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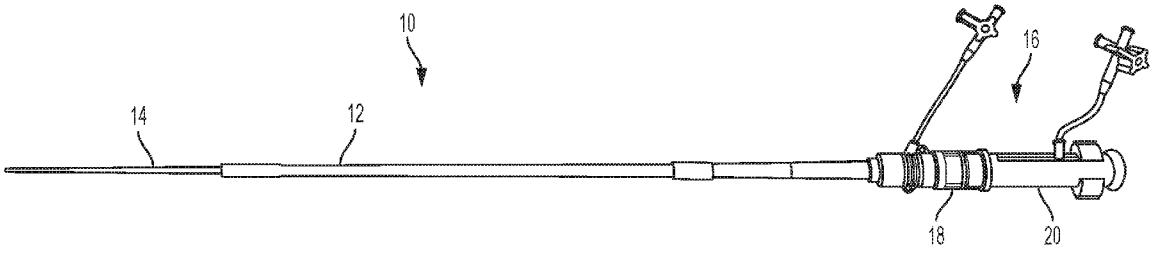


FIG. 1

(57) Abstract: A system for introducing a delivery apparatus into a patient's vasculature. Tire system, may include a sheath having a lumen and configured to he inserted into the patient's vasculature. An introducer has a channel for receiving a guide wire and is configured to be positioned within the lumen of the sheath. A plug is coupled to the introducer and is configured to move from, a first position in which the plug has a first diameter to a second position in which the plug has a second diameter that is greater than the first diameter and greater than the interior diameter of the sheath, the plug being configured to slide within the lumen in a direction from the distal end of the sheath towards the proximal end of the sheath to expand the sheath in the direction radially outward from the lumen.

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INTRODUCER SHEATH WITH EXPANDABLE INTRODUCER

FIELD:

[0001] The present application concerns embodiments of a system for introducing a delivery apparatus into a patient's vasculature. The delivery apparatus may comprise a catheter-based technology for repairing and/or replacing heart valves, as well as for delivering an implant, such as a prosthetic heart valve to a heart via the patient's vasculature.

BACKGROUND:

[0002] Delivery apparatuses are used to implant prosthetic devices, such as a prosthetic heart valve, at locations inside the body that are not readily accessible by surgery or where access without invasive surgery is desirable. For example, aortic, mitral, tricuspid, and/or pulmonary prosthetic heart valves can be delivered to a treatment site using minimally invasive surgical techniques. The delivery apparatuses may comprise endovascular catheter assemblies.

[0003] An introducer sheath may be used to introduce a delivery apparatus into a patient's vasculature (e.g., the femoral artery). An introducer sheath generally has an elongated sleeve that is inserted into the vasculature and a housing that contains one or more sealing valves that allow a delivery apparatus to be placed in fluid communication with the vasculature with minimal blood loss.

[0004] Conventional methods of accessing a vessel, such as a femoral artery, prior to introducing the delivery apparatus include dilating the vessel using multiple dilators or sheaths that progressively increase in diameter. This repeated insertion and vessel dilation can increase the time the procedure takes, as well as the risk of damage to the vessel.

[0005] Accordingly, improvements in systems, apparatuses, and methods of introducing a delivery apparatus into a patient's vasculature are desired.

SUMMARY

[0006] The present disclosure is directed to systems, apparatuses, and methods of introducing a delivery apparatus into a patient's vasculature. The system may include a sheath and an introducer positioned therein for introduction to the patient's vasculature. The introducer may

include a plug, or an expandable portion of the introducer, for expansion at a position distal of the distal end of the sheath. Upon expansion, the plug, or expandable portion of the introducer, may be withdrawn in a proximal direction through the sheath to expand the sheath prior to insertion of the delivery apparatus. The sheath accordingly may be expanded without requiring insertion of multiple dilators or sheaths that progressively increase in diameter.

[0007] The plug, or expandable portion of the introducer, may be integrated into the introducer such that the introducer operates as a standard introducer for the sheath to gain access to the vasculature.

[0008] The plug, or expandable portion of the introducer, may be sized such that a transient expansion of the sheath occurs upon the plug being withdrawn through the sheath. The transient expansion may expand a portion of the sheath at a time, to reduce the pulling force required by the plug and to reduce the possibility of the plug being stuck within the sheath. The expansion of the sheath may comprise a preconditioning of the sheath prior to introduction of the delivery apparatus. The preconditioning of the sheath may allow for a lower push force for the delivery apparatus as it is passed through the sheath and into the patient's vasculature.

[0009] Embodiments of the present disclosure include a system for introducing a delivery apparatus into a patient's vasculature. The system may include a sheath having a distal end, a proximal end, an interior diameter, a lumen, and a length extending from the distal end to the proximal end. The sheath may be configured to be inserted into the patient's vasculature and to expand in a direction radially outward from the lumen. An introducer may have a channel for receiving a guide wire and may be configured to be positioned within the lumen of the sheath. A plug may be coupled to the introducer and configured to move from a first position in which the plug has a first diameter to a second position in which the plug has a second diameter that is greater than the first diameter and greater than the interior diameter of the sheath, the plug in the first position being configured to fit within the lumen, and the plug in the second position having a length that is less than the length of the sheath and being configured to slide within the lumen in a direction from the distal end of the sheath towards the proximal end of the sheath to expand the sheath in the direction radially outward from the lumen.

[0010] Embodiments of the present disclosure include a system for introducing a delivery apparatus into a patient's vasculature. The system may include a sheath having a distal end, a proximal end, an interior diameter, a lumen, and a length extending from the distal end to the

proximal end. The sheath may be configured to be inserted into the patient's vasculature and to expand in a direction radially outward from the lumen. An introducer may have a channel for receiving a guide wire and may be configured to be positioned within the lumen of the sheath. The introducer may have an expandable portion including a plurality of supports, the expandable portion configured to move from a first position in which the plurality of supports are flattened and have a first diameter to a second position in which the plurality of supports extend radially outward from the introducer and have a second diameter that is larger than the first diameter and the interior diameter of the sheath, the expandable portion being configured to slide within the lumen in the second position to expand the sheath in the direction radially outward from the lumen.

[0011] Embodiments of the present disclosure include a method that may include inserting a guide wire into a patient's vasculature. The method may include inserting a guide wire into a patient's vasculature. The method may include inserting an introducer and a sheath into the patient's vasculature over the guide wire, the sheath extending around the introducer and having a distal end and a proximal end and having a lumen, and being configured to expand in a direction radially outward from the lumen. The method may include activating a plug positioned in the patient's vasculature to move from a first position in which the plug has a first diameter to a second position in which the plug has a second diameter that is greater than an interior diameter of the sheath. The method may include sliding the plug in the second position through the lumen of the sheath in a direction from the distal end of the sheath towards the proximal end of the sheath to expand the sheath in the direction radially outward from the lumen.

BRIEF DESCRIPTION OF THE DRAWINGS

[0012] Features and advantages of the systems, apparatuses, and methods as disclosed herein will become appreciated as the same become better understood with reference to the specification, claims, and appended drawings wherein:

[0013] FIG. 1 illustrates a side view of a system according to an embodiment of the present disclosure.

[0014] FIG. 2 illustrates a side view of the sheath shown in FIG. 1.

[0015] FIG. 3 illustrates a cross sectional view of the sheath shown in FIG. 2 along line A-A in FIG. 2.

[0016] FIG. 4 illustrates a side view of the introducer shown in FIG. 1.

[0017] FIG. 5 illustrates a close-up side view of the distal end of the introducer shown in FIG. 4.

[0018] FIG. 6 illustrates a close-up perspective side view of the introducer housing shown in FIG. 4 disassembled, with an inner shaft and an outer shaft shown in cross-section.

[0019] FIG. 7 illustrates a cross sectional view of the system shown in FIG. 1 along a midline of the system.

[0020] FIG. 8A illustrates a close-up side view of the distal end of the sheath and the introducer shown in FIG. 1.

[0021] FIG. 8B illustrates a close-up side view of the control housing shown in FIG. 1.

[0022] FIG. 9 illustrates a close-up side view of the distal end of the sheath and the introducer shown in FIG. 1.

[0023] FIG. 10A illustrates a close-up side view of the distal end of the sheath and the introducer shown in FIG. 1.

[0024] FIG. 10B illustrates a close-up side view of the control housing shown in FIG. 1.

[0025] FIG. 11A illustrates a close-up side view of the distal end of the sheath and the introducer shown in FIG. 1.

[0026] FIG. 11B illustrates a close-up side view of the control housing shown in FIG. 1.

[0027] FIG. 12A illustrates a side view of the system shown in FIG. 1.

[0028] FIG. 12B illustrates a schematic view of a portion of a sheath shown in FIG. 1.

[0029] FIG. 13A illustrates a cross sectional view of introducer shown in FIG. 8A along line B-B in FIG. 8A.

[0030] FIG. 13B illustrates a cross sectional view of introducer shown in FIG. 10A along line C-C in FIG. 10A.

[0031] FIG. 14A illustrates a side view of a system according to an embodiment of the present disclosure, with a portion cut away.

[0032] FIG. 14B illustrates a side view of the system shown in FIG. 14A.

[0033] FIG. 14C illustrates a side view of the system shown in FIG. 14A.

[0034] FIG. 15A illustrates a side view of a portion of a system according to an embodiment of the present disclosure, with a portion cut away.

[0035] FIG. 15B illustrates a side view of the portion of system shown in FIG. 15A.

[0036] FIG. 15C illustrates a side view of the portion of system shown in FIG. 15A.

[0037] FIG. 16A illustrates a side view of a portion of a system according to an embodiment of the present disclosure, with a portion cut away.

[0038] FIG. 16B illustrates a side view of the portion of system shown in FIG. 16A.

[0039] FIG. 16C illustrates a side view of the portion of system shown in FIG. 16A.

[0040] FIG. 17 illustrates a chart of reduced push force of the delivery apparatus through an expanded sheath of the system, according to an embodiment of the present disclosure.

[0041] FIG. 18 illustrates a side view of a delivery apparatus, according to an embodiment of the present disclosure.

[0042] FIG. 19 illustrates a flow chart of a method, according to an embodiment of the present disclosure.

DETAILED DESCRIPTION

[0043] FIG. 1 illustrates an embodiment of a system **10** for introducing a delivery apparatus into a patient's vasculature. The system **10** may include a sheath **12** and an introducer **14**. The introducer **14** may be positioned within a lumen of the sheath **12**, as shown in FIG. 1. A control housing **16** may be positioned at a proximal end of the system and may include a sheath housing **18** and an introducer housing **20**. The sheath housing **18** and introducer housing **20** may couple together, as shown in FIG. 1.

[0044] The sheath **12** and introducer **14** are shown in an insertion configuration, for insertion together into the patient's vasculature. Upon insertion into the patient's vasculature, the introducer **14** may be withdrawn longitudinally from the sheath **12**, leaving the sheath **12** within the patient's vasculature. Features of the sheath **12** and the introducer **14** individually are discussed below, as well as the operation of the sheath **12** and introducer **14** together.

[0045] FIG. 2 illustrates the sheath **12** separated from the introducer **14**. The sheath **12** comprises an elongate body that may have a cylindrical shape. The sheath **12** has a distal end **22** and a proximal end **24** and a length extending from the distal end **22** to the proximal end **24**.

[0046] The sheath **12** is configured to be inserted into a patient's vasculature. The sheath **12** may comprise an introducer sheath that is used to introduce a delivery apparatus into the patient's vasculature.

[0047] The vasculature may comprise the blood vessels of the patient's body which may include the femoral artery or other vessels of the patient's body. The vasculature, such as the femoral artery, may be narrow or stiff, and may be difficult to easily insert a delivery apparatus therein. For example, the delivery apparatus may be larger than the vasculature, or may be unwieldy to penetrate through the skin or vasculature of the patient to pass therethrough by itself. Also, the vasculature may be too fragile to receive the delivery apparatus without use of an introducer sheath.

[0048] The sheath **12** accordingly may be inserted into the patient's vasculature prior to the delivery apparatus being introduced, to provide an entryway or guide path for the delivery apparatus to introduce the delivery apparatus into the patient's vasculature. After the sheath **12** is inserted, the sheath **12** may remain positioned within and surrounded by the patient's vasculature. The delivery apparatus may then be passed through the lumen of the sheath **12** for introduction into the patient's body. The sheath **12** may remain in the vasculature until a desired time to remove the sheath **12**.

[0049] The sheath **12** may be inserted into the vasculature percutaneously or a portion of the patient's body may be surgically opened for the sheath **12** to access the vasculature.

[0050] The delivery apparatus may be configured in a manner such as the delivery apparatus **11** shown in FIG. 18. The delivery apparatus **11** may comprise a device for delivering an implant **13**, or other type of implantable device, to a patient. The delivery apparatus **11** may comprise a catheter, and may include a steerable guide catheter **15** (also referred to as a flex catheter) and a balloon catheter **17** extending through the guide catheter **15**. The guide catheter **15** and the balloon catheter **17** may be adapted to slide longitudinally relative to each other to facilitate delivery and positioning of the implant **13** at an implantation site in the patient's body. The delivery apparatus **11** may comprise an endovascular catheter assembly for endovascular deployment of the implant **13**.

[0051] The implant **13** may comprise a prosthetic device, such as a prosthetic heart valve to be delivered to replace a heart valve of the patient. The prosthetic heart valve may be an aortic, mitral, tricuspid, and/or pulmonary heart valve for implantation. The prosthetic heart valve may be an expandable heart valve that is passed through the patient's vasculature in an

undeployed configuration and then is expanded into a deployed configuration when placed in the desired position (e.g., at the heart valve to be replaced). The delivery apparatus **11** may be configured to pass through the patient's vasculature to deliver the implant **13** to the desired location (e.g., the location of the heart valve to be replaced). Upon being placed in the desired position, a deployment device, such as the balloon of the balloon catheter **17** may deploy the heart valve in position. In other embodiments, other forms of implants may be utilized, such as stents or filters, or diagnostic devices, among others. In other embodiments, other forms of delivery apparatuses than shown in FIG. 18 may be utilized.

[0052] The delivery apparatus **11** passes through the lumen of the sheath **12** to reach a desired position in the patient's body. As shown in FIG. 18, the delivery apparatus **11** may pass through an opening at the proximal end of the sheath **12** (the sheath housing **18** is not shown in FIG. 18) for passage through the lumen of the sheath **12** and the vasculature of the patient.

[0053] The delivery apparatus and the systems disclosed herein may be used in transcatheter aortic valve implantation (TAVI). The delivery apparatus and the systems disclosed herein may be utilized for transarterial access, including transfemoral access, to a patient's heart.

[0054] Referring back to FIG. 2, the sheath housing **18** may be positioned at the proximal end **24** of the sheath **12**. The sheath housing **18** may comprise a cylindrical body and may include a coupler **21** for coupling to another housing or component of the system. The sheath housing **18** may include an internal chamber **19** (marked in FIG. 7) for the delivery apparatus **11** to be passed through to be delivered to the patient's vasculature. The sheath housing **18** may be configured to remain external to the patient's vasculature when the sheath **12** is inserted therein and may be configured to remain external to the patient's skin for a percutaneous implantation of the sheath **12**. The sheath housing **18** may be configured for a user (such as a surgeon) to grip to manipulate the sheath **12**.

[0055] The sheath **12** may include a strain relief portion **26** at the proximal end **24** of the sheath **12**. The strain relief portion **26** may be sized larger than a proximate portion of the sheath **12** and may seal the entry point of the vasculature, to reduce the possibility of blood or other fluid being released between the exterior surface of the sheath **12** and the vasculature. The sheath housing **18** may include a fluid port **28** for passing fluid such as blood to or from the patient's vasculature. Tubing **30** with a valve **31** may be coupled to the fluid port **28**, for passing fluid through the fluid port **28** and for sealing flow of the fluid through the fluid port **28**.

[0056] FIG. 3 illustrates a cross sectional view of the sheath **12** along line A-A in FIG. 2. The sheath **12** has a lumen **32** and one or more walls surrounding the lumen **32**. In the embodiment shown in FIG. 3, the walls may include an inner tubing wall **34** that surrounds the lumen **32** and an outer tubing wall **36** that surrounds the inner tubing wall **34**.

[0057] The inner tubing wall **34** may have an interior surface that comprises the interior surface **38** of the sheath **12**. The inner tubing wall **34** may include a thick portion **40** and a thin portion **42**. The inner tubing wall **34** may be folded upon itself such that a fold exists at the thin portion **42**, as shown in FIG. 3. The fold may result in a channel **44** being positioned between the inner tubing wall **34** and the outer tubing wall **36**. A seal **46** (marked in FIG. 2) may be positioned along the length of the sheath **12** to prevent blood or other fluid flow from passing through the channel **44** and out of the proximal end **24** of the sheath **12**.

