is upstream, in the main or large branch pulmonary arteries, it can severely compromise total blood flow within the lungs, and therefore the entire body. This can result in low blood pressure and shock. If the obstruction is downstream, in large to medium pulmonary artery branches, it can prevent a significant portion of the lung from participating in the exchange of gases to the blood resulting in low blood oxygen and buildup of blood carbon dioxide.

[0007] There are many existing techniques to reestablish blood flow through an occluded vessel. Embolectomies, for example, are a surgical technique involving incising a blood vessel and placing a balloon-tipped device (such as the Fogarty catheter) at the location of the occlusion. The balloon is then inflated at a point beyond the clot and used to withdraw the obstructing material back to the point of incision. The obstructing material is then removed by the surgeon. Although such surgical techniques have been useful, exposing a patient to surgery may be traumatic and best avoided when possible. Additionally, the use of a Fogarty catheter may be problematic due to the possible risk of damaging the interior lining of the vessel as the catheter is being withdrawn.

[0008] Percutaneous methods are also utilized for reestablishing blood flow. A common percutaneous technique is referred to as balloon angioplasty where a balloon-tipped catheter is introduced to a blood vessel (e.g., typically through an introducing catheter). The balloon-tipped catheter is then advanced to the point of the occlusion and inflated to dilate the stenosis. Balloon angioplasty is appropriate for treating vessel stenosis, but it is generally not effective for treating acute thromboembolisms as none of the occlusive material is removed and restenosis regularly occurs after dilation. Another percutaneous technique involves placing a catheter near the clot and infusing streptokinase, urokinase, or other thrombolytic agents to dissolve the clot. Unfortunately,

thrombolysis typically takes hours to days to be successful. Additionally, thrombolytic agents can cause hemorrhage, and in many patients the thrombolytic agents cannot be used at all.

[0009] Various devices exist for performing a thrombectomy or removing other foreign material. However, such devices have been found to have structures which are either highly complex, cause trauma to the treatment vessel, or lack the ability to be appropriately fixed against the vessel. Furthermore, many of the devices have highly complex structures that lead to manufacturing and quality control difficulties as well as delivery issues when passing through tortuous or small diameter catheters. Less complex devices may allow the user to pull through the clot, particularly with inexperienced users, and such devices may not completely capture and/or collect all of the clot material.

[0010] Thus, there exists a need for improved systems and methods for embolic extraction.

BRIEF DESCRIPTION OF THE DRAWINGS

[0011] Many aspects of the present technology can be better understood with reference to the following drawings. The components in the drawings are not necessarily to scale. Instead, emphasis is placed on illustrating clearly the principles of the present disclosure.

[0012] Figure 1 is a partially schematic side view of a clot removal system configured in accordance with the present technology.

[0013] Figure 2 is a side view of a locking syringe configured in accordance with the present technology.

[0014] Figure 3A is a side view of a locking syringe configured in accordance with the present technology.

[0015] Figure 3B is a side view of an adaptor for connecting the locking syringe of Figure 3A to the clot removal system of Figure 1 configured in accordance with the present technology.

[0016] Figure 3C is a side view of the adaptor of Figure 3B coupled to the locking syringe of Figure 3A.

[0017] Figure 3D is a side view of the locking syringe of Figure 3A coupled to the clot removal system of Figure 1 via the adaptor of Figure 3B.

[0018] Figure 4A is a perspective side view of another pressure source configured in accordance with the present technology, and Figures 4B and 4C are enlarged schematic side views of the pressure source of Figure 4A during operation.

[0019] Figure 5 is a cross-sectional side view of an automatic release syringe configured in accordance with the present technology.

[0020] Figure 6 is a perspective top view of a syringe configured in accordance with the present technology.

[0021] Figure 7 is a side view of an over-wire locking syringe configured in accordance with the present technology.

[0022] Figure 8 is a flow diagram of a process or method for operating a clot removal system in accordance with the present technology.

[0023] Figures 9A–9C are side views of a proximal portion of the clot removal system of Figure 1 during a clot removal procedure using the locking syringe of Figure 3 in accordance with the present technology.

[0024] Figures 10A and 10B are schematic illustrations of a distal portion of the clot removal system of Figure 1 during a clot removal procedure in accordance with the present technology.

[0025] Figure 11 is a partially schematic side view of another clot removal system configured in accordance with the present technology.

[0026] Figure 12 is a flow diagram of another process or method for operating a clot removal system in accordance with the present technology.

[0027] Figures 13A–14C are schematic illustrations of a distal portion of the clot removal system of Figure 11 during a clot removal procedure in accordance with the present technology.

[0028] Figure 15 is a flow diagram of another process or method for operating a clot removal system in accordance with the present technology.

[0029] Figures 16A–16E are schematic illustrations of a distal portion of the clot removal system of Figure 11 during a clot removal procedure in accordance with the present technology.

[0030] Figure 17 is a partially schematic side view of another clot removal system configured in accordance with the present technology.

[0031] Figures 18A–18H are side views of a distal portion of the clot removal system shown of Figure 17 during a clot removal procedure in accordance with the present technology.

[0032] Figure 19 is a perspective side view of a pressure source for filtering blood from aspirated clot material during a clot removal procedure configured in accordance with the present technology.

[0033] Figure 20A is a partially-exploded side view of a filter device and pressure source configured in accordance with the present technology.

[0034] Figure 20B is a perspective side view of the syringe of Figure 20A coupled to the filter device of the Figure 20A.

[0035] Figure 20C is a side view of the filter device and syringe of Figure 20B coupled to the clot removal system of Figure 1.

[0036] Figures 20D and 20E are side views of the syringe of Figure 20A coupled to the clot removal system of Figure 1 for reintroducing blood to a patient.

[0037] Figure 21A is a partially-exploded side view of a filter device, a pressure source, and a reinfusion syringe configured in accordance with the present technology.

[0038] Figure 21B is a perspective side view of the filter device of Figure 21A coupled to the pressure source and the reinfusion syringe of Figure 21A.

[0039] Figure 22 is a partially-exploded side view of a filter device configured in accordance with the present technology.

[0040] Figure 23 is a partially-exploded side view of a filter device configured in accordance with the present technology.

[0041] Figure 24 is an enlarged isometric view of the clot removal system of Figure 1 configured in accordance with the present technology.

[0042] Figure 25 is an enlarged isometric view of the clot removal system of Figure 1 configured in accordance with the present technology.

DETAILED DESCRIPTION

[0043] The present technology is generally directed to methods and systems for removing clot material from a blood vessel of a human patient. In some embodiments, a catheter can be intravascularly positioned within a blood vessel such that a distal portion (e.g., a distal opening) of the catheter is positioned proximate to clot material within the blood vessel. The catheter can be fluidly coupled to a pressure source via a valve or other fluid control device positioned outside of the patient. With the valve closed, the pressure source can be activated to charge a vacuum chamber of the pressure source with a vacuum. The valve can then be opened to apply the vacuum to the catheter to thereby aspirate at least a portion of the clot material from the blood vessel into the catheter. In some embodiments, an interventional device can be delivered through the catheter and used to engage the clot material before and/or after the vacuum is applied to the catheter.

[0044] In one aspect of the present technology, the pressure source is configured to generate a vacuum and store the vacuum before the pressure source is fluidly connected to the catheter. Therefore, opening the fluid control device can instantaneously or nearly instantaneously apply the stored vacuum pressure to the catheter, thereby generating suction throughout the catheter. In particular, the suction is applied at the distal portion of the catheter proximate to the clot material. Pre-charging or storing the vacuum before applying the vacuum to the catheter can generate greater suction forces (and corresponding fluid flow velocities) at and/or near the distal portion of the catheter compared to, for example, simply activating the pressure source while it is fluidly connected to the catheter. The greater suction forces generated by application of the stored vacuum can be used to aspirate or otherwise remove clot material from within a blood vessel of a human patient.

[0045] Although many of the embodiments are described below with respect to devices, systems, and methods for treating a pulmonary embolism, other applications and other embodiments in addition to those described herein are within the scope of the technology (e.g., intravascular

procedures other than the treatment of emboli, intravascular procedures for treating cerebral embolism, intravascular procedures for treating deep vein thrombosis (DVT), etc.). Additionally, several other embodiments of the technology can have different configurations, states, components, or procedures than those described herein. Moreover, it will be appreciated that specific elements, substructures, advantages, uses, and/or other features of the embodiments described with reference to Figures 1–25 can be suitably interchanged, substituted or otherwise configured with one another in accordance with additional embodiments of the present technology. Furthermore, suitable elements of the embodiments described with reference to Figures 1–25 can be used as standalone and/or self-contained devices. A person of ordinary skill in the art, therefore, will accordingly understand that the technology can have other embodiments with additional elements, or the technology can have other embodiments without several of the features shown and described below with reference to Figures 1–25.

[0046] With regard to the terms "distal" and "proximal" within this description, unless otherwise specified, the terms can reference a relative position of the portions of a catheter subsystem with reference to an operator and/or a location in the vasculature. Also, as used herein, the designations "rearward," "forward," "upward," "downward," etc. are not meant to limit the referenced component to use in a specific orientation. It will be appreciated that such designations refer to the orientation of the referenced component as illustrated in the Figures; the systems of the present technology can be used in any orientation suitable to the user.

[0047] The headings provided herein are for convenience only and should not be construed as limiting the subject matter disclosed.

I. Selected Embodiments of Clot Removal Systems

[0048] Figure 1 is a partially schematic side view of a clot treatment or clot removal system comprising an aspiration assembly 10 ("assembly 10") configured in accordance with an embodiment of the present technology. In the illustrated embodiment, the assembly 10 includes a catheter subsystem 100, a tubing subsystem 120, and a pressure source 140. The catheter subsystem 100 includes a catheter 102 (e.g., an aspiration catheter) comprising an elongated shaft defining a lumen 104 and having a distal portion 103a and a proximal portion 103b. The catheter subsystem 100

further includes a valve 106 that can be integral with or coupled to the proximal portion 103b of the catheter 102.

[0049] In the illustrated embodiment, the valve 106 includes a distal portion 107a, a proximal portion 107b, and a lumen 109 extending therethrough from the distal portion 107a to the proximal portion 107b. The valve 106 further includes a flow controller (obscured in Figure 1) in the lumen 109. In some embodiments, the valve is a hemostasis valve that is configured to maintain hemostasis during a clot removal procedure by preventing fluid flow in the proximal direction through the valve 106 as various components such as delivery sheaths, pull members, guidewires, interventional devices, other aspiration catheters (e.g., as described in detail with reference to Figures 11–16E), etc., are inserted through the valve 106 to be delivered through the catheter 102 to a treatment site in a blood vessel. The valve 106 further includes a branch or side port 108 positioned distally of the flow controller in the lumen 109 and configured to fluidly couple the lumen 104 of the catheter 102 to the tubing subsystem 120. In the illustrated embodiment, the valve 106 includes buttons 101 that can be actuated (e.g., depressed) to open a conduit within the lumen 109. In some embodiments, the valve 106 can be a valve of the type disclosed in U.S. Patent Application No. 16/117,519, filed August 30, 2018, and titled "HEMOSTASIS VALVES AND METHODS OF USE," which is incorporated herein by reference in its entirety. In some embodiments, the proximal portion 107b of the valve 106 is further configured to be detachably coupled (e.g., via a snap-fit arrangement) to a retraction/aspiration device for aspirating the lumen 104 of the catheter 102 and/or for retracting an interventional device, catheter, delivery sheath, catheter, etc., positioned within the lumen 104. Specific details of such retraction/aspiration devices and associated methods are disclosed in U.S. Patent Application No. 9,526,864, filed June 9, 2015, and titled "RETRACTION AND ASPIRATION DEVICE FOR TREATING EMBOLISM AND ASSOCIATED SYSTEMS AND METHODS," which is incorporated herein by reference in its entirety.

[0050] The tubing subsystem 120 fluidly couples the catheter subsystem 100 to the pressure source 140. More specifically, the tubing subsystem 120 can include one or more tubing sections 124 (individually labeled as a first tubing section 124a and a second tubing section 124b), at least one fluid control device 126 (e.g., a valve), and at least one connector 128 for fluidly coupling the tubing subsystem 120 to the pressure source 140 and/or other suitable components. More specifically, in the

illustrated embodiment, the fluid control device 126 is a stopcock that is fluidly coupled to (i) the side port 108 of the valve 106 via the first tubing section 124a and (ii) the connector 128 via the second tubing section 124b. In some embodiments, the fluid control device 126 can define a lumen having a diameter (or other cross-sectional dimension) that is greater than or equal to a diameter of the lumen 104 of the catheter 102, a diameter of the first tubing section 124a, and/or a diameter of the second tubing section 124b.

[0051] The fluid control device 126 is externally operable by a user to regulate the flow of fluid therethrough and, specifically, from the lumen 104 of the catheter 102 to the pressure source 140. In other embodiments, the fluid control device 126 can be a clamp that can be actuated (e.g., compressed or squeezed by the hand of a user) to partially or fully restrict fluid flow through the tubing section 124a and/or the tubing section 124b. In yet other embodiments, the fluid control device 126 can be omitted and its functionality incorporated into the pressure source 140 (e.g., as described in detail below with reference to Figure 5). In some embodiments, the fluid control device 126 can include a quick-release mechanism (e.g., a spring-loaded apparatus) for rapidly opening, unclamping, etc., the fluid control device 126 to (e.g., instantaneously or nearly instantaneously) fluidly connect the pressure source 140 and the catheter 102. In some embodiments, the fluid control device 126 can be opened/closed automatically (e.g., by a motor, switch, etc.). When the pressure source 140 is pre-charged with a vacuum, as described in detail below, such a quick-release fluid control device 126 can reduce the time needed for pressure in the assembly 10 to equalize after opening of the fluid control device 126, and can thereby increase suction forces generated at the distal portion 103a of the catheter 102.

[0052] In some embodiments, the connector 128 is a quick-release connector (e.g., a quick disconnect fitting) that enables rapid coupling/decoupling of the catheter 102 and the fluid control device 126 to/from the pressure source 140. In other embodiments, the tubing subsystem 120 can have more or fewer tubing sections, connectors, and/or fluid control devices, and can have other suitable configurations. In some embodiments, one or more of the components can be permanently connected and/or integrally formed.

[0053] The pressure source 140 is configured to generate (e.g., form, create, charge, build-up, etc.) a vacuum (e.g., negative relative pressure) and store the vacuum for subsequent application to the catheter subsystem 100. Further details of suitable pressure sources are described in detail below with reference to Figures 2–7. During operation of the assembly 10, a user can first close the fluid control device 126 before activating the pressure source 140 to build up vacuum pressure within the pressure source 140 (e.g., a vacuum chamber of the pressure source 140). In some embodiments, the user can control or select the volume of the generated vacuum. In this manner, a vacuum is charged within the pressure source 140 before the pressure source 140 is fluidly connected to the catheter subsystem 100. To aspirate the lumen 104 of the catheter 102, the user can open the fluid control device 126 to fluidly connect the pressure source 140 to the catheter subsystem 100 and thereby apply or release the vacuum stored in the pressure source 140 to the lumen 104 of the catheter 102. Opening of the fluid control device 126 instantaneously or nearly instantaneously applies the stored vacuum pressure to the tubing subsystem 120 and the catheter 102, thereby generating suction throughout the catheter 102. In particular, the suction is applied at the distal portion 103a of the catheter 102. In one aspect of the present technology, pre-charging or storing the vacuum before applying the vacuum to the lumen 104 of the catheter 102 is expected to generate greater suction forces (and corresponding fluid flow velocities) at and/or near the distal portion 103a of the catheter 102 compared to simply activating the pressure source 140 while it is fluidly connected to the catheter 102. As described in detail below, the suction forces generated by application of the stored vacuum can be used to aspirate or otherwise remove clot material from within a blood vessel of a human patient.

II. Selected Embodiments of Pressure Sources for Use with Clot Removal Systems

[0054] As described in detail above with reference to Figure 1, the assembly 10 of the present technology includes a pressure source (e.g., a vacuum source, negative pressure source, etc.) configured to charge a vacuum that can be applied to the catheter subsystem 100 to generate suction forces for aspirating clot material from within a blood vessel. In general, the pressure source can be any suitable source or combination of sources for generating and/or storing negative pressure. In some embodiments, the pressure source can be a pump (e.g., an electric pump coupled to a vacuum chamber) while, in other embodiments, the pressure source can include one or more syringes that can be actuated or otherwise activated by a user of the assembly 10 to generate and store a vacuum therein.

[0055] Figure 2 is a side view of a pressure source 240 comprising a vacuum-pressure locking syringe ("syringe 240") configured in accordance with the present technology. In some embodiments, the syringe 240 can be of the kind sold under the trademark "VacLok" by Merit Medical System, Inc. In the illustrated embodiment, the syringe 240 includes a plunger 242 slidably and rotatably positioned within a chamber or barrel 244. The barrel 244 is shown as transparent in Figure 2 for the sake of clarity. The plunger 242 includes a seal 243 and a plurality of index members 246 defining slots 248 between adjacent pairs thereof. A tab member 245 projects inwardly from the interior surface of the barrel 244 and is configured to be removably positioned in the slots 248 for locking the plunger 242 in position relative to the barrel 244. In some embodiments, the barrel 244 can be made of a transparent material that permits a user to visualize material (e.g., clot material) within the barrel 244 and to visualize the relative position between the slots 248 and tab member 245 for locking the syringe 240.

[0056] Referring to both Figures 1 and 2 together, the syringe 240 further includes a tip 247 for coupling the syringe 240 to the tubing subsystem 120. In the illustrated embodiment, the tip 247 is a standard luer connector that can be coupled to the connector 128 via one or more suitable adaptors. The tip 247 further defines a lumen or bore 249 having an inner diameter D_1. In some embodiments, the diameter D_1 is about 0.103", or about 0.080" to about 0.200", or about 0.100" to about 0.150", or about 0.100" to about 0.110". In some embodiments, the inner diameter D_1 is about 14 French.

[0057] During operation of the assembly 10, a user can first close the fluid control device 126 and then grip the plunger 242 and/or the barrel 244 to withdraw (e.g., retract) the plunger 242 at least partially out of the barrel 244 to thereby generate a vacuum in the barrel 244. Once the user has withdrawn the plunger 242 to a sufficient or desired volume, the user can lock the plunger 242 by rotating the plunger 242 relative to the barrel 244 such that the tab member 245 is positioned within a corresponding one of the slots 248. In other embodiments, the syringe 240 may not be a locking syringe, and the user can instead hold the plunger 242 in position relative to the barrel 244. Moreover, the user can control the volume of the vacuum—by withdrawing the plunger 242 more or less—to provide a desired amount or level of suction/aspiration upon opening of the fluid control device 126. In some embodiments, the syringe has a volume of about 60 cc or less than about 60 cc.

[0058] Figure 3A is a side view of a pressure source 340 comprising a vacuum-pressure locking syringe ("syringe 340") configured in accordance with the present technology. The syringe 340 can have some features generally similar to the features of the syringe 240 described above with reference to Figure 2. For example, the syringe 340 includes a plunger 342 slidably and rotatably positioned within a barrel 344, and the plunger 342 includes a plurality of index members 346 defining slots 348 between adjacent pairs thereof. The barrel 344 is shown as transparent in Figure 3A (and Figure 3C) for the sake of clarity. While withdrawing the plunger 342, a user can lock the plunger 342 at a specified volume by rotating the plunger 342 relative to the barrel 344 such that a tab member 345 on the interior surface of the barrel 344 is positioned within a corresponding one of the slots 348. In some embodiments, the syringe 340 has a maximum volume of about 60 cc or greater than 60 cc.

[0059] In the illustrated embodiment, the syringe 340 includes a large-bore tip 347, such as a Toomey tip, defining an inner lumen or bore 349. In some embodiments, the bore 349 can have an inner diameter D_2 that is greater than or equal to the largest inner diameter of the assembly 10 (e.g., of the catheter 102 and tubing subsystem 120). In certain embodiments, the tip 347 can be about 26 French or greater. Accordingly, referring to Figures 2 and 3A together, the diameter D_2 can be greater than the dimension D_1. For example, the dimension D_2 can be about two, three, four, or more times greater than the diameter D_1.

[0060] Figure 3B is a side view of an adaptor 350 for connecting the syringe 340 to the catheter subsystem 100 configured in accordance with the present technology. Figure 3C is a side view of the adaptor 350 coupled to the syringe 340, and Figure 3D is a side view of the syringe 340 coupled to the tubing subsystem 120 via the adaptor 350. The adaptor 350 is shown as partially transparent in Figure 3C for the sake of illustration. Referring to Figure 3B, the, the adaptor 350 includes (i) a first portion 351 defining a first lumen or bore 352 having an inner diameter D_3, (ii) a second portion 353 defining a second lumen or bore 354, and (iii) a stepped surface or interface 355 between the first and second portions 351, 353. The first portion 351 can further include a seal 357 such as an O-Ring around an exterior surface thereof.

[0061] Referring to Figures 3A–3D together, the second bore 354 of the adaptor 350 is configured to removably receive the tip 347 of the syringe 340 therein. In some embodiments, the

tip 347 can be snuggly received in the second bore 354 via an interference fit. In some embodiments, a seal (e.g., an O-ring) can be positioned between an exterior surface of the tip 347 and an interior surface of the second bore 354. In other embodiments, the syringe 340 can be permanently coupled or integrally formed with the adaptor 350. The first portion 351 of the adaptor 350 is configured to be removably positioned within the connector 128 of the tubing subsystem 120 to fluidly couple the syringe 340 to the tubing subsystem 120. In some embodiments, the first portion 351 of the adaptor 350 can be pushed into the connector 128 until the interface 355 abuts the connector 128. When the first portion 351 of the adaptor 350 is positioned within the connector 128, the seal 357 seals the interface between the connector 128 and the adaptor 350.

[0062] The diameter D_3 of the first bore 352 of the adaptor 350 can be selected to be about the same as or greater than the greatest inner diameter of the assembly 10 (e.g., of the catheter 102 and the tubing subsystem 120). For example, the catheter 102 can be about 9 French or greater, and the diameter D_3 can be selected to be larger than the size of the catheter 102. Accordingly, when the fluid control device 126 is open, the continuous lumen between the catheter 102 and the syringe 340 can have a generally constant diameter and/or does not contain any narrowing at the interface between the syringe 340 and the tubing subsystem 120. That is, the adaptor 350 can connect the syringe 340 and the tubing subsystem 120 without any restriction or narrowing of the fluid path. In contrast, a standard luer connector (e.g., the syringe 240) can only provide a continuous lumen for catheters of about 8 French or smaller. Any narrowing of the fluid pathway between the catheter 102 and the syringe 340 can reduce the volumetric flow rate (e.g., suction forces and fluid velocities) that can be generated when a vacuum stored in the syringe 340 is applied to the catheter 102.

[0063] In general, the syringe 340 and the adaptor 350 can reduce the fluid resistance in the assembly 10 and therefore facilitate a more rapid pressure equalization in the assembly 10 when the fluid control device 126 is opened to apply the charged vacuum to the catheter 102. In some embodiments, for example, when the syringe 240 (Figure 2) is charged with a 60 cc vacuum and the fluid control device 126 is opened, the pressure in the assembly 10 can take about 1–2 seconds to equalize. In contrast, when the syringe 340 is charged with a 60 cc vacuum and the fluid control device 126 is opened, the pressure in the assembly 10 can take less than about 1 second (e.g., about 0.5 seconds) to equalize. More specifically, Table 1 illustrates representative pressure equalization times

and associated flow rates when the syringe 240 is coupled to a 20 French catheter (i.e., the catheter 102). Table 2 illustrates representative pressure equalization times and associated flow rates when the syringe 340 and the adaptor 350 are coupled to a 20 French catheter (i.e., the catheter 102).

Table 1

Pressure Equalization Time (seconds)	Flow Rate (cc/sec)
2.0	30.0
1.9	31.6
1.8	33.3
1.7	35.3
1.6	37.5
1.5	40.0
1.4	42.9
1.3	46.2

Table 2

Pressure Equalization Time (seconds)	Flow Rate (cc/sec)
0.9	66.7
0.8	75.0
0.7	85.7
0.6	100.0
0.5	120.0
0.4	150.0
0.3	200.0
0.2	300.0

0.1	600.0

[0064] In each instance, the syringe 340 provides for relatively faster equalization times and correspondingly greater flow rates. It is expected that the more rapid pressure equalization and flow rates provided by the syringe 340 will provide correspondingly greater suction forces at the distal portion 103a of the catheter 102. That is, in general, it is expected that increasing the bore size of a syringe used to provide vacuum pressure will provide greater suction forces over a smaller period of time (e.g., will provide a larger vacuum impulse). In some embodiments, the greater suction forces can facilitate the removal of clot material from a blood vessel of a patient even where the clot material is strongly lodged or attached within the blood vessel (e.g., a chronic clot).

[0065] Moreover, as shown in Figure 3D, the adaptor 350 can couple the syringe 340 to the connector 128 without the need for any intervening tubing sections or additional adaptors. This arrangement can minimize the total length, volume, etc., of the components fluidly coupling the catheter 102 to the syringe 340. It is expected that the magnitude of suction forces generated at the distal portion 103a of the catheter 102—e.g., when a vacuum charged in the syringe 340 is applied to the catheter 102 by opening of the fluid control device 126—is proportional to the length of the fluid path between the pressure source 340 and catheter 102. Thus, operation of the assembly 10 with the syringe 340 and adaptor 350 is expected to increase the suction forces generated at the distal portion 103a of the catheter 102. In some embodiments, the greater suction forces can facilitate the removal of clot material from a blood vessel of a patient even where the clot material is strongly lodged or attached within the blood vessel (e.g., a chronic clot).

[0066] Figure 4A is a side perspective view a pressure source 400 including the syringe 340 ("primary syringe 340") shown in Figures 3A–3D and a secondary syringe 460 configured in accordance with the present technology. The secondary syringe 460 can include a plunger 462 slidably positioned within a chamber or barrel 464. The primary and secondary syringes 340, 460 can have the same volume or different volumes. In the illustrated embodiment, a tip 463 of the secondary syringe 460 is coupled to a first one-way valve (e.g., a check valve) 470 via a coupling member 465, such as a tube. The first one-way valve 470 is configured to fluidly connect the

secondary syringe 460 to the ambient environment or another device coupled to the first one-way valve 470. A second one-way valve (e.g., a check valve) 472 spans between and is configured to fluidly connect the primary syringe 340 to the secondary syringe 460. More specially, in the illustrated embodiment the second one-way valve 472 is connected between the first portion 351 of the adaptor 350 and the coupling member 465. In other embodiments, the second one-way valve 472 can couple the primary and secondary syringes 340, 460 in different manners. For example, the second one-way valve 472 can span between and directly connect the barrels 344,464. The primary and secondary syringes 340, 460 can be coupled or fastened together via one or more connectors 474 that fix the positions of the barrel 344, 464 relative to one another.

[0067] In some embodiments, the second one-way valve 472 is a normally-open check valve configured to (i) permit fluid (e.g., air) flow from the primary syringe 340 and the adaptor 350 to the secondary syringe 460 and (ii) inhibit fluid flow in the opposite direction from the secondary syringe 460 into the primary syringe 340. In some embodiments, the second one-way valve 472 has a cracking (e.g., opening) pressure of about 0 psi. In one aspect of the present technology, this arrangement maximizes the magnitude of the vacuum that can be charged within the primary syringe 340. That is, the cracking pressure of the second one-way valve 472 does not reduce the effective vacuum within the primary syringe 340. In other embodiments a normally-closed or other type of valve could be used for the second one-way valve 472. However, in such embodiments the vacuum efficiency of the pressure source 400 would be reduced by the cracking pressure of the second one-way valve 472. Similarly, the first one-way valve 470 can be a check valve configured to (i) permit fluid flow from the secondary syringe 460 to the ambient environment (or other device) and (ii) inhibit fluid flow in the opposite direction from the ambient environment into the secondary syringe 460.

[0068] Figures 4B and 4C are enlarged schematic side views of the pressure source 400 during operation. More specifically, Figures 4B and 4C illustrate fluid flow paths through the first and second one-way valves 470, 472 during retraction and advancement, respectively, of the plunger 462 through the barrel 464 of the secondary syringe 460. Referring first to Figures 4A and 4B together, during retraction/withdrawal of the plunger 462, (i) the first one-way valve 470 is closed to inhibit fluid from flowing into the secondary syringe 460 while (ii) the second one-way valve is open 472 to

permit fluid to flow from the primary syringe 340, the catheter subsystem 100 (Figure 1), and/or the tubing subsystem 120 (Figure 1) into the secondary syringe 460. This flow path is indicated by the arrows R in Figure 4B. Referring to Figures 4A and 4C together, during advancement of the plunger 462, (i) the first one-way valve 470 is open to permit fluid flow (e.g., fluid expulsion) from the secondary syringe 460 to the ambient environment (or other device) while (ii) the second one-way valve 472 is closed to inhibit fluid flow from the secondary syringe 460 into (e.g., back into) the primary syringe 360, the catheter subsystem 100, and/or the tubing subsystem 120. This flow path is indicated by the arrows A in Figure 4C.

[0069] Referring to Figures 1 and 3A–4C together, the pressure source 400 can be coupled to the tubing subsystem 120 by coupling the primary syringe 340 to the connector 128 (e.g., as shown in Figure 3D). When the pressure source is coupled to the tubing subsystem 120, retraction of the plunger 462 of the secondary syringe 460 evacuates an evacuatable volume of the assembly 10. For example, when the fluid control device 126 is closed, retraction of the plunger 462 of the secondary syringe 460 evacuates fluid, through the second one-way valve 472, from (i) the primary syringe 340 (e.g., from the barrel 344, the tip 347, and/or the adaptor 350) and (ii) the portion of the tubing subsystem 120 between the fluid control device 126 and the primary syringe 340. This can enable a greater charged/stored vacuum to be generated for subsequent application to the catheter subsystem 100 for aspirating clot material. In some embodiments, the plunger 462 of the secondary syringe 460 can be withdrawn/advanced (e.g., "cycled") one or more times before withdrawing the plunger 342 of the primary syringe 340 to evacuate air from (i) the tip 347 of the primary syringe 340 and/or (ii) the portion of the tubing subsystem 120 between the fluid control device 126 and the tip 347. In other embodiments, the plunger 462 of the secondary syringe 460 can alternatively or additionally be withdrawn after withdrawing the plunger 342 of the primary syringe 340 to further evacuate the barrel 344 of the primary syringe 340. In some embodiments, the plunger 462 can be cycled when the fluid control device 126 is open to, for example, facilitate the removal of clot material stuck or clogged within the catheter subsystem 100. That is, cycling the secondary syringe 460 when the fluid control device 126 is open can generate vacuum pressure and suction in the catheter 102 to aid in the aspiration/removal of clot material.

[0070] In some embodiments, the volumes of the primary and secondary syringes 340, 460 can be selected based on one or more desired characteristics of a clot removal procedure using the pressure source 400. For example, the secondary syringe 460 can have a larger volume than the primary syringe 340 to permit a high vacuum to be charged within the primary syringe 340 while also limiting blood loss from the patient.

[0071] In one aspect of the present technology, the pressure source 340 permits a greater vacuum to be generated without increasing the volume of the primary syringe 340. For example, the vacuum generated by the primary syringe 340 alone is directly proportional to the volume of the primary syringe 340. Thus, to generate a greater vacuum using the primary syringe 340 alone, the volume of the primary syringe 340 must be increased. In contrast, inclusion of the secondary syringe 460 in the pressure source 400 and the configuration of the first and second one-way valves 470, 472 allows the (e.g., maximum) generated vacuum to be independent of the volume of the primary syringe 340. Therefore, for example, the generated vacuum can be increased without correspondingly increasing the volume of blood withdrawn from the patient when applying the vacuum to the catheter subsystem 100.