[0058] The outer tubing wall **36** may have an exterior surface that comprises the exterior surface **37** of the sheath **12**. The outer tubing wall **36** may include multiple layers, including an inner layer **48** and an outer layer **50** extending around the inner layer **48**.

[0059] Reinforcements **52** may be provided in the sheath **12**. The reinforcements **52** may comprise elongate rods that may be positioned between the inner layer **48** and the outer layer **50** of the outer tubing wall **36** and may extend along the length of the sheath **12**. The reinforcements **52** may provide strength to the sheath **12**.

[0060] The sheath **12** may have an outer diameter **54** and an interior diameter **56**. The outer diameter **54** may be the diameter of the exterior surface **37** of the sheath, and the interior diameter **56** may be the diameter of the interior surface **38** of the sheath **12**.

[0061] The sheath **12** may be configured to expand in a direction radially outward from the lumen **32**. The sheath **12** may be configured to expand in a variety of manners, and may be flexible in a direction radially outward from the lumen **32**. For example, in the embodiment shown in FIG. 3, the inner tubing wall **34** and the outer tubing wall **36** may each be configured to expand in a direction radially outward from the lumen **32**. The inner tubing wall **34** and the outer tubing wall **36** may both be flexible to allow for expansion in the direction radially outward from the lumen **32**.

[0062] The inner tubing wall **34** may be configured such that the thin portion **42** is more flexible than the thick portion **40** and accordingly fully or partially unfolds to expand the fold when a force is applied to the inner tubing wall **34** radially outward from the lumen **32**. The unfolding of the inner tubing wall **34** allows the inner tubing wall **34** to expand in the direction

radially outward from the lumen **32**. The outer tubing wall **36** may be stretchable and may correspondingly expand in the direction radially outward from the lumen **32** by the force of the inner tubing wall **34** pressing against the outer tubing wall **36**.

[0063] The expansion of the sheath **12** in the direction radially outward from the lumen **32** may result in an increased size of the lumen **32**, the interior diameter **56**, and the outer diameter **54**.

[0064] In other embodiments, other manners of expansion may be utilized, for example stretchable walls or walls that are otherwise flexible may be utilized without the use of a fold or channel in a wall of the sheath **12**, or other methods may be utilized. In one embodiment, a compressible wall may be utilized to expand the sheath **12**. The sheath **12** may expand by the interior diameter **56** being increased in size, or both the interior diameter **56** and outer diameter **54** being increased in size.

[0065] The sheath **12** may be configured for a localized expansion, in which the expansion occurs at a location where an object is passing therethrough.

[0066] The sheath **12** may be configured to expand to allow for a relatively low-profile, or narrow outer diameter **54**, insertion into the patient's vasculature. The narrow outer diameter **54** may be sized to fit within the patient's vasculature with relatively low insertion push force. The narrow outer diameter **54**, however, may correspond to a narrow interior diameter **56**. The narrow interior diameter **56** may be too narrow to receive the delivery apparatus **11** or may result in relatively high insertion push force to be provided by the delivery apparatus **11**. The expansion of the sheath **12** in the direction radially outward from the lumen **32** increases the interior diameter **56** of the sheath **12** and may thus reduce the insertion push force that is needed for the delivery apparatus **11**.

[0067] The sheath **12** may be elastic, and may be biased in a direction towards the lumen **32**. The sheath **12** accordingly may attempt to contract or otherwise reduce in size. The reduction in size may occur in a variety of manners. For example, in the embodiment shown in FIG. 3, the outer tubing wall **36** may be elastic and configured to apply a force in a direction radially towards the lumen **32** upon being forced in a direction radially outward from the lumen **32** by the inner tubing wall **34**. The outer tubing wall **36**, upon expansion, may apply a compressive force to the inner tubing wall **34**. This compressive force may serve to reduce the size of the lumen **32** and the interior diameter **56** of the sheath **12**. In other embodiments, the entirety of the sheath wall may be elastic and biased in the direction radially towards the lumen **32**. In

other embodiments, other means may be utilized to bias the sheath **12** in the direction towards the lumen **32**.

[0068] The sheath **12** may be configured such that the elastic restoring force of the sheath **12** does not fully move the sheath **12** back to its pre-expanded size. For example, in the embodiment shown in FIG. 3, the sheath **12** is shown in a pre-expanded configuration. The sheath **12** has an interior diameter **56**. The sheath may be expanded by an object being passed through the lumen **32** of the sheath that has a diameter larger than the interior diameter **56** of the sheath **12**. Upon the sheath **12** being expanded, the interior diameter **56** will increase to a larger size (due to the larger diameter of the object). The outer diameter **54** may also increase to a larger size. Upon the object being passed through the sheath **12**, the sheath **12** may elastically return towards the lumen **32**, but not fully back to the size or diameter shown in FIG. 3. The resulting interior diameter **56** of the sheath may be larger than the diameter in the pre-expanded configuration, but not larger that its diameter when the object is passing through. Similarly, the resulting outer diameter **54** may be larger than the diameter in the pre-expanded configuration, but not larger that its diameter when the object is passing through. Thus, the sheath **12** may be configured for a partial return to its pre-expanded configuration and size.

[0069] The sheath **12** may be configured to be elastic (e.g., partially return to a pre-expanded configuration) to allow for a reduction in the size of the outer diameter **54** upon the delivery apparatus **11** being passed therethrough. The reduced size of the outer diameter **54** may allow for ease of removal of the sheath **12** from the patient's vasculature and reduced stress being applied to the vasculature when the delivery apparatus **11** is not positioned within the sheath **12**.

[0070] Referring to FIG. 4, the introducer **14** may be utilized to introduce the sheath **12** into the vasculature of the patient's body. The introducer **14** is configured to be positioned within the lumen of the sheath **12** to introduce the sheath **12** into the vasculature of the patient's body, as shown in FIG. 1.

[0071] FIG. 4 illustrates the introducer **14** separated from the sheath **12**. The introducer **14** comprises an elongate body having a distal end **60**, a proximal end **62** (marked in FIG. 7) and a length extending from the distal end **60** to the proximal end **62**. The introducer **14** may be configured to have a length that is greater than the length of the sheath **12**, such that a portion of the introducer **14** extends beyond the distal end **22** of the sheath **12** (marked in FIG. 2). The introducer **14** may include a tip **64**. The tip **64** may be tapered down to the distal end **60** of the

introducer **14**. The tapered distal tip **64** may be configured to extend beyond the distal end **22** of the sheath **12** when the introducer **14** is positioned within the lumen of the sheath **12**, as shown in FIGS. 1 and 7.

[0072] The introducer **14** may include an outer shaft **66** (marked in FIGS. 5 and 7) that extends along a length of the introducer **14**. The outer shaft **66** may have a proximal end **68** (marked in FIG. 7) and a distal end **70** and a length extending from the distal end **70** to the proximal end **68**. The outer shaft **66** may comprise a tube extending around a portion of the introducer, such that the portion of the introducer **14** that is within the outer shaft **66** comprises an inner shaft **72** (marked in FIGS. 5 and 7) and such that the outer shaft **66** comprises an outer tube. The introducer **14** may comprise a two-part shaft (inner shaft **72** and outer shaft **66**).

[0073] FIG. 5 illustrates a close-up view of the distal end **70** of the outer shaft **66**, with a portion cut away to show the inner shaft **72** within the outer shaft **66**. The inner shaft **72** portion may comprise a portion **74** of the introducer and the tip **64** may comprise a thicker portion **76** of the introducer **14** such that the portion **74** is a thin portion **74** and the portion **76** is a thick portion **76**. The introducer **14** may transition between the inner shaft **72** portion to the thick portion **76** at a step **75**.

[0074] A plug **78** may be coupled to the introducer **14**. The plug **78** may comprise an expandable portion of the introducer **14**. The plug **78** accordingly may be integral with the introducer **14**. The plug **78** may comprise a plurality of supports **80**. The plurality of supports **80** may be separated from each other by a respective slit **82** or other form of separation between the supports **80**. The supports **80** may comprise slats that are separated by slits **82**. The supports **80** and slits **82** may extend longitudinally along the introducer **14**.

[0075] The supports **80** may include proximal supports **84** and distal supports **86**, each of which may be configured to pivot at pivot portions **88** of the plug **78**. The proximal supports **84** and distal supports **86** may couple to each other at a pivot portion **90** of the plug **78**, which may be a central pivot portion **90**. The pivot portions **88**, **90** however, may be unpivoted, or flattened, in the position shown in FIG. 5.

[0076] A distal portion of the plug **78** may include additional supports **92** separated by slits **94**.

[0077] The plug **78** may be configured to be integral with the outer shaft **66**, as shown in FIG. 5. The supports **80** may each be integral with the outer shaft **66**. The slits **82**, **94** may comprise slits in the outer shaft **66**. As such, the plug **78** may be a portion of the outer shaft **66**, and may be activated by manipulation of the outer shaft **66**.

[0078] The plug **78** may be configured to move from a first position in which the plug **78** has a first diameter to a second position in which the plug **78** has a second diameter that is greater than the first diameter. The plug **78** is shown in FIG. 5 in a first position, in which the plug **78** is flattened, or in an unexpanded configuration or undeployed configuration. The supports **80** extend along the longitudinal axis of the introducer **14** and around the inner shaft **72** of the introducer **14**. The plug **78** has a diameter **96** in the first position. The plug **78** may move to a second position, as shown in FIG. 10A, in which the plug **78** is in an expanded configuration, or deployed configuration, and has a diameter **98** that is greater than the diameter **96**, and greater than the interior diameter **56** of the sheath **12** (marked in FIG. 3). The supports **80** in the second position extend radially outward from the introducer **14**.

[0079] The plug **78** in the first position may be configured to fit within the lumen **32** of the sheath **12**. The plug **78** may have a diameter **96** that is sized to fit within the lumen **32** of the sheath **12**. The diameter **96** may be substantially equal to or less than to the diameter **100** of the thick portion **76** of the introducer **14** (which is the outer diameter of the introducer **14**). Thus, the plug **78** in the first position may fit within the lumen **32** without increasing the size of the lumen **32** or otherwise expanding the sheath **12**. The diameter **100** of the introducer **14** may be configured to be at or less than the interior diameter **56** of the sheath **12**.

[0080] Referring to FIGS. 4 and 6, the introducer housing **20** may be positioned at the proximal end of the introducer **14**. FIG. 6 illustrates a disassembled view of the introducer housing **20**, with the outer shaft **66** and inner shaft **72** shown in cross section. An outer shaft housing **102** and an inner shaft housing **104** are shown separated from an interior chamber **106** of the introducer housing **20**.

[0081] The introducer housing **20** may be configured to couple to the sheath housing **18**. The introducer housing **20** may be configured as a control device for controlling the introducer **14** and the plug **78**. The introducer housing **20** may include an interior chamber **106**. The introducer housing **20** may include a slide channel **108** and locks **103**, **105**, **107**. The slide channel **108** may be configured as a cut-out in the body of the introducer housing **20**, and the locks **103**, **105**, **107** may be configured as cut-outs in the body of the introducer housing **20** in a transverse direction as the slide channel **108**.

[0082] The introducer housing **20** may include a distal end **109** and a proximal end **111** and a length extending from the distal end **109** to the proximal end **111**. The distal end **109** may include an opening **113** that extends around a portion of the sheath housing **18**, particularly the

coupler **21** (marked in FIG. 2). A securing device such as a securing ring **115** may extend over the body of the introducer housing **20** at the coupler **21** to couple the introducer housing **20** to the sheath housing **18**. The proximal end **111** of the introducer housing **20** may include an opening **117** for a guide wire **114** (marked in FIG. 7) to extend through. The introducer housing **20** may be configured for a user (such as a surgeon) to grip to manipulate the introducer **14** and the plug **78**.

[0083] The introducer housing **20** may include an outer shaft housing **102** and an inner shaft housing **104**. The outer shaft housing **102** and the inner shaft housing **104** may be positioned within the interior chamber **106** of the introducer housing **20**. The outer shaft housing **102** and the inner shaft housing **104** may be configured to move relative to each other to control the plug **78** and separately control the outer shaft **66** and the inner shaft **72**.

[0084] The outer shaft housing **102** may couple to the proximal end **68** of the outer shaft **66** (marked in FIG. 7). The outer shaft housing **102** may include a fluid port **110** for passing fluid such as blood to or from the patient's vasculature. Tubing **97** with a valve **99** (marked in FIG. 4) may be coupled to the fluid port **110** for passing fluid through the fluid port **110** and for sealing flow of the fluid through the fluid port **110**.

[0085] The outer shaft housing **102** may be configured to move relative to the body of the introducer housing **20** and relative to the sheath housing **18** and the inner shaft housing **104**, such that the outer shaft housing **102** and the outer shaft **66** may move relative to the inner shaft **72** and the sheath **12**.

[0086] The outer shaft housing **102** may be configured to slide longitudinally within the interior chamber **106** of the introducer housing **20** with the fluid port **110** extending through the slide channel **108**. The outer shaft housing **102** may also be configured to rotate within the body of the introducer housing **20** around the longitudinal axis that the outer shaft **66** extends along. The outer shaft housing **102** may be configured to rotate around this longitudinal axis to have the fluid port **110** rotate in and out of the lock **103** and lock **105**.

[0087] The inner shaft housing **104** may couple to the proximal end **62** (marked in FIG. 7) of the inner shaft **72**. The inner shaft housing **104** may include a control surface **112** that may be positioned exterior of the body of the introducer housing **20** when the inner shaft housing **104** is positioned within the interior chamber **106** of the introducer housing **20**. The connection between the body of the inner shaft housing **104** and the control surface **112** may extend through the slide channel **108**, such that the body of the inner shaft housing **104** is within the

interior chamber **106** and the control surface **112** is exterior. The control surface **112** may be configured for a user (such as a surgeon) to manipulate to control the inner shaft **72** and the plug **78**.

[0088] The inner shaft housing **104** may be configured to move relative to the body of the introducer housing **20** and relative to the sheath housing **18** and the outer shaft housing **102**, such that the inner shaft housing **104** and the inner shaft **72** may move relative to the outer shaft **66** and the sheath **12**.

[0089] The inner shaft housing **104** may be configured to slide longitudinally within the interior chamber **106** of the introducer housing **20**. The inner shaft housing **104** may also be configured to rotate within the body of the introducer housing **20** around the longitudinal axis that the inner shaft **72** extends along. The inner shaft housing **104** may be configured to rotate around this longitudinal axis to have the connection between the body of the inner shaft housing **104** and the control surface **112** rotate in and out of the lock **105** and lock **107**.

[0090] The introducer **14** is configured to be inserted into, and positioned within the lumen **32** of the sheath **12**, upon the introducer **14** and sheath **12** being introduced into the patient's vasculature. The introducer **14** preferably comprises a rigid body with sufficient strength to guide the sheath **12** into the patient's vasculature, with sufficient flexibility to allow for flexible movements of the introducer **14** and sheath **12** together. The tapered tip **64** of the introducer is preferably shaped to improve ease of penetration and access of the patient's vasculature by opening the interior of the vasculature as the introducer **14** and sheath **12** together are inserted into the vasculature. The tip **64** may be configured to be soft and flexible to reduce the possibility of damaging the patient's vasculature.

[0091] The sheath **12** and introducer **14** may be configured to be held in an insertion configuration in which the sheath **12** is positioned around the introducer **14** when introduced into the patient's vasculature. An insertion configuration is shown in FIG. 1. The sheath **12** and introducer **14** may be held in position relative to each other by the coupling between the sheath housing **18** and the introducer housing **20**. The tip **64** of the introducer **14** extends beyond the distal end **22** of the sheath **12**. The introducer **14** is held in position relative to the sheath **12** such that a length of the introducer **14** extends beyond the distal end **22** of the sheath **12** and the plug **78** is within the lumen of the sheath **12**. This position of the introducer **14** and the plug **78** relative to the sheath **12** may be referred to as an insertion position, for introduction into the patient's vasculature.

[0092] The sheath **12** and introducer **14** in the insertion configuration may be introduced into the patient's vasculature by being slid over a guide wire **114** (marked in FIG. 7) that has been previously introduced into the patient's vasculature. The sheath **12** in this configuration is preferably sized to fit within the vasculature of the patient, and has a relatively low profile, or narrow outer diameter.

[0093] FIG. 7 illustrates a cross sectional view of the system shown in FIG. 1 along a midline of the system.

[0094] As shown in FIG. 7, the introducer **14**, including the inner shaft **72** of the introducer **14**, may include an internal channel **116** that extends along its length, from the distal end **60** of the introducer **14** to the proximal end **62** of the introducer **14** (the proximal end of the inner shaft **72**). The channel **116** is configured to receive a guide wire **114** that the introducer **14** extends over when the introducer **14** is inserted into the vasculature of the patient's body.