[0072] In some embodiments, (e.g., as described in greater detail below with reference to Figure 19), the primary syringe 340 of the pressure source 400 can be replaced with a simple pressure vessel or other volume, such as a canister, barrel, tube, etc. In such embodiments, a vacuum can be generated in the canister simply by cycling the secondary syringe 460 one or more times. In some embodiments, the secondary syringe 460 can comprise a pump or vacuum source other than a syringe. Likewise, the secondary syringe 460 or other vacuum source can be fluidly coupled to the primary syringe 340 in other manners (e.g., via a different arrangement of check valves) to produce the same or similar flow patterns as shown in Figures 4B and 4C. Moreover, in some embodiments the first and second one-way valves 470, 472 can be other types of flow control devices that are mechanically activated/deactivated (e.g., opened and closed) rather than passively operated via pressure differentials within the pressure source 400. For example, the flow control devices 470, 472 can be mechanically coupled to the plunger 462 of the secondary syringe 460 such that cycling the plunger 462 activates/deactivates the flow control devices 470, 472 to operate the pressure source 400 in the manner illustrated in Figures 4B and 4C.

[0073] Figure 5 is a side cross-sectional view of a pressure source 540 comprising an automatic release syringe ("syringe 540") configured in accordance with the present technology. In general, the syringe 540 is configured to automatically apply a charged vacuum of a selected volume to the catheter subsystem 100 without requiring the actuation of an intervening fluid control device, such as the fluid control device 126 shown in Figure 1. The syringe 540 can have some features generally similar to the features of the syringes 240, 340 described in detail above with reference to Figures 2 and 3A–3D. For example, the syringe 540 includes a first plunger 542 slidably positioned within a chamber or barrel 544. The first plunger 542 further includes a first seal 543 that engages an interior surface of the barrel 544 such that a vacuum is formed within the barrel 544 as the first plunger 542 is withdrawn through the barrel 544. Likewise, referring to both Figures 1 and 5 together, the syringe 540 includes a tip 547 (e.g., a Toomey tip) for coupling the syringe 540 to the tubing subsystem 120 (e.g., via a Toomey tip adaptor) and defining a bore 549. In some embodiments, the bore 549 has a relatively large diameter selected to provide rapid pressure equalization in the assembly 10 after a vacuum stored in the syringe 540 is released.

[0074] The first plunger 542 can further include (i) a grip portion 541 configured to be engaged by a user for retracting the first plunger 542 and (ii) a lumen 581 extending lengthwise therethrough. In the illustrated embodiment, a plunger assembly 582 is slidably positioned within and extends through the lumen 581 of the first plunger 542. The plunger assembly 582 includes (i) a second plunger 583 and (ii) a release member 584 slidably and/or rotatably positioned within a lumen 585 of the second plunger 583. The release member 584 includes an engagement member 586 configured to engage the grip portion 541 of the first plunger 542 when the first plunger 542 is withdrawn from the barrel 544. The second plunger 583 includes a second seal 587 configured to engage and seal an interior surface of the bore 549 of the syringe 540 to enable a vacuum to be formed in the barrel 544 as the first plunger 542 is withdrawn through the barrel 544. That is, the second seal 587 can seal (e.g., fluidly disconnect) the barrel 544 of the syringe from the tubing subsystem 120 and the catheter subsystem 100. In some embodiments, the syringe 540 can further include an O-ring 579 or other suitable component for sealing an interface between the first and second plungers 542, 582 to maintain the vacuum formed within the barrel 544, while also permitting the first plunger 542 to move (e.g., translate) relative to the second plunger 583.

[0075] The plunger assembly 582 further includes a locking mechanism (not shown) configured to permit/inhibit the release member 584 from moving longitudinally relative to the second plunger 583. In some embodiments, for example, rotation of the release member 584 in a first direction relative to the second plunger 583 can lock the two components in position, while rotation of the release member 584 in a second direction relative to the second plunger 583 can unlock the two components so that the release member 584 can be withdrawn or pushed into the lumen 585 of the second plunger 583. In other embodiments, the release member 584 and the second plunger 583 can be integrally formed or permanently locked together.

[0076] The plunger assembly 582 enables (i) a user of the syringe 540 to select a desired volume for a vacuum to be formed in the syringe 540 and (ii) the automatic release or application of a generated vacuum via opening (e.g., unplugging) of the bore 549. Specifically, during operation of the syringe 540, a user can first unlock the release member 584 and slide the release member 584 to a position corresponding to a desired vacuum volume. For example, the release member 584 can have tick marks 588 or other indicia along its length that correspond to a volume of the syringe 540 (e.g., a vacuum chamber volume). After selecting a desired volume, the user can lock the release member 584 relative to the second plunger 583 (e.g., by rotating the release member 584) to inhibit relative movement of the two components. After locking the release member 584, the user can grasp the grip portion 541 to retract the first plunger 542 relative to the barrel 544 and the plunger assembly 582 to generate a vacuum within the barrel 544 between the first and second seals 543, 587. When the first plunger 542 has been retracted to the desired volume, the grip portion 541 engages the engagement member 586 of the release member 584 such that further retraction of the first plunger 542 simultaneously retracts the plunger assembly 582. As the plunger assembly 582 is retracted, the second seal 587 of the second plunger 583 is pulled out of the bore 549, thereby releasing the vacuum stored in the barrel 544. In this manner, the syringe 540 provides for the automatic release of charged vacuum pressure at a specified volume and with a single retraction of the first plunger 542. Put differently, the syringe 540 has a built-in fluid control device and thus eliminates the need for a separate fluid control device 126 and/or an additional step for opening the fluid control device 126.

[0077] Figure 6 is a top perspective view of a pressure source 640 comprising a syringe ("syringe 640") configured in accordance with the present technology. The syringe 640 can include

some features generally similar to the features of the syringes 240, 340, and 540 described in detail above with reference to Figures 2–3D and 5. For example, the syringe 640 includes a plunger 642 slidably positioned within a barrel 644, and a tip 647 (e.g., a large-bore tip). In the illustrated embodiment, the syringe 640 further includes a lever or handle 690 operably coupled to the plunger 642. The handle 690 provides mechanical leverage for withdrawing the plunger 642 to create a vacuum within the barrel 644. More specifically, the handle 690 can be coupled to a crossbar 691 that rotates relative to the plunger 642 via actuation (e.g., rotation) of the handle 690. The crossbar 691 can be coupled to a gear (obscured in Figure 6) configured to engage a track 692 on the plunger 642. Accordingly, rotation of the handle 690 in a first direction retracts the plunger 642 relative to the barrel 644 to charge a vacuum in the barrel 644. And, rotation of the handle 690 in a second (e.g., opposite) direction advances the plunger 642 into the barrel 644 to, for example, expel fluid, material, etc., from the barrel 644.

[0078] In one aspect of the present technology, the handle 690 provides additional mechanical leverage relative to a standard syringe, and can thus reduce the force (e.g., strain, energy, etc.) required by a user of the syringe 640 to form a vacuum in the syringe 640. Therefore, use of the syringe 640 can reduce the time needed to remove clot material with the assembly 10. In some embodiments, the syringe 640 can have a volume greater than 60 cc (e.g., greater than 80 cc, greater than 100 cc, greater than 120 cc, greater than 140 cc, etc.). In a particular embodiment, for example, the syringe 640 can have a volume of about 140 cc. With such large volumes, it may be difficult for some users to manually retract the plunger 642 without the additional mechanical leverage provided by the handle 690. Thus, the syringe 640 can enable the use of larger volume syringes that can generate correspondingly greater suction forces in the catheter subsystem 100.

[0079] Referring again to Figure 1, it is expected that less tortuous (e.g., more linear) fluid paths between the pressure source 140 and the catheter subsystem 100 will produce greater suction forces and corresponding fluid velocities at the distal portion 103a of the catheter 102 when stored vacuum pressure is applied to the catheter subsystem 100. Accordingly, in some embodiments the side port 108 of the valve 106 can be formed to have an angle A that is less than about 90°, less than about 75°, less than about 60°, less than about 45°, less than about 30°, less than about 15° etc. Reducing the relative angle between the side port 108 and the lumen 109 of the valve 106 (and thus

the lumen 104 of the catheter 102) reduces the tortuosity of the fluid path between the pressure source 140 and the catheter 102. Moreover, in some embodiments, the pressure source 140 can be coupled to the proximal portion 107b of the valve 106 instead of or in addition to the side port 108 to provide a more linear fluid path between the pressure source 140 and the catheter 102. For example, Figure 24 is an enlarged isometric view of the assembly 10 showing the pressure source 340 coupled directly to the proximal portion 107b of the valve rather than to the connector 128 of the tubing subsystem 120 and the side port 108 of the valve 106. Although the pressure source 340 is illustrated in Figure 24, any of the pressure sources described in detail above with reference to Figures 2–6 can be configured to be coupled to the proximal portion 107b of the valve 106 rather than the side port 108. In other embodiments, the side port 108 can be omitted and the valve 106 and the tubing subsystem 120 can be coupled to the catheter 102 via a Y-connector. For example, Figure 25 is an enlarged isometric view of the assembly 10 showing the valve 106 and the tubing subsystem 120 coupled to the catheter 102 via a Y-connector 2590. In yet other embodiments, the tubing system 120 is linearly coupled to the catheter 102, and the valve 106 protrudes at an angle from the catheter 102.

[0080] In some embodiments, however, a guidewire or other component is positioned within the valve 106 during the duration of a clot removal procedure (e.g., for delivering interventional devices to a treatment site within a patient). Accordingly, in some embodiments, to facilitate coupling of the pressure source 140 to the proximal portion 107b of the valve 106—even when a guidewire is inserted therethrough—the pressure source 140 can be a syringe configured for over-wire delivery. For example, Figure 7 is a side view of a pressure source 740 comprising a vacuum-pressure locking syringe ("syringe 740") configured in accordance with the present technology for delivery and operation over a guidewire 794. The syringe 740 can have some features generally similar to the features of the syringe 340 described in detail above with reference to Figure 3. For example, the syringe 740 includes a plunger 742 slidably and rotatably positioned within a barrel 744. The barrel 744 is shown as transparent in Figure 7 for the sake of clarity. In the illustrated embodiment, the plunger 742 includes a lumen 796 (shown in broken lines) extending longitudinally therethrough. The guidewire 794 can be inserted through the lumen 796 of the plunger 742 such that the syringe 740 can be advanced over the guidewire 794 for attachment to the proximal portion 107b of the valve 106. The syringe 740 can further include one or more sealing components (e.g., valves, O-rings, etc.; not

shown) for maintaining a seal between the guidewire 794 and the plunger 742 to permit build-up and storage of a vacuum in the barrel 744.

[0081] In general, one skilled in the art will understand that the various embodiments of pressure sources disclosed herein may be combined to, for example, include multiple pressure sources or pressure sources having different components or combinations of components. For example, in some embodiments the secondary syringe 460 (Figures 4A–4C) can be coupled via one or more one-way valves to the syringes 240, 540, 640 or 740 (Figures 2 and 5–7, respectively) to generate additional vacuum. In some embodiments, multiple pressure sources can be coupled to the catheter 102 via the tubing subsystem 120 and/or via the valve 106. Moreover, the individual pressure sources can be the same or different, and can be coupled to the catheter subsystem 100 via a single fluid control device, such as the fluid control device 126, or can be coupled to the catheter subsystem 100 via separate fluid control devices. Therefore, the profile of the vacuum applied to the catheter 102 can be selected or adjusted by using multiple different pressure sources. For example, a specific vacuum profile can depend at least on (i) the individual characteristics of the multiple pressure sources (e.g., volume, bore-size, etc.), (ii) the manner in which the pressure sources are coupled to the catheter subsystem 100 (e.g., via individual valves, via the same valve, etc.), and (iii) the timing of the application or release of the vacuum of each pressure source to the catheter subsystem 100 (e.g., staggered release, simultaneous release, etc.). As one example, in some embodiments, the syringe 240 (Figure 2) and the syringe 340 (Figure 3) can both be coupled to the tubing subsystem 120 via, for example, a Y-connector. After charging both syringes 240, 340 with vacuum pressure, opening the fluid control device 126 can simultaneously apply the combined vacuum to the catheter 102. The larger-bored syringe 340 can provide a short but powerful impulse of vacuum pressure, while the smaller-bored syringe 240 can provide a longer and more sustained vacuum pull. This combination can apply a large, fast-acting suction force to dislodge and capture clot material in the catheter 102, and simultaneously apply a more sustained suction force to capture more clot material.

III. Selected Embodiments of Methods of Clot Removal

[0082] Figure 8 is a flow diagram of a process or method 800 for operating a clot removal system including the assembly 10 to remove clot material from within a blood vessel (e.g., a pulmonary blood vessel) of a human patient in accordance with the present technology. Figures 9A–9C are side views of a proximal portion of the assembly 10, and Figures 10A and 10B are schematic illustrations of a distal portion of the assembly 10, during a clot removal procedure in accordance with embodiments of the present technology. In particular, Figures 9A–9C are side views of the assembly 10 including the syringe 340 and adaptor 350 (Figures 3A–3D), and Figures 10A and 10B are side views of the catheter 102 with the distal portion 103a of the catheter 102 positioned proximate to an embolism or clot material PE within a blood vessel BV (e.g., a pulmonary blood vessel). Although some features of the method 800 are described in the context of the embodiments shown in Figures 1, 3A–3D, and 9A–10B for the sake of illustration, one skilled in the art will readily understand that the method 800 can be carried out using other suitable systems and/or devices described herein. In particular, although described in the context of the syringe 340, the method 800 can be carried out using any one or combination of the pressure sources described in detail above with reference to Figures 2–7.

[0083] At block 802, the method 800 includes positioning the distal portion 103a of the catheter 102 proximate to clot material within a blood vessel of a human patient (e.g., at a treatment site). For example, in the embodiment illustrated in Figure 10A, a distal terminus of the distal portion 103a of the catheter 102 is positioned proximate to a proximal portion of the clot material PE. It is expected that reducing the distance between the distal terminus of the catheter 102 and the proximal portion of the clot material PE—without contacting the clot material PE with the catheter 102—will maximize the suction forces on the clot material PE when the fluid control device 126 is opened. It is also expected that reducing the distance (e.g., clearance) between the inner diameter of the blood vessel BV and the outer diameter of the catheter will maximize the suction forces on the clot material PE. However, in other embodiments, the distal terminus of the catheter 102 can be positioned at least partially within the clot material PE, or the distal terminus of the catheter 102 can be positioned distal of the clot material PE.

[0084] Access to the pulmonary vessels can be achieved through the patient's vasculature, for example, via the femoral vein. In some embodiments, the catheter subsystem 100 can include an introducer (e.g., a Y-connector with a hemostasis valve; not shown) that can be partially inserted into the femoral vein. A guidewire (not shown) can be guided into the femoral vein through the introducer and navigated through the right atrium, the tricuspid valve, the right ventricle, the pulmonary valve, and into the main pulmonary artery. Depending on the location of the embolism, the guidewire can be guided to one or more of the branches of the right pulmonary artery and/or the left pulmonary artery. In some embodiments, the guidewire can be extended entirely or partially through the clot material PE. In other embodiments, the guidewire can be extended to a location just proximal of the clot material PE. After positioning the guidewire, the catheter 102 can be placed over the guidewire and advanced (e.g., as indicated by arrow A1) to a position proximate to the clot material PE as illustrated in Figure 10A.

[0085] In some embodiments, to confirm the position of the distal portion 103a of the catheter 102, a contrast agent can be injected through the catheter 102 and viewed using fluoroscopic imaging techniques, as is known in the art. In some embodiments, the valve 106 can be opened to determine the position of the distal portion 103a of the catheter 102 relative to the clot material PE. For example, the activation buttons 101 can be depressed to open the lumen 109 of the valve 106. If there is substantially no back-bleeding through the valve 106, the operator can determine that the distal portion 103a of the catheter 102 is fully engaged with the clot material PE. Conversely, if there is some back-bleeding through the valve 106, the operator can determine that the distal portion 103a of the catheter is not fully engaged with the clot material PE. Accordingly, to locate the distal portion 103a of the catheter 102 just proximal of the clot material PE, the operator can (i) first determine that distal portion 103a of the catheter is fully engaged with the clot material PE by activating the valve 106 and detecting no back-bleeding and (ii) then reposition the catheter 102 (e.g., by withdrawing the catheter 102 proximally) and activate the valve 106 until back-bleeding is detected—thereby confirming that the distal portion 103a of the catheter 102 is positioned proximal of the clot material PE. In some embodiments, the valve 106 can be opened during retraction of the catheter 102 until back-bleeding is detected. In other embodiments, the valve 106 can be closed during retraction of the catheter 102, and the catheter 106 can be retracted a set (e.g., predetermined)

distance before the valve 106 is opened again. In one aspect of the present technology, determining the position of the distal portion 103a of the catheter 102 via activation of the valve 106 can be used when it is difficult to determine the position of the catheter 102 via radiographic techniques. In contrast, many conventional hemostasis valves cannot be activated in this manner.

[0086] In some embodiments, the guidewire can then be withdrawn while, in other embodiments, the guidewire can remain and can be used to guide other catheters (e.g., delivery catheters, additional aspiration catheters, etc.), interventional devices, etc., to the treatment site. It will be understood, however, that other access locations into the venous circulatory system of a patient are possible and consistent with the present technology. For example, the user can gain access through the jugular vein, the subclavian vein, the brachial vein, or any other vein that connects or eventually leads to the superior vena cava. Use of other vessels that are closer to the right atrium of the patient's heart can also be advantageous as it reduces the length of the instruments needed to reach the pulmonary embolism.

[0087] At block 804, the method 800 includes coupling a pressure source (e.g., the syringe 340) to the catheter 102 via the fluid control device 126. For example, in the embodiment illustrated in Figure 9A, the tip 347 (shown in Figures 3A and 3C but obscured in Figure 9A) of the syringe 340 can be coupled to the connector 128 via the adaptor 350. Once the syringe 340 is coupled to the catheter 102, (i) opening the fluid control device 126 fluidly connects the syringe 340 to the lumen 104 of the catheter 102, and (ii) closing the fluid control device 126 fluidly disconnects the syringe 340 from the lumen 104 of the catheter 102. The fluid control device 126 is in an open position in Figure 9A.

[0088] At block 806, the method 800 includes activating the syringe 340 to generate a vacuum while the fluid control device 126 is closed. For example, as shown in Figure 9B, the user can first actuate the fluid control device 126 to close the fluid control device 126, and then retract the plunger 342 to generate a vacuum in the barrel 344 of the syringe 340. The user can subsequently lock the plunger 342 relative to the barrel 344, as described in detail above, to store or maintain a vacuum of known volume in the syringe 340. In this manner, the syringe 340 can be pre-charged with a vacuum before the vacuum is applied to the catheter 102. In contrast, many conventional

aspiration techniques include activating a negative pressure source (e.g., a pump, a syringe, etc.) while the pressure source is fluidly connected to a lumen to be aspirated. In some embodiments, when the pressure source 400 with the secondary syringe 460 (Figures 4A–4C) is used with the primary syringe 340; the secondary syringe 460 can be cycled one or more times before or after retracting the plunger 342 to increase the vacuum pressure.

[0089] At block 808, the method 800 includes opening the fluid control device 126 to apply the vacuum to the lumen 104 of the catheter 102. For example, with reference to Figure 9C, the user can actuate (e.g., twist a handle of) the fluid control device 126 to open the fluid control device 126 and apply the vacuum stored in the syringe 340 to the catheter subsystem 100. As shown in Figure 10B, application of the vacuum causes suction at the distal tip 103a of the catheter 102 (e.g., as indicated by arrow A2) that aspirates at least a portion of the clot material PE from the blood vessel BV and into the lumen 104 of the catheter 102. In some embodiments, opening the fluid control device 126 instantaneously or nearly instantaneously generates suction at the distal portion 103a of the catheter 102. In certain embodiments, application of the vacuum can generate suction for less than about 1 second (e.g., about 0.5 second), substantially less than about 1 second (e.g., about 0.3 second, about 0.1 second, etc.) less than about 2 seconds, or greater than about 2 seconds—until the pressure in the assembly 10 equalizes. In some embodiments, depending on the volume of the vacuum chamber formed in the syringe 340 and the dimensions of the catheter subsystem 100 and the tubing subsystem 120 (e.g., where the syringe 340 has a volume that is greater than or about equal to a volume of the catheter subsystem 100), at least some of the clot material PE can be aspirated entirely through the lumen 104 of the catheter 102 and into the barrel 344 of the syringe 340. In some such embodiments, the user can determine whether subsequent steps for treating the clot material PE are necessary or desirable by visualizing the amount of clot material collected in the syringe 340. Figure 9C, for example, illustrates the syringe 340 and the tubing subsystem 120 after the fluid control device 126 has been opened to apply the vacuum stored in the syringe 340 to the catheter 102. In the illustrated embodiment, some of the clot material PE is visible in the syringe 340.

[0090] In some embodiments, the fluid control device 126 or another fluid control device can be intermittently operated to provide discrete bursts of suction. For example, the fluid control device 126 can be quickly opened and closed to provide a first burst of suction (e.g., vacuum release)

without fully equalizing the pressure in the assembly 10. The fluid control device 126 can then be opened again to provide a second burst of suction, or opened and closed repeatedly to provide a desired suction pattern. In some embodiments, the assembly 10 can be specifically configured to facilitate the application of multiple bursts of suction. For example, (i) the fluid control device 126 can be spring-loaded, electronically controlled, etc., to rapidly open and close the valve, and/or (ii) the pressure source 140 can have a large vacuum chamber and/or small bore size to increase the time required for pressure in the assembly 10 to equalize (e.g., to increase a discharge time of the pressure source 140).

[0091] Sometimes, as shown in Figure 10B, discharging the vacuum stored in the pressure source to aspirate the lumen 104 of the catheter 102 may not remove all of the clot material PE (or a desired amount of the clot material PE) from the blood vessel BV. That is, a single aspiration may not adequately remove the clot material PE from the blood vessel BV. In such instances, the user of the assembly 10 may wish to again apply vacuum pressure (conduct an "aspiration pass") to remove all or a portion of the remaining clot material PE in the blood vessel BV. In such instances, the pressure source can be disconnected from the tubing subsystem 120 and drained (e.g., aspirated clot removal removed) before the method 800 returns to block 802. For example, the adaptor 350 and the syringe 340 can be decoupled from the connector 128, and the plunger 342 can be pushed into the barrel 344 to expel the clot material PE and associated fluid from the barrel 344 via the tip 347. With the distal portion of the catheter 102 positioned proximate to the remaining clot material PE (e.g., unmoved relative the last aspiration pass), the pressure source can then be re-coupled to the connector 128 (block 804), primed again (block 806), and the vacuum pressure discharged (block 808) to aspirate all or a portion of the remaining clot material PE.

[0092] Blocks 802–808 can be repeated until a desired amount of clot material is removed from the patient or until the catheter 102 becomes clogged. In some embodiments, to check for clogging of the catheter 102, the fluid control device 126 and/or the valve 106 can be opened to check for back bleeding. A lack of back bleeding can indicate that the catheter 102 is likely clogged. Similarly, if the barrel 344 of the syringe 340 contains mostly air and relatively little blood and clot material (e.g., less than 5–10 cc) after aspiration of the catheter 102 (block 808), it can indicate that the catheter 102 is likely clogged. When the catheter 102 is clogged or a sufficient amount of clot material PE has

been removed from the patient, the method 800 can proceed to block 810 and the catheter 102 can be removed from the patient. When the catheter 102 is clogged, the catheter 102 can be flushed and cleared prior to reentry into the patient (block 802). In other embodiments, a different (e.g., new, unused, etc.) catheter can be inserted into the patient and positioned to remove the remaining clot material PE from the patient.

[0093] In some embodiments, rather than removing the catheter 102 from the patient if the catheter 102 is clogged, the syringe 340 can be recharged and used to apply one or more subsequent vacuum pulses to the catheter 102. More specifically, the fluid control device 126 can be closed and the syringe 340 can be removed from the connector 128 and evacuated to remove the clot material and blood therein. Then, blocks 804–808 can be repeated to apply another pulse of vacuum to the catheter 102. That is, rather than removing the catheter 102 after a clog is detected, the syringe 340 can be "cycled" until the vacuum force on the clot material PE overcomes the forces between the clot material PE and the catheter 102 and sucks the clot material PE into the syringe 340. In some embodiments, when the pressure source 400 with the secondary syringe 460 (Figures 4A–4C) is used with the primary syringe 340, the secondary syringe 460 can be cycled one or more times to increase the vacuum in the assembly 10 (e.g., in the catheter 102) and thus increase the suction force exerted against the clot material PE. That is, rather than removing the catheter 102 after a clog is detected, the secondary syringe 460 can be cycled until the vacuum force on the clot material PE overcomes the forces between the clot material PE and the catheter 102 and sucks the clot material PE into the syringe 340. In some embodiments, as described in detail below with reference to Figures 15–16E, a second clot removal assembly can be telescoped through the first assembly 10 to facilitate removal of the clogged clot material PE.

[0094] In some embodiments, an interventional device such as a clot removal and/or clot treatment device can be delivered to the treatment site through the catheter 102 for engaging and facilitating clot removal before and/or after application of a stored vacuum to the catheter 102. Suitable interventional devices and associated methods are disclosed in U.S. Patent Application No. 9,526,864, filed June 9, 2015, and titled "RETRACTION AND ASPIRATION DEVICE FOR TREATING EMBOLISM AND ASSOCIATED SYSTEMS AND METHODS," and U.S. Patent Application No. 8,784,434, filed March 15, 2013, and titled "METHODS AND APPARATUS FOR

TREATING EMBOLISM," both of which are incorporated herein by reference in their entireties. In some embodiments, for example, the user can first advance an interventional device to the treatment site and at least partially engage the clot material PE with the interventional device to loosen (e.g., scour) the clot material PE. Such loosening of the clot material PE can facilitate the removal of the clot material PE upon a subsequent aspiration pass. Likewise, in some embodiments, the user can use an interventional device to engage residual clot material PE (Figure 10B) after a first aspiration pass.

IV. Selected Embodiments of Telescoping Clot Removal Systems and Associated Methods of Clot Removal

[0095] Figure 11 is a partially schematic side view of another clot treatment or clot removal system configured in accordance with the present technology. In the illustrated embodiment, the clot removal system includes a first aspiration assembly 20 and a second aspiration assembly 30. The first and second aspiration assemblies 20, 30 ("assemblies 20, 30") can include some features generally similar to the features of the aspiration assembly 10 described in detail above with reference to Figures 1–10B. For example, the first aspiration assembly 20 includes (i) a first catheter subsystem 1000 having a first catheter 1002 and a first valve 1006, (ii) a first tubing subsystem 1020 having a first fluid control device 1026 (e.g., a stopcock), and (iii) a first pressure source 1040 that can be fluidly coupled to the first catheter subsystem 1000 via the first tubing subsystem 1020. Likewise, the second aspiration assembly 30 includes (i) a second catheter subsystem 1100 having a second catheter 1102 and a second valve 1106, (ii) a second tubing subsystem 1120 having a second fluid control device 1126 (e.g., a stopcock), and (iii) a second pressure source 1140 that can be fluidly coupled to the second catheter subsystem 1100 via the second tubing subsystem 1120.

[0096] The first and second catheters 1002, 1102 each comprise an elongated shaft defining a lumen 1004, 1104 and having a distal portion 1003a, 1103a, respectively. The first and second valves 1006, 1106 each include (i) a distal portion 1007a, 1107a, (ii) a proximal portion 1007b, 1107b, (iii) a lumen 1009, 1109 extending therethrough, and (iv) a flow controller (obscured in Figure 10) in the lumen 1009, 1109, respectively. The first fluid control device 1026 is operable to regulate or control fluid flow between (e.g., fluidly connect or disconnect) the first pressure source 1040 and the first catheter subsystem 1000. The second fluid control device 1126 is operable to regulate or control

fluid flow between (e.g., fluidly connect or disconnect) the second pressure source 1140 and the second catheter subsystem 1100.

[0097] In the illustrated embodiment, the second catheter 1102 has a smaller cross-sectional dimension (e.g., diameter) than the first catheter 1002 so that the second catheter 1102 can be inserted through the first valve 1006 and into the lumen 1004 of the first catheter 1002. In some embodiments, the second catheter 1102 can be telescoped through the lumen 1004 of the first catheter 1002 until the distal portion 1103a of the second catheter 1102 extends beyond a distal terminus of the first catheter 1002. Accordingly, the second catheter 1102 can be longer than the first catheter 1002. In some embodiments, the second catheter 1102 can have a size of 16 French or smaller and the first catheter 1002 can have a size of 20 French or greater. The first valve 1006 can provide a hemostatic seal that inhibits fluid flow (e.g., blood flow) through the first valve 1006 and from the first catheter subsystem 1000 when the second catheter 1102 is positioned within the first catheter 1002. In some embodiments (e.g., as described in detail below with reference to Figures 14A–14C), a sealing member 1499 can be positioned between the first catheter 1002 and the second catheter 1102 for sealing the lumen 1004 of the first catheter 1002 when the second catheter 1102 is advanced distally past the sealing member.

[0098] In some embodiments, the first and second pressure sources 1040, 1140 ("pressure sources 1040, 1140") are separate sources each configured to generate and store a vacuum for subsequent application to the first and second catheter subsystems 1000, 1100, respectively, as described in detail above with reference to Figures 1–10B. In other embodiments, one or both of the pressure sources 1040, 1140 can be configured to provide sustained negative pressure rather than a charge or burst of stored vacuum pressure. In yet other embodiments, one of the pressures sources 1040, 1140 can be omitted, or the pressure sources 1040, 1140 can be fluidly coupled and/or integrally formed.

[0099] Figure 12 is a flow diagram of a process or method 1280 for operating a clot removal system including the assemblies 20 and 30 to remove clot material from within a blood vessel (e.g., a pulmonary blood vessel) of a human patient in accordance with the present technology. Figures 13A–13C are schematic illustrations of a distal portion of the assemblies 20, 30 during a clot

removal procedure in accordance with the present technology. Figures 14A–14C are schematic side views of a distal portion of the assemblies 20, 30 during a clot removal procedure and including an optional sealing member in accordance with the present technology. Although some features of the method 1280 are described in the context of the embodiments shown in Figures 11 and 13A–14C for the sake of illustration, one skilled in the art will readily understand that the method 1280 can be carried out using other suitable systems and/or devices.

[0100] At block 1282, the method 1280 includes intravascularly positioning the first catheter 1002 within a human patient. Figure 13A, for example, illustrates the first catheter 1002 after it has been advanced (e.g., as indicated by arrow A1) to a position within a blood vessel BV (e.g., a pulmonary blood vessel). More specifically, the first catheter 1002 can be advanced within the blood vessel BV until the distal portion 1003a of the first catheter 1002 is positioned proximal to clot material PE within the blood vessel BV. In some embodiments, the position of the distal portion 1003a of the first catheter 1002 relative to the clot material PE can be determined by activating the first valve 1006 and determining whether there is back-bleeding through the first valve 1006, as described in detail above. In the illustrated embodiment, the clot material PE is located within a branch (e.g., a reduced diameter portion) of the blood vessel BV. In some embodiments, access to the blood vessel BV can be achieved using an introducer and guidewire as described in detail above with reference to Figure 8.

[0101] At block 1284, the method 1280 includes advancing the second catheter 1102 through the first catheter 1002 until the distal portion 1103a of the second catheter 1102 is positioned proximate to the clot material PE within the blood vessel BV (e.g., at a treatment site). To advance the second catheter 1102 through the first catheter 1002, the user can first insert the distal portion 1103a of the second catheter 1102 through the first valve 1006 before advancing the second catheter 1102 (e.g., as indicated by the arrow A1) through the lumen 1004 of the first catheter 1002. In some embodiments, the first valve 1006 can be actuated (e.g., by depressing one or more buttons) to open the lumen 1009 of the first valve 1006 so that the second catheter 1102 can be inserted therethrough. In some embodiments, the position of the distal portion 1103a of the second catheter 1102 relative to the clot material PE can be determined by activating the second valve 1106 and determining whether there is back-bleeding through the second valve 1106, as described in detail

above. In other embodiments, the (smaller) second catheter 1102 can be intravascularly positioned proximate to the clot material PE before intravascularly positioning the (larger) first catheter 1002. In such embodiments, the second catheter 1102 can act as a guide or rail for guiding the advancement of the first catheter 1002 to the treatment site.