[0095] The tip **64** of the introducer **14** may couple to the inner shaft **72** portion of the introducer **14** via a threaded connection **118**. In other embodiments, other forms of connections may be utilized.

[0096] The outer shaft **66** is shown to extend over the inner shaft **72** from the distal end **70** of the outer shaft **66** to the proximal end **68** of the outer shaft **66**. The plug **78** is in the first position and positioned within the sheath **12**.

[0097] The outer tubing wall **36** of the sheath **12** is shown extending over the inner tubing wall **34** of the sheath **12**, which accordingly extends over the introducer **14** and the plug **78**. The channel **44** of the sheath **12** is shown extending proximally from the distal end **22** of the sheath **12**. The sheath **12** at the distal end **22** may be configured with a taper to allow for a smooth tapered transition between the introducer **14** and the sheath **12** at a distal opening **119** of the sheath **12**. The distal opening **119** may be at the distal end **22** of the sheath **12** and configured for the introducer **14** and plug **78** to pass therethrough.

[0098] The proximal end **24** of the sheath **12** may couple to an outer housing **120**, or distal housing, of the sheath housing **18**. The outer housing **120** may be threaded or otherwise coupled to an inner housing **122**, or proximal housing, of the sheath housing **18**. The inner housing **122** may include the interior chamber **19** that may transfer fluids to or from the system, for example, via the fluid port **28**, and may receive the introducer **14**, including the inner shaft **72** and outer shaft **66**. A movable wall **124** comprising a plurality of flaps may be positioned

in the interior chamber **19** and may form a seal around the introducer **14** when the introducer **14** is positioned within the sheath **12** and passes through the movable wall **124**.

[0099] The introducer housing **20** is shown coupled to the coupler **21**. The introducer housing **20** may be positioned over the coupler **21**. The securing ring **115** may extend over the introducer housing **20** at the coupler **21** to couple the introducer housing **20** to the sheath housing **18** with a press fit or the like.

[0100] The outer shaft housing **102** is shown positioned within the interior chamber **106** of the introducer housing **20**. A seal **128** may be positioned within the outer shaft housing **102** and may seal the connection between the outer shaft housing **102** and the inner shaft **72** such that fluid does not leak when the outer shaft housing **102** moves relative to the inner shaft **72**.

[0101] The outer shaft housing **102** in FIG. 7 is locked in position relative to the other components of the system. The locked position in FIG. 7 is caused by the fluid port **110** being positioned in the lock **105**. The locked position prevents the outer shaft housing **102** and the outer shaft **66** from sliding relative to other components of the system.

[0102] The inner shaft housing **104** is shown to include an internal channel **131** that allows the guide wire **114** and the proximal end **62** of the introducer **14** to pass therethrough.

[0103] The inner shaft housing **104** in FIG. 7 is locked in position relative to the other components of the system. The locked position in FIG. 7 is caused by the connection between the body of the inner shaft housing **104** and the control surface **112** being positioned in the lock **107** (the lock **107** is shown in FIG. 6). The locked position prevents the inner shaft housing **104** and the inner shaft **72** from sliding relative to other components of the system.

[0104] The system shown in FIG. 7 is in a configuration for insertion into the patient's vasculature. The components are preferably locked in position relative to each other such that the components do not slide or otherwise move relative to each other upon insertion, aside from the system sliding along the guide wire **114**.

[0105] Upon the system being placed in the desired position within the patient's body, the plug **78** may be activated from the first position to the second position and the introducer **14** may be withdrawn from the sheath **12**. Such an operation leaves the sheath **12** in position within the patient's vasculature, in position to introduce a delivery apparatus (such as delivery apparatus **11** shown in FIG. 18).

[0106] FIGS. 8A and 8B illustrate a step in the movement of the plug **78** from the first position to the second position. In FIG. 8A, the introducer **14** and plug **78** have been moved to an advanced configuration, in an advanced position distally beyond the opening **119** of the sheath **12**. The introducer **14** and plug **78** have slid distally relative to the sheath **12**. The sliding movement of the introducer **14** and plug **78** may be by a defined distance. The introducer **14** and plug **78** slide relative to the guide wire **114** (shown in FIG. 7). The plug **78** preferably remains in the first position during this movement to the advanced position. Preferably the sheath **12** does not slide within the patient's vasculature during this movement. In an embodiment in which the plug **78** is coupled to, or a part of the outer shaft **66**, the outer shaft **66** may slide relative to the sheath **12** as well to move the plug **78** into the desired position.

[0107] Referring to FIG. 13A, a cross sectional view of the introducer **14** is shown along line B-B in FIG. 8A. The plurality of supports **80** are shown to extend along the inner shaft **72** and are separated by slits **82**.

[0108] The movement of the introducer **14** and plug **78** in FIG. 8A may be produced by the movement of the outer shaft housing **102** and the inner shaft housing **104** relative to the body of the introducer housing **20**. FIG. 8B shows the movement of the housings **102**, **104**. In FIG. 8B, the outer shaft housing **102** has released from the lock **105** by being rotated out of the lock **105**. The outer shaft housing **102** may rotate around the longitudinal axis that the outer shaft **66** extends along to rotate out of the lock **105**. The inner shaft housing **104** may also rotate out of the lock **107**. Upon both housings **102**, **104** being unlocked, they may each slide longitudinally within the introducer housing **20** and slide distally to the distal end of the slide channel **108**. The housings **102**, **104** may slide a defined length to correspondingly extend the introducer **14** and plug **78** the defined length from the opening **119** of the sheath **12** shown in FIG. 8A. The introducer **14** accordingly may be sized to have a length that is greater than the sheath **12** by at least the length of the plug **78** in the first position, to allow the plug **78** to be slid out from the end of the sheath **12**. The outer shaft housing **102**, and particularly the fluid port **110**, may rotate within the introducer housing **20** to lock into lock **103**.

[0109] Upon the outer shaft housing **102** being locked into lock **103**, the outer shaft **66** and accordingly the plug **78** may be held in position relative to the sheath **12**. The inner shaft **72**, however, may be able to slide proximally relative to the outer shaft **66**, the plug **78**, and the sheath **12**. This movement may be available because the inner shaft housing **104** is not locked relative to the introducer housing **20**. The inner shaft housing **104** may slide longitudinally

proximally relative to the introducer housing **20**, with the outer shaft housing **102** being locked into lock **103**, to retract the inner shaft **72** relative to the plug **78**.

[0110] FIG. 9 illustrates a view of the inner shaft **72** of the introducer **14** being partially retracted, or partially slid proximally, relative to the plug **78**. The plug **78** is in an intermediate position between the first position (as represented in FIG. 8A) and the second position (as represented in FIG. 10A). The arrow shown in FIG. 9 illustrates the movement of the inner shaft **72** of the introducer **14** relative to the plug **78**. A portion of the introducer **14**, for example the step **75** of the introducer **14**, may press against the plug **78** in the proximal direction to apply a force to the plug **78**. The force of the introducer **14** applied by the introducer **14** to the plug **78** causes the plug to move from the first position to the second position. The force of the introducer **14** against the plug **78** may cause the distal portion of the plug **78** to overlap the thick portion **76** of the introducer **14**. The slits **94** may allow for expansion of the distal portion such that the distal portion flares open and may form an angled portion of the plug **78** tapering outward in the distal direction.

[0111] The supports **80** may bow outward from the inner shaft **72** of the introducer **14**. The proximal supports **84** and distal supports **86** may each pivot at opposite angles relative to each other. The proximal supports **84** and distal supports **86** may each pivot about respective pivot portions **88**, **90**.

[0112] The inner shaft **72** of the introducer **14** may continue to slide proximally relative to the sheath **12** and outer shaft **66** until the inner shaft **72** of the introducer **14** reaches a position shown in FIG. 10A. The plug **78** may be positioned on the introducer **14** such that the plug **78** moves from the first position to the second position at a position distal the opening **119** of the sheath **12**, and exterior of the lumen of the sheath **12**, when the introducer **14** is positioned within the lumen **32**. The introducer **14** has continued to apply a force against the plug **78** in the proximal direction until the proximal supports **84** have overlapped the distal supports **86**. The distal supports **86** have folded under the respective proximal supports **84**. The supports **80** are configured to bend to move the plug **78** from the first position to the second position. The respective supports **80** overlap upon itself in the second position. The supports in this configuration form a plurality of protrusions extending outward from the introducer **14**. The distal portion of the plug **78** that overlaps the thick portion **76** of the introducer **14** forms a bump **127** that the supports **84**, **86** are positioned over, and the bump **127** supports the supports **84**, **86** to increase the diameter **98** of the plug **78**. The supports **84**, **86** together form a conical shape tapering outward in the distal direction. The plug **78** in this position (the second position)

has a diameter **98** that is greater than the diameter **96** of the plug in the first position (as shown in FIG. 5), and is greater than the interior diameter **56** of the sheath **12**, as is marked in FIG. 3. The plug **78** in this position is in a deployed configuration, or expanded configuration.

[0113] The plug **78** in the second position extends radially outward from the introducer **14**. The plug **78** in the second position has a length that is less than the length of the sheath **12** and is configured to slide within the lumen **32** in a direction from the distal end **22** of the sheath **12** towards the proximal end **24** of the sheath **12** to expand the sheath **12** in a direction radially outward from the lumen **32**. The length of the plug **78** in the second position may, in one embodiment, be less than 2% the length of the sheath **12**. The length of the plug **78** in the second position may in one embodiment be less than 5% the length of the sheath **12**. The length of the plug **78** in the second position may in one embodiment be less than 10% the length of the sheath **12**. The length of the plug **78** in the second position in other embodiments may be less than 20%, 30%, 40% or 50% the length of the sheath **12**, among other lengths. The plug **78** may be positioned on the introducer **14** such that the entirety of the plug **78** in the second position is closer to the distal end **60** of the introducer **14** than the proximal end **62** of the introducer **14**.

[0114] Referring to FIG. 13B, a cross sectional view of the introducer **14** is shown along line C-C in FIG. 10A. The plurality of supports **80** are shown to extend outward radially from the inner shaft **72**. The number of supports **80** is shown to be six in FIG. 13B, however, in other embodiments the number may be greater or lesser. In one embodiment, one support may be utilized.

[0115] FIG. 10B illustrates the position of the outer shaft housing **102** and the inner shaft housing **104** relative to the introducer housing **20** when the plug **78** is in the position shown in FIG. 10A. The introducer housing **20** remains coupled to the sheath housing **18**. The outer shaft housing **102** remains locked in the lock **103**. The inner shaft housing **104**, however, has slid proximally relative to the outer shaft housing **102** and has been placed into lock **105** by being rotated into lock **105**. The distance between the outer shaft housing **102** and the inner shaft housing **104** may be a defined distance, defining a relative distance of movement between the inner shaft **72** of the introducer **14** and the plug **78**.

[0116] Upon the plug **78** being moved to the second position, and the outer shaft housing **102** and the inner shaft housing **104** being locked in position in the introducer housing **20**, the introducer housing **20** may be released from the sheath housing **18**. The securing device such

as the securing ring **115** may be released and the introducer housing **20** may be pulled proximally from the sheath housing **18**. The plug **78** may enter the opening **119** of the sheath **12** and slide relative to the sheath **12** within the lumen of the sheath **12**.

[0117] FIG. 11A illustrates the plug **78** and introducer **14** being slid proximally within the lumen of the sheath **12**. The plug **78** has entered the opening **119** of the sheath **12**. FIG. 11B illustrates the configuration of the introducer housing **20** in which the introducer housing **20** is released from the sheath housing **18** and moved proximally. The movement of the introducer housing **20** retracts or withdraws the introducer **14** from the sheath **12**, while leaving the sheath **12** in place within the patient's vasculature.

[0118] The increased diameter of the plug **78** in the second position, as the plug **78** is slid proximally through the sheath's **12** lumen causes the sheath **12** to expand. The interior diameter **56** and lumen **32** (marked in FIG. 3) of the sheath **12** are increased by the radial pressing force applied by the plug **78** to the interior surface **38** of the sheath **12** (also marked in FIG. 3).

[0119] The plug **78** preferably has a length that is less than the length of the sheath **12**, such that as the plug **78** is slid proximally through the lumen of the sheath **12**, a transient expansion of the sheath **12** occurs. Thus, only a portion of the sheath **12** has a force applied to it and has a localized expansion caused by the plug **78** at a given moment. The plug **78** may be coupled to the introducer **14** such that withdrawal of the introducer **14** through the lumen **32** in the proximal direction causes the plug **78** to enter the opening **119** of the sheath **12** and slide within the lumen **32** in the proximal direction to transiently expand the sheath **12** in the direction radially outward from the lumen **32**. The transient force to a portion of the sheath **12** allows for a lesser force to be applied to the sheath **12** than if the entirety of the sheath **12** were expanded at once. In addition, the sliding motion of the plug **78** reduces static friction that may exist between the plug **78** and the interior surface of the sheath **12**. The sliding motion also reduces the possibility of the plug **78** becoming stuck in the lumen, due to the kinetic energy provided to the plug **78** and the reduction of adhesive forces that may exist between the outer surface of the plug **78** and the interior surface of the sheath if the plug **78** were deployed within the lumen.

[0120] FIG. 12A illustrates the transient expansion of the sheath **12**. The plug **78** is being slid proximally relative to the sheath **12**. The location of the plug **78** within the sheath is marked in FIG. 12A as reference number **129**. The plug **78** may expand the sheath **12** at the position of the plug **78** and may leave an increased size in the sheath **12** in the distal portion of the

sheath **12**. FIG. 12B illustrates a representation of the movement of the plug **78** within the sheath **12**. In FIG. 12B, the plug **78** has not yet passed through the proximal portion of the sheath **12** marked as portion **130**. The plug **78** is within the portion of the sheath **12** marked as portion **132**. The plug **78** has passed through the portion of the sheath **12** marked as portion **134**. The diameter of the sheath **12** at portion **132** is larger than in portion **130** because the plug **78** has not yet passed through portion **130**. The diameter of the sheath **12** at portion **134** may be less than the diameter at portion **132** because the sheath may be elastic and biased in a direction radially towards the lumen. The plug **78** accordingly may be configured to transiently expand a distal portion of the sheath **12**, and then a central portion of the sheath **12**, and then a proximal portion of the sheath **12** in successive order, rather than expanding a distal, central, and proximal portion of the sheath **12** all at one time. The plug **78** may be sized or have a length relative to the length of the sheath **12** to only expand a portion of the sheath **12** at one time.

[0121] The sheath **12** may be configured to partially return to a pre-expanded configuration, as discussed previously. The difference in diameter between portion **134** and portion **130**, however, may decrease the insertion push force of a delivery apparatus inserted through the sheath **12** after the introducer **14** and plug **78** have been removed from the sheath **12**.

[0122] The plug **78** and introducer **14** may continue to be withdrawn from the sheath **12** until completely removed from the lumen of the sheath **12**. Upon their removal, a delivery apparatus such as the apparatus **11** shown in FIG. 18 may be inserted into the sheath **12** in a distal direction with a reduced pushing force due to the expanded lumen size.

[0123] The system allows for insertion of the sheath **12** and the introducer **14** into the patient's vasculature with a relatively low-profile, or narrow outer diameter. As the introducer **14** is removed from the sheath **12** to leave the sheath **12** positioned within the patient's vasculature, the plug **78** serves to expand the sheath **12**, providing a larger lumen **32** size and larger interior diameter **56**. The sheath **12** may partially return to a pre-expanded configuration upon the plug passing therethrough (as marked as portion **134** in FIG. 12B), however, the enhanced size of the sheath **12** nonetheless reduces insertion push force required for the delivery apparatus to be inserted through the sheath **12**. The sheath **12** accordingly may be preconditioned for introduction of the delivery apparatus via a plug **78** integrated with the introducer **14**.

[0124] The system provides benefits over prior methods of sheath expansion. In prior methods, once the introducer (without a plug) is removed from the sheath, one or more dilator rods may

be inserted through the sheath in the distal direction to progressively expand the size of the sheath. These prior methods may include multiple steps (e.g., insert sheath and introducer, remove introducer, insert and remove multiple dilator rods) before insertion of the delivery apparatus. The system may alleviate these issues by allowing removal of the introducer with the expanded plug to expand the sheath, without multiple dilator rods needing to be inserted into the sheath. The system may thus provide a reduced number of steps during a medical procedure.

[0125] In other prior methods, the delivery apparatus is simply pushed through the sheath without the sheath being pre-expanded by a dilator rod or otherwise.

[0126] FIG. 17 illustrates a chart of reduced push force of the delivery apparatus through an expanded sheath **12** of the system. The vertical axis of the chart displays push force in Newtons. The horizontal axis corresponds to select portions of the sheath **12** (the seal **46**, the body of the sheath **12** between the seal and the tip, and the tip at the distal end **22** of the sheath **12**).