[0102] Figure 13A illustrates the second catheter 1102 after it has been advanced through the first catheter 1002 and past a distal terminus of the first catheter 1002 to position a distal terminus of the second catheter 1102 proximate to a proximal portion of the clot material PE. In other embodiments, the distal terminus of the second catheter 1102 can be positioned at least partially within the clot material PE, or the distal terminus of the second catheter 1102 can be positioned distal of the clot material PE. In one aspect of the present technology, because the second catheter 1102 has a smaller cross-sectional dimension than the first catheter 1002, the second catheter 1102 can be advanced to narrower (e.g., more distal) treatment sites within the blood vessel BV. In the embodiment illustrated in Figure 13A, for example, the first catheter 1002 may be too large to be positioned within the branch of the blood vessel BV, while the second catheter 1102 can be positioned within the branch proximate to or within the clot material PE.

[0103] At block 1286, the method 1280 includes coupling the second pressure source 1140 to the second catheter 1102 via the second fluid control device 1126. For example, any one or combination of the pressure sources described in detail above with reference to Figures 2–7 can be coupled to the second catheter 1102 via the second tubing subsystem 1120. Once the second pressure source 1140 is coupled to the second catheter 1102, (i) opening of the second fluid control device 1126 fluidly connects the second pressure source 1140 to the lumen 1104 of the second catheter 1102, and (ii) closing of the second fluid control device 1126 fluidly disconnects the second pressure source 1140 from the lumen 1104 of the second catheter 1102. In some embodiments, the method 1280 can further include coupling the first pressure source 1040 to the first catheter 1002 (e.g., via the first tubing subsystem 1020).

[0104] At block 1288, the method 1280 includes activating the second pressure source 1140 to generate a vacuum while the second fluid control device 1126 is closed. In particular, the second pressure source 1140 can be activated to build-up or pre-charge a vacuum for subsequent application

to the second catheter 1102. In some embodiments, the first pressure source 1040 can also be activated to generate and store a vacuum for subsequent application to the first catheter 1002.

[0105] At block 1290, the method 1280 includes opening the second fluid control device 1126 to apply the vacuum stored in second pressure source 1140 to the lumen 1104 of the second catheter 1102. As shown in Figure 13B, application of the vacuum causes suction (e.g., as indicated by arrow A2) that aspirates at least a portion of the clot material PE from the blood vessel BV and into the lumen 1104 of the second catheter 1102. In some embodiments, opening the second fluid control device 1126 instantaneously or nearly instantaneously generates suction at the distal portion 1103a of the second catheter 1102. In one aspect of the present technology, pre-charging or storing the vacuum before applying the vacuum to the lumen 1104 of the second catheter 1102 is expected to generate greater suction forces (and corresponding fluid flow velocities) at and/or near the distal portion 1103a of the second catheter 1102 compared to simply activating the second pressure source 1140 while it is fluidly connected to the second catheter 1102.

[0106] In some embodiments, where the first pressure source 1040 is also activated to generate and store a vacuum (e.g., at block 1288), the method 1280 can further comprise opening the first fluid control device 1026 to generate suction at the distal portion 1003a of the first catheter 1002. One skilled in the art will understand that the suction profile in the blood vessel BV can be selected or modified based on the characteristics of the pressure sources 1040, 1140 (e.g., volume, bore size, etc.) and the timing of the opening of the first and second fluid control devices 1026, 1126. For example, the first fluid control device 1026 can be opened at the same time as the second fluid control device 1126 to generate a combined and relatively large suction force in the blood vessel BV. In other embodiments, the first fluid control device 1026 can be opened after the second fluid control device 1126 to generate staggered or stepped suction forces in the blood vessel BV. For example, the first fluid control device 1026 can be opened after the second fluid control device 1126 to aspirate any of the clot material PE (i) remaining in the blood vessel BV after aspiration of the second catheter 1102 and/or (ii) stuck to or extending from the second catheter 1102. In other embodiments, the first pressure source 1040 can be a pump or other source for providing sustained negative pressure—rather than a built-up charge of negative pressure—and thus can generate sustained (e.g., constant) suction at the distal portion 1003a of the first catheter 1002. In some such embodiments,

the first fluid control device 1026 can remain open during the clot removal procedure to provide sustained suction throughout the procedure.

[0107] In some embodiments, an interventional device can be delivered through the second catheter 1102 and used to engage the clot material PE before and/or after the vacuum is applied to the second catheter 1102. Specific details of suitable interventional devices and associated methods of use are disclosed in, for example, provisional U.S. Patent Application No. 16/258,344, filed January 25, 2019, and titled "SINGLE INSERTION DELIVERY SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED SYSTEMS AND METHODS," which is incorporated herein by reference in its entirety.

[0108] At block 1292, the method 1280 includes retracting the second catheter 1102 proximally through the first catheter 1002. In some embodiments, multiple aspiration passes can be performed with the second catheter 1102 before retracting the second catheter 1102. In some embodiments, as shown in Figure 13C, the first pressure source 1040 or another pressure source coupled to the first catheter 1002 can be activated to generate suction (e.g., as indicated by arrow A3) at the distal portion 1003a of the first catheter 1002 during retraction of the second catheter 1102. The suction can be constant or provided in one or more bursts, as described in detail above. In some embodiments, the second catheter 1102 can be fully withdrawn from the patient and disposed of or cleaned (e.g., flushed with a sterile liquid) for reuse.

[0109] Sometimes, the clot material PE is not fully pulled into the second catheter 1102 when the vacuum is applied to the second catheter 1102 (block 1290) and can therefore stick to or dangle from the distal portion 1103a of the second catheter 1102. Figure 14A, for example, is an enlarged view of the distal portion of the assemblies 20, 30 shown in Figure 13C and illustrating a portion of the clot material PE stuck to or dangling from the distal portion 1103a of the second catheter 1102. In the illustrated embodiment, an optional seal 1499 is disposed between the first and second catheters 1002, 1102 to facilitate the removal of such dangling clot material PE. More specifically, the seal 1499 (shown in cross-section) can be disposed between an outer surface of the second catheter 1102 and an inner surface of the first catheter 1002. The seal 1499 can be an O-ring, grommet, or other suitable component that fluidly disconnects the lumen 1004 of the first

catheter 1002 from the blood vessel BV when the second catheter 1102 is positioned therethrough (e.g., when the distal terminus of the second catheter 1102 is positioned distally of the seal 1499).

[0110] Figures 14B and 14C are enlarged views of the distal portion of the assemblies 20, 30 and illustrating further retraction of the second catheter 1102 (and the dangling clot material PE) into the lumen 1004 of the first catheter 1002. In some embodiments, the first pressure source 1040 can be activated to charge a vacuum in the lumen 1004 of the first catheter 1002. For example, after the second catheter 1102 is advanced through the first catheter 1002 and past the seal 1499 (e.g., block 1284)—thereby sealing the lumen 1004 of the first catheter 1002—the operator can open the first fluid control device 1026 and activate the first pressure source 1040 to build up the vacuum in the lumen 1004 of the first catheter 1002. Referring to Figure 14C, when the distal terminus of the second catheter 1102 is retracted proximally past the seal 1499, the lumen 1004 of the first catheter 1002 becomes fluidly connected to the blood vessel BV and the vacuum is instantaneously or nearly instantaneously released to generate suction (e.g., as indicated by arrows A4). In the illustrated embodiment, the suction acts to separate or otherwise dislodge the clot material PE from the second catheter 1102 and pull the clot material PE proximally through the lumen 1004 of the first catheter 1002. In this manner, a second burst of suction is automatically applied via the first catheter 1002 during retraction of the second catheter 1102. In one aspect of the present technology, the user does not need to take any additional step to release the vacuum stored in the first catheter 1002—as release is automatically triggered by retraction of the second catheter 1102.

[0111] At block 1294, the user can determine whether it is necessary or desirable to redeploy the second catheter 1102 or another catheter through the first catheter 1002 in order to remove any residual clot material PE that was not removed during the first aspiration pass and/or any clot material located elsewhere in the blood vessel BV (e.g., to initiate a second aspiration pass). In some embodiments, the operator can visualize the amount of clot material PE collected in the first pressure source 1040 and/or the second pressure source 1140 to at least partially determine whether another aspiration pass is needed. In other embodiments, the operator can rely on imaging (e.g., fluoroscopic imaging) of the blood vessel BV or other techniques known in the art to determine whether an additional aspiration pass is necessary or desirable.

[0112] If another pass is not needed (e.g., the clot material PE was adequately removed), the user can elect to fully withdraw the assemblies 20, 30 from the patient at block 1296. If clot material PE remains in the vessel, the method can return to block 1284. In particular, the same second catheter 1102 can be cleaned (e.g., flushed with saline) and advanced again through the first catheter 1002 until the distal portion 1103a of the second catheter 1102 is positioned proximate to the remaining clot material PE within the blood vessel BV. In some embodiments, a new second catheter 1102 can be used for each pass to reduce the likelihood of contamination (e.g., reintroduction of clot material PE). In some embodiments, the first catheter 1002 can be aspirated (e.g., via the first pressure source 1040) prior to redeployment of the second catheter 1102 to, for example, remove any clot material PE that may be in the first catheter 1002 to inhibit its reintroduction into the blood vessel BV as the second catheter 1102 is advanced therethrough during another pass. Once the desired amount of clot material PE has been removed from the patient, the assemblies 20, 30 may be fully withdrawn from the patient (block 1294).

[0113] In one aspect of the present technology, the method 1280 provides for an aspiration catheter to be deployed multiple times without requiring that the first catheter 1002 be removed after each deployment. Accordingly, the present technology allows for only a single insertion of a guide catheter during a procedure including multiple passes to remove clot material—increasing the speed of the procedure and reducing trauma to the patient since the guide catheter does not need to be reintroduced (e.g., advanced through the vasculature and past the heart) before each pass. Moreover, in certain embodiments, the present technology can enable the first catheter 1002 to be relocated to an alternate treatment site within the patient without removing the first catheter 1002 from the patient and, therefore, without reintroducing the first catheter 1002 through the heart. For example, the first catheter 1002 can be relocated to another treatment site within the lungs including a treatment site in the opposite lung. More specifically, (i) a dilator can be reintroduced into the first catheter 1002, (ii) the first catheter 1002 can be withdrawn into the main pulmonary artery, (iii) a guidewire can be redirected to the new treatment site, (iv) the first catheter 1002 can be advanced over the guidewire to the new treatment site, and (v) the dilator can be removed.

[0114] Figure 15 is a flow diagram of another process or method 1580 for operating a clot removal system including the assemblies 20, 30 (Figure 1) to remove clot material from within a

blood vessel (e.g., a pulmonary blood vessel) of a human patient in accordance with the present technology. Figure 16A is an enlarged side view of a distal portion of the first assembly 20, and Figures 16B–16E are side views of a distal portion of the assemblies 20, 30 during a clot removal procedure in which clot material clogs the first assembly 20 in accordance with the present technology. Although some features of the method 1580 are described in the context of the embodiments shown in Figures 11 and 16A–16E for the sake of illustration, one skilled in the art will readily understand that the method 1580 can be carried out using other suitable systems and/or devices.

[0115] Some features of the method 1580 are generally similar to those of the methods 880 and/or 1280 described in detail above with reference to Figures 8 and 12, respectively. For example, at block 1582 the method includes intravascularly positioning the first catheter 1002 of the first assembly 20 within a human patient. At block 1584, the method 1580 includes coupling the first pressure source 1040 to the first catheter 1002 via the first fluid control device 1026. For example, any one or combination of the pressure sources described in detail above with reference to Figures 2–7 can be coupled to the second catheter 1002 via the first tubing subsystem 1020. At block 1586, the method 1580 includes activating the first pressure source 1040 to generate a vacuum while the first fluid control device 1026 is closed. In particular, the first pressure source 1040 can be activated to build-up or pre-charge a vacuum for subsequent application to the first catheter 1002. At block 1588, the method 1580 includes opening the first fluid control device 1026 to apply the vacuum stored in the first pressure source 1040 to the lumen 1004 of the first catheter 1002. As described in detail above, opening the first fluid control device 1026 instantaneously or nearly instantaneously generates suction at the distal portion 1003a of the first catheter 1002.

[0116] Sometimes, however, clot material is not fully pulled into the first catheter 1002 and/or clogs the first catheter 1002 when the vacuum is applied to the first catheter 1002 (block 1588). Figure 16A, for example, is an enlarged view of the distal portion of the first assembly 20 illustrating a portion of clot material PE that extends beyond from the distal portion 1003a of the first catheter 1002 and blocks/clogs the lumen 1004 of the first catheter 1002. As such, a portion of the clot material PE is not within the first catheter 1002. Accordingly, at block 1590, the method 1580 can include determining whether the first catheter 1002 is clogged. In some embodiments, the

operator can determine that the first catheter 1002 is clogged based on the vacuum chamber of the first pressure source 1040 containing little to no clot material PE and blood. For example, since the clot material PE clogs the first catheter 1002, the vacuum chamber of the first pressure source 1040 cavitates when the first fluid control device 1026 is opened. If the first catheter 1002 is not clogged, the method 1580 can proceed to block 1598 and the first catheter 1002 can be withdrawn from the patient or the operator can perform another aspiration pass (e.g., as described in detail above with reference to blocks 808 and 810 of the method 800 shown in Figure 8).

[0117] If the first catheter 1002 is clogged, the method 1580 can proceed to block 1592 which includes advancing the second catheter 1102 through the first catheter 1002 until the distal portion 1103a of the second catheter 1102 is positioned in or proximate to the clogging clot material PE. For example, Figure 16B illustrates the second catheter 1102 after it has been advanced to a position within the first catheter 1002 in which the distal terminus of the second catheter 1102 is at or proximate to the clogging clot material PE. To advance the second catheter 1102 through the first catheter 1002, the user can first insert the distal portion 1103a of the second catheter 1102 through the first valve 1006 (Figure 11) before advancing the second catheter 1102 through the lumen 1004 of the first catheter 1002.

[0118] At block 1594, the method 1580 includes activating the second pressure source 1140 (Figure 11) coupled to the second catheter 1102. More specifically, the second pressure source 1140 (e.g., any one or combination of the pressure sources described in detail above with reference to Figures 2–7) can be coupled to the second catheter 1102 via the second fluid control device 1126 (Figure 11), and the second pressure source 1140 can be activated to build-up or pre-charge a vacuum while the second fluid control device 1126 is closed. The second fluid control device 1126 can then be actuated to apply the vacuum stored in the second pressure source 1140 to the lumen 1104 of the second catheter 1102. In other embodiments, the second pressure source 1140 can simply provide a sustained vacuum rather than an instantaneous release of vacuum. That is, in some embodiments the second pressure source 1140 is not pre-charged with a vacuum.

[0119] Applying the vacuum to second catheter 1102 can aspirate at least a portion of the clogging clot material PE into the second catheter 1102 and/or suck the clot material PE against the

distal terminus of the second catheter 1102. Figure 16C, for example, illustrates a portion of the clot material PE stuck to or extending from the distal portion 1103a of the second catheter 1102 after aspirating the second catheter 1102. In the embodiment illustrated in Figure 16C, the added vacuum pressure generated through the second catheter 1102 is still not enough to break apart the clot material PE such that it can be fully aspirated through the first and/or second catheters 1002, 1102. That is, the clot material PE clogs the lumen 1004 of the first catheter 1002. In other embodiments, the added vacuum pressure from the second pressure source 1140 is sufficient to break apart the clot material PE such that it is aspirated into, for example, the vacuum chambers of the first and/or second pressure sources 1040, 1140.

[0120] At block 1596, the method can include retracting the second catheter 1102 and the clot material PE through the lumen 1004 of the first catheter 1002. For example, Figure 16D illustrates retracting the second catheter 1102, which in turn retracts the attached clot material PE, through the lumen 1004 of the first catheter 1002. In some embodiments, the second catheter 1102 and clot material PE can be fully withdrawn through the first catheter 1002. In other embodiments, retracting the clot material PE through the first catheter 1002 causes the clot material PE to break apart and be aspirated into the vacuum chambers of the first and/or second pressure sources 1040, 1140. Figure 16E, for example, illustrates the clot material PE breaking apart as the vacuum of the first and/or second pressure sources 1040, 1140 is instantaneously or nearly instantaneously released to suck the clot material PE proximally (e.g., as indicated by arrows A5).

[0121] At block 1598, the first and second catheters 1002, 1102 can be withdrawn from the patient or the operator can perform another aspiration pass using one or both of the first and second catheters 1002, 1102.

[0122] In one aspect of the present technology, the method 1580 removes clot material even when a first aspiration pass clogs the first catheter 1002. More particularly, the second catheter 1102 can be used to remove clogged clot material PE without requiring the first catheter 1002 and the clogged clot material PE to be withdrawn through the blood vessel BV.

V. Additional Selected Embodiments of Clot Removal Systems and Associated Methods of Clot Removal

[0123] From the foregoing, it will be appreciated that specific embodiments of the present technology have been described herein for purposes of illustration, but that various modifications may be made without deviating from the scope of the present technology. For example, in many of the embodiments described above, stored vacuum pressure can be used to aspirate or suck clot material from a blood vessel and into a catheter without the need to engage an interventional device with the clot material. However, one skilled in the art will understand that the aspiration devices and techniques disclosed herein can be used in conjunction with any suitable interventional device and/or during a clot removal procedure utilizing an interventional device. In some embodiments, for example, a clot removal system can be configured to apply stored vacuum pressure to a guide catheter to generate a burst of suction while an interventional device is retracted into and/or through the guide catheter.

[0124] Figure 17, for example, is a partially schematic view of a clot removal system 1700 ("system 1700") configured in accordance with the present technology. The system 1700 includes some features generally similar to the features of the clot removal system described in detail above with reference to Figure 1. For example, the system 1700 includes a catheter or sheath 1702 comprising an elongated shaft, and a valve 1706 coupled to a proximal portion of the sheath 1702. The valve 1706 has a side port 1708 that fluidly couples a lumen of the sheath 1702 to a tubing subsystem 1720 and a pressure source 1740 (shown schematically). A fluid control device 1726 (e.g., a stopcock or clamp; shown schematically) is operable to fluidly disconnect or connect the pressure source 1740 from/to the lumen of the sheath 1702. The pressure source 1740 can be any suitable pressure source for generating and storing vacuum pressure, as described in detail above.

[0125] In the illustrated embodiment, the system 1700 further includes (i) a self-expanding (e.g., mesh) funnel 1780 coupled to a proximal portion of the sheath 1702 and (ii) an interventional device (e.g., a thrombus extraction device) 1790. In the illustrated embodiment, the interventional device 1790 includes an expandable coring element (e.g., a first portion) 1792 coupled to an expandable cylindrical element (e.g., a second portion) 1794. In some embodiments, the interventional device 1790 is configured to self-expand from a compressed delivery state to an

expanded deployed state. The interventional device 1790 is shown in the deployed state in Figure 17. An elongated shaft 1782 and/or one or more shafts positioned within the elongated shaft 1782 (e.g., an intermediate shaft 1884 and an inner shaft 1886 as shown in Figures 18E and 18F, respectively) are coupled to the interventional device 1790 and configured to retract, advance, and/or manipulate (e.g., move between the delivery and deployed states) the interventional device 1790. In some embodiments, the system 1700 can be generally the same as or similar to any of the clot removal systems disclosed in U.S. Patent Application Publication No. 2018/0193043, filed April 26, 2017, and titled "DEVICES AND METHODS FOR TREATING VASCULAR OCCLUSION," which is incorporated herein by reference in its entirety.

[0126] In the illustrated embodiment, the system 1700 is shown intravascularly positioned within a blood vessel BV of a human patient and proximate to clot material DV (e.g., a deep vein thrombus) within the blood vessel BV. Specifically, Figure 17 shows the system 1700 after (i) advancing the sheath 1702 to a position proximate to a proximal portion 1785b of the clot material DV, (ii) deploying the funnel 1780, (iii) deploying the interventional device 1790 from the sheath 1702 (e.g., by advancing the interventional device 1790 through the valve 1706 and the sheath 1702 to a position distal of a distal portion 1785a of the clot material DV), and (iv) expanding the interventional device 1790 from the compressed delivery state to the deployed state.

[0127] Figures 18A–18H are enlarged views of a distal portion of the system 1700 during a clot removal procedure in accordance with the present technology. In general, Figures 18A–18H illustrate the proximal retraction of the interventional device 1790 through the clot material DV to capture at least a portion of the clot material DV, and the subsequent joint retraction of the interventional device 1790 and the captured clot material DV into the funnel 1780 and the sheath 1702. In one aspect of the present technology, charged vacuum pressure generated in the vacuum source 1740 can be applied to the sheath 1702 at one or more times during the illustrated process to generate suction for aspirating the captured clot material DV through the sheath 1702 and/or to inhibit clogging of the sheath 1702.

[0128] Referring first to Figure 18A, proximal retraction of the interventional device 1790 causes the coring element 1792 to separate and/or core the distal end portion 1785a of the clot

material DV from the walls W of the blood vessel BV. As shown in Figure 18B, continued proximal retraction of the interventional device 1790 through the clot material DV causes the cylindrical element 1794 to capture the distal end portion 1785a of the clot material therein. Figures 18C–18E illustrate further proximal retraction of the interventional device 1790 which causes further separation, coring, and/or capture of the clot material DV. As seen in Figure 18E, the proximal end portion 1785b of the clot material DV is cored and captured as the interventional device 1790 is proximally retracted toward the funnel 1780 and the sheath 1702. As further shown in Figure 18E, a first radiopaque marker 1887a can be positioned on a distal end portion of the inner shaft 1884 and a second radiopaque marker 1887b can be positioned on a distal end portion of the sheath 1702.

[0129] In some embodiments, as shown in Figure 18F, the interventional device 1790 can be proximally retracted until a portion of the coring element 1792 is contained (e.g., positioned) within the funnel 1780. More specifically, the interventional device 1790 can be proximally retracted until a mouth 1895 of the coring element 1792 is contained within the funnel 1780. In some embodiments, the containment of the mouth 1895 within the funnel 1780 can be fluoroscopically verified by visualization of the radiopaque markers 1887 (Figure 18E). In some embodiments, for example, the mouth 1895 can be determined as wholly contained within the funnel 1780 via fluoroscopic monitoring based on the alignment of the distal end portion of the inner shaft 1884 (e.g., the first radiopaque marker 1885a) relative to the distal end portion of the sheath 1702 (e.g., the second radiopaque marker 1885b). In some embodiments, when the mouth 1895 of the coring element 1792 is positioned within the funnel 1780, the interventional device 1790 can be moved or transformed from the expanded deployed state to the compressed delivery state to compress and secure the clot material DV captured by the interventional device 1790. In some embodiments, for example, the intermediate shaft 1884 can be unlocked and/or decoupled from the inner shaft 1886 (e.g., via user actuation of a plunger or other device) such that the inner shaft 1886 can be advanced distally relative to the intermediate shaft 1884 to collapse or compress the interventional device 1790.

[0130] After the interventional device 1790 has been collapsed, the interventional device 1790 can be proximally retracted through the funnel 1780 and into the sheath 1702 as depicted in Figure 18G. As shown in Figure 18H, the interventional device 1790 can continue to be proximally retracted until the interventional device 1790 and the captured clot material DV are fully contained

within the sheath 1702. In some embodiments, the interventional device 1790 and the captured clot material DV can then be withdrawn through the sheath 1702 and the valve 1706 (Figure 17), and from the patient's body.

[0131] In some embodiments, the collapse of the interventional device 1790 and/or the retraction of the interventional device 1790 into the funnel 1780 and/or the sheath 1702 can result in one or more portions of the clot material DV breaking away from the clot material DV contained in the interventional device 1790. For example, all or a portion of the captured clot material DV can be extruded through pores of the (e.g., mesh) cylindrical element 1794 as the interventional device 1790 collapses. In some embodiments, any such clot material can be captured by the funnel 1780. Referring to Figure 17, in some embodiments, the pressure source 1740 can be activated to charge a vacuum, and the fluid control device 1726 can subsequently be opened to apply the charged vacuum to the sheath 1702 (as described in detail above). The vacuum can be applied to the sheath 1702 at any point during retraction of the interventional device 1790. As shown in Figures 18G and 18H, application of the vacuum can generate instantaneous or nearly instantaneous suction (e.g., as indicated by arrows A6) at the distal end portion the sheath 1702 that can aspirate the extruded portions and/or other portions of the clot material DV into and/or through the sheath 1702. In particular, the generated suction can aspirate some or all of the clot material DV captured by the funnel 1780. Moreover, in some embodiments, application of a vacuum from the pressure source 1740 can facilitate smooth retraction of the captured clot material DV through the sheath 1702. For example, a burst of suction generated by application of the vacuum can help inhibit clogging of the sheath 1702, and/or help resolve (e.g., break apart) a clog formed in the sheath 1702 during retraction.

VI. Selected Embodiments of Clot Removal Systems Having Filters and Associated Methods of Clot Removal

[0132] The systems and methods for clot removal described herein can include applying a pre-charged vacuum to generate suction for aspirating clot removal from the blood vessel of a patient. In one aspect of the present technology, aspiration of the clot material also aspirates blood from the patient. It can be advantageous to reintroduce the aspirated blood to the patient to lessen the trauma to the patient—especially where the removal procedure may comprise multiple aspiration passes that

can together withdraw a significant amount of blood. However, the aspirated blood is often mixed with clot material and is therefore not suitable for reintroduction into the patient. Figures 19–20E illustrate various devices for filtering aspirated blood from removed clot material to reintroduce the aspirated blood into the patient without reintroducing a significant amount of clot material.

[0133] For example, Figure 19 is a perspective side view of a pressure source 1900 for filtering blood from aspirated clot material during a clot removal procedure configured in accordance with the present technology. The pressure source 1900 is generally similar to the pressure source 400 described in detail above with reference to Figures 4A–4C. For example, the pressure source 1900 includes the secondary syringe 460 ("syringe 460") and the first and second one-way valves 470 and 472. However, the secondary syringe 460 is coupled to a canister 1940 rather than the primary syringe 340 (Figures 4A–4C). The canister 1940 includes a tip (obscured) coupled to the adaptor 350 and is configured to be removably positioned within the connector 128 of the tubing subsystem 120 (Figure 1) to fluidly couple the canister 1940 to the tubing subsystem 120. Because the canister 1940 does not include a plunger or other component for changing a volume thereof, the syringe 460 is the only vacuum source for evacuating the canister 1940 (e.g., via repeated cycling of the secondary syringe 460).

[0134] In the illustrated embodiment, the canister 1940 further includes a filter 1942. The canister 1940 is shown as transparent in Figure 19 for the sake of clarity. The filter 1942 is coupled to and/or covers a removable end cap 1944 having a blood separation port 1946. In operation, when blood and clot material are aspirated into the canister 1940 (e.g., via any of the methods described in detail above), the filter 1942 separates the blood from the clot material within the canister 1940. The filtered blood can be removed via the blood separation port 1946. For example, a syringe (not shown) or other device can be fluidly coupled to the blood separation port 1946 and used to draw the blood through the filter 1942 and out of the canister 1940. The filtered blood can then be reintroduced to the patient via, for example, the fluid control device 126 and/or the connector 128 of the tubing subsystem 120. Once the blood is removed from the canister 1940, the end cap 1944 can be removed from the canister 1940 (e.g., by unscrewing the end cap 1944 from the body of the canister 1940) for removing the captured clot material. In some embodiments, the filter 1942 is attached to the end

cap 1944 such that removing the end cap 1944 removes the filter 1942 and permits clot material to be dumped, scooped, or otherwise removed from the canister 1940.

[0135] Figures 20A–20E illustrate a filter device 2050 for filtering blood from aspirated clot material during a clot removal procedure configured in accordance with the present technology. The filter device 2050 is configured as an in-line filter for use with, for example, one or more of the pressure sources described in detail above with reference to Figures 2–7. For example, Figure 20A is a partially-exploded side view of the filter device 2050 and the pressure source 340 (Figures 3A–3D). In the illustrated embodiment, the filter device 2050 comprises a filter portion 2060 that is removably positionable within a barrel portion 2070. In the illustrated embodiment, the barrel portion 2070 includes a barrel 2072 that defines a chamber 2074, and a large bore tip 2076 configured to fluidly couple the chamber 2074 to external components, such as the tubing subsystem 120 (e.g., as shown in Figure 20C). The filter portion 2060 includes a seal 2062 configured to engage (i) an interior surface of the barrel 2072 when the filter portion 2060 is positioned within the chamber 2074 of the barrel portion 2070 and (ii) an exterior surface of the syringe 340 (e.g., an exterior surface of the barrel 344) when the syringe 340 is inserted into the filter device 2050. In other embodiments, the filter portion 2060 can be permanently attached to or integrally formed with the barrel portion 2070. The filter portion 2060 further includes a filter (e.g., a mesh) 2064 configured (e.g., sized and shaped) to inhibit clot material from passing therethrough. In some embodiments, the filter 2064 can be configured to inhibit clots larger than about 100 μm (e.g., larger than about 110 μm) from passing therethrough.

[0136] Figure 20B is a perspective side view of the syringe 340 coupled to the filter device 2050. The barrel 2072 of the barrel portion 2070 is shown as transparent in Figure 20B (and Figures 20C–20E) for the sake of clarity. In the illustrated embodiment, the seal 2062 is positioned between the exterior surface of the barrel 344 of the syringe 340 and the interior surface of the barrel 2072 of the barrel portion 2070. The filter 2064 is positioned around (e.g., covers) the tip 347 of the syringe 340 to inhibit clot material from entering the barrel 344 of the syringe 340 during operation.

[0137] Figure 20C is a side view of the filter device 2050 and syringe 340 coupled to the tubing subsystem 120 of the assembly 10. More specifically, the tip 2076 can be inserted into the connector 128 of the tubing subsystem 120 as described in detail above. When the filter device 2050 and the syringe 340 are coupled to the tubing subsystem 120, the filter device 2050 is positioned in-line (e.g., in series) with the syringe 340. In the embodiment illustrated in Figure 20C, the plunger 342 of the syringe 340 has been withdrawn to generate negative pressure in the combined volume of the barrels 2072 and 344. As described in detail above, opening the fluid control device 126 nearly instantaneously applies the negative pressure to the catheter 102 to generate suction therein. When clot material and blood are aspirated through the catheter 102 and the tubing subsystem 120, the filter portion 2060 inhibits the clot material from entering the barrel 344 of the syringe 340. Thus, aspirated blood is collected in the barrel 344 of the syringe 340 while the aspirated clot material is collected in the barrel 2072 of the barrel portion 2070 of the filter device 2050. In this manner, clot material and blood can be separated during aspiration.

[0138] In one aspect of the present technology, separating the blood from the clot material such that the blood is within the syringe 340 permits the blood to be easily reintroduced to the patient. For example, Figures 20D and 20E are side views of the syringe 340 coupled to the tubing subsystem 120 of the assembly 10 for reintroducing blood to a patient. In some embodiments, as shown in Figure 20D, the syringe 340 can be decoupled from the filter device 2050 and directly coupled to the connector 128. With the fluid control device 126 in an open position, the blood can then be reintroduced to the patient through the assembly 10 by depressing the plunger 342 of the syringe 340. In some embodiments, as shown in Figure 20E, the syringe 340 can be decoupled from the filter device 2050 and directly coupled to a port on the fluid control device 126. With the fluid control device 126 in a closed position, the blood can then be reintroduced to the patient through the assembly 10 by depressing the plunger 342 of the syringe 340. Referring to Figures 20A–20E together, after or before reintroducing filtered blood to the patient, the filter portion 2060 of the filter device 2050 can be removed from the barrel portion 2070 so that the collected clot material can be removed and the filter device 2050 cleaned. In some embodiments, the filter device 2050 and a coupled pressure source can be used to filter blood from clot material after—as opposed to during—an aspiration pass. For example, the filter device 2050 and coupled pressure source could be used to

withdraw blood and clot material collected in the canister 1940 of the pressure source 1900 (e.g., where the canister 1940 does not include the filter 1942).