[0127] The lower bars **136**, **138**, **140** in the chart correspond to the push force required for a delivery apparatus through a sheath that has been pre-expanded according to the systems, apparatuses, and methods of the present disclosure. The bar **136** corresponds to the push force required at the seal **46**. The bar **138** corresponds to the push force required through the body of the sheath **12** between the seal and the tip. The bar **140** corresponds to the push force required through the tip at the distal end **22** of the sheath **12**.

[0128] The upper bars **142**, **144**, **146** in the chart correspond to the push force required for a delivery apparatus through an expandable sheath that has not been pre-expanded according to the present disclosure. The bar **142** corresponds to the push force required at a seal of the unexpanded sheath. The bar **144** corresponds to the push force required through the body of the unexpanded sheath between the seal and the tip. The bar **146** corresponds to the push force required through the tip at a distal end of the unexpanded sheath.

[0129] The push force is shown to reduce for the pre-expanded sheath according to the systems, apparatuses, and methods of the present disclosure. The push force at the seal **46** is approximately 15% less for the pre-expanded sheath according to the present disclosure (about 18N versus 21N). The push force through the body of the unexpanded sheath between the seal and the tip is approximately 18% less for the pre-expanded sheath according to the present disclosure (about 15.5N versus 19N). The push force at the tip at a distal end of the unexpanded

sheath is approximately 27% less for the pre-expanded sheath according to the present disclosure (about 22.5N versus 31N).

[0130] Accordingly, the systems, apparatuses, and methods of the present disclosure may result in a reduced push force for a delivery apparatus, as well as reducing a number of steps performed during a medical procedure, among other beneficial results.

[0131] FIGS. 14A–16C illustrate variations of embodiments of systems for introducing a delivery apparatus into a patient's vasculature. The features of the embodiments of FIGS. 14A–16C may be utilized with or applied to the embodiments of FIGS. 1–13B, and the features of the embodiments of FIGS. 1–13B may be utilized with or applied to the embodiments of FIGS. 14A–16C.

[0132] FIGS. 14A, B, and C illustrate an embodiment of a system **148** in which the plug **150** comprises an inflatable body. The plug **150** may comprise an expandable portion of the introducer **154** that is coupled to the introducer **154**. The system includes a sheath **152**, and an introducer **154**. The sheath **152** may be configured similarly as the sheath **12** in the embodiments of FIGS. 1–13B. The system may include a control housing **156** that may be positioned at a proximal end of the system and may include a sheath housing **158** and an introducer housing **160**. A fluid port **162** may couple to the sheath housing **158** for passing fluid through the sheath **152**. Tubing **164** may be coupled to the fluid port **162** for passing fluid through the fluid port **162**, and may include a valve for sealing flow of the fluid through the fluid port **162**. A fluid port **166** may couple to the introducer housing **160** for passing fluid through the introducer **154** and to the plug **150**. Tubing **168** may be coupled to the fluid port **166** for passing fluid through the fluid port **166**, and may include a valve for sealing flow of the fluid through the fluid port **166**. The sheath **152** and introducer **154** may be inserted into the patient's vasculature in a similar manner as the system discussed in regard to FIGS. 1–13B.

[0133] FIG. 14A illustrates the system in an insertion configuration, in which the introducer **154** is positioned within the sheath **152** and the plug **150** and introducer **154** are in an insertion position within the sheath **152**. The plug **150** is flattened, or in an unexpanded configuration or undeployed configuration, within the sheath **152**. The sheath housing **158** and introducer housing **160** may be locked in position relative to each other to lock the corresponding sheath **152** and introducer **154** in position relative to each other and to secure the plug **150** within the lumen of the sheath **152**.

[0134] A cut-away portion of the sheath **152** and introducer **154** is shown in FIG. 14A. The introducer **154** may include an internal lumen **169** configured to convey a fluid or other material to or from the plug **150**. The internal lumen **169** may be utilized to inflate the plug **150** with fluid, which may be provided by the fluid port **166** and tubing **168**. The introducer **154** may also include an internal channel **155**, similar to the channel **116** of the introducer **14**, for receiving a guide wire.

[0135] FIG. 14B illustrates the system in an advanced configuration, in which the introducer is advanced distally through the sheath **152** and the plug **150** is exterior of the sheath **152**. The plug **150** and introducer **154** are in an advanced position distal of the sheath **152**. The plug **150** is flattened, or in an unexpanded configuration or undeployed configuration. The plug **150** may be in the first position, which may be a deflated state of the plug **150**. The introducer housing **160** may be advanced distally towards the sheath housing **158** to advance and expose the plug **150**.

[0136] In the advanced position, the plug **150** may be inflated to move to the second position and increase the diameter of the plug **150**.

[0137] FIG. 14C illustrates the plug **150** inflated to the second position, or the expanded configuration, or deployed configuration. The plug **150** in the second position has a length that is less than the length of the sheath **152** and has a diameter that is larger than the interior diameter of the sheath **152**. The plug **150** may extend radially outward from the introducer **154**. The plug **150** may comprise an inflatable body such as a balloon. The plug **150** may have a tapered shape that tapers outward from a proximal portion of the plug **150** to a distal portion of the plug **150**. The plug **150** may have a conical shape to ease entry into the sheath **152** when the plug **150** is pulled proximally. The plug **150** may be activated to the second position by being inflated via fluid passing through the fluid port **166**.

[0138] The plug **150** may be pulled through the sheath **152** in a similar manner as discussed in regard to FIGS. 1–13B. The plug **150**, when retracted or withdrawn through the sheath **152** serves to expand the sheath **152** in a similar manner as discussed in regard to FIGS. 1–13B. A transient expansion may result, as discussed in regard to the embodiments of FIGS. 1–13B.

[0139] FIGS. 15A, B, and C, illustrate an embodiment of a system in which the plug **170** comprises a bellows structure. The system includes a sheath **172** and an introducer **174**. The sheath **172** may be configured similarly as the sheath **12** in the embodiments of FIGS. 1–13B. The plug **170** may comprise an expandable portion of the introducer **174** that is coupled to the

introducer **174**. The system may also include a control housing positioned at a proximal end of the system and may include a sheath housing and an introducer housing in a similar manner as discussed in regard to FIGS. 1–13B.

[0140] FIG. 15A illustrates a close-up view of the distal end **176** of the sheath **172**, with a portion cut-away. The introducer **174** may include an inner shaft **171** and an outer shaft **173** in a similar manner as discussed in regard to FIGS. 1–13B. The inner shaft **171** may include an internal channel **175**, similar to the channel **116** of the introducer **14**, for receiving a guide wire.

[0141] The plug **170** may be integral with the outer shaft **173**. The introducer **174** may include a thicker portion **177** coupled to the thinner portion (represented by inner shaft **171**) at a step **179**.

[0142] The plug **170** may comprise a plurality of supports **178** separated by respective pivot portions **180**. The supports **178** may comprise walls and the pivot portions **180** may comprise creases between the walls. The supports **178** may be coupled to the outer shaft **173** of the introducer **174** in a similar manner as the supports **80** of the plug **78** in FIGS. 1–13B.

[0143] The introducer **174** and plug **170** may be positioned within the lumen of the sheath **172** in an insertion configuration, for insertion together into the patient's vasculature. The plug **170** and introducer **174** may be in an insertion position within the sheath **172**. The plug **170** may be flattened, or in an unexpanded configuration or undeployed configuration. The plug **170** may be in the first position.

[0144] FIG. 15A illustrates the system in the advanced configuration. The introducer **174** and plug **170** may move to an advanced position, distal of the distal end **176** of the sheath **172** in a similar manner as discussed in regard to the embodiments of FIGS. 1–13B. The plug **170** is positioned exterior of the lumen of the sheath **172**. The plug **170** remains in the first position, and is flattened or in an undeployed or unexpanded configuration.

[0145] FIG. 15B illustrates the plug **170** in the second position, or in an expanded configuration, or deployed configuration. The plug **170** has compressed such that the supports **178**, in the form of walls, bend to increase the diameter of the plug **170**. The supports **178** bend to move the plug **170** from the first position to the second position. The supports **178** extend radially outward from the introducer **174**. The extension of the supports **178** outward from the introducer **174** increases the diameter of the plug **170** to be greater than the interior diameter of the sheath **172**. The plug **170** may be activated from the first position to the second position

by the force of the thicker portion **177** or step **179** against the plug **170**, in a similar manner as discussed in regard to the embodiments of FIGS. 1–13B. The plug **170** in the second position has a length that is less than the length of the sheath **172**.

[0146] FIG. 15C illustrates the plug **170** retracted or withdrawn through the sheath **172**. The plug **170** may be pulled through the sheath **172** in a similar manner as discussed in regard to FIGS. 1–13B. The plug **170**, when pulled through the sheath **172** serves to expand the sheath **172** in a similar manner as discussed in regard to FIGS. 1–13B. A transient expansion may result, as discussed in regard to the embodiments of FIGS. 1–13B.

[0147] FIGS. 16A, B, and C, illustrate an embodiment of a system in which the plug **182** comprises a self-expanding structure. The system includes a sheath **184** and an introducer **186**. The sheath **184** may be configured similarly as the sheath **12** in the embodiments of FIGS. 1–13B. The plug **182** may comprise an expandable portion of the introducer **186** that is coupled to the introducer **186**. The system may also include a control housing positioned at a proximal end of the system and may include a sheath housing and an introducer housing in a similar manner as discussed in regard to FIGS. 1–13B.

[0148] FIG. 16A illustrates a close-up view of the distal end **188** of the sheath **184**, with a portion cut-away. The introducer **186** may include an inner shaft **190** and an outer shaft **192** in a similar manner as discussed in regard to FIGS. 1–13B. The inner shaft **190** may include an internal channel **191**, similar to the channel **116** of the introducer **14**, for receiving a guide wire. The plug **182** may be integral with the outer shaft **192**. The introducer **186** may include a thicker portion **194** coupled to the thinner portion (represented by inner shaft **190**) at a step **196**.

[0149] The plug **182** may comprises a plurality of supports **198** slidably disposed along the inner shaft **190**. The supports **198** may comprise arms and may be made of a self-expanding material such as nitinol. The self-expanding material may be configured to automatically expand upon being moved exterior of the lumen of the sheath **184**. Nitinol, for example, may respond to the patient's body heat to transform into an expanded configuration upon being moved exterior of the lumen of the sheath **184**. The supports **198** may be coupled to the outer shaft **192** of the introducer **186** in a similar manner as the supports **80** of the plug **78** in FIGS. 1–13B.

[0150] The introducer **186** and plug **182** may be positioned within the lumen of the sheath **184** in an insertion configuration, for insertion together into the patient's vasculature. The plug **182**

and introducer **186** may be in an insertion position within the sheath **184**. The plug **182** may be flattened, or in an unexpanded configuration or undeployed configuration. The plug **182** may be in the first position.

[0151] FIG. 16A illustrates the system in the advanced configuration. The introducer **186** and plug **182** may be moved to an advanced position distal of the distal end **188** of the sheath **184** in a similar manner as discussed in regard to the embodiments of FIGS. 1–13B. The plug **182** is positioned exterior of the lumen of the sheath **184**. The plug **182** remains in the first position, and is flattened or in an undeployed or unexpanded configuration.

[0152] FIG. 16B illustrates the plug **182** in the second position, or in an expanded configuration, or deployed configuration. The supports **198** of the plug **182** have self-expanded to a larger configuration outward from the introducer **186** to increase the diameter of the plug **182** to be greater than the interior diameter of the sheath **184**. The supports **198** extend radially outward from the introducer **186**. The supports **198** bend to move the plug **182** from the first position to the second position. The plug **182** in the second position has a length that is less than the length of the sheath **184**. The plug **182** may be activated from the first position to the second position by being moved exterior of the lumen of the sheath **184**, and the plug **182** may self-expand to the second position.

[0153] FIG. 16C illustrates the plug **182** retracted or withdrawn through the sheath **184**. The plug **182** may be pulled through the sheath **184** in a similar manner as discussed in regard to FIGS. 1–13B. The plug **182**, when pulled through the sheath **184** serves to expand the sheath **184** in a similar manner as discussed in regard to FIGS. 1–13B. A transient expansion may result, as discussed in regard to the embodiments of FIGS. 1–13B.

[0154] FIG. 19 illustrates a method that may utilize the systems and apparatuses disclosed herein. The method may comprise a method of pre-conditioning a sheath for introduction of a delivery apparatus therethrough. The method may first include a step **200** of inserting a guide wire into a patient's vasculature. The step may include accessing the patient's vasculature and passing the guide wire therein until reaching the desired position within the patient's body. The method may then include a step **202** of inserting an introducer and a sheath into the patient's vasculature over the guide wire. The introducer and sheath may be configured as the embodiments of the introducers and sheaths disclosed herein. The sheath may extend around the introducer and may have a distal end and a proximal end and may have a lumen, and may be configured to expand in a direction radially outward from the lumen. The introducer may

be positioned within the lumen of the sheath upon introduction, as disclosed herein. The sheath and introducer may be in an insertion configuration, with the introducer and plug, or expandable portion of the introducer, in an insertion position within the lumen of the sheath. The plug, or expandable portion of the introducer, may be flattened or in an unexpanded or undeployed configuration within the lumen of the sheath upon insertion into the patient's vasculature.

[0155] The method may include a step **204** of activating the plug, or expandable portion of the introducer, positioned within the patient's vasculature to move from a first position in which the plug has a first diameter to a second position in which the plug has a second diameter that is greater than an interior diameter of the sheath. The step of activating may include any of the methods disclosed herein, including advancing the plug, or expandable portion of the introducer, beyond the distal end of the sheath and pressing against the plug, inflating the plug, or simply extending the plug beyond the distal end of the sheath in a self-expanding embodiment (e.g., an embodiment using nitinol or the like), including other methods of activation.

[0156] The method may include a step **206** of sliding the plug, or the expandable portion of the introducer, through the lumen of the sheath in a direction from the distal end of the sheath towards the proximal end of the sheath to expand the sheath in the direction radially outward from the lumen. The plug, or expandable portion of the introducer, is in the second position with a diameter greater than the interior diameter of the sheath. The expansion of the sheath may comprise a transient expansion, as disclosed herein.

[0157] Additional steps may include introducing a delivery apparatus through the pre-expanded sheath, in a manner disclosed herein.

[0158] The steps of the method may be modified, excluded, or added to, with systems, apparatuses, and methods disclosed herein. Methods are not limited to the method described in regard to FIG. 19, and may also include any other means or methods disclosed herein.

[0159] The embodiments of systems, apparatuses, and methods disclosed herein may be modified or combined as desired. The sheaths disclosed herein may have a variety of shapes, including a cylindrical cross section, rectangular cross section, or other shape, for example a hexagonal cross section or other shape. The introducers disclosed herein may have a variety of shapes with a different structure than disclosed herein. The means for activating the plug may be varied, for example the configuration of locks in the introducer housing may be varied

or a different apparatus for activating the plug may be used. The configuration of the housings disclosed herein may be varied, or may be excluded in certain embodiments.

[0160] Any of the systems, apparatuses, and methods disclosed herein may be modified to utilize self-expanding materials or structures, such as nitinol. For example, the plug **78** described in regard to FIGS. 1–13B may be modified to be self-expanding, and utilize a material such as nitinol.

[0161] The materials used in the sheaths and introducers and plugs disclosed herein may be varied as desired. The introducers may be made of HDPE or LDPE or other materials as desired. The plugs, or expandable portions of the introducers, may be made of nylon, HDPE, a shape memory material (such as nitinol), ABS, PEBAX, or urethane, or other materials.

[0162] The sizes of the sheaths utilized may be varied as desired. In one embodiment a 14-F sheath, with a 5.9 millimeter outer diameter may be utilized. In other embodiments, a lesser or greater outer diameter may be utilized. A 16-F, 18-F, or 20-F size sheath, or other size sheath may be utilized as desired. In one embodiment, a sheath having a length of 36 centimeters, or a lesser or greater length may be utilized.

[0163] The features of the sheaths may be implemented independently of the introducers, which may also be implemented independently of the plugs. The various apparatuses of the system may be implemented independently.

[0164] In closing, it is to be understood that although aspects of the present specification are highlighted by referring to specific embodiments, one skilled in the art will readily appreciate that these disclosed embodiments are only illustrative of the principles of the subject matter disclosed herein. Therefore, it should be understood that the disclosed subject matter is in no way limited to a particular methodology, protocol, and/or reagent, etc., described herein. As such, various modifications or changes to or alternative configurations of the disclosed subject matter can be made in accordance with the teachings herein without departing from the spirit of the present specification. Lastly, the terminology used herein is for the purpose of describing particular embodiments only, and is not intended to limit the scope of systems, apparatuses, and methods as disclosed herein, which is defined solely by the claims. Accordingly, the systems, apparatuses, and methods are not limited to that precisely as shown and described.