[0139] Figures 21A and 21B illustrate a filter device 2150 for filtering blood from aspirated clot material during a clot removal procedure configured in accordance with the present technology. The filter device 2150 is configured for use with, for example, one or more of the pressure sources described in detail above with reference to Figures 2–7. For example, Figure 21A is a partially-exploded side view of the filter device 2150 and the pressure source 340 (Figures 3A–3D). In the illustrated embodiment, the filter device 2150 includes a housing 2152 defining a chamber 2154, a filter 2156 configured to be positioned within the housing 2152, and a cap assembly 2160 configured to be releasably coupled to the housing 2152 (e.g., via a threaded connection, snap-fit connection, etc.). In some embodiments, the filter 2156 can have a porosity of between about 50–200 microns.

[0140] The housing 2152 can include a port 2153 configured to be removably, fluidly coupled to the pressure source 340 via a tubing subsystem 2120. In the illustrated embodiment, the tubing subsystem 2120 includes tubing sections 2124 (individually labeled as a first tubing section 2124a and a second tubing section 2124b), a fluid control device 2126 (e.g., a valve, stop cock, clamp, etc.), and a connector 2128 (e.g., a large bore connector) for fluidly coupling the tubing subsystem 2120 to the pressure source 340. In the illustrated embodiment, the cap assembly 2160 includes a fluid connector 2162 (e.g., a standard Luer or large bore connector) configured to be connected to a receiving/reinfusion syringe 2170 via, for example, a tubing section 2164. In some embodiments, the cap assembly 2160 can include a valve (e.g., a one-way valve, a check valve, etc.) that provides for one-way fluid flow through filter assembly 2150.

[0141] In operation, during a clot removal procedure, the pressure source 340 can be decoupled from the connector 128 (Figure 1) after an aspiration pass and when the pressure source 340 is full of blood and clot material. After connecting the filter device 2150 to the receiving syringe 2170, the pressure source 340 can be coupled to the filter device 2150. For example, Figure 21B is a perspective side view of the filter device 2150 coupled to (i) the pressure source 340 via the tubing subsystem 2120 and (ii) the reinfusion syringe 2170 via the tubing section 2164. More specifically, referring to Figures 21A and 21B together, the tip 347 of the pressure source 340 can be coupled to

the connector 2128 of the tubing subsystem 2120, and a tip 2172 of the reinfusion syringe 2170 can be coupled to the tubing section 2164. In other embodiments, the filter device 2150 can be coupled to the pressure source 340 and/or the reinfusion syringe 2170 in other manners (e.g., directly such that the all or part of the tubing subsystem 120 is omitted). Alternatively, the filter device 2150 can be directly attached to the side port 108 (Figure 1), an IV line (not shown), or another suitable connection point for reintroducing blood to the patient,

[0142] After coupling the pressure source 340 to the filter device 2150, the fluid control device 2128 can be opened to fluidly connect the pressure source 340 to the filter device 2150. Then, the operator can depress the plunger 342 of the pressure source 340 to drive the blood and clot material from the pressure source 340 into and/or through the filter device 2150. The filter 2156 of the filter device 2150 filters the blood from the clot material such that the blood flows into the reinfusion syringe 2170 and the clot material remains in the chamber 2154 of the filter device 2150. For example, as shown in Figure 21B, blood B fills the reinfusion syringe 2170 and clot material PE remains within the chamber 2154 of the filter device 2150 after depressing the plunger 342 of the pressure source 340 in the direction indicated by the arrow H.

[0143] Next, the reinfusion syringe 2170 can be decoupled from the filter device 2150 so that the blood B can be reintroduced to the patient. For example, the reinfusion syringe 2170 could be directly coupled to a port on the fluid control device 126 (Figure 1). The cap assembly 2160 can be decoupled from the housing 2152 of the filter device 2150 to, for example, permit an operator to remove the clot material PE collected in the housing 2152 and thereby clean and prepare the filter device 2150 for another use.

[0144] Figure 22 is a partially-exploded side view of a filter device 2250 for filtering blood from aspirated clot material during a clot removal procedure configured in accordance with the present technology. The filter device 2250 is configured for use with, for example, one or more of the pressure sources described in detail above with reference to Figures 2–7. In general, the filter device 2250 is generally similar to the filter device 2150 described in detail with reference to Figures 21A and 21B. For example, the filter device 2250 includes a housing 2252 defining a chamber 2254, a filter 2256 configured to be positioned within the housing 2252, and a cap

assembly 2260 configured to be releasably coupled to the housing 2252. However, in the illustrated embodiment the filter device 2250 includes a port 2253 that is directly connected to a connector 2228 configured to be coupled to a pressure source (e.g., the pressure source 340 shown in Figures 3A–3D). The cap assembly 2260 includes a fluid connector 2162 (e.g., a standard Luer or large bore connector) configured to be connected to a reinfusion syringe, a sheath, an IV line, etc., (not shown). In some embodiments, the fluid connector 2262 is angled relative to the filter 2260 and/or the housing 2252. For example, the fluid connector 2262 is formed to have an approximately right angle in Figure 22. In one aspect of the present technology, this arrangement makes the filter device more ergonomic during use.

[0145] Figure 23 is a partially-exploded side view of a filter device 2350 for filtering blood from aspirated clot material during a clot removal procedure configured in accordance with the present technology. The filter device 2350 is configured for use with, for example, one or more of the pressure sources described in detail above with reference to Figures 2–7. The filter device 2350 is generally identical to the filter device 2250 described in detail with reference to Figure 22—including, for example, the housing 2252 ("a first housing 2252"), the filter 2256 ("a first filter 2256"), and the cap assembly 2260 including the fluid connector 2262 ("a first fluid connector 2262"). However, in the illustrated embodiment a second housing 2382 and a second filter 2386 are fluidly connected to the fluid connector 2262. The second housing 2382 includes a second fluid connector 2384 that can be fluidly connected to a reinfusion syringe, a sheath, an IV line, etc., (not shown). The second filter 2386 is configured to provide a second stage of filtration. For example, in some embodiments the first filter 2256 has a larger porosity than the second filter 2386. For example, the first filter 2256 can have a porosity of between about 50–200 microns and the second filter 2386 can have a porosity of between about 50–170 microns.

[0146] In general, one skilled in the art will understand that the various embodiments of filter devices disclosed herein may have different components or combinations of components. For example, the filter devices 2050, 2150, 2250, and/or 2350 ("the filter devices") could be utilized with any of several different pressure sources other than the syringe 340 (e.g., those shown in Figures 2 and 4–7). In some embodiments, the filter devices can be formed as a component of the tubing

subsystem 120 (Figure 1). Moreover, the filter devices can include any number of filters and/or housings to provide any number of filtration stages.

VII. Examples

[0147] Several aspects of the present technology are set forth in the following examples: [[TO ADD ONCE CLAIMS ARE FINALIZED]]

Conclusion

[0148] The above detailed descriptions of embodiments of the technology are not intended to be exhaustive or to limit the technology to the precise form disclosed above. Although specific embodiments of, and examples for, the technology are described above for illustrative purposes, various equivalent modifications are possible within the scope of the technology as those skilled in the relevant art will recognize. For example, although steps are presented in a given order, alternative embodiments may perform steps in a different order. The various embodiments described herein may also be combined to provide further embodiments.

[0149] From the foregoing, it will be appreciated that specific embodiments of the technology have been described herein for purposes of illustration, but well-known structures and functions have not been shown or described in detail to avoid unnecessarily obscuring the description of the embodiments of the technology. Where the context permits, singular or plural terms may also include the plural or singular term, respectively.

[0150] Moreover, unless the word "or" is expressly limited to mean only a single item exclusive from the other items in reference to a list of two or more items, then the use of "or" in such a list is to be interpreted as including (a) any single item in the list, (b) all of the items in the list, or (c) any combination of the items in the list. Additionally, the term "comprising" is used throughout to mean including at least the recited feature(s) such that any greater number of the same feature and/or additional types of other features are not precluded. It will also be appreciated that specific embodiments have been described herein for purposes of illustration, but that various modifications may be made without deviating from the technology. Further, while advantages associated with some embodiments of the technology have been described in the context of those embodiments, other

embodiments may also exhibit such advantages, and not all embodiments need necessarily exhibit such advantages to fall within the scope of the technology. Accordingly, the disclosure and associated technology can encompass other embodiments not expressly shown or described herein.

CLAIMS

I/We claim:

1. An aspiration system with accelerated response, comprising:

an aspiration pump in communication with a first chamber;

an aspiration catheter configured for placement into fluid communication with the first chamber by way of an aspiration tube;

a second chamber in between the aspiration pump and the catheter; and

a valve between the second chamber and the aspiration catheter;

wherein upon opening of the valve with negative pressure in the first and second chambers, fluid flow between the second chamber and the first chamber causes rapid aspiration into the second chamber.

2. The aspiration system of claim 1 wherein:

the first chamber comprises a first barrel of a first syringe;

the pump comprises a plunger of the first syringe slidably received in the first barrel; and

the second chamber comprises a second barrel of a second syringe.

3. The aspiration system of claim 1 wherein:

the valve comprises a stopcock valve; and

the aspiration tube comprises a first tubing section coupled to the second chamber and one side of the stopcock valve and a second tubing section coupled to the other side of the stopcock valve.

4. The aspiration system of claim 1 wherein:

the valve comprises a stopcock valve;

the aspiration tube comprises a first tubing section coupled to the second chamber and one side of the stopcock valve and a second tubing section coupled to the other side of the stopcock valve;

the first chamber comprises a first barrel of a first syringe;

the pump comprises a plunger of the first syringe slidably received in the first barrel; and

the second chamber comprises a second barrel of a second syringe, and wherein the second syringe further comprises a second plunger slidably received in the second barrel.

5. The aspiration system of claim 1, further comprising a one-way valve between the first chamber and the second chamber configured to block flow from the first chamber to the second chamber and allow flow from the second to the first chamber.

6. The aspiration system of claim 5 wherein the first syringe comprises a secondary pressure source and the second syringe comprises a primary pressure source.

7. The aspiration system of claim 6 wherein the first plunger is rotationally received in the first barrel and the second plunger is rotatably received in the second barrel.

8. The aspiration system of claim 1 wherein a negative pressure in the first chamber causes fluid flow from the second chamber to the first chamber when the valve is opened.

9. The aspiration system of claim 1 wherein the first chamber and the second chamber are configured such that both the first chamber and the second chamber can both be at a negative pressure at the same time, and wherein upon opening the valve the negative pressure in the first chamber contributes to a rapid pressure drop in the catheter.

10. An aspiration system with accelerated response, comprising:

an aspiration pump in communication with a first chamber;

an aspiration catheter configured for placement into fluid communication with the first chamber by way of an aspiration tube;

a second chamber in between the aspiration pump and the catheter; and

a valve between the second chamber and the aspiration catheter;

wherein upon opening of the valve with negative pressure in the first and second chambers, fluid flow between the second chamber and the first chamber causes rapid decrease in pressure in the aspiration catheter.

ABSTRACT OF THE DISCLOSURE

Systems and methods for the intravascular treatment of clot material within a blood vessel of a human patient are disclosed herein. A method in accordance with embodiments of the present technology can include, for example, positioning a distal portion of a catheter proximate to the clot material within the blood vessel. The method can further include coupling a pressure source to the catheter via a tubing subsystem including a valve or other fluid control device and, while the valve is closed, activating the pressure source to charge a vacuum. The valve can then be opened to apply the vacuum to the catheter to thereby aspirate at least a portion of the clot material from the blood vessel and into the catheter.

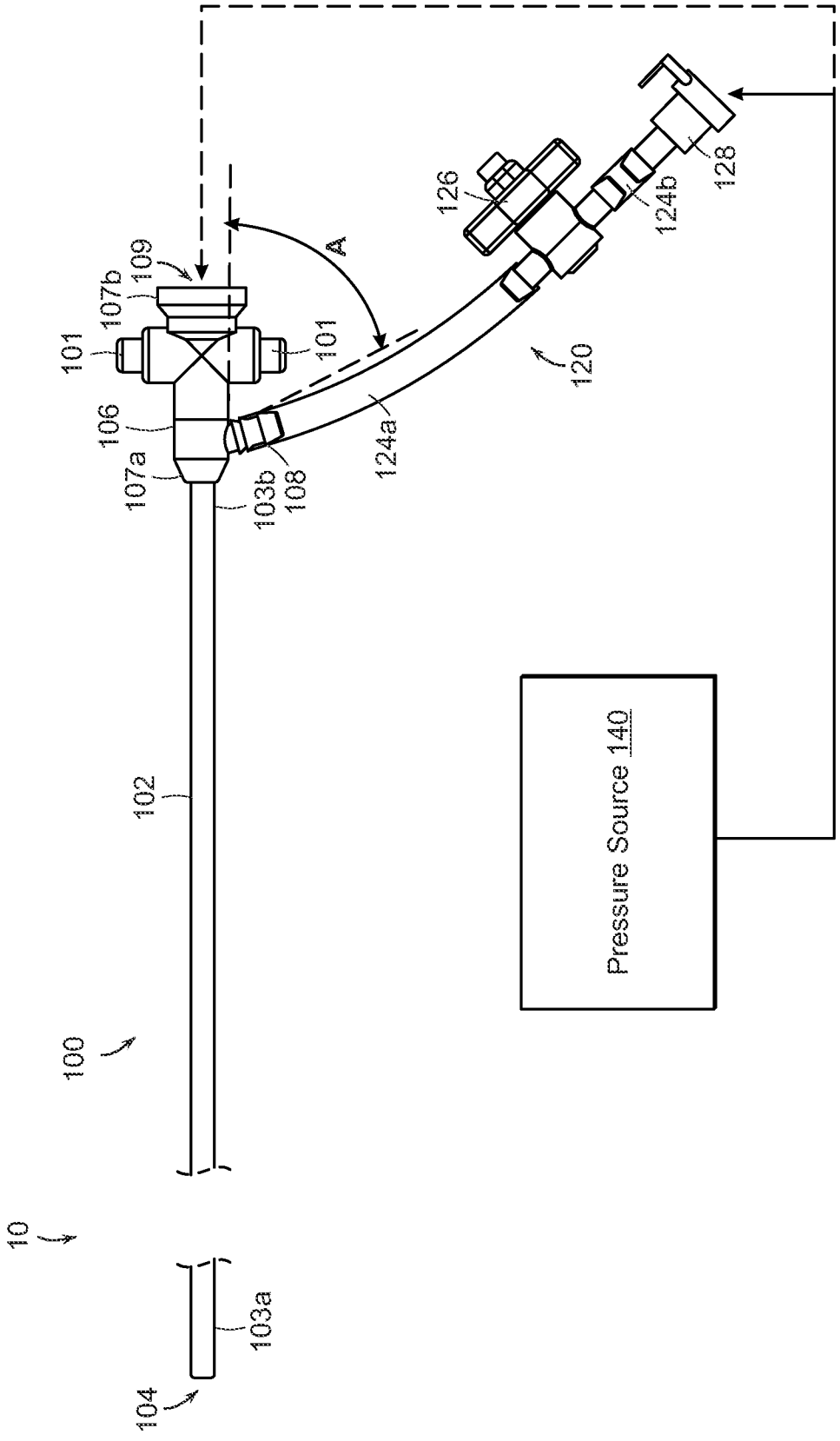

A
10
100
101
101
102
103a
103b
104
106
107a
107b
108
109
120
124a
124b
126
128
Pressure Source 140

FIG. 1

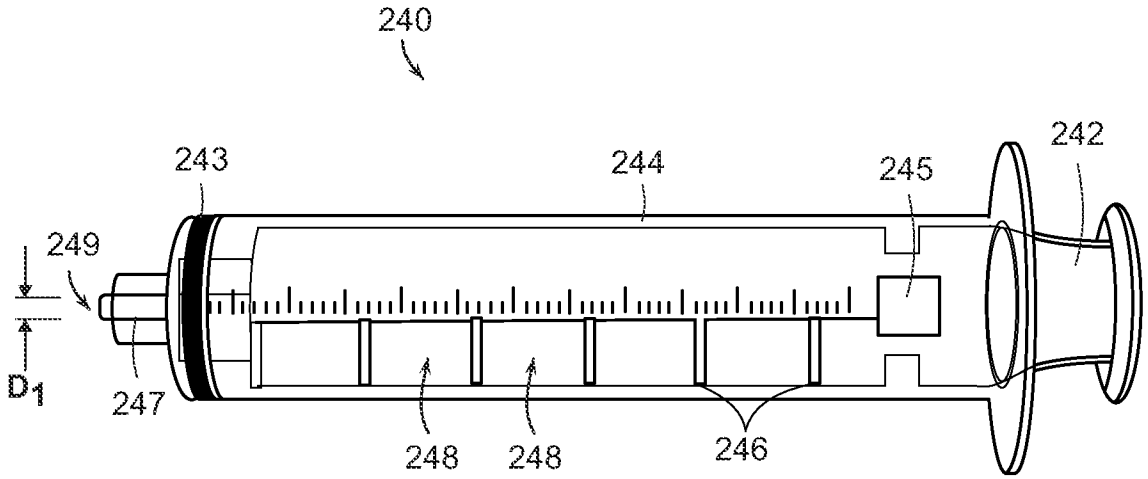

240
243
244
245
242
249
D_1
247
248
248
246

FIG. 2

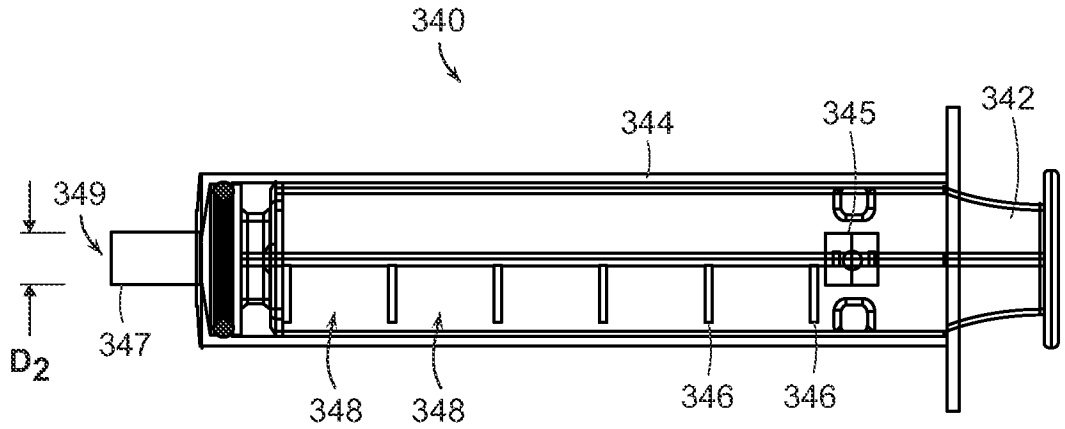

340
344
345
342
349
D_2
347
348
348
346
346

FIG. 3A

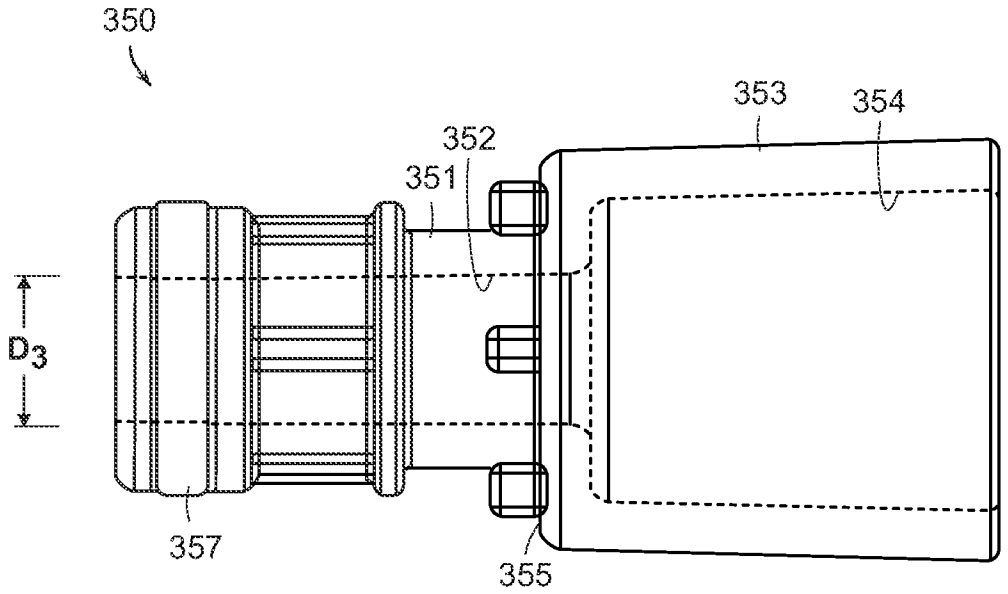


FIG. 3B

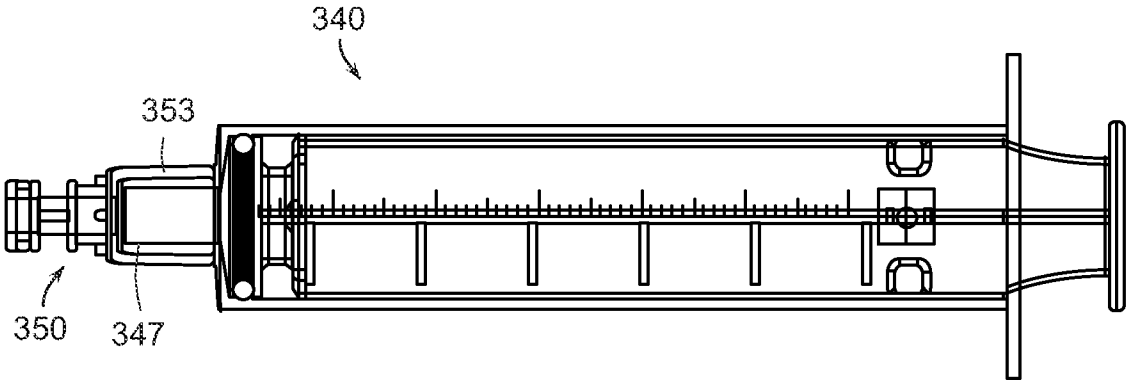


FIG. 3C

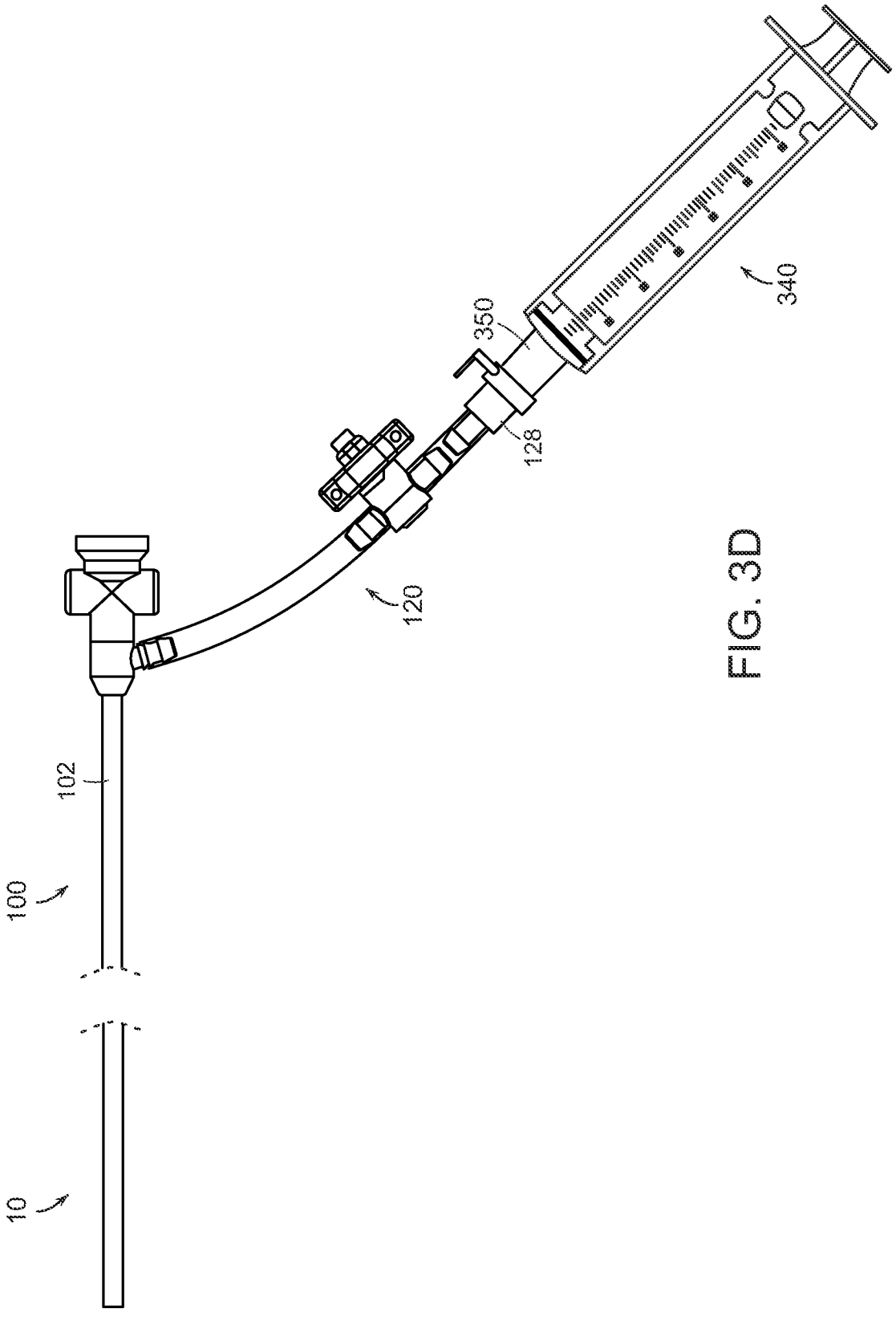
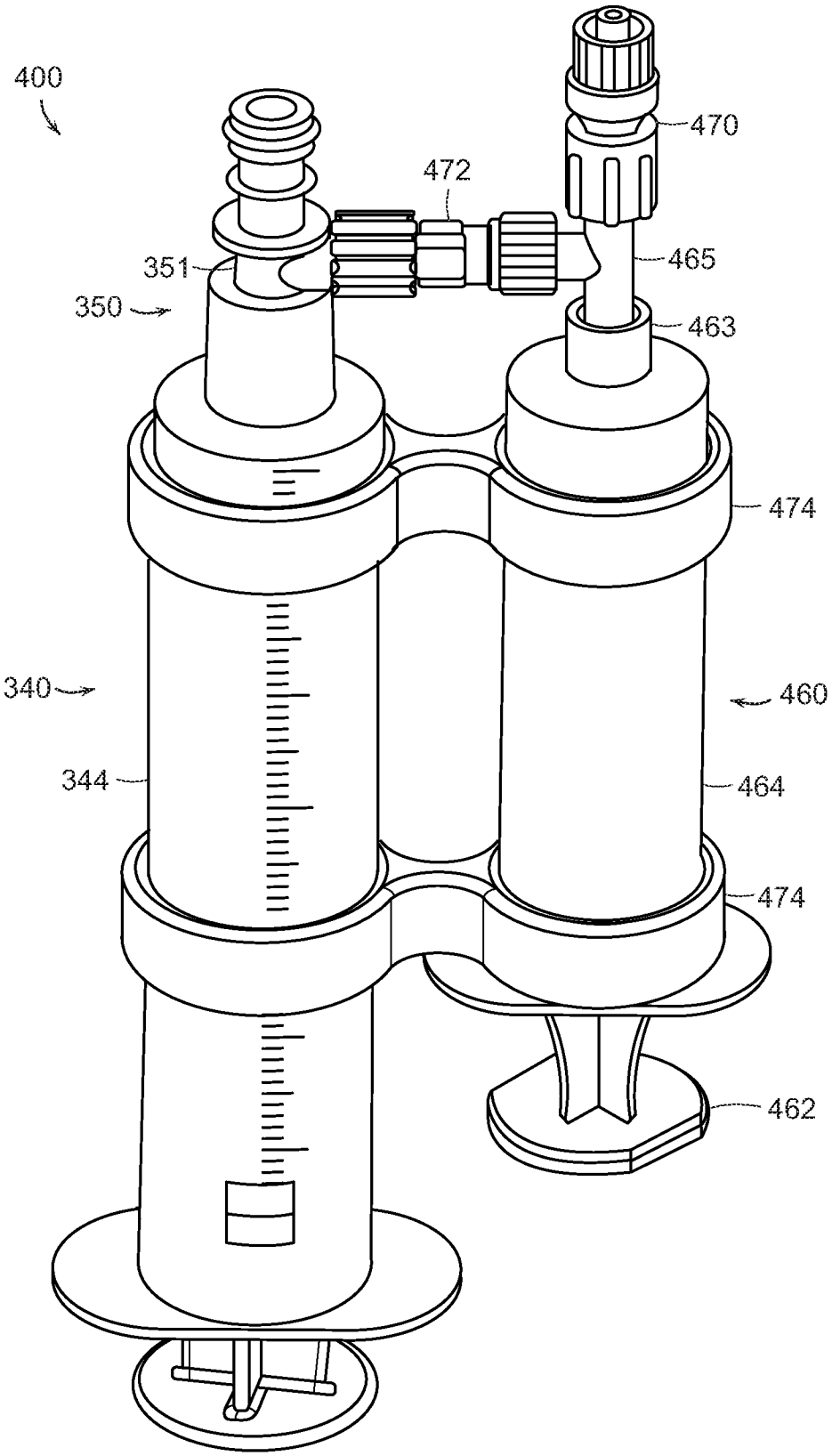