[0165] Certain embodiments of systems, apparatuses, and methods are described herein, including the best mode known to the inventors for carrying out the same. Of course, variations on these described embodiments will become apparent to those of ordinary skill in the art upon

reading the foregoing description. The inventor expects skilled artisans to employ such variations as appropriate, and the inventors intend for the systems, apparatuses, and methods to be practiced otherwise than specifically described herein. Accordingly, the systems, apparatuses, and methods include all modifications and equivalents of the subject matter recited in the claims appended hereto as permitted by applicable law. Moreover, any combination of the above-described embodiments in all possible variations thereof is encompassed by the systems, apparatuses, and methods unless otherwise indicated herein or otherwise clearly contradicted by context.

[0166] Groupings of alternative embodiments, elements, or steps of the systems, apparatuses, and methods are not to be construed as limitations. Each group member may be referred to and claimed individually or in any combination with other group members disclosed herein. It is anticipated that one or more members of a group may be included in, or deleted from, a group for reasons of convenience and/or patentability. When any such inclusion or deletion occurs, the specification is deemed to contain the group as modified thus fulfilling the written description of all Markush groups used in the appended claims.

[0167] Unless otherwise indicated, all numbers expressing a characteristic, item, quantity, parameter, property, term, and so forth used in the present specification and claims are to be understood as being modified in all instances by the term "about." As used herein, the term "about" means that the characteristic, item, quantity, parameter, property, or term so qualified encompasses an approximation that may vary, yet is capable of performing the desired operation or process discussed herein.

[0168] The terms "a," "an," "the" and similar referents used in the context of describing the systems, apparatuses, and methods (especially in the context of the following claims) are to be construed to cover both the singular and the plural, unless otherwise indicated herein or clearly contradicted by context. All methods described herein can be performed in any suitable order unless otherwise indicated herein or otherwise clearly contradicted by context. The use of any and all examples, or exemplary language (e.g., "such as") provided herein is intended merely to better illuminate the systems, apparatuses, and methods and does not pose a limitation on the scope of the systems, apparatuses, and methods otherwise claimed. No language in the present specification should be construed as indicating any non-claimed element essential to the practice of the systems, apparatuses, and methods.

[0169] All patents, patent publications, and other publications referenced and identified in the present specification are individually and expressly incorporated herein by reference in their entirety for the purpose of describing and disclosing, for example, the compositions and methodologies described in such publications that might be used in connection with the systems, apparatuses, and methods. These publications are provided solely for their disclosure prior to the filing date of the present application. Nothing in this regard should be construed as an admission that the inventors are not entitled to antedate such disclosure by virtue of prior invention or for any other reason. All statements as to the date or representation as to the contents of these documents is based on the information available to the applicants and does not constitute any admission as to the correctness of the dates or contents of these documents.

CLAIMS

WHAT IS CLAIMED IS:

1. A system for introducing a delivery apparatus into a patient's vasculature, the system comprising:

a sheath having a distal end, a proximal end, an interior diameter, a lumen, and a length extending from the distal end to the proximal end, the sheath being configured to be inserted into the patient's vasculature and to expand in a direction radially outward from the lumen;

an introducer having a channel for receiving a guide wire and being configured to be positioned within the lumen of the sheath; and

a plug coupled to the introducer and configured to move from a first position in which the plug has a first diameter to a second position in which the plug has a second diameter that is greater than the first diameter and greater than the interior diameter of the sheath, the plug in the first position being configured to fit within the lumen, and the plug in the second position having a length that is less than the length of the sheath and being configured to slide within the lumen in a direction from the distal end of the sheath towards the proximal end of the sheath to expand the sheath in the direction radially outward from the lumen.

2. The system of claim 1, wherein the sheath is elastic and biased in a direction radially towards the lumen.

3. The system of claim 1 or claim 2, wherein the sheath includes an inner tubing wall that is folded upon itself.

4. The system of any of claims 1–3, wherein the introducer has a distal end and a proximal end and a length extending from the distal end to the proximal end, the length of the introducer being greater than the length of the sheath.

5. The system of any of claims 1–4, wherein the distal end of the sheath includes an opening configured for the introducer and the plug to pass therethrough.

6. The system of claim 5, wherein the plug is positioned on the introducer such that the plug moves from the first position to the second position at a position distal to the opening of the sheath when the introducer is positioned within the lumen.

7. The system of claim 5 or claim 6, wherein the plug is coupled to the introducer such that withdrawal of the introducer through the lumen in the direction from the distal end of the sheath towards the proximal end of the sheath causes the plug in the second position to enter the opening of the sheath and slide within the lumen to transiently expand the sheath in the direction radially outward from the lumen.

8. The system of any of claims 1–7, wherein the plug in the second position extends radially outward from the introducer.

9. The system of any of claims 1–8, wherein the plug includes a plurality of supports that are configured to bend to move the plug from the first position to the second position.

10. The system of any of claims 1–9, wherein the plug includes a plurality of supports, each of the plurality of supports including a proximal support and a distal support configured such that the proximal support overlaps the distal support when the plug is in the second position.

11. The system of claim 10, wherein the plurality of supports include slats that are separated by slits.

12. The system of any of claims 1–9, wherein the plug comprises a bellows structure.

13. The system of any of claims 1–12, wherein the introducer includes an outer shaft and an inner shaft, and the plug is integral with the outer shaft.

14. The system of claim 13, further comprising an introducer housing positioned at a proximal end of the introducer.

15. The system of claim 14, wherein the introducer housing includes an outer shaft housing coupled to the outer shaft, and an inner shaft housing coupled to the inner shaft, and the outer shaft housing is configured to move relative to the inner shaft housing.

16. The system of claim 15, wherein the outer shaft housing is configured to move relative to the inner shaft housing to cause the plug to move from the first position to the second position.

17. The system of claim 15 or claim 16, wherein the outer shaft housing and the inner shaft housing are both configured to slide within an interior chamber of the introducer housing, and the outer shaft housing is configured to rotate within the introducer housing to lock the outer shaft housing to a lock of the introducer housing.

18. The system of any of claims 13–17, wherein the introducer includes a tip that is coupled to the inner shaft.

19. The system of any of claims 1–18, wherein the introducer includes a step, and the plug is configured such that a force applied by the step to the plug causes the plug to move from the first position to the second position.

20. The system of any of claims 1–8, wherein the plug includes an inflatable body.

21. The system of claim 20, further comprising a fluid port for passing fluid to the inflatable body.

22. The system of any of claims 1–21, wherein the plug has a conical shape in the second position.

23. The system of any of claims 1–22, wherein the plug is self-expanding.

24. A system for introducing a delivery apparatus into a patient's vasculature, the system comprising:

a sheath having a distal end, a proximal end, an interior diameter, a lumen, and a length extending from the distal end to the proximal end, the sheath being configured to be inserted into the patient's vasculature and to expand in a direction radially outward from the lumen;

an introducer having a channel for receiving a guide wire and being configured to be positioned within the lumen of the sheath, the introducer having an expandable portion including a plurality of supports, the expandable portion configured to move from a first position in which the plurality of supports are flattened and have a first diameter to a second position in which the plurality of supports extend radially outward from the introducer and have a second diameter that is larger than the first diameter and the interior diameter of the

sheath, the expandable portion being configured to slide within the lumen in the second position to expand the sheath in the direction radially outward from the lumen.

25. The system of claim 24, wherein the sheath is elastic and biased in a direction radially towards the lumen.

26. The system of claim 24 or claim 25, wherein the sheath includes an inner tubing wall that is folded upon itself.

27. The system of any of claims 24–26, wherein the introducer has a distal end and a proximal end and a length extending from the distal end to the proximal end, and the length of the introducer is greater than the length of the sheath.

28. The system of any of claims 24–27, wherein the distal end of the sheath includes an opening configured for the expandable portion to pass therethrough.

29. The system of claim 28, wherein the expandable portion is positioned on the introducer such that the expandable portion moves from the first position to the second position exterior of the sheath when the introducer is positioned within the lumen.

30. The system of claim 28 or claim 29, wherein the expandable portion is positioned on the introducer such that withdrawal of the introducer through the lumen in the direction from the distal end of the sheath towards the proximal end of the sheath causes the expandable portion in the second position to enter the opening of the sheath and slide within the lumen to transiently expand the sheath in the direction radially outward from the lumen.

31. The system of any of claims 24–30, wherein the plurality of supports are configured to bend to move the plurality of supports from the first position to the second position.

32. The system of any of claims 24–31, wherein each of the plurality of supports includes a proximal support and a distal support configured such that the proximal support overlaps the distal support when the expandable portion is in the second position.

33. The system of claim 32, wherein the plurality of supports include slats that are separated

by slits.

34. The system of any of claims 24–31, wherein the expandable portion comprises a bellows structure.

35. The system of any of claims 24–34, wherein the introducer includes an inner shaft and an outer shaft, and the expandable portion is integral with the outer shaft.

36. The system of claim 35, further comprising an introducer housing positioned at a proximal end of the introducer.

37. The system of claim 36, wherein the introducer housing includes an outer shaft housing coupled to the outer shaft, and an inner shaft housing coupled to the inner shaft, and the outer shaft housing is configured to move relative to the inner shaft housing.

38. The system of claim 37, wherein the outer shaft housing is configured to move relative to the inner shaft housing to cause the expandable portion to move from the first position to the second position.

39. The system of claim 37 or claim 38, wherein the outer shaft housing and the inner shaft housing are both configured to slide within an interior chamber of the introducer housing, and the outer shaft housing is configured to rotate within the introducer housing to lock the outer shaft housing to a lock of the introducer housing.

40. The system of any of claims 35–39, wherein the introducer includes a tip that is coupled to the inner shaft.

41. The system of any of claims 24–40, wherein the introducer includes a step, and the expandable portion is configured such that a force applied by the step to the expandable portion causes the expandable portion to move from the first position to the second position.

42. The system of any of claims 24–41, wherein the expandable portion has a conical shape in the second position.

43. The system of any of claims 24–42, wherein the expandable portion is self-expanding.

44. A method comprising:

inserting a guide wire into a patient's vasculature;

inserting an introducer and a sheath into the patient's vasculature over the guide wire, the sheath extending around the introducer and having a distal end and a proximal end and having a lumen, and being configured to expand in a direction radially outward from the lumen;

activating a plug positioned in the patient's vasculature to move from a first position in which the plug has a first diameter to a second position in which the plug has a second diameter that is greater than an interior diameter of the sheath; and

sliding the plug in the second position through the lumen of the sheath in a direction from the distal end of the sheath towards the proximal end of the sheath to expand the sheath in the direction radially outward from the lumen.

45. The method of claim 44, wherein the sheath is elastic and biased in a direction radially towards the lumen.

46. The method of claim 44 or claim 45, wherein the sheath includes an inner tubing wall that is folded upon itself.

47. The method of any of claims 44–46, wherein the introducer has a distal end and a proximal end and a length extending from the distal end to the proximal end, the length of the introducer being greater than a length of the sheath.

48. The method of any of claims 44–47, wherein the distal end of the sheath includes an opening configured for the introducer and the plug to pass therethrough.

49. The method of any of claims 44–48, wherein the step of activating the plug includes advancing the plug distally out of the lumen.

50. The method of any of claims 44–49, wherein the plug moves from the first position to the second position exterior of the lumen.

51. The method of any of claims 44–50, wherein the expansion of the sheath in the direction

radially outward from the lumen comprises a transient expansion.

52. The method of any of claims 44–51, wherein the plug in the second position extends radially outward from the introducer.

53. The method of any of claims 44–52, wherein the plug includes a plurality of supports that are configured to bend to move the plug from the first position to the second position.

54. The method of any of claims 44–53, wherein the plug includes a plurality of supports, each of the plurality of supports including a proximal support and a distal support configured such that the proximal support overlaps the distal support when the plug is in the second position.

55. The method of claim 54, wherein the plurality of supports include slats that are separated by slits.

56. The method of any of claims 44–53, wherein the plug comprises a bellows structure.

57. The method of any of claims 44–56, wherein the introducer includes an outer shaft and an inner shaft, and the plug is integral with the outer shaft.

58. The method of claim 57, further comprising an introducer housing positioned at a proximal end of the introducer.

59. The method of claim 58, wherein the introducer housing includes an outer shaft housing coupled to the outer shaft, and an inner shaft housing coupled to the inner shaft, and the outer shaft housing is configured to move relative to the inner shaft housing.

60. The method of claim 59, wherein the step of activating the plug includes moving the outer shaft housing relative to the inner shaft housing to cause the plug to move from the first position to the second position.

61. The method of claim 59 or claim 60, wherein the outer shaft housing and the inner shaft housing are both configured to slide within an interior chamber of the introducer housing, and the outer shaft housing is configured to rotate within the introducer housing to lock the outer

shaft housing to a lock of the introducer housing.

62. The method of any of claims 57–61, wherein the introducer includes a tip that is coupled to the inner shaft.

63. The method of any of claims 44–62, wherein the introducer includes a step, and the step of activating the plug includes applying a force with the step to the plug to cause the plug to move from the first position to the second position.

64. The method of any of claims 44–52, wherein the plug includes an inflatable body.

65. The method of claim 64, wherein the step of activating the plug includes inflating the plug.

66. The method of claim 64 or claim 65, further comprising a fluid port for passing fluid to the inflatable body.

67. The method of any of claims 44–66, wherein the plug has a conical shape in the second position.

68. The method of any of claims 44–67, wherein the plug is self-expanding.

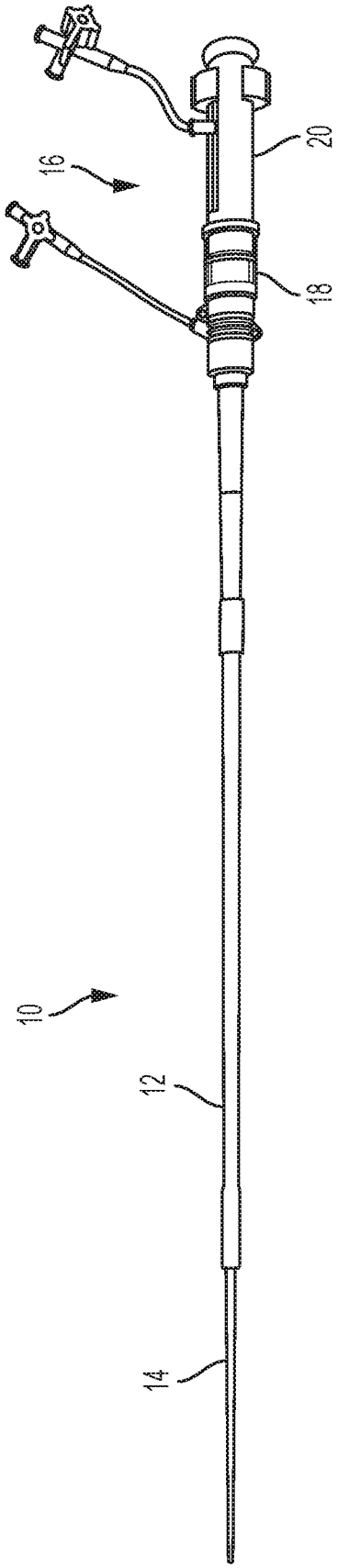


FIG. 1

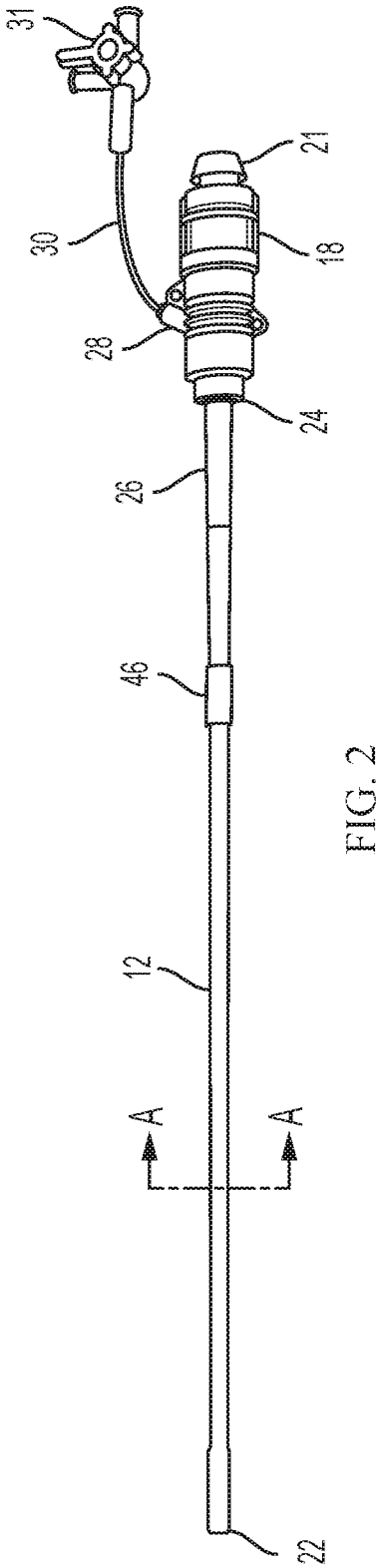


FIG. 2

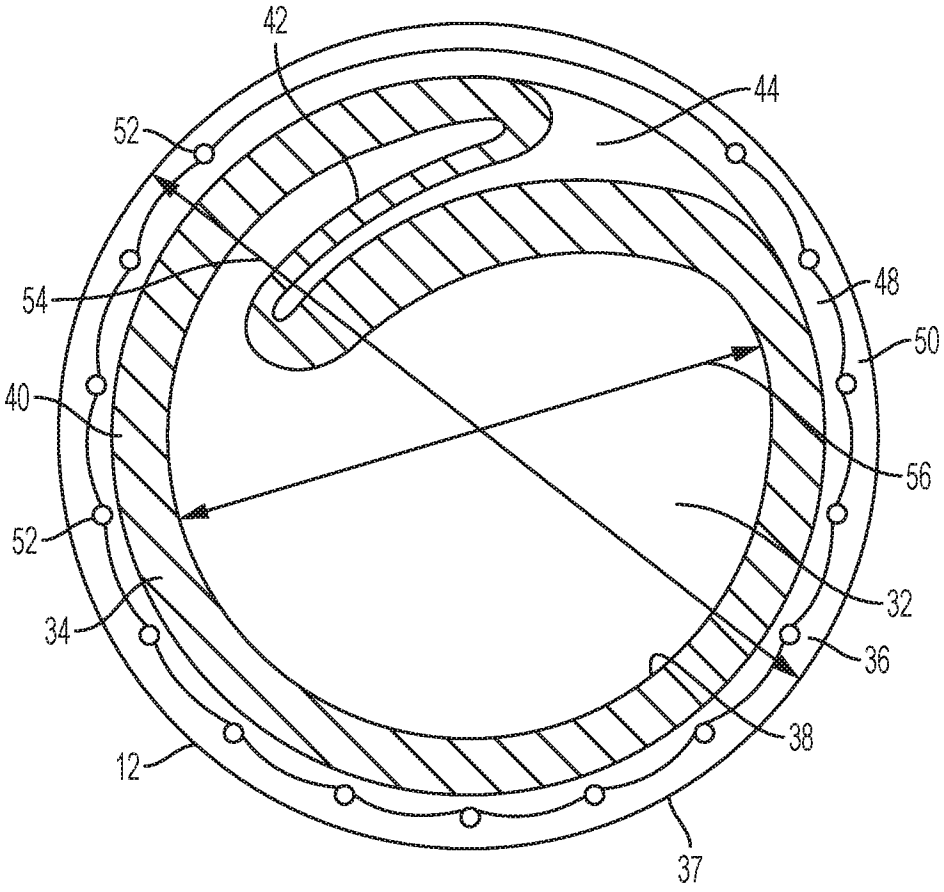


FIG. 3

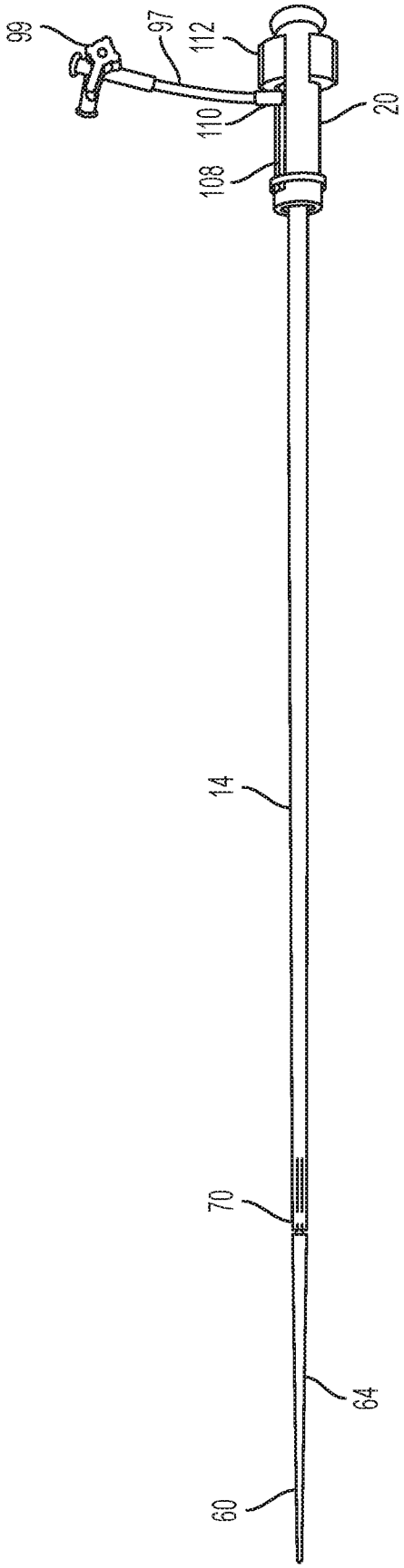

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97
112
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108
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14
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64
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FIG. 4