FIG. 3D

FIG. 4A



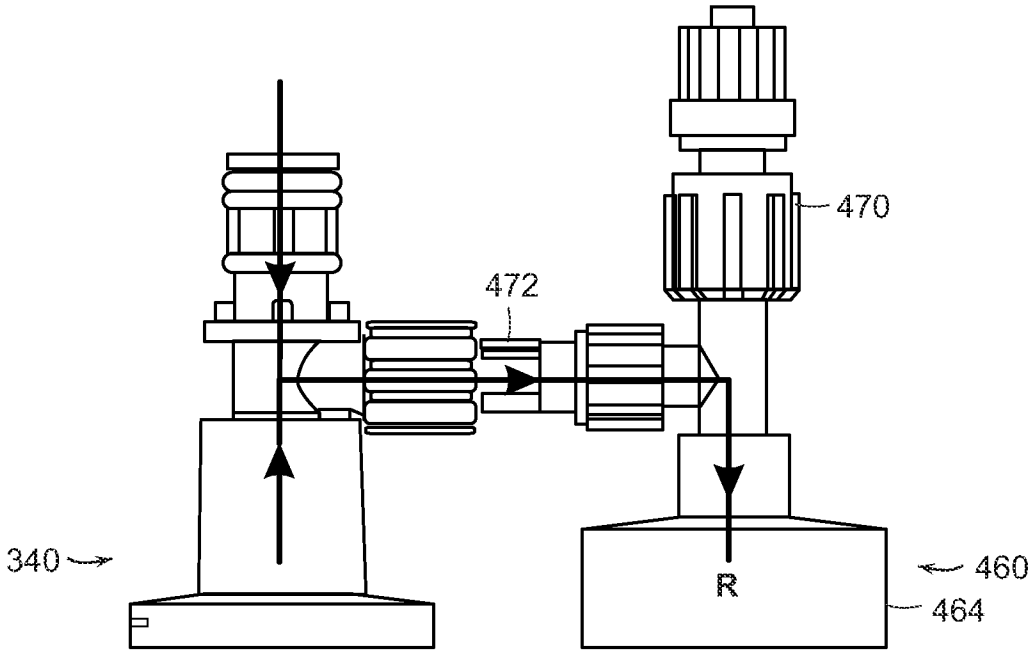


FIG. 4B

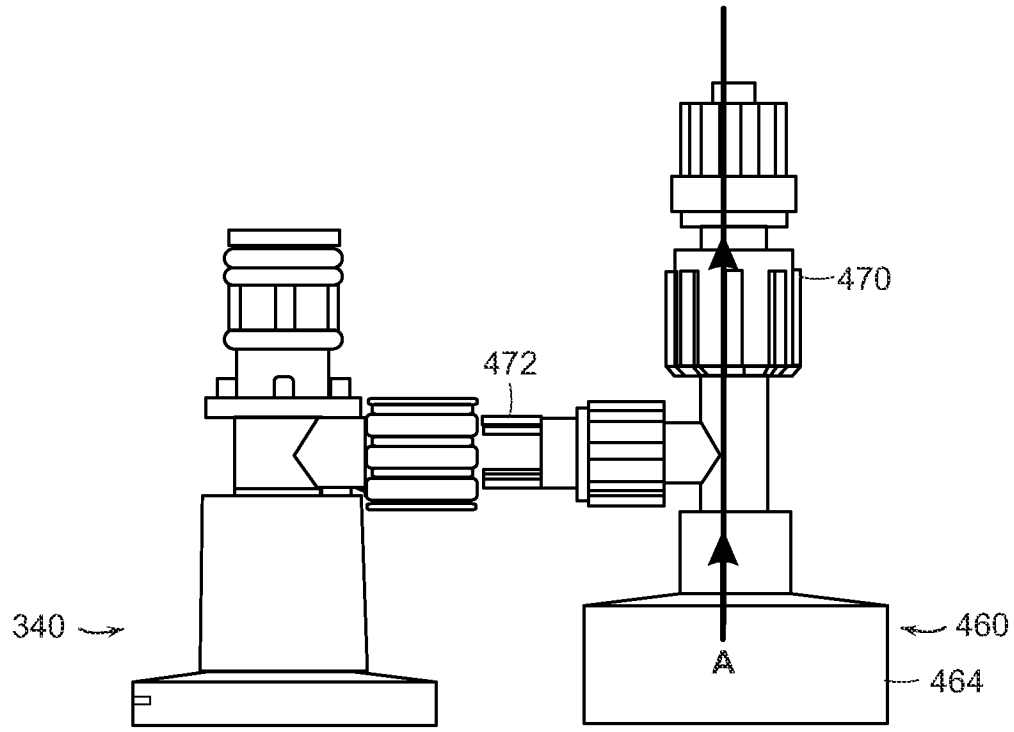


FIG. 4C

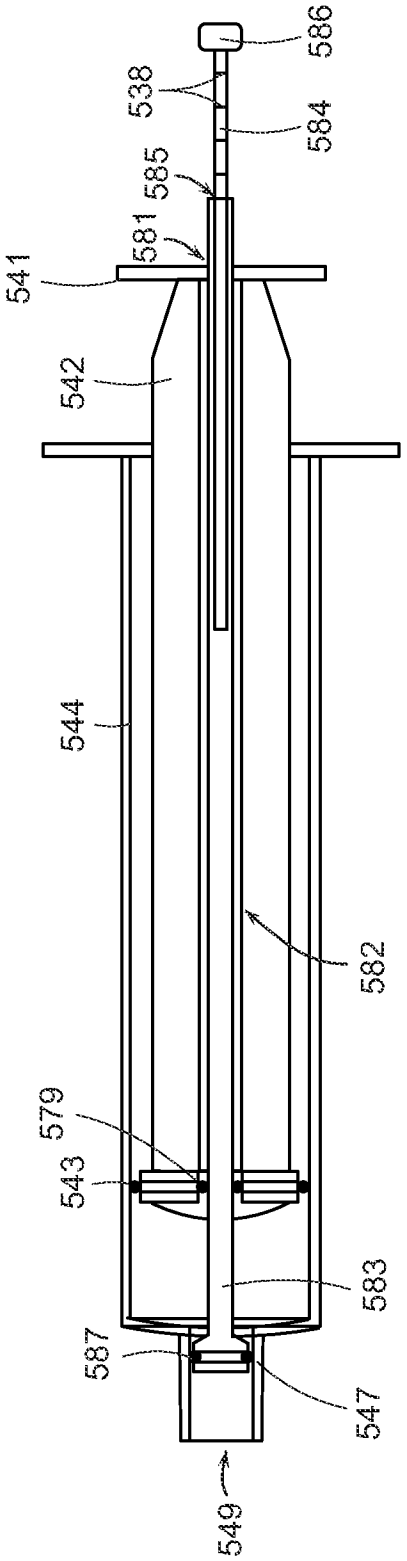


FIG. 5

FIG. 6

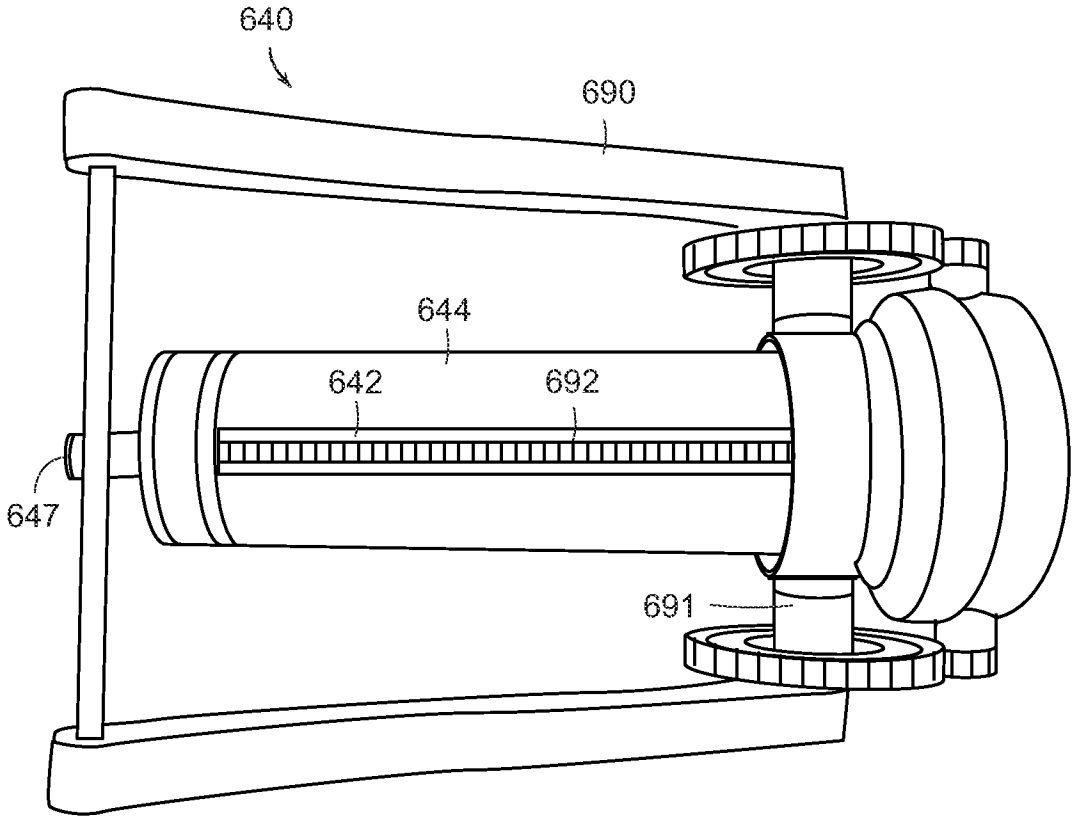
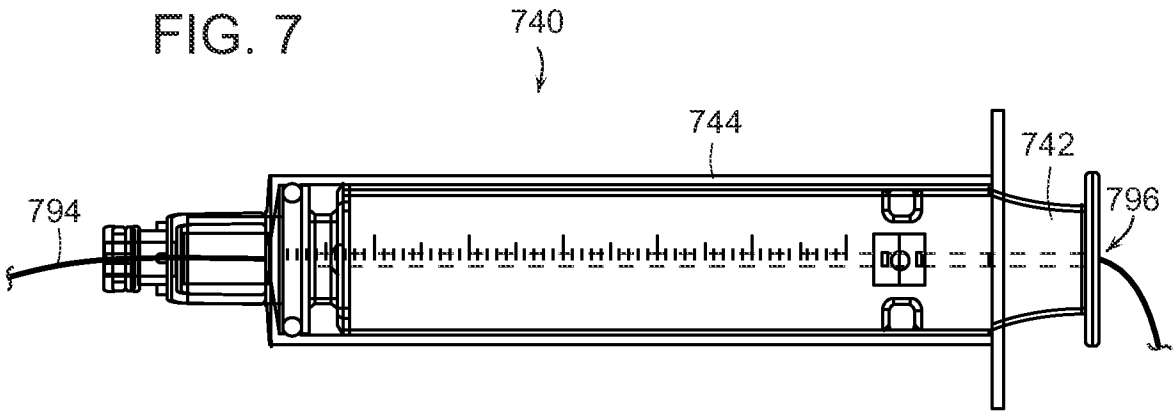


FIG. 7



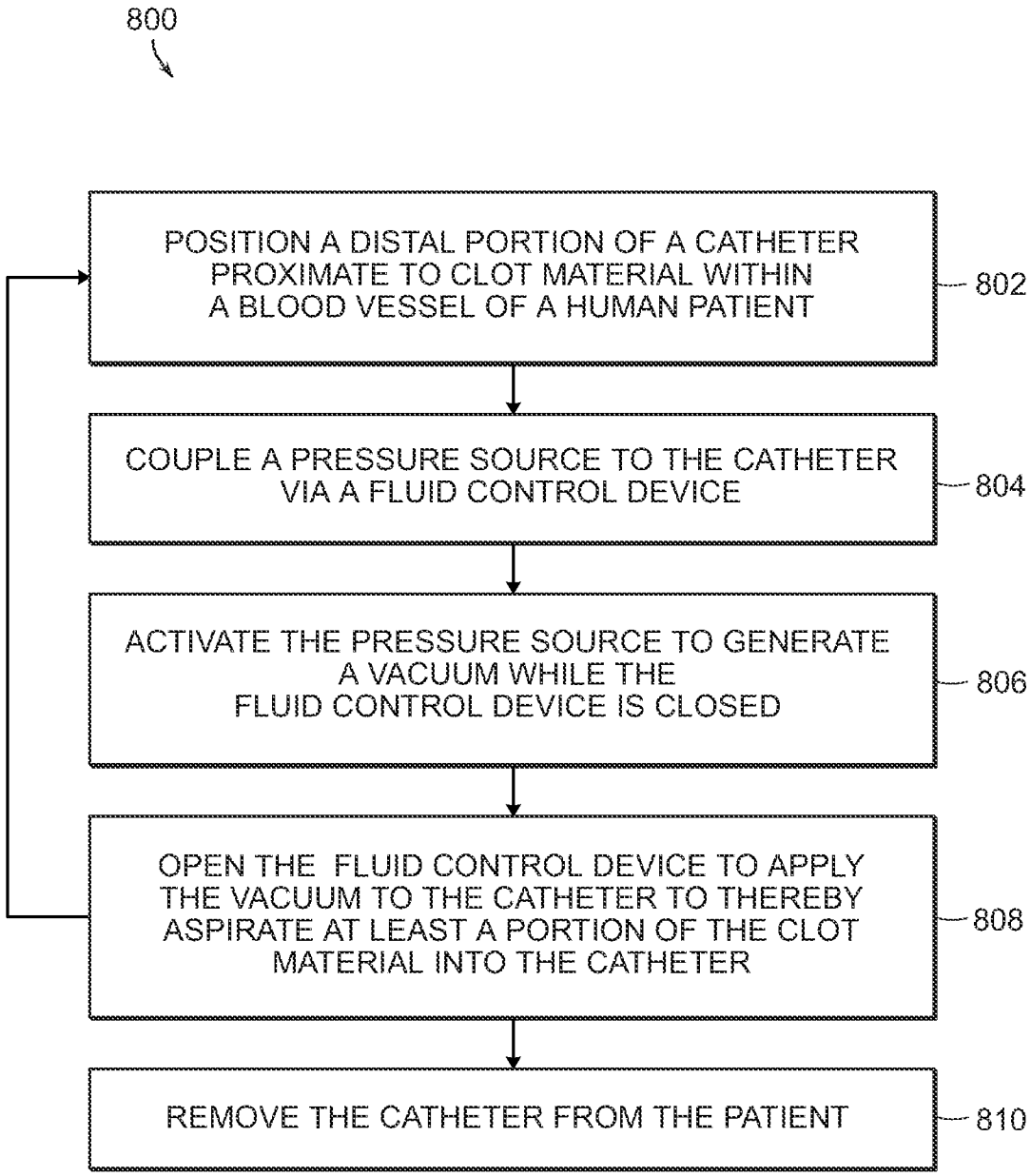

800
POSITION A DISTAL PORTION OF A CATHETER PROXIMATE TO CLOT MATERIAL WITHIN A BLOOD VESSEL OF A HUMAN PATIENT
802
COUPLE A PRESSURE SOURCE TO THE CATHETER VIA A FLUID CONTROL DEVICE
804
ACTIVATE THE PRESSURE SOURCE TO GENERATE A VACUUM WHILE THE FLUID CONTROL DEVICE IS CLOSED
806
OPEN THE FLUID CONTROL DEVICE TO APPLY THE VACUUM TO THE CATHETER TO THEREBY ASPIRATE AT LEAST A PORTION OF THE CLOT MATERIAL INTO THE CATHETER
808
REMOVE THE CATHETER FROM THE PATIENT
810

FIG. 8

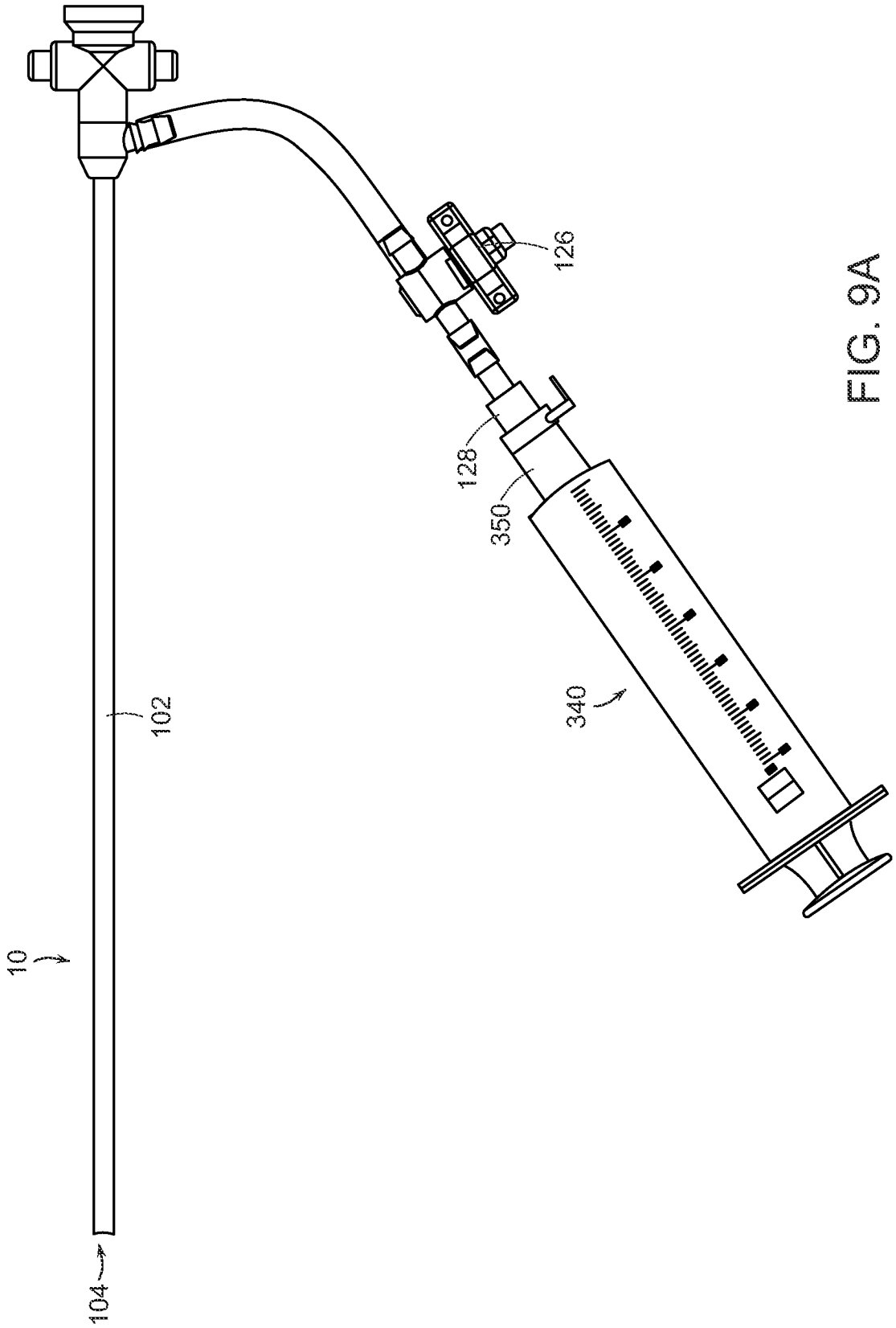


FIG. 9A

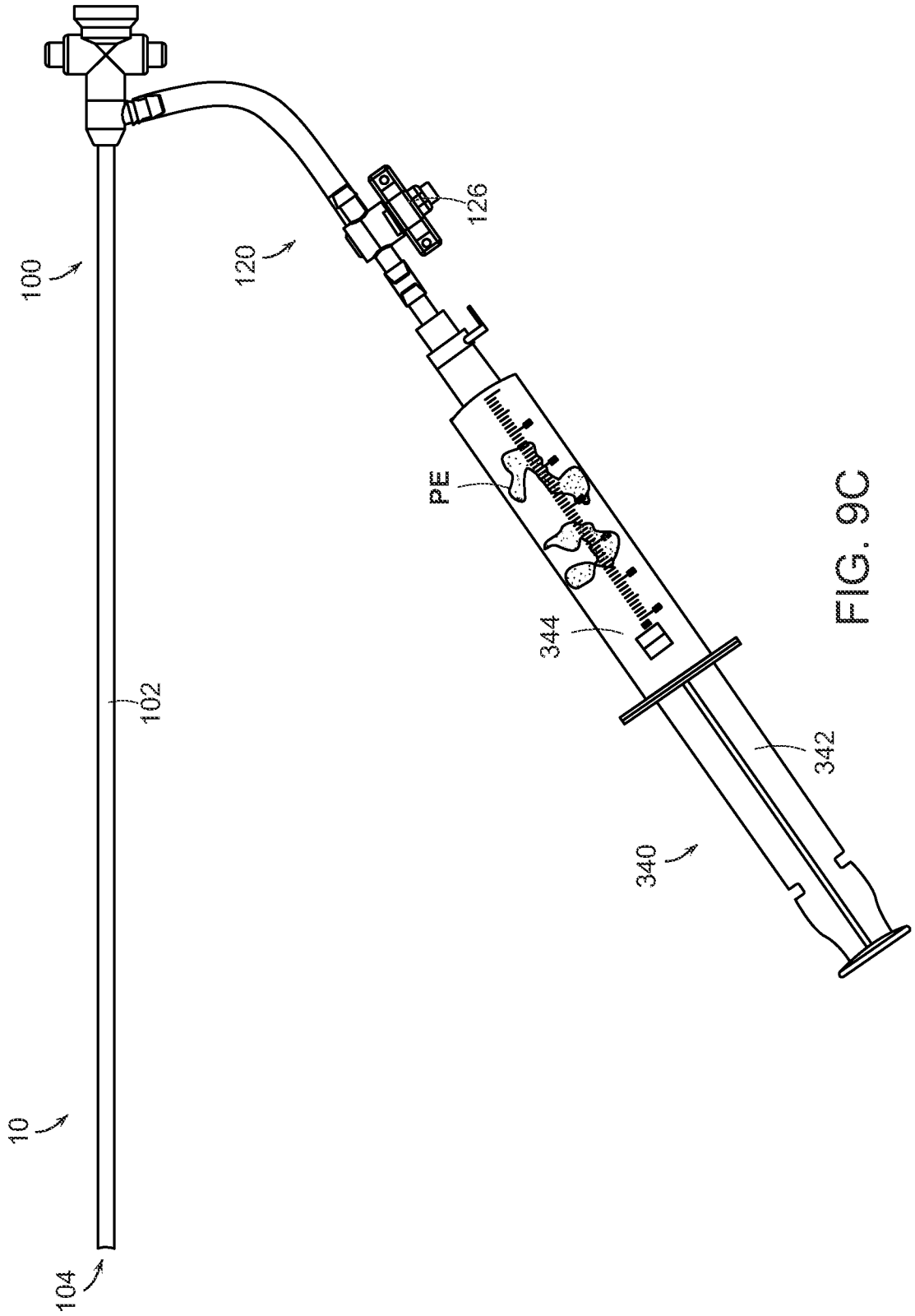


FIG. 9C

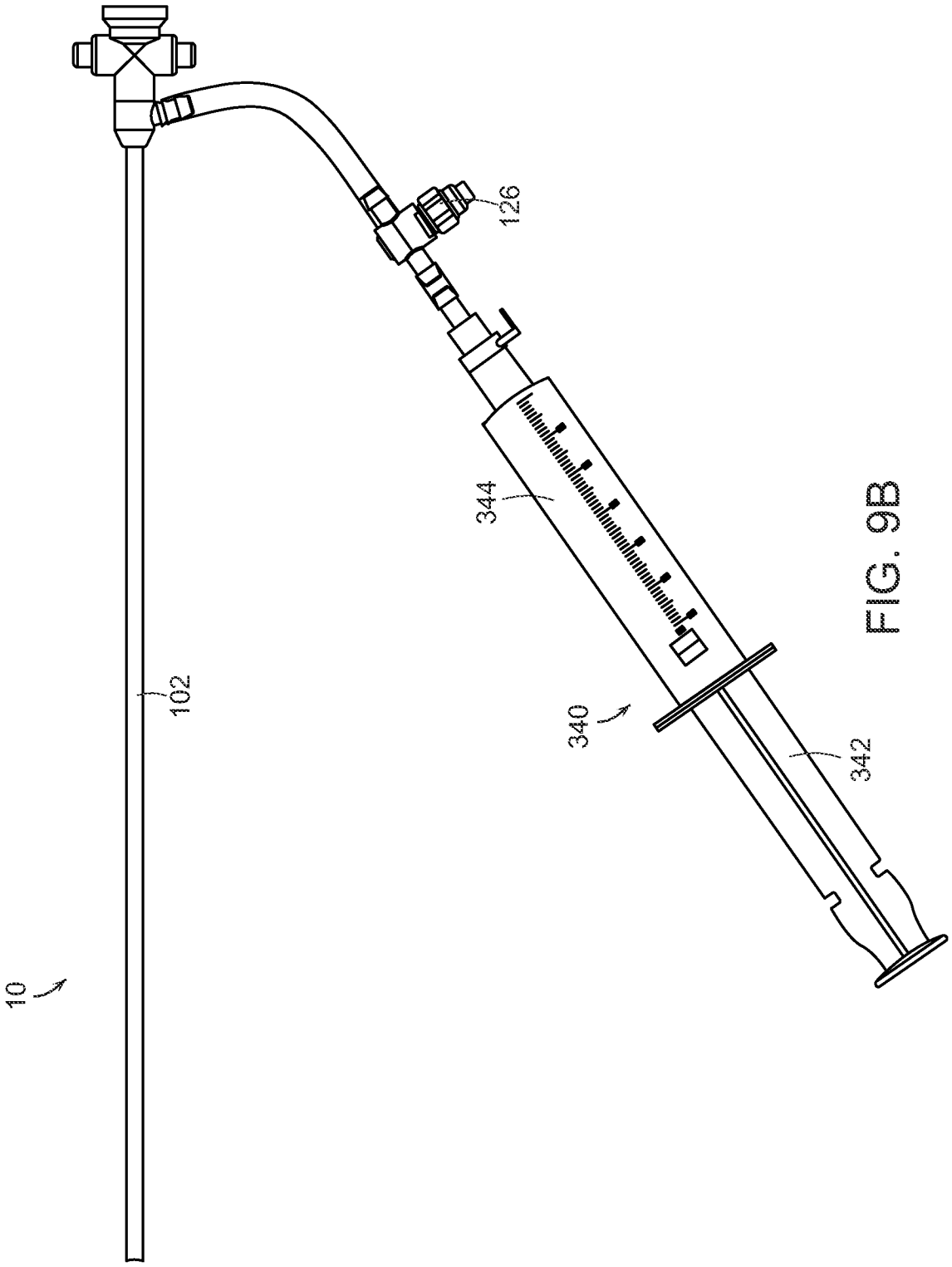


FIG. 9B

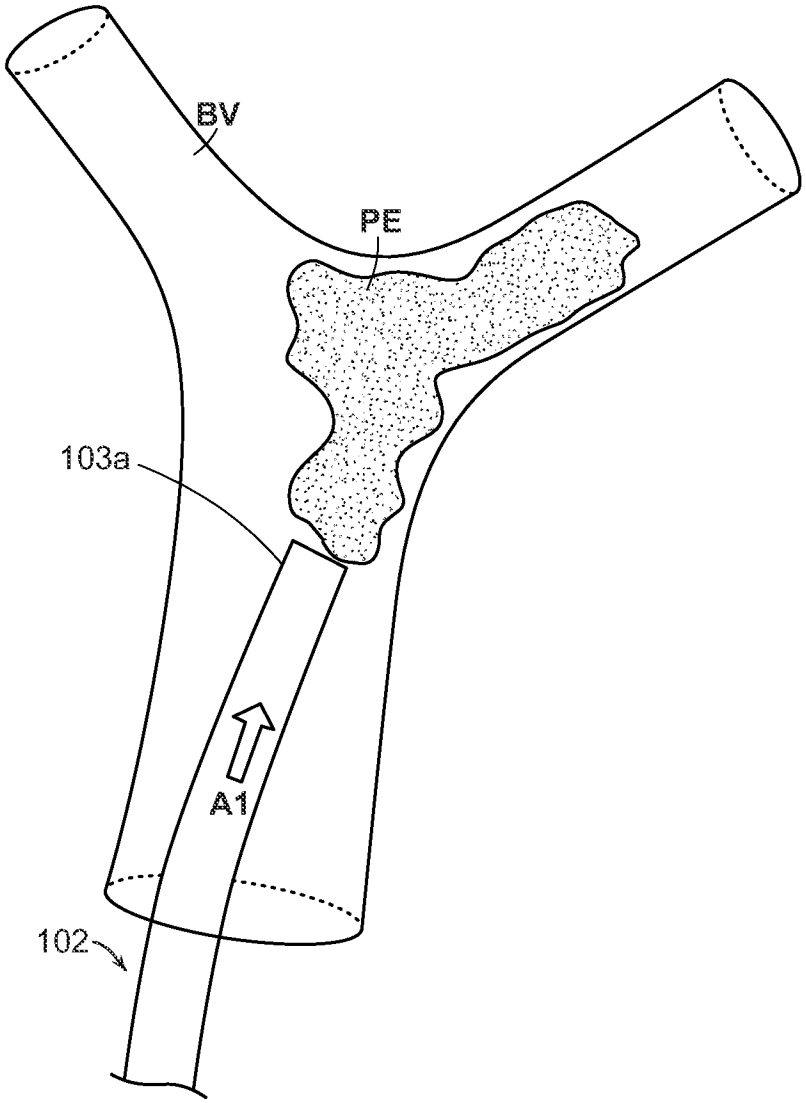


FIG. 10A

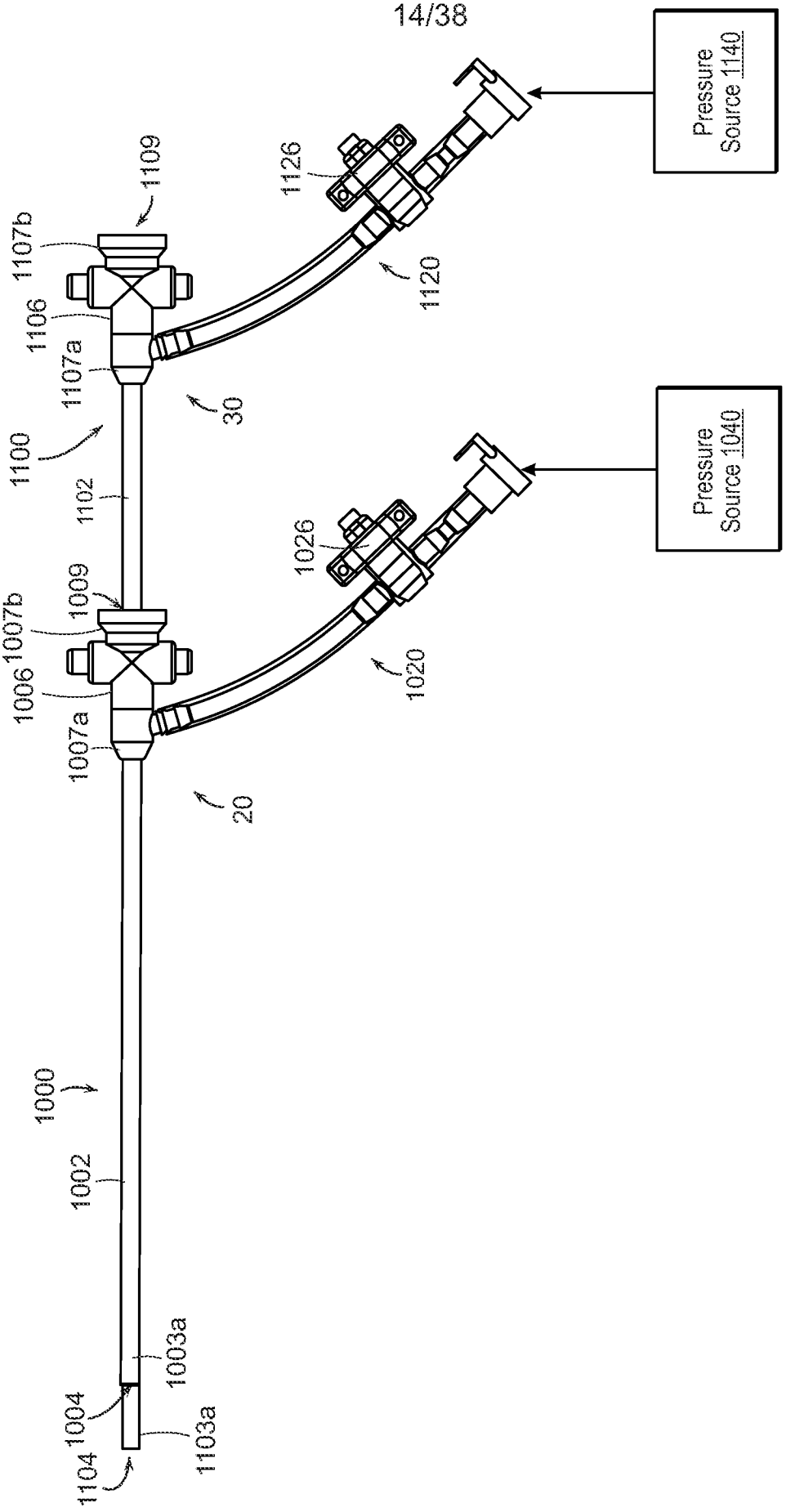

Pressure Source 1140
Pressure Source 1040
1109
1126
1107b
1106
1107a
1120
30
1100
1102
1026
1009
1007b
1006
1007a
1020
20
1000
1002
1003a
1004
1103a
1104