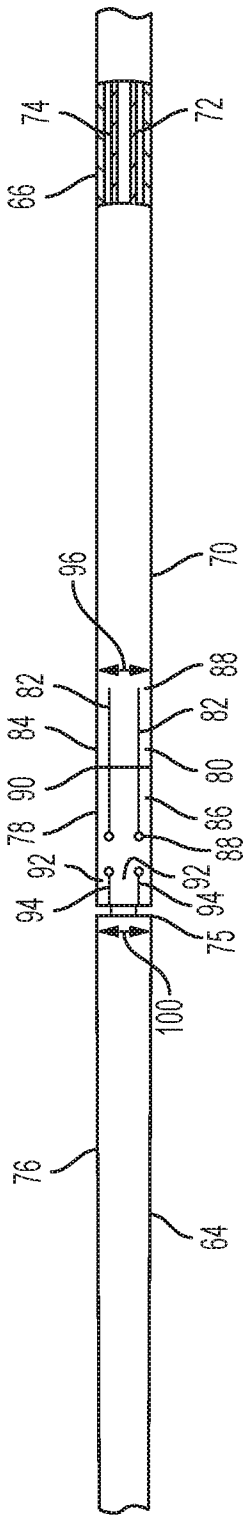

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76
64

FIG. 5

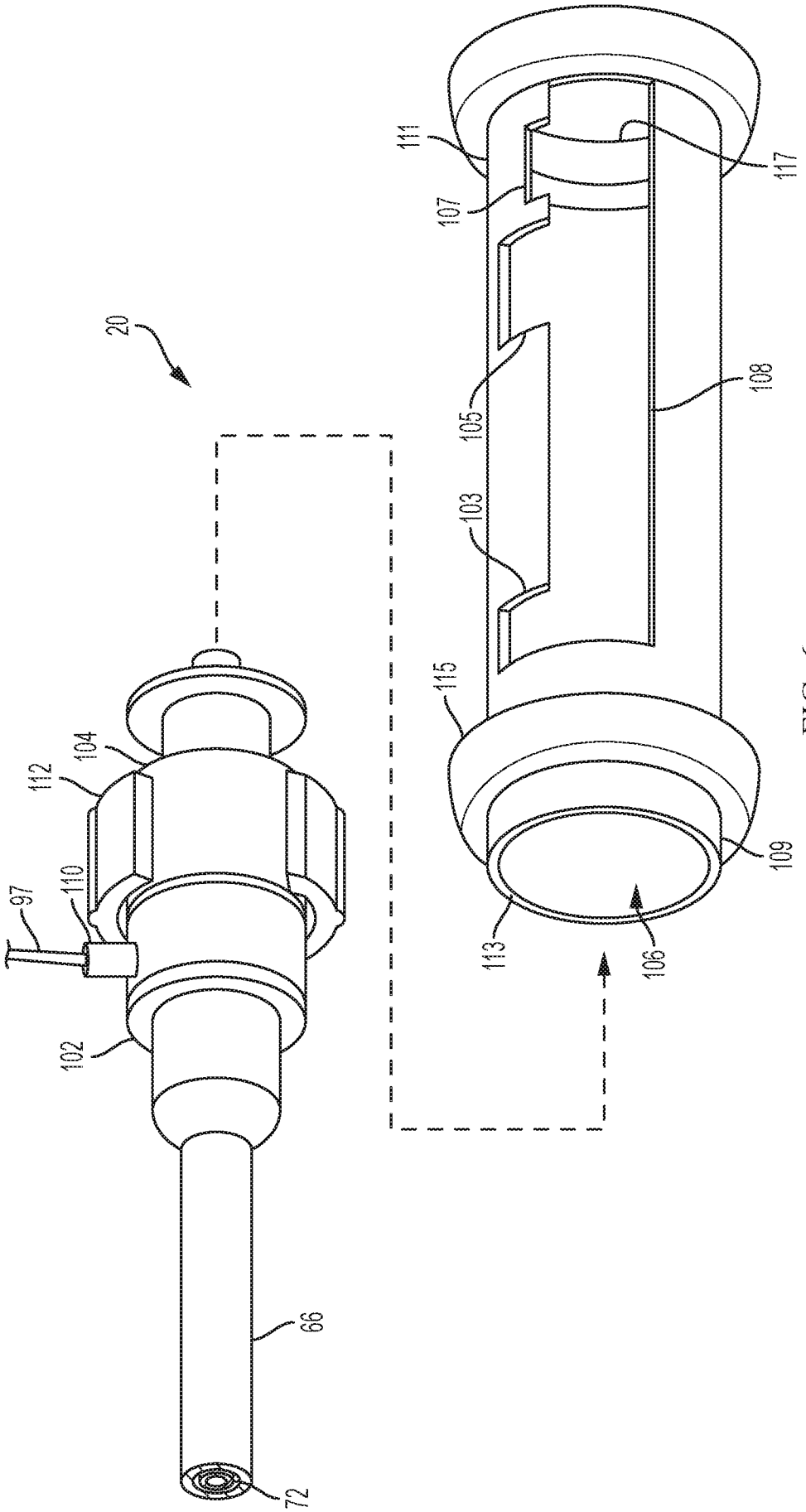

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FIG. 6

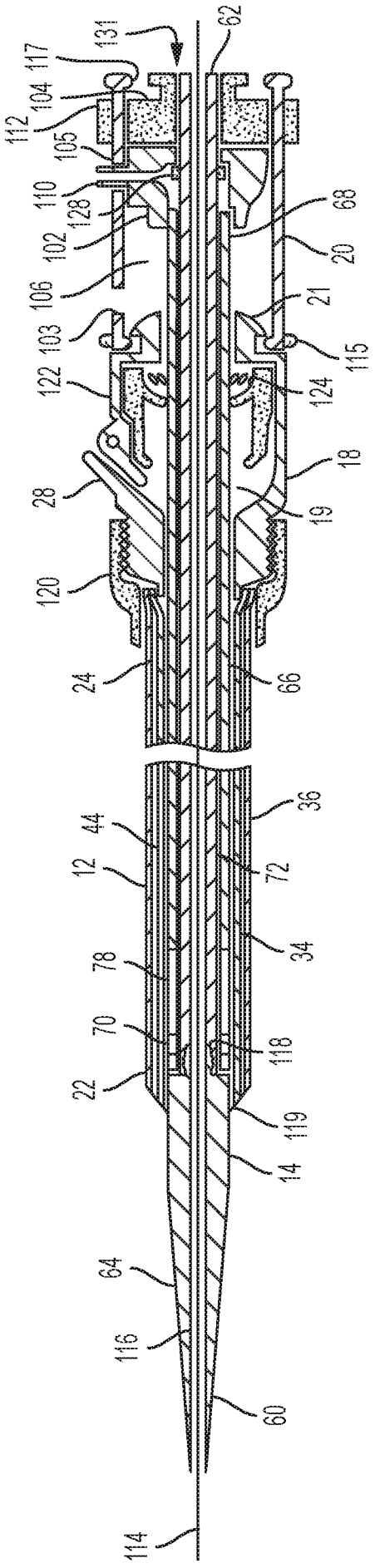

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FIG. 7

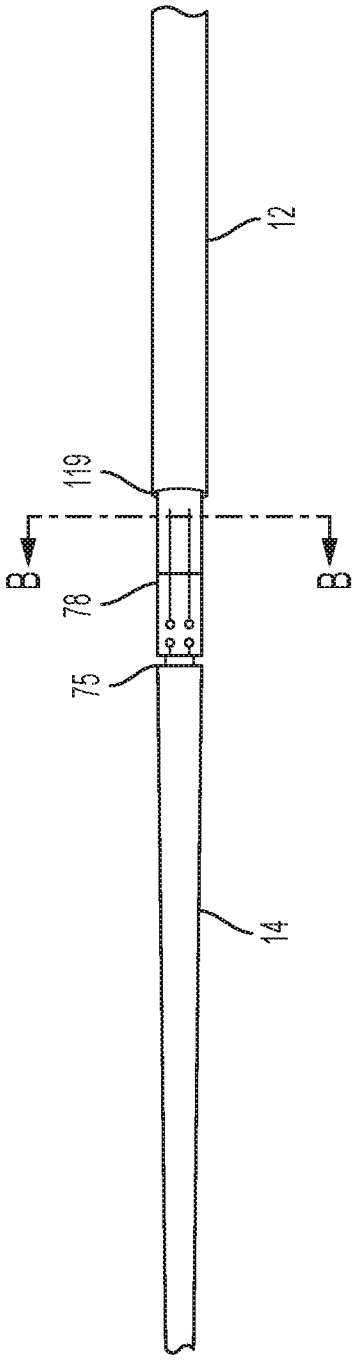


FIG. 8A

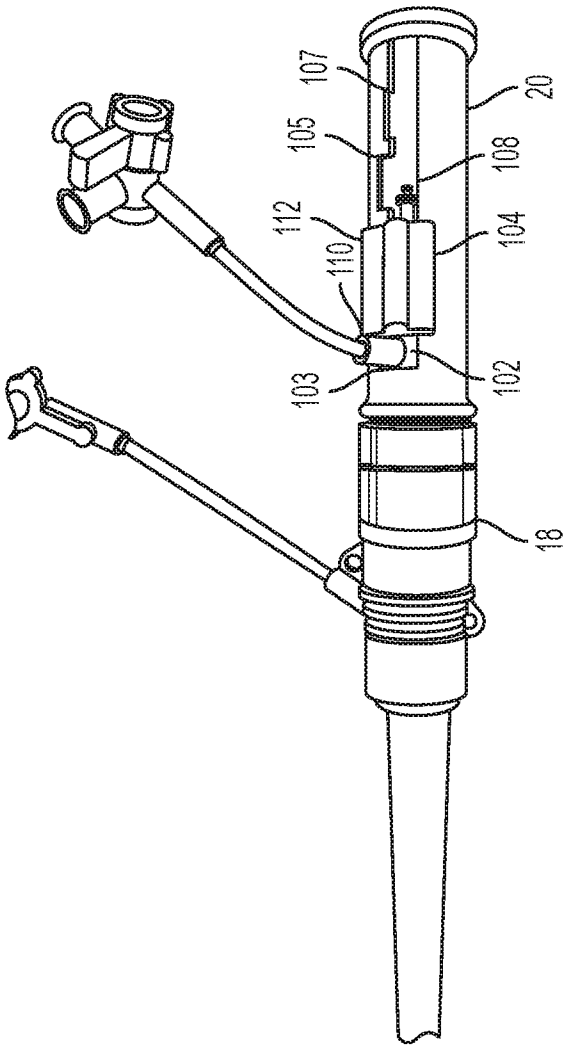


FIG. 8B

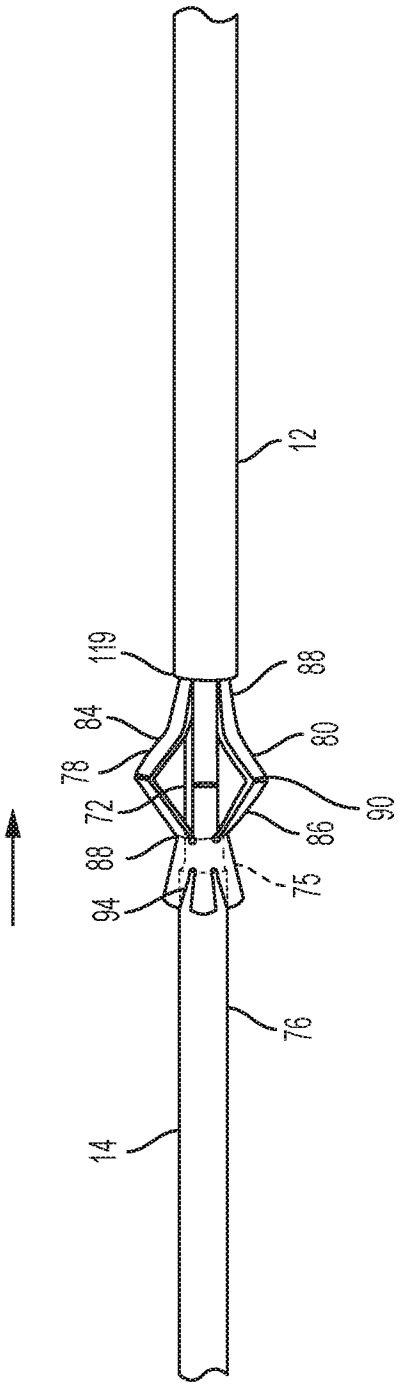


FIG. 9

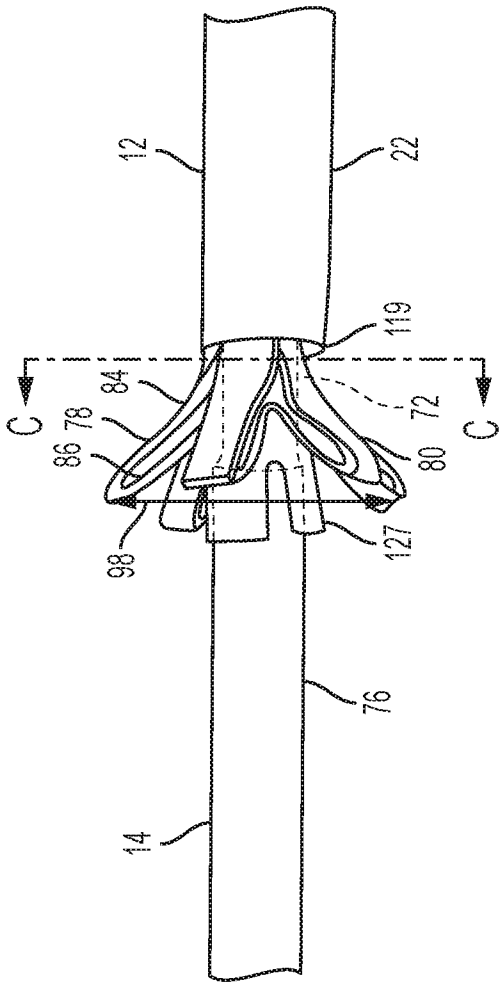


FIG. 10A

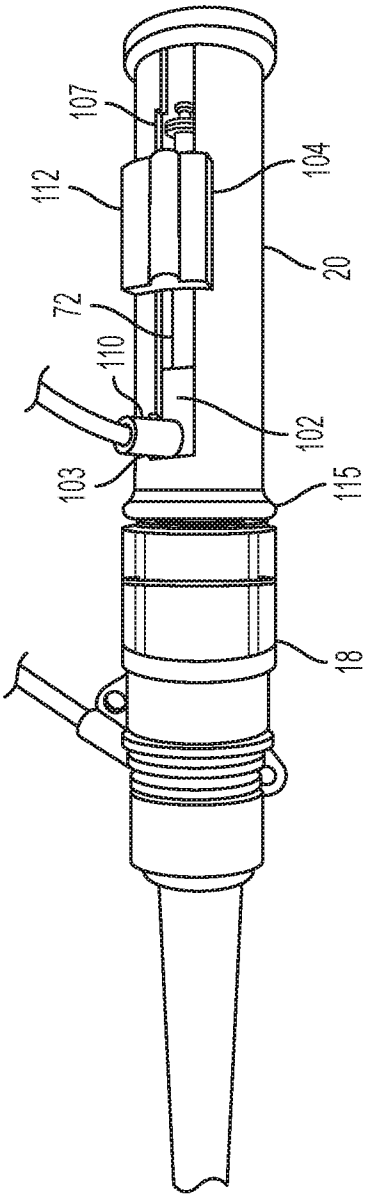


FIG. 10B

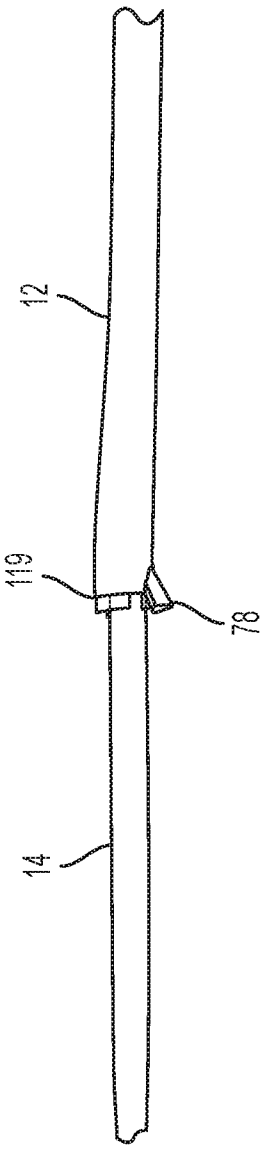


FIG. 11A

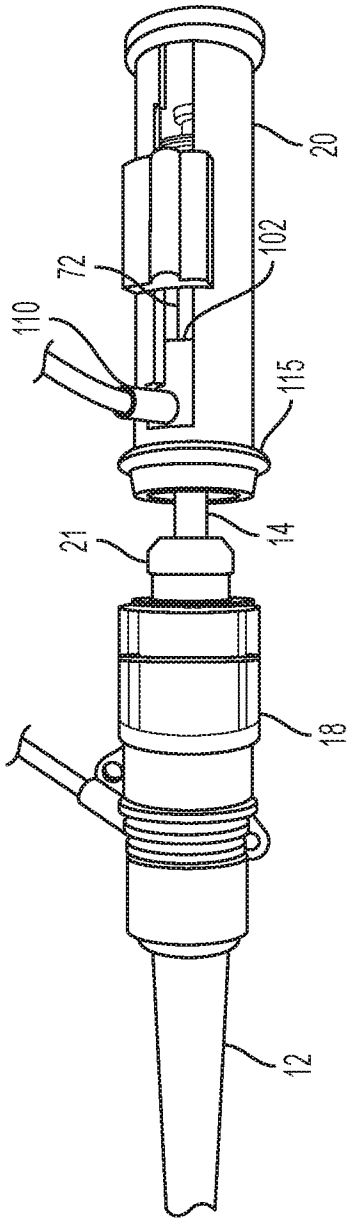


FIG. 11B

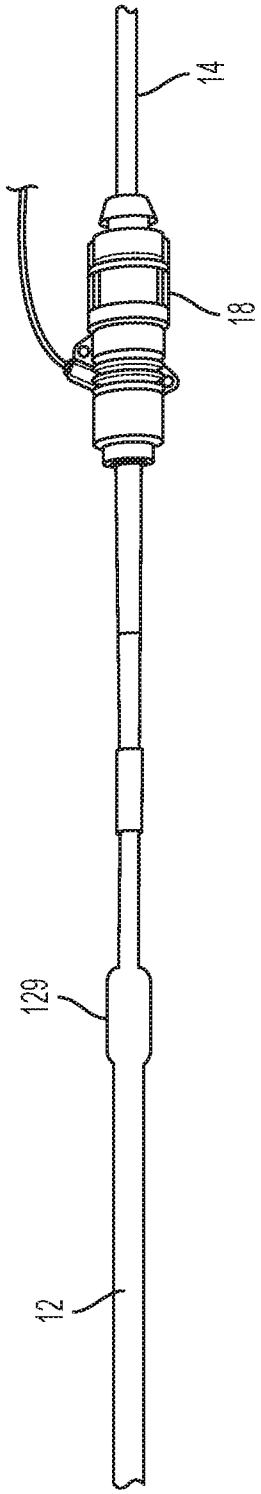


FIG. 12A

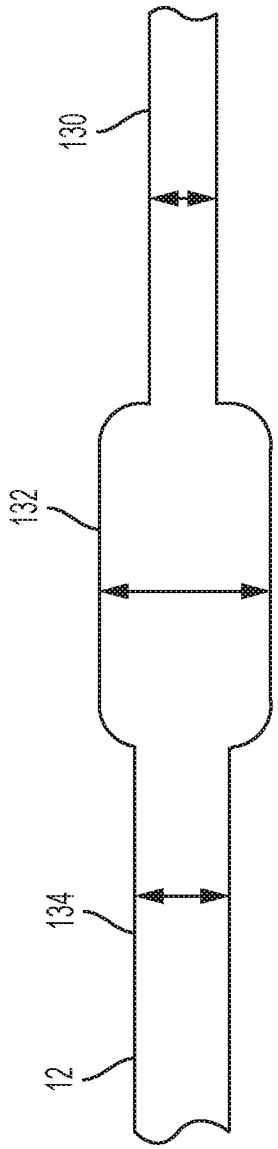


FIG. 12B

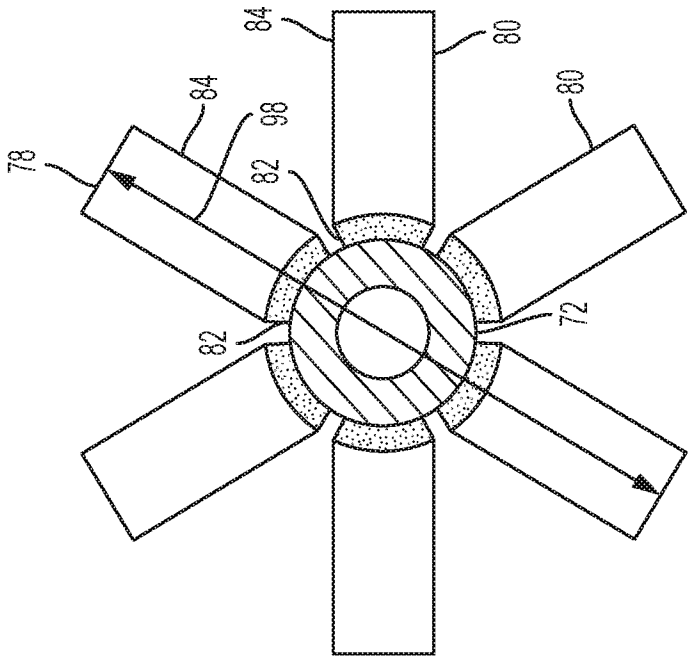


FIG. 13B

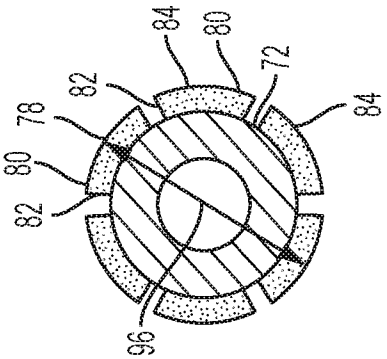


FIG. 13A

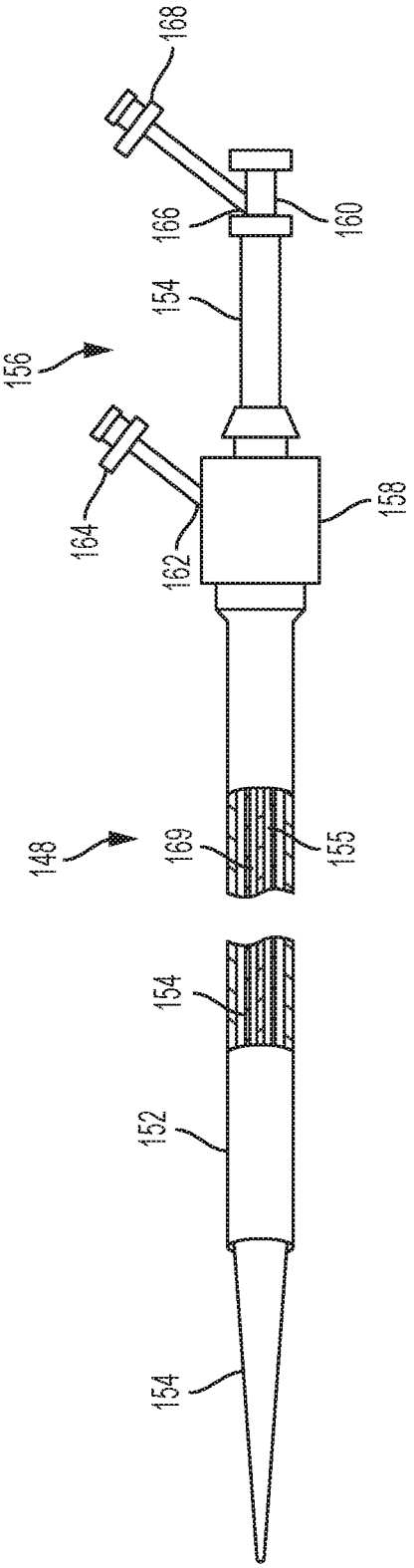


FIG. 14A

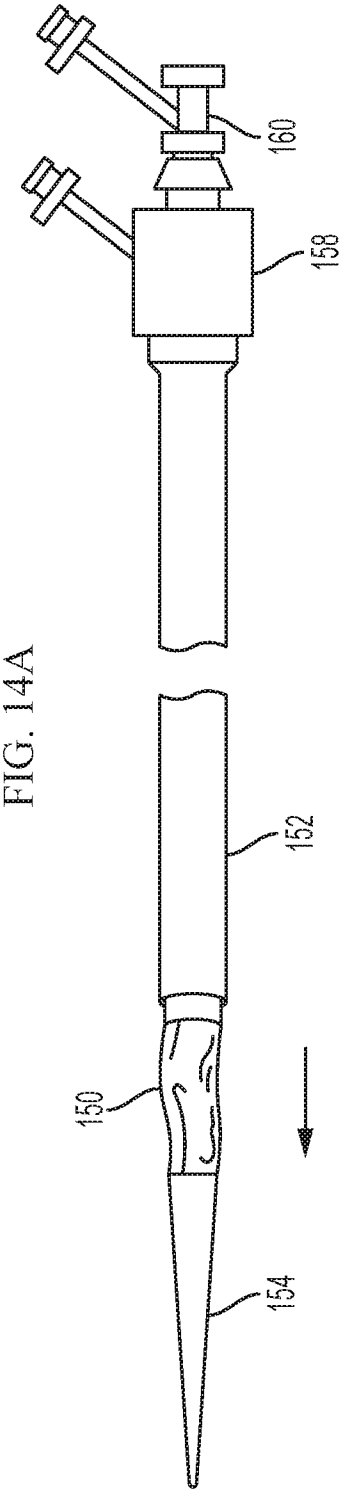


FIG. 14B

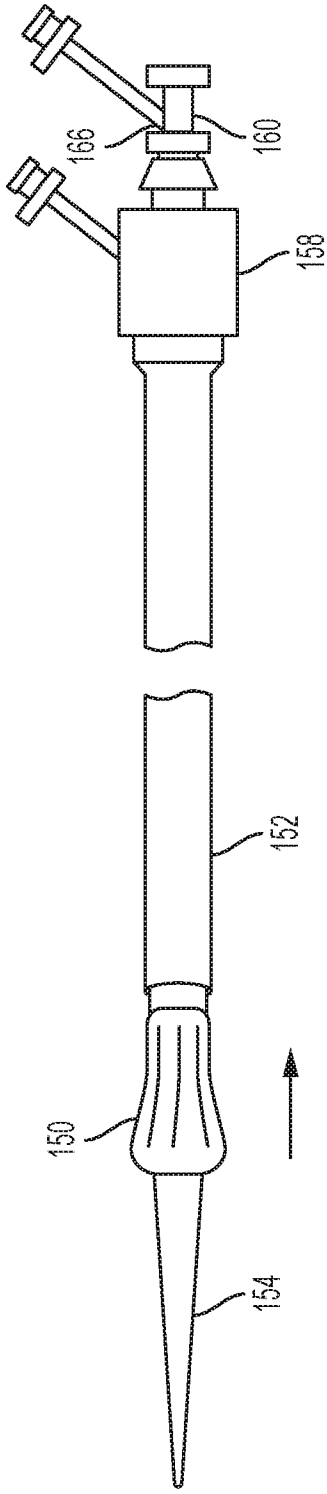


FIG. 14C

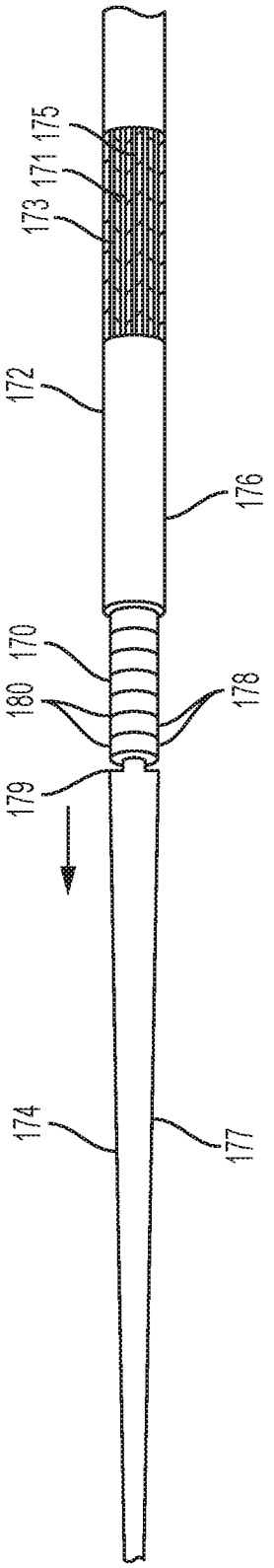


FIG. 15A

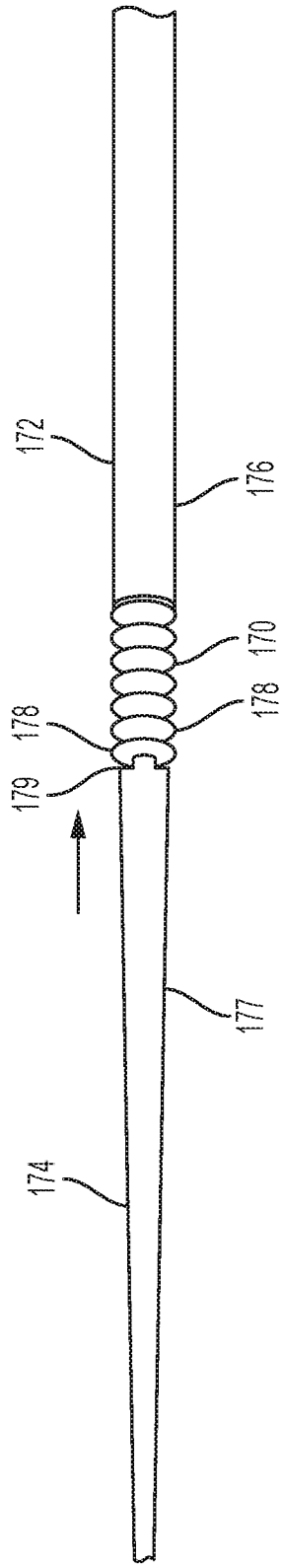


FIG. 15B