FIG. 11

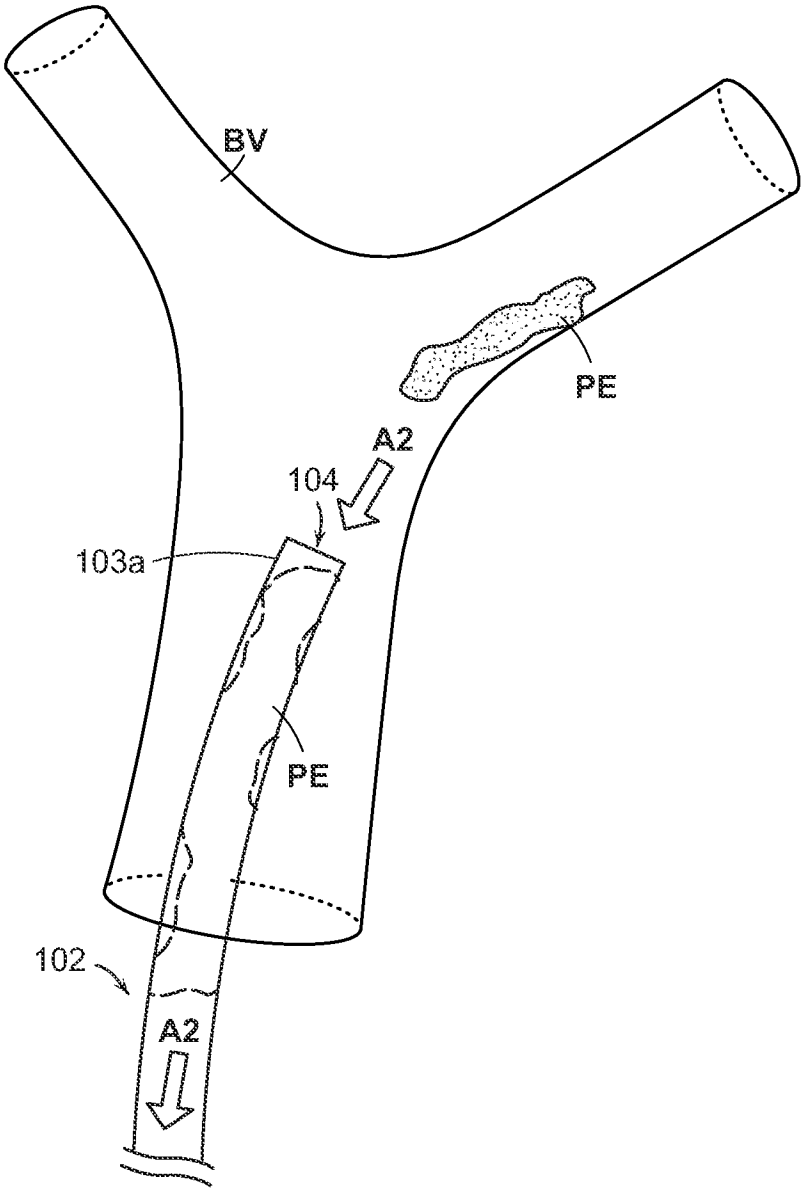


FIG. 10B

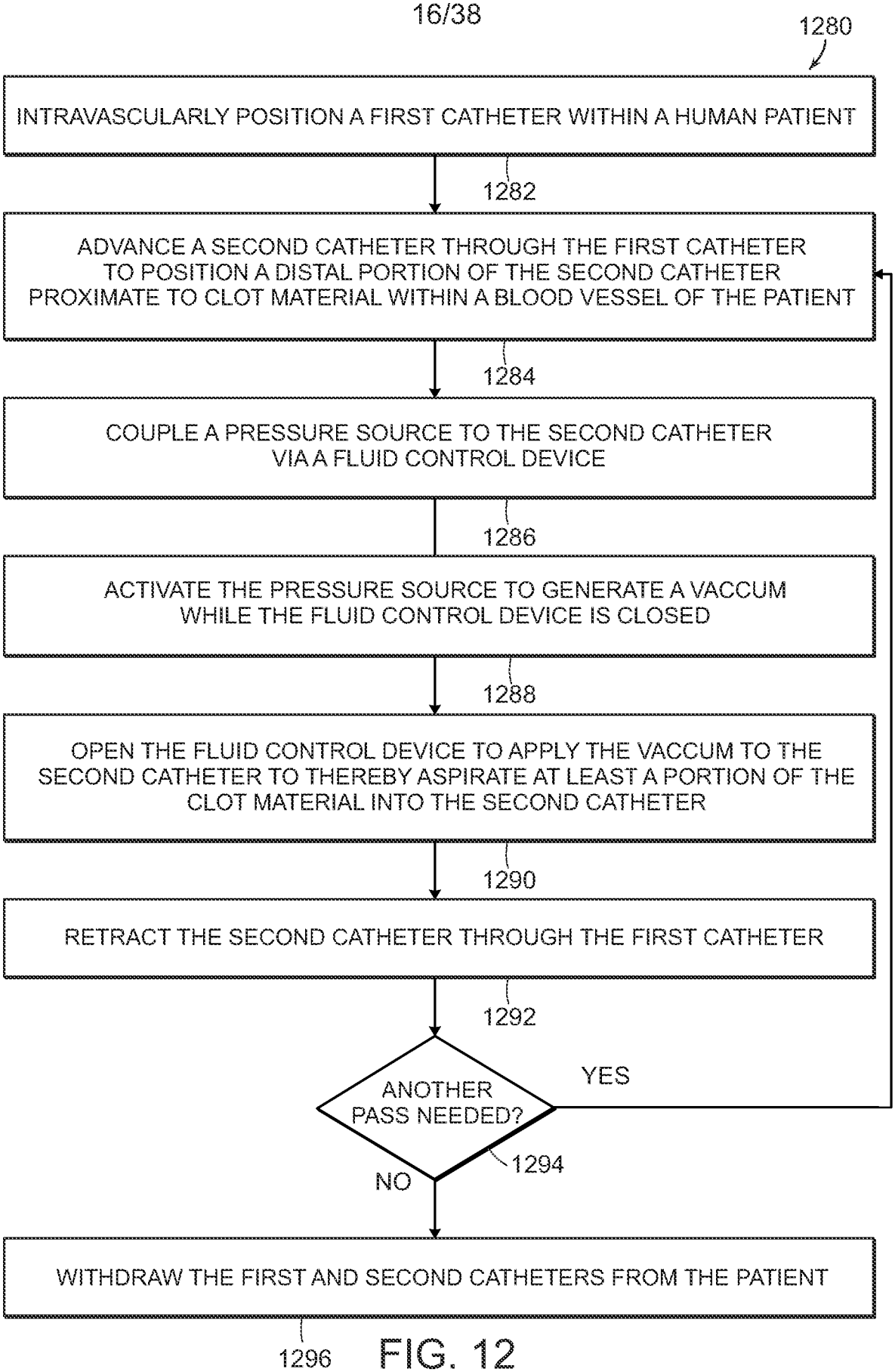

1280
INTRAVASCULARLY POSITION A FIRST CATHETER WITHIN A HUMAN PATIENT
1282
ADVANCE A SECOND CATHETER THROUGH THE FIRST CATHETER TO POSITION A DISTAL PORTION OF THE SECOND CATHETER PROXIMATE TO CLOT MATERIAL WITHIN A BLOOD VESSEL OF THE PATIENT
1284
COUPLE A PRESSURE SOURCE TO THE SECOND CATHETER VIA A FLUID CONTROL DEVICE
1286
ACTIVATE THE PRESSURE SOURCE TO GENERATE A VACCUM WHILE THE FLUID CONTROL DEVICE IS CLOSED
1288
OPEN THE FLUID CONTROL DEVICE TO APPLY THE VACCUM TO THE SECOND CATHETER TO THEREBY ASPIRATE AT LEAST A PORTION OF THE CLOT MATERIAL INTO THE SECOND CATHETER
1290
RETRACT THE SECOND CATHETER THROUGH THE FIRST CATHETER
1292
ANOTHER PASS NEEDED?
YES
1294
NO
WITHDRAW THE FIRST AND SECOND CATHETERS FROM THE PATIENT
1296

FIG. 12

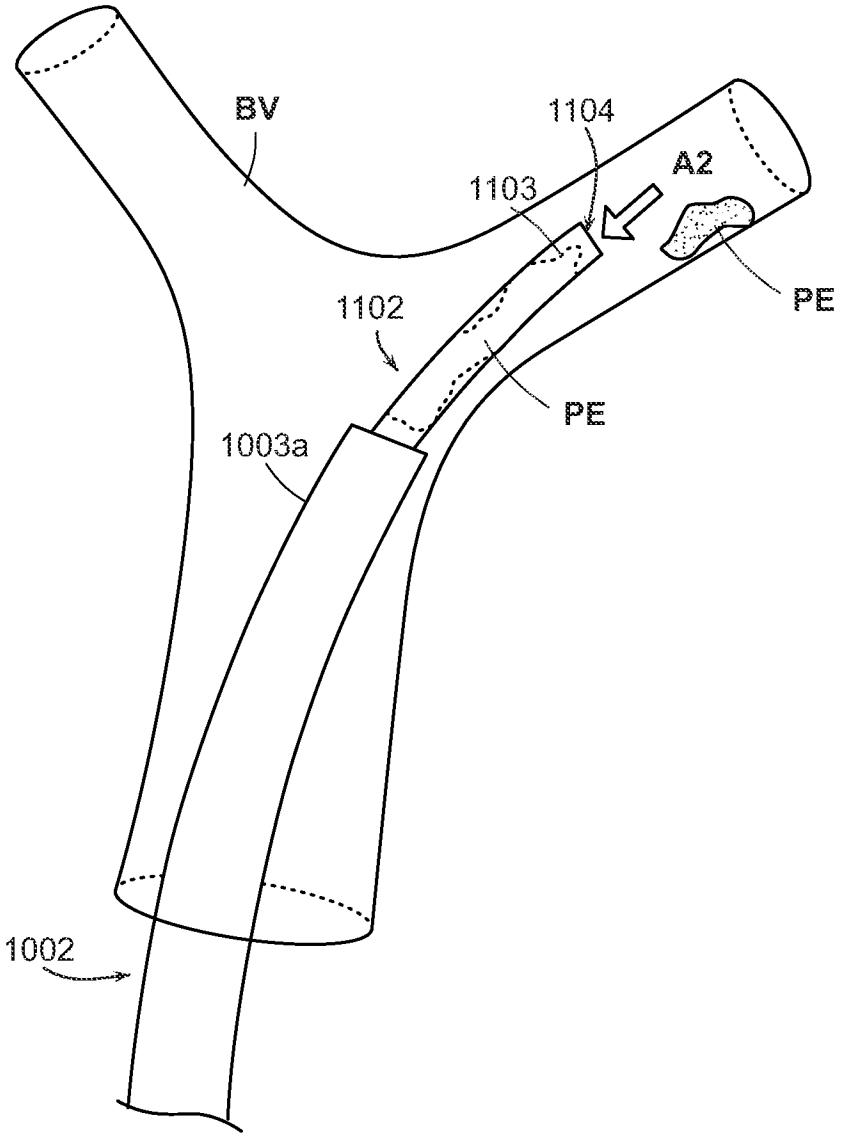


FIG. 13B

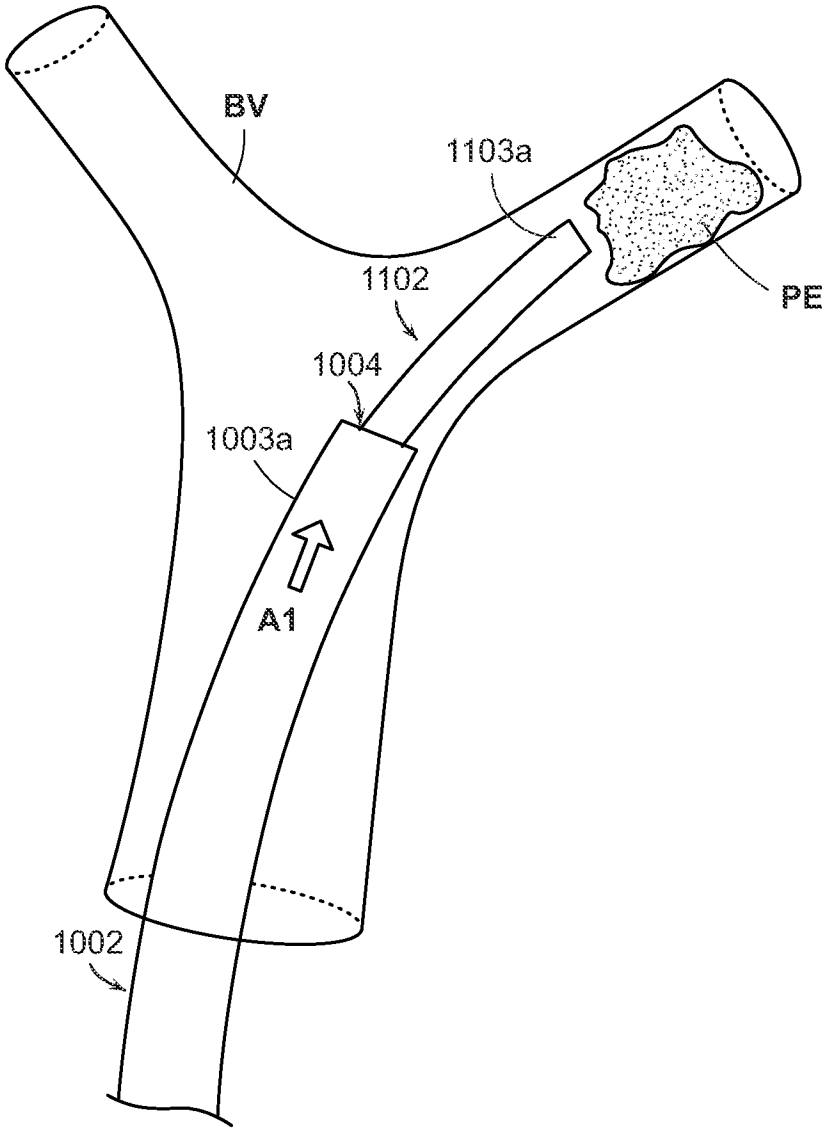


FIG. 13A

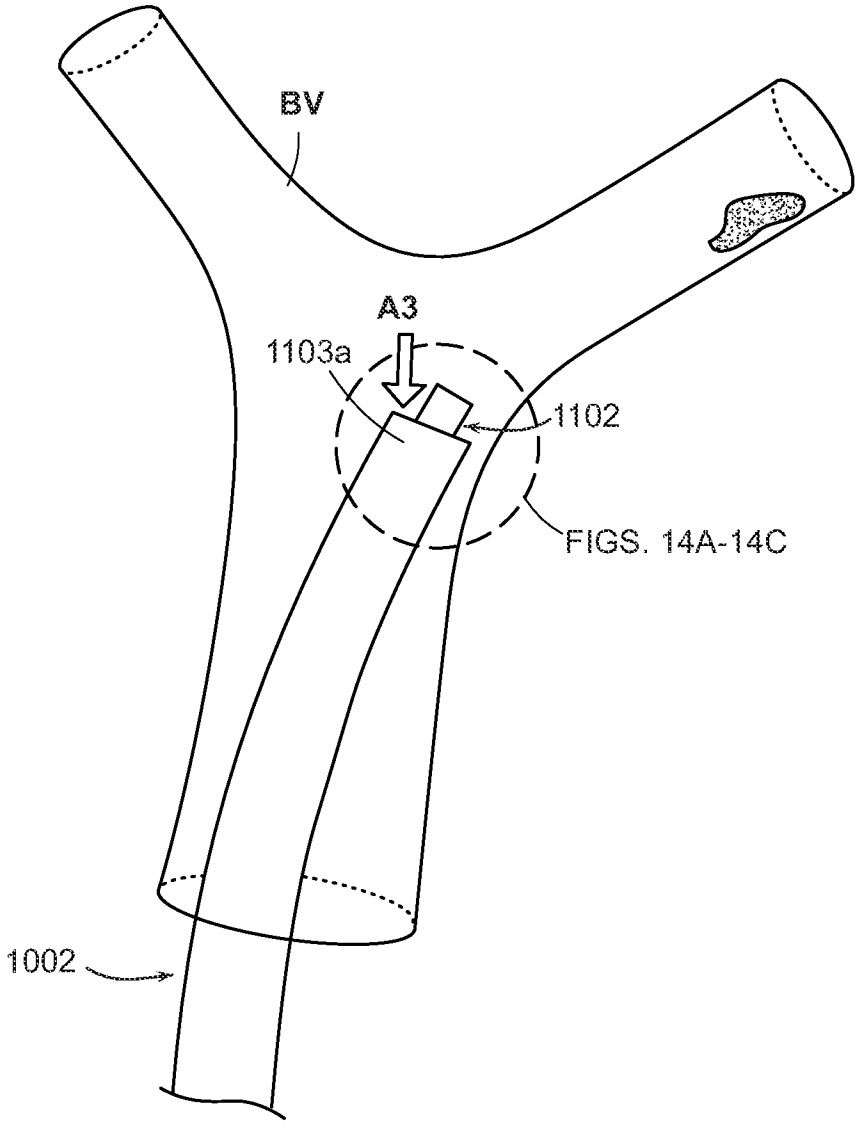


FIG. 13C

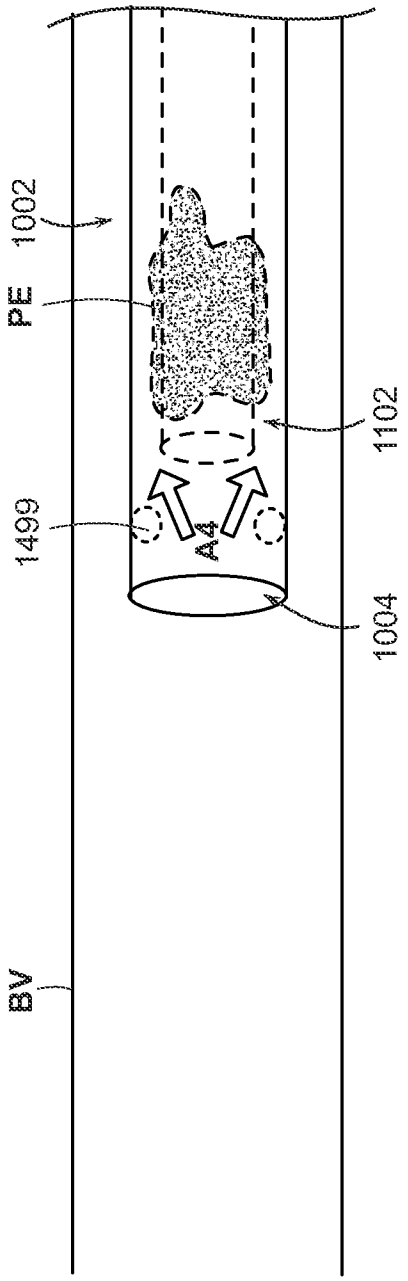


FIG. 14C

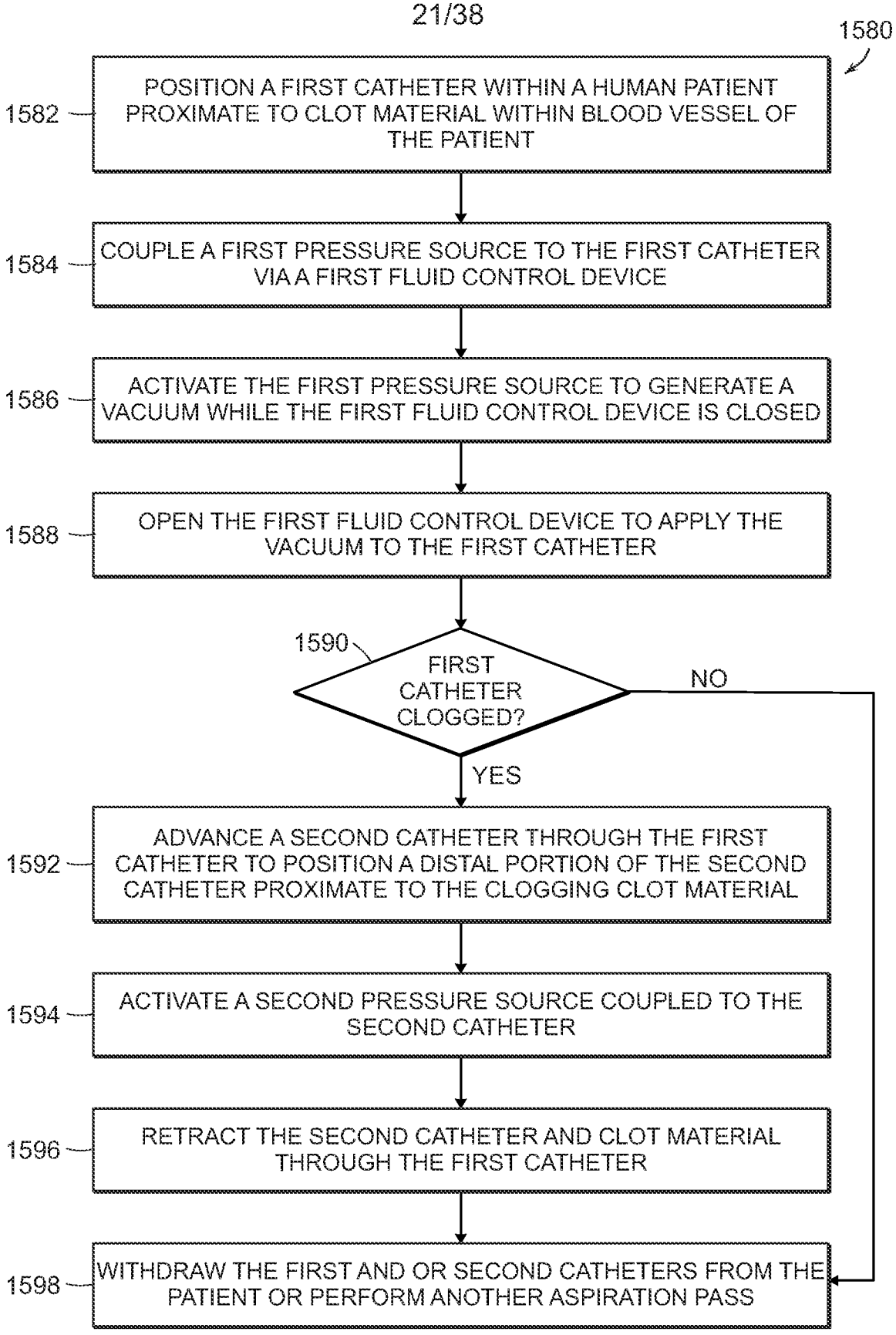

1580
1582
POSITION A FIRST CATHETER WITHIN A HUMAN PATIENT PROXIMATE TO CLOT MATERIAL WITHIN BLOOD VESSEL OF THE PATIENT
1584
COUPLE A FIRST PRESSURE SOURCE TO THE FIRST CATHETER VIA A FIRST FLUID CONTROL DEVICE
1586
ACTIVATE THE FIRST PRESSURE SOURCE TO GENERATE A VACUUM WHILE THE FIRST FLUID CONTROL DEVICE IS CLOSED
1588
OPEN THE FIRST FLUID CONTROL DEVICE TO APPLY THE VACUUM TO THE FIRST CATHETER
1590
FIRST CATHETER CLOGGED?
NO
YES
1592
ADVANCE A SECOND CATHETER THROUGH THE FIRST CATHETER TO POSITION A DISTAL PORTION OF THE SECOND CATHETER PROXIMATE TO THE CLOGGING CLOT MATERIAL
1594
ACTIVATE A SECOND PRESSURE SOURCE COUPLED TO THE SECOND CATHETER
1596
RETRACT THE SECOND CATHETER AND CLOT MATERIAL THROUGH THE FIRST CATHETER
1598
WITHDRAW THE FIRST AND OR SECOND CATHETERS FROM THE PATIENT OR PERFORM ANOTHER ASPIRATION PASS