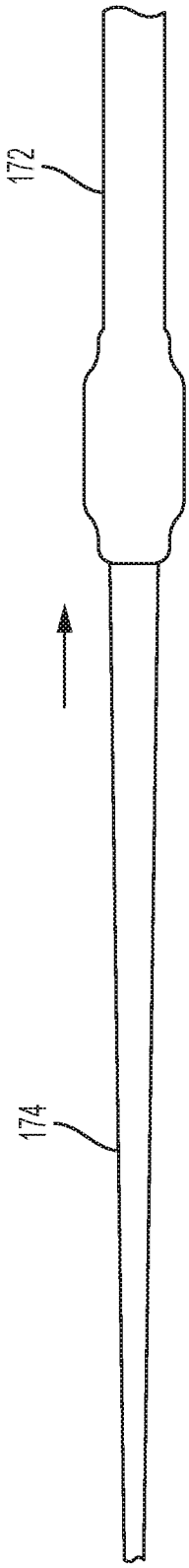


FIG. 15C

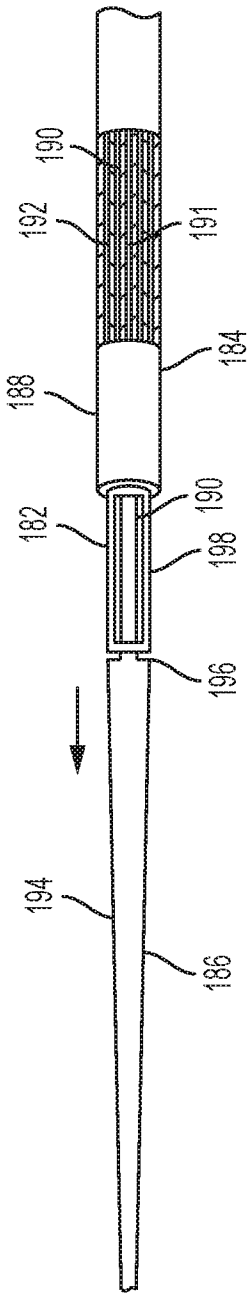


FIG. 16A

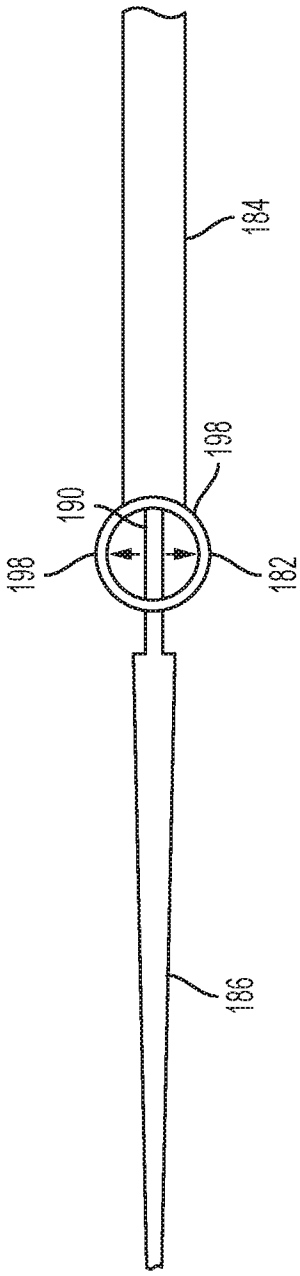


FIG. 16B

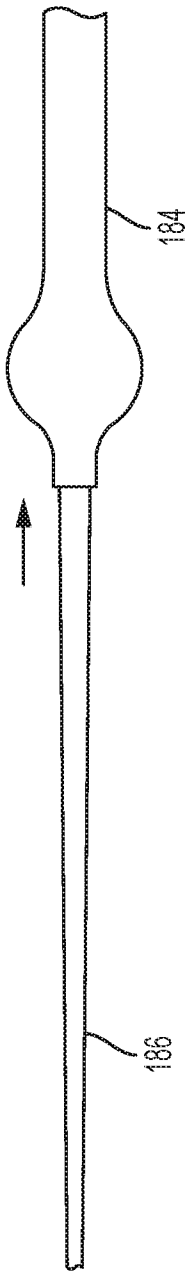


FIG. 16C

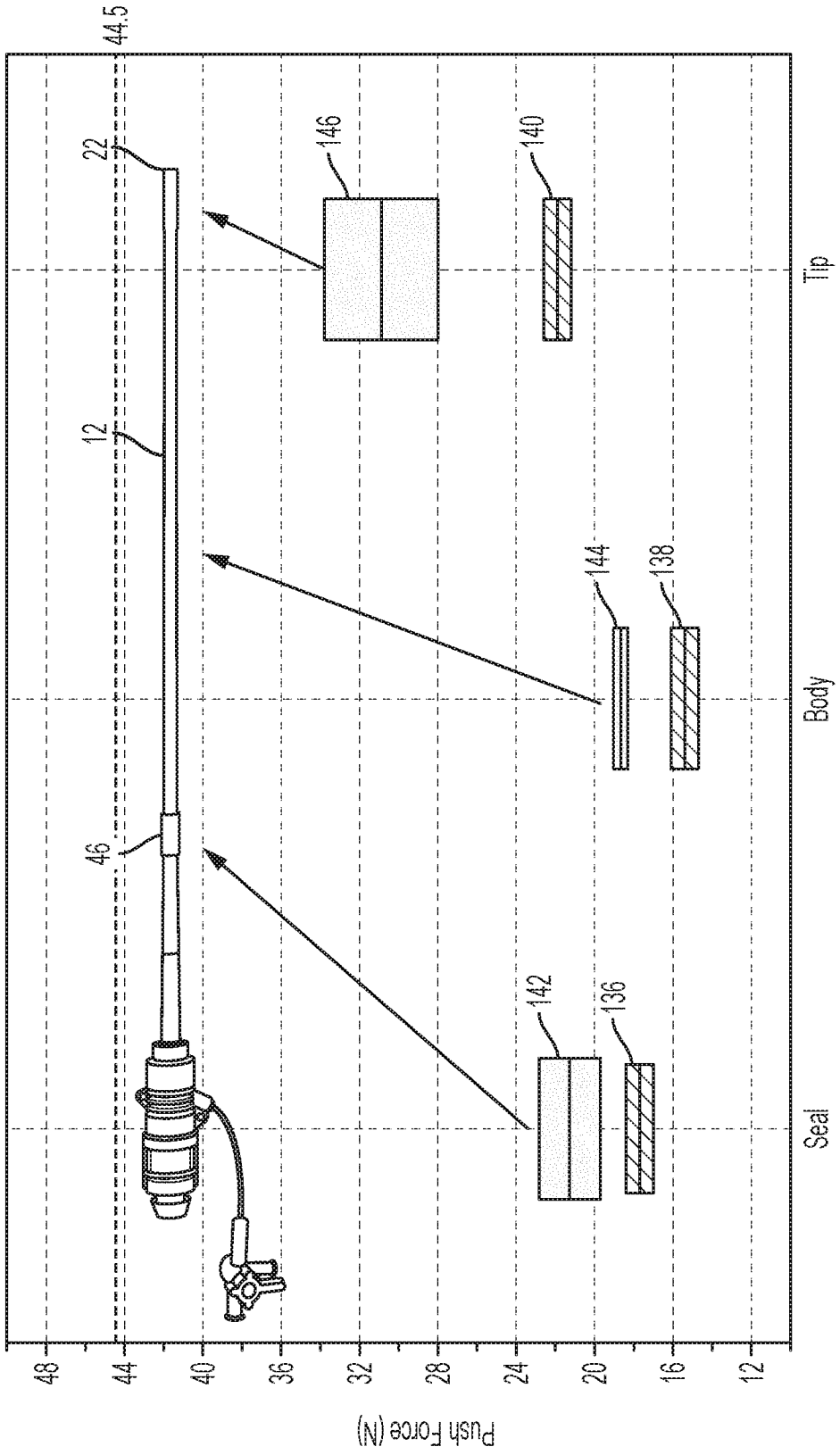

44.5
22
12
46
146
140
144
138
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136
Tip
Body
Seal
48
44
40
36
32
28
24
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16
12
Push Force (N)

FIG. 17

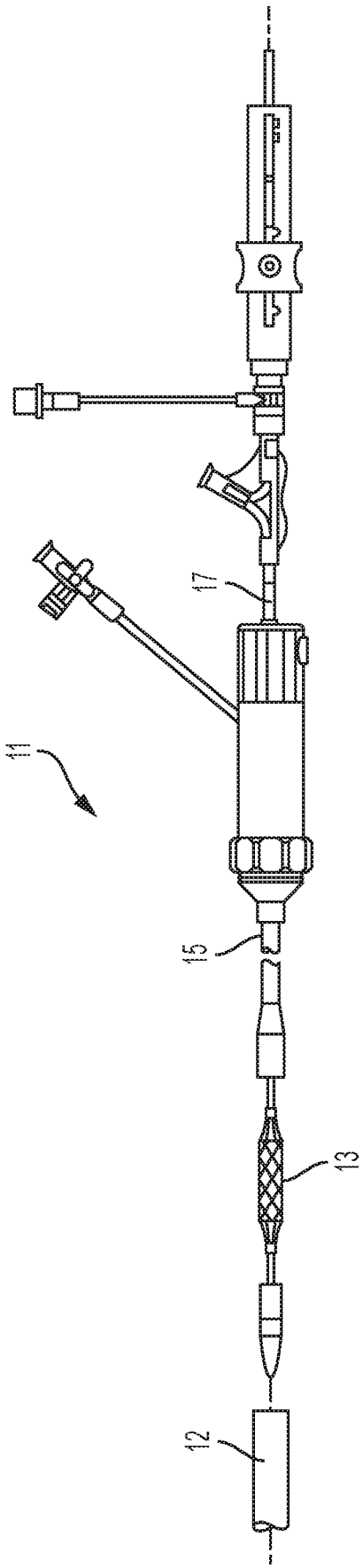


FIG. 18

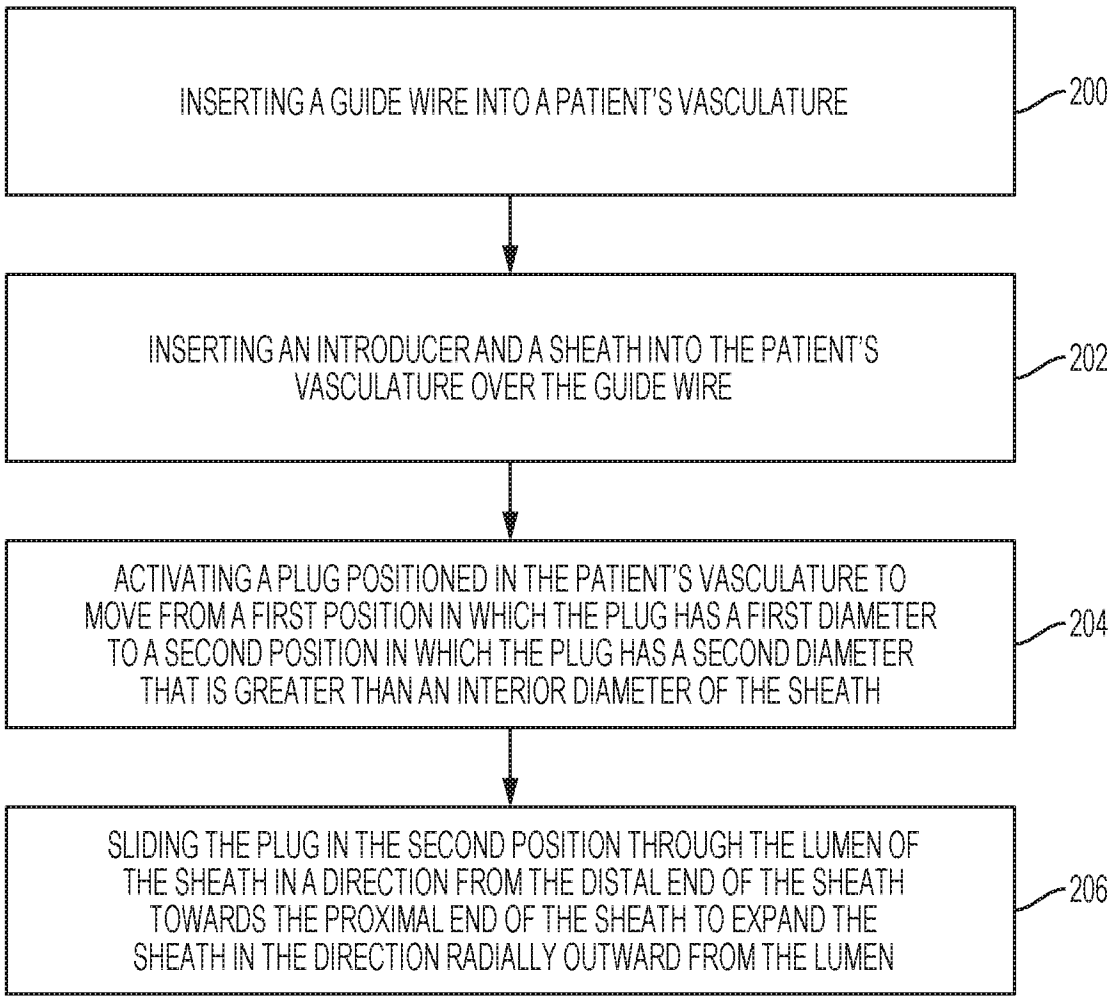

INSERTING A GUIDE WIRE INTO A PATIENT'S VASCULATURE
200
INSERTING AN INTRODUCER AND A SHEATH INTO THE PATIENT'S VASCULATURE OVER THE GUIDE WIRE
202
ACTIVATING A PLUG POSITIONED IN THE PATIENT'S VASCULATURE TO MOVE FROM A FIRST POSITION IN WHICH THE PLUG HAS A FIRST DIAMETER TO A SECOND POSITION IN WHICH THE PLUG HAS A SECOND DIAMETER THAT IS GREATER THAN AN INTERIOR DIAMETER OF THE SHEATH
204
SLIDING THE PLUG IN THE SECOND POSITION THROUGH THE LUMEN OF THE SHEATH IN A DIRECTION FROM THE DISTAL END OF THE SHEATH TOWARDS THE PROXIMAL END OF THE SHEATH TO EXPAND THE SHEATH IN THE DIRECTION RADIALLY OUTWARD FROM THE LUMEN
206

FIG. 19