FIG. 15

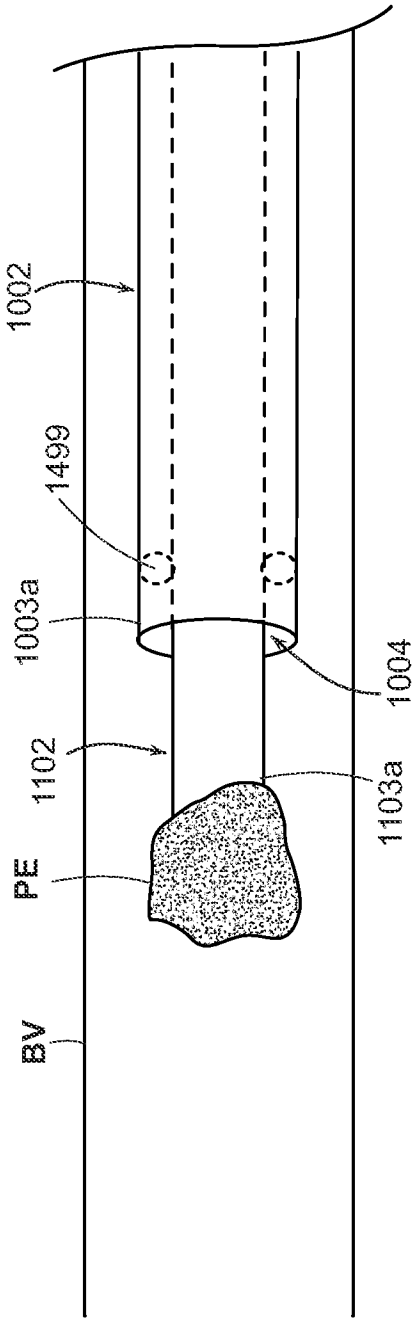


FIG. 14A

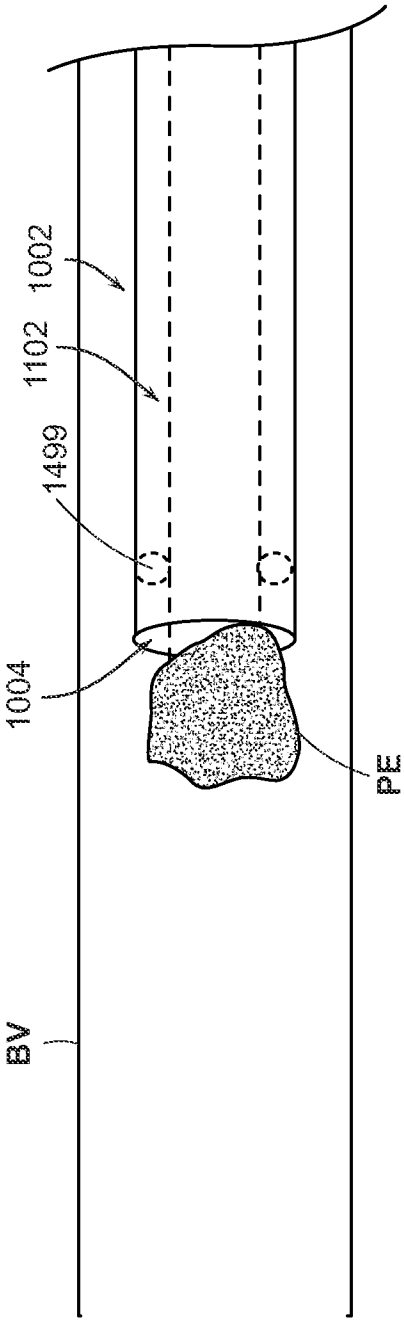


FIG. 14B

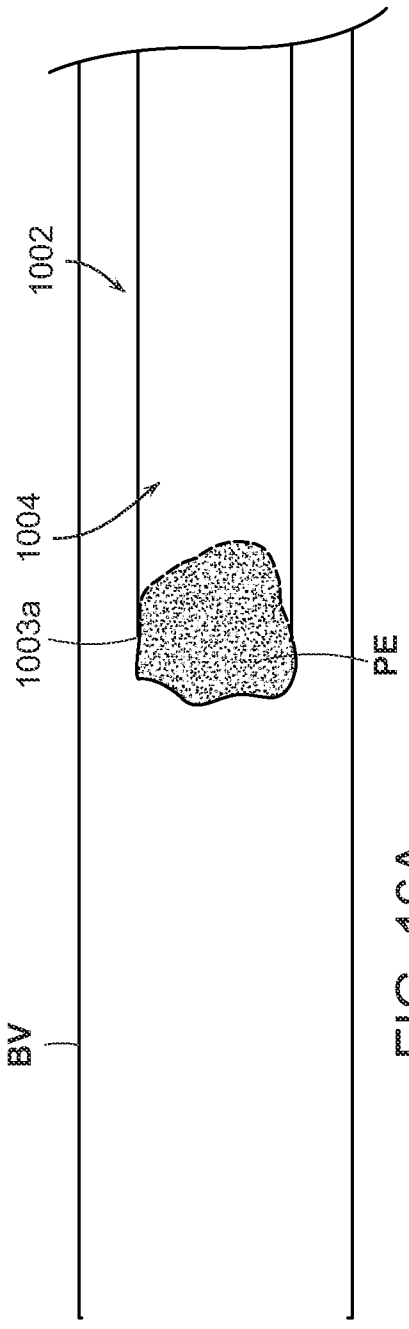


FIG. 16A

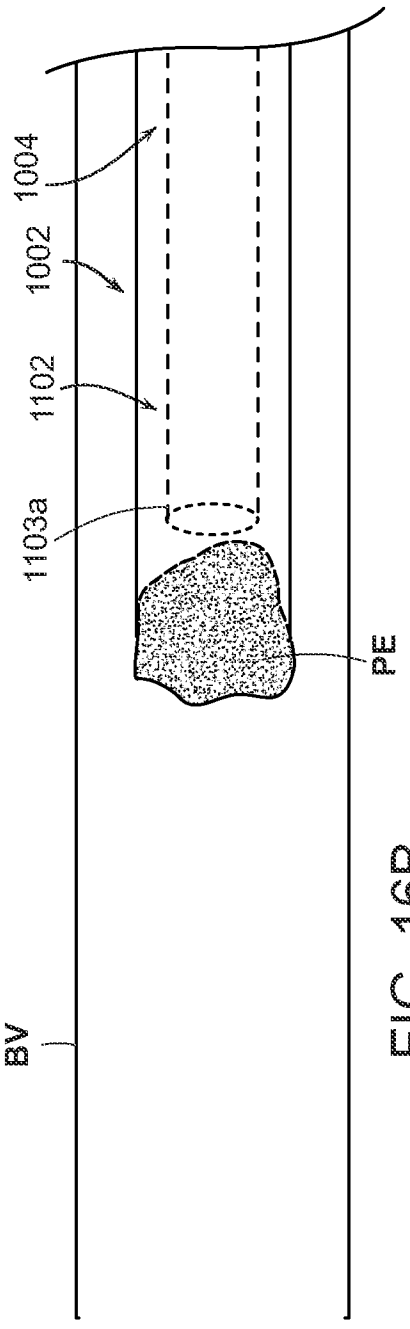


FIG. 16B

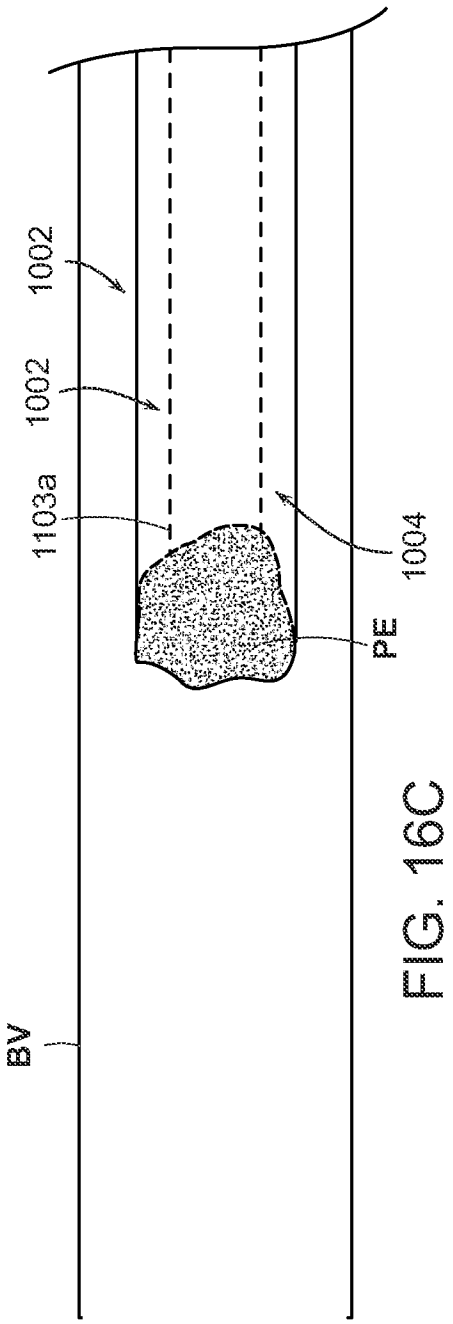


FIG. 16C

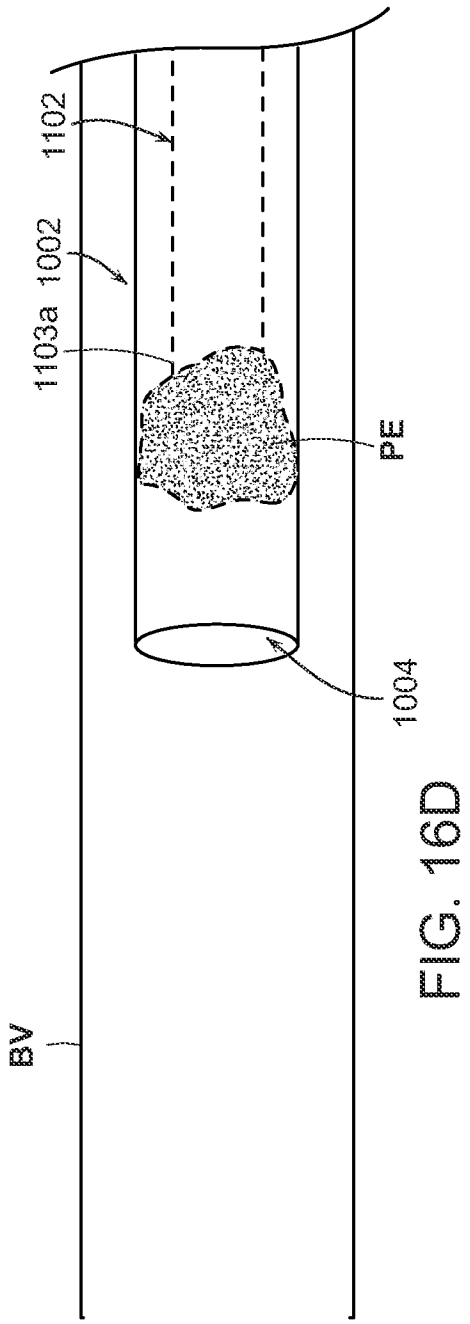


FIG. 16D

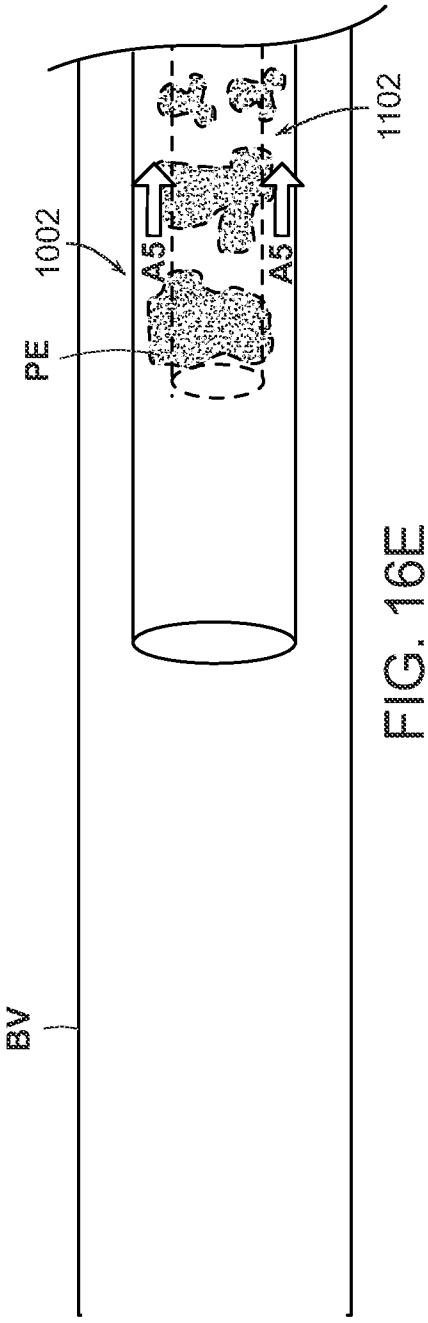


FIG. 16E

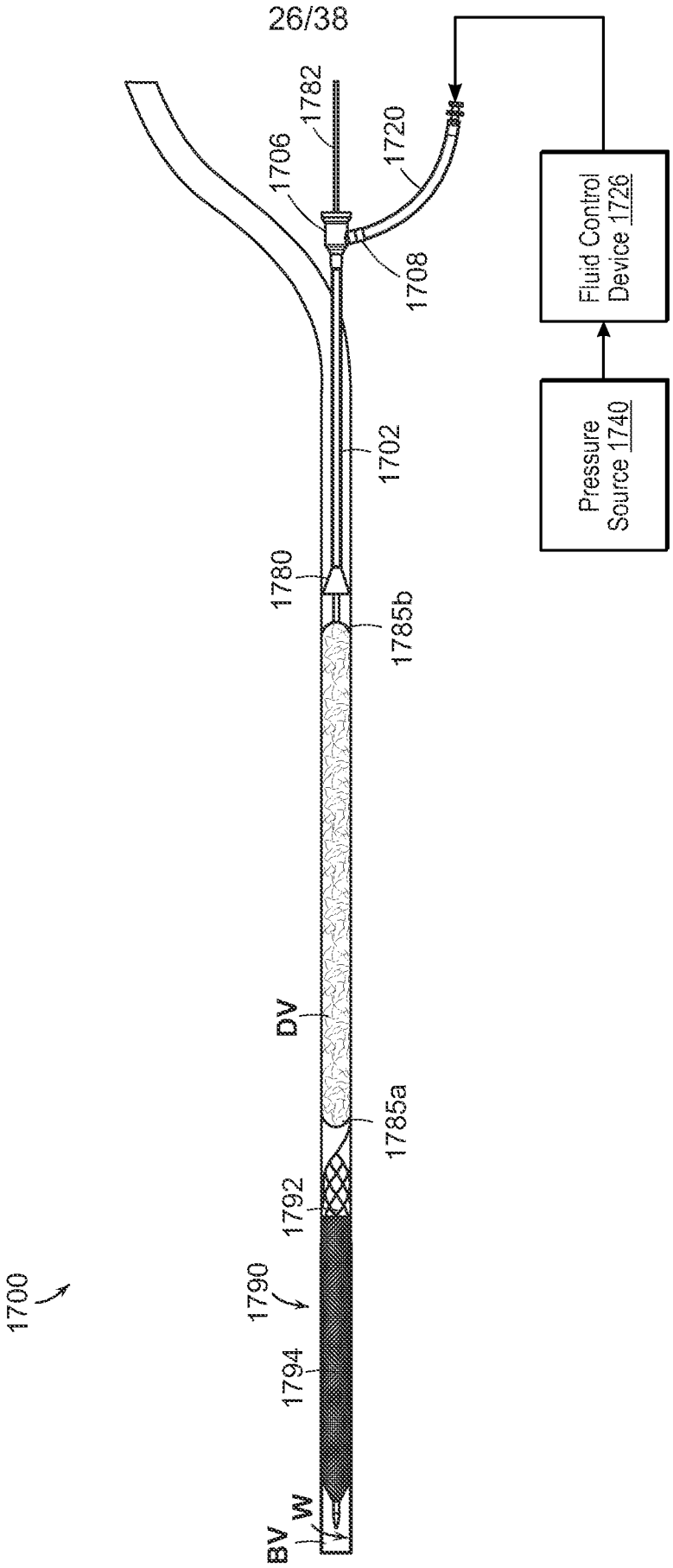

1700
1782
1706
1720
1708
1702
1780
1785b
DV
1785a
1792
1790
1794
BV
W
Fluid Control Device 1726
Pressure Source 1740

FIG. 17

FIG. 18A

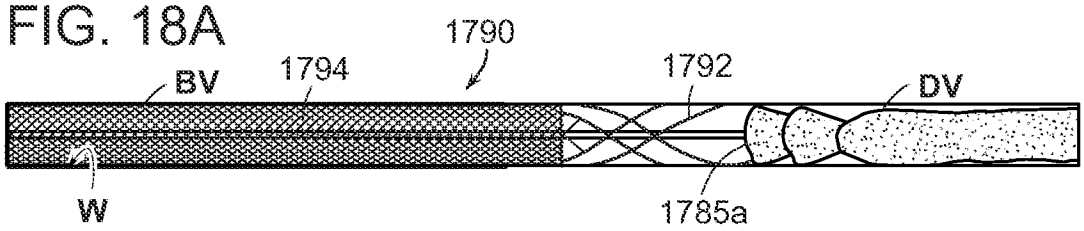


FIG. 18B

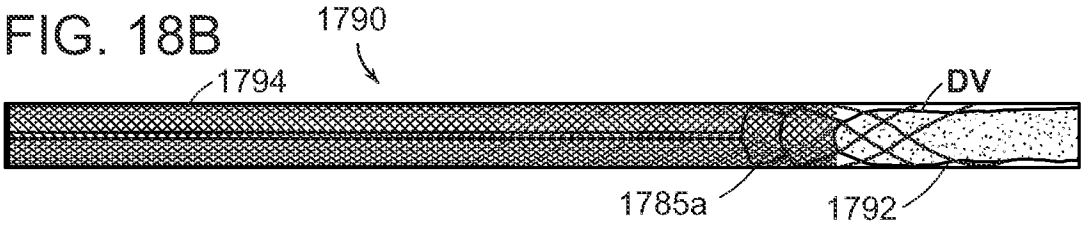


FIG. 18C

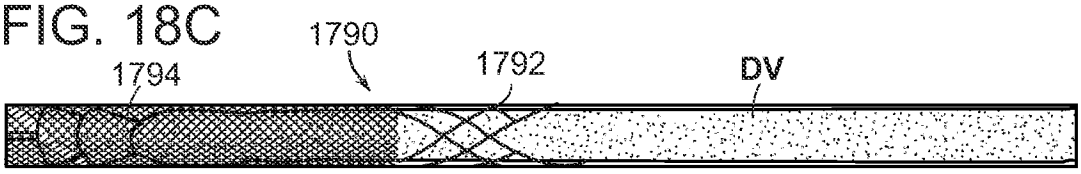


FIG. 18D

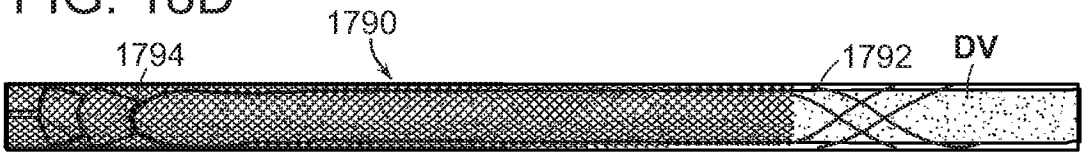


FIG. 18E

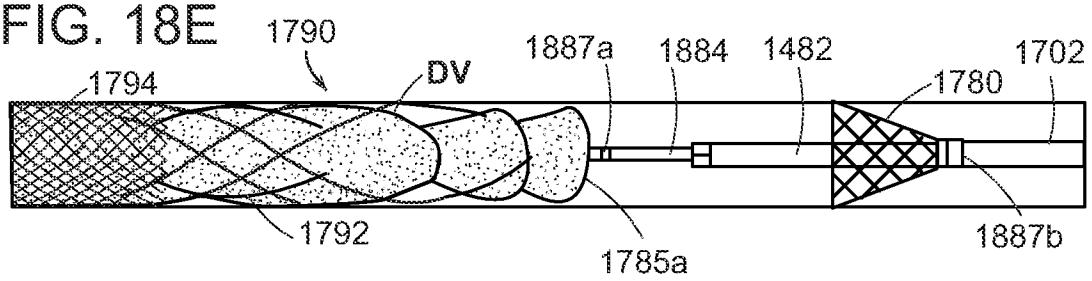


FIG. 18F

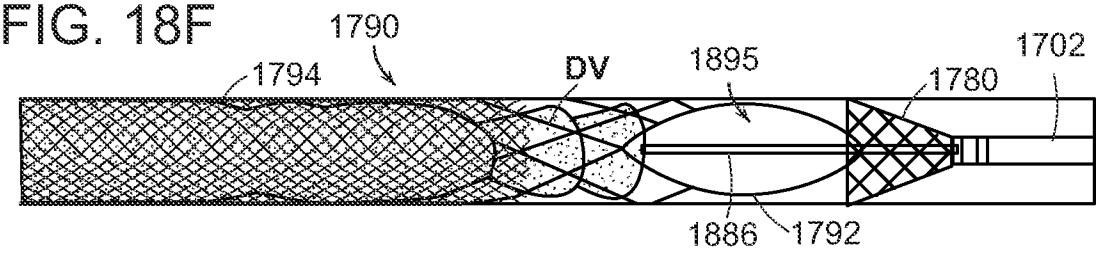


FIG. 18G

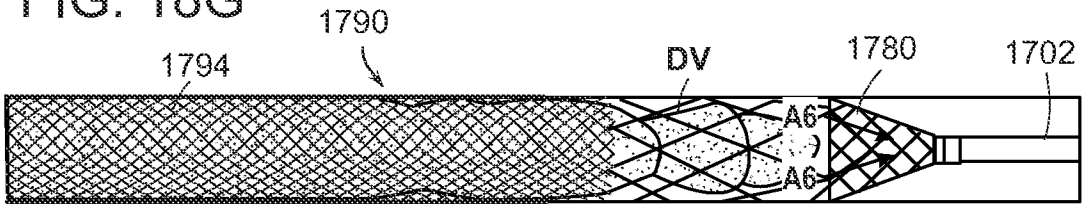
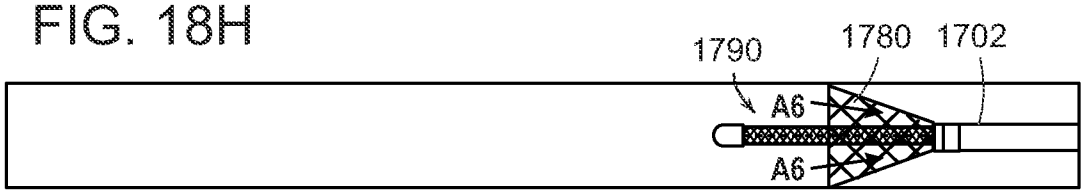


FIG. 18H



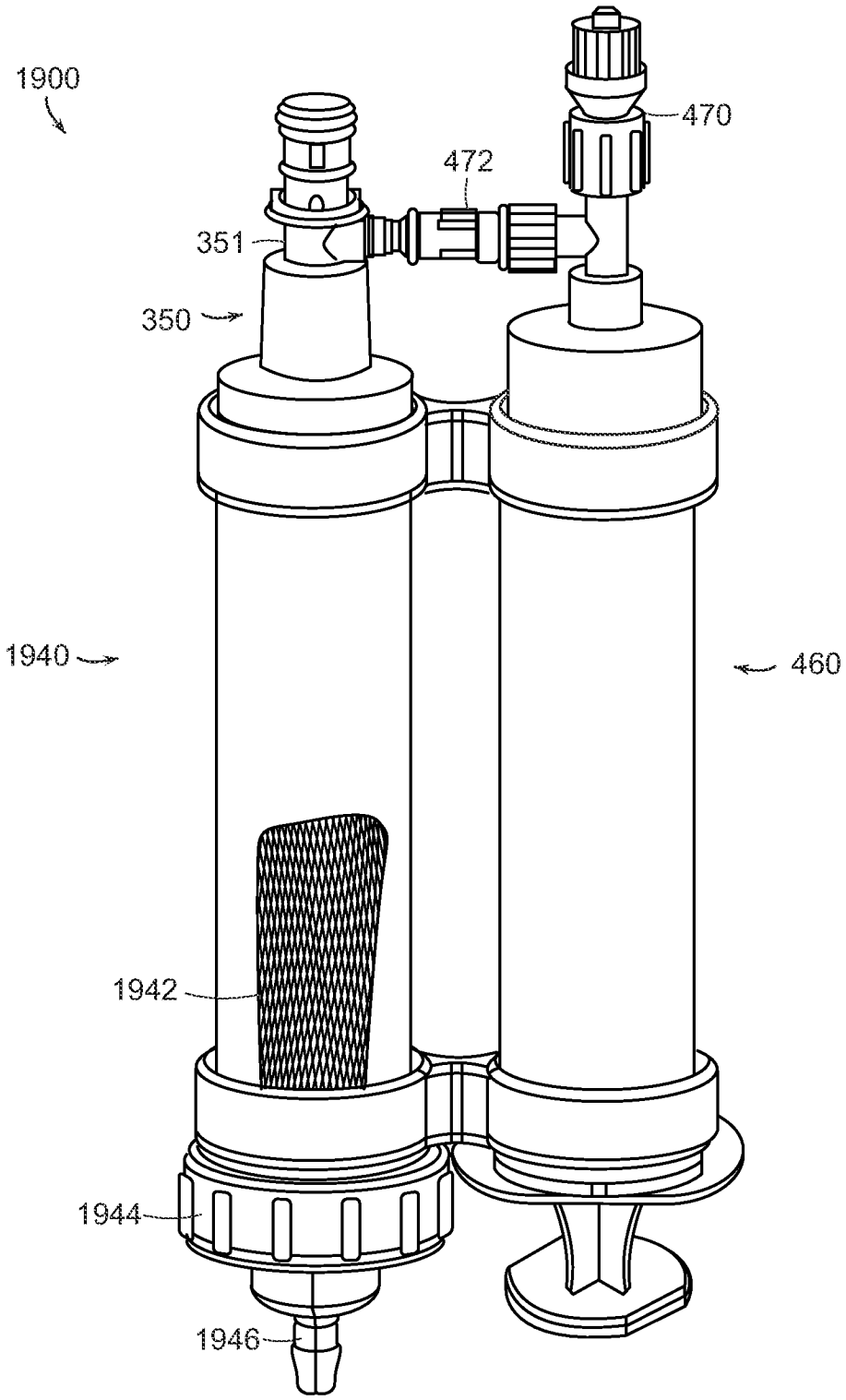


FIG. 19

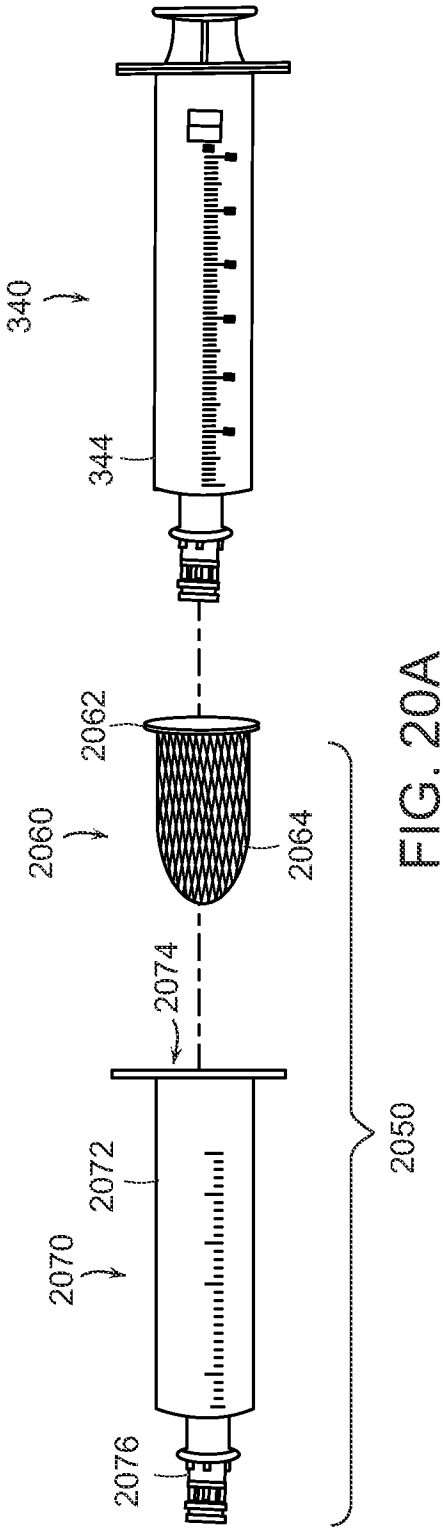


FIG. 20A

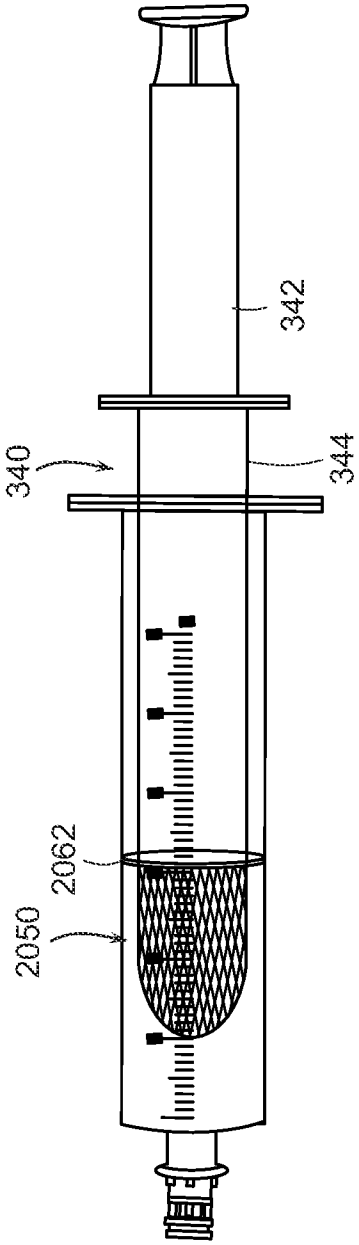


FIG. 20B

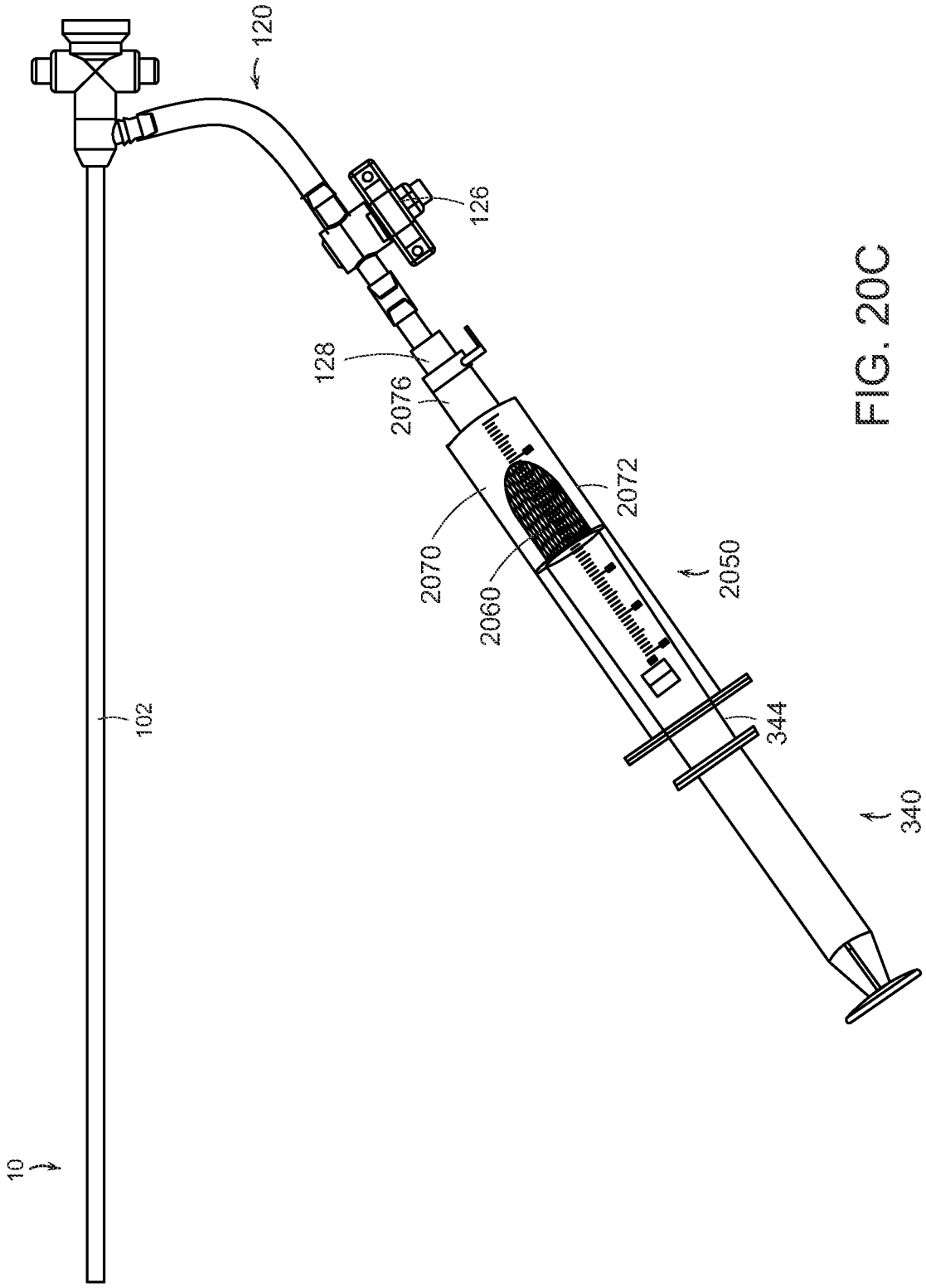


FIG. 20C

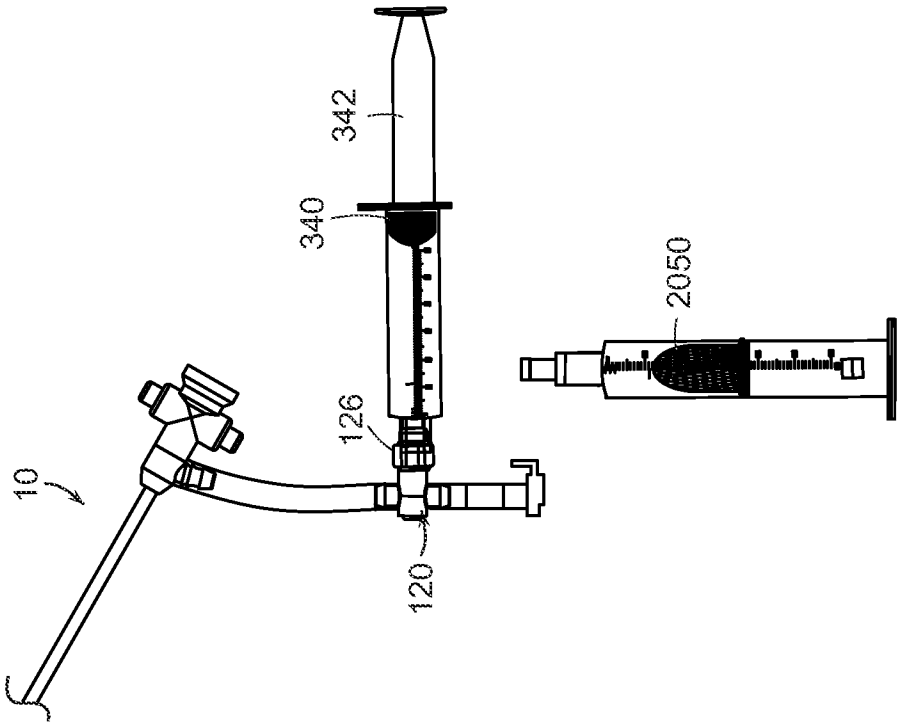


FIG. 20E

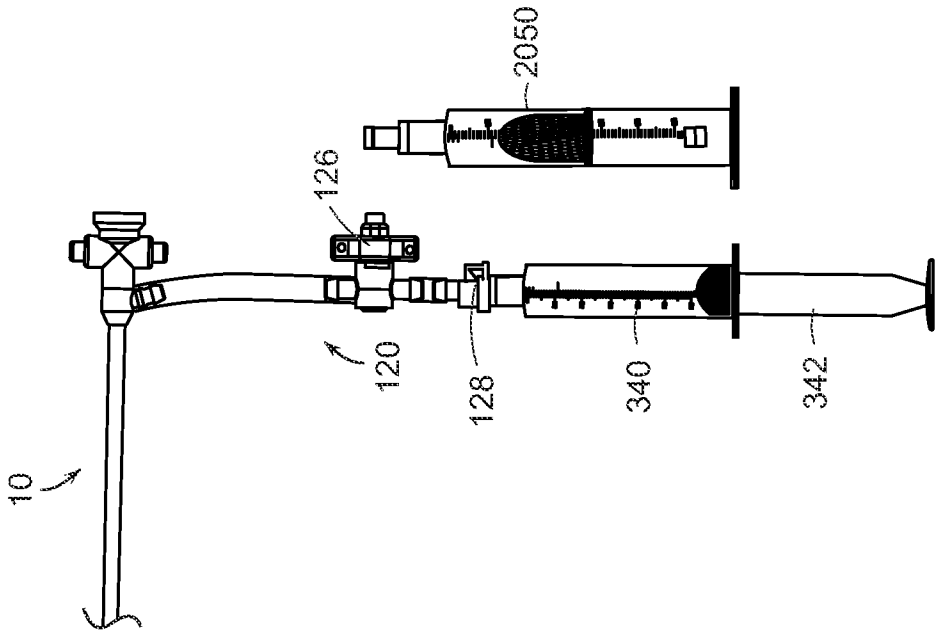


FIG. 20D

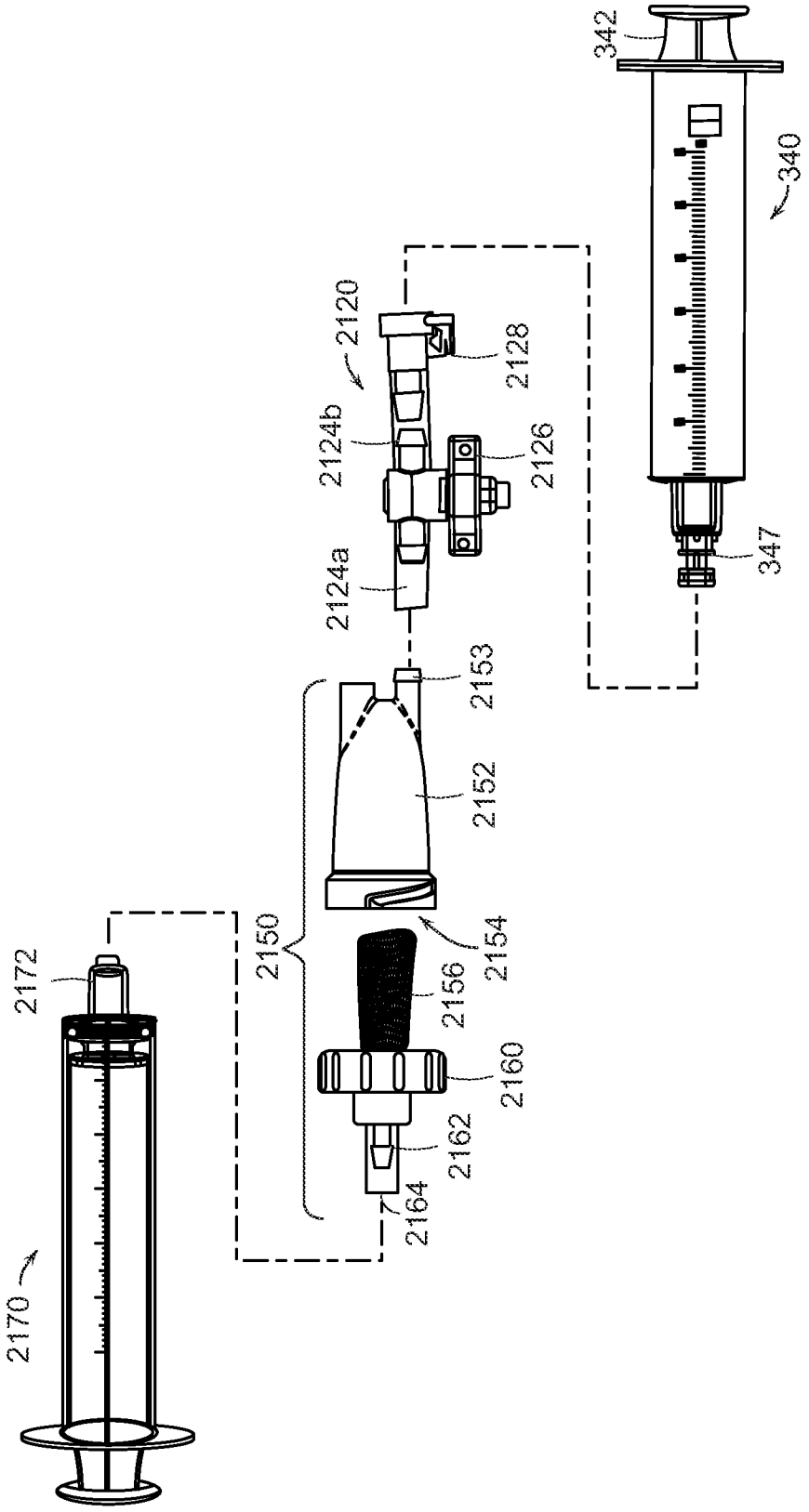

342
340
347
2120
2128
2124b
2126
2124a
2153
2152
2150
2154
2156
2160
2162
2164
2172
2170

FIG. 21A

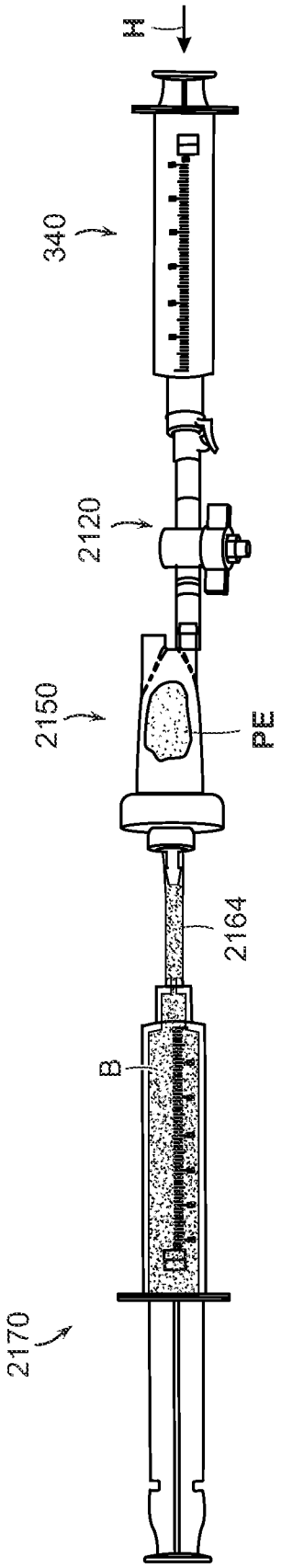


FIG. 21B

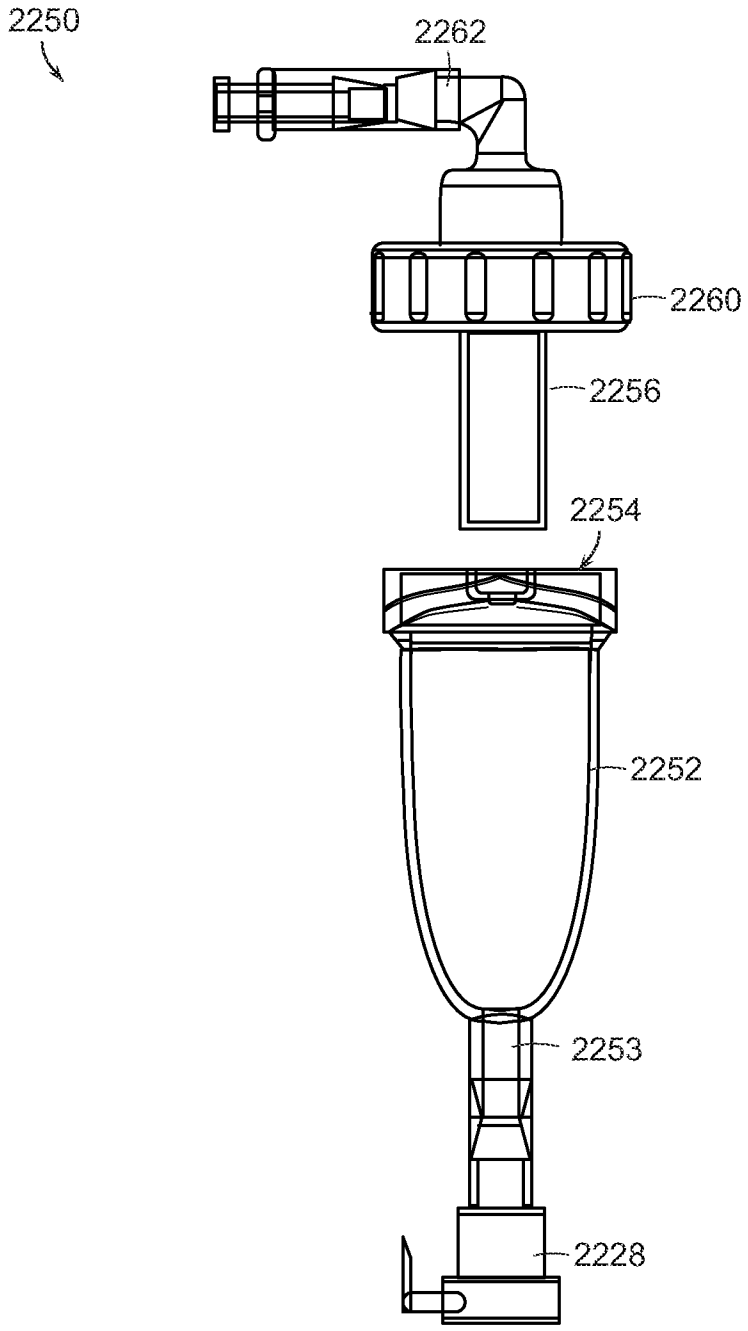


FIG. 22

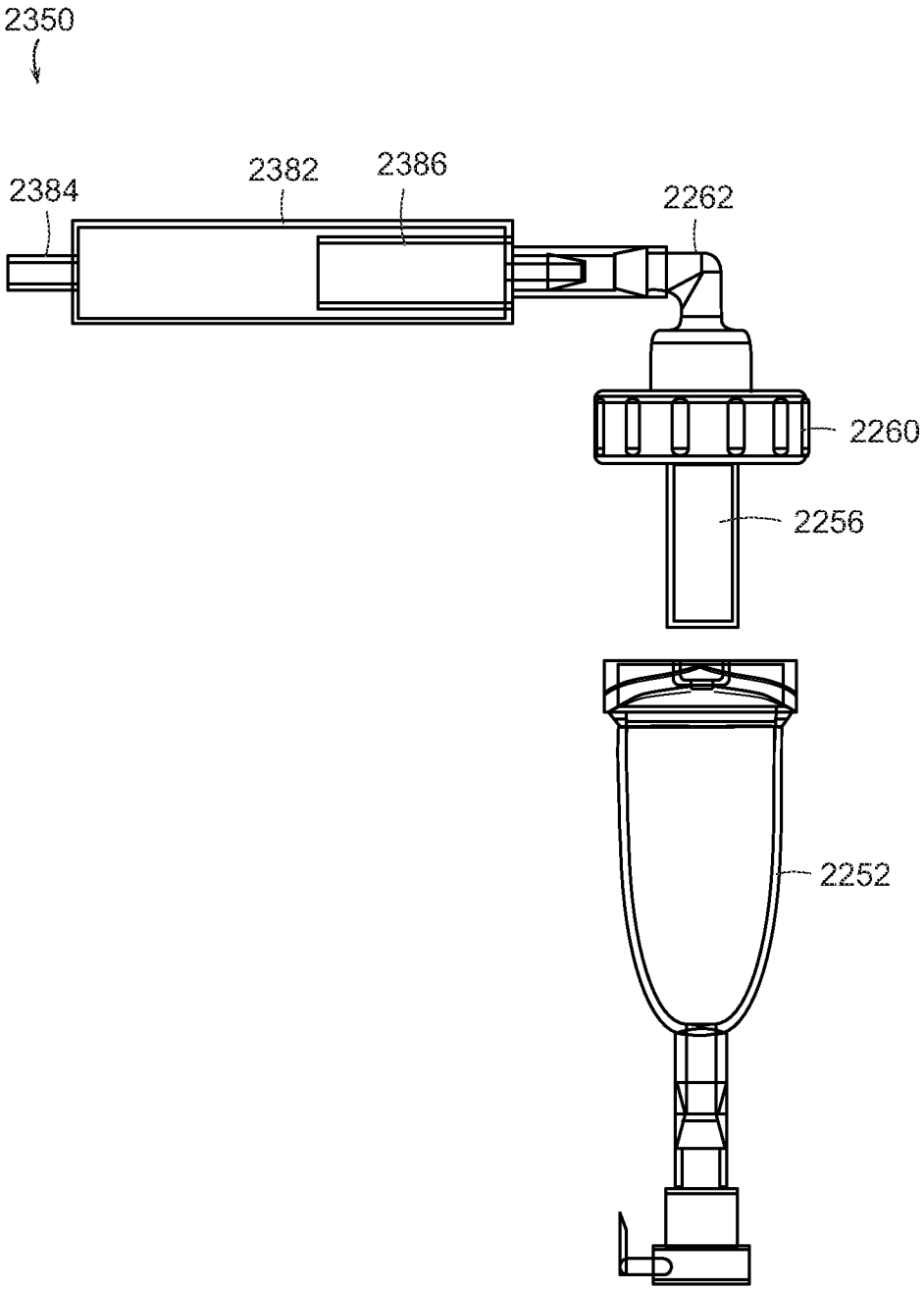


FIG. 23

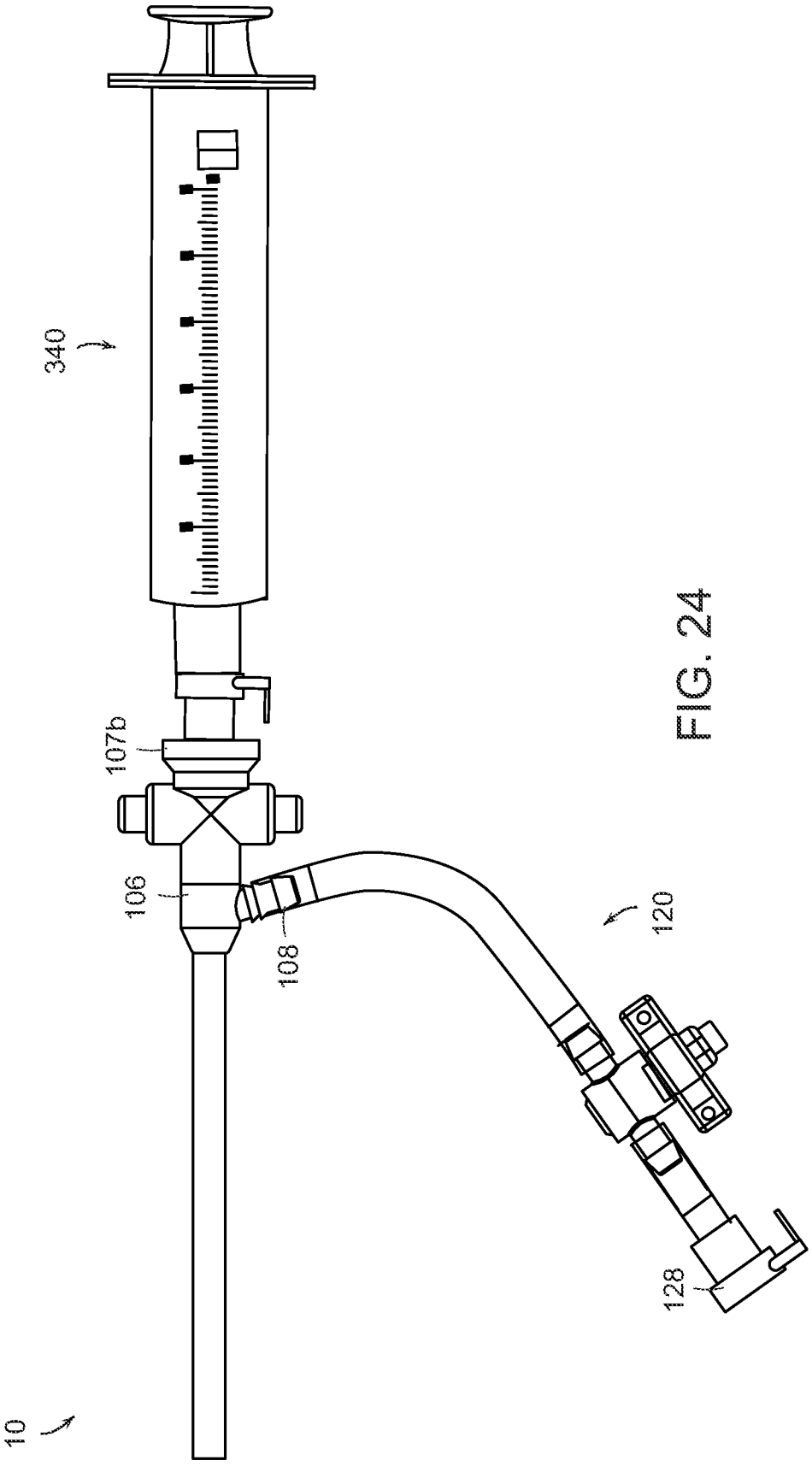


FIG. 24

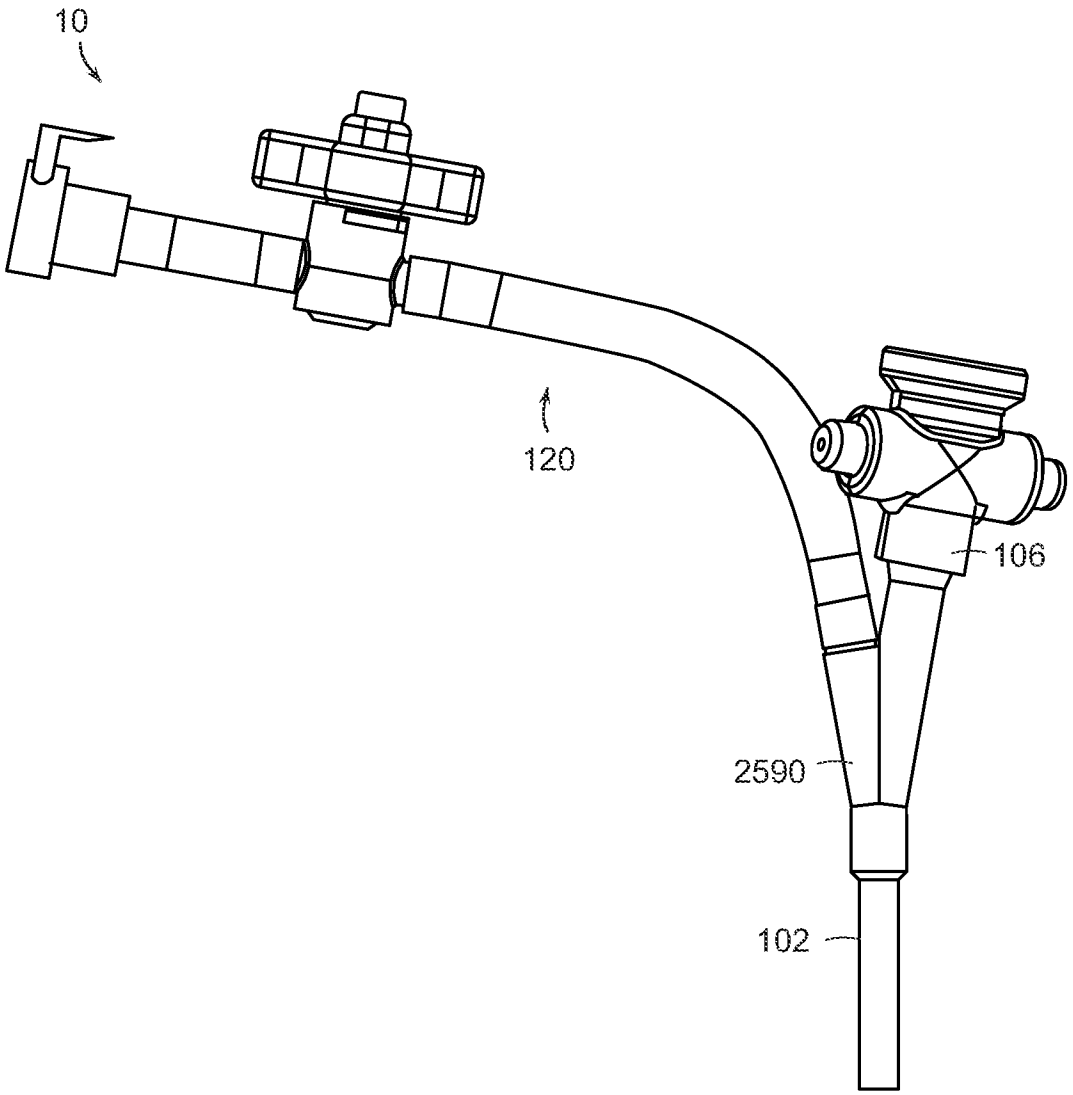


FIG. 25

Electronic Patent Application Fee Transmittal

Application Number:	
Filing Date:	
Title of Invention:	SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED DEVICES AND METHODS
First Named Inventor/Applicant Name:	Ben Merritt
Filer:	Paul T Parker/JiYoung Anderson
Attorney Docket Number:	111552-8018.US03

Filed as Large Entity

Filing Fees for Track I Prioritized Examination - Nonprovisional Application under 35 USC 111(a)

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Basic Filing:				
UTILITY APPLICATION FILING	1011	1	320	320
UTILITY SEARCH FEE	1111	1	700	700
UTILITY EXAMINATION FEE	1311	1	800	800
REQUEST FOR PRIORITIZED EXAMINATION	1817	1	4200	4200
Pages:				
Claims:				
Miscellaneous-Filing:				
PROCESSING FEE, EXCEPT PROV. APPLS.	1830	1	140	140

Description	Fee Code	Quantity	Amount	Sub-Total in USD($)
Petition:				
Patent-Appeals-and-Interference:				
Post-Allowance-and-Post-Issuance:				
Extension-of-Time:				
Miscellaneous:				
		Total in USD ($)		**6160**

Electronic Acknowledgement Receipt

EFS ID:	46195823
Application Number:	17865315
International Application Number:	
Confirmation Number:	7298
Title of Invention:	SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED DEVICES AND METHODS
First Named Inventor/Applicant Name:	Ben Merritt
Customer Number:	25096
Filer:	Paul T Parker/JiYoung Anderson
Filer Authorized By:	Paul T Parker
Attorney Docket Number:	111552-8018.US03
Receipt Date:	14-JUL-2022
Filing Date:	
Time Stamp:	21:01:44
Application Type:	Utility under 35 USC 111(a)

Payment information:

Submitted with Payment	yes
Payment Type	CARD
Payment was successfully received in RAM	$6160
RAM confirmation Number	E20227DL02093801
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	Track One Request	Track-One-Request-111552-8018US3.PDF	877345 13040a5b8ce6be326f76bd1e8e220ebb4fdf23c0	no	2
Warnings:					
Information:					
2	Application Data Sheet	ADS-111552-8018US3.PDF	1823375 ce8e8018f0d630da6c0effbe1ee49189bd1bda8d	no	9
Warnings:					
Information:					
3	Authorization for Extension of Time all replies	General_Fee_Authorization-111552-8018US3.PDF	96120 6a74e561da10ec0cad65e0f776f4d1f0a96e7a56	no	2
Warnings:					
Information:					
4	Oath or Declaration filed	Signed_Declaration-parent-111552-8018US3.PDF	143905 3bc48aced069b47b2f52bc31b57af62ede42a018	no	4
Warnings:					
Information:					
5	Power of Attorney	POA_Trans-111552-8018US3.PDF	624574 2d89c57adc4577666c1a7cd951beee2576706a01	no	1
Warnings:					
Information:					
6	Power of Attorney	US_POA-signed_2021-Inari.PDF	108448 8899207ebdb0676c00b7c2d622cb7ba46f34795b	no	1
Warnings:					
Information:					

7		Track-One_CON_Application-111552-8018US3.PDF	239637 e400b7868c73d2f495ccca6519055908373714b9	yes	56
	Multipart Description/PDF files in .zip description				
	Document Description		**Start**	**End**	
	Specification		1	52	
	Claims		53	55	
	Abstract		56	56	
Warnings:					
Information:					
8	Drawings-only black and white line drawings	Drawings-111552-8018US3-pto.PDF	1886438 600750a8776fc2c672e5d6f7c5f2b97cab4aa877	no	38
Warnings:					
Information:					
9	Fee Worksheet (SB06)	fee-info.pdf	48145 22d3b55655b978eb5743ece88fe7492c296fc6c6	no	2
Warnings:					
Information:					
		Total Files Size (in bytes):	5847987		

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.

Doc Code: TRACK1.REQ
Document Description: TrackOne Request

PTO/AIA/424 (04-14)

CERTIFICATION AND REQUEST FOR PRIORITIZED EXAMINATION UNDER 37 CFR 1.102(e) (Page 1 of 1)

First Named Inventor:	Ben Merritt	Nonprovisional Application Number (if known):	Not Yet Assigned
Title of Invention:	SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED DEVICES AND METHODS		

APPLICANT HEREBY CERTIFIES THE FOLLOWING AND REQUESTS PRIORITIZED EXAMINATION FOR THE ABOVE-IDENTIFIED APPLICATION.

1. The processing fee set forth in 37 CFR 1.17(i)(1) and the prioritized examination fee set forth in 37 CFR 1.17(c) have been filed with the request. The publication fee requirement is met because that fee, set forth in 37 CFR 1.18(d), is currently $0. The basic filing fee, search fee, and examination fee are filed with the request or have been already been paid. I understand that any required excess claims fees or application size fee must be paid for the application.

2. I understand that the application may not contain, or be amended to contain, more than four independent claims, more than thirty total claims, or any multiple dependent claims, and that any request for an extension of time will cause an outstanding Track I request to be dismissed.

3. The applicable box is checked below:

I. ☑ Original Application (Track One) - Prioritized Examination under § 1.102(e)(1)

i. (a) The application is an original nonprovisional utility application filed under 35 U.S.C. 111(a). This certification and request is being filed with the utility application via EFS-Web.

---OR---

(b) The application is an original nonprovisional plant application filed under 35 U.S.C. 111(a). This certification and request is being filed with the plant application in paper.

ii. An executed inventor's oath or declaration under 37 CFR 1.63 or 37 CFR 1.64 for each inventor, **or** the application data sheet meeting the conditions specified in 37 CFR 1.53(f)(3)(i) is filed with the application.

II. ☐ Request for Continued Examination - Prioritized Examination under § 1.102(e)(2)

i. A request for continued examination has been filed with, or prior to, this form.
ii. If the application is a utility application, this certification and request is being filed via EFS-Web.
iii. The application is an original nonprovisional utility application filed under 35 U.S.C. 111(a), or is a national stage entry under 35 U.S.C. 371.
iv. This certification and request is being filed prior to the mailing of a first Office action responsive to the request for continued examination.
v. No prior request for continued examination has been granted prioritized examination status under 37 CFR 1.102(e)(2).

Signature /Paul T. Parker/	Date 2022-07-14
Name (Print/Typed) Paul T. Parker	Practitioner Registration Number 38,264

Note: *This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4(d) for signature requirements and certifications. Submit multiple forms if more than one signature is required.**

☑ *Total of 1 forms are submitted.

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.

PTO/AIA/14 (11-15)
Approved for use through 04/30/2017. 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	111552-8018.US03
	Application Number	
Title of Invention	SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED DEVICES AND METHODS	

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
	Ben		Merritt	

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

City	State/Province	Country of Residence
San Clemente	CA	US

Mailing Address of Inventor:

Address 1	c/o Inari Medical, Inc.
Address 2	6001 Oak Canyon, Suite #100

City	State/Province	Postal Code	Country
Irvine	CA	92618	US

Inventor 2 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Jacqueline		Macias	

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

City	State/Province	Country of Residence
Fullerton	CA	US

Mailing Address of Inventor:

Address 1	c/o Inari Medical, Inc.
Address 2	6001 Oak Canyon, Suite #100

City	State/Province	Postal Code	Country
Irvine	CA	92618	US

Inventor 3 Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Brian	Michael	Strauss	

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

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	111552-8018.US03
	Application Number	
Title of Invention	SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED DEVICES AND METHODS	

City	San Clemente	State/Province	CA	Country of Residence	US

Mailing Address of Inventor:

Address 1	c/o Inari Medical, Inc.
Address 2	6001 Oak Canyon, Suite #100

City	Irvine	State/Province	CA
Postal Code	92618	Country	US

Inventor 4 — Remove

Legal Name

Prefix	Given Name	Middle Name	Family Name	Suffix
	Thomas		Tu	

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

City	Louisville	State/Province	KY	Country of Residence	US

Mailing Address of Inventor:

Address 1	c/o Inari Medical, Inc.
Address 2	6001 Oak Canyon, Suite #100

City	Irvine	State/Province	CA
Postal Code	92618	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	25096		
Email Address	patentprocurement@perkinscoie.com	Add Email	Remove Email

Application Information:

Title of the Invention	SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED DEVICES AND METHODS		
Attorney Docket Number	111552-8018.US03	Small Entity Status Claimed	☐
Application Type	Nonprovisional		
Subject Matter	Utility		
Total Number of Drawing Sheets (if any)	38	Suggested Figure for Publication (if any)	2

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	111552-8018.US03
	Application Number	
Title of Invention	SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED DEVICES AND METHODS	

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.

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	25096		

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	16/536185	2019-08-08

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	111552-8018.US03
	Application Number	
Title of Invention	SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED DEVICES AND METHODS	

Prior Application Status	Expired		Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
16/536185	Claims benefit of provisional	62/718269	2018-08-13
Prior Application Status	Expired		Remove
Application Number	Continuity Type	Prior Application Number	Filing or 371(c) Date (YYYY-MM-DD)
16/536185	Claims benefit of provisional	62/718248	2018-08-13
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.

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	111552-8018.US03
	Application Number	
Title of Invention	SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED DEVICES AND METHODS	

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 (11-15)
Approved for use through 04/30/2017. 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	111552-8018.US03
	Application Number	
Title of Invention	SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED DEVICES AND METHODS	

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	Inari Medical, Inc.		
Mailing Address Information For Applicant:			
Address 1	6001 Oak Canyon, Suite #100		
Address 2			
City	Irvine	**State/Province**	CA
Country	US	Postal Code	92618
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 (11-15)
Approved for use through 04/30/2017. 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	111552-8018.US03
	Application Number	
Title of Invention	SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED DEVICES AND METHODS	

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	/Paul T. Parker/			Date (YYYY-MM-DD)	2022-07-14
First Name	Paul T.	Last Name	Parker	Registration Number	38,264

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

Application Data Sheet 37 CFR 1.76	Attorney Docket Number	111552-8018.US03
	Application Number	
Title of Invention	SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED DEVICES AND METHODS	

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.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
Ben Merritt et al.

Application No.: Not Yet Assigned	Confirmation No.: N/A
Filed: Concurrently Herewith	Art Unit: Not Yet Assigned
For: SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED DEVICES AND METHODS	Examiner: Not Yet Assigned

AUTHORIZATION FOR: EXTENSIONS OF TIME UNDER 37 C.F.R. § 1.136(a)(3) AND PAYMENT OF FEES UNDER 37 C.F.R. § 1.17

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

Dear Commissioner:

With respect to the above-identified application, the Commissioner is authorized to treat any concurrent or future reply requiring a petition for an extension of time under 37 C.F.R. § 1.136(a)(3) for its timely submission as incorporating a petition therefor for the appropriate length of time.

The Commissioner is also authorized to charge any extension of time fees or other fees that may be required under 37 C.F.R. § 1.17 for any paper filed concurrently herewith or in the future, or credit any overpayment, to Deposit Account No. 50-0665.

Dated: July 14, 2022

Respectfully submitted,

By /Paul T. Parker/
Paul T. Parker
Registration No.: 38,264

Perkins Coie LLP
P.O. Box 1247
Seattle, WA 98111-1247
Phone: (206) 359-3258
Fax: (206) 359-7198

Attorney for Applicant

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

Title of Invention	SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED DEVICES AND METHODS

As the below named inventor, I hereby declare that:

This declaration is directed to:

- [ ] The attached application, or
- [x] United States application or PCT international application number 16/536,185 filed on August 8, 2019.

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.

I hereby state that I have reviewed and understand the contents of the above identified application, including the claims, as amended by any amendment.

I acknowledge the duty to disclose information material to patentability as defined in 37 C.F.R. 1.56 including for continuation-in-part applications, material information which became available between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.

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: Thomas Tu Date: Mar 23, 2020

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.

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

Title of Invention	SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED DEVICES AND METHODS

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 16/536,185 filed on August 8, 2019 .

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.

I hereby state that I have reviewed and understand the contents of the above identified application, including the claims, as amended by any amendment.

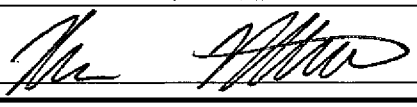
I acknowledge the duty to disclose information material to patentability as defined in 37 C.F.R. 1.56 including for continuation-in-part applications, material information which became available between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.

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: Ben Merritt Date: 2/5/2020

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.

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

Title of Invention	SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED DEVICES AND METHODS

As the below named inventor, I hereby declare that:

This declaration is directed to:

- [ ] The attached application, or
- [x] United States application or PCT international application number 16/536,185 filed on August 8, 2019.

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.

I hereby state that I have reviewed and understand the contents of the above identified application, including the claims, as amended by any amendment.

I acknowledge the duty to disclose information material to patentability as defined in 37 C.F.R. 1.56 including for continuation-in-part applications, material information which became available between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.

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: Jacqueline Macias Date: 02/06/2020

Signature: Jacqueline Macias

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.

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

Title of Invention	SYSTEM FOR TREATING EMBOLISM AND ASSOCIATED DEVICES AND METHODS

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 16/536,185 filed on August 8, 2019.

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.

I hereby state that I have reviewed and understand the contents of the above identified application, including the claims, as amended by any amendment.

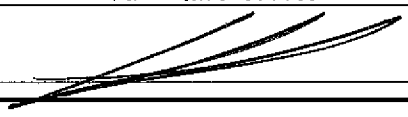
I acknowledge the duty to disclose information material to patentability as defined in 37 C.F.R. 1.56 including for continuation-in-part applications, material information which became available between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.

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: Brian Michael Strauss Date: 06 Feb 2020

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.